
Welcome to the Pitt HRP's Community Education Session:
SINGLE IRB

Meet Your Pitt IRB Reliance Team

Jeannie Barone, Director HRPO
Melissa Miklos, Associate Director, HRPO
Deane Quillen, Associate Director of Reliance

Megan Dalzell, Reliance Specialist
Megan Frame, Reliance Specialist
Natalie Novak, Reliance Specialist
Lauren Runkel, Reliance Specialist

Before we get started…

Type general Reliance questions in the Q&A box

- Project specific questions – irb.reliance@pitt.edu
- General IRB questions – askIRB@pitt.edu
- PittPRO submission specific questions – Assigned IRB coordinator

Following today's session:

- Presentation slides
- Summary of questions and responses
- Reliance Request checklists & link
- Link to a brief, anonymous feedback survey

Before we get started…

Disclaimer: Information provided here is *subject to change*.
For the most up-to-date information:

www.hrpo.pitt.edu > Guidance & Forms > *Reliance Guidance*

Today's Topics

Single IRB 101:
General Overview of Reliance

IRB of Record:
What it means for Pitt to Serve as the Lead Site

--Break: 10 minutes--

Ceding IRB Oversight:
Acting as a Participating Site in a Multicenter Project

Role of the Research Coordinator:
Tips and Considerations when coordinating an sIRB

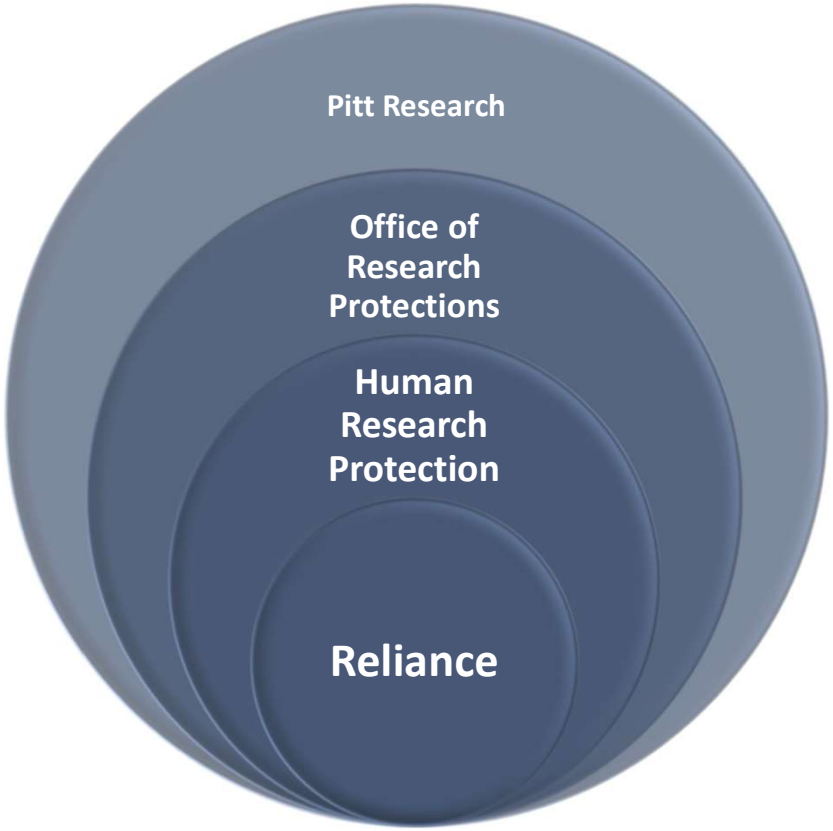
Individual Investigator Agreements:
Who is Eligible and How to Submit a Request


Single IRB 101
What Does it Mean?
&
Where Do I Start?
University of Pittsburgh

Presentation Overview

- Pitt Reliance
- What is Human Subjects Research?
- Common Reliance terms
- What is sIRB?
- sIRB requirement & exceptions
- Online Reliance portals
- Ancillary reviews
- When is sIRB needed?
- When is sIRB not appropriate?
- Glossary
- Additional considerations
- Happy to provide guidance & consult

Who we are...



Pitt Reliance

- Part of Pitt HRP
- IRB members
- Alongside Exempt / Expedited and Full Board Coordinators
- Review studies where Pitt is IRB of Record; conduct administrative review of ceded submissions
- Facilitate execution of Reliance agreements
- Provide guidance to researchers regarding need for Reliance

…and what we cover

Human Subjects Research

Human Subject: living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual ***or*** *identifiable private information*

Research: systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Engaged *(one or more of the following)*

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*

Terminology

Reliance : Single IRB : sIRB

IRB model in which one IRB provides oversight for all study sites on a given project

IRB of Record : Lead IRB : Central IRB : The sIRB

IRB charged with providing oversight for all study sites on a given project

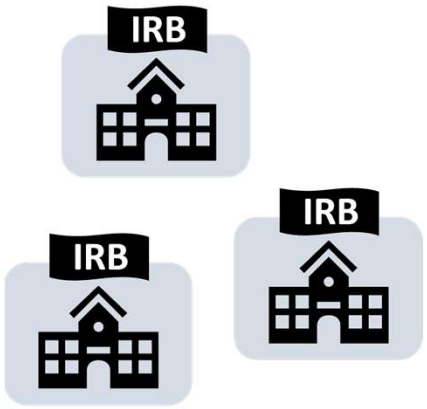
Ceding site : Relying site : Participating site

Institution relying on another IRB to provide IRB oversight on a given project

Local considerations : Local context

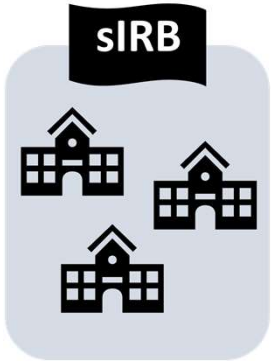
Policies, local laws, required language, and other local requirements communicated by the ceding site to the IRB of Record in order to conduct their review

What is Single IRB (sIRB)?



Traditional

- Multiple sites
- Multiple IRBs
- Initial, CR, mod reviews at each site
- Little communication between IRBs



Single IRB (sIRB)

- Multiple sites
- One IRB
- Single IRB review at initial, CR, and mod
- Direct & indirect communication between IRBs throughout life of study
- Reliance agreement

When Pitt is IRB of Record, the **Pitt study team is responsible for submitting in PittPRO all necessary information related to Continuing Review, Modifications, and RNIs** on behalf of **all sites**.

Types of Reliance Agreements

IRB Authorization Agreement (IAA)

- Pitt/UPMC researcher collaborating with researcher(s) at outside institution
- Outlines role of each IRB (relying vs. IRB of Record)
- Between the relying institution and the institution serving as the IRB of Record
- Study specific, site specific (though some master agreements extend beyond a single project)

Letter of Indemnification (LOI)

- Outlines allocation of liability; as-needed basis
- Between the relying institution and the institution serving as the IRB of Record
- Institution specific, directional, often involve each institution's Legal Counsel

Individual Investigator Agreement (IIA)

- Individual outside Pitt/UPMC, typically without an IRB of their own, collaborating with Pitt/UPMC researcher
- Outlines expectations and responsibilities of that individual
- Between the institution and the external individual
- Study specific and person specific

Pitt Reliance **does not** handle Data Use Agreements (DUAs) or Material Transfer Agreements (MTAs).
If you think your study may need a DUA or MTA, consult with the Office of Sponsored Programs.

Online Single IRB Platforms

SMART IRB

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Online platforms that act as a hub for study teams and Reliance representatives conducting and facilitating multi-site research.

Document Reliance

Communicate Local Context

Share Approved Documents

SMART IRB & IREx are not IRBs.

SMART IRB Agreement

In addition to the online portal, SMART IRB has also developed the **SMART IRB Master Common Reciprocal IRB Authorization Agreement**

Streamlines Reliance execution by outlining terms and conditions while still offering some flexibility (flex terms)

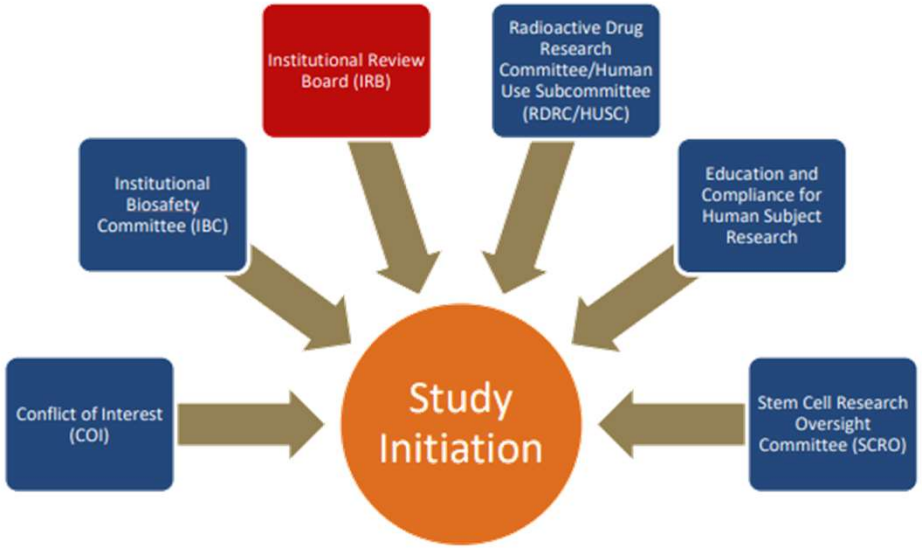
Pitt generally prefers to utilize this existing SMART Agreement when entering into Reliance with another institution who is signed on.

Over 1,000 institutions, including Pitt, UPMC, and MWRI, are signatories (SMART members).

Even when using the SMART Master Agreement, Reliance must still be requested, and a Letter of Acknowledgment (LOA) must still be executed in order to document Reliance arrangements for each site and study .

IRB review is just one piece of the puzzle.

- Reliance agreements cover **IRB OVERSIGHT ONLY!**
- Reliance agreements **<u>do not</u>** cover any required local ancillary reviews.



- Examples of ancillary reviews include:
  - Radiation Safety
  - Conflict of Interest
  - Institutional Biosafety Committee
  - IND/IDE Support

These ancillary reviews take place at the **<u>local institution</u>** regardless of whether your institution is relying or acting as the IRB of Record.

Reliance is nothing new…

...Its required use is.

National Institutes of Health

January 28, 2018

The **NIH** mandated the use of single IRBs as a **contingency for funding multi-site studies**, with the expectation that a single IRB of Record will be used in the ethical review of non-exempt human subjects research carried out at more than one site in the United States.

Revised Common Rule

January 20, 2020

The revised Common Rule requires that all institutions located in the United States that are **engaged in cooperative human subjects research conducted or supported by a Federal department or agency** rely upon approval by a single IRB for the portion of the research that is conducted in the United States.

sIRB is **not required** for non-domestic and exempt level research.

Multi-site versus Cooperative Research

Multi-site Research

Multi-site research use the same research procedures outlined in a single protocol that are carried out at multiple institution.

Cooperative Research

Cooperative (or “collaborative”) research involves two or more U.S. research sites where each site is conducting a different part of a research protocol under the direction/control of the lead PI.

Both are subject to Single IRB review requirement.

Some exceptions apply.

sIRB is **not mandated** if either…

More than single IRB review is required by law

(e.g., Tribal law)

Funding agency has granted an exception

Pitt HRP cannot grant a sIRB exception.

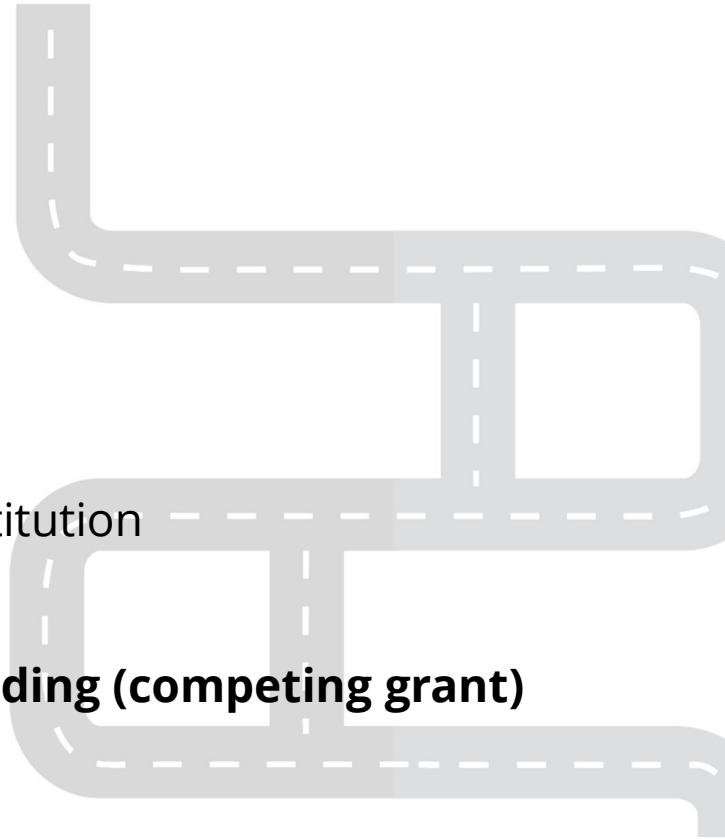
Consult with your Program Officer / funding agency if you would like to request an exception.

Roads to Reliance

- **Planned from the start (time of grant proposal writing & initial IRB submission)**

- **Post-award / Post-study start**
  - Investigator relocates
  - Adding a site to bolster recruitment
  - New collaborator who is affiliated with another institution

- **Ongoing multi-site study receives new federal funding (competing grant) that prompts sIRB**



When is Single IRB NOT Appropriate?

- Pitt HRP will **NOT** enter into Reliance:
  - For Exempt level research
  - With Institutions located outside of the United States
  - Other circumstances on a case-by-case basis

- Pitt HRP **MAY DECLINE** to serve as the IRB of Record:
  - Research activities not taking place here (e.g. no local clinical site)
  - Use of sIRB isn't mandated by funding
  - sIRB fees not budgeted*

- **Pitt HRP reserves the right to decline Reliance for any project.**

* Many institutions, including Pitt, charge fees for IRB services rendered to external sites. These fees can be incorporated into your grant budget. **Consult with Pitt Reliance early** to ensure sIRB fees are appropriately budgeted when Pitt is proposed as the sIRB.

Considerations when using Single IRB

- Whether relying or acting as the lead site, ensure that study staff are well trained in single IRB procedures (see Reliance guidance)
- Communicate with your Reliance team / IRB during project planning so appropriate considerations can be made within grant.
- Ensure study team at institution identified as IRB of Record is adequately resourced (may consider additional regulatory support staff depending on size and complexity of study)
- Ensure each site is communicating with their local IRB about their intent to utilize sIRB, local requirements, etc.

Links & helpful information can be found on the
Pitt HRP A-Z Guidance Website!

HRPO.PITT.EDU → Guidance & Forms → "R" → Reliance Guidance → IRB of Record

Study Team "Meet-and-Greets"

- We are ***more than happy*** to set up a call with you, your study team, and your relying site(s) study teams to discuss processes, expectations and guidelines for your specific study.
- Understanding the process from the beginning saves everyone time and frustration in the long run!
- Please reach out to irb.reliance@pitt.edu to discuss a Meet-and-Greet for your study!


THANK YOU
Up next... IRB of Record 101
University of Pittsburgh

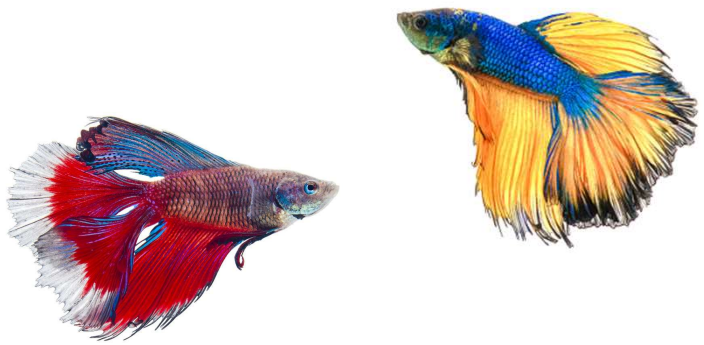

IRB of RECORD
What Does it Mean?
&
Where Do I Start?
University of Pittsburgh

Presentation Overview

- What does it mean to be IRB of Record?
- What are the responsibilities of the Pitt IRB Reliance Team?
- What are the responsibilities of the Pitt Study Team?
- What are the responsibilities of the Relying Site?
- sIRB Fees
- When to Reach Out
- Reliance Steps
  - Request a Budget and Letter of Support
  - Generate a STUDY ID in PittPRO
  - Submit a Reliance Request
  - Submit your PittPRO application
- Summary of Steps
- Onboarding a relying site
- FAQs

What Does it Mean when Pitt Serves as "IRB of Record"?

- The University of Pittsburgh IRB will provide the **IRB OVERSIGHT** for all US sites involved in your research project.
- Each "Relying site" will sign a Reliance Agreement ceding IRB oversight to the University of Pittsburgh IRB.
- Remember that Pitt will NOT conduct any ancillary reviews for relying sites! PittPRO will, however, facilitate ancillary reviews for Pitt as a site.



What are the Responsibilities of the Pitt IRB Reliance Team?

- Conduct **IRB regulatory review** of the research study. This includes:
  - Initial reviews
  - Modifications related to any site involved in the project
  - Continuing reviews
  - Reviews of DSMB reports
  - Reviews of any other documents submitted by the Principal Investigator of the Study
- Provide an approved study-wide informed consent form template for use at all sites.
- Work with participating sites to establish reliance agreements and other agreements as appropriate.
- Review reportable events for all relying sites.
  - Reviews of submitted unanticipated problems that involve risks to subjects or others

What are the Responsibilities of the Pitt Study Team?

- Maintain the PittPRO application.
  - Submit modifications, continuing reviews, reportable events, etc. FOR ALL SITES
- Collect relying site consent documents and local context information.
- Distribute Pitt IRB approved materials to sites .
  - Protocols, template/approved consent forms, recruitment materials, approval letters, etc.
- Act as the liaison between relying site study teams and the Pitt IRB
- Monitor AEs, SAEs, reportable events for all sites and handle appropriately when necessary.
- If applicable, maintain the SMART or IREx website for your study.
- Other responsibilities as outlined in your study plan.

What are the Responsibilities of the Relying Site's Study Team?

- Use the Pitt IRB approved and distributed materials.
- Relay any relevant local context information to the Pitt study team.
- Complete any required local ancillary reviews relevant to the study.
- Maintain local IRB submissions as applicable.
- Inform IRB of Record of any conflicts of interest and provide a management plan that has been approved at the relying site.
- Ensure study staff are qualified, maintain appropriate training, and meet the relying sites standards for eligibility to conduct research.
- Remain independently responsible for their own HIPAA compliance.
- Notify the Pitt study team within twenty-four hours of becoming aware of a suspension or restriction of Relying Site investigator or other personnel involved in the Study, or the discovery of serious or continuing non-compliance, or an unanticipated problem that involves risks to subjects within the Study.

sIRB Fees

- Using Single IRB comes with associated fees.
- The NIH allows for these fees to be included in the overall grant budget.
- These fees vary depending on the size and duration of your study.
- Pitt's fees are consistent with IRB fees across the US.
- You will need to incorporate sIRB costs into your overall grant budget.
- **Failure to budget for sIRB fees may lead to the Pitt HRP declining to act as IRB of Record.**
- A new fee budget must be requested EACH TIME you re-submit your grant application.

sIRB Fee Structure

CURRENT FEE STRUCTURE

Initial Review-
- No Fee

Initial Onboarding Fee-
- $2,100 per site
- Charged at the time of on-boarding

Modification Fee-
- $400 per MOD per on-boarded site
- Applies to modifications that effect the entire project

Continuing Review Fee-
- $250 per on-boarded site at time of CR

FEES SUBJECT TO CHANGE!

SAMPLE FEE BUDGET

Initial onboarding fee – charged at the time of on-boarding MOD

Each relying site:	$2,100
# of Relying Sites:	2
Initial budget calculation:	$4,200

Modification fee – charged per MOD submitted that **affects the entire project**

Each Relying Site: $400

Initial budget calculation is made based on an average of 4 MODs/year and the max # of Relying Sites to participate in the project

Years of grant:	5
MOD Total:	$16,000

Continuing Review – charged annually

Each relying site $/year:	$250
CR Total:	$2,500

Total Budget: $22,700 for a **5** year grant

When do I Reach Out to the Reliance Team?

BEFORE SUBMITTING YOUR GRANT APPLICATION!

- **Request your Fee Budget and optional Letter of Support.**
- **Letter of Support (LOS)**
  - Can be a valuable tool in obtaining funding from a sponsoring agency.
  - Let's the sponsor know that the Pitt IRB is aware of and willing to serve as IRB of Record for the project.

How do I Request My Budget and LOS?

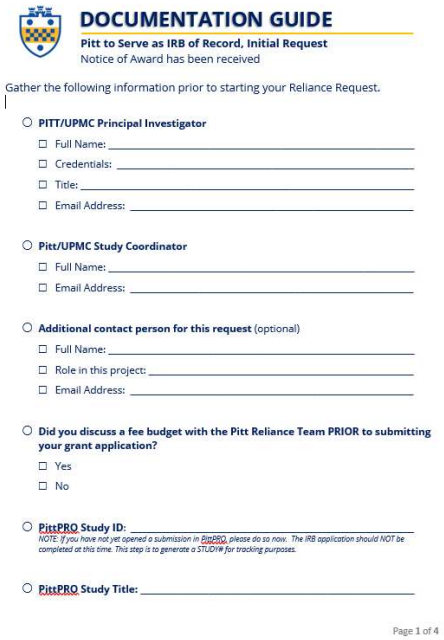
- Use the online Reliance Request Qualtrics Survey!
- Select “Fee Budget and optional Letter of Support” as the reason for your request.

LET’S DO A LIVE DEMO!

Request Summary

Prepare for your request by gathering the following information:

- Study Title (verbatim from the grant application)
- RFA/RFP number (if applicable)
- Pitt/UPMC Principal Investigator information
- Pitt/UPMC Research Coordinator information
- Additional contact person information (optional)
- Funding agency
- U01 grant information, if applicable
- Risk level, if known
- Maximum number of relying US sites
- Length of the grant (in years)
- Grant deadline
- FILE UPLOAD- Research plan or human subjects section of the grant



DOCUMENTATION GUIDE

Pitt to Serve as IRB of Record, Initial Request

Notice of Award has been received

Gather the following information prior to starting your Reliance Request.

○ **PITT/UPMC Principal Investigator**
- ☐ Full Name: _____
- ☐ Credentials: _____
- ☐ Title: _____
- ☐ Email Address: _____

○ **Pitt/UPMC Study Coordinator**
- ☐ Full Name: _____
- ☐ Email Address: _____

○ **Additional contact person for this request** (optional)
- ☐ Full Name: _____
- ☐ Role in this project: _____
- ☐ Email Address: _____

○ **Did you discuss a fee budget with the Pitt Reliance Team PRIOR to submitting your grant application?**
- ☐ Yes
- ☐ No

○ **PittPRO Study ID:** _____
NOTE: If you have not yet opened a submission in PittPRO, please do so now. The IRB application should NOT be completed at this time. This step is to generate a STUDY# for tracking purposes.

○ **PittPRO Study Title:** _____

Page 1 of 4

DOWNLOAD THE CHECKLIST PRIOR TO STARTING YOUR REQUEST!

HRPO.PITT.EDU → Guidance & Forms → "R" → Reliance Guidance

What Happens After I Submit the Request?

1. The Pitt Reliance team will receive a notification that your request has been submitted.
2. We will review your information **in the order in which it was received.**
    - If you have an *urgent* request, please email irb.reliance@pitt.edu
3. We will draft your fee budget and (optional) LOS.
4. You will receive an email from irb.reliance@pitt.edu with your fee budget and (optional) LOS.
5. Submit these documents with your grant application.

I’ve Received my Notice of Award (NOA)

What should I do next?

- **Once you have received confirmation that your study will be funded…..**
- Open a new submission in PittPRO.
  - **This step is solely to generate a STUDY# for tracking purposes**.
  - **DO NOT** complete the entire application at this point.
  - Insert “sIRB” in front of the short title under the ‘BASIC INFORMATION’ section in PittPRO.

I Have My Study ID! What's Next?

- After generating a STUDY ID in PittPRO, it's time to submit a formal reliance request!
- Similar to the LOS and/or Fee Budget request, you will again complete the Qualtrics survey
- Select "Pitt to Serve as IRB of Record" as the reason for your request.

LETS DO A LIVE DEMO!

Request Summary

Prepare for your request by gathering the following information:

- Pitt/UPMC Principal Investigator information
- Pitt/UPMC Research Coordinator information
- Additional contact person information, optional
- PittPRO Study Title and ID
- Funding information U01 grant information, if applicable
- Research office processing funding
- Reason for reliance request
- Risk level
- Local research site locations
- Drug, device, PHI, EFIC information, where applicable
- Maximum number of sites approved to rely on Pitt (per the provided budget)
- FILE UPLOAD- Research plan or human subjects section of the grant

DOWNLOAD THE CHECKLIST PRIOR TO STARTING YOUR REQUEST!

HRPO.PITT.EDU → Guidance & Forms → "R" → Reliance Guidance

I Submitted My Request.

What Should I Do Now?

1. The Pitt Reliance team will review your request **in the order in which it was received**.
   - We do our best to review requests within 7-10 business days.

2. We will review all your information and confirm that reliance is appropriate.
   - Keep an eye out for an email from irb.reliance@pitt.edu! We may need more information.

3. You will receive an email with our decision and directions for the next steps.

Pitt IRB has Agreed to Serve as IRB of Record.

What Should I do Next?

- **The next step is to complete your PittPRO application!**
- Some helpful tips:
  - Take your time and be thorough.
  - Keep it broad; only use Pitt-specific language where necessary.
  - DO NOT create consent form templates for the relying sites.
  - Be sure to upload all subject facing documents, scripts, advertisements, etc.
  - Be clear in your wording.
  - Consider bullet points, timelines, paragraph headings, etc.
  - When you are ready, the Principal Investigator will submit the application for review.

PittPRO

I've Submitted my PittPRO Application.

What's Next?

- Your study will undergo IRB review.
- **Understand that reviews TAKE TIME!**
  - Full board reviews require extra time.
  - As IRB of Record, we are thorough in our review as protocol/documents will be shared with relying sites.
- Be Responsive:
  - The Pitt IRB team may reach out to you with questions during pre-review.
  - Replying to these questions in a timely manner will help to move this process along.
- Respond to comments:
  - You may receive comments back more than once.
  - Respond to these comments as efficiently and thoroughly as possible.
  - Ask questions if you don't understand a comment.
- Once all comments have been addressed and the review is complete, your study will be approved in PittPRO.

My Study is Approved in PittPRO!

Can we Start Recruiting Patients?

- While technically your research study can begin AT THE PITT SITE ONLY, you may have additional reviews that need to be conducted prior to the start of recruitment.
    - DoD review
    - DSMB review
    - Funding Agency Review
- It is very common that these entities will require additional changes.
- You MUST submit a modification in PittPRO to reflect these changes before we will reach out to relying sites.
- You may be required to provide assurances to the Pitt IRB that all additional reviews have been completed and all changes have been approved before we move forward with any reliance communications.

Summary of Steps

1. Submit a Qualtrics survey - Fee Budget and optional Letter of Support
2. Submit your Grant Application
3. Upon Notice of Award, generate a STUDY ID in PittPRO (do not submit)
4. Submit a Qualtrics survey - Pitt to serve as IRB of Record
5. Complete your PittPRO application
6. Once approved, complete any additional required reviews, as applicable
7. Submit a modification in PittPRO in response to the additional reviews
8. Once approved, recruitment can begin at Pitt and you can begin to submit On-boarding Reliance Requests for relying sites!

On-Boarding a Relying Site

- Onboarding relying sites is a specific process that can vary from study to study.
- It is the responsibility of the study team to collect all applicable information from the relying site in preparation for onboarding.
- Individual study on-boarding consultations are offered by the Pitt Reliance Team and are HIGHLY recommended.
- Once your study has received PittPRO approval, please reach out to irb.reliance@pitt.edu to set up this consultation.
- We are also available to host a call between the Pitt IRB, Pitt study team and relying site study teams to ensure all study team members are aware of responsibilities and expectations.

Frequently Asked Questions

What if I want to add additional sites after the study begins?

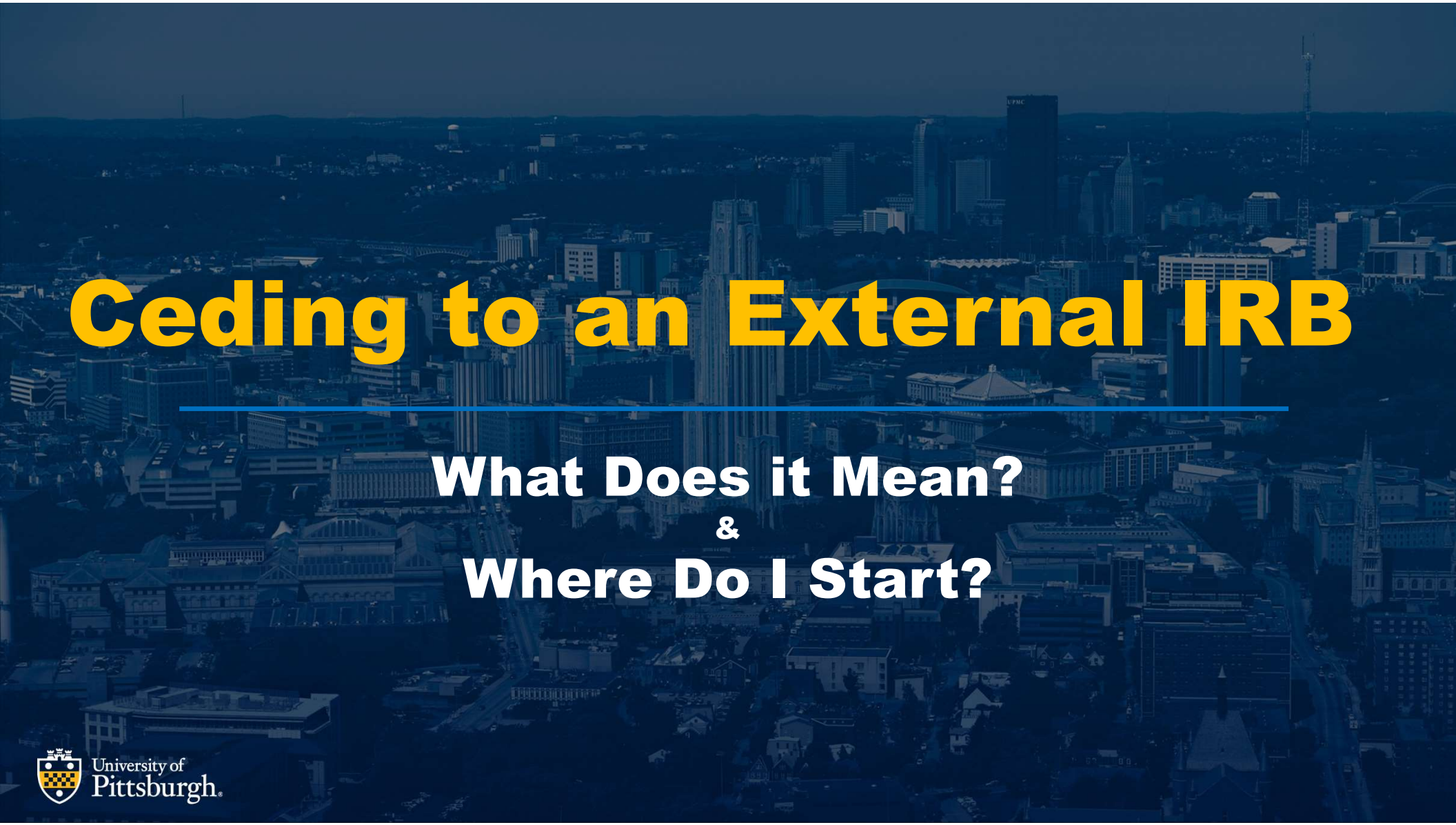
We create your budget based on the estimated number of sites communicated in your budget request. If you exceed that number, we will draft a new budget for you to submit to the sponsor for approval.

What is the expected timeframe from the time I receive my Notice of Award to when we can begin to onboard sites to the study?

There are a lot of factors that go into the timeline of events for your study. Risk level and review type, ancillary reviews, sponsor/DSMB reviews, thoroughness of your application and responsiveness of your team can all play a part. Remember that we are creating the foundation for your project, and we want your project to succeed. We do our best to move forward in a timely manner but know that it can take several weeks to months before you're ready to start reaching out to relying sites.


THANK YOU
Up next... Ceded Projects 101
University of Pittsburgh


Break Time!
Let's Meet Back in 10 Minutes...


Ceding to an External IRB
What Does it Mean?
&
Where Do I Start?
University of Pittsburgh

Presentation Overview:

- What does it mean to cede to an external IRB?
- When is Reliance Appropriate?
- Considerations
- Online Reliance Request System
- When to Reach Out
- Reliance Steps
  - (In limited circumstances) Request a Letter of Support
  - Create a new study to generate a STUDY ID in PittPRO
  - Submit a Reliance Request
  - Submit your PittPRO application
- Modifications
- Continuing Review
- Meet-N-Greets

What Does it Mean to Cede IRB oversight?

- An External IRB will provide the **IRB OVERSIGHT** for your research project.
- The Pitt PI is still responsible for complying with all university/state/local regulations.
- Local context still falls under Pitt IRB oversight.
  - Exception to the informed consent policy, local ancillary reviews, etc.

What is the purpose of ceding?

- Lessens the burden on institutions and research staff.
- Less documents are required to be reviewed locally.
  - Recruitment & data collection materials are not required to be uploaded.
    - Note: The PI is responsible for following all university policies.
- Not all PittPRO sections are required to be completed.

When is Ceding IRB Oversight Appropriate?

Below are some examples of when we may cede IRB oversight to an external IRB

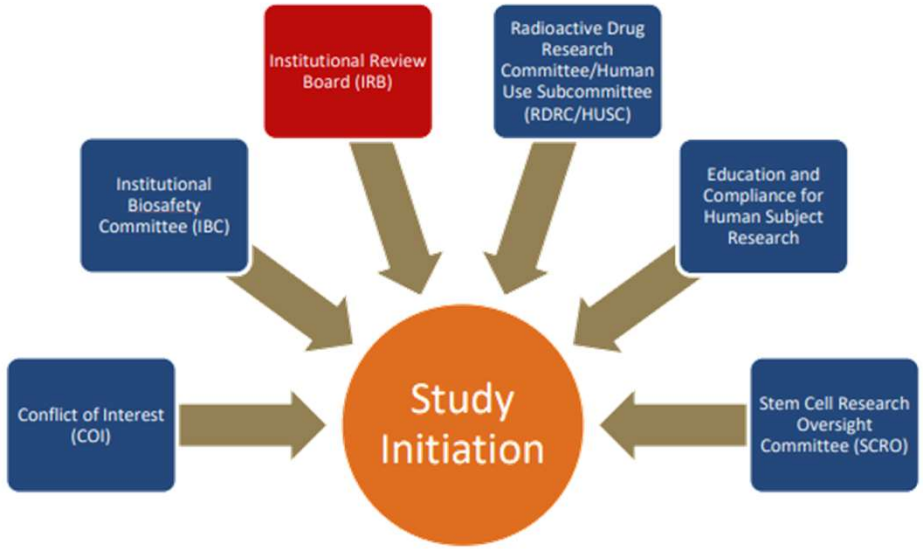
- When another institution is the primary awardee of the funding
- When required by the source of funding or a national consortium
- When a commercial IRB has already been listed as the IRB of record for a study and Pitt now a collaborating entity
- Other circumstances on a case-by-case basis

The Pitt HRP will **NOT** cede IRB oversight:

- For Exempt-level research
- With Institutions located outside of the United States
- Other circumstances on a case-by-case basis

Keep in Mind…

- The reliance agreement covers **IRB OVERSIGHT ONLY!**
- This agreement **<u>does not</u>** cover any local ancillary reviews required by Pitt.
  - Examples include:
    - If your study involves an X-ray or radiation, it will likely require Radiation Safety
    - Conflict of Interest
    - Institutional Biosafety Committee for research involving recombinant or synthetic nucleic acid molecules
    - Drug/Device studies may require IND/IDE Support
- The Pitt/UPMC/Magee site is still responsible for completing these reviews on a local level.



When do I Reach Out to the Reliance Team?

IT IS BEST TO CONTACT US ONCE YOU THINK YOU MAY BE INVOLVED IN MULTI-SITE RESEARCH!

- **If you are having discussions with other institutions about collaborating on a multi-site project reach out to irb.reliance@pitt.edu with as much information as possible so we can best guide you on taking the appropriate steps.**

- Helpful information to have before contacting Pitt Reliance:
  - What is the source of funding and who is the primary awardee (or anticipated awardee)?
  - What institution will be IRB of Record?
  - What activities will Pitt/UPMC be involved in?
  - Are there any conflicts of interest?

Reliance Steps

Overview of the basic steps required:

1. **Request a Letter of Support** (In limited circumstances)
2. **Create a new study to generate a STUDY ID in PittPRO**
   - Do not submit the application at this time
3. **Submit a Reliance Request**
   - Reliance team reviews the request
4. **Submit your PittPRO application**

I Have My Study ID! What's Next?

- After generating a STUDY ID in PittPRO, it's time to submit a formal reliance request!
- Select "**Pitt to Cede IRB Oversight to Another Institution**" as the reason for your request.

DOWNLOAD THE CHECKLIST PRIOR TO STARTING YOUR REQUEST!

HRPO.PITT.EDU → Guidance & Forms → "R" → Reliance Guidance

I Submitted My Request.

What Should I Do Now?

- The Pitt Reliance team will receive a notification that your request has been submitted.
- We will review your information **in the order in which it was received**.
- We will review all your information and notify you whether reliance is appropriate.
  - Pages 4-5 under *Timeline Overview when Pitt Cedes IRB Oversight* in our guidance document outline the steps that happen between submitting the reliance request and when to submit the PittPRO application pitt_cede_irb_review_v17_01.03.2022.pdf
  - If you have an *urgent* request, please email irb.reliance@pitt.edu

The IRB of Record approved Pitt/UPMC as a relying site.

What Should I do Next?

The next step is to complete your PittPRO application!

- Some helpful tips:
  - Carefully follow the instructions on pages 6-7 of the cede guidance document
    - pitt_cede_irb_review_v17_01.03.2022.pdf
  - Cede submissions require limited documents to be uploaded
    - Recruitment & data collection materials are not required
  - When you are ready, the Principal Investigator will submit the application for review

PittPRO

I've Submitted my PittPRO Application.

What's Next?

- Your study will be reviewed in the order in which it is submitted.
- Be Responsive:
  - The Pitt IRB team may reach out to you with questions during pre-review.
  - Replying to these questions in a timely manner will help to move this process along.
- Respond to comments:
  - You may receive comments back more than once.
  - Respond to these comments as efficiently and thoroughly as possible.
  - Ask questions if you don't understand a comment.
- Once all comments have been addressed and the review is complete, your study will be activated in PittPRO.

My Study is Activated in PittPRO!

What now?

Congratulations! You can begin your research activities as approved by the IRB of Record.

There are limited circumstances in which a "**Modification**" is required to be submitted.

1. Continuing review
2. Pitt/UPMC study staff and/or site changes
3. Research procedures that affect ancillary review(s) or local context

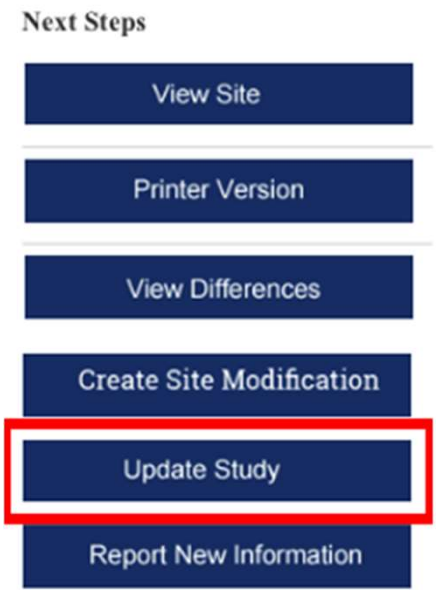
There are limited circumstances in which a **Letter** is issued for cede projects.

1. Initial activation
2. Pitt/UPMC PI change
3. Continuing review acknowledgement
4. If the IRB of Record requests one (please ensure you add this to the modification summary)

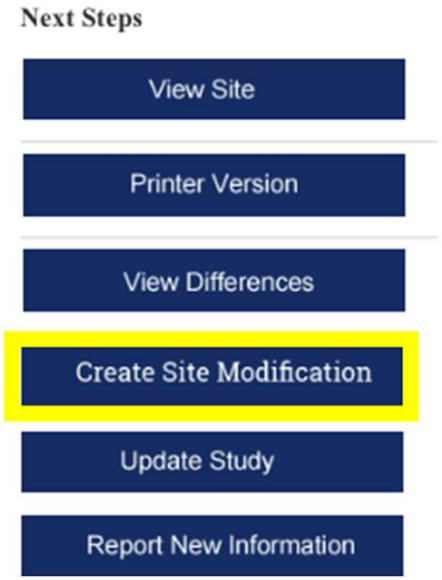
Modifying a Cede Submission

There are two FUNCTIONS that are available to modify a cede submission

- **Update Study**
  - This does not get sent to the IRB coordinators box for review, but if there are changes that need review, you will need to submit the *Create Site Modification* function as well. This function is automatically "finalized".



- **Create Site Modification**
  - This is the function that will be reviewed by the IRB coordinator. It is the only function that is sent to the IRB coordinator and will receive an official acknowledgement.



Modifying a Cede Submission

Each function opens different sections within the cede submission.

NOTE:
With **Create Site Modifications** if you select only "*Study Team Changes*" vs "*Other parts of the study*", in the modification scope section, different sections will be available.

When in doubt, select **both** options to ensure you have access to all the sections within that function.

Please review pages 8-10 of the cede guidance document for more detailed information on modifying cede submissions.

"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

Submitting Continuing Review Documentation

After the IRB of Record reviews and approves the study Continuing Review, the Pitt study team *must* submit the following documents in **TWO STEPS**:

NOTE: Cede submissions will always show active in the system and do not move into a "lapsed" state even if the expiration date has passed. **Pay attention to the expiration date.**

Documents to Submit:

1. Continuing Review IRB approval letter from the IRB of Record (via Update Study)
2. Updated protocol, *if changes were made during the last year* (via Update Study)
3. IRB of Record approved Pitt/UPMC consent(s) with updated approval dates, *if applicable* (via Create Site Modification)

Steps to Take:

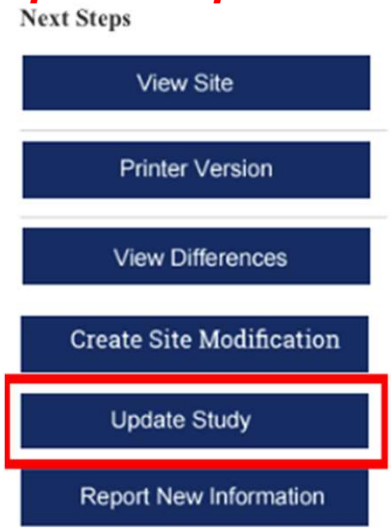
Both, an UPDATE STUDY function and a CREATE SITE MODIFICATION function will need to be completed to submit the required documentation.

- Even if there are no consent updates, a *create site modification* **must** be submitted to update the expiration date within PittPRO.
- Follow the instructions on pages 8-10 of the cede guidance document.

Submitting Continuing Review Documentation

STEP 1- UPDATE STUDY

1. Open an Update Study



Study Update Information

1. * **Summarize the updates:**
   To submit continuing review information

2. Add statement above

3. Upload documents

Main Study-Related Documents

1. **Consent form templates:**

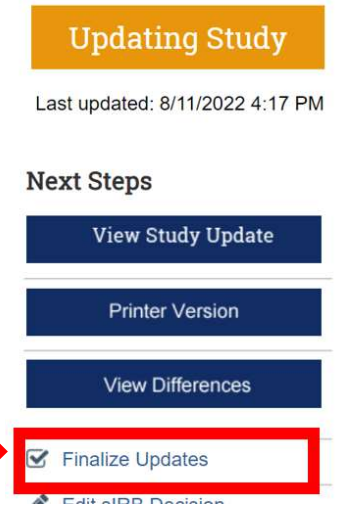
Document	Category	Date Modified	Document History
There are no items to display			

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

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:** *Upload the CR and protocol (if applicable)*

Document	Category	Date Modified	Document History
View ACTG A5379 Continuing Review Approval (0.01)	Other	1/5/2022	History
View ACTG A5379 Continuing Review Approval(0.01)	Other	1/5/2021	History

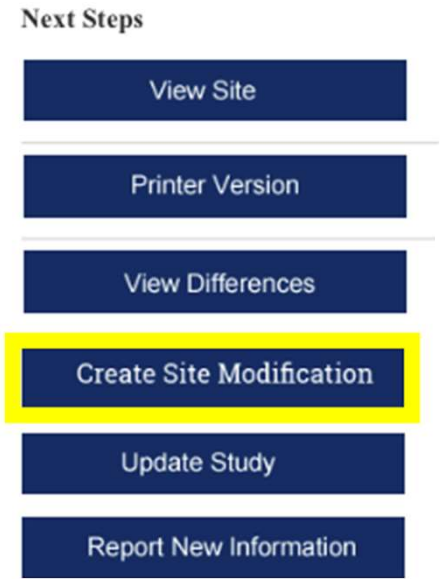


4. The PI must press *"finalize updates"*

Submitting Continuing Review Documentation

STEP 2- CREATE SITE MODIFICATION

1. Open a Create Site Modification



Modification scope:
Study team and research location information
Other parts of the site

2. Select BOTH options above

Modification Information

1. **Study enrollment status:**
Subjects are currently enrolled

2. **Notification of subjects:** (check all that apply)
There are no items to display

3. * **Summarize and justify the modifications:**
Submitting continuing review documentation

3. Add statement above in item #3

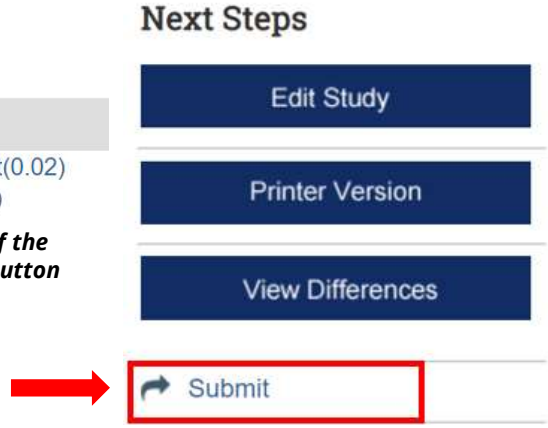
4. Upload consent forms, if applicable

Local Site Documents

1. **Consent Forms:**

Document
View ACTG A5379 Pregnancy Consent(0.02)
View ACTG A5379 Main Consent(0.03)

NOTE: stack the new consents on-top of the previous consents using the "update" button



5. The PI must press *"submit"*

Summary of Steps

1. Create a new study to generate a STUDY ID in PittPRO (do not submit)
2. Submit a Qualtrics survey – "**Pitt to Cede IRB Oversight"**
3. Reliance is executed, local documents reviewed, as applicable
4. IRB of Record approval of Pitt
5. Complete your PittPRO application
6. Pitt HRP Reviews and Activates the PittPRO application
7. All steps complete!

Please note, there are more steps detailed within the cede guidance document, pages 4-5, under "Timeline Overview When Pitt Cedes Oversight".


THANK YOU
Up next... Role of the Research Coordinator
University of Pittsburgh


Role of the
Research Coordinator
Tips & Considerations
University of
Pittsburgh

Presentation Overview:

- What is the importance of a Research Coordinator?
- Examples of Research Coordinator tasks.
- The Research Coordinator as a Liaison
- Organization is key!
- Creating a Hub for Study Documents
- The Importance of Adequate Staffing
- Recommendations & Tips

What is the Importance of a Research Coordinator?

- Having a qualified, focused and organized research coordinator on your study staff can help to facilitate a successful outcome for your research project!
- The research coordinator will wear many hats during the course of the study.
- The Pitt HRP Reliance Team recognizes and appreciates the workload of the research coordinator and are here to help!

Examples of Research Coordinator Tasks

- Maintaining the PittPRO application.
  - The research coordinator is typically responsible for submitting modifications, continuing reviews, reportable events, etc.
- Coordinating relying site trainings and site visits
  - Data training, protocol training, remote/in-person site visits, etc.
  - Conducting training for new relying site study personnel throughout the study.
- Distribution of study materials
- Serving as the liaison between study teams and the Pitt IRB.
- Fielding questions and concerns from relying site study teams.
- Remember, the RC will most likely also be recruiting and following Pitt subjects too!

The Research Coordinator as a Liaison

- One of the most important roles of the research coordinator is serving as the liaison between relying sites and the Pitt IRB.
- The RC will be corresponding with sites that may not be familiar with the sIRB process.
- The RC will be responsible for collecting site-specific forms (consents, local contexts, etc.).
- It is important that the individual that serves as the research coordinator is *accessible* and *responsive* to the relying sites and the Pitt IRB during regular hours.
- It is important to be firm and patient! This is a critical role, and you will be managing a lot of different personalities.

Organization is Key!

With so many responsibilities and activities to track, organization will be your best friend!

SITE TRACKING:

- Where sites are in the onboarding process
- Site-specific details
- Contacts
- Recruitment numbers

STUDY TRACKING:

- Changes to protocol
- Important dates such as renewals, approvals, changes, etc.
- Material distributions
- Site visits, training completion, etc.

INTERNAL TRACKING:

- Subject tracking
- Payments
- Appointments

- Get to know organization apps like Excel, OneDrive, SharePoint and more!
- Take advantage of online tutorials to see what system will work best for your needs.

Create a Hub for Study Documents

- All study team members, internal and external, should have easy access to study documents such as:
  - Consent forms
  - Recruitment materials
  - Questionnaires and patient materials
  - Approval documents
  - Protocols

- We recommend building an **electronic** regulatory binder:
  - Build it directly into your study's database.
  - Can be done through IREx or SMART.
  - Create a OneDrive folder.

The Importance of Adequate Staffing

- Depending on the size and scope of your project, it may be beneficial to have more than one research coordinator and/or assistants.
- In most cases, Pitt will also be a site engaged in the research.
- Having one individual accountable for **both** the single IRB responsibilities and the “Pitt as a site” responsibilities can be burdensome.
- Consider building a % effort for dedicated coordinators/assistants into the budget.
- While students can be a big help to research projects, they do not always have the time to dedicate to the responsibilities of being a lead research coordinator.

Recommendations & Tips

- Hold monthly/ bi-monthly research coordinator calls with relying sites.
- Conduct weekly/biweekly internal staff meetings with your team.
- Consider a quarterly newsletter to keep sites engaged.
- Know your contacts! Budget/grants officer, sIRB coordinator, NIH officer, etc.
- Take advantage of training opportunities whenever possible!
- Be patient, ask questions, and know we are here to help!


THANK YOU
Up next... Individual Investigator Agreements
University of Pittsburgh

Individual Investigator Agreements

What Is an IIA?
Who Is Eligible?
How Do I Get Started?

University of Pittsburgh

Presentation Overview

- What is an Individual Investigator Agreement (IIA)?
- What does an IIA look like?
- When is an IIA appropriate?
- What does “Engaged in human subjects research” mean?
- What if the individual is affiliated with an external institution?
- What are some examples of when an IIA would be appropriate?
- What training certificates are required? CITI/CPRET
- How do I request an IIA?
- What happens after I submit my request?
- FAQs

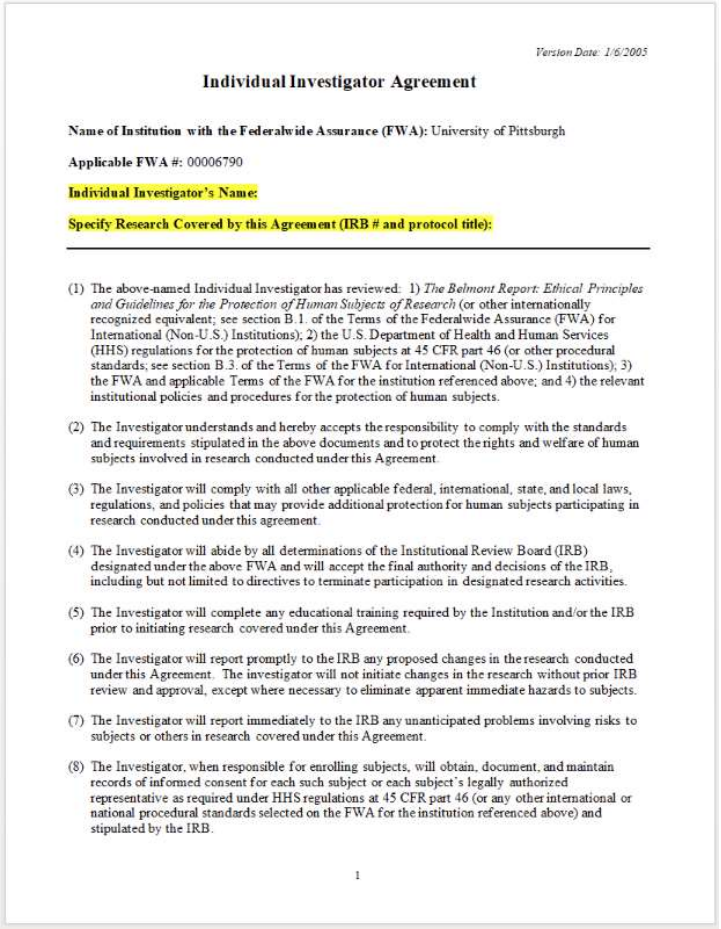
What is an Individual Investigator Agreement?

- **External individual:** An individual who is not acting as an affiliate of either Pitt or UPMC

- **Individual Investigator Agreement:** A formal agreement executed between Pitt and the external individual, describing the expectations and responsibilities of the individual in relation to the research project.

- IIAs are **STUDY SPECIFIC** and **PERSON SPECIFIC**. This means a new IIA must be executed for each person on a study regardless if that person has an executed IIA for another study.

What Does an IIA Look Like?



Version Date: 1/6/2005

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): University of Pittsburgh

Applicable FWA #: 00006790

Individual Investigator's Name:

Specify Research Covered by this Agreement (IRB # and protocol title):

---

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

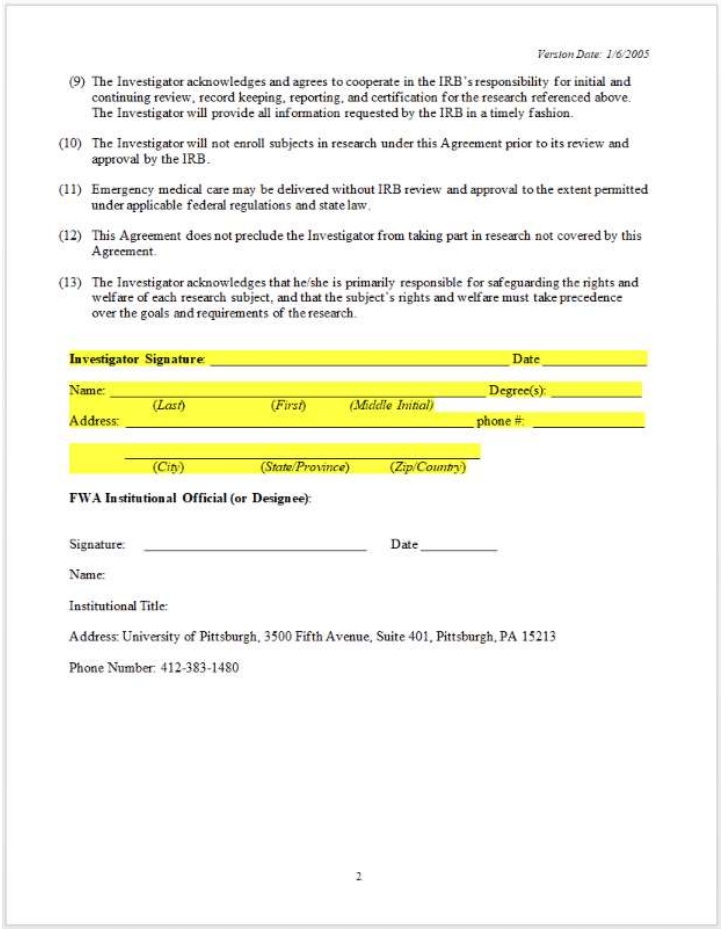
(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

1



Version Date: 1/6/2005

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _____

Name: _____ Degree(s): _____
(Last) (First) (Middle Initial)

Address: _____ phone #: _____

_____
(City) (State/Province) (Zip/Country)

FWA Institutional Official (or Designee):

Signature: _____ Date _____

Name:

Institutional Title:

Address: University of Pittsburgh, 3500 Fifth Avenue, Suite 401, Pittsburgh, PA 15213

Phone Number: 412-383-1480

2

If applicable:

- An additional numbered item will address insurance.
- A parental signature line will be included if investigator is a minor.

When is an IIA Appropriate?

- **For an IIA to be executed, typically the individual must be:**
  - Engaged in human subjects research
  - Working in collaboration with a Pitt or UPMC researcher
  - NOT collaborating as an affiliate of another institution with its own IRB

What is “Engaged in Human Subjects Research”?

An individual is considered “engaged” in human subjects research if <u>ANY</u> of the following apply:

- Obtaining informed consent
- Implementing/administering research intervention
- Obtaining data about research subjects through intervention/interaction
- Obtaining or accessing **identifiable** private information about research subjects

Because of this, IIAs would NOT be needed if the individual is <u>ONLY</u>:

- Assisting with study development
- Assisting with recruitment (not consenting)
- Conducting *<u>de-identified</u>* data analysis
- Accessing *<u>de-identified</u>* research data

What if the external person is affiliated with an institution that has its own IRB?

- If the individual affiliated with (i.e., works for or attends classes at) a university or hospital, they may have access to / be covered by their own IRB.

- Pitt Reliance may consult with the individual's IRB to determine whether their activities are being conducted as part of their affiliation with that institution, thus engaging the institution.

  - If institution is engaged, either:
    - Execute a reliance agreement, or Institutional Authorization Agreement, with the person's affiliated IRB. (sIRB)

      --OR--

    - The individual seeks IRB approval from their home IRB for their activities. (Traditional)

  - If the person is affiliated with an institution but will be conducting activities related to this study completely OUTSIDE of their regular job duties and OUTSIDE of their institution, an IIA may be appropriate.

  (We may either reach out to the other IRB ourselves or request proof (i.e. email correspondence)) that they are in agreement that the individual is not conducting activities as part of their affiliation with that institution.)

Examples of When an IIA is Appropriate

Sam is a licensed physical therapist at a local, independently owned PT clinic in a rural town. She will be providing a research-related physical therapy session to study participants that live in her area. Sam will be compensated for her time.

An IIA would NOT be appropriate if.....

- The PT clinic was part of Allegheny General Hospital or Penn State University, both of which have their own IRBs.

Examples of when an IIA is appropriate

Sally is a liaison at the Urban League of Pittsburgh. She regularly works with a population that fits the specific eligibility criteria for your research project. Because of this, she has been asked to help with recruiting individuals for your study. Although she will not consent subjects, she will also help administer questionnaires to subjects while they are in her building. She will receive compensation for her efforts.

An IIA would NOT be appropriate if.....

- Sally was not administering questionnaires.
- Because she would only be advertising for the study, she is not directly involved in human subjects research.

Examples of when an IIA is appropriate

Greg is a programmer working at a tech company. He has experience in data analysis and will be receiving and analyzing identifiable data for a research study. The work Greg will be doing is outside of his job duties and he will be compensated for his time.

An IIA would NOT be appropriate if.....

- Greg was a statistician for the University of Delaware and using University of Delaware software for the analysis.
- Greg would only be analyzing de-identified data.

Training Certifications

- Any outside individual that will be engaged in a Pitt/UPMC research study **must** complete human subjects research training.

- Individuals have two options:
  - **Collaborative Institutional Training Initiative (CITI)**
  - **Community Partner Research Ethics Training (CPRET)**

CITI Training

- The CITI program is a national website used by numerous institutions to train and certify research staff.
- Consists of self-paced training modules and tests focused on general research topics such as Human Subjects Research, Responsible Conduct of Research, Good Clinical Practice, Conflicts of Interest and more.
- The specific modules required for your research study will vary. Check your PittPRO study homepage!
- Individuals may have completed CITI training modules at their home institutions.
- Certificates of completion will need to be uploaded into the IIA request.
- *Recommend if t*he individual will participate in various research projects and has access to the CITI website.

Website: citi.pitt.edu ★ Technical Support: citi_support@pitt.edu

CPRET Training

Pitt CTSI

- Community Partner Research Ethics Training (CPRET) training is offered through Pitt's Clinical and Translational Science Institute (CTSI).
- Consists of a custom created, self-viewed presentation that is tailored to the individual's participation in a specific research study.
- Reviews ethical and safe practices related to a specific study.
- A CPRET training certificate listing the specific study must be uploaded in the IIA request.
- Particularly relevant for investigators engaged in clinical and translational research involving community partners

Website: https://ctsi.pitt.edu/education-training/community-partners-research-ethics-training/ ★ To Schedule: ctsi@pitt.edu

Frequently Asked Questions

Should I add the individual to PittPRO?

- We discourage study teams from adding the individual to PittPRO unless they are obtaining informed consent.
- They may need a Pitt sponsored email account, HSConnect account, CITI account linked and potentially additional steps.

Consider the purpose of adding the person to PittPRO:

- **Access to PittPRO?** Modifications and distribution of materials can be done by the coordinator. Consider a OneDrive folder where everyone has access to documents such as questionnaires, protocol, recruitment materials, etc.
- **Named in publication?** A person DOES NOT need to be listed in PittPRO in order to be an author or mentioned in any publication!

How Do I Request an IIA?

- Use the online Reliance Request Qualtrics Survey!
- Select "**Individual Investigator Agreement**" as the reason for your request.

LET'S DO A LIVE DEMO!

Request Summary

Prepare for your request by gathering the following information:

- PittPRO Study ID and Title
- Approval status
- Pitt/UPMC Principal Investigator information
- Pitt/UPMC Research Coordinator information
- Additional contact person information (optional)
- External Individual information
  - Full name
  - Educational credentials (if applicable)
  - Address
  - Email
  - Phone
  - Over or under the age of 18
- Individual's affiliated institution information (if applicable)
- Roles of the external individual
- Brief description of the following:
  - Role of the external individual
  - Pitt/UPMC locations where the individual will conduct research related activities
  - Relevant dates, milestones, deadlines
  - Compensation details (if applicable)
  - Expense details (if applicable)
- **FILE UPLOAD:** CITI or CPRET training certificate(s)

DOWNLOAD THE CHECKLIST PRIOR TO STARTING YOUR REQUEST!

What Happens After I Submit the Request?

1. The Pitt Reliance team will receive a notification that your request has been submitted.
2. We will review your information **in the order in which it was received.**
    - If you have an *urgent* request, please email irb.reliance@pitt.edu
3. If appropriate, we will draft the IIA.
4. The draft will be sent to the external individual for review and signature.
5. Once returned, the IIA will be signed by a member of the Reliance Team.
6. The fully executed IIA will be distributed to all parties, including your PittPRO IRB coordinator.
7. This individual is now able to begin contributing to your project as outlined in the approved protocol.

Frequently Asked Questions

Does the IIA have an expiration date?

- Because IIAs are study-specific, it is valid for the duration of the study.

Besides CITI/CPRET training, are there other educational requirements for an individual to contribute to a study?

- No! Anyone from a high school student to an MD/PhD can contribute to your study! Note that IIAs for anyone under the age of 18 will require a parent's signature.

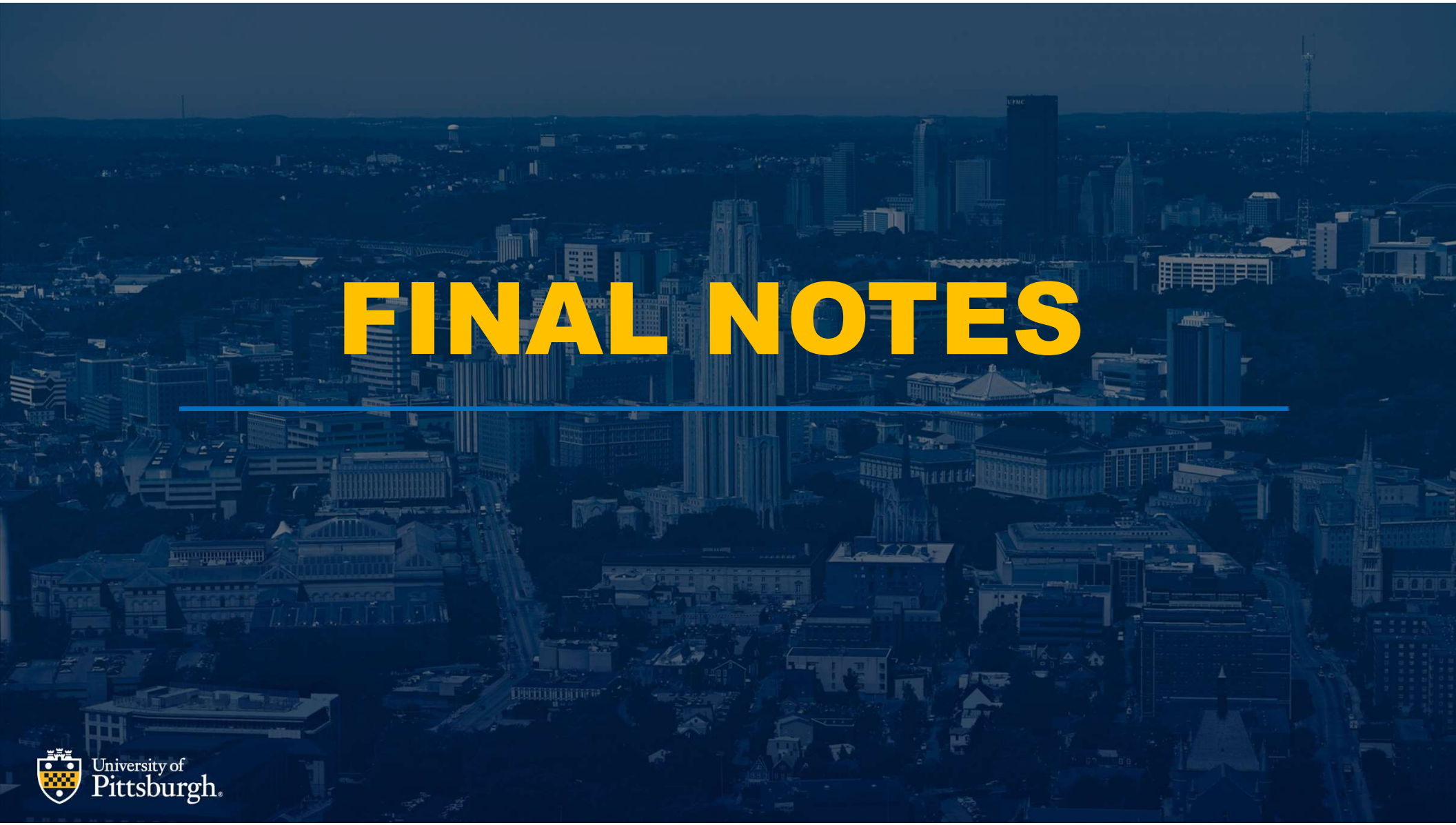
Frequently Asked Questions

Is a PittPRO modification needed once my external collaborator's IIA is fully signed?

If you anticipate that you may involve external collaborators we advise including language in your initial submission similar to the following:

> *Community center staff may administer questionnaires and assist with focus group facilitation. We will consult with Pitt Reliance to ensure any necessary IIAs or other agreements are in place prior to those activities taking place.*

Once each IIA is fully executed, you, and the external collaborator, will be provided a copy for your records, we will upload the IIA administratively in PittPRO – no mod needed!


FINAL NOTES
University of Pittsburgh

Study Team "Meet-and-Greets"

Just a Reminder...

- We HIGHLY recommend scheduling a personalized training session with the Pitt IRB.
- These can be:
  - Internally, between your team and the Pitt IRB **and/or**
  - Externally, between the Pitt study team, relying site teams, and the Pitt IRB!
- Understanding the process from the beginning saves everyone time and frustration in the long run!
- Please reach out to irb.reliance@pitt.edu to discuss a Meet-and-Greet for your study!

Watch for a follow up email from us!

- We will be providing all attendees with:
  - PDF of this presentation
  - Reliance Request Preparation checklists
  - Link to the Reliance Request Qualtrics Survey
  - Summary of questions and responses
- Please take a moment to complete the BRIEF, anonymous Qualtrics survey to provide feedback

YOUR OPINION MATTERS!

Upcoming Community Education

- **The Role of a Coordinator:** Navigating the Role of a Research Coordinator on an IRB of Record Project
- **Ceded Projects 101**: Being a Relying Site in a Multicenter Research Project
- **Navigating PittPRO:** Tips & Tricks for building your IRB of Record and Cede submissions in PittPRO.
- **On-Boarding a New Site:** How to get a Relying Site up and running in your IRB of Record Project.
- **VIDEOS!**
  - We are developing short videos to assist the research community with tasks such as submitting a continuing review, creating a study modification, navigating PittPRO and more!

Have a recommendation for a community training session?
EMAIL US YOUR IDEA!
irb.reliance@pitt.edu


THANK YOU!
We Look Forward to Working With You!
University of Pittsburgh