This document includes:

Reliance on an External Institutional Review Board Under the SMART IRB Master Reliance Agreement
(Updated 10/12/2022)

Multi-Site Relying under SMART IRB

Extending UMass Chan Institutional Review Board Oversight to an External Participating Site or Collaborator Under the SMART IRB Master Reliance Agreement
(Updated 10/12/2022)

Multi-Site Reviewing with pSites under SMART IRB

Reliance on an External Institutional Review Board Under the SMART IRB Master Reliance Agreement
(Updated 10/12/2022)

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, including Advarra and several other independent IRBs.

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 research is not phase 1 or first-in-human.
The IRB at the SMART IRB participating site is willing to review for UMass Chan.
The research does not require a HIPAA waiver, or the reviewing IRB is willing to issue the waiver for UMass Chan.

If you wish to rely on an external IRB that is part of SMART IRB and your study meets the criteria above, follow the approval process outlined below.

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, 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.

Approval Process

If the study meets the criteria above or 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
    - If you cannot find the institution, contact 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. Explain that you are seeking to rely on the reviewing IRB through SMART IRB and are requesting that the reviewing IRB be added in RMS eIRB.
- 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:

- For independent IRBs such as Advarra, UMass Chan requires the use of the SMART IRB Online Reliance System
- Most academic IRBs will provide their required templates; if there is none, ask the UMass Chan IRB for its template *Letter of Acknowledgment and Selection of Terms that are Flexible under the SMART IRB Agreement*
- If the SMART IRB reliance for a specific study will be documented in the SMART IRB Online Reliance System, a member of the UMass Chan study team will need a user account. Visit https://smartirb.org/reliance/ to request investigator access. Negotiate with the lead site who will initiate the reliance request in the system.

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 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-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 current site-specific materials (e.g., consents)
	Update Study Materials to upload IRB study reapproval letter 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.

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 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.* *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 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.*

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

UMass Chan MEDICAL SCHOOL

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

UMass Chan MEDICAL SCHOOL

Extending UMass Chan Institutional Review Board Oversight to an External Participating Site or Collaborator Under the SMART IRB Master Reliance Agreement

(Updated 10/12/2022)

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 Update Study Details to notify the UMass Chan IRB if a site is being closed independently of the entire study.

UMass Chan MEDICAL SCHOOL

For IRB Office Use Only

Document Version History:

Date	Status
02/10/2022	Initial Post
07/13/2022	Minor revisions
10/11/2022	Revised to update study/site closure process

UMass Chan MEDICAL SCHOOL

Date: Friday, March 25, 2022 3:48:57 PM

Print Close

STUDY00000140

View: SF: Basic Study Information

Basic Study Information

1. * **Title of study:**
   Multi-Site Reviewing study WITH a p-site (participating site) (UMass Chan is the IRB of Record) – Model Study for File Management

2. * **Short title:**
   Multi-Site Reviewing study WITH a p-site (participating site) (UMass Chan is the IRB of Record) – Model Study for File Management

3. * **Brief description:**
   Multi-Site Reviewing study WITH a p-site (participating site) (UMass Chan is the IRB of Record) – Model Study for File 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. * **Will your IRB act as the single IRB of record for other participating sites?**
   ● **Yes** ○ No

7. * **Local principal investigator:**
   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	STUDY00000140-ISP-Info for UMass Chan & common across sites_v1_3.12.22.docx(0.01)	IRB Protocol	3/22/2022	History

	Document	Category	Date Modified	Document History
View	Multi-site Study with p-site Master Protocol v2.0 03.14.2022.docx(0.01)	IRB Protocol	3/15/2022	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.

STUDY00000140

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	U67HL2335618S4		Multi-site Rev with p-site NIH Grant document v2.1 01.52.22.docx

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

Emergency Medicine

3. Additional Departments involved in the Study:

Organization	Parent Organization
Family Med & Community Health	Family Med & Comm Health

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
Allison Blodgett	Co-Investigator Project Director/Manager	no	yes	noreply@huronclick.com	508/856-4271
Andrea Robinson	Research Coordinator	no	yes	noreply@huronclick.com	

2. External team member information:

Name	Description
Do NOT upload HRP-215 for P-SITES here! Upload 1 HRP-215 per p-site on p-site page(0.03)	

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
Allison Blodgett	1/28/2021 8/22/2018	1/28/2024 8/21/2022	Human Research Conflict of Interest mini-course
Andrea Robinson	5/4/2020 10/15/2020	5/4/2023 10/15/2023	Human Research Good Clinical Practice Course for Clinical Trials Involving Drugs (ICH focus)

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	Beaumont Rehabilitation and Skilled Nursing Centers at Worcester			
View	HEALTH ALLIANCE	NA	NA	NA
View	UMMMC-UNIVERSITY 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
Acetaminophen		acetaminophen package insert v3.0 01.Dec.2021.pdf
Investigational Drug Multi-site reviewing study with p-site		MSReviewing+p-site InvestigationalDrug_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-659632	Investigator	

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

	Document	Category	Date Modified	Document History
View	MSReviewing+p-site Investigational drug IND FDA_letter_01.Nov.2021.pdf(0.01)	Drug Attachment	3/15/2022	History

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 (Multi-site Reviewing study with p-site)	no	Investigational device IFU_v3.1 01Dec2021 MSRev p-site study.pdf

2. * Device exemptions applicable to this study: IDE

3. * Identify each IDE or HDE number:

IDE / HDE Number	IDE / HDE Holder	Other Holder
IDE-12237789	Investigator	

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

	Document	Category	Date Modified	Document History
View	Investigational device IDE FDA_letter_01.Nov.2021 MSRev psite study.pdf(0.01)	Device Attachment	3/15/2022	History

Study-Related Documents

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

	Document	Category	Date Modified	Document History
View	MSRev+p-site_Consent_MasterTemplate_v3_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	MSRev+p-site_Consent_Spanish_Master_Template_v3 Dec.5.22.docx(0.01)	Consent Form	3/15/2022	History
View	MSRev+p-site Master_Fact Sheet_template_v.3.0_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	MSRev+p-site Master_Fact Sheet_Spanish_template_v.3.0_Dec 5 2021.docx(0.01)	Consent Form	3/15/2022	History
View	MSRev+p-site Assent_MasterTemplate_v3_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	MSRev+p-site Master_Assent_Spanish_v1.1_Dec.21.2021.docx(0.01)	Consent Form	3/15/2022	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
View	MSRev+p-site recruitment_Magnet design template V1.0.March.14.2022.docx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site recruitment_Magnet template spanish.V1.0.March.14.2022.docx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site study-wide_Website_v3_Jan.12.2022.docx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site study recruitment Flyer_template_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site study recruitment Flyer_Spanish_template_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site Master_SCRIPT_telephone_recruitment_v1.0_Jan.12.2022.docx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site Master_SCRIPT_telephone_recruitment_SPANISH_v1.0_Jan.12.2022.docx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site Master_Recruitment_Presentation_v2.0_Nov.22.2021.pptx(0.01)	Recruitment Materials	3/15/2022	History
View	MSRev+p-site Master_Recruitment_Presen_Spanish_v2.0_Nov.22.202.pptx(0.01)	Recruitment Materials	3/15/2022	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY00000140 Study Wide DCF REDCapForms_v3.1_Jan.03.2022.docx(0.01)	Data Collection Forms	3/22/2022	History
View	STUDY00000140 Study Wide eCaseReportForms_v3_Dec 22.2021.pdf(0.01)	Data Collection Forms	3/22/2022	History

	Document	Category	Date Modified	Document History
View	STUDY00000140 StudyWideTEMPLATE Data_Collection_Sheet_Subj ID key_v1_Jan.5.22.xlsx(0.01)	Data Collection Forms	3/22/2022	History
View	MSRev+p-site Study Wide DataCollectionSheet_v3_05.Jan2022.docx(0.01)	Data Collection Forms	3/22/2022	History
View	MSRev+p-site DSMB_charter_document_October 5 2021.pdf(0.01)	DSMB Charter/Data Monitoring Plan	3/22/2022	History
View	STUDY00000140 STUDY WIDE HIPAA_waiver_v1.2_05.Jan.2022.docx(0.01)	HIPAA	3/22/2022	History
View	STUDY00000140 STUDYWIDE HIPAA_Authorization_stand alone_v1_05.12.21.docx(0.01)	HIPAA	3/22/2022	History
View	STUDY00000140 MASTER FU visit Video Transcript & link to video v2 Jan.09.22.docx(0.01)	Other	3/22/2022	History
View	STUDY00000140 STUDY WIDE Other Document Type v1.0_01.16.2022.docx(0.01)	Other	3/16/2022	History
View	certificate_of_translation_Spanish MASTER docs_17.01.2022.pdf(0.01)	Other	3/16/2022	History
View	STUDY00000140 Other STUDY WIDE subject retention material_v1_1212.21.pdf(0.01)	Retention Materials	3/16/2022	History
View	MSRev+p-site Study-wide Subject Newsletter Jan.02.2022.pdf(0.01)	Retention Materials	3/16/2022	History
View	STUDY00000140 TEMPLATE_script_telephone_follow-up_visit_ver1.2_12.12.2021.docx(0.01)	Retention Materials	3/16/2022	History
View	MSRev+p-site MASTER script_email_Notification_v1.2_Jan.02.2022.docx(0.01)	Retention Materials	3/16/2022	History
View	MSRev+p-site MASTER script_Spanish_email_Notification_v1.2_Jan.02.2022.docx(0.01)	Retention Materials	3/16/2022	History
View	MSRev+p-site Study subject appt reminder card.TEMPLATE.v1.0_Dec 12 2021.pdf(0.01)	Retention Materials	3/16/2022	History
View	STUDY00000140 MASTER Subject_Survey_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/16/2022	History
View	STUDY00000140 MASTER Subject_Survey_Spanish.v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/16/2022	History
View	STUDY00000140 MASTER Interview Guide for Study Staff_v1_01.02.2022.docx(0.01)	Study Measures	3/16/2022	History
View	STUDY00000140 MASTER Study Pain Measuring Tool_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/15/2022	History
View	STUDY00000140 MASTER Study Pain Measuring Tool_Spanish.v3.0_Jan.2.22.docx(0.01)	Study Measures	3/15/2022	History
View	STUDY00000140 MASTER Subj_Diary_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/15/2022	History

	Document	Category	Date Modified	Document History
View	STUDY00000140 MASTER Subj_Diary_Spanish_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/15/2022	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	STUDY00000140_Consent_UMassChan.specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	STUDY00000140_Consent_Spanish_UMassChan.specific_v3 Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	STUDY00000140_Fact Sheet_UMassChan.specific_v.3.0_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	STUDY00000140_Fact Sheet_Spanish_UMassChan.specific_v.3.0_Dec 5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	STUDY00000140_Assent_UMassChan.specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/15/2022	History
View	STUDY00000140_Assent_Spanish_UMassChan specific_v1.1_Dec.21.2021.docx(0.01)	Consent Form	3/15/2022	History

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

	Document	Category	Date Modified	Document History
View	STUDY00000140_recruitment Flyer_UMassChan.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/15/2022	History
View	STUDY00000140 recruitment Flyer_Spanish_UMass.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/15/2022	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY000000140 UMassChan IBC letter Jan.06.2022.pdf(0.01)	Approval Letters	3/16/2022	History
View	STUDY000000140 UMassChan COI committee letter Jan.06.2022.pdf(0.01)	Approval Letters	3/16/2022	History
View	STUDY00000140 UMass Only HIPAA_Authorization_stand alone_v1_Jan05.22.docx(0.01)	HIPAA	3/16/2022	History
View	certificate_of_translation_Spanish docs_UMass specific_17.Jan.2022.pdf(0.01)	Other	3/16/2022	History

Suggested attachments:

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

Date: Friday, March 25, 2022 3:50:10 PM

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SITE00000009

View: SF: Basic Site Information

Basic Site Information

1. * **Short title:**

   Johns Hopkins University School of Medicine (for IRB) Participating Site for Multi-Site Reviewing study WITH a p-site (participating site) (UMass Chan is the IRB of Record) – Model Study for File Management

2. * **Local principal investigator:**

   Heather Tessier

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

   ● **Yes** ○ No

4. * **Brief description of activities this site will perform:** (enter "ALL" if this site will perform all procedures in the protocol)

   NOTE: Until we are on the IRB Exchange, the Local PI should be the same as the UMass Chan PI.

   Put "ALL" here if site will perform all study procedures. Otherwise, describe what this site will be doing as part of the research.

Additional Local Funding Sources

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

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
TAKEDA PHARMACEUTICALS NORTH AMERICA INC			

Local Site Documents

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

	Document	Category	Date Modified	Document History
View	STUDY00000140_Consent_JHU p-site_specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000140_Consent_Spanish_JHU p-site_specific_v3 Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000140_Fact Sheet-JHU p-site_specific_v.3.0_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000140_Fact Sheet_Spanish_JHU p-site_specific_v.3.0_Dec.2.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000140_Assent_JHU p-site_specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000140_Assent_Spanish_JHU p-site specific_v1.1_Dec.21.2021.docx(0.01)	Consent Form	3/22/2022	History

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

	Document	Category	Date Modified	Document History
View	MSRev+p-site study recruitment Flyer_JHU specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/22/2022	History
View	MSRev+p-site study recruitment Flyer_JHU specific_Spanish_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/22/2022	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY00000140 JHU site COI committee letter Jan.31.2022.pdf(0.01)	Approval Letters	3/25/2022	History

	Document	Category	Date Modified	Document History
View	STUDY00000140 JHU site biosafety committee letter Jan.31.2022.pdf(0.01)	Approval Letters	3/25/2022	History
View	STUDY00000140 JHU Only - HIPAA_Authorization_stand alone_v1_Jan05.22.docx(0.01)	HIPAA	3/25/2022	History
View	MSRev+p-site JHU_specific HRP-215-FORM-Non-Umass Personnel List_03.12.22.docx(0.01)	Other	3/25/2022	History
View	certificate_of_translation_Spanish docs_JHU specific_17.Jan.2022.pdf(0.01)	Other	3/23/2022	History
View	MSRev+p-site JHU P-site Supplement-Local context document V2_Jan.12.22.docx(0.01)	pSite Supplement/Local Context Form	3/23/2022	History

Suggested attachments:

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