UMass Chan MEDICAL SCHOOL

This document includes:

Extending UMass Chan Institutional Review Board Oversight to an External Participating Site or Collaborator Under the SMART IRB Master Reliance Agreement
(Updated 02/10/2022)

Multi-Site Reviewing & pSite is part of 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 & pSite is not part of SMART IRB

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SMART IRB is not an IRB.

SMART IRB is an initiative developed under an award from the National Center for Advancing Translational Sciences ("NCATS") of the National Institute of Health ("NIH") to support single IRB (sIRB) review. SMART IRB includes:

- A master IRB reliance agreement that permits eligible institutions that join it ("Participating Institutions") to cede review of human subjects research to other Participating Institutions' IRBs
- A set of standard operating procedures (SOPs) to guide implementation of the reliance relationship among Participating Institutions
- An optional centralized online system to support sign-on, reliance determinations, and harmonization

UMass Chan is a signatory to SMART IRB.

Click here (https://smartirb.org/participating-institutions/) to see all SMART IRB participating sites, which includes more than 900 institutions.

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 sites or collaborators, also referred to as participating sites or pSites.

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 *Letter of Acknowledgment and Selection of Terms that are Flexible under the SMART IRB 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.

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.

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- 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)

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- 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.
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