Reliance on WCG IRB
(Updated 3/28/2023)

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

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

Although UMass Chan may rely upon WCG for review of specific research projects, the Institution is still responsible for the conduct of that research. Therefore, the UMass Chan IRB must be aware of and approve of the submission being sent to WCG through an administrative review. WCG will not review any UMass Chan study without written clearance from the UMass Chan IRB.

In order for the UMass Chan IRB to be able to extend this agreement to include a specific research study all of the following conditions must apply:

The sponsor of the research is a for-profit entity/company.
The project was designed and written by the sponsor.
The sponsor holds all INDs/IDEs for the project.
The research is a multicenter project.
The research is not phase 1 or first-in-human.
The research is currently reviewed by WCG for other sites.

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

To initiate a request to use WCG for a study that does NOT meet the criteria in the table above, email IRBreliance@umassmed.edu with a copy of the protocol, master consent, name of the UMass Chan PI, and description of how UMass Chan will be involved. In addition, requests should include:

- A description of the investigational product, including how it is administered and its risks
- Proposed staffing and their experience with clinical research and Phase I trials
- The setting in which research procedures will occur
- Safety measures, including the plan for coordinating care for subjects in the absence of a 24-hour inpatient clinical trials unit. For example, explain which service subjects would be admitted to and how care will be coordinated and communicated between the clinical team and the study team.

To initiate a request to use WCG for a study that DOES meet the criteria in the table above, simply complete the following Approval Process:

Approval Process

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

In RMS eIRB:

- Initiate a multi-site relying study and select *WCG IRB (for IRB)* as the external IRB.

- Verify that all study staff have completed CITI human subjects training, conflict of interest training, and if a clinical trial, GCP training.
- Upload the following Study-Wide Documents:
    - WCG IRB approved master protocol
    - Investigator brochure (if applicable)
    - IRB approved master consent and/or assent templates
    - Most current WCG IRB approval letter for study (this is the WCG approval for the protocol and any study-wide materials such as consent form templates)
- Upload the following Local Study Documents
    - Red-line copies of site-specific materials based on the WCG IRB-approved templates (e.g., draft consent form for use at UMass Chan)
        - Follow the pointers in Consent Form Tips
    - UMass Chan HIPAA Authorization Stand Alone Form unless using a compound consent and authorization
    - Completed UMass Chan HRP-508 TMEPLATE pSite Supplement and Communication Plan
    - Copy of PI's medical license
    - Current CV for PI
    - Any other required UMass Chan approvals, which must be obtained before submitting to WCG IRB, e.g.,
        - IBC registration or an explanation in the pSite form as to why IBC registration is not required
        - RSC approval or a copy of the *Questions for PI* documenting why RSC approval is not required
        - Gene and Cell Therapy Advisory Committee approval
        - COI approval and mitigation plan
    - For investigational drug studies, a copy of the PI's Mass Controlled Substances Researcher Registration (Type: Researcher, Schedule: IND)
- **The UMass Chan IRB does NOT need a copy of every study document approved by WCG** (e.g. study measurement documents, master recruitment materials, etc.).

Once all required documents have been uploaded into RMS eIRB, the PI has submitted the study, and the submission is in Pre-Review (and is no longer in Pre-Submission), the UMass Chan IRB will conduct an administrative review which includes the following activities:

- Confirming that the PI is not restricted as per the Investigator's Manual
- Reviewing the list of active study staff for current CITI training
- Reviewing the uploaded documents to assure that the study meets the conditions of the reliance agreement and local requirements
- Notifying the study team of any issues, including required changes to the consent form, through Pre-Review Clarifications Requested in eIRB

- Sending a written determination to the study team (via Add Comment) indicating that the application may be submitted to WCG IRB

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

Once WCG approves UMass Chan as a site:

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

Once the UMass Chan IRB verifies that the approved documents match the ones that were cleared for submission, it will acknowledge receipt.

PI POST-WCG APPROVAL RESPONSIBILITIES:

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

Once WCG IRB approval is granted, WCG IRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to WCG for review. However, the annual continuing review and other items listed below must also be submitted to the UMass Chan IRB through RMS eIRB.

Information to Also Submit to UMass Chan IRB	**RMS eIRB Function**
All changes in study staff, including changes in PI	Create Site Modification
Proposed changes to research injury compensation language or conflict of interest declarations	Create Site Modification
Unanticipated problems involving risks to subjects or others, reports of serious and/or continuing non-compliance, or IRB suspension or termination through RMS eIRB – when the information involves a UMass Chan subject or investigator	Report New Information
Notification of reapproval plus current site-specific materials, study-wide protocol, and IB if not already in RMS	Create Site Modification to upload current site-specific materials (e.g., consents)
	Update Study Materials to upload IRB study/site reapproval letter(s) and current study-wide protocol and IB
Closure of the study or UMass Chan as a site	Update Study Materials to upload closure letter

See the following pages for more information:

General Tips

- Make sure you are working from the most recent instructions and from IRB approved templates.
- Read through the instructions in full before starting and prepare your materials offline.
- Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings.
- Make sure all ancillary reviews are complete.
- Request a Connexus account if you do not have one (https://identity-connexus.wcgirb.com/Account/SignIn)
- Ask the sponsor, clientservices@wcgirb.com, or UMass Chan-WIRB Account Manager Jon Gellert (jgellert@wirb.com) to invite you to the protocol in Connexus and to send you the WCG approved template consent(s).
- See eIRB Course 4: Multi-Site Relying Study Submission Process.

Administrative Review and Consent Form Tips

- **Use the UMass Chan research injury language from the UMass Chan consent form template.**
  - The UMass Chan boilerplate is consistent with the clinical trial agreement and the requirements of the Contracting Guide. The Contracting Guide is shared early in the contract process with the sponsor. The guide includes a Subject Injury Coverage Statement that outlines prohibited language. Study teams should only submit for administrative review redline consents that use the UMass Chan research injury language.
- If the consent includes references to the European Economic Area's General Data Protection Regulation (GDPR), obtain administrative review from privacyandcompliance@umassmed.edu before submitting the draft in RMS eIRB. If you see references to data controllers or local data protection authorities in Europe, the consent likely requires review by Privacy and Compliance.
- All research happens under the auspices of the Medical School.
  - Ensure that UMass Chan Medical School, 55 Lake Ave North, Worcester Massachusetts 01655 is listed in the WCG application as the name of the Company/Institution/Organization and as the first Physical address where subjects will be seen or where research will

take place. A hospital address can be entered as an additional location if applicable.

- Ensure that the informed consent conveys that UMass Chan Medical is conducting the research. When research at UMass Chan happens in a clinical setting, subjects may be seen at, e.g., UMass Memorial Medical Center.
- When the consent or authorization discusses disclosure of protected health information, it must cite as applicable UMass Memorial Medical Center or UMass Memorial Health as the covered entities that hold the protected health information.
- If the UMass Memorial logo appears, the UMass Chan logo must also be present.

- Remove any language in which subjects give up rights or ownership of samples or information collected about them.
  - The clinical trial agreement provides the sponsor a right of use, not ownership.
  - The consent can inform subjects that they will have no rights related to discoveries made as part of the research and that they will not share in any profits.
- Ensure that the consent does not overpromise coverage of possible related expenses. The following UMass Chan boilerplate is suggested for clinical research consents when the consent does not have similar language.
  - *You or your insurance will not have to pay for tests and procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.*

    <u>Drug name or agent</u> will be provided to you at no cost; however, you or your insurance may be billed for the administration of this drug or agent.
- Do not overpromise confidentiality.
  - There are many groups at UMass Chan and UMMH that will necessarily have appropriate access to identifiable information about subjects, including through OnCore and EPIC.
  - The consent may not permit subjects to opt out of the study doctor notifying a subject's regular doctors about the subject's participation in the research. Due to safety concerns, UMass Chan does not permit these opt-outs. Study teams may remove or revise these opt-outs.
- When a HIPAA authorization is necessary, the consent must include a complete HIPAA authorization, or the study team can add a UMass Chan

	HIPAA Stand Alone Authorization Form. See *HRP-330 – WORKSHEET – HIPAA Authorization* to evaluate whether a consent is a compound consent and authorization.
	• A HIPAA authorization must permit disclosure to UMass Chan and UMMH. The following UMass Chan boilerplate is suggested when the consent does not have similar language.
	  ○ *The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing, and compliance offices*
	• Consents must provide a 24-hour contact number for studies that are greater than minimal risk
	• If the research includes pregnancy testing of minors, add the corresponding language from the UMass Chan consent template:
	  ○ *If you could get pregnant, you will have pregnancy testing as part of this study. Only you will be told the results. If you are a minor and are found to be pregnant, we will talk to you about getting appropriate healthcare and the support of an adult. A positive pregnancy test means that you cannot be in this study. Because you will be asked to leave the study, your parents may find out that you are pregnant. If you are uncomfortable with pregnancy testing, then you should not be in this study.*

PREPARING THE WCG INITIAL REVIEW SUBMISSION FORM:

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

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

WIRB CONTACT INFORMATION:

Jon Gellert | Account Manager, Institutions
Office: (800) 562-4789
Direct Line: (360) 570-1309
Cell: (253) 256-9371
jgellert@wirb.com | www.wirb.com

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For IRB Office Use Only

Document Version History:

Date	Status
02/10/2022	Initial Post
04/06/2022	Addition of Example of WCG IRB Multi-site Relying Study in RMS eIRB - Model for File Management
07/13/2022	Minor revisions
10/11/2022	Revised to update study/site closure process
3/15/2023	Revised to clarify how to get started, added Gene Therapy Committee, and updated links
3/28/2023	Revised several UMass Chan eIRB SharePoint site links so that they point at the folders the documents are in, not at the documents themselves. This will allow those documents to be updated as needed without having to update these instructions.

UMass Chan MEDICAL SCHOOL

Date: Monday, April 4, 2022 12:06:03 PM

Print Close

STUDY00000144

View: SF: Basic Study Information

Basic Study Information

1. * **Title of study:**
   Example WCG IRB Multi-site Relying Study - Model for document Management

2. * **Short title:**
   Example WCG IRB Multi-site Relying Study - Model for document Management

3. * **Brief description:**
   Example WCG IRB Multi-site Relying Study - Model for document Management

   UMass Chan Relying on an External IRB (External IRB = IRB of Record), in this case WCG IRB

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:**
   Heather Tessier

__Please note__ that unless and 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.

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:**
   WCG IRB (for IRB)

2. **External study ID:**
   WCG IRB ID# EXAMPLE: 20211334

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.

STUDY00000144

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
TAKEDA PHARMACEUTICALS NORTH AMERICA INC			

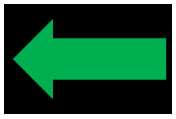
2. * Department / Division / Institute Responsible for the Study:

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	yes	

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	4/1/2022	History
View	External IRB Approved Master_Template_Assent_v1_Dec.21.21.docx(0.01)	Consent Form	4/1/2022	History
View	External IRB Approved Master_Pregnant Partner_form.V1_Dec.12.21.docx(0.01)	Consent Form	4/1/2022	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	STUDY00000144 UMassChan specific COI committee letter Jan.31.2022.pdf(0.01)	Approval Letters	4/4/2022	History
View	STUDY00000144 UMassChan Rad Safety approval letter 1.30.22.pdf(0.01)	Approval Letters	4/4/2022	History
View	STUDY00000144 UMassChan Rad Safety Questions for PI document 1.30.22.pdf(0.01)	Approval Letters	4/4/2022	History

Please note: once the *Site Specific Approval Letter for UMass Chan* is received from the External IRB, it should be **uploaded as a NEW document** to this section and **categorized as an Approval Letter.**

EXAMPLE: *External IRB UMass Chan Site approval Letter 03Mar2022.pdf*

Please see the associated SOP here: (https://www.umassmed.edu/ccts/irb/reliance-agreements/) for additional details.

	Document	Category	Date Modified	Document History
View	STUDY00000144 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 study UMassChan PI Medical License 5.21.2021.docx(0.01)	Other	3/24/2022	History
View	MSRelying study UMassChan PI current CV signed and dated Sep.22.2021.docx(0.01)	Other	3/24/2022	History
View	MSRelying UMassChan PI MA Controlled Substance Researcher Registration for invest drug study 4.1.2021.docx(0.01)	Other	3/24/2022	History
View	MSRelying study UMassChan HRP508 P-site Supplement&Communication Plan 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