Information Sheet for Scientific Approvers

This document will provide you with the basic instructions for your role as a scientific approver in OSIRIS. All listed approvers have been designated by their chair or administrator and it is important to notify us when you no longer will serve this role. Email us at irb@pitt.edu if you have any questions or concerns.

- Access the study for scientific review
- Request changes
- Assign the review to another person
- Approve for scientific merit

Scientific Review

Every research protocol involving human subjects should receive a formal scientific review, usually at the department or school level, prior to its review by the IRB. This review ordinarily addresses the scientific merit of the study and, depending on the nature of the research project, may also address availability of research subjects, resource utilization, and financial support. Studies that have undergone a scientific review as a condition of funding (e.g., NIH-funded research) will not ordinarily require a departmental review.

http://www.provost.pitt.edu/documents/GUIDELINES%20FOR%20ETHICAL%20PRACTICES%20IN%20RESEARCH-FINALrevised2-March%202011.pdf

Notification of Required Review

- Email notification
  - You will receive an email notification as soon as the PI submits the study for review. Scientific approval is required before any other reviews are permitted. As noted below, the email provides a link to OSIRIS and the study to be reviewed.
Login

- Go to [www.osiris.pitt.edu](http://www.osiris.pitt.edu)
  - All users must have completed the research ethics training before access is granted
    - Go to [www.citi.pitt.edu](http://www.citi.pitt.edu) for more information
- Under My Roles (located on the top left side of the page)
  - Select **Scientific Reviewer** role so the page displays projects requiring your review
    - If the PI and Staff role is selected, only your research studies will be displayed

Access the study

- **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 the **My Home** link located in the top right corner of the page

- **Studies and Modifications**
  - 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 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 questions

- **Reviewer Version** displays all the questions and responses
  - *Best method for reviewing* the application

- **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
  - **Issue Scientific Approval**
    - Scientific reviewer approves the application
  - **Assign Read Only Reviewers**
    - Enables other individuals access to the study
  - **Terminated**
    - No further reviews will take place
  - **Send Comments to Study Team**
    - Use only to send general comments to the investigator which do not require changes to the application

**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 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 most of the uploaded documents (e.g., grant, sponsor’s documents, drug/device brochures, consent forms, fiscal review forms)

- When **writing your comments**, please remember to identify the question for which you are commenting
  - For example, 1.3 Background: Briefly describe previous findings or observations
    - Sample reviewer comment: 1.3 - You failed to provide the results of previous animal studies conducted to support the science for this project.

### Assign Read Only Reviewers

- If you are a member of the study team or do not have the expertise to review a study, you can assign another individual to conduct the review.
  - This assigned reviewer can access the study but must provide the comments back to you as the study is locked and not editable until you request changes
  - Access to the study is removed once the study is approved

- Click on Assign Read Only Reviewers
  - Select **Add** under the Action section
  - Type the **name of the person** in the field or use the Add button
  - **Provide instructions** to the reviewer on how you wish them to communicate with you
  - Click the **OK** button in the bottom right corner of the textbox (note that OK button is not displayed in the screen shot below)

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**Assign Read Only Reviewers**

<table>
<thead>
<tr>
<th>Current State</th>
<th>Scientific Review</th>
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<td>My Activities</td>
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**Scientific Review Process Demo**

- **Study Title:** Demo of Scientific Review Process
- **PI:** Richard Guide
- **Study Coordinator:**
- **IRB Staff:**
- **Review Type:** Expedited

**Assign Read Only Reviewers**

- **Instructions:**
  - Use this activity to add or remove read only access for reviewers.
  - Read only access means anyone appearing in the list below can log into the website and view this project but will not edit the project.
  - This is typically used to grant access to reviewers who have a need to view the project but not add the project.
  - You can add or remove multiple people at a time. Choose the desired action and then select the persons to add/remove.

- **Current Read Only Reviewers** - the following persons currently have read only access to this project:
  - There are no items to display.

- **Action:** indicate if you want to add people or remove people from read only access:
  - **Add**:
    - Click the 'Add' button to search and select the name(s) to be added as reviewer(s):
  - **Remove**:
    - Click the 'Remove' button to search and select the name(s) to be removed as reviewer(s):

- **Comments/Instructions**: Add any notes or instructions for the reviewers. This will be sent in an email notification and appear in the history log of the project.

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Send questions or comments to the PI

- Click on **Changes Requested by Scientific Reviewer**
  - A textbox is available to add your comments
  - Another option is to upload a memo/letter with the requested changes
  - The process of requesting changes unlocks the study for editing 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 select the document on your computer
    - Click **OK** to upload the document into OSIRIS
Scientific Approval Determination

- Scientific merit has been established and the study is ready for IRB review
  - Click on **Issue Scientific Approval**
    - If you are a member of the research team and also the scientific approver for your department
      - Document in the textbox that you did not participate in the scientific review
  - Click **OK** and the study will be submitted for further reviews

General Comments

- If you are requesting changes to the application
  - Go to My Activities and click on Changes Requested by Scientific Reviewer
  - Send Comments to Study Team does not unlock the study for editing

- Please note: The study is locked for editing 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