Information Sheet for Investigators and Research Team

OSIRIS is a web-based application that was created to improve human subject protections and to enable the IRB to better serve the research community. The application is based on the use of a question and answer format using smart forms. Based on your response to specific smart form questions the system may branch to additional questions which you must address.

OSIRIS presents the investigator the unique opportunity to submit one application for the entire review process. All required pre-IRB reviews will be conducted based on the response to smart form questions and once approved, OSIRIS will notify the IRB office that their review is permitted.

This information sheet is designed to provide you with the basic tools to initiate the submission of a new study. Information sheets will be periodically updated as enhancements to the system are completed. You are strongly encouraged to review the instructions on-line so you will have access to the most current version. Since this system is a web-based application we have prepared an on-line tutorial for the research community. The IRB has open hours from 9-11 am, Tuesdays and Thursdays, in Suite 105 to assist users. Please contact Patty Orndoff (orndoffpa@upmc.edu) to schedule training or arrange an alternate time/date.

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All key personnel involved with Human Subject Research are required to complete specific modules in Research & Practice Fundamentals (RPF) training. Only those individuals who have completed the required training will be granted access to OSIRIS.

Required modules include: Module 1 - Research Integrity, and Module 2a (Biomedical) or 2b (Social/Behavioral) - Human Subjects Research. Responsible Conduct of Research training modules are available at: **http://cme.hs.pitt.edu**.

To Login

- Go https://www.osiris.pitt.edu
- Click on **Login** (top right hand corner of page)
- Enter **Username** (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 to you
  - Go to https://www.osiris.pitt.edu and **Login** again
- To end your session, click the **Logoff** button (top right hand corner of page)

The following information will guide you through the process of submitting a new study electronically. 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 form(s)**
5. **Responding to reviewer comments**

To Create a New Study

- Under **Create** (located on the left hand side of the page)
  - Click on 

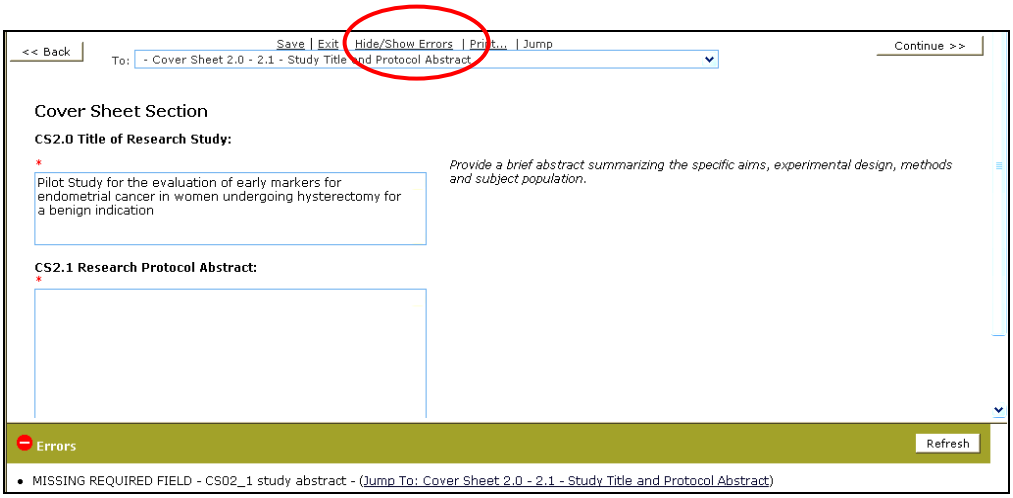
- **Initiation of smart form questions,** broken down by sections
  - **Triage section**
  - **Cover Sheet section**
  - **Protocol sections (1-7)**
  - Answer the questions which may branch to additional questions based on your response

- Click on **Continue button**
  - Saves your response as you proceed through the forms **(VERY IMPORTANT)**
  - Located at the top and bottom section of every page

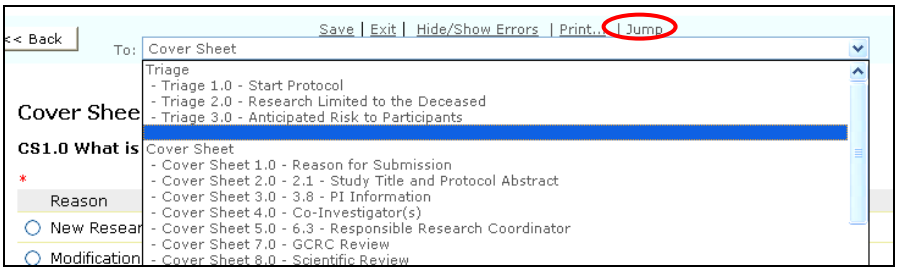
- **Red asterisk ***
  - Indicates a required response
  - If you fail to complete a question that was required, the following message will appear: "Could not update the study due to one or more errors: there were problems submitting this form…"

- Options available at the top of each page-descriptions available below
  - Save | Exit | Hide/Show Errors | Print… | Jump

    - **Save**
      - Be sure to click the Save button before existing the system
    - **Exit**
      - Will take you back to the summary page
    - **Hide / Show Errors**
      - Lists all the questions that need to be answered
      - Provides a hyperlink to the question which is located at the bottom of the page
      - Click **Refresh** and the system will update and remove all pages that have been addressed



- **Print**
  - Prints current page
- **Jump**
  - Allows you to go to a specific page in the smart forms



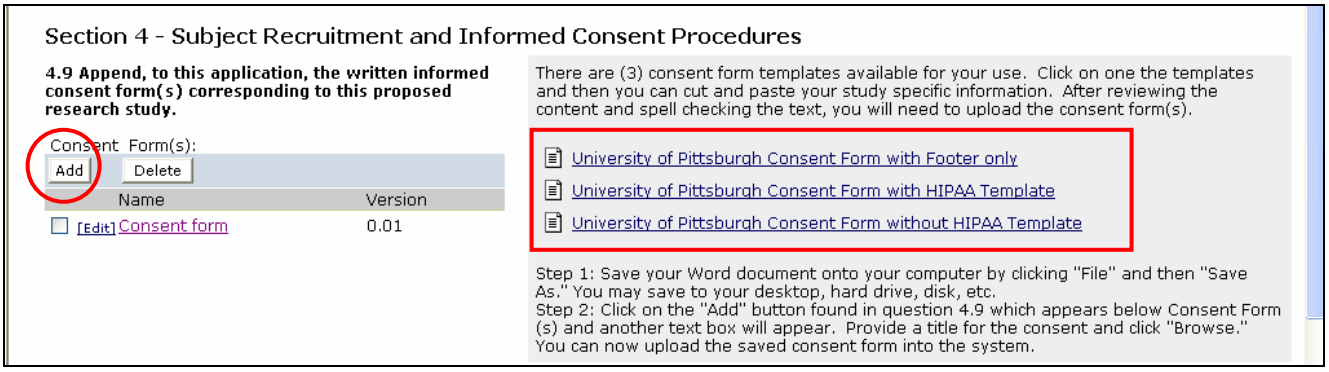
Warning: If you "Exit" without clicking the "Save" button, a confirmation box will appear and warn you to save your work before exiting. If fail to click "Save", the information on that page will not be recorded.

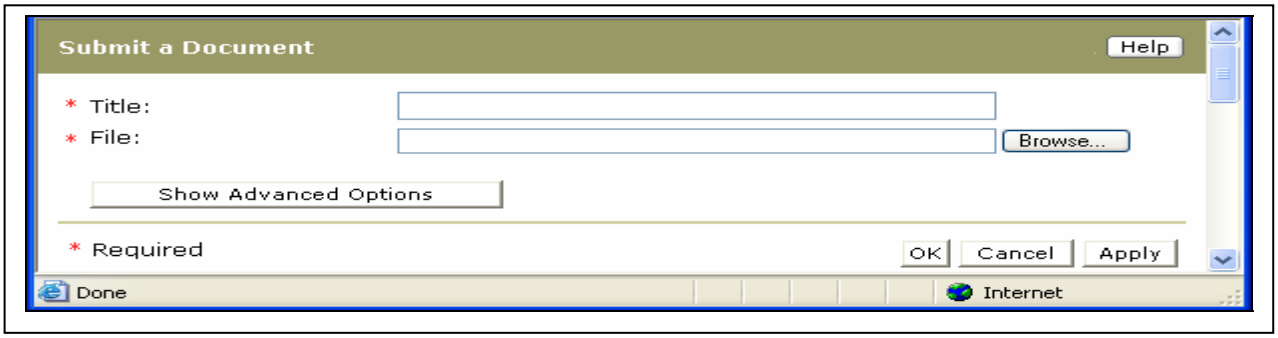
All attachments will need to be submitted electronically for review. If the document is available in an electronic format the following instructions will guide you through the process. If only a paper copy of the required documentation is available, you will need to scan the document and then follow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

1. **Go to Edit study and select the specific section**
2. **Click on the Add button and another window will pop-up known as a browser window**
3. **You will name the document and click browse to identify the current source of document**
4. **You will then click OK and document will automatically be placed in the specified section**

To Upload a document

- Click on **Edit Study**
  - Click on the **Add** button as shown below
  - A new **Browser window** will open
    - Title: add the title of the document
    - File: click on Browse and upload the document (e.g., desktop, disk)
    - Click OK to add the document to your OSIRIS submission





To Scan a document

Paper copies of required documentation such as sponsor protocols, investigator brochures, and correspondence must be scanned and 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.

The approval documentation process for the consent forms has been changed. You will no longer be required to add the IRB approval text in your consent form(s) (e.g., approval date, IRB number). OSIRIS now requires that the IRB staff perform a procedure called watermarking during the approval process. This process automatically publishes the approval information on the bottom of each page of your consent form(s). This is accomplished by using a footer template for all consent form(s).

To Upload the consent form(s)

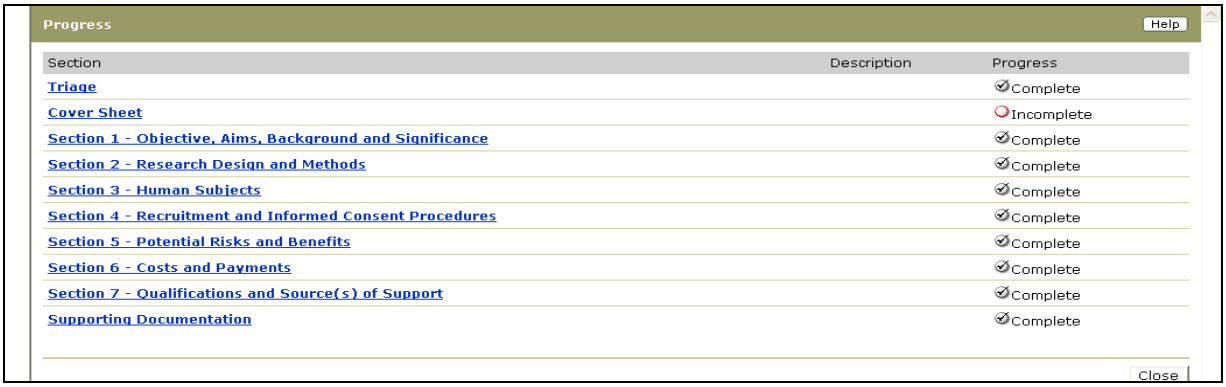
- Click on **Edit Study**
  - Consent form templates are available in **Section 4, question 4.9**
  - 3 template formats are available for your use:
    - 2 consent form templates with footer embedded (cut and paste your text)
      NOTE: Do Not Use the consent form templates available on the IRB website as they do not have the OSIRIS required footer
      - with HIPAA language
      - without HIPAA language
    - footer template only
  - Follow the instructions as outlined in the previous section for uploading the document into OSIRIS

- **Preparation of the consent form(s)** for IRB approval documentation
  - If you do not use the consent form templates with the footer embedded, you will need to insert the footer template into your consent form(s)
  - An example of the consent form footer is displayed below
  - Since OSIRIS will automatically add the date, IRB# and version fields once approved, it is important that the footer has the following specifications to ensure readability:
    - 12 Font for page numbering and participant's initials
    - **9 Font for shaded section of the footer**

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 enter information into their designated study. This section will demonstrate how to identify the study you wish to edit, completion of your study using View Smart Form Progress and submitting the study for review.

To Return to Your Study

- **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
- Go to **My Tasks**
  - All new studies will stay in Pre Submission until the PI clicks on the Submit button
- The **Studies** tab displays all studies you are associated with in any state
  - Click on the name of the study which will take you to the project workspace
- Click on **View Smart form Progress**
  - Checks your progress to ensure that you completed all the required questions



- Click on **Edit Study**
  - Use this view to make changes to the protocol or consent form(s) as needed

Submit your study

- Click on **Finish**
  - 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**
  - Only the Principal Investigator may click on the Submit button
  - Located only in the PI's folder as an option on the study under **My Activities**

Submit Application

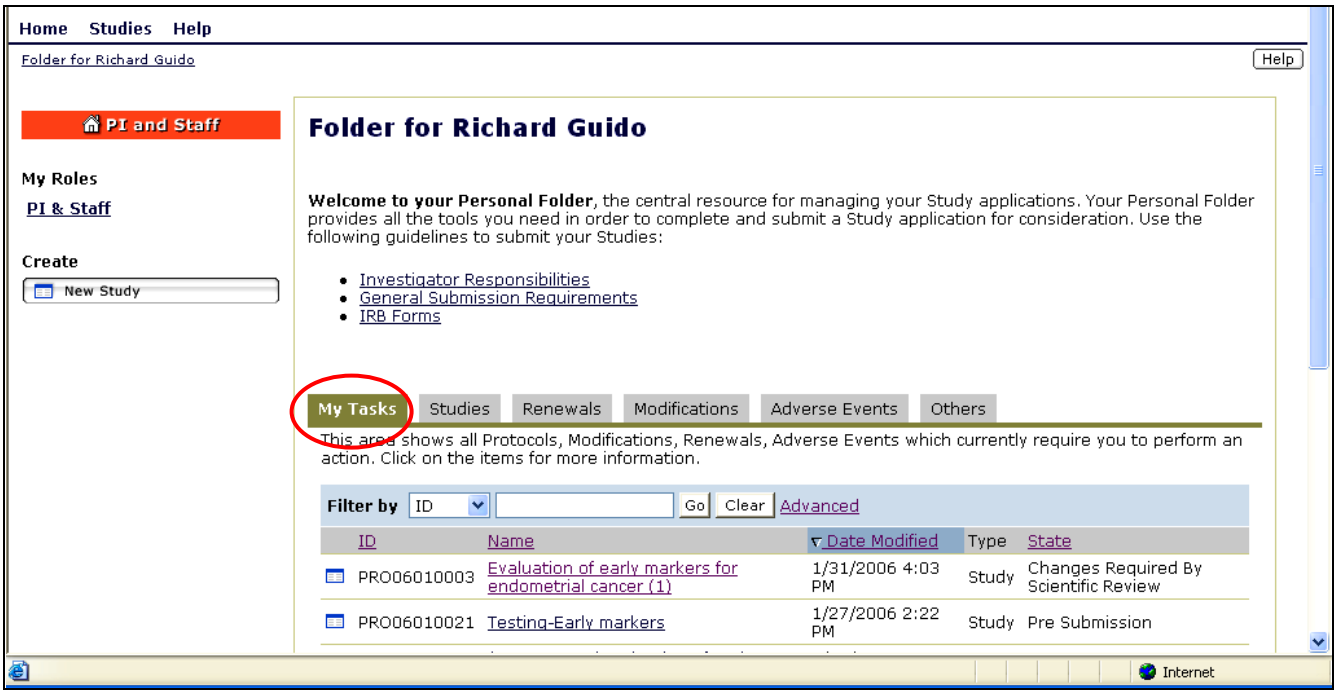
- When the PI clicks **Submit Application**, the system will automatically check to make sure all the required questions have been addressed.
- If the system identifies incomplete sections within the smart forms, a window will pop up listing all the incomplete areas. The top of the page is labeled "**Errors.**" 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 the reviewers.

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 edits are permitted. When a reviewer requests changes, OSIRIS then unlocks the study and editing is permitted. OSIRIS will track every change made in the smart form questions. 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 the IRB. This is your to-do list which requires your attention. Remember to make the requested changes in the protocol or consent form(s) if required.

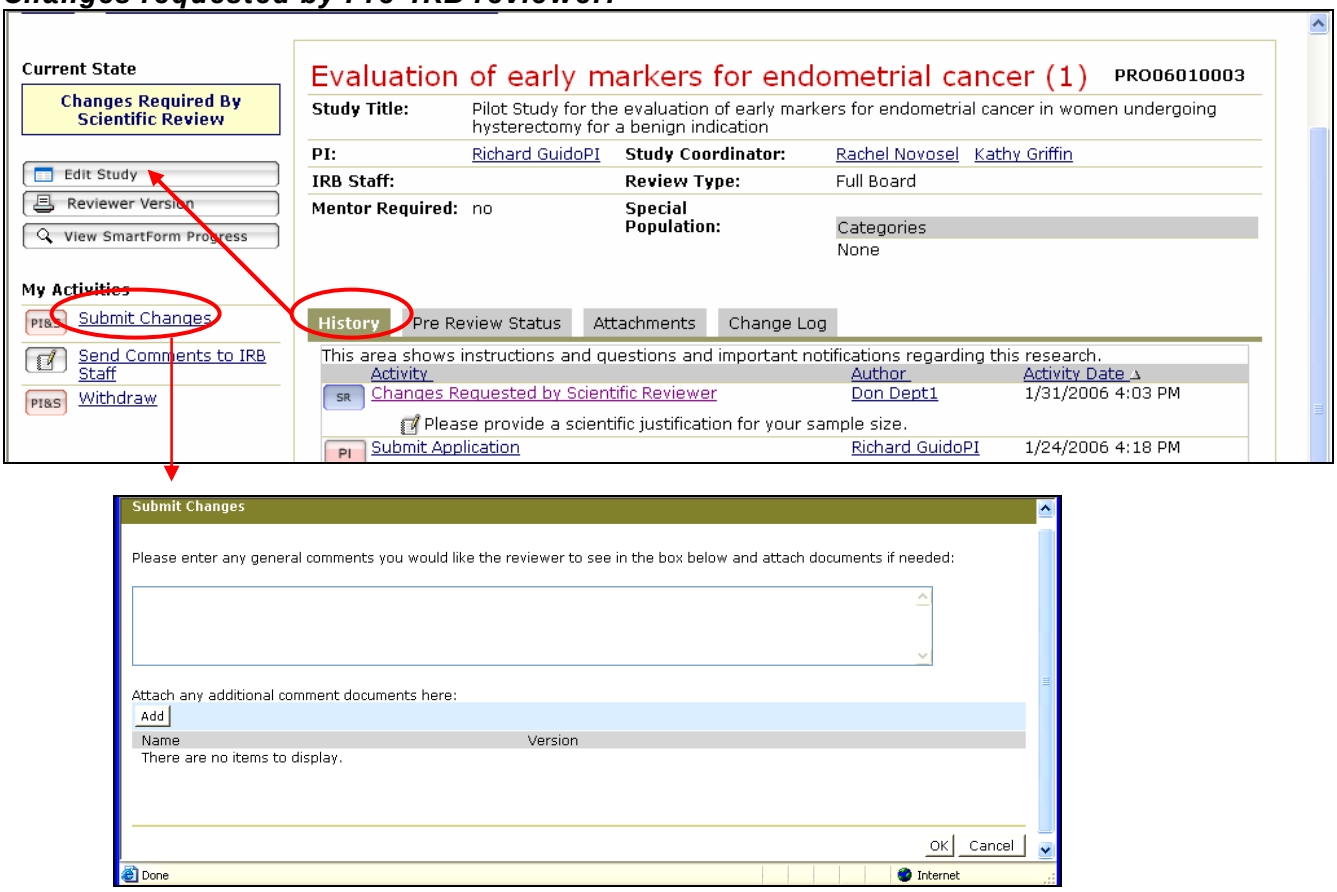
To Respond to comments

- **Login**
  - **My Home**
- Go to **My Task**
  - Search for the study which requires a response to comments
  - You will already have received an email notification that changes are requested
  - Both the PI and study coordinator will be notified
  - The notifications will contain a hyperlink to the study workspace

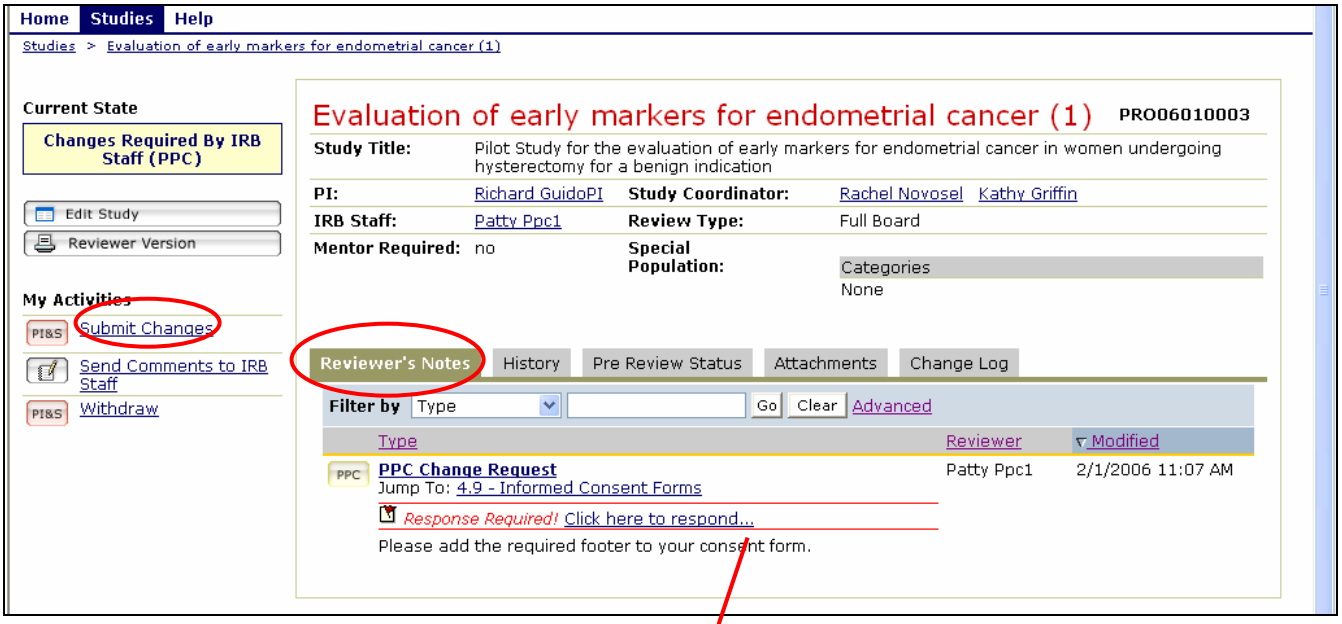


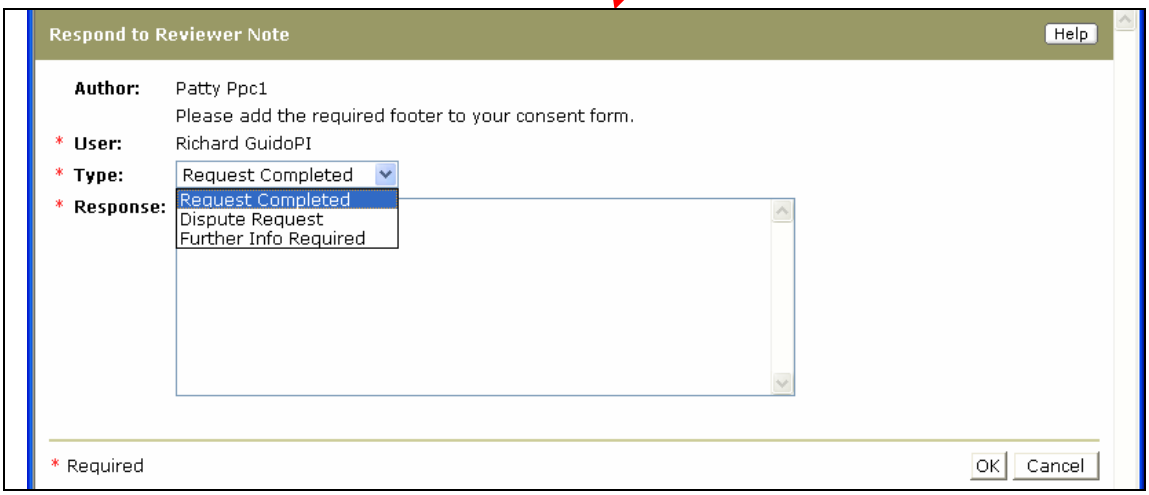
- View request for changes or clarifications
  - **History**
    - Available for all Pre-IRB review comments
    - Every activity performed is recorded in this section
  - **Reviewer Notes**
    - Available only when responding to IRB requests
- Click on **Edit Study**
  - Use this button to make changes to the protocol or consent form(s)
  - **Make the requested changes** to the study and/or consent form(s)
  - Click **Save** and then **Exit**
- Go to **My Activities**
  - Click on **Submit Changes**
  - Allows you to acknowledge that you made the requested changes
- Click on **Logoff** to end the session

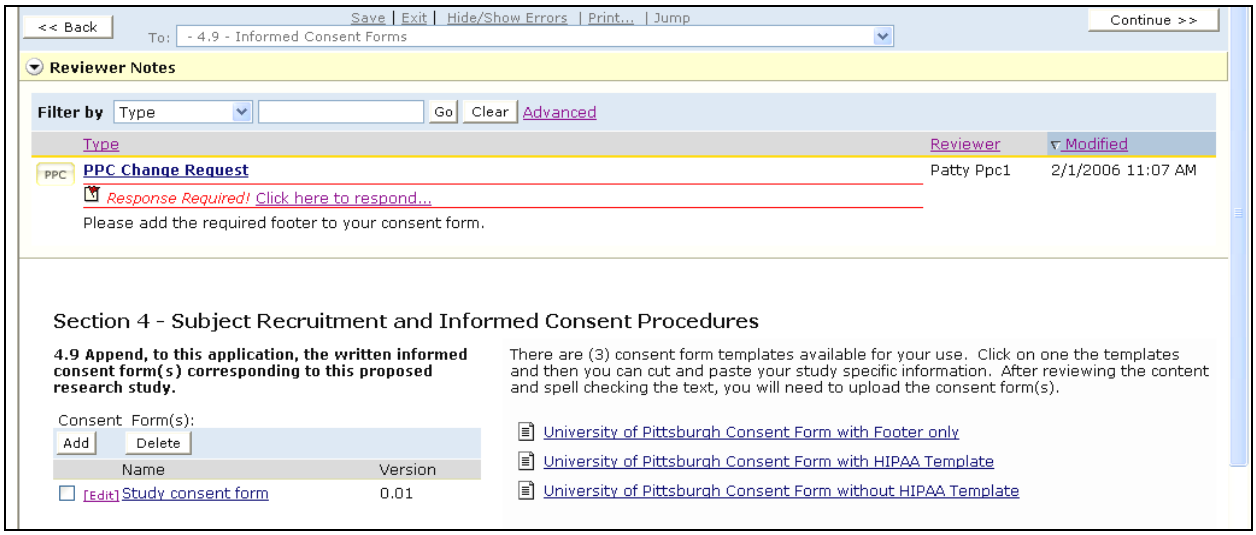
Changes requested by Pre-IRB reviewer:

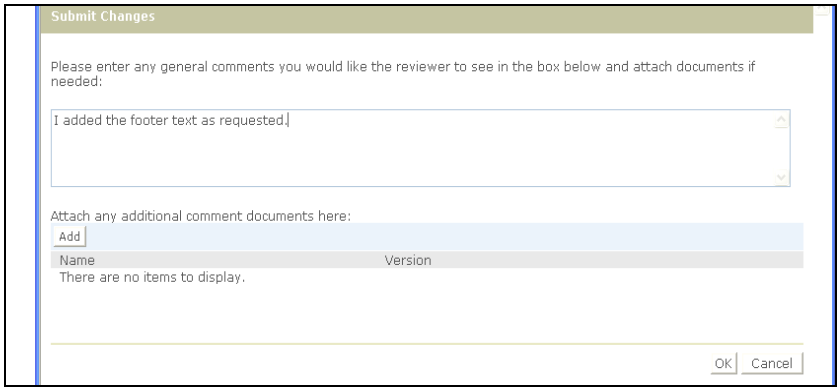


The IRB may request changes to application or clarifications that will just require a response. You can respond by going to the Reviewer's Notes and use the Click here to respond link. If changes are required within the application you can either use the Edit Study button located in My Activities or use the Jump To: link available from the Reviewer's Notes section. To complete your response click on the Submit Changes button found in My Activities.









Below is an example of an approved study. The approval letter is found in summary section under Approval Letter. The approved consent form(s) are available in the Attachments section or in View Study, Section 4.9.