

## Information Sheet for Scientific Reviewers

This information sheet will provide you with instructions for your role as a scientific 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 scientific 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 **Logoff** 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 **Scientific 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., Scientific Review, 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 scientific reviewer is permitted to perform
  - **Changes Requested by Scientific 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 Scientific Reviewer**
    - Scientific 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 Scientific 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**