



RAP IRB
CREATING A SINGLE-SITE STUDY

Complete a new study for one the following submission types

- Initial Exempt Determinations. Submit only if you have self-assessed that your research meets one of the "exempt" categories of human subjects research.
Initial Expedited and Full Board review. Submit only if you are requesting an initial review of human subjects research.
Approval in Principle. Submit only if your sponsored research is in the development phase and you do not have definite plans for the involvement of human subjects research.
Human Subjects Research Determination. Submit only if you are requesting a determination that your research does not meet the definition of Human Subjects Research.

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RAP Tips

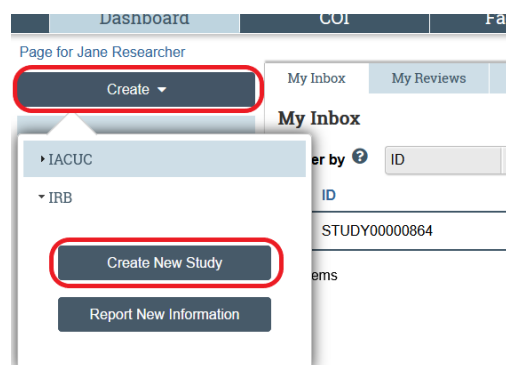
- When selecting from drop-down lists, use the percentage sign (%) as a wildcard to maximize your search results. For example, "%geography" will bring up sources with "geography" anywhere in the name.
- You can save your work by clicking "Save" in the lower right corner of the page. Choosing "Continue"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

Determine if your study is a single-site or multi-site/collaborative study.

1. A *single-site study* is project where only the University of Oregon and its investigators are [engaged](#) in the research. This includes research personnel working under the direct direction and supervision of UO investigator(s) through an [Individual Investigator Agreement \(IIA\)](#). **A single-site study can have multiple research locations, but only one IRB is involved.**
2. A *multi-site or collaborative study* is a project where multiple institutions with an IRB are [engaged](#) in the research. This happens when UO investigators collaborate with one or more non-UO researchers from institution(s) with an IRB.
3. If your study is a multi-site study, [see the guidance for creating a multi-site study](#):
 - i) Create a Multi-Site Study Submission - **UO Reviewing IRB**
 - ii) Create a Multi-Site Study Submission - **UO Relying IRB**
4. If you have any questions on whether your study is single or multi-site, contact RCS at researchcompliance@uoregon.edu or (541) 346-2510.

Login and Create Submission

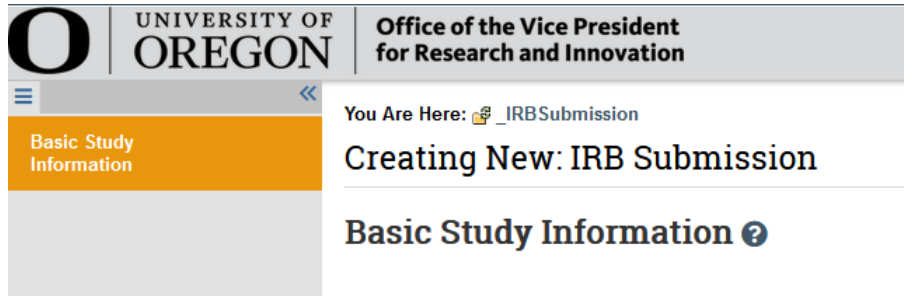
1. Go to irb.rap.uoregon.edu and login using your Duck ID. If you are having issues logging in, email [RCS](#).
2. Once logged in, the system will take you to your dashboard. Click "Create", then click the caret for "IRB." Choose "Create New Study" from the options.





Basic Study Information

- Complete the information on the **Basic Study Information** smart form.
- All fields with an asterisk are required.



1. **Title of the Study.** Enter your study title.
2. **Short Title.** Select a short title for your study. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters. The short title identifies the study throughout the IRB module, such as in your inbox and in the IRB's list of submissions to review.
3. **Basic Description and Risk Assessment.** Briefly describe the research and explain if this research is either greater than minimal risk or no greater than minimal risk. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. When describing the research and risk assessment, consider the following:
 - The central question the research is intended to answer
 - The primary objectives
 - The methods used
4. **What kind of study is this?** Choose "Single-site study". **If you believe your study is a multi-site/collaborative study, refer to the following guidance documents (see most recent versions on [RAP guidance page](#)):**
 - i) Create a Multi-Site Study Submission - **UO Reviewing IRB**
 - ii) Create a Multi-Site Study Submission - **UO Relying IRB**
5. **Will an external IRB act as IRB of record for this study?** Choose "no". Only choose "yes" if another IRB has reviewed or will review this research and the investigator is requesting UO to rely on the IRB review of another institution and refer to the multi-site study guide.
6. **Local principal investigator.** Enter the principal investigator (PI). This field will default to the person creating the study. If you are completing this at the direction of the PI, click the icon with three dots and search for the correct individual from the list.
7. **Does the local principal investigator have any financial interest related to this research?** To determine how to answer this question, see the [COI website](#) for more information regarding financial conflicts of interest.
8. **Attach the application form, appendices, and any other materials identified on the application form.** Depending on the type of request, submit the following.

NOTE: Only attach the materials listed in table 1 below to question 8. Recruitment materials, consent forms, research instruments and other protocol materials will be attached later in or **Local Site Documents** where otherwise solicited.



Table 1: Basic Study Information
Question 8 Attachments

See most recent versions of all documents in the [Forms and Guidance website](#).

Initial Exempt Determination

- Exempt Determination Application
- Applicable category worksheet(s)
 - Exempt Category 1 – Research Conducted in Established or Commonly Accepted Educational Settings
 - Exempt Category 2 – Educational Tests, Surveys, Interviews, Observations of Public Behavior
 - Exempt Category 3 – Benign Behavioral Intervention
 - Exempt Category 4 – Secondary Research for which Consent is not Required
 - Exempt Category 5 – Research and Demonstration Projects on Public Benefit or Service Programs
 - Exempt Category 6 – Taste and Food Quality Evaluation and Consumer Acceptance Studies
- COI Form for Principal Investigator (if a potential conflict of interest is identified)
- Research Plan (optional but recommended for exempt research)
- Applicable research plan appendices
 - Appendix D – HIPAA
 - Appendix E – Research Involving Genetic Information/Tests

Initial expedited or full board review

- Initial Review Application
- COI Form for Principal Investigator (if a potential conflict of interest is identified)
- Research Plan
- Applicable research plan appendices
 - Appendix A – Drugs and Other Substances
 - Appendix B – Investigational Devices
 - Appendix C – Ionizing Radiation
 - Appendix D – HIPAA
 - Appendix E – Research Involving Genetic Information/Tests

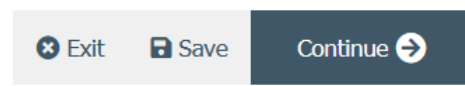
Approval-in-Principal

- Approval in Principal Application
- COI Form for Principal Investigator (if a potential conflict of interest is identified)

Human Subjects Research Determination

- Human Subjects Research Determination worksheet

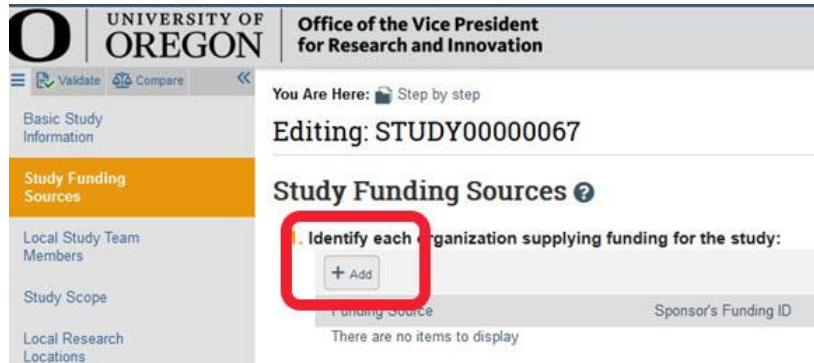
9. Select "Continue" at the lower right side of the screen to access the next smart form. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".





Study Funding Sources

- For sponsored research, complete the information on the **Study Funding Sources** smart form.
- Select "+Add" and a pop-up window will appear.



1. **Funding Organization.** Click the icon with three dots and choose the funding organization from the list. You can search for your funding source by typing in the name in the field at the top of the screen and clicking the "Go" button. If your funding source is new and does not appear on the list, [email](#) Research Compliance Services so it can be added.
 - i) 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.
 - ii) If the funding is from an internal source (e.g., Start-up funds), select the department distributing the award.
2. **Sponsor's funding ID (assigned by external sponsor).** Enter if applicable. This is the number assigned by the Sponsor.
3. **Grants office ID (assigned internally).** If Sponsored Project Services (SPS) facilitates the distribution of the award, include the EPCS number as the Grants office ID.
4. **Attach Funding and Sponsorship form and the human subjects portion of the grant application.** Attach applicable forms/materials here. See the [Forms and Guidance website](#) for the most recent versions of all forms.

Table 2: Study Funding Sources Question 4 Attachments
<ul style="list-style-type: none"> • Funding and Sponsorship form • Human subjects portion of the grant application, if applicable <p>See the Forms and Guidance website for the most recent versions of all forms.</p>

5. Select "OK" or "OK and Add Another" at the lower side of the screen to save the information and close the window.
6. 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".

Local Study Team Members

- Enter Study Team members in the **Local Study Team Members** smart form.



1. *Add all other UO study team members below.* Select "+Add" and a pop-up window will appear.

- i) *Study team member.* Click the icon with three dots and choose the team member from the list. You can search for UO study team members by typing in their last name in the field at the top of the screen and clicking the "Go" button. Add information about each person that is engaged in human subject research (HSR) activities. To be considered engaged in HSR activities, an individual must interact with participants and/or identifiable participant information for research purposes. You do not need to add the principal investigator here.
 - Do not add the study's primary contact person for IRB communications here unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default and can be changed later.
 - If you have difficulty finding the person in the list, try typing the beginning of the first or last name. Contact the IRB staff for assistance if a person is not listed in the system.
- ii) *Role in Research.* Choose which best describes the team members role. Note, all student led research requires one [faculty advisor](#).
- iii) *Is the team member involved in the consent process?* Answer "yes" or "no".
- iv) *Does the team member have a financial interest related to this research?* Answer "yes" or "no". See the [COI website](#) for more information regarding financial conflicts of interest.
- v) *Is the team member involved in the consent process?* Answer "yes" or "no".
- vi) *Is the team member interacting with participants and/or identifiable participant information for research purposes?* Answer "yes" or "no".
- vii) *Is the team member participating in the design, conduct, or reporting of research?* Answer "yes" or "no".
- viii) *Attach relevant training materials and/or Human Subjects Conflict of Interest form.*



Table 3: Local Study Team Members Question 1 Attachments, UO Team
<ul style="list-style-type: none"> • If applicable, <ul style="list-style-type: none"> ○ Relevant training materials ○ Human Subjects Conflict of Interest Form (UO team members) <p>See the Forms and Guidance website for the most recent versions of all forms.</p>

2. External team member information.

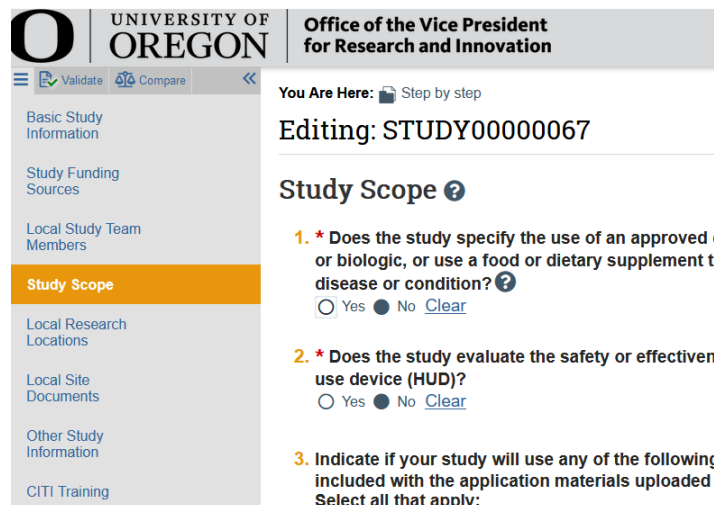
Attach the research personnel form for external research team members who were not listed for selection in the previous question. These include individuals not affiliated with the University of Oregon. Do not attach information about team members you were able to select in the previous question. For people listed in the system, the information should be added to their profiles in the system instead. If you are unsure how to proceed, contact Research Compliance Services for assistance.

Table 4: Local Study Team Members Question 2 Attachments, External Team
<ul style="list-style-type: none"> • External research personnel list (for external team members not listed in question 1). • If applicable, <ul style="list-style-type: none"> ○ Individual Investigator Agreement (IIA) ○ Relevant training materials ○ Human Subjects Conflict of Interest Form (external team members) <p>See the Forms and Guidance website for the most recent versions of all forms.</p>

3. 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".

Study Scope

➤ Complete the information on the **Study Scope** smart form. All fields with an asterisk are required.





1. *Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?* Answer “yes” or “no”.
 - “Specify the use of” means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care.
 - If “yes” is chosen, a new smart form will be available to add additional information regarding the drug(s).
2. *Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?* Answer “yes” or “no”.
 - If “yes” is chosen, a new smart form will be available to add additional information regarding the device(s).
3. *Indicate if your study will use any of the following (ionizing radiation, protected health information, genetic materials/tests). Ensure applicable addendums are included with the application materials uploaded on the **Basic Study Information** smart form.* Select all that apply.
4. *If this research involves recruiting subjects from the University of Oregon Human Subjects Pools, indicate which pool/s below.* Select all that apply.
 - See the [Participant Pools](#) for subject pool requirements. Attach debriefing materials and, if required by the subject pool coordinator, documentation of debriefing clearance on the **Local Site Documents** smart form.
5. *Does this study meet the definition of clinical trial under sponsor requirements (e.g., NIH), FDA, or 2018 HHS regulations?*
 - See the [RCS Clinical Trials](#) page for additional information. Keep in mind the following:
 - All individuals involved in the design, conduct, oversight, and management of the clinical trial must complete Good Clinical Practice (GCP) training. Current training dates must appear in the CITI Training list.
 - For NIH sponsored research that meets the definition of clinical trial, research must be registered with and any results submitted to [clinicaltrials.gov](#) per program requirements. This may be required by other sponsors or federal agencies.
 - For non-exempt research reviewed under the 2018 Revised Common Rule, the informed consent form must be posted to a federal website after the study is closed to recruitment and no later than 60 days after the last study visit by any subject.
6. 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”.

Local Research Locations

- Complete the information on the **Local Research Locations** smart form.
- All fields with an asterisk are required.



1. *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. If you are not physically on campus, use your campus office as the location where research will be overseen.
2. *Will activities take place at non UO campus locations?* Identify any research locations that are not part of the University of Oregon campus.
3. 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".

Drugs

- If you answered "yes," to question 1 under **Study Scope**, the **Drugs** smart form will appear.

1. *List all drugs, biologics, foods, and dietary supplements to be used in the study.* Click on "Add" and list each drug separately. Click "Add" and a pop-up window will appear.



i) *Select the drug.*

(a) Click the icon with three dots to select the drug from a list. Use the percentage sign (%) as a wildcard to maximize your search results. For example, typing "%chloride" will bring up all entries with "chloride" in the name.

(b) If you are unable to find the drug in the list, enter the names in the fields provided.

ii) *Attach files related to this drug.* Attach the following applicable materials.

Table 5: Drugs Question 1 Attachments
<ul style="list-style-type: none"> • Package insert • Investigator brochure • Verification of each IND number (one of these) <ul style="list-style-type: none"> ○ Sponsor protocol with the IND number ○ Communication from the FDA or sponsor with the IND number

iii) *Click "OK" or "OK and Add Another" in the lower right-hand corner to exit the screen.*

2. *Will the study be conducted under any IND numbers?* If "yes", a pop-up window will appear requesting information on each IND. Information related to IND numbers should be attached under the previous question.

- If this is an investigator-initiated drug study and you are not using an IND number, be sure the protocol document fully describes:
 - All drugs used in the research, including the purpose of their use and their regulatory approval status
 - Your plans to store, handle, and administer those drugs so they will be used only on subjects and only by authorized investigators
 - Exemptions from IND requirements are described in 21 CFR 312.2(b).

3. *Attach files.* Attach any additional files not related to one of the specific drugs listed above.

Devices

➤ If you answered "yes," to question 2 under **Study Scope**, the **Devices** smart form will appear.

1. Select each device the study will use as an HUD or evaluate for safety or effectiveness. Click on "Add" and list each separately. Click "Add" and a pop-up window will appear.



i) Select the device.

(a) Click the icon with three dots to select the device from a list. Use the percentage sign (%) as a wildcard to maximize your search results. For example, typing "%needle" will bring up all entries with "needle" in the name.

(b) If you are unable to find the device in the list, enter the names in the fields provided.

ii) Attach files related to this device. Attach the following applicable materials.

Table 6: Devices Question 2 Attachments
<ul style="list-style-type: none"> • Product labeling/device instructions • Investigator brochure (if applicable, e.g., combination drug/device) • Verification of IDE or HDE (one of these) <ul style="list-style-type: none"> ○ Sponsor protocol with the IDE/HDE number ○ Communication from the FDA or sponsor with the IDE/HDE number

iii) Click "OK" or "OK and Add Another" in the lower right-hand corner to exit the screen.

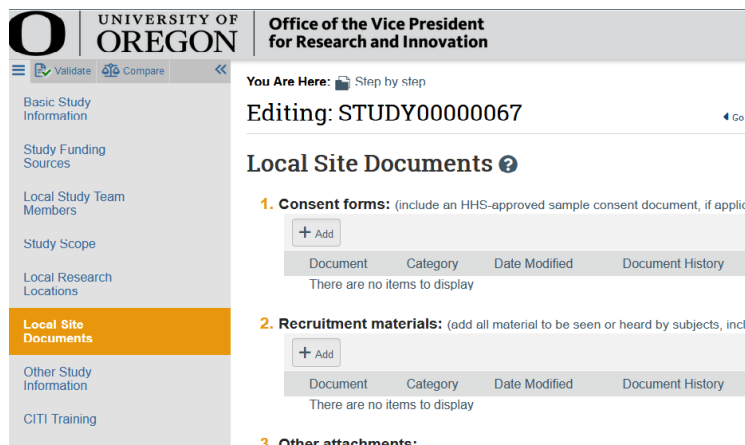
2. Device exemptions applicable to this study. Select which applies.

- If this is an investigator-initiated device study and you are not claiming an IDE, be sure the protocol document fully describes:
 - All devices used in the research, including the purpose of their use and their regulatory approval status
 - Your plans to store, handle, and administer those devices so they will be used only on subjects and only by authorized investigators
 - Exemptions from IDE requirements are described in [21 CFR 812.2\(c\)](#)

3. Attach files. Attach any additional files not related to one of the specific drugs listed above.

Local Site Documents

- Complete the information on the **Local Site Documents** smart form.
- All fields with an asterisk are required.



1. Consent Forms. If applicable, attach all consent materials.

- If consent will not be documented in writing, attach a script of information to be provided orally to subjects.



- The IRB must approve the use of translated consent materials. Because it is common that consent materials require revisions prior to approval, researchers may either: (i) provide translated consent materials in their IRB application; **or** (ii) after the English version of the consent materials have been approved.

<i>Table 7: Local Site Documents</i> Question 1 Attachments, Informed Consent
<ul style="list-style-type: none"> ○ Informed Consent ○ Passive Parental Consent (opt-out consent) ○ Oral consent scripts ○ Assent Forms ○ Translations and Translated Materials

2. *Recruitment materials.* If applicable, attach all recruitment materials. Recruitment materials consists of **all communication seen or heard by potential participants**. For additional information on recruiting subjects see the [Recruiting Research Participants](#) page.

<i>Table 8: Local Site Documents</i> Question 2 Attachments, Recruitment
<ul style="list-style-type: none"> ○ Recruitment flyers ○ Print media, such as newspaper ads ○ Verbal/email recruitment and screening scripts ○ Social media/online advertising/MTurk HIT ○ Video advertisement

3. *Other attachments.* If applicable, attach any other materials not otherwise submitted.

<i>Table 9: Local Site Documents</i> Question 3 Attachments, Other Site Documents
<ul style="list-style-type: none"> ○ 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 boards/committee information ○ Release form for translators and transcribers ○ All other related documents not attached elsewhere

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".

Other Study Information

- Complete the information on the **Other Study Information** smart form.
- All fields with an asterisk are required.



1. *Provide the anticipated start and end date for human subject research (month and year).* Provide the dates you would like to begin interacting with human subjects/identifiable information. Remember that no human subjects research activities, including recruiting potential participants, may take place until approval.
2. *Choose from the following which best describes the application type.* Choose "Initial Review Application" if you are requesting that UO rely on the review of another institution.
3. *What is the Principal Investigator's role at the U of O?* Answer which best describes the PI role for this research.
4. *Under which unit is the investigator conducting this research?* Click the icon with three dots and choose from the options that appear.
 - 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.
5. 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".

CITI Training

- Review CITI training for University of Oregon investigators. If CITI records do not show up for individual investigators,
 - Check the investigator is listed under **Local Study Team Members**.
 - Check the investigator has completed the correct courses. There are only a limited number of courses that will satisfy [human subjects training requirements](#).
 - Check that the investigator name and email in CITI are an exact match what is listed in the RAP. **To integrate properly, the individuals CITI profile must use the preferred first name as listed in DuckWeb and the last name and email address as listed in the University of Oregon database (Banner).** CITI training information will not populate if all three do not match. If an individual has listed a preferred name in DuckWeb, the preferred name will display in the RAP.

Student Research

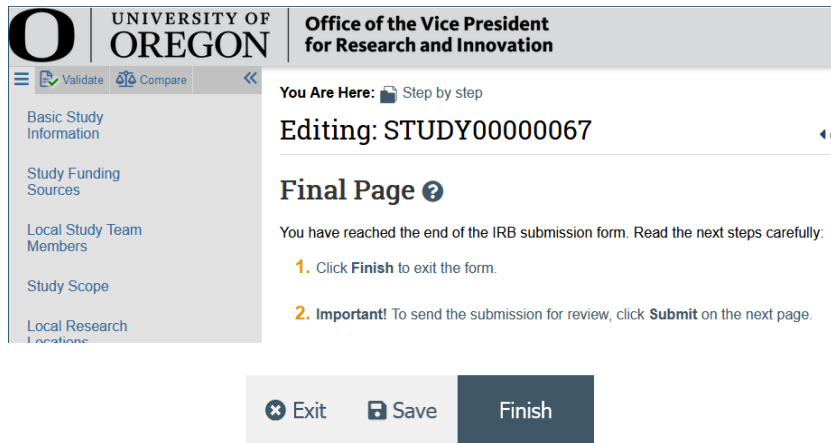
1. Your faculty advisor must be listed in the study under **Local Study Team Members**.
2. You must assign your faculty advisor as a *PI Proxy*.



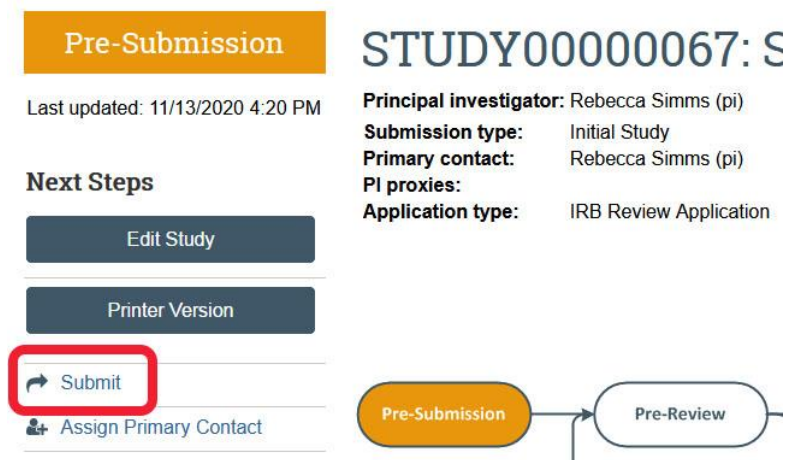
- To confirm your faculty advisor’s approval for your project, he/she must complete an ancillary review.
- For instructions on how to add your faculty advisor as a *PI Proxy* and *Ancillary Reviewer*, see our guidance, [Student Led Research Ancillary Review Instructions for Students](#).

Submit Application

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



- You will be taken to your study page in the pre-submission state. Select “Submit” from the choices at the left side of the screen.



- 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.



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 protocol 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.