



RAP IRB CREATING AN APPROVAL IN PRINCIPLE (AIP)

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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.
- 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.
- 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. [Only the PI or PI Proxy can "Submit"](#).

Approval in Principle (AIP) Tips

- 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
- No human subjects research may begin until you have IRB approval. AIP approval does not constitute IRB approval.
- Answer the Smart Form Questions as best as you can, these questions will need to be reviewed for accuracy when submitting for IRB review.
- Once your protocol materials are developed and you are ready for initial review or you need to extend your AIP approval date, **select Continuing Review and Modification** when applying.
 - The only way to extend the approval date in the RAP is through a continuing review.
 - You do NOT need to submit a continuing review application when extending an AIP or submitting for initial review.
 - When extending the AIP, be sure to update your anticipated start date.
 - When submitting for initial review, be sure to carefully review ALL the Smart Form questions.
- If you are planning on relying on the review of another IRB, you will have to Create a New Study in order to initiate review. [See our guidance on creating a multi-site study when UO is the relying IRB.](#)



Login and Create New Study

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" and 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.
 4. *What kind of study is this?* Choose "Single-site study".
 - i) Even if you anticipate that this study will be collaborative once the human subject activity is initiated, select "Single-site study" for an AIP.
 - ii) Institutions typically will not enter into reliance agreements until the human subjects activities have been defined.
 - iii) Contact RCS if you think a reliance agreement must be established prior to study development.
 5. *Will an external IRB act as IRB of record for this study?* Select "no".
 6. *Local principal investigator.* Enter the principal investigator (PI).
 7. *Does the local principal investigator have any financial interest related to this research?* To determine how to answer this question, see the [RCS website](#) for more information regarding financial conflicts of interest.
 8. *Attach the AIP application form.*
 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

- 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.
 - i) [Funding and Sponsorship form](#)
 - ii) Human subjects portion of the grant application, if applicable
 5. Select "OK" or "OK and Add Another" at the lower side of the screen to save the information and close the window.

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 [RCS 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.*

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 but are under the direct supervision of the UO PI. 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.

Study Scope

- Complete the information on the Study Scope smart form. All fields with an asterisk are required.
- If you are unsure, use your best guess at this time, when an initial review application is submitted, these answers will have to be reviewed for accuracy.

Local Research Locations

- Complete the information on the **Local Research Locations** smart form. All fields with an asterisk are required.
 - Use your UO campus office when submitting an AIP.
 - When an initial review application is submitted, these answers will have to be reviewed for accuracy.
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.

Local Site Documents

- Until human research activities are developed, there will be nothing to upload here.
- Local site documents will need to be submitted with the initial review application.

Other Study Information

- Complete the information on the **Other Study Information** smart form. All fields with an asterisk are required.
 - If you are unsure, use your best guess at this time, when an initial review application is submitted, these answers will have to be reviewed for accuracy.
1. *Provide the anticipated start date (month and year).* Provide the date anticipate you will begin interacting with human subjects/identifiable information.
 - i) Remember that no human subjects research activities, including recruiting potential participants, may take place until approval.
 - ii) UO will use the anticipated start date as the expiration date of the AIP.
 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.



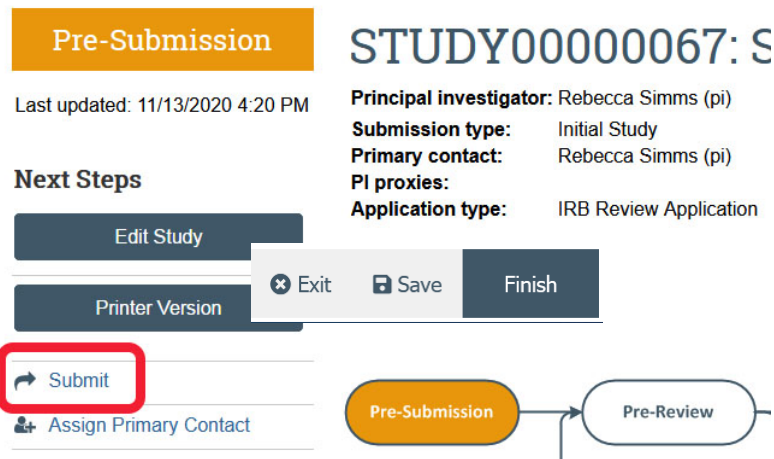
3. *What is the Principal Investigator’s role at the U of O?* Answer which best describes the PI role for this research.
4. *Under which unit is the investigator conducting this research?* Click the icon with three dots and choose from the options that appear.
 - Use the percentage sign (%) as a wildcard to maximize your search results. For example, "%geography" will bring up sources with "geography" anywhere in the name.

Student Research

1. Your faculty advisor must be listed in the study under **Local Study Team Members**.
2. You must assign your faculty advisor as a *PI Proxy*.
3. To confirm your faculty advisor’s approval for your project, he/she must complete an ancillary review.
4. For instructions on how to add your faculty advisor as a *PI Proxy* and *Ancillary Reviewer*, see our guidance, [Student Led Research Ancillary Review Instructions for Students](#).

Submit Application

- [Only the PI or a PI Proxy can “Submit”](#).
1. Once you are ready to submit your application, select “Finish” at the lower right side of the final page.
 2. You will be taken to your study page in the pre-submission state. Select “Submit” from the choices at the left side of the screen.



3. If you have not entered required information on any smart form, you will be prompted to the pages to edit. Once all the required information is entered, you will see the submit screen. Once you have 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.