Pitt IRB Cedes Oversight to External Institution for a Multi-Site Study

Contents

Overview

This guidance is specific to research involving a Reliance/Single IRB (sIRB) mechanism for multi-site research. As one of the leading academic research centers in the nation, researchers at the University of Pittsburgh frequently collaborate with external investigators and institutions. In an effort to reduce duplicate submission and oversight by multiple IRBs for the same project, the University of Pittsburgh Human Research Protections (Pitt HRP) offers reliance opportunities. This guidance is intended to:

- Outline PI and study team responsibilities when the Pitt IRB is ceding oversight to an external IRB for a Multi-Site Study
- Provide step-by-step instructions for Pitt/UPMC investigators

The Pitt HRP will <u>not</u> enter reliance for the following scenarios:

- Institutions located outside of the United States

- In most cases, the Pitt HRP will not enter into reliance agreements for (1) exempt research projects and/or (2) non-NIH funded research limited to chart review. If a request is submitted for this type of project, a determination will be made on a case-by-case basis, based on the justification provided.

The Pitt HRP reserves the right to decline entering reliance, for any project.

- Due to NIH and DHHS' mandates for use of a sIRB, if a decision is made to decline reliance on a federally-funded project that requires sIRB, the project will be unable to be implemented at our site.
- If a decision is made to decline reliance on project that does not have federal funding, reliance will not be executed, and the Pitt investigator should submit directly to the Pitt IRB for oversight.

Pitt Investigators should never commit to using an sIRB mechanism without first communicating with the Pitt HRP. Contact the Pitt HRP Reliance Team (irb.reliance@pitt.edu) before (1) committing to the use of an sIRB with external parties and/or (2) completing "Site Activation" paperwork from an external party about Pitt/UPMC site(s).

Definitions

Engaged: The Pitt HRP utilizes the guidance document issued by the Office of Human Research Protections to determine engagement: Engagement of Institutions in Human Subjects Research (2008). Examples of when an institution/individual is engaged in human subjects research include:

1. Receiving direct federal funding for research (i.e. Primary Awardee of the grant)
2. Obtaining data about research subjects through intervention/interaction
3. Obtaining identifiable private information about research subjects
4. Obtaining informed consent
5. Implementing/administering research intervention

Single IRB Review (Reliance): A legal arrangement that allows one IRB to review the research on behalf of other engaged institutions.

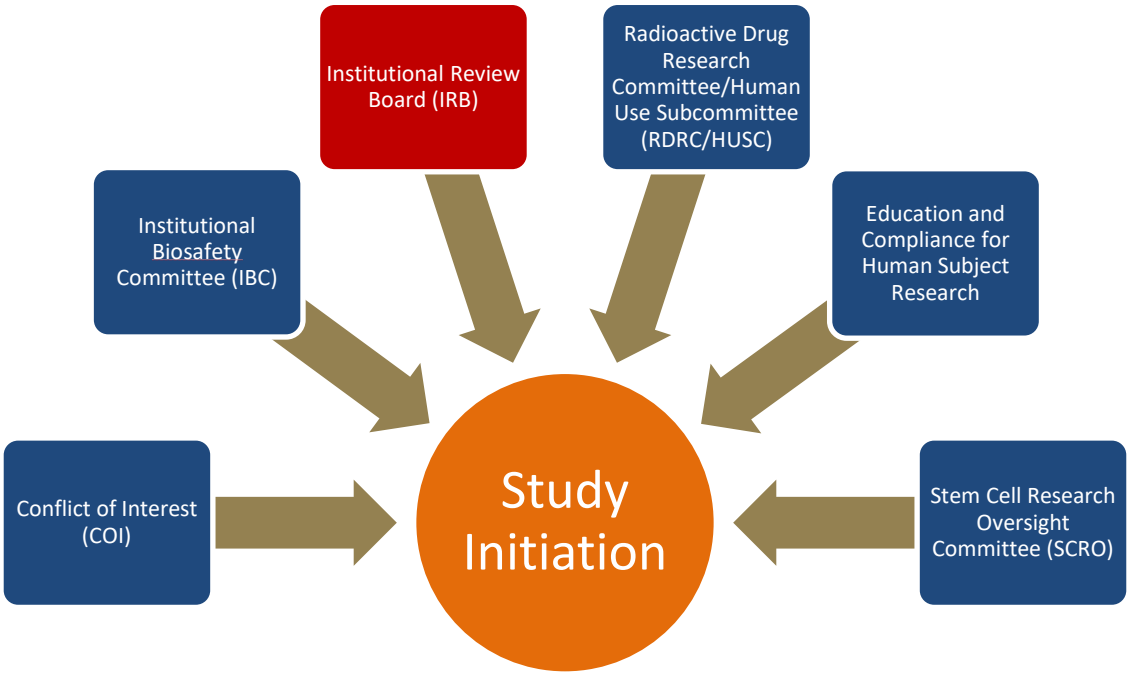
IRB of Record (Reviewing IRB): The IRB that reviews and makes required regulatory determinations.

Relying Site: Institution that cedes IRB responsibilities to the IRB of Record.

Reliance Agreement: A document (e.g., IRB Authorization Agreement, Master Service Agreement, etc.) signed by two or more institutions engaged in human subjects research that permits one or more individuals/institutions to cede review to another IRB. The signed Agreement permits a single IRB to review human subject research activities for more than one individual/site.

Note, Reliance Agreements for sIRB review are used to cede ONLY the IRB review of projects. All institutionally-required ancillary reviews must still be obtained locally (e.g., Conflict of Interest, Human Stem Cell, Institutional Biosafety, IND/IDE Support, Radiation Safety, etc.) Oversight of these ancillary reviews still require local review and approval regardless of

ceding IRB review.



Federal Policy

Effective January 25, 2018, the National Institutes of Health (NIH) mandated the use of single IRBs as a contingency for funding of domestic multi-site studies submitted after that date. The NIH issued this policy to establish the expectation that a single IRB of Record will be used in the ethical review of non-exempt human subjects research projects funded by the NIH that are carried out at more than one site in the United States (Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research).

Effective January 20, 2020, the U.S. Department of Health & Human Services requires all domestic multi-site research projects supported by federal funding to utilize a sIRB mechanism, regardless of specific funding agency, under the Revised Common Rule.

Pitt/UPMC Study Team Responsibilities

- Obtaining a Letter of Support from the Pitt HRP (*if requested by the Lead study team)*
- Creation of an External IRB application in PittPRO
- Submission of Reliance Request to the Pitt HRP via online Reliance Request System
- Acting as the primary liaison between the Lead study team, IRB of Record and Pitt HRP
- Inserting local site language into the IRB-approved consent template (provided by the Lead study team) and emailing it to irb.reliance@pitt.edu for the Pitt IRB to insure all necessary local language has been included for our site
- Assist the Pitt HRP in completion of local context surveys (provided by the Lead study team)
- Submission of External IRB application in PittPRO
- Submission of applicable modifications/amendments (see page 5 for listing), continuing review materials and pertinent new reportable information in the External Pathway of OSIRIS
- Dissemination of local site materials to the Lead study team and/or IRB of Record

- Ensuring that all engaged Pitt/UPMC affiliates are appropriately licensed and credentialed to complete the described research
- Ensuring all engaged Pitt/UPMC affiliates have completed required research training. Training requirements are available here: ORP Training Table List
- Ensuring all required local ancillary reviews are completed
- Ensuring all engaged Pitt/UPMC affiliates have declared any Conflicts of Interest and implementing any COI management plans required by the Pitt COI Office
- Ensuring all institutional requirements, beyond the Pitt HRP, have been met at Pitt/UPMC (e.g., execution of a Data Use Agreement (DUA) and/or Material Transfer Agreement (MTA) with the Pitt Office of Sponsored Programs).
- Maintaining compliance with the IRB of Record's policy and procedures

General Inquiries

All sIRB inquiries/issues should be directed to irb.reliance@pitt.edu, to ensure that the Reliance Team is promptly receiving all inquiries for response. Please do **not** email Jeannie Barone, Allison Gerger, Michelle LeMenager, or Deane Quillen's personal email boxes regarding sIRB issues, it slows our ability to effectively respond.

Requesting a Grant Letter of Support

There is typically no requirement that Letters of Support be provided by Relying Sites for inclusion with a grant application. However, it is a requirement that the Lead PI of the grant obtain confirmation from each site indicating their willingness to rely on a specific sIRB. If you receive a request for written confirmation of willingness to cede, please submit a request for a Letter of support using the Reliance Request System.

Letters of support are not formal reliance agreements. If the project is funded, formal reliance agreements will then be put in place.

Note, if you receive any type of paperwork that needs to be completed related to the study after grant submission, but before the protocol is even written, contact irb.reliance@pitt.edu for completion assistance.

Timeline Overview When Pitt Cedes Oversight

1	Pitt/UPMC study team creates an External IRB application in PittPRO to generate a STUDY# for the project. The application does not need to be completed at this time. This step is solely to generate a STUDY# for tracking purposes.
2	Pitt/UPMC study team submits reliance request in online Reliance Request System. The reliance request system will prompt you to provide the STUDY# of the study you created in Step 1.
3	Pitt HRP reviews reliance request at sIRB meeting to determine if reliance is appropriate.
4	Pitt HRP communicates decision as to whether they will permit reliance and begins communication with IRB of Record to determine type of agreement to be used, whether one of the online reliance software platforms (i.e., IRB Reliance Exchange (IREx) will be utilized & facilitates agreement execution.
5	If requested by the IRB of Record, Pitt/UPMC study team receives Local Context Survey for completion.

6	**Note, this step will <u>not</u> apply to *all* studies.** If the study includes procedures that require ancillary reviews such as: ○ Exposure to radiation (Radiation Safety) ○ Use of recombinant DNA (Institutional Biosafety) ○ Pitt held IND or IDE (Investigator-Sponsored IND and IDE Support) You must complete your External IRB application with as much information as you have available at this time and **<u>Submit</u>**. This will trigger local ancillary reviews that are required and provide any pertinent consent language that will need to be inserted into the study consent template. If any Pitt/UPMC study members have a Conflict of Interest, email the COI office at coi@pitt.edu and alert them COI Review is needed and inquire as to what materials the COI Office needs to conduct their review. For more information, including ancillary review timelines, contact the office responsible for the ancillary review (www.orp.pitt.edu).
7	If consent will be obtained at Pitt/UPMC, the Pitt/UPMC study team receives <u>IRB-approved</u> consent template from Lead site and uses tracked changes to insert local language, <u>including any required ancillary review language</u> that was provided by the ancillary entity during step 6 above. **Before inserting local language, confirm the templates provided to you by the Lead site have been approved by the IRB of Record.** The Pitt HRP will provide the Pitt/UPMC Study Team a guidance document outlining locally required consent language. Then, the Pitt/UPMC study team emails the tracked changes version of the consent template to irb.reliance@pitt.edu for the Pitt HRP to review to ensure all required local language has been included prior to submission for formal IRB by the IRB of Record.
8	Pitt/UPMC study team emails the Local Context Survey and consent with local language inserted to irb.reliance@pitt.edu for review.
9	The Pitt HRP completes the Local Context Survey and signs-off on the local consent form prior to the Pitt/UPMC study team submitting the documents to IRB of Record for IRB approval.
10	IRB of Record approves Modification/Amendment adding Pitt/UPMC as a relying site.
11	Pitt/UPMC study team fully completes the External IRB application and submits in PittPRO.
12	Pitt HRP reviews and activates the External IRB application.
13	Pitt/UPMC study team submits EXT Activation Letter to Pitt Office of Sponsored Programs for grant/contract execution.
14	Pitt/UPMC study team may begin the project.

Requesting Pitt IRB to Cede Review to External Institution

The first step in requesting that the Pitt IRB cede its oversight to an external IRB for a project is completing and submitting a request using the Reliance Request System.

Note, you cannot save work in the Reliance Request System and return to it later. A request must be made in one sitting. Therefore, the Pitt HRP created the *Overview of Reliance Request System Content* guidance document, which can be found at www.hrpo.pitt.edu → Guidance & Forms → "R" for Reliance Guidance. This document outlines all information and materials you will need to have available to submit a reliance request.

Upon receipt of this paperwork, the Pitt HRP holds a weekly sIRB meeting to review all reliance requests to determine if reliance is appropriate based on the details of the project.

When ceding IRB oversight to an external IRB, the Pitt study team is responsible for complying with the policies and procedures of the institution serving as the IRB of Record for the project.

Creating an External IRB application in PittPRO

When Pitt is ceding oversight to an external IRB, an external IRB application is submitted to the Pitt IRB for registration. The purpose of the External Pathway is two-fold:

- To ensure local ancillary reviews are completed at Pitt (e.g., RDRC/HUSC, Biosafety, O3iS)
- To track and report projects that the Pitt IRB has ceded oversight

Note, the Pitt IRB does not "approve" this application, but will acknowledge receipt and formally activate the study to be conducted at the Pitt/UPMC site.

The following information must be completed prior to submitting an External IRB application in PittPRO for activation:

- The Reliance Agreement indicating that Pitt will cede IRB review has been fully executed
- The Pitt Study Team has received the initial IRB approval letter, modification/amendment approval letter officially on-boarding Pitt/UPMC as a Relying Site, approved protocol, and approved Pitt/UPMC consent(s) (*if consent will be obtained at Pitt/UPMC*)

Login to PittPRO (www.pittpro.pitt.edu) and select the "Create New Study" button and address the following:

PittPRO section	Instruction
Basic Information	
4. *What kind of study is this?*	Select "Multi-site or Collaborative study".
5. *Will an external IRB act as IRB of record?*	Select "yes".
6. *Lead principal investigator:*	Leave this item blank; do **not** list the Lead PI.
7. *Local principal investigator:*	List the Pitt/UPMC PI.
9. *Attach the protocol*	Leave this item blank; do **not** upload the protocol here.
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)	

External IRB	
1. *External IRB:*	Select the IRB of Record in this section.
2. *External study ID:*	Leave this item blank; do **not** list the external study ID.
3. *Specify the reason the study should be reviewed by an external IRB:*	Specify the reason why the study is being reviewed by an external IRB (e.g., Required as a contingency of funding, required by consortium, etc.).
Additional Local Funding Sources	
1. *Identify each organization supplying funding for the local site:*	Leave this item blank; do **not** list additional local funding sources.
Main Study-Related Documents	
1. *Consent form templates:*	Leave this item blank.
2. *Recruitment material templates:*	Leave this item blank.
3. *Other attachments:*	Upload the following in this section: • IRB of Record approved protocol • Initial IRB approval letter from the IRB of Record (Note, this document includes all regulatory determinations for the study) • Modification/Amendment approval letter from the IRB of Record officially on-boarding Pitt/UPMC as a relying site
Local Site Documents	
1. *Consent Forms:*	If consent will be obtained at Pitt/UPMC, upload the IRB of Record approved Pitt/UPMC consent(s)
2. *Recruitment materials:*	Leave this item blank.
3. *Other attachments:*	If applicable, upload forms required for any local ancillary reviews (e.g., the UPMC Fiscal Review form, HUSC form, etc.).

Note, the *Recruitment Methods* section not exposed for external IRB submissions in PittPro. If Pitt+Me will be used as a recruitment method, please email askirb@pitt.edu for the Pitt HRP to administratively add this ancillary review to the submission.

Transitioning an Activated EXT application from OSIRIS into PittPRO

All activated EXT applications in OSIRIS must be submitted into PittPRO at this time. The Pitt HRP has created "shells" of each activated EXT application in OSIRIS. Once the shell has been created, it will appear in the PittPRO Inbox.

To complete the External IRB application:

1. Login to PittPRO

2. Open the External IRB application
3. Re-create the OSIRIS application in PittPRO by copy/pasting content from OSIRIS
4. Use the following chart when transferring information from OSIRIS to PittPRO
5. PI press "Submit" button

Note, some of the content in OSIRIS no longer has a home in PittPRO (e.g., risk determination).

PittPRO section	OSIRIS section	Additional Instruction
Basic Information		
1. *Title of study*	CS2.0	This section has already been completed.
2. *Short title*	First item in OSIRIS	This section has already been completed.
3. Brief Description	CS2.1	This section has already been completed.
4. *What kind of study is this?*	N/A	This section has already been completed.
5. *Will an external IRB act as IRB of record?*	N/A	This section has already been completed
6. *Lead principal investigator:*	N/A	Leave this item blank; do **not** list the Lead PI.
7. *Local principal investigator:*	CS3.0	This section has already been completed.
8. *Does the local principal investigator have a financial interest related to this research?*	7.3	This section has already been completed.
9. *Attach the protocol*	EXT1.0	Leave this item blank; do **not** upload the protocol here.
Basic Local Site Information		
1. *Brief description of activities this site will perform:*	N/A	Enter "ALL" if this site will perform all procedures in the protocol). Otherwise, describe what the research team here will do related to the study.
External IRB		
1. *External IRB:*	T1.0	This section has already been completed.
2. *External study ID:*	N/A	Leave this item blank; do **not** list the external study ID.
3. *Specify the reason the study should be reviewed by an external IRB:*	N/A	Specify the reason why the study is being reviewed by an external IRB (e.g., Required as a contingency of funding, required by consortium, etc.).
Funding Sources		
1. *Indicate all sources of support (e.g. No Support/Internal/External):*	7.2	

2. *Identifying each organization supplying funding for the study*	N/A	When searching for a Funding Organization do **not** use acronyms, you must search for the full name. Use % as a wildcard to search for part of a name. 1) Can be left blank 2) Can be left blank 3) If Pitt is the Awardee Institution, upload grant application 4) Indicate if Pitt is Primary Awardee
Additional Local Funding Sources		
1. *Identify each organization supplying funding for the local site:*	N/A	Leave this item blank; all funding sources should be included on the main funding sources page
Study Team Members		
1. *Identify each person involved in the design, conduct, or reporting of the research (includes PI):*	CS3.0 – PI CS4.0 – Co-Is CS5.0 – CS6.3 – Research Staff	This section has already been completed.
2. *External team member information*	N/A	Leave this item blank; do **not** upload relying site external team members in this section.
3. *Have you verified that all members of the research team have the appropriate expertise, credentials, training, and if applicable, child clearances and/or hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB application?*	N/A	This section has already been completed.
Study Scope		
1. *Will Protected Health Information be collected?*	Not previously addressed in OSIRIS	
2. *Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?*	CS9.1 – IDS CS10.0 – O3IS 2.1	This section has already been completed.
3. *Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?*	2.2 CS10.0 – O3IS	This section has already been completed.
4. *Is this application being submitted to convert an approved study from OSIRIS to PittPRO? (Tip Sheet)*	N/A	This section has already been completed.

5. *Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after reviewing this HUSC guidance, does your research protocol require HUSC review? (If yes, upload the HUSC form in the Local Supporting Documents section). If you are unsure of review requirement, select yes.*	CS12.0	This section has already been completed.
Research Sites		
1. *Choose all sites that apply:*	CS15.0 CS7.0 – CTRC	Select the Pitt/UPMC sites where research procedures will be conducted.
2. *Describe the availability of resources and the adequacy of the facilities to conduct this study:*	CS15.2	
Main Study-Related Documents		
1. *Consent form templates:*	N/A	Leave this item blank
2. *Recruitment material templates:*	N/A	Leave this item blank
3. *Other attachments:*	EXT1.0	Upload the following in this section: • IRB of Record approved protocol • Initial IRB approval letter from the IRB of Record (Note, this document includes all regulatory determinations for the study) • Modification/Amendment approval letter from the IRB of Record officially on-boarding Pitt/UPMC as a relying site • **If the study is due for CR, upload the CR IRB approval letter from the IRB of Record**
Local Site Documents		
1. *Consent Forms:*	EXT1.0	If consent will be obtained at Pitt/UPMC, upload the IRB of Record approved Pitt/UPMC consent(s)
2. *Recruitment materials:*	EXT1.0	Leave this item blank.
3. *Other attachments:*	CS14.0	If applicable, upload forms required for any local ancillary reviews (e.g., the UPMC Fiscal Review form, HUSC form, etc.).
Electronic Data Management		
1. *Will only anonymous data be collected?* If yes, select all identifiers to be collected during any phase of the research including screening:	Data security assessment form uploaded in EXT1.0	Do **not** upload the data security assessment form in the external IRB application. Transfer all information from the data security assessment form into these sections.

a. *Will you be collecting any of the following **location data**: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.?* b. *Will you be collecting any **date information** such as birth date, death, admission, discharge, date of surgery/service?* c. *List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:* d. *Will you be collecting any data subject to the General Data Protection Regulation (GDPR)?* *For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?* *Will data be HIPAA de-identified?* *Briefly describe your plan to store coded data separately from the identifiable data:*		
2. *Will sensitive data be collected (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?*		
3. *Select all locations where data will be stored or accessed (including e.g., personal / employer laptop or desktop):*		
4. *Select all technologies being used to collect data or interact with subjects:*		
Ancillary Reviews		
2. *Additional ancillary reviews the PI may choose to include as needed for the research:*	CS17.0 - Human Stem Cell Research (hSCRO) CS13.0 - Biosafety Cover Sheet	

Modifying an Activated External IRB Application

Once the External IRB application has been activated in PittPRO, there are limited circumstances in which changes need to be made to the application. The *only* times that an External IRB application should be modified are as follows:

There are two ways to modify an external IRB application in PittPRO, dependent upon the section that needs to be modified. See the chart below to determine which type of modification must be submitted for the specific section that requires the change.

Note, for some instances, the "Create Site Modification" function and the "Update Study" functions will need to be utilized if the proposed changes fall into the respective PittPRO section. If this is needed, the "Update Study" function should be completed *prior* to the "Create Site Modification" function.

"Update Study" function	"Create Site Modification" function
Basic Study Information	
	Basic Site Information
External IRB	
Study Funding	
	Additional Local Funding Sources
	Local Study Team
Study Scope	
	Local Research Locations
Study Related Documents	
	Local Site Documents
Drugs	
Devices	
	Consent Process
	Electronic Data Management
	Conflict of Interest
	Ancillary Review
	Clinical Trials Info

To modify an activated External IRB application using the "Update Study" function in PittPRO:

1. Login to PittPRO
2. Open the External IRB application in PittPRO
3. Select the "Update Study"
4. Complete and save the edits
5. PI press "Finalize Updates" function on the main page of the Update

To modify an activated External IRB application using the "Create Site Modification" function in PittPRO:

1. Login to PittPRO

2. Open the External IRB application in PittPRO
3. Select the "Create Site Modification" button
4. Select "Modification / Update"
5. Select "Study Team and research location information" and "Other parts of the study" under the "Modification scope" item
6. Complete and save the edits
7. PI press "Submit" button

Note the following:

- *Changes to the Fiscal Review Form (after activation) should be emailed to Joe Bickus at bickusjh@upmc.edu; do **not** upload revised Fiscal Review Forms in the external IRB application.*
- *If Pitt+Me is being added as a recruitment method, please email askirb@pitt.edu for the Pitt HRP to administratively add this ancillary review to your submission.*

Submitting Continuing Review (CR) for an External IRB application

After the IRB of Record reviews and approves the study CR, the Pitt study team must submit the following documents:

- CR IRB approval letter from the IRB of Record
- Updated protocol (if changes were made during the last year)
- IRB of Record approved Pitt/UPMC consent(s) with updated approval dates (if applicable)

Submitting CR documentation must occur in two steps, as the "Update Study" and "Create Site Modification" functions in PittPRO allow for revisions to separate sections in the external IRB submission. Please complete the following:

(Step 1) Submitting CR documentation using the "Update Study" function in PittPRO:

1. Login to PittPRO
2. Open the External IRB application in PittPRO
3. Select the "Update Study"
4. Include the following in the "Summarize the updates" section: "Submitting continuing review documentation."
5. Upload the following under the "Main Study-Related Documents" section, item #3:
    - Using the "Add" button, upload the CR IRB approval letter from the IRB of Record [Do **not** replace any of the approval documents in this section]
    - Using the "Update" button, upload the most current version of the protocol (if changes were made during the last year) [Note, this should be stacked on top of the previous protocol]
6. Save changes
7. PI press "Finalize Updates" function on the main page of the Update

(Step 2) Submit CR documentation using the "Create Site Modification" function in PittPRO:

1. Select the "Create Site Modification" button
2. Select "Modification / Update"
3. Select "Study Team and research location information" and "Other parts of the study" under the "Modification scope" item
4. Include the following in the "Modification Information" section: "Submitting continuing review documentation."
5. Upload the following under the "Local Site Documents" section, item #1:

- Using the "Update" button, upload the most current version of the consent document(s) with revised approval/expiration dates, if applicable [Note, these should be stacked on top of the previous consent(s)]

6. Save changes
7. PI press "Submit" button

Closing an Activated External IRB application

Closing an external IRB application in PittPRO is an administrative action taken by the IRB coordinator assigned to the submission. To close an activated external IRB application, please complete the following:

1. Select the "Add Comment" function on the main page of the submission
2. Add a comment confirming the following:

> *Requesting to close the study. We confirm that the following is true:*
> - *Study is permanently closed to enrollment*
> - *All subjects have completed all study-related interventions*
> - *Collection of private identifiable information is complete*
> - *Analysis of private identifiable information is complete*
> - *Analysis of samples is complete*
> - *Remaining study activities are limited to de-identified data analysis OR all activities are complete including data analysis*

3. Attach any correspondence and/or reports related to the study closure

Upon receipt of the study team's confirmation above, the IRB coordinator will administratively close the study.

Reportable New Information (RNI)

Reportable new information should be submitted to the Reviewing IRB based on that Reviewing IRB's reporting guidelines. If the Reviewing IRB makes a determination of serious and/or continuing non-compliance and/or unanticipated problem involving risk to subject or others, at the Pitt/UPMC site, follow the instructions below and provide a copy of the RNI and the correspondence from the Reviewing IRB.

To submit Reportable New Information for an activated External IRB application:

1. Login to PittPRO
2. Select "Report New Information"
3. Complete and save the Reportable New Information
4. PI press "Submit RNI" button

SIRB Fees

The NIH issued a policy permitting the institution that is acting as the Reviewing IRB on a sIRB project to charge the Relying Sites for their services (Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research).

The Pitt HRP does **not** charge fees when ceding IRB oversight to an external IRB; however, the IRB of Record for the project reserves the right to charge Relying Sites for their oversight. **Contact the Reviewing IRB to determine what fees may apply.**

Other Research Agreements

If data and/or materials will be transmitted to/from Pitt and the Reviewing IRB, additional agreements may need to be obtained from the Pitt Office of Sponsored Programs (e.g., data use agreement, material transfer agreement, etc.). The IRB Reliance Agreement does **not** cover this transfer of data/materials. For more information, contact the Pitt Office of Sponsored Programs.

Dissolving Reliance Agreements

Once reliance has been established between two institutions, if one institution determines they no longer plan to implement the project at their site, reliance must be formally dissolved through a written memo between the Relying Site IRB and Reviewing IRB.