

External: Single Site Study

Creating a new External Single Study – Step by Step Instructions

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

External Studies are reviewed by an external IRB, i.e., the IRB of record for the study. External studies still must be submitted to the IRB system to update the Human Subjects Research Database.

The steps for creating a new study are outlined below.

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

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.

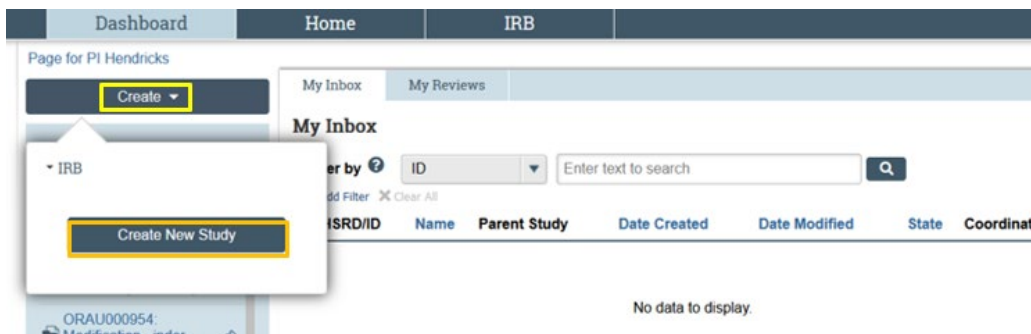
(If you are a new Principal Investigator (PI) the Recently Viewed will be blank).



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

When you open an existing 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 screenshot displays the IRB system workspace for a study titled "ORAU000955: IRB 10 Test". The interface is annotated with several key elements:

- Header:** Located at the top right, it displays the user's name "Hello, PI Hendricks" and a dropdown arrow.
- Top Navigation:** A horizontal bar below the header containing links for "Dashboard", "Home", "IRB", "Submissions", "Meetings", "Library", "Help Center", and "Reports".
- Breadcrumb Links:** A path starting with "IRB > IRB 10 Test" and a "Study Breadcrumb" link.
- Study Breadcrumb:** A green bracket highlights the "Study Breadcrumb" link.
- Activities:** A vertical sidebar on the left lists various actions such as "Submit", "Assign Primary Contact", "Assign PI Proxy", "Manage Ancillary Reviews", "Manage Guest List", "Add Related Grant", "Add Comment", "Copy Submission", and "Discard".
- Resources Tabs:** A horizontal bar above the activity history table, containing tabs for "History", "Funding", "Project Contacts", "Documents", "Reviews", and "Snapshots".
- Activity History:** A table below the tabs showing a list of activities, including "Created Study" by "Hendricks, PI" on "8/26/2022 3:15 PM".

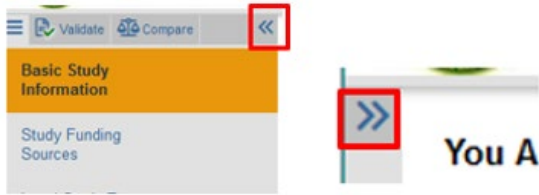
The key elements shown (from top to bottom) are:

- **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 to create a new study, 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: ?

- Question 4. What kind of study is this?
 - 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? ?

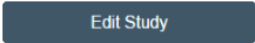
Multi-site or Collaborative study

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 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 10. Which IRB should oversee this study? Select your site IRB, even if your site IRB is relying on an external IRB for review.
 - **NOTE:** A study involving multiple DOE sites is submitted to the Central DOE IRB (CDOEIRB).
- Question 11. 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 left side of the home page.



External IRB

Select the external IRB and specify the reason the study is reviewed by an external IRB. The External study ID is the ID assigned to the study by the sIRB. You can use it as a reference when you correspond with the external IRB.

Note: If the External IRB you are adding here does not show in the list, please contact your IRB administrator to have them add the External IRB to the system.

External IRB

1. * External IRB: ?

2. External study ID: ?

3. Specify the reason the study should be reviewed by an external IRB:

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, they 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

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? 
 Yes No [Clear](#)
2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? 
 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, An 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

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			

Local Site Documents

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

For number 3, *Other attachments*, upload the external IRB’s approval letter, which should include the approval date, expiration date (if needed), Review type and category (e.g., Exempt 4). When you attach the document, select “Other” for the category.

*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

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

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)

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

3. Other attachments:

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](#)

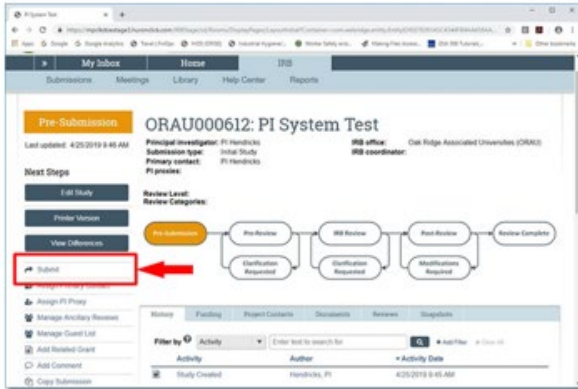
Final Page

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

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.



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.

Pre-Submission ORAU000702: 1.23 External Multisite

Last updated: 1/24/2019 10:44 AM

Principal investigator: PI Hendricks
Submission type: Initial Study
Primary contact: PI Hendricks
PI proxies:

IRB office: Oak Ridge Associated Universities (ORAU)
IRB coordinator:
External study ID:

Next Steps

- Edit Study
- Printer Version
- View Differences
- Submit**
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Correspond with sIRB
- Add Comment
- Copy Submission
- Discard

Review Level:
Review Categories:

History Funding Project Contacts Documents Reviews Snapshots

Filter by Activity Enter text to search for + Add Filter X Clear All

Activity	Author	Activity Date
Study Created	Hendricks, PI	1/24/2019 10:35 AM

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

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? 

Yes No [Clear](#)

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


+ 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

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: 

IDE number
 HDE number
 Claim of abbreviated IDE (nonsignificant risk device)
 Exempt from IDE requirements
[Clear](#)

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

+ 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 taken 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
<input type="checkbox"/> Australia
<input type="checkbox"/> Canada
<input type="checkbox"/> England
<input type="checkbox"/> United Kingdom
<input type="checkbox"/> France
<input type="checkbox"/> Japan
<input type="checkbox"/> Russia
<input type="checkbox"/> Uganda
<input type="checkbox"/> China
<input type="checkbox"/> 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>.