Single Site Study

Creating a new Single Study – Step by Step Instructions

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

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.

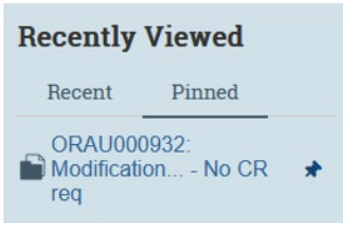
** If you are submitting a new study to the Central DOE IRB, the Central DOE IRB requires that Principal Investigators (PI) include a signed *HRP-422: Checklist Required Training* for each member of the research team who interacts with human subjects or uses their identifiable private information every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

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.

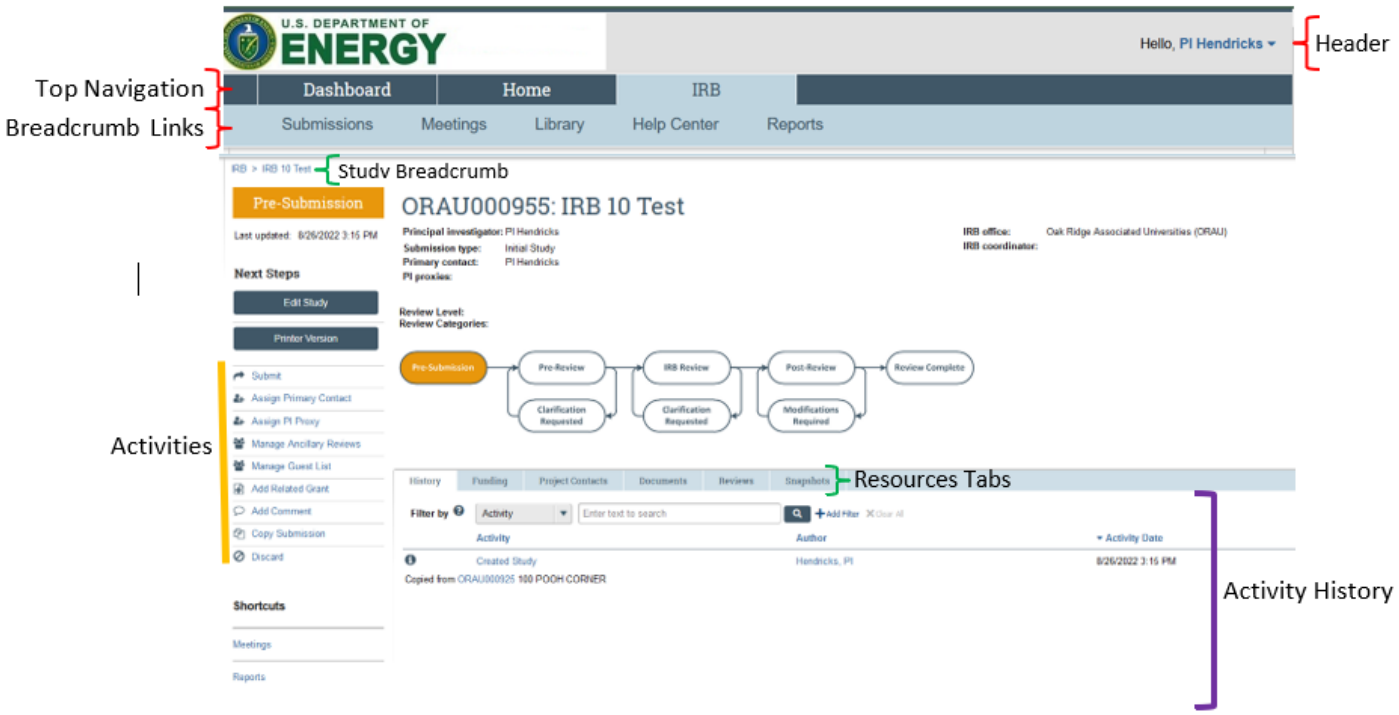
Click on the **Create** - **Create New Study** button.

Navigation Elements within a Study

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.



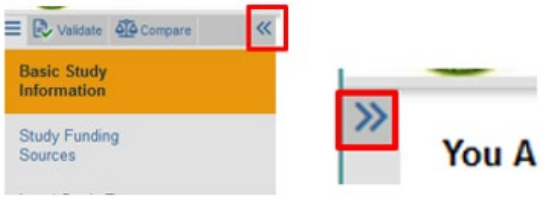
The key elements shown (from top to bottom) are:

- **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.



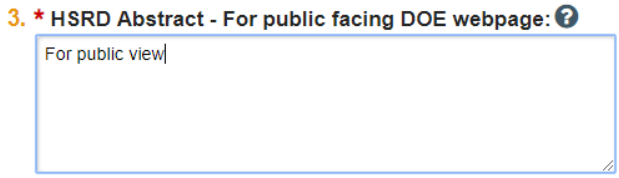
Filling out the FORM

Basic Study Information

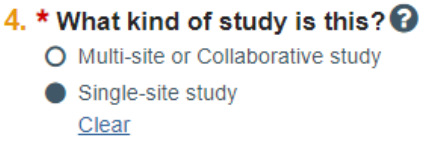
Enter all information on this page, including attaching your protocol document at the end of the page. If a protocol is not written the application form may be enough information for review, however, the board may request a protocol be written.

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.)

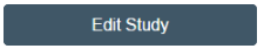


- Question 4. What kind of study is?
  - Multi-site or Collaborative study: A multi-site study involves research from a single protocol carried out at multiple institutions. A collaborative study is one where two or more institutions coordinate to complete a portion of the research outlined in a specific 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.



- 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.
  - **NOTE**: A study involving multiple DOE sites is submitted to the Central DOE IRB (CDOEIRB).

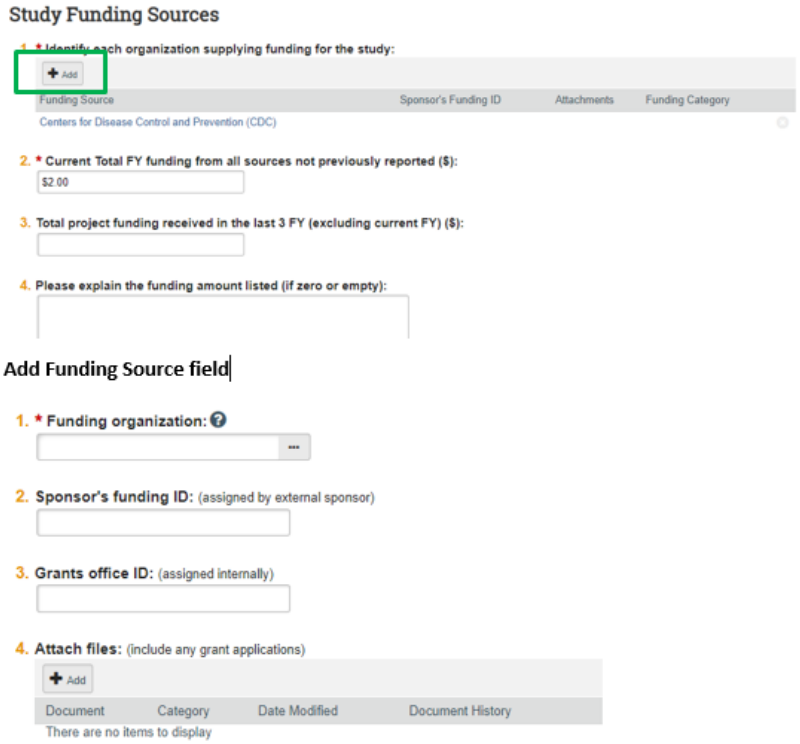
- Question 11. Attach the protocol.
    - *Please check with your IRB Administrator if there is a specific site protocol that is used. It may be available in your Site Library. Attach your protocol.

Tip- At this point all the basic information for the study has been entered. Click the Save button at the bottom. 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. 

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.



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.

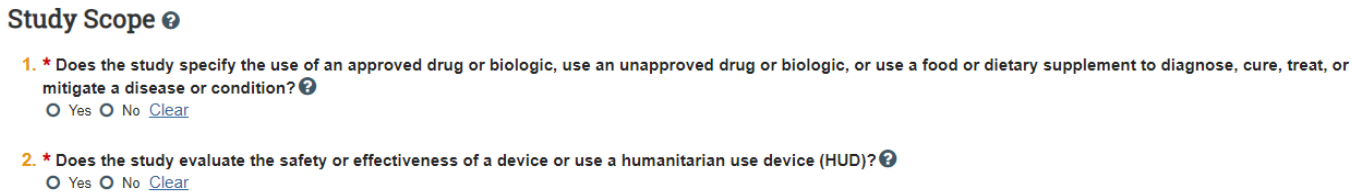
- Researchers outside your institution (external team members) can be added using the *Add* under "External team member information". Add the CV/Resume for the researcher and "title" it with the researcher's name. Ignore the "Show Advanced Options" button.

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.

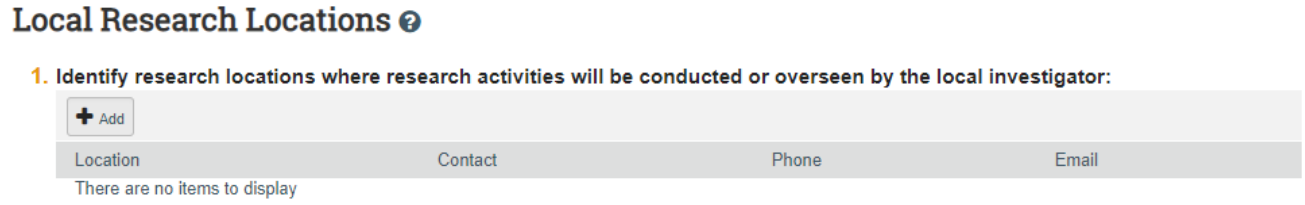
Study Scope

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.



Local Research Locations

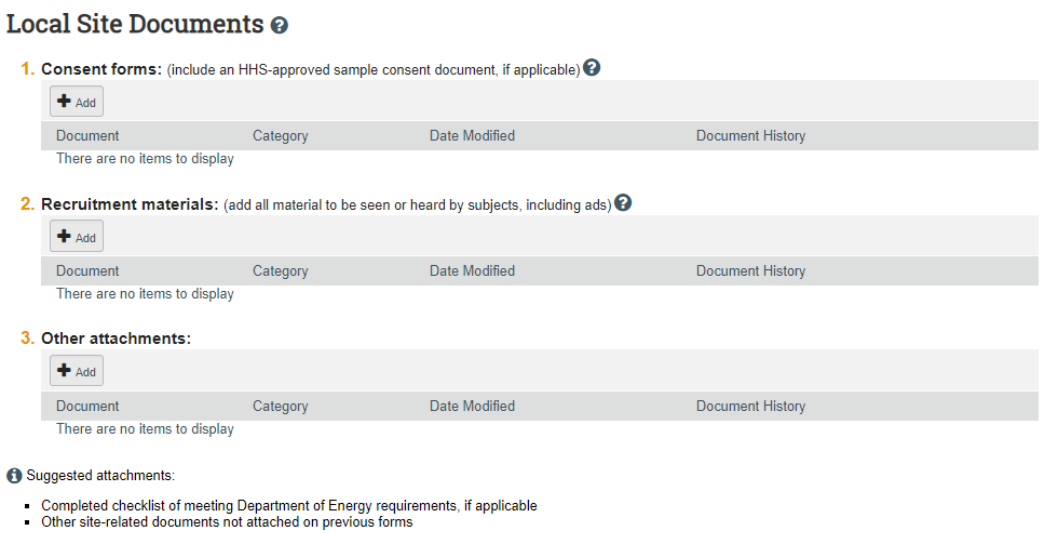
Add local research locations where research activities will be conducted or overseen by the local PI on this page. For example, an PI has an appointment at the university. If the PI conducts research in a local elementary school, a nursing home, or a private physician's office, those may be considered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



Local Site Documents

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

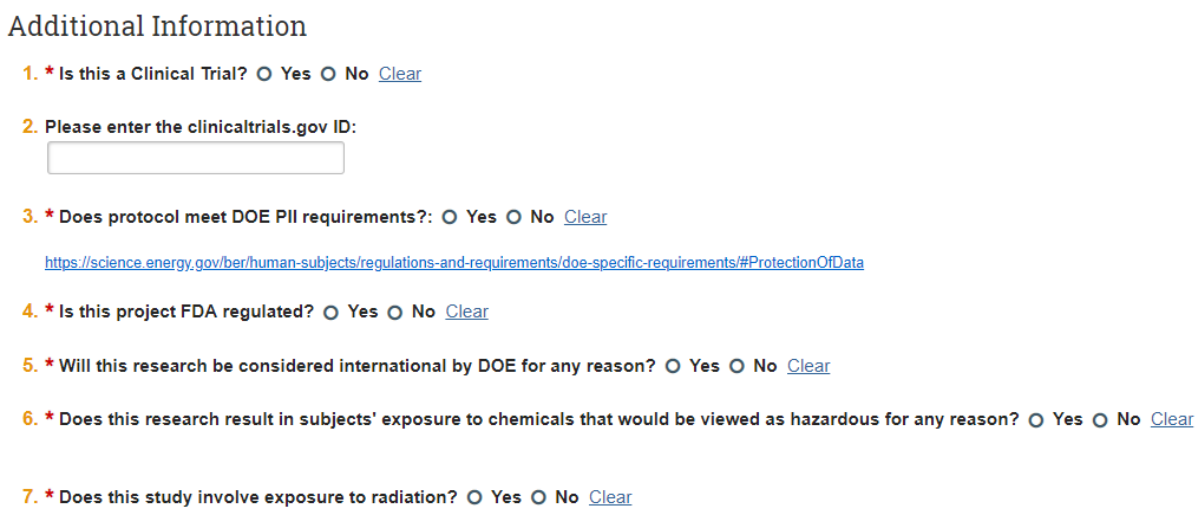
*Please check with your IRB Administrator if there is a specific site consent form(s) that is used. It may be available in your Site Library.



Additional Information

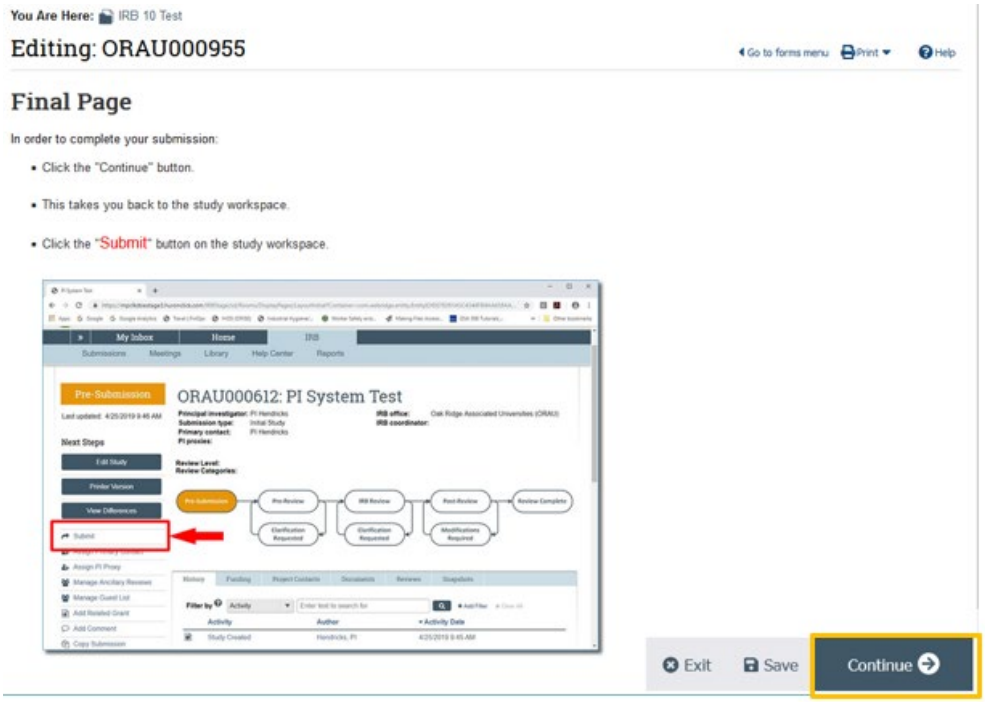
Answer the yes/no questions on the Additional DOE Information page. If you answer yes to any of these questions additional information will be required. For help, see Appendix B "Additional Questions for International" below.

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



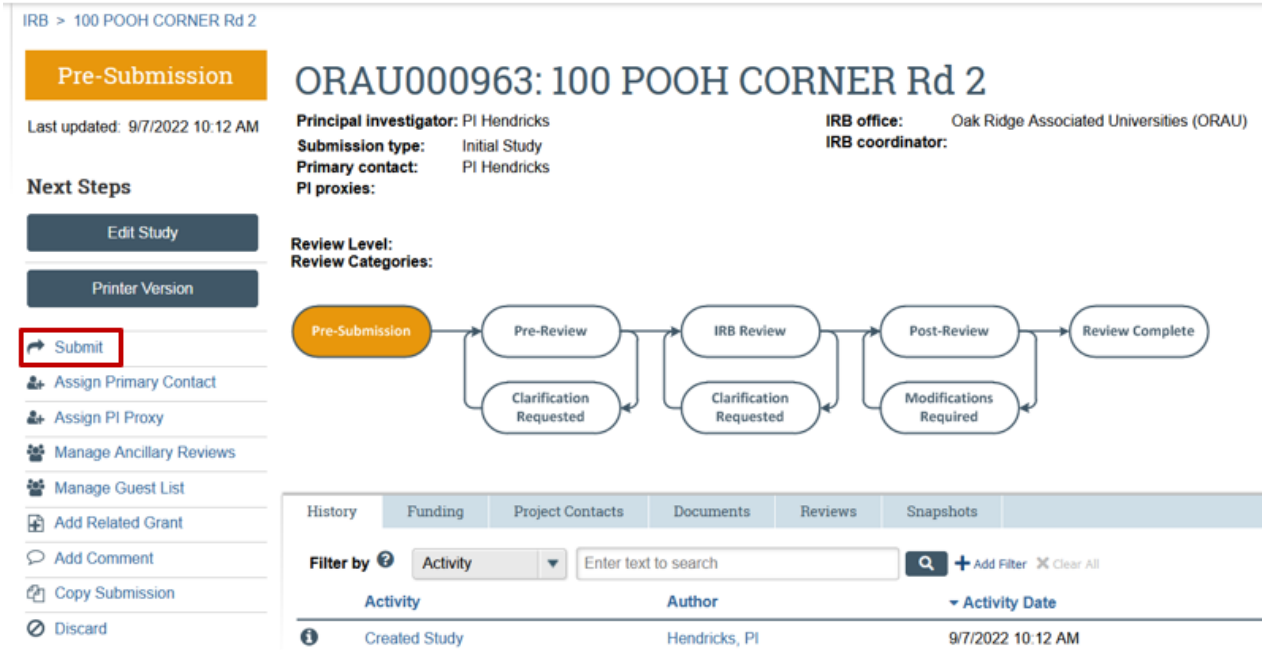
Final Page

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



Submitting your study for IRB review

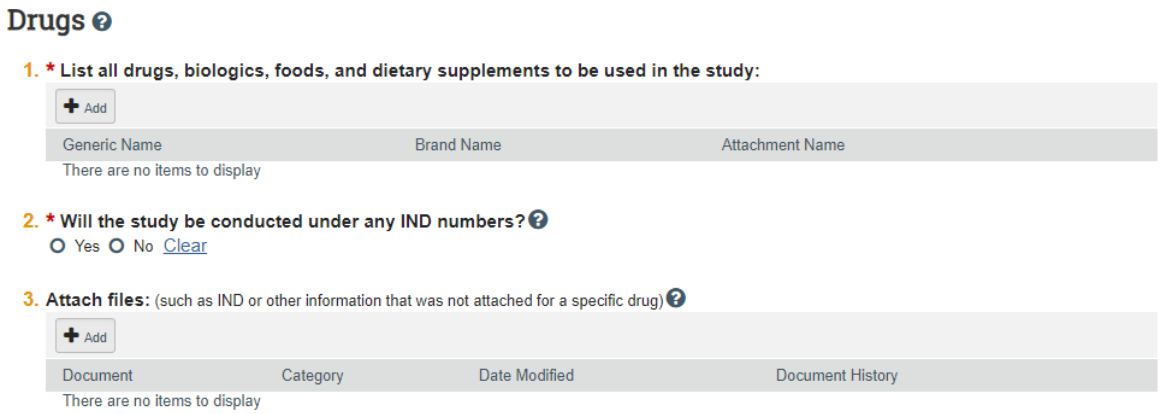
- Once your study information is complete and you are ready to submit it to the IRB for review, you will need to click the **Submit button** on the left-hand side of the study home page.
- **NOTE**: Clicking the **Discard** button below the Submit button will delete the study information and attachments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



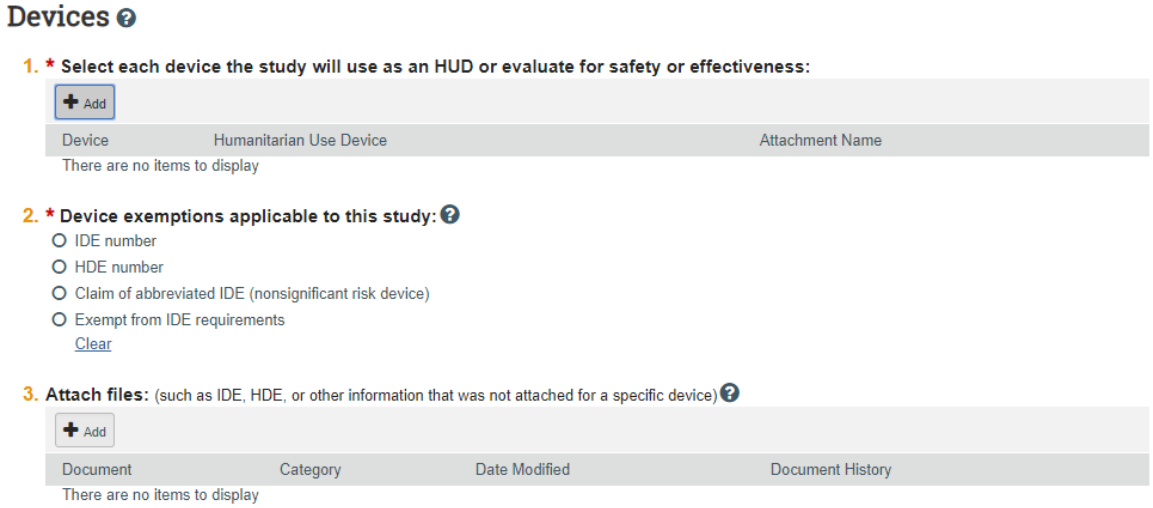
Appendix A: Drugs and Devices

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



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



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.

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.