Study Closure

Please Note: The following process is for research studies. If your project was determined by the IRB to be 'Not Human Research' please contact Alice Pasvogel (apasv@arizona.edu) for instructions.

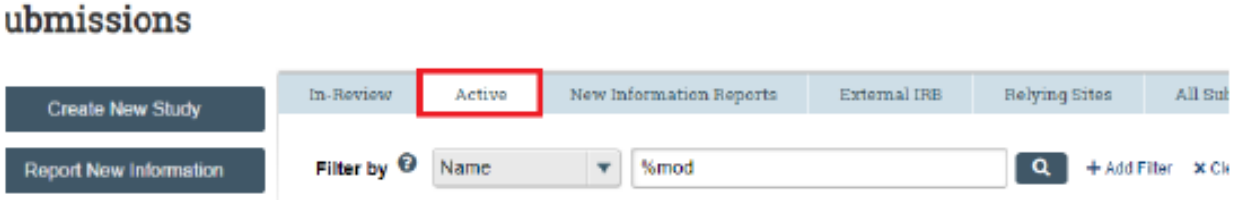
To close a research study, submit a Continuing Review (CR).

Go to UAccess (https://uaccess.arizona.edu) and click on eIRB. Log in using your UANet ID and Password.

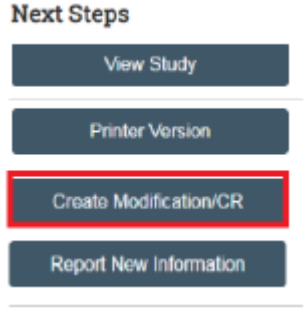
In the Top Navigator, click **IRB** and then **Submissions**.



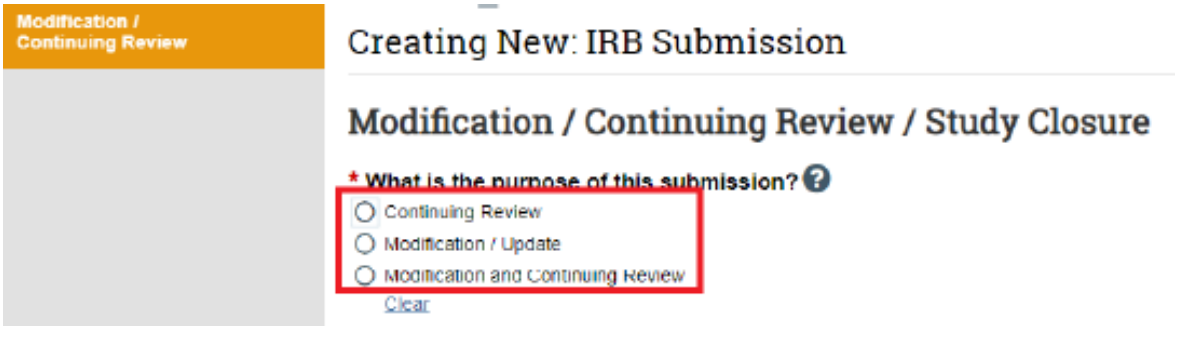
On the IRB page, click the **Active** tab and open the approved study.



From the menu on the left, click **Create Modification/CR**.



Select **Continuing Review** if you are submitting a study closure.



Complete all questions on the **Continuing Review / Study Closure Information** page. Pay attention to the following:

a. **Enrollment totals** (the number of participants in your study):
   - **Specify enrollment totals at this investigator's sites** (specify the total number of participants in your study)
   - **Specify enrollment totals at this investigator's sites since last approval** (specify the total number of participants in your study since approval or since the last Continuing Review if you previously submitted a Continuing Review)
   - **Specify enrollment totals study-wide** (specify the total number who participated in your study from all sites)
   - Please note, these numbers, the number of participants in your study, will all be the same if your study was at one only site and you have not previously submitted a Continuing Review.

b. **Research milestones**: Select all answers that apply in this section. Since you will be concluding the study, select the following:
   - ☐ 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 subjects were enrolled)
   - ☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)

   If these four research milestones are checked, enrollment closed, study protocol completed, and collection and analysis of identifiable private information complete, the study will be closed. You will be asked to acknowledge that the study will be closed.

c. **Check the items that are true since the last IRB approval for all sites involved in the study**: Note that if any item in this section is left unchecked, additional explanation is required. You can upload the explanation by submitting the *Renewal Supplemental Form* or another supporting document under **Attach supporting documents**. The Renewal Supplemental Form can be found at https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index or create your own form and provide an explanation for each unchecked item. Include the Study Title, Study Number, Principal Investigator Name, and the specific item(s) being addressed.

d. **Attach supporting documents**: use this section to attach the Renewal Supplemental Form or your form if explanation of unchecked items is needed, data monitoring reports, publications, and additional supporting documents.

Complete all remaining Smart Form pages.

Click **Continue** to move through the pages and select **Finish** on the last page.

If Alice Pasvogel is listed as Primary Contact on the study, please send her an email (apasv@arizona.edu) and include the study number (CR00000121) in the email. Once she has reviewed the form, she will let you know when it is ready to submit. Once you receive notification from Alice Pasvogel that the form is ready to submit, submit the form in eIRB.

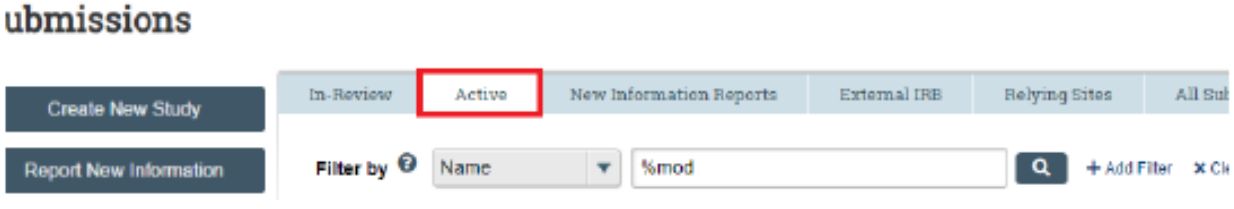
From the submission workspace, click **Submit**. Click **OK** to agree to the terms.

Continuing Reviews can be found on the **Follow-On Submissions** tab of the Study workspace. Note that follow-on submissions (Modifications, CRs, and RNIs) always generate new ID numbers. Use the breadcrumb trail or reference the short title to locate associated submissions.

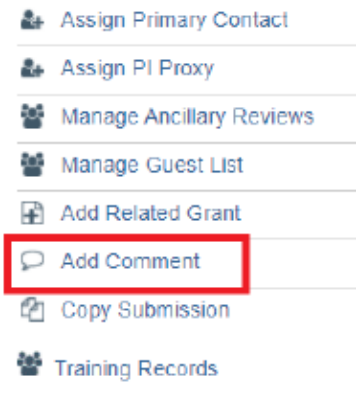
Submitting Closures for Deferred Studies in eIRB

Closures for deferred studies, those using an external IRB, should be submitted via the main study workspace Comment section in eIRB.

On the IRB page, click the **Active** tab and open the approved study.



From the list on the left side of the screen, select 'Add Comment':



Attach the Closure Notice from the external IRB to the Comment. Indicate who should receive an email that a comment has been submitted. It is important to select notify "IRB Coordinator" to ensure that your submission is processed. Also select "PI/PI Proxy/Primary Contact".



Once processed, the study status will be updated with the change; you can log-into the study workspace to view the study update.