

## Information Sheet for Ancillary Reviewers

This information sheet will provide you with instructions for your role as an ancillary reviewer. The IRB has open office hours to assist users with the process from 9-11am, Tuesdays and Thursdays, in Room 105. Please contact [Patty Orndoff](mailto:orndoffpa@upmc.edu) ([orndoffpa@upmc.edu](mailto:orndoffpa@upmc.edu)) if you need assistance with the review process or to schedule training.

### Notification of Required Review

- Email notification
  - You will receive an email notification indicating the need for your ancillary review, provide a link to OSIRIS, and also include the PI's name and study title
- Log onto OSIRIS
  - All users must have completed 2 education modules (Research Integrity and Human Subjects Research) before access to OSIRIS is permitted
  - Need assistance
    - Email us at [irb@pitt.edu](mailto:irb@pitt.edu)

### Login

- Go to <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 **Logout** button (top right-hand corner of page)

### Overview of ancillary reviewer workspace

- Under **My Roles** (located on the left-hand side of the page)
  - Select **Ancillary Reviewer** role as you may have multiple roles
- **My Tasks** tab located in mid-section of the page
  - Displays all projects you are required to review
  - Click on the hyperlinked title of the project you wish to review
  - You can return to page displaying **My Tasks** anytime by clicking on **My Home** tab located in the top right hand corner of the page
- **Studies, Modifications, and Renewal**
  - Lists all projects for which you have access to review and includes a Search function
    - **Filter by** allows you to search by **Study ID**, **Study Name**, **PI last or first name**, or **State** of submission and then type in the information
    - If you wish to enter only part of the number or name, insert the **%** sign prior to the number or letters to conduct the search
    - Click on the hyperlink for **ID**, **Name**, **Date Modified**, or **State** to change the order of display (e.g., date modified = display the oldest or newest project first)

### Overview of study workspace

- **Current State** located on the left hand side of the page
  - Lists the review state of the project (e.g., Ancillary, IRB Review, Approved)
- **Edit Study** displays the page by page view of the smartform questions
- **Reviewer Version** displays the summary version of all smartform questions and PI responses. It does not display the Help Text normally available from the right hand side
- **View Smartform Progress** provides a process whereby the investigator can make sure all the required smartform questions have been addressed

- **My Activities** displays all the functions the ancillary reviewer is permitted to perform
  - **Changes Requested by Ancillary Reviewer**
    - Permits the investigator to respond to your comments
    - The application is locked down and editable by the investigator only if the reviewer request changes
  - **Approve Application by Ancillary Reviewer**
    - Ancillary reviewer approves the application and no changes are permitted
  - **Terminated**
    - The application is stopped and no further reviews will occur
  - **Send Comments to Study Team**
    - Use only to send general comments to the investigator which do not require changes to the application
  
- **Study Views**
  - **History** tab
    - Displays all the past activities associated with the study
  - **Pre Review** tab
    - Displays all the required pre-IRB reviews indicating whether approved or pending approval
  - **Attachments**
    - Displays specific documents/forms uploaded by the investigator (e.g., consent(s), sponsor protocols/brochures, grant applications, questionnaires)
  - **Change Log** tab
    - Displays all changes to smartform questions but not the changes to uploaded documents

### Initiate your review

There are 2 sections you will need to access in order to conduct your review: **Reviewer Version** and the **Attachment** section.

- Click on **Reviewer Version** button located on the left-hand side of the page
  - Provides a view of the entire OSIRIS application on one continuous page
    - When you have completed your review, click on the browser's back button located at top right-hand corner of the page which will close the browser and you will be returned to the summary page
  
- Click on the **Attachments** tab available from the mid-section of the summary page
  - Contains all uploaded documents (e.g., grant, sponsor's documents, drug/device brochures, consent forms, fiscal review forms) which may be necessary for your review
  
- When writing your comments, please remember to identify the question for which you are commenting
  - For example, **4.1 Will potential research subjects be identified through the use of advertisements?**
    - Sample reviewer comment: 4.1 - You failed to include the advertisements for review and approval

### Send questions or comments to the PI

- Under **My Activities** section of a project's workspace
  - Click on **Changes Requested**
    - A textbox is available to add your requests or you may cut and paste from another document
    - Another option is to upload a memo/letter with the requested changes
    - The process of requesting changes unlocks the project and allows the investigator to make the requested changes
    - OSIRIS automatically sends an email notification to the PI and Study Coordinator notifying them of your request

- **Instructions for uploading a document** (e.g., guidance document, memo/letter, forms)
  - Click on the **Add** button
  - **Browser window** will open
  - Title: add the title of the document
  - File: click on Browse and upload the document (e.g., desktop, computer file)
  - Click OK to upload the document into OSIRIS

### Response to comments and approval determination

- The PI will submit the changes for your review
- You will receive an **Email notification**
  - The email notification will indicate the investigator has responded to your comments, provide a link to OSIRIS, and include the investigator's name and study title
- **Logon** to OSIRIS
- Click on the "**History**" tab located in mid-section of the summary page
  - Review the changes and comments from the PI

After reviewing the response to comments, you will have 3 options: Request changes, Approve, or Terminate the project.

- Under **My Activities** section of a study's workspace
  - Click on **Changes Requested**
    - OSIRIS sends an email notification to the PI and Study Coordinator
    - The process of requesting changes unlocks the project and allows the PI to make the requested changes
  - Click on **Approve**
    - A text box is available to make comments if needed
  - Click on **Terminate** study
    - The project is disapproved and no further review will occur
- Remember to click **OK** to save your work before closing the window
- The ancillary reviewer will continue to have access to the project if needed

**You have now reviewed the project, made a determination, and completed your role as an ancillary reviewer.**

### General Comments

- "**Send Comments to Study Team**"
  - Be careful when using this link as this is just an FYI comment which does not require any action
- If you are requesting changes to the application
  - Go to "**My Activities**" and click on "**Changes Requested by Ancillary Reviewer**"
- Please note: The system is locked down once the PI clicks on the submit button and the research team is not able to make any changes unless a reviewer requests one
- Be careful not to approve a project until all the **requested changes have been verified**