

Reviewer Information Sheet for Committee Members

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 responses to specific smart form questions the system may branch to additional questions.

OSIRIS presents the investigator the unique opportunity to submit one application for the entire review process. In addition, it provides all committee members access to all the documents submitted for review.

This information sheet is designed to provide you with the basic tools to initiate your review of an OSIRIS application. 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.

Please contact [Patty Orndoff \(orndoffpa@upmc.edu\)](mailto:orndoffpa@upmc.edu) or Melissa Miklos (miklosm@upmc.edu) with any questions, concerns or to schedule training. All questions regarding a specific research application should be directed to the listed IRB Coordinator. If you experience technical problems please email us at irb@pitt.edu. Since this system is a web-based application we are able to provide you with on-line assistance.

Feel free to contact the IRB Office (412-383-1480) at any time for assistance.

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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)

Confirm/Decline Meeting Attendance

- Under **My Roles**
 - Click on **Committee Member** (opens view of all member activities)
- Click on **My Meetings** tab
 - Select the committee meeting which requires you to Confirm or Decline
- Under **My Activities**
 - Click on the **Confirm or Decline** button
- A new web browser window will appear, **click on the OK button** available at the bottom-right corner of the window
 - You may need to scroll down to see the button

Initiate your review

- Under **My Roles** (located on the left-hand side of the page)
 - Select **Committee Member**
- Click on **My Meetings** tab
 - Select the committee meeting for which you wish to initiate a review
- The **Meeting Agenda** is available on the upper left-hand side of the page
 - Click on the Meeting Agenda button on the upper left-hand side which permits access to all the items on the agenda
 - Click on the hyperlinked title of agenda item you wish to review
 - When you have finished reviewing that item, close the browser window and you will be returned to the meeting agenda
 - **Paper items** will be reviewed off-line

Add Reviewer Notes

Two methods are available to add reviewer notes: View Study or Reviewer Version

- Click on **View Study button**
 - Page by page review of the agenda item
 - Click on **Add button**, write your reviewer note, and **click the OK button before closing** the window
- Click on **Reviewer Version button** (preferred method)
 - Provides a view of the entire IRB protocol on one page
 - Click on the [\[reviewer notes\]](#) link which will automatically take you to the specific page where you can **Add** your reviewer note
 - Remember to click on the [\[reviewer notes\]](#) link found at the **top of each question or set of questions**
 - When you have completed your comment(s), click on the **RED** button located in top right-hand corner of the page which will close the browser (most browsers) and you will be returned to the meeting agenda
- If more than one question exists on the page, 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
- Edit your reviewer notes
 - Click on **View Study button** go to the reviewer note you wish to edit (Add, Delete, Next or Previous buttons available)
 - Click on the reviewer note (e.g., [Committee Comment \(Private\)](#))
 - Window pops up and you can edit your comments
 - Ability to edit comments before or during the convened meeting
 - You can cut and paste your comments from a Word document
 - You can cut and paste sections from the application and add to your reviewer comments

Assigned as Primary, Secondary, or Non-Scientific Reviewer

- The **My Tasks** tab
 - Lists all agenda items which you are assigned
 - Preferred method for review is using the **Meeting Agenda** as outlined previously
- Under **My Activities** section of a study's workspace
 - Click on **Complete Review** which is based on your reviewer role (primary, secondary, non-scientific)
- Window opens which contains 3 sections
 - **My Reviewer Notes** – publishes all your reviewer notes
 - Viewable only to you and the IRB staff
 - **Brief Summary** – synopsis of study to be presented at convened meeting
 - Viewable by all committee members and IRB staff
 - **Add attachments-** click on add and browser opens
 - Upload the checklist - Designated reviewers assigned to **NEW STUDIES** are required to complete the **checklist**

- Upload the consent document(s) if track changes utilized for review
- Upload any other supporting documents
- **Instructions for uploading a document** (e.g., checklist, consent)
 - 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, disk)
 - Click OK to publish the document into OSIRIS
- Remember to click **OK** to save your work before closing the window

You have now reviewed the study, added reviewer notes as needed, and completed your role as an assigned reviewer.

How to review a study that was reconsidered

- From the Reconsidered study workspace
 - Review all of the previous meeting comments by opening the “**Letter to PI**”
 - Click on [\[View\]](#) in the summary section located to the right of the “**Letter to PI**”
 - Displays all the committee comments for reconsidering the study
- Click on the first comment in the letter you wish to review
 - Example: 1. [2.6 - Experimental Interventions](#) Please provide detailed information on each research procedure to be conducted.
 - Be sure to click on the hyperlink ([2.6 - Experimental Interventions](#)) which will open another page directly in the OSIRIS application
- Click on the Committee Change Request to view the committee and PI comments



- This Opens a textbox displaying both the comment from the committee and the PI's response
- Close the window or click on “Cancel” when your review of this comment is completed
- Add an additional comment regarding the PI's response
 - Click on the “**Add**” button in the Reviewer notes section as you normally do to add other comments
- To go back to the letter to view the committee comments for reconsideration
 - Click on the “<<**Back**” button located directly about the “**Reviewer Note**” section
 - You are now back to the “Letter to PI” where you can click on the next comment and continue your review
- Other Review Options
 - Using “**View Study**”
 - Go to the study workspace and click on “**View Study**”
 - Click on the “**Next**” button in the “**Reviewer Note**” section to review all the “**Committee Change Request**” comments
 - Again use the “**Add**” button in the Reviewer Notes section to add your comment
 - Using the “**Change Log**”
 - Go to the study workspace and click on “**Change Log**”
 - Click on the hyperlink “[Change Log: Page 5.12...](#)” to display the highlighted changes within the OSIRIS application

Reviewer Notes

IRB Reviewer Notes

Meeting Minutes

History

Attachments

Change Log

Shows all changes made after submission!

[Activity](#)



[Change Log: Page 5.12 - 5.13 - Participation Offers Direct Benefit, Monitoring Plan](#)



[On Page 5.12 - 5.13 - Participation Offers Direct Benefit, Monitoring Plan](#)