

**Legacy Studies**  
**How to Make your Study Complete/Whole**  
**Submitting Modifications and Continuing Review**

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## Determine if your project has been fully migrated

1. Log in to the [RAP](#) using your Duck ID and look at your studies. See our guidance on [Accessing your studies in the RAP](#) for help finding your studies.
2. For each of your studies in the RAP, click on the Documents tab

Submissions Meetings Reports Library Help Center

IRB > New Study Example 1

**Approved**

Entered IRB: 10/17/2024 11:16 AM  
Initial approval: 10/17/2024  
Initial effective: 10/17/2024  
Effective: 10/17/2024  
Approval end: 10/16/2025  
Last updated: 10/17/2024 11:18 AM

**STUDY00001427: New Study Example 1**

Principal investigator: Jane Researcher  
Submission type: Initial Study  
Primary contact: Jane Researcher  
PI proxies:  
Application type: IRB Review Application

IRB office: Research Compliance Services  
IRB coordinator:  
Letter: Correspondence\_for\_STUDY00001427.pdf(0.01) ...  
Regulatory authority: 2018 Requirements

**Next Steps**

- View Study
- Printer Version
- Create Modification/CR
- Report New Information

Assign Primary Contact  
Assign PI Proxy  
Manage Ancillary Reviews  
Manage Guest List  
Add Comment  
Copy Submission

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested → IRB Review → Clarification Requested → Post-Review → Modifications Required → Review Complete

**Documents tab**

History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Snapshots	Training
<b>Study Related Documents</b>							
Draft		Category	Final	Last Finalized		Document History	
Initial Review Application Form.docx		IRB Protocol	Initial Review Application Form.pdf	10/17/2024 11:18 AM		History	
Research Plan version 1 minimal risk.docx		IRB Protocol	Research Plan version 1 minimal risk.pdf	10/17/2024 11:18 AM		History	
<b>Site Related Documents</b>							
Draft		Category	Final	Last Finalized		Document History	
Interview Questions.docx		Data Collection Materials	Interview Questions.pdf	10/17/2024 11:18 AM		History	
Flyer Recruitment (minimal risk).docx		Recruitment Materials	Flyer Recruitment (minimal risk).pdf	10/17/2024 11:18 AM		History	
Consent Form version 1.docx		Consent Form	Consent Form version 1.pdf	10/17/2024 11:18 AM		History	

3. Look at the materials in the documents tab and confirm whether all of your current study documents are uploaded. If not, your study is not fully migrated, and a modification will be needed to fully transition your study documents to the RAP. Follow the directions below to make your study complete/whole.

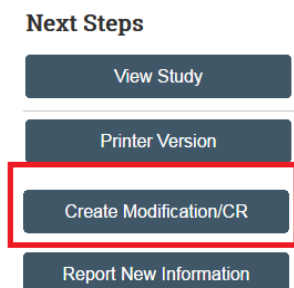
## Preparing to Make your Study Complete/Whole

- The submission where you migrate your materials and complete the study record will take extra time and consideration. Some previously approved information and documents, but not all, have been migrated to the IRB module of the RAP. In addition to updating study information and documents, all currently approved study materials must be uploaded in the RAP. **The only way to add/change information to a RAP record and make the study complete/whole is through a modification.**
- Before you start a modification, review each section of your existing project in the RAP to ensure the information that was already migrated is accurate. Click View Study for your project in the RAP to see the information in your submission.
- **Questions marked with a red asterisk (\*) are required.** If you see any missing information in sections marked with a red asterisk, those sections will need to be updated in a modification.
- Ensure **ALL** approved study materials are uploaded. See [this table](#) for guidance on where to upload documents.
- Prepare your documents for a modification if one is needed.

- For modifications with no changes to the study (i.e., complete the migration of a legacy study), find the following:
    - *All previously approved study materials. **Note:** if you are having trouble finding those materials, please contact RCS to request assistance by emailing [researchcompliance@uoregon.edu](mailto:researchcompliance@uoregon.edu).*
  - For modifications with proposed changes to the study, prepare the following:
    - *A Modification Application (available in the [Forms and Applications section of our website](#)).*
    - *Revised materials with the proposed changes tracked*
    - *All other previously approved study materials.*
  - For continuing reviews, you will need to open a Modification/Continuing Review (MOD/CR) submission to extend the approval period and upload the necessary materials. For MOD/CRs, please prepare the following:
    - *A Continuing Review Application (see in the [Forms and Applications section of our website](#)).*
    - *All previously approved study materials*
- In addition to our [FAQs](#), guidance can be found on our [website](#). Use the guidance document appropriate for your type of study, including:
- Create a Single-Site Study
  - Create a Multi-Site Study where UO is the reviewing IRB
  - Create a Multi-Site Study where the UO is the relying IRB
  - Modify Study
  - Continuing Review/Study Closure

## How do I get started?

- To fully migrate your study to the RAP, additional information must be entered, and all study documents must be uploaded in order to make your study complete/whole. The only way to upload documents and update information to a RAP record is through a modification. See the steps below to get started.
1. Login to the RAP. Go to [irb.rap.uoregon.edu](http://irb.rap.uoregon.edu) and login using your Duck ID.
  2. Access your study. Open the study you want to update. See our [guide for help accessing your study](#).
  3. *Next Steps.* Create a Modification or a Modification/CR by selecting "Create Modification/CR" on the main study page from the selections on the left side.



4. *What is the purpose of this submission?* Select "Modification/Update" or "Modification and Continuing Review." **Note:** If the expiration date for your study is within the next 60 days, select "Modification and Continuing Review." Otherwise, select "Modification/Update". **DO NOT select "Continuing Review".**

**Modification / Continuing Review**

\* What is the purpose of this submission? ?

☒ Continuing Review

☐ Modification / Update

☐ Modification and Continuing Review

[Clear](#)

5. *Modification Scope:* Select both "study team member information" AND "other parts of the study".

**Modification / Continuing Review / Modification Scope**

\* What is the purpose of this submission? ?

☐ Continuing Review

☐ Modification / Update

☒ Modification and Continuing Review

[Clear](#)

**Modification scope:**

☒ Study team member information

☒ Other parts of the study

**Note:** if you are unable to select one or both of these options, this likely means that you already have a modification in progress that will need to be approved or discarded before you can create this new modification. The follow-on submissions tab will show you all current and past modifications.

6. *Modification Information:*

- Study enrollment status:* select which, if any, of the options apply to your study.
- Notification of subjects:* select which, if any, of the options apply to your study. **Note:** if nothing is changing about your study that would require informing current or past participants about, you can leave both of the notification boxes unchecked.
- Summarize the modifications:* Provide a brief description of what, if anything, is being modified. If the purpose of the modification is to

complete the migration, state this here and note that nothing is changing (e.g., migration only, no changes).

7. Select "Continue" on the lower right corner.

- Navigation for each section will appear on the left side of the screen. The section currently being viewed will be shown highlighted in orange. Some study information has been migrated. Please review information that was migrated to ensure it is current and accurate. Some study information needs to be entered. All approved study materials need to be uploaded.
  - See "[What Information was Migrated](#)" below for information on what was migrated for each study.
  - See "[What information do I need to add/update and what materials do I need to upload?](#)" for details on what information needs to be updated and materials need to be uploaded.

## What Information was migrated?

### 1. CITI

- Current CITI training for individuals affiliated with the University of Oregon will show up in the submission for each person listed on the protocol as long as the CITI profile information is an exact match to what is listed in the RAP.
  - To integrate properly, the individual's first name in their CITI profile must match the [preferred first name](#) as listed in DuckWeb. The last name and email address must match what is listed in the University of Oregon database (Banner).
  - The CITI profile must also be affiliated with the University of Oregon to integrate properly.

### 2. Basic Study Information:

a. *Title of the Study*

b. *Short Title*

- The study title and short title are automatically populated here. The study title should remain unchanged whenever possible, but you can enter a different title, such as a study nickname, if you wish for the short title. The short title identifies the study throughout the IRB system, such as in your RAP inbox and in the IRB's list of submissions to review.

c. *What kind of study is this?*

- This question asks whether the study is a single-site study or a Multi-site or collaborative study. If you are not working with any external collaborators who are engaged in the research, your study will be single-site (see our [HSR Definitions Document](#) for more information). This question should be filled automatically, but if the study is multi-site or



collaborative, additional questions will need to be answered. These questions help determine which institution will be the IRB of record for the study. Please contact [RCS](#) with any questions.

- If a study is an multi-site or collaborative submission where UO is the IRB of record for another institution engaged in the research, the participating sites (pSites) will need to be established in the RAP. RCS will work with you at the time of submission to help with this process.

*d. Local Principal Investigator - University of Oregon PI name:*

- If the study is collaborative or multi-site and UO is relying on an external IRB, you *may* also be prompted to enter the lead principal investigator who will generally be the PI at the external non-UO institution.

*e. Does the local Principal Investigator have a financial interest related to this research?*

- If the answer is "Yes", the PI must also complete a COI Form (locate form in the [Application Attachments section of the Applications, Forms and Guidance website](#)). The COI form for the Local PI can be attached to the final question in the Basic Study Information section. If any other investigators have conflicts, their forms will be attached later in the Local Study Team Members section.

### **3. Study Funding Sources:**

- For studies funded via Sponsored Project Services, the name of the primary funding source and the EPCS number should populate automatically for previously linked funding.

### **4. Local Study Team Members:**

- The names of individuals associated with University of Oregon should migrate automatically. Additional information will need to be completed for each study team member, including yes/no responses to their study role. Click on the name of each study team member and answer the additional questions as applicable.

### **5. Study Scope:**

- If the study involves Drugs or Devices, the appropriate questions are marked "yes" but additional questions may need to be answered and documents uploaded.

## **What information do I need to add/update and what materials do I need to upload?**

### **1. Assign [Primary Contact and PI Proxy\(s\)](#) as needed.**

- ONLY the PI will receive system notifications unless other study team members are assigned as a Primary Contact and/or PI Proxy(ies).

- Primary Contacts will receive notifications regarding upcoming deadlines, comments submitted through the RAP, and updates to submission status.
- PI Proxies will also receive notifications and are able to make changes and submit study materials on behalf of the PI.
- If the PI depends on others to track research, it is imperative they update the Primary Contact and/or PI Proxy(ies) so that the appropriate individuals receive notifications.
- For student research, the faculty advisor must be assigned as a PI Proxy.
- PI Proxy can only be assigned on the main study page on the [parent study](#) (not in a MOD/CR or modification).

## 2. Basic Study Information section:

*Note: Questions marked with a red asterisk (\*) are required.*

### *a. Short Title:*

- The study title is automatically populated here, but you can enter a different title, such as a study nickname, if you wish. The short title identifies the study throughout the IRB system, such as in your RAP inbox and in the IRB's list of submissions to review.

### *b. Basic Description and Risk Assessment:*

- Enter a brief description of the research and explain if it is either greater than minimal risk or no greater than minimal risk.

### *c. Attach the application form(s) and Research Plan, if applicable.*

Note: If you are proposing changes at this time, the changes should be tracked. Please use Word documents whenever possible.

- Depending on the type of study (exempt or non-exempt), the following documents should be uploaded to this section:

- **Modification Application**

- A Modification Application is *only* required if the investigator is proposing changes at this time. If the purpose of submitting a modification is simply to complete the migration of a legacy study in the RAP and upload previously approved materials, a Modification Application is not required.

- **Research Plan or Exempt Determination form**

- If the study is exempt, an Exempt Determination form and appropriate Exempt Category worksheet (e.g., Exempt Category 2 worksheet) should be uploaded. Note: Some older studies may not have an exempt category worksheet. Include if you have it.
- If the study is non-exempt (expedited or full board), a research plan should be uploaded here.



- **COI Form for Principal investigator.**

- Submit only if you have identified a COI for the PI.

### **3. Study Funding Sources section:**

#### *a. Update funding sources.*

- Add funding documents for external funding sources (i.e. for research coming from an organization or entity outside of the University of Oregon). This includes a Funding & Sponsorship form and a copy of the human-subjects research activities described in the grant for each EPCS record. Although the funding information should automatically migrate, these documents do not.
- See the [Study Funding Sources Quick Reference](#) for more details on how to complete the Study Funding Sources section.

### **4. Local Study Team Members section:**

#### *a. Local (UO) Study Team Members:*

- Study team members should automatically be migrated into the RAP. However, not all of their roles are updated. Click on the names of the existing team members and answer yes/no to study team members financial interest, consenting, interacting, and DCR (Design and Conduct of Research) questions. If an individual team member has identified a conflict, upload their COI form here.
- Add any new UO affiliated study team members engaged in human subjects research. Do not add the Principal Investigator (PI) to this section.
- All questions related to study team member roles must be completed for each UO affiliated team member or the RAP will not allow you to submit the modification.

#### *b. External Team Members:*

- If there are external team members (unaffiliated with University of Oregon) **not covered** under an institutional reliance agreement (e.g., IAA, Smart IRB), complete the [external team members/personnel form](#) and attach here.
- Individuals with no institutional affiliation must have a completed Individual Investigator Agreement (IIA). The IIA and any other relevant information, including a current CITI certification, needs to be attached here.
- Do not include information about team members you were able to select under Local Study Team Members.



## 5. Study Scope section:

- a. *Indicate if the study uses ionizing radiation, protected health information (HIPAA), or genetic information.*
  - Additional questions may populate depending on the responses to these questions and appropriate addendums should be uploaded in the corresponding locations.
    - Appendix A - Drugs and Other Substances
    - Appendix B - Medical Devices
    - Appendix C - Ionizing Radiation
    - Appendix D - HIPAA (use of PHI)
    - Appendix E - Genetic Materials
- b. *Indicate if recruiting through UO Human Subjects Pools.*
  - If recruiting through a UO Human Subjects Pool, upload the approval correspondence from the Pool Coordinator for the study debrief. The debrief itself is not required.
- c. *Answer whether the study is a [clinical trial](#).*

## 6. Local Research Locations section:

- a. *Identify campus research locations where research activities will be conducted or overseen by the local investigator.*
  - Click the icon with the three dots and choose the campus location(s) that best describe where the research will take place or will be overseen. 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.
  - If you are not physically on campus, use your campus office as the location where research will be overseen.
- b. *Will activities take place at non UO campus locations?*
  - Identify any research locations that are not part of the University of Oregon campus.

## 7. Drugs section:

- a. *If question #1 under the Study Scope section was 'yes', a Drugs section will appear.*
  - List all drugs, biologics, foods, and dietary supplements being used in the research, even if they will not be investigational
  - Attach an Appendix A for each item listed.
  - Attach safety information and other related materials for each drug listed, such as:
    - Package insert

- Investigator brochure
- Verification of each IND number (one of these)
  - Sponsor protocol with the IND number
  - Communication from the FDA or sponsor with the IND number

## 8. Devices section:

a. *If question #2 under the Study Scope section was "yes", the Devices section will appear.*

- Select the device.
- Answer the device exemptions applicable to the study.
- Attach an Appendix B for each device listed.
- Attach safety information and other related materials about each device, such as.
  - Product labeling/device instructions
  - Investigator brochure
  - Verification of IDE or HDE (one of these)
    - Sponsor protocol with the IDE/HDE number
    - Communication from the FDA or sponsor with the IDE/HDE number

## 9. Local Site Documents section:

a. *Consent forms:* If applicable, attach all consent material, including:

- Informed Consent
- Passive Parental Consent (opt-out consent)
- Oral consent scripts
- Translations and Translated Materials

b. *Recruitment materials:* If applicable, attach all recruitment materials, such as:

- Recruitment flyers
- Print media, such as newspaper ads
- Verbal/email recruitment and screening scripts
- Social media/online advertising/MTurk HIT
- Video advertisement

c. *Other attachments:* Attach any other materials not otherwise solicited, such as:

- Research instruments
- Debriefing materials
- Permissions and approvals (e.g., human subjects pool coordinator, school districts, owner of a bulletin board, listserv, etc.)
- Data use agreements
- Data safety monitoring plans

- Data safety monitoring board/committee information
- Release form for translators and transcribers
- All other related study materials documents not otherwise solicited

#### **10. Other Study Information section:**

- Anticipated Start Date:* Provide the date you started HSR activities (including recruiting participants) or anticipate you will start HSR activities for continuing review and modifications.
- Anticipated End Date:* Provide the date you anticipate you will no longer be working with participants or identifiable participant information/specimens.
- Choose from the following which best describes the application type. Select which application type describes the study.*
  - *IRB Review Application:* Choose if your research was reviewed as Expedited or Full Board.
  - *Exempt Determination Application:* Choose if your research was given an Exempt determination.
  - *Approval in Principle Application:* Choose if your research was previously issued an AIP and is still under development. If you are submitting a modification to apply for IRB approval, select either “IRB Application” or “Exempt Determination Application”.
- What is the Principal Investigator’s role at the U of O?*
  - If the PI is a student, their Faculty Advisor must be listed as study personnel and added as a PI Proxy on the study.
  - The Faculty Advisor will need to complete a Faculty Advisor Ancillary review for all study submissions (continuing review, modification/continuing review, or modification).
- Under which unit is the investigator conducting this research? Add the college, department, or other unit that is most appropriate.*
  - 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. See the [RAP Quick Reference - Units](#) for additional information.

#### **What can I do to prepare?**

- 1. Locate your most recently approved materials.**
- 2. Make sure your CITI profile name and email address match what is listed in the RAP.**
  - To integrate properly, the individual's first name in their CITI profile must match the [preferred first name](#) as listed in DuckWeb. The last name and email address must match what is listed in the University of Oregon database (Banner).

### **3. Identify who will act as your PI Proxy.**

- See our [quick reference](#) for information on PI Proxies and Primary Contact.

### **4. Reach out to RCS with any questions!**

- Email us at [researchcompliance.uoregon.edu](mailto:researchcompliance.uoregon.edu) and we would be happy to answer any questions!