UMass Chan MEDICAL SCHOOL

STANDARD OPERATING PROCEDURES

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HRP-092 – SOP – COVID-19 Risk Mitigation Planning

1. PURPOSE

1.1. This policy establishes designations followed by the [Organization].

2. POLICY

2.1. [Document Manager]:

2.1.1. For IRB Documents: Allison Blodgett, PhD, CIP, IRB Director of Operations, or designee

2.1.2. For Contracts: Danielle Howard, Director, Clinical Research Operations, or designee

2.1.3. For Grants: Amy Miarecki, Associate Vice Chancellor, Grants & Contracts, or designee

2.1.4. For Conflicts of Interest: Anthony Rothschild, MD, Chair of the Committee on Oversight of Individual Financial Conflicts of Interest in Research with Human Subjects, or designee

3. REFERENCES

3.1. None

1 PURPOSE

1.1 This policy establishes the definitions followed by the human research protection program. This is a non-exhaustive list and regulatory agencies should be referenced for complete definitions where applicable.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

3.2 Assurance of Compliance (Human Subjects) or Federalwide Assurance: An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule.

3.3 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

3.4 Certificate of Confidentiality: A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

3.5 Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

3.6 Classified Research: Research involving any information or material, regardless of its physical form or characteristics, that is owned by the United States Government, and determined pursuant to Executive Order 12356, April 2, 1982, or prior orders to require protection against unauthorized disclosure, and is so designated.

3.7 Clinical Investigation: A synonym for Research as Defined by FDA.

3.8 Clinical Trial: As defined by NIH, a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.9 COI Office: The Office of Management has been designated as the COI Office by the UMass Chan Provost and Chief Research Officer

3.10 Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

3.11 Committee Review: All review processes that require a convened IRB.

3.12 Compassionate Use: A potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

3.13 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or a member of the individual's Immediate Family has any of the following interests in the sponsor or product or service being tested:

3.13.1 Involvement in the design, conduct, or reporting of the research.

3.13.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.

3.13.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

3.13.4 Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.

3.13.5 Board or executive relationship, regardless of compensation.

3.13.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

3.13.7 Any other reason for which the individual believes that he or she cannot be independent.

3.14 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

3.15 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

3.16 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

3.17 Emergency Use: The use of an unapproved drug, biologic, or device on an individual in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

3.18 End Approval Date: The last date that a study is IRB approved and the last date that a study can be conducted without undergoing continuing review.

3.19 Expiration Date: The date after the end date of the approval period. This is the lapse date in eIRB.

3.20 Finding of Non-Compliance: Non-Compliance in fact.

3.21 Human Research: Any activity that either:[1]

3.21.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

3.21.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.22 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

3.22.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.22.2 Interaction: Communication or interpersonal contact between investigator and subject.

3.22.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

[1] The terms "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.

3.22.4 Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

3.22.5 Identifiable Biospecimen: A biospecimen for which the identity or the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

3.23 Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

3.24 Immediate Family: Spouse, domestic partner, and (their) parents, children, brothers, and sisters; and dependent children.

3.25 Institutional Official/ Organizational Official (IO/OO):

3.25.1 Institutional Official (IO): Term utilized by DHHS.

3.25.1.1 The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA)[2]. The IO is the Vice Provost, Clinical and Translational Research.

3.25.2 Organizational Official (OO): Term utilized by AAHRPP.

3.25.2.1 An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity[3].

3.26 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

3.27 Investigation: A searching inquiry for facts; detailed or careful examination.

3.28 Investigator: The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

3.29 Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

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[2] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html

[3] AAHRPP Evaluation Instrument (2018-10-15); http://www.aahrpp.org/apply/web-document-library/domain-i-organization

3.29.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

3.29.2 See HRP-013 - SOP - LARs, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.

3.30 Meeting Chair: The IRB member running a convened IRB meeting. The Meeting Chair may be an IRB chair, an IRB vice-chair, or an IRB member temporarily designated by a Meeting Chair.

3.31 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[4]

3.31.1 For research involving prisoners Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3.31.2 When following Department of Defense regulations, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

3.32 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

3.33 Non-Committee Review: Any of the following:

3.33.1 Determination of whether an activity is Human Research.

3.33.2 Determination of whether Human Research is exempt from regulation.

3.33.3 Reviews of non-exempt research using the expedited procedure.

3.33.4 Determinations of which subjects can continue in expired research.

3.33.5 Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.

3.34 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

3.34.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements

3.35 Non-significant Risk Device: An investigational device that is not a Significant Risk Device.

3.36 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

3.37 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures

[4] The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

3.37.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

3.38 Protocol Exception: A one-time, intentional action or process that departs from the approved protocol. Protocol Exceptions are generally for a single subject (e.g., the subject does not meet eligibility criteria or is allergic to one of the medications provided as supportive care). IRB approval of the Protocol Exception is required prior to implementation by the study team.

3.39 Related to the Research: A financial interest is Related to the Research when the interest is in:

3.39.1 A sponsor of the research; or

3.39.2 A product or service being tested

3.40 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.40.1 The following activities are not considered Research as Defined by DHHS:

3.40.1.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

3.40.1.2 Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

3.40.1.2.1 Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

3.40.1.2.2 Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.

3.40.1.2.3 Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3.40.1.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

3.40.1.4 Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

3.40.1.5 Secondary research involving non-identifiable newborn screening blood spots.

3.41 Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

3.41.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

3.41.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

3.41.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.42 Restricted: Applies to investigators who are delinquent in meeting IRB requirements. A status for investigators indicating that new submissions will not be accepted for review.

3.43 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.43.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.44 Significant Risk Device: An investigational device that:

3.44.1 Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

3.44.2 Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

3.44.3 Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

3.44.4 Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

3.45 Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

3.46 Suspension of IRB Approval: An action of the IRB, IRB Chair, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

3.47 Systematic: Having or involving a system, method, or plan

3.48 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.49 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

3.49.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.49.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

3.49.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

3.49.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 HRP-013 - SOP - LARs, Children, and Guardians

7 REFERENCES

7.1 45 CFR §46.102.

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)

7.3 AAHRPP elements I.1.A, I.1.E, I.5.D, I.6.B, I.7.C, I-9, II.1.D, II.2.A, II.2.B, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.4.A, III.1.B, III.2.D

1. PURPOSE

1.1. This policy establishes designations followed by the [Organization].

2. POLICY

2.1. [Conflicts of Interests Officer]: Anthony Rothschild, MD, Chair of the Committee on Oversight of Individual Financial Conflicts of Interest in Research with Human Subjects, or designee
2.2. [Organization]: University of Massachusetts Worcester
2.3. [Organizational Official]: Katherine Luzuriaga, MD, Vice Provost, Clinical and Translational Research, or designee
2.4. [Institutional Official]: Katherine Luzuriaga, MD, Vice Provost, Clinical and Translational Research, or designee
2.5. [HRPP Administrator]: Allison Blodgett, PhD, CIP, Director of IRB Operations, or designee
2.6. [IRB Executive Chair]: Jesica Pagano-Therrien, PhD, RN, CPNP, or designee
2.7. [Chief Research Officer]: Terence R. Flotte, MD, Executive Deputy Chancellor, Provost and Dean of the School of Medicine, or designee

3. REFERENCES

3.1. None

UMass Chan MEDICAL SCHOOL	SOP: Observation of Consent Process			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-012	10/12/2021	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.
1.2 The process begins when the IRB determines that the consent process should be observed.
1.3 The process ends when the IRB determines that the consent process no longer should be observed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB may consider observation of the consent process when:
- 3.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.
- 3.1.2 There are Allegations or Findings of Non-Compliance.
- 3.1.3 The nature of the research indicates that the consent process can be improved through observation.

3.2 The IRB Chair, Vice Chair, Institutional Official/ Organizational Official (IO/OO), or designee designates who conducts the observation. The IRB may have the observation conducted by:
- 3.2.1 IRB or HRPP staff.
- 3.2.2 IRB members.
- 3.2.3 A person recommended by the investigator.
- 3.2.4 An independent person hired by the IRB but paid for by the investigator's funds.

4 RESPONSIBILITIES

4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

5.1 Observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's Legally Authorized Representative (LAR), and that informed consent was freely given by the subject or the LAR.
- 5.1.1 If no, indicate that consent is not legally effective, and the prospective subject may not be entered into the research.
- 5.1.2 If yes, document in writing that the consent process was observed, and that informed consent was freely given by the subject or LAR.

5.2 At the conclusion of the observation period or as requested by the IRB, Institutional Official/ Organizational Official (IO/OO), or designee, provide a summary of consent processes observed and outcomes.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None

UMass Chan MEDICAL SCHOOL	SOP: LARs, Children, and Guardians			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	06/21/2022	C. Loeb	J. Healy	1 of 2

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
- 1.1.1 Legally Authorized Representative (LAR)
- 1.1.2 Children
- 1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.
- 3.1.1 When research is conducted in Massachusetts the following individuals meet this definition:
  - 3.1.1.1 For medical research and minimal risk non-medical research:
    - 3.1.1.1.1 Health care agent: Massachusetts law provides for proxy consent for medical decisions to be given on behalf of an individual who does not have the capacity to consent. The law allows a competent adult to appoint a designated person as his or her "health care agent." M.G.L. c. 201D. If the person then becomes incapacitated, and is in need of medical care, the health care proxy becomes empowered to make medical decisions on his or her behalf. If no health care agent has been appointed in advance, then medical care providers are authorized by the law to accept consent from "responsible parties," under common law principles, usually meaning the individual's next-of-kin. M.G.L. c. 201D, §16. It is generally accepted in Massachusetts that if research involves the provision of medical care, a health care agent, whether appointed or holding that status by virtue of being a "responsible party," may consent to that treatment and to the accompanying research.
    - 3.1.1.1.2 Guardian: Under Massachusetts law, a guardian is an individual, organization or agency, if any, that has been appointed legal guardian of the person found to be incompetent by a court of competent jurisdiction.
  - 3.1.1.2 For all other research conducted in Massachusetts, the Office of the General Counsel shall be consulted to determine whether or not the individuals proposed to serve as legally authorized representatives are considered Legally Authorized Representatives.
- 3.1.2 For research outside Massachusetts, the Office of the General Counsel determines which individuals are LARs.

3.2 DHHS and FDA's Subpart D applies to all research involving children.

3.3 When research is conducted in Massachusetts all individuals under the age of 18 years are children.
- 3.3.1 Exceptions exist for emancipated minors as defined below. Contact legal counsel for more information:
  - 3.3.1.1 Married/widowed/divorced individuals
  - 3.3.1.2 A parent;

3.3.1.3 A member of the armed forces;
3.3.1.4 An individual living apart from parents and managing his or her own finances; or
3.3.1.5 A female who is pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion
3.3.1.5.1 If the research procedures involve abortion, a female under the age of 18 who is not and has never been married is considered to be a child.

3.3.2 Exceptions exist for individuals under the age of 18 when the research procedures are limited to:
3.3.2.1 Diseases dangerous to the public health;
3.3.2.2 Drug dependency (other than alcohol dependency).
3.3.2.3 Pregnancy, unless the procedures involved in the research include abortion as described in 2.3.3 below.

3.3.3 Individuals who can document that they are legally authorized to consent on behalf of the child to general medical care may serve as a guardian. Under Massachusetts law, a child's guardian is an individual, organization or agency, if any, that has been appointed through a court process as legal guardian for that child.

3.3.4 For research conducted outside of Massachusetts, the Office of the General Counsel shall be consulted to determine who meets the definition of guardian for a child. Before obtaining permission for a child to take part in research from someone who is not a parent, contact the Office of the General Counsel.

3.3.5 For research outside Massachusetts, a determination of who is a child is to be made by the Office of the General Counsel.

3.4 Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care[1]. Before obtaining permission from an individual who is not a parent, contact legal counsel.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402
7.2 21 CFR §50.3
7.3 AAHRPP elements I.1.G, I-9, II.4.B

[1] This is the DHHS and FDA definition of "guardian"

1. PURPOSE

1.1. This procedure establishes the process to manage allegations of undue influence of the HRPP.

1.1.1. Undue influence is defined as a real or perceived action that may influence the review of human subjects research outside of the scientific, regulatory and ethical principles that guide review of such research. Such action may include, but is not limited to, attempts to influence decisions based upon financial concerns of the Organization or a department; personnel actions such as denying promotion or tenure; or verbal harassment.

1.2. This procedure begins when the [Organizational Official] learns of an allegation of undue influence of the HRPP.

1.3. This procedure ends when any undue influence of the HRPP has been mitigated.

2. POLICY

2.1. Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process, and may not discuss business development with IRB members.

2.2. Staff may explain written procedures to individuals involved in the review process.

2.3. Individuals in the [Organization] may not

2.3.1. Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.

2.3.2. Communicate the [Organization]'s financial issues regarding specific protocols to individuals responsible for the review process.

2.3.3. Answer questions about the [Organization]'s business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.

2.3.4. Attempt to influence the review of human subjects research through real or perceived action on any performance review, promotion or tenure decision of any IRB member, IRB staff or any individual involved in the conduct or review of human subjects research.

2.4. When the IRB does not follow written procedures, the [Organization] can require the IRB to re- review the submission and can disapprove research approved by the IRB.

2.5. All individuals in the [Organization] are required to ensure that allegations of undue influence of the HRPP or review process are reported to the [Organizational Official] within 5 days of becoming aware of the allegation.

3. RESPONSIBILITY

3.1. The [Organizational Official] carries out these procedures or ensures that others carry them out.

4. PROCEDURE

4.1. Gather information to determine the veracity of the report using discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:

4.1.1. Interviews of individuals inside and outside the [Organization]

4.1.2. Review of records inside and outside the [Organization]

4.1.3. Consultation with internal or external entities

4.2. If the report has no basis in fact, take no further action under this SOP.

4.3. Take appropriate steps to eliminate the undue influence using discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:

4.3.1. No action
4.3.2. Verbal counseling
4.3.3. Education
4.3.4. Recommend reassignment of duties
4.3.5. Recommend termination of employment

4.4. Document the findings and actions, if any, related to undue influence of the HRPP.

5. REFERENCES

5.1. 21 CFR §56.109(a), §56.109(f), §56.112, §56.113
5.2. 45 CFR §46.109(a), §46.109(e), §46.112, §46.113

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SOP: IRB Member Review Expectations			
Document No.:	**Edition No.:**	**Effective Date:**	**Page:**
HRP-019	**001**	**10/12/2021**	**Page 1 of 3**

1. PURPOSE

1.1. This policy establishes the expectations of IRB members for IRB reviews.
1.2. For convened IRB meetings, this policy applies to all members who will be present with voting status.
1.3. For review using the expedited procedure, this policy applies to the Designated Reviewer who fulfills the roles described for the primary presenter, and the scientific/scholarly reviewer, or obtains consultation for these roles.

2. POLICY

2.1. Treat all oral and written information obtained as part of the review process as confidential, and do not disclose or use confidential information without prior authorization.
2.2. For each review consider whether you have a Conflicting Interest.

2.2.1. Know the definition of Conflicting Interest.
2.2.2. If you have a Conflicting Interest, do not participate in that review (including discussion or voting) except to provide information requested by the IRB.

2.3. Attend meetings you are committed to attend.

2.3.1. If you cannot attend a meeting you previously committed to attend, immediately notify HRPP staff.

2.4. In advance of the meeting:

2.4.1. Review the submitted materials as directed in (See Table 1 in REFERENCES).
2.4.2. Consider the criteria in all applicable worksheets and checklists.
2.4.3. If during your review, you:

2.4.3.1. Need answers to questions about the submitted materials, ask Meeting Chair or HRPP staff.
2.4.3.2. Need minutes or other information in the IRB record that you cannot access directly, ask the HRPP staff.
2.4.3.3. Think one or more criteria are not met, consider what specific and directive changes would make the protocol approvable.

2.4.4. If you are the primary presenter:

2.4.4.1. Fill out applicable checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.
2.4.4.2. Review all submitted materials for consistency, including the following when they exist:

2.4.4.2.1. The complete protocol including any previously approved protocol modifications
2.4.4.2.2. Investigator brochure
2.4.4.2.3. HHS-approved protocol
2.4.4.2.4. HHS-approved template consent document

2.4.4.3. Prepare to lead the discussion at the meeting.

2.4.5. If you are the prisoner representative and the protocol involves prisoners as research subjects, determine whether the criteria in “CHECKLIST: Prisoners (HRP-415)” are met, be present when the protocol is reviewed, and provide a review either orally or in writing.

2.4.6. If you are an IRB member with scientific or scholarly expertise, additionally review the submitted materials in enough depth to evaluate whether the materials accurately describe the subject risks, subject benefits, and knowledge to result, whether alternative procedures could consistent with sound research design could reduce risk, and whether the research design is sound enough to yield the expected knowledge.

2.5. At meetings

2.5.1. Share your unique input to get all the issues on the table.

2.5.1.1. If you have a question, ask.
2.5.1.2. If you have information that has not been discussed, share it.

2.5.2. We think critically and use the criteria for approval to decide whether to approve research.

2.5.2.1. If you have a concern, problem, or recommended change, be able to base it on the criteria for approval. If you are unsure of the basis, ask.
2.5.2.2. If you think a criterion for approval is not met, say so.
2.5.2.3. If you think the criteria for approval are not met, do not vote for approval.

2.5.3. Make decisions by majority rule, not consensus.

2.5.3.1. Listen and learn from the group, but think and vote independently
2.5.3.2. Know that dissent is healthy and expected.
2.5.3.3. Respect the opinions of others

2.6. Improve your knowledge over time.

2.6.1. Participate in required and optional continuing education.
2.6.2. Accept constructive feedback.

3. REFERENCES *(see next page)*

3.1.

	Initial Review	Review of a Modification	Continuing Review	Review of New Information
	• Review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:	• Review the summary of the modification. • Determine which criteria in applicable worksheets and checklists are affected. • Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:	• Review the continuing review progress report and attachments. • Determine which criteria in applicable worksheets and checklists are affected. • Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:	• Review the new information and attachments. • Determine which criteria in applicable worksheets and checklists are affected. • Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:
Review of Research	• Initial application form(s) • Protocol • Any consent document(s) and script(s) • Any recruitment materials • Any reports of consultants • Any other information all IRB members were asked to review	• Protocol • Previously approved modifications not reflected in the current protocol, or a summary thereof • Any consent document(s) and script(s) • Any recruitment materials • Any reports of consultants • Any other information all IRB members were asked to review	• Protocol • Previously approved modifications not reflected in the current protocol, or a summary thereof • Any consent document(s) and script(s) • Any recruitment materials • Any reports of consultants • Any other information all IRB members were asked to review	• Protocol • Previously approved modifications not reflected in the current protocol, or a summary thereof • Any consent document(s) and script(s) • Any recruitment materials • Any reports of consultants • Any other information all IRB members were asked to review
Review of HUD Use	• HDE approval order • Description of the device • Product labeling • Any patient information packet • A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures.	• Description of the device • Product labeling • Any patient information packet • A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures	• Description of the device • Product labeling • Any patient information packet • A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures	• Description of the device • Product labeling • Any patient information packet • A summary of the proposed use of the device, including screening procedures, the HUD procedure, and patient follow-up visits, tests, or procedures

3.2. Humanitarian Device Exemption (HDE) Program, https://www.fda.gov/media/74307/download

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SOP: Incoming Items				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the item is a request either for this IRB to review for another Participating Site (pSite) or for this institution to rely on an external IRB, follow HRP-803 - SOP - Reliance Pre-Review.

5.2 If the item is a request for an approval or determination[1] by this institution's IRB that does not include other pSites, follow HRP-021 - SOP - Pre-Review.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow HRP-805 - SOP - External IRB Updates.

5.3.1 If the item includes new or modified contact information, update the contact information.

5.4 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

5.5 If the item is an investigator's request to continue subjects in expired research have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.

5.6 If the item does not fit into the above categories:

5.6.1 If the item is a question, concern, or complaint:

5.6.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

5.6.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

5.6.2 Follow HRP-024 - SOP - New Information.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

6.3 HRP-024 - SOP - New Information

6.4 HRP-063 - SOP - Expiration of IRB Approval

6.5 HRP-803 - SOP - Reliance Pre-Review

6.6 HRP-805 - SOP - External IRB Updates

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.4.A, I.5.D, I.7.C, I-9, II.2.A, II.2.B, II.2.E-II.2.E.2, II.2.F-II.2.F.3

[1] A "request for an approval or determination" includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research. Submission of an updated list study personnel is not considered a modification of research and is therefore not a "request for an approval or determination."

1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.

3.2 Single subject protocol exceptions are reviewed as modifications to previously approved research. [1]

3.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.

3.4 Changes to study personnel are not considered a modification to previously approved research when the study personnel meet the qualifications described in the IRB approved study.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:

- 5.1.1 Evaluate whether the investigator made the required modifications.
- 5.1.2 If the investigator made the required modifications, follow HRP-052 - SOP - Post-Review to issue an approval.
- 5.1.3 If the investigator did not make the required modifications or made unrequested modifications, execute the “Request Pre-Review Clarification” activity from the investigator. Offer the investigator the opportunity to correct the submission.
  - 5.1.3.1 If the investigator will correct the submission, have the investigator make changes then execute the “Submit Changes” activity and stop processing the current submission until changes are received.
  - 5.1.3.2 If the investigator will not correct the submission, have the investigator execute the “Submit Changes” activity to resubmit and continue processing.

5.2 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Final Contingencies” section.

[1] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.

5.3 If the information is not complete, contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to provide additional information.

5.3.1 Continue processing once the investigator responds to the request for additional information.

5.4 If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.

5.4.1 If the investigator withdraws the submission, stop processing the current submission.

5.4.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Director.

5.5 Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review, and/or HRP-323 - WORKSHEET - Criteria for Approval HUD as references:

5.5.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.

5.5.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.5.3 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow HRP-031 - SOP - Non-Committee Review Preparation and HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

6 MATERIALS

6.1 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
6.2 HRP-024 - SOP - New Information
6.3 HRP-031 - SOP - Non-Committee Review Preparation
6.4 HRP-040 - SOP - IRB Meeting Preparation
6.5 HRP-052 - SOP - Post-Review
6.6 HRP-308 - WORKSHEET - Pre-Review
6.7 HRP-310 - WORKSHEET - Human Research Determination
6.8 HRP-311 - WORKSHEET - Engagement Determination
6.9 HRP-312 - WORKSHEET - Exemption Determination
6.10 HRP-313 - WORKSHEET - Expedited Review
6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD

7 REFERENCES

7.1 7.1 AAHRPP elements I.1.A, I-2, I.6.B, I.7.A, I-9, II.2.A-D, II.2.E-II.2.E.2, II.2.F-II.2.F.3

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SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-023	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to review notifications of:
- 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
- 1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
- 1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the IRB receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer has:
- 1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
- 1.3.2 Notified the physician and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.

3.3 Emergency uses and device compassionate uses cannot be claimed as research.

3.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug “Request for Authorization to Use Alternative IRB Review Procedures” identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

4 RESPONSIBILITIES

4.1 A Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Determine if the notification/request is one of the following:
- 5.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).
  - 5.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. Set a 5-day reminder to request the 5-day report.
  - 5.1.1.2 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage using HRP-024 - SOP - New Information as Non-Compliance.
- 5.1.2 Compassionate use of a device. If so, use HRP-325 - WORKSHEET - Device Compassionate Use to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use HRP-314 - WORKSHEET - Criteria for Approval to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[1] and indicate the results of this determination to the IRB staff.

5.1.3.1 Execute the "Submit Designated Review" activity. In the "Notes" section document that the decision is to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 CFR § 56.105 of the requirements in § 56.108(c).

5.1.4 If none of the above, stop processing the request and inform the physician or submitter.

5.2 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 HRP-024 - SOP - New Information
6.2 HRP-314 - WORKSHEET - Criteria for Approval
6.3 HRP-322 - WORKSHEET - Emergency Use
6.4 HRP-325 - WORKSHEET - Device Compassionate Use

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
7.2 21 CFR §812.36; 21 CFR §812.47.
7.3 21 CFR § 56.105; 21 CFR § 56.108(c).
7.4 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.
7.5 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry; https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf
7.6 AAHRPP element 1.7.C

[1] *"The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use."* Per FDA correspondence dated 10/10/17

1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives an information item.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

1.4 Unless otherwise authorized by the Organizational Official, new information will be reviewed and a determination issued within 30 days of receipt

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official for further action.

3.2 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency or national organization.

3.2.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.3 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

3.4 Substantiated allegations related to classified Department of Defense (DOD) HSR must be reported immediately.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.1.1 Is this an Allegation of Non-Compliance?

5.1.2 Is this a Finding of Non-Compliance?

5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.2 If you are unable to answer a question, consult the IRB chair or IRB director.

5.3 If the IRB chair and IRB director are unable to answer a question, follow HRP-025 - SOP - Investigations.

5.4 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

5.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.4.1.2 If no, follow any other corresponding sections.

5.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.4.3 Non-Serious/Non-Continuing Non-Compliance

5.4.3.1 Determine whether the individual or group responsible for the Non-Compliance has developed and implemented a suitable corrective action plan.

5.4.3.2 If the individual or group responsible for the Non-Compliance is unwilling or unable to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

5.4.4.1 If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, please see below for additional considerations to aid in decision-making.

5.4.4.2 Confirm your decision with the IRB chair or IRB director.

5.4.4.3 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.5 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB director to consider a Suspension of IRB Approval following the HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

5.6 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.6.1 Confirm that the subject is currently a Prisoner.

5.6.1.1 If the subject is currently not a Prisoner no other action is required.

5.6.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

5.6.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.6.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.6.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.6.2.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner,

5.6.3 For Department of Defense (DOD) research, have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.6.3.1 Promptly report all decisions to the Department of Defense (DOD).

5.6.3.2 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

5.7 If the information involves any of the following, complete and send HRP-529 - LETTER - AAHRPP Notice of Information Item to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.7.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.7.2 Litigation, arbitration, or settlements initiated related to human research protections.

5.7.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.

5.9 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, complete review and prepare and send letter per HRP-052 - SOP - Post-Review.

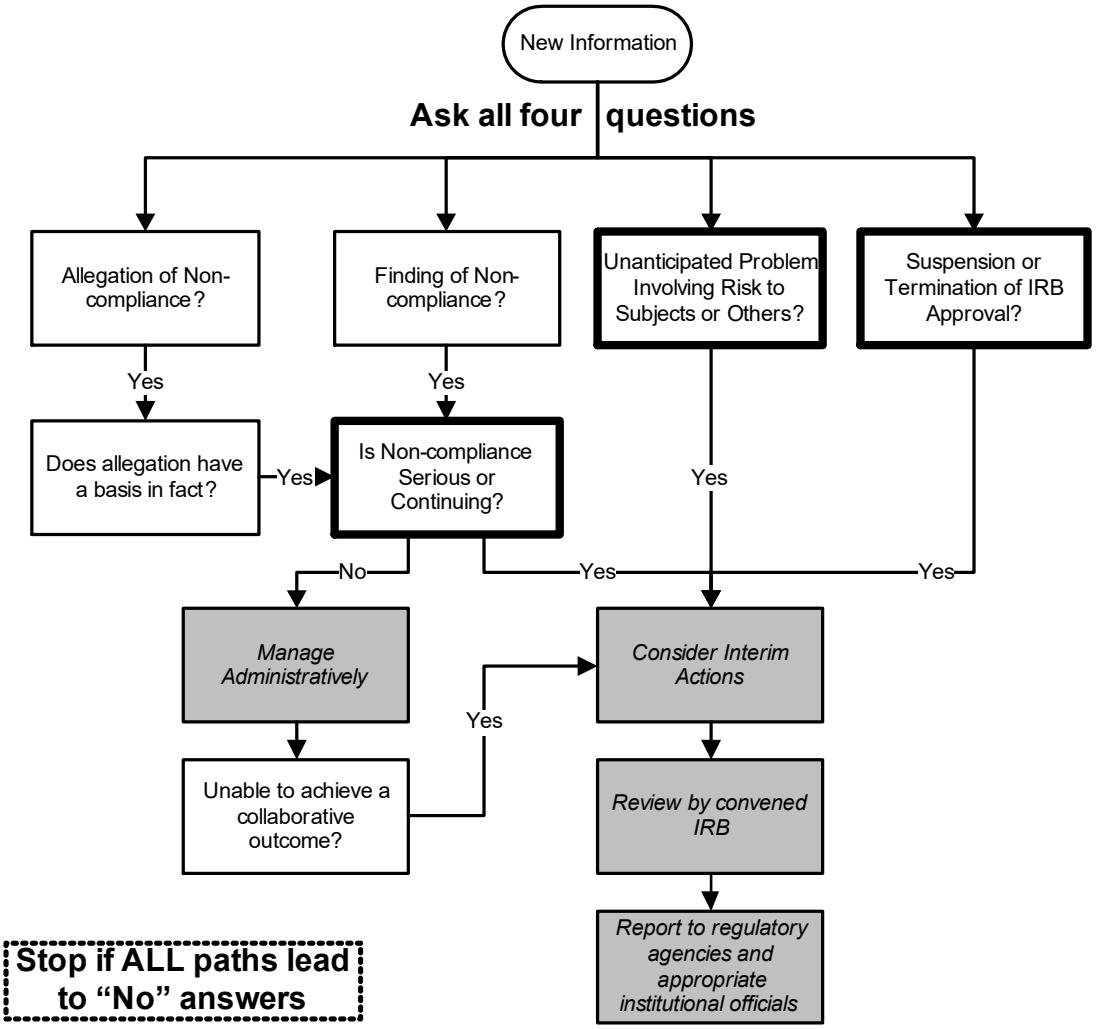
6 MATERIALS

6.1 HRP-025 - SOP – Investigations
6.2 HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
6.3 HRP-052 - SOP - Post-Review
6.4 HRP-529 - LETTER - AAHRPP Notice of Information Item

7 REFERENCES

7.1 21 CFR §56.108(b)
7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
7.3 AAHRPP elements I.5.A, I.5.D, I-9, II.2.D, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.4.A, III.2.D

7.4 Flowchart



UMass Chan MEDICAL SCHOOL

SOP: Investigations				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-025	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to conduct investigations.
1.2 The process begins when the IRB staff members and chair cannot answer a question required by HRP-024 - SOP - New Information.
1.3 The process ends when the investigation is complete and the answer has been provided to the Institutional Official/Organizational Official (IO/OO) or designee.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The IO/OO or designee:
4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
4.1.2 Appoints a chair of the investigative committee.
4.1.3 Charges the investigative committee with the question to be answered.
4.2 The investigative committee carries out these procedures within 60 days.
4.3 Investigative committee members make their decisions based on a preponderance of the evidence.
4.4 Investigative committee decisions are made by majority vote.
4.5 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

5 PROCEDURE

5.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.
5.2 Determine what information to gather and what individuals to interview.
5.3 Gather information and interview individuals.
5.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request a court stenographer to record all interviews.
5.5 Repeat information gathering and interviews until a decision can be made.
5.6 The investigative committee provides a written report of the investigative committee's decision to the IO/OO or designee.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

7 REFERENCES

7.1 AAHRPP elements I.5.D, I-9, II.2.G

UMass Chan MEDICAL SCHOOL

SOP: Suspension or Termination Issued Outside of Convened IRB

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-026	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the Organizational Official / Institutional Official (IO/OO) or designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.

1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The IRB chair, IRB Vice Chair, or Director of IRB Operations may institute a Suspension of IRB Approval when in the opinion of the IRB chair or Director of IRB Operations subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.

3.2 The IO/OO, Chief Research Officer, or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.

3.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.

4 RESPONSIBILITIES

4.1 The individual instituting a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE

5.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.

5.2 Ask the investigator for a list of Human Subjects currently involved in the research.

5.3 Ask the investigator whether any actions are required to protect those subjects' rights and welfare or to eliminate an apparent immediate hazard.

5.4 Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:

- 5.4.1 Transferring subjects to another investigator.
- 5.4.2 Making arrangements for clinical care outside the research.
- 5.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.
- 5.4.4 Requiring or permitting follow-up of subjects for safety reasons.
- 5.4.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
- 5.4.6 Notification to current Human Subjects.
- 5.4.7 Notification to former Human Subjects.

5.5 Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow HRP-041 - SOP - IRB Meeting Conduct for convened IRB review of the item.

5.6 Complete and send to the investigator HRP-515 - LETTER - Suspension or Termination.

6 MATERIALS

6.1 HRP-041 - SOP - IRB Meeting Conduct

6.2 HRP-515 - LETTER - Suspension or Termination

7 REFERENCES

7.1 21 CFR §56.108(b)(3), 21 CFR §56.113
7.2 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113
7.3 AAHRPP elements I-9, II.2.D, II.2.G, II.2.H

UMass Chan MEDICAL SCHOOL

SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Post-Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-027	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to communicate the review of:
- 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
- 1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
- 1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.

1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 IRB staff carry out these procedures.

5 PROCEDURE

5.1 For emergency use of a drug, biologic, or device in a life-threatening situation:
- 5.1.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:
  - 5.1.1.1 Complete HRP-570 - LETTER - Pre-Rev EU - Crit Met and send to the physician.
  - 5.1.1.2 Set a 5-day deadline for receipt of the 5-day report.
- 5.1.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete HRP-571 - LETTER - Pre-Rev EU - Crit Not Met and send to the physician.
- 5.1.3 If the Designated Reviewer has indicated that the actual use described in the 5-day report followed FDA regulations, complete HRP-572 - LETTER - Review of EU - Crit Met and send to the physician.
- 5.1.4 If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:
  - 5.1.4.1 Complete HRP-573 - LETTER - Review of EU - Crit Not Met and send to the physician.
  - 5.1.4.2 Manage under HRP-024 - SOP - New Information as Non-Compliance.

5.2 For compassionate use of a device, complete HRP-574 - LETTER - Device Compassionate Use.

5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-570 - LETTER - Pre-Rev EU - Crit Met

6.3 HRP-571 - LETTER - Pre-Rev EU - Crit Not Met

6.4 HRP-572 - LETTER - Review of EU - Crit Met
6.5 HRP-573 - LETTER - Review of EU - Crit Not Met
6.6 HRP-574 - LETTER - Device Compassionate Use
6.7 HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
7.2 21 CFR §812.36; 21 CFR §812.47.
7.3 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.
7.4 AAHRPP element I.7.C

1 PURPOSE

1.1 This procedure establishes the process for an IRB chair to designate IRB members who can conduct Non-Committee Reviews.

1.2 The process begins when the IRB chair instructs IRB staff to designate an Experienced IRB Member to conduct Non-Committee Reviews.

1.3 The process ends when the IRB member has been noted in the IRB roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.

5.2 Review list of IRB members designated to conduct Non-Committee Reviews in the “Assign Designated Reviewer” activity.

5.3 Verify that the IRB member is an Experienced IRB Member.

5.4 Update HRP-601 - DATABASE - IRB Roster to indicate that the IRB member is a Designated Reviewer.

5.5 Use the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).

7.3 AAHRPP elements I.1.A, I-9, II.2.A, II.2.B, II.2.D, II.2.F-II.2.F.3

UMass Chan MEDICAL SCHOOL	SOP: Non-Committee Review Preparation			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-031	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to prepare for a Non-Committee Review.

1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.

1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1.1 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer.

5.1.2 If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened IRB would result in a more timely review, schedule the protocol to be reviewed by the convened IRB.

5.1.3 Execute the “Assign Designated Reviewer” activity

5.2 Execute the “Assign Designated Reviewer” activity to send to the Designated Reviewer within three business days of receipt of a complete submission.

6 MATERIALS

6.1 HRP-301 - WORKSHEET - Review Materials

6.2 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)

7.3 7.3 AAHRPP elements I.1.A, I.1.F, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3

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SOP: Non-Committee Review Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
1.2 The process begins when the Designated Reviewer has the provided materials.
1.3 The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The Designated Reviewer may not disapprove research.
3.2 The Designated Reviewer utilizes all applicable worksheets in the review of research.
3.3 All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.
3.4 All applicable criteria for approval in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent when appropriate).

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Consider whether you have a Conflicting Interest. If not:
- 5.1.1 Review all materials.
- 5.1.2 Determine the required level of review:
  - 5.1.2.1 Not Human Research,
  - 5.1.2.2 Human Research not Engaged,
  - 5.1.2.3 Exempt Human Research (including exempt Human Research that requires Limited IRB Review),
  - 5.1.2.4 Human Research approved using the expedited procedure, or
  - 5.1.2.5 Human Research that requires review by a convened IRB.
- 5.1.3 If consultation is needed follow HRP-051 - SOP - Consultation.
- 5.1.4 Execute the “Submit Designated Review” activity.
- 5.1.5 Return all materials and completed checklists to the IRB staff within 5 business days of receipt of materials.
- 5.1.6 Destroy any temporary copies of materials.

6 MATERIALS

6.1 HRP-051 - SOP – Consultation
6.2 HRP-312 - WORKSHEET - Exemption Determination
6.3 HRP-314 - WORKSHEET - Criteria for Approval
6.4 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

7 REFERENCES

7.1 21 CFR §56.110(b).
7.2 45 CFR §46.110(b).
7.3 AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.2.A-C, II.2.F-II.2.F.3, II.5.A

UMass Chan MEDICAL SCHOOL

SOP: IRB Meeting Preparation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting.
1.2 The process begins when the agenda is closed, approximately seven days before a meeting date.
1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The IRB does not place limits on the number of items on the agenda.
3.2 At least one IRB member or consultant is responsible for scientific/scholarly review of research.
3.3 Protocols are reviewed by IRB members and consultants with sufficient expertise.
3.4 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
3.5 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
3.6 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.
3.7 Review materials are provided to all IRB members at least 7 days before convened meetings unless an exception is approved by the IRB Director, IRB Chair, or Meeting Chair.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
5.2 Consult HRP-601 - DATABASE - IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.
5.3 Review all submissions placed on the agenda for a convened IRB meeting.
5.4 Prepare an agenda for the meeting.
- 5.4.1 Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer to each agenda item.
- 5.4.2 Ensure that at least one IRB member who has scientific/scholarly expertise in the area of research will use “HRP-320 – WORKSHEET – Scientific or Scholarly Review” and be present for each agenda item. The primary reviewer and scientific/scholarly reviewer may be the same individual.
- 5.4.3 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in HRP-001 - SOP - Definitions. If so, assign another scientific/scholarly reviewer.

5.5 Use HRP-305 - WORKSHEET - Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.
- 5.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.
- 5.5.2 Follow the procedures in HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.

5.6 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

5.6.1 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.

6 MATERIALS

6.1 HRP-001 - SOP – Definitions
6.2 HRP-051 - SOP – Consultation
6.3 HRP-305 - WORKSHEET - Quorum and Expertise
6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.108(b)
7.2 21 CFR §56.108(b)
7.3 AAHRPP elements I.1.F, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2

1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.
1.2 The process begins when the IRB members gather for a convened meeting.
1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
3.2 The Meeting Chair votes as a regular member.
3.3 Meetings are conducted in person or via teleconference.
3.4 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest.
3.5 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
3.6 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
3.7 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
3.8 The worksheets and checklists described in HRP-301 - WORKSHEET - Review Materials and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.

4 RESPONSIBILITIES

4.1 The Meeting Chair carries out these procedures, unless otherwise noted.
4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE

5.1 Call the meeting to order.
5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
5.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.
5.4 For each agenda item:
  5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Quorum and Expertise are not met.[1]
  5.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.
5.5 For each agenda item involving the initial review, modification or continuing review of a protocol:

[1] “Tabled” is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.

5.5.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.

5.5.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

5.5.3 Have the individual(s) with scientific/scholarly expertise discuss the scientific or scholarly review.

5.5.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in HRP-314 - WORKSHEET - Criteria for Approval and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

5.5.5 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

5.5.6 Make a motion for one of the following actions:

5.5.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

5.5.6.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes

5.5.6.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.

5.5.6.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.6.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.7 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.5.7.1 Ensure that the required modifications include all final contingencies in the Pre-Review activity.

5.5.7.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

5.6 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

5.6.1 Have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.6.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.6.3 Make a motion for the IRB's determination(s) regarding the action items (e.g. the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

5.6.4 Open the floor for additional discussion.

5.6.5 Call for a vote.

5.6.5.1 Only IRB members may vote.

5.6.5.2 If a member and an alternate are both present, only one may vote.

5.6.5.3 Consultants may not vote.

5.6.5.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively. A tie vote for a motion of Approve or Modifications Required to Secure Approval is considered to be an IRB decision of Defer.)

5.6.6 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.6.7 Provide any written information provided by a member or consultant to the IRB staff.

5.7 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation
6.2 HRP-301 - WORKSHEET - Review Materials
6.3 HRP-305 - WORKSHEET - Quorum and Expertise
6.4 HRP-308 - WORKSHEET - Pre-Review
6.5 HRP-314 - WORKSHEET - Criteria for Approval
6.6 HRP-315 - WORKSHEET – Advertisements
6.7 HRP-316 - WORKSHEET – Payments
6.8 HRP-317 - WORKSHEET - Short Form of Consent Documentation
6.9 HRP-318 - WORKSHEET - Additional Federal Agency Criteria
6.10 HRP-321 - WORKSHEET - Review of Information Items
6.11 HRP-323 - WORKSHEET - Criteria for Approval HUD
6.12 HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
6.13 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
6.14 HRP-412 - CHECKLIST - Pregnant Women
6.15 HRP-413 - CHECKLIST - Non-Viable Neonates
6.16 HRP-414 - CHECKLIST - Neonates of Uncertain Viability
6.17 HRP-415 - CHECKLIST - Prisoners
6.18 HRP-416 - CHECKLIST - Children
6.19 HRP-417 - CHECKLIST - Cognitively Impaired Adults
6.20 HRP-418 - CHECKLIST - Non-Significant Risk Device
6.21 HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

7 REFERENCES

7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
7.2 45 CFR §46.109, §46.116, §46.117.
7.3 AAHRPP elements I.1.F, I.5.A, I.5.D, I.6.B, I.7.A, I-9, II.1.B, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3

UMass Chan MEDICAL SCHOOL

SOP: IRB Meeting Attendance Monitoring				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-042	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.
1.2 The process begins when the IRB staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.
1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 At meetings consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is appropriately convened.
5.2 Before each protocol consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “EXPERTISE REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.
5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting continues to be appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately convened.

6 MATERIALS

6.1 HRP-305 - WORKSHEET - Quorum and Expertise

7 REFERENCES

7.1 45 CFR §46.108(b)
7.2 21 CFR §56.108(c)
7.3 AAHRPP elements II.1.D, II.1.E, II.2.D

1 PURPOSE

1.1 This procedure establishes the process to record minutes for convened meetings.
1.2 The process begins when the meeting is called to order.
1.3 The process ends when the minutes are approved by the IRB chair, vice chair, meeting chair, or IRB Director.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Minutes are to comply with regulatory and guidance requirements.
3.2 Minutes are to record separate deliberations for each action.
3.3 Minutes are officially approved on behalf of the IRB by the IRB chair, vice chair, meeting chair, or IRB Director.
3.4 IRB members may make corrections to minutes.
3.5 The IRB writes minutes and makes them available for review within 21 days of the meeting date. Minutes are made available to the
  3.5.1 Institutional Official/ Organizational Official (IO/OO)
  3.5.2 Director, Clinical Research Operations
  3.5.3 Quality Improvement Manager
3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.A note to file and associated corrections may be added if errors in the minutes are identified through internal quality control mechanisms.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Execute the “Convene Meeting” activity
5.2 Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table”)
  5.2.1 Name.
  5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, prisoner representative, or alternate member.
  5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
  5.2.4 Whether the member was present by teleconference.
5.3 Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count.
5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the HRP-601 - DATABASE - IRB Roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the HRP-601 - DATABASE - IRB Roster, then 11/2=5.5 and the next whole number is 6.
5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.
5.6 Record the meeting start time.
5.7 For each submission reviewed record in the “Submit Committee Review” activity or “Submit RNI Committee Review” activity, as appropriate:

5.7.1 Motion: Approved, Modifications Required to Secure Approval, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.

5.7.2 Risk Level: Minimal Risk or more than Minimal Risk.

5.7.3 Last Day of Approval Period: Record the study expiration date.

5.7.4 Recommended Changes and Reasons: If the motion is Modifications Required to Secure Approval or deferral/disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate "None."

5.7.5 Controverted Issues and their Resolutions: Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was none. If no controverted issues, indicate "None."

5.7.6 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, enter "See attached Supporting Documents" and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate "None."

5.7.7 RNI Determinations: Record the determination of unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.

5.7.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.

5.7.9 Additional Information and Notes: At the discretion of IRB staff, note information useful to understand the agenda item. For example, a brief history of prior IRB actions

5.7.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.

5.7.11 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.

- 5.7.11.1 For: Voting for the motion.
- 5.7.11.2 Against: Voting against the motion.
- 5.7.11.3 Abstain: Present for the vote, but not voting "For" or "Against."
- 5.7.11.4 Absent: Listed under "Members Present" but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: "For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0"
- 5.7.11.5 Recused: Listed under "Members Present" but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: "For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0"
- 5.7.11.6 Substitutions: Listed under "Members Present" When regular members and their alternate(s) are listed under "Members Present" and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: "For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)"

5.7.12 For an Unanticipated Problem Involving Risks to Subjects or Others, in the "Submit RNI Committee Review," document the IRB's determination as to whether a protocol or consent document modification is warranted, and if so, document the IRB's determination as to whether previously enrolled subjects must be notified of the modification and, if so, when such notification must take place and how such notification must be documented.

5.8 Record the meeting end time.

5.9 Execute the "Prepare Minutes" activity and combine the attendee information with the generated submission-specific determinations.

5.10 Within 2-4 business days revise minutes for accuracy and notify the IRB chair, vice chair, meeting chair, or IRB Director for review and approval.

5.11 Once approved by the IRB chair or IRB manager, execute the "Close Meeting" activity and email minutes to IRB Members.

5.12 IRB members have 7 days to review the minutes. If no comments or revisions are received within 7 days, the minutes will be considered accepted.

5.13 Attach the following documents to the meeting workspace:

5.13.1 List of protocols granted approval using the expedited procedure.

5.14 Execute the "Approve Minutes" activity.

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)

7.3 AAHRPP elements I-9, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.5.B

1 PURPOSE

1.1 This procedure establishes the process for the organization to review research that is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved.

1.2 This process begins when the IRB determines that research involving children, pregnant women, or fetuses as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects' health or welfare.

1.3 The process ends when the Institutional Official/ Organizational Official (IO/OO) or designee communicates a decision to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 When research is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved, this organization will conduct its own review that parallels the regulatory process.

3.2 The criteria used to make a determination are:

3.2.1 That the research in fact satisfies the conditions of IRB approvable research in HRP-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST - Children, or HRP-412 - CHECKLIST - Pregnant Women.

3.2.2 All of the following criteria are met:

3.2.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women, fetuses or neonates.

3.2.2.2 The research will be conducted in accordance with sound ethical principles;

3.2.2.3 Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by HRP-314 - WORKSHEET - Criteria for Approval, HRP-413 - CHECKLIST - Non-Viable Neonates, HRP-414 - CHECKLIST - Neonates of Uncertain Viability, or HRP-416 - CHECKLIST – Children.

4 RESPONSIBILITIES

4.1 The IO/OO or designee carries out these procedures.

5 PROCEDURE

5.1 Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.

5.2 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.

5.3 Inform potential experts that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.

5.4 Publish in a form accessible to the public:

5.4.1 A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.

5.4.2 The date and location of the expert panel meeting (to be held a minimum of 30 days after the notice is posted).

5.4.3 Indicate that the panel meeting will be open to the public and that the public will be given an opportunity to comment at the panel meeting.

5.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting to be considered by the panelists (which will allow the public 21 days to comment on posted materials).

5.4.5 Indication that the panelists' reports/recommendations (see below) will be posted 14 days after the panel meets.

5.4.6 Invite comments for up to 30 days after the meeting of the convened panel for review and consideration by the panel.

5.5 Open the meeting to the public.

5.6 After the convened panel discussion occurs and public comments are received, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

5.7 Post panel reports on the organization's website for informational purposes for 30 days after the panel meeting.

5.8 Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:

5.8.1 The organization approves support of the research as submitted;

5.8.2 The organization approves support of the research, but with required and/or recommended modifications; or

5.8.3 The organization disapproves support of the research.

5.9 Inform the IRB and the investigator.

5.10 Post the decision on the organization's Website.

6 MATERIALS

6.1 HRP-314 - WORKSHEET - Criteria for Approval

6.2 HRP-412 - CHECKLIST - Pregnant Women

6.3 HRP-413 - CHECKLIST - Non-Viable Neonates

6.4 HRP-414 - CHECKLIST - Neonates of Uncertain Viability

6.5 HRP-416 - CHECKLIST - Children

7 REFERENCES

7.1 45 CFR §46.207, 45 CFR §46.407

7.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 AHRPP elements I.1.D, II.1.D, II.2.E-II.2.E.2, II.4.A

UMass Chan MEDICAL SCHOOL	SOP: Conflicting Interests of IRB Members			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-050	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.
1.2 The process begins when an IRB member is asked to review an IRB submission.
1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

4.1 IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

5.1 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.
5.2 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.
5.3 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.
5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 21 CFR §56.107(e).
7.2 45 CFR §46.107(e).
7.3 https://www.umassmed.edu/officeofmanagement/conflicts-of-interest/
7.4 AAHRPP elements I-9, II.1.D

UMass Chan MEDICAL SCHOOL

SOP: Consultation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-051	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process for the IRB to obtain consultants.
1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.
1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

4 RESPONSIBILITIES

4.1 For review by a convened IRB, IRB staff members carry out these procedures.
4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
  5.1.1 IRB members from other committees
  5.1.2 Other employees of the organization
  5.1.3 External consultants
5.2 Contact the consultant and determine availability for review.
5.3 Determine whether the consultant has a Conflicting Interest as defined in HRP-001 - SOP – Definitions. If so, obtain another consultant.
5.4 Use HRP-301 - WORKSHEET - Review Materials to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
5.5 For review by the convened IRB:
  5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.
  5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.
5.6 For Non-Committee Review:
  5.6.1 Directly obtain the information (oral or written) from the consultant.
  5.6.2 Document information received with the name of the consultant.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions
6.2 HRP-301 - WORKSHEET - Review Materials

7 REFERENCES

7.1 21 CFR §56.107(f)
7.2 45 CFR §46.107(f)
7.3 AAHRPP elements I.1.F, I-9, II.1.D, II.1.E, II.2.E-II.2.E.2

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR

1.2.2 An IRB meeting has adjourned, and the IRB chair or IRB director has approved the minutes; OR

1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB reports its findings and actions to the investigator.

3.2 The IRB reports its findings and actions to the institution.

3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

3.4 Communication of review results to investigators are to be completed within 30 days of the IRB meeting or receipt of the completed Non-Committee Review materials.

3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

3.6 Reporting directly to a regulatory agency is not required if the agency has been notified by alternate mechanisms.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 When a review specialist is logged into the electronic IRB system using a valid username and password, and uses the system to generate correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed by the analyst under the authority of the IRB chair and the IRB director.

5 PROCEDURE

5.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation

5.2 Refer to HRP-302 - WORKSHEET - Approval Intervals to calculate approval intervals (if applicable).

5.3 Execute the “Finalize Documents” to stamp and accept all changes for attached documents.

5.3.1 Execute the “Prepare Letter” activity and modify the letter as needed.

5.3.2 Execute the “Send Letter” activity.

5.4 Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any paper-based letters need to be sent and send all applicable letters within 30 business days.

5.4.1 Refer to HRP-303 - WORKSHEET - Communication of Review Results and send all applicable letters to the Principal Investigator within 5 business days.

5.4.1.1 Have letter signed by the signatory in the template letter.

5.4.1.2 Send the letter to the inside addresses and cc list as directed by the letter.

5.4.2 Use HRP-520 - LETTER - External Report NOT Including OHRP or HRP-526 - External Report to DOD to send to outside agencies within 30 business days from the determination of a reportable problem.

5.4.2.1 When sending to DHHS only, complete the OHRP Incident Report Online Form.[1]

5.4.2.2 If reporting to both DHHS and any other outside agency concurrently, utilize the OHRP Incident Report Form and HRP-520a.

5.4.2.3 If reporting to other outside agencies NOT including DHHS, complete HRP-520 or HRP-526 as appropriate.

5.5 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, execute the "Suspend" activity in the study workspace, and document that the enrollment to the study remains suspended.

5.6 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

5.6.1 Use HRP-520 - LETTER - External Report NOT Including OHRP or HRP-526 – External Report to DOD to send to outside agencies within 30 business days from the determination of a reportable problem.

5.6.2 The following individuals must receive notification:

5.6.2.1 Organizational Official (OO)

5.6.2.2 Sponsor or Contract Research Organization, when the research is sponsored

5.6.2.3 Office responsible for oversight of the grant or contract, when research is funded

5.6.2.4 Legal Counsel

5.6.2.5 Risk Management

5.6.2.6 Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually identifiable information

5.6.2.7 Information Security Officer, when the information involves violations of information security requirements

5.6.2.8 Government agency (e.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting

5.6.2.9 The local research ethics committee or equivalent, when the research is international or collaborative research involving collaboration with a local research ethics committee or equivalent

5.6.2.10 Additional contacts, when required by any relevant agreement

5.6.2.11 Other individuals or organizations, when determined to be appropriate by the IRB Director, IRB Chair, or Organizational Official

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation
6.2 HRP-302 - WORKSHEET - Approval Intervals
6.3 HRP-303 - WORKSHEET - Communication of Review Results
6.4 HRP-520 - LETTER - External Report NOT Including OHRP
6.5 HRP-520a - LETTER – External Report OHRP and Other Agencies
6.6 HRP-526 – External Report to DOD

7 REFERENCES

[1] See: https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)

7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 AAHRPP elements I.1.A, I.5.D, I-9, II.1.D, II.1.E, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, III.2.D

UMass Chan MEDICAL SCHOOL

SOP: Institutional Conflicts of Interest

Document No.:	Effective Date:	Page:
HRP-054	06/21/202210/12/2021	Page 1 of 1

1. PURPOSE

1.1. This procedure establishes the process to evaluate and manage financial interests of the [Organization].
1.2. This procedure begins when the [Organization] identifies an organizational financial interest that can affect the conduct of research.
1.3. This procedure ends when the HRPP staff members have been provided an updated list of the [Organization]'s financial interests.

2. POLICY

2.1. An organizational financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:

2.1.1. Licensing, technology transfer, patents
2.1.2. Investments of the [Organization]
2.1.3. Gifts to the [Organization] when the donor has an interest in the research
2.1.4. Financial interests of senior administrators
2.1.5. Other financial interests

2.2. Senior administrators are required to disclose their financial interests to the [Conflict of Interests Officer]:

2.2.1. Upon joining the [Organization]
2.2.2. Every year
2.2.3. When there are changes to financial interests

2.3. The [Organization] considers investments under the control of independent investment managers (e.g., endowment) to be equivalent to diversified mutual funds and therefore not subject to disclosure under this policy.
2.4. Organizational officials are to disclose any change in the [Organization]'s financial holdings not controlled by the [Organization]'s investment managers.
2.5. The evaluation and management of an organizational conflict of interest may not vary by funding or regulatory oversight.

3. RESPONSIBILITY

3.1. The [Conflicts of Interests Officer] carries out these procedures.

4. PROCEDURE

4.1. Update the list of investments with information about the name of the company, the names of related companies, and affected products or services.
4.2. Provide the updated list to the HRPP staff member handling the list of investments.

5. REFERENCES

5.1. 42 CFR §50
5.2. 45 CFR §94
5.3. AAHRPP elements I.6.A, I-9

1. PURPOSE

1.1. This procedure establishes the process to evaluate and manage individual and institutional financial interests Related to the Research.
1.2. This procedure begins when an IRB submission includes a disclosure of a financial interest that has not been evaluated under "UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL POLICY FOR PROMOTING OBJECTIVITY IN BIOMEDICAL RESEARCH":
1.3. This procedure ends when the [Organization] decides that the financial interest is not a conflict of interest, or informs the IRB of the management plan.

2. POLICY

2.1. The document "UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL POLICY FOR PROMOTING OBJECTIVITY IN BIOMEDICAL RESEARCH":

2.1.1. Describes when individuals are considered to have an institutional responsibility
2.1.2. Describes when individuals subject to this policy are required to complete financial conflicts of interest training
2.1.3. Defines "Significant Financial Interest"
2.1.4. Describes actions that can be taken in response to violations of this policy or proscribed management plans
2.1.5. Describes retention requirements for records related to disclosures and management of financial conflicts of interest

2.2. The financial disclosure threshold for Human Research does not vary by funding or regulatory oversight.
2.3. The IRB has the authority to decide whether a financial interest and its management, if any, allow the research to meet criteria for approval.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures.

4. PROCEDURE

4.1. Stop review of the submission.
4.2. Refer individual financial interests to the UMass Chan Committee on Oversight of Individual Financial Conflicts of Interest in Research with Human Subjects.
4.3. Refer institutional financial interests to the UMass Chan Committee on Oversight of Institutional Financial Conflicts of Interest in Research with Human Subjects.
4.4. Once the campus committee review is completed, the IRB is provided with the written report and review of the submission resumes. When the UMass system-wide COI committee review is additionally required, IRB approval will occur after review and receipt of the final letter of determination from the Chair of the UMass COI Systems Committee.

5. REFERENCES

5.1. 42 CFR §50
5.2. 45 CFR §94
5.3. HRP-380 – WORKSHEET – Financial Interest Management
5.4. AAHRPP elements I.6.A, I.6.B, I.7.A

1. PURPOSE

1.1. This procedure establishes the process to conduct periodic evaluations related to the HRPP.
1.2. This procedure will occur at least once yearly.
1.3. This procedure ends when evaluations and corrective actions are completed.

2. POLICY

2.1. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making “BROCHURE: Should I Take Part in Research (HRP-104)” available to the public.

3. RESPONSIBILITY

3.1. The [Organizational Official] delegates individuals to carry out these procedures.

4. PROCEDURE

4.1. Evaluate, in consultation with the [IRB Executive Chair] and [HRPP Administrator] as appropriate:

4.1.1. General performance of the HRPP, such as:

4.1.1.1. Feedback from investigators, research staff, sponsors, and subjects
4.1.1.2. Subject outreach plan per SOP: Community Outreach and Engagement.
4.1.1.3. Results of regulatory audits
4.1.1.4. Results of continuous improvement activities
4.1.1.5. New requirements
4.1.1.6. Compliance with policies and procedures
4.1.1.7. Compliance with regulatory requirements
4.1.1.8. Status of action items from previous reviews

4.1.2. HRPP resources for:

4.1.2.1. Space
4.1.2.2. Personnel
4.1.2.3. HRPP educational program
4.1.2.4. Legal counsel
4.1.2.5. Conflicts of interests
4.1.2.6. Quality improvement

4.1.3. Number of IRBs relative to the volume and types of research reviewed
4.1.4. The composition of IRBs relative to “WORKSHEET: IRB Composition (HRP-304)”
4.1.5. Completion of training by IRB members, chairs, vice-chairs, and staff
4.1.6. Evaluate the knowledge and performance of each IRB member, chair, vice-chair, and staff

4.1.6.1. Consult with the [IRB Executive Chair] on the performance of IRB members and staff members.

4.1.6.1.1. Periodicity:

4.1.6.1.1.1. The IRB Chair and Co-Chair and IRB staff will be evaluated yearly.
4.1.6.1.1.2. IRB members will be evaluated one year after an IRB member has been appointed to a committee and two years after that

4.1.6.1.2. Obtain updated résumés or curricula vitae from each IRB member and IRB staff member.
4.1.6.1.3. Send the appropriate IRB member the self evaluation.
4.1.6.1.4. Member of the IRB will meet with the Chair or Vice Chair and complete a formative evaluation.
4.1.6.1.5. Provide each individual with a summary of the individual's evaluation

4.1.7. Whether IRB members, IRB chairs, IRB vice-chairs, and HRPP staff members have completed required training
4.1.8. The effectiveness of the subject outreach plan
4.1.9. The HRPP's emergency preparedness plan

4.2. A copy of the evaluation will be given to the [Organizational Official].

4.3. Take actions as needed to:

4.3.1. Reallocate, add, or modify HRPP resources
4.3.2. Modify the number of IRBs
4.3.3. Modify the composition of IRBs
4.3.4. Remove individuals with persistent knowledge and performance gaps
4.3.5. Correct knowledge and performance gaps of individuals
4.3.6. Arrange for individuals to take missing training
4.3.7. Modify the subject outreach plan
4.3.8. Modify policies and procedures
4.3.9. Modify the emergency preparedness plan
4.3.10. Provide additional training or modify existing activities, and

4.4. Update IRB registrations at http://ohrp.cit.nih.gov/efile/.
4.5. Update organizational registrations more than four years old at http://ohrp.cit.nih.gov/efile/FwaRenew.aspx.

5. REFERENCES

5.1. 21 CFR §56.106 and §56.107
5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E
5.3. AAHRPP elements I.1.A, I-2, I.4.B, II.1.A-D

SOP: Human Research Protection Program Quality Assurance/Quality Improvement Program

NUMBER	DATE	AUTHOR	APPROVED BY
HRP-061	10/12/2021	M. Johnson	K. Luzuriaga

1. PURPOSE

1.1 This Standard Operating Procedure defines the Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement function at the University of Massachusetts Medical School.

2. REVISIONS FROM PREVIOUS VERSION

2.1 None

3. AUTHORITY AND SCOPE

3.1 Under the general authority of the University of Massachusetts Medical School Human Research Protection Program (HRPP) [HRP-101], the Quality Assurance/Quality Improvement (QA/QI) Program is overseen by the Director, Office of Clinical Research and the Quality Improvement Manager, Center for Clinical and Translational Science (CCTS). The HRPP QA/QI Program includes the following:

3.1.1 **Post Approval Monitoring:** Conducted based upon selection of the Quality Improvement Manager or at the request of the IRB, Organizational Official, Institutional Official or Director, Office of Clinical Research. Circumstances where Post Approval Monitoring may occur include, but are not limited to;

- Monthly selection of active human research studies with enrolled participants;
- Investigator Initiated Studies;
- Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;
- Re-assessment of studies previously reviewed to evaluate adherence to corrective action plans and ongoing compliance; or
- Studies assessed by the IRB to include a high degree of risk (adverse events, type of study, or vulnerable populations);

3.1.2 **Directed or For-Cause Review:** Conducted at the request of the Institutional Review Board (IRB), Organizational Official or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:

- As part of an ongoing corrective action;
- To support a review associated with an RNI or IRB's assessment of potential noncompliance, and/or;
- When there are concerns regarding whether the rights and welfare of participants enrolled in research are adequately protected.

3.1.3 **Voluntary Reviews:** Conducted upon request of Principal Investigator to support self-assessment and improvement efforts by Investigator and Study Team.

3.1.4 **IRB Minutes Review:** Conducted quarterly to assure compliance and support the operations of the IRB.

3.1.5 **Human Research Protection Program Quality Improvement:** Conducted quarterly to track and improve overall satisfaction and institutional compliance with human research protection program requirements.

4. RESPONSIBILITIES

4.1 The Quality Improvement Manager, CCTS (QIM) is responsible for ensuring these procedures are carried out.

5. PROCEDURE

5.1 Post Approval Monitoring:

5.1.1 Selection and Scheduling:

5.1.1.1 The Quality Improvement Manager, CCTS (QIM) selects studies as follows:

5.1.1.1.1 Through QIM selection via review of a report from the IRB of 1) active studies (exempt, expedited/non-committee and full committee review) 2) with a consent form (not waiver of consent) and 3) with reported enrollment, and selects 6-10 studies to review for the upcoming month; or

5.1.1.1.2 Through request by the IRB, Organizational Official, Institutional Official or Director, Office of Clinical Research to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

5.1.1.2 The QIM contacts the Principal Investigator and Study Coordinator (by phone or email) to:

5.1.1.3 Schedule the review in a timely manner;

5.1.1.4 Provide an overview of the scope, process and required workspace needed for the review; and

5.1.1.5 Provide a copy of the Quality Improvement Review Checklist to be used for review to the Investigator and Study Coordinator.

5.1.2 Review Procedures:

5.1.2.1 In advance of the review visit, the QIM reviews the protocol information on file with the IRB;

5.1.2.2 On the day of the review, the QIM will meet with the Investigator and designated study staff at the open and close of the review if possible. The investigator will arrange for a private work area for the conduct of the review. At a minimum, designated study staff should make themselves available for documentation retrieval, answer any questions or provide clarification as may be needed;

5.1.2.3 The investigator will provide the following study files (as applicable) for the QIM's review:

5.1.2.3.1 All study related regulatory documents;

5.1.2.3.2 Subject screening/enrollment log;

5.1.2.3.3 Case report forms;

5.1.2.3.4 Source documents;

5.1.2.3.5 Informed consents, assents and HIPAA for all enrolled and screened participants

5.1.2.3.6 Study drug accountability logs (to be reviewed in the Investigational Pharmacy, as applicable);

5.1.2.3.7 Device accountability logs (as applicable);

5.1.2.3.8 Lab logs (as applicable);

5.1.2.3.9 Other documents/files as requested that support the study administration;

5.1.2.4 Research records are expected to be maintained by study team in a review-ready state at all times. Study team will have an opportunity to locate and provide materials or documentation not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

5.1.3 Findings

5.1.3.1 Finding types may include, but are not limited to:

5.1.3.1.1 No further action necessary;

5.1.3.1.2 Minor administrative issue (non-Reportable New Information) with best practice recommendation for corrective action;

5.1.3.1.3 Reportable New Information finding with best practice recommendation for corrective action.

5.1.3.1.4 Major finding indicating potential scientific misconduct and/or harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by QI Manager to the Director of Clinical Research, Organizational Official, Institutional Official, IRB Chair and IRB Director.

5.1.3.1.5 Potential misconduct will also be reported to the Research Integrity Officer for UMass Chan Medical School in accordance with the University of Massachusetts Medical Center Policy for Responding to Allegations of Scientific Misconduct.

5.1.4 Documentation and Distribution of Findings

5.1.4.1 QIM uses the Quality Improvement Review Checklist to document observations, findings and any concerns.

5.1.4.2 At the conclusion of the review, the QIM verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations and next steps.

5.1.4.3 The QIM generates a written report of findings and recommendations. The written report of findings is shared with the PI, designated study team and Director, Office of Clinical Research.

5.1.4.4 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing, to the QIM. The QIM will add the provided information as an appendix to the report.

5.1.4.5 The QIM may monitor submission of Reportable New Information reports as recommended in the review findings. If a Reportable New Information is not submitted as recommended, the QIM may send reminder and timeframe for completion to study team. If the study team has not completed follow up with in timeframe specified for Reportable New Information in HRP-214) and Investigator Manual HRP-103, *What are my obligations after IRB approval*; QIM may directly report findings to IRB Chair and IRB Director.

5.1.4.6 Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.

5.2 Directed or For Cause Review

5.2.1 Selection and Scheduling

5.2.1.1 The IRB Chair, Organizational Official or the Institutional Official ("Requestor") may request a directed or for-cause review.

5.2.1.2 The Requestor will notify the investigator of a directed or for-cause review by official notification to the investigator with a cc to the QI Manager. This request will include the scope, timing, scheduling process and next steps including distribution of audit findings.

5.2.1.2.1 The QIM may contact Requestor to seek additional clarification from the Requestor to ensure the requested audit is appropriately responsive.

5.2.1.3 Unless directed to contact investigator sooner, the QIM will contact investigator by the next business day following receipt of the audit request to schedule the review and will work with investigator and study team to schedule review within the timeline established by the requestor.

5.2.1.3.1 If scheduling and/or completion of audit will not be possible within the established timeframe due to circumstances beyond the investigator's control, the QIM will notify the Requestor and request additional guidance.

5.2.1.3.2 As research records are expected to be maintained in an audit-ready state at all times, time needed for record preparation is not an acceptable reason to request delay.

5.2.2 Review Procedures

5.2.2.1 Review procedures will follow those outlined in 5.1.2, above

5.2.2.2 In circumstances where there is concern over integrity of records, the HRPP QA/QI staff will seek guidance from the Research Integrity Office

5.2.3 Documentation and Distribution of Findings

5.2.3.1 The report and associated findings are shared with the Requestor, IRB Chair, IRB Director, and the Director, Office of Clinical Research. The findings are also cc'd to the Investigator.

5.2.3.2 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing, to the QIM. The QIM will add the provided information as an appendix to the report and re-distribute.

5.3 Voluntary Reviews

5.3.1 The QIM makes the "Investigator Self-Assessment (HRP-901)" and "Investigator Self-Assessment Instructions (HRP-902)" available to investigators and study teams;

5.3.2 The Principal Investigator, or study team member with Principal Investigator's support, may ask for a voluntary review/assistive review by the QIM.

5.3.2.1 The review procedures will follow those outlined in 5.1.2, above.

5.4 IRB Minutes Reviews

5.4.1 Within [5] business days of meeting minutes completion by IRB staff, the QIM or designee reviews the IRB minutes for compliance with HRP-043 [IRB Meeting Minutes];

5.4.2 The QIM uses the IRB Minutes Review Checklist to guide and document the review;

5.4.3 The QIM prepares a report of findings, if any, and meets with the IRB Manager or designee to debrief on findings;

5.4.4 The IRB Manager or designee develops a corrective action plan based on the findings or provides clarification to findings, and communicates the findings and corrective action plan as appropriate.

5.5 Human Research Protection Program Quality Improvement

5.5.1 Routine Monitoring Trends Assessment

5.5.1.1 On a Quarterly basis or as requested by the Organization Official or designees, the QIM will provide a report of general trends and findings from the Routine or Not for Cause reviews to the Director, Office of Clinical Research, Organizational Official, IRB Director, IRB Chair and others as necessary.

5.5.1.2 The QIM and individuals listed in 5.5.1.1 will review the findings and develop corrective and education action plans as necessary.

5.5.1.3 The QIM will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 5.5.1.1.

6. MATERIALS

Clinical Trials Quality Improvement Inspection Checklist
HRP-043 [SOP: IRB Meeting Minutes]
HRP-431 [CHECKLIST: Minutes Quality Improvement Assessment]
HRP-901 [Investigator Self-Assessment]
HRP-902 [Investigator Self-Assessment Instructions]

7. REFERENCES

45 CFR 46.103(b)(5); 45CFR46.109(e); 21CFR56.108(b); 21CFR56.109(f), AAHRPP I.5.A, I.5.B

UMass Chan MEDICAL SCHOOL

SOP: Daily Tasks				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-062	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to complete daily tasks required to monitor the research review process.
1.2 The process begins each day.
1.3 The process ends when the tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 CITI checks its database for individuals whose training will lapse in the next 90 days and sends a reminder.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible for carrying out this procedure.

5 PROCEDURE

5.1 Check for emergency uses where the IRB has not received a report, within 5 days:
- 5.1.1 Complete and send HRP-551 - LETTER - Failure to Submit EU Report.
- 5.1.2 Consider placing the principal investigator on the Restricted list.
- 5.1.3 Process the failure to submit as a Finding of Non-Compliance under HRP-024 - SOP - New Information.

5.2 Check for emergency uses where the IRB has not received a standing protocol for subsequent use within 30 days:
- 5.2.1 Complete and send HRP-551 - LETTER - Failure to Submit EU Report.
- 5.2.2 Consider placing the principal investigator on the Restricted list.
- 5.2.3 Process the failure to submit as a Finding of Non-Compliance under HRP-024 - SOP - New Information.

5.3 Check for individuals whose training has lapsed:
- 5.3.1 Complete and send HRP-554 - LETTER - Failure to Undergo Training.
- 5.3.2 Consider placing the principal investigator on the Restricted list.
- 5.3.3 Process the failure to submit as a Finding of Non-Compliance under HRP-024 - SOP - New Information.
- 5.3.4 If the individual is an IRB member, Follow HRP-083 - SOP - IRB Membership Removal.

6 MATERIALS

6.1 HRP-024 - SOP - New Information
6.2 HRP-083 - SOP - IRB Membership Removal
6.3 HRP-535 - LETTER - Annual Reminder
6.4 HRP-551 - LETTER - Failure to Submit EU Report
6.5 HRP-553 - LETTER - Failure to Submit EU Protocol
6.6 HRP-554 - LETTER - Failure to Undergo Training

7 REFERENCES

7.1 AAHRPP elements I.1.A, I.7.C, II.2.E-II.2.E.2, II.2.F-II.2.F.3

UMass Chan MEDICAL SCHOOL	SOP: Expiration of IRB Approval			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-063	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.

1.2 The process begins when the Designated Reviewer is notified of a request by an investigator of a request for current subjects to continue in expired research.

1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 If continuing research is granted “Modifications Required to Secure Approval” and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

4.1 A Designated Reviewer is responsible to follow these procedures.

5 PROCEDURE

5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.

5.2 Do not allow new subjects to be enrolled under any circumstances.

5.3 Determine which subjects can continue in the research based on these principles:

5.3.1 In general, research procedures should be safely discontinued.

5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.

5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.

5.4 Communicate with the investigator using HRP-532 - LETTER - Conti Subj Expired Research.

6 MATERIALS

6.1 HRP-532 - LETTER - Conti Subj Expired Research

7 REFERENCES

7.1 AAHRPP elements II.2.E-II.2.E.2, II.2.F-II.2.F.3

UMass Chan MEDICAL SCHOOL

SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-064	10/12/2021	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.

1.2 The process begins when an investigator contacts the University of Massachusetts Center for Clinical and Translational Science (UMCCTS) for certification of the genomic data sharing plan.

1.3 The process ends when the Institutional Official/ Organizational Official (IO/OO) has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Investigators must request certification from the UMCCTS prior to investigator submission of large-scale human genomic data or approval of funding.

3.2 Investigators must provide a completed draft of the applicable certification form for UMCCTS review.

4 RESPONSIBILITIES

4.1 The IRB Director or designee verifies for the IO/OO that all data meet criteria for submission to the data repository.

5 PROCEDURE

5.1 Use HRP-332 - WORKSHEET - NIH GDS Institutional Certification to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to a NIH-designated data repository.

5.2 Populate the applicable NIH Extramural Institutional Certification form. Pass the letter to the IO/OO for review and certification.

5.2.1 Provide NIH Provisional Institutional Certification when required by investigators prior to IRB review of the data sharing plan.

5.3 Save a copy of the signed form in UMCCTS records.

5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification form for the investigator to forward to the NIH.

6 MATERIALS

6.1 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

7 REFERENCES

7.1 National Institutes of Health Final Genomic Data Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

7.2 NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) (https://osp.od.nih.gov/wp-content/uploads/PTC_for_IRBs_and_Institutions.pdf)

7.3 NIH Institutional Certification Forms (https://osp.od.nih.gov/scientific-sharing/institutional-certifications/)

7.4 Provisional Institutional Certification (https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf)

1 PURPOSE

1.1 This SOP establishes the process for initiating a response to an emergency/disaster situation impacting the HRPP or HRPP operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from:

1.1.1 Extreme weather events.

1.1.2 Natural disasters.

1.1.3 Man-made disasters.

1.1.4 Infectious disease outbreaks.

1.2 The process starts when an emergency/disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.

1.3 The process ends when the impact to the HRPP and the conduct of Human Research is assessed, and appropriate guidance is provided to HRPP personnel and the broader Human Research community.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 HRPP leadership defers to designated institutional leadership and institution-wide disaster and emergency response planning and limits HRPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans.

3.2 The HRPP evaluates its emergency response plans at least annually in accordance with the HRP-101 - Human Research Protection Program Plan and HRP-060 - SOP - Annual Evaluations of the HRPP.

4 RESPONSIBILITIES

4.1 The IRB Director or designee is responsible for carrying out these procedures

5 PROCEDURE

5.1 If an emergency/disaster has occurred, or there is an imminent possibility of an upcoming emergency/disaster, assess the nature of the event and the appropriate response.

5.1.1 Consult HRP-101 - Human Research Protection Program Plan to reference existing HRPP specific or institution specific emergency preparedness plans or information already in place.

5.1.2 Contact the IO/OO and or designated institutional personnel responsible for institutional level emergency preparedness, and determine whether there are new or revised institution level emergency preparedness plans relevant to the current or anticipated emergency.

5.1.2.1 If yes, proceed in accordance with those plans and determine whether further contact or notification of the human research community is necessary.

5.2 Assess whether the emergency/disaster could impact HRPP operations:

5.2.1 If the current or anticipated emergency/disaster will prevent any upcoming IRB meetings from properly convening in-person, and an in-person meeting was planned, determine whether the meeting can be conducted virtually or via teleconference.

5.2.1.1 If yes, work with IRB members and staff to arrange for a virtual meeting. Follow HRP-040 - SOP - IRB Meeting Preparation to confirm quorum and availability of IRB members.

5.2.1.2 If a virtual meeting is also not feasible under the circumstances caused by the emergency/disaster, determine whether to cancel or reschedule the meeting(s).

5.2.1.3 If currently approved Human Research has or will expire prior to IRB review due to the IRB meeting cancelation/rescheduling, follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2 If IRB staff will be unable to complete their protocol processing and review responsibilities during the emergency/disaster, or if capacity will be limited for a period of time:

5.2.2.1 Work with the staff to use any available capacity to prioritize protocol processing, pre-review, and review of continuing review submissions.

5.2.2.2 If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2.3 Work with the IO/OO to notify the research community of the IRB Office's limited capacity to process and review submissions.

5.2.2.4 When the emergency/disaster no longer presents a limitation to IRB Office functions, work with the IO/OO to notify the IRB members and staff and research community that normal business operations have resumed.

5.2.3 If impact to local HRPP operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.

5.2.3.1 If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO/OO to identify appropriate candidates for external IRB reliance and follow HRP-801 - SOP - Establishing Authorization Agreements.

5.2.4 If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disaster, consult with local IT support and or electronic system vendors to implement alternative procedures to access data/backup data.

5.3 Assess whether the emergency/disaster could necessitate additional flexibility in IRB review processes. If yes:

5.3.1 Review HRP-352 - WORKSHEET - Additional Emergency-Disaster Review Considerations with the IRB Chair(s) and staff in advance of upcoming IRB meetings.

5.3.2 Communicate to IRB Members (including Designated Reviewers performing non-committee reviews) that the additional considerations in the worksheet may be incorporated into IRB reviews where appropriate to maximize regulatory flexibility while continuing to assure research subject safety during the emergency/disaster.

5.3.3 Determine whether additional communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster and notify the community as appropriate.

5.4 Assess whether the emergency/disaster could impact some or all investigators' ability to conduct Human Research. If yes:

5.4.1 Notify the research community of the need for protocol-specific emergency/disaster risk mitigation planning. Use HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan.

5.4.2 Provide investigators with copies of (or links to) HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.3 Provide investigators with copies of (or links to) HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning.

5.4.4 If the emergency/disaster could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarify what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).

5.4.5 When the emergency/disaster no longer presents a limitation to Human Research activities, work with the IO/OO to notify the research community that normal business operations have resumed.

5.5 Evaluate whether the nature of the emergency/disaster may pose additional threats or risk to specific aspects of the institutions research activities or facilities. (For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some chemical. Biological, or radiologic facilities to a greater extent than other facilities.)

5.5.1 If yes, and if broader institution-level emergency/disaster preparedness measures do not already address these specific activities or facilities, work with the IO/OO and appropriate institutional leadership to escalate and address any additional threats or risks.

6 MATERIALS

6.1 HRP-060 - SOP - Annual Evaluations of the HRPP
6.2 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
6.3 HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning
6.4 HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning
6.5 HRP-352 - WORKSHEET - Additional Emergency-Disaster Review
6.6 HRP-542 - LETTER - Implementation of HRPP Emergency-Disaster Response Plan
6.7 HRP-801 - SOP - Establishing Authorization Agreements

7 REFERENCES

7.1 AAHRPP Element I.1.H

1 PURPOSE

1.1 This procedure establishes the process to maintain IRB records.
1.2 The process begins when records are received or created.
1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records are stored in the eIRB system.
3.2 IRB policies and procedures are stored in the eIRB system, on the IRB website, and HRPP shared drive.
3.3 Correspondence not related to a specific protocol are stored on the HRPP shared drive.
3.4 IRB records are to include:
- 3.4.1 Protocol files.
- 3.4.2 Minutes of IRB meetings.
- 3.4.3 Copies of all correspondence between the IRB and the investigators.
- 3.4.4 Current and all previous IRB member rosters.
- 3.4.5 Current and all previous IRB member files.
- 3.4.6 Current and all previous policies and procedures.

3.5 Protocol files are to include, as applicable:
- 3.5.1 All submitted materials.
- 3.5.2 Protocols.
- 3.5.3 Investigator brochures.
- 3.5.4 Scientific evaluations, when provided by an entity other than the IRB.
- 3.5.5 Recruitment materials.
- 3.5.6 Consent documents.
- 3.5.7 DHHS-approved sample consent document and protocol, when they exist.
- 3.5.8 Progress reports submitted by investigators.
- 3.5.9 Reports of injuries to subjects.
- 3.5.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- 3.5.11 Data and safety monitoring board reports.
- 3.5.12 Amendments.
- 3.5.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.5.14 Documentation of non-compliance.
- 3.5.15 Correspondence between the IRB and investigator related to the protocol.
- 3.5.16 Significant new findings and statements about them provided to subjects.
- 3.5.17 For initial and continuing review of research by the expedited procedure:
  - 3.5.17.1 The specific permissible category.
  - 3.5.17.2 Description of action taken by the reviewer.
  - 3.5.17.3 Any findings required under the regulations.
  - 3.5.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.
- 3.5.18 For exemption determinations the specific category of exemption.
- 3.5.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.
  - 3.5.19.1 Waiver or alteration of the consent process.

3.5.19.2 Research involving pregnant women, fetuses, and neonates.
3.5.19.3 Research involving Prisoners.
3.5.19.4 Research involving children.
3.5.19.5 Research involving adults unable to consent.
3.5.19.6 Significant/non-significant device determinations.

3.5.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

3.5.21 The institution will maintain record of all research conducted by the organization reviewed by an external IRB. Records will include all materials identified in section 3.2

3.6 Policies and procedures include:
- 3.6.1 Checklists.
- 3.6.2 Forms.
- 3.6.3 SOPs.
- 3.6.4 Template letters.
- 3.6.5 Template minutes.
- 3.6.6 Worksheets.

3.7 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings are stored in the eIRB system.

5.2 Store all protocol-specific information (communications, documents, determinations) in the eIRB system. Store all corresponding paper legacy files in a secure physical location.

5.3 File correspondence NOT related to a specific protocol in a file related to that person or topic on the shared drive.

5.4 IRB member rosters: File in IRB member roster folder on the shared drive.

5.5 IRB membership records (e.g., curricula vita and resumes): File in IRB member files on the shared drive.

5.6 Policies and procedures:
- 5.6.1 File current policies and procedures in the IRB Library in the electronic system.
- 5.6.2 File replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 7.1 AAHRPP elements I.1.A, I-9, II.5.A

UMass Chan MEDICAL SCHOOL

SOP: Standard Operating Procedures				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-071	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.

1.2 The process begins when the IRB director or Institutional Official/ Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.

1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The IRB director carries out these procedures.

5 PROCEDURE

5.1 For a new standard operating procedure, assign a number.

5.2 Assign an author and approver.

5.3 Have the author create or update the standard operating procedure following HRP-505 - TEMPLATE SOP or update the associated checklist or worksheet.

5.4 Have the approver review and approve the document.

5.5 Once approved by the approver:

5.5.1 Update the approval/effective date.

5.5.2 File and maintain the approved new or revised document in the standard operating procedure files.

5.5.3 Post the approved procedure on the Human Research Protection Program Web site.

5.5.4 File and retain the previous version in the standard operating procedure files.

5.5.5 Send an email to affected individuals informing them of the change.

6 MATERIALS

6.1 HRP-505 - TEMPLATE SOP

7 REFERENCES

7.1 7.1 AAHRPP elements I-9, II.5.A

UMass Chan MEDICAL SCHOOL

SOP: IRB Records Retention				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-072	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.
1.2 The process begins every three months.
1.3 The process ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.
3.2 Protocol files are to be retained as long as required by law and then destroyed.
3.3 All records not in protocol files are retained indefinitely.
3.4 Records may be maintained in printed form or electronically.
3.5 Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.
3.6 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
3.7 Records maintained that document compliance or non-compliance with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
3.8 All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.
5.2 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.
5.2.1 In the case of multi-center research, three years is referenced to the organization’s involvement in the research, not the entire study.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 AAHRPP elements I.1.A, I-9, II.5.A, 11.5B

1 PURPOSE

1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.

1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.

1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed), and all members have completed training (if needed).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 IRB registrations on file with OHRP will be made or updated as follows:

3.2.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.

3.2.2 Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB chairperson,

3.2.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

5 PROCEDURE

5.1 For new IRBs:

5.1.1 Determine from the IO/OO or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the “IRB Scope” tab of HRP-601 - DATABASE - IRB Roster.

5.1.1.1 Select:

5.1.1.1.1 At least five individuals to serve as IRB members.

5.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.

5.1.1.1.3 At least one of the individuals to be the IRB chair.

5.1.1.2 Follow HRP-082 - SOP - IRB Membership Addition for each IRB member.

5.1.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.

5.1.1.4 Notify the IRB manager when all individuals have completed training.

5.1.1.5 Using the “Create Committee” SmartForm, create the new committee in the system.

5.1.1.6 Once training is completed, add committee members to the system with the Committee Member role.

5.1.1.7 Assign any designees eligible to conduct non-committee reviews using the “Update Eligible Designated Reviewers” activity.

5.2 Register the new IRB, or update an existing IRB’s OHRP registration as required by this policy, by following the instructions available at the OHRP website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html

6 MATERIALS

6.1 HRP-082 - SOP - IRB Membership Addition
6.2 HRP-202 - FORM - IRB Member Information
6.3 HRP-304 - WORKSHEET - IRB Composition
6.4 HRP-560 - LETTER - IRB Appointment
6.5 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.103, 45 CFR §46.107, 45 CFR §46.108, 45 CFR §46.115(a)(5)
7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)
7.3 AAHRPP elements I.1.A, II.1.A-C

UMass Chan MEDICAL SCHOOL	SOP: IRB Removal			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-081	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB.

1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) or designee determines that an IRB is no longer needed.

1.3 The process ends when the IRB is unregistered with OHRP and the Federalwide Assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 For internal IRBs:

5.1.1 For each IRB member who will no longer serve as an IRB member prepare HRP-561 - LETTER - IRB Thank You, have them signed by the IO/OO or designee and send to the former IRB members.

5.1.2 Unregister the IRB with OHRP.[1]

5.1.3 Remove the IRB from the FWA.[2]

5.1.4 Remove members from HRP-601 - DATABASE - IRB Roster.

5.1.5 Remove the individual's Committee Member role in the system.

5.1.6 File:

5.1.6.1 DATABASE: IRB Roster (HRP-601)

5.1.6.2 FWA

5.1.6.3 HRP-561 - LETTER - IRB Thank You

5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

6.1 HRP-561 - LETTER - IRB Thank You

6.2 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)

7.3 AAHRPP elements II.1.A, II.1.C

[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[2] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

1 PURPOSE

1.1 This procedure establishes the process to appoint and re-appoint an IRB member.

1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB in consultation with the Institutional Official/ Organizational Official (IO/OO) (this may be a completely new IRB member, or re-appointment of a previous member).

1.3 The process ends when the IRB roster is updated and the new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 IRB members /alternates are appointed for an initial term. Members/alternates are eligible for re-appointment at the end of their term.

3.3 The [IRB Executive Chair] should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.

3.4 IRB chairs and vice-chairs:

- 3.4.1 Discharge the [IRB Executive Chair]'s responsibilities when the [IRB Executive Chair] is unable to do so
- 3.4.2 Discharge the responsibilities assigned by the [IRB Executive Chair]
- 3.4.3 Assist in the operation of the IRB

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

4.2 The IO/OO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

5 PROCEDURE

5.1 Have the individual complete HRP-202 - FORM - IRB Member Information.

5.2 Obtain a copy of the individual's résumé or curriculum vita.

5.3 Use the information in the completed HRP-202 - FORM - IRB Member Information and the individual's résumé or curriculum vita to determine if the individual qualifies as a scientist or nonscientist, and if they are affiliated or unaffiliated.

5.4 Interview the individual to assess suitability and availability.

- 5.4.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
- 5.4.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IO/OO or designee will be consulted before proceeding with the appointment.

5.5 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.

5.6 Add the individual to HRP-601 - DATABASE - IRB Roster.

5.7 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.

5.8 Prepare HRP-560 - LETTER - IRB Appointment for the individual.

5.9 Provide to the IO/OO or designee for review and approval:

- 5.9.1 HRP-202 - FORM - IRB Member Information.
- 5.9.2 Résumé or curriculum vita.
- 5.9.3 Completed HRP-560 - LETTER - IRB Appointment.

5.10 If not approved, select another individual and restart at 5.1.

5.11 Once the appointment letter is signed:

5.11.1 Send the signed HRP-560 - LETTER - IRB Member Appointment to the individual.
5.11.2 If the individual requires training, schedule the individual for training.
5.11.3 Update the registration of all affected IRBs.[1]

5.12 File:
5.12.1 HRP-601 - DATABASE - IRB Roster
5.12.2 Signed IRB appointment/re-appointment letter
5.12.3 HRP-202 - FORM - IRB Member Information.
5.12.4 Résumé or curriculum vita.
5.12.5 Any other signed agreements

5.13 Notify the IRB director when the individual has completed training.
5.13.1 Assign individual the “Committee Member” role in the system.
5.13.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

6 MATERIALS

6.1 HRP-202 - FORM - IRB Member Information
6.2 HRP-304 - WORKSHEET - IRB Composition
6.3 HRP-560 - LETTER - IRB Appointment
6.4 HRP-561 - LETTER - IRB Thank You
6.5 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5)
7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)
7.3 AAHRPP elements I.1.E, II.1.A-C

[1] See http://www.hhs.gov/ohrp/assurances/. Use Web site: http://ohrp.cit.nih.gov/efile/.

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SOP: IRB Membership Removal				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-083	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB member.
1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.
1.3 The process ends when the IRB registration is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The Institutional Official/ Organizational Official (IO/OO) or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB director and IRB chair(s).
3.2 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Remove the individual from HRP-601 - DATABASE - IRB Roster.
5.2 Complete HRP-304 - WORKSHEET - IRB Composition to ensure that the IRB is appropriately constituted.
  5.2.1 If not, identify one or more replacement members and follow HRP-082 - SOP - IRB Membership Addition.
5.3 Prepare HRP-561 - LETTER - IRB Thank You, have it signed by the IO/OO or designee and send to the individual.
5.4 Update the registration of all affected IRBs.[1]
5.5 File:
  5.5.1 HRP-601 - DATABASE - IRB Roster
  5.5.2 HRP-561 - LETTER - IRB Thank You
5.6 Remove individual's "Committee Member" role in the system.
  5.6.1 If applicable, update the "Update Eligible Designated Reviewers" activity.

6 MATERIALS

6.1 HRP-082 - SOP - IRB Membership Addition
6.2 HRP-304 - WORKSHEET - IRB Composition
6.3 HRP-561 - LETTER - IRB Thank You
6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)
7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)
7.3 AAHRPP elements II.1.A, II.1.C

[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

UMass Chan MEDICAL SCHOOL

SOP: IRB Meeting Scheduling and Notification				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-084	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.
1.2 The process begins when additional meetings need to be scheduled.
1.3 The process ends when sufficient meetings are scheduled.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Whenever possible the IRB schedules meetings at least 30 days in advance at a frequency specified by the [Organizational Official].
3.2 Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research.
3.3 Additional meetings may be scheduled on an ad hoc basis.

4 RESPONSIBILITIES

4.1 The IRB director carries out these procedures.

5 PROCEDURE

5.1 Create a schedule of meetings for each IRB.
    5.1.1 Execute the “Create Meeting” SmartForm in the system for each scheduled meeting.
5.2 Post the schedule on the organization’s Web site.
5.3 Notify the following individuals of the updated schedule:
    5.3.1 IRB members.
    5.3.2 Institutional Official / Organizational Official (IO/OO) or designee.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 ICH-GCP E6 3.3.2
7.2 AAHRPP elements I-9, II.2.D

1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.

1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.

1.3 The process ends when a subject or the subject's LAR provides legally effective informed consent or declines to do so.

1.4 Other procedures may be suitable when approved by the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

- 3.1.1 Adults unable to consent
- 3.1.2 Children
- 3.1.3 Neonates of uncertain viability
- 3.1.4 Nonviable neonates
- 3.1.5 Pregnant women
- 3.1.6 Prisoners
- 3.1.7 Individuals unable to speak English

3.2 The short form of consent documentation may be use only if affirmatively approved by the IRB.

- 3.2.1 The short form is a standard template translated into the subject's language.
- 3.2.2 The summary is the English version of the long form.
- 3.2.3 The short form is intended for use in situations where a non-English speaking subject is encountered unexpectedly. When a study team anticipates enrolling a reasonable number of speakers of a given language into a study, then the existing consent document should be translated into that language prior to enrolling subjects. Once a study team has used a short form in a given language a maximum of three times, then the existing consent document should be translated into that language as there is a demonstrated need with respect to ongoing enrollment

3.3 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

3.4 In this procedure "subject/representative" means:

- 3.4.1 The subject when the subject is an adult capable of providing consent.
- 3.4.2 LAR when the subject is an adult unable to give consent.
- 3.4.3 One or both biological or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

3.5 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative

3.6 If the subject is an adult unable to consent:

- 3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
- 3.6.2 Permission is obtained from a LAR.
- 3.6.3 A LAR must be in the class or persons approved by institutional policy or the IRB. See HRP-013 - SOP - LARs, Children, and Guardians.

3.7 If the subject is a child:
- 3.7.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
- 3.7.2 Permission is obtained from both parents unless:
  - 3.7.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
  - 3.7.2.2 Only one parent has legal responsibility for the care and custody of the child; or
  - 3.7.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
- 3.7.3 In the absence of a parent permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

3.8 If the subject/representative cannot speak English:
- 3.8.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak the language that the subject understands.

3.9 Conduct all discussions in a private and quiet setting.

3.10 Any knowledgeable individual may:
- 3.10.1 Review the study with subject/representative to determine preliminary interest.
- 3.10.2 If the subject/representative is interested, notify an investigator.
- 3.10.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 If the consent process will be documented in writing with the long form of consent documentation:
- 5.1.1 Obtain the current IRB approved consent form.
- 5.1.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in a language understandable to the subject/representative.
- 5.1.3 Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.
- 5.1.4 If the subject/representative cannot read obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.
- 5.1.5 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. When allowed by institutional policy, the interpreter may be a member of the research team, a family member, or friend of the subject/representative.
- 5.1.6 Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. When applicable, the consent document will begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the

subject/representative understands what it would be like to take part in the research study.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).

5.2.2 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in a language understandable to the subject/representative.

5.2.3 Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.

5.2.4 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. When allowed by institutional policy, the interpreter may be a member of the research team, family member, or friend of the subject/representative.

5.2.5 Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.2.6 Have the interpreter translate the summary (not the short consent form) to the subject/representative. When applicable, the summary will begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

5.2.7 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

5.2.8 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB:

5.3.1 Obtain the current IRB approved script.

5.3.2 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

5.3.3 When possible provide a copy of the script to the subject/representative.

5.3.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. When allowed by institutional policy, the interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.3.5 Read the script (or have an interpreter translated the script) with the subject/representative. When applicable, the script will begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the

subject/representative understands what it would be like to take part in the research study.

5.4 Invite and answer the subject/representative's questions.

5.5 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

5.6 When possible, invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.7 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

- 5.7.1 The subject/representative understands the information provided.
- 5.7.2 The subject/representative does not feel pressured by time or other factors to make a decision.
- 5.7.3 The subject/representative understands that there is a voluntary choice to make.
- 5.7.4 The subject/representative is capable of making and communicating an informed choice.

5.8 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.9 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.10 If the subject/representative agrees to take part in the research study:

- 5.10.1 If the subject is a child:
  - 5.10.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.
  - 5.10.1.2 Request the assent (affirmative agreement) of the child unless:
    - 5.10.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
    - 5.10.1.2.2 The IRB determined that assent was not a requirement.
  - 5.10.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.
- 5.10.2 If the subject is an adult unable to consent:
  - 5.10.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.
  - 5.10.2.2 Request the assent (affirmative agreement) of the adult unless:
    - 5.10.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
    - 5.10.2.2.2 The IRB determined that assent was not a requirement.
  - 5.10.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
- 5.10.3 Obtain written documentation of the consent process according to HRP-091 - SOP - Written Documentation of Consent.

6 MATERIALS

6.1 Long form of consent documentation:

- 6.1.1 Consent form

6.2 Short form of consent documentation:

- 6.2.1 Short consent form

6.2.2 Summary (same information as the English consent form used for long form of consent documentation)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

6.4 HRP-013 - SOP - LARs, Children, and Guardians

6.5 HRP-091 - SOP - Written Documentation of Consent

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116

7.3 AAHRPP element I-9

1 PURPOSE

1.1 This procedure establishes the process to document the informed consent process in writing.
1.2 The process begins when a subject agrees to take part in a research study.
1.3 The process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure.
1.4 Other procedures may be suitable when approved by the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
3.2 In this procedure "subject/representative" means:
- 3.2.1 The subject when the subject is an adult capable of providing consent.
- 3.2.2 The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent.
- 3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child's general medical care.

3.3 If the consent process requires an impartial witness:
- 3.3.1 The impartial witness is to be present during the entire consent discussion and attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
- 3.3.2 The impartial witness may not be a person involved in the research.

3.4 The short form of consent documentation may be used only if affirmatively approved by the IRB.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 If the consent process will be documented in writing with the long form of consent documentation:
- 5.1.1 Verify that the consent form is in language understandable to the subject/representative.
- 5.1.2 Print the name of the following individuals on the consent document:
  - 5.1.2.1 Subject/Representative
  - 5.1.2.2 Person obtaining consent
  - 5.1.2.3 Impartial witness, if any
- 5.1.3 Have the following individuals personally sign and date the consent document:
  - 5.1.3.1 Subject/Representative
  - 5.1.3.2 Person obtaining consent
  - 5.1.3.3 Impartial witness, if any
- 5.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:
  - 5.1.4.1 Assent of the child was obtained.

5.1.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.1.5 Provide copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Verify that the short form consent document is in language understandable to the subject/representative.

5.2.2 Print the name of the following individuals on the short form consent document and the summary:

5.2.2.1 Subject/Representative

5.2.2.2 Person obtaining consent

5.2.2.3 Impartial witness

5.2.3 Have the following individuals personally sign and date the short form consent document and the summary:

5.2.3.1 Subject/Representative

5.2.3.2 Person obtaining consent

5.2.3.3 Impartial witness

5.2.4 If the IRB required written documentation of assent, note on the signature block on the short form consent document one of the following:

5.2.4.1 Assent of the child was obtained.

5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.2.5 Provide a copy of the signed and dated short form consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short form consent document and summary.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.

5.3.1 If the subject/representative declines, take no further action.

5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation

5.4 If the research includes procedures which are or can affect clinical care, a copy of the signed consent form must be placed in the UMass Memorial medical record, either by uploading to e-medical record or sending in hard copy to Health Information Management (HIM) department.

5.5 Retain the signed and dated documents in the study records for the greater of:

5.5.1 Three years after completion of the research.

5.5.2 Six years after completion of the research for signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations

5.5.3 For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

5.5.4 For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the consent process will be documented in writing with the short form of consent documentation:

6.2.1 Short form consent document

6.2.2 Summary (same content as the long form of consent documentation)

7 REFERENCES

7.1 21 CFR §50.27

7.2 45 CFR §46.117

7.3 AAHRPP element I-9

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

TO: University of Massachusetts Medical School Faculty and Staff

FROM: Katherine Luzuriaga, MD, Vice Provost for Clinical and Translational Research
Carol Bova, PhD, RN, ANP, IRB Chair

DATE: March 25, 2021

RE: **HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent – Temporary exceptions for research requiring written documentation of consent during the COVID-19 pandemic**

The memo is based on the following FDA guidance document, released March 2020 and updated January 27, 2021: *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards*. The memo replaces a similar version initially released and updated in March 2020 pertaining to temporary exceptions for COVID-19 therapeutic trials. This memo is consistent with the clinical system mandate to minimize the exchange of items to reduce the risk of infection.

GENERAL PRINCIPLES:

Unless the IRB has explicitly approved alternative procedures for a given research study, study teams must obtain the written informed consent of a subject prior to conducting any research procedures.

Study teams must have IRB approval to enroll a subject via their legally authorized representative (LAR).

Consent forms and signature blocks that contain sensitive information must be transferred securely, e.g., in person or through mail or secure email. Health information is sensitive information.

Links to consent forms in DocuSign or REDCap that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly.

Study teams that implemented the original March 2020 memo and have not yet updated studies under direct UMMS IRB oversight must submit a Modification to bring their recruitment and consent procedures up to date **by April 30, 2021**.

Investigators conducting industry-sponsored research or research reviewed by an external IRB (not the UMMS IRB) should continue to obtain prior approval for all consent procedures that do not involve a subject signing a paper form and providing that signed form to the study team prior to the start of research procedures.

ALTERNATIVES TO SIGNED PAPER CONSENTS

REDCap

FDA guidance states: *When an electronic system that is Part 11 compliant is not available, regulated entities must have an alternate means of obtaining required signatures (e.g., handwritten wet ink signatures executed on documents, handwritten stylus or finger-drawn signatures executed on electronic documents that are then printed or appropriately witnessed).*

Although the standard UMMS REDCap instances are not 21 CFR Part 11 compliant, REDCap does support handwritten stylus or finger-drawn signatures that are executed on electronic documents and that can then be printed or appropriately witnessed.

Links to consent forms in REDCap that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly and walk them through the consent.

Copies of consents that are personally signed and dated by subjects or their LARs should be sent to them via mail or secure email or individuals should be provided a means to download copies from REDCap.

Each subject's study file should include documentation of the consenting process such as a progress note that documents how informed consent was obtained, that the subject was given sufficient time to review the consent, that all of the subject's questions were answered, that informed consent was obtained prior to participation in the trial, and that a copy of the signed consent was given to the subject.

DocuSign

Links to consent forms in DocuSign that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly and walk them through the consent.

Until there is a UMMS instance of DocuSign that is 21 CFR Part 11 compliant, DocuSign should not be used for FDA regulated research.

Subject or LAR signs consent and transmits a photo of the signature block per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession
- A photograph of the signed consent form is taken and is provided to the investigator
    - Signature blocks that include sensitive information should be transferred using secure means (e.g., secure email)

- Study team enters photograph into the study records along with an attestation that states how the photograph was obtained and that it is a photograph of the informed consent document signed by the subject or LAR

Subject or LAR signs consent with independent witness attestation instead of photo per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call – including the required independent witness
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession
- When using a witness, documentation in the trial records includes: (1) a signed and dated attestation by the witness who participated on the call that the subject or LAR confirmed their agreement to participate in the trial and signed the informed consent document; and (2) a signed and dated attestation by the investigator/designee stating why the signed informed consent document was not retained (e.g., due to potential contamination of the document by infectious material)

Subject or LAR receives consent but is unable to print it out or sign it electronically with independent witness attestation per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call – including the required independent witness
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered and that they would like to participate in the trial
- Subject or LAR signs and dates a blank piece of paper with a written statement that they voluntarily agree to participate in Protocol # and Brief Title, and then provides that document to the study team by mail, (secure) email, or in person at a later visit
    - Protocol titles that include sensitive information should be transferred using secure means (e.g., secure email)
- Independent witness signs and dates attestation that patient confirmed agreement and signed paper
- Consent documentation once received is appended to a copy of the consent document that was reviewed with the subject or their LAR
- If consent documentation will be received after research procedures are initiated, the case history for each trial participant must document that informed consent was obtained prior to participation in the trial

Please contact Allison Blodgett, Director of IRB Operations (Allison.Blodgett@umassmed.edu), with any questions or concerns.

UMass Chan MEDICAL SCHOOL	SOP: Study-Specific COVID-19 Risk Mitigation Planning			
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-092	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 This SOP describes the process for:

1.1.1 Determining whether study-specific risk mitigation plans are needed to address additional research subject safety considerations associated with the COVID-19 pandemic;

1.1.2 Developing study-specific COVID-19 risk mitigation plans;

1.1.3 Communicating study modifications to the IRB; and

1.1.4 Documenting any implemented modifications or deviations from the protocol in the research record.

1.2 The process begins when the investigator considers whether a study-specific risk-mitigation plan is necessary during the COVID-19 pandemic.

1.3 The process ends when the investigator develops the risk mitigation plan or determines that no plan is necessary.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 UMass Chan Medical School provides Coronavirus (COVID-19) Related Guidance to Researchers via a central website that houses memos, joint guidance documents, job aids, and other relevant communications for the conduct of human subjects research during the COVID-19 pandemic: https://www.umassmed.edu/ccts/covid-19/

4 RESPONSIBILITIES

4.1 Investigators are responsible to carry out these procedures.

5 PROCEDURE

5.1 Determine whether a COVID-19 risk mitigation plan should be developed for each Human Research project the investigator is leading. A COVID-19 risk mitigation plan should be developed unless one of the following is true:

5.1.1 Research does not involve in-person interaction with research subjects.

5.1.2 Research can be conducted as written while adhering to social distancing[1] requirements and institutional COVID-19 policies and requirements.

5.1.3 Research is externally sponsored, and Sponsor has already developed a COVID-19 risk mitigation plan for the research.

5.1.4 Research has been voluntarily placed on hold for recruitment and all research procedures (with the exception of necessary follow up procedures to be done consistently with social distancing requirements and institutional COVID-19 policies and requirements).

5.2 If an external sponsor has developed a COVID-19 risk mitigation plan for the research, skip to step 5.4.

5.3 For all other research involving in-person interactions with research subjects for which the research cannot otherwise be conducted in accordance with social distancing recommendations and institutional COVID-19 policies and requirements, develop a risk

[1] Social distancing recommendations include the following: that people stay at home as much as possible, going out only for critical needs like groceries and medicines, or to exercise and enjoy the outdoors in wide open spaces. Other recommendations include avoiding gatherings of more than 10 people, no handshakes, regular handwashing, and, when encountering someone outside of your immediate household, trying to remain at least 6 feet apart. (Source: NIH Director's Blog, March 19, 2020)

mitigation plan in consideration of the potential for direct therapeutic benefit associated with the research.

5.3.1 For research that *does not* offer potential for direct therapeutic benefit (and is not a Phase I trial with no treatment alternatives):

5.3.1.1 Develop a plan to place study recruitment and study activities on voluntary hold.

5.3.1.2 Notify the IRB if study recruitment and research activities cannot be placed on hold for any research requiring in-person interaction but offering no potential for direct therapeutic benefit.

5.3.2 For research that *does* offer potential for direct therapeutic benefit (or Phase I trial with no treatment alternatives):

5.3.2.1 Determine whether study should be voluntarily placed on hold to recruitment and/or study conduct, or

5.3.2.2 Develop more detailed risk mitigation plan, considering the items included in WORKSHEET: Protocol-Specific COVID-19 Risk Mitigation Planning, based on the FDA's "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic."

5.4 Notify the IRB and applicable ancillary review committees (e.g. DSMB, DSMC, etc.) of risk mitigation plan:

5.4.1 If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within 5 business days following the standard pathway to submit Reportable New Information.

5.4.2 For all other study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic, submit a study modification to the IRB following the standard pathway to submit Modifications.

5.5 Document mitigation plan details in study record in accordance with sponsor and regulatory agency requirements, and in accordance with the information listed in "HRP-350 - WORKSHEET - Research-Specific COVID-19 Risk Mitigation Plan."

6 MATERIALS

6.1 HRP-350 - WORKSHEET - Research-Specific COVID-19 Risk Mitigation Plan

7 REFERENCES

7.1 FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

7.2 AAHRPP elements I.1.D, III.2.D

UMass Chan MEDICAL SCHOOL

GENERAL DOCUMENTS

HRP-100 – Huron HRPP Toolkit Table of Contents
HRP-101 – HUMAN RESEARCH PROTECTION PROGRAM PLAN
HRP-102 – Flowcharts
HRP-103 – Investigator Manual
HRP-104 – BROCHURE – Should I Take Part in Research
HRP-105 – OHRP FDA Written Procedure Crosswalk
HRP-106 – FLOWCHART – Study-Specific COVID-19 Risk Mitigation Plan
HRP-107 – Existing IRB Regulatory Pathways and Processes Relevant to COVID.Updates Tracked
HRP-108 – FLOWCHART – Study-Specific Emergency-Disaster Risk Mitigation Planning

Note that the INVESTIGATOR GUIDANCE listed below has moved to HRP-103 – Investigator Manual

PRIOR INVESTIGATOR GUIDANCE	CURRENT INVESTIGATOR MANUAL
HRP-800 – Investigator Obligations	p. 11, What are my obligations after IRB approval?
HRP-801 – Prompt Reporting Requirements	p. 12, Complete the Report New Information SmartForm within five business days for any of the following information items
HRP-810 – Additional DOD Obligations	p. 36, Appendix A-4, Additional Requirements for Department of Defense (DOD) research
HRP-811 – Additional DOE Obligations	p. 38, Appendix A-5, Additional Requirements for Department of Energy (DOE) Research
HRP-812 – Additional DOJ Obligations	p. 41, Appendix A-6, Additional Requirements for Department of Justice (DOJ) Research
HRP-813 – Additional ED Obligations	p. 45, Appendix A-7, Additional Requirements for Department of Education (ED) Research
HRP-814 – Additional EPA Obligations	p. 46, Appendix A-8, Additional Requirements for Environmental Protection Agency (EPA) Research
HRP-815 – Additional FDA Obligations	p. 21, Appendix A-2, Additional Requirements for FDA-Regulated Research
HRP-816 – Additional ICH-GCP Obligations	p. 28, Appendix A-3, Additional Requirements for Clinical Trials (ICH-GCP)

Note that the INVESTIGATOR GUIDANCE listed below has moved to HRP-090 and HRP-091

PRIOR INVESTIGATOR GUIDANCE	CURRENT INVESTIGATOR MANUAL
HRP-802 – Informed Consent	HRP-090 – SOP – Informed Consent Process for Research
HRP-803 – Documentation of Informed Consent	HRP-091 – SOP – Written Documentation of Consent

HRPP Toolkit – Document List 4.5

UMass Chan MEDICAL SCHOOL

Standard Operating Procedures	*Worksheets*
HRP-001 - SOP - Definitions	HRP-301 - WORKSHEET - Review Materials
HRP-003 - SOP - Designations (UMass Chan)	HRP-302 - WORKSHEET - Approval Intervals
HRP-012 - SOP - Observation of Consent Process	HRP-303 - WORKSHEET - Communication of Review Results
HRP-013 - SOP - LARs, Children, and Guardians	HRP-304 - WORKSHEET - IRB Composition
HRP-018 - SOP - Undue Influence on the HRPP (UMass Chan)	HRP-305 - WORKSHEET - Quorum and Expertise
HRP-019 - SOP - IRB Member Review Expectations (UMass Chan)	HRP-306 - WORKSHEET - Drugs and Biologics
HRP-020 - SOP - Incoming Items	HRP-307 - WORKSHEET - Devices (see HRP-407 CHECKLIST)
HRP-021 - SOP - Pre-Review	HRP-308 - WORKSHEET - Pre-Review
HRP-023 - SOP - Emerg and Device Comp Use Review	HRP-309 - WORKSHEET – Ancillary Review Matrix
HRP-024 - SOP - New Information	HRP-310 - WORKSHEET - Human Research Determination
HRP-025 - SOP - Investigations	HRP-311 - WORKSHEET - Engagement Determination
HRP-026 - SOP - Susp or Term Issued Outside of Conv IRB	HRP-312 - WORKSHEET - Exemption Determination
HRP-027 - SOP - Emerg Use Comp Use Indiv Pt Access Post Rev	HRP-313 - WORKSHEET - Expedited Review
	HRP-314 - WORKSHEET - Criteria for Approval
HRP-030 - SOP - Designated Reviewers	HRP-315 - WORKSHEET - Advertisements
HRP-031 - SOP - Non-Committee Review Preparation	HRP-316 - WORKSHEET - Payments
HRP-032 - SOP - Non-Committee Review Conduct	HRP-317 - WORKSHEET - Short Form of Consent Documentation
HRP-040 - SOP - IRB Meeting Preparation	HRP-318 - WORKSHEET - Additional Federal Agency Criteria
HRP-041 - SOP - IRB Meeting Conduct	HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
HRP-042 - SOP - IRB Meeting Attendance Monitoring	HRP-320 - WORKSHEET - Scientific or Scholarly Review
HRP-043 - SOP - IRB Meeting Minutes	HRP-321 - WORKSHEET - Review of Information Items
HRP-044 - SOP - Not Otherwise Approvable Research	HRP-322 - WORKSHEET - Emergency Use
HRP-050 - SOP - Conflicting Interests of IRB Members	HRP-323 - WORKSHEET - Criteria for Approval HUD
HRP-051 - SOP - Consultation	HRP-324 - WORKSHEET - Contracts
HRP-052 - SOP - Post-Review	HRP-325 - WORKSHEET - Device Compassionate Use
HRP-054 - SOP - Institutional Conflicts of Interests (UMass Chan)	HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs
HRP-055 - SOP - Financial Conflicts of Interests (UMass Chan)	HRP-327 - WORKSHEET - Performance Evaluation for IRB Members
HRP-060 - SOP - Annual Evaluations of the HRPP	HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff
HRP-061 - SOP - HRPP QA QI Program (UMass Chan)	HRP-330 - WORKSHEET - HIPAA Authorization
HRP-062 - SOP - Daily Tasks	HRP-331 - WORKSHEET - FERPA Compliance
HRP-063 - SOP - Expiration of IRB Approval	HRP-332 - WORKSHEET - NIH GDS Institutional Certification
HRP-064 - SOP - NIH GDS Institutional Certification	HRP-333 - WORKSHEET - Certificate of Confidentiality
HRP-065 - SOP - Response Plan for Emergencies-Disasters Impacting the HRPP	HRP-350 - WORKSHEET - Research-Specific COVID-19 Risk Mitigation Plan
HRP-070 - SOP - IRB Records	HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning
HRP-071 - SOP - Standard Operating Procedures	HRP-352 - WORKSHEET - Additional Emergency-Disaster Review Considerations
HRP-072 - SOP - IRB Records Retention	HRP-380 - WORKSHEET – Financial Interest Management (UMass Chan)
HRP-080 - SOP - IRB Formation and Registration	
HRP-081 - SOP - IRB Removal	
HRP-082 - SOP - IRB Membership Addition	***Checklists***
HRP-083 - SOP - IRB Membership Removal	HRP-401 - CHECKLIST - Pre-Review
HRP-084 - SOP - IRB Meeting Scheduling and Notification	HRP-402 - CHECKLIST - Non-Committee Review
HRP-090 - SOP - Informed Consent Process for Research	HRP-407 - CHECKLIST - Devices (UMass Chan)
HRP-091 - SOP - Written Documentation of Consent	HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

HRP-091b - SOP – HRP-803 GUIDANCE COVID19 Exceptions Written Documentation of Consent (UMass Chan)	HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
HRP-092 - SOP - COVID-19 Risk Mitigation Planning	HRP-412 - CHECKLIST - Pregnant Women
General Documents	HRP-413 - CHECKLIST - Non-Viable Neonates
HRP-100 - Huron HRPP Toolkit Table of Contents	HRP-414 - CHECKLIST - Neonates of Uncertain Viability
HRP-101 - Human Research Protection Program Plan	HRP-415 - CHECKLIST - Prisoners
HRP-102 - Flowcharts	HRP-416 - CHECKLIST - Children
HRP-103 - Investigator Manual	HRP-417 - CHECKLIST - Cognitively Impaired Adults
HRP-103p - Investigator Manual – pSite (not in use)	HRP-418 - CHECKLIST - Non-Significant Risk Device
HRP-104 - Brochure - Should I Take Part in Research?	HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
HRP-105 - OHRP FDA Written Procedure Crosswalk	HRP-430 - CHECKLIST - Investigator Quality Improvement (not in use, see HRP-901 Investigator Self-Assessment)
HRP-106 - FLOWCHART Study-Specific COVID-19 Risk Mitigation Plan	HRP-431 - CHECKLIST - Minutes Quality Improvement
HRP-107 - Existing IRB Regulatory Pathways and Processes Relevant to COVID	HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning	
Forms	***Databases***
HRP-202 - FORM - IRB Member Information	HRP-601 - DATABASE - IRB Roster
HRP-211 - FORM - Basic Study Information	
HRP-212 - FORM - Continuing Review	
HRP-213 - FORM - Modification	
HRP-214 - FORM - Reportable New Information	
HRP-215 - FORM – Non-UMass Personnel List (UMass Chan)	
HRP-219 - FORM - COVID-19 Modification (not in use)	
General Templates	
assent_20211012	
authorization_20211012	
authorization_to_conatct_20211012	
factsheet_20211012	
HIPAA Waiver of Authorization 20211012	
HRP-500 - TEMPLATE BROAD CONSENT DOCUMENT (not in use)	
HRP-501 - TEMPLATE MINUTES	
HRP-502 - TEMPLATE CONSENT DOCUMENT	
HRP-503 - TEMPLATE PROTOCOL	
HRP-503a - TEMPLATE SBS PROTOCOL (not in use)	
HRP-504 - TEMPLATE LETTER - School Permission to Conduct Research	
HRP-505 - TEMPLATE SOP	
HRP-506 - TEMPLATE CONSENT DOCUMENT - Emergency Use or Compassionate Device Use	
HRP-507 - TEMPLATE CONSENT DOCUMENT - Short Form	
HRP-508 - TEMPLATE Site Supplement to Sponsor Protocol (pSite Supplement and Comm Plan)	
HRP-509 - TEMPLATE - VA Minutes Supplement (na)	
request-for-not-human-subject-research-determination_20211012	
Template Letters – Post-Review	
HRP-510 - TEMPLATE LETTER - Approval	
HRP-511 - TEMPLATE LETTER - Closure	
HRP-512 - TEMPLATE LETTER - Modifications Required to Secure Approval	
HRP-513 - TEMPLATE LETTER - Not Human Research Determination	
HRP-514 - TEMPLATE LETTER - Exemption	
HRP-515 - TEMPLATE LETTER - Suspension or Termination	

HRP-515b - TEMPLATE LETTER - Lifting of Suspension (UMass Chan)
HRP-516 - TEMPLATE LETTER - Deferral
HRP-517 - TEMPLATE LETTER - Disapproval
HRP-518 - TEMPLATE LETTER - Tabled
HRP-519 - TEMPLATE LETTER - Information Item
HRP-520 - TEMPLATE LETTER - External Report NOT Including OHRP
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Human Research Protection Program

Plan[1]

March 20, 2023

[1] This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

Table of Contents

Scope

Throughout this document "Institution" refers to the University of Massachusetts Chan Medical School.

Purpose

This Institution is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Institution's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Institution's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Institution.

Clinical Trial

As defined by NIH, a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, this Institution is considered engaged in Human Research when this Institution's employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. This Institution follows OHRP guidance on "Engagement of Institutions in Research"[2] to apply this definition and exceptions to this definition.

Human Research:

Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Subjects" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by FDA and involves "Human Subjects" as defined by FDA ("FDA Human Research").

[2] http://www.hhs.gov/ohrp/policy/engage08.html

Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

- **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[3]

The following activities are not considered Research as Defined by DHHS:

[3] For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
    - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
    - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
    - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots.

Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Mission

The mission of this Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.

Ethical Requirements

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional Official/Organizational Official (IO/OO), and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report":

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

This Institution commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by one of the institutionally designated IRBs.

Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's IRBs and do not need to be submitted to one of the Institution's IRBs unless there is a question regarding whether the activity is Human Research.

When this Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Institution is engaged in FDA Human Research, this Institution commits to apply the FDA regulations relevant to the protection of Human Subjects.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office. A designated reviewer will provide a written determination in response to written requests.

After a study is completed, this Institution does not consider the return of results to former subjects to be Human Research.

Other Requirements

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring

- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs
- Requiring that research staff are knowledgeable about local laws and procedures

Exempt human subjects research has no Expiration Date.

For non-exempt human subjects research, the maximum approval interval before continuing review is required is three years. This reduces burden on investigators conducting minimal risk research, while supporting the Institution in its oversight of non-exempt research and the generation of corresponding metrics.

For clinical trials, this Institution commits to apply the "International Conference on Harmonization – Good Clinical Practice E6" (ICH-GCP) where they are consistent with FDA and HHS regulations.

This Institution prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees").

The IRB reviews payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") and does not allow them unless the possibility of coercion and undue influence is minimized.

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

When Human Research is conducted or funded by the Department of Justice (DOJ), this Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D[4]. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

[4] Quick applicability table for DHHS Subparts:

	DHHS	DOD	DOE	ED	EPA
Subpart B	X	X	X		X
Subpart C	X	X	X		
Subpart D	X	X	X	X	X

When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1C which includes the requirements to apply 10 CFR §745 and Subparts B, C, and D of 45 CFR §46, as applicable, and additional DOE requirements outlined in HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel's interpretation of study-specific GDPR requirements.

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Program

The categories of Human Research overseen include:

- International research
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Education (ED)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Federally funded research
- Research involving fetuses.
- Research involving *in vitro* fertilization.
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an abbreviated IDE.
- Research involving devices that require an IDE issued by FDA.
- Investigator held abbreviated IDE.
- Investigator held IND or IDE.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving children as subjects.

- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Research involving a waiver of consent for planned emergency research.
- Emergency use of a test article in a life-threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form of consent documentation.
- Research that includes processing or holding personal data of subjects residing in the European Union.

The categories of Human Research not overseen include:

- Classified Research (Research involving any information or material, regardless of its physical form or characteristics, that is owned by the United States Government, and determined pursuant to Executive Order 12356, April 2, 1982 or prior orders to require protection against unauthorized disclosure, and is so designated. A security clearance is required to review classified research.)
- Research conducted or funded by the Veteran Administration (VA) without VA IRB oversight

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site: https://www.umassmed.edu/ccts/irb/.

Human Research Protection Program Components

Institutional Official/Organizational Official (IO/OO)

The Vice Provost, Clinical and Translational Research is designated as the IO/OO.

The IO/OO and the Chief Research Officer have the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire research review staff.
- Determine what IRBs the Institution will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Prohibit publication of research
- Require destruction of research samples or data
- Create policies and procedures related to the Human Research Protection Program that are binding on the Institution.
- Determine that information represents Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval

- Suspend or terminate research approved by one of the Institution's IRBs.
- Take personnel action against employees related to Serious Noncompliance or Continuing Noncompliance
- Disapprove research approved by one of the Institution's IRBs.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The IO/OO has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Ensure that the IRB Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research protection program.
- Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

All members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.

- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the IO/OO.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO/OO.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

IRBs

IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Relying on an External IRB

This Institution may rely upon IRBs of another institution or organization provided one of the following is true:

- The IRBs are part of an AAHRPP accredited institution or organization.
- The IRBs are not part of an AAHRPP accredited institution or organization, but where reasonable steps have been taken to ensure that subjects are adequately protected. For example, for research that is no greater than Minimal Risk, there may be an assurance that the IRBs will adhere to applicable ethical standards and regulations. For research that is greater than Minimal Risk, the institutions may agree on more extensive oversight.
- The IRBs are part of an established reliance network (e.g. Smart IRB) that has established contractual and SOP-level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
- The sIRB has been pre-determined by study sponsor or grant or established by prior arrangement.
- This Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human Research carried out at this institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures

that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the IO/OO. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
- Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

This institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.

Serving as the IRB of Record

When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in HRP-103 - INVESTIGATOR MANUAL.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO/OO.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the IO/OO, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the Institution.
- Determine who meets the definition of "legally authorized representative" and "children" when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.
- Determine whether any Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland conforms with EU General Data Protection Regulations (GDPR).

Department Chairs

Department Chairs have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the IO/OO.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Grants and Contracts

The Office of Clinical Research has the responsibility to review clinical research agreements, including industry-funded clinical trial agreements for compliance with Human Research Protection Program policies and procedures.

The Office of Sponsored Programs and the Office of Technology Management have the responsibility to review federal grants and non-clinical contracts for compliance with Human Research Protection Program policies and procedures.

Education and Training

This plan is made available to the human research community via the IRB website. To maintain awareness of HRPP policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the research community by way of various email list-serve groups targeted to appropriate audiences.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO/OO, must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Training is valid for a three-year period, after which time refresher training must be completed.

Investigators and research staff must complete the initial and continuing training described in HRP-103 - INVESTIGATOR MANUAL.

HRPP staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The HRPP emergency preparedness plan will be made available to the IRB members, IRB staff, and human research community via the IRB website and targeted communications. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

Emergency Preparedness

The organization routinely assesses potential emergency scenarios and threats to the institution to improve its emergency preparedness and response plan. The IRB Director, or their designee, collaborates with organizational leadership to develop, implement, and assess, emergency preparedness procedures for the HRPP.

Depending on the nature of the event, the IRB Director will collaborate with institutional leadership to determine the types of research that might continue and the types that the organization may need to temporarily postpone. The organization proactively identifies external IRBs on which it can rely on temporarily during an emergency.

The IRB staff will work with IT resources and/or electronic system vendors to ensure continuity of operations in the event that electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The IRB Director will collaborate with the vendor of the IRB's electronic system to ensure that records are maintained on a secure server that is accessible in the event of an emergency. To the extent the organization relies on paper records, the HRPP will implement an alternative process for records management while records are inaccessible.

The organization will implement alternative review procedures, including leveraging online and virtual platforms, to ensure that IRB meetings can continue in scenarios where the IRB cannot meet in person. In instances where the convened IRB is unable to meet and IRB

approval for a study may lapse, the IRB Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of already enrolled subjects.

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:

Allison Blodgett, PhD, CIP
UMass Chan Director of IRB Operations
362 Plantation St.
Worcester, MA 01605
Email: allison.blodgett@umassmed.edu or irb@umassmed.edu
(508) 856-4271 or (508) 856-4261

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Individuals are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, IO/OO, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/OO has the responsibility to investigate all other reports and take corrective actions as needed.

Individuals who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO/OO or designee.

To make such reports, contact the IO/OO:

Katherine Luzuriaga, MD
Vice Provost, Clinical and Translational Research
362 Plantation St., Ambulatory Care Center
AC7-207
Worcester, MA 01605
Email: Katherine.Luzuriaga@umassmed.edu
(508) 856-6282

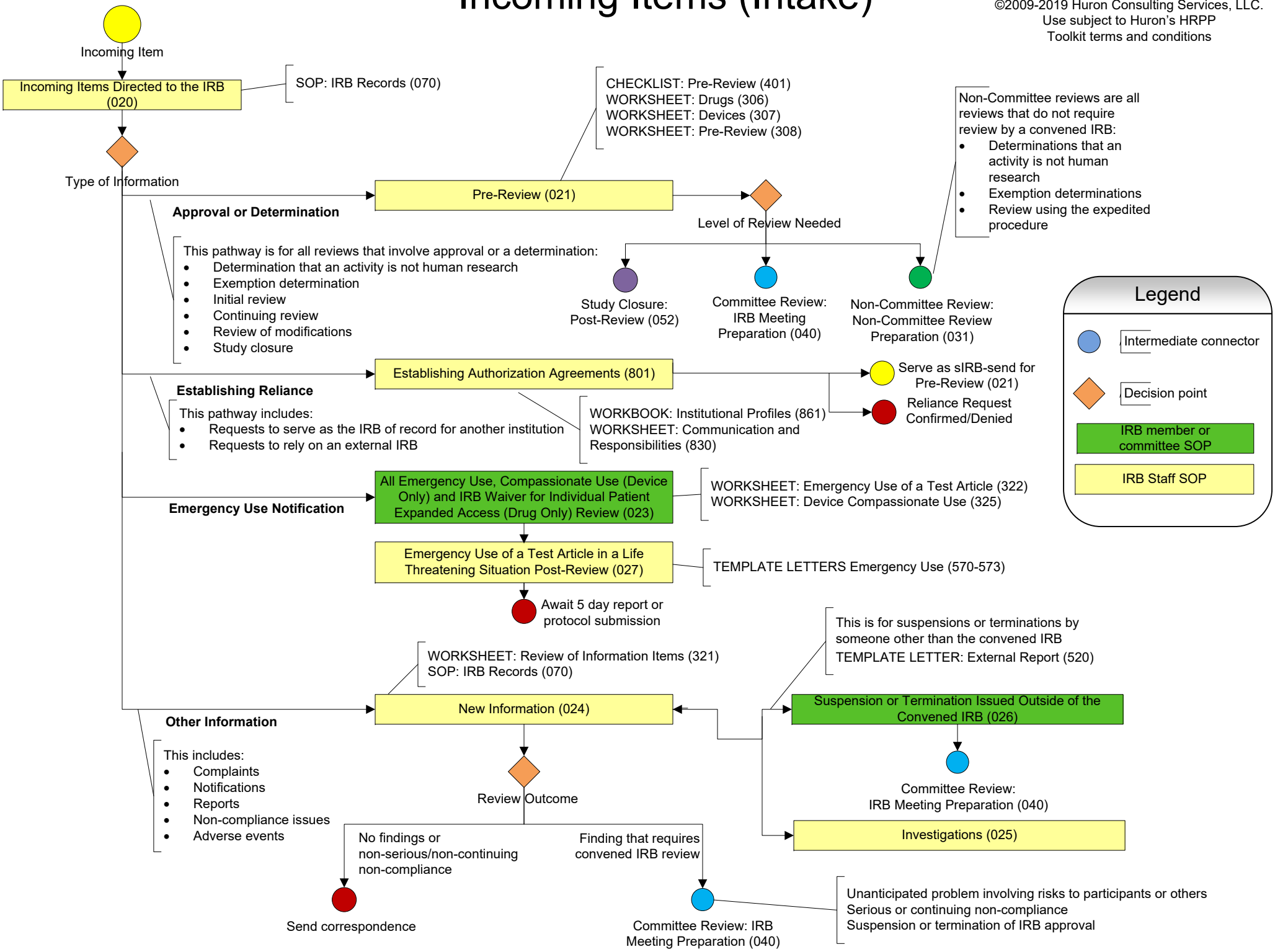
Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

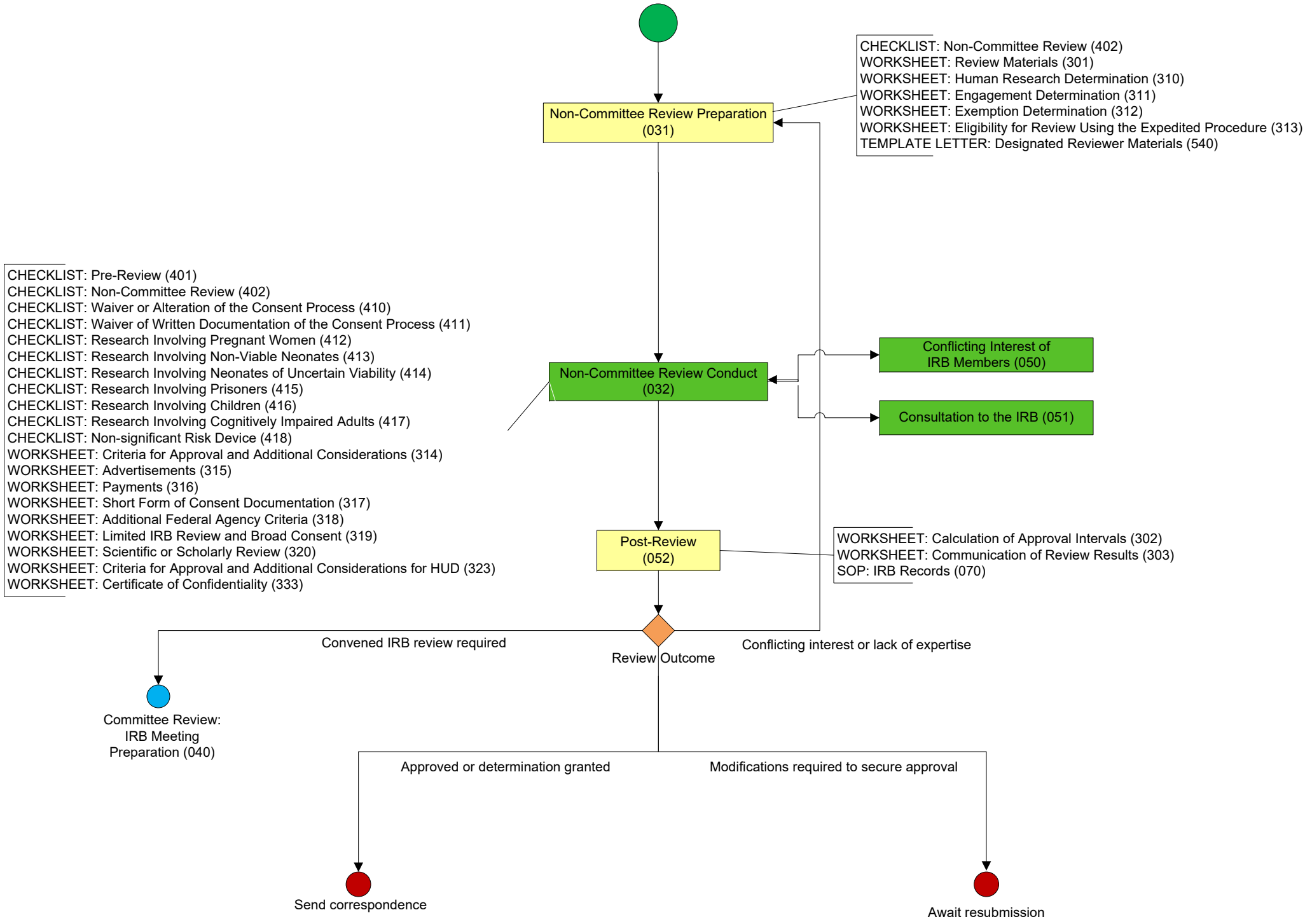
Disciplinary Actions

The IO/OO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO/OO such actions are required to maintain the Human Research Protection Program.

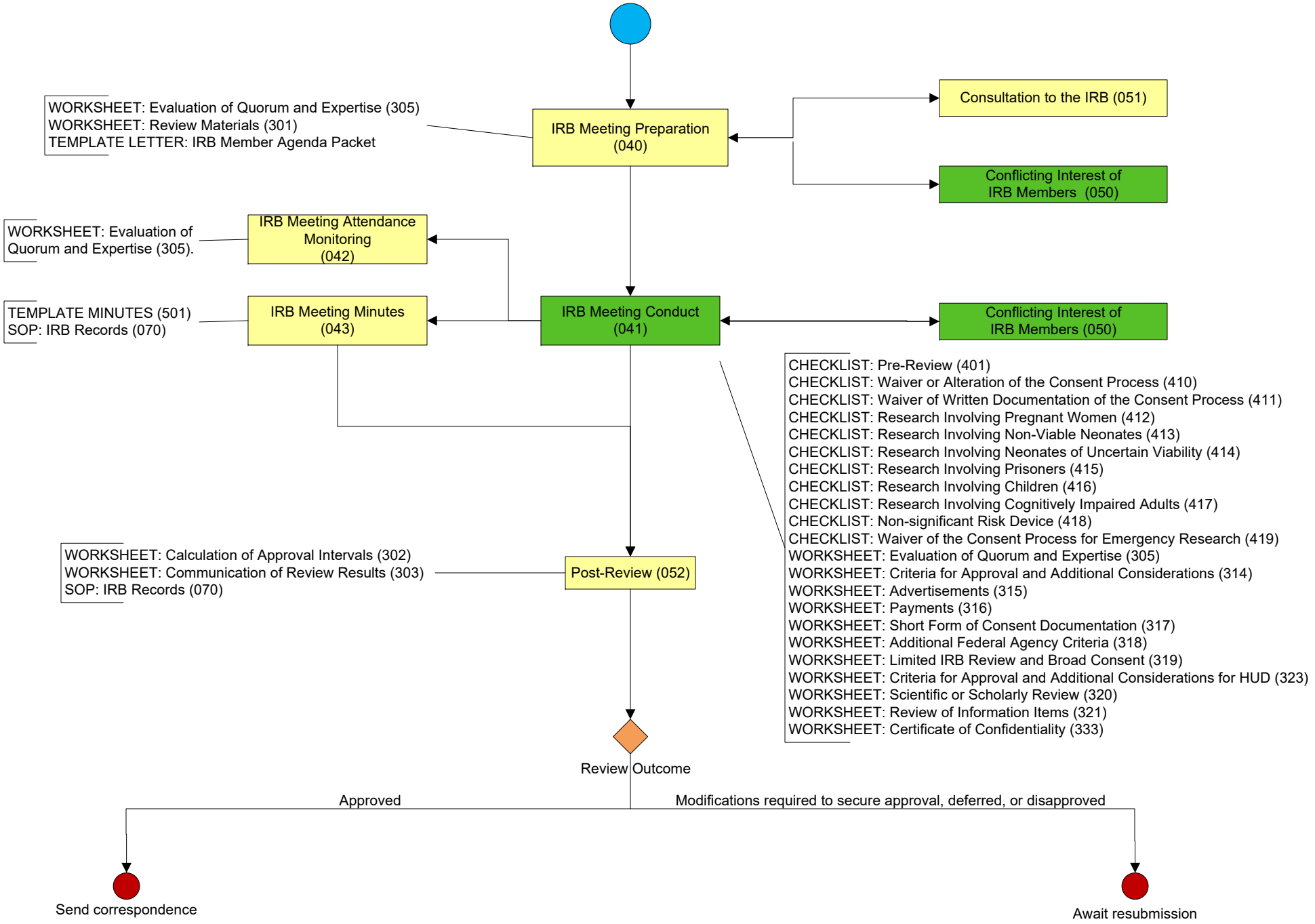
Incoming Items (Intake)



Non-Committee Review



Convened IRB Review



UMass Chan MEDICAL SCHOOL

Investigator Manual[1]

September 15, 2025

[1] This document satisfies AAHRPP element I.1.A, I.1.C-I.1.F, I-3, I.4.C, I.5.C, I.5.D, I.6.B, I.7.A-I.7.C, I-9, II.2.A, II.2.C, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.5.A, II.5.B, III.1.A, III.1.B, III.1.D, III.1.E, III.1.F, III.2.A, III.2.C, III.2.D

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Scope

The UMass Chan IRB serves as the IRB of record for all human research conducted by UMass faculty and investigators at the Medical School or at associated research locations, including the campuses of UMass Memorial Medical Center and the member hospitals of UMass Memorial Health.

Throughout this document "institution" refers to the UMass Chan Medical School[2] as all research happens under the auspices of the Medical School.

What is the purpose of this manual?

This document, HRP-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: "What training does my staff and I need in order to conduct Human Research?"

What is Human Research?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this institution considers to be "Human Research." An algorithm for determining whether an activity is Human Research can be found in HRP-310 - WORKSHEET - Human Research Determination, located in the IRB Policies & Procedures section of the IRB Web site. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and determination of exempt Human Research). If you have questions about whether an activity is Human Research, contact the IRB Office who will provide you with a determination. If you wish to have a written determination, provide a written request to the IRB Office.

What is the Human Research Protection Program?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this institution's overall plan to protect subjects in Human Research.

- The mission of the Human Research Protection Program.
- The ethical principles that the institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.

[2] Known as University of Massachusetts Medical School prior to 9/7/2021

- When the institution becomes "engaged in Human Research" and when someone is acting as an agent of the institution conducting Human Research.
- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the institution.

Who can serve as a principal investigator (PI)?

The following table outlines the PI eligibility requirements:

Position/Title	PI Eligibility
UMass Chan & UMMH employed faculty	Eligible upon faculty appointment at any rank
UMass Chan & UMMH Affiliate Faculty	Eligible if paid by UMass Chan or UMMH; otherwise may be a co-investigator
Adjunct Faculty	Not eligible; may serve as co-investigator with any necessary IRB reliance agreements
Visiting Faculty	Eligible while at UMass Chan if approved by the sponsoring Department Chair and the Institutional Official
Retired & Emerita Faculty	Eligible if approved by the Department Chair and the Institutional Official
Non-Faculty	Eligible if paid employee of UMass Chan or UMMH and provided a faculty advisor oversees the conduct of the research; Onsite vendor employees with UMass Chan or UMMH posts are similarly eligible with a faculty advisor and any necessary reliance agreements
Fellows, Residents, Trainees and Students	Eligible, provided a faculty advisor oversees the conduct of the research and if allowed by the Department
Faculty employed by other UMASS campus (Amherst, Boston, Dartmouth, & Lowell)	Not eligible; may serve as co-investigator with any necessary IRB reliance agreements

Exceptions to the PI eligibility requirements may be granted upon approval by the Department Chair and Institutional Official.

Can a student or trainee be principal investigator (PI)?

If the Principal Investigator is a student, resident, fellow, or other trainee, the UMass Chan IRB requires that a Faculty Advisor be appointed to oversee the conduct of the research. As Faculty Advisor, this individual is expected to oversee and train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research. The Faculty Advisor is also responsible to assure that the research is conducted in accordance with Institutional Policies and Procedures and the Investigator Manual (HRP-103). The IRB may, at its discretion, require a faculty member to function as PI, with a student, resident or other trainee functioning in a co-investigator role. This decision will be made on a case-by-case basis.

What training do my staff and I need to conduct Human Research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

Investigators and staff conducting research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Investigators and staff conducting clinical trials must also complete the online CITI GCP program.

The CITI site can be accessed at http://www.citiprogram.org/.

The IRB will accept completion of the CIRTification program as an alternative to the CITI Program for community members who collaborate on UMass Chan research projects. Community members include those who are not students or employees of UMass Chan/UMMH or other academic institutions. CIRTification is a web-based human research protections training program tailored for community research partners. At UMass Chan, this program is specifically and only for community members that do not have an eIRB account who will work on UMass Chan studies.

The CIRTification site can be accessed at https://training.ccts.uic.edu/.

On a case-by-case basis, the IRB can approve alternative training.

Training is valid for a three-year period, after which time the training must be repeated.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

What financial interests do my staff and I need to disclose to conduct Human Research?

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institutional responsibility.

All individuals involved in the design, conduct, or reporting of research are required to disclose the financial interests in the New Study SmartForm in the electronic IRB system.

- On submission of an initial review.
- As part of continuing review.
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Individuals with reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

- Joining the institution
- Financial conflicts policies are revised in a manner that changes investigator requirements
- Non-compliant with financial conflicts policies and procedures

Additional details can be found in HRP-055 - SOP - Financial Conflicts of Interests.

How do I submit new Human Research to the IRB?

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

- Obtain the financial interest status ("yes" or "no") of each research staff.
- Obtain the agreement of research staff to his/her role in the research.

When am I restricted from submitting new Human Research to the IRB?

If a continuing review application is not received by the date requested in an approval letter, you will be restricted from submitting new human research until the completed application has been received.

If a study has lapsed, you will be restricted from submitting new human research until the study has been closed or reapproved.

If you fail to submit the report of an emergency use of an unapproved drug, biologic, or device within working five days or the IRB application for initial review within 30 days, you will be restricted from submitting new Human Research until the report and IRB application for initial review have been received.

If Clinicaltrials.gov compliance requirements are not met, you will be restricted from submitting new human research until the requirements have been satisfied.

If Oncore CTMS record compliance requirements are not met, you will be restricted from submitting new human research until the requirements have been satisfied.

How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?

This Institution utilizes the IRB to review and approve the use of a HUD before it can be used at a facility for clinical care. You can refer to HRP-323 - WORKSHEET - Criteria for Approval HUD for additional information regarding the criteria that the IRB uses to review and approve HUD uses. The clinical use of a HUD is not considered Human Research but must still be submitted for review and approval by the IRB prior to clinical use (with the exception of emergency use). An informed consent form is not required by the IRB for HUD use.

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

- Obtain the financial interest status ("yes" or "no") of each research staff.
- Obtain the agreement of research staff to his/her role in the research.

How do I request to rely on an external IRB?

Complete the New Study SmartForm in the electronic IRB system, indicate that an External IRB will serve as the IRB of Record and attach all requested supplements. Have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

How do I request that this IRB serve as the IRB of record (Single IRB or sIRB) for my collaborative or multi-site research study?

Contact the IRB Office at IRBreliance@umassmed.edu to ensure that the UMass Chan IRB is able to serve in this capacity. Complete this step prior to drafting any grant or funding proposals that call on the UMass Chan IRB to review for external collaborators or sites.

On the New Study SmartForm in the electronic IRB system, indicate if the study is a multi-site or collaborative research study, then select "Yes" to the question "Will your IRB act as the single IRB of record for other participating sites?" Complete the rest of the New Study SmartForm and attach all available supplements. Participating sites are added by executing the "Add Participating Site" activity. Have the SmartForm submitted by the PI by clicking the "Submit" activity.

How do I write an Investigator Study Plan?

Use HRP-503 - TEMPLATE Investigator Study Plan as a starting point for drafting a new Investigator Protocol and reference the instructions in italic text for the information the IRB looks for when reviewing research. Here are some key points to remember when developing an Investigator Protocol:

- The italicized bullet points in HRP-503 - TEMPLATE Investigator Study Plan serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. All italicized comments are meant to be deleted prior to submission.
- For specified items described in the sponsor's protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents within the Investigator Protocol rather than repeat information.
- When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy when making changes to the Investigator Protocol.
- If you believe your activity may not be Human Research, contact the IRB Office prior to developing your Investigator Protocol.

- Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate.
- You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.
    - Individuals who are not yet adults (infants, children, teenagers)
    - Pregnant women
    - Prisoners
- If your research will involve obtaining informed consent, you may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria
    - Adults unable to provide legally effective consent
    - Non-English speaking subjects – If you are specifically excluding non-English speaking subjects, you must provide a robust justification based on scientific rationale for the exclusion. Exclusions based solely on cost or convenience are not permissible.
- If you are conducting community-based participatory research, you may contact the University of Massachusetts Center for Clinical and Translational Science (UMCCTS) Community Engagement and Collaboration Core for information about:
    - Research studies using a community-based participatory research design
    - Use of community advisory boards
    - Use of participant advocates
    - Partnerships with community-based institutions or organizations

  Visit https://libraryguides.umassmed.edu/CTSACE/CER_Consultation

How do I create a consent document?

Use HRP-502 - TEMPLATE CONSENT DOCUMENT to create a consent document. You may use any format or style as long as the required information is included.

Note that all long form consent documents and all summaries for short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the "Long Form of Consent Documentation" section in HRP-314 - WORKSHEET - Criteria for Approval, to ensure that these elements are addressed. When using the short form of consent documentation, the appropriate signature block from HRP-502 - TEMPLATE CONSENT DOCUMENT should be used on the short form.

If your research study meets the requirements for an exemption and there are interactions with subjects, you may use an abbreviated process for obtaining consent. Consent can be verbal, but

should provide the following information to participants through a written landing page, recruitment letter or email, information sheet, or written script:

- The subject is being asked to participate in a research study;
- A description of the procedure(s) the participant will be asked to complete;
- The expected duration of the subject's participation;
- The extent, if any, to which confidentiality will be maintained;
- Participation is voluntary; and
- The investigator's name and contact information.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective subjects?

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

> (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR
>
> (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

Contact the IRB Office with additional questions or for further guidance regarding the requirement to obtain HIPAA authorization or a waiver to obtain HIPAA authorization for recruitment purposes.

What are the different regulatory classifications that research activities may fall under?

Submitted activities may fall under one of the following five regulatory classifications:

- Not "Human Research": Activities must meet the institutional definition of "Human Research" to fall under IRB oversight. Activities that do not meet this definition of are not subject to IRB oversight or review. Review the IRB Office's HRP-310 - WORKSHEET - Human Research Determination for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.

- "Human research that does not engage the institution": Some human research requires review by an IRB, but is not the responsibility of the organization. The criteria for this determination is in "WORKSHEET: Engagement (HRP-311)" Contact the IRB Office in cases if you are uncertain whether human research is the responsibility of the organization.
- Exempt: Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Office's HRP-312 - WORKSHEET - Exemption Determination for reference on the categories of research that may be exempt.
- Review Using the Expedited Procedure: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the IRB Administration's HRP-313 - WORKSHEET - Expedited Review for reference on the categories of research that may be reviewed using the expedited procedure.
- Review by the Convened IRB: Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, defer research or disapprove research:

- Approval: Made when all criteria for approval are met. See "How does the IRB decide whether to approve Human Research?" below.
- Modifications Required to Secure Approval: Made when IRB members require specific modifications to the research before approval can be finalized.
- Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.
- Deferred: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve Human Research?

The criteria for IRB approval can be found in HRP-312 - WORKSHEET - Exemption Determination for exempt Human Research and HRP-314 - WORKSHEET - Criteria for Approval for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the IRB Web site.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.

You are encouraged to use the checklists to write your Investigator Study Plan in a way that addresses the criteria for approval.

What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- If the IRB has approved the Human Research: The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.
- If the IRB requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.
- If the IRB defers the Human Research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable and give you an opportunity to respond in writing. In most cases if the IRB's reasons for the deferral are addressed in a modification, the Human Research can be approved
- If the IRB disapproves the Human Research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

What are my obligations after IRB approval?

1) Do not start Human Research activities until you have the final IRB approval letter.
2) Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3) Comply with all requirements and determinations of the IRB.
4) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

5) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
6) Update the IRB office with any changes to the list of study personnel.
7) Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
    a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
    b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
    c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
    d) Protect the rights, safety, and welfare of subjects involved in the research.
8) Not enroll the following subject populations unless the IRB affirmatively approved a protocol to include them:
    a) Adults unable to consent
    b) Children
    c) Neonates of uncertain viability
    d) Nonviable neonates
    e) Pregnant women
    f) Prisoners
    g) Individuals unable to speak English
9) Submit to the IRB:
    a) Proposed modifications as described in this manual. (See "How do I submit a modification?")
        i) Single subject protocol exceptions should be submitted via the modification process.
    b) A continuing review application as requested in the approval letter. (See "How do I submit continuing review?")
    c) A continuing review application when the Human Research is closed. (See "How Do I Close Out a Study?")
10) If research approval expires, stop all research activities and immediately contact the IRB.
11) Complete the Report New Information SmartForm within five business days for any of the following information items requiring prompt reporting:
    a) Information that indicates a new or increased risk, or a new safety issue. For example:
        i) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
        ii) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
        iii) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
        iv) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm

v) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
vi) Any changes significantly affecting the conduct of the research

b) Harm experienced by a subject or other individual, which in the opinion of the investigator, is **unexpected** and **probably related** to the research procedures.
   i) A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   ii) A harm is "probably related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
c) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
d) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
e) Written reports of study monitors when they contain findings that also fit one of the other categories of reportable new information.
f) Failure to follow the protocol due to the action or inaction of the investigator or research staff.
g) Breach of confidentiality.
h) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
i) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
j) Complaint of a subject that cannot be resolved by the research team.
k) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
l) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
m) State medical board or hospital medical staff actions

12) Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest and on submission of continuing review.
13) Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
14) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
15) See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do not override the baseline requirements of this section.
16) If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after

recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.

a) If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.
b) Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.

What are my obligations as the overall study PI for an sIRB study?

1) Coordinate with HRPP personnel to determine whether this institution's IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
2) Identify all sites that will be engaged in the human research and requiring oversight by the IRB.
3) Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
4) Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.
5) Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
6) Provide relying site investigators with the policies of the reviewing IRB.
7) Provide relying site investigators with the IRB-approved versions of all study documents.
8) Help prepare and submit IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
9) Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
10) Ensure that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.
11) Provide site investigators with all determinations and communications from the reviewing IRB.
12) Submit reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
13) Report the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the relying site of their lapse in approval and applicable corrective actions.
14) Provide study records to the relying institution, reviewing IRB or regulatory agencies upon request.

What are my obligations as investigator when relying on an external IRB?

1) Obtain appropriate approvals from this institution prior to seeking review by another IRB.
2) Comply with determinations and requirements of the reviewing IRB.
3) Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination prior to IRB review.
4) Notify the reviewing IRB when local policies that impact IRB review are updated.
5) Cooperate in the reviewing IRB's responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
6) Disclose conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
7) Promptly report to the reviewing IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
8) When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.
9) Promptly report to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
10) Provide the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB's reporting policy.
11) Report non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
12) Specify the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.

How do I document consent?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor requires a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects or read who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

- The subject or representative signs and dates the short form consent document.
- The individual obtaining consent signs and dates the summary.

- The witness to the oral presentation signs and dates the short form consent document and the summary.
- Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

How do I submit a modification?

Complete the Modification SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received. Updates to the list of study personnel will be acknowledged unless the update represents a modification to the research.

How do I submit a continuing review?

Complete the Continuing Review SmartForm in the electronic IRB system, attach all requested supplements, and have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications either as a combined Modification and Continuing Review or as a separate request for modification using the Modification SmartForm the electronic system.

If the approval of Human Research expires, all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

How do I close out a study?

Complete the Continuing Review SmartForm in the electronic IRB system, attach all requested supplements, and have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

You may submit a continuing review to close research (end the IRB's oversight) when:

- The protocol is permanently closed to enrollment
- All subjects have completed all protocol related interventions and interactions
- No additional identifiable private information about the subjects is being obtained

- Your analysis of private identifiable information is completed

How long do I keep records?

Maintain your Human Research records, including signed and dated consent documents for at least three years after completion of the research.

Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

If your Human Research is FDA regulated, see Appendix A-2.

For additional information, see the section entitled Human Subjects Research Supplement to University of Massachusetts Chan Guidance on Retention of Research Data.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Contact the IRB Office or IRB chair immediately to discuss the situation. If there is no time to make this contact, see HRP-322 - WORKSHEET - Emergency Use for the regulatory criteria allowing such a use and make sure these are followed. Use HRP-506 - TEMPLATE CONSENT DOCUMENT - Emergency or Compassionate Device Use to prepare your consent document. You will need to submit a report of the use to the IRB within five working days of the use and for drugs and biologics, submit an IRB application for initial review within 30 days.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is "research" as defined by FDA, the individual getting the test article is a "subject" as defined by FDA, and therefore is governed by FDA regulations for IRB review and informed consent. Emergency use of an unapproved device without prior IRB review is not "research" as defined by FDA and the individual getting the test article is not a "subject" as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a "subject" as defined by DHHS and their results cannot be included in prospective "research" as that term is defined by DHHS.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB Web Site at https://www.umassmed.edu/ccts/irb/

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Office at:

Allison Blodgett, PhD, CIP
UMass Chan Director of IRB Operations
362 Plantation Street AC7-215

Worcester MA 01605
508-856-4271
allison.blodgett@umassmed.edu

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contact the IRB Office, follow the directions in HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN under “Reporting and Management of Concerns.”

Appendix A-1 *Additional Requirements for DHHS-Regulated Research*[3]

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.
2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.
3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.
4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.
5. When research is covered by a certificate of confidentiality, researchers:
    a. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    b. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
    c. May disclose information only when:
        i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
        ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

[3] http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html

iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
iv. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

d. Researchers must inform participants of the protections and limitations of certificates of confidentiality (see language in HRP-502 - TEMPLATE CONSENT DOCUMENT).
    i. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.
    ii. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.
e. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

Appendix A-2 *Additional Requirements for FDA-Regulated Research*

1. When a subject withdraws from a study:[4]
    a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
    b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
    c. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
    d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent.
    e. An investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.
2. For FDA-regulated research involving investigational drugs:
    a. Investigators must abide by FDA restrictions on promotion of investigational drugs:[5]
        i. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
        ii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.
        iii. An investigator must not commercially distribute or test market an investigational new drug.

[4] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf
[5] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7

b. Follow FDA requirements for general responsibilities of investigators[6]
   i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.
   ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.
   iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.

c. Follow FDA requirements for control of the investigational drug[7]
   i. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
   ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.

d. Follow FDA requirements for investigator recordkeeping and record retention[8]
   i. Disposition of drug:
      1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
      2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.
   ii. Case histories.
      1. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
      2. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.
   iii. Record retention: An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no

[6] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60
[7] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61
[8] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

e. Follow FDA requirements for investigator reports[9]
   i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
   ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.
   iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
   iv. Financial disclosure reports:
      1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
      2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

f. Follow FDA requirements for assurance of IRB review[10]
   i. An investigator must assure that an IRB that complies with the requirements set forth in 21 CFR §56 will be responsible for the initial and continuing review and approval of the proposed clinical study.
   ii. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

g. Follow FDA requirements for inspection of investigator's records and reports[11]
   i. An investigator must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62.
   ii. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

[9] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64
[10] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66
[11] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68

h. Follow FDA requirements for handling of controlled substances[12]
    i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

3. For FDA-regulated research involving investigational devices:
    a. General responsibilities of investigators.[13]
        i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 CFR §50.
    b. Specific responsibilities of investigators[14]
        i. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining IRB and FDA approval.
        ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.
        iii. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
        iv. Financial disclosure:
            1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.
            2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.
        v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining

[12] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69
[13] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100
[14] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110

supply of the device or otherwise dispose of the device as the sponsor directs.

c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:[15]
    i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
    ii. Records of receipt, use or disposition of a device that relate to:
        1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
        2. The names of all persons who received, used, or disposed of each device.
        3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
    iii. Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. Such records must include:
        1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
        2. Documentation that informed consent was obtained prior to participation in the study.
        3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
        4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.
    iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
    v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

d. Inspections[16]
    i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where

[15] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140
[16] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145

devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

iii. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

e. Prepare and submit the following complete, accurate, and timely reports[17]

i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

ii. Withdrawal of IRB approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

iv. Deviations from the investigational plan:

1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.
2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB also is required.

v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

[17] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150

vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Appendix A-3 *Additional Requirements for Clinical Trials (ICH-GCP)*

1. The clinical trial should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice (GCP) and the applicable regulatory requirements. The rights, safety, and well-being of the participants are the most important considerations and should prevail over interests of science and society.
2. Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches.
    a. The available nonclinical and clinical information on an investigational product(s) should be adequate to support the proposed clinical trial.
    b. Clinical trials should be scientifically sound and reflect the state of knowledge and experience with the investigational product(s), including, if applicable, the condition being treated, diagnosed, or prevented; the current understanding of the underlying biological mechanism (of both the condition and the investigational product); and the population for which the investigational product is intended.
    c. There should be periodic review of current scientific knowledge and approaches to determine whether modifications to the trial are needed, since new or unanticipated information may arise once the trial has begun.
3. Investigator's Qualifications and Training
    a. The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications.
    b. The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information, and/or in other information sources provided by the sponsor.
4. Resources
    a. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of eligible participants within the recruitment period as agreed with the sponsor.
    b. The investigator should have sufficient time, an adequate number of available and qualified staff, and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
5. Responsibilities
    a. The investigator may delegate trial-specific activities to other persons or parties. The investigator may be supported by the sponsor in the identification of a suitable service provider(s); however, the investigator retains the final decision on whether the service provider intended to support the investigator is appropriate based on information provided to the sponsor. The investigator retains the ultimate responsibility and should maintain appropriate oversight of the persons or parties undertaking the activities delegated to ensure the rights, safety, and well-being of the trial participants and reliability of the data. The level of investigator oversight of the delegated activities should depend on the nature of

the delegated activities and be proportionate to the importance of the data being protected and the risks to trial participant safety and data reliability.

b. The investigator should ensure that all persons or parties to whom the investigator has delegated trial-related activities are appropriately qualified and are adequately informed about the relevant aspects of the protocol, the investigational product(s), and their assigned trial activities (including activities conducted by staff provided by other parties in accordance with local regulatory requirements). Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfill their delegated trial activities that go beyond their usual training and experience.
c. The investigator should ensure a record is maintained of the persons and parties to whom the investigator has delegated trial-related activities. Documentation of delegation should be proportionate to the significance of the trial-related activities. In situations where the activities are performed as part of clinical practice, delegation documentation may not be required.
d. Agreements made by the investigator/institution with service providers for trial-related activities should be documented.
e. The investigator/institution should permit monitoring and auditing by the sponsor, inspection by the appropriate regulatory authority(ies) and, in accordance with applicable regulatory requirements, review by IRB(s).

6. Communication with IRB
    a. Submission to the IRB may be made by the investigator/institution or sponsor in accordance with applicable regulatory requirements.
    b. Before initiating a trial, the investigator/institution should have a documented and dated approval from the IRB for the trial protocol, informed consent materials, participant recruitment procedures (e.g., advertisements), and any other trial-related information to be provided to participants.
    c. As part of the investigator's/institution's or sponsor's (in accordance with applicable regulatory requirements) submission to the IRB, a current copy of the Investigator's Brochure or basic product information brochure should be provided. If the Investigator's Brochure or basic product information brochure is updated during the trial, the IRB should receive the current version in accordance with applicable regulatory requirements.
    d. As the trial progresses, the investigator/institution or sponsor should provide any updates to the participant information to the IRB in accordance with applicable regulatory requirements.
    e. The investigator or sponsor should submit documented summaries of the trial status to the IRB in accordance with local regulatory requirements or upon request.
    f. The investigator or the sponsor should promptly communicate to the IRB and, where applicable, to the institution any changes significantly affecting the conduct of the trial and/or increasing risk to participants.
7. Compliance with Protocol
    a. The investigator/institution should sign the protocol, or an alternative contract, to confirm agreement with the sponsor.

b. The investigator/institution should comply with the protocol, GCP, and applicable regulatory requirements.
c. The investigator should document all protocol deviations. In addition to those identified by the investigator themselves, protocol deviations related to their trial participants and their conduct of the trial may be communicated to them by the sponsor. In either case, the investigator should review the deviations, and for those deviations deemed important, the investigator should explain the deviation and implement appropriate measures to prevent a recurrence, when applicable.
d. The investigator should follow the protocol and deviate only where necessary to eliminate an immediate hazard(s) to trial participants. In case of deviations undertaken to eliminate immediate hazard to trial participants, the investigator should inform the sponsor promptly.
e. The investigator should report information on the immediate hazard, the implemented change, and the subsequent proposed protocol amendment, if any, to the IRB and, where applicable, regulatory authorities.

8. Premature Termination or Suspension of a Trial
    a. If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial participants and should assure appropriate therapy and follow-up for the participants.
    b. Where the investigator terminates or suspends their involvement in a trial without prior agreement by the sponsors, the investigator should promptly inform the institution, where applicable, the sponsor, the IRB, and the regulatory authorities in accordance with applicable regulatory requirements and should provide a detailed explanation of the reasons.
    c. If the sponsor terminates or suspends a trial, the investigator/institution, or the sponsor, in accordance with applicable regulatory requirement(s), should promptly inform the IRB and the regulatory authorities and should provide an appropriate explanation.
    d. If the IRB terminates or suspends its approval of a trial, the investigator should inform the institution, where applicable, and the investigator/institution should promptly notify the sponsor.
9. Participant Medical Care and Safety Reporting
    a. Medical Care of Trial Participants
        i. A qualified physician or, where appropriate, a qualified dentist (or other qualified healthcare professionals in accordance with local regulatory requirements) who is an investigator or a sub-investigator for the trial, should have the responsibility for trial-related medical care and decisions.
        ii. Other appropriately qualified healthcare professionals may be involved in the medical care of trial participants, in line with their normal activities and in accordance with local regulatory requirements.
        iii. During and following participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a participant

when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

iv. The investigator should inform the participant's primary physician about the participant's involvement in the trial if the participant has a primary physician and agrees to the primary physician being informed.

b. Safety Reporting

i. Adverse events and/or abnormal test results required for safety evaluations (as outlined in the protocol) should be reported to the sponsor according to the reporting requirements and within the time periods specified in the protocol. Unfavorable medical events occurring in participants before investigational product administration (e.g., during screening) should be considered and reported to the sponsor if required by the protocol.

ii. All serious adverse events (SAEs) should be reported immediately (after the investigator reasonably becomes aware of the event) to the sponsor. The investigator should also include an assessment of causality. In accordance with applicable regulatory requirements, the protocol may identify SAEs not requiring immediate reporting, for example, deaths or other events that are endpoints. Subsequent information should be submitted as a follow-up report, as necessary.

iii. For reported deaths, the investigator should supply the sponsor, the IRB and, where applicable, the regulatory authority with any additional requested information (e.g., autopsy reports and terminal medical reports) when they become available.

iv. The investigator may delegate activities for safety reporting to qualified investigator site staff but retains the overall responsibility for safety of participants under their responsibility and compliance with the reporting requirements.

10. Informed Consent of Trial Participants

a. In obtaining and documenting informed consent (paper or electronic format), the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. The informed consent process should include the following:

i. Prior to consenting and enrolling participants, the investigator should have the IRB's documented approval of the informed consent materials and process.

ii. The information should be as clear and concise as possible, use simple language, and avoid unnecessary volume and complexity. This is to ensure that the trial participants or their legally acceptable representatives have an adequate understanding of the objectives of the trial, alternative treatments, potential benefits and risks, burdens, their rights, and what is expected of the participants to be able to make an informed decision as to their participant in the trial.

iii. Varied approaches (e.g., text, images, videos and other interactive methods) may be used in the informed consent process, including for

providing information to the participant. The characteristics of the potential trial population (e.g., participants may lack familiarity with computerized systems) and the suitability of the method of obtaining consent should be taken into consideration when developing the informed consent materials and process. When computerized systems are used to obtain informed consent, trial participants may be given the option to use a paper-based approach as an alternative.

iv. Obtaining consent remotely may be considered where appropriate.

v. Whether the informed consent process takes place in person or remotely, the investigator should assure themselves of the identity of the participant (or legally acceptable representative) in accordance with applicable regulatory requirements.

b. The participant or the participant's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the participant's willingness to continue trial participation. The communication of this information and confirmation of the willingness to continue trial participation should be documented. New information that could impact a participant's willingness to continue participation should be assessed to determine if re-consent is needed (e.g., depending on the stage of the trial, consideration should be given to whether the new information is relevant only to new participants or to existing participants). If re-consent is needed (e.g., information on emerging safety concerns), new information should be clearly identified in the revised informed consent materials. Revised informed consent materials should receive the IRB's approval in advance of use.

c. Neither the investigator, nor the investigator site staff, should coerce or unduly influence a participant to participate or to continue their participation in a trial.

d. None of information provided to the participant or the participant's legally acceptable representative during the informed consent process should contain any language that causes the participant to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their service providers from liability for negligence.

e. The informed consent process should be conducted by the investigator or other investigator site staff delegated by the investigator, in accordance with applicable regulatory requirements. If the participant is unable to provide informed consent themselves (e.g., minors, patients with severely impaired decision making capacity), the participant's legally acceptable representative should provide their consent on behalf of the participant.

f. The information provided during the informed consent process and translations should be relevant, clear, simple, concise, and understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.

g. Before informed consent may be obtained, the investigator, or investigator site staff delegated by the investigator, in accordance with the protocol and conditions of IRB approvals, should provide the participant or the participant's legally acceptable representative ample time unless justified (e.g., in an emergency

situation) and opportunity to inquire about trial details and to decide whether or not to participate in the trial. Questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.

h. Prior to trial participation in the trial, the informed consent form should be signed and dated by the participant or by the participant's legally acceptable representative, where appropriate, by an impartial witness, and by the investigator or delegated investigator site staff who conducted the informed consent discussion. By signing the consent form, the investigator or delegated investigator site staff attests that the informed consent was freely given by the participant or the participant's legally acceptable representative and the consent information was accurately explained to and apparently understood by the participant or the participant's legally acceptable representative. The informed consent process may involve a physical or an electronic signature and date.
i. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible and the participant's legally acceptable representative is not possible and the participant's legally acceptable representative is not available, enrollment of the participant should require measures described in the protocol and/or elsewhere, with documented approval by the IRB, to protect the participant's rights, safety, and well-being and to ensure compliance with applicable regulatory requirements. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible, and consent as appropriate should be requested.
j. If a participant or the legally acceptable representative is unable to read, an impartial witness should be present (remotely or in-person) during the entire informed consent discussion. After the informed consent form and any other information is read and explained to the participant or the participant's legally acceptable representative, and they have orally consented to the participant's trial participation, and if capable of doing so, have signed and dated the informed consent form, the witness should sign and date the consent form. By signing the consent form, the witness attests that the consent information was accurately explained to, and apparently understood by, the participants or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.
k. The informed consent discussion and the informed consent materials to be provided to participants should explain the following as applicable:
    i. The purpose of the trial
    ii. That the trial involves research and a summary of the experimental aspects of the trial
    iii. The trial's investigational product(s) and the probability for random assignment to the investigational product, if applicable
    iv. The trial procedures to be followed, including all invasive procedures
    v. What is expected of the participants

vi. The reasonably foreseeable risks or inconveniences to the participant and, when applicable, the participant's partner, and to an embryo, fetus, or nursing infant
vii. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this
viii. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks
ix. The compensation and/or treatment available to the participant in the event of trial related injury
x. Any anticipated prorated compensation to the participant for trial participation
xi. Any anticipated expenses to the participant for trial participation
xii. That the participant's trial participation is voluntary, and the participant may decide to stop taking the investigational product or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled
xiii. The follow-up procedure for participants who stopped taking the investigational product, withdrew from the trial, or were discontinued from the trial
xiv. The process by which the participant's data will be handled, including in the event of the withdrawal or discontinuation of participation, in accordance with applicable regulatory requirements
xv. That by agreeing to participate in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of reviewing trial activities and/or reviewing or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), the IRB, and in accordance with applicable regulatory requirements.
xvi. That records identifying the participant will be kept confidential and, to the extent permitted by the applicable regulatory requirements, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements.
xvii. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue trial participation
xviii. The person(s) to contact for further trial information and the trial participant's rights, and whom to contact in the event of suspected trial-related injury
xix. The foreseeable circumstances and/or reasons under which the participant's trial participation may be terminated

xx. The expected duration of the trial participant's participation
xxi. The approximate number of participants involved in the trial
xxii. That trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it when this information is available from the sponsor

l. Prior to participation, the participant or the participant's legally acceptable representative should receive a copy (paper or electronic) of the signed informed consent form and any other informed consent materials provided, in accordance with applicable regulatory requirements. During trial participation, the participant or the participant's legally acceptable representative should receive a copy of the consent form updates and any other updated informed consent materials provided.
m. When a minor is to be included as a participant, age-appropriate assent information should be provided and discussed with the minor as part of the consent process, and assent from the minor to enroll in the trial should be obtained as appropriate. A process for re-consent should be considered if, during the course of the trial, the minor reaches the age of legal consent, in accordance with applicable regulatory requirements.
n. When a clinical trial includes participants who may only be enrolled in the trial with the consent of the participant's legally acceptable representative, the participants should be informed about the trial in a manner that facilitates their understanding and, if capable, the participant should sign and date the informed consent form or assent form as appropriate.

11. End of Participation in a Clinical Trial
    a. When a participant decides to stop treatment with the investigational product, stop trial visits, or completely withdraw from a trial; is discontinued from the trial; or reaches the routine end of the trial, the investigator should follow the protocol and other sponsor instructions to determine appropriate follow-up measures. This may include instructions to avoid unnecessary loss of already collected critical data in accordance with applicable regulatory requirements.
    b. Although a participant is not obliged to provide a reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights. The investigator should consider if a discussion with the participant or the participant's legally acceptable representative is appropriate. This discussion should focus on the reasons for withdrawal to determine if there are ways to address the concerns such that the participant could reconsider withdrawal without unduly influencing the participant's decision. The investigator or delegated investigator site staff should consider explaining to the participant the value of continuing their participation to minimize trial participants withdrawal. In this process, the investigator should ensure that it does not interfere with the participant's decision to refuse or withdraw participation at any time.
    c. Where relevant, the investigator should inform the participant about the trial results and treatment received when this information is available from the sponsor after unblinding, with due respect to the participant's preference to be informed.
12. Investigational Product Management

a. Responsibility for investigational product(s), including accountability, handling, dispensing, administration, and return, rests with the investigator/institution. The sponsor may facilitate aspects of investigational product management (e.g., by providing forms and technical solutions, such as computerized systems, and arranging distribution of investigational product to trial participants).
b. When the investigator/institution delegates some or all of their activities for investigational product(s) management to a pharmacist or another individual in accordance with local regulatory requirements, the delegated individual should be under the oversight of the investigator/institution.
c. Where the investigator has delegated activities related to investigational product management or aspects of these activities have been facilitated by the sponsor, the level of investigator oversight will depend on a number of factors, including the characteristics of the investigational product, route and complexity of administration, level of existing knowledge about the investigational product's safety, and marketing status.
d. The investigator/institution and/or pharmacist or other appropriate individual should maintain records of the product's delivery, the inventory, the use by each participant (including documenting that the participants were provided the doses specified by the protocol), and the return to the sponsor and destruction or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial participants. For authorized medicinal products, alternative approaches to the aforementioned may be considered, in accordance with local regulatory requirements.
e. The investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s).
f. The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.
g. When applicable, the investigator or a person designated by the investigator/institution should explain the correct use of the investigational product(s) to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions properly.
h. The investigational product may be shipped to the participant's location or supplied to/dispensed at a location closer to the participant (e.g., at a local pharmacy or local healthcare center). The investigational product may be administered at the participant's location by investigator site staff, the participant themselves, or a caregiver or a healthcare professional.
i. Investigational product management should be arranged and conducted in accordance with applicable regulatory requirements, and safeguards should be in place to ensure product integrity, product use per protocol, and participant safety.

13. Randomization Procedures and Unblinding
    a. The investigator should follow the trial's randomization procedures, if any, and in the case of an investigator-blinded trial, should ensure that the treatment randomization code is broken only in accordance with the protocol. In the case of an emergency, to protect participant safety, the investigator should be prepared

and capable from the start of the trial to perform unblinding without undue delay and hindrance. The investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, emergency unblinding to protect trial participant, unblinding due to an SAE) of the investigational product(s).

14. Records
    a. In generating, recording, and reporting trial data, the investigator should ensure the integrity of data under their responsibility, irrespective of the media used.
    b. The investigator/institution should maintain adequate source records that include pertinent observations on each of the trial participants under their responsibility. Source records should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source records should be traceable, should not obscure the original entry, and should be explained if necessary (via an audit trail). The investigator should define what is considered to be a source record(s), the methods of data capture, and their location prior to starting the trial and should update this definition when needed. Unnecessary transcription steps in between the source record and the data acquisition tool should be avoided.
    c. The investigator should be provided with timely access to data by the sponsor and be responsible for the timely review of data, including relevant data from external sources that can have an impact on, for example, participant eligibility, treatment, or safety (e.g., central laboratory data, centrally read imaging data, other institution's records and, if appropriate, electronic patient-reported outcome (ePRO) data). The protocol may provide exceptions for access, for instance, to protect blinding.
    d. The investigator should ensure that data acquisition tools and other systems deployed by the sponsor are used as specified in the protocol or trial-related instructions.
    e. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the data acquisition tools completed by the investigator site (e.g., case report form (CRF)) and in any other required reports (e.g., SAE reports). The investigator should review and endorse the reported data at important milestones agreed upon with the sponsor (e.g., interim analysis).
    f. Data reported to the sponsor should be consistent with the source records or the discrepancies explained. Changes or corrections in the reported data should be traceable, should be explained (if necessary), and should not obscure the original entry.
    g. The investigator/institution should implement appropriate measures to protect the privacy and confidentiality of personal information or trial participants in accordance with applicable regulatory requirements on personal data protection.
    h. Data reported to the sponsor should be identified by an unambiguous participant code that can be tracked back to the identity of the participant by the investigator/institution.
    i. For systems deployed by the investigator/institution that maintain and retain trial data/information, the investigator/institution should ensure that such data are

protected from unauthorized access, disclosure, dissemination, or alteration and from inappropriate destruction or accidental loss.

j. When using computerized systems in a clinical trial, the investigator/institution should do the following:
    i. For systems deployed by the investigator/institution, ensure that appropriate individuals have secure and attributable access.
    ii. For systems deployed by the sponsor, notify the sponsor when access permissions need to be changed or revoked from an individual.
    iii. For system deployed by the investigator/institution specifically for the purposes of clinical trials, ensure the requirements for computerized systems in section 4 of ICH GCP Annex 1[18] are addressed proportionate to the risks to participants and to the importance of the data.
    iv. Where equipment for data acquisition is provided to trial participants by the investigator, ensure that traceability is maintained and participants are provided with appropriate training.
    v. Ensure that incidents in the use and operation of computerized systems, which in the investigator/institution's judgment may have a significant and/or persistent impact on the trial data or system security, are reported to the sponsor and, where applicable, to the IRB.

k. The investigator/institution should maintain the trial records as specified in Appendix C of ICH GCP Annex 1 and as required by the applicable regulatory requirement(s). The investigator/institution should have control of all essential records generated by the investigator/institution before and during the conduct of the trial.

l. The investigator/institution should retain the essential records for the required retention period in accordance with applicable regulatory requirements or until the sponsor informs the investigator/institution that these records are no longer needed, whichever is the longest. The investigator/institution should take measures to ensure availability, accessibility, and readability and to prevent unauthorized access and accidental or premature destruction of these records.

m. The investigator/institution should keep the sponsor informed of the name of the person responsible for maintaining the essential records during the retention period; for example, when the investigator site closes or an investigator leaves the site.

n. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

15. Reports

a. Upon completion of the trial, the investigator, where applicable, should inform the institution. The investigator/institution should provide the IRB with a summary of the trial's outcome, and, if applicable, the regulatory authorities with any required reports.

[18] https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

Appendix A-4 *Additional Requirements for Department of Defense (DOD) research*

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
5. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
6. There may be specific educational requirements or certification required.
7. When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution's education and training policies to ensure the personnel are qualified to perform the research.
8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
    a. Prohibit an individual from receiving pay of compensation for research during duty hours.
    b. An individual may be compensated for research if the participant is involved in the research when not on duty.
    c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
    d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
9. Surveys performed on DOD personnel must be submitted, reviewed, and approved by the DOD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DOD components, additional review is required. Consult the Department of Defense funding component to coordinate this review.
10. When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
    a. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD-affiliated personnel's genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
    b. Research will apply an HHS Certificate of Confidentiality

c. DoD Component security review

11. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
12. Other specific requirements of the Department of Defense research are found in the "Additional Requirements for Department of Defense (DOD) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-5 *Additional Requirements for Department of Energy (DOE) Research*

(See DOE Order 443.1C)

1. Research that involves one or more of the following must be submitted to the appropriate IRB for human subjects research review and determination:
    a. Study of humans in a systematically modified environment. These studies include but are not limited to intentional modification of the human environment:
        i. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
        ii. Study in occupied homes or offices that:
            1. Manipulate the environment to achieve research aims.
            2. Test new materials.
            3. Involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
    b. Use of social media data
    c. Human Terrain Mapping (HTM)
    d. All exempt HSR determinations must be made by the appropriate IRB and/or IRB office.
2. Personally identifiable information collected and/or used during HSR projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program, current version. The Central DOE IRBs require submission of DOE's HRP- 490-CHECKLIST-Reviewing Protocols that use Personally Identifiable Information (PII) if your research includes PII.
3. You must report the following to the DOE human subjects research Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) prior to initiation of any new human subjects research project, even if it meets the regulatory definition of exempt human subjects research as outlined in 10 CFR Part 745.104, involving:
    a. An institution without an established Institutional Review Board (IRB);
    b. A foreign country;
    c. The potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups);
    d. Research subjects in a protected class (prisoners, children, individuals with impaired decision making capability, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope; or
    e. The generation or use of classified information.

4. The IRB must be notified immediately and the DOE HSP Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) must be notified

within 48 hours and consulted regarding planned corrective actions if any of the following occur:

a. Adverse events. Notify the IRB for all adverse events and the DOE/NNSA HSP Program Manager if the IRB determines them to be significant, as defined in DOE Order 443.1C.
b. Unanticipated problems and complaints about the research.
c. Any suspension or termination of IRB approval of research
d. Any significant non-compliance with HSP Program procedures or other requirements.
e. Any finding of a suspected or confirmed data breach involving PII in printed or electronic form. Report immediately to the IRB, the DOE/NNSA HSP Program Manager(s), and the DOE-Cyber Incident Response Capability, in accordance with the requirements of the CRD associated with DOE O 206.1.
f. Serious adverse events and corrective actions taken must be reported immediately to the IRB and the DOE/NNSA HSP Program Manager(s). The time frame for "immediately" is defined as upon discovery.

5. Requirements for human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts, and including Human Terrain Mapping research.
6. Researchers conducting human subjects research in any other country or on citizens or other individuals residing in that country must be cognizant of country-specific human subjects research requirements and consult the IRB regarding applicability of such requirements.
7. No human subjects research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR §745.103.
8. Human subjects research involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.
9. Human subjects research that involves DOE Federal and/or contractor employees must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the Federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the organization responsible for IRB review.

10. Classified and unclassified human subjects research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.
11. If applicable, federally funded HSR must comply with the requirements of the Paperwork Reduction Act.
12. Other specific requirements of DOE research can be found in the "Additional Requirements for Department of Energy (DOE) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-6 *Additional Requirements for Department of Justice (DOJ) Research*

Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons

1. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3. The research design must be compatible with both the operation of prison facilities and protection of human subjects.
4. Investigators must observe the rules of the institution or office in which the research is conducted.
5. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6. The research must be reviewed and approved by the Bureau Research Review Board.
7. Incentives cannot be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both: No longer in Bureau of Prisons custody. Participating in authorized research being conducted by Bureau employees or contractors.
8. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
9. Except as noted in the consent statement to the subject, you must not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
10. Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
11. If you are conducting a study of special interest to the Office of Research and Evaluation but the study is not a joint project involving Office of Research and Evaluation, you may be asked to provide Office of Research and Evaluation with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
12. Required elements of disclosure additionally include:
    a. Identification of the investigators.
    b. Anticipated uses of the results of the research.

c. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
d. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
e. A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.

13. You must have academic preparation or experience in the area of study of the proposed research.
14. The IRB application must include a summary statement, which includes:
    a. Names and current affiliations of the investigators.
    b. Title of the study.
    c. Purpose of the study.
    d. Location of the study.
    e. Methods to be employed.
    f. Anticipated results.
    g. Duration of the study.
    h. Number of subjects (staff or inmates) required and amount of time required from each.
    i. Indication of risk or discomfort involved as a result of participation.
15. The IRB application must include a comprehensive statement, which includes:
    a. Review of related literature.
    b. Detailed description of the research method.
    c. Significance of anticipated results and their contribution to the advancement of knowledge.
    d. Specific resources required from the Bureau of Prisons.
    e. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    f. Description of steps taken to minimize any risks.
    g. Description of physical or administrative procedures to be followed to: Ensure the security of any individually identifiable data that are being collected for the study.
    h. Destroy research records or remove individual identifiers from those records when the research has been completed.
    i. Description of any anticipated effects of the research study on institutional programs and operations.
    j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
16. The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.

17. You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.
18. At least once a year, you must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
19. At least 12 working days before any report of findings is to be released, you must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
20. You must include an abstract in the report of findings.
21. In any publication of results, you must acknowledge the Bureau's participation in the research project.
22. You must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
23. Prior to submitting for publication the results of a research project conducted under this subpart, You must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
24. Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the "Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Additional Requirements for DOJ Research Funded by the National Institute of Justice

1. The project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer.
2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3. The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
5. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
    a. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.
    b. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
    c. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.

d. The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
e. Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons

6. Other specific requirements of the Department of Justice (DOJ) Research Funded by the National Institute of Justice can be found in the "Additional Requirements for Department of Justice (DOJ) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-7 *Additional Requirements for Department of Education (ED) Research*

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children[19] involved in the research[20] must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
4. Other specific requirements of the Department of Education (ED) Research can be found in the "Additional Requirements for Department of Education (ED) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

[19] Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.
[20] Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

Appendix A-8 *Additional Requirements for Environmental Protection Agency (EPA) Research*

1. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
2. Intentional exposure of pregnant women or children to any substance is prohibited.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women (45 CFR §46 Subpart B) and additional DHHS requirements for research involving children (45 CFR §46 Subpart D.)
4. Research involving children must meet category #1 or #2.
5. Other specific requirements of the Environmental Protection Agency (EPA) Research can be found in the "Additional Requirements for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-9 ***Single IRB Studies***

1. That National Institutes of Health expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
    a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
    b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
    c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.
2. The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

    The following research is not subject to this provision:
    a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
    b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
    c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.
3. If the Institution engages in research conducted or funded by the Veterans Administration (VA), prior VA IRB review and approval must be obtained. Engagement of the Institution is determined by HRP-311 – WORKSHEET – Engagement Determination. The Principal Investigator is responsible to follow VA procedures to establish the VA IRB as the IRB of record or to obtain an exception from the sIRB requirement from the VA. If an exception is granted, the UMass Chan IRB will conduct a parallel IRB review.

However, UMass Chan IRB approval is contingent on VA IRB approval to ensure compliance with VA requirements.

Appendix A-10 *Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)*

1. Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland is subject to EU General Data Protection Regulations.
2. For all prospective Human Research subject to EU GDPR, contact institutional legal counsel or your institution's Data Protection Officer to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
    a. Any applicable study design elements related to data security measures.
    b. Any applicable procedures related to the rights to access, rectification, and erasure of data.
    c. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
3. Where FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with Appendices A-1 and A-2 above.

Appendix A-11 *Emergency/Disaster Preparedness Considerations for Investigators Conducting Human Research*

Investigators conducting human research should be aware of the following additional considerations associated with managing Human Research during an emergency/disaster scenario (e.g., extreme weather events, natural disasters, man-made disasters, infectious disease pandemics, etc.) related to investigators' ongoing interactions with research subjects and the institutional review board (IRB) in such cases.

During Emergency/Disaster Scenarios: Deciding Whether a Study-Specific Risk Mitigation Plan for Ongoing Research Is Needed

In general, investigators should develop a study-specific emergency/disaster risk mitigation plan for their research unless one of the following is true:

- Research does not involve in-person interaction with research subjects.
- Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event.
- The research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.
- The research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event).

Tools and Resources for Developing Study-Specific Emergency/Disaster Risk Mitigation Plans for Ongoing Research

Review "HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning" and "HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Plan" for general guidance on developing study-specific risk mitigation plans.

Voluntary Holds on Human Research Activities

Investigators may voluntarily elect to place all recruitment, enrollment, and research procedures on temporary hold during emergency/disaster scenarios if doing so will better ensure the safety of research subjects and would not create any additional risks to the safety and welfare of research subjects. Such voluntary holds on research activity do not require IRB notification or review.

Submitting Study-Specific Emergency/Disaster Risk Mitigation Plans for IRB Review

If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.

For all other study modifications made to ensure the ongoing safety of research subjects during emergency/disaster scenarios, submit a study amendment and all relevant new or modified study materials to the IRB.

Other Reportable New Information Considerations During Emergency/ Disaster Scenarios

The IRB's list of reportable events includes two items for which additional clarification and guidance may be helpful during emergency/disaster scenarios:

- ***"Failure to follow the protocol due to the action or inaction of the investigator or research staff."*** Emphasis on action or inaction of the investigator or research staff has been added because this requirement does not include action or inaction of the research subject. For example, study teams may notice an increase in the number of subjects who do not arrive for scheduled research visits under emergency/disaster circumstances. Failure of a research participant to appear for a scheduled research visit is not noncompliance due to action or inaction by the investigator or research staff, and therefore does not require reporting to the IRB.
- ***"Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject."*** During emergency/disaster scenarios, there will be cases where there is sufficient time to receive IRB approval of any proposed modifications to previously approved research, and in such cases, investigators should follow standard IRB procedures for submitting modifications. However, there will be other cases where investigators must make more immediate changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants. Such changes may be implemented without IRB approval, but are required to be reported to the IRB within five business days afterward in accordance with IRB policies and procedures for submitting reportable new information.

Human Subjects Research Supplement to University of Massachusetts Chan Guidance on Retention of Research Data

Maintaining accurate and appropriate records with respect to original Research Data is an essential component of any research project. It is necessary to support and substantiate findings, to protect intellectual property rights, to facilitate management of the research program of UMass Chan, to enable data sharing, and to ensure compliance with federal regulations, UMass Chan policies and sponsor requirements.

A. Record Retention for Human Subjects/Clinical Research--Investigators

The Study Principal Investigator is responsible for management and retention of research data and records. These records include:

Type of Record	Baseline Retention	Additional considerations
Regulatory Documentation, Including: • IRB Approval letters • IRB Correspondence • IRB approved versions of study documents • Correspondence with Federal Agencies	Minimum of three years after completion of the research or closure with the IRB[21]	Longer retention for: • HIPAA (Waiver of Authorization, accounting of disclosures): minimum of 6 years[22] • FDA: minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[23] • ICH/GCP[24]: minimum of 2 years after last approval of marketing application or discontinuation. • Funder Agreement/Award: per terms of the Agreement/Award • Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University[25]
Signed Informed Consent Forms (ICF) (if applicable)	Minimum of three years after completion of the research or closure with the IRB	Longer retention for: • HIPAA (combined ICF/Authorization): minimum of 6 years • FDA: minimum of 2 years past approval or discontinuation • ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation. • Funder Agreement/Award: per terms of the Agreement/Award

[21] See HRP-103, Investigator Manual, p. 17
[22] See HRP-103, Investigator Manual, p. 17
[23] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11
[24] See HRP-103, Investigator Manual, Appendix A-3
[25] See Records Management, Retention, and Disposition Policy, Policy 1.02.04

		• Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University
Signed Authorization forms or IRB Waiver of Authorization (if applicable)	Minimum of 6 years	Longer retention for: • FDA: minimum of 2 years past approval or discontinuation (if combined with Authorization), or minimum of 2 years past final report for electronic records[26]ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation (if combined with ICF) • Funder Agreement/Award: per terms of the Agreement/Award • Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University
Accounting of Disclosures (if applicable)	Minimum of 6 years	

General research data	Minimum of three years after completion of the research or closure with the IRB	Longer retention for:
		• FDA: minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[6]
		• ICH/GCP[27]: minimum of 2 years after last approval of marketing application or discontinuation.
		• Funder Agreement/Award: per terms of the Agreement/Award
		  ○ For Federal: minimum of three years, up to seven years, depending on specific funding agency requirement.[28]
		  ○ For National Institutes of Health Awards: per terms of award, NIH Grants Policy Statement (3 years following closeout of grant/contract agreement[29]) and data management and sharing plan (DMSP)[30]

[26] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11
[27] See HRP-103, Investigator Manual, Appendix A-3
[28] OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations); various regulations including 45 CFR 74 and 45 CFR 92
[29] See Section 8.4.2 of the NIH Grants Policy Statement
[30] See NIH Data Management and Sharing Policy

		• Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University

FDA regulated Human Research, including:
• Informed Consent documentation
• Deviations
• Adverse Events
• Drug/Device handling records.
• Case Report Forms
• Source Documents
	Minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[31]	Longer retention for:
		• Source Documents: portions may be subject to record retention policy of holding organization i.e. UMass Memorial Medical Center.
		• HIPAA (combined ICF/Authorization): minimum of 6 years
		• ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation.
		• Funder Agreement/Award: per terms of the Agreement/Award
		  ○ For Federal: minimum of three years, up to seven years, depending on specific funding agency requirement.[32]
		  ○ For National Institutes of Health Awards: per terms of award, NIH Grants Policy Statement (3 years following closeout of grant/contract agreement[33]) and data management and sharing plan (DMSP)[34]
		• Children: until age 21
		• Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University

Student-led Research	Minimum of three years after award of degree or abandonment.	Longer retention as outlined above.

[31] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11
[32] OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations); various regulations including 45 CFR 74 and 45 CFR 92
[33] See Section 8.4.2 of the NIH Grants Policy Statement
[34] See NIH Data Management and Sharing Policy

B. Storage of Records

All research records must be retained and stored in accordance with UMass Chan policies, standards, guidelines and best practices, including any and all requirements promulgated by UMass Chan Information Technology.

C. Transfer of Records--Departing Principal Investigator

If the Investigator leaves UMass Chan, the Investigator must leave the original research, data, notebooks at UMass Chan and only take a copy of those materials with them. If the research is ongoing, the new UMass Chan Principal Investigator will become the primary data custodian. If the research is concluded, an individual within the Principal Investigator's department must be appointed as data custodian. For research that is subject to FDA regulations, applicable requirements may mandate a report of change in record responsibility to the FDA within 10 working days after the transfer[35].

[35] Device: 21 CFR 812.140(e)

UMass Chan MEDICAL SCHOOL

Should I take part in a research study?

Here are some things you should know.

What is an IRB?

The Institutional Review Board (IRB) is a group of people who review and approve human research. The IRB includes medical people, scientists, and people from the local community. They review human research to make sure it is well-planned and ethical.

The IRB serves to protect your rights and your welfare before and during the research study. For example, the IRB makes sure that any risks are as small as possible. The IRB does not decide for you. The IRB decides whether it is right to ask people whether they want to take part in a research study. The IRB also reviews each research study while it is going on to make sure volunteers are protected.

Should I take part in a research study?

Thousands of research studies are being conducted each year. These research studies have contributed to health improvements for many people from every walk of life.

None of the advances in health care would be possible without people willing to volunteer to take part in research study. You may be asked to volunteer for a research study approved by this IRB. This pamphlet aims to help you understand your rights as a research study volunteer. It will help you to decide if you should take part in a research study. It will try to help you understand some of what is needed for a good research study. We urge you to review this information and discuss it with other people you trust.

Who will see my records?

Like your medical record, the information in your research study record will be confidential. Information will be given only to the people who need it. This includes researchers and staff who carry out the research study. This includes the Institutional Review Board (IRB), the company or group funding the research study, and various government oversight agencies. It is important for these groups to be able to look at your records, so they can ensure that the research study is conducted using acceptable research practices.

What is a research study?

A research study is an organized activity to learn more about a problem or answer questions. Scientists conduct many different kinds of studies. For example, a research study may test if a treatment is safe and effective. A research study may be done to find out what health care practices work best. A research study may be done to determine the best way to prevent an illness. A research study may use a

survey or an interview to understand feelings people have about their health. One type of research study is a clinical trial. A clinical trial is a research study that will try to decide whether new treatments are safe and effective. In clinical trials, treatments are often compared with placebos to check the effectiveness of that treatment. A placebo is an inactive substance which may resemble an active substance. However, it typically has no value to treat or prevent an illness.

Who will answer my questions?

The research team will explain the research study to you. The consent form includes this explanation. You should take your time when you read the consent form.

If you have any questions, ask the research staff. If you don't understand something, ask them to explain it to you so you do understand. The information will be given to you in a language that you know. If English isn't your native tongue, ask for an interpreter to be present when you are discussing the research study with the research staff.

You can take the information home. You can discuss it with your family, friends, a health care provider, or others before you decide whether or not to take part in the research study. If you decide to take part in the research study, you will be asked to sign the consent form.

The informed consent process is more than just signing a piece of paper. It is a process that goes on throughout the research study. During the research study, you may be told of new findings, benefits or risks. At that time, you can decide whether or not to continue to take part in the research study. You may decide not to take part. You may change your mind and leave the research study before it starts. You may also leave at any time during the research study or the follow-up period.

Why should I volunteer for a research study?

There are many reasons to participate in research study.

You may want to:

- Help find a cure for an illness
- Help other people who are sick
- Help find ways to provide better care
- Help scientists find out more about how the human body and mind work
- Take part in a research study that is trying to find a better treatment for a condition that you have.

If you decide to take part in a research study, you do so as a VOLUNTEER. That means YOU decide whether or not you will take part. If you choose to do so, you have many important rights.

What is informed consent?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to

volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the "informed consent form" that goes over these facts, so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer.

Are there benefits to being in a research study?

There may or may not be a direct benefit to you if you take part in a research study. For example, your health or a health condition you have may get better as a result of your participation in the research study. It may stay the same. It may get worse. No one can predict what will happen with a research study or how it might affect you. The research study may not help you personally. The research study may result in information that will help others in the future.

Are there risks or side effects in a research study?

Sometimes research procedures and treatments may cause discomfort and bad side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research study may not be known completely when you start the research study. The research staff will discuss with you known possible risks, so you can decide if you want to volunteer. If you do volunteer, the research staff will tell you about any new risks that they learn about during the research study for as long as you take part in the research study.

What questions should I ask before I agree to take part in a research study?

Before you decide to volunteer to take part in a research study, you need to know as much as possible about the research study. If there are any issues that concern you, be sure to ask questions. You might want to write your questions down in advance or take this booklet with you. The following is a list of sample questions. Not every question will apply to every research study.

- Who is doing this research study and what question might it answer?
- Will this research study help in understanding my condition? If so, how?
- What tests or procedures will be done?
- Is it possible that I will receive a placebo (inactive substance)?
- Will I have to make extra trips?
- What could happen to me, good and bad, if I take part in the research study?
- How long will this research study last?

- What will happen to any specimens that I give?
- Who has reviewed and approved this research study?
- Could my condition get worse during the research study?
- What will happen if it does?
- What other options or choices do I have if I decide not to take part in this research study?
- Who will be in charge of my care? Will I be able to continue to see my own doctor?
- Will I be charged anything or paid anything to be in this research study?
- If I decide to participate in this research study, how will it affect my daily life?
- What will happen to me at the end of the research study?
- Will I be told the results of the research study?
- Who will find out that I am taking part in this research study?
- How do I end my participation in this research study if I change my mind?
- Whom do I contact for questions and information about the research study?

Remember, if you do not understand the answer to any of your questions, ask again. Ask the person to explain the answer in a way you can understand it. If you forget the answers to the questions during the research study, just ask them again.

What if I do not want to take part in a research study?

If anyone asks you to take part in a research study, you have the right to say "no."

Remember:

- Your decision will not affect how we treat you.
- You need to weigh both the risks of the research study and the benefits.
- It may be helpful to talk with family members, friends, or your health care providers.
- If you decide to volunteer for a research study, you can change your mind and stop or leave the research study at any time. Your decision will not affect how we treat you.

Who will answer my questions?

If you have questions about research at UMass Chan Medical School, please contact the individual listed below:

Allison Blodgett, PhD, CIP
UMass Chan Director of IRB Operations
362 Plantation Street AC7-215
Worcester MA 01605
allison.blodgett@umassmed.edu
508-856-4271

Please call this number if you have concerns or complaints, or just want to talk to someone about research at this organization.

UMass Chan MEDICAL SCHOOL

OHRP FDA Written Procedure Crosswalk		
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HRP-105	10/12/2021	1 of 10

The purpose of this document is to provide cross reference between IRB written procedure guidance prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) [1] as published in May 2018 and the standard delivered HRPP Toolkit. This document is to be used for the purposes of determining what information should be covered in written procedures rather than a tool for assessing compliance. It may be utilized for HRPP self-evaluation and/or as audit/inspection support.

Activity as Defined by Guidance:	Relevant HRPP Toolkit ID Numbers and Notes:
I. IRB Initial and Continuing Review of Research; Reporting IRB Findings and Actions	
REGULATORY REQUIREMENT – Each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]	
RECOMMENDATIONS – Operational details should include information about:	
1. Conducting review at a meeting of the convened IRB[2], including:	
Documents submitted to the IRB for review (e.g., protocol, informed consent form, recruitment materials).	HRP-040 - SOP - IRB Meeting Preparation
Reviewer system utilized by the convened IRB (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Documents routinely distributed to all IRB members and those that may be distributed to specific IRB members (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Range of possible actions the convened IRB can take.	HRP-041 - SOP - IRB Meeting Conduct
Format of a convened meeting (e.g., in person, videoconferencing, other mechanism).	HRP-041 - SOP - IRB Meeting Conduct
Defining and maintaining quorum and the process followed if quorum is lost.[3]	HRP-042 - SOP - IRB Meeting Attendance Monitoring
Managing IRB members/alternates with conflicting interests.	HRP-050 - SOP - Conflicting Interests of IRB Members
2. Conducting review via expedited review procedures,[4] including:	
Documents submitted to the IRB for review.	HRP-021 - SOP - Pre-Review
Reviewer system utilized for expedited review (e.g., IRB chairperson or other experienced reviewer(s) designated by the chairperson from among the members of the IRB).	HRP-030 - SOP - Designated Reviewers

[1] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc
[2] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn4
[3] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn5
[4] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn6

Range of possible actions the designated expedited reviewer can take.	HRP-032 - SOP - Non-Committee Review Conduct
Method used for keeping all IRB members advised of research proposals approved via expedited review.	HRP-043 - SOP - IRB Meeting Minutes
3. Determining that the criteria for IRB approval of research are met.[5]	HRP-314 - WORKSHEET - Criteria for Approval
4. Reviewing the informed consent form and the informed consent process,[6] including:	
Consideration of the required and additional elements of informed consent.	HRP-314 - WORKSHEET - Criteria for Approval
Translation of the informed consent form for non-English speaking subjects, when applicable.	HRP-090 - SOP - Informed Consent Process for Research
For HHS-conducted or -supported research, consideration of a waiver or alteration of the consent procedure.[7]	HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
For both HHS-conducted or -supported research and FDA-regulated research, consideration of a waiver of documentation of consent.	HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
5. Considering whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional safeguards have been included to protect the rights and welfare of these subjects.[8]	HRP-314 - WORKSHEET - Criteria for Approval
6. Reviewing studies requesting an exception from informed consent requirements for emergency research.[9]	HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
7. For FDA-regulated research, assessing whether the investigator and/or sponsor determined that an investigational new drug application (IND) or investigational device exemption (IDE) is required for the proposed study, if applicable, and the basis for this determination.[10]	HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices
8. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination.[11]	HRP-418 - CHECKLIST - Non-Significant Risk Device

[5] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn7
[6] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn8
[7] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn9
[8] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn10
[9] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn11
[10] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn12
[11] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn13

9. For HHS-conducted or -supported research, determining the applicability of additional protections for pregnant women, human fetuses and neonates, and for prisoners.[12]	HRP-412 - CHECKLIST - Pregnant Women HRP-413 - CHECKLIST - Non-Viable Neonates HRP-414 - CHECKLIST - Neonates of Uncertain Viability HRP-415 - CHECKLIST - Prisoners
10. Reviewing research involving children as subjects in accordance with applicable regulations.[13]	HRP-416 Children
11. Reviewing the qualifications of the investigator(s) and study staff, and the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies, if applicable.	Note: HRP-314 - WORKSHEET - Criteria for Approval requires that the research has the resources necessary to protect subjects (i.e. time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.). However, as the parameters of these resources will vary based on institutional capabilities and research protocol requirements, institutionally specific language should be incorporated into HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN. HRP-103 - INVESTIGATOR MANUAL HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices
12. Determining and documenting the effective date of initial approval, and calculating the date for subsequent continuing review.	HRP-041 - SOP - IRB Meeting Conduct
13. Communicating the IRB's findings and actions to both the investigator and the institution,[14] including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator any modifications or clarifications required by the IRB as a condition of approval.	HRP-052 - SOP - Post-Review HRP-303 - WORKSHEET - Communication of Review Results HRP-512 - LETTER - Mods Req to Secure Approval
Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review

[12] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn14
[13] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn15
[14] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn16

Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-052 - SOP - Post-Review
14. For FDA-regulated research, reviewing a request for expanded access or treatment use.[15]	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
15. For FDA-regulated research, reviewing the emergency use of a test article.[16]	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
16. For FDA-regulated research, reviewing a request for the use of a Humanitarian Use Device (HUD).[17]	HRP-323 - WORKSHEET - Criteria for Approval HUD
II. Frequency of IRB Review; Verification Regarding Material Changes	
REGULATORY REQUIREMENT – Each IRB must follow written procedures for determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review [45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2)]	
RECOMMENDATIONS – Operational details should include information about:	
17. Determining the approval period/continuing review interval of the proposed research, including:	HRP-302 - WORKSHEET - Approval Intervals
General criteria used to make these determinations (e.g., the nature of the study and risks posed by the study; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; whether the study involves novel therapies).	HRP-041 - SOP - IRB Meeting Conduct
Documenting the approval period/continuing review interval (e.g., in the IRB meeting minutes or elsewhere in the IRB records).	HRP-041 - SOP - IRB Meeting Conduct
Communicating the IRB's determinations regarding the approval period/continuing review interval to the investigator.	HRP-052 - SOP - Post-Review
18. Determining whether the proposed research requires verification from sources other than the investigator, such as the sponsor, or other third party, that no material changes have occurred since the last IRB review, including the general criteria utilized to make the determination (e.g., complex projects; investigators with previous compliance issues;	HRP-212 - FORM - Continuing Review

[15] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn17
[16] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn18
[17] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn19

continuing review report indicates changes not previously reported; randomly selected projects).	
III. Reporting of Proposed Changes to the IRB; Prior IRB Review and Approval of Changes	
REGULATORY REQUIREMENT – Each IRB must follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects [45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4)]	
RECOMMENDATIONS – Operational details should include information about:	
19. Reporting changes in research to the IRB, including:	
Informing investigators that they may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (e.g., through training programs, materials for investigators, specific directives included in approval letters to investigators).	HRP-103 - INVESTIGATOR MANUAL
Ensuring that changes in research are being reported to the IRB before they are initiated (e.g., random audits of research records).	HRP-103 - INVESTIGATOR MANUAL HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
Process for notifying the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.	HRP-103 - INVESTIGATOR MANUAL
20. Reviewing changes in research, including:	
What might qualify as a minor change in research.	HRP-313 - WORKSHEET - Expedited Review
Documents submitted to the IRB for changes in research.	HRP-213 - FORM - Modification
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take.	HRP-041 - SOP - IRB Meeting Conduct HRP-402 - CHECKLIST - Non-Committee Review
Assessment of whether the IRB-approved informed consent form requires revision.	HRP-314 - WORKSHEET - Criteria for Approval
21. Communicating the IRB's findings and actions for changes in research to both the investigator and the institution,[18] including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator and the institution any modifications or clarifications required by the IRB as a condition of approval.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes HRP-052 - SOP - Post-Review

[18] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn20

Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review
Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes
IV. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval	
REGULATORY REQUIREMENT – Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing noncompliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval [45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b)]	
RECOMMENDATIONS – Operational details should include information about:	
22. Identifying who is responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any:[19]	HRP-024 - SOP - New Information
Unanticipated problems involving risks to human subjects or others.	HRP-024 - SOP - New Information
Serious or continuing noncompliance.	HRP-024 - SOP - New Information
Suspension or termination of IRB approval.	HRP-024 - SOP - New Information HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
23. Reviewing information about unanticipated problems involving risks to human subjects or others,[20] including:	
What might qualify as an unanticipated problem involving risks to human subjects or others, including adverse events that should be considered unanticipated problems.	HRP-214 - FORM - Reportable New Information
Documents submitted to the IRB regarding an unanticipated problem (e.g., written summary of the unanticipated problem, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information
24. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations,[21] including:	
What might qualify as serious or continuing noncompliance.	HRP-001 - SOP - Definitions

[19] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn21
[20] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22
[21] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn23

Documents submitted to the IRB regarding serious or continuing noncompliance (e.g., written summary of the noncompliance, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information
25. Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects,[22] including:	
Circumstances in which suspending or terminating IRB approval might be appropriate.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Consideration of subjects already enrolled (e.g., informing subjects about the suspension or termination).	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Orderly termination of the study, or transfer of the study or study subjects, if applicable.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Communicating the reason(s) for the IRB's decision to suspend or terminate approval of the research.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
V. Additional Topics the Institution/IRB May Consider:	
Scope and Authority	
26. The development and scope of the written procedures (e.g., who is responsible for preparing and maintaining them, including writing, revising, and approving; how often they are reviewed and updated, who they apply to; what happens if they are not followed).	HRP-061 - SOP - Monthly Evaluations of the HRPP
27. The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
28. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
29. Important regulatory definitions that guide the IRB's review processes and procedures (e.g., the definition of research, clinical investigation, human subject, minimal risk).	HRP-001 - SOP - Definitions
30. Other relevant federal regulations that may apply to human subject research (e.g., Health Insurance Portability and Accountability Act regulations, Department of Defense regulations).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
31. Which institutional office(s) or official(s), if any, is responsible for further review and	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM

[22] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn24

approval, or disapproval, of research that is approved by the IRB.[23]	PLAN
32. The IRB's relationship to the administration of the institution, the other committees and department chairpersons within the institution, the research investigators, other institutions, and the regulatory agencies.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
IRB Membership	
33. The number of members on the IRB.[24]	HRP-080 - SOP - IRB Formation and Registration
34. Ensuring diversity in IRB membership (e.g., representation of both genders, multiple professions, scientific and nonscientific members, nonaffiliated members). [25]	HRP-304 - WORKSHEET - IRB Composition HRP-601 - DATABASE - IRB Roster
35. Selecting and appointing the IRB chairperson, the members, and alternate members if any, including:	
The length of term or service, general description of duties, attendance requirements, performance evaluation, including removal if necessary.	HRP-082 - SOP - IRB Membership Addition HRP-083 - SOP - IRB Membership Removal
The qualifications of the IRB chairperson, members and any alternate members.[26]	HRP-082 - SOP - IRB Membership Addition HRP-304 - WORKSHEET - IRB Composition
The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated.[27]	HRP-082 - SOP - IRB Membership Addition HRP-202 - FORM - IRB Member Information
36. Defining what constitutes a conflicting interest for the IRB chairperson, members, and alternate members, and managing any such conflicting interest, including recusal from a meeting to ensure that a chairperson, member, or alternate member with a conflicting interest does not vote or count towards the quorum.[28]	HRP-050 - SOP - Conflicting Interests of IRB Members
37. Training and education provided to the IRB chairperson, IRB members, alternate members, administrative support staff, and investigators.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
IRB Functions and Operations	
38. Determining whether a study is subject to IRB review (e.g., what types of studies must be reviewed, which regulations apply, who makes the determination).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

[23] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn25
[24] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn26
[25] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27
[26] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn28
[27] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn29
[28] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn30

39. Determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations, including who makes the determination.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
40. Implementing cooperative IRB review arrangements, when applicable, such as joint review, reliance on the review of another qualified IRB, or similar arrangements aimed at avoiding duplication of effort.[29]	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
41. Process for reporting the emergency use of an FDA-regulated test article to the IRB.[30]	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
42. The use of consultants by the IRB,[31] including a description of the process to identify the need for a consultant, to choose a consultant, and the consultant's participation in the review of research.	HRP-041 - SOP - IRB Meeting Conduct
43. Identifying and managing an investigator with a conflicting interest.	HRP-055 - SOP - Financial Conflicts of Interests
44. Determining the applicability of state and local laws.[32]	**Note: As state and local law varies from institution to institution, local language should be incorporated into relevant Toolkit documents as needed.**
45. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses.	HRP-062 - SOP - Daily Tasks HRP-063 - SOP - Expiration of IRB Approval
46. Handling subject complaints, problems, concerns and questions about rights as a research subject.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN HRP-024 - SOP - New Information
47. Administrative support staff duties.	**Note**: Individual SOPs indicate the party responsible for carrying out procedures. HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN specifies additional duties and responsibilities in the Components section.
48. Keeping the IRB informed of study completion and close out to ensure record retention in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b).	HRP-103 - INVESTIGATOR MANUAL
49. Registering the IRB and maintaining IRB registration[33] via the HHS Internet-based	HRP-080 - SOP - IRB Formation and Registration

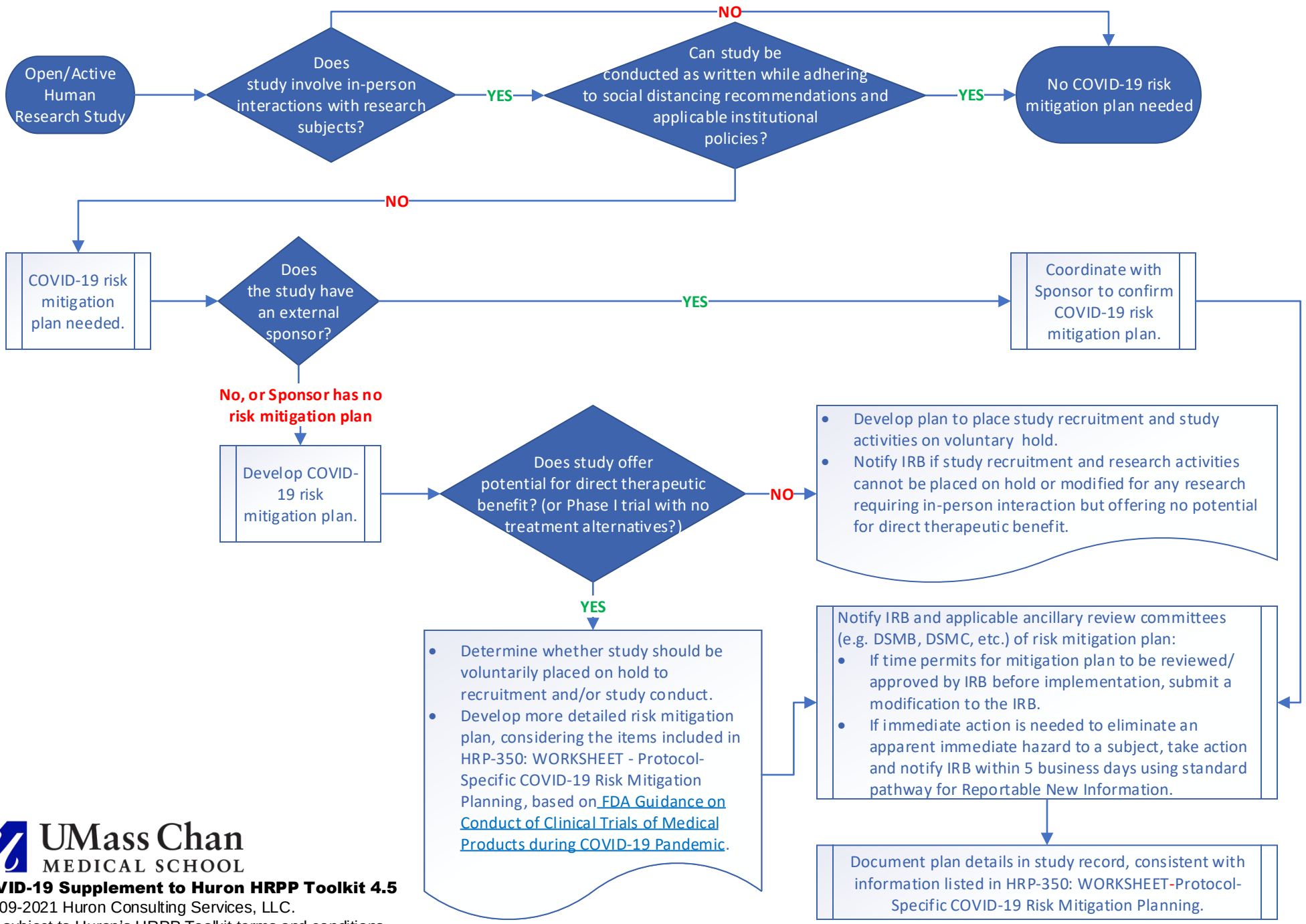
[29] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn31
[30] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn32
[31] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn33
[32] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn34

registration system.[34]	
50. Providing access to information about IRB requirements and written procedures (e.g., posting the information on a website accessible to the investigators, sponsors, and others).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
51. Contingency plans for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
IRB Records	
52. Maintaining records required to be retained,[35] and other records (e.g., IRB member training records).	HRP-072 - SOP - IRB Records Retention
53. Where records are stored (e.g., on site, off-site archives), and the format for record storage (e.g., hard copy, electronic or both).	HRP-070 - SOP - IRB Records
54. Preparing and maintaining minutes of IRB meetings.[36]	HRP-043 - SOP - IRB Meeting Minutes
55. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection.[37]	HRP-072 - SOP - IRB Records Retention

[33] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn35
[34] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn36
[35] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn37
[36] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn38
[37] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn39

Decision Guide for Study-Specific COVID-19 Risk Mitigation Planning[1]

[1]This flowchart satisfies AAHRPP elements: I.1.D, III.2.D



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IRB Reference:
Existing Regulatory Pathways and Processes Relevant to COVID-19

As institutional review boards (IRBs) continue to adapt to the new challenges associated with managing human research protection programs (HRPPs) during the COVID-19 pandemic, IRB leadership should ensure that their administrators and reviewers are familiar with several categories of research that are infrequently seen at many institutions but may become more applicable during the coming months as the pandemic is managed.

Public Health Surveillance Activities

The revised Common Rule included additional carve-outs to the Department of Health and Human Services (HHS) definition of "research," one of which excluded certain public health surveillance activities. Specifically, the following activities are not considered research as defined by HHS:

- *Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.*
    - *Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.*
    - *Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.*
    - *Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).*

HRPP leaders are advised to remind IRB administrators and staff to be aware of these carve-outs in the event that your offices receive any questions or submissions involving applicable COVID-19 public health surveillance activities. And if you have not yet incorporated these carve-outs into your current policies and procedures, please do so.

Emergency Use of a Test Article[1]

Biomedical research institutions may experience an increase in requests from physicians/investigators for the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval (i.e., emergency use).

Biomedical IRBs that have limited prior experience with emergency use situations may need to refresh their understanding of applying these procedures. The Food and Drug Administration's (FDA) "Emergency Use of an Investigational Drug or Biologic" guidance provides additional information.

Whenever possible, physicians should notify the IRB of a proposed emergency use of a drug, biologic or device in a life-threatening situation in advance of the use. But when there is insufficient time to notify the IRB in advance of the use, FDA regulations do permit emergency uses to be reported to the IRB within five working days after the use.

[1] Please note that emergency investigational new drugs (INDs) and protocols are a subset of individual patient access.

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Expanded Access

FDA regulations include pathways to allow access to investigational drugs and biologics outside of standard clinical trials. The expanded access pathways are available for serious or life-threatening diseases where there are no comparable or satisfactory alternatives, and where potential patient benefit from the investigational drug or biologic justifies the potential risks. Expanded access pathways are available for single patients, intermediate-sized patient groups, and broader access (treatment IND). FDA guidance on "Expanded Access to Investigational Drugs for Treatment Use" provides further clarification on the considerations associated with expanded access.

Single Patient Expanded Access

There is a unique IRB review pathway associated with some single patient expanded access requests. As described in the FDA's guidance on "Individual Patient Expanded Access Applications: Form FDA 3926," a physician submitting an individual patient expanded access IND may request authorization to obtain concurrence by the IRB chairperson or by a designated IRB member before the treatment use begins, in lieu of obtaining IRB review and approval at a convened IRB meeting.

Per Huron correspondence with the FDA, "concurrence" by the IRB chairperson (or designated IRB member) involves considering the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use.

Initially, the investigational drug remdesivir had been available for use in COVID-19 patients under single patient expanded access. However, the manufacturer (Gilead Sciences) later announced that the drug would no longer be available under the single patient expanded access pathway except for pregnant women and children less than 18 years of age with confirmed COVID-19 and severe manifestations of disease. And as of May 1, 2020 the FDA issued an emergency use authorization (EUA) for remdesivir. Currently the EUA allows remdesivir to be distributed and used by licensed healthcare providers to treat adults and children hospitalized with COVID-19. For more details on the EUA regulatory pathway, please see the section referenced below.

Expanded Access (i.e., Treatment IND or Protocol)

It appears likely that drug manufacturers seeking to make investigational drugs intended for use in COVID-19 treatment will seek to use expanded access pathways on a larger scale than single patient expanded access pathways allow. This pathway is intended to accelerate access to specific medical products and to enable the collection of data from all participating patients.

Gilead now has a remdesivir expanded access protocol in place; please refer to the following for additional information:

- https://www.gilead.com/purpose/advancing-global-health/covid-19/emergency-access-toremdesivir-outside-of-clinical-trials
- https://clinicaltrials.gov/ct2/show/NCT04323761

IRB administrators and reviewers should be reminded that standard IRB submission and review processes should be followed in cases of treatment INDs; the option for IRB chairperson concurrence in lieu of IRB review is not an option for this pathway.

Planned Emergency Research

Another possible regulatory pathway with potential future relevance to the COVID-19 pandemic is associated with "planned emergency research" for which exceptions to informed consent processes may

be granted. This pathway is described in FDA regulations, Office for Human Research (OHRP) guidance and FDA guidance.

This pathway allows a waiver of the applicability of the regulatory requirements for obtaining and documenting informed consent for a strictly limited class of research, involving research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained.

Given the length of time typically required to address the public disclosure and community consultation requirements associated with this particular class of research, it is unlikely that IRBs will be called upon to review such research in the immediate future, but IRBs should remain aware of this category and the additional review responsibilities associated with this research, should such activities emerge in the future.

Emergency Use Authorizations

The emergency use authorization (EUA) authority, under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), allows for unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear (CBRN) threat agents when there are no adequate, approved and available alternatives.

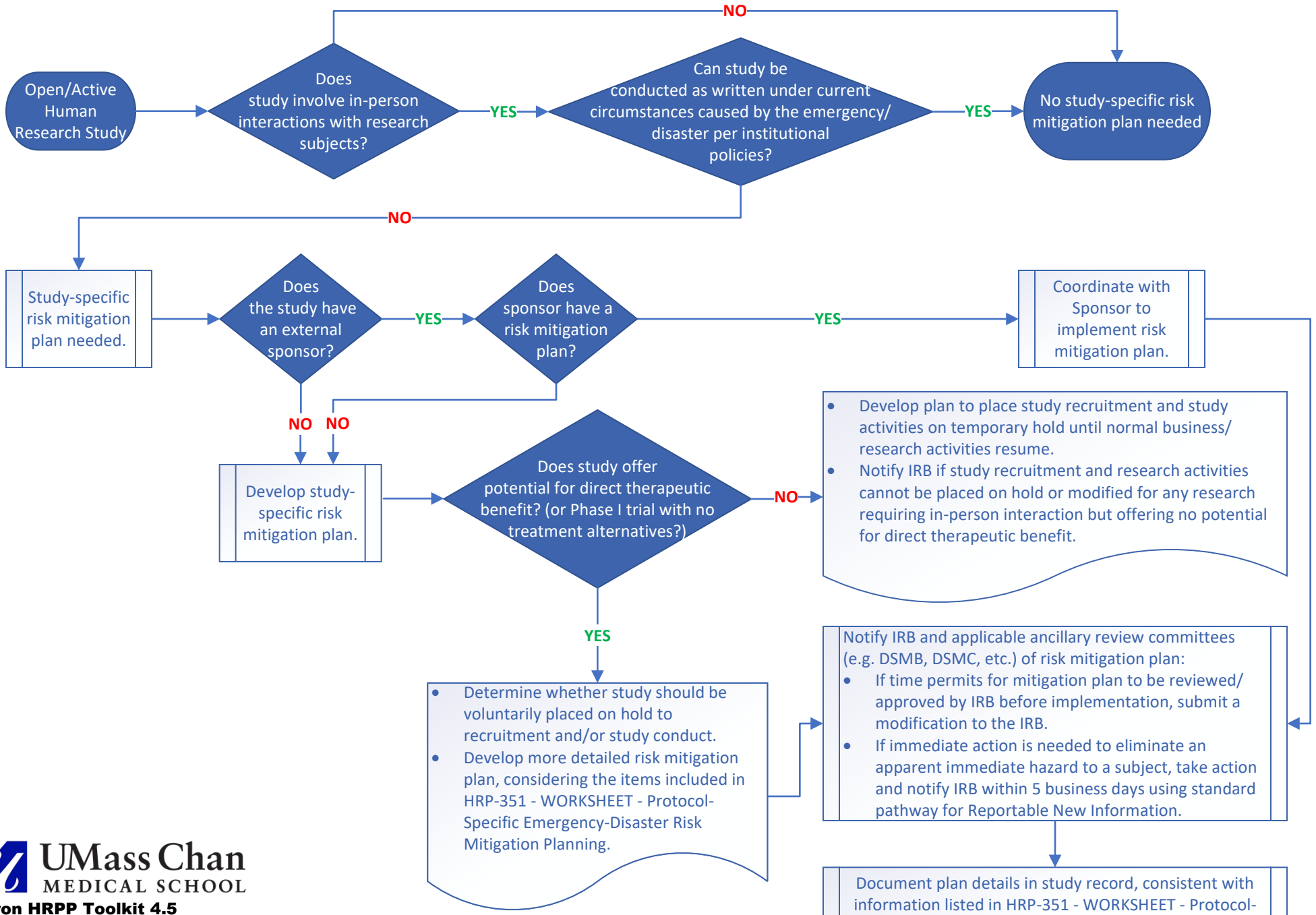
The FDA's EUA authority is separate and distinct from the use of a medical product under an investigational application (i.e., investigational new drug application (IND) or investigational device exemption (IDE)), section 561 expanded access authorities, and section 564A emergency use authorities)[2]. Therefore, once the FDA issues an EUA, then subsequent use of the drug or device in the clinical setting is not considered research and subject to IND/IDE requirements, and is not subject to IRB review.

There have been many EUAs issued during the COVID-19 pandemic. One example of a therapeutic EUA that was issued permitted the emergency use of hydroxychloroquine sulfate and chloroquine sulfate supplied from the Strategic National Stockpile to treat adults and adolescents "who weigh 50 kg or more and are hospitalized with COVID-19, for whom a clinical trial is not available, or participation is not feasible."[3] Of note, the FDA revoked the EUA for hydroxychloroquine sulfate and chloroquine sulfate on June 15th, 2020.

IRBs may be asked questions about whether IRB review is required for COVID-19-specific diagnostic tests, other medical devices or therapeutics. One important question for IRBs to ask is whether the item or treatment in question has been issued an EUA or is applying for an EUA.

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorizationmedical-products-and-related-authorities [3] https://www.fda.gov/media/136534/download

Decision Guide: Study-Specific Emergency-Disaster Risk Mitigation Planning



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WORKSHEETS

HRP-301 – WORKSHEET – Review Materials
HRP-302 – WORKSHEET – Approval Intervals
HRP-303 – WORKSHEET – Communication of Review Results
HRP-304 – WORKSHEET – IRB Composition
HRP-305 – WORKSHEET – Quorum and Expertise
HRP-306 – WORKSHEET – Drugs and Biologics
HRP-309 – WORKSHEET – Ancillary Review Matrix
HRP-308 – WORKSHEET – Pre-Review
HRP-310 – WORKSHEET – Human Research Determination
HRP-311 – WORKSHEET – Engagement Determination
HRP-312 – WORKSHEET – Exemption Determination
HRP-313 – WORKSHEET – Expedited Review
HRP-314 – WORKSHEET – Criteria for Approval
HRP-315 – WORKSHEET – Advertisements
HRP-316 – WORKSHEET – Payments
HRP-317 – WORKSHEET – Short Form of Consent Documentation
HRP-318 – WORKSHEET – Additional Federal Agency Criteria
HRP-319 – WORKSHEET – Limited IRB Review and Broad Consent
HRP-320 – WORKSHEET – Scientific or Scholarly Review
HRP-321 – WORKSHEET – Review of Information Items
HRP-322 – WORKSHEET – Emergency Use
HRP-323 – WORKSHEET – Criteria for Approval HUD
HRP-324 – WORKSHEET – Contracts
HRP-325 – WORKSHEET – Device Compassionate Use
HRP-326 – WORKSHEET – Performance Evaluation for IRB Chairs
HRP-327 – WORKSHEET – Performance Evaluation for IRB Members
HRP-328 – WORKSHEET – Annual Performance Evaluation Criteria for IRB Staff
HRP-330 – WORKSHEET – HIPAA Authorization
HRP-331 – WORKSHEET – FERPA Compliance
HRP-332 – WORKSHEET – NIH GDS Institutional Certification
HRP-333 – WORKSHEET – Certificate of Confidentiality
HRP-350 – WORKSHEET – Research-Specific COVID-19 Risk Mitigation Plan
HRP-351 – WORKSHEET – Protocol-Specific Emergency-Disaster Risk Mitigation Planning
HRP-352 – WORKSHEET – Additional Emergency-Disaster Review Considerations
HRP-380 – WORKSHEET – Financial Interest Management

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WORKSHEET: Review Materials		
NUMBER	DATE	PAGE
HRP-301	06/21/2022	1 of 6

The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review. This worksheet lists the information that each IRB member/Designated Reviewer, scientific/scholarly reviewer, or consultant needs to review and the worksheets or checklist to be used. For individuals who have electronic (computer) access to or provided all information, this document describes the subset of materials the IRB member is expected to access and review. For individuals who are provided a subset of the information, this document describes the subset of materials the IRB staff are to provide to each individual.[1]

1 GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS

☐ List of protocols approved using the expedited procedure.
☐ Information for Other Business items
☐ Educational Materials

[1] This document satisfies AAHRPP elements I.1.F, I.5.D, I-9, II.1.B, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3

2 FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members	Additional Items for the Scientific/Scholarly Reviewer	Items for Consultants and Individuals without reviewer access to the submission
Include: ☐ HRP-314 - WORKSHEET - Criteria for Approval Include when the protocol involves these items: ☐ HRP-315 - WORKSHEET - Advertisements ☐ HRP-316 - WORKSHEET - Payments ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent ☐ HRP-412 - CHECKLIST - Pregnant Women ☐ HRP-413 - CHECKLIST - Non-Viable Neonates ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability ☐ HRP-415 - CHECKLIST - Prisoners ☐ HRP-416 - CHECKLIST - Children ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research	Include: ☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review Include when they exist: ☐ Scientific evaluation	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

3 FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members	Documents for Consultants and Individuals without reviewer access to the submission
Include: ☐ HRP-314 - WORKSHEET - Criteria for Approval Include when the protocol involves these items: ☐ HRP-315 - WORKSHEET - Advertisements ☐ HRP-316 - WORKSHEET - Payments ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent ☐ HRP-412 - CHECKLIST - Pregnant Women ☐ HRP-413 - CHECKLIST - Non-Viable Neonates ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability ☐ HRP-415 - CHECKLIST - Prisoners ☐ HRP-416 - CHECKLIST - Children ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

4 FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members	Additional Documents for the Scientific/Scholarly Reviewer	Documents for Consultants and Individuals without reviewer access to the submission
Include: ☐ HRP-314 - WORKSHEET - Criteria for Approval Add when modification involves these items: ☐ HRP-315 - WORKSHEET - Advertisements ☐ HRP-316 - WORKSHEET - Payments ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent ☐ HRP-412 - CHECKLIST - Pregnant Women ☐ HRP-413 - CHECKLIST - Non-Viable Neonates ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability ☐ HRP-415 - CHECKLIST - Prisoners ☐ HRP-416 - CHECKLIST - Children ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research	Include: ☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review (if the amendments are substantive)	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

5 FOR EACH PROBLEM (UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS, OR SERIOUS OR CONTINUING NON-COMPLIANCE)

Documents for All IRB Members, Alternate IRB Members, Primary Reviewer, Prisoner Representative, and Scientific/Scholarly Reviewer	Documents for Consultants and Individuals without reviewer access to the submission
Include: ☐ HRP-321 - WORKSHEET - Review of Information Items ☐ HRP-314 - WORKSHEET - Criteria for Approval Add when the problem involves a protocol and the new information affects these items: ☐ HRP-315 - WORKSHEET - Advertisements ☐ HRP-316 - WORKSHEET - Payments ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent ☐ HRP-412 - CHECKLIST - Pregnant Women ☐ HRP-413 - CHECKLIST - Non-Viable Neonates ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability) ☐ HRP-415 - CHECKLIST - Prisoners ☐ HRP-416 - CHECKLIST - Children ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

Documents for All IRB Members and Alternate IRB Members	Documents for Consultants and Individuals without reviewer access to the submission
6 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW	
Include: ☐ HRP-323 - WORKSHEET - Criteria for Approval HUD	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.
7 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW	
Include: ☐ HRP-323 - WORKSHEET - Criteria for Approval HUD	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.
8 FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS	
Include when modified: ☐ HRP-323 - WORKSHEET - Criteria for Approval HUD	Include: ☐ Cover letter to consultants Include as appropriate materials provided to any other reviewer.

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WORKSHEET: Approval Intervals

NUMBER	DATE	PAGE
HRP-302	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for IRB staff members who send communications after an IRB review where the letter needs to include approval and Expiration Dates. This worksheet describes how to make these calculations.[i]

	TYPE OF REVIEW	APPROVAL DATE	EFFECTIVE DATE	END APPROVAL DATE[ii]
Initial Review	Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day[iii]
	Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	Date the IRB Office verified that the required modifications had been made	
	Designated Reviewer granted approval	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	APPROVAL DATE plus the approval interval minus one day. None for exempt research.
	Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review	Date the IRB Office verified that the required modifications had been made	Date the IRB Office verified that the required modifications had been made	
Continuing ≤30 d	Convened IRB granted approval	Previous END APPROVAL DATE plus one day.	Previous END APPROVAL DATE plus one day	Previous END APPROVAL DATE plus current approval interval[iv]
	Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review			
	Designated Reviewer granted approval			
	Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review			
Continuing >30 d	Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day[v]
	Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	Date the IRB Office verified that the required modifications had been made	
	Designated Reviewer granted approval	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	APPROVAL DATE plus the approval interval minus one day
	Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review	Date the IRB Office verified that the required modifications had been made	Date the IRB Office verified that the required modifications had been made	
Modifications	Convened IRB granted approval to modifications to previously approved research.	Date of convened IRB meeting	Date of convened IRB meeting	Previous END APPROVAL DATE[vi], except no end date for exempt research.
	Convened IRB required modifications to secure approval of modifications to previously approved research; subsequently verified by Non-Committee Review	Date of convened IRB meeting	Date the IRB Office verified that the required modifications had been made	
	Designated Reviewer granted approval to modifications to previously approved research	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	
	Designated Reviewer required modifications to secure initial approval of modifications to previously approved research; subsequently verified by Non-Committee Review	Date the Designated Reviewer required modifications to secure approval	Date the IRB Office verified that the required modifications had been made	

[i] This document satisfies AAHRPP elements II.2.E-II.2.E.2

[ii] Last date that the protocol is approved. The Expiration Date or lapse date in eIRB is the date after this date, which is the first date that the protocol is no longer approved. Determination letters refer to the End Approval Date as the expiration date.

[iii] For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007.

[iv] For example, if the last date of the approval interval was April 14, 2008, and the convened IRB approved research on March 16, 2008 for one year, the end date of the next approval interval is April 14, 2008 + one year = April 14, 2009. if the last date of the approval interval was April 14, 2008, and the convened IRB approved research on March 16, 2008 for six months, the end date of the approval interval is April 14, 2008 + six months = November 14, 2008.

[v] For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007.

[vi] For example, if the last date of the approval interval was April 14, 2008, and the convened IRB approved a modification on November 16, 2007, the end date of the approval interval remains April 14, 2008.

System-Generated Letter Templates:

The purpose of this worksheet is to provide support for staff who send communications after an IRB review.[1]

IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee:	COMPLETE THE FOLLOWING TEMPLATE LETTER AND TO ALL INDIVIDUALS LISTED IN CC LIST
Approved protocol	HRP-510 - TEMPLATE LETTER - Approval
Approved a participating site	HRP-870 - TEMPLATE LETTER - Site Approval
Acknowledged a protocol closure	HRP-511 - TEMPLATE LETTER - Closure
Required modifications to protocol to secure approval	HRP-512 - TEMPLATE LETTER - Mods Req to Secure Approval
Required site modifications to secure approval	HRP-872 - TEMPLATE LETTER - Site Modifications Required to Secure Approval
Determined that the activity is not Human Research	HRP-513 - TEMPLATE LETTER - NHR Determination
Determined that the activity is Human Research in which the organization is not engaged	HRP-527 - TEMPLATE LETTER – Not Engaged
Suspension or Termination of IRB Approval	HRP-515 - TEMPLATE LETTER - Suspension or Termination
Agreed to provide IRB review for an external site engaged in a multi-site or collaborative study	HRP-851 - TEMPLATE LETTER - Invitation Decision
Agreed to cede IRB review to an external IRB	HRP-857 - TEMPLATE LETTER - Acknowledge External IRB
Acknowledged study modifications approved by an external IRB	HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update
Reviewed an information item	HRP-519 - TEMPLATE LETTER - Information Item
Reviewed site information item	HRP-879 - TEMPLATE LETTER - Review of Site Information Item
THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB	
Deferred protocol	HRP-516 - TEMPLATE LETTER - Deferral
Deferred site	HRP-876 - TEMPLATE LETTER - Site Deferral
Disapproved protocol	HRP-517 - TEMPLATE LETTER - Disapproval
Disapproved site	HRP-877 - TEMPLATE LETTER - Site Disapproval

[1] This document satisfies AAHRPP elements I.1.A, I.5.D, I-9, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, III.2.D

The purpose of this worksheet is to provide support for staff who send communications after an IRB review or at the discretion of the IRB.	
THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB	
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - TEMPLATE LETTER - SR NSR Device
Approved a waiver of the consent process for planned emergency research	HRP-525 - TEMPLATE LETTER - OHRP Notif Emerg Waiver
THE FOLLOWING NOTIFICATIONS ARE SENT AT THE IRB'S DISCRETION:	
Tabled the protocol	HRP-518 - TEMPLATE LETTER – Tabled *(Place on the agenda for the next IRB meeting)*
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency not including OHRP	HRP-520 - TEMPLATE LETTER - External Report NOT Including OHRP
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency and OHRP	HRP-520a - LETTER - External Report OHRP and Other Agencies and OHRP Incident Report Form[2]
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency to DOD, or to DOD and OHRP	HRP-526 - External Report to DOD
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - TEMPLATE LETTER - SR NSR Device
Approved research conducted or funded by DHHS involving prisoners as subjects	HRP-522 - TEMPLATE LETTER - Cert Prisoner Research Subpart C Certification Form[3]
Approved not otherwise approvable research involving children, pregnant women, or neonates	HRP-523 - TEMPLATE LETTER - Not Otherwise Appro Research
Approved a waiver of the consent process for planned emergency research	HRP-525 - TEMPLATE LETTER - OHRP Notif Emerg Waiver
Certification of approval of prisoner research for DOD research	HRP-522 - TEMPLATE LETTER - Cert Prisoner Research
Review of otherwise not approvable research to OHRP/FDA	HRP-523 - TEMPLATE LETTER - Not Otherwise Appro Research
Continuation of subjects in expired research	HRP-532 - TEMPLATE LETTER - Conti Subj Expired Research
Investigator Quality Improvement assessment	HRP-534 - TEMPLATE LETTER - Investigator QI Assessment
IRB Member Appointment	HRP-560 - TEMPLATE LETTER - IRB Appointment
IRB Member Thank You	HRP-561 - TEMPLATE LETTER - IRB Thank You
IRB Member Appreciation	HRP-562 - TEMPLATE LETTER - IRB Appreciation
Pre-Review of Emergency Use (Criteria Met)	HRP-570 - TEMPLATE LETTER - Pre-Rev EU - Crit Met
Pre-Review of Emergency Use (Criteria Not Met)	HRP-571 - TEMPLATE LETTER - Pre-Rev EU - Crit Not Met
Review of Emergency Use (Criteria Met)	HRP-572 - TEMPLATE LETTER - Review of EU - Crit Met

[2] See: https://www.hhs.gov/sites/default/files/irpt-pra-incident-report-form.pdf

[3] OHRP Guidance: Prisoner Research Certification (2020) requires institutions to submit the Subpart C Certification form when conducting research involving prisoners. OHRP encourages electronic submission of Subpart C certifications to subpartc@hhs.gov

Review of Emergency Use (Criteria Not Met)	HRP-573 - TEMPLATE LETTER - Review of EU - Crit Not Met
Failure to Submit Emergency Use Report	HRP-551 - TEMPLATE LETTER - Failure to Submit EU Report
Failure to Submit Emergency Use Protocol	HRP-553 - TEMPLATE LETTER - Failure to Submit EU Protocol

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WORKSHEET: IRB Composition

NUMBER	DATE	PAGE
HRP-304	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for IRB staff reviewing whether the IRB is appropriately composed. This worksheet is to be used. It does not need to be completed or retained. Note: All IRB members are voting members. There are no "non-voting IRB members."[1]

1 Objective Composition (Check if **"Yes".** All must be checked)

☐	The IRB has at least five members, not counting alternate IRB members.
☐	The IRB does not consist entirely of men or entirely of women. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*
☐	The IRB does not consist entirely of members of one profession. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*
☐	The IRB has at least one member who has primary concerns are in scientific areas.
☐	The IRB has at least one member who has primary concerns are in non-scientific areas.
☐	The IRB has at least one member who is unaffiliated with the institution and whose Immediate Family is unaffiliated with the institution.

2 Subjective Composition (Check if **"Yes".** All must be checked)

☐	The qualifications of alternate members are comparable to the primary member to be replaced.
☐	The members have varying backgrounds to promote complete and adequate review of research activities commonly reviewed.
☐	The IRB is sufficiently qualified through its experience, expertise, diversity in terms of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of Human Subjects.
☐	The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and has the ability to ascertain the acceptability of proposed research in terms of these areas.
☐	The IRB has the ability to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.
☐	The IRB possesses the professional competence necessary to review research activities.
☐	If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, Prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB includes of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.
☐	The IRB has at least one member who represents the perspective of research subjects.
☐	The IRB has no members responsible for business development.
☐	The IRB has no members that own equity in the organization.

3 Additional Requirements (Check if **"Yes".** All must be checked)

☐	The IRB has an IRB chair.
☐	There are sufficient alternate IRB members.

4 Composition of an IRB that Reviews Research Involving Prisoners (Check if **"Yes".** If the IRB reviews research involving Prisoners, all must be checked)

☐	A majority of the Board (exclusive of Prisoner members) has no association with the prison(s) involved, apart from their membership on the Board.
☐	At least one voting member of the Board is a Prisoner, or a Prisoner representative with appropriate background and experience to serve in that capacity, including a working knowledge of the population to be recruited, a reasonable familiarity with the operations of the prison or confinement facility, and any other legally imposed restrictive conditions involved in the research. (The Prisoner representative may be an alternate member who becomes a voting member when needed.)

5 Scope and Composition (Check if **"Yes".** All must be checked)

☐	This IRB conducts: (Select one)		List limitations on types of reviews:
	☐	All reviews without limitation.	
	☐	Limited to the following types of reviews:	
☐	The type of research reviewed matches the description in the roster.		
☐	The composition of the IRB is appropriate to the types of research reviewed.		

[1] This document satisfies AAHRPP elements I-9, II.1.A, II.1.B, II.1.C

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WORKSHEET: Quorum and Expertise

NUMBER	DATE	PAGE
HRP-305	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for staff who monitor attendance at convened IRB meetings. This worksheet evaluates whether the members present at the meeting comprise a quorum. IRB staff are to consult this worksheet in preparation of meetings and when monitoring attendance at convened meetings. This worksheet is to be used. It does not need to be completed or retained.[1]

	1 Quorum Requirements (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	Greater than half of the IRB members *(will be/are)* present.
☐	At least one member whose primary concerns are in scientific areas *(will be/is)* present.
☐	At least one member whose primary concerns are in non-scientific areas *(will be/is)* present.
☐	At least one unaffiliated member *(will be/is)* present.
☐	At least one member who represents the general perspective of subjects *(will be/is)* present.
☐	If both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will be/are*) present, only one *(will be/is)* voting and only one *(will be/is)* counting towards quorum. **("N/A" if both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will NOT be/are NOT*) present) N/A:** ☐
☐	In order for a DOE IRB to vote on a new or amended protocol that requires full board review, there must be a minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member. For classified research, the unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor. **("N/A" if DOE regulations do not apply) N/A:** ☐

	2 Expertise Requirements (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	At least one member or consultant with scientific or scholarly expertise in the area of research *(will be/is/was)* involved in the review.
☐	At least one member or consultant with knowledge of the local context *(will be/is)* involved in the review.
☐	At least one member or consultant able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.
☐	When the research involves Prisoners as subjects: An IRB member who is a Prisoner or a Prisoner representative with appropriate background and experience to serve in that capacity *(will be/is)* involved in the review as a voting member. The Prisoner representative may attend the meeting by phone, video-conference, or Webinar, as long as the representative is able to participate in the meeting as if they were present in person. **("N/A" if no Prisoners.) N/A:** ☐
☐	When the research involves an investigational drug or device: An IRB member who is a licensed physician *(will be/is)* involved in the review. **("N/A" if no drugs or devices.) N/A:** ☐
☐	When the research involves populations vulnerable to coercion or undue influence: An IRB member or consultant who is knowledgeable about or experienced in working with such subjects *(will be/is)* involved in the review.[2] **("N/A" if no populations vulnerable to coercion or undue influence.) N/A:** ☐
☐	When the research involves other specific expertise: An IRB member or consultant who has that expertise (professional competence) *(will be/is)* involved in the review. **("N/A" if no specific expertise needed.) N/A:** ☐
☐	For international research the IRB has knowledge of local laws and the cultural context of the country where research is going to be conducted Including: (Can be through consultation with a local IRB, government agency, or other qualified consultant.) **("N/A" if not international research.) N/A:** ☐ • Appropriate expertise and knowledge of the country(ies) either through IRB members or consultants. • Knowledge of cultural context. • Application of the same processes for initial review, continuing review, and review of modifications to previously approved research; post-approval monitoring; handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others; and consent process and document and other language issues as applied to domestic research. • Coordination and communication with local IRBs or ECs when appropriate.
☐	For community-based participatory research the IRB has done one of the following: **("N/A" if not community-based participatory research.) N/A:** ☐ • Educated IRB members on community-based participatory research. • Included IRB members with expertise in community-based participatory research • Obtained consultation with expertise in community-based participatory research

[1] This document satisfies AAHRPP elements I-3, I.4.C, I-9, II.1.B, II.1.E, II.2.D, II.2.E-II.2.E.2, II.4.A

[2] 45 CFR §46.107(a): "If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects."

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WORKSHEET: Drugs and Biologics

NUMBER	DATE	PAGE
HRP-306	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs. This worksheet is to be used. It does not need to be completed or retained.[i]

1 Drug Applicability

☐ Does the activity involve any the following? **(Check all that apply) If "No" to both, FDA regulations do not apply.**

- ☐ In the United States: The use of a drug[ii] or a biological product (biologic)[iii] in one or more persons other than use of an approved drug in the course of medical practice[iv].
- ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[v].

2 IND Requirements[vi] (Check if **"Yes"**. One must be **"Yes"** If all are **"No"** IND information is not complete.)

☐	The drug has a valid IND. (Complete Sections 3 and 4)
☐	The drug is exempt from the IND requirements (Complete Section 5)
☐	The research is conducted outside of the United States and is conducted under ICH-GCP.

3 IND Validation (Check if **"Yes"**. At least one must be **"Yes"** If all are **"No"** IND cannot be validated.)

☐	Sponsor protocol imprinted with the IND number.
☐	Written communication from the sponsor documenting the IND number.
☐	Written communication from the FDA documenting the IND number. *(Required if the investigator holds the* IND.*)*

4 Drug or Biologic Control (Check if **"Yes"**. Must be **"Yes"** If **"No"** information regarding drug control is incomplete.)

☐	The plan for storage, control, and dispensing of the drug or biologic is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent.[vii]

5 IND Exemptions (Check if **"Yes"**. All criteria for one category must be **"Yes"** to be met. If none are met, the drug is not exempt from an IND.)

☐ **Category #1 - Lawfully Marketed Drugs (21 CFR 312.2(b)(1)) or Biologics**

☐	The drug or biologic is lawfully marketed in the United States.
☐	The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
☐	The research is not intended to support a significant change in the advertising for the product.
☐	The research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
☐	The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7.

☐ **Category #2 - Serological Tests (21 CFR 312.2(b)(2))**

☐	A clinical investigation for an in vitro diagnostic[viii] biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin.
☐	The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
☐	The diagnostic test is shipped in compliance with 21 CFR §312.160.

☐ **Category #3 - Placebos (21 CFR 312.2(b)(5))**

☐	A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND.

☐ **Category #4: Bioavailability/Bioequivalence Studies (21 CFR 320.31(b) and (d))**

☐	The active moiety in the drug product is identical to that in an FDA approved drug.
☐	The drug product is not radioactively labeled.
☐	The drug product is not cytotoxic.
☐	The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.
☐	The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1).

☐ **Category #5: Radioactive Drugs for Research Use (21 CFR 361.1)**

☐	The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)

☐ **Category #6: Cold Isotopes for Research Use (FDA enforcement discretion[ix])**

☐	The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.
☐	The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.
☐	The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies.
☐	The quality of the cold isotope meets relevant quality standard.

6	**IND Oversight for investigators who hold the IND** (Check if **"Yes"**. One of the following must be **"Yes"** if the investigator holds the IND)
☐	The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.
☐	An audit has documented that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

[i] This document satisfies AAHRPP elements I.7.A, I.7.B

[ii] The term ''drug'' means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[iii] The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[iv] "Other than the use of an approved drug in the course of medical practice" refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[v] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[vi] If there are questions about which category is appropriate, have the investigator apply for an IND following 21 CFR §312.23.

[vii] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. The investigator must maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.

[viii] An in vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health Service Act.

[ix] (FDA Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs)) Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013: https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf.

UMass Chan MEDICAL SCHOOL

WORKSHEET: Pre-Review		
NUMBER	DATE	PAGE
HRP-308	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for IRB staff conducting screening of submission materials.[1]

1 ALL REVIEWS

☐ Determine the laws that apply to the Human Research and indicate in the "Regulatory Oversight" section of the Pre-Review Activity.
☐ Determine whether any investigators or research staff are Restricted. If so, list their names and the reasons in the "Restrictions" section of the Pre-Review Activity.
☐ Determine whether the Human Research has received all required ancillary reviews (per HRP-309 -WORKSHEET – Ancillary Review Matrix) and approvals by the appropriate committees and officials.
☐ If the Human Research could be subject to EU GDPR, send for legal counsel review.
☐ If there is a HIPAA authorization, review using HRP-330 - WORKSHEET - HIPAA Authorization.
☐ If a HIPAA waiver of authorization is required, grant using HRP-441 - CHECKLIST - HIPAA Waiver of Authorization.
☐ Determine whether the submission is for a Single-Site Study, Collaborative Study, or Multi-Site Study.
☐ **Note any missing materials necessary for review in the "Missing Materials" section of the Pre-Review Activity:**
☐ Complete eIRB application
☐ Investigator Protocol
☐ Consent document(s) or script(s)
☐ Data collection instruments
☐ Written material to be seen or heard by subjects
☐ Determine whether any new information has been provided. (For example, a new risk.) If so, follow HRP-024 - SOP- New Information.

2 INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)

☐ If the research involves the use of a drug use HRP-306 - WORKSHEET - Drugs.
☐ If the research involves the use of a device (including a humanitarian use device) use HRP-407 - CHECKLIST - Devices.
☐ Note any special determinations that need to be made by the convened IRB or Designated Reviewer in the "Special Determinations" section of the Pre-Review Activity.
☐ If the device meets the abbreviated IDE requirements, note "Non significant device determination" in the "Special Determinations" section of the Pre-Review Activity.

Note any missing materials necessary for review in the "Missing Materials" section of the Pre-Review Activity:

☐ Qualifications of the key personnel
☐ Complete sponsor protocol (including DHHS protocol)
☐ DHHS-approved sample consent document
☐ Investigator brochure for investigational drug
☐ Package insert for marketed drugs
☐ Institutional Profile
☐ Executed Reliance Agreement(s)
☐ Product information for medical devices
☐ For the Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA

Note missing/inappropriately answered Investigator Protocol sections in the "Missing Materials" section of the Pre-Review Activity:

☐ IRB Review History
☐ Objectives
☐ Background
☐ Setting
☐ Resources Available
☐ Prior Approvals
☐ Study Design
☐ Recruitment Methods
☐ Inclusion/Exclusion Criteria
☐ Compensation for Injury
☐ Local Number of Subjects
☐ Total Number of Subjects
☐ Study Timelines
☐ Study Endpoints
☐ Procedures Involved
☐ Data and Specimen Banking
☐ Data Management
☐ Confidentiality
☐ Provisions to Monitor Data
☐ Withdrawal of Subjects
☐ Risks to Subjects
☐ Potential Benefits to Subjects
☐ Provisions to Protect Privacy
☐ Economic Burden to Subjects
☐ Consent Process
☐ Consent Documentation
☐ Vulnerable Populations
☐ Drugs or Devices
☐ Multi-Site Research
☐ Community-Based Participatory Research
☐ Sharing of Results

"Notes" section of the Pre-Review Activity:

☐ Research is subject to regulations not overseen or conducted by the organization
☐ Positive financial declaration without a Conflict of Interest report
☐ Protocol information relates to an item in the list of institutional financial interests
☐ An IND is required and there is no IND
☐ An IND is required and there is insufficient documentation
☐ An IDE/HDE is required and there is no IDE/HDE
☐ An IDE/HDE is required and there is insufficient documentation
☐ There are inadequate provisions to control the drug(s)
☐ There are inadequate provisions to control the device(s)
☐ There are inadequate provisions for an investigator held IND
☐ There are inadequate provisions for an investigator held IDE
☐ External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA)
☐ The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are Legally Authorized Representatives (LAR) do not match.
☐ The research involves children and statements by the investigator and legal counsel regarding who can provide permission for the child if an individual is not a parent do not match.

[1] This document satisfies AAHRPP elements I-9, II.2.C

3	**INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB (when the modification affects one of the following)**
☐	The site record includes all of the following: ☐ Completed Basic Information Page ☐ Completed Local Funding Sources Page (if relevant) ☐ Site Informed Consent Document ☐ All other documents required by the Study
4	**CONTINUING REVIEW**
☐	If Continuing review is not required, ask the investigator to discard the submission.
☐	Note missing Continuing review form in the "Missing Materials" section of the Pre-Review Activity.
5	**MODIFICATION**
☐	Note missing modification form in the "Missing Materials" section of the Pre-Review Activity.
6	**STUDY CLOSURE**
☐	Confirm that the research meets the criteria for closure and note in the Study Closure Section of the Pre-Review Activity.

UMass Chan MEDICAL SCHOOL

WORKSHEET: Ancillary Review Matrix		
NUMBER	DATE	PAGE
HRP-309	04/13/2023	1 of 8

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review of a new study or a modification to an existing study. This worksheet helps to ensure coordination of review and approval across offices and functions.

- Identifying and obtaining ancillary reviews is the responsibility of the researcher.
- The IRB checks for ancillary reviews during the pre-review of a submission.
- For each type of Ancillary Review as listed below, researchers work directly with the designated points of contact for the responsible office/entity to ensure compliance.
- Ancillary reviews are not checked by the IRB if a project does not meet the federal definition of Human Subject Research.

The impact of an ancillary review group's approval on the IRB's review process varies.

- Typically, final IRB approval is held until the ancillary group concludes their review.
- In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
- The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria even if exempt studies are an affected IRB submission type.
- Documentation of approval by an ancillary review group is provided to the researcher. The researcher is responsible for uploading that documentation in the "Other attachments" section of the RMS eIRB application to which it relates.
- In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending. Requests may be declined.
- Ancillary reviews that are required for IRB review/approval are not the same requirements for study activation. Study activation requirements are different and managed by Clinical Research Operations.

The tables below highlight the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.

COMPLETE PRIOR TO SUBMISSION TO IRB

Organization	Review type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review
Conflict of Interest	UMass Chan and, if applicable, Five Campus Committee	Financial interest related to the research	Exempt and Non-Exempt Subjects Research	COI@umassmed.edu	*https://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/* ***The outcome of the UMass Chan Campus COI Committee review must be provided in writing for IRB review; final fully signed mitigation plans, when applicable, must be provided for IRB approval.***
Institutional Biosafety Committee (IBC)	UMass Chan	Research involving: a. recombinant and synthetic nucleic acids (e.g. human gene transfer studies), infectious agents, and toxins, or b. the processing of and/or experimentation with human blood, secretions, and/or tissues in clinical or basic research laboratories	Non-Exempt Human Subjects Research	IBC@umassmed.edu	*https://umassmed.sharepoint.com/sites/IBC (intranet only)* ***The outcome of IBC review for type (a) studies must be provided in writing for IRB review. Type (b) are not required to be in place for IRB approval.***
Radiation Safety Committee (RSC)	UMass Chan	Research with internally administered radioisotopes or external sources of ionizing radiation, which are experimental or protocol driven (i.e., would not normally be	Non-Exempt Human Subjects Research	Sassan.Abdollahzadeh@umassmed.edu	*Studies involving radiation, even when standard of care, should use the "Questions for PI" checklist from the Subcommittee on Human Uses (SHU) of the Radiation Safety Committee (RSC) to explain why RSC approval is or is not needed.*

		required by the subject's medical condition)			***The outcome of RSC review must be provided in writing for IRB review.***
Students as Subjects	UMass Chan	The SAS Ad Hoc Advisory Group reviews projects involving sensitive topics that will purposely recruit students from the UMass Worcester campus as human subjects	Exempt and Non-Exempt Human Subjects Research	Anne.Larkin@umassmed.edu	***The outcome of SAS review must be provided in writing for IRB review.***
UMCCTS Protocol Review Committee (PRC)	UMass Chan	• Greater-than-minimal risk investigator-initiated clinical trials that have not undergone external peer review • Other investigator-initiated studies at the request of the investigator or IRB	Non-Exempt Human Subjects Research	https://www.umassmed.edu/ccts/request-services/	https://www.umassmed.edu/ccts/research-resources/protocol-review-committee/ ***The outcome of PRC review must be provided in writing for IRB review.***
Gene and Cell Therapy Advisory Committee	UMass Chan	Gene therapy trials	Non-Exempt Human Subjects Research	CCTS TRAcs portal: https://umassmed.sharepoint.com/sites/ccts/SitePages/Study-Feasibility-Checklist.aspx AND https://www.umassmed.edu/ccts/request-services/	https://umassmed.sharepoint.com/sites/ccts/SitePages/Gene-Therapy-Advisory-Committee.aspx ***The outcome of Gene and Cell Therapy Advisory Committee review must be provided in writing for IRB review.***

COMPLETED/IDENTIFIED DURING IRB PRE-REVIEW

Organization	Review type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review
See table above plus:					
Clinical Engineering	UMass Memorial	Use of a medical device that has a power source in a clinical setting for research purposes	Non-Exempt Human Subjects Research	508-334-1111	Call Clinical Engineering Department
Embryonic Stem Cell Research Oversight (ESCRO)	UMass Chan	Research involving human embryonic stem cells (hESCs)	Exempt and Non-Exempt Human Subjects Research	Nathaniel.Hafer@umassmed.edu	*Contact Dr. Hafer*

COMPLETED PRIOR TO ISSUING FINAL IRB APPROVAL

IRB approval/determination is withheld until corresponding documentation is provided to the IRB

Organization	Review type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review
Conflict of Interest	UMass Chan and, if applicable, Five Campus Committee	Financial interest related to the research	Exempt and Non-Exempt Human Subjects Research	COI@umassmed.edu	*https://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/* ***The outcome of the UMass Chan Campus COI Committee review must be provided in writing for IRB review; final fully signed mitigation plans, when applicable, must be provided for IRB approval***
Institutional Biosafety Committee (IBC)	UMass Chan	Research involving: a. recombinant and synthetic nucleic acids (e.g. human gene transfer studies), infectious agents, and toxins, or b. the processing of and/or experimentation with human blood, secretions, and/or tissues in clinical or basic research laboratories	Non-Exempt Human Subjects Research	IBC@umassmed.edu	*https://umassmed.sharepoint.com/sites/IBC (intranet only)* ***The outcome of IBC review for type (a) studies must be provided in writing for IRB review. Type (b) are not required to be in place for IRB approval.***
Radiation Safety Committee (RSC)	UMass Chan	Research with internally administered radioisotopes or external sources of ionizing radiation, which are experimental or protocol driven (i.e., would not normally be	Non-Exempt Human Subjects Research	Sassan.Abdollahzadeh@umassmed.edu	*Studies involving radiation, even when standard of care, should use the "Questions for PI" checklist from the Subcommittee on Human Uses (SHU) of the Radiation Safety Committee (RSC) to explain why RSC approval is or is not needed.*

		required by the subject's medical condition)			***The outcome of RSC review must be provided in writing for IRB review.***
Gene and Cell Therapy Advisory Committee	UMass Chan	Gene therapy trials	Non-Exempt Human Subjects Research	CCTS TRAcs portal: https://umassmed.sharepoint.com/sites/ccts/SitePages/Study-Feasibility-Checklist.aspx AND https://www.umassmed.edu/ccts/request-services/	https://umassmed.sharepoint.com/sites/ccts/SitePages/Gene-Therapy-Advisory-Committee.aspx ***The outcome of Gene and Cell Therapy Advisory Committee review must be provided in writing for IRB review.***

EXTERNAL IRB STUDIES - RELYING ON AN EXTERNAL IRB AS THE IRB OF RECORD

Studies reviewed by an external IRB must still adhere to local requirements. The IRB will require the ancillary review documentation listed below prior to releasing new studies for external IRB review. Study teams are responsible for obtaining ancillary reviews prior to initiating human subjects research. Study teams are also responsible for managing the ancillary reviews for modifications to externally reviewed studies.

Organization	Review type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review
Conflict of Interest	UMass Chan and, if applicable, Five Campus Committee	Financial interest related to the research	Non-Exempt Human Subjects Research	COI@umassmed.edu	*https://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/* ***The outcome of the UMass Chan Campus COI Committee review must be provided in writing for UMass Chan IRB administrative review; final fully signed mitigation plans, when applicable, must also be provided***
Institutional Biosafety Committee (IBC)	UMass Chan	Research involving: c. recombinant and synthetic nucleic acids (e.g. human gene transfer studies), infectious agents, and toxins, or d. the processing of and/or experimentation with human blood, secretions, and/or tissues in clinical or basic research laboratories	Non-Exempt Human Subjects Research	IBC@umassmed.edu	*https://umassmed.sharepoint.com/sites/IBC (intranet only)* ***The outcome of all applicable IBC reviews must be provided in writing for UMass Chan IRB administrative review.***
Radiation Safety Committee (RSC)	UMass Chan	Research with internally administered radioisotopes or external sources of ionizing radiation, which are	Non-Exempt Human Subjects Research	Sassan.Abdollahzadeh@umassmed.edu	*Studies involving radiation, even when standard of care, should use the "Questions for PI" checklist from the Subcommittee on*

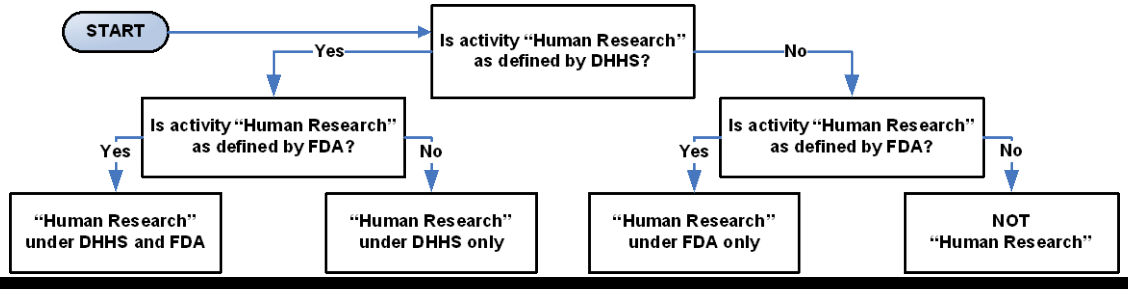
		experimental or protocol driven (i.e., would not normally be required by the subject's medical condition)			*Human Uses (SHU) of the Radiation Safety Committee (RSC) to explain why RSC approval is or is not needed.* ***The outcome of RSC review must be provided in writing for UMass Chan IRB administrative review.***
Students as Subjects	UMass Chan	The SAS Ad Hoc Advisory Group reviews projects involving sensitive topics that will purposely recruit students from the UMass Worcester campus as human subjects	Non-Exempt Human Subjects Research	Anne.Larkin@umassmed.edu	***The outcome of SAS review must be provided in writing for UMass Chan IRB administrative review.***
Gene and Cell Therapy Advisory Committee	UMass Chan	Gene therapy trials	Non-Exempt Human Subjects Research	CCTS TRAcs portal: https://umassmed.sharepoint.com/sites/ccts/SitePages/Study-Feasibility-Checklist.aspx AND https://www.umassmed.edu/ccts/request-services/	https://umassmed.sharepoint.com/sites/ccts/SitePages/Gene-Therapy-Advisory-Committee.aspx ***The outcome of Gene and Cell Therapy Advisory Committee review must be provided in writing for UMass Chan IRB administrative review.***

UMass Chan MEDICAL SCHOOL

WORKSHEET: Human Research Determination

NUMBER	DATE	PAGE
HRP-310	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated. This worksheet is to be used. It does not need to be completed or retained.[i]



1 Research as Defined by DHHS Regulations[ii] (Check if **"Yes".**)

- ☐ Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)
- ☐ Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)
- ☐ Is the systematic investigation designed to develop or contribute to knowledge? (Designed: Observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: Truths, facts, information.)
- ☐ Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)

2 Human Subject Under DHHS Regulations (Check if **"Yes".**)

- ☐ Is the investigator conducting the Research gathering information or biospecimens *about living* individuals?

3 Human Subject Under DHHS Regulations (Check if **"Yes".**)

- ☐ Will the investigator use, study, or analyze information or biospecimens obtained through either of the following mechanisms? Specify which mechanism(s) apply, if yes:
  - ☐ Physical procedures or manipulations of those individuals or their environment for Research purposes ("Intervention").
  - ☐ Communication or interpersonal contact with the individuals. ("Interaction").

4 Human Subject Under DHHS Regulations (Check if **"Yes"**)

- ☐ Will the investigator gather data that is either? Specify which category(s) apply if yes:
  - ☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").
  - ☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will **NOT** be made public, such as a medical record (i.e. "Private information").
- ☐ Can the individuals' identities be readily ascertained or associated with the information by the investigator (i.e. "Identifiable Private Information")?
- ☐ Can the individuals' identities be readily ascertained or associated with the biospecimens (i.e., "Identifiable Biospecimen")?

If all items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.

5 Human Research Under DHHS Regulations (Check if "**Yes**")

- ☐ Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?

If checked, the activity is Human Research under DHHS regulations.

6 Human Research Under FDA Regulations (Check if "**Yes**")

- ☐ Does the activity involve any of the following? **(Check all that apply)**
  - ☐ In the United States: The use of a drug[iii] in one or more persons other than use of an approved drug in the course of medical practice[iv].
  - ☐ In the United States: The use of a device[v] in one or more persons that evaluates the safety or effectiveness of that device.
  - ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[vi].
  - ☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[vii].

If **"Yes",** the activity is Human Research under FDA regulations.

If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under organizational policy.

7 Engagement (Complete if the activity is Human Research. (Check if **"Yes"**)

- ☐ The organization is engaged in Human Research. Use HRP-311 - WORKSHEET - Engagement Determination.

Comments:

[i] This document satisfies AAHRPP elements I.1.A, III.1.A

[ii] The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

[iii] The term ‘‘drug’’ means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[iv] “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[v] The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[vi] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[vii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

UMass Chan MEDICAL SCHOOL

WORKSHEET: Engagement Determination		
NUMBER	DATE	PAGE
HRP-311	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for Designated Reviewers making engagement determinations when there is uncertainty regarding whether the organization is engaged in Human Research. For the purpose of this worksheet, "Engagement" means that the organization's human research protection program is responsible for the Human Research. For the purposes of being subject to DHHS or other federal agency that has adopted "The Common Rule" engagement applies only to non-exempt Human Research. This worksheet is to be used. It does not need to be completed or retained.[i]

The organization is engaged in the research if the first item in section 2 is true regardless of whether the organization's involvement is limited to one or more of the items in section 3.

The organization is engaged in the research if any item other than the first item in section 2 is true except when the organization's involvement is limited to one or more of the items in section 3

1 FDA Exception for "Engagement" (Check if "**Yes**")

☐ **ONLY FDA regulations apply to this Human Research as indicated in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review/Submit Pre-Review activity (DHHS regulations or any other Federal agency that has adopted the Common Rule are NOT checked in in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review /Submit Pre-Review activity).**

If ONLY FDA regulations apply, **STOP**. The FDA does not have a comparable process that aligns with OHRP's engagement guidance since FDA regulations govern sponsors (and parties they contract with), clinical investigators, and IRBs (and do not address institutions/organizations). If an organization is conducting certain activities of FDA (only) regulated Human Research, determining whether an institution/organization requires IRB oversight depends on many details such as:

- What type of activities are being conducted.
- What the protocol requires.
- Who is conducting the activities.
- Where the activities are being conducted.
- For what purpose the activities are being conducted.

FDA recommends referring to FDA Information Sheet "Use of Investigational Products When Subjects Enter a Second Institution, *Guidance for Institutional Review Boards and Clinical Investigators* (January 1998)" for guidance and to contact the sponsor and/or applicable FDA review division for assistance.[1]

2 Conditions Under Which an Organization is Engaged

☐	The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt Human Research, even where all activities involving Human Subjects are carried out by employees or agents[2] of another organization.
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures
☐	The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment.
☐	The organization's employees or agents interact for Research purposes with any Human Subject of the Research.
☐	The organization's employees or agents obtain the informed consent of Human Subjects for the Research.
☐	The organization's employees or agents obtain for Research purposes Identifiable Private Information or Identifiable Biospecimens from any source for the Research. It is important to note that, in general, the organization's employees or agents obtain Identifiable Private Information or Identifiable Biospecimens for Human Research are considered engaged in the Research, even if the organization's employees or agents do not directly interact or intervene with Human Subjects.

3 Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 1 is Met

☐	The organization's employees or agents perform commercial or other services for investigators provided that **ALL** of the following conditions also are met:	
	☐	The services performed do not merit professional recognition or publication privileges.
	☐	The services performed are typically performed by those organizations for non-Research purposes.

[1] Huron email correspondence with FDA GCP Program dated October 13, 2020.

[2] An organization's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. Contact legal counsel for additional information regarding whether an individual is an agent of the organization.

	☐	The organization's employees or agents do not administer any study Intervention being tested or evaluated under the protocol.	
☐	The organization is not selected as a Research site but its employees or agents provide clinical trial-related medical services that are dictated by the protocol that would typically be performed as part of routine clinical monitoring or follow-up of Human Subjects enrolled at a study site by clinical trial investigators provided that **ALL** of the following conditions also are met:		
	☐	The organization's employees or agents do not administer the study Interventions being tested or evaluated under the protocol.	
	☐	The clinical trial-related medical services are typically provided by the organization for clinical purposes.	
	☐	The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.	
	☐	When appropriate, investigators from an organization engaged in the Research retain responsibility for **ALL** of the following:	
		☐	Overseeing protocol-related activities.
		☐	Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
☐	The organization was not initially selected as a Research site but the organization's employees or agents administer the study Interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization engaged in the Research determines that it would be in the Human Subject's best interest to receive the study Interventions being tested or evaluated under the protocol and **ALL** of the following are true:		
	☐	The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.	
	☐	Investigators from the organization engaged in the Research retain responsibility for **ALL** of the following:	
	☐	☐	Overseeing protocol-related activities.
		☐	Ensuring the study Interventions are administered in accordance with the IRB-approved protocol.
		☐	Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol. and
	☐	An IRB designated on the engaged organization's federalwide assurance (FWA) is informed that study Interventions being tested or evaluated under the protocol have been administered at an organization not selected as a Research site.	
☐	The organization's employees or agents do **ANY** of the following:		
	☐	Inform prospective Human Subjects about the availability of the Research.	
	☐	Provide prospective Human Subjects with information about the Research but do not obtain Human Subjects' consent for the Research or act as representatives of the investigators.	
	☐	Provide prospective Human Subjects with information about contacting investigators for information or enrollment.	
	☐	Seek or obtain the prospective Human Subjects' permission for investigators to contact them.	
☐	The organization is permitting use of its facilities for Intervention or Interaction with Human Subjects by investigators from another organization.		
☐	The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.		
☐	The organization's employees or agents:		
	☐	Obtain coded Private Information or human biological specimens from another organization involved in the Research that retains a link to individually identifying information; and	
	☐	Are unable to readily ascertain the identity of the Human Subjects to whom the coded information or specimens pertain.	
☐	The organization's employees or agents access or utilize individually Identifiable Private Information only while visiting an organization that is engaged in the Research, provided their Research activities are overseen by the IRB of the organization that is engaged in the Research.		
☐	The organization's employees or agents access or review Identifiable Private Information for purposes of study auditing.		
☐	The organization's employees or agents receive Identifiable Private Information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.		
☐	The organization's employees or agents author a paper, journal article, or presentation describing a Human Research study.		

[i] This document satisfies AAHRPP element I.1.A

UMass Chan MEDICAL SCHOOL

WORKSHEET: Exemption		
NUMBER	DATE	PAGE
HRP-312	06/21/2022	1 of 4

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet is to be used. It does not need to be completed or retained.[i]

1	**GENERAL EXCLUSIONS FROM EXEMPTIONS** (Check if **"Yes"**. If any are checked, the research is not exempt.)
☐	The research is FDA-regulated.[ii]
☐	The research involves Prisoners, conducted or funded by DHHS, Dept. of Defense (DOD) and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
☐	The research involves interactions with Prisoners.[iii]
☐	The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).[iv]

2	**Criteria for approval of exempt research (Check if "Yes")**	
☐	The research involves no more than Minimal Risk to subjects. **(Must be checked.)**	
☐	Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) **(Must be checked.)**	
☐	There are interactions with subjects: **(If checked, all of the following must also be checked.)**	
	☐	There will be a consent process
	☐	The consent process will disclose that the activities involve research.
	☐	The consent process will disclose the procedures to be performed.
	☐	The consent process will disclose the expected duration of the subject's participation.
	☐	The consent process will disclose the extent, if any, to which confidentiality will be maintained.
	☐	The consent process will disclose that participation is voluntary.
	☐	The consent process will disclose the name and contact information for the investigator.
	☐	There are adequate provisions to maintain the privacy interests of subjects.

2018 Requirements

NOTE: For Exempt determinations on or after January 21, 2019, complete section 3. If this study is subject to Pre-2018 Common Rule requirements or is DOJ-regulated, move to sections 4 and 5 below.

3	**The research falls into one or more of the following categories** (One or more categories must be checked)	
☐	1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	
☐	2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR ☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)**	
	☐	If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and at least one of the following criteria is met: ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; OR ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational achievement, or reputation.

☐	3(i). Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: ☐ (A) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR ☐ (B) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR ☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)** (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
☐	4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: ☐ (i) The identifiable private information or identifiable biospecimens are publicly available; OR ☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR ☐ (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR ☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
☐	5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs[v] ☐ (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
☐	6.[vi] Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.
☐	7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts limited IRB review **(See HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)**
☐	Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use. **(See HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)**

Pre-2018 Requirements:

NOTE: If this study is subject to 2018 Common Rule requirements, complete section 3 above.

4 One of the following is true:

☐ ☐ The research is DOJ-regulated.

☐ The review is related to research determined to be exempt prior to January 21, 2019, and the organization continues to apply Pre-2018 requirements to some or all research initiated prior to January 21, 2019.

5 The research falls into one or more of the following categories (one or more categories must be checked)

☐ ☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)

☐ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In addition:

☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("N/A" if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.)**

☐ 3. Research involving the use of educational tests[vii], survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 4.[viii] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **(For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes.")**

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of Dept. or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if **"Yes"**. All must be checked)

- ☐ The program under study delivers a public benefit[ix] or service[x].
- ☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.
- ☐ There is no statutory requirement that the project be reviewed by an IRB.
- ☐ The project does not involve significant physical invasions or intrusions upon the privacy of subjects.
- ☐ The funding agency concurs with the exemption.

☐ 6.[xi] Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

[i] This document satisfies AAHRPP elements I-9, II.2.A, II.2.B, II.2.C, II.3.F, II.4.A, II.5.A

[ii] The organization's policy is to not grant exemptions to FDA-regulated research in category (6).

[iii] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative.

[iv] DOE O 443.1C

[v] Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

[vi] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

[vii] Includes cognitive, diagnostic, aptitude, and achievement tests

[viii] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.

[ix] For example, financial or medical benefits as provided under the Social Security Act

[x] For example, social, supportive, or nutrition services as provided under the Older Americans Act

[xi] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

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WORKSHEET: Expedited Review		
NUMBER	DATE	PAGE
HRP-313	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. This worksheet is to be used. It does not need to be completed or retained.[i]

☐ **Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedure[ii]**

1 Additional Criteria for Research Involving Prisoners[iii] (Check if **"Yes" or "N/A"**. Must be checked)

☐ The research involves interaction with prisoners, is minimal risk, and the prisoner representative concurs with this determination, and the prisoner representative must review the research[iv]. (**"N/A"** if no prisoners as subjects OR no prisoner interaction.) ☐ **N/A**

Initial or continuing review must meet criteria set 3. Modifications can meet either criteria set 2 or 3.

2 Minor Modifications (Check if **"Yes" or "N/A"**. All must be checked)

☐ The modifications do not affect the design of the research.

☐ The modifications add no more than Minimal Risk to subjects.

☐ All added procedures fall into categories (1)-(7) below. (**"N/A"** if no added procedures) ☐ **N/A**

3 Initial Review, Continuing Review, or Modifications (Check if **"Yes"** or **"N/A"**. All must be checked)

☐ The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (**"N/A"** if the research falls into category (8)(b))

☐ Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than Minimal Risk. (**"N/A"** if the research falls into category (8)(b))

☐ The research is **NOT** classified[v] (if the research is classified, UMass Chan will rely on an external IRB)

☐ The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)**

- ☐ (1)(a) Clinical studies of drugs when an IND is not required.
- ☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh ≥110 pounds where the amount drawn is ≤550 ml[vi]/8 week period and collection occurs at most 2 times/week[vii].
- ☐ (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (50 ml or 3 ml/kg[viii]/whichever is less, per 8 week period), and the frequency with which it will be collected (at most 2 times/week[ix].)
- ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive[x] means.[xi]
- ☐ (4) Collection of data through noninvasive procedures[xii] (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.[xiii]
- ☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.
- ☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☐ (7)(a) Research on individual or group characteristics or behavior[xiv]
- ☐ (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

  For research approved on or after 1/21/2019, this does not include scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; this is deemed not to be research per 45 CFR 46. 102(l)(1).
- ☐ (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects[xv]. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
- ☐ (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source[xvi].

☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.[xvii]

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[i] This document satisfies AAHRPP elements I-9, II.2.F-II.2.F.3, II.5.A

[ii] Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff Document issued on September 6, 2019 states, "For continuing review [of the HUD], an IRB may use an expedited review procedure in which a chairperson or one or more experienced reviewers carries out the review, similar to the expedited review procedure described at 21 CFR 56.110(b)."

[iii] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative; OHRP Prisoner Research FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html

[iv] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18).

[v] Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, "Classified National Security Information," December 29, 2009

[vi] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[vii] Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

[viii] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[ix] Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

[x] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

[xi] Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[xii] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

[xiii] Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[xiv] Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

[xv] Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

[xvi] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). OHRP 2018 Requirements FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html

[xvii] Ibid.

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WORKSHEET: Criteria for Approval

NUMBER	DATE	PAGE
HRP-314	09/15/2025	1 of 4

The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")[i]

1	**General Considerations** (Check if **"Yes"** or **"N/A"**. All must be checked)	
☐	The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.	
☐	For initial review the principal investigator is not Restricted. **("N/A" if not initial review) N/A:** ☐	
☐	Materials are complete.	
2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)	
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.	
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐	
☐	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.[ii]	
☐	Selection of subjects is equitable.[iii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)	
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk) N/A:** ☐ [iv]	
☐	There are adequate provisions to protect the privacy of subjects.[v]	
☐	There are adequate provisions to maintain the confidentiality of data.[vi]	
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vii] **("N/A" if no vulnerable subjects) N/A:** ☐	
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**	
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **Permanently closed to enrollment** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**	
☐	Additional applicable criteria[viii] are met **("N/A" if none)**	
3	**Additional Considerations (**Check all that apply.)	
☐	Does the research involve no more than Minimal Risk to subjects?	
☐	Does the research require Continuing review? **(Note that for FDA or DOJ overseen research or research subject to Pre-2018 Requirements, there is no option not to require Continuing review.)** The research does not require Continuing review if one of the following apply: ☐ The research is eligible for expedited review. **(See HRP-313 – WORKSHEET - Expedited Review)** ☐ The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.	
☐	Should review take place more often than annually?[ix] If so, specify period.	
☐	Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[x] **("N/A" if initial) N/A:** ☐	
☐	Does information need to be provided to subjects because it may affect their willingness to continue participation? **("N/A" if initial) N/A:** ☐	
4	**Primary Reviewer Criteria for Initial review** (Check if **"Yes"** or **"N/A"**. All must be checked; May be determined by a primary reviewer)	
☐	The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)	
☐	The plan for communication among sites is adequate to protect subjects. **("N/A" if not a Multi-Site Study where PI is the lead or not initial) N/A:** ☐	
☐	There are no inconsistencies between the DHHS grant and protocol. **("N/A" if research subject to 2018 Requirements or if there is no DHHS grant.) N/A:** ☐	
	Complete remaining items when applicable	
5	**Consent Process** (Check if **"Yes"**. All must be checked)	
☐	The investigator will obtain the legally effective informed consent of the subject or LAR.	
☐	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether to participate.	
☐	The circumstances of consent minimize the possibility of coercion or undue influence.	
☐	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.	

☐	The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. (**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐
☐	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
☐	Consent will disclose the elements in **Section 7: Elements of Consent Disclosure**

6 Long Form of Consent Documentation (Check if **"Yes"** or **"N/A"**. All must be checked)

☐	The written consent document is accurate, complete, and consistent with the protocol.
☐	The written consent document embodies the elements in **Section 7: Elements of Consent Disclosure**
☐	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐	The subject or LAR will sign and date the consent document.
☐	The person obtaining consent will sign and date the consent document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.
☐	If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("N/A" if no signature line) N/A:** ☐
☐	When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **("N/A" if all subjects are able to read) N/A:** ☐

7 Elements of Consent Disclosure (Check if **"Yes"** or **"N/A"**. All must be checked)

Required: *(*Can be omitted if there are none.)*

- ☐ The study involves research.
- ☐ The purposes of the research.
- ☐ The expected duration of the subject's participation.
- ☐ The procedures to be followed.
- ☐ Identification of any procedures, which are experimental.*
- ☐ Any reasonably foreseeable risks or discomforts to the subject.*
- ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.*
- ☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
- ☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
- ☐ How to contact the research team for questions, concerns, or complaints about the research.
- ☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
- ☐ Whom to contact in the event of a research-related injury to the subject.
- ☐ Participation is voluntary.
- ☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Required for Clinical Trials that Follow ICH-GCP

- ☐ The approval of the IRB.
- ☐ The trial's investigational product(s) and probability for random assignment to each treatment, if applicable.
- ☐ What is expected of the participants.
- ☐ When applicable, the reasonably foreseeable risks or inconveniences to the participant's partner, an embryo, fetus, or nursing infant.
- ☐ When applicable, the reasonably expected benefits to the participant's partner, an embryo, fetus, or nursing infant.
- ☐ When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- ☐ The process by which the participant's data will be handled, including in the event of withdrawal or discontinuation of participation in accordance with regulatory requirements.
- ☐ That by agreeing to participate in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of viewing trial activities and/or revising or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), and in accordance with applicable regulatory requirements, the IRB.
- ☐ If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements.
- ☐ Trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it.

Required for FDA-Regulated Research

- ☐ The possibility that the Food and Drug Administration may inspect the records.

☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- ☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
- ☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(**N/A if research is subject to Pre-2018 Requirements) N/A:** ☐

Required for More than Minimal Risk Research

☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.

☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

☐ The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.

☐ The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.

☐ For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Additional: (Include when appropriate.)

☐ The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.

☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.

☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

☐ Any additional costs to the subject that may result from participation in the research.

☐ The consequences of a subject's decision to withdraw from the research.

☐ Procedures for orderly termination of participation by the subject.

☐ Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.

☐ Approximate number of subjects involved in the study.

☐ Method, amount, and schedule of all payments.

☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. (**N/A if research is subject to Pre-2018 Requirements)**

☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**N/A if research is subject to Pre-2018 Requirements)**

☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (**N/A if research is subject to Pre-2018 Requirements)**

☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects. [xi]

☐ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

8 Additional Considerations for Electronic Consent (Check if "Yes" or "N/A". All must be checked)

☐	Electronic consent document includes all elements in **Section 7-Elements of Consent Disclosure**
☐	The date of the electronic signature will be captured **(N/A if waiver of documentation of consent is requested and justified) N/A:** ☐
☐	Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
☐	Electronic consent process includes age appropriate materials to facilitate comprehension.
☐	Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
☐	Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
☐	Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.
☐	Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
☐	The informed consent process outlines in detail how any included documents will be utilized.

☐	Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.
☐	For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identity and assent when the child initially presents to the investigator. **(N/A if the research is not an FDA-Regulated Clinical Trial) N/A: ☐**

[i] This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F

[ii] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[iii] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[iv] When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5)

[v] The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be "sensitive" or "private." The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects' potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c)

[vi] The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c)

[vii] When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

[viii] HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments; HRP-318 - WORKSHEET - Additional Federal Agency Criteria; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST - Prisoners; HRP-416 - CHECKLIST - Children; HRP-417 - CHECKLIST - Cognitively Impaired Adults; HRP-418 - CHECKLIST - Non-Significant Risk Device.

[ix] Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB's experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

[x] Implement when the veracity of the information provided is questioned.

[xi] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

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WORKSHEET: Advertisements		
NUMBER	DATE	PAGE
HRP-315	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating advertisement meant to be seen or heard by subjects. This worksheet is to be used. It does not have to be completed or retained.[1]

1	**Context** (Check if **"Yes"**. All must be checked)	
☐	The application describes the mode of communication	
☐	For printed advertisements, the final copy is being reviewed	
☐	For audio/video tape, the tape is the final version	
2	**The advertisement:** (Check if **"Yes"**. All must be checked)	
☐	Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol	
☐	Does NOT promise "free treatment," when the intent is only to say subjects will not be charged for taking part in the research	
☐	Does NOT include exculpatory language	
☐	Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type	
☐	The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as: • The name and address of the investigator or research facility • The condition under study or the purpose of the research • In summary form, the criteria that will be used to determine eligibility for the study • A brief list of participation benefits, if any • The time or other commitment required of the subjects • The location of the research and the person or office to contact for further information	
3	**For FDA-Regulated research, the advertisement:** (Check if **"Yes"**. All must be checked)	
☐	Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation	
☐	Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device	
☐	Does NOT use terms, such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.	
☐	Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.	

[1] This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E

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WORKSHEET: Payments		
NUMBER	DATE	PAGE
HRP-316	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating payments to subjects or their Legally Authorized Representatives. This worksheet is to be used. It does not have to be completed or retained.[1]

1	**Requirements for Payments** (Check if **"Yes"**. All must be checked)	
☐	All payments are described in the protocol including: (Check if **"Yes"**. All must be checked)	
	☐	Amount
	☐	Method
	☐	Timing of disbursement
☐	Credit for payment accrues as the study progresses.	
☐	Payment is not contingent upon completing the entire study.	
☐	The amount of payment and the proposed method and timing of disbursement is neither coercive nor presented undue influence.	
☐	Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn and is evaluated in context of any reimbursement or compensation payment included in the study.	
☐	All information concerning payment, including the amount and schedule of payments, is in the informed consent document.	
☐	Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved.	

[1] This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E

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WORKSHEET: Short Form of Consent Documentation		
NUMBER	DATE	PAGE
HRP-317	06/21/2022	1 of 1

The purpose of this checklist is to provide support for IRB members or Designated Reviewers using HRP-314 - WORKSHEET - Criteria for Approval when reviewing research involving the short form of consent documentation. This worksheet is to be used. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")[1]

1	**Short Form of Consent Documentation** (Check if **"Yes".** All must be checked)
☐	The written consent document states that the elements of consent have been presented orally to the subject or the subject's LAR.
☐	There is written summary of what is to be said to the subject or LAR that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 - WORKSHEET - Criteria for Approval.
☐	The consent document and summary are accurate and complete.
☐	An impartial witness is present during the entire consent discussion.
☐	For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject's LAR.
☐	The subject or the subject's LAR will sign and date the short form consent document.
☐	The witness will sign and date the short form consent document and the summary.
☐	The person obtaining consent will sign and date the summary.
☐	When a subject or the subject's LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's LAR, and that consent was freely given.
☐	A copy of the signed and dated summary will be given to the person signing the document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.

[1] This document satisfies AAHRPP elements II.3.F, III.1.F

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WORKSHEET: Additional Federal Agency Criteria

NUMBER	DATE	PAGE
HRP-318	12/9/2022	1 of 6

The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. This worksheet must be used. It does not need to be completed or retained.[1]

1	**Additional Criteria For Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research within the BOP.
☐	The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing.
☐	The research design is compatible with both the operation of prison facilities and protection of human subjects.
☐	The investigator will observe the rules of the institution or office in which the research is conducted.
☐	Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR 512.
☐	All research proposals will be reviewed by the BOP IRB.
☐	The project has an adequate research design and will contribute to the advancement of knowledge about corrections.
☐	The selection of subjects within any one organization is equitable.
☐	Incentives will not be offered to help persuade inmate subjects to participate. Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are no longer in BOP custody and are participating in authorized research being conducted by BOP employees or contractors.
☐	If a non-employee of the BOP will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has been provided to the agency.
☐	Except as noted in the consent statement to the subject, the investigator will not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
☐	Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person will not be stored in, or introduced into, an electronic retrieval system.
☐	Required elements of disclosure include all of the following: ☐ Anticipated uses of the results of the research. ☐ A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable). ☐ A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility. ☐ Identification of the investigators. ☐ A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
☐	The investigator has academic preparation or experience in the area of study of the proposed research.
☐	The IRB application includes a statement regarding assurances and Certification required by federal regulations, if applicable.
☐	The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.
2	**Additional Criteria for Department of Justice (DOJ) Research Funded by National Institute of Justice (NIJ)** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research funded by NIJ.
☐	Projects have a privacy certificate approved by the NIJ human subjects protection officer.
☐	All investigators and research Staff have signed employee confidentiality statements, which are maintained by the investigator.
☐	Identification of the funding agency(ies).
☐	A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.
☐	Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.

[1] This document satisfies AAHRPP elements I.1.A, I.1.D, I.1.F, I-2, I-3, I-9, II.2.D, II.2.F-II.2.F.3, II.2.I, II.3.B, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.4.C, III.1.C, III.1.E, III.1.F, III.2.C, III.2.D

☐	A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials. ☐ At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research. ☐ At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall not include an abstract in the report of findings. ☐ In any publication of results, the research shall acknowledge the Bureau's participation in the research project. ☐ The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau. ☐ Prior to submitting for publication the results of a research project conducted under this subpart, the research shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

3	**Additional Criterion for the Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance.
☐	If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB's determinations and approval will be submitted to the Environmental Protection Agency (EPA) Human Subjects Research Review official for final review and approval before the research can begin.
☐	If the research involves children, the research must either be: ☐ observational research not involving greater than Minimal Risk or ☐ observational research involving greater than Minimal Risk but presenting prospect of direct benefit.
☐	If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.
☐	If the research involves the use of Broad Consent, the research can only be Exempt under category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research.

4	**Additional Criteria for Department of Energy (DOE) Research** (Check if **"Yes or N/A"**. All must be checked)

☐	For research that involves Personally Identifiable Information (PII) or Protected Health Information (PHI), the protocol addresses the following DOE requirements:
	• Keeping PII/PHI confidential.
	• Protecting PII/PHI during storage and transmission.
	• Releasing PII/PHI, when required, only under a procedure approved by the responsible IRB and DOE.
	• Using PII/PHI only for purposes of the IRB-approved project.
	• Handling and marking documents containing PII/PHI as "containing PII or PHI."
	• Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI.
	• Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project, as required by Office of Management and Budget Circular No. A-133; (d) when required by law; or (e) with the consent of the participant/guardian.
	• Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives and stand-alone computers using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.
	• Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the current DOE password requirements:
	  ○ Minimum of twelve (12) non-blank characters
	  ○ Must contain a lowercase letter
	  ○ Must contain an uppercase letter
	  ○ Must contain a number or special character
	  ○ Must contain a nonnumeric in the first and last position
	  ○ Must not contain the user ID

- Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.
- Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.
- Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer.
- Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter.
- Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII.
- Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63).
- Reporting the loss or suspected loss of PII/PHI immediately upon discovery to (1) the DOE funding office program manager, or, if funded by a DOE laboratory, the DOE laboratory Program Manager and (2) the DOE HSP Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting.
- Classified projects that use PII/PHI must also comply with all requirements for conducting classified research.

☐ For classified human subjects research (in whole or in part):

- Exemptions (as per 10 CFR §745.104) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required.
- A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR §745.104.
- The identity of the sponsoring Federal agency will be disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than Minimal Risk to subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects.
- The informed consent document will state that the project is classified, what that means for the purposes of that project, and what part of the research that applies to.
- The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.
- Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, Director of the Office of Science and Technology Policy (OSTP) or designee, and then the Director of National Intelligence (ODNI) or designee, in that order. The Director of OSTP (or designee), or the Director of National Intelligence (or designee) will review and approve or disapprove the research, or will convene or designate an IRB that is, to the extent possible, made up of unaffiliated members with the appropriate qualifications and clearance to approve or disapprove the research.
- Information on each project that is classified must be submitted annually (or in accordance with the directions and schedules provided by the appropriate HSP program manager) by the responsible HSP program managers.
- If the IRB believes that the project, in whole or in part, can be thoroughly reviewed in an unclassified manner, a request for a waiver from some or all of the requirements of classified HSR can be submitted. The study-specific waiver request must be signed by the IRB Chair, and reviewed and approved by the appropriate HSP Program Manager (and if the waiver request relates to an intelligence-related project, also the DOE Office of Intelligence and Counterintelligence (IN)). A list of waiver requests and the actions taken will be provided.
- HSR that is classified, in whole or in part, must not be initiated without IRB approval. After IRB approval, the DOE IO reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.

☐ For research involving protected classes:

- Prisoners, children, and individuals with impaired decision making [*sic*] must be conducted in accordance with the appropriate Subpart(s) of 45 CFR §46.
- Proper protections are in place for DOE/NNSA federal and/or contractor employees who may be subject to coercion or undue influence. DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.

5 Additional Criterion for Department of Education (ED) Research (Check if **"Yes"** or **"N/A"**. All must be checked)

☐	If prior consent[2] or written documentation of consent or parental permission is waived, the research does NOT involve gathering information about any of the following: • Political affiliations or beliefs of the student or the student's parent • Mental or psychological problems of the student or the student's family • Sex behavior or attitudes • Illegal, anti-social, self-incriminating, or demeaning behavior • Critical appraisals of other individuals with whom respondents have close family relationships • Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers • Religious practices, affiliations, or beliefs of the student or student's parent • Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)
6	**Additional Criteria for Department of Defense (DOD) Research** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.
☐	The review has considered (and will document) the scientific merit of the research; within consideration of scientific merit, feasibility, of study completion should be considered.[i]
☐	For research that involves DOD-affiliated personnel, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.
☐	For research that takes place on a DOD facility, the key investigator must receive approval from the command or DOD Component HRPP or its delegate responsible for the facility.
☐	The research does **NOT** involve Prisoners of war or detainees as subjects.[ii]
☐	The research does not involve the testing of chemical or biological agents, which is prohibited, pursuant to Section 1520a of Title 50, U.S.C, unless exceptions for research for prophylactic, protective, or other peaceful purposes apply, ☐ Explicit written approval from DOHRP was obtained prior to the initiation of excepted testing of chemical or biological agents involving HSR.
☐	Military personnel will not be paid for research conducted while on duty.[iii] ☐ If the research targets military personnel where subjects will be paid, then the informed consent should advise military personnel to check with their supervisor before accepting payment for participation in this research.
☐	If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required: **(Check if "Yes" or NA. All must be checked):** ☐ If the research includes risks to their fitness for duty (e.g., health, availability to perform job, data breach), then the informed consent form must inform DOD-affiliated personnel about these risks and that they should seek command or Component HRPP guidance before participating. ☐ If the research includes potential risks for revocation of clearance, credentials, or other privileged access or duty, then the informed consent form must inform DOD-affiliated personnel about these risks. ☐ Research involves greater than Minimal Risk: The IRB has appointed an ombudsperson[iv] who does not have a conflict of interest with the research and is not a part of the research team and will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsperson should be available to address concerns about participation. ☐ If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required: • The research is subject to DOD Component security review and DOHRP approval. • The research will apply an HHS Certificate of Confidentiality • Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security.
☐	If the research is subject to Section 980 of Title 10, U.S.C., consent will be obtained unless waived by the DOHRP.[v] The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).

[2] Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any survey, analysis, or evaluation funded by the Department of Education.

☐	The key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) for research that requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.
☐	If consent is obtained from the experimental subject's legal representative (for cognitively impaired subjects), the intention of the research must be to be beneficial to the subject[vi].
☐	Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research.
☐	Military and civilian supervisors, officers, and others in the chain of command will not be present at any recruitment sessions or during the consent process for any DoD-affiliated personnel.[vii]
☐	When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review.
☐	The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.
☐	When conducting multi-site research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.

☐	Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.[viii]
	• Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:
	  ○ May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
	  ○ Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
	• The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

☐	Research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHRP prior to research starting.
☐	If the research involves emergency medicine research, the Secretary of Defense must approve a waiver of the advance informed consent in accordance with provision 10 USC 980.
☐	If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions: **(Check if "Yes" or "N/A". All must be checked.)** ☐ Applicable national laws and requirements of the foreign country will be followed. ☐ When a DoD-affiliated person who is also a citizen of the host nation is a research subject, where differences in applicable standards exist between the United States and the host nation, the standard that is most protective of human subjects will be applied. ☐ Take into consideration the cultural sensitivities in the setting where the research will take place[ix].
☐	For research that is conducted in a foreign country, unless it is conducted by a DOD overseas institution, or involves subjects who are DOD-affiliated personnel that are U.S. citizens, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.
☐	When Broad Consent is used, DOHRP notification is required.
☐	Refer to HRP-833 - WORKSHEET - Considerations for Serving as the sIRB for considerations when serving as the sIRB for a DOD institution.

7	**Additional Criteria for Department of Defense (DOD) Research Involving Classified Information[x]** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The convened IRB approved the research.
☐	Waivers of consent are prohibited.
☐	Approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) and DOHRP approval will be obtained.[xi]
☐	No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.01.

[i] The IRB may rely on outside experts to provide an evaluation of the scientific merit.

[ii] This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practice.

[iii] Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

[iv] A person who acts as an impartial and objective advocate for human subjects participating in research.

[v] Section 980 of Title 10, U.S.C. applies to research financed by DOD appropriated funds. The requirement for consent may be waived by the DOHRP if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

[vi] Section 980 of Title 10, U.S.C.

[vii] If applicable, excluded superiors or those in the chain of command may participate in separate human subjects research recruitment sessions.

[viii] See: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1, and http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2

[ix] SECNAVINST 3900.39E 29 MAY 2018, Section 3.d.

[x] DOD-supported research is considered classified when:

- Classified information is required for IRB review and oversight of the research.
- Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.
- Classified information is provided to, or by, research subjects.

DOD-conducted or -supported research is not considered classified when:

- The research is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.
- Research that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.
- If the research constitutes an authorized operation activity, then it is not HSR.

[xi] The DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR.

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WORKSHEET: Limited IRB Review and Broad Consent

NUMBER	DATE	PAGE
HRP-319	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews and/or reviewing broad consent. This worksheet is to be used. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative (LAR)")[1]

Method for limited IRB review: (check one)

☐	Limited IRB review, for research as a condition of exemption, conducted via expedited review[i]
☐	Limited IRB review, for research as a condition of exemption, performed by the convened IRB.

1 The research falls into one the following exempt categories: (One or more categories must be checked)

☐	Category 2 (iii): Research that only includes Interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) where the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true[ii]: **(Check if "Yes")** ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
☐	Category 3 (i)(C): Research involving benign behavioral Interventions[iii] in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the Intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true [iv][v]:**(Check if "Yes")** ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
☐	Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research. The following must all be true[vi]: **(Check if "Yes")** ☐ Broad consent for storage, maintenance, and secondary research use of Identifiable Private Information or Identifiable Biospecimens is obtained. **(See Section 2: Criteria for Broad Consent)** ☐ Broad consent is appropriately documented or waiver of documentation is appropriate. **(One must be checked below)** ☐ **Section 3: Broad Consent (Long Form)** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **HRP-317 - WORKSHEET - Short Form of Consent Documentation)** ☐ If there is a change made for research purposes in the way the Identifiable Private Information or Identifiable Biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
☐	Category 8: Secondary research for which broad consent is required: Research involving the use of Identifiable Private Information or Identifiable Biospecimens for secondary research use. The following must all be true: **(Check if "Yes")** ☐ Broad consent for the storage, maintenance, and secondary research use of the Identifiable Private Information or Identifiable Biospecimens was obtained. ☐ Documentation of informed consent or waiver of documentation of consent was obtained for the broad consent. ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. ☐ The research to be conducted is within the scope of the broad consent that was obtained. ☐ The investigator does not include returning individual research results to subjects as part of the study plan[vii].

2 Criteria for Broad Consent (Check if **"Yes" or "N/A", all must be checked**)

Broad Consent Process	
☐	The investigator will obtain the legally effective informed consent of the subject or LAR.
☐	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence
☐	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
☐	The subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
☐	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability from negligence.
Elements of Broad Consent Disclosure	
☐	A description of any reasonably foreseeable risks or discomforts to the subject.
☐	A description of any benefits to the subject or to others that may reasonably be expected from the research.
☐	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

[1] This document satisfies AAHRPP elements II.2.A, II.2.B, II.2.C, II.3.F, II.3.G

☐	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
☐	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit **(N/A if not using biospecimens ☐)**
☐	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) **(N/A if not using biospecimens ☐)**
☐	A general description of the types of research that may be conducted with the Identifiable Private Information or Identifiable Biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted
☐	A description of the Identifiable Private Information or Identifiable Biospecimens that might be used in research, whether sharing of Identifiable Private Information or Identifiable Biospecimens might occur, and the types of institutions or researchers that might conduct research with the Identifiable Private Information or Identifiable Biospecimens
☐	A description of the period of time that the Identifiable Private Information or Identifiable Biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the Identifiable Private Information or Identifiable Biospecimens may be used for research purposes (which period of time could be indefinite)
☐	Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's Identifiable Private Information or Identifiable Biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies **(N/A if subjects will be provided details about specific research studies ☐)**
☐	Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject **(N/A if research results will be disclosed to subjects in all circumstances ☐)**
☐	An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable Private Information or Identifiable Biospecimens, and whom to contact in the event of a research-related harm

3	**Broad Consent Long Form of Consent Documentation (Check if "Yes" or "N/A". All must be checked)**
☐	The written consent document is accurate, complete, and consistent with the protocol.
☐	The written consent document embodies the elements in **Section 2-Elements of Broad Consent Disclosure**
☐	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐	The subject or LAR will sign and date the consent document.
☐	The person obtaining consent will sign and date the consent document.
☐	A copy of the signed and dated consent document will be given to the person signing the document.
☐	If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **(N/A if no signature line ☐)**
☐	When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **(N/A if all subjects are able to read ☐)**

[i] 45 CFR §46.110(b)(1)
[ii] 45 CFR §46.111(a)(7)
[iii] For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
[iv] 45 CFR §46.111(a)(7)
[v] If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
[vi] 45 CFR §46.111(a)(8)
[vii] This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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WORKSHEET: Scientific or Scholarly Review

NUMBER	DATE	PAGE
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The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity. IRB members conducting scientific or scholarly review are to use this worksheet but do not need to complete or retain it. Consultants providing scientific or scholarly review are to complete this worksheet and provide it to IRB staff who will retain it in the files.[1]

	1 **Overall Scientific and Scholarly Validity** (Check if **"Yes".** All must be checked)
☐	The protocol accurately describes the research in a clear, detailed protocol in terms of: • Objectives • Background • Setting • Procedures • Data and safety monitoring plan • Risks • Potential benefits • Alternatives to participation
☐	There is no other way to do this research that would reduce risks to subjects and still answer the scientific question.
☐	There are no other monitoring procedures needed that would reduce risks to subjects and not affect the science.
☐	The research is likely to answer its proposed question.
☐	The protocol fairly portrays the knowledge expected to result.

	2 **Clinical Trials** (Check if **"Yes"** or **"N/A".** All must be checked if the research is a Clinical Trial.)
☐	The available nonclinical and clinical information on an investigational product is adequate to support the Clinical Trial.
☐	The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
☐	The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period.
☐	The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
☐	The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
☐	A qualified physician or, where appropriate, a qualified dentist (or other qualified healthcare professionals in accordance with local regulatory requirements) who is an investigator or a sub-investigator for the trial will have the overall responsibility for trial-related medical care and decisions.

Comment on the above:

[1] This document satisfies AAHRPP elements I.1.F, I-9, II.2.E-II.2.E.2, II.3.A

UMass Chan MEDICAL SCHOOL

WORKSHEET: Review of Information Items

NUMBER	DATE	PAGE
HRP-321	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the convened IRB reviewing Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval, and Termination of IRB Approval. This worksheet is to be used. This worksheet does not need to be completed or retained.[1]

1 Considerations

☐	Modify the protocol.	☐	Terminate IRB approval.
☐	Modify the information disclosed during the consent process.	☐	Suspend IRB approval.
☐	Provide additional information to current subjects (whenever the information may relate to the subject's willingness to continue).	☐	Transfer subjects to another investigator.
☐	Provide additional information to past subjects.	☐	Make arrangements for clinical care outside the research.
☐	Have current subjects re-consent.	☐	Allow continuation of some research activities under the supervision of an independent monitor.
☐	Increase the frequency of continuing review.	☐	Require follow-up of subjects for safety reasons.
☐	Observe the research.	☐	Require adverse events or outcomes to be reported to the IRB and the sponsor.
☐	Observe the consent process.	☐	Obtain additional information.
☐	Require additional training of the investigator.	☐	Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.
☐	Notify investigators at other sites.	☐	Refer to other organizational entities.
☐	Other:		

[1] This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G

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WORKSHEET: Emergency Use		
NUMBER	DATE	PAGE
HRP-322	06/21/2022	1 of 2

The purpose of this worksheet is to provide support for investigators conducting an emergency use of unapproved drug, biologic, or device in a life-threatening situation, and to provide support Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")[1]

Emergency Use of an Unapproved Drug or Biologic[2]

1	**Exemption Criteria for Emergency Use of an Unapproved Drug or Biologic** (Check if **"Yes".** All must be checked)
☐	The patient is (was) confronted by a disease or condition that is (was) either: ☐ Life-threatening (diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival). ☐ Severely debilitating (diseases or conditions that cause major irreversible morbidity).
☐	The situation necessitates (necessitated) the use of the investigational drug or biologic.
☐	No generally acceptable alternative for treating the patient is (was) available.
☐	There is (was) insufficient time to obtain IRB approval.
☐	The treating physician will document (has documented) in the medical record that the above findings were met.
☐	The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.
☐	The FDA has (had) issued an IND or will authorize (has authorized) shipment of the test article in advance of the IND submission.
☐	The use is (was) **NOT** subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination.

Section 2 or 3 must be met

2	**Consent criteria** (Check if **"Yes"**. All must be checked)
☐	Informed consent will be (was) sought from the patient or the patient's LAR, in accordance with and to the extent required by 21 CFR §50. See HRP-314 - WORKSHEET - Criteria for Approval.
☐	Informed consent will be (was) documented using HRP-506 - TEMPLATE CONSENT DOCUMENT - Emergency or Compassionate Device Use in accordance with and to the extent required by 21 CFR §50.27. See HRP-314 - WORKSHEET - Criteria for Approval.
3	**Exception Criteria for Consent** (Check if **"Yes"**. All must be checked)
☐	The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.
☐	Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
☐	Time is (was) insufficient to obtain consent from the patient's LAR.
☐	There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.
☐	The treating physician will document (has documented) in the medical record that the above findings were met.
☐	The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.
☐	A physician uninvolved in the clinical Investigation will certify (has certified) in the medical record that the above findings were met.
☐	If certification took place after the use of the drug or biologic, all of the following are true: **("N/A" if certification took place before the use)**
	☐ Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient.
	☐ Time is (was) insufficient time to obtain the independent determination a physician uninvolved in the clinical Investigation.
	☐ The treating physician will document (has documented) in the medical record that the above findings were met.
	☐ The treating physician's report to the IRB within 5 working days will document that the above findings were met.

[1] This document satisfies AAHRPP element I.7.C

[2] Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR §50 and 21 CFR §56.

Emergency Use of an Unapproved Device[3]	
4	**Criteria for Emergency Use of an Unapproved Device** (Check if **"Yes"** or **"N/A"**. All must be checked)
☐	The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device.
☐	The situation necessitates (necessitated) the immediate use of the device.
☐	No generally acceptable alternative for treating the patient is (was) available.
☐	There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE.
☐	There is (was) substantial reason to believe that benefits will (would) exist.
☐	The treating physician will document (has documented) in the medical record that the above findings were met.
☐	The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.
☐	A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.
☐	One of the following is true: ☐ There is (was) no IDE. ☐ The treating physician wants (wanted) to use the device in a way not approved under an existing IDE. ☐ The treating physician is (was) not part of the IDE study.
☐	One of the following is true: ☐ There is an IDE and the treating physician has (had) authorization from the sponsor. ☐ There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 working days.
☐	The treating physician will follow (has followed) the procedures below if time permits (check all that apply): ☐ Concurrence of the IRB Chair. ☐ Informed consent from the patient or LAR. ☐ Clearance from the institution as specified by policy.
	The use is (was) **NOT** subject to DHHS regulation See (HRP-310 - WORKSHEET - Human Research Determination.

[3] FDA does not consider the emergency use of an unapproved device to be clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

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WORKSHEET: Criteria for Approval for HUD		
NUMBER	DATE	PAGE
HRP-323	10/12/2021	1 of 1

The purpose of this worksheet is to provide support for the convened IRB when evaluating an application to use a Humanitarian Use Device (HUD). This worksheet is to be used. It does not have to be completed or retained. (LAR = "subject's Legally Authorized Representative")

1	**Humanitarian Use Device:** (Check if **"Yes"**. All must be checked)	
☐	The FDA has issued an approved Humanitarian Device Exemption (HUD) for this device.[1]	
☐	The HUD is **not** being used to evaluate its safety and effectiveness. **(If the HUD is being used to evaluate its safety and effectiveness complete HRP-314 - WORKSHEET - Criteria for Approval)**	
2	**General Considerations** (Check if **"Yes"**. All must be checked)	
☐	The convened IRB (or Designated Reviewer) has adequate expertise to review this HUD application. **(If "No", obtain consultation.)**	
☐	Materials are complete. **(If "No," the HUD application cannot be approved.)**	
3	**Criteria For Approval Of HUD:** (Check if **"Yes"**. All must be checked) Applies to all reviews: initial, continuing, and modifications.	
☐	Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.	
☐	Risks to patients are reasonable in relation to the proposed use of the device.	
☐	There are adequate provisions to protect the privacy of patients.	
☐	There are adequate provisions to maintain the confidentiality of patient data.	
☐	The proposed use of the HUD is within the scope of the indication approved in the HDE.	
☐	The institution has approved the use of the HUD as a clinical service.	
4	**Additional Considerations** (Check all that apply.)	
☐	**For Initial Review:** Should there be any limitations on the use of the HUD? (e.g., limitations based on one or more measures of disease progression, prior to use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB chair, or appropriate follow-up precautions and evaluations.)	
☐	**For Continuing Review and Modifications:** Is there information that needs to be provided to current patients because it may affect their willingness to receive/use the HUD?	
5	**Consent Process** (Check if **"Yes"**. All must be checked)	
☐	The HUD labeling states that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.	
☐	Patients or their LAR will be informed of the patient labeling provided by the manufacturer.	
☐	Patients or their LAR will be given sufficient opportunity to consider whether or not to receive/use the HUD; or when HUD is used in emergent situations, patients or their LAR will be given information about the HUD after its use/receipt.	
☐	Information regarding the HUD will be communicated in language understandable to the patient.	
☐	If a patient information packet is available, the physician will give it to patients or representatives before the patient receives the device whenever feasible. The IRB does not require a consent document for the use of a Humanitarian Use Device.	

[1] https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions

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WORKSHEET: Contracts		
NUMBER	DATE	PAGE
HRP-324	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for individuals reviewing contracts and other funding agreements and the budgets associated with those contracts. This worksheet is to be used when reviewing contracts and funding agreements. It does not need to be completed or retained.[1]

1	**Requirements** (Check if **"Yes"** or **"N/A".** All must be checked)
☐	The contract or funding agreement indicates who will provide care for subject injury and who is responsible to pay for it. **("N/A" if the research involves no more than Minimal Risk to subjects.) N/A:** ☐
☐	The above description of who will provide care for subject injury and who is responsible to pay for it is consistent with the consent document. **("N/A" if the research involves no more than Minimal Risk to subjects.) N/A:** ☐
☐	The contract or funding agreements requires the sponsor to promptly report (within 30 days) to the Organization any findings that could affect the safety of participants or influence the conduct of the study. **("N/A" if the research involves no more than Minimal Risk to subjects.)[2] N/A:** ☐
☐	The contract or funding agreement obligates the sponsor to provide the results of data and safety monitoring reports to the investigator within a specified time-frame. The time frames should cover routine and urgent reports. Alternatively, the time frame may be based on a specific triggering event (such as completion of data analysis), or left open- ended or the requirement can be included or referred to in a survivor clause. **("N/A" if the research involves no more than Minimal Risk of injury, the research does not have a data and safety monitoring plan or the investigator is responsible for the data and safety monitoring plan.) N/A:** ☐
☐	The contract or funding agreement includes a description of the right of investigators to publish data that is consistent with the organization's policy regarding the publication of findings from sponsored research. **("N/A" if the organization has no policy regarding the publication of research results.) N/A:** ☐
☐	The contract or funding agreement obligates the sponsor to communicate to the investigator results uncovered after study closure that directly affect subject safety. This obligation may be limited to a number of years after study closure. **("N/A" if the research does not involve medical procedures.)[3] N/A:** ☐
☐	The contract, funding agreement, or associated budget **does not include** "finder's fees" (payments to professionals in exchange for referrals of subjects.)

[1] This document satisfies AAHRPP elements I.8.A, I.8.B, I.8.C, I.8.D, I.8.E, II.3.C-II.3.C.1

[2] The intent of this element is that if the sponsor is responsible for having an on-site study monitor periodically review the conduct of the research and the monitor finds serious problems with the research, such as Serious or Continuing Non-Compliance, lack of supervision of the research, or falsification or fabrication of data, this information will make it back to the organization. Per IRB policy (see "HRP-214 - FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.

[3] The intent of this element is that if a study is closed and the sponsor subsequently learns that the study procedures cause problems that indicate that subjects should undergo medical care to mitigate risks, the sponsor will notify the investigator. The investigator and IRB will determine how to take action on this information. Per IRB policy (see "HRP-214 - FORM - Reportable New Information"), investigators are required to promptly provide this information to the IRB.

UMass Chan MEDICAL SCHOOL

WORKSHEET: Compassionate Use of an Unapproved Medical Device

NUMBER	DATE	PAGE
HRP-325	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for investigators conducting non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) and to provide support Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")[1]

Compassionate Use of an Unapproved Device[2]

1	**Criteria for Compassionate Use of an Unapproved Device** (Check if **"Yes**." All must be checked.)
☐	The patient is confronted by a serious disease or condition.
☐	No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available.
☐	The probable risk to the patient is not greater than the probable risk from the disease
☐	The patient does not meet the inclusion criteria for an IDE study.
☐	The treating physician will document in the medical record that the above findings were met.
☐	The treating physician has/will obtain approval from FDA for the use.
☐	If an IDE exists for the device, the sponsor has authorized its use.
☐	An independent assessment from an uninvolved physician will be included in the submission to FDA.
☐	All institutional clearances have been obtained.
☐	Concurrence of an IRB Chair has been (will be) obtained.
☐	The treating physician will report any problems as a result of the device use to the IRB and sponsor.
☐	The treating physician will provide follow-up information (if applicable) of the use and give it to the sponsor, the FDA and the IRB.
☐	The use is **NOT** research subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination.
2	**Consent criteria** (Check if **"Yes"**. All must be checked)
☐	Informed consent will be sought from the patient or the patient's LAR.[3]
☐	Informed consent will be documented using HRP-506 - TEMPLATE CONSENT DOCUMENT - Emergency or Compassionate Device Use.[4]

[1] This document satisfies AAHRPP element I.7.C

[2] FDA does not consider the compassionate use of an unapproved device to be a clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

[3] FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50.

[4] FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR §50.27.

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WORKSHEET: Performance Evaluation for IRB Chairs

NUMBER	DATE	PAGE
HRP-326	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the Institutional Official/ Organizational Official (IO/OO) or designee when evaluating the performance of the IRB Chair(s) as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet is to be used but does not need to be completed and retained.[1]

	1 Considerations when evaluating IRB Chairs – Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Number of meetings attended and chaired out of total number of meetings
☐	Number of protocols reviewed via Non-Committee Review
☐	Number of protocols reviewed that went to the convened IRB
☐	Number of reviews completed as the primary reviewer
☐	Timeliness of reviews
☐	Completion of required checklists
☐	Completion of educational requirements
☐	Attendance at educational sessions
	2 Consideration when evaluating IRB Chairs – Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Leadership of the IRB
☐	Ability to lead meetings
☐	Preparedness for meetings
☐	Knowledge of regulations and identification of areas for improvement
☐	Communication with investigators
☐	Communication with organizational officials
☐	Communication with IRB staff
☐	Ability to work with IRB staff
☐	Ability to help investigators
☐	Issues related to being a general IRB member
☐	**Notes:**

[1] This document satisfies AAHRPP element I.1.E

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WORKSHEET: Performance Evaluation for IRB Members

NUMBER	DATE	PAGE
HRP-327	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the IRB Chair or IRB Director when evaluating the performance of the IRB Members and Alternates as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet is to be used but does not necessarily need to be completed and retained.[1]

	1 Considerations when evaluating regular and alternate IRB members – Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Number of meetings attended out of total number of meetings
☐	Number of exempt determinations made
☐	Number of protocols reviewed via Non-Committee Review
☐	Number of protocols reviewed that went to the convened IRB
☐	Number of reviews completed as the primary reviewer
☐	Timeliness of reviews
☐	Completion of required checklists
☐	Completion of educational requirements
☐	Attendance at educational sessions
☐	Number of educational sessions conducted
	2 Considerations when evaluating regular and alternate IRB members – Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Preparedness for meetings
☐	Contribution to IRB meetings
☐	Quality of reviews
☐	Knowledge of regulations and identification of areas for improvement
☐	Knowledge of organizational policies and procedures and identification of areas for improvement
☐	Communication with investigators
☐	Communication with IRB staff
☐	Ability to work with IRB staff

Notes:

[1] This document satisfies AAHRPP element I.1.E

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WORKSHEET: Performance Evaluation for IRB Staff

NUMBER	DATE	PAGE
HRP-328	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the IRB Chair or IRB Director when evaluating the annual performance of the IRB staff as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet is to be used but does not necessarily need to be completed and retained.[1]

	1 Considerations when evaluating IRB staff – Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Workload – handles workload efficiently
☐	Number of protocols reviewed via Non-Committee Review
☐	Number of protocols processed
☐	Timeliness of processing materials
☐	Completion of checklists and documentation
☐	Prepares agendas in a timely manner
☐	Prepares convened IRB minutes in a timely manner
☐	Completion of educational requirements
☐	Attendance at educational sessions
☐	Number of educational sessions conducted
☐	Attainment and maintenance of certification (e.g., CIM or CIP)
	2 Considerations when evaluating IRB staff – Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)
☐	Preparedness for meetings
☐	Quality of pre-reviews
☐	Completes and maintains convened IRB minutes and records efficiently and correctly
☐	Knowledge of regulations and identification of areas for improvement
☐	Knowledge of organizational policies and procedures and identification of areas for improvement
☐	Communication with IRB chairs, IRB staff, investigators, and study staff
☐	Ability to help investigators

Notes:

[1] This document satisfies AAHRPP element I.1.E

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WORKSHEET: HIPAA Authorization

NUMBER	DATE	PAGE
HRP-330	10/12/2021	1 of 1

The purpose of this checklist is to provide support for IRB staff when evaluating whether a HIPAA authorization is valid. IRB staff are to consult this worksheet to review HIPAA authorizations. This worksheet is to be used. It does not need to be completed or retained.

	1 **CORE ELEMENTS** (Check if **"Yes".** All must be checked)
☐	A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
☐	The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
☐	The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
☐	A description of each purpose of the requested use or disclosure.
☐	An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. (The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.)
☐	Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.
	2 **REQUIRED STATEMENTS** (Check if **"Yes".** All must be checked)
☐	The individual's right to revoke the authorization in writing or by notifying the study team.[1]
☐	The authorization either: • Describes the exceptions to the right to revoke the authorization. • References the Notice for Privacy Practices for Protected Health Information which describes the exceptions to the right to revoke the authorization.
☐	The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either of the following: • The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization. • The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.
☐	The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this authorization.
	3 **OTHER REQUIREMENTS** (Check if **"Yes".** All must be checked)
☐	The authorization is written in plain language.
☐	The individual will be provided with a copy of the signed authorization.
☐	If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.
☐	The authorization is either a separate document or incorporated into the written consent document for research.
☐	No material information in the authorization is known to be false.

[1] [Adapted from Baystate Health memo to Clinical Trial Sponsors re Withdrawal of Consent/Authorization, dated February 12, 2013] On January 25, 2013, the Office of Civil Rights (OCR) published the Final Rule modifying HIPAA regulations, 45 CFR Parts 160 and 164 in the Federal Register, Vol. 78, No. 17. The Commentary considered the recommendations of the Secretary's Advisory Committee on Human Research Protections that revocations of authorization for future research be permitted orally. Although the OCR declined to make a regulatory change at this time they did state that "…uses and disclosures pursuant to an authorization are permissive and not required, and thus, a covered entity may cease using or disclosing protected health information pursuant to an authorization based on an individual's oral request if it chooses to do so." (p.5612). UMass Chan standard operating procedures incorporate this permitted interpretation of HIPAA requirements, which expands rather than restricts the right of subjects to withdraw authorization.

When relying on an oral statement of the intent to withdraw, UMass Chan researchers will confer with the subject to determine if their intent is to withdraw in part or in full from the research, and if in part, what activities they agree to continue. The subject's wishes and the details of the discussion will be recorded in the research file. This will provide sufficient documentation of the withdrawal of consent and revocation of authorization.

UMass Chan MEDICAL SCHOOL

WORKSHEET: FERPA Compliance

NUMBER	DATE	PAGE
HRP-331	06/21/2022	1 of 3

The purpose of this worksheet is to provide support when determining whether personally identifiable information can be released from student education records[1] or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education). This worksheet is to be used. It does not need to be completed or retained.[2]

Requirements for Disclosure (one of the following categories must be met)

☐	The parent or eligible student will provide a signed and dated written consent that discloses: ☐ The records that may be disclosed; ☐ The purpose of the disclosure ☐ The party or class of parties to whom the disclosure may be made ☐ If a parent or adult student requests, the school will provide him or her with a copy of the records disclosed ☐ If the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.
☐	The disclosure is to other school officials, including teachers, within the agency or institution whom the agency or institution has determined to have legitimate educational interests. A contractor, consultant, volunteer, or other party to whom an agency or institution has outsourced institutional services or functions may be considered a school official under this paragraph provided that the outside party— • Performs an institutional service or function for which the agency or institution would otherwise use employees; • Is under the direct control of the agency or institution with respect to the use and maintenance of education records; and • Is subject to the requirements of §99.33(a) governing the use and redisclosure of personally identifiable information from education records.
☐	The disclosure is, subject to the requirements of 34 CFR §99.34, to officials of another school, school system, or institution of postsecondary education where the student seeks or intends to enroll, or where the student is already enrolled so long as the disclosure is for purposes related to the student's enrollment or transfer.
☐	The disclosure is, subject to the requirements of 34 CFR §99.35, to authorized representatives of— • The Comptroller General of the United States; • The Attorney General of the United States; • The Secretary; or • State and local educational authorities.
☐	The disclosure is in connection with financial aid[3] for which the student has applied or which the student has received, if the information is necessary for such purposes as to: • Determine eligibility for the aid; • Determine the amount of the aid; • Determine the conditions for the aid; or • Enforce the terms and conditions of the aid.
☐	The disclosure is to State and local officials or authorities to whom this information is specifically— • Allowed to be reported or disclosed pursuant to State statute adopted before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and the system's ability to effectively serve the student whose records are released; or • Allowed to be reported or disclosed pursuant to State statute adopted after November 19, 1974, subject to the requirements of 34 CFR §99.38. (A State from further limiting the number or type of State or local officials to whom disclosures may be made.)

[1] The term "education records" is defined to mean, with certain exceptions, those records that are: (1) directly related to a student, and (2) maintained by an educational agency or institution or by a party acting for the agency or institution. 20 U.S.C. § 1232g(a)(4)(A); 34 CFR § 99.3 (definition of "education records"). For instance, a student's health records, including immunization records, maintained by an educational agency or institution (such as by an elementary or secondary school nurse) would generally constitute education records subject to FERPA. Joint Guidance on the Application of the Family Educational Rights and Privacy Act (FERPA) And the Health Insurance Portability and Accountability Act of 1996 (HIPAA) To Student Health Records.

[2] This document satisfies AAHRPP elements II.3.G, II.4.B, III.2.C

[3] Financial aid means a payment of funds provided to an individual (or a payment in kind of tangible or intangible property to the individual) that is conditioned on the individual's attendance at an educational agency or institution.

☐	The disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to: Develop, validate, or administer predictive tests; Administer student aid programs; or Improve instruction. Where: ☐ The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information; ☐ The information is destroyed when no longer needed for the purposes for which the study was conducted ☐ The school enters into a written agreement with the organization that: ☐ Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed ☐ Requires the organization to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement; ☐ Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students, as defined in this part, by anyone other than representatives of the organization with legitimate interests ☐ Requires the organization to destroy or return to the school all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be returned or destroyed
☐	The disclosure is to accrediting organizations to carry out their accrediting functions.
☐	The disclosure is to parents, as defined in 34 CFR §99.3, of a dependent student, as defined in section 152 of the Internal Revenue Code of 1986.
☐	The disclosure is to comply with a judicial order or lawfully issued subpoena where one of the following is true: ☐ The school makes a reasonable effort to notify the parent or eligible student of the order or subpoena in advance of compliance, so that the parent or eligible student may seek protective action, unless the disclosure is in compliance with— • A Federal grand jury subpoena and the court has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed; • Any other subpoena issued for a law enforcement purpose and the court or other issuing agency has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed; or • An *ex parte* court order obtained by the United States Attorney General (or designee not lower than an Assistant Attorney General) concerning investigations or prosecutions of an offense listed in 18 U.S.C. 2332b(g)(5)(B) or an act of domestic or international terrorism as defined in 18 U.S.C. 2331. ☐ The disclosure is to the court when the school initiates legal action against a parent or student ☐ The disclosure is to the court when a parent or eligible student initiates legal action against the school,
☐	The disclosure is in connection with a health or safety emergency, under the conditions described in §99.36.
☐	The disclosure is information the school has designated as "directory information", under the conditions described in §99.37.
☐	The disclosure is to the parent of a student who is not an eligible student or to the student.
☐	The disclosure, subject to the requirements in 34 CFR §99.39, is to a victim of an alleged perpetrator of a crime of violence or a non-forcible sex offense. The disclosure may only include the final results of the disciplinary proceeding conducted by the institution of postsecondary education with respect to that alleged crime or offense. The institution may disclose the final results of the disciplinary proceeding, regardless of whether the institution concluded a violation was committed.
☐	The disclosure[4] is to a parent of a student at an institution of postsecondary education regarding the student's violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance if— • The institution determines that the student has committed a disciplinary violation with respect to that use or possession; and • The student is under the age of 21 at the time of the disclosure to the parent.
☐	The disclosure concerns sex offenders and other individuals required to register under section 170101 of the Violent Crime Control and Law Enforcement Act of 1994, 42 U.S.C. 14071, and the information was provided to the school under 42 U.S.C. 14071 and applicable Federal guidelines.

[4] This section does not supersede any provision of State law that prohibits an institution of postsecondary education from disclosing information.

☐	The disclosure is of records in which the school or other party has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. "Not personally identifiable" means information that includes none of the following: • Student's name and other direct personal identifiers, such as the student's social security number or student number. • Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name. • Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting. • Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.
☐	The disclosure is of records in which are de-identified student level data from education records for the purpose of education research by attaching a code to each record that may allow the recipient to match information received from the same source, provided that— • The school or other party that releases de-identified data does not disclose any information about how it generates and assigns a record code, or that would allow a recipient to identify a student based on a record code; • The record code is used for no purpose other than identifying a de-identified record for purposes of education research and cannot be used to ascertain personally identifiable information about a student; and • The record code is not based on a student's social security number or other personal information.

UMass Chan MEDICAL SCHOOL

WORKSHEET: NIH GDS Institutional Certification

NUMBER	DATE	PAGE
HRP-332	10/12/2021	1 of 2

The purpose of this worksheet is to allow the IRB Director or designee to evaluate whether an investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository. This worksheet is to be used. It does not need to be completed or retained.

Investigator Name	
Project Title	
IRB Number (if any)	
Name of Person Completing Worksheet	

1 Institutional Certification Requirements (ALL must be checked "Yes")

☐ **Yes** ☐ **No**	The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
☐ **Yes** ☐ **No**	Limitations on the research use of the data, as expressed in the informed consent documents, are delineated. ☐ **N/A for submission to an unrestricted-access database.**
☐ **Yes** ☐ **No**	The identities of research participants will not be disclosed to NIH-designated data repositories.
☐ **Yes** ☐ **No**	The protocol for collection of genomic and phenotype data is consistent with 45 CFR §46.
☐ **Yes** ☐ **No**	Data submission and subsequent data sharing for research purposes are consistent with the informed consent and explicitly disclosed to study participants from whom the data were or will be obtained.
☐ **Yes** ☐ **No**	Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results
☐ **Yes** ☐ **No**	To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
☐ **Yes** ☐ **No**	The investigator's plan for de-identifying datasets is consistent with the standards outlined in Section IV.C.1 of the NIH Final Genomic Data Sharing Policy. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

If you cannot select "Yes" to all items above, then stop. You cannot certify that the data submission criteria have been met. Communicate with the investigator to let her or him know that you cannot proceed with the Institutional Certification process without changes to the investigator's data sharing plan.

2 Unrestricted- or Controlled-Access Database

Choose the type of database to which the investigator will submit:

☐ Unrestricted-Access Database ☐ Controlled-Access Database

Check if applies: ☐ Sensitive genomic summary results[i] are only to be made available through controlled-access.
Explanation:

If Controlled-Access Database selected above, specify one of the data use limitations[ii] below for appropriate secondary use. These limitations must be included in the GDS Institutional Certification to the NIH.

General Research Use: Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.

Health/Medical/Biomedical: Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Disease-specific: Use of the data must be related to the specific disease.
List disease:

☐ Other:

Additional modifiers, if appropriate (check all that apply):

☐ IRB Approval Required	☐ Publication Required	☐ Collaboration Required	☐ Not-for-profit Use Only	☐ Methods Development Research	☐ Genetic Studies Only

[i] Genomic summary results (GSR) are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies;

allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values). GSR may be considered to have particular sensitivities related to individual privacy or potential for group harm.

[ii] Standard NIH data use limitations: https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf. Additional modifiers to standard data use limitations may be indicated if appropriate and should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

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WORKSHEET: Certificate of Confidentiality		
NUMBER	DATE	PAGE
HRP-333	06/21/2022	1 of 1

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a Certificate of Confidentiality is required or appropriate for a study. This worksheet is to be used. It does not have to be completed or retained.[1]

1	**Considerations for Certificate of Confidentiality** (Check if **"Yes"**)	
☐	There is a process of informed consent.	
☐	The research is funded by the National Institutes of Health (NIH) and is biomedical, behavioral, clinical, or other research.[i] If **"Yes,"** a CoC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request. [ii]	
☐	The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS. [iii]	
	If "**Yes**," answer the following:	
	☐	The research is collecting personally identifiable information.
	☐	The research is sensitive.[iv]
	☐	The research is collecting information that if disclosed could significantly harm or damage the participant.[v]
2	**Certificate of Confidentiality for Research Language is included in Consent** (If "Yes" in #1, must be **"Yes"**)	
☐	The consent document includes information describing the CoC and its purpose and its applicability to the research.	

[i] NOT-OD-17-109: Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

[ii] To identify appropriate HHS agency for CoC request; https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1

[iii] Online Certificate of Confidentiality System; https://auth.nih.gov/iTrustGateway/Default.aspx?TYPE=33554433&REALMOID=06-5807c3f7-b083-45f1-adb1-db80ca5cb984&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-jeABPYEu%2fp%2bemXLDSAj1EOFiRlGv9qfbJmuw7fe6Wig0qkH%2bz5BoOZgj%2f4Q0KTjg&TARGET=-SM-HTTPS%3a%2f%2fcoc%2eod%2enih%2egov%2f

[iv] Examples of sensitive research activities include but are not limited to the following: collecting genetic information; collecting information on psychological well-being of subjects; collecting information on subjects' sexual attitudes, preferences or practices; collecting data on substance abuse or other illegal risk behaviors; studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

[v] A CoC would not be appropriate for secondary use of information that exists outside of the research (e.g., information in a medical record).

[1] This document satisfies AAHRPP element II.3.E

The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research to ensure the ongoing safety of research subjects during the COVID-19 pandemic. Challenges to study conduct may arise, for example, from:

- Quarantines.
- Site closures.
- Travel limitations.
- Institutional policies or mandates that limit research activities.
- Interruptions to the supply chain for the investigational product.
- Other considerations if site personnel or trial subjects become infected with COVID-19.

These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using test articles or adhering to protocol-mandated visits and tests. The following worksheet contains various considerations when investigators are responsible for protocol-specific COVID-19 risk mitigation planning.[1]

1. **General Exclusions:** If any of the following are true, development of a COVID-19 risk mitigation plan for research may not be needed.

☐	Research does not involve in-person interaction with research subjects.
☐	Research can be conducted as written while adhering to social distancing requirements and institutional COVID-19 policies and requirements.
☐	Research is externally sponsored, and the sponsor has developed a COVID-19 risk mitigation plan for the research.
☐	Research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with social distancing requirements and institutional COVID-19 policies and requirements).

2. **General Considerations for Creating a Study-Specific COVID-19 Risk Mitigation Plan.** The following are additional considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during the COVID-19 pandemic. The considerations below do not represent an exhaustive list and are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff, sponsors and institutional review boards (IRBs) in their efforts to address the new risks to research subjects and others posed by the COVID-19 pandemic.

☐	Modifications to Recruitment and Enrollment Processes (Select any that are appropriate for the research.): ☐ Temporarily discontinue study recruitment efforts and initiatives. ☐ Temporarily discontinue enrollment of new research subjects. ☐ Incorporate additional COVID-19 screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment. ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.
☐	Additional Modifications to Minimize Risk (Select any that are appropriate for the research.): ☐ Withdraw some or all current research subjects from the research. ☐ Modify study visit procedures so that visits can be completed via phone. ☐ Modify study visit procedures so that visits can be completed virtually. ☐ Modify study visit procedures so that visits can be completed at subjects' local lab, clinical or imaging center.

[1] This document satisfies AAHRPP elements I.1.D, III.2.D

	☐ Incorporate additional COVID-19 screening procedures for research subjects or study personnel that will be completed prior to in-person visits. ☐ Incorporate other additional safety monitoring procedures. Describe: Click or tap here to enter text. ☐ If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites. ☐ Modify timing and scope of specific study visits to account for essential versus nonessential study procedures. ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.
☐	For FDA-Regulated Research: Modifications to Investigational Drug/Biologic/Device Access and Administration (Select any that are appropriate for the research.): ☐ For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery methods (e.g., investigational product can be shipped to the subject's residence). ☐ For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel). ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

3. Research Record and Study Documentation Considerations for COVID-19-Specific Study Modifications: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic.

☐	For protocol wide study restrictions or modifications necessitated by COVID-19, documentation related to any of the following elements are included in the research record where applicable and appropriate to the research: ☐ Changes in study conduct ☐ Duration of those changes ☐ Which trial participants were impacted ☐ How those trial participants were impacted ☐ Other relevant actions that were taken. Describe: Click or tap here to enter text.
☐	For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, the research record includes documentation related to the reasons for failing to obtain the efficacy assessment (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment). ☐ Specific information in case report forms explains the basis of any missing data, including the relationship to COVID-19 for missing protocol-specified information.
☐	For FDA-regulated research where changes in the protocol include any of the following, the research record includes documentation that changes were made in consultation with the applicable FDA review division where feasible and appropriate: ☐ Amendments to data management and/or statistical analysis plans ☐ Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel) ☐ Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens

4. Communication Plan to Subjects: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic.

☐	A research subject communication plan describing the study-specific modifications being made to ensure the ongoing safety of research subjects during the COVID-19 pandemic has been developed for implementation with all current (and where applicable, prospective) research subjects. This plan includes: ☐ What information will be communicated to current (and where applicable, prospective) research subjects ☐ Who will communicate the information ☐ When the information will be communicated ☐ How the information will be communicated

5. IRB Notification and Approval (Where Applicable): One of the following must be true.

☐	If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.
☐	For all other study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic, a study amendment is submitted to the IRB using the standard pathways for modifications.

UMass Chan MEDICAL SCHOOL

WORKSHEET: Protocol-Specific Emergency/Disaster Risk Mitigation Planning

NUMBER	DATE	PAGE
HRP-351	06/21/2022	1 of 2

The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator's ability ensure the ongoing safety of research subjects. Challenges to study conduct may arise, for example, from:

- Extreme weather events.
- Natural disasters
- Man-made disasters
- Infectious disease outbreaks

These challenges may lead to difficulties in conducting protocol-specified procedures, including administering or using test articles or adhering to protocol-mandated visits and tests. The following worksheet contains various considerations when investigators are responsible for protocol-specific emergency/disaster risk mitigation planning.[1]

1 General Exclusions: If any of the following are true, development of a protocol-specific risk mitigation plan for research may not be needed.

☐	Research does not involve in-person interaction with research subjects.
☐	Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event.
☐	Research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.
☐	Research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event).

2 General Considerations for Creating a Protocol-Specific Emergency/Disaster Risk Mitigation Plan. The following are additional considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during an emergency/disaster situation. The considerations below do not represent an exhaustive list and are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff, sponsors and institutional review boards (IRBs) in their efforts to address the new risks to research subjects and others posed by current or anticipated emergencies/disasters.

☐	Modifications to Recruitment and Enrollment Processes (Select any that are appropriate for the research.): ☐ Temporarily discontinue study recruitment efforts and initiatives. ☐ Temporarily discontinue enrollment of new research subjects. ☐ Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment (e.g., for infectious disease outbreaks). ☐ Other relevant actions should be taken. Describe: **Click or tap here to enter text.**
☐	Additional Modifications to Minimize Risk (Select any that are appropriate for the research.): ☐ Withdraw some or all current research subjects from the research. ☐ Modify study visit procedures so that visits can be completed via phone. ☐ Modify study visit procedures so that visits can be completed virtually. ☐ Modify study visit procedures so that visits can be completed at subjects' local lab, clinical or imaging center. ☐ Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to in-person visits (e.g., for infectious disease outbreaks). ☐ Incorporate other additional safety monitoring procedures. Describe: Click or tap here to enter text. ☐ If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites. ☐ Modify timing and scope of specific study visits to account for essential versus nonessential study procedures. ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.
☐	For FDA-Regulated Research: Modifications to Investigational Drug/Biologic/Device Access and Administration (Select any that are appropriate for the research.): ☐ For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery methods (e.g., investigational product can be shipped to the subject's residence). ☐ For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel). ☐ Other relevant actions should be taken. Describe: **Click or tap here to enter text.**

[1] This document satisfies AAHRPP element I.1.H

3 Research Record and Study Documentation Considerations when implementing Emergency/Disaster-Specific Study Modifications: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects in emergency/disaster situations.

☐ For protocol wide study restrictions or modifications necessitated by the emergency/disaster situation, documentation related to any of the following elements are included in the research record where applicable and appropriate to the research:
- ☐ Changes in study conduct
- ☐ Duration of those changes
- ☐ Which trial participants were impacted
- ☐ How those trial participants were impacted
- ☐ Other relevant actions that were taken. Describe: Click or tap here to enter text.

☐ For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, the research record includes documentation related to the reasons for failing to obtain the efficacy assessment (e.g., identifying the specific limitation imposed by the emergency/disaster leading to the inability to perform the protocol-specified assessment).
- ☐ Specific information in case report forms explains the basis of any missing data, including the relationship to the emergency/disaster for missing protocol-specified information.

☐ For FDA-regulated research where changes in the protocol include any of the following, the research record includes documentation that changes were made in consultation with the applicable FDA review division where feasible and appropriate:
- ☐ Amendments to data management and/or statistical analysis plans
- ☐ Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel)
- ☐ Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens

4 Communication Plan to Subjects: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during emergency/disaster situations.

☐ A research subject communication plan describing the study-specific modifications being made to ensure the ongoing safety of research subjects during the emergency/disaster situation has been developed for implementation with all current (and where applicable, prospective) research subjects. This plan includes:
- ☐ What information will be communicated to current (and where applicable, prospective) research subjects
- ☐ Who will communicate the information
- ☐ When the information will be communicated
- ☐ How the information will be communicated

5 IRB Notification and Approval (Where Applicable): One of the following must be true.

☐ If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.

☐ For all other study modifications made to ensure the ongoing safety of research subjects throughout an ongoing emergency/disaster situation, a study amendment is submitted to the IRB.

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WORKSHEET: Additional Emergency-Disaster Review Considerations

NUMBER	DATE	PAGE
HRP-352	06/21/2022	1 of 1

The purpose of this worksheet is to provide IRB members with additional considerations that may become relevant when reviewing Human Research during an emergency/disaster situation. These additional considerations may provide additional and necessary flexibility for study teams while continuing to assure research subject safety during the emergency/disaster. This worksheet is to be used when directed to do so by the IRB Chair or staff. It does not need to be completed or filed.[1]

1	**More widespread use of waivers of documentation of consent for minimal risk research**: Additional use of waivers of documentation of consent may be appropriate if the following items are true. (Check if "Yes." All must be checked)
☐	The research involves no more than Minimal Risk to the subjects.
☐	The research involves only interaction, not intervention, with subjects.
☐	The emergency/disaster may create additional challenges in notifying participants of changes to consent documents.
☐	The research meets one of the eligibility categories for waiver of written documentation of consent listed in HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
2	**Alternate mechanisms for safety monitoring.** (Check if "Yes." All must be checked)
☐	The research involves protocol-specified visits to the investigational site.
☐	Research subjects may not be able to come to the investigational site for protocol-specified visits due to the emergency/disaster.
☐	Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) are available.
☐	Alternative methods for safety assessments can feasibly be implemented.
☐	Alternative methods for safety assessments would be sufficient to assure the safety of trial participants.
3	**Additional flexibility in oversight of research not subject to federal regulations.** (Check if "Yes." All must be checked)
☐	The research is not covered by federal regulations.
☐	One or more of the following options is feasible and appropriate during an emergency/disaster to provide necessary flexibility for study teams while continuing to assure research subject safety: ☐ Extend continuing review dates during the anticipated period an emergency. ☐ Allow minor changes to be reported to the IRB or EC without requiring IRB or EC approval prior to implementation.
4	**Other mechanisms for additional flexibility not described above**. In addition to the options above, additional considerations in providing added flexibility to study teams during emergency/disaster situations may be appropriate where any of the following is true. (Check if "Yes")
☐	Additional institution-level information related to emergency/disaster planning (and not otherwise specified above) provides additional guidance in providing additional flexibility or support to study teams managing research during and emergency/disaster.
☐	Federal guidance or communications related to managing research during the emergency/disaster is issued and provides additional flexibility or resources.

[1] This document satisfies AAHRPP element I.1.H

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WORKSHEET: Financial Interest Management

Document No.:	Edition No.:	Effective Date:	Page:
HRP-380	001	10/12/2021	1 of 1

This worksheet is used to consider management plans for financial conflicts of interests of investigators.

1. Should the investigator be involved in:		
1.1	●	Subject recruitment?
1.2	●	Determination of whether the subject meets inclusion/exclusion criteria?
1.3	●	Consent process?
1.4	●	Research interventions or procedures?
1.5	●	Clinical treatment of subjects, separate from the research interventions or procedures?
1.6	●	Clinical evaluation of subjects during the research, separate from the research interventions or procedures?
1.7	●	Adverse event evaluation and reporting?
2. Considerations for a management plan		
2.1	●	Disclosure of the financial interests to subjects
2.2	●	Public disclosure of the financial interests
2.3	●	Appointment of an independent research monitor
2.4	●	Change of personnel or personnel responsibilities
2.5	●	Disqualification of personnel from participation in all or a portion of the research
2.6	●	Reduction of the financial interest
2.7	●	Elimination of the financial interest
2.8	●	Severance of relationships that create financial conflicts
2.9	●	Modification of the research plan
2.10	●	Involvement of external individuals in key portions of the research
2.11	●	Transfer of IRB responsibilities
2.12	●	Retrospective review
2.13	●	Mitigation report
2.14	●	Monitor the implementation of the management plan

3. Notes

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HRP-401 – CHECKLIST – Pre-Review
HRP-402 – CHECKLIST – Non-Committee Review
HRP-407 – CHECKLIST – Devices
HRP-410 – CHECKLIST – Waiver or Alteration of Consent Process
HRP-411 – CHECKLIST – Waiver or Written Documentation of Consent
HRP-412 – CHECKLIST – Pregnant Women
HRP-413 – CHECKLIST – Non-Viable Neonates
HRP-414 – CHECKLIST – Neonates of Uncertain Viability
HRP-415 – CHECKLIST – Prisoners
HRP-416 – CHECKLIST – Children
HRP-417 – CHECKLIST – Cognitively Impaired Adults
HRP-418 – CHECKLIST – Non-Significant Risk Device
HRP-419 – CHECKLIST – Waiver of Consent Process for Emergency Research
HRP-431 – CHECKLIST – Minutes Quality Improvement Assessment
HRP-441 – CHECKLIST – HIPAA Waiver of Authorization

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CHECKLIST: Pre-Review		
NUMBER	DATE	PAGE
HRP-401	06/21/2022	1 of 1

The purpose of this checklist is to provide support for IRB staff conducting Pre-review. This checklist is to be completed by the IRB staff, signed, dated, and retained.[1]

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

Regulatory Oversight *(Check all that apply)*

☐	**Common Rule Requirements prior to January 21, 2019**					☐	**Common Rule Requirements as of January 21, 2019**		
☐	DHHS	☐	DOD	☐	DOJ	☐	EPA	☐	Other Federal Agency
☐	FDA	☐	DOE	☐	ED	☐	VA[2]	☐	ICH-GCP
☐	OCR	☐	NSF	☐	Tribal Law	☐	EU GDPR	☐	None

Restrictions (Check if applicable)

☐	Principal investigator is Restricted

Missing Materials

Special Determinations (Check all that apply)

☐	Children	☐	Not significant risk device (FDA)	☐	Waiver/alteration of the consent process
☐	Wards	☐	Non-viable neonates	☐	Waiver of HIPAA authorization
☐	Pregnant women	☐	Neonates of uncertain viability	☐	Waiver of consent documentation
☐	Prisoners	☐	Individuals with impaired decision-making capacity	☐	Waiver of consent for emergency research
☐	Students/Employees			☐	Broad Consent

Protocol Tracking (Check all that apply)

☐	Social/ Behavioral/ Education	☐	Biomedical/Clinical	☐	Clinical Trial
☐	Single-Site Study	☐	Collaborative Study (Lead Site)	☐	Multi-Site Study (Lead Site)
☐	Deception	☐	Collaborative Study (Participating Site)	☐	Multi-Site Study (Participating Site)
☐	Certificate of Confidentiality	☐	Other		

Notes

STUDY CLOSURE

☐	Research can be closed.

Sign		**Date**	

[1] This document satisfies AAHRPP elements I.1.A, I.1.E, I.6.A, I.6.B, I.7.A, I.7.C. I-9, II.3.G, II.4.B, III.2.C

[2] The conduct of VA regulated research also requires VA IRB oversight per the HRPP Plan.

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CHECKLIST: Non-Committee Review		
NUMBER	DATE	PAGE
HRP-402	06/21/2022	1 of 2

The purpose of this checklist is to provide support for Designated Reviewers conducting Non-Committee Review. This checklist is to be completed by the Designated Reviewer, signed, dated, and retained.[1]

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

☐	Initial review	☐	Modification	☐	Request for Human Research or engagement determination
☐	Continuing review			☐	Review of Modifications Required to Secure Approval

1 REVIEWER CRITERIA (Check if **"Yes."** All must be checked. **Otherwise, sign the form, and return all materials.)**

☐ I do **not** have a Conflicting Interest.

2 REVIEW LEVEL (Select one of the following)

Level		Documents to use	Categories
☐	Not Human Research	HRP-310 - WORKSHEET - Human Research Determination	
☐	Human Research Not Engaged	HRP-311 - WORKSHEET - Engagement Determination	
☐	Exempt	HRP-312 - WORKSHEET - Exemption Determination HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent	☐ (1) Educational settings ☐ (2)(i) Tests, surveys, interviews, or observation (non-identifiable) ☐ (2)(ii) Tests, surveys, interviews, or observation (low risk) ☐ (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review ☐ (3)(i)(A) Benign behavioral interventions (non-identifiable) ☐ (3)(i)(B) Benign behavioral interventions (low risk) ☐ (3)(i)(C) Benign behavioral interventions (identifiable); and for which limited IRB review was conducted via expedited review ☐ (4) Secondary research on data or specimens (no consent required) ☐ (5) Demonstration projects ☐ (6) Taste and food quality ☐ (7) Storage or maintenance of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review ☐ (8) Secondary research use of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review
☐	Expedited	HRP-313 - WORKSHEET - Expedited Review HRP-314 - WORKSHEET - Criteria for Approval	☐ Minor modifications to previously approved research ☐ (1)(a) Drug studies ☐ (1)(b) Device studies ☐ (2)(a) Blood samples from healthy, non-pregnant adults ☐ (2)(b) Blood samples from others ☐ (3) Noninvasive biological specimens ☐ (4) Noninvasive procedures

[1] This document satisfies AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.1.D, II.2.A-II.2.C, II.2.F-II.2.F.3, II.5.A, II.5.B

			☐ (5) Data, documents, records, or specimens ☐ (6) Voice, video, digital, or image recordings ☐ (7)(a) Behavioral research ☐ (7)(b) Social science methods ☐ (8)(a) Long-term follow-up ☐ (8)(b) No subjects enrolled ☐ (8)(c) Data analysis ☐ (9) Convened IRB determined Minimal Risk

3 DETERMINATION (Select one of the following)

☐	Meets criteria
☐	Modifications required to meet criteria
☐	Send to convened IRB

Additional information: Describe modifications required to secure approval, if required in section 3 above. Or, if review must be sent to the convened IRB, provide rationale for this determination (e.g. describe why research cannot be approved via expedited review, explain why research appearing on the expedited review list is actually more than Minimal Risk, etc.):

4 Continuing Review (for Expedited Review only)

☐	Continuing review not required.
☐	Continuing review required. Rationale:

Attach required completed checklists and documentation of protocol-specific findings justifying regulatory determinations.

Reviewer Signature:		**Date:**	

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CHECKLIST: Devices		
NUMBER	DATE	PAGE
HRP-407	06/21/2022	1 of 3

The purpose of this checklist is to determine and document whether IDE requirements for FDA-regulated device research are met.[i]

IRB Number & Short Title:	
Investigator:	

1 Device Applicability (Check if **"Yes"**. If either is **"Yes"** use the rest of the worksheet. Otherwise FDA device regulations do not apply.)

☐	Does the activity involve the following? **(Check all that apply)** ☐ In the United States: The use of a device[ii] in one or more persons that evaluates the safety or effectiveness of that device. ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iii]. ☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[iv].
☐	Does this involve a humanitarian use device?

2 IDE/HDE Requirements[v] (Check if **"Yes"**. One must be **"Yes"** If all are **"No"** IDE/HDE information is not complete.)

☐	The device has an IDE or HDE. (Complete Sections 3 and 4. Complete Section 7, if applicable.)
☐	The device qualifies for an abbreviated IDE. (Complete Section 4 and 5)
☐	The device is exempt from the IDE requirements. (Complete Section 6)
☐	The FDA intends to exercise enforcement discretion of this device (Complete Section 8)

3 IDE/HDE Validation (Check if **"Yes"**. At least one must be **"Yes"** If all are **"No"**, IDE/HDE cannot be validated.)

☐	Sponsor protocol imprinted with the IDE/HDE number.
☐	Written communication from the sponsor documenting the IDE/HDE number.
☐	Written communication from the FDA documenting the IDE/HDE number. *(Required if the investigator holds the IDE/HDE.)*

4 Device Control (Check if **"Yes"**. Must be **"Yes"** If **"No"**, information regarding device control is incomplete.)

☐	The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.[vi]

5 Abbreviated IDE (Check if **"Yes"**. All must be **"Yes"**)

☐	The device is not banned by the FDA.
☐	The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)
☐	The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[vii]
☐	The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46)
☐	The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)
☐	The investigator will not market or promote the device. (21 CFR §812.7)

6 IDE Exemptions (Check if **"Yes"**. All criteria under one category must be **"Yes"** for a category to be met. If none of the categories is met, the device is not exempt from an IDE.)

Cat. #1	☐	The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.)
	☐	The device is FDA-approved/cleared.[viii]
	☐	The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.
Cat. #2	☐	The device is a diagnostic device.
	☐	The sponsor will comply with applicable requirements in 21 CFR 809.10(c).
	☐	The testing is noninvasive.[ix]
	☐	The testing does not require an invasive sampling procedure that presents significant risk.
	☐	The testing does not by design or intention introduce energy into a subject
	☐	The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure.
Cat. #3	☐	The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
Cat. #4	☐	The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

7	**IDE Oversight for investigators who hold the IDE** (Check if **"Yes"**. One of the following must be **"Yes"** if the investigator holds the IDE)
☐	The FDA regulatory requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.
☐	An audit documents that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

8	**Devices in which the FDA intends to exercise enforcement discretion**[x] (Check if **"Yes"**. If any are "Yes," the device is not subject to the device regulatory requirements at this time[xi].)
☐	A software function that helps patients (i.e. users) self-manage their diseases or conditions without providing specific treatment or treatment suggestions.
☐	A software function that automates simple tasks for health care providers.

[i] This document satisfies AAHRPP elements I.7.A, I.7.B

[ii] The term ''device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Due to changes to Section 3060 of the 21st Century Cures act, the term "device" does not include **software function** that is intended for:

a. administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

b. maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

c. serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

   i. such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

   ii. such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

   iii. such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; or

d. transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

To review the FDA's guidance regarding the changes to the existing medical definition due to the 21st Century Cures Act, please visit this website: https://www.fda.gov/media/109622/download.

To review software functions that are the focus of the FDA's regulatory oversight, please review the following guidance: https://www.fda.gov/media/80958/download.

[iii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[v] If there are questions about which category is appropriate, have the investigator apply for an IDE following 21 CFR §812.20.

[vi] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

[vii] The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf)

[viii] In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

[ix] Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf

[x] Examples of software functions where the FDA is exercising enforcement discretion can be found in the Policy for Device Software Functions and Mobile Medical Apps.

[xi] For software and mobile apps in this category, the FDA strongly recommends that manufacturers that may meet the definition of a device follow the Quality System regulation (that includes good manufacturing practices) in the design and development of their device software functions, and initiate prompt corrections to their devise, when appropriate, to prevent patient and user harm.

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CHECKLIST: Waiver or Alteration of Consent Process

NUMBER	DATE	PAGE
HRP-410	06/21/2022	1 of 3

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.
- Use a separate checklist for each waiver or alteration determination for a study.

IRB Number & Short Title:	
Investigator:	

The research must meet one of the following four sets of criteria

	1 Waiver or Alteration of Consent Process[2] (Check if **"Yes"**. All must be checked)
☐	The research is **NOT** FDA-regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	The research involves no more than Minimal Risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐	If the research involves using Identifiable Private Information or Identifiable Biospecimens, the research could **NOT** practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research does not use identifiable private information or biospecimens, or if the research is not subject to the 2018 Rule) ☐ N/A** *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*
☐	Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent. **(N/A if broad consent not used for the research, or if the research is not subject to the 2018 Rule) ☐ N/A**
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[3]. **(N/A if waiving informed consent, or if the research is not subject to the 2018 Rule) ☐ N/A**

2 Waiver or Alteration of Consent Process[4] (Check if **"Yes"**. All must be checked)

[1] This document satisfies AAHRPP elements I-9, II.3.G, II.5.A, II.5.B, III.1.F

[2] 45 CFR §46.116(f)

[3] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk.

☐	The research **IS** FDA-regulated.
☐	The clinical investigation involves no more than Minimal Risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	The clinical investigation could not practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*

3	**Waiver or Alteration of Consent Process**[5] (Check if "**Yes**." All must be checked.)
☐	The research is **NOT** FDA-regulated.
☐	The research does **NOT** involve non-viable neonates.
☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. *Provide protocol specific findings justifying this determination:*
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. One must be checked)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. *Provide protocol specific findings justifying this determination:*
☐	The research could **NOT** practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent **(N/A if broad consent not used for the research, or if the research is not subject to the 2018 Rule)** ☐ **N/A**
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent. **(N/A if waiving informed consent, or if the research is not subject to the 2018 Rule)** ☐ **N/A**

4	**Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens**[6] (Check if **"Yes"**. All must be checked)
☐	The research does not involve Human Subjects as Defined by DHHS.
☐	The study involves an in vitro diagnostic device investigation.
☐	The testing is noninvasive.
☐	The testing does not require an invasive sampling procedure that presents significant risk.
☐	The testing does not by design or intention introduce energy into a subject.
☐	The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
☐	For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."
☐	For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

[5] 45 CFR §46.116(e)
[6] Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006

☐	The study uses one of more of the following: **(Check all boxes that are true. One must be checked)** ☐ Specimens collected for routine clinical care or analysis that would have been discarded. ☐ Specimens obtained from specimen repositories. ☐ Leftover specimens that were previously collected for other research purposes.
☐	The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject.
☐	One of the following is true: **(Check all boxes that are true. One must be checked)** ☐ Specimens are not coded where "Coded" means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen. ☐ Neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.
☐	One of the following is true: **(Check all boxes that are true. One must be checked)** ☐ The specimens are not accompanied by clinical information. ☐ Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.
☐	The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.
☐	The specimens are provided to the investigator(s) without identifiers.
☐	The supplier of the specimens has established policies and procedures to prevent the release of personal information.

5	**Waiver of Informed Consent for Planned Emergency Research**[7]
☐	The research meets the criteria in **HRP-419 - CHECKLIST - Waiver of Consent for Emergency Research**.

[7] 21 CFR §50.24 and 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research – November 1, 1996

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CHECKLIST: Waiver of Written Documentation of Consent		
NUMBER	DATE	PAGE
HRP-411	06/21/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves the waiver of written documentation of consent. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.
- Use a separate checklist for each waiver determination for a study.

IRB Number & Short Title:	
Investigator:	

The research must meet one of the following sets of criteria

1 Waiver of Written Documentation of Consent[2] (Check if **"Yes"**. All must be checked)

☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 – WORKSHEET - Criteria for Approval**.**
☐	The research presents no more than Minimal Risk of harm to subjects.
☐	The research involves no procedures for which written consent is normally required outside of the research context.

Select one of the following: **(One must be checked)**

☐ Written information describing the research **is to be provided** to the subject or the subject's Legally Authorized Representative (LAR).

☐ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.

2 Waiver of Written Documentation of Consent[3] (Check if **"Yes"**. All must be checked)

☐	The research is not FDA-regulated.
☐	The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 - WORKSHEET: Criteria for Approval**.**
☐	The only record linking the subject and the research would be the consent document.
☐	The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.
☐	Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Select one of the following: **(One must be checked)**

☐ Written information describing the research **is to be provided** to the subject or the subject's LAR.

☐ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.

3 Waiver of Written Documentation of Consent[4] (Check if **"Yes"**. All must be checked)

☐	The research is not FDA-regulated.
☐	The research is subject to the 2018 Rule.

[1] This document satisfies AAHRPP elements II.3.G, III.1.F
[2] 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(1)(ii)
[3] 45 CFR §46.117(c)(1)(i)
[4] 45 CFR §46.117(c)(1)(iii)

☐	The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 – WORKSHEET- Criteria for Approval**.**
☐	The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm.
☐	The research presents no more than Minimal Risk of harm to subjects.
☐	There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select one of the following: (One must be checked)

☐ Written information describing the research is to be provided to the subject or the subject's LAR.

☐ Written information describing the research does not need to be provided to the subject or the subject's LAR.

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CHECKLIST: Pregnant Women		
NUMBER	DATE	PAGE
HRP-412	06/21/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

IRB Number & Short Title:	
Investigator:	

Research must meet one of the following three sets of criteria in Sections 1-3.

1	**Non-Federally Regulated Minimal Risk Research** (Check if **"Yes"**. All must be checked)
☐	The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS or Environmental Protection Agency (EPA)
☐	The research involves no more than Minimal Risk to pregnant women and fetuses.
☐	The research is not funded by Department of Defense, or does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects.

2	**Research Involving Pregnant[i] Women[ii]** (Check if **"Yes"**. All must be checked)
☐	Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. **(N/A if not scientifically appropriate.)☐ N/A** *Provide protocol specific findings justifying this determination:*
☐	One of the following is true**: (Check box that is true)** ☐ The risk to the fetus[iii] is caused solely by Interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. ☐ There is no prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than Minimal Risk, and the purpose of the research is the development of important biomedical[iv] knowledge which cannot be obtained by any other means *Provide protocol specific findings justifying this determination:*
☐	Any risk is the least possible for achieving the objectives of the research. *Provide protocol specific findings justifying this determination:*
☐	If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is **NOT** greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained. **(N/A if research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.)☐ N/A** *Provide protocol specific findings justifying this determination:*
☐	If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, except that the father's consent need **NOT** be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. **(N/A if research does not hold out the prospect of direct benefit to the fetus.)☐ N/A** *Provide protocol specific findings justifying this determination:*
☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. *Provide protocol specific findings justifying this determination:*

[1]This document satisfies AAHRPP elements I.1.D, I-9, II.4.A, II.4.B, II.5.A, II.5.B

☐	For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(N/A if research does not enroll children who are pregnant.)**☐ **N/A** *Provide protocol specific findings justifying this determination:*
☐	No inducements, monetary or otherwise, will be offered to terminate a pregnancy. *Provide protocol specific findings justifying this determination:*
☐	Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. *Provide protocol specific findings justifying this determination:*
☐	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*
3	**Research Involving Pregnant Women that is NOT Otherwise Approvable**[v] (All must be **"Yes"**)
☐	The research does **NOT** meet the requirements of 45 CFR §46.204. *Provide protocol specific findings justifying this determination:*
☐	The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. *Provide protocol specific findings justifying this determination:*

[i] "Pregnancy" encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

[ii] 45 CFR §46.204

[iii] "Fetus" means the product of conception from implantation until delivery

[iv] For Department of Defense (DOD) research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge." In addition, it is our understanding that there was no intent to exclude social behavioral research from being conducted under these regulations, and therefore, biomedical knowledge does not exclude social behavioral knowledge.

[v] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B of 45 CFR §46 and the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Organizational Official has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

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CHECKLIST: Non-Viable Neonates		
NUMBER	DATE	PAGE
HRP-413	06/21/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves non-viable neonates as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

IRB Number & Short Title:	
Investigator:	

The research must meet one of the following two sets of criteria.

	1 Research Involving Non-Viable[i] Neonates[ii] (Check if **"Yes"**. All must be checked)
☐	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. *Provide protocol specific findings justifying this determination:*
☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. *Provide protocol specific findings justifying this determination:*
☐	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*
☐	Vital functions of the neonate will not be artificially maintained. *Provide protocol specific findings justifying this determination:*
☐	The research will not terminate the heartbeat or respiration of the neonate. *Provide protocol specific findings justifying this determination:*
☐	There will be no added risk to the neonate resulting from the research. *Provide protocol specific findings justifying this determination:*
☐	The purpose of the research is the development of important biomedical knowledge[iii] that cannot be obtained by other means. *Provide protocol specific findings justifying this determination:*
☐	The legally effective informed consent of both parents of the neonate is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest. *Provide protocol specific findings justifying this determination:*
☐	The consent of a Legally Authorized Representative (LAR) of either or both of the parents of a nonviable neonate will not be obtained. *Provide protocol specific findings justifying this determination:*

	2 Research Involving Neonates that is Not Otherwise Approvable[iv] (Check if **"Yes"**. All must be checked)
☐	The research does **NOT** meet the requirements of §46.205. *Provide protocol specific findings justifying this determination:*
☐	The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. *Provide protocol specific findings justifying this determination:*

[1] This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B

[i] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

[ii] 45 CFR §46.205

[iii] It is our understanding that there was no intent to exclude social behavioral research from being conducted under these regulations, and therefore, biomedical knowledge does not exclude social behavioral knowledge.

[iv] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B or Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Organizational Official (IO/OO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

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CHECKLIST: Neonates of Uncertain Viability

NUMBER	DATE	PAGE
HRP-414	06/21/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves neonates of uncertain viability as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
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IRB Number & Short Title:	
Investigator:	

The research must meet one of the following two sets of criteria

1	**Research Involving Neonates[i] of Uncertain Viability[ii]** (Check if **"Yes"**. All must be checked)
☐	Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. *Provide protocol specific findings justifying this determination:*
☐	Individuals engaged in the research will have no part in determining the viability of a neonate. *Provide protocol specific findings justifying this determination:*
☐	One of the following is true: **(Check box that is true)** ☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective. ☐ The purpose of the research is the development of important biomedical knowledge[iii] which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. *Provide protocol specific findings justifying this determination:*
☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. **("N/A" if the consent process is waived)** *Provide protocol specific findings justifying this determination:*
☐	The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's Legally Authorized Representative (LAR) is obtained in accord with the regulations, except that the consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest. **("N/A" if the consent process is waived)** *Provide protocol specific findings justifying this determination:*

2	**Research Involving Neonates of Uncertain Viability that is Not Otherwise Approvable[iv]** (Check if **"Yes"**. All must be checked)
☐	The research does **NOT** meet the requirements of §46.205. *Provide protocol specific findings justifying this determination:*
☐	The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. *Provide protocol specific findings justifying this determination:*

[1] This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B

[i] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

[ii] 45 CFR §46.205

[iii] It is our understanding that there was no intent to exclude social behavioral research from being conducted under these regulations, and therefore, biomedical knowledge does not exclude social behavioral knowledge.

[iv] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B or Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Organizational Official (IO/OO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

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CHECKLIST: Prisoners		
NUMBER	DATE	PAGE
HRP-415	06/21/2022	1 of 2

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves Prisoners as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
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IRB Number & Short Title:	
Investigator:	

The research must meet one of the following two sets of criteria

1 Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated (Check if **"Yes"**. All must be checked)

☐	The research is **NOT** conducted or funded by DHHS or Veterans Administration (VA).
☐	The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.
☐	The incarceration does not put the rights and wellbeing of the subject in jeopardy.
☐	The Prisoner representative has been consulted.
☐	The terms of the subject's confinement does not inhibit the ethical conduct of the research.
☐	There are no other significant issues preventing the research from continuing as approved.
☐	This approval is limited to the individual subject and does not allow recruitment of Prisoners.
☐	One of the following is true: **(Check all that are true)** ☐ The subject will be at increased risk of harm if withdrawn from the research. ☐ The research presents no more than Minimal Risk[i] and no more than inconvenience to the subjects.

2 Research Involving Prisoners[ii] as Subjects[iii] (Check if **"Yes**." All must be checked)

☐	The research under review represents one of the following categories of research: **(At least one must be checked.)** ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than Minimal Risk[i] and no more than inconvenience to the subjects. ☐ Study of prisons as institutional structures or of Prisoners as incarcerated persons, provided that the study presents no more than Minimal Risk[i] and no more than inconvenience to the subjects. ☐ Research on conditions particularly affecting Prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).[iv] ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject where one of the following is true: **(One box must be checked)** ☐ All groups may benefit from the research. ☐ Prisoners are assigned to control groups which may not benefit from the research [v] ☐ Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk[i] and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research. *Provide protocol specific findings justifying this determination:*

[1] This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B

☐	Any possible advantages accruing to the Prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. *Provide protocol specific findings justifying this determination:*
☐	The risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers. *Provide protocol specific findings justifying this determination:*
☐	Procedures for the selection of subjects within the prison are fair to all Prisoners and immune from arbitrary Intervention by prison authorities or Prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available Prisoners who meet the characteristics needed for that particular research project. *Provide protocol specific findings justifying this determination:*
☐	The information is presented in language which is understandable to the subject population. *Provide protocol specific findings justifying this determination:*
☐	Adequate assurance exists that parole boards will not take into account a Prisoner's participation in the research in making decisions regarding parole, and each Prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. *Provide protocol specific findings justifying this determination:*
☐	If the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual Prisoners' sentences, and for informing subjects of this fact. *Provide protocol specific findings justifying this determination:*
☐	A Prisoner representative reviewed the research focusing on the requirements of this checklist.[vi]
☐	The Prisoner representative received all materials pertaining to the research.
☐	For convened IRB review, the Prisoner representative presented either orally or in writing at the meeting or for review using the expedited procedure the Prisoner representative concurred that the research involves no more than Minimal Risk[i] to the Prisoner subjects.

[i] "*Minimal risk*" for research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

[ii] "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

[iii] If the research is DHHS-regulated, the research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section.

[iv] If the research is DHHS-regulated, the research may proceed only after OHRP has reviewed and approved the research. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section.

[v] If the research is DHHS-regulated, the research may proceed only after OHRP has reviewed and approved the research. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section.

[vi] For review using the expedited procedure, the prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer.

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CHECKLIST: Children		
NUMBER	DATE	PAGE
HRP-416	12/9/2022	1 of 5

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves children as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

Use a separate checklist for each child determination for a study.

IRB Number & Short Title:	
Investigator:	

1	**The research meets all of the following:** (Check if **"Yes".** All must be checked)			
☐	The research falls into one of the following categories of research involving children[i]: (Check box that is true)			
	☐ Section 2 Criteria	☐ Section 3 Criteria	☐ Section 4 Criteria	☐ Section 5 Criteria
☐	Adequate provisions are made for soliciting the permission of parents or guardians[ii]. **(Complete Section 7)**			
☐	Adequate provisions are made for soliciting the assent[iii] of the children. **(Complete Section 12)**			
☐	One of the following is true related to applicability of research involving wards[iv]: **(Check the one that is true)** ☐ The research falls into Section 2 or 3 **OR** does **NOT** involve wards of the state or any other agency, institution, or entity ☐ The research falls into Section 4 or 5 **AND** involves wards of the state or any other agency, institution, or entity **(Complete Section 6)**			

2	**Research involving children under 21 CFR §50.51/45 CFR §46.404** (Check if **"Yes".** All must be checked)
☐	No greater than Minimal Risk to children is presented. *Provide protocol specific findings justifying this determination:*
Return to Section 1.	

3	**Research involving children under 21 CFR §50.52/45 CFR §46.405** (Check if **"Yes".** All must be checked)
☐	The research involves greater than Minimal Risk to subjects. *Provide protocol specific findings justifying this determination:*
☐	The research presents the prospect of direct benefit to the individual subjects. *Provide protocol specific findings justifying this determination:*
☐	One of the following is true**. (Check box that is true**) ☐ The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject. ☐ The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being. *Provide protocol specific findings justifying this determination:*
☐	The risk is justified by the anticipated benefit to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. *Provide protocol specific findings justifying this determination:*
Return to Section 1.	

4	**Research involving children under 21 CFR §50.53/45 CFR §46.406** (Check if **"Yes".** All must be checked)

[1] This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B

☐	The research involves greater than Minimal Risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject. *Provide protocol specific findings justifying this determination:*
☐	The risk represents a minor increase over Minimal Risk where the researcher has presented sufficient evidence that the procedures, population, and the qualifications of research personnel support all of the following to be true:[v] **(Check boxes that are true. All must be checked.**) ☐ The increase in the probability and magnitude of harm is only slightly more than minimal risk. ☐ Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period). ☐ There is no, or an extremely small probability, that participants will experience as severe the potential pain, discomfort, stress, or harm associated with the procedure. *Provide protocol specific findings justifying this determination:*
☐	The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. *Provide protocol specific findings justifying this determination:*
☐	The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. *Provide protocol specific findings justifying this determination:*

Return to Section 1.

5 Not otherwise approvable research involving children under 21 CFR §50.54/45 CFR §46.407[vi] (Check if **"Yes".** All must be checked)

☐	The research does not meet the requirements of Sections 2, 3, or 4 *Provide protocol specific findings justifying this determination:*
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. *Provide protocol specific findings justifying this determination:*

Return to Section 1.

6 Research involving wards of the state or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 (Check if **"Yes".** All must be checked)

☐	One of the following is true: **(Check box that is true**) ☐ The research is related to their status as wards. ☐ The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. *Provide protocol specific findings justifying this determination:*
☐	An advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis for research approved under §50.53 or §50.54/§46.406 or §46.407. *Provide protocol specific findings justifying this determination:*
☐	The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child's participation in the research. *Provide protocol specific findings justifying this determination:*
☐	The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. *Provide protocol specific findings justifying this determination:*

Return to Section 1.

7	**Adequate provisions for soliciting the permission of parents or guardians** (Check if **"Yes".** All must be checked)
☐	One of the following is true: **(Check box that is true)** ☐ Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. ☐ Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. **(Cannot be selected for Section 4 or 5 criteria)** ☐ Parental permission is waived under criteria in Section 8 ☐ Parental permission is waived under criteria in Section 9 ☐ Parental permission is waived under criteria in Section 10 ☐ Parental permission is waived under criteria in Section 11
Return to Section 1.	

8	**Waiver of Parental Permission under 45 CFR §46.408(c)** (Check if **"Yes".** All must be checked)
☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. *Provide protocol specific findings justifying this determination:*
☐	An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. *Provide protocol specific findings justifying this determination:*
☐	The waiver is not inconsistent with Federal, State, or local law. *Provide protocol specific findings justifying this determination:*
Return to Section 1.	

9	**Waiver of Parental Permission under 45 CFR §46.116(f)** (Check if **"Yes".** All must be checked)
☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research involves no more than Minimal Risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	The research could not practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*
☐	If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research is subject to Pre-2018 Requirements OR if research does not use identifiable private information or biospecimens) ☐ N/A** Provide protocol specific findings justifying this determination:
☐	Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens cannot be granted for those who refused to provide broad consent. **(N/A if research is subject to Pre-2018 Requirements OR broad consent not used for the research) ☐ N/A**
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[2]. **(N/A if research is subject to Pre-2018 Requirements OR if waiving informed consent) ☐ N/A**
Return to Section 1.	

10	**Waiver of Parental Permission under FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects"[vii]** (Check if "**Yes**." All must be checked.)
☐	The research **IS** FDA-regulated.

[2] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

☐	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐	The clinical investigation could not practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*

Return to Section 1.

11 Waiver of Parental Permission under 45 CFR §46.408(c)/45 CFR §46.116(e) (Check if "Yes". All must be checked)

☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. *Provide protocol specific findings justifying this determination:*
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check boxes that are true)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. *Provide protocol specific findings justifying this determination:*
☐	The research could not practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*

Return to Section 1.

12 Adequate provisions to solicit the assent of children (Check if **"Yes".** All must be checked)

☐	Assent will be obtained from: **(Check box that is true)** ☐ All children. **(Complete Section 14)** ☐ None of the children. **(Complete Section 13)** ☐ Some children. **(Complete Section 13 and Section 14. The protocol needs to describe which children will not be asked for assent)**

Return to Section 1.

13 Reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c) (Check if **"Yes".** All must be checked)

☐	One or more of the following are true. **(Check all boxes that are true.)** ☐ The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted. ☐ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research ☐ Assent is waived under Section 15 criteria ☐ Assent is waived under Section 16 criteria

Return to Section 1.

14 Documentation of assent (Check if **"Yes".** All must be checked)

☐	If **"Yes"**, specify the process for documentation: ☐ Investigator will document assent in the consent signature block. ☐ Other **(NOTE: The protocol needs to describe the process of assent documentation)**

Return to Section 1.

15 Waiver of child assent under 45 CFR §46.408(a)/45 CFR §46.116(f)/21 CFR §50.55(d) (Check if **"Yes".** All must be checked)

☐	The research involves no more than Minimal Risk to the subjects.
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects.

☐	The research could not practicably be carried out without the waiver or alteration
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
☐	If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research is FDA regulated, is subject to Pre-2018 Requirements OR if does not use identifiable private information or biospecimens)** ☐ **N/A**

Return to Section 1.

16 Waiver of Child Assent under 45 CFR §46.408(a)/45 CFR §46.116(e) (Check if **"Yes".** All must be checked)

☐	The research is not FDA-regulated.
☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. At least one must be checked.)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs.
☐	The research could not practicably be carried out without the waiver or alteration.

Return to Section 1.

[i] "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

[ii] "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

[iii] "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent, 45 CFR §46.402(b).

[iv] "Wards" are "Children" who are cared for and the responsibility of the state or any other agency, institution or entity.

[v] Where "minor increase over minimal risk" is based on SACHRP *Recommendations regarding risk in research involving children*; 18-Apr-2005.

[vi] 45 CFR §46.407. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart D of Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Organizational Official (IO/OO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

[vii] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk.

UMass Chan MEDICAL SCHOOL

CHECKLIST: Cognitively Impaired Adults

Document No.:	Effective Date:	Page:
HRP-417	06/21/2022	1 of 2

This checklist is used to determine and document whether non-exempt Human Research involving adults lacking decision making capacity can be approved. (see Footnotes 1 and 2)[1]

All items in Sections 1-3 must be considered when applicable.
All criteria in Sections 1, 5, 6, 7, or 8 must be met.
All criteria in Section 9 must be met.

1.		**Research involving no more than <Minimal Risk> to subjects**
1.1	☐	The research involves no more than <Minimal Risk> to subjects
1.2	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
2.		**Considerations for all research**
2.1	●	Does the population targeted for recruitment represent the population with the least degree of impairment compatible with the aims of the study?
2.2	●	Does the research involve risks or discomforts that are greater for subjects who lack capacity than unimpaired subjects?
2.3	●	Have appropriate procedures for assessing capacity to consent to enroll in the study, if necessary, been described in the protocol or other submission materials?
2.4	●	Does the process to assess capacity provide reasonable assurances that the evaluator's judgments will be impartial?
2.5	●	Should the investigator follow a process so that individuals who are not capable under routine procedures might be capable? (see Footnote 3)
3.		**Considerations when subjects might experience fluctuating functional abilities**
3.1	●	Does the consent process include plans to avoid, if feasible, periods during which subjects are likely to experience greater than normal impairment?
3.2	●	Should provisions be included to anticipate fluctuations in capacity? (see Footnote 4)
4.		**Considerations for research involving greater than <Minimal Risk> to subjects**
4.1	●	Has the experimental intervention been tested on animals or humans with unimpaired functional abilities?
4.2	●	Does the protocol or other submission materials include a written description of procedures for minimizing risk?
4.3	●	Is there documentation of the importance of knowledge to be obtained by answering the research question?
4.4	●	Should one or more independent monitors be appointed to assist with various aspects of the study? (see Footnote 5)
4.5	●	Should a list of resources and referrals offered to subjects to assist them in coping with any foreseeable harm?
4.6	●	Should there be a written rationale for the inclusion of subjects with diminished functional abilities?
4.7	●	Should continuing review be conducted more frequently than annually?
4.8	●	Should there be a description of procedures for withdrawing subjects or terminating the study?
4.9	●	Should there be procedures for screening LARs and informing them of their responsibilities?
5.		**Research involving a drug, biologic, or device with no anticipated direct benefit to the subject** *ICH-GCP 4.8.14*
5.1	☐	The objectives cannot be met with research involving subjects who can give consent personally
5.2	☐	Unless an exception is justified, subjects have a disease or condition for which the investigational product is intended
5.3	☐	The foreseeable risks to the subjects are low (no greater than a minor increase over minimal risk)
5.4	☐	The negative impact on the subject's well-being is minimized and low
5.5	☐	The research is not prohibited by law
5.6	☐	Subjects will be closely monitored and withdrawn if they appear to be unduly distressed
5.7	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
6.		**Research with anticipated direct benefit to the subject**
6.1	☐	The knowledge likely to be gained will improve the understanding of the condition, disease or behavior affecting the subject population
6.2	☐	The research holds out the prospect of direct benefit for the individual subject where the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
6.3	☐	The research is not prohibited by law
6.4	☐	Subjects will be closely monitored and withdrawn if they appear to be unduly distressed
6.5	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
7.		**Research with anticipated direct benefit to the subject that is available only in the research**
7.1	☐	There is a direct anticipated clinical benefit to the subjects that is available only in the context of the research
7.2	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
8.		**Not otherwise approvable research**
8.1	☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of an important problem
8.2	☐	The research will be conducted in accordance with sound ethical principles.
8.3	☐	There are adequate provisions for soliciting the permission of an LAR and assent of subjects (see Section 9)
8.4	☐	The IRB has documented the above determinations in the minutes along with protocol-specific findings justifying these determinations

[1] This document satisfies AAHRPP elements I-9, II.1.A, II.4.A, II.4.B, II.5.B

9. Adequate provisions for soliciting assent (see Footnote 6)		
9.1	☐	Assent is required of:
		☐ All subjects
		☐ All subjects determined by the investigator to be capable of assent
		☐ None of the subjects
9.2	☐	Written documentation of assent:
		☐ Is not required
		☐ Will be documented by a statement of the research team on the consent form

10. Notes

IRB Number & Short Title:	
Investigator:	

11. Footnotes	
11.1	Use this Checklist when the research includes individuals who have a condition of a type and severity likely to lead to affect capacity to consent, such as acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders.
11.2	Prospective adult subjects with impairments to functional abilities are presumed to be capable of providing consent unless there is substantial evidence otherwise. The mere presence of a condition that leads to diminished functional abilities should not be considered as indicative of a lack of capacity to consent.
11.3	Such methods might include: 1. designing a stepwise consent process, which involves a waiting period between each phase of the process: capacity assessment, initial presentation of information, and obtaining consent; 2. enhanced presentation of consent information during initial presentation and/or immediately prior to obtaining consent, including: repetition of information (especially misunderstood information), both oral and written presentation of information, multi-media presentation of information, interactive questioning, and written study summaries; 3. continuous dissemination of consent information throughout the course of the study; and 4. conducting the consent process in an environment in which the subject is comfortable.
11.4	Such methods might include: 1. Re-evaluating subjects' capacity over the course of the study 2. Designation of an individual to serve as an LAR 3. Involving potential LARs in the consent process 4. Asking subjects to document their wishes regarding participation 5. Avoiding consent when subjects are likely to experience greater than normal impairment 6. Obtaining consent of subjects who regain capacity
11.5	For example, a subject advocate, such as a member of the target population or family member thereof, or an employee of an organization that advocates for the target population; an individual with expert knowledge of the relevant psychological or physical condition who will monitor the consent of subjects; a health care professional to serve as a consultant to subjects; or a safety and data monitoring committee.
11.6	The content of the assent process should depend on the degree of risk and extent of likely impairments to subjects' functional abilities and should increase in rigor as risk and functional abilities increase.

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CHECKLIST: Non-Significant Risk Device

NUMBER	DATE	PAGE
HRP-418	06/21/2022	1 of 1

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves an abbreviated IDE This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

IRB Number & Short Title:	
Investigator:	

1	**SIGNIFICANT RISK DEVICE STUDY** (Check if **"Yes."** If any are checked, the device is a significant risk device.)	
☐	Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.	
☐	Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.	
☐	Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.	
☐	Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.	
2	**NON-SIGNIFICANT RISK DEVICE STUDY**[i] (Check if **"Yes."**)	
☐	Meets none of the above criteria.	
☐	The submission includes a brief explanation that the device is NSR or there is documentation that the FDA has determined the device to be NSR.	
☐	The FDA NSR determination is provided, the convened IRB agrees with the sponsor's explanation that the device is NSR, or the convened IRB has documented its own rationale that the device is NSR below.	
3	**RATIONALE (Describe)**	

[i] Excerpted from FDA.gov on 9/5/2021, https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process:
Nonsignificant risk devices are devices that do not pose a significant risk to the human subjects. Examples include most daily-wear contact lenses and lens solutions, ultrasonic dental scalers, and Foley catheters.

A nonsignificant risk device study requires only IRB approval prior to initiation of a clinical study. Sponsors of studies involving nonsignificant risk devices are not required to submit an IDE application to the FDA for approval. Submissions for nonsignificant device investigations are made directly to the IRB of each participating institution. Sponsors should present to the reviewing IRB an explanation why the device does not pose a significant risk. If the IRB disagrees and determines that the device poses a significant risk, the sponsor must report this finding to the FDA within five working days [§812.150(b)(9)]. The FDA considers an investigation of a nonsignificant risk device to have an approved IDE when the IRB concurs with the nonsignificant risk determination and approves the study.

The sponsor also must comply with the abbreviated IDE requirements under §812.2 (b).

The following FDA guidance document provides examples of NSR and SR devices: Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies (January 2006), https://www.fda.gov/media/75459/download.

[1] This document satisfies AAHRPP elements II.5.A, II.5.B

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CHECKLIST: Waiver of Consent for Emergency Research

NUMBER	DATE	PAGE
HRP-419	06/21/2022	1 of 3

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver of consent for planned emergency research. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

IRB Number & Short Title:	
Investigator:	

	1 Waiver of the Informed Consent Process for Planned Emergency Research (Check if **"Yes"** or **"N/A."** All must be checked)
☐	The research is **NOT** subject to regulation by a Common Rule agency other than DHHS.
☐	The research does **NOT** involve prisoners as subjects.
☐	The research does **NOT** involve pregnant women, fetuses, non-viable neonates, or neonates of uncertain viability.
☐	The IRB has reviewed and approved consent procedures and a consent document in accordance with HRP-314 - WORKSHEET - Criteria for Approval.
☐	The Human Subjects are in a life-threatening situation. *Provide protocol specific findings justifying this determination:*
☐	Available treatments are unproven or unsatisfactory. *Provide protocol specific findings justifying this determination:*
☐	The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions. *Provide protocol specific findings justifying this determination:*
☐	Obtaining informed consent is not feasible because the subjects will not be able to give their informed consent as a result of their medical condition. *Provide protocol specific findings justifying this determination:*
☐	Obtaining informed consent is not feasible because the intervention under investigation must be administered before consent from the subject's Legally Authorized Representative (LAR) is feasible. *Provide protocol specific findings justifying this determination:*
☐	Obtaining informed consent is not feasible because there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research. *Provide protocol specific findings justifying this determination:*
☐	Participation in the research holds out the prospect of direct benefit to the subjects because they are facing a life-threatening situation that necessitates intervention. *Provide protocol specific findings justifying this determination:*
☐	Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subject. *Provide protocol specific findings justifying this determination:*
☐	Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity. *Provide protocol specific findings justifying this determination:*

[1] This document satisfies AAHRPP elements I-9, II.4.C, II.5.B

☐	The research could not practicably be carried out without the waiver. *Provide protocol specific findings justifying this determination:*
☐	The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a LAR for each subject within that window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review. *Provide protocol specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn. *Provide protocol specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits. *Provide protocol specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. *Provide protocol specific findings justifying this determination:*
☐	Additional protections of the rights and welfare of the subjects will include establishment of an independent data monitoring committee to exercise oversight of the research. *Provide protocol specific findings justifying this determination:*
☐	If obtaining informed consent is not feasible and a LAR is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review. *Provide protocol specific findings justifying this determination:*
☐	Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the investigation and other information contained in the informed consent document. *Provide protocol specific findings justifying this determination:*
☐	There is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. *Provide protocol specific findings justifying this determination:*
☐	If a LAR or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible. *Provide protocol specific findings justifying this determination:*
☐	If a subject is entered into research with waived consent and the subject dies before a LAR or family member can be contacted, information about the research is to be provided to the subject's LAR or family member, if feasible. *Provide protocol specific findings justifying this determination:*
☐	The investigator will interpret "family member" to mean any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship. *Provide protocol specific findings justifying this determination:*
☐	The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with this waiver. *Provide protocol specific findings justifying this determination:*
☐	If the research is FDA-regulated, the protocol is being performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies this protocol as including subjects who are unable to consent (even if an IND for the same drug product or an IDE for the same device already exists). **("N/A" if not FDA-regulated) N/A:** ☐
☐	If the research is FDA-regulated, a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the research has concurred with the above findings. **("N/A" if not FDA-regulated) N/A:** ☐
☐	If the research is NOT FDA-regulated, the research is not subject to regulations codified by the FDA at title 21 CFR part 50. **("N/A" if FDA-regulated) N/A:** ☐

If an IRB determines that it cannot approve a protocol because it does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly (no longer than within 30 days) in writing to the investigator and the sponsor.

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CHECKLIST: Minutes Quality Improvement Assessment

NUMBER	DATE	PAGE
HRP-431	10/12/2021	1 of 3

The purpose of this checklist is to allow individuals to conduct a quality improvement self-assessment of IRB minutes.

IRB Number	
Meeting Date	
Name of Person Completing Checklist	
Date Completed	

1 General Minutes Requirements

☐ Yes ☐ No			Does the "Attendance Table" record each voting member (regular members and alternates) present at the meeting at any time?
☐ Yes ☐ No			Does the "Attendance Table" record any member in attendance who did not vote at any time?
☐ Yes ☐ No			Does the "Attendance Table" record each member's name?
☐ Yes ☐ No			Does the "Attendance Table" record which members were chairs or vice chairs?
☐ Yes ☐ No			Does the "Attendance Table" record each member's status as an unaffiliated member or affiliated member? OR, does the IRB Roster attached to the minutes include this information?
☐ Yes ☐ No			Does the "Attendance Table" record each member's status as a scientific member or non-scientific member? OR, does the IRB Roster attached to the minutes include this information?
☐ Yes ☐ No			When a member is a representative of vulnerable population, does the "Attendance Table" record that member's representative capacity? *(Prisoners, children, cognitively impaired adults)* OR, does the IRB Roster attached to the minutes include this information?
☐ Yes ☐ No			Does the "Attendance Table" record for each alternate member the name of IRB member for whom alternate is substituting.
☐ Yes ☐ No			Does the "Attendance Table" record whether any members were present by teleconference and if so indicate them by name?
☐ Yes ☐ No			Do the minutes record the total number of members present on the current IRB roster excluding alternate IRB members?
☐ Yes ☐ No			Do the minutes correctly record the number of members required for a quorum? *(Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.)*
☐ Yes ☐ No	☐ N/A		Do the minutes indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions? (**"N/A"** if no members were present by teleconference)
☐ Yes ☐ No			Do the minutes record the meeting start time?
☐ Yes ☐ No			Do the minutes record the meeting end time?
☐ Yes ☐ No			Do the minutes record a summary of each business item that was discussed?

2 Requirements for Each Protocol Reviewed

☐ Yes ☐ No			Do the minutes record a protocol ID?
☐ Yes ☐ No			Do the minutes record a protocol title?
☐ Yes ☐ No			Do the minutes record an investigator name?
☐ Yes ☐ No	☐ N/A		Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research?
☐ Yes ☐ No			If the minutes record a consultant report, does it summarize the key information provided by the consultant. (**"N/A"** if there were no consultant reports)
☐ Yes ☐ No	☐ N/A		Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate "None."
☐ Yes ☐ No	☐ N/A		If the minutes record controverted issues is there a "Controverted Issue/Resolution" table? (**"N/A"** if there were no controverted issues)
☐ Yes ☐ No	☐ N/A		If the minutes record controverted issues does the "Controverted Issue/Resolution" table summarize the controverted issue? (**"N/A"** if there were no controverted issues)
☐ Yes ☐ No	☐ N/A		If the minutes record controverted issues does the "Controverted Issue/Resolution" table include a resolution or a statement that there was no resolution? (**"N/A"** if there were no controverted issues)

☐ Yes ☐ No	Do the minutes record a motion as one of the following: Approved, Modifications Required to Secure Approval, Deferred, Disapproved?
☐ Yes ☐ No	For initial or continuing review do the minutes record the period of approval for the motion?
☐ Yes ☐ No	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No	Do the minutes list the names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (**"N/A"** if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (**"N/A"** if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table (taking into account cases in which both a regular and alternate IRB member are present at the meeting)?
☐ Yes ☐ No	Do minutes document the level of risk determined by the convened IRB as either Minimal Risk or more than Minimal Risk?
☐ Yes ☐ No ☐ N/A	If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults do the minutes either say "See IRB Records" or include one of more of the "Determination/Protocol Specific Findings" tables in HRP-501 - TEMPLATE - MINUTES? (**"N/A"** if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ N/A	If the minutes say "See IRB records for this protocol" is the corresponding completed checklist(s) in the IRB records? (**"N/A"** if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ N/A	If the minutes include one of more of the "Determination/Protocol Specific Findings" tables, is the table completed? (**"N/A"** if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ N/A	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document? (**"N/A"** if a DHHS-approved sample consent form was not reviewed)
☐ Yes ☐ No ☐ N/A	Do minutes document the rationale for a significant/non-significant device determination? (**"N/A"** if abbreviated IDE devices were not reviewed.)
☐ Yes ☐ No ☐ N/A	Do minutes document modifications required to secure approval? (**"N/A"** if there were no modifications required to secure approval) Otherwise, include the "Modifications Required to Secure Approval Table" in HRP-501 - TEMPLATE - MINUTES.
☐ Yes ☐ No ☐ N/A	When minutes document modifications required to secure approval is the "Modifications Required to Secure Approval Table" included? (**"N/A"** if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ N/A	When minutes document modifications required to secure approval does the "Modifications Required to Secure Approval Table" include a reason (basis) for each modification? (**"N/A"** if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ N/A	When minutes document modifications required to secure approval does the "Modifications Required to Secure Approval Table" describe the required modifications in such a way that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval? (**"N/A"** if there were no modifications required to secure approval).
☐ Yes ☐ No ☐ N/A	If a protocol was tabled, do the minutes indicate this and provide the reason for tabling? (**"N/A"** if there were no tabled protocols)
☐ Yes ☐ No ☐ N/A	If a protocol was deferred or disapproved do the minute document the reasons? (**"N/A"** if there were no deferred or disapproved protocols)
☐ Yes ☐ No ☐ N/A	If a protocol was deferred do the minute document recommended changes? (**"N/A"** if there were no deferred or disapproved protocols)
3 Requirements for Each Problem Reviewed (☐ N/A if no problems were reviewed)	
☐ Yes ☐ No	Do the minutes describe the problem?
☐ Yes ☐ No	Do the minutes describe whether the problem was serious or continuing non-compliance, an Unanticipated Problem Involving Risks to Subjects or Others, or a Suspension of IRB Approval or Termination of IRB Approval?
☐ Yes ☐ No ☐ N/A	Do the minutes record a protocol ID? (**"N/A"** if there were no specific protocol involved)
☐ Yes ☐ No ☐ N/A	Do the minutes record a protocol title? (**"N/A"** if there were no specific protocol involved)
☐ Yes ☐ No ☐ N/A	Do the minutes record an investigator name? (**"N/A"** if there were no specific investigator involved)

☐ Yes ☐ No ☐ N/A	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate "None" or record using the "Controverted Issue/Resolution" table. If there was no resolution, indicate this.
☐ Yes ☐ No	If the minutes record controverted issues is there a "Controverted Issue/Resolution" table? (**"N/A"** if there were no controverted issues)
☐ Yes ☐ No ☐ N/A	If the minutes record controverted issues does the "Controverted Issue/Resolution" table summarize the controverted issue? (**"N/A"** if there were no controverted issues)
☐ Yes ☐ No ☐ N/A	If the minutes record controverted issues does the "Controverted Issue/Resolution" table include a resolution or a statement that there was no resolution? (**"N/A"** if there were no controverted issues)
☐ Yes ☐ No	Do the minutes document the motion?
☐ Yes ☐ No	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No	Do the minutes list the names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (**"N/A"** if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ N/A	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (**"N/A"** if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table (taking into account cases in which both a regular and alternate IRB member are present at the meeting)?

4 Minutes Efficiency

Indicate the number of days between the meeting and the finalization of the minutes:

UMass Chan MEDICAL SCHOOL

CHECKLIST: HIPAA Waiver of Authorization

NUMBER	DATE	PAGE
HRP-441	06/21/2022	1 of 1

The purpose of this checklist is to provide support for the UMass Chan IRB to document a waiver or alteration of HIPAA authorization. This checklist is to be used. This checklist needs to be completed, signed, dated, and retained.

IRB Number & Short Title:	
Investigator:	

1 SCOPE (Check all that apply)

☐	Waiver of HIPAA authorization for recruitment
☐	Waiver of HIPAA authorization for conduct of study
☐	Alteration of HIPAA authorization to not require signature of the individual and date (e.g. verbal)
☐	Alteration of HIPAA authorization (include specifics of alteration below in "Notes" section; refer to HRP-330 - WORKSHEET - HIPAA Authorization)

2 DOCUMENTATION OF WAIVER APPROVAL (Check if **"Yes".** All must be checked)

☐	The description of the PHI for which use or access is needed is included in the HIPAA waiver form and is necessary for the research.	
☐	The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (Check if **"Yes"**. All must be checked)	
	☐	An adequate plan to protect the identifiers from improper use and disclosure.
	☐	An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
	☐	Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by 45 CFR 164.512(i).
☐	The research could **NOT** practicably be conducted without the waiver or alteration.	
☐	The research could **NOT** practicably be conducted without access to and use of the protected health information.	

Notes:

The designated reviewer signing below has determined that the above requirements are met and that access to the protected health information described in the protocol is necessary, and has waived or altered the requirement for authorization. For waivers issued through Committee Review, the designated reviewer has been authorized by the IRB Chair to sign on behalf of the UMass Chan IRB.

Reviewer Signature:		**Date:**	

UMass Chan MEDICAL SCHOOL	**sIRB DOCUMENTS**

HRP-801 – SOP – Establishing Authorization Agreements
HRP-802 – SOP – Institutional Profile Management
HRP-803 – SOP – Reliance Pre-Review
HRP-804 – SOP – External IRB Post-Review
HRP-805 – SOP – External IRB Updates
HRP-815 – FORM – Institutional Profile
HRP-830 – WORKSHEET – Communication and Responsibilities
HRP-832 – WORKSHEET – Considerations for Ceding IRB Review
HRP-833 – WORKSHEET – Considerations for Serving as the sIRB
HRP-861 – WORKBOOK – Institutional Profiles

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SOP: Establishing Authorization Agreements				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-801	06/21/2022	C. Loeb	K. Luzuriaga	1 of 2

1 PURPOSE

1.1 The purpose of this process is to execute Authorization Agreements with other institutions.[i]

1.2 This process begins when an institution/organization has been identified for a potential Authorization Agreement.

1.3 This process ends when an Institutional Profile has been established.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 HRP-101 - Human Research Protection Program Plan details the criteria for reviewing for or relying on other institutions/organizations.

3.2 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for iREX or the SMART IRB platform are acceptable.

3.3 The institution may leverage the SMART IRB agreement, the OHRP Authorization Agreement template or create a local Authorization Agreement to establish reliance.

4 RESPONSIBILITIES

4.1 The IRB staff generally carries out these procedures. The IO/OO or HRPP Director may also participate in reliance determinations.

5 PROCEDURE

5.1 Determine whether an Authorization Agreement is already in place between or among the institutions in question.

5.1.1 If a valid Authorization Agreement is already in place, proceed with HRP-803 - SOP – Reliance Pre-Review.

5.1.2 If no Authorization Agreement is in place, and one is required, proceed with step 5.2 below.

5.2 Determine whether the criteria for reviewing for or relying on other institutions/organizations are met:

5.2.1 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.2.1.1 If the criteria have not been met, do not execute an Authorization Agreement. Communicate this to the other institution/organization.

5.2.2 If there is a request for your institution to rely on another institution's IRB, use HRP-832 - WORKSHEET - Considerations for Ceding IRB Review to inform your determination of whether your institution will rely on another institution's IRB.

5.2.3 If an institution is requesting to rely on your institution's IRB, use HRP-833 - WORKSHEET - Considerations for Serving as the sIRB to inform your determination of whether your institution's IRB will serve as the sIRB.

5.3 If the criteria have been met, execute an Authorization Agreement with that institution/organization.

5.3.1 Indicate in the agreement the conditions under which you serve as the IRB of record for that institution/organization.

5.3.2 Indicate in the agreement the conditions under which that institution/organization will serve as the IRB of record for you.

5.3.3 Include the following in the Authorization Agreement, or as (an) addendum(s):

5.3.3.1 A communication plan. Use HRP-830 - WORKSHEET - Communication and Responsibilities to create a communication plan.

5.3.3.2 Consent form instructions, including instructions for the institution/organization to provide local contact information and details regarding compensation for research-related injuries.

5.3.3.3 Recruitment material instructions.
5.3.3.4 New information reporting instructions.
5.3.3.5 Required terms.
5.3.3.6 Negotiable terms.
5.3.3.7 The process for adding participating sites or additional research to existing agreements.
5.3.3.8 Relevant tribal, state, or non-US laws, regulations, or policies, such as age of majority, circumstances that affect the age of consent, who can serve as a Legally Authorized Representative, and other information that may not be identified elsewhere in the Authorization Agreement.

5.3.4 Record the collected information in the Institutional Profile SmartForm.
5.3.5 File the HRP-815 - FORM - Institutional Profile and the Authorization Agreement (and any addendums) together for future reference.

6 MATERIALS

6.1 HRP-101 - Human Research Protection Program Plan
6.2 HRP-803 - Reliance Pre-Review
6.3 HRP-815 - FORM - Institutional Profile
6.4 HRP-830 - WORKSHEET - Communication and Responsibilities
6.5 HRP-832 - WORKSHEET - Considerations for Ceding IRB Review
6.6 HRP-833 - WORKSHEET - Considerations for Serving as the sIRB
6.7 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 SMART IRB Agreement: https://smartirb.org/agreement/
7.2 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

[i] If your institution participates in the NCATS SMART IRB program, then you may choose to replace this SOP with SMART IRB documentation or to supplement this SOP with SMART IRB documentation.

1 PURPOSE

1.1 The purpose of this process is to manage Institutional Profiles.

1.2 This process begins when this institution receives updated information from another institution/organization that impacts the content of the Institutional Profile.

1.3 This process ends when updated information has been communicated to appropriate parties.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Any substantive changes to an Institutional Profile must be the result of an amended Authorization Agreement. Any non-substantive changes, e.g., contact information updates, do not require an amended Authorization Agreement.

3.2 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for iREX or the SMART IRB platform are acceptable.

4 RESPONSIBILITIES

4.1 IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 Update the Institutional Profile SmartForm with the amended Authorization Agreement and with the new or updated information about the external institution/organization.

5.2 Determine whether the updates impact any existing studies. If so, develop a plan for how to address the impact.

5.3 Communicate these updates and any plans to address impacts to appropriate parties as needed.

6 MATERIALS

6.1 HRP-815 - FORM - Institutional Profile

6.2 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 None.

1 PURPOSE

1.1 The purpose of this process is to conduct pre-review for submissions where this institution is being asked to rely on an external IRB, or where this institution is asked to assume IRB oversight of external Participating Sites (pSite).

1.2 This process begins when a request to rely or cede oversight is submitted for pre-review.

1.3 This process ends when reliance on the external IRB is confirmed or this institution confirms it will assume oversight for external Participating Sites (pSite).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

3.2 An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB policy and/or the revised Common Rule cooperative research provision (§46.114).

3.3 Studies utilizing the NCI CIRB may be submitted directly to NCI CIRB without first requesting reliance.

4 RESPONSIBILITIES

4.1 IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 If the item is a submission of approval documents for a study already reviewed by and approved by an external IRB[1].

5.1.1 Check the submission materials for completeness. This includes:

5.1.1.1 The Basic Information SmartForm and External IRB SmartForm pages.

5.1.1.2 Study related documents, if this is a multi-site or collaborative study relying on an external IRB.

5.1.1.3 Local site documents, if this is a single-site study relying on an external IRB.

5.1.2 Use HRP-309 - WORKSHEET - Ancillary Review Matrix to identify any ancillary reviews that are needed before reliance can be confirmed.

5.1.3 Review for local context to determine whether local requirements are satisfied:

5.1.3.1 If consent and/or assent template(s) were provided by the Sponsor or lead site, confirm that the local consent document is uploaded to the Local Site Documents page and includes the required local language.

5.1.3.2 If recruitment templates were provided by the Sponsor or lead site, confirm that the revised local versions are uploaded to the Local Site Documents page and aligns with local recruitment policies.

5.1.4 Execute the “Request Pre-Review Clarification” activity to send a request for any missing materials to the local study team.

[1] This includes, per institutional policy, external IRB studies for which local confirmation of reliance is not required prior to submission to the IRB of record. This would also include NCI CIRB submissions.

5.1.5 Once all required ancillary reviews and local requirements are complete, execute the "Confirm Reliance" activity.

5.1.6 Refer to HRP-804 - SOP - External IRB Post-Review.

5.2 If the item is a request for this institution to rely on another IRB[2]:

5.2.1 Identify the external IRB.

5.2.2 Consult the Institutional Profiles tab to determine whether there is sufficient information about the external IRB to confirm reliance. Determine whether an existing Authorization Agreement covers the study activities for the external IRB identified.

5.2.3 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and create a new Institutional Profile.

5.2.4 Once the required information is obtained and the necessary agreements are in place, check the submission materials for completeness. This includes:

5.2.4.1 The Basic Information SmartForm and External IRB SmartForm pages.

5.2.4.2 Study related documents, if this is a multi-site or collaborative study relying on an external IRB.

5.2.4.3 Local site documents, if this is a single-site study relying on an external IRB.

5.2.5 Consult HRP-309 - WORKSHEET - Ancillary Review Matrix to identify the ancillary reviews that must be completed prior to submission to an external IRB.

5.2.6 Review for local context to determine whether local requirements are satisfied:

5.2.6.1 If consent and/or assent template(s) were provided by the Sponsor or lead site, confirm that the local consent document is uploaded to the Local Site Documents page and includes the required local language.

5.2.6.2 If recruitment templates were provided by the Sponsor or lead site, confirm that the revised local versions are uploaded to the Local Site Documents page and aligns with local recruitment policies.

5.2.7 Execute the "Request Pre-Review Clarification" activity to send a request for any missing materials to the local study team.

5.2.8 Once all required ancillary reviews and local requirements are complete, execute the "Confirm Reliance" activity.

5.2.9 Refer to HRP-804 - SOP - External IRB Post-Review.

5.3 If the item is a request for this institution to serve as the single IRB of record (sIRB) for an external pSite:

5.3.1 Review the submission and identify all pSites (Note: pSites can only be approved after the approval of the main study).

5.3.2 Access the Institutional Profile database in the IRB system and:

5.3.2.1 Confirm that all pSites have an active profile

5.3.2.2 Determine whether an existing Authorization Agreement covers the study activities for each pSite identified.

5.3.2.3 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and create a new Institutional Profile.

5.3.3 Once all the information is complete and the authorization agreement has been executed, execute the "Submit invitation Decision" activity to notify the pSite that this IRB will serve as the IRB of Record for their participation in the study.

5.3.4 If necessary, re-assign the submission to IRB staff able to proceed with Pre-Review.

[2] This includes, per institutional policy, external IRB studies for which local confirmation of reliance is required prior to submission to the IRB of record.

6 MATERIALS

6.1 HRP-309 - WORKSHEET - Ancillary Review Matrix
6.2 HRP-801 - SOP - Establishing Authorization Agreements
6.3 HRP-804 - SOP - External IRB Post-Review
6.4 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 None.

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SOP: External IRB Post-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-804	06/21/2022	C. Loeb	K. Luzuriaga	1 of 1

1 PURPOSE

1.1 The purpose of this process is to conduct post-review for submissions where this institution is being asked to rely on an external IRB.

1.2 This process begins when a request to cede oversight has been submitted and pre-review has been completed.

1.3 This process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 For studies where IRB oversight has been ceded to an external IRB:

5.1.1 Execute the “Record sIRB Decision” activity and complete the form with the information in the external IRB approval letter. Upload the external IRB determination letter in the designated space for “External IRB Approval Letter” if not already attached under “Other Attachments” in the study application.

5.1.2 Execute the “Finalize Documents” activity if necessary.

5.1.3 Execute the “Prepare Letter” activity to generate and edit HRP-857 - LETTER - Acknowledge External IRB.

5.1.4 Execute the “Send Letter” activity.

6 MATERIALS

6.1 HRP-857 - LETTER - Acknowledge External IRB

7 REFERENCES

7.1 None.

1 PURPOSE

1.1 The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB.

1.2 This process begins when the local site submits newly approved materials from the external IRB.

1.3 This process ends when an external IRB submission has been updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 An investigator relying on an external IRB must update the study with changes approved by the external IRB, including providing notification of Continuing Review approval, using the “Update Study Details” activity.

3.2 If changes are made to local site documents on an externally reviewed multi-site study, including local consent documents, recruitment materials, or local study team members the investigator must update the site using the “Create Site Modification” activity.

4 RESPONSIBILITIES

4.1 IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 If the item includes updates to the local site (Site Modification for study team members or other parts of the site), review the updates in accordance with the roles and responsibilities of your institution as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.

5.1.1 If the item is not satisfactory:

5.1.1.1 Request clarifications from the Investigator by executing the “Request Pre-Review Clarification” Activity.

5.1.1.2 When the investigator responds to the clarification request, confirm that the requested clarifications were made.

5.1.2 When all updates to the local site are satisfactory, accept them by executing the “Accept Site Updates” activity.

5.1.3 When all updates to the local site have been accepted, execute the “Record sIRB Decision” activity (when applicable) and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.1.4 If applicable, execute the “Finalize Documents” and then the “Send Letter” activities.

5.2 If the item is an update to the overall study (Update to Study Details for funding, study scope, or study related documents and template), review the updates in accordance with the roles and responsibilities of your institution as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.

5.2.1 If the investigator has completed the submission via the “Finalize Updates” activity in the system:

5.2.1.1 The assigned IRB Coordinator uses the link in the email notification to navigate to the Study Update submission workspace. The IRB Director monitors or designee monitors for applicable submissions and may reassign the IRB Coordinator.

5.2.1.2 Review the study updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.2.1.2.1 If yes, from the main study workspace, execute the “Return to Post Review” activity.

5.2.1.2.2 Execute the edit “sIRB Decision” activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.2.1.2.3 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.2.1.2.4 If no, no further action is necessary.

5.2.1.3 If the item includes study updates that are not satisfactory:

5.2.1.3.1 Contact the investigator by posting a comment in the submission workspace with requested changes. Instruct the investigator to submit these changes by creating a new Study Update; or

5.2.1.3.2 Execute the “Update Study Details” activity in the main study workspace to make additional changes on behalf of the investigator. Notify the investigator of these changes by posting a comment in the study workspace.

5.2.1.3.3 If the study update includes changes to the sIRB decision, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.2.1.3.3.1 If applicable, execute the “Finalize Documents” and then the “Send Letter” activities.

5.2.2 If the IRB Coordinator is the one to execute the “Finalize Updates” activity in the system:

5.2.2.1 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.2.2.1.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.2.2.1.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.2.2.1.3 If no, no further action is necessary.

5.2.2.2 If the item includes other updates and are not satisfactory:

5.2.2.2.1 Contact the investigator by posting a comment in the submission workspace with requested changes. Instruct the investigator to edit the submission.

5.2.2.2.2 When the investigator edits the submission, confirm that the requested changes were made.

5.2.2.3 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.2.2.3.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.

5.2.2.3.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.2.2.3.3 If no, no further action is necessary.

5.2.3 To the extent the system allows, the IRB Coordinator may use Add Comment to acknowledge receipt.

6 MATERIALS

6.1 HRP-830 - WORKSHEET - Communication and Responsibilities

6.2 HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update

7 REFERENCES

7.1 None.

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FORM: Institutional Profile		
NUMBER	DATE	PAGE
HRP-815	06/21/2022	1 of 2

The purpose of this form is to record information about the Authorization Agreement established with another institution/organization. If there is more than one Authorization Agreement with another institution/organization, indicate so in the fields below, and describe nuances for those agreement in the spaces provided.[1]

Institution:			
Institutional Official:			
FWA number:			
FWA expiration date:			
FWA information:	(attach any relevant documentation, if applicable)		
IRB Registration information:	(attach any relevant documentation, if applicable)		
IORG number:			
IRB roster:	Attach separately		
Tribes, states or non-US locations in which this institution conducts FWA-approved research:		**Age of Majority:**	
		Age of Majority:	
		Age of Majority:	
Relevant tribal, state, or non-US laws, regulations, or policies:	Attach separately any relevant descriptions of tribal, state, or non-US laws, regulations, or policies that are not identified below, such as circumstances that would affect age of consent and who can serve as a Legally Authorized Representative.		

Quality Control

Describe the IRB quality control mechanisms in place to ensure the integrity of the IRB-review process at this site.

Quality control mechanism:	☐ **AAHRPP Accredited**	☐ **Established QA/QI Program**	
	☐ **OHRP IRB Self-Assessment**	☐ **Other**	
		If other, describe:	
Status:		**Date of most recent review:**	

Agreements and Communication

Authorization Agreement 1 (Attach agreement separately)**:**	**Effective Date:**		**Expiration Date:**	
	Notes:			
Authorization Agreement 2 (Attach agreement separately)**:**	**Effective Date:**		**Expiration Date:**	
	Notes:			
Communication plan: If not described in the Authorization Agreement, indicate the plan for communicating with this site.				

[1] This document satisfies AAHRPP elements I-9, II.5.B

Consent form instructions: Provide site-specific information that must be included in consent forms used at this site.	
Recruitment material instructions: Provide site-specific content or procedural information regarding the recruitment process.	
Route RNIs to this institution for review when they are the sIRB:	☐ **Yes** - RNIs will be routed directly to the sIRB for multi-site studies ☐ **No** - RNIs will be routed locally before being sent to the sIRB for review

Staff members who will serve as points of contact for this institution:

Name:		**Name:**		**Name:**	
Role:		**Role:**		**Role:**	
Phone		**Phone:**		**Phone**	
Email:		**Email:**		**Email:**	

Eligibility and Reliance

This institution is eligible to be a participating site on a multi-site study.	☐ **Yes**	☐ **No**
This institution is eligible to be a single IRB of record on a multi-site study.	☐ **Yes**	☐ **No**
This Institutional Profile is currently active.	☐ **Yes**	☐ **No**

The purpose of this worksheet is to provide support for the IRB staff, HRPP staff or an Investigator when developing a communication plan and identifying roles and responsibilities of the IRB of Record, Relying sites and/or the Overall PI or Lead Study Team.[1]

1 Organizational Responsibilities

Activity	Responsible Party
Education and Training: Providing education to researchers and research staff.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Conducting Scientific Review	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Ensuring concordance between any applicable grant and the IRB application. (Research under Pre-2018 Requirements only).	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Organization responsible for deciding whether allegations of non-compliance has basis in fact.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Organization responsible for deciding whether each incident of non-compliance is serious or continuing.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Obtaining management plans for researcher and research staff conflicts of interest. **NOTE:** If the relying organization maintains responsibility for this issue, the management plan must be provided	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Managing organizational conflicts of interest.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Ensuring continued oversight of active studies until closure or a mutually agreed upon transfer of the studies should early termination of the reliance agreement occur.	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Privacy Board for issuing waivers of HIPAA authorization	☐ Reviewing IRB ☐ Relying IRB ☐ Other:
Notes:	

2 Study-Specific Responsibilities

Training & Qualifications: Providing the IRB of record with confirmation that study teams at relying sites have completed relevant trainings and are qualified to conduct the proposed research.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Local Context Information: Providing local context information (e.g., consent language, local laws, institutional requirements) to the reviewing IRB.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Ensuring organizational compliance with the requirements of other parts of the local HRPP and communicating to the external IRB. This	☐ Reviewing IRB ☐ Relying IRB Contact

[1] This document satisfies AAHRPP element I-9

includes obtaining approval from other internal review committees prior to IRB or EC approval.	☐ Lead Study Team ☐ Relying Study team ☐ Other:
IRB Application Materials: Preparing and submitting the study materials for initial or continuing review or submitting modifications to the sIRB.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Site-specific Materials: Preparing and submitting site-specific materials to the sIRB.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
IRB Determinations and IRB-Approved Documents: Providing sIRB determinations and approved study materials to participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Templates: Providing study document templates (e.g., consent forms, recruitment materials) to participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Policies of the sIRB: Providing the lead study team with all relevant sIRB policies	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
pSite Continuing Review Information: Obtaining and collating CR information from all participating sites.[2]	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Reportable New Information: Reporting RNI information to the sIRB for participating sites.	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Closing a Study: Reporting study closures to the sIRB	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:

[2] See SMART IRB's Guidance on Continuing Review Content Recommendations for Single IRB for recommendation on how to manage continuing review processes: https://smartirb.org/assets/files/CR-ContentRec-HSC-TableExtract.pdf

NIH Genomic Data Sharing (GDS) Studies: Submission of Institutional Certification (Consult with Genomic Program Administrator from the funding NIH Institute or Center to discuss the appropriate certification)	☐ Reviewing IRB ☐ Relying IRB Contact ☐ Lead Study Team ☐ Relying Study team ☐ Other:
Notes:	

UMass Chan MEDICAL SCHOOL

WORKSHEET: Considerations for Ceding IRB Review

NUMBER	DATE	PAGE
HRP-832	06/21/2022	1 of 1

The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite's IRB to serve as sIRB.[1] This worksheet may be used as a working document for the IRB staff or HRPP staff during the process of evaluation and may be saved until a determination has been made.

1 General Exclusion Criteria. The following are circumstances in which the institution will not cede IRB review for a multisite study.

☐	The institution does not maintain an OHRP-approved Federalwide Assurance (FWA)
☐	The institution is not engaged in the research activities.
☐	The study is determined to not involve Human Research.
☐	The study is determined to be Exempt, unless limited IRB review is required.

2 Considerations to Cede IRB Review to Commercial IRBs. The institution will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether to cede IRB review to a Commercial IRB (e.g. Advarra, WIRB, etc.). (At least one of the following considerations should be true)

☐	The project is commercially sponsored research
☐	The institution's IRB lacks sufficient expertise to conduct the IRB review
☐	The institution is the lead site of a multi-site project and the IRB lacks sufficient resources to provide oversight of the project
☐	There is an institutional conflict of interest or a single IRB mandate.
☐	Other relevant considerations: Click or tap here to enter text.

3 General Considerations for Ceding IRB Review to Other (Non-Commercial) IRBs. The following are additional considerations for evaluating the institution's willingness to cede IRB Review to an institution with a valid OHRP-approved Federalwide Assurance (FWA). (At least one of the following considerations should be true)

☐	Ceding IRB review is mandatory or optional. Comments: Click or tap here to enter text.
☐	The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study. Comments: Click or tap here to enter text.
☐	The reviewing IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns. (e.g. recruitment of socially or economically disenfranchised populations, local cultural mores or unique clinical circumstances) Comments: Click or tap here to enter text.
☐	Whether ceding IRB review could create or mitigate unique institutional risks, such as conflicts of interest Comments: Click or tap here to enter text.
☐	The financial implications of the decision—this includes: a) analysis of lost research opportunities (i.e. unwillingness of a sponsor or funder to allow local, non-ceded IRB review) b) the additional administrative time and costs associated with establishing authorization agreements Comments: Click or tap here to enter text.
☐	Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB Comments: Click or tap here to enter text.

[1] This document satisfies AAHRPP element I-9

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WORKSHEET: Considerations for Serving as the sIRB

NUMBER	DATE	PAGE
HRP-833	10/12/2021	1 of 1

The purpose of this worksheet is to provide information on considerations that the institution will evaluate when considering requests for the institution's IRB to serve as single IRB of record for multi-site or collaborative research. This worksheet may be used as a working document for the IRB staff or HRPP staff during the process of evaluation and may be saved until a determination has been made.

1	**General Exclusion Criteria.** The following are circumstances in which the institution might not serve as the sIRB for a multisite study.
☐	The institution is not listed as the prime awardee of federal grant ☐ The institution is not the prime awardee, the lead PI/site will be responsible for identifying the sIRB, such as an accredited IRB from a designated pSite or a commercial IRB Comments:Click or tap here to enter text.
☐	The study is not federally funded (and PI does not anticipate NIH or federal funding)
☐	The study is commercially sponsored
☐	The institution is not engaged in the research activities
☐	The study is determined to be Exempt
☐	The study is determined to not involve Human Research
2	**Study Considerations for Serving as sIRB for other institutions.** The institution will evaluate on a case-by-case basis serving as the sIRB. The following characteristics of the study will be evaluated to determine whether the institution and study team can adequately support and oversee the research.
☐	Complexity of protocol/risk level of study Comments: Click or tap here to enter text.
☐	Number, type and location of participating sites Comments: Click or tap here to enter text.
☐	Principal Investigator experience Comments: Click or tap here to enter text.
☐	Study team is adequately resourced and prepared to facilitate the multi-site study Comments: Click or tap here to enter text.
☐	Participating site(s) are adequately resourced and prepared to participate in the multi-site study Comments: Click or tap here to enter text.
☐	FDA regulated research activities are included in the study Comments: Click or tap here to enter text.
3	**Additional Considerations for Serving as sIRB.** The following are additional considerations for evaluating the Institution's ability to serve as the sIRB for a multisite study.
☐	The institution's IRB has sufficient expertise to conduct the IRB review Comments: Click or tap here to enter text.
☐	Institution's HRPP Stakeholders (Sponsored Projects Administration, Quality Assurance Program, etc.) have adequate resources to support or monitor the research activities Comments: Click or tap here to enter text.
☐	Ability for the institution to comply with the relevant local context considerations of the participating site(s) Comments: Click or tap here to enter text.
☐	Preference to outsource sIRB function to a commercial IRB Comments: Click or tap here to enter text.
☐	Other relevant considerations (e.g., vulnerable populations, conflicts of interest, costs, etc.) Comments: Click or tap here to enter text.