

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 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 on page 22 of this document.

The first step to requesting Pitt act as IRB of Record is submitting a request for sIRB fee budget.

You can submit a request for an sIRB fee budget in our online [Reliance Request System](#). On the third data collection page of the system, simply select “sIRB Fee Budget and/or Letter of Support for grant submission” and complete the prompts.

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

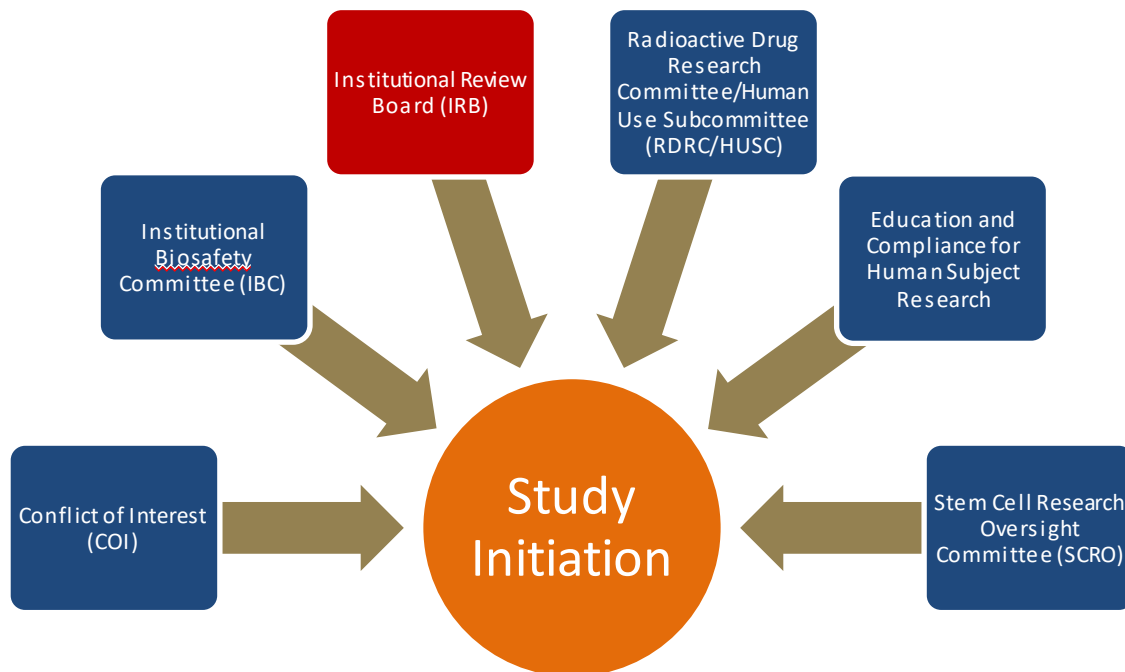
Single IRB Review (Reliance): A legal arrangement that allows one IRB to review the research on behalf of other engaged institutions.

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

- 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 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 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, to ensure that the Reliance Team is promptly receiving all requests 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.

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 *new* 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 Grant Letter of Support & sIRB Fee Budget

It is an NIH requirement for 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 must obtain confirmation from each site indicating their willingness to rely on the specified sIRB.

In addition to your Letter of Support, the Pitt HRP will also provide an sIRB fee budget for inclusion in the grant application budget. 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 on page 22 of this document.

Pitt IRB of Record - Timeline Overview

1	Pitt/UPMC study team 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 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 the reliance request at sIRB meeting to determine if reliance is appropriate.
4	The Pitt HRP communicates to the Pitt/UPMC study team whether reliance will be used.
5	Pitt/UPMC study team submits IRB application <i>with Pitt/UPMC site only</i> for review and approval. Note, the Pitt/UPMC site may begin research activities following this approval.

6	<p>Note, this step will <u>not</u> apply to <i>all</i> studies.</p> <p>If applicable, the Pitt/UPMC study team 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>
7	<p>Following IRB review/approval of the initial IRB application, Pitt/UPMC study team 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 Pitt HRP will begin communication with relying site HRPP to determine what type of agreement will be used and facilitates agreement execution.</p>
8	<p>Relying Site study team(s) work w/their local Human Research Protection Program (HRPP) to complete the reliance agreement, Local Context Survey and local language in the consent template(s).</p>
9	<p>Relying Site(s) submit completed Local Context Survey and consent(s) to Pitt/UPMC study team .</p>
10	<p>Pitt/UPMC study team 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>
11	<p>Pitt IRB reviews/approves onboarding modification .</p>
12	<p>Pitt/UPMC study team disseminates IRB-approved materials to relying site(s).</p>
13	<p>Pitt/UPMC study team submits approval letter(s) to Pitt Office of Sponsored Programs for grant/contract execution.</p>
14	<p>The relying sites may begin the project when indicated by their local site policies.</p>

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.).

Requesting Pitt IRB to Serve as IRB of Record

The first 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 → 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 the [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.

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) and select the “Create New Study” button and address the following:

PittPRO section	Instruction
Basic Information	
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 not upload the protocol here.
Funding Sources	
1. <i>Indicate all sources of support (e.g. No Support/Internal/External):</i>	
2. <i>Identifying each organization supplying funding for the study:</i>	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. <ul style="list-style-type: none"> 1) Can be left blank 2) Can be left blank 3) Upload grant application and completed sIRB Fee Sheet 4) Indicate if Pitt is Primary Awardee
Research Sites	
1. <i>Choose all sites that apply:</i>	Select the Pitt/UPMC sites where research procedures will be conducted. <p>Do not select “External Sites/ Other”, as relying sites will be onboarded in a later modification.</p>
Main Study-Related Documents	
1. <i>Consent form templates:</i>	Upload the consent template(s).

	For instructions how to create a consent template, see the “Instructions for Creating a Multi-Site Protocol and Consent Template” section below.
3. <i>Other attachments:</i>	Upload the multi-site protocol. For instructions how to create a multi-site protocol, see the “Instructions for Creating a Multi-Site Protocol and Consent Template” section below.
Study Design	
1. <i>Total number of subjects to be enrolled at this site:</i>	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.
8. <i>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):</i>	Include the total number of subjects to be enrolled at each site that is relying on the Pitt IRB, including the Pitt/UPMC site. If this is unknown, only include the total number of subjects to be enrolled at the Pitt/UPMC site. Enrollment numbers for relying sites can be included in a later modification the sites are on-boarded.
Consent Forms	
1. <i>Consent Forms:</i>	Upload the Pitt/UPMC consent form(s).

Once the Pitt IRB approves the initial IRB application and fiscal review (if required) is completed, the research procedures may begin at Pitt/UPMC **only**.

Transitioning an approved Pitt IRB of Record application from OSIRIS into PittPRO

All approved Pitt IRB of Record applications in OSIRIS must be submitted into PittPRO at this time. The Pitt HRP has created “shells” of each approved Pitt IRB of Record application in OSIRIS. Once the shell has been created, it will appear in the PittPRO Inbox.

To create and submit the Pitt IRB of Record application in PittPRO:

1. Login to PittPRO
2. Open the Pitt IRB of Record 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

General Notes:

- Some of the content in OSIRIS no longer has a home in PittPRO (e.g., risk determination).
- Study team members no longer involved and documents that are no longer being used (and will not be used in the future) can be removed but ANY other changes are **not** permitted at the time of transition.

- Do **not** rename documents during this process. The IRB coordinator assigned to the transition will be conducting a historical review between OSIRIS and PittPRO to ensure consistency. Renaming documents can cause a delay in the review process.

PittPRO section	OSIRIS section	Additional Instruction
Basic Information		
1. <i>Title of study:</i>	CS2.0	Include “sIRB” at the beginning of the title of study.
2. <i>Short title:</i>	First item in OSIRIS	Include “sIRB” at the beginning of the short title.
3. <i>Brief Description:</i>	CS2.1	
4. <i>What kind of study is this?</i>	N/A	Select “Multi-site or Collaborative study”.
5. <i>Will an external IRB act as IRB of record?</i>	N/A	Select “no”.
6. <i>Will Pitt act as the single IRB of Record?</i>	N/A	Select “yes”.
7. <i>Local principal investigator:</i>	CS3.0	This section has already been completed.
8. <i>Does the local principal investigator have a financial interest related to this research?</i>	7.3	
9. <i>Attach the protocol:</i>	CS11.0	Leave this item blank; do not upload the protocol here.
Funding Sources		
1. <i>Indicate all sources of support (e.g. No Support/Internal/External):</i>	7.2	It is important to list ALL funding sources in this section. It is especially important since PittPRO will be integrated into the PERIS solution at some point. We need to ensure consistent information between the two systems.
2. <i>Identifying each organization supplying funding for the study:</i>	7.2	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. <ul style="list-style-type: none"> 1) Can be left blank 2) Can be left blank 3) Indicate if Pitt is Primary Awardee 4) Upload grant application <p>If a Fee Sheet was included, this is the section where it will be uploaded. Upload this document under item #4.</p>
Study Team Members		
1. <i>Identify each person involved in the design, conduct, or reporting of the research (includes PI):</i>	CS3.0 – PI CS4.0 – Co-Is	Include research coordinators, as there is no other place to list personnel in the application.

	CS5.0 – CS6.3 – Research Staff	Include qualifications if the research coordinator will be conducting research procedures (e.g., obtaining informed consent, administering measures, etc.).
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	Prior to approval, this must be verified.
Study Scope		
1. Will this study actively recruit any of the following populations?	CS16.0 2.19.2 2.21 3.4 3.5 3.6 3.7 3.8 4.10	The selections made on this page will determine which branching pages are displayed.
2. Will any waivers be requested?	2.14.2 4.6 4.7 4.8	Be sure to be accurate in making selections on this page. This is what the system uses to provide the necessary pages of the application required for completion. For waivers, choose the correct option: <ul style="list-style-type: none"> • Waiver/alteration of consent means that a complete waiver was previously approved (no consent process) or part of the consent process was altered (Section 4.7) • Waiver to document consent means that some type of “verbal” or “click for consent” consent process was approved (Section 4.6) • Waiver/Alteration of HIPAA means that a waiver of HIPAA Authorization was previously approved (Section 2.14.2)
3. Will this study involve any of the following?	2.13 2.6 2.15 2.15.4 3.9 4.14	

4. Will Protected Health Information be collected?	2.14 2.14.1	
5. Other requests?	2.3.1 2.4 2.12	
6. Determining Scientific Review:	CS8.0	This item must list the department that was selected for Scientific Review in OSIRIS. Note, this selection is for documentation purposes and will <u>not</u> re-trigger scientific review.
7. Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?	CS1.1.1	
8. Does the study (1) use an approved drug or biologic, (2) use an unapproved drug or biologic, or (3) use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?	CS9.0 - 10.1 2.1	
9. Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?	CS9.0 - 10.1 2.2	
10. Is this application being submitted to convert an approved study from OSIRIS to PittPRO?	Protocol # & study expiration date are found on the OSIRIS study title page	Select "yes". Enter the OSIRIS study number (starting with either PRO or IRB) into OSIRIS ID section. If the OSIRIS application is due to expire within the next 3 months , complete and upload the "HRP-720-OSIRIS.Conversion.Continuing Review" document in this section. This document can be found in PittPRO → Library → General tab
11. Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after review this HUSC guidance, does your research protocol require HUSC review? (If yes, upload the HUSC form in the	CS12.0	

<i>Local Supporting Documents section). If you are unsure of review requirement, select yes.</i>		
Research Sites		
<i>1. Choose all sites that apply:</i>	CS15.0	Select the Pitt/UPMC sites where research procedures will be conducted. Select "External Sites/ Other" to open item #2 described below.
<i>2. Identify other research locations where the investigator will conduct or oversee the research:</i>	CS15.0 (gray text box)	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"> 1. Do <u>not</u> select the research location in this item; simply complete the following fields: <ol style="list-style-type: none"> a. Location name c. Contact name d. Contact phone e. Contact email 2. Click the <i>Add</i> button and upload: (1) the fully executed agreement or letter of acknowledgement and (2) the completed local context form.
<i>3. Describe the availability of resources and the adequacy of the facilities to conduct this study:</i>	CS15.2	
Main Study-Related Documents		
<i>1. Consent form templates: Upload the consent template(s).</i>	CS11.0	
<i>2. Recruitment material templates: Upload recruitment templates, if any</i>	4.1	Leave this item blank.
<i>3. Other attachments: Upload the multi-site protocol.</i>	CS11.0	
Recruitment Methods		
<i>Will you be recruiting individuals for participation in this study? If yes,</i> <i>1. Describe who will be recruiting individuals for participation for this study:</i>	4.2	
<i>2. Select all methods to be used for recruitment:</i>	4.1	
<i>3. Provide details on your recruitment methods:</i>	4.2	

4. Describe all compensation/incentives offered to participants and timing of these offers:	6.2	
5. Recruitment materials (attach all material to be seen or heard by subjects, including advertisements and scripts):	4.1	<p>Leave at least a 1" margin on recruitment material so that the approval watermark applied by the system is visible.</p> <p>If an advertisement with pull tabs is used, upload that document under 'Supporting Documents' section, as the watermark will be "pulled off" with the tabs.</p> <p>At this time, material designed using Microsoft Publisher has not been able to be watermarked. If this software is needed, upload those ads into 'Supporting Documents' section.</p>
Study Aims		
1. Describe the purpose, specific aims, or objectives and state the hypotheses to be tested:	1.1 1.2	
2. Describe the relevant prior experience and gaps in current knowledge including preliminary data. Provide for the scientific or scholarly background for, rationale for, and significance of the research based on existing literature and how it will add to existing knowledge:	1.3 1.4	
Study Design		
1. Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):	3.11	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.
2. Describe and explain the study design:	2.3	<p>Do not include the research activities in this section.</p> <p>Summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study.</p>
3. Describe the primary and secondary study endpoints:	2.17	Do not include endpoints for withdrawing subjects in this section, as this is addressed elsewhere in the application. This section should reflect the main outcome variables that will be evaluated in this study.
4. Provide a description of the following timelines:	2.11	

<p><i>Duration of an individual subject's active participation:</i></p> <p><i>Duration anticipated to enroll all subjects:</i></p> <p><i>Estimated date for the investigator to complete this study (complete primary analyses):</i></p>		
5. List the inclusion criteria:	3.13	
6. List the exclusion criteria:	3.14	
7. Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?	3.5	
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):	3.12 2.18	Include the total number of subjects to be enrolled at each site that is relying on the Pitt IRB, including the Pitt/UPMC site.
Research Activities		
1. Provide a detailed description of all research activities (including screening and follow-up procedures) that will be performed for the purpose of this research study. This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.	2.5 2.6 2.7	There are no longer separate sections to outline screening and follow up procedures. All procedures being done (screening, study, and follow-up) go under this section. They should appear in that order with headings as applicable: screening – study procedures – follow-up.
2. Upload a copy of all materials used to collect data about subjects: (Attach all surveys, interview/focus group scripts, and data collection forms except for case report forms, SCID or KSADS):	2.8	
3. Will blood samples be obtained for research purposes?	2.6.1	
Consent Process		

1. Indicate where consent process will take place and at what point consent will be obtained:	4.12	
2. Describe the steps that will be taken to minimize coercion and undue influence, including assurance that there is sufficient time for subjects to make an informed decision:	4.11.1	
3. For studies that involve multiple visits, describe the process to ensure ongoing consent:	4.12	
4. Steps to be taken to ensure subjects' understanding:	4.12	
5. Are you requesting an exception to the IRB policy related to the informed consent process:	4.13	Only request this exception if it was approved previously in OSIRIS.
Consent Forms		
1. Consent Forms:	4.9	Remove footers on ALL PAGES of the consent document(s). If these are finalized, This will force the study team to have to submit a modification to make a correction because the IRB staff no longer has administrative functions. Instructions: Open the draft consent document from OSIRIS, save the document to your computer, remove the footer from all pages but leave a 1" margin at the bottom of each page so the watermark in PittPRO is visible, correct any formatting issues but DO NOT make any wording changes. This is the consent version that will be uploaded into PittPRO.
Electronic Data Management		
1. Will only anonymous data be collected? If yes, select <u>all identifiers</u> to be collected during any phase of the research including screening: 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.?	Data security assessment form uploaded in 5.15	Do not upload the data security assessment form in the IRB of Record application. Transfer all information from the data security assessment form into these sections.

<p>b. Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?</p> <p>c. List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:</p> <p>d. Will you be collecting any data subject to the General Data Protection Regulation (<u>GDPR</u>)?</p> <p>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?</p> <p>Will data be HIPAA de-identified?</p> <p>Briefly describe your plan to store coded data separately from the identifiable data:</p>		
<p>2. Will sensitive data be collected (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?</p>		
<p>3. Select all locations where data will be stored or accessed (including e.g., personal/ employer laptop or desktop):</p>		
<p>4. Select all technologies being used to collect data or interact with subjects:</p>		
Data Safety and Monitoring		
<p>1. Describe your plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor:</p>	<p>5.13</p>	

2. Describe your plan for sharing data and/or specimens:	5.8	
3. If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:	5.15	
Risk and Benefits		
1. Enter all reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to subjects' participation in the research:	5.1 5.4 5.5	
2. Describe the steps that will be taken to prevent or minimize risks:	5.1.1	
3. Financial risks - will the subject or insurer be charged for any research required procedures?	6.1	
4. Describe the steps that will be taken to protect subjects' privacy:	5.14	
5. What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:	5.2	
6. Describe the potential benefit that individual subjects may experience from taking part in the research or indicate if there is no direct benefit. Do not include benefits to society or others:	5.12	
7. Do you anticipate any circumstances under which subjects might be withdrawn from the research without their consent?	5.7	
8. Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and data already collected:	5.16	

Conflict of Interest		
1. Is this FDA covered Clinical trial?	N/A	
2. Does this study involve a Non-Significant Risk Device and you anticipate including the results as part of any type of submission to the FDA for approval of this device?	N/A	
3. Is this study funded in part or whole by a PHS Agency?	7.3	
4. Does any investigator involved in this study (select all that apply):	7.3	
5. Provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):	7.3	
Ancillary Reviews		
1. Ancillary reviews or notifications selected below are required based on previous answers to questions. If a selection is incorrect, return to the appropriate page and adjust the answers to questions on that page:		
2. Additional ancillary reviews the PI may choose to include as needed for the research:	CS17.0 CS13.0	
Good Clinical Practice		
1. Regardless of funding source, is this study a clinical trial (<u>as defined by the NIH</u>)?	CS18.0	
ClinicalTrials.gov Information		
2. Was this study registered, or will it be registered, on ClinicalTrials.gov?	Last item in OSIRIS	
Local Supporting Documents		
1. Attach any additional supporting documents not previously uploaded.	References and other Attachments	Upload a document including: <ul style="list-style-type: none"> An explanation of each item left unchecked under item #4 in the completed "HRP-720-OSIRIS.Conversion.Continuing Review" document A list enrollment numbers for each relying site (including the Pitt/UPMC)

		<p>Do not “data dump” into this section. There are places throughout the application to upload documents. Only include documents in this section if there is not another section in PittPRO to put them.</p> <p>Note, do <u>not</u> upload the following, as these are uploaded in specified sections above:</p> <ul style="list-style-type: none"> • Fully executed agreement or letter of acknowledgement • Local context forms for relying site(s) • sIRB fee sheets
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Instructions for Creating a Multi-Site Protocol and Consent Template

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.

Instructions for creating a Multi-site Protocol

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](#).

Instructions for creating a Consent Template

The purpose of the consent template is to ensure that all sites involved in the study are consenting subjects with the same information, except for state laws and local policies. This document must use the same language as the Pitt/UPMC consent but leaves blank areas where the relying site must insert their local language. The IRB recommends inserting “<Insert local language here>” in sections that the relying site is permitted to edit.

The sections of the consent that relying sites are permitted to edit are as follows:

- Institutional letterhead
- Local study staff & contact information
- Local HIPAA language (if applicable)
- Local compensation for injury language (if the procedures have the potential to cause physical harm)
- Local data storage and/or retention requirements
- Local compensation (if applicable)
- If the institution has additional local requirements and/or state laws that must be addressed by adding language or sections to the consent. **Note, any requests, by the relying site, to alter additional aspects of the consent form not listed above, require written justification.** The justification can be logged as a comment within the consent template. The justification must include citation of the relying site’s **written** policies, procedures or state laws that make the additional revisions necessary.

The consent template(s) must also include the Pitt IRB footer, as each relying site consent will be watermarked at the time of modification to on-board the relying site.

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 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	Instruction
Study Team Members	
2. <i>External team member information:</i>	Leave this item blank; do not upload relying site external team members in this section.
Study Scope	
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”.
Research Sites	
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"> 1. Do <u>not</u> select the research location in this item; simply complete the following fields: <ol style="list-style-type: none"> a. Location name c. Contact name d. Contact phone e. Contact email 2. Click the <i>Add</i> button and upload: (1) the fully executed agreement or letter of

	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.
Study Design	
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.
Consent Forms	
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, the IRB application will need to specify these details in the appropriate PittPRO item. For instance, if the consent process will be conducted differently at relying sites, the “Consent Process” section must include specify how each site is consenting, using break out paragraphs for each relying site.

Research may not begin at a relying site until all the following have occurred:

- 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

Continuing Review / Study Closure Information	
1. Specify enrollment totals:	The enrollment numbers must reflect the total enrollment numbers across all sites.

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

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 → 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 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 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) 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 <i>prior</i> to June 1, 2021
<ul style="list-style-type: none"><i>Initial onboarding fee for each relying site</i> The initial onboarding fee (\$1,000/\$2,000) will be submitted when the modification application is reviewed and approved.<i>Modification fee for entire duration of grant</i> The modification fee (\$1,750) for the first year of the grant will be submitted when the IRB application is initially reviewed and approved.<i>Continuing review fee for duration of grant</i> 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 <i>on/after</i> to June 1, 2021
<ul style="list-style-type: none"><i>Initial onboarding fee for each relying site</i> The initial onboarding fee (\$2,100 x # of relying site) will be charged when the modification to onboard relying site(s) is submitted.<i>Modification (that affects the entire project) fee</i> The modification fee (\$400 x # of onboarded relying sites) will be charged when the modification is submitted.<i>Continuing review fee</i>

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.