

Single Site or Multi-site Study: MODIFICATION

Creating a Modification – Step by Step Instructions

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

A Modification is submitted if the following study elements have changed:

- the Principal Investigator (PI)
- study staff (adding or removing)
- annual funding or total funding
- total number of subjects, and/or
- any aspect of the protocol, consent form, or other supporting documents.

The steps for creating a modification (MOD) are outlined below. Single site and multi-site studies follow the same process.

Steps for creating a new study, 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>.

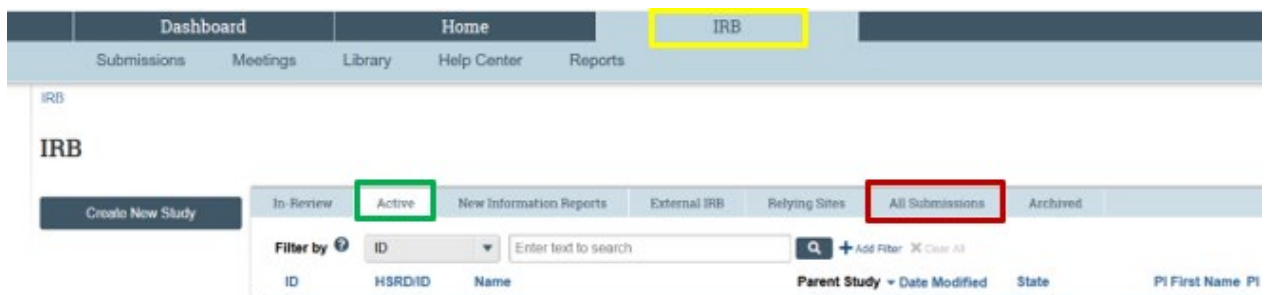
Dashboard and Navigation Elements within a Study

For detailed information about this, see the *Single Site Study - Creating a New Study* job aid.

Creating a Modification

Log in to the IRB system.

Click on the “IRB” tab on the top navigation bar and locate the study that the modification is needed for under the “Active” or “All Submissions” tab. Once you have located the study, click on the name of the study to open the workspace.



On the study workspace, click “Create Modification/CR”.

Dashboard	Home	IRB	
Submissions	Meetings	Library	Help Center Reports

IRB > 100 POOH CORNER ? Help

Approved

ORAU000925: 100 POOH CORNER

Entered IRB: 6/20/2022 12:52 PM
 Initial approval: 7/15/2022
 Initial effective: 7/15/2022
 Effective: 7/15/2022
 Last updated: 7/15/2022 1:28 PM

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

IRB office: Oak Ridge Associated Universities (ORAU)
IRB coordinator:
Letter: [Correspondence_for_ORAU000925.pdf\(0.01\)](#) ...
Regulatory authority: 2018 Requirements

Review Level: Exempt
Review Categories: (2)(iii) Tests, surveys, interviews, or observation (identifiable), and for which limited IRB review was conducted via expedited review

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

Filling out the FORM

Select “Modification / Update” for the purpose of the submission.

Modification / Continuing Review / Study Closure

IMPORTANT! - Continuing Review must be selected below for Closure.
The Continuing Review option is not available for External Multi-Site Modifications

- * What is the purpose of this submission? ?
- Continuing Review
 - Modification / Update
 - Modification and Continuing Review
- [Clear](#)

Select the type of information the modification will involve.

- * What is the purpose of this submission? ?
- Continuing Review
 - Modification / Update
 - Modification and Continuing Review
- [Clear](#)
- i** To change the PI, choose 'Other parts of the study/site' scope
- Modification scope:**
- Study team member information
 - Other parts of the study

NOTE: “Other parts of study” does **not** show the study team member page. To change a part of your study **and** study staff, you must select **both** options.

However, you can only submit one MOD type at a time. For example, you cannot have two study staff MODs open, but you can have a study staff MOD and other parts of the study MOD open at the same time.

Complete the Modification information section summarizing the changes/updates.

Modification Information

1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes


i Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Summarize the modifications: 

Study Team Member Information

Deleting a study staff member

Click on the “X” to delete the staff member.

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

						
	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
	Christopher Robin	Researcher Who Interacts with Human Subjects and/or Their Identifiable Data	no	yes	crobin@100acres.net	

Adding a study staff member

- Study team members 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.

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	
Update	Christopher Robin	Researcher Who Interacts with Human Subjects and/or Their Identifiable Data	no	yes	crobin@100acres.net		

2. External team member information: ?

+ Add	
Name	Description
There are no items to display	

PI Proxy

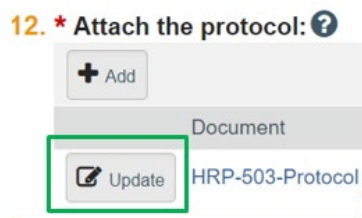
Only a PI or PI proxy (staff member that can submit on behalf of the PI) can submit to the IRB. The PI proxy has to be listed as staff in the IRB submission. Alert the IRB coordinator if you want to make a staff member a PI proxy for the study.

Other parts of study

*Please check with your IRB administrator if a site-specific modification form is required. It may be available in your Site Library.

If “Other parts of study” was selected

- Make any changes to the smartform
- Attach any new or updated forms in the appropriate smartform pages (e.g., consent forms on the Local Site Documents page).
 - a. If updating the document, click on the “Update button” next to the document. **Do not upload a track-changed document.** Click the OK button. See screen shot below:



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.

IRB > 100 POOH CORNER > Modification / Update #1 for Study 100 POOH CORNER Help

Pre-Submission

Last updated: 9/2/2022 1:16 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Update HSRD Information

Manage Ancillary Reviews

Add Comment

Discard

ORAU000956: Modification / Update #1 for Study 100 POOH CORNER

Principal investigator: PI Hendricks
Submission type: Modification / Update
Primary contact: PI Hendricks

IRB office: Oak Ridge Associated Universities (ORAU)
IRB coordinator:
Regulatory authority: 2018 Requirements

Review Level:
Review Categories:

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graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Clarification Requested]
    C --> B
    B --> D[IRB Review]
    D --> E[Clarification Requested]
    E --> D
    D --> F[Post-Review]
    F --> G[Modifications Required]
    G --> F
    F --> H[Review Complete]
    
```

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 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., 100 Pooh Corner) followed by the follow-on submission (e.g., Modification Name) name.

Dashboard Home IRB

Submissions Meetings Library Help Center Reports

IRB > **100 POOH CORNER** > Modification / Update #1 for Study 100 POOH CORNER Help

Pre-Review

Entered IRB: 9/2/2022 3:08 PM
 Last updated: 9/2/2022 3:08 PM

Next Steps

ORAU000956: Modification / Update #1 for Study 100 POOH CORNER

Principal investigator: PI Hendricks
Submission type: Modification / Update

IRB office: Oak Ridge Associated Universities (ORU)
IRB coordinator:

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