

**Pitt IRB Serves as the IRB of Record for a Multi-Site Study**

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**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 Protection (Pitt HRP) offers reliance opportunities.

This guidance is intended to:

- Outline the Pitt/UPMC PI and study team responsibilities when the Pitt IRB is the IRB of Record for a Multi-Site Study
- Provide step-by-step instructions for Pitt/UPMC investigators

**The Pitt HRP will not enter reliance for the following scenarios:**

- Exempt-level research
- Institutions located outside of the United States

**The Pitt HRP reserves the right to decline to act as IRB of Record for any project.**

There are several factors that the HRP must consider when determining whether it is appropriate for Pitt to act as IRB of Record. These decisions are made on a case-by-case basis. Examples of factors that are considered include:

- Whether sIRB fees were budgeted for the study
- Number of sites to rely on Pitt IRB
- Study risk level
- Complexity of study design
- Available resources

**The Pitt HRP charges sIRB fees to act as the IRB of Record for external sites.**

The Pitt HRP does charge sIRB fees when acting as IRB of Record. Failure to budget for sIRB fees may lead to the Pitt HRP declining to act as IRB of Record. Details of our sIRB fee structure is available later in this document.

**Pitt Investigators should never commit to using an sIRB mechanism without first communicating with the Pitt HRP.**

To ensure your grant/proposal submission timeline is not disrupted, the Pitt HRP needs to hear from Pitt study teams at the time they are writing grants/proposals that require the use of sIRB. The Pitt Reliance Team needs to determine at this early timepoint if we are willing to act as IRB of Record and if we are, to provide an sIRB fee budget for inclusion in the grant/proposal budget.

If the Pitt HRP declines to act as IRB of Record the study team will then need to identify an alternative academic center or commercial IRB to act as IRB of Record and allow time to obtain an sIRB fee budget from them prior to grant/proposal submission.

## 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

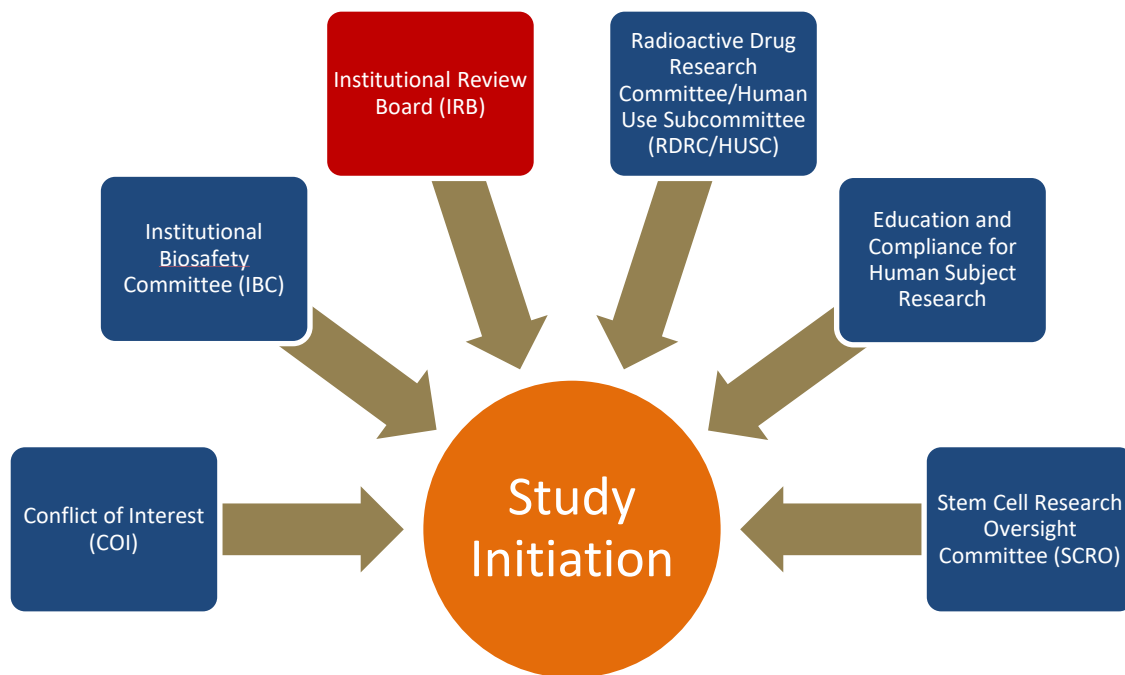
**Single IRB Review (Reliance):** A legal arrangement that allows one IRB to review the research on behalf of other engaged institutions.

**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 permit 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 multi-site studies. 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 as Lead Study Team

- For NIH-funded research, creating an sIRB plan, obtaining a Letter of Support and sIRB fee budget from the Pitt HRP to include in the NIH grant submission
- Creating a grant budget that reflects the additional sIRB fees associated with Pitt acting as IRB of Record. For example:
  - The administrative fee of covering IRB oversight for external sites (*see sIRB fees on page 8 for details*)
  - Large scale, complex projects should budget to hire both a Reliance Program Manager and a Project Coordinator. The Reliance Program Manager is needed to coordinate the project on a national level and the Project Coordinator is needed to execute the daily needs of Pitt/UPMC acting as a data collection site.

Reliance Program Manager Role	Project Coordinator Role
<ul style="list-style-type: none"> <li>➤ Coordinates project on <b>national</b> level</li> <li>➤ Point person for communication</li> <li>➤ Responsible for <u>all</u> IRB-related submissions (new, modifications, continuing review, RNI)</li> <li>➤ Dissemination of materials and updates</li> </ul>	<ul style="list-style-type: none"> <li>➤ Coordinates <b>daily</b> activities of the Pitt/UPMC data collection site</li> <li>➤ Implement Manual of Operations</li> <li>➤ Training staff locally</li> <li>➤ Maintain regulatory binder</li> </ul>

- Submission of Reliance Request to the Pitt HRP through the online Reliance Request System.
- Submission of initial protocol (including creation of a consent template), modifications, continuing review and reportable new information to the Pitt HRP
- Dissemination of IRB approvals, including materials, to relying sites
- Dissemination of IRB determinations of serious and/or continuing non-compliance and/or unanticipated problem involving risk to subject or others, to the relying site(s) where the event occurred
- Working with the Pitt HRP to establish reliance with relying sites and determining factors such as:
  - The type of agreement to be utilized
  - Whether one of the online reliance software platforms (i.e., IRB Reliance Exchange – IREx) will be utilized to establish reliance
- Ensuring 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 engaged Pitt/UPMC affiliates have declared any Conflicts of Interest (COI) and implementing any COI management plans required by the Pitt COI
- Acting as the primary contact for the relying site research teams and the Pitt HRP
- 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 Office of Research)

## General Inquiries

All sIRB inquiries/issues should be directed to [irb.reliance@pitt.edu](mailto:irb.reliance@pitt.edu), to ensure that the Reliance Team is promptly receiving all inquiries for response. Please do **not** email HRP staff's personal email boxes regarding sIRB issues, as it slows our ability to effectively respond.

## Preparing an NIH sIRB grant application

See Section D “NIH Grant Application/Contract Proposal Preparation” of the [NIH FAQ Single IRB Policy and Multi-site Research](#) and (for specific details) Section 3.2 of the [PHS Human Subjects and Clinical Trials Information Form Application Guide](#).

NIH expects the following information in grant applications for multi-site research on and after January 25, 2018:

- An sIRB plan describing the use of an sIRB, unless otherwise stated in the RFP or solicitation for contracts. The content of the sIRB plan must include:
  - Describe how you will comply with the NIH Single IRB (sIRB) policy. If you are requesting an exception for some or all participating sites, follow the [NIH Guidance Requesting an Exception](#).
  - Provide the name of the IRB that will serve as the Reviewing IRB.
  - An Indication that all identified participating sites have agreed to rely on the proposed Reviewing IRB and that any sites added after receipt of award will rely on the Reviewing IRB.
  - Briefly describe how communication between sites and the Reviewing IRB will be handled.
  - Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the Reviewing IRB and participating sites.
  - Indicate which institution or entity will maintain records of the authorization/reliance agreements and the communication plan.
- Inclusion of sIRB fee budget in the grant budget
- A Letter of Support from the Pitt HRP

## Requesting a sIRB Fee Budget & Grant Letter of Support

The *first step* to requesting Pitt act as IRB of Record is submitting a request for sIRB fee budget for inclusion in the grant application budget. Details of our sIRB fee structure is available later in this document. You can submit a request for an sIRB fee budget in our online [Reliance Request System](#). **Failure to budget for sIRB fees may lead to the Pitt HRP declining to act as IRB of Record.**

If applicable, the funding agency may require the Lead PI to obtain a Letter of Support from their own IRB indicating willingness to serve as the Reviewing IRB. This Letter of Support should be requested using the [Reliance Request System](#). Also, the Lead PI may need to obtain confirmation from each site indicating their willingness to rely on the specified sIRB.

## Requesting Pitt IRB to Serve as IRB of Record

The *second step* in requesting that the Pitt IRB serve as the IRB of Record 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](http://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 information, the Pitt HRP holds weekly sIRB meetings to review all reliance requests to determine if reliance is appropriate based on the details of the project.

## Requesting Additional Relying Site(s) after Reliance Request has been submitted

Additional relying sites may be requested after the initial reliance request has been submitted to the Pitt HRP using [Appendix A](#). Upon receipt of this information, the Pitt HRP holds weekly sIRB meetings to review all reliance requests to determine if reliance is appropriate based on the details of the site.

### Pitt IRB of Record - Timeline Overview

1	<p><b>Pitt/UPMC study team</b> submits sIRB fee budget request in online Reliance Request System. Upon receipt of this request, the <b>Pitt HRP</b> will provide an sIRB fee budget for inclusion in the grant applicable budget.</p> <p>If applicable, the <b>Pitt HRP</b> will also provide a grant letter of support.</p>
2	<p><b>Pitt/UPMC study team</b> creates a “New Study” in the PittPRO to generate a STUDY# for the project. Insert “sIRB” in front of the short title under the ‘BASIC INFORMATION’ section in PittPRO. The application does <b>NOT</b> need to be completed at this time. This step is solely to generate a STUDY# for tracking purposes.</p>
3	<p><b>Pitt/UPMC study team</b> 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 2.</p>
4	<p><b>Pitt HRP</b> reviews the reliance request at sIRB meeting to determine if reliance is appropriate.</p>
5	<p><b>Pitt HRP</b> communicates to the Pitt/UPMC study team whether reliance will be used.</p>
6	<p><b>Pitt/UPMC study team</b> submits IRB application <i>with Pitt/UPMC site only</i> for review and approval.</p> <p><b>Note:</b> The Pitt/UPMC site may begin research activities following this approval.</p>
7	<p><b>Note, this step will NOT apply to all studies.</b></p> <p>If applicable, the <b>Pitt/UPMC study team</b> will send the IRB approval and IRB-approved documents to any external entity that requires review and approval (e.g., Military HRP, DSMB, etc.)</p>
8	<p>Following IRB review/approval of the <u>initial IRB application</u>, <b>Pitt/UPMC study team</b> disseminates IRB-approved materials (initial IRB approval letter, IRB-approved protocol, approved consent template) and local context survey to relying sites for completion.</p> <p>Concurrently, the <b>Pitt HRP</b> will begin communication with relying site Human Research Protection Program (HRPP) to determine what type of agreement will be used and facilitates agreement execution.</p>
9	<p><b>Relying Site study team(s)</b> work w/their local HRPP to complete the reliance agreement, Local Context Survey and local language in the consent template(s).</p>
10	<p><b>Relying Site study team(s)</b> submit completed Local Context Survey and consent(s) to <b>Pitt/UPMC study team</b>.</p>
11	<p><b>Pitt/UPMC study team</b> submits a modification in PittPRO to onboard relying site(s). You can batch sites when on-boarding or submit one MOD at a time, whatever your preference.</p>
12	<p><b>Pitt HRP</b> reviews/approves onboarding modification.</p>
13	<p><b>Pitt/UPMC study team</b> disseminates IRB-approved materials to relying site(s).</p>

14	<b>Pitt/UPMC study team</b> submits approval letter(s) to Pitt Office of Sponsored Programs for grant/contract execution.
15	The relying sites may begin the project when indicated by their local site policies.

**Note:** The relying site’s HRPP may have additional requirements prior to ceding review to the Pitt IRB. The relying site study team should contact their local HRPP to ensure compliance with local policy. For instance, only IRB oversight is ceded; the relying site is responsible for conducting any necessary ancillary reviews for their site (e.g., COI, Radiation Safety, IBC, etc.).

## Creating a Pitt IRB of Record application in PittPRO

When Pitt is serving as the IRB of Record, the initial IRB application must **only** describe the research being conducted at the Pitt/UPMC site. The initial application may be submitted prior to finalization of Reliance Agreement(s). Note, there is no requirement that a separate Coordinating Center application be submitted when using the sIRB mechanism.

Login to PittPRO ([www.pittpro.pitt.edu](http://www.pittpro.pitt.edu)) and select the “Create New Study” button and address the following:

PITTPRO SECTION	
<b>BASIC INFORMATION</b>	<b>INSTRUCTION</b>
1. <i>Title of study:</i>	Include “sIRB” at the beginning of the title of study.
2. <i>Short title:</i>	Include “sIRB” at the beginning of the short title.
4. <i>What kind of study is this?</i>	Select “Multi-site or Collaborative study”.
5. <i>Will an external IRB act as IRB of record?</i>	Select “NO”.
6. <i>Will your IRB act as the single IRB of record for other participating sites?</i>	Select “YES”.
9. <i>Attach the protocol:</i>	Leave this item blank; do <b>not</b> upload the protocol here.
<b>FUNDING SOURCES</b>	<b>INSTRUCTION</b>
1. <i>Indicate all sources of support (e.g., No Support/Internal/External):</i>	Indicate all sources of support (e.g., No Support/Internal/External)
2. <i>Identifying each organization supplying funding for the study:</i>	Select the ‘Add’ button to identify each source of funding and address the following: <ol style="list-style-type: none"> <li>1. When searching for a Funding Organization do <b>not</b> use acronyms, you must search for the full name. Use % as a wildcard to search for part of a name.</li> <li>2. Enter the Sponsor’s funding ID.</li> <li>3. Enter the Grants office ID.</li> <li>4. Upload the FULL grant application in this section for review.</li> </ol>

	<p>5. Indicate whether (YES OR NO) Pitt is the awardee institution.</p> <p>Note: If applicable, the Pitt HRP will provide a completed fee sheet to the study team for signature and upload under item #4.</p>
RESEARCH SITES	INSTRUCTION
1. <i>Choose all sites that apply:</i>	<p>Select the Pitt/UPMC sites where research procedures will be conducted.</p> <p>DO <b>NOT</b> SELECT “EXTERNAL SITES/ OTHER”, as relying sites will be onboarded in a later modification.</p>
MAIN STUDY-RELATED DOCUMENTS	INSTRUCTION
1. <i>Consent form templates:</i>	<p>Leave this item blank.</p> <p>The Pitt HRP will create and provide consent template(s) for upload in this section.</p>
3. <i>Other attachments:</i>	<p>Upload the multi-site protocol.</p> <p>For instructions how to create a multi-site protocol, see the “Instructions for Creating a Multi-Site Protocol” section below.</p>
STUDY DESIGN	INSTRUCTION
1. <i>Total number of subjects to be enrolled at this site:</i>	<p>This number should reflect the total number of subjects to be enrolled across all sites that are relying on the Pitt IRB, this includes the Pitt/UPMC site.</p>
CONSENT FORMS	INSTRUCTION
1. <i>Consent Forms:</i>	<p>Upload the Pitt/UPMC consent form(s).</p>

Once the Pitt HRP approves the initial IRB application, and all ancillary reviews are completed, research procedures may begin at the Pitt/UPMC site only.

## Instructions for Creating a Multi-Site Protocol

The Multi-site Protocol and Consent Template documents are included in the initial IRB application for review and approval. Upon approval, the **Pitt/UPMC study team** may disseminate the IRB approved multi-site protocol and consent form template to relying sites.

The purpose of the multi-site protocol is to outline standard operating procedures for a research study, to ensure the same protocol and procedures are being done across all sites involved in the study. For instructions how to create a multi-site protocol, login to PittPRO, select the “LIBRARY” option on the left side of the screen, select the “TEMPLATES” tab, and select [HRP-503-Template-Protocol](#).



## Creating a Modification to add Relying Sites

Relying Sites may be added one-at-a-time or batched, by adding multiple sites in one modification.

For minimal risk studies, this modification may include other changes.

For Greater than Minimal Risk studies, **these modifications *MUST* be limited to changes related to on-boarding the relying site(s)**. Onboarding Mods can be processed as an Expedited submission. All other changes must be submitted in a separate modification, as these may need to go to Full Committee for review.

The following must be completed prior to the submitting a modification to on-board a relying site:

- The Reliance Agreement for that relying site has been fully executed
- The relying site has completed the Local Context Survey and local consent/assent form(s) and returned them to the Pitt/UPMC study team

To modify an approved Pitt IRB of Record Application:

1. Login to PittPRO
2. Open the Pitt IRB of Record application
3. Select the “Create Modification/CR” button
4. Select “Modification / Update”
5. Select “Study team and research location information” AND/OR “Other parts of the site”
6. Use the following chart to complete and save edits
7. PI press “SUBMIT” button

PITTPRO SECTION	
<b>STUDY TEAM MEMBERS</b>	<b>INSTRUCTION</b>
2. <i>External team member information:</i>	Leave this item blank; do <b>not</b> upload relying site external team members in this section.
<b>STUDY SCOPE</b>	<b>INSTRUCTION</b>
4. <i>Will Protected Health Information be collected?</i>	If protected health information (PHI) will be collected from a <u>non-UPMC/Pitt</u> HIPAA covered entity (i.e., the relying site), select “Other Institutions’ Medical Records”.
<b>RESEARCH SITES</b>	<b>INSTRUCTION</b>
1. <i>Choose all sites that apply:</i>	Select “External Sites/ Other” to open item #2 described below.
2. <i>Identify other research locations where the investigator will conduct or oversee the research:</i>	To <u>add</u> relying site(s), click the ‘Add’ button and include the following in the text box that populates: <ol style="list-style-type: none"> <li>1. Do <b>not</b> select the research location in this item; simply complete the following fields:               <ol style="list-style-type: none"> <li>a. Location name</li> <li>c. Contact name</li> <li>d. Contact phone</li> <li>e. Contact email</li> </ol> </li> <li>2. Click the <i>Add</i> button and upload: (1) the fully executed agreement or letter of</li> </ol>

	acknowledgement and (2) the completed local context form.
3. Describe the availability of resources and the adequacy of the facilities to conduct this study:	Using break out paragraphs, describe the availability of resources and the adequacy of the facilities to conduct this research for each site that is being on-boarded.
<b>STUDY DESIGN</b>	<b>INSTRUCTION</b>
8. Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):	If this has not been completed already, include the total number of subjects to be enrolled at each site that is being on-boarded in this modification.
<b>CONSENT FORMS</b>	<b>INSTRUCTION</b>
1. Consent Forms:	Upload a tracked changes version of the consent document(s) for each relying site that is being on-boarded. This should track the language the relying institution inserted into the template.

If any aspect of the study will be conducted differently at a relying site, *as outlined in Part 1 of the Local Context Form for the Relying Site*, the IRB application will need to reflect these differences in the appropriate PittPRO item. For example, if the consent process will be conducted differently at relying site, the “Consent Process” section must include a breakout paragraph specifying how subjects will be consented at that relying site.

Research may not begin at a relying site until the following has been completed:

- Pitt IRB approves the modification to on-board the relying site
- All local institutional requirements have been met for the relying site
- Grant/contract execution has been completed through the Pitt Office of Sponsored Programs

## Submitting Continuing Review (CR) for a Pitt IRB of Record application

When creating a CR for a Pitt IRB of Record application in PittPRO, all items should be addressed “across all sites”, with the exception of item #3.

To create a CR for an approved Pitt IRB of Record application:

1. Login to PittPRO
2. Open the Pitt IRB of Record application
3. Select the “Create Modification/CR” button
4. Select “Continuing Review”
5. Use the following chart to complete and save edits
6. PI press “Submit” button

<b>CONTINUING REVIEW / STUDY CLOSURE INFORMATION</b>	
1. Specify enrollment totals:	The enrollment numbers must reflect the total enrollment numbers across all sites.

2. <i>Research milestones:</i>	<p>This item must reflect the most conservative milestones across all sites.</p> <p>For instance, if Pitt site is closed to enrollment, but a relying site is open to enrollment, do <b>not</b> select “Study is permanently closed to enrollment”, as this milestone does not apply to all sites.</p>
3. <i>Do any investigators or research staff have a financial interest related to the research that was not described in the previous application?</i>	<p>This item must reflect whether Pitt/UPMC investigators have a financial interest.</p> <p>Do <b>not</b> consider relying sites here, as this is a local context issue.</p>
4. <i>Check the items that are true since the last IRB approval for all sites involved in the study:</i>	<p>This item must reflect events across all sites.</p>
5. <i>Attach supporting documents:</i>	<p>Upload a document including:</p> <ul style="list-style-type: none"> <li>• An explanation of each item left unchecked under item #4</li> <li>• List enrollment numbers for each relying site (including the Pitt/UPMC)</li> </ul>

## Reportable New Information (RNI)

Reportable new information should be submitted to the Pitt IRB based on Pitt’s reporting guidelines (found at [www.hrpo.pitt.edu](http://www.hrpo.pitt.edu) > Policies and Procedures > Chapter 17 – Reportable New Information). If the Pitt IRB makes a determination of serious and/or continuing non-compliance and/or unanticipated problem involving risk to subject or others, a copy of the RNI and the correspondence from the Pitt IRB must be disseminated to the relying site where the event occurred.

To create a RNI for an approved Pitt IRB of Record application:

1. Login to PittPRO
2. Select “Report New Information”
3. Complete and save the Reportable New Information
4. Press “Submit RNI” button

## SIRB Fee Budget

The NIH issued a policy permitting the institution that is acting as IRB of Record 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](#)).

Given the amount of effort involved in oversight of collaborating sites, starting on June 1, 2021, the University of Pittsburgh Human Research Protection (HRP/IRB) will require that all NIH studies requesting that the Pitt IRB serve as the IRB of record submit a budget for direct costs to support this work.

For NIH-funded projects, the research teams must contact the Pitt Reliance Team ([irb.reliance@pitt.edu](mailto:irb.reliance@pitt.edu)) at least *four* weeks in advance of grant application due dates to arrange for the development of a budget and letter of support (if applicable). **The IRB reserves the right to decline to serve as the IRB of record if funds were not budgeted for this purpose.**

In addition, the [signatory agencies](#) of the Common Rule also require the use of a single IRB of record for multi-site research. Although no guidance has been issued from the Federal government regarding budgeting for these projects, Pitt HRP does have a policy in place that compensation for our services is required when Pitt acts as the single IRB of Record for external sites.

Pitt is willing to act as IRB of Record these studies provided that the IRB service fees are supported either through the grant or departmental funds. For non-NIH funded projects, it is preferable for study teams to contact the Reliance Team four weeks in advance of needing a budget. However, the Pitt HRP understands that may not always be possible. It is important that the Pitt HRP provide a budget and discuss whether the grant or departmental funds can/will be used to cover sIRB fees prior to the study team submitting a formal reliance request to our office. This budgetary information will be needed for us to make an informed decision about our ability to serve as IRB of Record for the study.

The Pitt HRP will provide the sIRB budget for your project at the time we provide your Letter of Support (if applicable). Both letters of support and budget requests must be submitted through the [Reliance Request System](#). The total sIRB Fee Budget should be included as direct line item in your grant budget.

The provided budget will be based on the maximum of relying sites indicated in the submitted sIRB Fee Budget request. If more than the max number of indicated relying sites are added in the future, the budget will need to be recalculated to add fees for the additional sites.

If the Pitt HRP has already provided a study team with an sIRB Fee budget for a grant that was received before June 1, 2021 that budget will be honored for the duration of the project. For all grants received June 1, 2021 or after the following fee schedule will be utilized.

#### Fee Budget – Grants funded *on/after* June 1, 2021

- **Initial onboarding fees** = \$2,100 per # of sites that will rely on the Pitt IRB\*  
This does **NOT** include Pitt/UPMC as a relying site.  
**For example, if there are two relying sites: \$2,100 x 2 relying sites = \$4,200**
- **Modification fees that affect the entire project** = \$400 per onboarded site  
Modification budget calculation is based on an average of 4 modifications per year and the max # of relying sites.  
**For example, if there are two sites and the grant duration is 5 years: \$400 x estimated 4 modifications per year x 2 relying sites x 5 years = \$16,000.**
- **Continuing Review fees** = \$250 per # of relying sites x grant duration (in years)  
**For example, if there are two sites and the grant duration is 5 years: \$200 x 2 relying sites x 5 years = \$2,000.**

Total example budget would be as follows:

*Initial onboarding*    \$4,200  
*Modifications*        \$16,000

*Continuing reviews \$2,000*

*\$22,200 = TOTAL sIRB fee budget for the duration for the duration of the 5-year grant*

Note, the Pitt HRP will honor the sIRB budget that was provided to the study team at the time of request.

## Processing sIRB Fees

The fee sheet will be provided by the Pitt HRP at the time of initial submission, modification, or continuing review. The study team will receive instruction to complete the highlighted sections of the Fee sheet including the 32-digit Pitt account number and signature for payment method. The completed and signed fee sheet must be uploaded in the reviewer-designated section in the PittPRO application.

Upon receipt of the fee sheet, the Pitt HRP will notify the ORP Business Manager to complete the interdepartmental charge (IDC) using the account number provided on the fee sheet. The Post Award Administrator that serves your area will keep a copy of the Fee Sheet so when charges hit the level reports, they can confirm the charge.

Do **not** email fee sheets directly to the ORP Business Manager; these fee sheets should solely be provided to the Pitt HRP as an attachment in the PittPRO application.

## Schedule of payment collection

Fees will be charged per the following schedule:

### Fee Schedule – Grants funded *prior* to June 1, 2021

- **Initial onboarding fee for each relying site**  
The initial onboarding fee (\$1,000/\$2,000) will be submitted when the modification application is reviewed and approved.
- **Modification fee for entire duration of grant**  
The modification fee (\$1,750) for the first year of the grant will be submitted when the IRB application is initially reviewed and approved.
- **Continuing review fee for duration of grant**  
The continuing review fee (\$500/\$1,000) **plus** the modification fee for the following year (\$1,750) will be submitted when the continuing review IRB application is reviewed and approved.

### Fee Schedule – Grants funded *on/after* to June 1, 2021

- **Initial onboarding fee for each relying site**  
The initial onboarding fee (\$2,100 x # of relying site) will be charged when the modification to onboard relying site(s) is submitted.
- **Modification (that affects the entire project) fee**  
The modification fee (\$400 x # of onboarded relying sites) will be charged when the modification is submitted.

- ***Continuing review fee***

The continuing review fee (\$250 x # of onboarded relying sites) will be charged when the continuing review is submitted.

## **Other Research Agreements**

If data and/or materials will be transmitted to/from Pitt and a relying site, 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 include this.** 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.