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

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Accessing PittPRO

Log-In Information

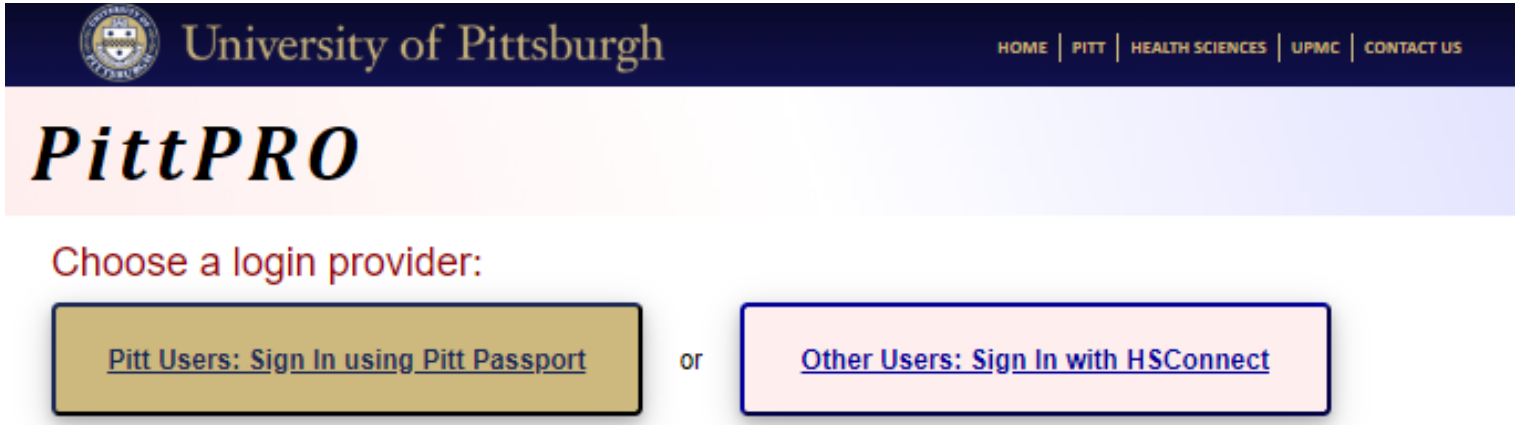
Use your Pitt HSConnect username and password:

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.



Use email address and password used to complete CITI modules

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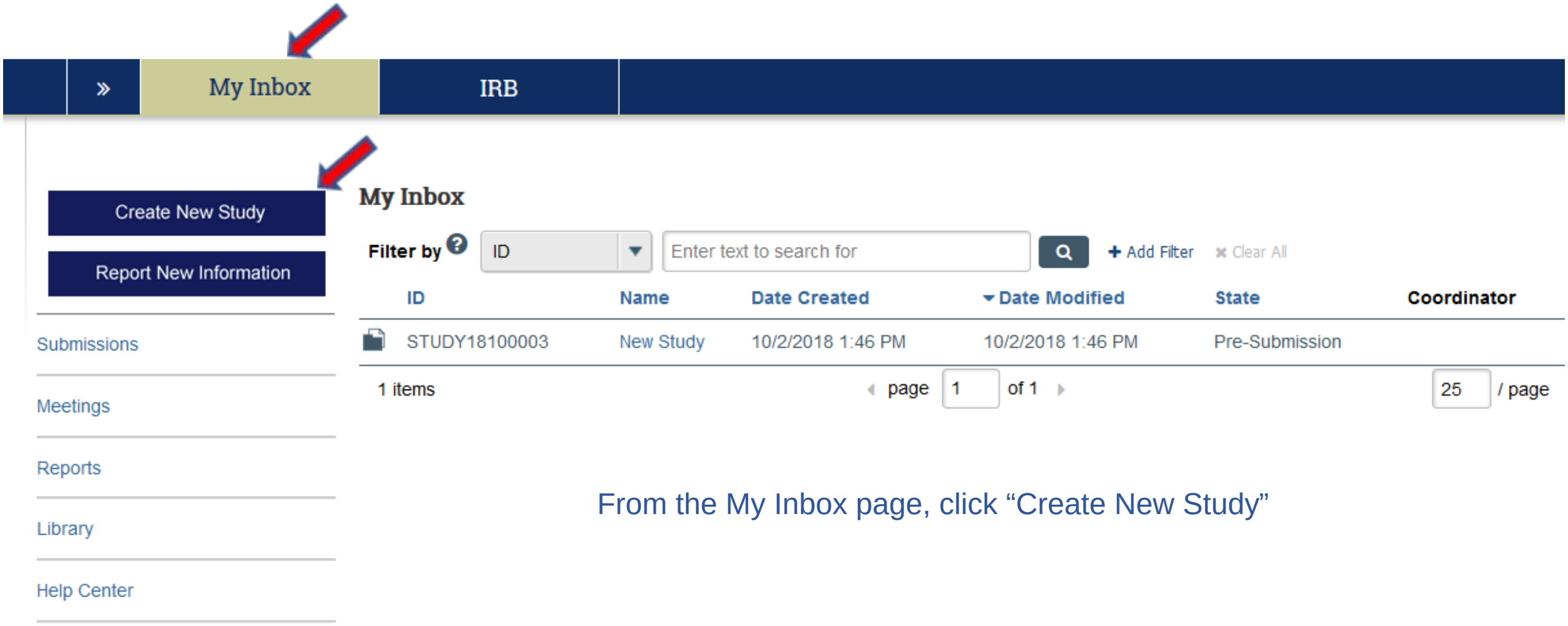
Create New Study



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

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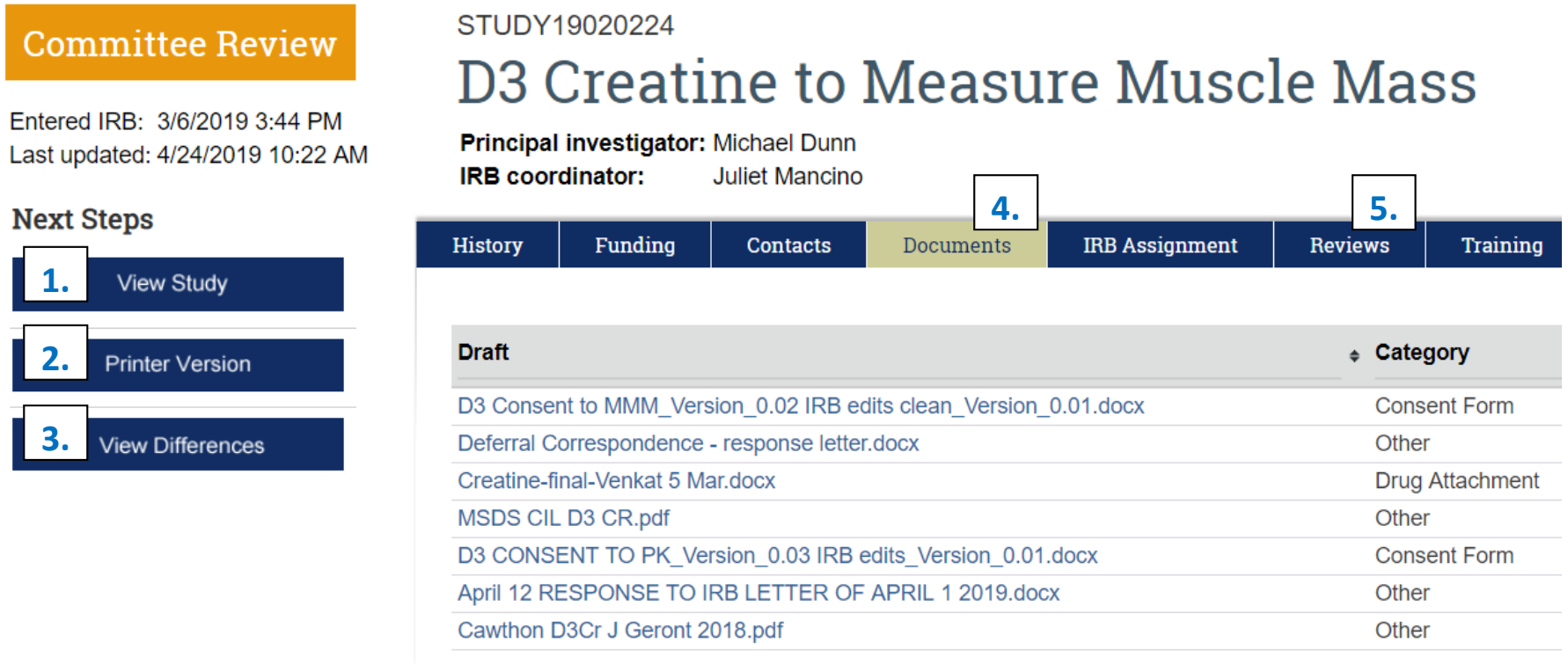
Navigating the Study Workspace



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

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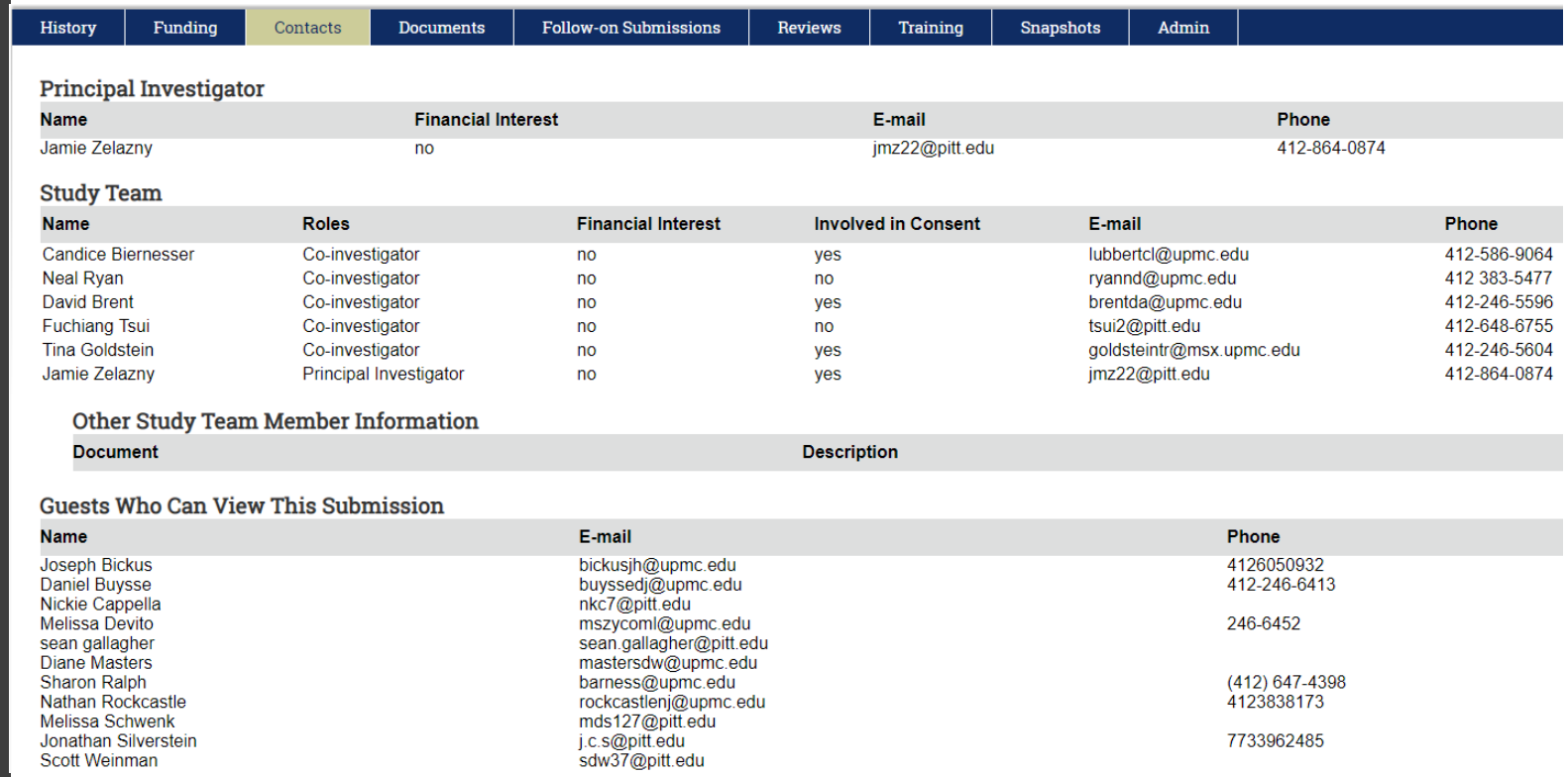
CONTACTS: Shows info for all who have access



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	

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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		
UPMC Care	UPMC | CARe	Diane Masters Melissa Schwenk Nickie Cappella Sharon Ralph Jonathan Silverstein	no			
UPMC OSPARS	UPMC | OSPARS	Joseph Bickus	no			

"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

Reviews: Shows Ancillary Details

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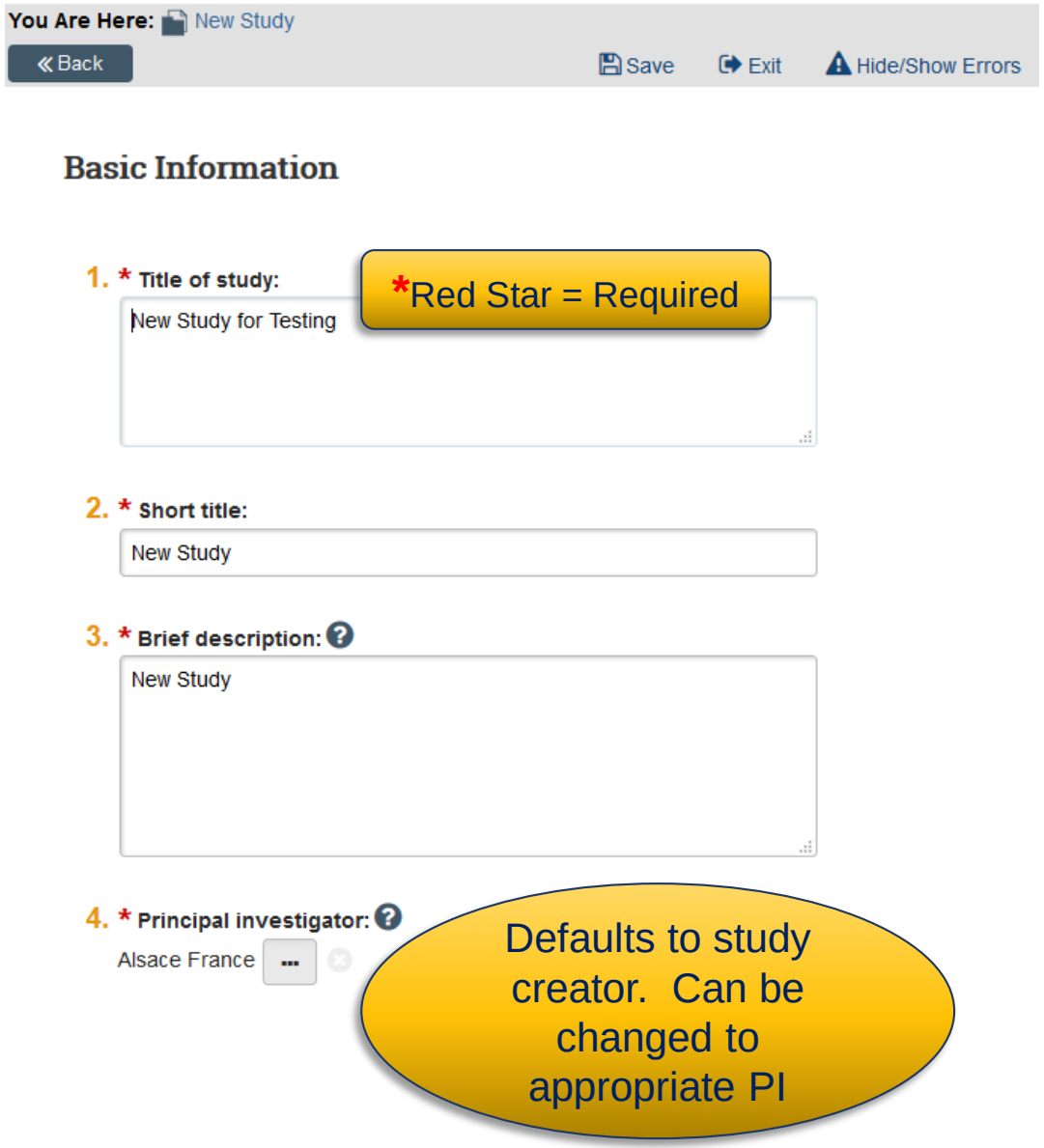
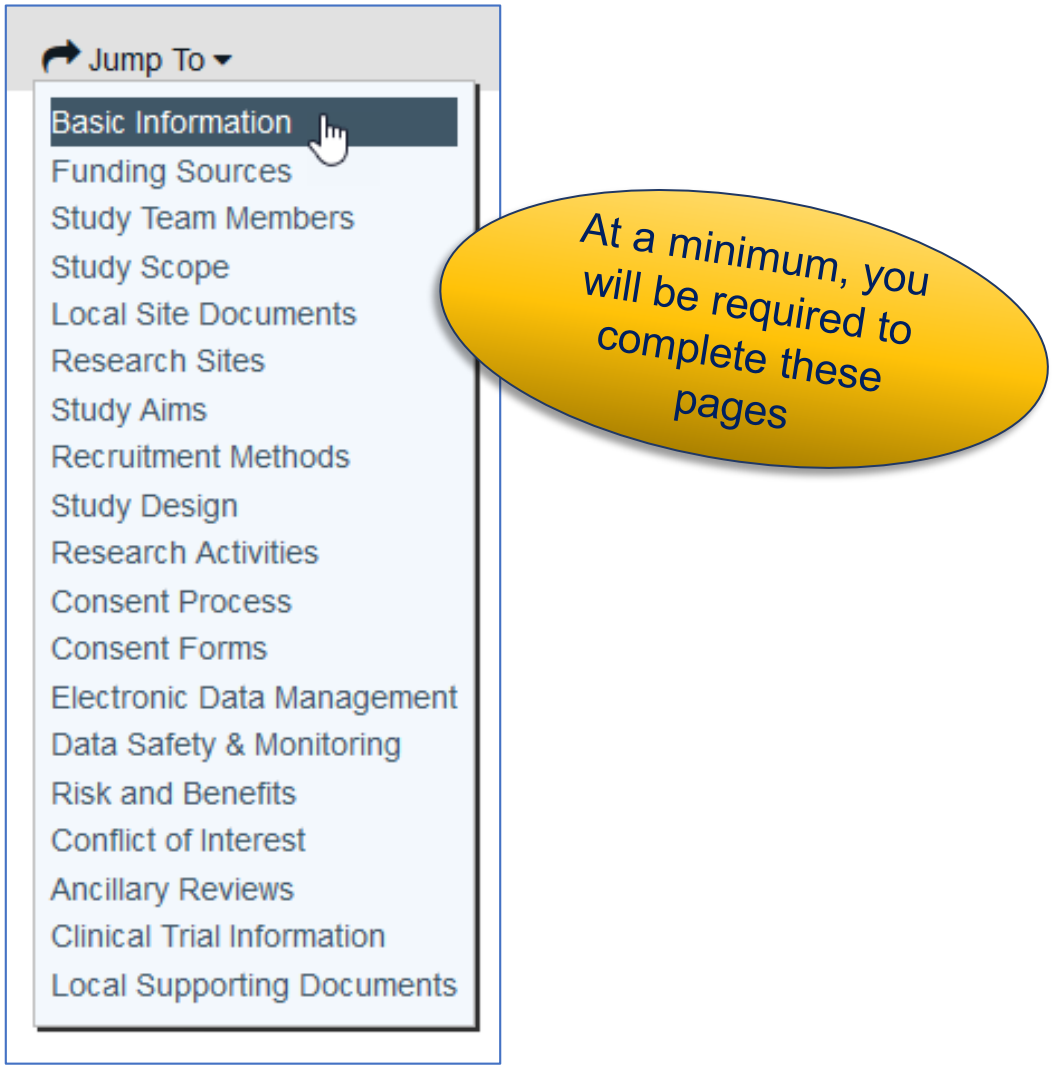
Basic Information and Other Required Pages

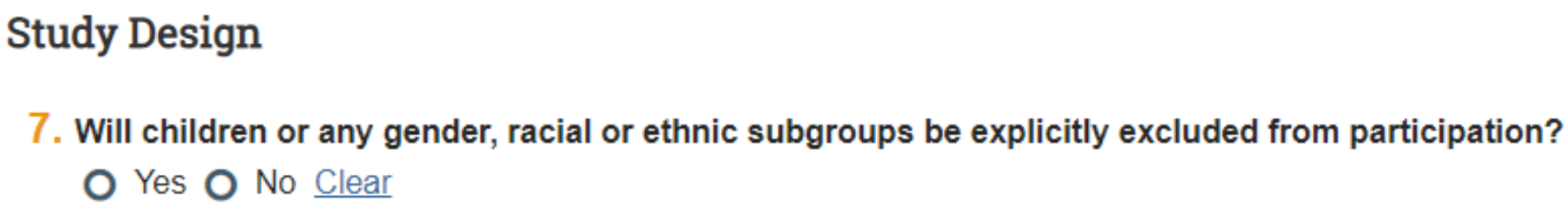




Red asterisk * = required response

No * means that it is not a required field.

However, if it is relevant to your study, you must answer



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New Study Created

IRB review does not begin until the Pre-Review state

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 | Enter text to search for | + 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

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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
Update	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
Update	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... view all
Update	Barry 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 ... view all

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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
   - [x] 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:**

+ Add

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

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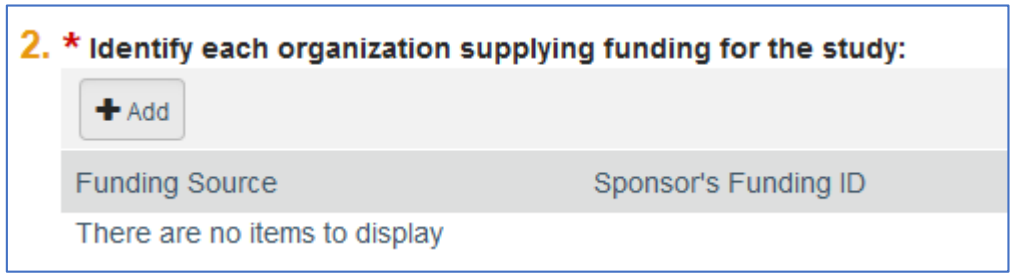
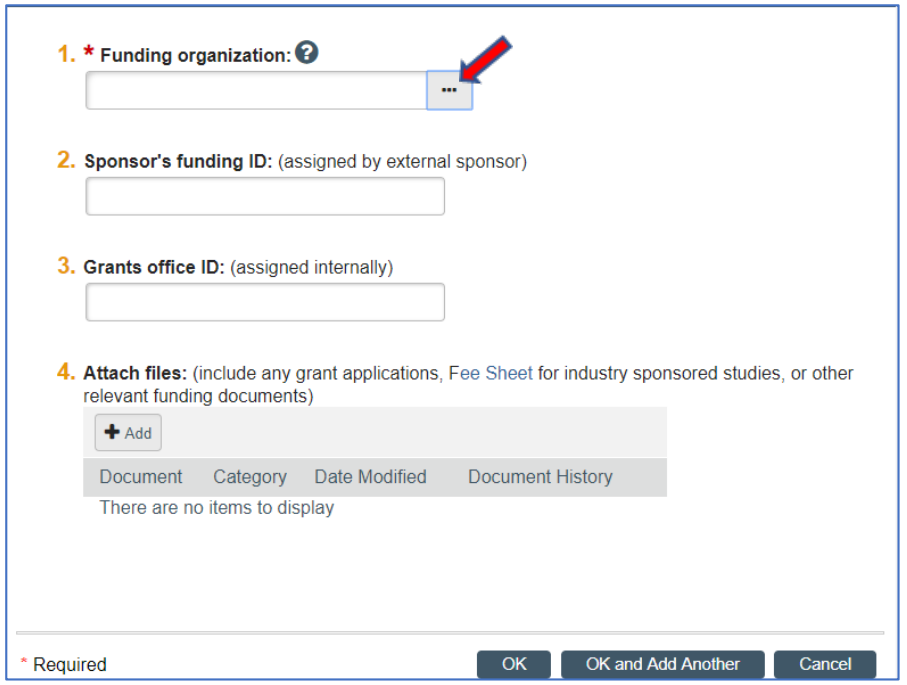
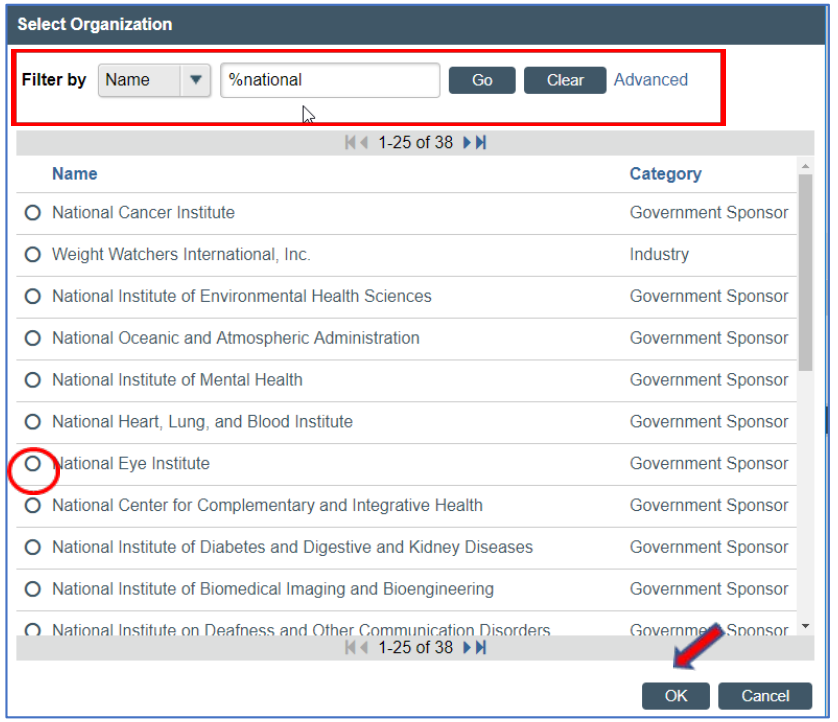
External Funding Sources



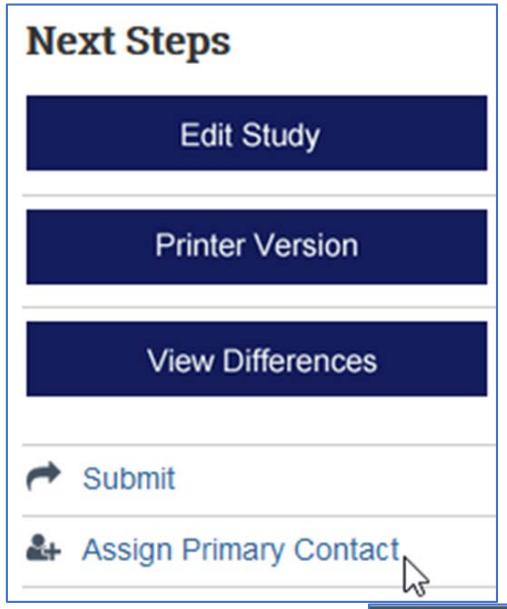
- Use % to search for name of source
- If not listed, email orp@pitt.edu so the new source can be added
- Try using different variables of names
- Leave Grant office ID blank

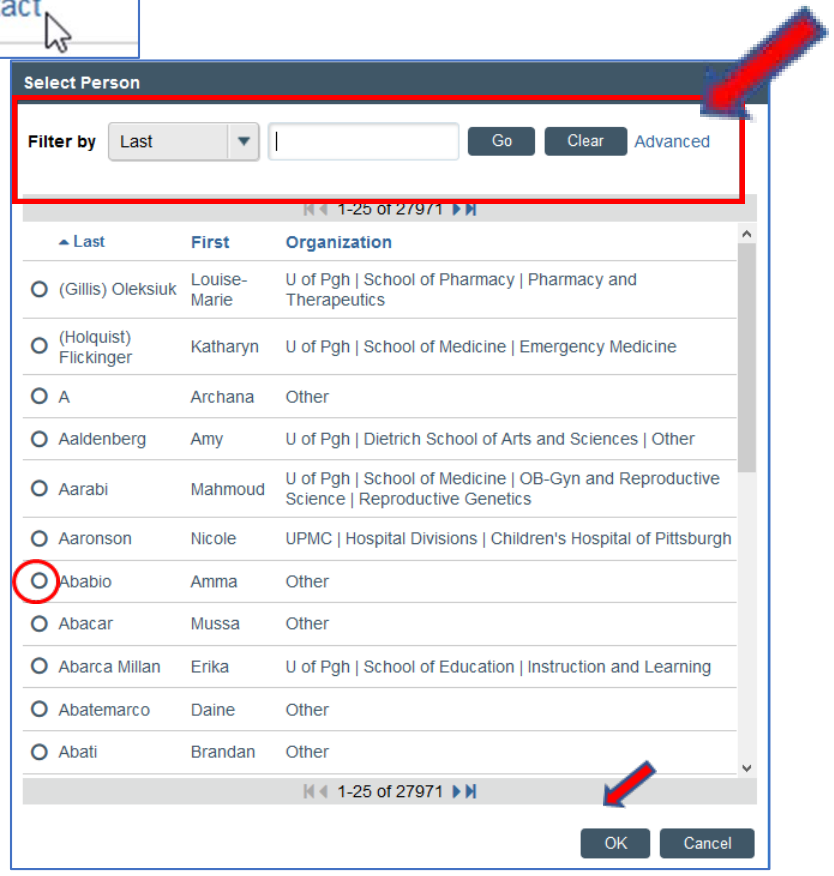




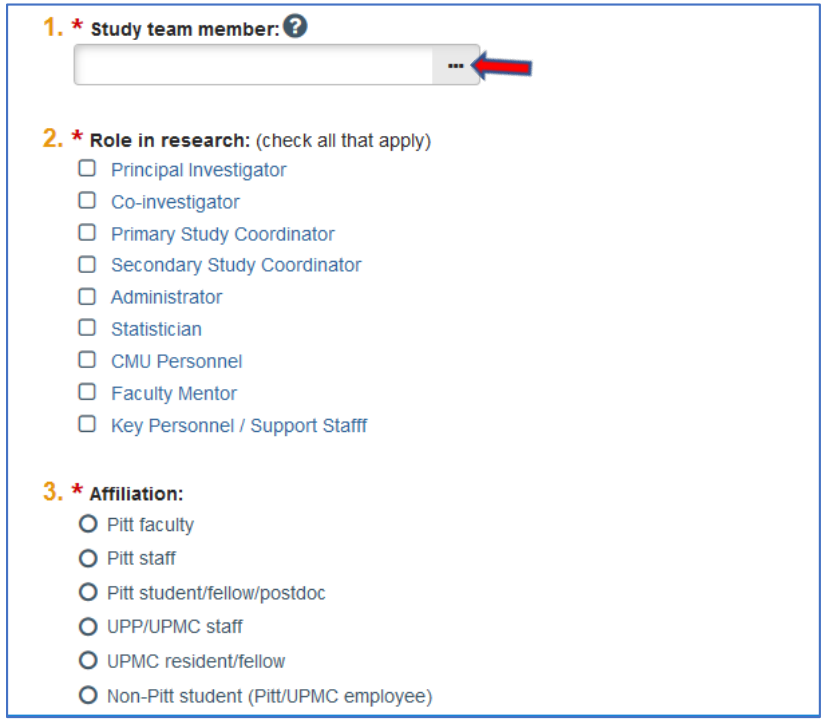
Assigning Non-Study Team Roles

- 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

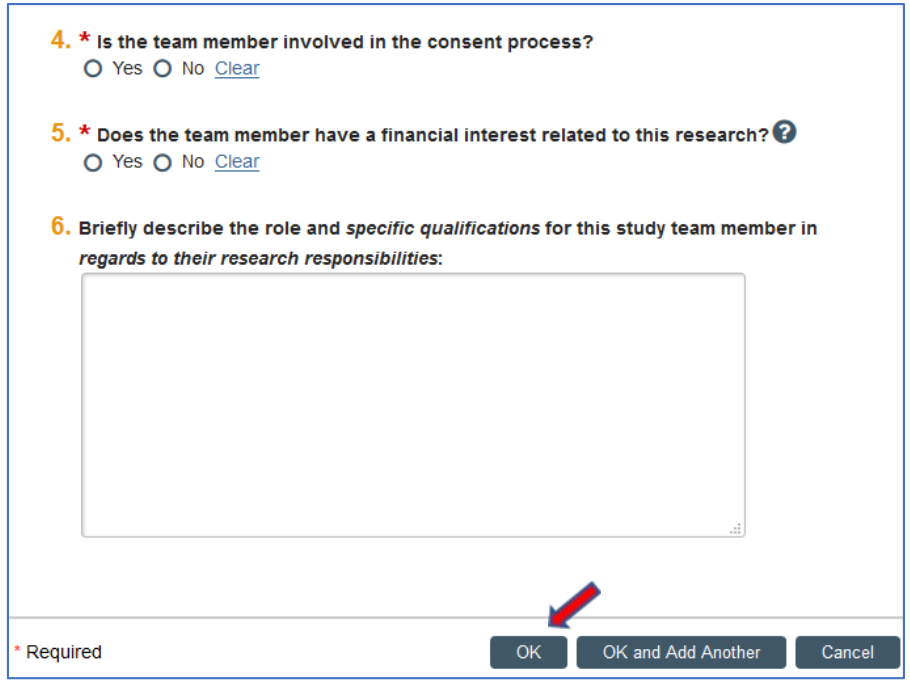




Study Team Members



- 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



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)

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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 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?**

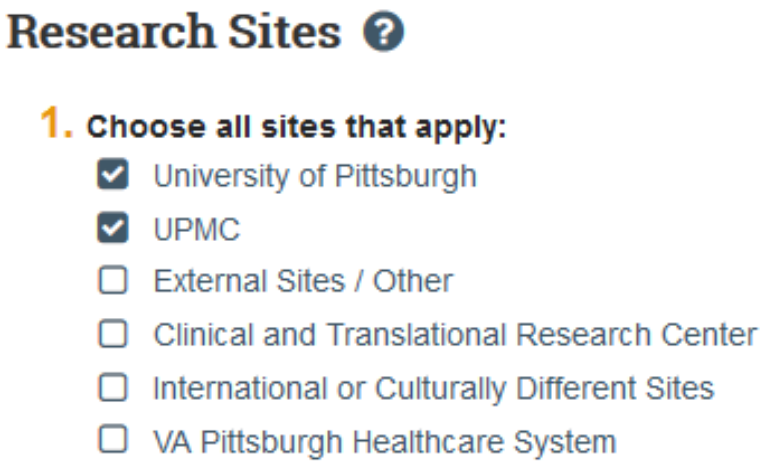
○ Yes ○ No Clear

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?**

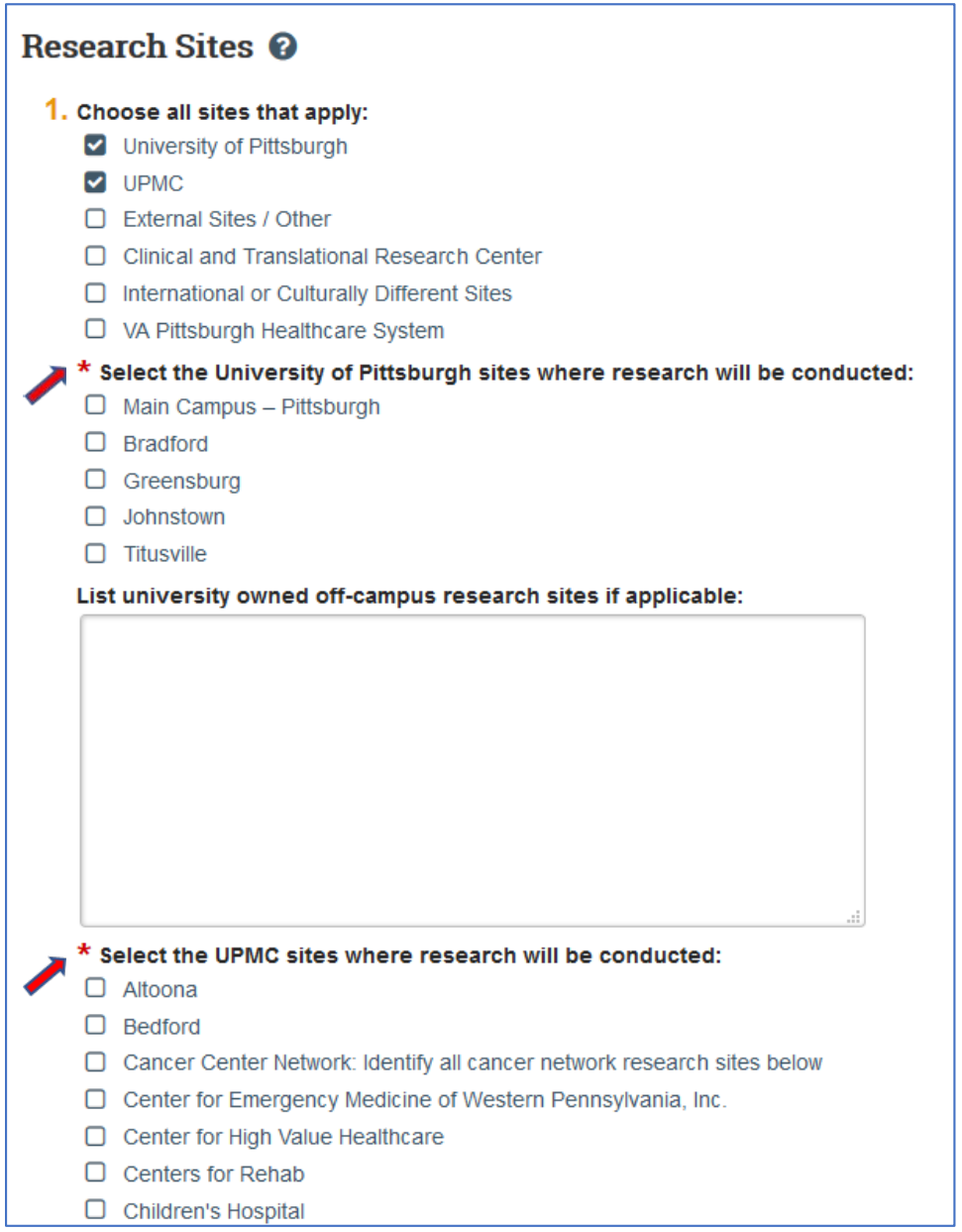
○ Yes ○ No Clear

Research Sites



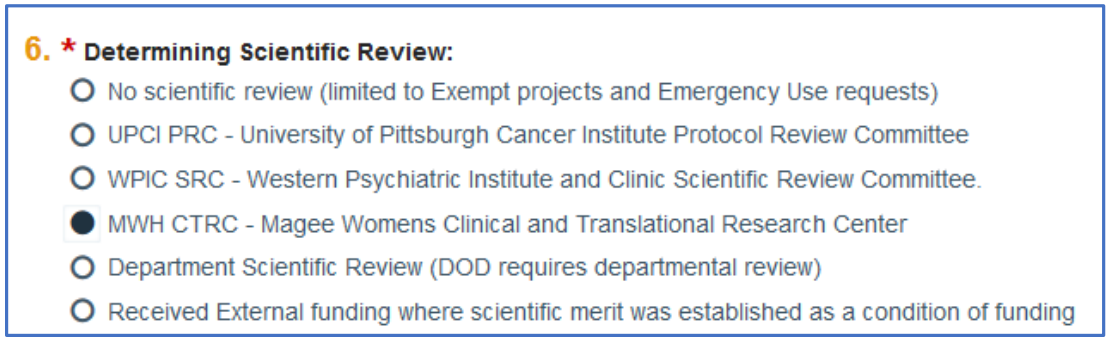
- Check all that apply
- Branches to additional questions

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



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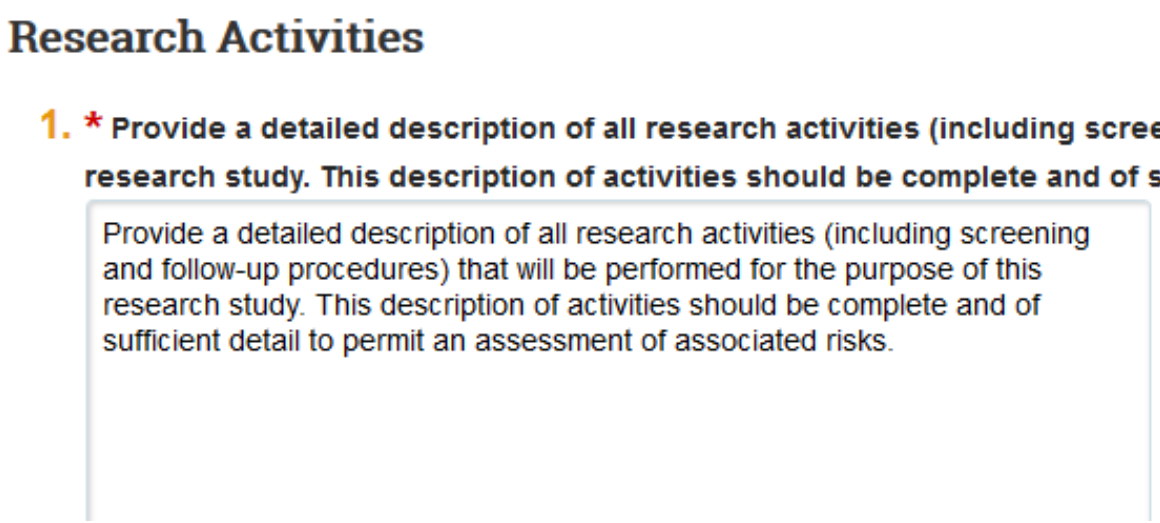
Research Activities



- 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

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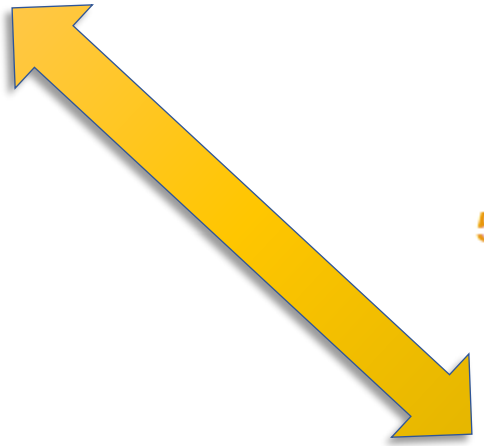
Consent Process

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

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

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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

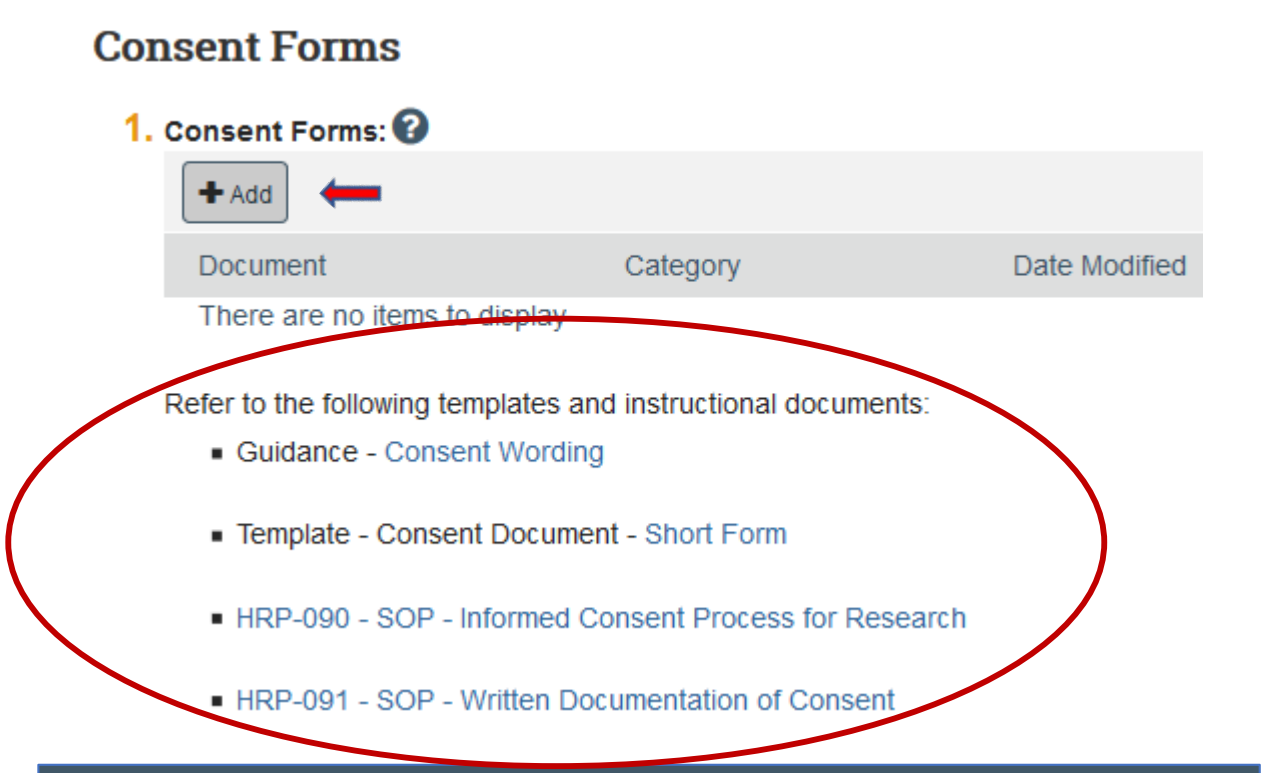
4. * Steps to be taken to ensure the subjects' understanding:

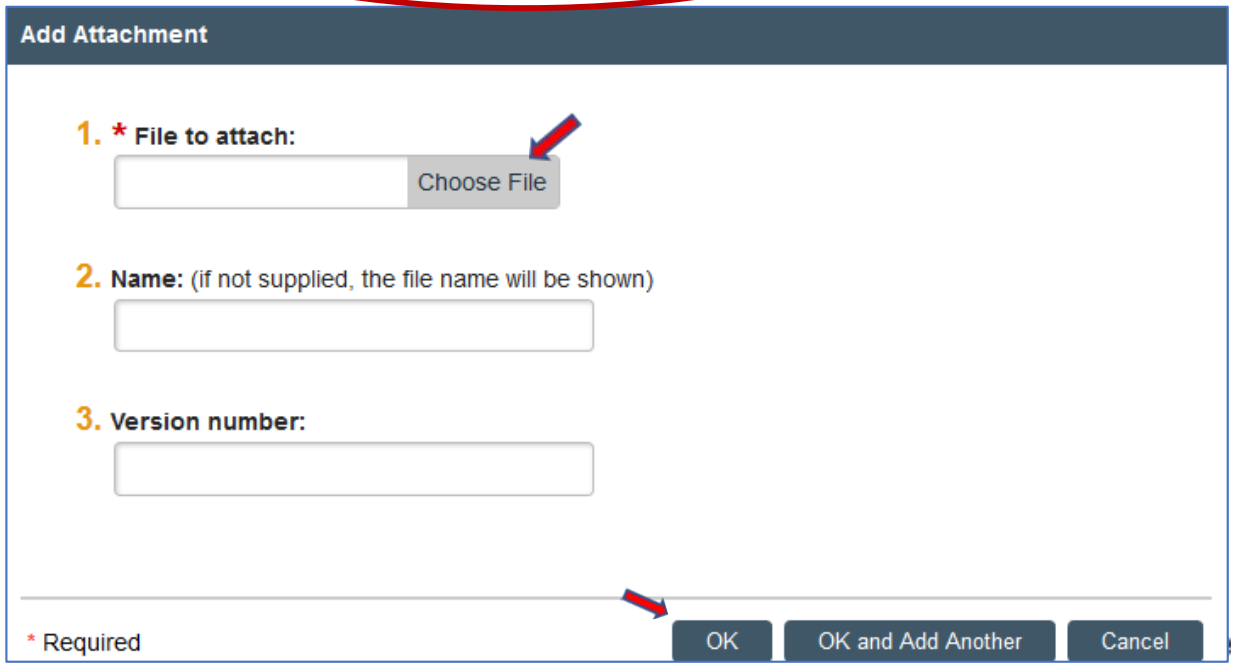
Include if there are any supplements to the consent forms (visual aids or other materials), how subjects will be prompted for questions, teach-back method to assess comprehension

Consent Forms

- Accept WORD or PDF formats
- Leave ~ 1 inch at bottom for watermarking
- Use track changes only
  - System removes during approval process

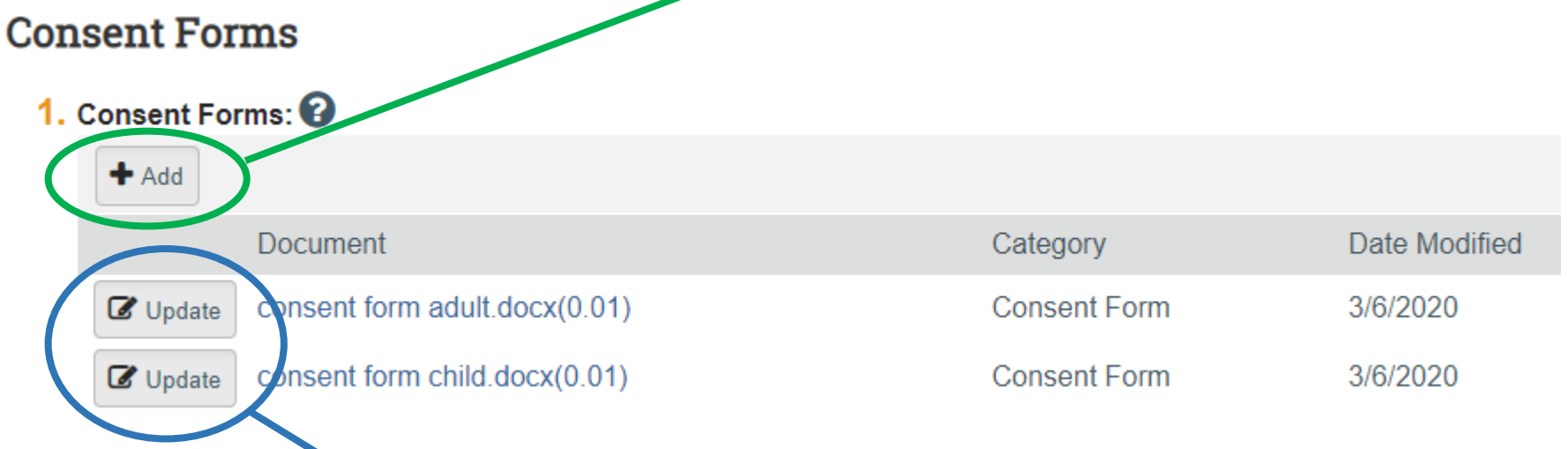
Use the tools available under Consent Guidance. Review of Chapter 13 – Informed Consent and Documentation is also advised





Add vs. Update

"Add" is to include a new document



"Update" is for a new version of an existing document

PittPRO | Pitt Protocol Review Online

Managing Consent Documents

Consent Forms

1. **Consent Forms:**

+ Add

	Document	Category	Date Modified	Document History
Update	Consent form adult TRACKED.docx(0.01)	Consent Form	3/9/2020	History
Update	Consent form child TRACKED.docx(0.01)	Consent Form	3/9/2020	History
Update	consent form adult.docx(0.01)	Consent Form	3/6/2020	History
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

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Waivers

2. * Will any Waivers be requested?

- [x] Waiver/Alteration of Consent
- [x] Waiver to Document Consent
- [x] 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 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 criterion are met **for each request**.*

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

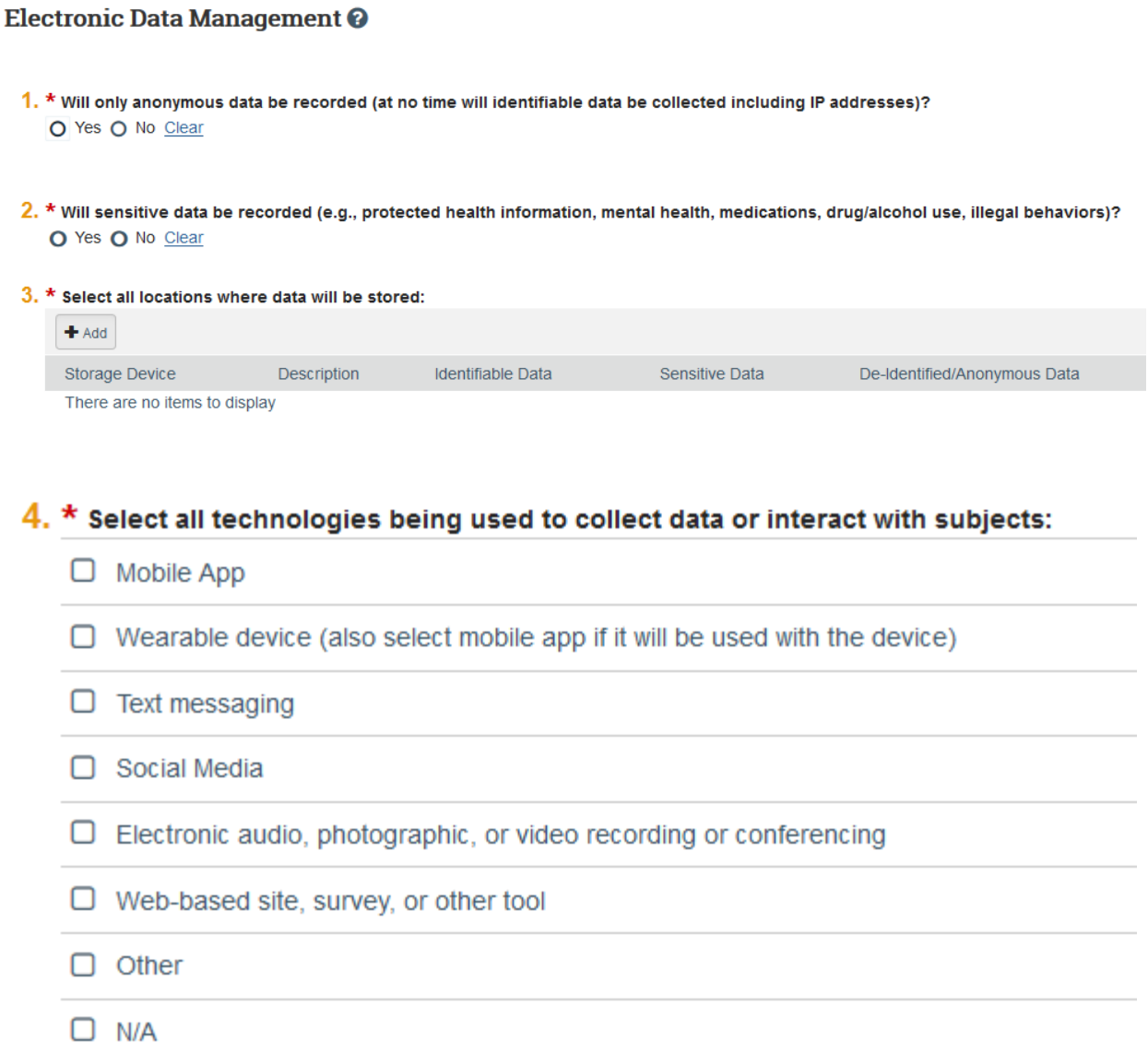
3. * The waiver or alteration will not adversely affect the rights and welfare of the subjects:

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



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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**)
- [x] 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
- [x] Scientific Review
- [x] UPMC (**CARe**)(required if using UPMC electronic medical records)
- [x] 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)

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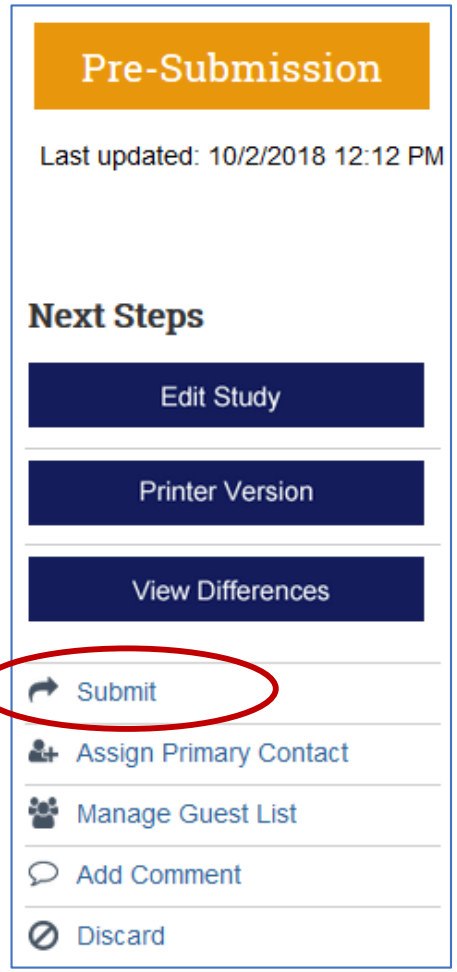
Notes on Ancillary Reviews

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)

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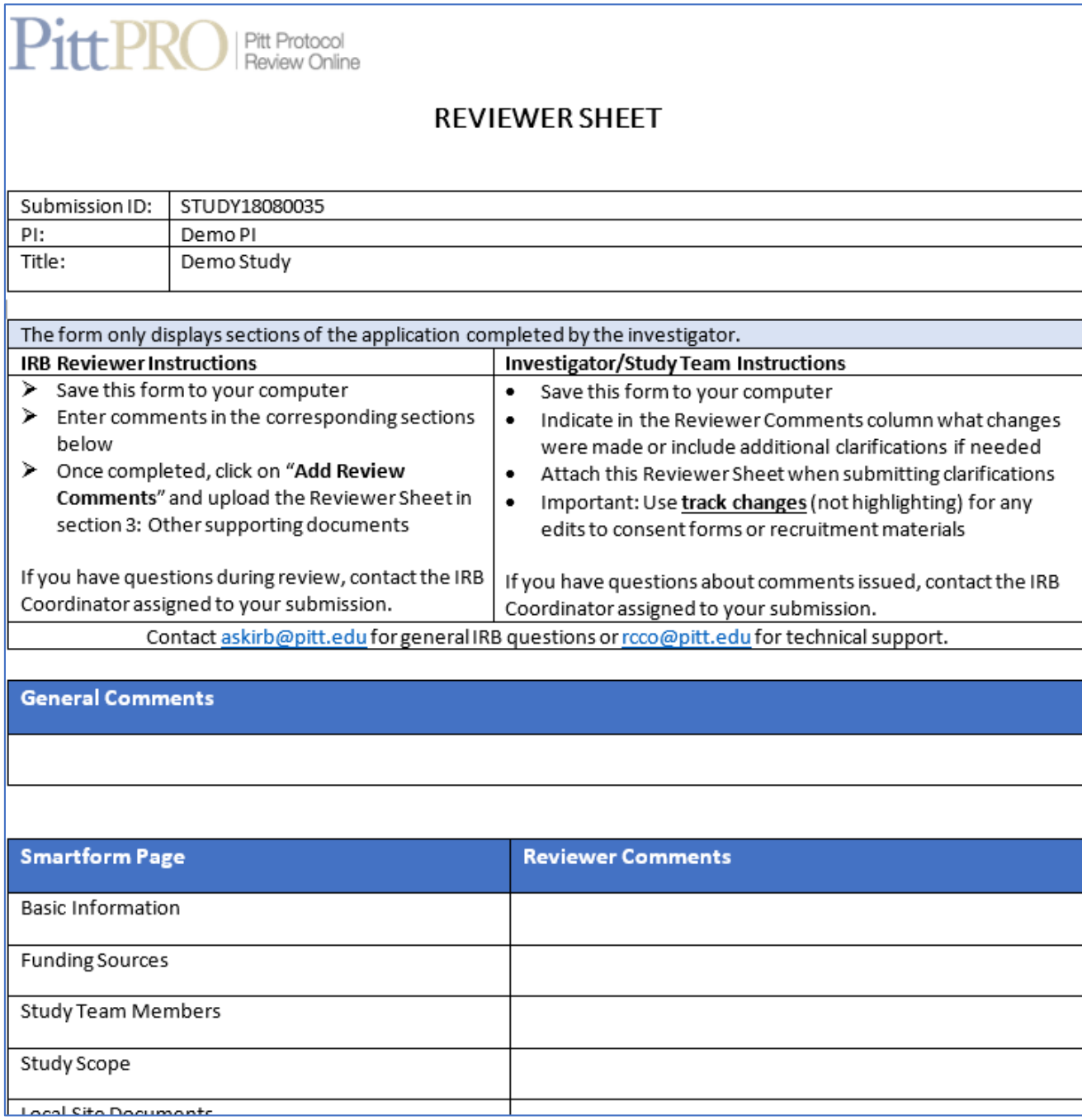
Responding to Comments

- 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



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REVIEWER SHEET

Submission ID:	STUDY18080035
PI:	Demo PI
Title:	Demo Study

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

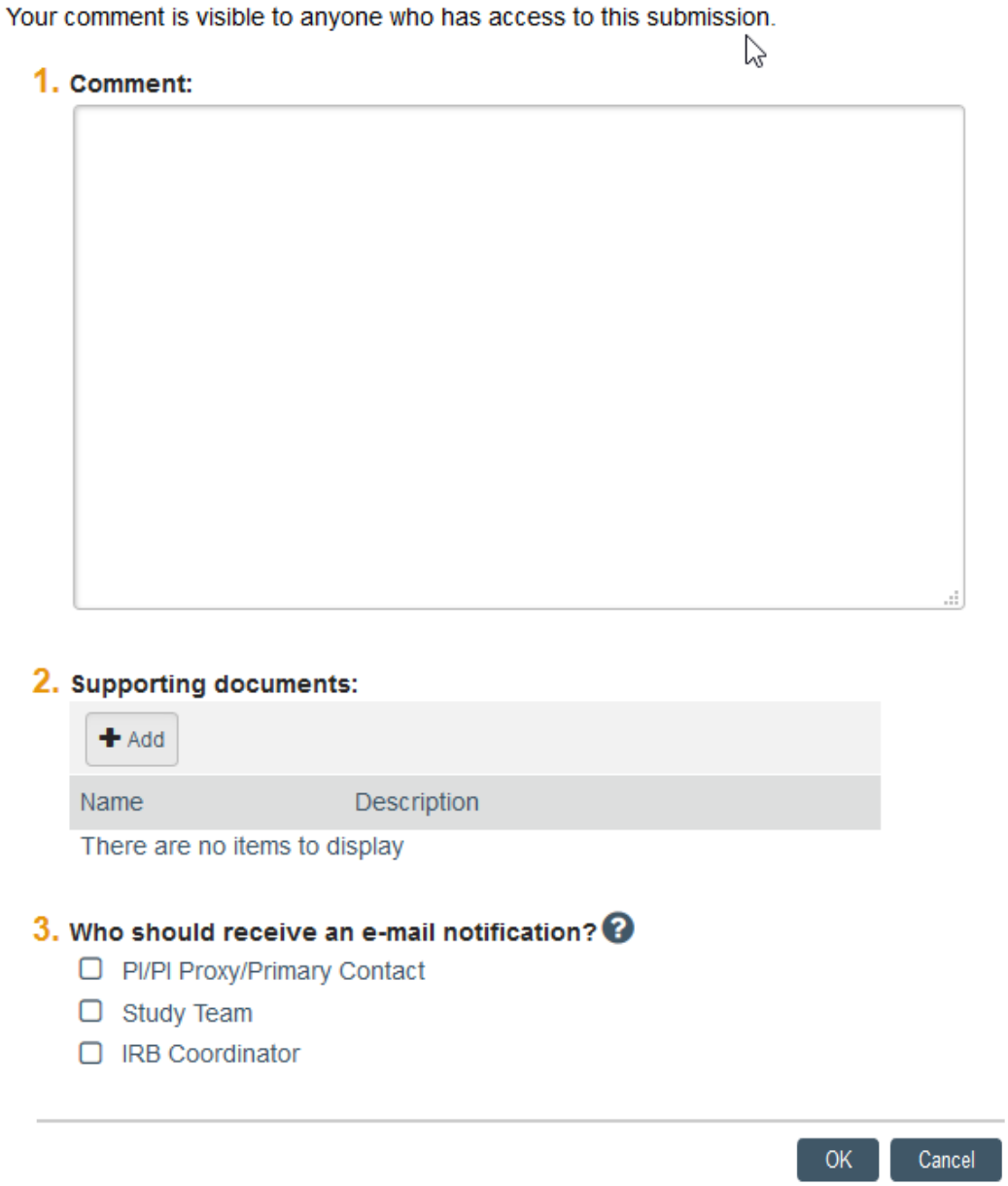
IRB Reviewer Instructions	Investigator/Study Team Instructions
➢ Save this form to your computer ➢ Enter comments in the corresponding sections below ➢ Once completed, click on "**Add Review Comments**" and upload the Reviewer Sheet in section 3: Other supporting documents If you have questions during review, contact the IRB Coordinator assigned to your submission.	• 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 about comments issued, contact the IRB Coordinator assigned to your submission.

Contact askirb@pitt.edu for general IRB questions or rcco@pitt.edu for technical support.

General Comments

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

Adding Comments



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

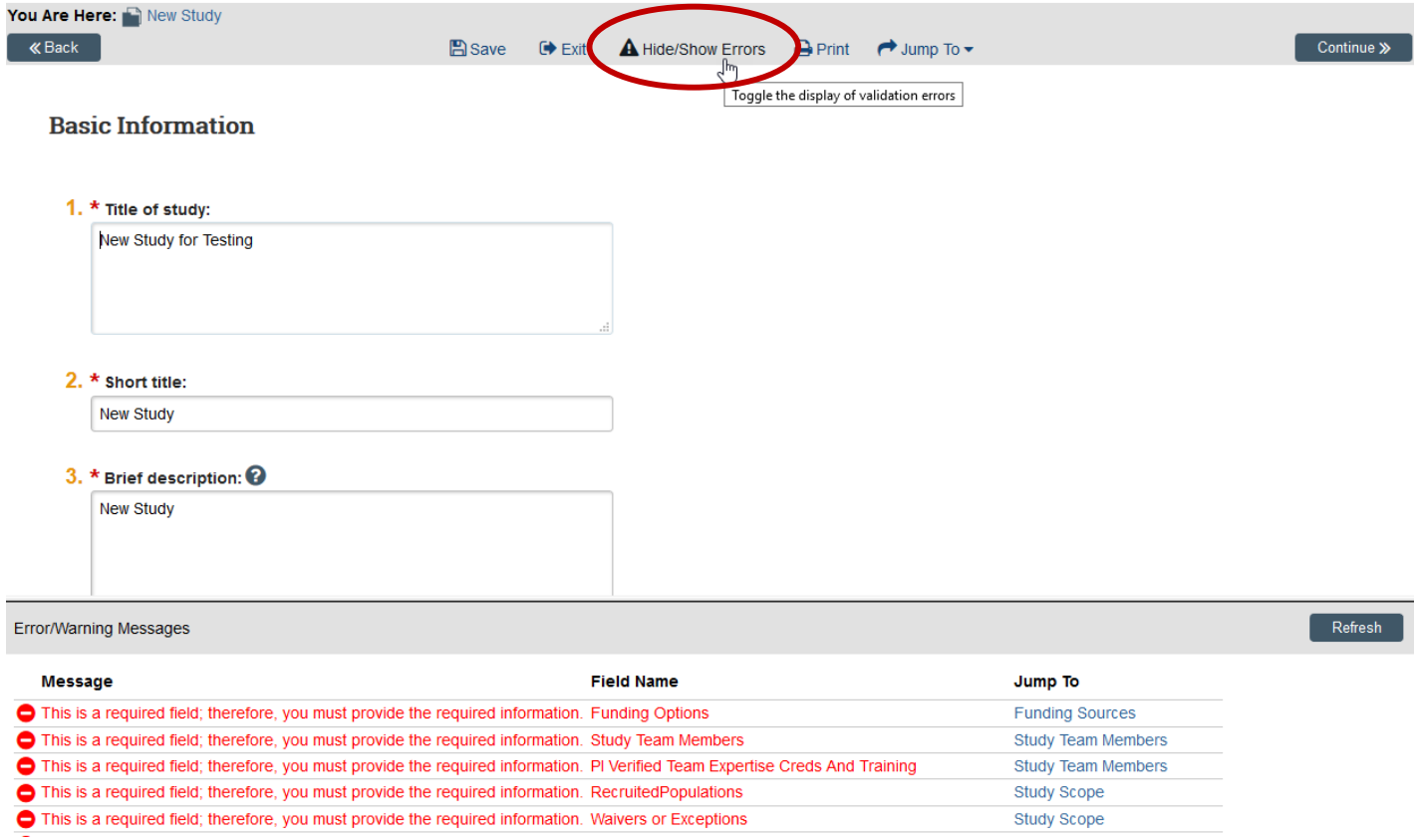
Hide/Show Errors

- 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



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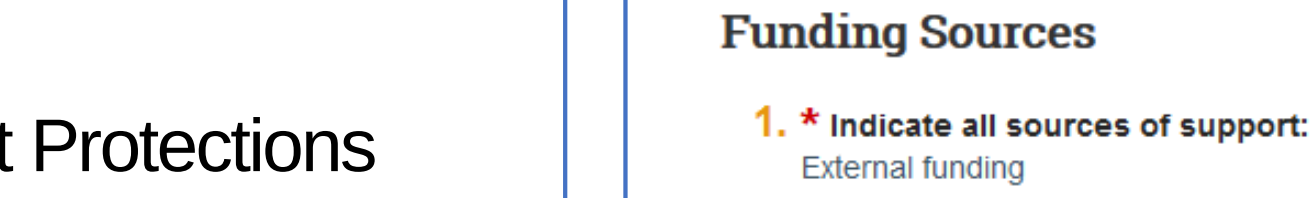
Training Records

Required Courses for all

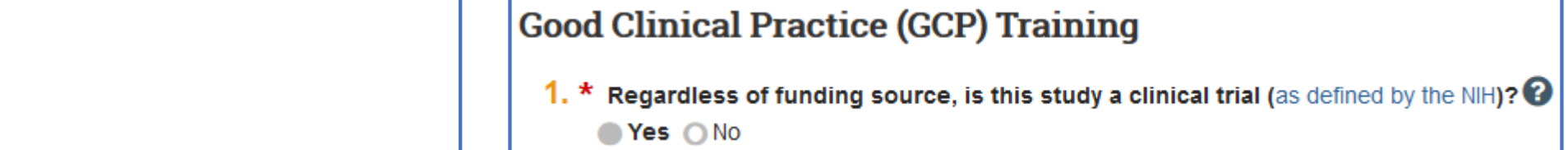
- Responsible Conduct of Research
- Human Subject Protections
  - Biomedical or
  - Social and Behavioral

Required based on selection

- Conflict of Interest



- Good Clinical Practice (GCP)



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

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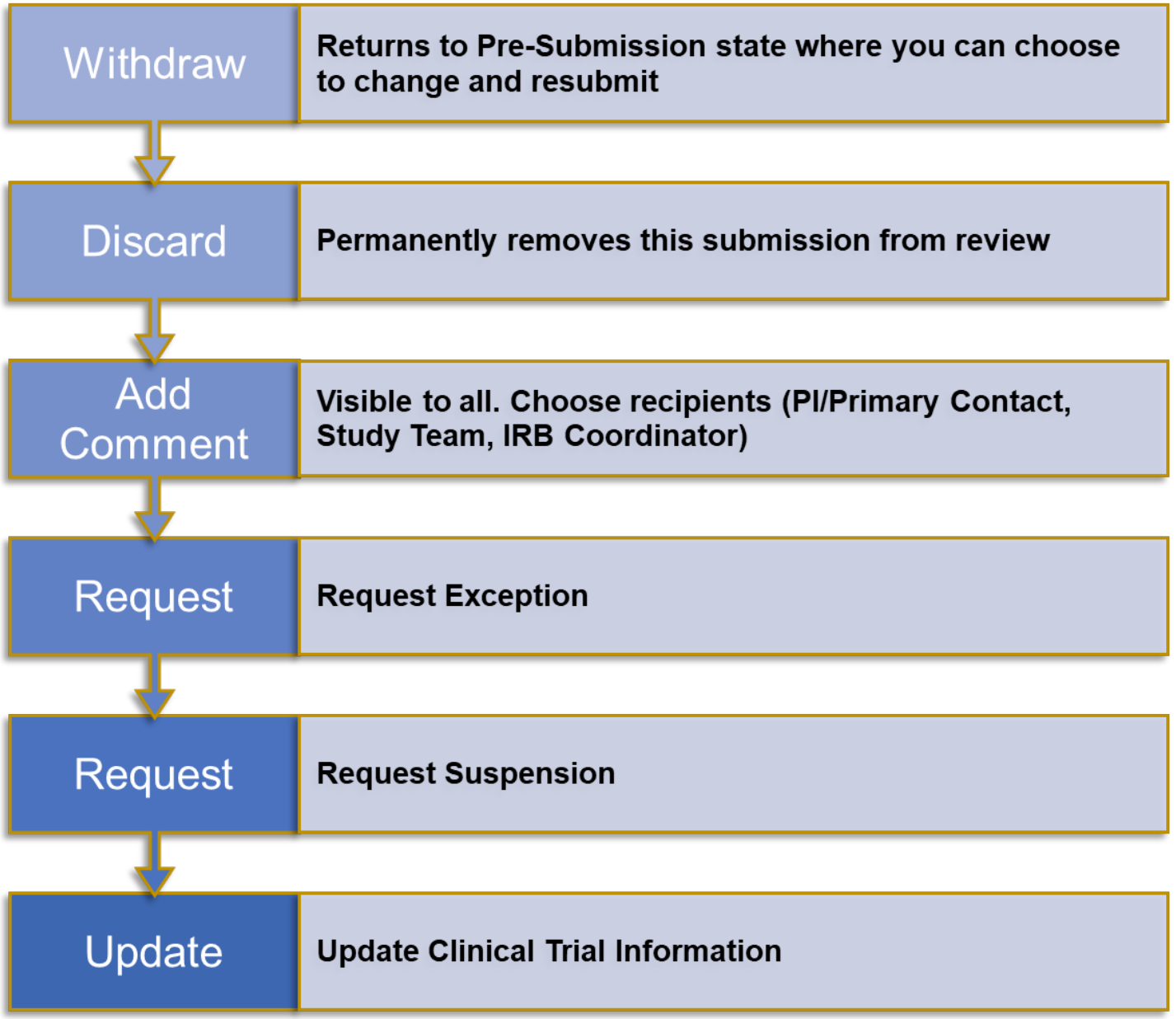
Other Activities



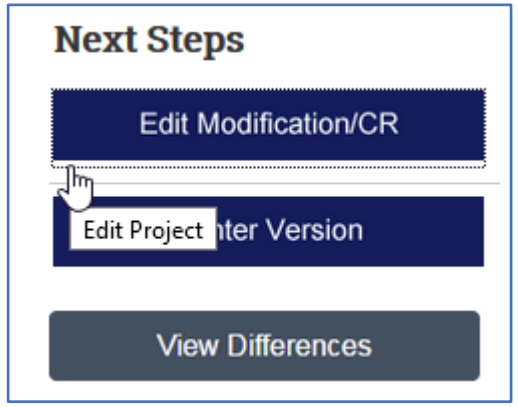
Approved Documents

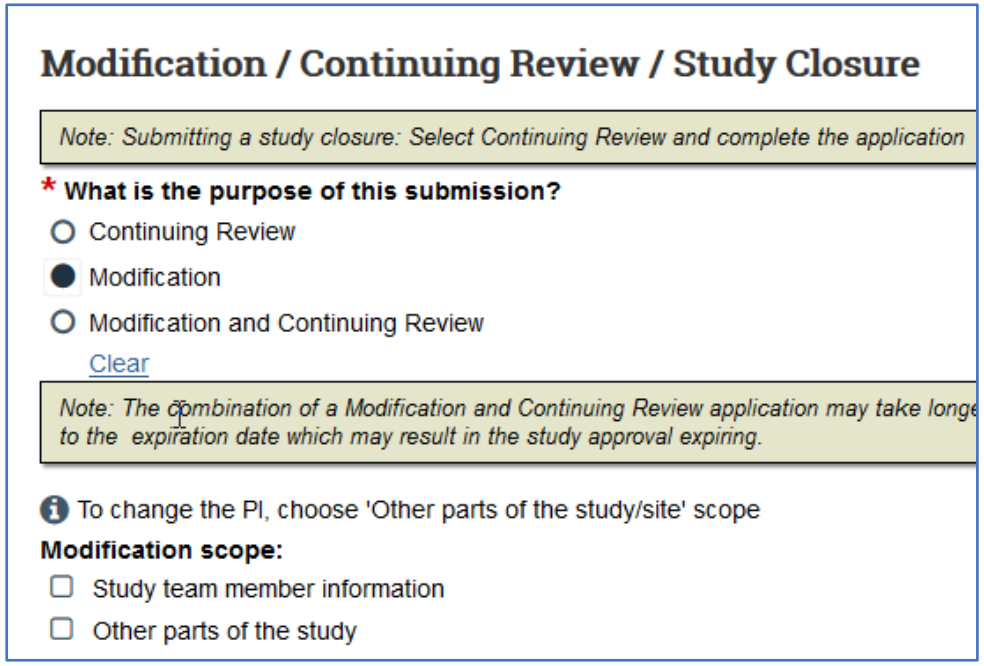
History | Funding | Contacts | Documents | Follow-on Submissions | Reviews | Training | ...

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





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!

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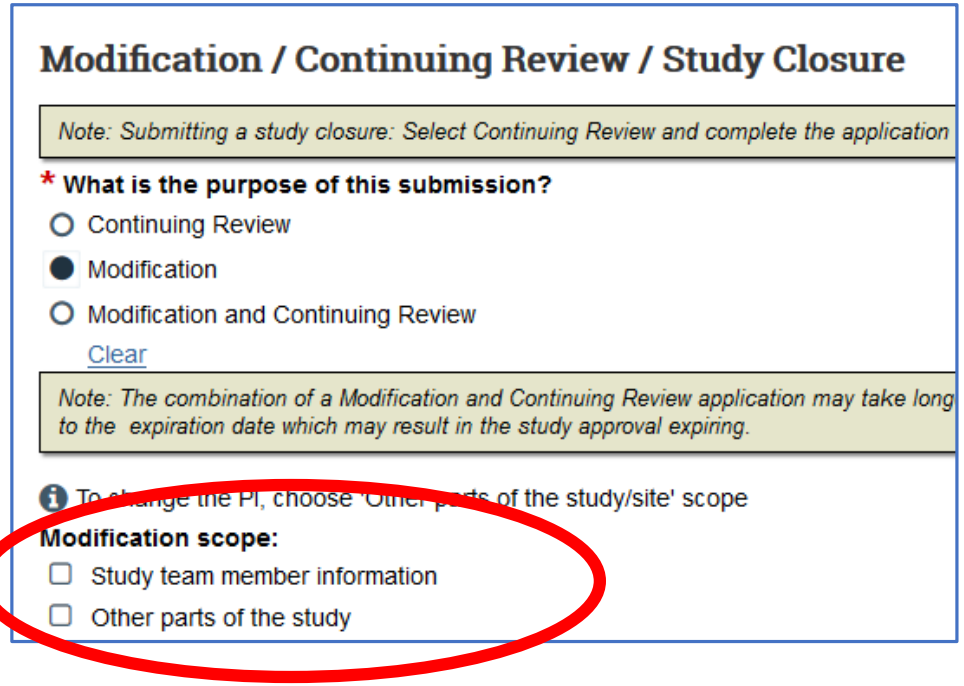
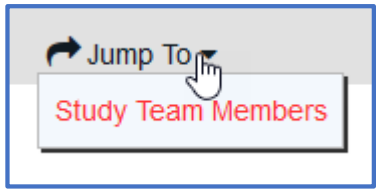
Modification Scope Selections



1st option



2nd option

Both options

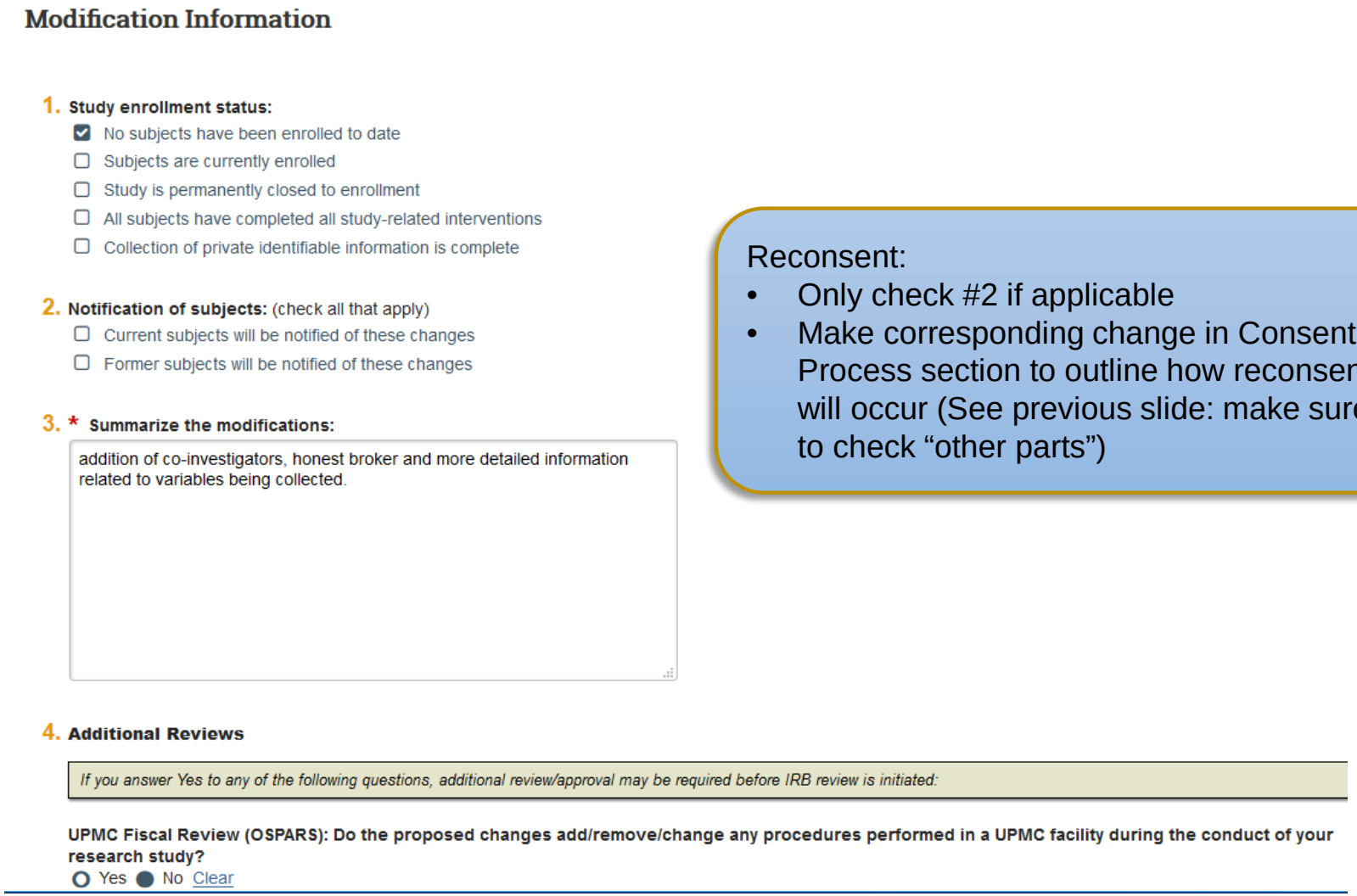
Choose option carefully!

- 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



Modification Information

1. **Study enrollment status:**
   - [x] 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”)

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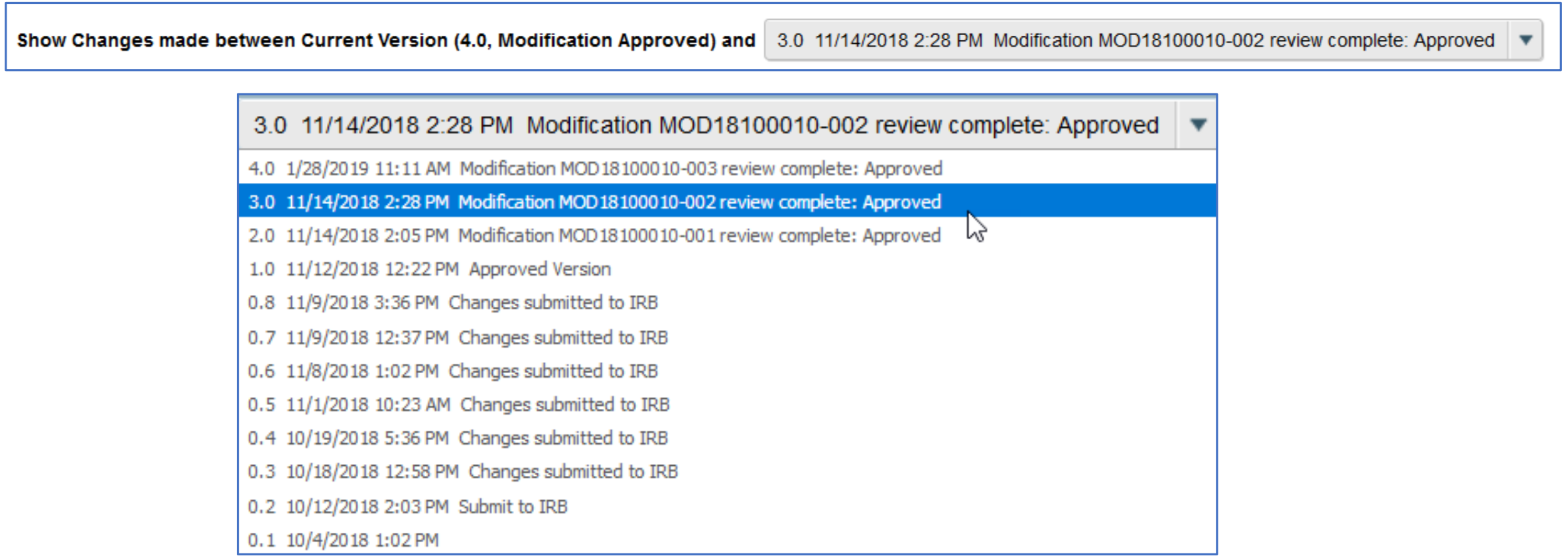
View Differences for Modifications

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



Examples of View Differences

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

- [x] 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

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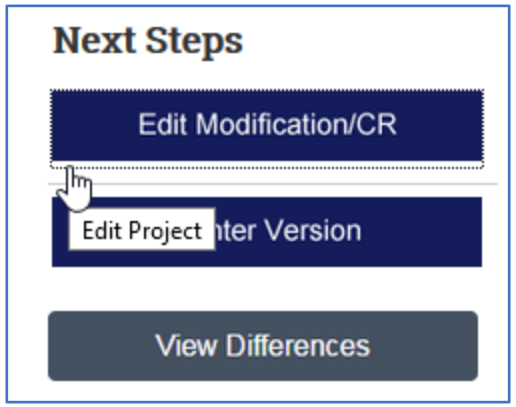
Create a Continuing Review or Study Closure – Go to Approved Study Workspace



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1. * **Specify enrollment totals:**

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:		
Study-wide:		

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.

Refer to the Study Status Guidance for Research Milestone details

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)

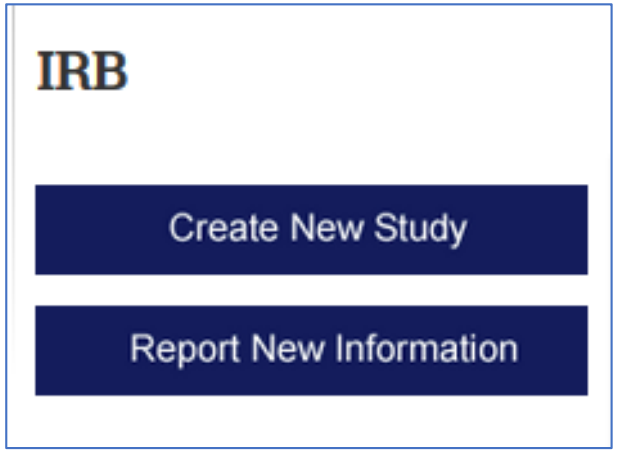
- [ ] NO subjects experienced unexpected harm
- [ ] Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- [ ] NO subjects withdrew from the study
- [ ] NO unanticipated problems involving risks to subjects or others
- [ ] NO complaints about the study
- [ ] 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

Be sure to attach supporting documents for any box left unchecked

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

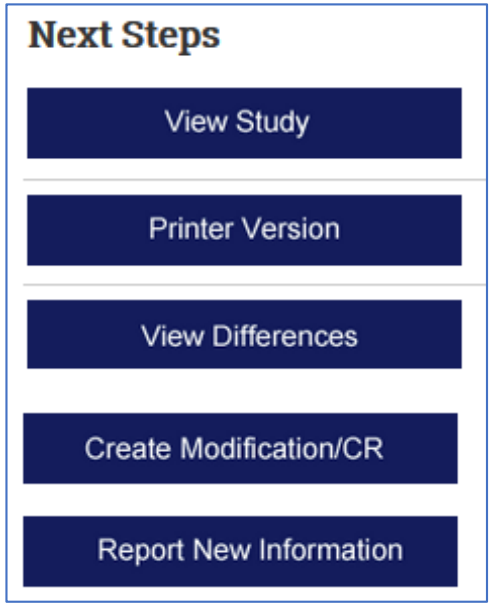
New Reportable Information (RNI)

Personal Folder



Can be created from either place

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

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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

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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

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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

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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

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Call us early and often

412-383-1480
Main IRB number

askirb@pitt.edu
General IRB questions

Irb.reliance@pitt.edu
Central IRB questions (aka sIRB)

orp@pitt.edu
Technical Issues

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