

# Getting Started in PittPRO

Contact [askirb@pitt.edu](mailto:askirb@pitt.edu) with questions or to set up a consultation

Contact [orp@pitt.edu](mailto:orp@pitt.edu) for technical or account issues

Contact [irb.reliance@pitt.edu](mailto:irb.reliance@pitt.edu) if you are submitting an sIRB protocol

# Accessing PittPRO

## Log-In Information

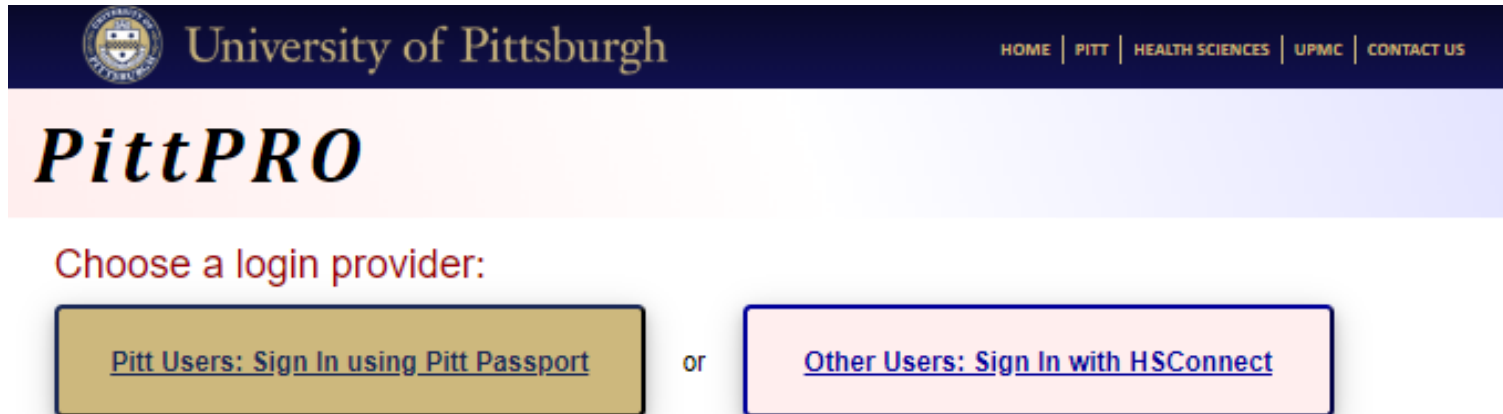
Use your Pitt HSConnect username and password:

LOGIN

Need to create a Pitt HSConnect account:

HS Connect

NOTE: It is important not to create duplicate accounts. If don't know whether you have an existing account or have any other questions, contact the HSConnect support team at 412-648-2222.



The screenshot shows the PittPRO login interface. At the top is a dark blue header with the University of Pittsburgh logo and name on the left, and navigation links (HOME | PITT | HEALTH SCIENCES | UPMC | CONTACT US) on the right. Below the header is a light blue banner with the text "PittPRO" in a large, bold, serif font. Underneath the banner, the text "Choose a login provider:" is displayed in red. Below this text are two rectangular buttons. The left button is gold and contains the text "Pitt Users: Sign In using Pitt Passport". The right button is light pink and contains the text "Other Users: Sign In with HSConnect". The word "or" is placed between the two buttons.

Use email address and password used to complete CITI modules

# Create New Study

»

My Inbox

IRB

Create New Study

Report New Information

Submissions

Meetings

Reports

Library

Help Center

My Inbox

Filter by ?

ID


Enter text to search for

+

Add Filter

×

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 ▶

25 / page

From the My Inbox page, click “Create New Study”

# Navigating the Study Workspace

## Committee Review

Entered IRB: 3/6/2019 3:44 PM  
Last updated: 4/24/2019 10:22 AM

### Next Steps

1. View Study
2. Printer Version
3. View Differences

STUDY19020224

## D3 Creatine to Measure Muscle Mass

**Principal investigator:** Michael Dunn

**IRB coordinator:** Juliet Mancino

4. 5.						
History	Funding	Contacts	Documents	IRB Assignment	Reviews	Training
Draft				Category		
D3 Consent to MMM_Version_0.02 IRB edits clean_Version_0.01.docx				Consent Form		
Deferral Correspondence - response letter.docx				Other		
Creatine-final-Venkat 5 Mar.docx				Drug Attachment		
MSDS CIL D3 CR.pdf				Other		
D3 CONSENT TO PK_Version_0.03 IRB edits_Version_0.01.docx				Consent Form		
April 12 RESPONSE TO IRB LETTER OF APRIL 1 2019.docx				Other		
Cawthon D3Cr J Geront 2018.pdf				Other		

1. **View Study:** opens submission pages. Click “Continue” to move through the pages and edit content
2. **Printer Version:** Shows the entire submission in one scrollable, printable page
3. **View Differences:** shows changes made between two submission versions
4. **Documents tab:** shows all documents attached to submission. Documents can also be access from Printer Version and View Study pages
5. **Reviews tab:** Shows completed IRB reviews and ancillaries

CONTACTS:  
Shows info for all  
who have access

History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Training	Snapshots	Admin
Principal Investigator								
Name		Financial Interest			E-mail		Phone	
Jamie Zelazny		no			jmz22@pitt.edu		412-864-0874	
Study Team								
Name		Roles	Financial Interest	Involved in Consent		E-mail		Phone
Candice Biernesser		Co-investigator	no	yes		lubbertcl@upmc.edu		412-586-9064
Neal Ryan		Co-investigator	no	no		ryannd@upmc.edu		412 383-5477
David Brent		Co-investigator	no	yes		brentda@upmc.edu		412-246-5596
Fuchiang Tsui		Co-investigator	no	no		tsui2@pitt.edu		412-648-6755
Tina Goldstein		Co-investigator	no	yes		goldsteintr@msx.upmc.edu		412-246-5604
Jamie Zelazny		Principal Investigator	no	yes		jmz22@pitt.edu		412-864-0874
Other Study Team Member Information								
Document				Description				
Guests Who Can View This Submission								
Name			E-mail				Phone	
Joseph Bickus			bickusjh@upmc.edu				4126050932	
Daniel Buysse			buyssedj@upmc.edu				412-246-6413	
Nickie Cappella			nkc7@pitt.edu					
Melissa Devito			mszycoml@upmc.edu				246-6452	
sean gallagher			sean.gallagher@pitt.edu					
Diane Masters			mastersdw@upmc.edu					
Sharon Ralph			barness@upmc.edu				(412) 647-4398	
Nathan Rockcastle			rockcastlenj@upmc.edu				4123838173	
Melissa Schwenk			mds127@pitt.edu					
Jonathan Silverstein			j.c.s@pitt.edu				7733962485	
Scott Weinman			sdw37@pitt.edu					

## Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
Data Security	U of Pgh   CSSD   Computing Services	Scott Weinman sean gallagher	yes	yes	approved the understanding only de-identified data is stored on the third party cloud provider server	
Scientific Review	WPIC SRC - Western Psychiatric Institute and Clinic Scientific Review Committee	Daniel Buysse Melissa Devito Nathan Rockcastle	yes	no	"No" under "Accepted" means that Ancillary has not yet approved	
UPMC Care	UPMC   CArE	Diane Masters Melissa Schwenk Nickie Cappella Sharon Ralph Jonathan Silverstein	no		A blank under "Accepted" means that Ancillary receives notification. Approval prior to IRB review is not necessary	
UPMC OSPARS	UPMC   OSPARS	Joseph Bickus	no			

**Reviews: Shows Ancillary Details**

# 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. Can be changed 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

## Study Design

7. Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?

☐ Yes ☐ No [Clear](#)



# New Study Created

# Pre-Submission

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

STUDY18100003

## New Study

**Principal investigator:** Alsace France

**IRB coordinator:**

IRB review does not begin until the Pre-Review state

## 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

Q

[+ Add Filter](#) [✕ Clear All](#)

### Activity

Author

▼ Activity Date



Study Created

France, Alsace

10/2/2018 1:46 PM

## Basic Information

1. \* Title of study:

Ask the IRB Demo Study 9.11.18

2. \* Short title:

HRPO Demo

3. \* Brief description: ?

This study is created to show the functions of the study scope

4. \* Principal investigator: ?

Melissa Miklos



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

☐ Yes ☒ No [Clear](#)

# Principal Investigator

Listed on the Basic Info page

# Principal Investigator

Detailed on Study Team Members page

Be sure to name the PI on this page and match it to Basic Info #4

## 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	E-mail	Phone	Qualifications	
<div><div>Update</div></div>	Tom Bivens (pi2)	Co-investigator	Pitt faculty	yes	testuser@clickcommerce.com	503.123.4567	Dr. Bivens will bear the responsibility of conducting the informed consent process with prospective subjects	<div><div></div></div>
<div><div>Update</div></div>	Melissa Miklos	Principal Investigator	Pitt staff	yes	mgm12@pitt.edu	412-383-1480	Melissa Miklos is the PI of this study. She is integral in the development of PittPRO and has the expertise to carry out the study. She will be abl... <div>view all</div>	<div><div></div></div>
<div><div>Update</div></div>	Darryl O'Neill (bso)	Co-investigator	Pitt faculty	no	testuser@clickcommerce.com	503.123.4567	Dr. O'Neill is a skilled tester in the area of IRB regulation. He has done numerous roll-outs of this type of software and will share his expertise ... <div>view all</div>	<div><div></div></div>

# Phases of Review



- **Pre-Submission** → Researcher is building the protocol
  - Scientific Review takes place when leaving this state
- **Pre-Review** → Ancillary Reviews and IRB review begins
- **IRB Review** → Committee Review or Expedited Review taking place
- **Post-Review** → Final clean-up prior to approval being granted
- **Review Complete** → Active state
- **Clarification Requested** → In Researcher's possession for corrections

## Funding Sources

1. \* Indicate all sources of support:

- ☐ No support
- ☐ Internal funding
- ☒ External funding

Do not choose “no support” if you have billable activities or are paying subjects. The IRB needs to know the source of the funds

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

<div>+ Add</div>			
Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
National Institute on Alcohol Abuse and Alcoholism			NIAA grant.docx

Include the grant cover sheet when uploading the grant. Salary and other financial details can be redacted

# External Funding Sources

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


+ Add

Funding Source

Sponsor's Funding ID

There are no items to display

- Use % to search for name of source
- If not listed, email [orp@pitt.edu](mailto:orp@pitt.edu) so the new source can be added
- Try using different variables of names
- Leave Grant office ID blank

1. \* Funding organization: ? 

2. Sponsor's funding ID: (assigned by external sponsor)

3. Grants office ID: (assigned internally)

4. Attach files: (include any grant applications, Fee Sheet for industry sponsored studies, or other relevant funding documents)

+ Add

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

\* Required

OK OK and Add Another Cancel

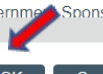
Select Organization

Filter by Name %national Go Clear Advanced

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Name	Category
<input type="radio"/> National Cancer Institute	Government Sponsor
<input type="radio"/> Weight Watchers International, Inc.	Industry
<input type="radio"/> National Institute of Environmental Health Sciences	Government Sponsor
<input type="radio"/> National Oceanic and Atmospheric Administration	Government Sponsor
<input type="radio"/> National Institute of Mental Health	Government Sponsor
<input type="radio"/> National Heart, Lung, and Blood Institute	Government Sponsor
<input checked="" type="radio"/> National Eye Institute	Government Sponsor
<input type="radio"/> National Center for Complementary and Integrative Health	Government Sponsor
<input type="radio"/> National Institute of Diabetes and Digestive and Kidney Diseases	Government Sponsor
<input type="radio"/> National Institute of Biomedical Imaging and Bioengineering	Government Sponsor
<input type="radio"/> National Institute on Deafness and Other Communication Disorders	Government Sponsor

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OK Cancel 

# Assigning Non-Study Team Roles

- Assign Primary Contact
  - Not listed as a member on the Study Team page
- Manage Guest List
  - Provide read-only access to the application
- **Advanced Search**
  - Enter First and Last Name

### Next Steps

Edit Study

Printer Version

View Differences

Submit

Assign Primary Contact

### Assign Primary Contact

\* Select a new primary contact to receive all communications from the IRB: ?

Rebecca Simms (PI) ...

Help

#### Assign Primary Contact

Select the person who will act as the study's main point of contact for communications with the IRB. The primary contact receives notifications, in addition to the principal investigator, when the IRB communicates a decision or requires the study staff to take action.

**Note:** If the primary contact is also engaged in the research, make sure the list of team members within the study includes the person.

OK Cancel

### Select Person

Filter by Last [ ] Go Clear Advanced

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	Last	First	Organization
<input type="radio"/>	(Gillis) Oleksiuk	Louise-Marie	U of Pgh   School of Pharmacy   Pharmacy and Therapeutics
<input type="radio"/>	(Holquist) Flickinger	Katharyn	U of Pgh   School of Medicine   Emergency Medicine
<input type="radio"/>	A	Archana	Other
<input type="radio"/>	Aaldenberg	Amy	U of Pgh   Dietrich School of Arts and Sciences   Other
<input type="radio"/>	Aarabi	Mahmoud	U of Pgh   School of Medicine   OB-Gyn and Reproductive Science   Reproductive Genetics
<input type="radio"/>	Aaronson	Nicole	UPMC   Hospital Divisions   Children's Hospital of Pittsburgh
<input type="radio"/>	Ababio	Amma	Other
<input type="radio"/>	Abacar	Mussa	Other
<input type="radio"/>	Abarca Millan	Erika	U of Pgh   School of Education   Instruction and Learning
<input type="radio"/>	Abatemarco	Daine	Other
<input type="radio"/>	Abati	Brandan	Other

1-25 of 27971

OK Cancel

# 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**
- Qualifications required for PI, Co-I, and Faculty Mentor – include how they are qualified to carry out their duties specific to this study
- Name not selectable until required Pitt CITI training 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 the [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 CTRC - 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](#)

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

- ☐ Yes ☐ No [Clear](#)

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

# 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

# CTRC Resources - Provide Access for CTRC Staff

- Scientific review MWH CTRC
- Study Scope

## 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 CTRC - 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

## 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 CTRC sites where research will be conducted:

- ☐ Magee Womens Clinical and Translational Research Center (MWH-CTRC)
- ☐ Montefiore Hospital Clinical and Translational Research Center (MUH-CTRC)
- ☐ Multidisciplinary Acute Care Research Organization (MACRO)
- ☐ Neuroscience Clinical and Translational Research Center (N-CTRC)
- ☐ Pediatric Clinical and Translational Research Center (P-CTRC)
- ☐ Newborn Nursery Clinical and Translational Research Center (Nursery-CTRC)
- ☐ Physical Therapy Clinical and Translational Research Center (PT-CTRC)
- ☐ UPCI Clinical and Translational Research Center (UPCI-CTRC)
- ☐ Older Adult Practice Based Research Network (OARN)
- ☐ Pediatric PittNet (PBRN)

# 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
 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
 Update	Margaret Hsieh	Principal Investigator	Pitt faculty	yes	Dr. Hsieh is Associate Professor of Emergency Mec room. Associate Chief, ED Staffing, UPMC Presbyte
 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:

This is not intended for reconsenting  
as the result of new risks or changes  
in the protocol

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
  - System removes during approval process

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: ?



+ Add			
Document	Category	Date Modified	
 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: ?

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

# Waivers

## 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

Requesting waivers for multiple research activities

- Each request must be addressed and labeled per section
- Only one set of waiver justifications displayed for all waivers selected

Waivers can be great tools in certain types of research.

Refer to [Chapter 13 Informed Consent and Documentation](#) for more information.

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


## Waiver/Alteration of Consent

### 1. \* Select all options that apply to the request to waive the requirement to obtain informed consent:

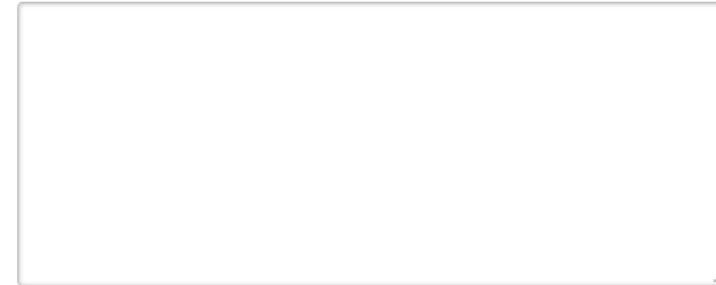
- ☐ Review of identifiable medical records (applies only for recruitment or charts reviews)
- ☐ Review of identifiable specimens
- ☐ Parental permission and/or child assent
- ☐ Alteration of informed consent process
- ☐ Other Minimal Risk activity

General Requirements: The Federal Policy [45 CFR 46.116 (d)] specifies in order for a waiver or alteration of consent to be approved, the request must meet the following four criteria. You **MUST** provide a justification addressing how each of these criteria are met **for each request**.

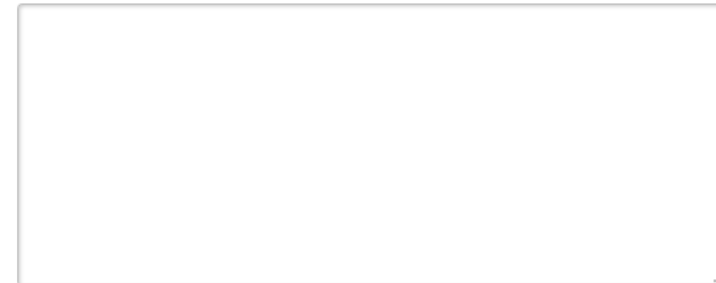
### 2. \* The research involves no more than minimal risk to the subjects:



### 3. \* The waiver or alteration will not adversely affect the rights and welfare of the subjects:



### 4. \* The research could not practicably be carried out without the waiver or alteration:



### 5. \* Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

# Electronic Data Management

- In Section 3
  - Include what is used to access the data as well (e.g., Pitt /UPMC /personal desktops and laptops)
- If asked how the data will be encrypted in transit or when stored
  - Response should include how the data is encrypted in transit (e.g. SSL or TLS) or when stored (e.g. Bitlocker, File Vault, SecureZip)
- Ask a question or request consultation
  - [A-Z Guidance, Data Security Guidance](#)

## Electronic Data Management ?

1. \* Will only anonymous data be recorded (at no time will identifiable data be collected including IP addresses)?

☐ Yes ☐ No [Clear](#)

2. \* Will sensitive data be recorded (e.g., protected health information, mental health, medications, drug/alcohol use, illegal behaviors)?

☐ Yes ☐ No [Clear](#)

3. \* Select all locations where data will be stored:

[+ Add](#)

Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
----------------	-------------	-------------------	----------------	------------------------------

There are no items to display

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

☐ Mobile App

☐ Wearable device (also select mobile app if it will be used with the device)

☐ Text messaging

☐ Social Media

☐ Electronic audio, photographic, or video recording or conferencing

☐ Web-based site, survey, or other tool

☐ Other

☐ N/A

# 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

## Risk and Benefits

### 3. Financial risks - will the subject or insurer be charged for any research required procedures?

☒ Yes ☐ No [Clear](#)

\* Address each procedure with a justification and indicate if charges are incurred for investigational drugs/devices. Address, if applicable, a contingency plan for those not able to cover the cost of participation:

Answer “no” if clinical results are used for research purposes. These are not research charges

### 5. What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:

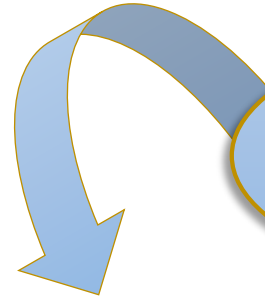
This is the plan for if a subject presents with an *unanticipated* medical condition not related to what is being studied

The plan for managing anticipated AEs is recorded in Data and Safety Monitoring #1



# 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



Clicking “?” for the Help Text reveals which questions triggered the 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
- ☐ Office of Investigator-Sponsored IND & IDE Support (O3IS)
- ☐ RCCO Business Manager (required for industry sponsored studies)
- ☐ Religious Directives
- ☒ Scientific Review
- ☒ UPMC (CARE)(required if using UPMC electronic medical records)
- ☒ 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)
- ☐ Radioactive Drug Research Committee (RDRC)(study involves the evaluation or use of procedures that emit ionizing radiation)

# Notes on Ancillary Reviews

## **Mentor**

- Faculty Mentor Acknowledgement
  - PI cannot submit until mentor agrees to provide oversight
- 

## **Scientific Review (SR)**

- If required, approval is needed before IRB review will take place
  - Email notification is generated from prefilled list in PittPRO
    - Reviewer can approve or clarifications can be requested
- 

## **Other Ancillary Reviews (ANC)**

- Managed in parallel with Pre-IRB Review
  - Cannot move out of Pre-IRB Review until all ANC completed except:
    - Radioactive Drug Research Committee (RDRC) and Institutional Biosafety Committee (IBC)
    - Both meet once a month. IRB review can proceed but final IRB approval not granted until RDRC and IBC approval
-

# 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
- 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)

# Responding to Comments

- Expedited reviewers may convey comments on the Reviewer Sheet
- Explain how each request was completed (or justify why it was not)
- Upload the completed Reviewer Sheet when submitting responses
  - If PI doesn't attach during the submit process
    - Study Coordinator can upload
    - Click on "Add Comment"
    - Q3 – select IRB Coordinator to receive the notification

<b>PittPRO</b>   Pitt Protocol Review Online	
REVIEWER SHEET	
Submission ID:	STUDY18080035
PI:	Demo PI
Title:	Demo Study
The form only displays sections of the application completed by the investigator.	
<b>IRB Reviewer Instructions</b> <ul style="list-style-type: none"><li>➤ Save this form to your computer</li><li>➤ Enter comments in the corresponding sections below</li><li>➤ Once completed, click on "Add Review Comments" and upload the Reviewer Sheet in section 3: Other supporting documents</li></ul> If you have questions during review, contact the IRB Coordinator assigned to your submission.	<b>Investigator/Study Team Instructions</b> <ul style="list-style-type: none"><li>• Save this form to your computer</li><li>• Indicate in the Reviewer Comments column what changes were made or include additional clarifications if needed</li><li>• Attach this Reviewer Sheet when submitting clarifications</li><li>• Important: Use <u>track changes</u> (not highlighting) for any edits to consent forms or recruitment materials</li></ul> If you have questions about comments issued, contact the IRB Coordinator assigned to your submission.
Contact <a href="mailto:askirb@pitt.edu">askirb@pitt.edu</a> for general IRB questions or <a href="mailto:rcco@pitt.edu">rcco@pitt.edu</a> for technical support.	
<b>General Comments</b>	
<b>Smartform Page</b>	<b>Reviewer Comments</b>
Basic Information	
Funding Sources	
Study Team Members	
Study Scope	
Local Site Documents	

# Adding Comments

Committee Review

Entered IRB: 2/13/2019 12:06 PM  
Last updated: 4/2/2019 9:37 AM

Next Steps

View Study

Printer Version

View Differences

Request Clarification by Committee Member

☒ Add Review Comments

☒ Add Comment

☐ Add Private Comment

Your comment is visible to anyone who has access to this submission.

1. Comment:

2. Supporting documents:

+ Add

Name	Description
There are no items to display	

3. Who should receive an e-mail notification? ?

- ☐ PI/PI Proxy/Primary Contact
- ☐ Study Team
- ☐ IRB Coordinator

OKCancel

Comments are *not* private!  
They are visible to anyone with access to the study

Select who receives comment.  
This controls only who receives a notification email

# Hide/Show Errors

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

**Proofreading goes a long way to cut down on comments from reviewers!**

“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

You Are Here: [New Study](#)

[Back](#) [Save](#) [Exit](#) [Hide/Show Errors](#) [Print](#) [Jump To](#) [Continue](#)

Toggle the display of validation errors

### Basic Information

1. \* Title of study:

New Study for Testing

2. \* Short title:

New Study

3. \* Brief description: ?

New Study

Error/Warning Messages [Refresh](#)

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>

# Training Records

## Required Courses for all

- Responsible Conduct of Research
- Human Subject Protections
  - Biomedical or
  - Social and Behavioral

## Required based on selection


- Conflict of Interest

### Funding Sources

1. \* Indicate all sources of support:  
External funding

- Good Clinical Practice (GCP)

### Good Clinical Practice (GCP) Training

1. \* Regardless of funding source, is this study a clinical trial (as defined by the NIH)? 
- ☒ Yes ☐ No

# IRB Tabs and Documents

## Library

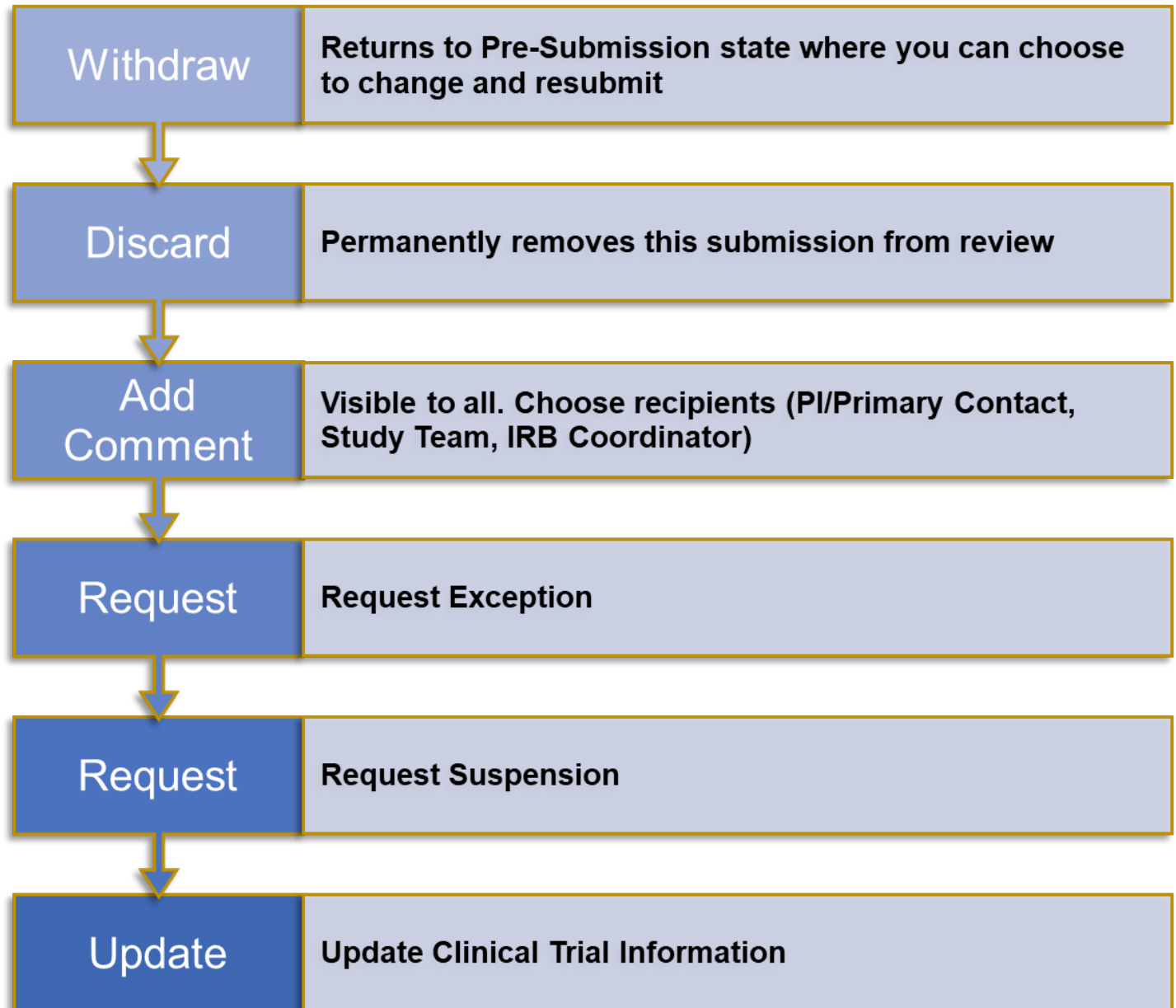
- General
  - Investigator Manual
  - Fee Sheet
  - Honest Broker Agreement
  - Exempt Forms
  - UPMC Fiscal Forms
- Worksheets
  - Approval criterion
- Checklists
  - Ensure compliance with regs
- Templates

## Help Center

- Guides
  - IRB Researcher's Quick Reference
  - Mentor and Scientific Review Reference



# Other Activities



# Approved Documents

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

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

# Create a MOD – Go to Approved Study Workspace

## Next Steps

Edit Modification/CR

Edit Project Inter 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

[Clear](#)

*Note: The combination of a Modification and Continuing Review application may take longer 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

## Reasons to use Modification and Continuing Review with caution:

- If Mod is expeditable but CR requires full board review, entire submission goes to FB
  - Mods at FB require two reviewers, sometimes three. May be delayed due to expertise
- If both go to FB and mod can't be approved or is approved subject to mods, CR could expire
- You can have a mod and a CR opened separately at the same time ago and they can go their separate ways to avoid the above delays

**Choose wisely!**

# 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

Jump To  
Study Team Members

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

Jump To

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

Jump To

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

### 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

### Modification Information page

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

#### 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](#)

#### 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”)

# View Differences for Modifications

- Go to the approved study workspace
- Click on View Differences

Show Changes made between Current Version (4.0, Modification Approved) and 3.0 11/14/2018 2:28 PM Modification MOD18100010-002 review complete: Approved ▼

3.0 11/14/2018 2:28 PM Modification MOD18100010-002 review complete: Approved ▼

4.0 1/28/2019 11:11 AM Modification MOD18100010-003 review complete: Approved

3.0 11/14/2018 2:28 PM Modification MOD18100010-002 review complete: Approved

2.0 11/14/2018 2:05 PM Modification MOD18100010-001 review complete: Approved

1.0 11/12/2018 12:22 PM Approved Version

0.8 11/9/2018 3:36 PM Changes submitted to IRB

0.7 11/9/2018 12:37 PM Changes submitted to IRB

0.6 11/8/2018 1:02 PM Changes submitted to IRB

0.5 11/1/2018 10:23 AM Changes submitted to IRB

0.4 10/19/2018 5:36 PM Changes submitted to IRB

0.3 10/18/2018 12:58 PM Changes submitted to IRB

0.2 10/12/2018 2:03 PM Submit to IRB

0.1 10/4/2018 1:02 PM

# Examples of View Differences

## 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

### ▼ Differences

Removed: Return of Results to Subjects or Others

## 4. Provide a description of the following study timelines:

### Duration of an individual subject's active participation:

About 8 hours **per events. Participation may last until August of 2019.**

Old Value: About 8 hours



# 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"/>	<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

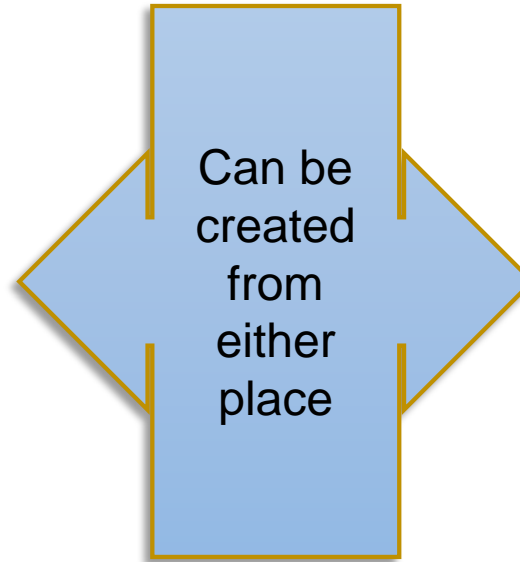
# New Reportable Information (RNI)

## Personal Folder

**IRB**

Create New Study

Report New Information



## Study Workspace

**Next Steps**

View Study

Printer Version

View Differences

Create Modification/CR

Report New Information

- 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

# Approval Letters

- List all approved documents
  - Appears as name displayed in application
- Consider the file names when uploading
  - Titled: Consent with track changes
  - Wording in approval letter: Consent with track changes
- Recommend using version or date in addition to file name

# General Comments

- System watermarks Consent Forms and Recruitment Materials
- Approval letter will list all approved documents uploaded
- Red asterisk \* = **required response**
  - Limited to manage exempt projects
- Managing your profile
  - Update in PittPRO
  - Update in HSConnect
  - Use employer email address
  - Pitt employees must use their Pitt email address

# Comments continued...

- Exempt Projects
  - If project initially not submitted as Exempt but during IRB review determined to meet one of the categories, the IRB staff may request you complete an exempt form for consistency.



- My Inbox
  - Action items
  - Pre-Submission, Clarification Requested
- IRB
  - Lists all studies where you are listed on the Contact page

# General Information

- All new studies (except sIRB) must be submitted in PittPRO
- External / sIRB studies where Pitt is not the IRB-of-Record will continue to be submitted in OSIRIS until additional updates are made to PittPRO (see [Single IRB Review](#) for more information)
- Coordinating Center (CC) applications will be submitted in PittPRO
  - CC Word document supplement displayed under General tab in IRB Library
- Use the Exempt Forms in PittPRO
- Upload documents in the correct sections due to programmed watermarking with IRB number and dates

# Tips for Success

- Play in the Sandbox
- Make sure you understand the study
- Recommend creating a study protocol
- Request a consultation with the IRB
- Ask for HELP

# Call us early and often



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@pitt.edu](mailto:orp@pitt.edu)  
Technical Issues