

Single Site or Multi-site Study: CONTINUING REVIEW or CLOSURE

Creating a Continuing Review or Closure – Step by Step Instructions

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

The steps for creating a continuing review or closure are outlined below. Single site and multi-site studies follow the same process. If there are any updates or changes to the study, you must submit a “Modification and Continuing Review” or a “Modification” separately.

Steps for creating a new study, modification, 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>.

Navigation Elements within a Study

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

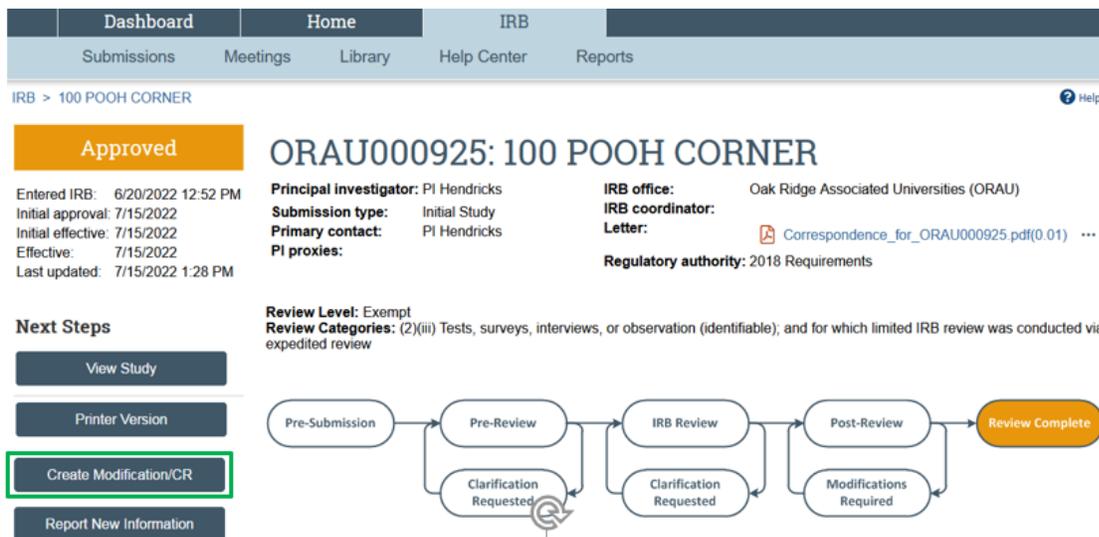
Creating a Continuing Review or Closure

Log in to the IRB system.

Click on the “IRB” tab on 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”.



Approved

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

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested (loop back to Pre-Review)

Modifications Required (loop back to IRB Review)

Filling out the FORM

Select “Continuing Review” 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](#)

Complete the questions on the continuing review page. For the project status results, provide a summary of what has been done on the study since the last review. Do not state “study is ongoing” or it will be returned to you.

10. * Project Status/Results:

Provide a brief summary of research activities since last reporting period [e.g. relevant recent literature, results, where you are in the project, etc).

Please **do not** only post "study is ongoing or study is complete", this will be returned to you to update.

Closure

If the study has closed, make sure to check all 4 boxes of the first Research Milestones.

- a. Check the box for “I acknowledge that this study will be closed”.

Important! - If the first four research milestones below are complete, the study will be closed to discontinue IRB oversight.

3. Research milestones: (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no PII was collected)
- Analysis of private identifiable information is complete OR not applicable (no PII was collected)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

* I acknowledge that this study will be closed

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

Last updated: 9/2/2022 3:33 PM

Next Steps

Edit Modification/CR

Printer Version

Submit

Update HSRD Information

Manage Ancillary Reviews

Add Comment

Discard

ORAU000957: Continuing Review for Study 100 POOH CORNER

Principal investigator: PI Hendricks
Submission type: Continuing Review
Primary contact: PI Hendricks

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



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

Dashboard Home IRB

Submissions Meetings Library Help Center Reports

IRB > **100 POOH CORNER** > Continuing Review for Study 100 POOH CORNER

Pre-Submission

ORAU000957: Continuing Review for Study 100 POOH CORNER

Last updated: 9/2/2022 3:33 PM

Principal investigator: PI Hendricks **IRB office:** Oak Ridge Associated Universities (ORAU)

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