Single Site or Multi-Site Study: Report New Information (RNI)

Reporting New Information (RNI) – Step by Step Instructions

The IRB system is available at https://irb.energy.gov

A RNI is submitted if there are issues related to but not limited to:

- Unanticipated problems
- Adverse events
- Non-compliance
- Subject complaints
- Protocol deviations
- Loss or potential loss of personally identifiable information (PII)
- Premature suspension or termination of protocol by the sponsor, investigator, or institution
- (Or others depending on your site)

Note: Studies that go to the Central DOE IRBs must be reported immediately. Check with your local site IRB Coordinator on timeline to submit an RNI to the Board.

The steps for reporting new information are outlined below. Single site and multi-site studies follow the same process.

Steps for creating a new study, modifications, continuing reviews, or closures for studies are different and documentation on those steps can be obtained by contacting your IRB administrator or can be found in the DOE library. If you do not know your IRB administrator, please visit the DOE website that lists the site IRB administrators at https://science.osti.gov/ber/human-subjects/IRBs.

Dashboard

When you log in, you will arrive on the Dashboard.

It has a left menu that lists studies recently reviewed by you. You can "pin" studies. This "pin" allows the user to "pin" an important study indefinitely for continued access. To "unpin" just click the pin icon.

(If you are a new Investigator the Recently Viewed will be blank).

- It will open in the "My Inbox" workspace.
- Any study you are working on but have not submitted to the IRB yet will appear in this area.
- Any studies that are awaiting actions by you will appear here.

Navigation Elements within a Study

Once you open a study, you see the study workspace. The workspace is your access point for:

- Viewing the study contents and details, including all actions performed on it
- Performing actions on the study

The figure below identifies the key workspace elements that help you find your way around the IRB system and perform actions on the study.
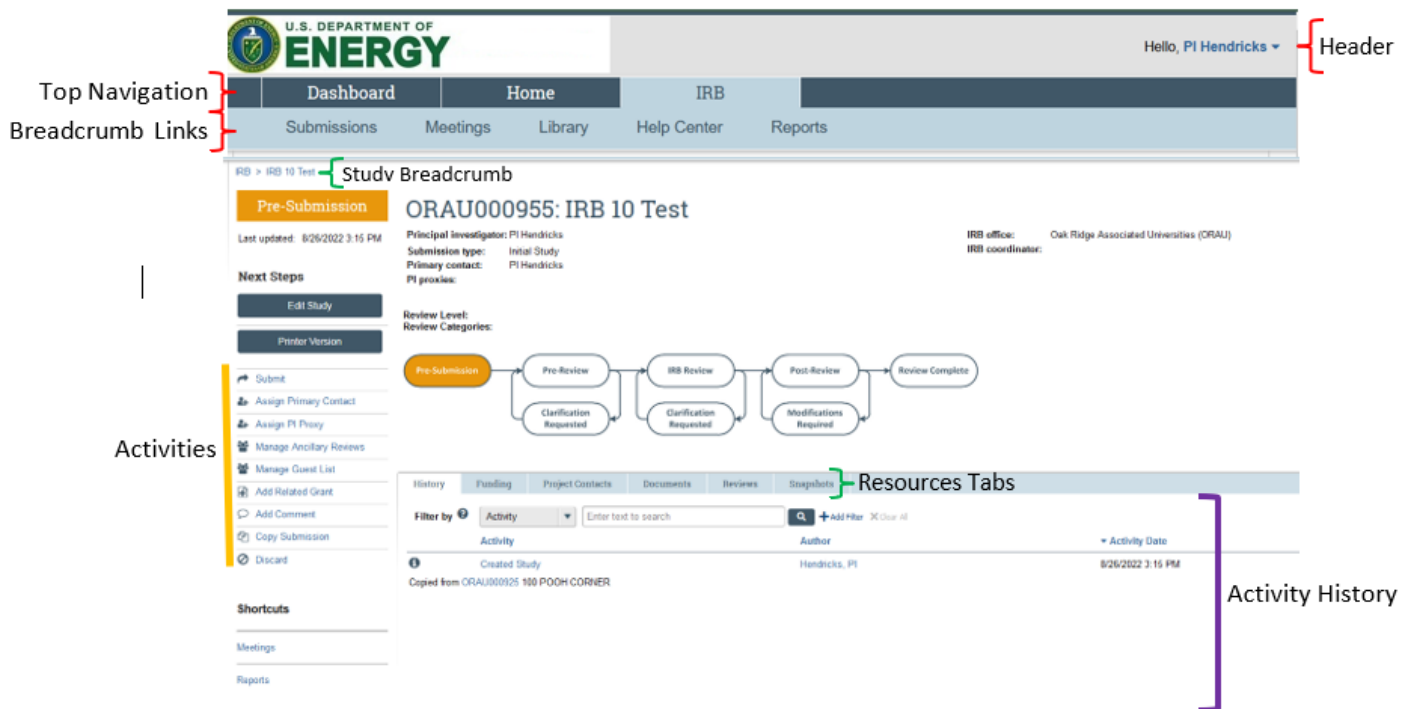
The key elements shown (from top to bottom) are:

- **Header**: Provides links to your profile and lets you log in and log off
- **Top navigation**: Provides links to My Inbox and the major sections of the system you are allowed to access
  - Breadcrumb navigator (>>): Tracks your movement through the hierarchy of pages and enables you to quickly move back to a previous location
- **Breadcrumb Links**: Provides links to documentation resources (similar to Shortcuts area)
- **Study Breadcrumb:** Provides a link back to parent study if on a follow-on submission
- **Activities**: Lets you take appropriate actions—such as viewing the study—based on the study's current status
- **Resource tabs**: Gives access to collected study information, such as the study team membership, documents attached to the study, and older versions of the study.
- **Activity history**: Displays the actions taken previously on this study

Creating a RNI

Log in to IRB system.

Click on the"IRB" tab on top navigation bar and locate the study that the RNI is needed for under the "Active" tab. Once you have located the study, click on the name of the study to open the workspace.

On the study workspace, click "Report New Information".

Filling out the FORM

Reportable New Information

Enter all information on this page.

Further guidance is below:

- The approved study that was selected displays under the "Related studies and modification" field.
- **This does not appear for single site studies. For non-External Multi-site study only.** Two additional questions appear and do not display the approved participating site (pSite). All active pSites are listed to choose from.
  - Reporting participating site
  - Affected participating site

6. Related studies and modifications: ⊙

ID	Short Title	Investigator	State	IRB Office
ORAU000698	1.23 Multi-site study	PI Hendricks	Approved	Oak Ridge Associated Universities (ORAU)

7. Reporting participating site:

8. Affected participating sites:

ID	Short Title	Investigator	State	IRB Office
There are no items to display				

9. Attach files containing supporting information:

Submitting your study for IRB review

- Once your study information is complete and you are ready to submit it to the IRB for review, you will need to click the **Submit RNI button** on the left-hand side of the study home page.
- **NOTE**: Clicking the **Discard** button below the Submit button will delete the study information and attachments you have entered. There is no way to recover a study once it has been discarded before submittal to the IRB for review.

After you have submitted the study for review, you will receive correspondence from the IRB through the IRB system. An email notification will be sent to your primary email listed in the IRB system to notify you of any waiting questions about your study or approvals of your study.

Returning to the Parent Study

To get back to the Parent study, click on the Parent study name at the top left corner of the page.

The Parent name will be listed first (e.g., IRB 10 Test) followed by the follow-on submission (e.g., RNI) name.

If you need any assistance while submitting to the IRB system, please contact your IRB administrator. If you do not know your IRB administrator, please visit the DOE website that lists the site IRB administrators at https://science.osti.gov/ber/human-subjects/IRBs.