UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB
CREATING A SINGLE-SITE STUDY

This is a guide to help researchers complete a new study in the RAP for one the following submission types:

- **Request for initial IRB approval when the University of Oregon (UO) will be the only institution with an IRB that is engaged in this research including:**
  - **Initial Exempt Determinations:** if research seems to meet one or more "exempt" categories (see exempt self-assessment tool)- submission and approval is still required prior to initiation
  - **Initial Expedited and Full Board review:** for initial review of non-exempt research
  - **Approval-in-Principle (AIP):** sponsored research with indefinite plans for human subjects that cannot be fully designed until early phases are completed
  - **Human Subjects Research Determination:** requesting a determination because you aren't sure your project is human subjects research or if UO is engaged

Table of Contents

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 ***Local Research Locations*** section or your unit 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 section.
- When in the smartform, use the navigation panel located on the left side of the page to skip between any of the sections to be completed.
- You can also exit the smartform by clicking "Save" and then "Exit" and return later to add information before submitting the study for review.
- The tables below will guide you when determining where specific attachments belong. Also see the Attachments guidance in the RAP Guidance website for more information.
- 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 a 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 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 a 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). See the Forms and Guidance website for the most recent versions of all forms, including the IIA template. ***A single-site study can have multiple research locations, but only one institution with an 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 or collaborative study, see the guidance for creating a multi-site study:
    - Create a Multi-Site Study Submission - ***UO Reviewing IRB***
    - 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.

Consider your submission type.

- Research studies determined to involve human subjects research must be reviewed by the IRB. There are three types of review; Exempt, Expedited, and Full Board. The IRB can also provide determinations for Approval in Principle and a Human Subjects Research Determination. Study teams can submit materials based on the anticipated review type and category, but the IRB will make the final determination regarding the correct type and category of review.
- **Exempt Determinations**. Research that is exempt is no greater than minimal risk and all research activities fall into at least one of the categories for exemption under federal regulations. Please use our Exempt Self-Assessment tool if you are unsure whether your study may qualify for an exempt review.
- **Expedited Review**. Research that is expedited is no greater than minimal risk and all research falls into at least one category for expedited review under federal regulations.
- **Full Board review.** Research that does not qualify for an exempt determination or expedited review, or that is determined to involve greater than minimal risk to participants must undergo full IRB review. Full Board review requires a study be considered by the fully convened IRB committee.
- **Approval in Principle**. UO offers Approval in Principle (AIP) determinations for sponsored research that requires IRB approval, but is in the development phase and does not have definite plans for the involvement of human subjects research yet. No human subjects research activities may occur under the AIP. Once definitive plans are made, a modification/continuing (MOD/CR) review must be submitted for approval in an IRB review category.
- **Human Subjects Research Determination**. A Human Subjects Research (HSR) Determination is a formal determination that a research study does not meet the definition of Human Subjects Research or that UO is not engaged. An HSR Determination may be needed if it is unclear whether the research meets the definition of Human Subjects Research or if the overall project is human subjects research but you need a determination that UO is not engaged and does not need to review the project.

Determine if your study was issued an Approval in Principle (AIP).

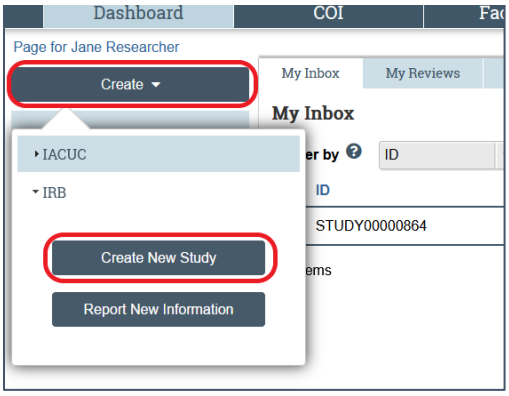
UO offers Approval in Principle (AIP) determinations for sponsored research that requires IRB approval, but is in the development phase and does not have definite plans for the involvement of human subjects research yet. No human subjects research activities may occur under the AIP. If your original study was an AIP, that will be noted on the IRB approval letter for your project in the RAP. Once definitive plans are made, a modification/continuing (MOD/CR) review must be submitted for approval in an IRB review category. If you are setting up a new AIP, refer to the separate Create AIP Guidance. However, if your study was issued an AIP already and now you are ready to create the MOD/CR to get approval to begin human subjects research, skip to the CREATE MOD/CR instructions for AIPs starting on page 4; otherwise continue below.

Login and Create Submission

CREATE A NEW SUBMISSION:

These instructions are appropriate for submissions that have not been issued an Approval in Principle (AIP). If you are creating a submission for an AIP skip to the CREATE A MOD/CR instructions on the next page.

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" under the IRB header from the options.

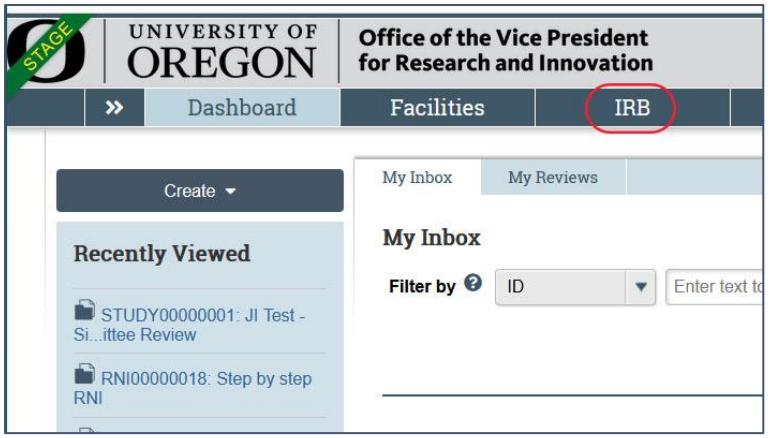


3. Skip to the section below titled Basic Study Information on page 5.

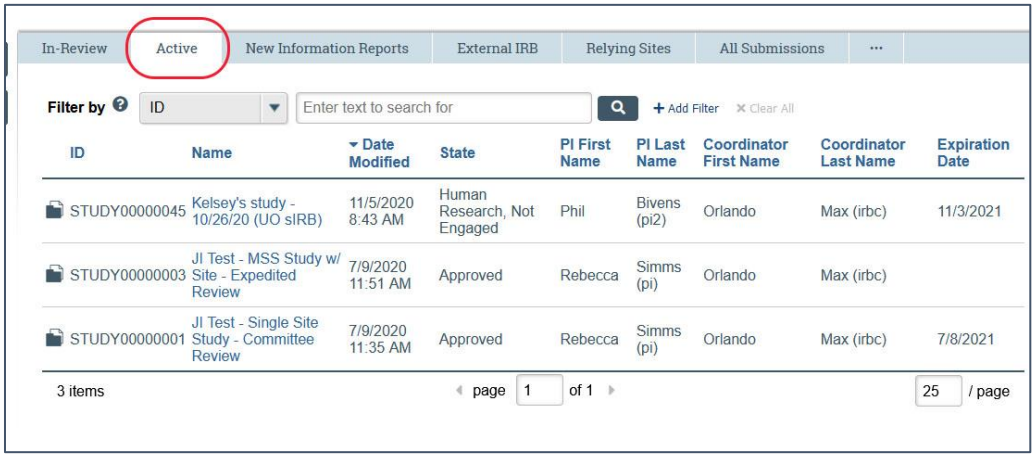
CREATE A MOD/CR (for AIPs only):

These instructions are appropriate for submissions that have been issued an Approval in Principle (AIP).

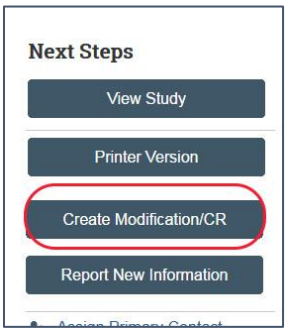
1. Go to irb.rap.uoregon.edu and login using your Duck ID. If you are having issues logging in, email RCS.
2. Once logged in, the system will take you to your **dashboard**. The projects in "My Inbox" require action from you in some way. **To view all your studies, click on "IRB" in the top navigation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



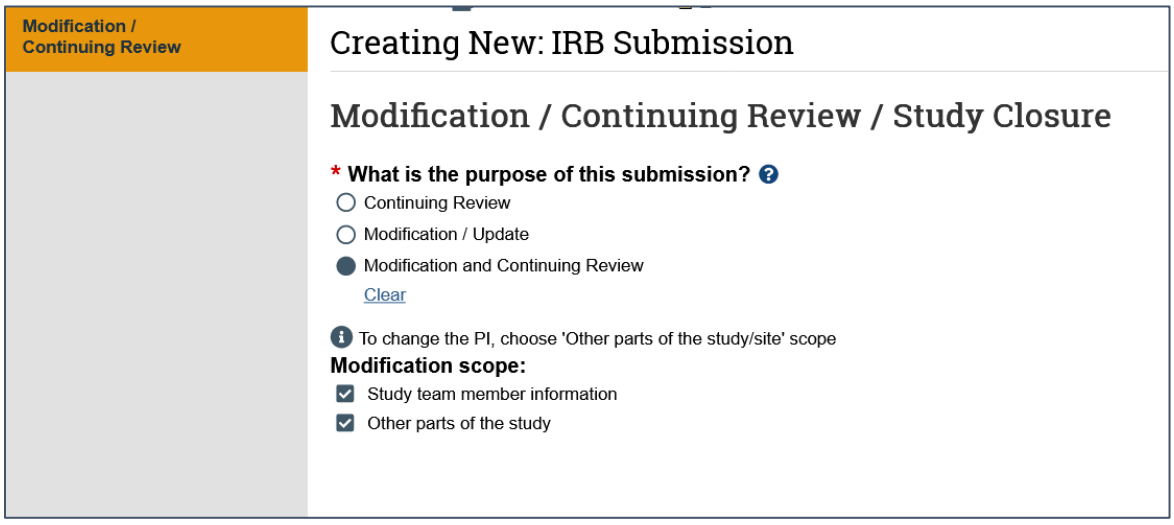
3. Choose the "Active" tab from the top navigation to find a previously approved study. For additional tips on accessing your study, see *Accessing your Study guidance*.



4. Click on the study that was established as an AIP. You will be taken to the study workspace. Choose Create Modification/CR" from the choices on the left-hand navigation.



5. Choose 'Modification and Continuing Review' as the submission purpose. Choose 'Study team member information' and 'Other parts of the study' as the Modification scope. If you do not see these options, please contact RCS.

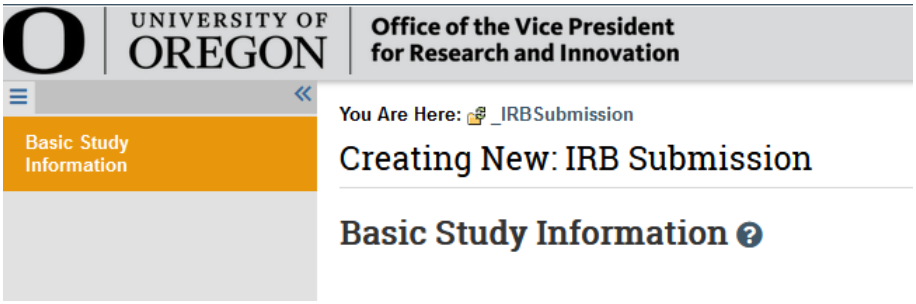


6. Complete the Continuing Review Information on the next page, marking zeros for Questions 1-3 regarding enrollment. No human subjects research may occur under AIPs, so no enrollment should have occurred. Do not upload any documents on this page. Continue to the next page.

7. Complete the Modification Summary page and continue to the next page:
   - In Question 1, select that no subjects have been enrolled to date.
   - Question 2 regarding notification of subjects should be blank.
   - In Question 3, summarize the modification by stating that you are submitting the human subjects materials.

Basic Study Information

- Complete the information on the ***Basic Study Information*** section (see more details below).
- All fields with an asterisk are required.



1. *Title of the Study*. Enter your full 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) rather than this guidance:***
    i. Create a multi-site study where ***UO is the reviewing IRB***
    ii. Create a multi-site study where ***UO is the 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. ***If an external IRB will be reviewing the research and act as the IRB of record, refer to the "Create a multi-site study where UO is the relying IRB" study guide on the RAP guidance website rather than this guidance***.

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. Also see our PI eligibility requirements website.

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. You can also contact the COI office at COI@uoregon.edu.

8. *Attach the application form(s) and Research Plan, if applicable.* Depending on the type of request, submit documents from Table 1 (see below).

    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 ***Local Site Documents*** or 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) (*only submit relevant category worksheets*)
  - 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 C – Ionizing Radiation
  - Appendix D – HIPAA
  - Appendix E – Research Involving Genetic Information/Tests

Approval-in-Principle

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

Human Subjects Research Determination

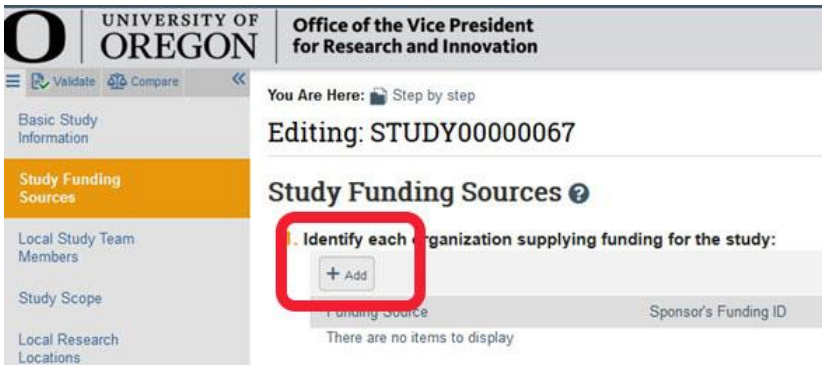
- Human Subjects Research Determination worksheet

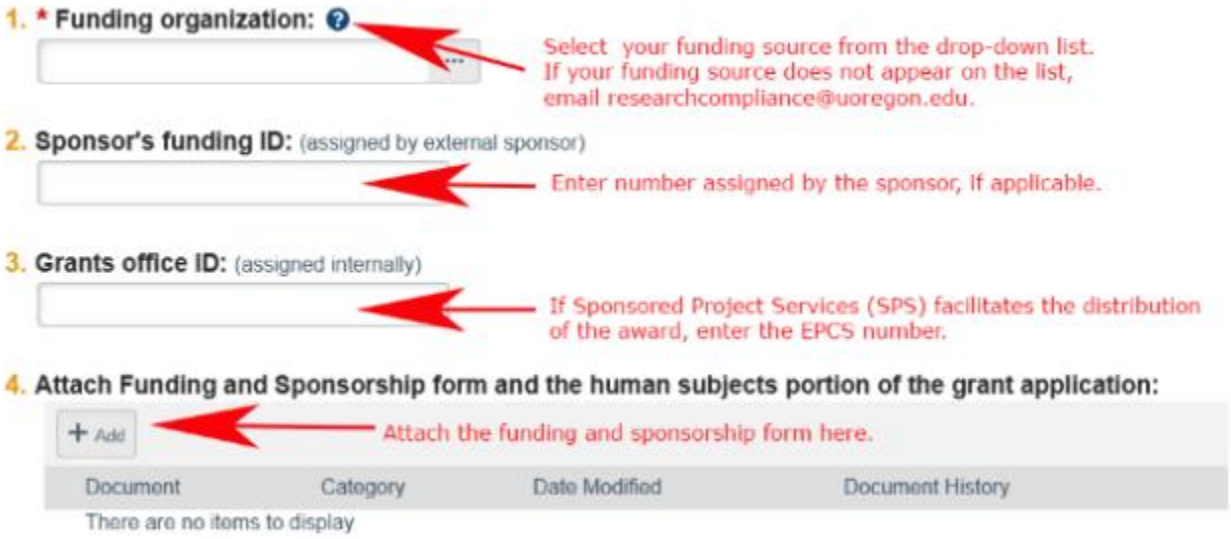
9. Select "Continue" at the lower right side of the screen to access the next section. Selecting continue will save your work. You may also select "Save" and then "Exit" and return at a later time by selecting the study and choosing "Edit Study".

Study Funding Sources

- For sponsored research, complete the information in the ***Study Funding Sources*** section.
- Please note that some federal agencies and departments and some funding sources may have additional research requirements such as additional consent language, monitoring requirements, etc. Please be sure to confirm with the sponsor whether they have specific research requirements that will need to be met.

1. Select "+Add" and a pop-up window will appear.





2. *Funding Organization.* You can either type in the name of the funding source (see tips below) into the 'Funding Organization' box and select the correct funding from the options displayed or you can 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 RCS so it can be added.
   - Use the percentage sign (%) as a wildcard to maximize your search results. For example, "%NIH" will bring up sources with "NIH" anywhere in the name.
   - If the funding is from an internal source (e.g., Start-up funds), select the department distributing the award.

i. *Sponsor's funding ID (assigned by external sponsor).* Enter if applicable. This is the number assigned by the Sponsor. For example, this may be R01 number assigned by NIH (e.g., 1 R01 CA 123456-01A1).

ii. *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.

iii. *Attach the Funding and Sponsorship form and the human subjects portion of the grant application.* Attach applicable forms/materials here by selecting the "+Add" button in question #4. This will open another pop-up window. Use the "Choose File" button to select a saved document to upload.

Table 2: **Study Funding Sources Question 4 Attachments**

- Funding and Sponsorship form
- Human subjects portion of the grant application, if applicable (e.g., EPCS Abstract)

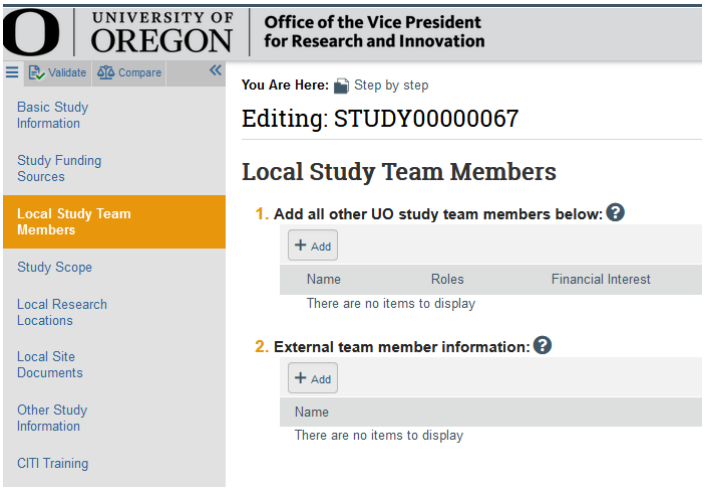
See the Forms and Guidance website for the most recent versions of all forms.

4. Select "OK" (or "OK and Add Another" if you are adding more than one sponsor) at the lower side of the screen to save the information and close the window. If you select "OK and Add Another", you will be prompted to add another funding source and funding documentation.

5. 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 "Exit" to return at a later time. You can return to the smartform by selecting the study and choosing "Edit Study".

Local Study Team Members

- Enter UO Study Team members in the ***Local Study Team Members*** section.



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

   i. *Study team member.* You can either type in the last name of the person (see tips below) into the 'Study team member' box and select the correct person from the options displayed or you can 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 or intervene with participants and/or identifiable participant information/specimens for research purposes.

- **Please do not add the PI or any non-UO affiliated study team members to this section.** 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 a person in the list, try typing the beginning of the first or last name. You can use the percentage sign (%) as a wildcard to maximize your search results (e.g. %Smith). This can be particularly helpful for people who have multiple last names or hyphenated last names. Contact RCS 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. The faculty advisor must also be listed as a PI Proxy on the main study workspace (see "Quick Reference - Primary Contacts and PI Proxies" in RAP Guidance).

iii. *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. If a study team member has a COI, a Human Subjects Conflict of Interest form should be attached.

iv. *Is the team member involved in the consent process?* Answer "yes" or "no".

v. *Is the team member interacting with participants and/or identifiable participant information for research purposes?* Answer "yes" or "no".

vi. *Is the team member participating in the design, conduct, or reporting (DCR) of research?* Answer "yes" or "no".

vii. *Attach relevant training materials and/or Human Subjects Conflict of Interest form.* If researchers do not have a conflict of interest and their CITI training was set up correctly (i.e., CITI training is affiliated with the UO and the researchers' names and email addresses match their UO details), it won't be necessary to upload supplementary materials in this section.

Table 3: **Local Study Team Members Question 1 Attachments, UO Team**
➢ If applicable, ○ Relevant training materials ○ Human Subjects Conflict of Interest Form (UO team members) See the Forms and Guidance website for the most recent versions of all forms.

2. *External team member information.* Complete if there are external study team members who are

   a. not affiliated with an institution with an FWA* OR

   b. are working on this project independent of any institutional affiliation (Independent Investigator)

   i. Complete the "External research personnel" form and attach other relevant documents here (e.g., CITI certification and COI disclosure form). See the Forms and Guidance website for the most recent versions of all forms.

ii. If your study is non-exempt (e.g. expedited or full board), individuals who meet one of the criteria (a and b) above must have a completed Individual Investigator Agreement (IIA). The IIA should be attached here. If you have an external study team member who is affiliated with an institution with an FWA, the study is not single site and a reliance agreement may be more appropriate. Please see the UO Collaborations and Reliance Arrangements website for additional information.

- Study team members who do not have an affiliation with the University of Oregon (UO) are considered external study team members. Do not include information about UO affiliated study team members in the External team member information section. *There are some circumstances in which a study team member who has an affiliation with the University of Oregon will be engaged in the research under their role with a different organization or are otherwise working on this research independent of their UO affiliation. Under these circumstances, the study team members may need to be listed as an external study team member and, if the research is non-exempt, will need a reliance agreement with their organization (e.g., IRB Authorization Agreement) or an Individual Investigator Agreement (IIA). If you are unsure whether a study team member should be added under the Local Study Team Member section or under the external study team member section, please contact RCS.*
- For more information about collaborative arrangements, please see the UO Collaborations and Reliance Arrangements website. The "Collaborations Flowchart" in the **Additional Resources** section can help you determine what type of collaborative arrangement is most appropriate for external study team members.

**The Federal Wide Assurance (FWA) is approved by the Office of Human Research Protections (OHRP) and is an assurance that an institution is in compliance with federal regulations for the protection of human subjects in research. If you are unsure whether an institution has an FWA, you can look up current FWAs in the OHRP database.*

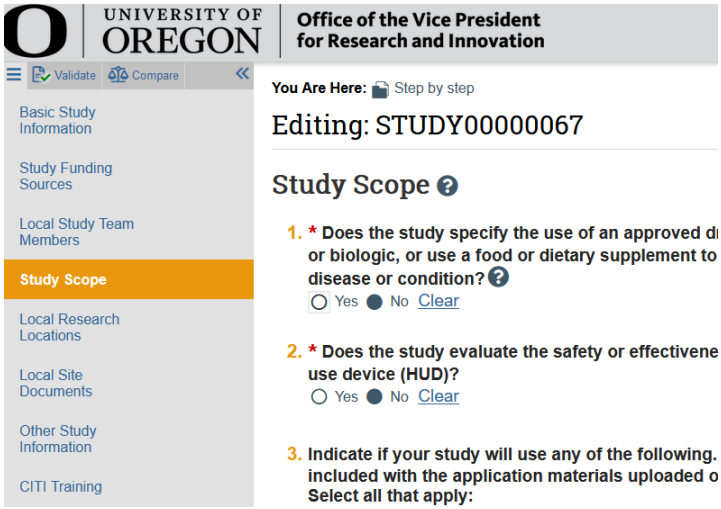
Table 4: **Local Study Team Members Question 2 Attachments, External Team**

➢ External research personnel form (for external team members only)
➢ If applicable,
  ○ Individual Investigator Agreement (IIA)
  ○ Relevant training materials (e.g., CITI certification)
  ○ Human Subjects Conflict of Interest Form (external team members)
See the Forms and Guidance website for the most recent versions of all forms.

3. 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 "Exit" and return at a later time by selecting the study and choosing "Edit Study".

Study Scope

- Complete the information on the ***Study Scope*** section. 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 research requires one or more subjects to use the drug, biologic, dietary supplement, or food <u>as part of study participation</u>, even if its use is considered low risk or consistent with what they would receive as standard of care.
   - Although not specifically listed in the RAP, placebos are included in this definition and should be listed as a drug with all of the required information (Appendix A, supplemental information, etc.) submitted.
   - If "yes" is chosen, a new section will be available to add additional information for the drug(s). Include Appendix A and appropriate supplemental information to determine drug related risks, contraindications, and dosing information (if applicable). For more information on appropriate materials and additional information about required reporting, see section ***Drugs*** below.

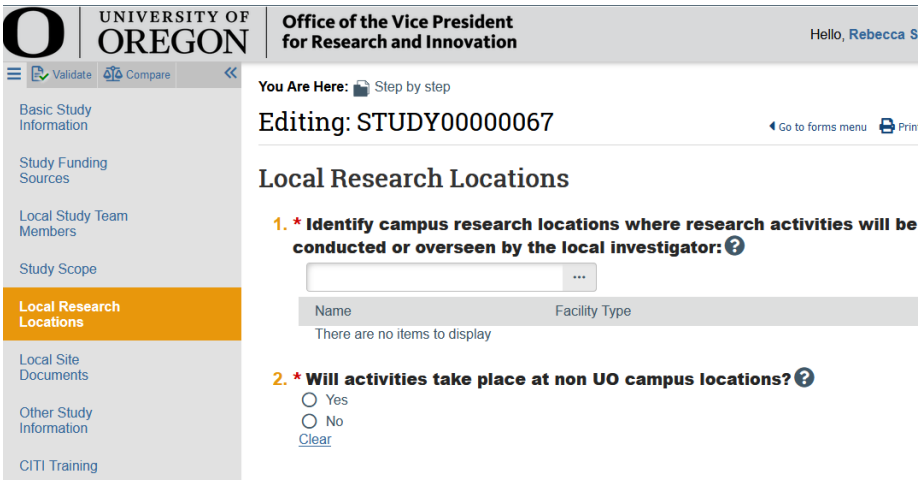
2. *Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?* Answer "yes" or "no".

   - When a study evaluates a device for safety or effectiveness, it is considered an investigational device. Generally, data is collected <u>about</u> an investigational device.
   - If you are using a device, but are not collecting information <u>about</u> the device, please be sure this is clear in the research plan. If you are not obtaining information about the device, you do not need to submit the device information outlined below. <u>However, the research plan should specifically address whether any devices being used as part of research activities will be a) evaluated for safety or effectiveness; b) used to impact the structure or function of the body, c) used to diagnose, cure, mitigate, treat, or prevent a disease; AND d) whether findings will be reported to the FDA</u>. The IRB will ultimately determine FDA status during review.
   - If "yes" is chosen, a new section will be available to add additional information about the device(s). Include Appendix B and appropriate supplemental information to determine device related risks, contraindications, and approved usage information (if applicable). For more information on appropriate materials and additional information about appropriate reporting, see section ***Devices*** below.

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*** *section.* 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*** section. This is usually an email confirmation from the subject pool coordinator.
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.
   - If your study is a clinical trial, 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.
     - Clinical Trial information and intent to comply with federal regulations should be included in the research plan submitted. NIH and FDA clinical trials also have a statement that is required in the informed consent. Please see the RCS Clinical Trials page and our Informed Consent Form Template Guidance for additional information and the required consent language.
     - For non-exempt research (e.g., expedited and full board) that is under the 2018 requirements and the study is federally funded, 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.
     - For NIH sponsored research and applicable FDA regulated research that meets the definition of clinical trial, research must be registered with clinicaltrials.gov within 21 calendar days after enrollment of the first participants and any results must be submitted to clinicaltrials.gov no later than one year after trial's completion date. This may be required by other sponsors or federal agencies, as well.
     - FDA Applicable Clinical Trials (ACT) must be reported to clinicaltrials.gov. FDA defines ACTs as: (1) Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance. The FDA has further elaborated the definition of an ACT.
     - Journals that follow the International Committee of Medical Journal Editors (ICMJE) policy require public registration of clinical trials at or before the time of first participant enrollment as a condition of publication.
6. 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 "Exit" and return at a later time by selecting the study and choosing "Edit Study".

Local Research Locations

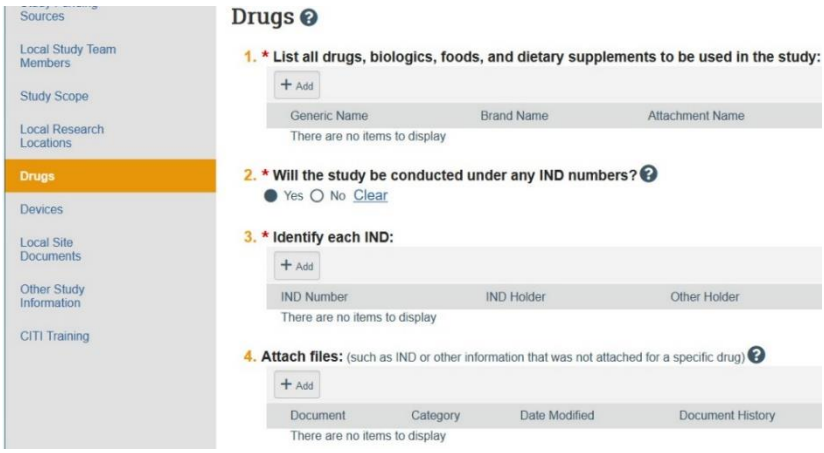
- Complete the information on the ***Local Research Locations*** section.
- All fields with an asterisk are required.



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. *If yes, describe and address any permissions and/or review processes required in the text box*
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 "Exit" and 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** section will appear.



8. *List all drugs, biologics, foods, and dietary supplements to be used in the study.* Click "Add" and a pop-up window will appear. List each drug separately.
   - Although not specifically listed in the RAP, placebos are included under this definition and should be added as a drug in this section.
   - All drugs, biologics, foods, dietary supplements, and placebos specified by the research should be reported and appropriate documents submitted, regardless of whether it is investigational (e.g., being studied as part of the research) or not (e.g. lidocaine as a numbing agent to minimize pain during a research related biopsy).
   - It should be clear in the research plan whether you are obtaining information about the drug, such as a) safety or effectiveness; b) impact of the drug on the structure or function of the body; AND c) whether findings may be reported to the FDA.
2. Select the drug.
   i. Either type the name of the drug into the 'Select the drug' box or 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.
   ii. If you are unable to find the drug in the list, enter the name in the field provided.
   iii. *Attach files related to this drug.* All drugs, biologics, foods, dietary supplements, and placebos are required to have an Appendix A attached and appropriate materials to assess risks, contraindications, and approved dosing (if applicable). Attach the following applicable materials.

Table 5: **Drugs** **Question 1 Attachments**

➢ Appendix A: Drugs and Other Substances
➢ 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

**Package inserts can often be found by searching the manufacturers' website or the FDA label database. An Investigator brochure is usually provided to study teams by the manufacturer when drugs are being evaluated.*

   iv. Click "OK" (or "OK and Add Another" if adding more than one drug) in the lower right corner to save the information and exit the screen. If you select "OK and Add Another" you will be prompted to add another drug and required attachments.
3. *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).

4. *Attach files.* Attach any additional files not related to one of the specific drugs listed above such as a copy of the IND communication from the FDA or other information not attached for a specific drug.

Devices

➢ If you answered "yes," to question 2 under **Study Scope**, the **Devices** section will appear.

1. *Select each device the study will use as an HUD or evaluate for safety or effectiveness*. Click on "Add" and a pop-up window will appear. List each investigational device separately.
   - ➢ Only investigational devices used in the research study need to be added and appropriate documents submitted.
   - ➢ It should be clear in the research plan if devices are being used for the FDA's approved indication, such as standard of care, assessment, or monitoring. You should specifically address whether the device will be a) evaluated for safety or effectiveness; b) used to impact the structure or function of the body, c) used to diagnose, cure, mitigate, treat, or prevent a disease; AND d) whether findings may be reported to the FDA.
2. Select the device.
   - i. Either type the name of the device in the 'Select the device' box or 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.
   - ii. If you are unable to find the device in the list, enter the name in the field provided.
   - iii. If the device is a Humanitarian Use Device (HUD), select "Yes" to the HUD question when adding the device. A HUD is a medical device that treats or diagnoses a rare disease or condition that affects no more than 8,000 people in the United States each year and they are rarely utilized at the University of Oregon. If you think your device might be a HUD, please contact RCS at researchcompliance@uoregon.edu or (541) 346-2510.
   - iv. *Attach files related to this device.* Only investigational devices used in the research study need to be added to the RAP and appropriate documents submitted. If you are using a device, but you are not collecting information about the device, it should be clear in the research plan that the device

is being used for the FDA's approved indication, such as standard of care, assessment, or monitoring; but you do not need to provide additional documentation. However, additional information may be requested for non-investigational devices if the IRB determines that the risk needs to be further assessed. This information will be submitted in a different section. Attach the following applicable materials for investigational devices.

Table 6: **Devices** **Question 1 Attachments**

➢ Appendix B: Investigational Devices
➢ Product labeling/device instructions*
➢ Investigator brochure (if applicable, e.g., combination drug/device)
➢ 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

**Please look for product labeling and/or device instructions on the manufacturer's website. The Investigator Brochure is usually provided by the manufacturer when a drug is being studied. You should obtain verification of an IDE or HDE directly from the FDA. Some approval information can be found on the FDA device website, including approved devices, 510K clearance, Premarket approvals (PMA), and Humanitarian Device Exceptions (HDE).*

v. Click "OK" (or "OK and Add Another" if adding more than one device) in the lower right-hand corner to exit the screen. If you click "Oka and Add Another", you will be prompted to add another device and the required attachments.

3. *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)

4. *Attach files.* Attach any additional files not related to one of the specific devices listed above.

Local Site Documents

➢ Complete the information on the ***Local Site Documents*** section.

➢ 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: (a) provide translated consent materials in their initial IRB application; ***or*** (b) provide translated consent materials as a modification after the English version of the consent materials have been approved.

Table 7: **Local Site Documents** **Question 1 Attachments, Informed Consent**
➢ 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.

Table 8: **Local Site Documents** **Question 2 Attachments, Recruitment**
➢ Recruitment flyers ➢ Print media, such as newspaper ads ➢ Verbal/email recruitment and screening scripts ➢ Social media/online advertising/MTurk HIT ➢ Video advertisement

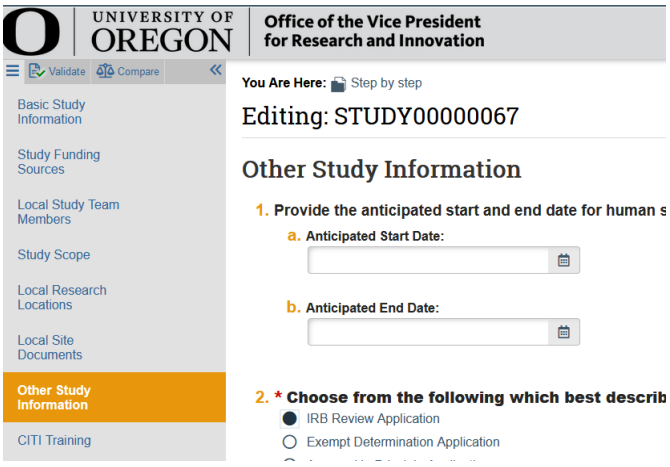
3. *Other attachments.* If applicable, attach any other materials not otherwise submitted.

Table 9: **Local Site Documents** **Question 3 Attachments, Other Site Documents**
➢ 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 boars/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 section. Selecting continue will save your work. You may also select "Save" and then "Exit" and return at a later time by selecting the study and choosing "Edit Study".

Other Study Information

- Complete the information on the ***Other Study Information*** section.
- 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 the study has been approved.
2. *Choose from the following which best describes the application type.* Select the type of review that best describes your study.

- ***IRB Review Application*.** Select this review type for non-exempt research including expedited or full board (greater than minimal risk) studies.
- ***Exempt Determination Application*.** Select this review type for exempt studies.
- ***Approval in Principle Application*.** Select this review type if you are requesting an Approval in Principle. Approval in Principle's should not include any human subjects research activities. There are other restrictions for when this review type is appropriate (see AIP website).
- ***Human Subjects Research Determination*.** Select this review type if you need a formal determination that your research is not human subjects research.

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. Also see the RAP Quick Reference - Units (Other Study Information section) for additional information.
5. 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" and return at a later time by selecting the study and choosing "Edit Study".

CITI Training

- The UO PI is responsible for ensuring all local study team members have current relevant certifications, including CITI certifications. New studies cannot be approved until all study team members have current CITI certifications on record.
- Review CITI training for University of Oregon investigators. If CITI records do not show up for individual investigators.
  - Confirm that the investigator is listed in the **Local Study Team Members** section**.**
  - Check that 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.

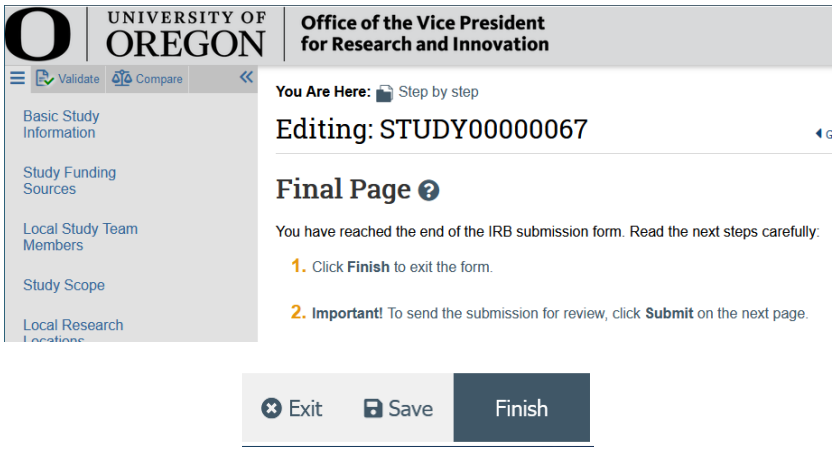
Student Research

- Your faculty advisor must be listed in the study under **Local Study Team Members**.
- You must assign your faculty advisor as a *PI Proxy* on the main study workspace.
- To confirm your faculty advisor's approval for your project, they must complete an ancillary review.
- For instructions on how to add your faculty advisor as a PI Proxy and Ancillary Reviewer, see our Student Led Research and Faculty Advisors website.
- The "Student Led Research Ancillary Review – Instructions for Student" and the "Student Led Research Ancillary Review – Instructions for Faculty Advisors" are available on the RAP Guidance website and

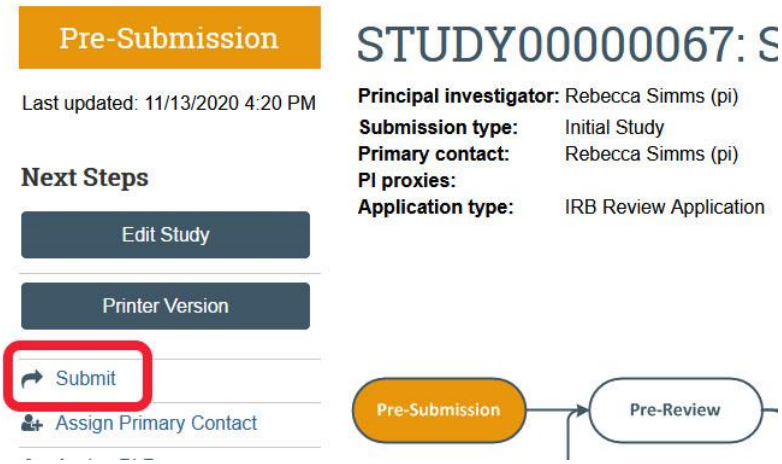
provide step-by-step instructions for both the student and the faculty advisor for creating and approving the ancillary review.

Submit Application

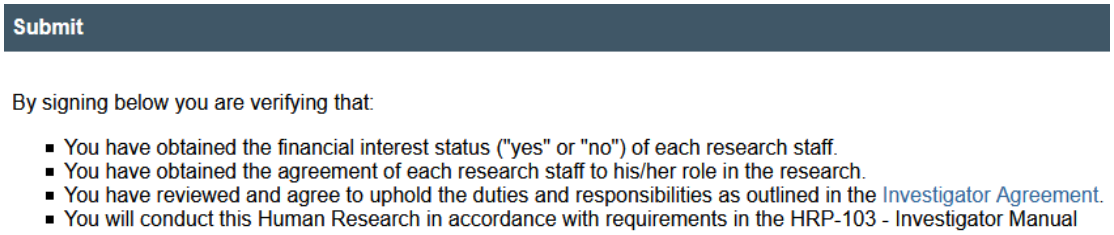
1. Once you are ready to submit your application, select "Finish" at the lower right side of the final page.



2. You will be taken to your study page in the pre-submission state. Select "Submit" from the choices at the left side of the screen. If you do not see the submit button, you are not the PI or PI proxy. See our "Submit Study Instructions (RAP)" guide on the [RAP Guidance website].



3. If any of the required details are missing, you will be prompted to go to the corresponding page(s) to edit and complete those details. Once all the required information is entered, click "Submit" again and you will see the submit screen. Once you have verified the information presented, click "OK" at the lower right corner of the screen.



4. Congratulations! Your protocol has been submitted for review. You can see that your study is now in the pre-review state. If it is still in pre-submission, the project was not successfully submitted. Once the project is submitted, 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 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. The PI will continue to receive notifications, even if a Primary Contact is selected.
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 even if they are not named on the study.
5. *Add Comment.* You may add additional information and supporting documentation to the submission or ask a question by choosing "Add Comment". The comment will be visible to anyone with access to the submission. If you need to send a communication directly to RCS, please be sure to check "IRB Coordinator" in the comment box to ensure the message is sent to RCS staff. Please note that any documents added as a comment are not being added into the official study documents and may need to be added to the official study record separately.
6. *Copy Submission.* You may create a copy of the submission. You will remain the PI for the new submission but the PI and other study information and documents can be changed.
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.