



RAP IRB MODIFY AN EXTERNAL IRB STUDY

Purpose: This document includes directions for researchers on how to modify an existing external IRB submission for a multi-site/collaborative project where the UO IRB is deferring oversight to another IRB.

Table of Contents

Overview 1

RAP Tips 1

Login and Create Modification and/or an external IRB Update 2

Modification Summary (only applicable to MODs, not EXTUPDATES) 5

Modification Details (only applicable to MODs, not EXTUPDATES) 6

Study Update Details (only applicable to EXTUPDATES, not MODs) 7

Student Research 7

Submit 8

Post submission options. 10

Overview

The documents in the Research Administration Portal (RAP) should reflect the most recent versions of the documents approved by the [IRB of record](#). The revised documents should first be submitted to the [IRB of record](#) and then can be updated in the RAP via either a modification or an external update. Depending on which section(s) of the RAP needs to be updated, you may need a modification, an external update, or both. Modifications permit changes to the Basic Site Information, Additional Local Funding Sources, Local Study Team Members, Local Research Locations and/or Local Site Documents sections (depending on the modification scope) and external updates permit changes to the Basic Study Information, External IRB, Study Funding Sources, Study Scope, and/or Study-Related Documents sections.

RAP Tips

- For assistance with terminology, see the [Human Subject Research Definitions](#).
- When searching for information for an open-ended question in the RAP smartform, such as in the **Other Study Information** section, 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 page of the smartform.
- When in the smartform, use the navigation panel on the left side of the page to skip between sections.
- You can also exit the smartform by clicking "Save" and then "Exit" and return later.
- 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 sections in the smartform and clicked "Finish", you must click "Submit" to submit the modification to RCS. For modifications, your submission will not enter the queue for review until it is submitted. However, there is no submit button for external IRB updates so researchers are asked to use the Add Comment button to request review. When using Add Comment, ensure you select "IRB Coordinator" in the "Who should receive an e-mail notification" section so RCS receives a notification.

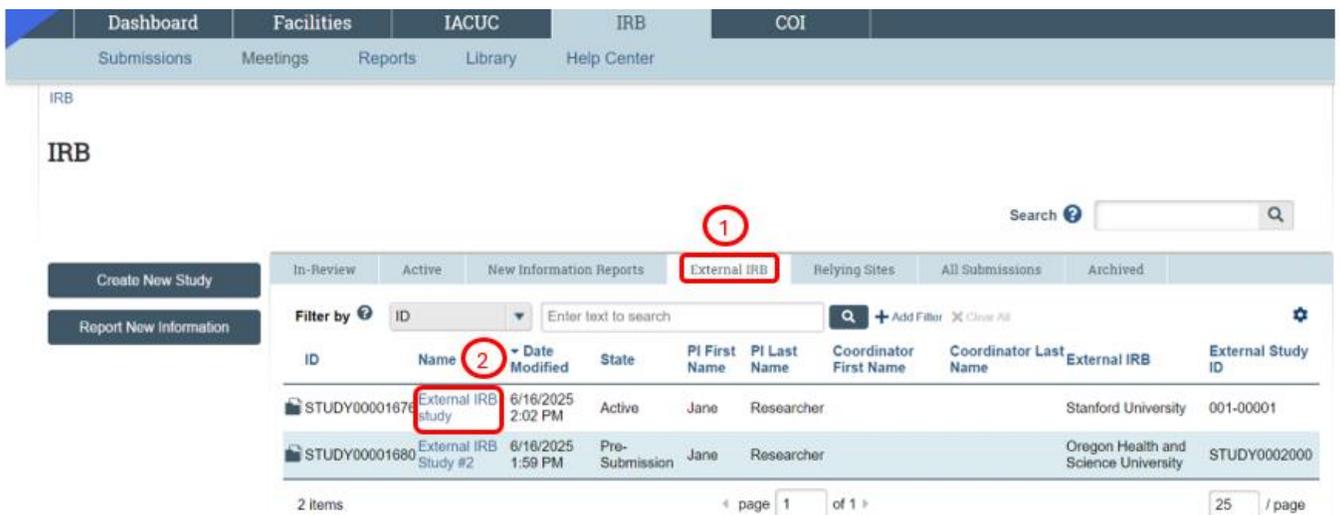


Login and Create Modification and/or an external IRB Update

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 "External IRB" tab from the top navigation to find a previously approved External IRB study. These studies do not show up in the Active tab like other study types. The Active tab only shows studies where the UO is the IRB of record.
4. From the list of studies in the External IRB tab, determine which one you need to modify. Only studies that have a State of "Active" have been approved and can be modified. If your study is still in the Pre-Submission, Pre-Review, Pending sIRB Review, Clarification Requested, Modifications Requested, or Post-Review states, your external IRB study has not yet been approved and no modification can be created. Once you have identified the Active External IRB study that you want to change, open that study by clicking on the name of the study from the list of active studies.





5. Determine which kind of submission type will be needed for your changes:

- Modifications to external IRB submissions (MODs): only permit changes to the following sections:
 - Basic Site Information
 - Additional Local Funding Sources
 - Local Study Team Members
 - Local Research Locations
 - Local Site Documents section
- External updates (EXTUPDATES): only permit updates to the following sections:
 - Basic Study Information
 - External IRB
 - Study Funding Sources
 - Study Scope,
 - Study-Related Documents

6. Prepare your modification/external update materials. Considerations below:

- The documents in the UO RAP should reflect the most recent versions of the documents approved by the [IRB of record](#). Work with your collaborators to identify and obtain all the new and revised documents that you need to provide.
- Since UO is not the IRB of record for an External IRB submission, you will generally need to get approval from the IRB of record first before submitting the modification to the UO IRB. However, there are times when the IRB of record wants the UO IRB's feedback before they will approve a modification. If possible, include a copy of the IRB of record's approval for the changes. If you submit the modification or external update without this external approval, we may send the study back so that you can upload the IRB of record's approval memo for the change prior to approval.
- Whenever possible, provide us with Microsoft Word versions of the study documents (e.g., consent form, protocol/research plan). If you are unable to provide versions in Word, provide a summary of the changes along with the updated materials

7. Create the Modification and/or External Update. The processes for each are described as follows:

- Modification (MOD):
 - a) Click Create Site Modification on the left side of the study workspace for your existing

External IRB project.



- b) Select the purpose of this submission. In most cases, Modification/Update will be the only option you can select.
- c) Select the modification scope. This selection cannot be changed later so choose carefully.
 - o Choose only "Study team member and research location information" as the scope if the changes do not affect any of the study materials (i.e., research plan, recruitment, consent forms). This selection will only allow you to add, remove or change those in the Local Study Team Members section (but not the PI) and/or the information in the Local Research Locations section.
 - o If you need to change anything in the Basic Local Site Information section (e.g., Local principal investigator at the UO, conflict of interest information for the UO PI, description of activities site will perform), the Additional Local Funding Sources section (i.e., funding coming to the UO, new UO EPCS number), and/or the Local Site Documents (e.g., UO versions of recruitment materials, consent forms or other local documents), select "Other parts of the site" as the modification scope.
 - o **If the changes to research personnel require changes to the study materials or if you need to modify your documents in addition to making personnel/study location related changes, choose BOTH "Study team and research location information" and "Other parts of the site".**

Note: Once you select a scope and click Continue, it cannot be changed. You also cannot have more than one mod of the same type open at the same time. For example, you could have a study team and research location only mod and an other parts of the site mod open at the same time but you can't have two study team and research location only mods or two other parts of the site mods open at the same time. If you select both scopes, you won't be able to create another modification of any kind until that mod is approved or discarded. If you accidentally selected the wrong scope, you can either click Exit and then Discard the modification using the Discard button on the modification (see screenshot below) or you can create a second modification with the other type of scope selected and submit two modifications rather than one. If you discard, make sure you are selecting Discard on the modification and not the [parent study](#).

The screenshot shows the IRB system interface for a modification. The top navigation bar includes Dashboard, Facilities, IACUC, IRB, and COI. The IRB section has sub-links for Submissions, Meetings, Reports, Library, and Help Center. The main content area is titled "MOD00002914: Modification / Update #2 for External IRB study" and includes details for the Principal Investigator (Jane Researcher), Submission type (Modification / Update), Primary contact (Jane Researcher), Institution (Stanford University), IRB office (Research Compliance Services), IRB coordinator, Regulatory authority (2018 Requirements), and Site (STUDY00001676). A flowchart illustrates the review process: Pre-Submission leads to Pre-Review, which can lead to Clarification Requested (looping back to Pre-Review) or Pending sIRB Review. Pending sIRB Review leads to Post-Review, which can lead to Modifications Required (looping back to Pending sIRB Review) or Review Complete. A red arrow points to the "Discard" button in the "Next Steps" sidebar.



- External update (EXTUPDATE):
 - a) Click Update Study Details on the left side of the study workspace for your existing External IRB project.

- b) In the box provided, summarize the changes you are making within this external update. If needed, provide rationale for making changes.

Modification Summary (only applicable to MODs, not EXTUPDATES)

- If you created an EXTUPDATE rather than a MOD, skip this section.
- Complete the information on the **Modification Summary** section.
 - All fields with an asterisk are required.

1. **Study Enrollment Status.** Select all that apply to the current state of this research. Ensure you do not select conflicting options (e.g., no subjects have been enrolled to date and subjects are currently enrolled).

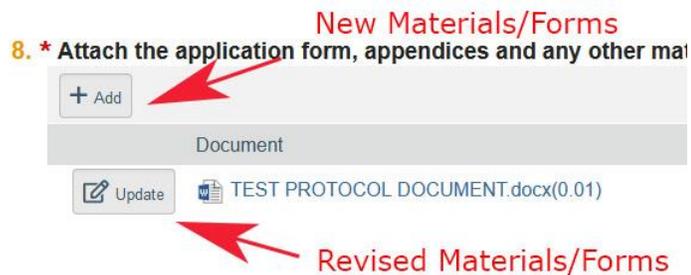


2. *Notification of Subjects.* Select all that apply. If none apply, select nothing. If notifying subjects, provide a description of how they will be notified in the Summarize the modifications field.
3. *Summarize the modifications.* Give a brief description of what is changing and describe the rationale 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 section. Selecting continue will save your work. You may also select "Save" and then "Exit" to return at a later time. To re-enter the modification after clicking Exit, you can select "Edit Modification".

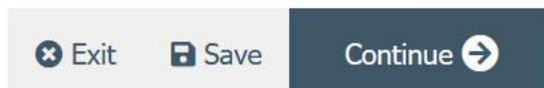


Modification Details (only applicable to MODs, not EXTUPDATES)

- If you created an EXTUPDATE rather than a MOD, skip this section.
- If you chose both the "Study team and research location information" and "Other parts of the site" as the scope, you can now edit the Basic Site Information section, Additional Local Funding Sources section, Local Study Team Members section, Local Research Locations section, and/or Local Site Documents section. If you only selected one of those scopes, the sections you can update will be limited (see more about this above on page 4). If you need to update other sections, you may also need an external update (see page 3 above for more information).
- Review each section of the smartform and update any information related to the modification.
- When revising approved materials, choose "Update" and attach the corresponding form over the existing version. This maintains the document history. When adding *new* materials, choose "Add".



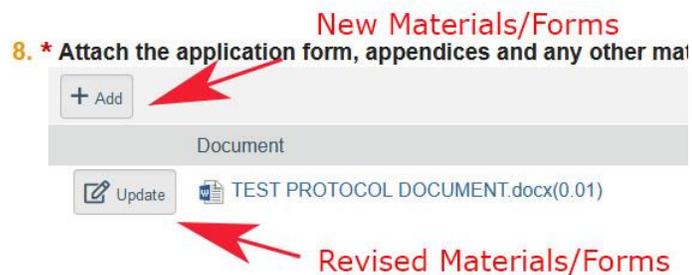
- Revised materials and tracking changes:
 - Revisions to Word documents do not require changes to be tracked or marked. The RAP system will create a red-line version of all Word documents.
 - All other non-Word formats require revisions to be tracked, highlighted, or summarized.
- Once you have made the necessary revisions, click "Save" and then "Exit". You may also continue through each page until the end and choose "Finish"



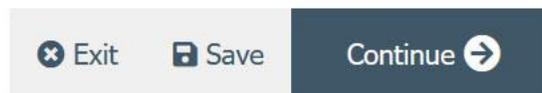


Study Update Details (only applicable to EXTUPDATES, not MODs)

- If you created a MOD rather than an EXTUPDATE, skip this section.
- You can now edit the Basic Study Information section, the External IRB section, the Study Funding Sources section, the Study Scope section and/or the Study-Related Document section. If you need to update other sections, you may also need a modification (see page 3 for more information).
- Some selections may not be able to be changed. For example, you will not be able to change your response to questions 4 and 5 in the Basic Study Information section (“What kind of study is this?” and “Will an external IRB act as the IRB of record for this study?”). Those selections are fundamental to the type of submission the project is in the RAP. If you want to change a multi-site/collaborative study to a single site study or if you want UO to become the IRB of record rather than an external IRB, a new project will need to be created in the RAP.
- Review each section of the smartform and update any information or documents related to what you are changing in the external update.
- When revising approved materials, choose “Update” and attach the corresponding form over the existing version. This maintains the document history. When adding *new* materials, choose “Add”.



- 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.
- Once you have made the necessary revisions, click “Save” and then “Exit”. You may also continue through each page until the end and choose “Finish”

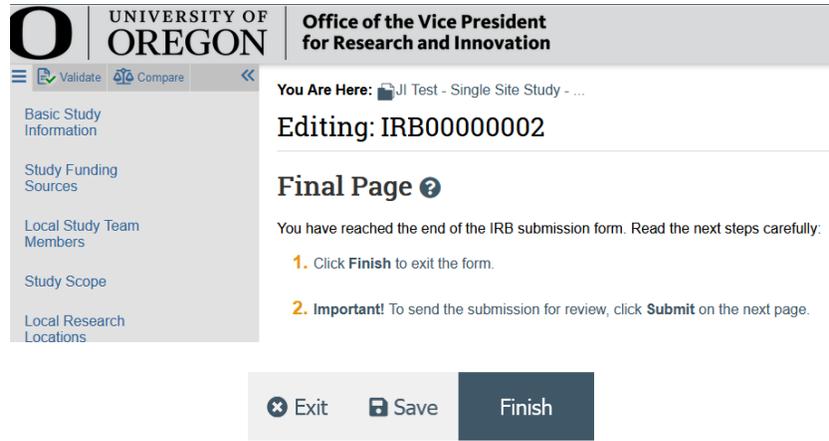


Student Research

1. Your faculty advisor must be listed in the study under **Local Study Team Members** and you must also assign your faculty advisor as a *PI Proxy*. This was likely done at the time of initial submission.
2. Your faculty advisor must complete an ancillary review to indicate their approval of the changes.
 - For instructions on how to add your faculty advisor as a *PI Proxy* and *Ancillary Reviewer*, see our guidance, [Ancillary Review - Instructions for students to add a faculty advisor](#). If you are the faculty advisor, use the [Ancillary Review - Instructions for faculty advisors to approve student led research](#) for directions on how to complete the ancillary review in the RAP.

Submit

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.
 - a) If you prepared a modification (not an external update), select "Submit" from the choices at the left side of the screen.



If you do not see a submit button, check to see if the submission number for your project starts with "MOD" or "EXTUPDATE". If it starts with "EXTUPDATE", skip to b) below. If your submission is a modification but you still do not see the submit button, you are likely not the PI or PI proxy. Only the Principal Investigator (PI) or a PI Proxy can see the "submit" button and submit a modification for review. For information on how to assign a PI proxy, see our [RAP Quick Reference – Primary Contacts and PI Proxies](#).

- b) If you prepared an external update (EXTUPDATE) rather than a modification (MOD), there is no submit button. When you are ready for review, use the "Add Comment" button, note in the Comment box that the update is ready for review, select "IRB Coordinator" in the notification section and then click ok. No supporting documents will be needed.



Updating Study EXTUPDATE0000023: Update #1 for External IRB study

Last updated: 6/16/2025 3:13 PM
 Principal investigator: Jane Researcher
 Submission type: Study Update
 Primary contact: Jane Researcher
 IRB office: Research Compliance Services
 IRB coordinator:
 Regulatory authority: 2018 Requirements

Next Steps

Edit Study Details
 Printer Version
 Manage Ancillary Reviews
 Add Comment
 Discard

Updating Study → Updates Complete

History Documents Reviews Snapshots

Filter by Activity Enter text to search + Add Filter X Clear All

Activity	Author	Activity Date
Minor Version Incremented	Researcher, Jane	6/16/2025 3:13 PM

Add Comment

Your comment is visible to anyone with access to this submission.

1. **Comment:**
 Ready for this External Update to be reviewed

2. **Supporting documents:**
 + Add
 Name Description
 There are no items to display

3. **Who should receive an e-mail notification?**
 PI/PI Proxy/Primary Contact
 Study Team
 IRB Coordinator

OK Cancel

- If your submission is a modification and you click the submit button but missed some of the required information, you will receive an error message and be prompted to edit the pages that are incomplete. After 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](#).

OK Cancel



4. Congratulations! Your modification or external update has been submitted for review. For modifications, you can see that your modification is now in the pre-review state. At this stage, you are no longer able to edit your modification, but you do have some options listed below. If your submission is an external update, the submission will remain in the "Updating Study" state until the updates are accepted.

Post submission options.

- Once your modification is in the pre-review state or you have notified RCS that an external update is ready for their review, there are several options:
 1. *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. To ensure RCS is notified, select "IRB Coordinator" in the comment box.
 2. *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.
 3. *Discard.* Choosing this action will permanently remove the submission. It won't be deleted (documents and information can still be seen by the study team and RCS) but after discard, the submission cannot be edited, submitted or reviewed. If you discard a modification/external update by mistake, you will need to create a new one for review and approval.