Reliance on WCG IRB
(Updated 11/19/2025)

This guidance reviews the process for use of WCG IRB (e.g., Western IRB or WIRB) for IRB review and oversight of research involving University of Massachusetts-Worcester investigators. UMass-Worcester maintains an Agreement for Services with WCG which sets forth understandings, authority, and responsibilities of both institutions.

The University of Massachusetts-Worcester, in an effort to create a framework that facilitates the review of industry-sponsored multicenter research, has an agreement with WCG IRB whereby the UMass Chan IRB may rely upon WCG IRB for IRB review and approval.

Although UMass Chan may rely upon WCG 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 WCG through a local context review. WCG 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 research study all of the following conditions must apply:

The sponsor of the research is a for-profit entity/company.
The project was designed and written by the sponsor.
The sponsor holds all INDs/IDEs for the project.
The research is a multicenter project.
The research is phase 2 or higher, or is a phase 1 or first-in-human trial that is managed by the Cancer Research Office.
The research is currently reviewed by WCG for other sites.

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

To initiate a request to use WCG for a study that does NOT 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, and description of how UMass Chan will be involved. 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 WCG for a study that DOES meet the criteria in the table above, simply complete the following Approval Process:

Approval Process

If the study meets the criteria above or UMass Chan has agreed to cede review to WCG:

In RMS eIRB:

- Initiate a multi-site relying study and select *WCG IRB (for IRB)* as the external IRB (Job Aid may be found HERE).
- 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:
    - WCG IRB approved master protocol
    - Investigator brochure (if applicable)
    - IRB approved master consent and/or assent templates
    - Most current WCG IRB approval letter for study (this is the WCG approval for the protocol and any study-wide materials such as consent form templates)
- Upload the following Local Study Documents
    - Red-line copies of site-specific materials based on the WCG IRB-approved templates (e.g., draft consent form for use at UMass Chan)
        - Follow the pointers in Consent Form Tips
    - UMass Chan HIPAA Authorization Stand Alone Form unless using a compound consent and authorization
    - Completed UMass Chan HRP-508 TMEPLATE pSite Supplement and Communication Plan
    - Copy of PI's medical license
    - Current CV for PI
    - Any other required UMass Chan approvals, which must be obtained before submitting to WCG IRB, 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
    - For investigational drug studies, a copy of the PI's Mass Controlled Substances Researcher Registration (Type: Researcher, Schedule: IND)
- **The UMass Chan IRB does NOT need a copy of every study document approved by WCG** (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 WCG IRB

Once the administrative review is complete, the study team should coordinate with the sponsor regarding the submission of the clearance letter and cleared documents to WCG through Connexus.

Once WCG approves UMass Chan as a site:

- Add the WCG liaisons to the workspace in Connexus as **Site Participants** with **Access Level: Manager** and **Invitee Represents: Institution**
    - WCG liaisons: allison.blodgett@umassmed.edu & christopher.phaiah@umassmed.edu
- Update the RMS eIRB application with the site-specific materials and WCG IRB site approval letter
- 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-WCG APPROVAL RESPONSIBILITIES:

If the PI is conducting an investigational drug study and has not been previously approved by WCG for a research study, WCG may contact you to conduct a site visit (at no cost to you).

Once WCG IRB approval is granted, WCG IRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to WCG 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

See the following pages for more information:

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.
- Request a Connexus account if you do not have one (https://identity-connexus.wcgirb.com/Account/SignIn)
- Ask the sponsor, clientcare@wcgclinical.com, or UMass Chan-WIRB Account Manager Glori Schmeckpeper (gschmeckpeper@wcgclinical.com) to invite you to the protocol in Connexus and to send you the WCG approved template consent(s).
- See eIRB Course 4: Multi-Site Relying Study Submission Process.
- See STUDY00000144 Example WCG IRB Multi-site Relying Drug&Device Study 06Apr2022.pdf.

Administrative Review and Consent Form Tips

- **Use the UMass Chan research injury language from the UMass Chan consent form 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 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 UMass Chan Medical School, 55 Lake Ave North, Worcester Massachusetts 01655 is listed in the WCG application as the name of the Company/Institution/Organization and as the first Physical address where subjects will be seen or where research will take place. A hospital address can be entered as an additional location if applicable.
    - Ensure that the informed consent conveys that UMass Chan Medical 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.*

      <u>Drug name or agent</u> 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 Stand Alone Authorization 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.*

PREPARING THE WCG INITIAL REVIEW SUBMISSION FORM:

Where the WCG form asks for:	**Choose/Indicate:**
Destination Institutional Review Board (IRB)	Western IRB (WIRB) even if the sponsor is working with a different IRB in the list
Submission Type	Site being added to existing protocol or change of principal investigator
Federal Funding	There is nothing to attach. UMass Chan has a Master Service Agreement on file with WCG.
Clinical Pharmacology Unit Services, (CPUS)	No, this is not a submission to WIRB CPU Service
IRB Determinations	NO – WCG may not issue an exemption YES – WCG may consider the research to be minimal risk
Principal Investigator (PI) Information/ Company/Institution/Organization	UMass Chan Medical School – All research at our site happens under the auspices of the Medical School
Translated Documents	Confirm with the sponsor that they will cover the cost of WCG's translation service before checking yes; if you do not have prior permission from the sponsor, you will be responsible for the cost of translation
Institutional Services	Yes, UMass Chan has a Master Services Agreement; name of organization is University of Massachusetts Medical School; WIRB Institution #81969
Principal Investigator (PI) Licensure Are all medical licenses on file with the IRB	NO – this is not a UMass Chan IRB function; you must provide a copy of the PI's medical license in RMS eIRB and in Connexus
The following questions apply to all research locations	NO – Our communities have a positive attitude NO – UMass Chan is covered by an MSA NO – There are no state or local laws to mention
Research Team Information	The number and type of personnel must match RMS eIRB
Research Team Training	Although WCG may permit options other than CITI, UMass Chan CITI requirements still apply
Legally Authorized Representatives	Institutional Policy – You must follow *HRP-013 Legally Authorized Representatives (LARs), Children and Guardians*

How will you verify who constitutes an LAR in the legal jurisdiction where the research is conducted?	See the Library in RMS eIRB or at the IRB SharePoint site https://umassmed.sharepoint.com/sites/RMS/IRB
Consent Form Processing Does your organization have pre-approved consent language on file with the IRB	YES – There is required research injury compensation language Start from the WCG IRB-approved template so that you can choose this method and option: *The IRB should review the attached forms that have the pre-approved consent language tracked (red-lined) onto the IRB-approved template.* Ensure the consent itself or the form provides 24-hour contact information unless the study is observational
HIPAA Waiver of Authorization	A partial or full waiver of authorization will come with the usual requirement for the Principal Investigator to complete the required Accounting of Disclosures https://www.umassmed.edu/ccts/research-resources/privacy-and-security/
Methods to Maintain Confidentiality	You must adhere to UMMS policy regarding data storage and encryption https://www.umassmed.edu/it/security/
Recruitment Bonuses	See *HRP-103 – Investigator Manual, page 11, Investigator Obligations* 14 and 15 before answering this question The Investigator Manual is available in the Library in RMS eIRB or at the IRB SharePoint site https://umassmed.sharepoint.com/sites/RMS/IRB
Special Instructions	If you require permission to use short forms to enroll speakers of languages other than English, add this information here

WCG CONTACT INFORMATION:

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For IRB Office Use Only

Document Version History:

Date	Status
02/10/2022	Initial Post
04/06/2022	Addition of Example of WCG IRB Multi-site Relying Study in RMS eIRB - Model for File Management
07/13/2022	Minor revisions
10/11/2022	Revised to update study/site closure process
3/15/2023	Revised to clarify how to get started, added Gene Therapy Committee, and updated links
3/28/2023	Revised several UMass Chan eIRB SharePoint site links so that they point at the folders the documents are in, not at the documents themselves. This will allow those documents to be updated as needed without having to update these instructions.
11/19/2025	Permit use of WCG for phase 1 and first-in-human trials that are managed by the Cancer Research Office; re-described administrative review as local context review; updated WCG contact information; updated links