



RAP IRB MODIFY A STUDY

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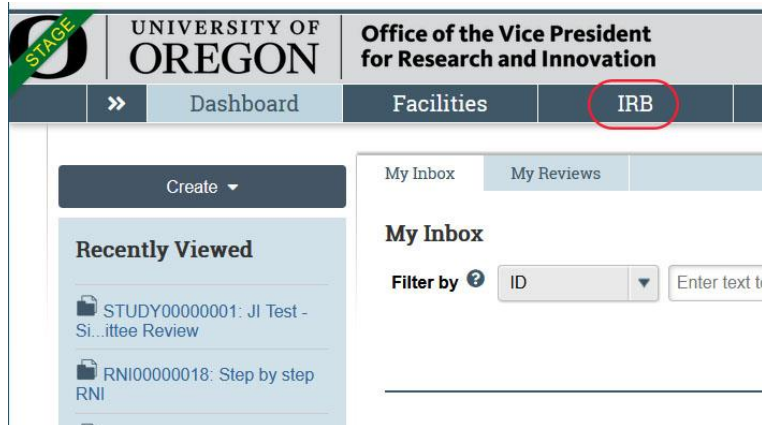
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RAP Tips

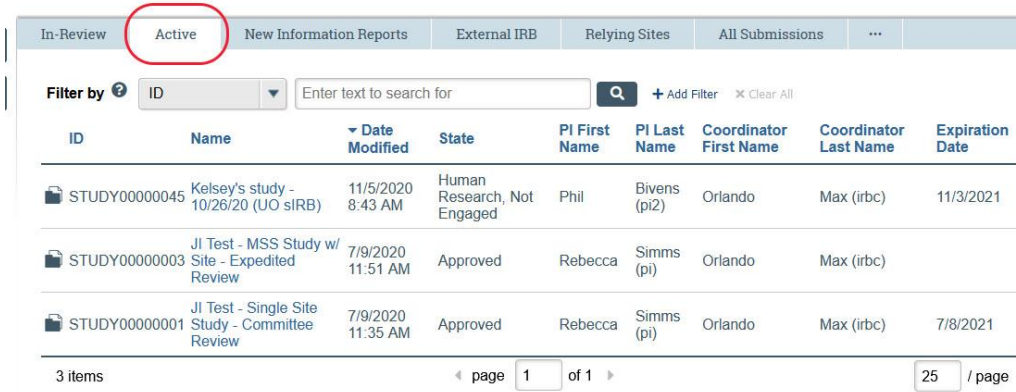
- When selecting from drop-down lists, use the percentage sign (%) as a wildcard to maximize your search results. For example, "%geography" will bring up sources with "geography" anywhere in the name.
- You can save your work by clicking "Save" in the lower right corner of the page. Choosing "Continue" 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 to RCS. Your submission will not enter the queue for review until it is submitted.

Login and Create Modification

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.



Editing: MOD00000026

Modification / Continuing Review /

*** What is the purpose of this submission? ?**

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

i To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

- Study team member information
- Other parts of the study

Active Modification For This Study

- Choose only "Study team member information" if the changes do not affect any of the study materials (i.e., research plan, recruitment, consent forms). **If the changes to research personnel require additional changes to the study materials, choose BOTH "Study team member information" and "Other parts of the study".**
- To change the principal investigator or any of the study materials, choose "Other parts of the study".
- **After you select the submission purpose and continue to the next form, the submission scope cannot be changed.**
- You cannot have more than one mod of the same type open at the same time. For example, you could have a study team member only mod and an other parts of the study mod open at the same time but you can't have two study team member mods or two other parts of the study mod open at the same time. If you select both study team member information and other parts of the study, you won't be able to create another modification of any kind until that mod is approved or discarded. However, you can create a continuing review submission (CR) even if you have a mod open.

Modification Summary

- Complete the information on the **Modification Summary** smart form.
- All fields with an asterisk are required.

The screenshot shows a web interface for 'Modification / Continuing Review'. The main content area is titled 'Modification Information' and contains three sections:

- 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
- 3. * Summarize the modifications: ?**

Below section 3 is a text input field with the placeholder text: 'Brief description of and describe the rationale for the proposed change(s).'

1. **Study Enrollment Status.** Enter your study title. Select which best applies to the current state of this research.

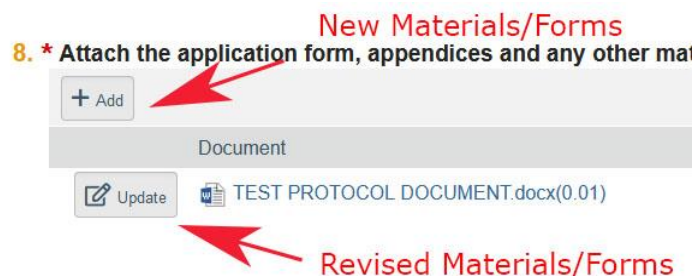


2. *Notification of Subjects.* Select all that apply. If none apply, select nothing. If notifying subjects, attach a description of how they will be notified to the Other attachments section of the **Local Site Documents** page or describe within the modification application. See the [forms and guidance web page](#) for a copy of the current modification application.
3. *Summarize the modifications.* Give a brief description of and describe the rationale for the proposed change(s). On subsequent pages, you can submit the updated Research Plan and revise all applicable protocol details/materials of your existing study (if other parts of the study was selected as the scope).
4. Select "Continue" at the lower right side of the screen to access the next smart form. 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".



Modification Details

- If you chose both the "Study team member information" and "Other parts of the study" scope, you can now edit the original local site documents and upload new documents, edit study team members, add funding sources, etc. If your study is a multi-site study, you will also have the option to edit and add study related documents.
1. Attach the completed supplemental modification application to question 8 under **Basic Study Information**. NOTE: All modifications require the submission of a Modification application. See the [forms and guidance web page](#) for a copy of the current modification application.
 2. Review each smart form and update any information related to the modification.
 3. Revised/new materials must be updated in the applicable smart form. E.g., a revised research plan must be updated in the **Basic Study Information** smart form, consent materials are updated/added to the **Other Study Information** smart form.
 4. When revising approved materials, choose "Update" and attach the corresponding form. When adding new materials, choose "Add".



5. Revised materials and tracking changes:
 - Revisions to Word documents do not require changes to be tracked or marked. The RAP system will create a red-line version of all Word documents.
 - All other formats require revisions to be tracked, highlighted, or marked.



6. Once you have made the necessary revisions, exit the study after saving any changes. You may also continue through each page until the end and choose "Finish"

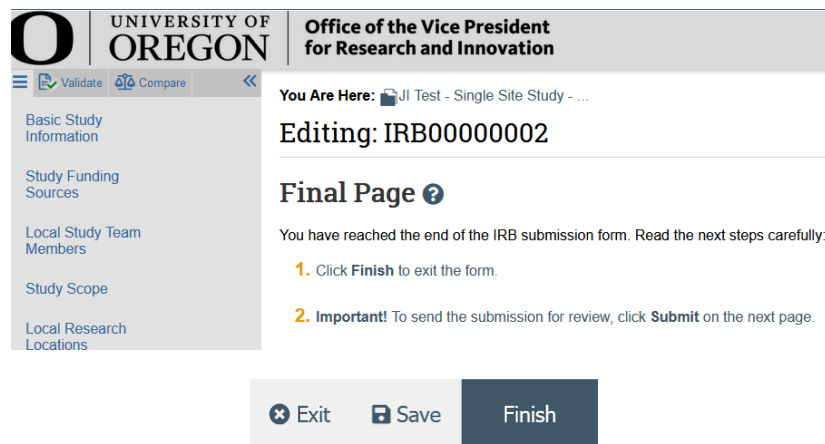


Student Research

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 modifications 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

Pre-Submission

Last updated: 12/30/2020 12:57 PM

MOD00000026: Modification Committee Review

Principal investigator: Rebecca Simms (pi)
Submission type: Modification / Update
Primary contact: Rebecca Simms (pi)
Parent Study ID: STUDY00000001
Study Expiration: 7/8/2021

Next Steps

- Edit Modification/CR
- Printer Version
- Submit**
- Manage Ancillary Reviews

Pre-Submission → Pre-Review

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 modification 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.