

# Getting Started

November 10, 2022

- This session is being recorded
- Upcoming session – IRB 101 for Exempt Studies on November 16, 2023
- Watch the HRP calendar for Expedited, sIRB and other specialized sessions

# Getting Access to the Systems



Set up HSConnect account with Pitt credentials when possible  
(DO NOT use Gmail, etc. if you need to switch your account, contact HSConnect)



Complete CITI training or link completed CITI training from another institution to Pitt account (<https://www.citi.pitt.edu/>)

- Responsible Conduct of Research
- Human Subjects Protection
- Good Clinical Practice



Build submission in PittPRO and submit for approval  
(same username and password as HSConnect and CITI)

Contact [askirb@pitt.edu](mailto:askirb@pitt.edu) or [orp\\_support@pitt.edu](mailto:orp_support@pitt.edu) if you have trouble logging into the system

# Logging into PittPRO

Sign in using Pitt or UPMC credentials, same username and password as CITI credentials



Pitt Passport

UPMC

Pitt Users and Sponsored Accounts use the button above to log in. (If you previously used Pitt Passport or a @pitt.edu address to log in)

UPMC Users use the button above to log in (If you previously used a @upmc.edu, @magee.edu or @chp.edu address to access this site)

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#### External User Information:

As of 11/09/2021 access to this University of Pittsburgh site will be restricted to people with Pitt or UPMC accounts. If you do not have a Pitt or UPMC account, [Click Here](#).

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<https://www.pittpro.pitt.edu/>

# Create New Study



- Create New Study
- Report New Information



## My Inbox

Filter by <sup>?</sup> ID   [+ Add Filter](#) [x Clear All](#)

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY18100003	New Study	10/2/2018 1:46 PM	10/2/2018 1:46 PM	Pre-Submission	

1 items

◀ page 1 of 1 ▶

/ page

Submissions

Meetings

Reports

Library

Help Center

# New Study Created

Pre-Submission

Last updated: 10/2/2018 1:46 PM

STUDY18100003

## New Study

Principal investigator: Alsace France  
IRB coordinator:

### Next Steps

Edit Study

Printer Version

View Differences

Submit

Assign Primary Contact

Manage Guest List

Add Comment

Discard



- History
- Funding
- Contacts
- Documents
- Reviews
- Training
- Snapshots

Filter by ? Activity

Activity	Author	Activity Date
Study Created	France, Alsace	10/2/2018 1:46 PM

# Phases of Review



**Pre-Submission** → Researcher is building the protocol

Scientific Review takes place when leaving this state

**Pre-Review** → Ancillary Reviews and IRB Pre-Review taking place

**IRB Review** → Committee Review or Exempt/Expedited Review taking place

**Post-Review** → Final clean-up prior to approval being granted

**Review Complete** → Active state

**Clarification/Modifications Requested** → In Researcher's possession for editing

# Basic Information and Other Required Pages

You Are Here: New Study

[← Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#)

## Basic Information

1. \* Title of study:

New Study for Testing

\*Red Star = Required

2. \* Short title:

New Study

3. \* Brief description: ?

New Study

4. \* Principal investigator: ?

Alsace France

Defaults to study creator. Change to appropriate PI

Jump To ▾

- Basic Information
- Funding Sources
- Study Team Members
- Study Scope
- Local Site Documents
- Research Sites
- Study Aims
- Recruitment Methods
- Study Design
- Research Activities
- Consent Process
- Consent Forms
- Electronic Data Management
- Data Safety & Monitoring
- Risk and Benefits
- Conflict of Interest
- Ancillary Reviews
- Clinical Trial Information
- Local Supporting Documents

At a minimum, you will be required to complete these pages

**Red asterisk \* =  
required response**

No \* means that it is not a required field.  
However, if it is relevant to your study, you  
must answer

## Basic Study Information

### 8. Attach the protocol: ?

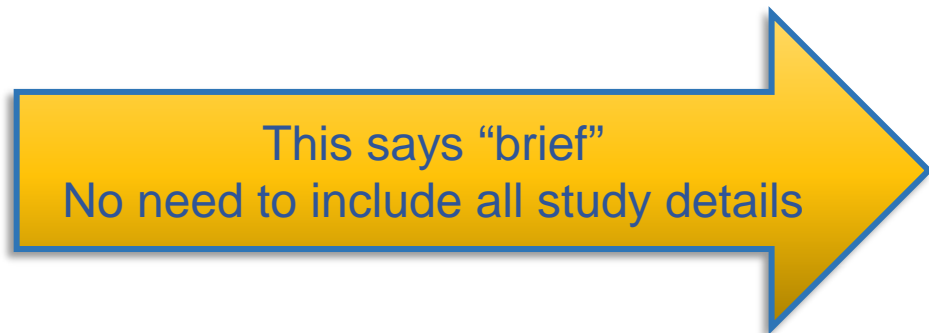
- Sponsor/Multicenter/Investigator-initiated protocol
- Coordinating Center supplement
- Emergency Use Consent/ Protocol/ FDA Form 3926
- Exempt Application form

+ Add

	Document	Category	Date Modified	Document History
<input checked="" type="checkbox"/> Update	prot.txt(0.01)	IRB Protocol	7/21/2022	History



## Basic Study Information



### 3. \* Brief description: ?

In a few words, summarize:

- The central question the research is intended to answer
- The primary objectives
- The methods used

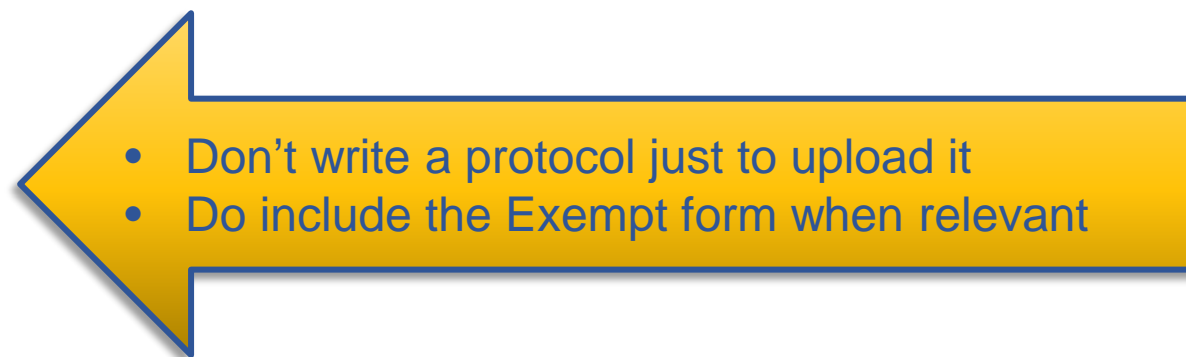
For example:

This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

### 8. Attach the protocol: ?

- Sponsor/Multicenter/Investigator-initiated protocol
- Coordinating Center supplement
- Emergency Use Consent/ Protocol/ FDA Form 3926
- Exempt Application form

+ Add			
	Document	Category	Date Modified
<input checked="" type="checkbox"/> Update	prot.txt(0.01)	IRB Protocol	7/21/2022



# Funding Sources

## Funding Sources

1. \* Indicate all sources of support:

- No support
- Internal funding
- External funding

2. \* Provide the source of your Internal funding:

3. \* Identify each organization supplying funding for the study:

<input type="button" value="+ Add"/>					
Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments	Pitt Awardee	Grant Recipient
National Institutes of Health	R01-1234		NIH grant to Pitt Investigator.docx	yes	Dr. U. Pitt

- **No support:**

- if subjects are being paid, or if billable procedures are being performed, you must have funding

- **External Funding:**

- Use % to search for funding source name
  - If your source is not listed, contact [askirb@pitt.edu](mailto:askirb@pitt.edu)
- You must upload the grant when Pitt is the awardee institution
  - include cover sheet
  - financial details can be redacted

# Study Team Members

## Study Team Members

1. \* Identify each person involved in the design, conduct, or reporting of the research (includes PI): ?

+ Add

Name	Roles	Affiliation	Involved in Consent
------	-------	-------------	---------------------

There are no items to display

- Select **Principal Investigator** (ensure PI matches Basic Info #4)
- Qualifications required for PI, Co-Is, and Faculty Mentor
- Ensure that those involved in consent have the credentials to do so (see Obtaining Consent Guidance)
- In order for someone to be listed in the system, CITI training must be completed.

1. \* Study team member: ?

2. \* Role in research: (check all that apply)

- Principal Investigator
- Co-investigator
- Primary Study Coordinator
- Secondary Study Coordinator
- Administrator
- Statistician
- CMU Personnel
- Faculty Mentor
- Key Personnel / Support Staff

3. \* Affiliation:

- Pitt faculty
- Pitt staff
- Pitt student/fellow/postdoc
- UPP/UPMC staff
- UPMC resident/fellow
- Non-Pitt student (Pitt/UPMC employee)

4. \* Is the team member involved in the consent process?

Yes  No [Clear](#)

5. \* Does the team member have a financial interest related to this research? ?

Yes  No [Clear](#)

6. Briefly describe the role and *specific qualifications* for this study team member in regards to their research responsibilities:

\* Required

OK

OK and Add Another

Cancel

# Study Scope Page

- Drives the branching questions
- Each selection will create a page specific to that issue
- Read carefully and enter a response or N/A for each section
- Consider consent process and use of waivers
- Scientific review entity (most non-federally funded studies require departmental scientific review)
- Consider Drug/Device questions (completion information available under [A-Z Guidance PittPRO Information](#))

# Study Scope

Check all that apply

## 1. \* Will this study actively recruit any of the following populations?

- Adults with impaired decision-making capacity
- Children (under the applicable law of the jurisdiction in which the research will be conducted (<18 years for PA))
- Children who are Wards of the State
- Employees of the University of Pittsburgh/UPMC
- Medical Students of University of Pittsburgh as primary research group
- Students of the University of Pittsburgh
- Neonates of uncertain viability
- Non-viable neonates
- Non-English speakers
- Nursing home patients in the state of Pennsylvania
- Pregnant women
- Prisoners
- N/A

Refer to the PittPRO Library under “Checklists” for guidance on requirements for each population

## 2. \* Will any Waivers be requested?

- Waiver/Alteration of Consent
- Waiver to Document Consent
- Waiver/Alteration of HIPAA
- Exception from consent for emergency research
- N/A

Waivers can be a great tool in certain types of research. Refer to [Chapter 13 Informed Consent and Documentation](#) for more information.

Contact [askirb@pitt.edu](mailto:askirb@pitt.edu) in advance for emergency research exceptions

**3. \* Will this study involve any of the following?**

- Specimens
- Honest Broker to provide data/specimens
- Return of Results to Subjects or Others
- Fetal tissue
- N/A

- Consider how data/specimens will be shared/stored throughout the protocol and beyond. Ensure consistency throughout
- Those seeking honest brokers should review [Honest Broker Guidance](#)

**4. \* Will Protected Health Information be collected?**

- Pitt medical records
- UPMC medical records
- Other Institutions' medical records
- N/A

All projects accessing or involving UPMC medical records must be submitted to R3 (Health Record Research Request) through the [Intake Form](#)

**5. \* Other Requests?**

- Deception (also requires Waiver/Alteration of Consent)
- Emergency Use / Single Patient Expanded Access
- Placebo Arm
- Withdraw from usual care
- N/A

**6. \* Determining Scientific Review:**

- No scientific review (limited to Exempt projects and Emergency Use requests)
- UPCI PRC - University of Pittsburgh Cancer Institute Protocol Review Committee
- WPIC SRC - Western Psychiatric Institute and Clinic Scientific Review Committee.
- MWH CTSC - Magee Womens Clinical and Translational Research Center
- Department Scientific Review (DOD requires departmental review)
- Received External funding where scientific merit was established as a condition of funding  
[Clear](#)

This means exactly what it says. Do not choose this if you are conducting anything other than an Exemption or Emergency Use

Choose "external" when there is evidence that review took place (NIH award notice or other documentation of award)

**7. \* Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?**

- Yes  No [Clear](#)

*Review the HRPO policy, if participating in research at the VA Pittsburgh Healthcare System or using funding from the VA*

**8. \* Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? ?**

- Yes  No [Clear](#)

**9. \* Does the study evaluate the safety or effectiveness of a device?**

- Yes  No [Clear](#)

Details on how to complete the drug and device pages can be found at [A-Z Guidance PittPRO Information](#)

**10. \* Is this application being submitted to convert an approved study from OSIRIS to PittPRO?**

- Yes  No [Clear](#)

# Research Sites

## Research Sites ?

### 1. Choose all sites that apply:

- University of Pittsburgh
- UPMC
- External Sites / Other
- Clinical and Translational Research Center
- International or Culturally Different Sites
- VA Pittsburgh Healthcare System

- Check all that apply
- Branches to additional questions

If the UPMC site is not listed, email [askirb@pitt.edu](mailto:askirb@pitt.edu) before submitting the application to ensure the site is under the jurisdiction of the University of Pittsburgh IRB

## Research Sites ?

### 1. Choose all sites that apply:

- University of Pittsburgh
- UPMC
- External Sites / Other
- Clinical and Translational Research Center
- International or Culturally Different Sites
- VA Pittsburgh Healthcare System

### \* Select the University of Pittsburgh sites where research will be conducted:

- Main Campus – Pittsburgh
- Bradford
- Greensburg
- Johnstown
- Titusville

List university owned off-campus research sites if applicable:

### \* Select the UPMC sites where research will be conducted:

- Altoona
- Bedford
- Cancer Center Network: Identify all cancer network research sites below
- Center for Emergency Medicine of Western Pennsylvania, Inc.
- Center for High Value Healthcare
- Centers for Rehab
- Children's Hospital



## Recruitment Methods

### 5. Recruitment materials: (attach all material to be seen or heard by subjects, including advertisements and scripts) ?

<input type="button" value="+ Add"/>				
Document	Category	Date Modified	Document History	
<input type="button" value="Update"/> Phone script for eligibility.docx(0.01)	Recruitment Materials	3/6/2020	History	

**Attach each attachment only once and in the appropriate section**

## Waiver to Document Informed Consent

### 3. \* Upload Scripts:

<input type="button" value="+ Add"/>			
Document	Category	Date Modified	
<input type="button" value="Update"/> Phone script for eligibility.docx(0.01)	Waiver Script	3/6/2020	

# Research Activities

## 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. ?

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.

- Research screening procedures
- Main research procedures
- Follow-up research procedures

Include a clear and accurate description of the research activities to ensure that the IRB has the complete depth and breadth of information to assess the risk/benefit ratio of the protocol as well as to ensure that the [Criteria for IRB Approval](#) have been met

## Study Team Members

1. \* Identify each person involved in the design, conduct, or reporting of the research (includes PI): ?

+ Add					
	Name	Roles	Affiliation	Involved in Consent	Qualifications
<input type="checkbox"/> Update	Jean Barone	Co-investigator	Pitt staff	yes	Ms. Barone has over 20 years experience in the res recruitment and consent process for the subjects. S
<input type="checkbox"/> Update	Margaret Hsieh	Principal Investigator	Pitt faculty	yes	Dr. Hsieh is Associate Professor of Emergency Mec room. Associate Chief, ED Staffing, UPMC Presbyte
<input type="checkbox"/> Update	Melissa Miklos	Primary Study Coordinator	Pitt staff	no	Ms. Miklos is responsible for all administrative aspe research and regulatory experience

# Consent Process

## Consent Process

5. \* Are you requesting an exception to the IRB policy related to the informed consent process:

Yes  No [Clear](#)

- \* Provide a justification and describe the qualifications of the individuals who will obtain consent: ?

We would like to request that Ms. Barone be able to obtain informed consent in Dr. Hsieh's absence. Ms. Barone is a licensed practitioner who has over 20 years experience in emergency medicine research. She works closely with the potential research subjects.

Persons obtaining consent need to be consistent with [Chapter 13 Obtaining Consent](#) and the [Obtaining Informed Consent for Human Subject Research Guidance](#)

## Consent Process

3. For studies that involve multiple visits, describe the process to ensure ongoing consent:

- Reconsent process for a mod can also appear here

Explain how you will recap the study at each visit. State if you will provide them with any written materials or have a verbal conversation

4. \* Steps to be taken to ensure the subjects' understanding:

Include if there are any supplements to the consent forms (visual aids or other materials), how subjects will be prompted for questions, teach-back method to assess comprehension

# Consent Forms

- Accept WORD or PDF formats
- Leave ~ 1 inch at bottom for watermarking
- Use track changes only when submitting responses
  - System removes during approval process
  - Don't include tracked changes on a new protocol submission

Use the tools available under [Consent Guidance. Review of Chapter 13 – Informed Consent](#) and Documentation is also advised

## Consent Forms

### 1. Consent Forms: ?

+ Add



Document

Category

Date Modified

There are no items to display

Refer to the following templates and instructional documents:

- Guidance - [Consent Wording](#)
- Template - [Consent Document - Short Form](#)
- [HRP-090 - SOP - Informed Consent Process for Research](#)
- [HRP-091 - SOP - Written Documentation of Consent](#)

### Add Attachment

#### 1. \* File to attach:

Choose File

#### 2. Name: (if not supplied, the file name will be shown)

#### 3. Version number:

\* Required

OK

OK and Add Another

Cancel

# Add vs. Update

“Add” is to include a new document

## Consent Forms

### 1. Consent Forms: ?

Document	Category	Date Modified
 + Add		
 Update consent form adult.docx(0.01)	Consent Form	3/6/2020
 Update consent form child.docx(0.01)	Consent Form	3/6/2020

“Update” is for a new version of an existing document

# Managing Consent Documents

## Consent Forms

### 1. Consent Forms: ?

<input type="button" value="+ Add"/>				
	Document	Category	Date Modified	Document History
<input type="button" value="Update"/>	<del>Consent form adult TRACKED.docx(0.01)</del>	Consent Form	3/9/2020	History
<input type="button" value="Update"/>	<del>Consent form child TRACKED.docx(0.01)</del>	Consent Form	3/9/2020	History
<input type="button" value="Update"/>	consent form adult.docx(0.01)	Consent Form	3/6/2020	History
<input type="button" value="Update"/>	consent form child.docx(0.01)	Consent Form	3/6/2020	History

- Only one version is necessary since PittPRO removes tracking when finalized
- Old versions can be compared using the “History” on the right
- Do not put duplicate versions, tracked or otherwise, in Supporting Documents

# Electronic Data Management

- Review [Electronic Data Management Tips](#) for assistance in filling out the form
- Refer to [Data Risk Classification and Compliance](#) to determine when data could be considered sensitive
- Refer to [Pitt IT Research Resources](#) for storage solutions and data sharing
- Request a [data security consultation](#) using the subject line, “Requesting data security consultation for research

## Electronic Data Management

1. \* Will only anonymous data be collected (select **NO** if identifiers will be recorded at anytime during the conduct of the study)?  
 Yes  No

Select all identifiers to be collected during any phase of the research including screening:

- Name:  Internet Protocol (IP) Address:   
 E-mail address:  Web Universal Resource Locators (URLs):   
 Social security #:  Social security # (for Vincent payment only):   
 Phone/Fax #:  Full face photo images or comparable images:   
 Account #:  Health plan beneficiary #:   
 Medical record #:  Device identifiers/serial numbers:   
 Certificate/license #:  Vehicle identifiers/serial #/license plate #:   
 Biometric identifiers, finger and voice prints:

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.?  
 Yes  No

\* b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?  
 Yes  No

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:

d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR)?  
 Yes  No

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?  
 Yes  No

\* Will the data be HIPAA de-identified?  
 Yes  No

\* Briefly describe your plan to store coded data separately from the identifiable data:  
 Identifiable data will be stored in a separate file with a link to the study ID. All data collected and stored for the study will be coded with the study ID and will not include identifiable data.

2. \* Will sensitive data be collected (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?  
 Yes  No

3. \* Select all locations where data will be stored or accessed (including e.g., **personal / employer laptop or desktop**):

Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
<small>View</small>	Server: UPMC Managed Server	no	no	yes
<small>View</small>	UPMC owned desktop, laptop or other device	no	no	no

4. \* Select all technologies being used to collect data or interact with subjects:

Other

5. \* Other Technologies:

name	Identifiable
DocuSign	yes
iMedidata RAVE EDC 2018.2.2	no



# Data and Safety Monitoring

## 2. \* Describe your plan for sharing data and/or specimens: ?

Investigators should include, at the very least, a broad sharing statement which addresses this issue.

As a reminder, the University requires data use or material transfer agreements to be in place when data or specimens are leaving the institution.

This question is about sharing for research purposes, not about regulatory access. Use the guidance for [Data Use Agreements \(DUA\)](#) and [Material Transfer Agreements \(MTA\)](#)

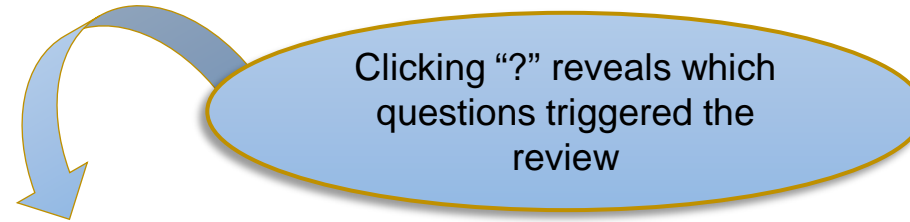
## 3. If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:

|

This question is not about sample sharing but who controls the samples after obtaining them from subjects

# Ancillary Reviews

- Dictated by answers throughout the protocol
- Few can be manually selected
- Link to info about ancillary office
- Scientific & Mentor in Pre-Submission
- Others simultaneous in Pre-Review



## 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:

- Conflict of Interest (COI)
- Clinical and Translational Research Center (CTRC)
- Data Security
- Honest Broker
- UPMC Investigational Drug Service
- Pitt Medical School Review
- Pitt+Me
- Office of Investigator-Sponsored IND & IDE Support (O3IS)
- Radioactive Drug Research Committee (RDRC)(study involves the evaluation or use of procedures that emit ionizing radiation)
- RCCO Business **Manager** (required for industry sponsored studies)
- Religious Directives
- Scientific Review
- Health Record Research Request (R3) (required if using UPMC clinical data and authorization for other UPMC data sources for research)
- UPMC Office of Sponsored Programs and Research **Support** (using UPMC facilities and/or UPMC patients during the conduct of the study)

2. Additional ancillary reviews the PI may choose to include as needed for the research:

- Human Stem Cell Oversight (hSCRO)
- Institutional Biosafety Committee (IBC)(study involves deliberate transfer of recombinant or synthetic nucleic acid molecules)

# Submit for Review

**Pre-Submission**

Last updated: 10/2/2018 12:12 PM

**Next Steps**

- Edit Study
- Printer Version
- View Differences
- Submit**
- Assign Primary Contact
- Manage Guest List
- Add Comment
- Discard



- Principal Investigator
  - Only person with access to submit a new study, continuing review or modification
  - If the PI left the institution, contact [askirb@pitt.edu](mailto:askirb@pitt.edu) to request a PI Proxy
- Reportable New Information (RNI)
  - Anyone can create RNI report and submit
- Double check that protocol was submitted (you'd be surprised how many times “submit” is not hit)

# Hide/Show Errors

- Always click “Hide/Show Errors” before submission
- Shows required fields that need completion

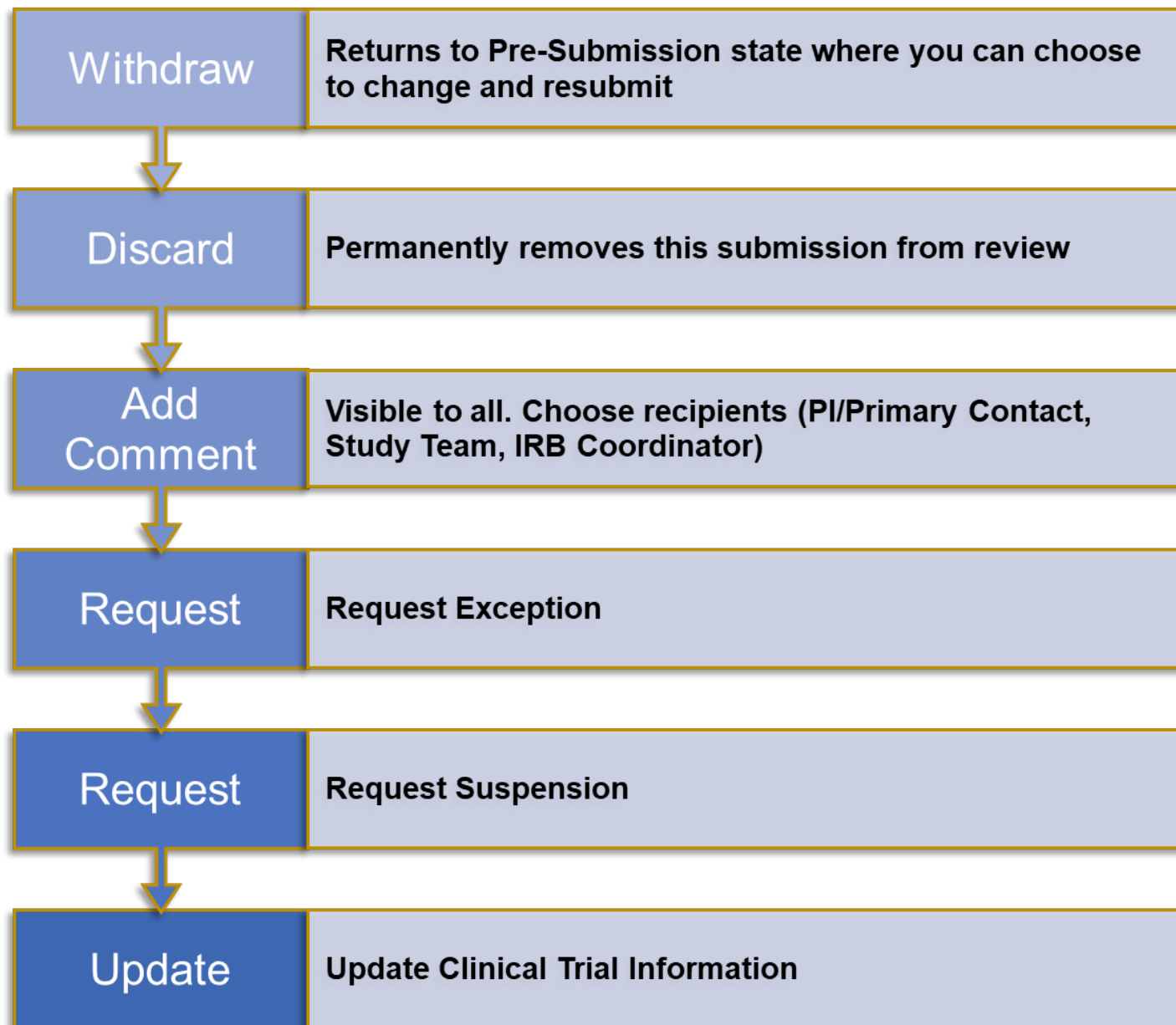
“Hide/Show Errors” does not:

- Identify non-starred fields that may need completion
- Remove notes to others such as “Dr. Smith, review this section for me”
- Show placeholders such as “x” that were placed in starred fields to move on

The screenshot shows the 'New Study' form in the PittPRO system. The 'Hide/Show Errors' button is circled in red. Below the form, a table of error messages is displayed:

Message	Field Name	Jump To
⊘ This is a required field; therefore, you must provide the required information.	Funding Options	<a href="#">Funding Sources</a>
⊘ This is a required field; therefore, you must provide the required information.	Study Team Members	<a href="#">Study Team Members</a>
⊘ This is a required field; therefore, you must provide the required information.	PI Verified Team Expertise Creds And Training	<a href="#">Study Team Members</a>
⊘ This is a required field; therefore, you must provide the required information.	RecruitedPopulations	<a href="#">Study Scope</a>
⊘ This is a required field; therefore, you must provide the required information.	Waivers or Exceptions	<a href="#">Study Scope</a>

# Other Activities



# Approved Documents

History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Training	...
Draft	Category	Final	Last Finalized	Document History			
<a href="#">Pitt+Me Ad</a>	Recruitment Materials	<a href="#">Pitt+Me Ad</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">RCCO Fee Sheet</a>	Sponsor Attachment	<a href="#">RCCO Fee Sheet</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">OSPARS Form</a>	Sponsor Attachment	<a href="#">OSPARS Form</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Main Consent</a>	Consent Form	<a href="#">Main Consent</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">FDA corres</a>	Drug Attachment	<a href="#">FDA corres</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Telephone script</a>	Waiver Script	<a href="#">Telephone script</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">FDA IND application</a>	Drug Attachment	<a href="#">FDA IND application</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Room Request.docx</a>	Sponsor Attachment	<a href="#">Room Request.docx</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Drug brochure</a>	Drug Attachment	<a href="#">Drug brochure</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Email for Listserve</a>	Recruitment Materials	<a href="#">Email for Listserve</a>	11/20/2018 1:38 PM	<a href="#">History</a>			
<a href="#">Tam Drug brochure</a>	Drug Attachment	<a href="#">Tam Drug brochure</a>	11/20/2018 1:38 PM	<a href="#">History</a>			

**Pulls out all documents attached to the protocol for access in a single place**

# Modification Scope Selections

## Both options

### Modification / Continuing Review / Study Closure

Note: Submitting a study closure: Select Continuing Review and complete the application

#### \* What is the purpose of this submission?

- Continuing Review
- Modification
- Modification and Continuing Review

[Clear](#)

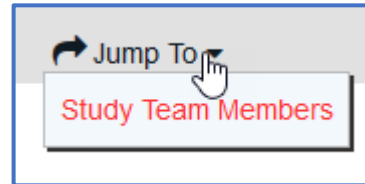
Note: The combination of a Modification and Continuing Review application may take long to the expiration date which may result in the study approval expiring.

**i** To change the PI, choose 'Other parts of the study/site' scope

#### Modification scope:

- Study team member information
- Other parts of the study

## 1<sup>st</sup> option



## 2<sup>nd</sup> option



### Choose option carefully!

- May need to discard Mod and start over if wrong option is chosen
- If you choose only "Study Team Members" you cannot edit other parts of the study (e.g. add a new consent form)

# Modifications Requested

## Modification Information

### 1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

### 2. Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes

### 3. \* Summarize the modifications:

addition of co-investigators, honest broker and more detailed information related to variables being collected.

### 4. Additional Reviews

*If you answer Yes to any of the following questions, additional review/approval may be required before IRB review is initiated:*

**UPMC Fiscal Review (OSPARS): Do the proposed changes add/remove/change any procedures performed in a UPMC facility during the conduct of your research study?**

Yes  No [Clear](#)

## Modification Information page

- Q3: Summarize and justify the modifications textbox
- Include the rationale and support for the changes being made

### Reconsent:

- Only check #2 if applicable
- Make corresponding change in Consent Process section to outline how reconsent will occur (See previous slide: make sure to check “other parts”)



# Create a Continuing Review or Study Closure

## – Go to Approved Study Workspace

**Next Steps**

Edit Modification/CR

Edit Project Enter Version

View Differences

### Modification / Continuing Review / Study Closure

*Note: Submitting a study closure: Select Continuing Review and complete the application*

**\* What is the purpose of this submission?**

- Continuing Review
- Modification
- Modification and Continuing Review

1. \* Specify enrollment totals:

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	<input type="text"/>	<input type="text"/>
Study-wide:	<input type="text"/>	

2. Research milestones: (select all that apply) ?

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

**i Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

3. \* Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? ?

- Yes  No [Clear](#)

4. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

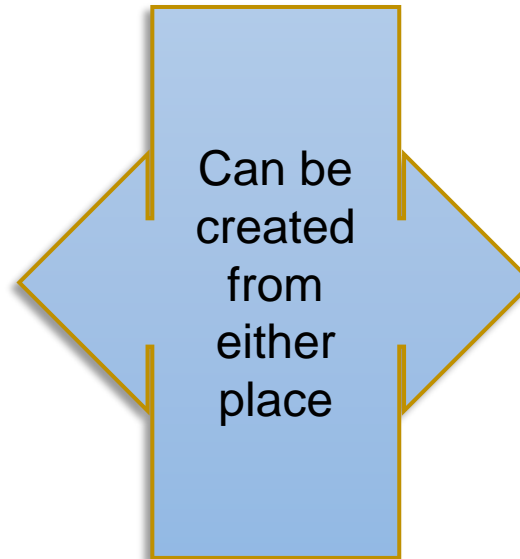
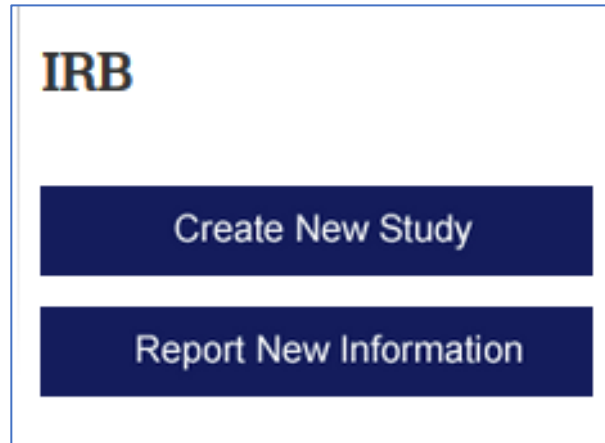
5. Attach supporting documents: (include an explanation of each item left unchecked above) ?

Refer to the Study Status  
Guidance for Research  
Milestone details

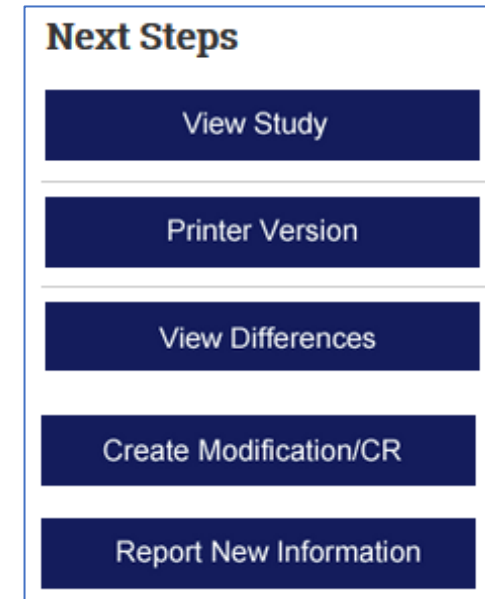
Be sure to attach supporting  
documents for any box left  
unchecked

# New Reportable Information (RNI)

## Personal Folder



## Study Workspace



- Any member of the research team can submit New Reportable Information
- Can be associated with several studies – ability to link to related studies and modifications

# General Comments



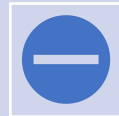
System watermarks Consent Forms and Recruitment Materials



Approval letter will list all approved documents uploaded

Naming documents

- Consent\_not approved
- Survey\_copyrighted.donotuse
- Questionnaire\_draft.donotuse



Red asterisk \* = **required response**

Limited to manage exempt projects



Please do not rename documents once approved unless absolutely necessary

Difficult for IRB review using the compare documents function



Managing your profile

Update in PittPRO

Update in HSConnect

Use employer email address (Pitt employees must use their Pitt email)

# A little proofreading goes a long way...

Protocols are often returned:

- missing documents,
- incomplete sections
- placeholders that are left behind



# Need Help?



412-383-1480  
Main IRB number

[askirb@pitt.edu](mailto:askirb@pitt.edu)  
General IRB questions

[Irb.reliance@pitt.edu](mailto:Irb.reliance@pitt.edu)  
Central IRB questions (aka sIRB)

[Orp\\_support@pitt.edu](mailto:Orp_support@pitt.edu)  
Technical Issues