

External Study: Closure

Requesting a Closure – Step by Step Instructions

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

A Principal Investigator cannot submit a continuing review to “close” the study for an external study. The steps for requesting a closure are outlined below. This applies to external single and multi-site studies.

Steps for creating a new study, modifications, 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>.

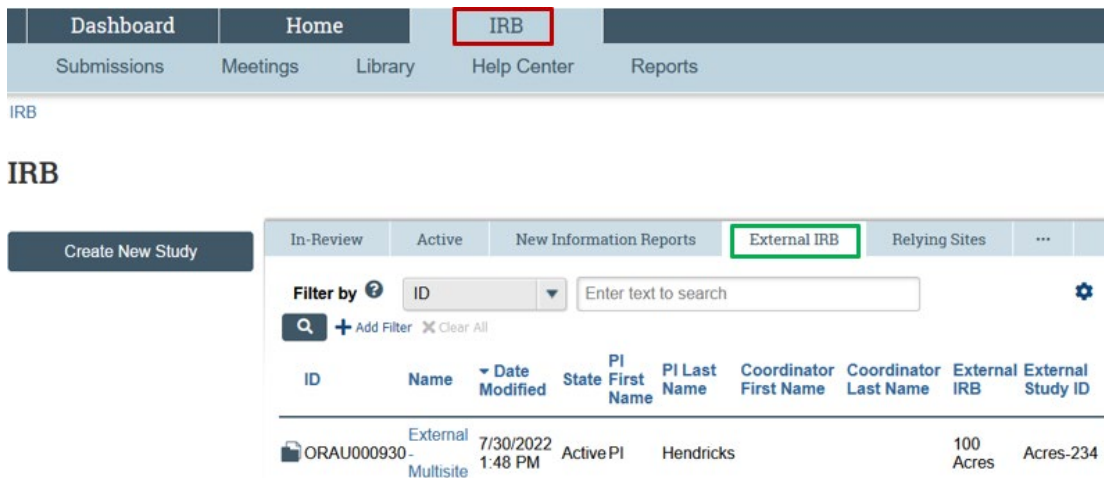
Dashboard and Navigation Elements within a Study

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

Request a Closure

Log in to IRB system.

Click on the “IRB” tab on top navigation bar and locate the study to be closed under the “External IRB” tab. Once you have located the study, click on the name of the study to open the workspace.



On the study workspace, click “Add Comment”. This is to alert the local site IRB Coordinator to close the study in the system. An email will be sent to the local site IRB Coordinator.



Do **not** select “Correspond with sIRB”. The email goes to the sIRB IRB Coordinator of the External IRB (e.g., the person listed as the point of contact for the external organization).

Filling out the Comment

1. Enter comments in the comment field. It can be something simple that states the study has closed.
2. Attach supporting documents if applicable.
3. Who should receive an e-mail notification? At a minimum, select the IRB Coordinator.

3. Who should receive an e-mail notification?

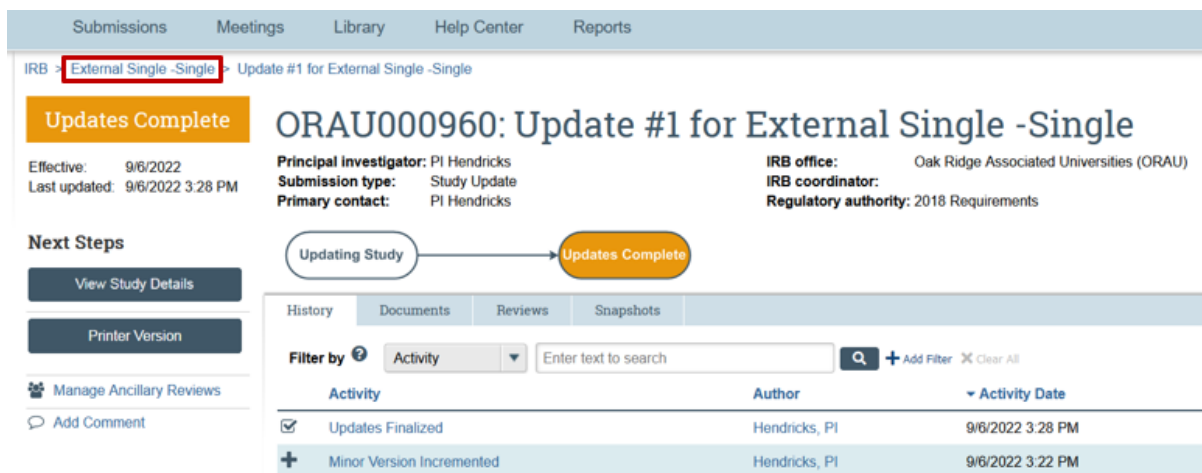
- PI/PI Proxy/Primary Contact
- Study Team
- IRB Coordinator

After you have submitted the closure comment 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.

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., External Single Single) followed by the follow-on submission (e.g., Update) name.



The screenshot shows the IRB system interface for study ORAU000960: Update #1 for External Single -Single. The breadcrumb trail is IRB > External Single -Single > Update #1 for External Single -Single. The status is 'Updates Complete'. The principal investigator is PI Hendricks, and the submission type is Study Update. The IRB office is Oak Ridge Associated Universities (ORAU). The activity history table is as follows:

Activity	Author	Activity Date
Updates Finalized	Hendricks, PI	9/6/2022 3:28 PM
Minor Version Incremented	Hendricks, PI	9/6/2022 3:22 PM

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>.