Getting Started in PittPRO

Contact askirb@pitt.edu with questions or to set up a consultation
Contact orp@pitt.edu for technical or account issues
Contact 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 you don't know whether you have an existing account or have any other questions, contact the HSConnect support team at 412-648-2222.

Choose a login provider:

- **Pitt Users: Sign in using Pitt Passport**
- **Other Users: Sign in with HSConnect**

Use email address and password used to complete CITI modules.
From the My Inbox page, click “Create New Study”
Navigating the Study Workspace

View Study: opens submission pages. Click "Continue" to move through the pages and edit content.

Printer Version: Shows the entire submission in one scrollable, printable page.

View Differences: shows changes made between two submission versions.

Documents tab: shows all documents attached to submission. Documents can also be accessed from Printer Version and View Study pages.

Reviews tab: Shows completed IRB reviews and ancillaries.
## CONTACTS:
Shows info for all who have access

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Financial Interest</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jamie Zolomy</td>
<td>no</td>
<td><a href="mailto:jmc22@pitt.edu">jmc22@pitt.edu</a></td>
<td>412-864-0874</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Team</th>
<th>Roles</th>
<th>Financial Interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candice Rearmoser</td>
<td>Co-investigator</td>
<td>no</td>
<td>yes</td>
<td><a href="mailto:luberto@upmc.edu">luberto@upmc.edu</a></td>
<td>412-586-9954</td>
</tr>
<tr>
<td>Neal Ryan</td>
<td>Co-investigator</td>
<td>no</td>
<td>no</td>
<td><a href="mailto:ryanrd@upmc.edu">ryanrd@upmc.edu</a></td>
<td>412-303-5477</td>
</tr>
<tr>
<td>David Brent</td>
<td>Co-investigator</td>
<td>no</td>
<td>yes</td>
<td><a href="mailto:brentda@upmc.edu">brentda@upmc.edu</a></td>
<td>412-248-5596</td>
</tr>
<tr>
<td>Fuchiang Thui</td>
<td>Co-investigator</td>
<td>no</td>
<td>no</td>
<td><a href="mailto:tsu9@pitt.edu">tsu9@pitt.edu</a></td>
<td>412-484-0705</td>
</tr>
<tr>
<td>Tina Goldstein</td>
<td>Co-investigator</td>
<td>yes</td>
<td>yes</td>
<td><a href="mailto:goldsteinr@mxs.upmc.edu">goldsteinr@mxs.upmc.edu</a></td>
<td>412-246-5694</td>
</tr>
<tr>
<td>Jamie Zolomy</td>
<td>Principal Investigator</td>
<td>no</td>
<td>yes</td>
<td><a href="mailto:jmc22@pitt.edu">jmc22@pitt.edu</a></td>
<td>412-864-0874</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Study Team Member Information</th>
<th>Document</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
No under “Accepted” means that Ancillary has not yet approved.

A blank under “Accepted” means that Ancillary receives notification. Approval prior to IRB review is not necessary.

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Organization</th>
<th>Person</th>
<th>Reqd</th>
<th>Accepted</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Security</td>
<td>U of Pgh</td>
<td>CSSD</td>
<td>Computing Services</td>
<td>Scott Woinman sean Gallagher</td>
<td>yes yes</td>
</tr>
<tr>
<td>Scientific Review</td>
<td>WPIC SRC - Western Psychiatric Institute and Clinic Scientific Review Committee</td>
<td>Daniel Buysse Melissa Devito Nathan Rockcastle</td>
<td>yes</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>UPMC Care</td>
<td>UPMC</td>
<td>CARE</td>
<td></td>
<td>Diane Masters Melissa Schwenk Nickie Cappella Sharon Ralph Jonathan Silverstein</td>
<td>no</td>
</tr>
<tr>
<td>UPMC OSPARS</td>
<td>UPMC</td>
<td>OSPARS</td>
<td></td>
<td>Joseph Bickus</td>
<td>no</td>
</tr>
</tbody>
</table>

Reviews: Shows Ancillary Details
Basic Information and Other Required Pages

1. *Title of study:
   - New Study for Testing

2. *Short title:
   - New Study

3. *Brief description:
   - New Study

4. *Principal investigator:
   - Defaults to study creator. Can be changed to appropriate PI

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

Red Star = Required
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
IRB review does not begin until the Pre-Review state.
Principal Investigator

Listed on the Basic Info page

4. * Principal investigator: Melissa Miklos

5. * Does the investigator have a financial interest related to this research?
   - Yes
   - No
   - Clear
**Principal Investigator**

Detailed on Study Team Members page

**Study Team Members**

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Affiliation</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
<th>Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tom Bivens</td>
<td>Co-investigator</td>
<td>Pitt faculty</td>
<td>yes</td>
<td><a href="mailto:testuser@clickcommerce.com">testuser@clickcommerce.com</a> 503.123.4567</td>
<td>503.123.4567</td>
<td>Dr. Bivens will bear the responsibility of conducting the informed consent process with prospective subjects</td>
</tr>
<tr>
<td>Melissa Miklos</td>
<td>Principal Investigator</td>
<td>Pitt staff</td>
<td>yes</td>
<td><a href="mailto:mgm12@pitt.edu">mgm12@pitt.edu</a></td>
<td>412-363-1480</td>
<td>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 able...[view all]</td>
</tr>
<tr>
<td>Larry Ó’Neill</td>
<td>Co-investigator</td>
<td>Pitt faculty</td>
<td>no</td>
<td><a href="mailto:testuser@clickcommerce.com">testuser@clickcommerce.com</a> 503.123.4567</td>
<td>503.123.4567</td>
<td>Dr. Ó’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...[view all]</td>
</tr>
</tbody>
</table>

Be sure to name the PI on this page and match it to Basic Info #4
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
Include the grant cover sheet when uploading the grant. Salary and other financial details can be redacted.
External Funding Sources

- Use % to search for name of source
- If not listed, email orp@pitt.edu so the new source can be added
- Try using different variables of names
- Leave Grant office ID blank
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
Study Team Members

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

   - Name
   - Roles
   - Affiliation
   - Involved in Consent

   There are no items to display

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)
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

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

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

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 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

4. * Will Protected Health Information be collected?
   - Pitt medical records
   - UPMC medical records
   - Other Institutions' medical records
   - N/A

5. * Other Requests?
   - Deception (also requires Waiver/Alteration of Consent)
   - Emergency Use / Single Patient Expanded Access
   - Placebo Arm
   - Withdraw from usual care
   - 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](#).

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

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  

   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  

9. * Does the study evaluate the safety or effectiveness of a device?
   - Yes  No  

10. * Is this application being submitted to convert an approved study from OSIRIS to PittPRO?
    - Yes  No  

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)

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

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

2. 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 (FBRN)
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.

- 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.
Persons obtaining consent need to be consistent with Chapter 13 Obtaining Consent and the Obtaining Informed Consent for Human Subject Research Guidance.
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.
Add vs. Update

“Add” is to include a new document

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

Consent Forms

1. Consent Forms:

- 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
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 in advance for emergency research exceptions.
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
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.

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 about sharing for research purposes, not about regulatory access. Use the guidance for Data Use Agreements (DUA) and Material Transfer Agreements (MTA).

   This question is not about sample sharing but who controls the samples after obtaining them from subjects.
Answer “no” if clinical results are used for research purposes. These are not research charges.

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

### 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 (O318)
- 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)

Clicking “?” for the Help Text reveals which questions triggered the review.
## 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

- 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

REVIEWER SHEET

<table>
<thead>
<tr>
<th>Submission ID:</th>
<th>STUDY18080035</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI:</td>
<td>Demo PI</td>
</tr>
<tr>
<td>Title:</td>
<td>Demo Study</td>
</tr>
</tbody>
</table>

The form only displays sections of the application completed by the investigator.

IRB Reviewer Instructions
- Save this form to your computer
- Enter comments in the corresponding sections below
- Once completed, click on “Add Review Comments” and upload the Reviewer Sheet in section 3: Other supporting documents

Investigator/Study Team Instructions
- Save this form to your computer
- Indicate in the Reviewer Comments column what changes were made or include additional clarifications if needed
- Attach this Reviewer Sheet when submitting clarifications
- Important: Use track changes (not highlighting) for any edits to consent forms or recruitment materials
- If you have questions during review, contact the IRB Coordinator assigned to your submission.

General Comments

Smartform Page   Reviewer Comments
Basic Information
Funding Sources
Study Team Members
Study Scope
Local Site Documents

Contact askirb@pitt.edu for general IRB questions or rcoc@pitt.edu for technical support.
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:
   - 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

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
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

- **Withdraw**: Returns to Pre-Submission state where you can choose to change and resubmit
- **Discard**: Permanently removes this submission from review
- **Add Comment**: Visible to all. Choose recipients (PI/Primary Contact, Study Team, IRB Coordinator)
- **Request Exception**
- **Request Suspension**
- **Update Clinical Trial Information**
Approved Documents

<table>
<thead>
<tr>
<th>Draft</th>
<th>Category</th>
<th>Final</th>
<th>Last Finalized</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitt+Me Ad</td>
<td>Recruitment Materials</td>
<td>Pitt+Me Ad</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>RCCO Fee Sheet</td>
<td>Sponsor Attachment</td>
<td>RCCO Fee Sheet</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>OSPARS Form</td>
<td>Sponsor Attachment</td>
<td>OSPARS Form</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Main Consent</td>
<td>Consent Form</td>
<td>Main Consent</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>FDA corres</td>
<td>Drug Attachment</td>
<td>FDA corres</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Telephone script</td>
<td>Waiver Script</td>
<td>Telephone script</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>FDA IND application</td>
<td>Drug Attachment</td>
<td>FDA IND application</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Room Request.docx</td>
<td>Sponsor Attachment</td>
<td>Room Request.docx</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Drug brochure</td>
<td>Drug Attachment</td>
<td>Drug brochure</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Email for Listserv</td>
<td>Recruitment Materials</td>
<td>Email for Listserv</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
<tr>
<td>Tam Drug brochure</td>
<td>Drug Attachment</td>
<td>Tam Drug brochure</td>
<td>11/20/2018 1:38 PM</td>
<td>History</td>
</tr>
</tbody>
</table>

Pulls out all documents attached to the protocol for access in a single place
Create a MOD – Go to Approved Study Workspace

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

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 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”)

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
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
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 event. Participation may last until August of 2019.
   
   Old Value: About 8 hours
Create a Continuing Review or Study Closure – Go to Approved Study Workspace

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?
- Continuing Review
- Modification
- Modification and Continuing Review

Note: Submitting a study closure: Select Continuing Review and complete the application
1. **Specify enrollment totals:**

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-wide:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**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)
New Reportable Information (RNI)

- 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

<table>
<thead>
<tr>
<th></th>
<th>Phone Number</th>
<th>Email Address</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>412-383-1480</td>
<td><a href="mailto:askirb@pitt.edu">askirb@pitt.edu</a></td>
<td>Main IRB number</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General IRB questions</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:Irb.reliance@pitt.edu">Irb.reliance@pitt.edu</a></td>
<td>Central IRB questions (aka sIRB)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:orp@pitt.edu">orp@pitt.edu</a></td>
<td>Technical Issues</td>
</tr>
</tbody>
</table>

PittPRO | Pitt Protocol Review Online