This document includes:

Reliance on an External Institutional Review Board
That is Not Under the SMART IRB Master Reliance Agreement
(Updated 02/10/2022)

Multi-Site Relying not under SMART IRB

Extending UMass Chan Institutional Review Board Oversight to an External Participating Site or Collaborator That is Not Under the SMART IRB Master Reliance Agreement
(Updated 02/10/2022)

Multi-Site Reviewing & pSites are not under SMART IRB

Reliance on an External Institutional Review Board
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(Updated 02/10/2022)

HRP-101 Human Research Protection Program and *HRP-832 WORKSHEET: Considerations for Ceding IRB Review* outline when UMass Chan may rely upon IRBs of another institution or organization.

Always check https://smartirb.org/participating-institutions/ to see if the reviewing IRB is a SMART IRB participating site, which includes Advarra, several other independent IRBs, and more than 900 institutions. If the reviewing IRB is a SMART IRB participating site – stop – and follow the SMART IRB – UMass Chan Multi-Site Relying instructions instead.

To request that UMass Chan establish a reliance agreement and cede IRB review to an external IRB that is not part of SMART IRB, contact IRBreliance@umassmed.edu with as much of the following as possible:

- Name of the UMass Chan PI
- Name of the reviewing IRB
- Confirmation that the reviewing IRB is willing to review for UMass Chan
- Copy of the protocol
- Copy of the master consent
- Description of how UMass Chan personnel are involved in the research
- HRP-508 pSite Supplement and Communication Plan or comparable document from the reviewing IRB

Requests for phase I or first-in-human trials should also 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.

If UMass Chan agrees to rely, follow the approval process outlined below. The UMass Chan IRB will ensure that the reviewing IRB is available in RMS eIRB.

Approval Process

If the UMass Chan IRB has agreed to cede review to the external IRB:

In RMS eIRB:

- Initiate a multi-site relying study and select the reviewing institution as the external IRB.
    - Use the percent symbol (%) to search for the name of the reviewing 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
    - IRB approved master protocol
    - Most current IRB approval letter for study
    - And as applicable
        - Investigator brochure
        - IRB approved consent form template
- Upload the following Local Study Documents
    - Completed UMass Chan HRP-508 pSite Supplement and Communication Plan or comparable document from the reviewing IRB
    - Any documents required by the reviewing IRB that require local HRPP/IRB review
    - Any other required UMass Chan approvals, which must be obtained before submitting to the reviewing 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
        - COI approval and mitigation plan
    - And as applicable
        - Red-line copies of site-specific materials based on the IRB-approved templates (e.g., draft consent form for use at UMass Chan)
        - UMass Chan HIPAA Research Authorization Form unless using a compound consent and authorization
- The UMass Chan IRB does not need a copy of every study document approved by the reviewing IRB.
- The UMass Chan IRB does need to know how the reliance will be documented
    - Most academic IRBs will provide their required templates; if there is none, ask the UMass Chan IRB for its IRB authorization agreement.

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 human subjects research 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 confirmation (via Add Comment) to the study team indicating that the application may be submitted to the reviewing IRB

Once the reviewing IRB has approved the study, the study team uploads the IRB 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-IRB APPROVAL RESPONSIBILITIES:

Once IRB approval is granted, the reviewing IRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to the reviewing IRB for review. However, the annual continuing review and other items listed below must also be submitted to 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 IRB reapproval letter and current site-specific materials (e.g., consents)
	Update Study Materials to upload current study-wide protocol and IB
Closure of the study or UMass Chan as a site	Create Site Modification

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 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 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 stand-alone HIPAA authorization. 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.*

Extending UMass Chan Institutional Review Board Oversight to an External Participating Site or Collaborator That is Not Under the SMART IRB Master Reliance Agreement
(Updated 02/10/2022)

HRP-101 Human Research Protection Program and *HRP-833 WORKSHEET: Considerations for Serving as the sIRB* outline when the UMass Chan IRB may serve as IRB of record for external collaborators or sites.

Always check https://smartirb.org/participating-institutions/ to see if the participating site is a SMART IRB participating site, which more than 900 institutions. If the participating site is a SMART IRB participating site, stop, and follow the SMART IRB – UMass Chan Multi-Site Reviewing instructions instead.

Requests to extend UMass Chan IRB oversight to an external participating site or collaborator will be considered by the UMass Chan IRB on a case-by-case basis.

Contact the UMass Chan IRB at IRBReliance@umassmed.edu before submitting a funded grant or proposal that involves UMass Chan reviewing for external participating sites or collaborators. A discussion is necessary to determine whether UMass Chan is able to serve as the single IRB.

UMass Chan investigators should be aware that they will be assuming responsibility to function as the lead site, that they will be responsible for all communication and IRB submissions from relying collaborators/sites, and that relying collaborators/sites will not have access to RMS eIRB.

When UMass Chan serves as the IRB of record, it is able to issue HIPAA waivers for relying sites.

UMass Chan IRB is unlikely to serve as IRB of record for studies that are greater than minimal risk.

To request that the UMass Chan IRB serve as the IRB of record for a participating site or collaborator, contact IRBreliance@umassmed.edu with as much of the following as possible:

- Name of the UMass Chan PI
- Study ID (if study is already in process or approved)
- Name of relying institution(s) and participating site (pSite) PI
- Whether the participating site PI has confirmed with their IRB/HRPP that it is willing to rely on the UMass Chan IRB
- Description of how participating site personnel are involved in the research
- HRP-508 pSite Supplement and Communication Plan (one per external site)

Approval Process

If UMass Chan has agreed to serve as the single IRB:

The participating site PI must still complete its local HRPP/IRB process for relying on UMass Chan for IRB oversight.

The UMass Chan IRB Office will work with the UMass Chan study team on the reliance documentation. We will provide you with our template IRB Authorization Agreement but can accommodate participating sites that require different documentation.

The UMass Chan study team will need to prepare the usual study-wide materials. The main investigator study plan will need to address the multi-site/collaborative nature of the research.

In addition, the UMass Chan study team will need to prepare the materials listed below, which pertain to the pSite:

- A completed HRP-215 Non-UMass Personnel Form for all study staff who are not in RMS eIRB
    - Do not upload CITI training records in RMS eIRB. External collaborators are responsible to complete their home institution's training. The UMass Chan PI is responsible to ensure that their study staff are appropriately trained.
- A separate HRP-508 pSite Supplement and Communication Plan form for each participating site – The UMass Chan IRB uses this form in part to obtain information from the relying HRPP/IRB that is needed to ensure that local context requirements are met
- Any participating site site-specific documents (e.g., consent form, recruitment materials) that are unique to the participating site
    - If there is a single consent or other document that encompasses all pSites, this should be submitted as part of the UMass Chan study-wide materials

If UMass Chan has agreed to serve as the single IRB for a new study, the PI will submit the study as a multi-site or collaborative study in RMS eIRB.

If UMass Chan has agreed to serve as the single IRB for an existing single-site study, the PI will submit a modification to change the study to multi-site/collaborative.

For the RMS eIRB submission:

- The first RMS eIRB approval process will be for the master templates, study-wide materials, UMass Chan specific materials, and completed HRP-215 Non-UMass Personnel Form.
- Participating sites will have their own pSite pages. For a new study, pSite page(s) can be added during the initial study creation process. For an existing single-site study modification, pSite page(s) cannot be added until the modification is approved. In each case, "Add Participating Sites" is available only for multi-site or collaborative studies. The function is not available to single site studies.
- Once the study or modification is approved, the PI will then upload the site-specific documents to the pSite page(s) and submit each participating site in RMS eIRB for activation. The submission will include that site's HRP-508 pSite Supplement and Communication Plan and any site-specific documents.
- Once the reliance agreement is finalized and the site is activated in RMS eIRB, the participating site will need to complete its local administrative review process.
- See eIRB Course 3: Multi-Site Reviewing Study Submission process

PI POST-IRB APPROVAL RESPONSIBILITIES:

Once IRB approval is granted and a participating (pSite) is activated, the UMass Chan IRB will maintain oversight of the study. The UMass Chan PI is responsible to submit RMS eIRB submissions (e.g., amendments, continuing reviews, reportable events) that are inclusive of the participating sites.

The UMass Chan PI is also responsible to use Create Site Modification to notify the UMass Chan IRB if a site is being closed independently of the entire study.