OSIRIS Guidance

OSIRIS is the IRB web-based application that was created to improve human subject protections and enable the IRB to better serve the research community. This application has a question and answer format using smart forms. Based on your response, the system may branch to additional questions related to main question.

OSIRIS presents the investigator the unique opportunity to submit one application for the entire review process. All required Pre-IRB reviews will be initiated based on your response to specific questions. Once the Pre-IRB reviews are approved, OSIRIS will forward your application for IRB review.

Based on your responses to the questions, other departments or committees will be granted access to your application and automated email notifications are generated (e.g., UPMC Fiscal, Investigational Drug Service). Therefore it is important to take the time to ensure you have answered the questions correctly. The email notifications are only sent during the initial submission process or if the project was withdrawn and resubmitted.

Only the names of those individuals who have completed the required CITI training courses will be selectable in OSIRIS. This applies to all users of OSIRIS (e.g., investigators, coordinators, scientific approvers, committee members, non-Pitt investigators).

Important: All users must complete the CITI training using the Pitt CITI Access Portal available at www.citi.pitt.edu.

This document is designed to provide you with the basic tools to build and submit your projects for review. Additional information is available from the IRB website (www.irb.pitt.edu).

E-mail us at irb@pitt.edu if you need OSIRIS assistance at any time and be sure to include your IRB number in the message. Contact Patty Orndoff, IRB Education Coordinator, to schedule training or if you need assistance building your application.

The entire IRB staff is available to assist you as needed and please do not hesitate to contact us. All contact information is available from the IRB website or just email your questions to askirb@pitt.edu.

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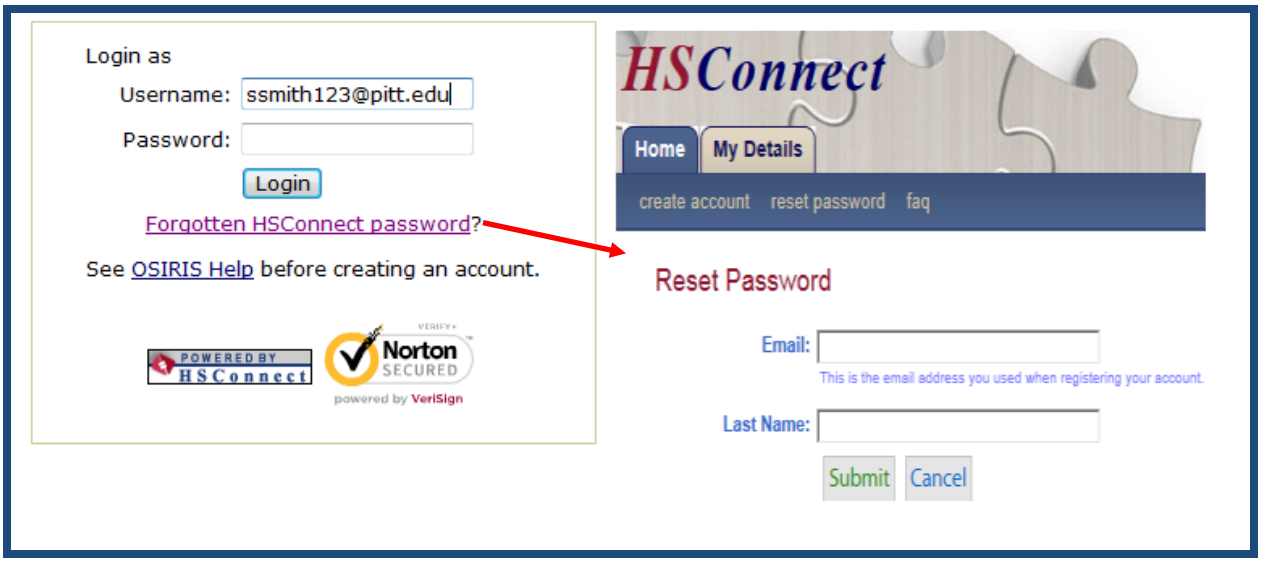
Required Research Training

All students, faculty and staff must complete specific training that may vary depending on your discipline and research activities. University of Pittsburgh training draws on resources provided by the Collaborative Institutional Training Institute (CITI), as well as by University of Pittsburgh Internet-based Studies in Education & Research (ISER).

- General training requirements: http://www.rcco.pitt.edu/ResearchTrainingRequirements.htm
- Always access CITI using the **Pitt CITI Access Portal**: http://www.citi.pitt.edu
- User will not be able to access OSIRIS until the required training has been completed. It will take approximately 24-48 hours after completion of the courses before access to OSIRIS is possible.
- This applies to University of Pittsburgh faculty, staff, or students and external investigators
  - It is highly recommended that all new users review the instruction sheet posted on the Pitt CITI Access Portal before initiating the process.
    - There is a procedure for linking existing CITI accounts but it only available the first time one enters the Pitt CITI Access Portal.

Login

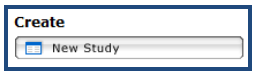
- Go to https://www.osiris.pitt.edu
- Click on Login located in top right corner of the page
- Enter **Username** (entire email address) and **Password** as registered with HSConnect
- If you have **Forgotten your password**
  - Click on link available from the login page and HSConnect will email your username and password directly to your email address
  - Go back to https://www.osiris.pitt.edu and click Login again



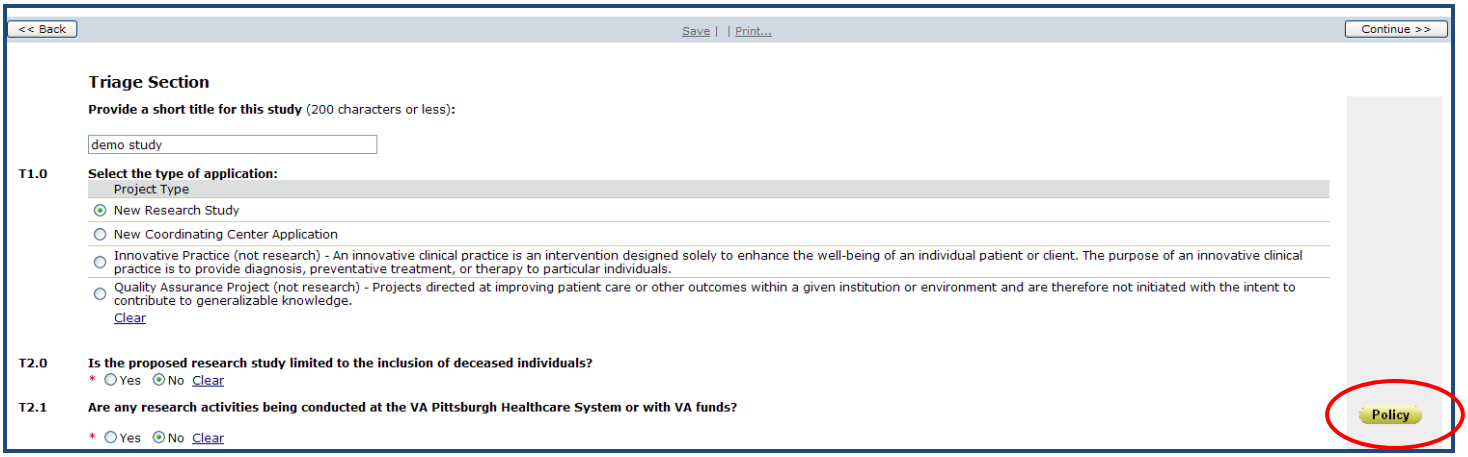
Create a New Study

The following information will guide you through the process of submitting a new study. If you need assistance at anytime, use the Help link available on each page or email us at irb@pitt.edu. Below is an overview of the submission process:

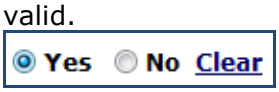
1. Pathway for creating a study by answering a series of branching questions
2. Instructions for uploading documents
3. Preparation of paper items for scanning
4. Special preparation of the consent forms
5. Responding to reviewer comments

- From your homepage which displays 'Folder for (your name)'
  - Click on New Study 

which is displayed on the left hand side of page
- There are three main sections in the New Study application
  - **Triage**
    - Type in a short title for display purposes as you will enter the long title later
    - Select the project review type and anticipated risk
  - **Cover Sheet**
    - Demographic information, selection of Pre-IRB review, and study site details
  - **Protocol**
    - Includes aims/objectives, study population, detailed information on all research activities, support and potential conflict of interest issues



- **HELP Text**
  - Gray area on the right side of the page may display a button (Policy, Resource, Guidance)
    - Click on the button to obtain additional information to assist you in answering the question
- If you change a response to a question that branches, remember to '**clear**' all of your responses to the branched questions before continuing (may include removing information typed into text boxes). OSIRIS holds all the responses so it is very important to clear those which are no longer valid.

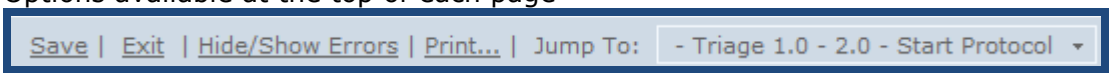


Basic Tips

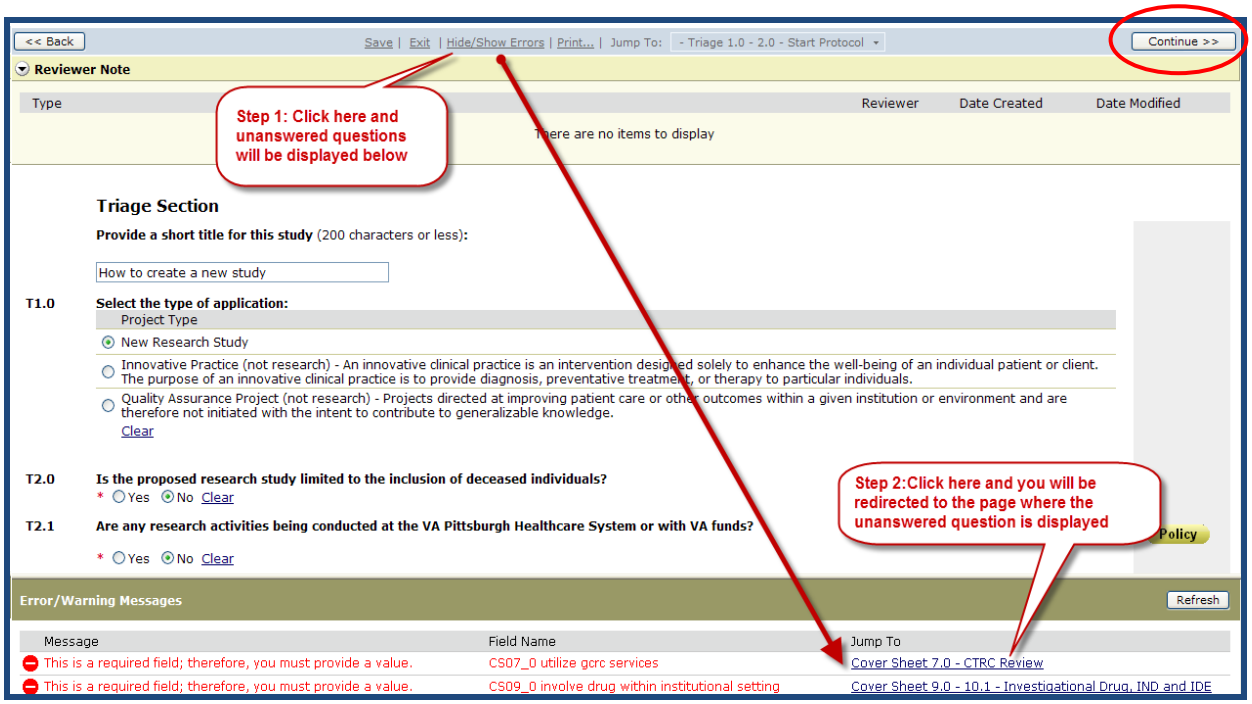
- **Continue button**
  - Saves your response as you proceed through the application
  - Located at the top and bottom section of every page

- **Red asterisk ***
  - Indicates a required response
  - If you fail to complete a question that was required, the following message will appear: "Could not update the study due to one or more errors: there were problems submitting this form…"

- Options available at the top of each page



  - **Save**
    - Click the Save button before existing the application or leaving your computer area
  - **Exit**
    - Will take you back to the summary page
    - **Exit** without clicking the **Save** button, a confirmation box will appear and warn you to save your work before exiting
  - **Hide/Show Errors**
    - Identifies outstanding issues that must be addressed
    - Hyperlink to the section is displayed at the bottom of the page
    - Click Refresh and the system will remove the completed items
  - **Print**
    - Allows you to print the current page displayed
  - **Jump To:**
    - Click the down arrow to access the main question for each section (does not display all the questions due to the branching process)
    - Allows you to jump to specific sections/questions in the application
    - Use the Continue >> button when first filling out the application

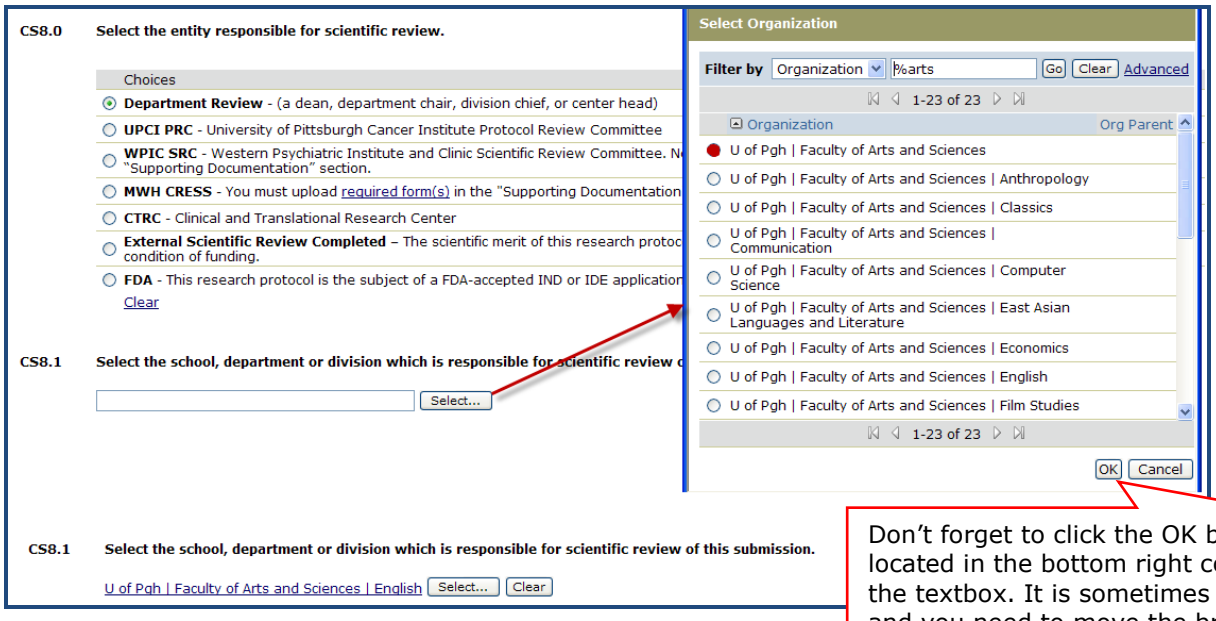


Selecting Study Team Members

- **Select Members for your research team**
  - Principal Investigator (PI)
    - Whoever creates a New Study is listed as the PI
      - If you are not the PI, be sure to give yourself a role in the study (e.g., Co-investigator, Study Coordinator) before selecting the name of the PI
      - If you remove your name from the application, you will no longer have access to the study
  - Only the names of those individuals who have completed the required training will be selectable
  - If you are including non- Pitt faculty, staff, or student, click on their name and make sure their affiliation is listed correctly (Pitt school or department should not be listed)

Selecting the Department for Scientific Review

- **Scientific Review**
  - If Department Review is requested, select the appropriate entity from the list
    - Each department has assigned individuals who are responsible for managing the scientific review process. You cannot designate an individual to conduct the review. The names are already programmed in OSIRIS and email notifications are sent to these specific individuals.
  - Use the % sign (wild card) in the 'Filter by' field to limit typing the entire name
  - If you selected the incorrect scientific reviewer option and have already submitted the application [do the following]:
    - Withdraw your study (you will not lose any of your work)
    - PI can then go to the **Withdrawn study workspace** and click on the **Resubmit** button found under My Activities. The study is placed back into the **Pre Submission** state and can be edited.
      - Go to question CS8.0 or 8.1 and select the correct department
      - An email notification will then be send to the scientific reviewer
  - **Important**: Failure to Withdraw and Resubmit the study will result in delays as the new scientific reviewer will not receive an email notification from OSIRIS - It becomes your responsibility



Don't forget to click the OK button located in the bottom right corner of the textbox. It is sometimes hidden and you need to move the browser bar down to display the button.

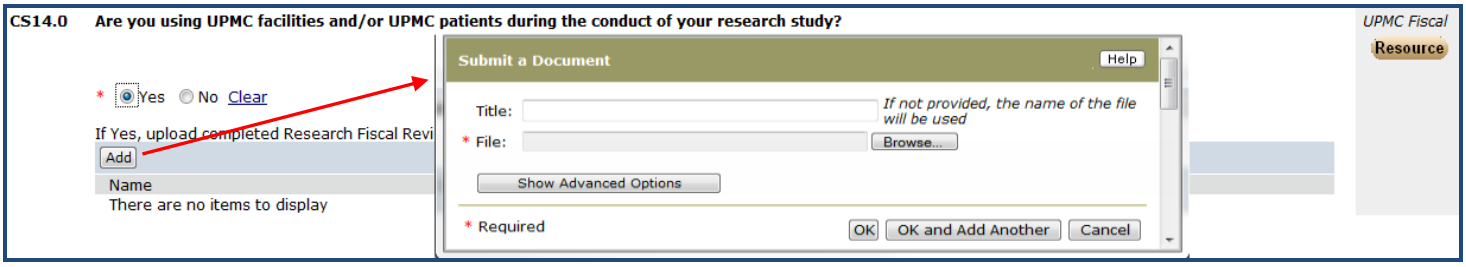
Upload a document

All attachments will need to be submitted electronically for review. If the document is available in an electronic format the following instructions will guide you through the process. If only a paper copy of the required documentation is available, you will need to scan the document and then follow the instructions for uploading a document. We will start with an overview for uploading documents and then a section on scanning documents:

- Click on the **Add** button and another window will pop-up known as a browser window
- Name the document and click browse to identify the current source of document
- Click OK and the document will automatically be placed in the specified section

- Click on the **Add** button as shown below
  - A new **Browser window** will open
  - **Title**: add the title of the document (suggest including a date or version# in the title)
  - **File**: click on Browse... and select the document on your computer
  - Click **OK** to add the document to your OSIRIS submission
  - Note the Resource button in the on the right side of page (link to UPMC forms)-This is an example of the HELP guidance.

Note: Always click on the uploaded document to ensure it opens properly before proceeding. If the reviewer is unable to view the document, it may result in a needless delay as changes will be requested to upload the document properly.



Managing your documents

- It is important that all documents are ***uploaded into the appropriate sections***. They may not be reviewed if they are "dumped" into the last section of the application, Supporting Documentation.

- Do not 'Add' documents when you are uploading a revision of an existing OSIRIS document. It becomes difficult for the reviewers and members of your research team to determine which version is current.
  - Use the **'Add'** button for **new documents** not currently displayed in OSIRIS - Add
  - Use the **'Upload Revision'** for **newer versions of existing documents** - Upload Revision

Scan a document

Paper copies of required documentation such as sponsor protocols, investigator brochures, and correspondence must be scanned or converted to electronic copies. It is preferred that the documents be scanned using an Adobe Acrobat PDF format but OSIRIS will accept MS Word or HTML format. Please scan in a resolution no greater than 300dpi to comply with the OSIRIS file size limits. Scanning at a greater resolution will result in unnecessary disk space usage.

Upload consent form

It is important that you **always start with a clean document** and do not edit an existing form. There are often hidden formatting problems which will prevent the IRB from approving in a timely manner. All consent forms in a WORD format require the IRB footer so the document can be watermarked (insert the dates and IRB #).

- Template is available on question 4.9
- You can use the template or copy and paste the footer to your form

It is very important that you manage your consent versions appropriately. Do not display multiple versions of the same consent form. If you are using only one consent form for your study, then only one should be displayed. It is recommended that you use highlighting to document your changes but it is also possible to use track changes.

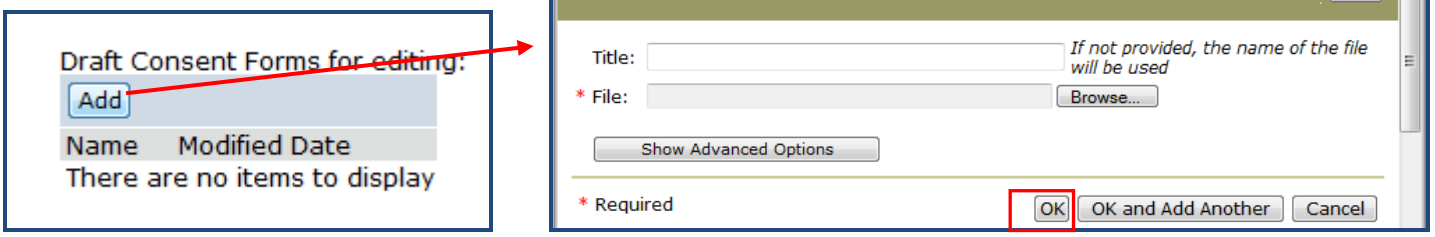
- Add for a brand new consent form
- Upload Revision to revise an existing consent form

Once you upload a consent form into OSIRIS, always go to OSIRIS to edit the document. Do not use forms saved on your computer as this may result in the wrong version being changed. This applies to all documents uploaded into OSIRIS.

- In order to open a document in OSIRIS and edit, you must first **save the document to your computer**. Then open the saved document to edit.
- If you wish to edit an 'approved consent form' already displayed in OSIRIS, you must download the '**Draft Consent Form'** from question 4.9.
  - When a study is approved, OSIRIS makes a copy of that document which is displayed as a 'Draft Consent Form'
  - Approved consent forms are locked and not editable

If you are being creative and using a new consent process or format (e.g., PDF brochure, electronic process), please contact us at irb@pitt.edu and we will be happy to assist you.

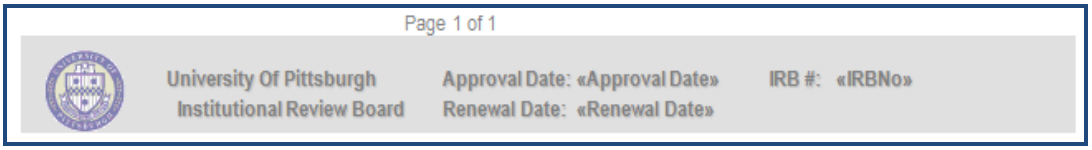
- Go to Section 4, question 4.9
  - Add a **new consent form**
    - A new Browser window will open
    - Title: add the title of the document
    - File: click on Browse... and select the document on your computer
    - Click **OK** to add the document to your OSIRIS submission



- Revise an **existing consent form**
  - Draft Consent Forms for editing: click on the **Name and save** to your computer
  - Open the consent form saved to your computer, make the edits, and save
  - Click on Upload Revision
  - A new Browser window will open
  - Title: Revise the existing title
  - File: click on Browse... and select the revised consent form from your computer
  - Click **OK** to add the document to your OSIRIS submission

Note: You cannot open a document from OSIRIS and edit. You must first save the document to your computer and then edit the saved item.

- **Preparation of the consent forms**
  - Use the consent form template or insert the **required footer** to your form
    - 9 Font for shaded section of the footer
  - If the IRB # or dates are displayed, then you did not use the required Draft Consent Form for editing

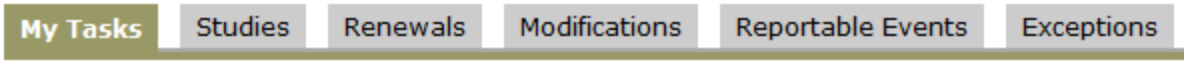


Return to Your Study

OSIRIS allows you to edit your study at anytime prior to the PI clicking on the submit button. Once the study is submitted for review, changes can occur only if requests are made by the reviewers. The system permits any listed member of the research team to edit the study. This section will demonstrate how to identify the study you wish to edit, identify which sections are not completed (View Smart Form Progress) and submit the study for review.

- **Login**
  - Opens to your personal folder also known as **My Home**
  - Always go to **My Home** if you get lost in the system
    - Link to **My Home** is located in top right-hand corner of the page
- **My Tasks**
  - **All projects will stay in Pre Submission state until the PI clicks on the submit button**

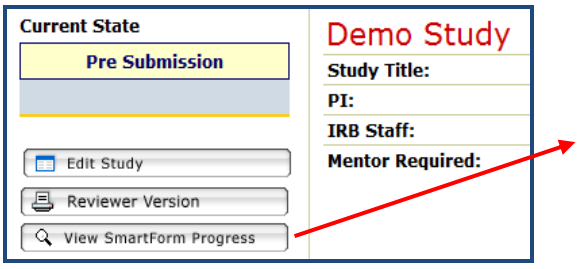
- **Studies** tab displays all studies you are associated with in any state
  - Click on the name of the study which will take you to that project workspace
  - Same process for Renewals, Modifications, Reportable Events, Exceptions

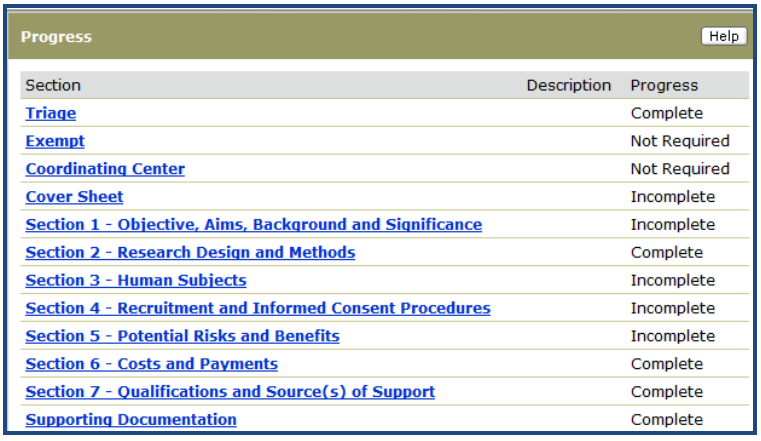


- **Edit Study**
  - Use this view to make changes to the IRB application

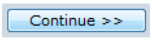
- **Reviewer Version**
  - Provides a display of all the questions and responses without the Help links

- **View Smart form Progress**
  - Identifies which sections are incomplete

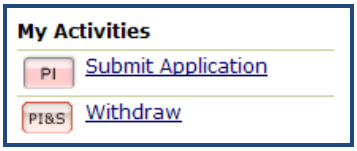




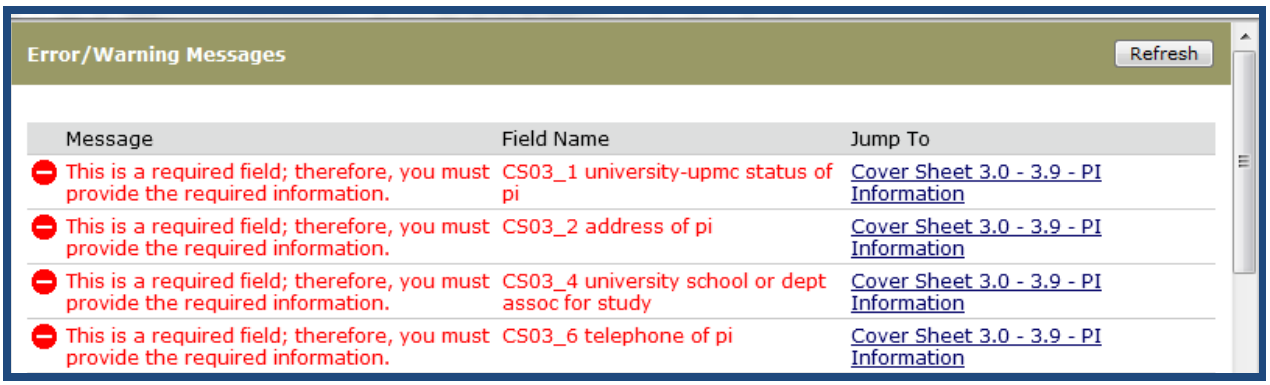
Submit your study

- Click on **Finish**
  - The  button is replaced with a finish button when you reach the end of the questions
  - You can click Finish once you reach the end of the smart forms
  - Any member of the research team may click on Finish
  - This **does not submit the project** for review

- Click on **Submit Application**
  - **Only the Principal Investigator has access to the Submit Application button**
  - Located only in the PI's folder as an option on the study under **My Activities**



  - When the PI clicks **Submit Application**, the system will automatically check to make sure all the required questions have been addressed
  - If the system identifies incomplete sections within the smart forms, a window will pop up listing all the incomplete areas. The top of the page is labeled "**Errors.**" Click on the 1st error and proceed thru the list of required questions to be addressed. You can click either **Continue** to save any changes to the page or click **Save** before proceeding to the next page.
  - As you complete each page, click **Refresh** on the ERROR page to have the system recheck and remove the completed items from the list.



- **Submit and no errors reported**
  - Click OK
  - Once the study is submitted for review, it is now locked down and no further changes are permitted unless changes are requested by a reviewer.

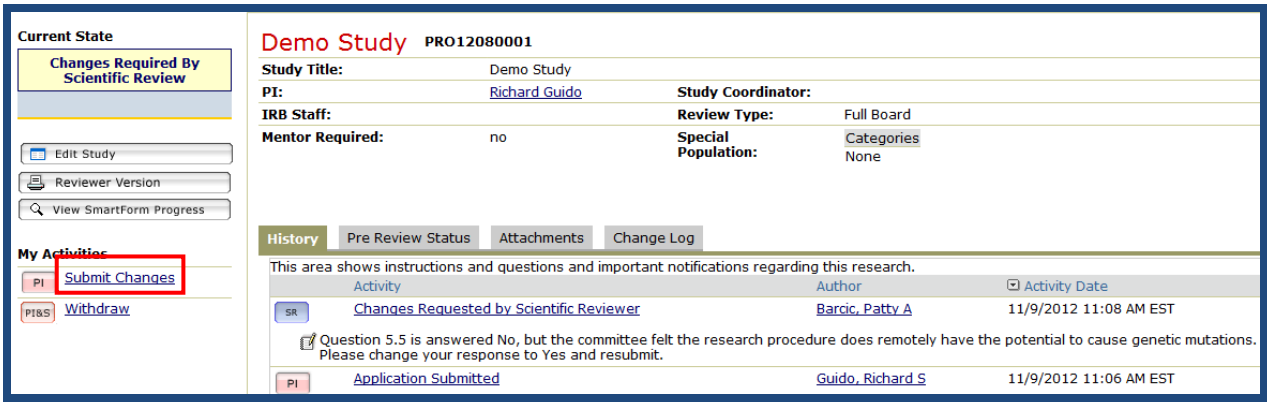
Respond to comments from non-IRB reviewer

You have submitted your study for review and have received an email notification that changes are requested. As stated previously, once you submit the study for review it is locked down and no further changes are permitted. The reviewer must request changes within the application to unlock it for editing. If they send you an email to make the changes but fail to request changes in OSIRIS, the application will be locked and you cannot edit the application.

- When a reviewer requests changes, OSIRIS unlocks the study and editing is permitted. OSIRIS will track every change made in the application(person, date, and time will be recorded)
- The first step is to login to OSIRIS and go to **My Tasks**. This section contains all the requests for changes or clarifications from Pre-IRB reviewers to IRB review. This is your to-do list which requires your attention. Remember to make the requested changes within the IRB application or any uploaded documents if required. Responses to the reviewer comments are not archived so remember to always edit the IRB application first before responding to the actual comment.
- There is a difference in the process for comments from the IRB versus other review entities within OSIRIS (e.g., scientific review, radiation safety).

- **Login**
  - Click on My Tasks
    - Search for the study which requires a response to comments
    - **Click on the Name** of the study you wish to review
  - PI and Primary Research Coordinator are notified by email that comments need addressed
    - The notifications display a hyperlink which will redirect to the study workspace

- Click on Edit Study and revise the application
- Once completed, the PI can click on PI Submit Changes to send it back to the reviewer



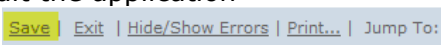
Respond to comments from IRB reviewer

The IRB may request a clarification response and/or direct edits to the application.

If no changes are required within the application:

- You can respond by going to the Reviewer's Notes and use the 'Click here to respond' link.

If changes are required within the application, it is a two-step process to respond:

- Step 1: Go to the page and edit the application
  - Be sure to click 'Save' 

before exiting the page
- Step 2: Let the reviewer know you made the requested change
  - Click 

to document the change was made
  - **Important**: This documentation does not stay with the application so make sure you edit your application if you wish to document your response

There are two ways to view the IRB reviewer comments:

- 1st way: Go to the study workspace, click on 

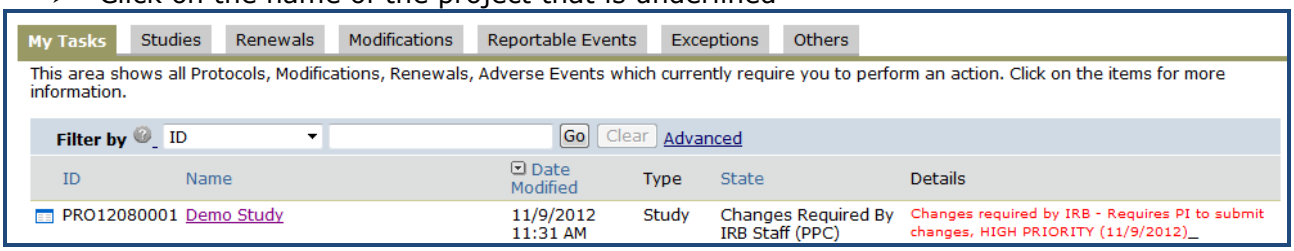
to view the comments
- 2nd way: Go to the study workspace, click on 

and then use the 

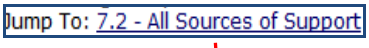
button to move through the comments

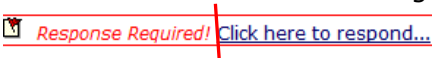
- All projects requiring your response will be displayed in 

in your personal folder
- Click on the name of the project that is underlined



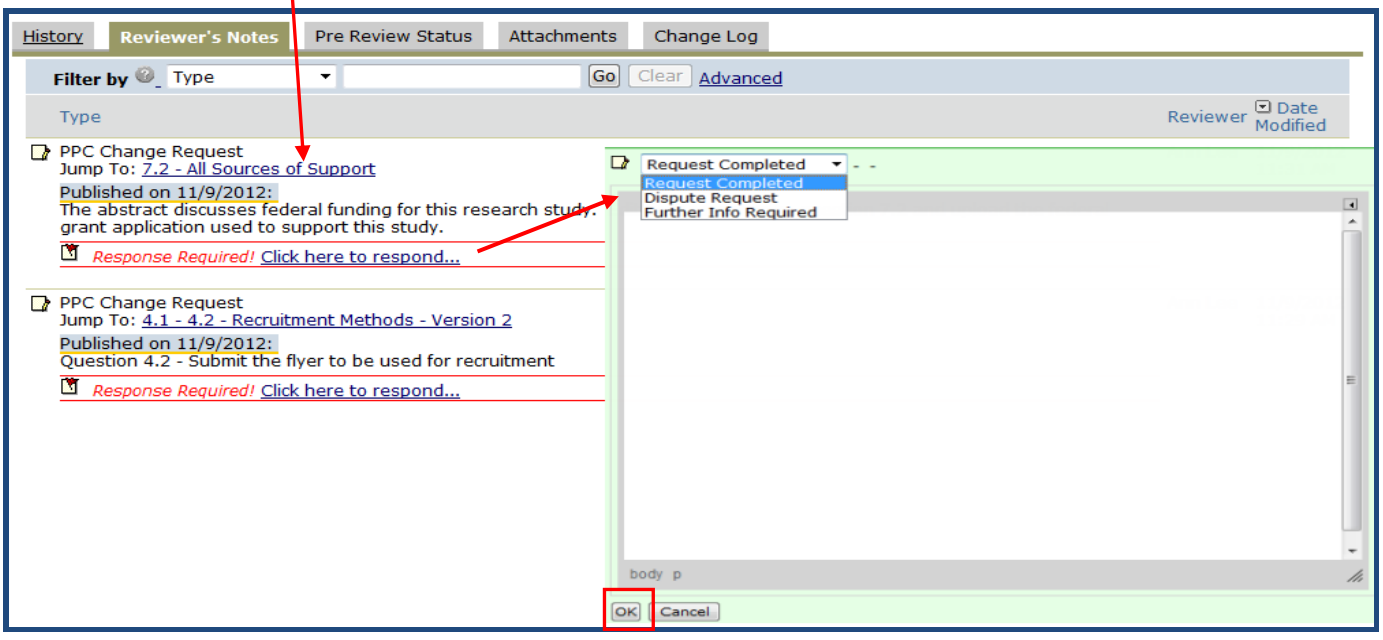
- Click 

to view all the comments
- Click 

to go the page to edit the application and **don't forget to save**
- Click 

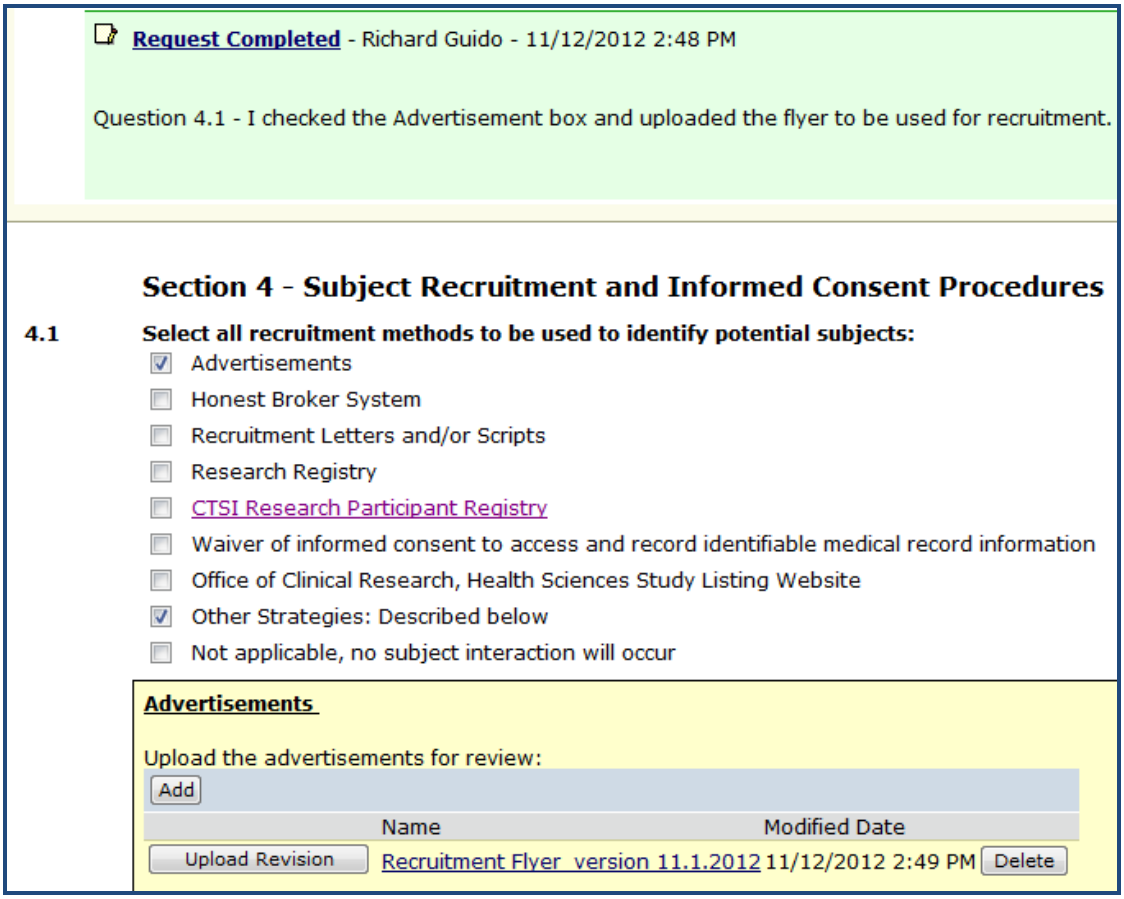
to select your response and click on 

to save



Alternate process: Click Edit Study and then click Next to reach the reviewer notes. Many find this a much easier process but it is still a 2-step response: edit the application and then select an option as noted above

- Below is an example of a page view where the investigator uploaded the flyer as requested and documented the response. Any study team member can respond and make changes, but only the PI can submit the changes.

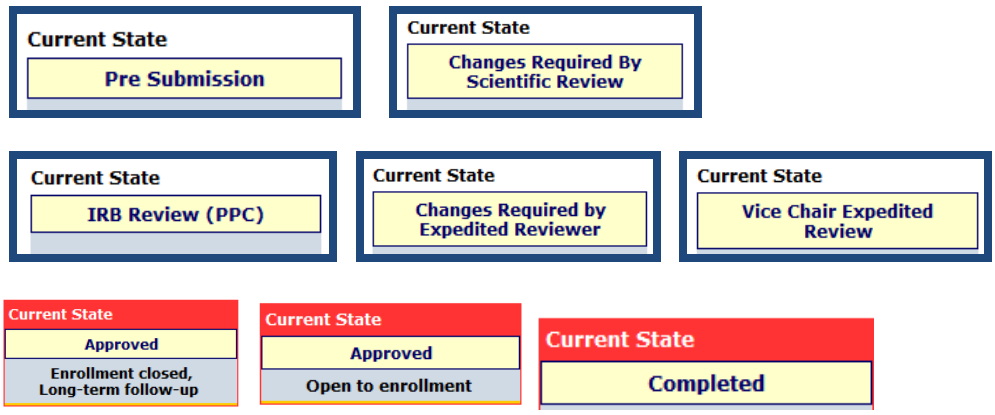


Current State

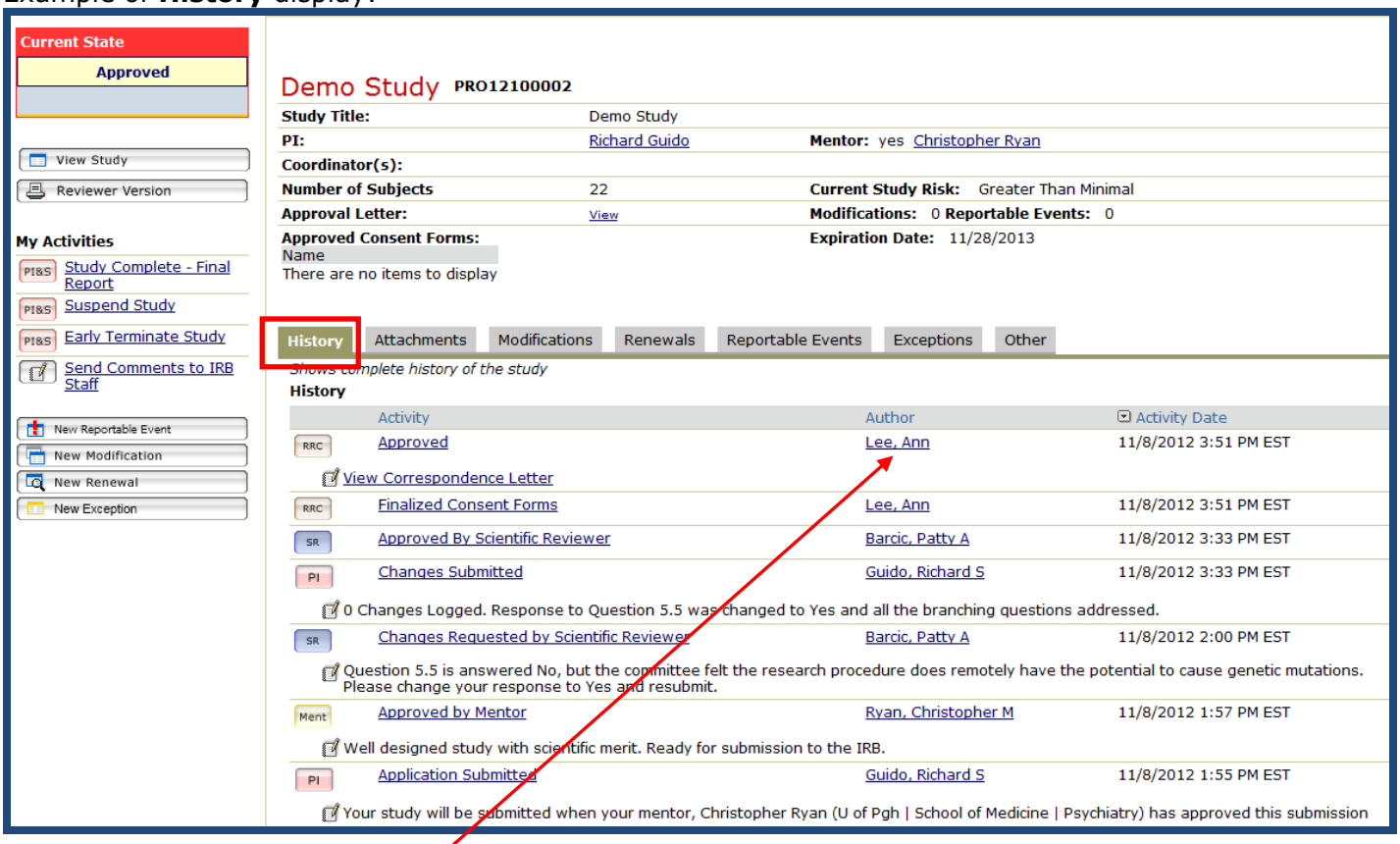
You can easily identify the current state of your study.

- **Current State** - displayed on the top left corner of each project summary page
  - Once a study has been Renewed, the field also displays the current status of enrollment
- **History tab** – provides a running list of all activities performed
  - Can easily identify the person requesting changes or clarifications
    - Provides the name, link for contact information, date/time activity performed

Examples of Current Study States:



Example of **History** display:



Note: Click on the Author's name to obtain contact information

Email Notifications

OSIRIS sends email notifications to specific persons/offices based on your response to questions.

Approvals may be needed from the following before IRB review will commence:

- Scientific review
- Radioactive Drug Research Committee (RDRC)
- Conflict of Interest Committee (COI)
- Institutional Biosafety Committee (IBC)
- Office for Investigator-Sponsored IND and IDE Support (O3IS)

Offices notified but approval not required before IRB approval can be granted:

- Investigational Drug Service (IDS)
- UPMC Office of Sponsored Programs and Research Support (OSPARS)
- UPMC Mercy Religious Directives Oversight Office
- Human Stem Cell Research Oversight (hSCRO)

Email notifications are always sent to the Principal Investigator and Primary Research Coordinator. All members of the research team will receive an email notification if the study is suspended, expired or completed.

Examples of email notifications sent to the PI and Primary Research Coordinator:

- Submitted for mentor review
- In IRB review
- Assigned for committee review
- Changes requested by reviewer
- Final report accepted
- Send comments to study team

Important Reminder: The IRB utilizes the information provided through HSConnect in order to communicate with research teams. It is important to remember to update your profile if it changes or at a minimum, annually. All changes must be made on the HSConnect site (www.hsconnect.pitt.edu). No changes can be made within the OSIRIS system.

Create a Modification

If you wish to make any changes once your study is approved, you will need to create a **New Modification**. The modification process produces a copy of the currently approved study. There are (2) types of modifications available. Please choose carefully.

1. Create a **Mod Lite** if the reason for the modification is '***change a member of the study team***' (except for the PI). This process does not copy the entire study but only specific questions related to changing study team members. You are not permitted to make any additional changes. The IRB review time is 24-48 hours.

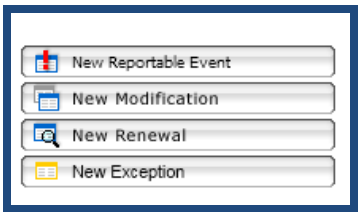
2. Create a **Full Modification** for all other changes. In this process, OSIRIS copies all sections of the currently approved study including attachments (uploaded documents). You can edit any of your responses, edit uploaded documents, or add new documents.

All edits to the application require a **justification/rationale** for each requested change. The IRB is unable to review/approve a modification without performing a risk/benefit assessment based on the justification/rationale for the changes.

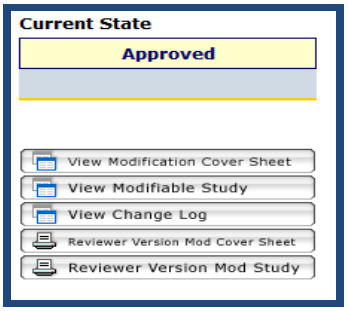
To complete your Modification Request, you will need to make the necessary changes to your IRB protocol, consent, or other documents. If any new questions were added to the OSIRIS application, you will be required to respond during this modification process.

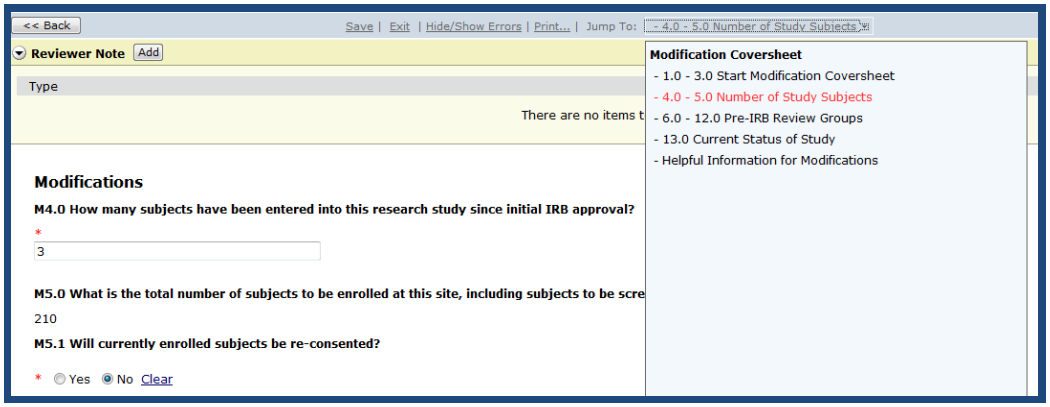
If you wish to revise an existing document, be sure to save the existing document to your computer, edit, and then click on the Upload Revision button. Do not use the ADD button and display several versions of the same document. The ADD button is reserved only for addition of new documents.

Step 1: Go the **Approved Study workspace** and click the button to create a **New Modification**

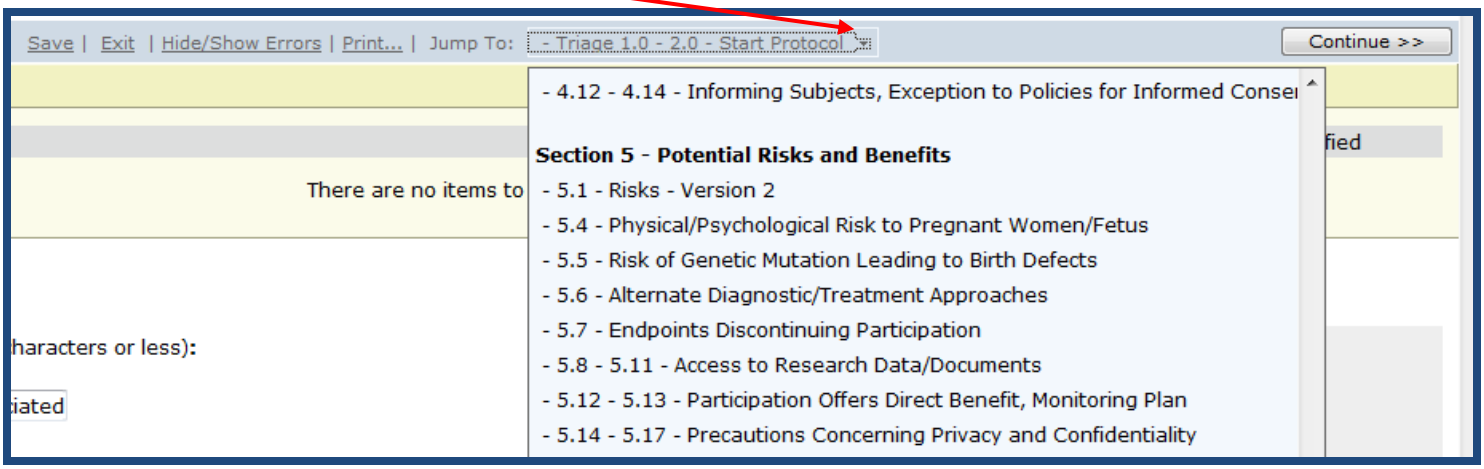


Step 2: Click on the View Modification Cover Sheet and answer the questions M1 - M13. Your responses determine if any Pre-IRB reviews are required.

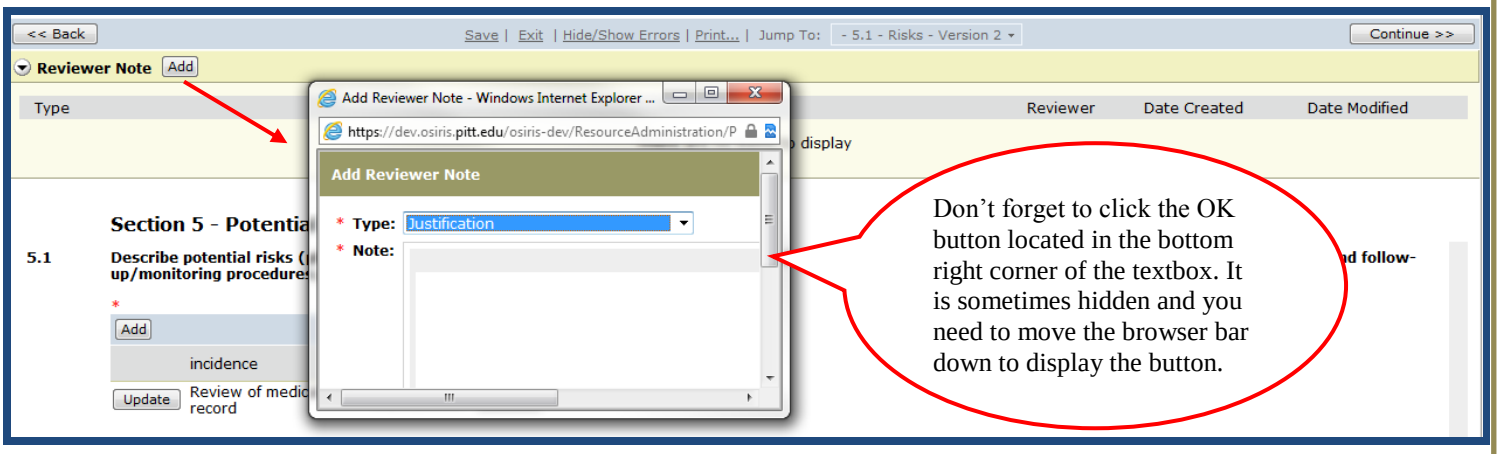




Step 3: Click on View Modifiable Study button to access a copy of the currently approved application. This link is also available on the last page of the modification coversheet. **DO NOT RE-ANSWER all the questions**. Use the **Jump To: link** located at the top of each page to go to the section you wish to edit.

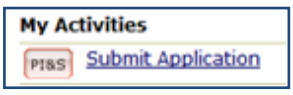


Step 4: Add a Justification on every page edited. Use the **Reviewer Note** located in the yellow header on the top left corner of each page to add your justification and include a summary of changes requested. Click on the '**Add**' button to add the required **scientific, clinical, or administrative rationale**.



***Tip**: Click on the **Hide/Show Errors link** noted located in the blue section at the top of each page to check for any errors (unanswered sections)and if found will be displayed at the bottom of the page. It is strongly recommended that you click on this link before sending to the PI for review.*

Step 5: The PI must review and submit for IRB review



Create a Renewal Report

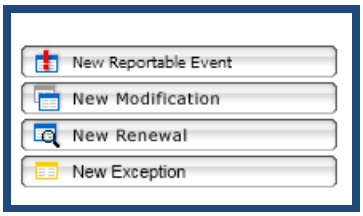
All expedited and full board studies are required to be reviewed and approved at least annually. The IRB committees have the latitude to require more frequent reviews based on the risk of the study.

You will need to go to the **Approved Study** workspace and click on the button **New Renewal**. You will answer a series of questions and complete a summary table of subject enrollment.

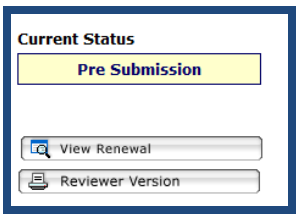
- If this study was previously renewed, be sure and review last year's Renewal Report. The IRB often finds discrepancies in the summary of subject enrollment. Go to the Approved Study workspace and click on the Renewal tab that displays all of the Renewal reports. Use the textbox to address any discrepancies or issues that you feel the IRB may question.

- It is important that you submit your Renewal at least 5 weeks prior to the expiration date. The federal regulations require that the IRB **approve the Renewal** before the expiration date (submitting the application does not constitute approval).

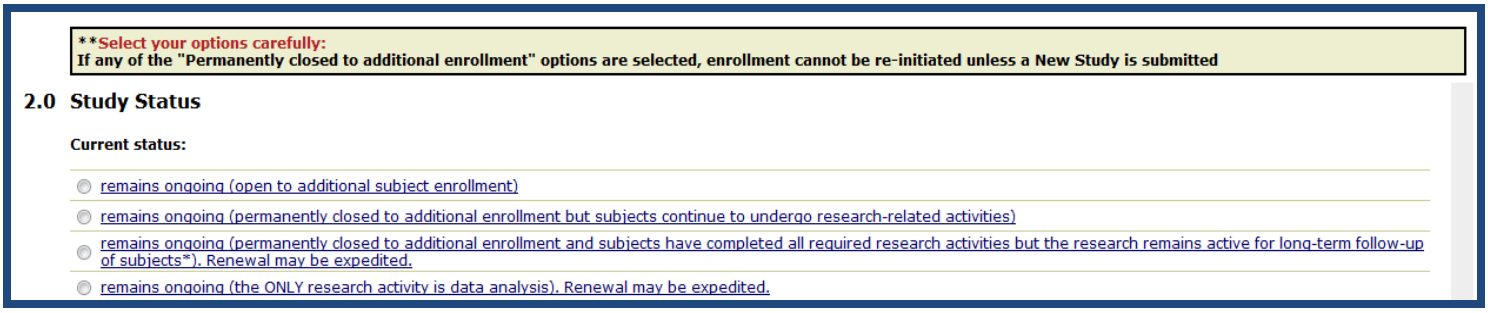
Step 1: Go the Approved Study workspace and click the button New Renewal



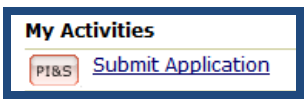
Step 2: Click on the View Renewal to answer the series of questions



Step 3: Answer the Study Status question carefully. If you select 'permanently closed to additional enrollment' and decide you wish to enroll additional subjects, you will be required **to submit a new study**.



Step 4: The PI must review and submit for IRB review



Point to Consider When Preparing your Renewal Report

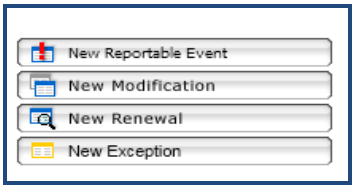
- **Data and Safety Monitoring reporting**
  - Local plan is the research team meeting
    - Answer the series of questions
  - Actual convened Data and Safety Monitoring Board (DSMB)
    - Answer the series of questions
    - Upload the most recent meeting minutes from the last convened meeting
    - Some are local while others are off-site at other institutions
    - Some studies require more elaborate monitoring – independent boards or special requirements (Department of Defense Studies (DoD) requires medical monitors)
- **No or low enrollment**
  - Provide a plan for increasing recruitment if you wish to continue the study
  - The IRB may assess whether it is acceptable to let the study continue if is likely the study will result in no generalizable outcomes
- **Reportable Events**
  - Remember you can submit a Reportable Event at anytime
    - If any issues are identified during the preparation of this report
    - If problems are identified during a DSMB meeting
- **Created a Related Modification**
  - You are permitted to submit a related modification **only if it is safety related issues**
    - If it is not for a safety related issues, you are required to wait until the Renewal is approved and then submit a Modification

Create a Reportable Event

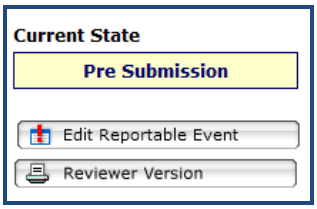
If you need to submit a Reportable Event, go to the **Approved Study** workspace and click on the **New Reportable Event** button. You will answer a series of questions and provide a detailed description of the event.

- You will select the type of report to be submitted: adverse event, other unanticipated problem involving risk to subjects or others, or deviation or non-compliance.
  - Review the HELP text definitions to determine the type of report to submit
- Reportable Events can be submitted at any time once the project is approved
  - This applies even if a Renewal, Modification or any other project is in process
- If you are unsure whether the event meets our reporting guidelines or have any other questions, please contact the IRB Adverse Event Coordinator before proceeding.
  - Contact Jamie Zelazny via email at zelaznyjh@upmc.edu

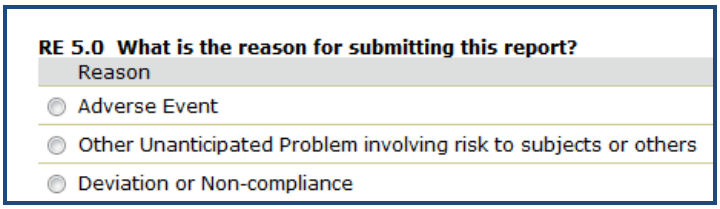
Step 1: Go the Approved Study workspace and click **New Reportable Event**



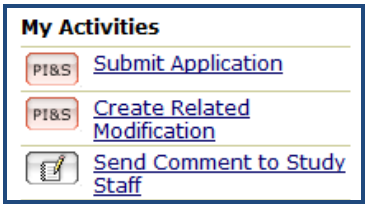
Step 2: Click on **Edit Reportable Event** and answer a series of questions.



Step 3: Answer a series of questions



Step 4: The PI must review and submit the report for IRB review. If needed, a Related Modification can be created and submitted with this Reportable Event.

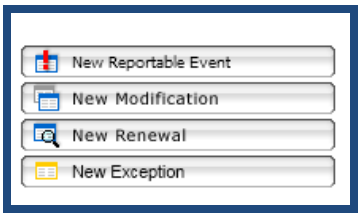


Create an Exception Request

Investigators must follow the IRB approved protocol and are not permitted to deviate from the plan unless there is an immediate risk to a research subject or IRB approval is obtained. It is possible to request an exception to deviate from the currently approved protocol but appropriate justification is required before the IRB will consider the request. In addition, approval may also be required from the sponsor and possibly the FDA.

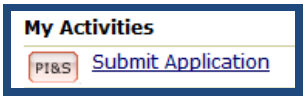
- The Exception Request is to be used for deviations that have not yet occurred. If you have already deviated from your protocol, you must submit a Reportable Event.
- If the need for requested exception is likely to be repeated in the future, the investigator will be instructed to submit a modification as only one exception may be approved by the IRB.

Step 1: Go the Approved Study workspace and click the button **New Exception**

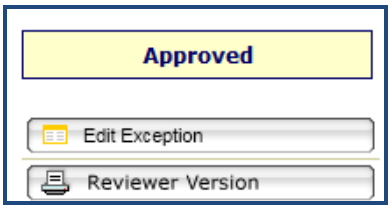


Step 2: You will answer a series of questions and provide a justification for the request.

Step 3: The PI must review and submit for IRB review



Step 4: The Exception Request will be reviewed by the IRB Chair or designee. You will receive an email notification informing you of the decision. You may not proceed until you receive the IRB Chair's determination.



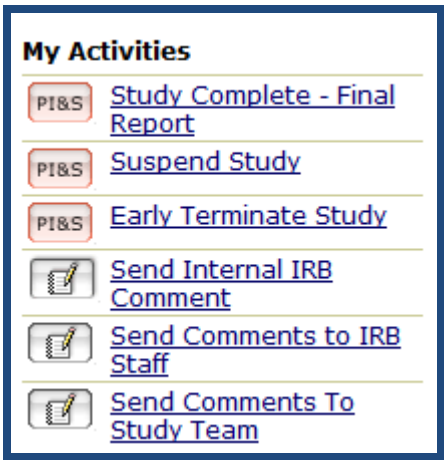
Note: Even if the sponsor approves the exception, it cannot be implemented with the University of Pittsburgh IRB approval.

Create a Final Report

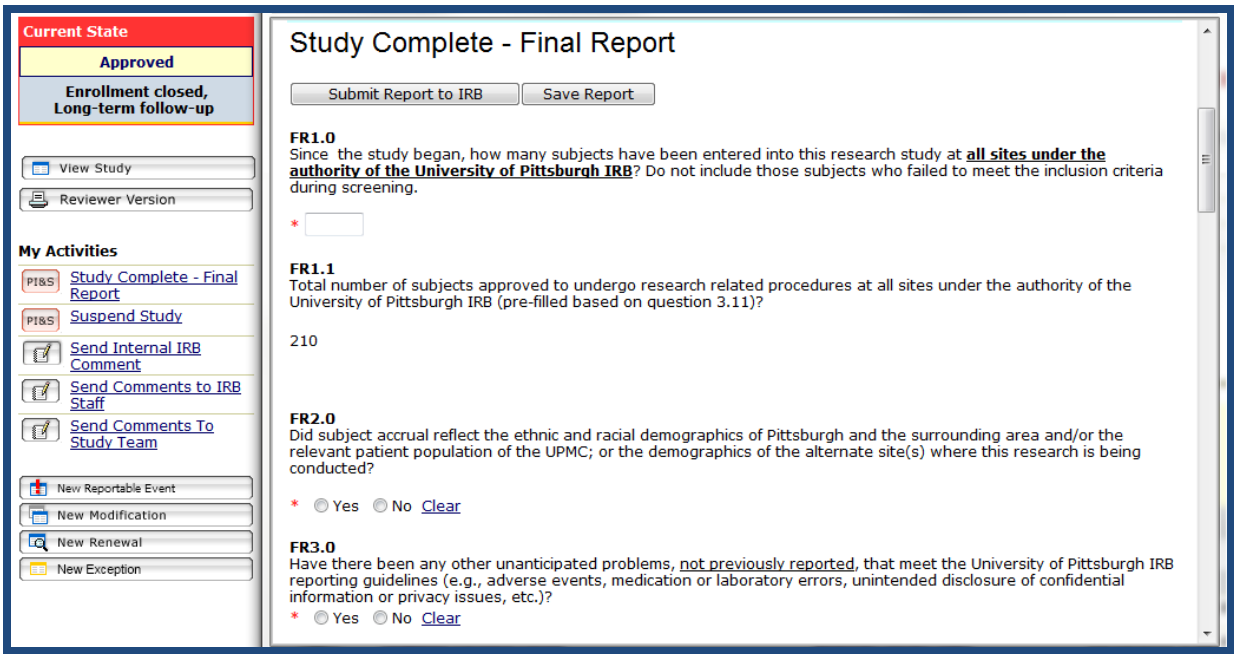
It is important that you close out your study and don't just let it expire. Just like the other submissions, you will be asked to respond to a series of questions.

- Two options:
  - Final Report-Study Completed
  - Early Termination
- If you are leaving the institution, it is your responsibility as the PI to either close the study or modify the study to add a new investigator to assume the role as PI. One of these options must be submitted and approved by the IRB before you leave.

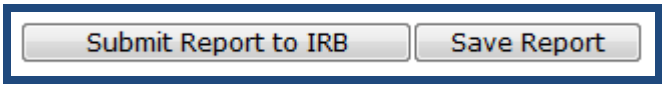
Step 1: Go the Approved Study workspace and select the appropriate activity: Study Complete-Final Report or Early Terminate Study

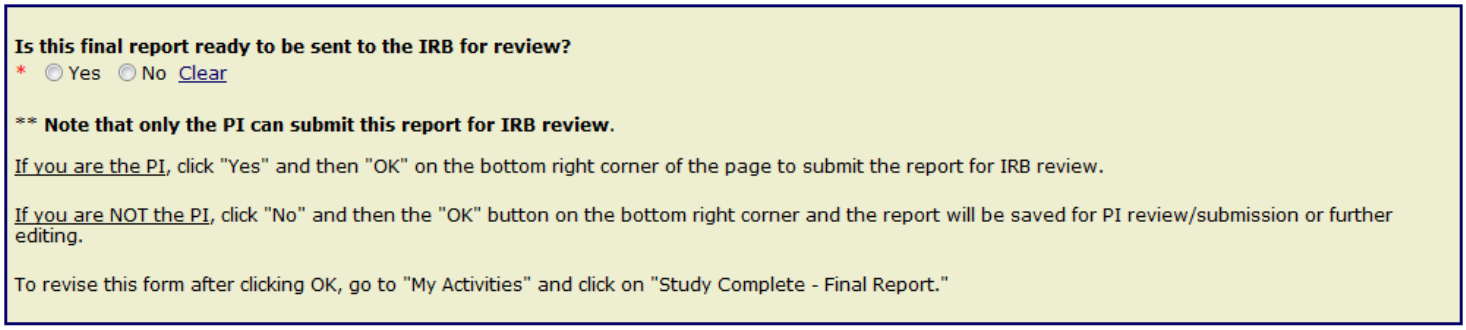


Step 2: A form will be displayed and you will be asked to respond to a series of questions.

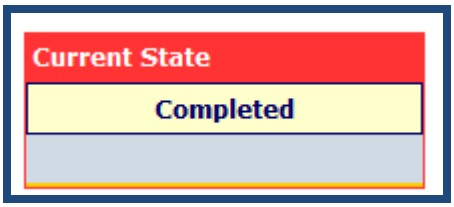


Step 3: It is important to note that if the PI answers the questions, he/she can just use the button at the top of the form to submit. If another member of the research team creates the document, the PI must review and submit the report.





Step 4: The report is reviewed by the IRB Chair and if acceptable, the current state on the Approved Study workspace will be display completed.



Create an Exempt Application

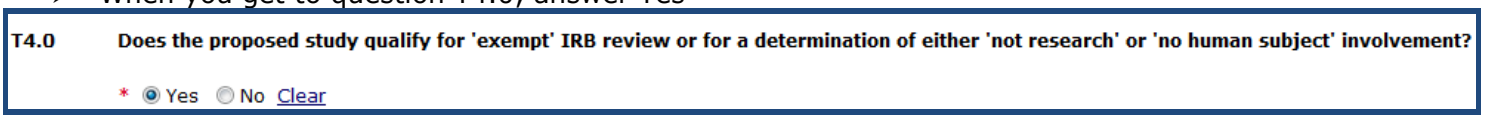
The IRB does not actually approve an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories' criteria.

- Annual review is not required and no expiration date will be listed on your approval letter
- It is very important that you close-out your project when completed or if you leave the university. Faculty mentors are responsible for oversight of student projects and should ensure exempt studies are completed and closed-out in OSIRIS before the student leaves the university.
- The Exempt Review process is also used for projects designated as 'Not Research' or' Does Not Involve Human Subjects'

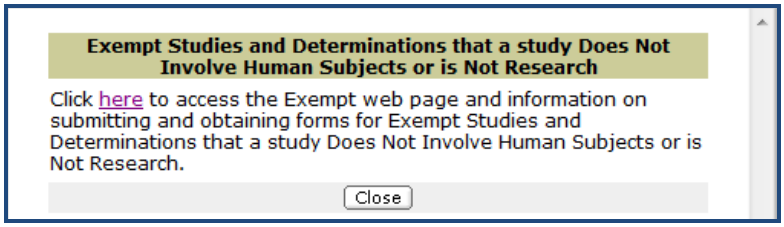
Students are strongly encouraged to meet with an IRB staff member before initiating the IRB application. This is especially important if the study is being conducting outside the U.S. or if children will be research subjects.

Important: Exempt applications have a special pathway in OSIRIS with limited questions – do not use the jump to menu to bypass questions until you have answered all the questions up to **E1.0** to set the exempt pathway.

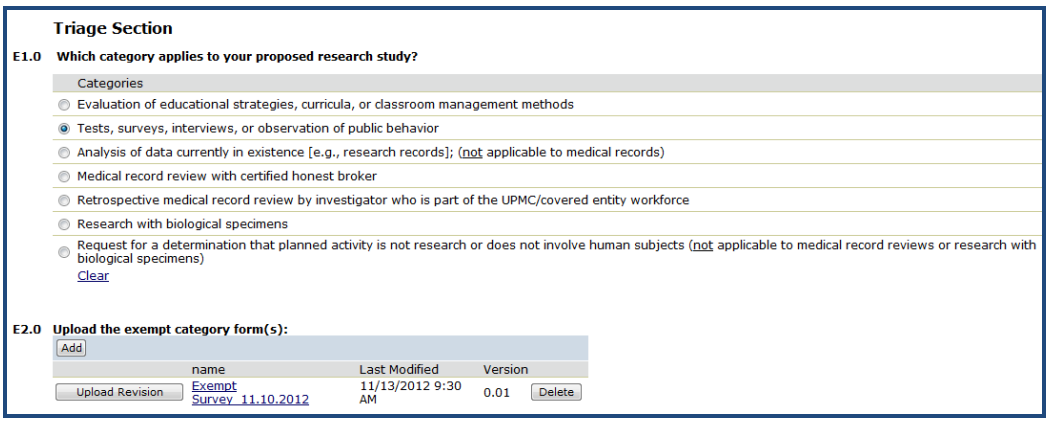
- Follow the steps to Create a New Study on page 4 of this document
- Use the continue button on the right side of the page to build your application
- When you get to question T4.0, answer Yes



- Click on Resource located to the right of T4.0 for detailed information before proceeding



- You are now in the Exempt Review pathway



Seek a "No human subjects" or "Not research" Determination

- Follow the same steps as are described above for an exempt determination
- It is normally best to use an exempt form that is specific to the type of project you plan to conduct.
    - You can specify which determination you are requesting in the uploaded exempt form.
    - The form "Not Research or Does Not Involve Human Subjects" is rarely used.
- Contact askirb@pitt.edu with any questions prior to completing the form.