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 11/09/2022)

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 11/09/2022)

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

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 11/09/2022)

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:

- Completed HRP-215 Non-UMass Personnel Forms (one per pSite) 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, and UMass Chan specific materials.
- 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, HRP-215 Non-UMass Personnel Form 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.

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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
11/09/2022	Added clarifying information regarding form HRP-215 (one form must be completed to each pSite)

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 11/09/2022)

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.

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- 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:

- Completed HRP-215 Non-UMass Personnel Forms (one for each pSite) for all study staff who are not in RMS eIRB
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- 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

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- 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, completed HRP-215 Non-UMass Personnel Form 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.

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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
11/09/2022	Added clarifying information regarding form HRP-215 (one form must be completed to each pSite)

UMass Chan MEDICAL SCHOOL

Date: Friday, March 25, 2022 4:55:25 PM

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STUDY00000143

View: SF: Basic Study Information

Basic Study Information

1. * **Title of study:**
   Example of a Multi-site Reviewing study WITH 1 Participating site (MSRev+p-site) Drug and Device study

2. * **Short title:**
   Example of a Multi-site Reviewing study WITH 1 Participating site (MSRev+p-site) Drug and Device study

3. * **Brief description:**
   Example of a Multi-site Reviewing study WITH 1 Participating site (MSRev+p-site) Drug and Device study

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	STUDY00000141-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.

STUDY00000143

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 a P-SITE 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
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)
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

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 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

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY00000143 Study Wide eCaseReportForms_v3_Dec 22.2021.pdf(0.01)	Data Collection Forms	3/22/2022	History
View	STUDY00000143 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 DSMB_charter_document_October 5 2021.pdf(0.01)	DSMB Charter/Data Monitoring Plan	3/22/2022	History

	Document	Category	Date Modified	Document History
View	STUDY00000143 STUDY WIDE HIPAA_waiver_v1.2_05.Jan.2022.docx(0.01)	HIPAA	3/22/2022	History
View	STUDY00000143 MASTER FU visit Video Transcript & link to video v2 Jan.09.22.docx(0.01)	Other	3/22/2022	History
View	certificate_of_translation_Spanish MASTER docs_17.01.2022.pdf(0.01)	Other	3/22/2022	History
View	MSRev+p-site Study-wide Subject Newsletter Jan.02.2022.pdf(0.01)	Retention Materials	3/22/2022	History
View	MSRev+p-site MASTER script_email_Notification_v1.2_Jan.02.2022.docx(0.01)	Retention Materials	3/22/2022	History
View	MSRev+p-site MASTER script_Spanish_email_Notification_v1.2_Jan.02.2022.docx(0.01)	Retention Materials	3/22/2022	History
View	MSRev+p-site Study subject appt reminder card.TEMPLATE.v1.0_Dec 12 2021.pdf(0.01)	Retention Materials	3/22/2022	History
View	STUDY00000143 MASTER Subject_Survey_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/22/2022	History
View	STUDY00000143 MASTER Subject_Survey_Spanish.v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/22/2022	History
View	STUDY00000143 MASTER Interview Guide for Study Staff_v1_01.02.2022.docx(0.01)	Study Measures	3/22/2022	History
View	STUDY00000143 MASTER Study Pain Measuring Tool_v3.0_Jan.02.2022.docx(0.01)	Study Measures	3/22/2022	History
View	STUDY00000143 MASTER Study Pain Measuring Tool_Spanish.v3.0_Jan.2.22.docx(0.01)	Study Measures	3/22/2022	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	STUDY00000143_Consent_UMassChan.specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000143_Consent_Spanish_UMassChan.specific_v3 Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000143_Fact Sheet_UMassChan.specific_v.3.0_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000143_Fact Sheet_Spanish_UMassChan.specific_v.3.0_Dec 5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000143_Assent_UMassChan.specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/22/2022	History
View	STUDY00000143_Assent_Spanish_UMassChan 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	STUDY00000143_recruitment Flyer_UMassChan.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/22/2022	History
View	STUDY00000143 recruitment Flyer_Spanish_UMass.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/22/2022	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	STUDY000000143 UMassChan IBC letter Jan.06.2022.pdf(0.01)	Approval Letters	3/25/2022	History
View	STUDY000000143 UMassChan COI committee letter Jan.06.2022.pdf(0.01)	Approval Letters	3/25/2022	History
View	STUDY00000143 STUDYWIDE HIPAA_Authorization_stand alone_v1_05.12.21.docx(0.01)	HIPAA	3/25/2022	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

UMass Chan MEDICAL SCHOOL

Date: Monday, March 28, 2022 10:19:11 AM

Print Close

SITE00000010

View: SF: Basic Site Information

Basic Site Information

1. * **Short title:**

   Johns Hopkins University School of Medicine (for IRB) Participating Site for Example of a Multi-site Reviewing study WITH 1 Participating site (MSRev+p-site) Drug and Device study

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)

   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.

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	STUDY00000143_Consent_JHU p-site_specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/28/2022	History
View	STUDY00000143_Consent_Spanish_JHU p-site_specific_v3 Dec.5.2021.docx(0.01)	Consent Form	3/28/2022	History
View	STUDY00000143_Assent_JHU p-site_specific_v3_Dec.5.2021.docx(0.01)	Consent Form	3/28/2022	History
View	STUDY00000143_Assent_Spanish_JHU p-site specific_v1.1_Dec.21.2021.docx(0.01)	Consent Form	3/28/2022	History
View	STUDY00000143_Fact Sheet-JHU p-site_specific_v.3.0_Dec.5.2021.docx(0.01)	Consent Form	3/28/2022	History
View	STUDY00000143_Fact Sheet_Spanish_JHU p-site_specific_v.3.0_Dec.2.2021.docx(0.01)	Consent Form	3/28/2022	History

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

	Document	Category	Date Modified	Document History
View	STUDY00000143_recruitment Flyer_JHU.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/28/2022	History
View	STUDY00000143_Spanish_recruitment Flyer_JHU.specific_Dec.12.2021.pdf(0.01)	Recruitment Materials	3/28/2022	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	MSRev+p-site JHU site COI committee letter Jan.31.2022.pdf(0.01)	Approval Letters	3/28/2022	History

	Document	Category	Date Modified	Document History
View	MSRev+p-site JHU site biosafety committee letter Jan.31.2022.pdf(0.01)	Approval Letters	3/28/2022	History
View	STUDY00000143 JHU Only - HIPAA_Authorization_stand alone_v1_Jan05.22.docx(0.01)	HIPAA	3/28/2022	History
View	STUDT00000143 JHU_specific HRP-215-FORM-Non-Umass Personnel List_03.12.22.docx(0.01)	Other	3/28/2022	History
View	certificate_of_translation_Spanish docs_JHU specific_17.Jan.2022.pdf(0.01)	Other	3/28/2022	History
View	MSRev+p-site JHU P-site Supplement-Local context document V2_Jan.12.22.docx(0.01)	pSite Supplement/Local Context Form	3/25/2022	History

Suggested attachments:

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