



RAP IRB CONTINUING REVIEW/STUDY CLOSURE

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RAP Tips

- When selecting from drop-down lists, use the percentage sign (%) as a wildcard to maximize your search results. For example, "%geography" will bring up sources with "geography" anywhere in the name.
- You can save your work by clicking "Save" in the lower right corner of the page. Choosing "Continue" saves your work and takes you to the next smart form.
- Use the navigation located on the left side of the page to skip between any of the forms to be completed. You can also exit the form and return later to add information before submitting the study for review.
- To withdraw your submission and return it to its pre-submission state, choose "Withdraw" from the options listed on the left side of the screen after you have accessed your study.
- To permanently remove the submission, choose "Discard" from the options listed to the left side of the screen after you have accessed your study.
- Once you have completed all forms and have clicked "Finish", **you must click "Submit" to submit the continuing review/study closure to RCS.** Your submission will not enter the queue for review until it is submitted.

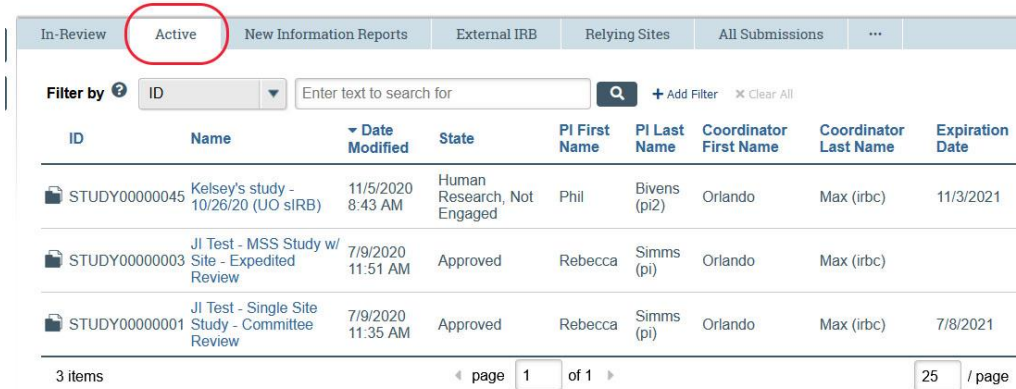
IMPORTANT: IF SUBMITTING A CONTINUING REVIEW FOR A LEGACY STUDY AND YOU HAVE NOT PREVIOUSLY UPLOADED ALL STUDY MATERIALS VIA A MODIFICATION, FOLLOW THE INSTRUCTIONS ON [THE MIGRATED STUDY GUIDANCE](#).

Login and Create Continuing Review

1. Go to irb.rap.uoregon.edu and login using your Duck ID. If you are having issues logging in, email RCS.
2. Once logged in, the system will take you to your **dashboard**. The projects in "My Inbox" require action from you in some way. **To view all your studies, click on "IRB" in the top navigation bar.**

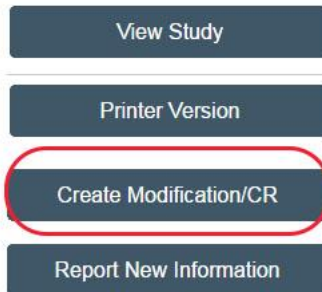


3. Choose the "Active" tab from the top navigation to find a previously approved study. For additional tips on accessing your study, see [Accessing your Study guidance](#).



4. Click on the study you wish to modify. You will be taken to the study workspace. Choose "Create Modification/CR" from the choices on the left-hand navigation.

Next Steps





- 5. Choose the submission purpose and scope from the choices shown. **Choose "Continuing Review" to close the study or to continue the study unchanged.** We do not recommend making changes at time of continuing review. If some *minor* changes are necessary, you can select Modification and Continuing Review. *If you propose changes, also see separate [RAP instructions](#) for Modifying a study.*

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

- Continuing Review
- Modification / Update
- Modification and Continuing Review

[Clear](#)

After you select the submission purpose and continue to the next form, the submission purpose cannot be changed.

Continuing Review/Study Closure Information

- Complete the information on the **Continuing Review/Study Closure Information** smart form.
- All fields with an asterisk are required.

Continuing Review / Study Closure Information

- * Specify enrollment totals at this investigator's sites: ?
- * Specify enrollment totals at this investigator's sites since last approval:
- * Specify enrollment totals study-wide: ?
- 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 su
 - 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)
 - Study is ongoing but UO IRB no longer providing oversight for study
 - Remaining study activities are limited to data analysis
 - Study remains active only for long-term follow-up of subjects

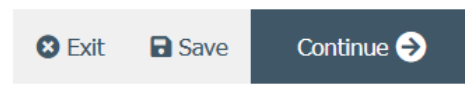
Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

Definition and Examples of Enrollment:

- **Definition:** a participant counts towards enrollment if they meet the definition of "human subject" at any point in their involvement.
 - This includes someone who signs the consent document but does not complete the study.
 - It also includes situations when researchers obtain identifiable private information or biospecimens about or from an individual, even if the researchers do not interact directly with the individual.



- Example: A potential participant who completes pre-screening prior to consent is not considered enrolled in the research unless the pre-screening data will also be used for research analyses or future research. However, if the pre-screening data will be used for research purposes or if an individual signs a consent form and there is further screening and screen fail at that point, that participant was enrolled and considered a withdrawal.
1. *Specify enrollment totals at this investigator's sites.* Total number of participants since the start of the study from the investigators site. This includes all sites at which the University of Oregon PI is responsible for the research, including all research locations identified for the study. This does not include participating sites.
 2. *Specify enrollment totals at this investigator's sites since last approval.* The number of participants enrolled since the last continuing review.
 3. *Specify enrollment totals study-wide.* The total number of participants enrolled study-wide since the start of the study. This includes all sites everywhere that are conducting this protocol, including participating sites.
 4. *Research milestones.* Select the option which best describes your research, if any.
 - i) Read each option carefully. Some of the options contain two different statements. If either statement is true, check the box. Do not check the box if it does not apply. Some milestones are mutually exclusive. For example, if your study is not permanently closed to enrollment and you may enroll new participants, then most of the other milestones will not apply.
 - ii) Usually, the second statement in each option is intended for studies that do not involve interventions or enrollment of subjects, such as chart review and secondary data analysis studies.
 - iii) If your research is currently enrolling subjects or you have not yet started enrollment, none of the choices will apply, unless you are transferring oversight of the research to another institution.
 - iv) In order for study to be closed, the first four milestones must be true and checked.
 5. *Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? Select "yes" or "no"*
 6. *Check the items that are true since the last IRB approval for all sites involved in the study? Check all boxes that apply to the research. An explanation must be attached for any unchecked boxes.*
 7. *Attach the continuing review or closure supplemental form, and other supporting documents: (include an explanation of each item left unchecked above).* Attach the Continuing Review Application or the Study Closure Form and any other supporting documents. Note: see the [Forms and Guidance website](#) for the most recent versions of all forms.
 8. Select "Continue" at the lower right side of the screen to access the screen. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".



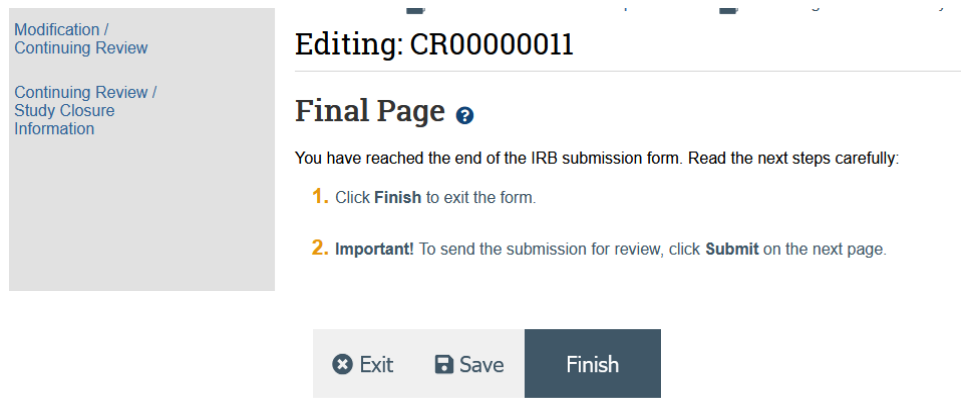


Student Research

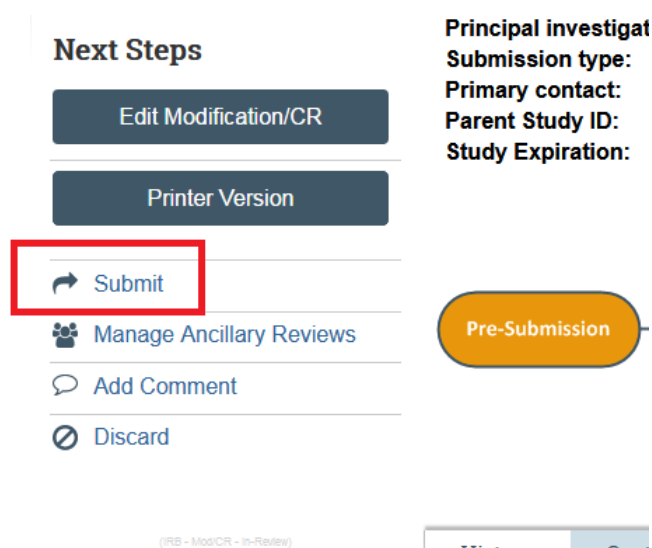
1. Your faculty advisor must be listed in the study under **Local Study Team Members**.
2. You must assign your faculty advisor as a *PI Proxy*.
3. To confirm your faculty advisor's approval for the continuing review/closure to your project, he/she must complete an ancillary review.
4. For instructions on how to add your faculty advisor as a *PI Proxy* and *Ancillary Reviewer*, see our guidance, [Student Led Research Ancillary Review Instructions for Students](#).

Submit Application.

1. Once you are ready to submit your application, select "Finish" at the lower right side of the final page.



2. You will be taken to your study workspace in the pre-submission state. **Select "Submit" from the choices at the left side of the screen.**





3. If you have not entered required information on any smart form, you will be prompted to the pages to edit. Once all the required information is entered, you will see the submit screen. Once you have verified the information presented, click "OK" at the lower right corner of the screen.

Submit

By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You have reviewed and agree to uphold the duties and responsibilities as outlined in the [Investigator Agreement](#).
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

4. Congratulations! Your continuing review/study closure has been submitted for review. You can see that your study is now in the pre-review state. At this stage, you are no longer able to edit your study, but you do have some options listed below.

Post submission options.

- Once your submission is in pre-review status, there are several options.
1. *Assign Primary Contact.* The person who will act as the study's main point of contact for communications with the IRB. When the RCS communicates a decision or requires action by the study staff, the primary contact receives notifications in addition to the principal investigator and PI proxies if assigned. If the primary contact is also engaged in the research, this person must be listed as a team member within the study. There can only be one primary contact listed on each study.
 2. *Assign a PI Proxy.* PI proxy(ies) may act on behalf of the PI of the study. PI proxy(ies) may submit a study for initial review, modify the study, and submit for continuing review. The PI may assign more than one proxy, but all proxies must be listed as a team member within the study.
 3. *Manage Ancillary Review.* The PI may assign an ancillary review. For example, student led research requires an [ancillary review by their faculty advisor](#). Contact RCS if the PI is unsure if ancillary reviews are required. RCS staff may also assign ancillary reviews.
 4. *Manage Guest List.* If you would like individuals not listed on the protocol to view the details of the submission, you may add them to the guest list.
 5. *Add Comment.* You may add additional information and supporting documentation to the submission by choosing "Add Comment". The comment will be visible to anyone with access to the submission.
 6. *Copy Submission.* You may create a copy of the submission. You will remain the PI for the new submission.
 7. *Withdraw.* If you would like to withdraw the submission for any reason, choose "withdraw". The submission will be reverted back to Pre-Submission status and you will be able to make edits. You may submit again when you are ready.
 8. *Discard.* Choosing this action will permanently remove the submission.