UMass Chan MEDICAL SCHOOL

Reliance on StrokeNet Central Institutional Review Board (CIRB)
(Updated 04/07/2023)

This guidance reviews the process for use of the StrokeNet CIRB for IRB review and oversight of research involving University of Massachusetts-Worcester (UMass) investigators. UMass maintains an Agreement with the StrokeNet National Coordinating Center CIRB at the University of Cincinnati which sets forth understandings, authority, and responsibilities of both institutions.

The University of Massachusetts-Worcester, in an effort to create a framework that will facilitate the review of multi-site research, has entered into an agreement with the StrokeNet CIRB whereby UMass may rely upon the StrokeNet CIRB for IRB review and approval of all StrokeNet research studies.

Although UMass Chan may rely upon the StrokeNet CIRB for review of specific research projects, the Institution is still responsible for the conduct of that research. Therefore, the UMass Chan IRB must be aware of and approve of the submission being sent to the StrokeNet CIRB through an administrative review. The StrokeNet CIRB will not review any UMass Chan study without written clearance from the UMass Chan IRB.

In order for the UMass Chan IRB to be able to extend this agreement to include a specific StrokeNet research study, all of the following conditions must apply:

The research is not phase 1 or first-in-human.

Research studies that **do NOT** meet the criteria above, including phase I or first-in-human trials, will be considered by the UMass Chan IRB on a case-by-case basis.

To initiate a request **to use StrokeNet CIRB for a study that <u>DOES NOT</u> meet the criteria in the table above**, email IRBreliance@umassmed.edu with a copy of the protocol, master consent, name of the UMass Chan PI, a description of how UMass Chan will be involved, and the name of the reviewing IRB. In addition, requests should include:

- A description of the investigational product, including how it is administered and its risks
- Proposed staffing and their experience with clinical research and Phase I trials
- The setting in which research procedures will occur
- Safety measures, including the plan for coordinating care for subjects in the absence of a 24-hour inpatient clinical trials unit. For example, explain which service subjects would be admitted to and how care will be coordinated and communicated between the clinical team and the study team.

To initiate a request to use StrokeNet CIRB for a study that <u>DOES</u> meet the criteria in the table above, <u>follow the approval process outlined below:</u>

<u>Approval Process</u>

In RMS eIRB:

- Initiate a multi-site relying study and select *UNIVERSITY OF CINCINNATI* as the external IRB.
- Verify that all study staff have completed CITI human subjects training, conflict of interest training, and if a clinical trial, GCP training.
- Upload the following Study-Wide Documents

  - CIRB approved master protocol
  - Investigator brochure (if applicable)
  - CIRB approved master consent and/or assent templates
  - Most current CIRB approval letter for study
- Upload the following Local Study Documents
  - Red-line copies of site-specific materials based on the CIRB-approved templates (e.g., draft consent form for use at UMass Chan)
  - UMass Chan HIPAA Authorization Stand Alone Form unless using a compound consent and authorization
  - Completed UMass Chan HRP-508 pSite Supplement and Communication Plan or comparable StrokeNet CIRB document
  - Any StrokeNet CIRB documents that require local HRPP/IRB review
  - Any other required UMass Chan approvals, which must be obtained before submitting to the StrokeNet CIRB, e.g.,
    - IBC registration or an explanation in the pSite form as to why IBC registration is not required
    - RSC approval or a copy of the *Questions for PI* documenting why RSC approval is not required
    - Gene and Cell Therapy Advisory Committee approval
    - COI approval and mitigation plan
- **The UMass Chan IRB does NOT need a copy of every study document approved by the StrokeNet CIRB** (e.g. study measurement documents, master recruitment materials, etc.).

Once all required documents have been uploaded into RMS eIRB, the PI has submitted the study, and the submission is in Pre-Review (and is no longer in Pre-Submission), the UMass Chan IRB will conduct an administrative review which includes the following activities:

- Confirming that the PI is not restricted as per the Investigator's Manual
- Reviewing the list of active study staff for current CITI training
- Reviewing the uploaded documents to assure that the study meets the conditions of the reliance agreement and local requirements
- Notifying the study team of any issues, including required changes to the consent form, through Pre-Review Clarifications Requested in eIRB
- Sending a written determination to the study team (via Add Comment) indicating that the application may be submitted to the StrokeNet CIRB

Once the administrative review is complete, the study team submits the corresponding application to the StrokeNet CIRB.

Once the StrokeNet CIRB has approved the study, the study team uploads the StrokeNet CIRB site approval letter and the final approved site-specific documents to Local Study Documents in RMS eIRB. The PI then submits the response.

Once the UMass Chan IRB verifies that the approved documents match the ones that were cleared for submission, it will acknowledge receipt.

PI POST-CIRB APPROVAL RESPONSIBILITIES:

Once StrokeNet CIRB approval is granted, the StrokeNet CIRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to the StrokeNet CIRB for review. However, the annual continuing review and other items listed below must also be submitted to the UMass Chan IRB through RMS eIRB.

Information to Also Submit to UMass Chan IRB	**RMS eIRB Function**
All changes in study staff, including changes in PI	Create Site Modification
Proposed changes to research injury compensation language or conflict of interest declarations	Create Site Modification
Unanticipated problems involving risks to subjects or others, reports of serious and/or continuing non-compliance, or IRB suspension or termination through RMS eIRB – when the information involves a UMass Chan subject or investigator	Report New Information
Notification of reapproval plus current site-specific materials, study-wide protocol, and IB if not already in RMS	Create Site Modification to upload current site-specific materials (e.g., consents)
	Update Study Materials to upload IRB study/site reapproval letter(s) and current study-wide protocol and IB
Closure of the study or UMass Chan as a site	Update Study Materials to upload closure letter

GENERAL TIPS

- Make sure you are working from the most recent instructions and from IRB approved templates.
- Read through the instructions in full before starting and prepare your materials offline.
- Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings.
- Make sure all ancillary reviews are complete.
- See eIRB Course 4: Multi-Site Relying Study Submission Process.

- **Use the UMass Chan research injury language from the UMass Chan HRP-502 Consent Document and HIPAA Authorization template.**
    - The UMass Chan boilerplate is consistent with the clinical trial agreement and the requirements of the Contracting Guide. The Contracting Guide is shared early in the contract process with the sponsor. The guide includes a Subject Injury Coverage Statement that outlines prohibited language. Study teams should only submit for administrative review redline consents that use the UMass Chan research injury language.
    - If the CTA does not include research injury coverage, you may be able to use the existing language in the consent template or the UMass Chan boilerplate for unfunded research.
- If the consent includes references to the European Economic Area's General Data Protection Regulation (GDPR), obtain administrative review from privacyandcompliance@umassmed.edu before submitting the draft in RMS eIRB. If you see references to data controllers or local data protection authorities in Europe, the consent likely requires review by Privacy and Compliance.
- All research happens under the auspices of the Medical School.
    - Ensure that the informed consent conveys that UMass Chan Medical School is conducting the research. When research at UMass Chan happens in a clinical setting, subjects may be seen at, e.g., UMass Memorial Medical Center.
    - When the consent or authorization discusses disclosure of protected health information, it must cite as applicable UMass Memorial Medical Center or UMass Memorial Health as the covered entities that hold the protected health information.
    - If the UMass Memorial logo appears, the UMass Chan logo must also be present.
- Remove any language in which subjects give up rights or ownership of samples or information collected about them.
    - The clinical trial agreement provides the sponsor a right of use, not ownership.
    - The consent can inform subjects that they will have no rights related to discoveries made as part of the research and that they will not share in any profits.
- Ensure that the consent does not overpromise coverage of possible related expenses. The following UMass Chan boilerplate is suggested for clinical research consents when the consent does not have similar language.

- *You or your insurance will not have to pay for tests and procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.*

  Drug name or agent will be provided to you at no cost; however, you or your insurance may be billed for the administration of this drug or agent.

- Do not overpromise confidentiality.
  - There are many groups at UMass Chan and UMMH that will necessarily have appropriate access to identifiable information about subjects, including through OnCore and EPIC.
  - The consent may not permit subjects to opt out of the study doctor notifying a subject's regular doctors about the subject's participation in the research. Due to safety concerns, UMass Chan does not permit these opt-outs. Study teams may remove or revise these opt-outs.
- When a HIPAA authorization is necessary, the consent must include a complete HIPAA authorization, or the study team can add a UMass Chan HIPAA Authorization Stand Alone Form. See *HRP-330 – WORKSHEET – HIPAA Authorization* to evaluate whether a consent is a compound consent and authorization.
- A HIPAA authorization must permit disclosure to UMass Chan and UMMH. The following UMass Chan boilerplate is suggested when the consent does not have similar language.
  - *The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing, and compliance offices*
- Consents must provide a 24-hour contact number for studies that are greater than minimal risk
- If the research includes pregnancy testing of minors, add the corresponding language from the UMass Chan consent template:
  - *If you could get pregnant, you will have pregnancy testing as part of this study. Only you will be told the results. If you are a minor and are found to be pregnant, we will talk to you about getting appropriate healthcare and the support of an adult. A positive pregnancy test means that you cannot be in this study. Because you will be asked to leave the study, your parents may find out that you*

	are pregnant. If you are uncomfortable with pregnancy testing, then you should not be in this study.

For IRB Office Use Only

Document Version History:

Date	Status
02/10/2022	Initial Post
04/06/2022	Modified to add Example of Multi-site Relying Study in eIRB – what to enter into UMass Chan RMS eIRB when starting a study that involves SMART IRB (including Advarra), NEALS IRB, Strokenet IRB, or Other IRB
07/13/22	Minor Revisions
10/11/22	Revised to update study/site closure process
03/29/2023	Revised to clarify how to get started, added Gene Therapy Committee, and updated links

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Date: Monday, April 4, 2022 5:31:23 PM

Print Close

STUDY00000146

View: SF: Basic Study Information

Basic Study Information

1. * Title of study:

Example of Multi-site Relying Study - what to enter into UMass Chan RMS eIRB when starting a study that involves SMART IRB (including Advarra), NEALS IRB, Strokenet IRB or Other IRB
- Model for document Management

2. * Short title:

Example of Multi-site Relying Study - what to enter into UMass Chan RMS eIRB when starting a study that involves SMART IRB (including Advarra), NEALS IRB, Strokenet IRB or Other IRB

3. * Brief description:

Example of Multi-site Relying Study
- what to enter into UMass Chan RMS eIRB when starting a study that involves SMART IRB (including Advarra), NEALS IRB, Strokenet IRB or Other IRB
- Model for document Management

4. * What kind of study is this?

Multi-site or Collaborative study

5. * Will an external IRB act as the IRB of record for this study?

● **Yes** ○ No

6. Lead principal investigator:

7. * Local principal investigator:

Please note *that unless/until UMass Chan is part of the Huron IRB Exchange, only UMass Chan personnel will appear in the Lead Principal Investigator selection box. Therefore, please leave this box blank.*

Heather Tessier

8. * Does the local principal investigator have a financial interest related to this research?

● **Yes** ○ No

9. Attach the protocol:

	Document	Category	Date Modified	Document History
View	External IRB Approved Master Protocol v1.2_Dec.12.2021.pdf(0.01)	IRB Protocol	3/23/2022	History

NOTICE

You have indicated in this application that there are study personnel who have a financial interest related to the research of this study. If you have not already done so, it is necessary that you contact coi@umassmed.edu to complete the necessary disclosure process. They are responsible for evaluating the conflict and, in conjunction with the PI, developing an appropriate mitigation plan.

This should be done immediately, **before** this application is submitted to the IRB for review.

Please note that the IRB will conduct the pre-review on this submission; however, it will **not** be able to process the application further than the pre-review without the approval letter from the COI committee. If the initial application is submitted without the approval letter, the submission **will** be returned to you with a pre-review clarification request to upload the approval letter. Once the letter is received, the application may proceed through the review process as the IRB has final authority to determine whether the conflict and its management plan allow the proposed research to meet criteria for approval.

Any questions regarding this process, the turnaround time, or any other questions may be directed to coi@umassmed.edu. Once the COI committee has reviewed and approved the mitigation plan, you will be required to upload that letter into eIRB.

Basic Local Site Information

1. * **Brief description of activities this site will perform:** (enter "ALL" if this site will perform all procedures in the protocol)
   In a few words, summarize your activities as a participating site in this multi-site or collaborative research study. If your site will be conducting all portions of the research, type “ALL.” If your site will be conducting only certain portions or the research, include a summary.

   For example:

   This study includes both adults and children as research subjects; however, at this site, we will include only children. Therefore, we will conduct only those procedures related to children.

External IRB

1. * **External IRB:**
   ADVARRA, INC.(for IRB)

2. **External study ID:**
   External IRB Study ID # goes here

3. **Specify the reason the study should be reviewed by an external IRB:**
   If this is a multi-site study, this could be because of the federal sIRB mandate, a sponsor's requirements, or institutional requirements.

   If you are not sure about the reason, you can leave this field blank.

STUDY00000146

View: SF: Study Funding Sources (not integrated with Grants)

Study Funding Sources

1. Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
NIH-NATIONAL INSTITUTES OF HEALTH			

2. * Department / Division / Institute Responsible for the Study:

Pediatrics

3. Additional Departments involved in the Study:

Organization	Parent Organization
Obstetrics & Gynecology	Obstetrics & Gynecology

Additional Local Funding Sources

1. Identify each organization supplying funding for the local site:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments

There are no items to display

On this page, identify all external funding sources that are providing funding to the local (UMass) site only, such as government agencies and local foundations. The main purpose is to help the IRB identify all studies associated with particular grants.

If funding comes from a specific internal UMass funding program, also identify that funding source.

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
Crystal Davis	Research Coordinator	no	yes	noreply@huronclick.com	508/856-5291

2. External team member information:

Name	Description
There are no items to display	

Please note: Form HRP-270 is NO LONGER REQUIRED.

Study Team Member Training Information:

Name	Date Report Completed	Date Report Expired	Curriculum
Heather Tessier	5/4/2020 7/10/2019 4/1/2020	5/4/2023 7/9/2022 3/31/2024	Human Research Good Clinical Practice Course for Clinical Trials Involving Drugs (ICH focus) Conflict of Interest mini-course
Crystal Davis	10/21/2019 5/1/2020 10/1/2020 11/8/2016	10/20/2022 5/1/2023 9/30/2024	Human Research Good Clinical Practice Course for Clinical Trials Involving Drugs (ICH focus) Conflict of Interest mini-course Responsible Conduct of Research

***Please note** that current CITI Conflict of Interest mini course training is required for all Local Study Team Members.*

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**

   ● **Yes** ○ No

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**

   ● **Yes** ○ No

3. * **Check 'Yes' if ANY of the below statements about this study are true. Otherwise check 'No'. Please see** OCRs OnCore Resources page **for more information.**

   ● **Yes** ○ No

- The protocol has an external funding source.
- The protocol plans to use or purchases any service from UMass Memorial Health Care or any of its affiliates, including UMass Memorial Medical Group.
- The protocol has or requires registration on ClinicalTrials.gov (has an NCT number).
- The protocol plans to use the UMass Center for Clinical and Translational Science (UMCCTS)Clinical Research Center (CRC) resources and or services.
- The protocol plans to use UMMS services that involve billable institutional fees (such as the UMass IRB or Investigational Drug Services).
- The protocol will involve the use of Epic or intends to use Epic for recruitment.
- The protocol plans to utilize UMCCTS' Conquering Diseases platform for recruitment.

Local Research Locations

1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

	Location	Contact	Phone	Email
View	ACC BUILDING-CLINICAL RESEARCH CENTER	NA	NA	NA
View	CLINTON HOSPITAL	NA	NA	NA
View	MARLBOROUGH HOSPITAL	NA	NA	NA
View	UMMMC-MEMORIAL CAMPUS	NA	NA	NA

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

Generic Name	Brand Name	Attachment Name
Investigational Drug Multi-site Relying Study		MSRelying Investigational Drug_IB_v3.0 01.Dec.2021.pdf

2. * Will the study be conducted under any IND numbers?

● **Yes** ○ No

3. * Identify each IND:

IND Number	IND Holder	Other Holder
IND-5689748	Sponsor	

4. Attach files: (such as IND or other information that was not attached for a specific drug)

Document	Category	Date Modified	Document History
There are no items to display			

Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

Device	Humanitarian Use Device	Attachment Name
Investigational Device	no	

2. * **Device exemptions applicable to this study:** IDE

3. * **Identify each IDE or HDE number:**

IDE / HDE Number	IDE / HDE Holder	Other Holder
IDE 327822541	Sponsor	

4. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

Document	Category	Date Modified	Document History
There are no items to display			

Study-Related Documents

1. Consent form templates: (include an HHS-approved sample consent document, if applicable)

	Document	Category	Date Modified	Document History
View	External IRB Approved Master_Template_Consent_v1_Dec.21.21.docx(0.01)	Consent Form	4/4/2022	History
View	External IRB Approved Master_Template_Assent_v1_Dec.21.21.docx(0.01)	Consent Form	4/4/2022	History
View	External IRB Approved Master_Pregnant Partner_form.V1_Dec.12.21.docx(0.01)	Consent Form	4/4/2022	History

2. Recruitment material templates: (add templates for all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History

There are no items to display

3. Other attachments:

	Document	Category	Date Modified	Document History
View	External IRB most current approval letter for study 01.21.22.pdf(0.01)	Approval Letters	3/23/2022	History

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable)

	Document	Category	Date Modified	Document History
View	MSRely_REDLINED_Consent_form with UMass Specific language.V1_Jan.3.22.docx(0.01)	Consent Form	4/4/2022	History
View	MSRely_REDLINED_Assent_form withUMass Specific language.V1_Jan.6.2022.docx(0.01)	Consent Form	4/4/2022	History
View	MSRely_REDLINED_Pregnant Partner_form withUMass Specific language.V1_12.1.21.docx(0.01)	Consent Form	4/4/2022	History

Please note that once the REDLINED versions of the Consent/Assent/Pregnant Partner forms are approved by the External IRB, the APPROVED documents will need to be uploaded **on top of** the previous redlined versions.

DO NOT DELETE the redlined versions. Please see the following Job Aid on the eIRB Sharepoint site for additional guidance about uploading documents to RMS eIRB:

eIRB JobAid File management in eIRB v1.0 10-20-2021 final.pdf

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History

There are no items to display

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY00000146 UMassChan specific COI committee letter Jan.31.2022.pdf(0.01)	Approval Letters	4/4/2022	History
View	STUDY00000146 UMassChan Rad Safety approval letter 1.30.22.pdf(0.01)	Approval Letters	4/4/2022	History
View	STUDY00000146 UMassChan Rad Safety Questions for PI document 1.30.22.pdf(0.01)	Approval Letters	4/4/2022	History

Please note: once the following documents have been received, they should be uploaded as NEW documents to this section:

Site Specific Approval Letter for UMass Chan from the External IRB

- **Categorize** as *'Approval Letter'*
- EXAMPLE: *External IRB UMass Chan Site approval Letter 03Mar2022.pdf*

FULLY EXECUTED Reliance Agreement

- **Categorize** as *'Other'*
- EXAMPLE: *(###)External IRB Name-UMass Worcester-PI name(s).pdf*

Please see the associated SOP: (https://www.umassmed.edu/ccts/irb/reliance-agreements/) for additional details.

	Document	Category	Date Modified	Document History
View	STUDY00000146 UMassChan IBC Approval letter Jan.31.2022.pdf(0.01)	Approval Letters	4/4/2022	History
View	MSRely study UMassChan HIPAA Auth form-if not using ICF with HIPAA-v1.01.23.22.docx(0.01)	HIPAA	4/4/2022	History
View	MSRelying UMassChan HRP508 P-site Supplement OR comparable doc from external IRB V2_Jan.12.22.docx(0.01)	pSite Supplement/Local Context Form	3/24/2022	History

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms