Multi-site or Collaborative Study

Creating a new Multi-site Study – Step by Step Instructions

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

A multi-site study involves research from a single protocol carried out at multiple institutions.

A collaborative study is where two or more institutions coordinate to complete a portion of the research outlined in a specific protocol.

One institution serves as the single IRB (sIRB) of record and other institutions serve as participating sites (pSite). The sIRB assumes review responsibility for the study at all sites, including the institution where the sIRB is located and any other participating institutions. The study submission describes all the research and study-related materials submitted to the sIRB. The pSite submission covers the study-related materials of a pSite. A multi-site study can be submitted and approved without adding a pSite to the study.

A multi-site study includes several parts:

- A **study** submission describes the research and the study-related details of the institution serving as the sIRB of record.
- **Site** submissions that represent the study-related details of each pSite.

The steps for creating a new study are outlined below.

Steps for creating modifications, continuing reviews, closures, or adverse events 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.

Make sure all documentation has been submitted with your study in the IRB system.

** If you are submitting a new study to the Central DOE IRB, the Central DOE IRB requires that Principal Investigators (PI) include a signed *HRP-422: Checklist Required Training* for each member of the research team who interacts with human subjects or uses their identifiable private information every year.

NOTE: A study involving multiple DOE sites is submitted to the Central DOE IRB (CDOERIB). The PI will select 'single-site study' for this kind of study.

Dashboard

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

It has a left menu that lists studies recently viewed 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.
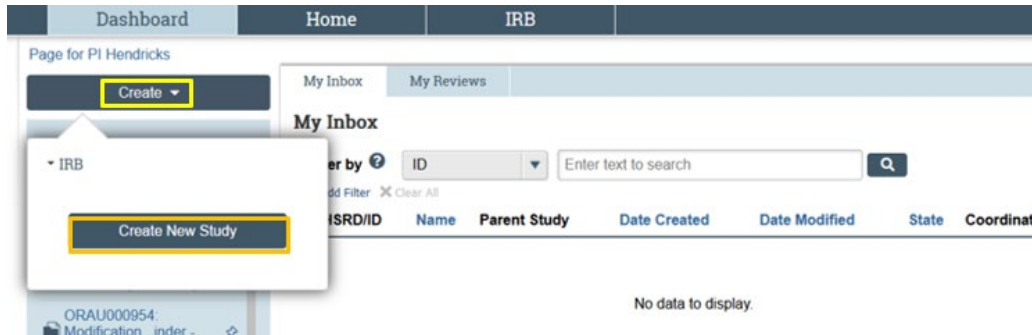
(If you are a new PI the Recently Viewed will be blank).

The Dashboard 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.
- To open the full IRB workspace, click on the IRB tab.

Click on the **Create** - **Create New Study** button.

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.
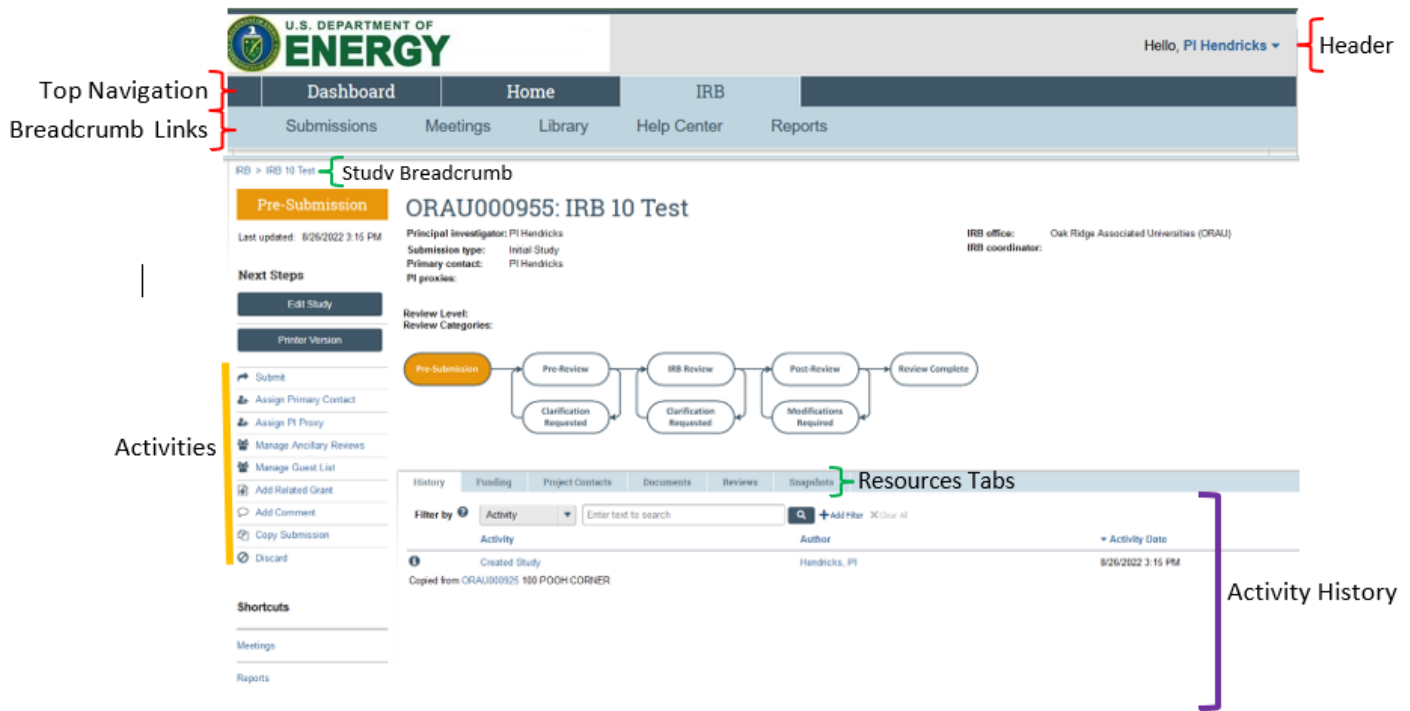
The key elements shown (from top to bottom) are:

- **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 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

Navigation Elements on the Smartform

Once you start the workflow, you will see navigation to other pages within the smartform on the left side. This will help you if you must jump to and edit any specific pages within the smartform.

To hide the navigation, click the close << icon. To reopen the navigation, click on the >> icon.

Filling out the FORM

Basic Study Information

Enter all information on this page, including attaching your protocol document at the end of the page. If a protocol is not written the application form may be enough information for review, however, the board may request a protocol be written.

Further guidance is below:

- Question 3. Abstract for HSRD field is used for the DOE Human Subjects Research Database (HSRD) and will be **published on a public facing website**. Please include a short general overview of your study that you are comfortable sharing with the **public.** (This is a required field.)

  3. * HSRD Abstract - For public facing DOE webpage: ❓

  ```
  For public view|
  ```

- Question 4. What kind of study is?
  - Multi-site or Collaborative study: A multi-site study involves research from a single protocol carried out at multiple institutions. A collaborative study is one where two or more institutions coordinate to complete a portion of the research outlined in a specific protocol. One institution serves as the single IRB of record.
    - **NOTE**: A study involving multiple DOE sites is submitted to the Central DOE IRB (CDOERIB). The PI will select 'single-site study' for this kind of study.
  - Single-site study: A single-site study is where all research occurs at one institution.

  4. * What kind of study is this? ❓
  - ⬤ Multi-site or Collaborative study
  - ⭕ Single-site study
  - Clear

- Question 5. Will an external IRB act as the IRB of record for this study? Only answer yes to this question if your IRB has agreed to an Institutional Authorization Agreement/Reliance Agreement with an external IRB reviewing your research. The external IRB reviews the study and acts as the IRB of record.
  - If more than one IRB will review the research the answer to this question is No.
  - If the study is going to the Central DOE IRB, the answer to this question is No.
- Question 6. Will your IRB act as the single IRB of record for other participating sites? (Only appears when select Multi-site study).
  - Select Yes if the IRB at your institution will be responsible for reviewing the submission on behalf of all sites participating in this study.
- Question 11. Which IRB should oversee this study? Select your site IRB.
  - **NOTE**: A study involving multiple DOE sites is submitted to the Central DOE IRB (CDOEIRB).
- Question 12. Attach the protocol.
  - *Please check with your IRB Administrator if there is a specific site protocol that is used. It may be available in your Site Library. Attach your protocol.

Tip- At this point all the basic information for the study has been entered. Click the Save button at the top. If you want to exit now, you can re-enter a study to edit information by clicking the Edit Study button on the

[Edit Study]

left side of the home page.

Study Funding Sources

Provide the funding information for your study. This will also be published in the HSRD if the funding is from a federal agency. To select the funding agency, select the *Add* button under "Identify each organization supplying funding for this study". The Organization added "ID" to show along with name and category for selecting a source.

- If the funding is from a federal agency that is not DOE please populate the Sponsor's funding ID.

- If the study is not funded an explanation must be provided.

Study Funding Sources

1. *Identify each organization supplying funding for the study:

[+ Add]

Funding Source	Sponsor's Funding ID	Attachments	Funding Category
Centers for Disease Control and Prevention (CDC)			

2. * Current Total FY funding from all sources not previously reported ($):

[$2.00]

3. Total project funding received in the last 3 FY (excluding current FY) ($):

[ ]

4. Please explain the funding amount listed (if zero or empty):

[ ]

Add Funding Source field

1. * Funding organization: ❓

[___]

2. Sponsor's funding ID: (assigned by external sponsor)

[ ]

3. Grants office ID: (assigned internally)

[ ]

4. Attach files: (include any grant applications)

[+ Add]

Document	Category	Date Modified	Document History
There are no items to display			

Local Study Team Members

Add additional study team members on this page.

- Study team members from your institution can be added by selecting the _Add_ button under "Identify each additional person involved in design, conduct, or reporting of the research". Do not include the PI here. Email (preferred email) now appears with name and organization when selecting a person.
  - **Note**: If the person you are adding here does not show in the list, please contact your IRB administrator to have them add the person to the system.
  - Only active accounts are shown, not deactivated accounts.
  - If a person is not listed as a staff member then cannot access the submission.
  - If you want a staff member to act on your behalf as a PI Proxy to submit a future follow-on submission to the IRB, the person must be listed on the Local Study Team Members page.
- Researchers outside your institution (external team members) can be added using the _Add_ under "External team member information". Add the CV/Resume for the researcher and "title" it with the researcher's name. Ignore the "Show Advanced Options" button.

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ❓

[+ Add]

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
There are no items to display					

2. External team member information: ❓

[+ Add]

Name	Description
There are no items to display	

PI Proxy

Only an PI or PI proxy (staff member that can submit on behalf of the PI) can submit to the IRB. The PI proxy has to be listed as staff in the IRB submission. Alert the IRB coordinator if you want to make a staff member a PI proxy for the study.

Study Scope

Answer the yes/no questions on the study scope page. If you answer yes to any of these questions additional information will be required. For help, see Appendix A "Additional Questions for Drugs or Devices" below.

Study Scope ❷

1. *** Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?** ❷
   ○ Yes ○ No Clear

2. *** Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?** ❷
   ○ Yes ○ No Clear

Local Research Locations

Add local research locations where research activities will be conducted or overseen by the local PI on this page. For example, A PI has an appointment at the university. If the PI conducts research in a local elementary school, a nursing home, or a private physician's office, those may be considered research locations.

Local Research Locations ❷

1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

   + Add

Location	Contact	Phone	Email
There are no items to display			

Study Related Documents

Any consent forms, information sheets, and recruitment materials that are required **study-wide** and that pSite will use should be attached here.

Study-Related Documents

1. **Consent form templates:** (include an HHS-approved sample consent document, if applicable)

   + Add

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

   + Add

Document	Category	Date Modified	Document History
There are no items to display			

3. **Other attachments:**

   + Add

Document	Category	Date Modified	Document History
There are no items to display			

❶ Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

Local Site Documents

Any consent forms, information sheets, and recruitment materials that are specific to **your site** should be attached here.

*Please check with your IRB Administrator if there is a specific site consent form(s) that is used. It may be available in your Site Library.

Local Site Documents ❷

1. Consent forms: (include an HHS-approved sample consent document, if applicable) ❷

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads) ❷

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

ⓘ Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

Additional Information

Answer the yes/no questions on the Additional DOE Information page. If you answer yes to any of these questions additional information will be required. For help, see Appendix B "Additional Questions for International" below.

- Clinical trial information
  - Any study that is a clinical trial must provide a clinicaltrials.gov ID

Additional Information

1. * Is this a Clinical Trial? ○ Yes ○ No _Clear_

2. Please enter the clinicaltrials.gov ID:

[   ]

3. * Does protocol meet DOE PII requirements?: ○ Yes ○ No _Clear_

https://science.energy.gov/ber/human-subjects/regulations-and-requirements/doe-specific-requirements/#ProtectionOfData

4. * Is this project FDA regulated? ○ Yes ○ No _Clear_

5. * Will this research be considered international by DOE for any reason? ○ Yes ○ No _Clear_

6. * Does this research result in subjects' exposure to chemicals that would be viewed as hazardous for any reason? ○ Yes ○ No _Clear_

**7. * Does this study involve exposure to radiation?** ○ Yes ○ No _Clear_

Final Page

Selecting _Continue_ will take you out of the study. **THIS WILL NOT SUBMIT YOUR STUDY FOR REVIEW.**

Editing: ORAU000955

◀ Go to forms menu 🖶 Print ▾ ❓ Help

Final Page

In order to complete your submission:

- Click the "Continue" button.

- This takes you back to the study workspace.

- Click the "Submit" button on the study workspace.

❌ Exit   💾 Save   **Continue** ➡
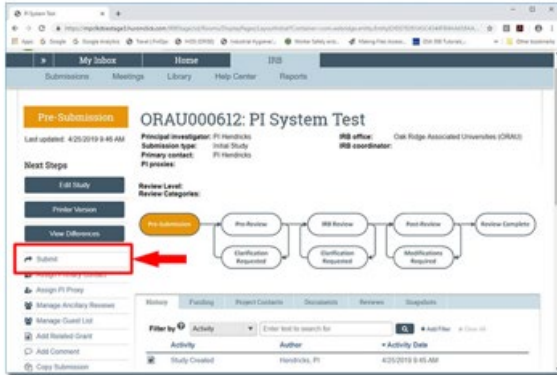
Submitting your study for IRB review

- 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 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.
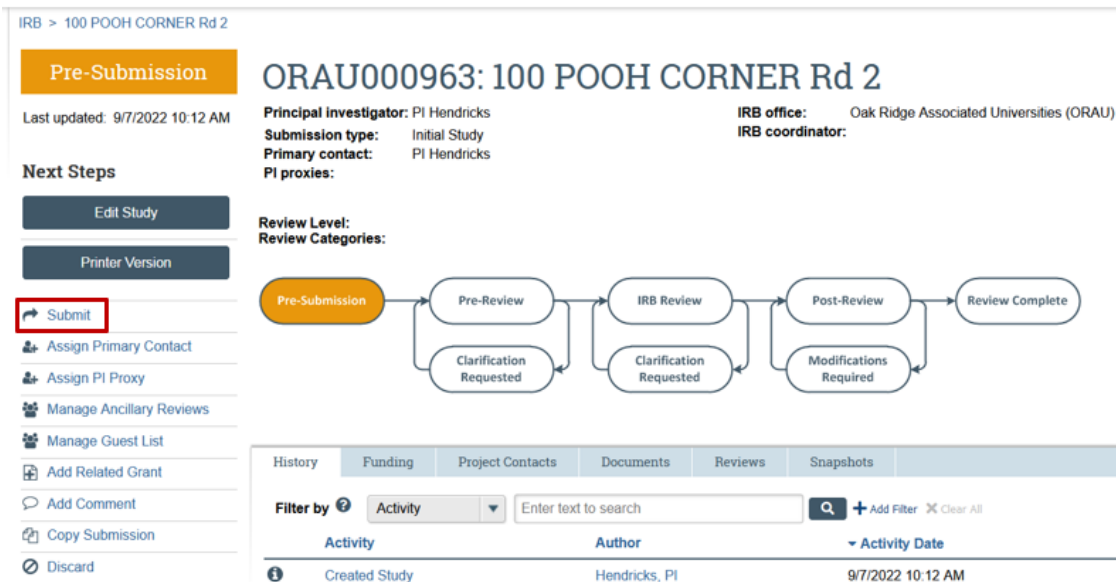
Managing Participating Sites

NOTE: Use caution if using pSite for a multi-site study. If you select a pSite, the workflow must be completed.

On the study workspace, click **Manage Participating Sites** button.

- You can only add a pSite if an Institutional Profile/account has been added to IRB. If you do not see your pSite, contact your IRB administrator.
- You can only add a PI if an account has been added to IRB. If you do not see the PI, contact your IRB administrator.

In the History, you will see a pSite has been listed but **not** created. In the Sites tab, you will see the site is listed as "participating sites pending creation'. The PI can add or delete pSites before the study is in the Pre-Review completed stage.

The pSite is created when the IRB Coordinator submits the study Pre-Review.

The PI cannot edit the site information and submit Site Materials before the study has been approved. See **Multisite_pSite - Edit a New Site**.

Appendix A: Drugs and Devices

Additional Questions for Drugs or Devices.

1. **Drugs –** Information about all drugs, biologics, foods, and dietary supplements should be entered on this page
   a. If using a drug, be sure to provide the name and generic if available
   b. If using an IND, a number must be supplied

Drugs ❷

1. *** List all drugs, biologics, foods, and dietary supplements to be used in the study:**

   ✚ Add

Generic Name	Brand Name	Attachment Name
There are no items to display		

2. *** Will the study be conducted under any IND numbers?** ❷
   O Yes O No _Clear_

3. **Attach files:** (such as IND or other information that was not attached for a specific drug) ❷

   ✚ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. **Devices –** Each device the study will use must be listed on this page.
   a. Provide information on HUD or device
   b. Device exemptions
   c. Additional documents for exemption number

Devices ❷

1. *** Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

   ✚ Add

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. *** Device exemptions applicable to this study:** ❷
   O IDE number
   O HDE number
   O Claim of abbreviated IDE (nonsignificant risk device)
   O Exempt from IDE requirements
   Clear

3. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device) ❷

   ✚ Add

Document	Category	Date Modified	Document History
There are no items to display			

Appendix B: International Study Information

Additional Questions for International studies. Answer the yes/no questions and the country(ies) where the study is taking place. There are 6 questions listed on the page.

International Study Information

1. *** Is the study conducted using non-U.S. subjects?**
   ○ Yes ○ No Clear

   If yes, please provide country or countries:

Country
☐ Australia
☐ Canada
☐ England
☐ United Kingdom
☐ France
☐ Japan
☐ Russia
☐ Uganda
☐ China
☐ South Korea

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.