

Scientific Review Process in OSIRIS

As part of the ongoing process to enhance the functionality of OSIRIS, the IRB has improved the process to conduct scientific reviews of human subject research studies, prior to their formal submission to the IRB. Until now, only the designated approvers from each scientific review entity had access to studies in OSIRIS. We have introduced a system whereby the designated approvers may assign individuals to conduct the scientific review by granting a "Read Only" access to the research study within OSIRIS. This will eliminate the need to export research proposals (including the protocol summary, consent forms, OSIRIS smart forms, multi-center protocol, drug and device information, investigator's brochure, etc.) from OSIRIS onto a server or to email individuals within your department, division, school, or center who review proposals for scientific merit. This process is described in more detail below:

1. Designated Approvers
2. Log into OSIRIS and go to the study to be reviewed
3. Go to "**My Activities**" and click on "**Assign Read Only Reviewers**"



Assign Read Only Reviewers

4. Text box pops up

The screenshot shows a web browser window with the URL https://www.osiris.pitt.edu/osiris/ResourceAdministration/Activityform?_webNew=all&ActivityTy.... The page content includes:

- 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 can not edit the project
 - This is typically used to grant access to reviewers who have a need to view the project but not edit 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 people 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:
A dropdown menu is shown with "Add" selected.
- Reviewers** - click the "Add" button to search and select the name(s) to be added as reviewer(s):
An "Add" button is visible. Below it, "There are no items to display" is shown.
- 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:
A large text input area is provided.

5. Action – select "**Add**" from the dropdown list to add reviewers or select "**Remove**" to remove reviewers previously assigned
6. Reviewers – click the "**Add**" button to build the list of reviewers (only those individuals who have completed the required education modules will be selectable)
7. Use the "**Comments/Instructions**" section to provide specific instructions to your reviewers
8. Click the "**OK**" button located in the bottom right-hand corner of the text box to save your work (currently hidden on this view) and an email will be sent by OSIRIS to all selected reviewers. This notification will inform the reviewer that they have Read Only access to an OSIRIS study.
9. The assigned reviewers will have access to review the study and also to review the response to comments
10. OSIRIS will automatically remove the "**Read Only**" access once the study is approved for scientific merit and assigned Read Only reviewers will no longer have access
11. The designated scientific approvers will continue to have access to all studies from their department, division, school, or center