UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB
CREATING AN APPROVAL IN PRINCIPLE (AIP)

Purpose: An Approval-in-Principle (AIP) submission can only be used for externally sponsored research when there is more than one phase of the research, the early phase does not involve any human subjects research (including secondary use of identifiable private information and/or human biospecimens for research) and there are indefinite plans for human subjects research in future phases but the specifics cannot yet be anticipated as they are still being developed. This guidance explains how to create, modify and renew an AIP submission in the Research Administration Portal (RAP). No human subjects research may begin under an 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.
- **After clicking "Finish", you must also click "Submit" to submit the study for review.** 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

- See the RCS AIP Guidance webpage for more information about Approval-in-Principle (AIP) requirements.
- When first creating the AIP submission, answer the smartform Questions as best as you can, these questions will need to be reviewed for accuracy when revising for human subjects activities later.
- After your AIP is approved in the RAP, a modification and continuing review (MODCR) submission will be needed to extend your AIP or to transition the AIP into a complete submission for human subjects research (HSR) activities. To do this, select Modification/CR on your project in the RAP. However, if your AIP is changing to an External IRB submission, a new study will be needed instead of a MODCR.
    - You do NOT need to submit a continuing review application when extending an AIP.

- If you are planning on requesting that UO rely on the review of an external IRB in the future, your AIP submission will still need to be set up as Single Site. The External IRB submission type in the RAP is only designed to allow External IRB submissions that are ready for the final reliance agreement to be executed which cannot be done for an AIP. A new submission will always be required for any AIP that later turns into an External IRB submission where UO will rely on another IRB. Fortunately, the AIP submission can be copied and then edited to capture the new details and documents for human subjects research activities so key details will not be lost.

Login and Create New Study (new 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. Click "Create", click IRB to expand the IRB section and choose "Create New Study" from the IRB options.

Modify and/or extend Existing AIP

- If you are creating a new AIP submission, you can skip this section.
- If you are modifying and/or requesting an extension to your existing AIP submission, you will click Create Modification/CR on your approved AIP submission in the RAP (also known as the parent study). Depending on your plans, the next steps may differ (see options and additional guidance below).
  - **If you are creating a modification and continuing review (MODCR) to convert your existing AIP into a complete IRB project** (i.e., submission that includes human subjects research details and documents for review), please refer to the initial RAP guidance for new submissions.
    - If you originally set up your project as a single site study, refer to the Create a single-site study RAP guidance for how to create a MODCR to convert the AIP to a complete IRB.
    - If you originally set up your AIP as a multi-site/collaborative study where UO will be IRB of record for other sites, you will need to refer the Create a multi-site study where UO is the reviewing IRB RAP guidance for how to create a MODCR for an AIP.
  - **If you are ready to do human subjects research and your AIP will need to be an external IRB submission where UO relies on another IRB:**
    - If your study will be multi-site/collaborative and UO will be relying on an external IRB, you will need to create a new study rather than a MODCR to provide the HSR documents/details. Refer to the Create a multi-site study where UO is the relying IRB for directions.
  - **If you are creating a modification to modify your funding, personnel or other details but the study will remain an AIP and does not need to be extended**, refer to our Quick Reference - Study Funding Sources and our Modify Study (RAP Instructions).
    - In the modification when you describe what is changing, please also note that the project will remain an AIP and no human subjects research (HSR) has been conducted or will be conducted until you receive approval to begin those HSR activities in the future.
  - **If you are creating a modification and continuing review (MODCR) to renew your existing AIP** and you are not yet ready to request approval for the study to involve human subjects research activities, follow these directions to create the MODCR:

    i) Click Create Modification/CR on your approved AIP submission in the RAP (parent study)

    ii) Select Modification and Continuing Review as the purpose of the submission

    iii) Select "Other parts of the study" as the scope (if this is not available to you, please note that this likely means that you already have a modification in progress which will either need to be submitted and approved or discarded before you can create this MODCR). If

you also need to add, remove or change study staff, you may also select "Study team member information" but "Other parts of the study" must be checked. Click Continue.

iv) On the Continuing Review / Study Closure Information page, include 0s for the enrollment numbers (assuming you have not enrolled any participants since your project was only an AIP) for items 1, 2 and 3.

v) Leave all the research milestones blank/unchecked in item 4.

vi) In item 5, indicate if you or any of the research staff named on the study have a financial conflict of interest. To determine how to answer this question, see the see the COI website for more information regarding financial conflicts of interest. You can also contact the COI office at COI@uoregon.edu.

vii) In item 6, check all the items that are true (e.g., no subjects experienced unexpected harm, adverse events have not taken place with greater frequency or severity than expected etc.)

viii) In a word document, provide a brief explanation of why you need more time than previously expected to do the preparatory activities that need to take place before you can do any of the human subjects research. In this document, confirm that no human subjects research has occurred. Use the +Add button in question 7 of the submission to attach this Word document. You do not need a continuing review application. Click continue.

ix) In the Modification information, confirm that no subjects/participants have been enrolled to date (check in item 1 if applicable)

x) If you have not enrolled any subjects/participants, you do not need to check anything in the Notification of subjects question (item 2 in Modification Information)

xi) In the Summarize the modifications section, explain what is changing (e.g., note that you are requesting to extend your existing AIP and are changing the anticipated start date to match your new time schedule and describe any other changes). Click Continue.

xii) Continue to any section that needs to be revised and update the details as needed. If the only thing you need to change is your anticipated start date for the human subjects research, click Other Study Information to jump to that section to update the date(s).

xiii) In the Other Study Information section, change your anticipated start date. This is the date you anticipate that you will be starting the human subjects parts of the project. Also review and change your anticipated end date (if needed). This is the date you anticipate that you will be done with the human subjects parts of the project. Click Continue.

xiv) Click Finish (or save and then exit)

xv) Click submit (see Submit Application section below for more information).

Basic Study Information

- Complete the information on the ***Basic Study Information*** page in the RAP smartform.
- 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?* **You will generally choose "Single-site study".**
   i) Even if you anticipate that this study will be collaborative once the human subject activity is initiated, we recommend selecting "Single-site study" for an AIP. However, if you know your study will be multi-site/collaborative *and* UO will definitely be the IRB of record (e.g., due to federal funding or other sIRB mandate), you can choose Multi-site or Collaborative if you also respond "No" to "Will an external IRB act as the IRB of record for this study?" and "Yes" to "Will your IRB act as the single IRB of record for other participating sites?". The RAP has some limitations for External IRB submissions (see additional information above on page 2).
   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 UO principal investigator (PI).

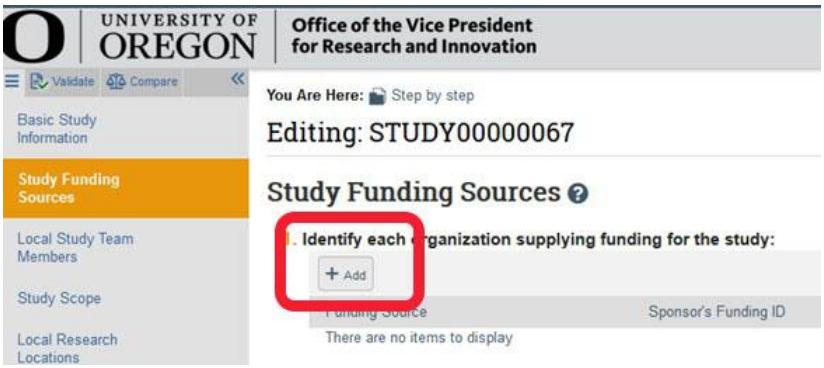
7. *Does the local principal investigator have any financial interest related to this research?* To determine how to answer this question, see the see the COI website for more information regarding financial conflicts of interest. You can also contact the COI office at COI@uoregon.edu.

8. *Attach a completed version of the AIP application form.*

9. Select "Continue" at the lower right side of the screen to access the next page of the smartform. Selecting continue will save your work. You may also select "Save" and "Exit" to return at a later time. To edit the details later, you will come back to the study in the RAP and choose "Edit Study".

Study Funding Sources (new AIP or Modification to AIP involving funding)

- For sponsored research, complete the information in the ***Study Funding Sources*** section. Only externally funded research is eligible for an AIP.
- When adding new funding, select "+Add" and a pop-up window will appear.



- When modifying existing funding, click on the funding source you need to edit. See additional resources:
  - Quick Reference - Study Funding Sources
  - Modify Study (RAP Instructions)

1. *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 Research Compliance Services so it can be added.
   i) 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.
   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 (e.g., 1 R01 CA 123456-01A1).
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 or the grant application, if applicable (obtain from EPCS)
5. 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.
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" 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 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. Do not 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. You can also use the % and a keyword to search for anyone with that keyword in their 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. 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) *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.* 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.

2. *External team member information.*

   This section is not applicable for AIP submissions. If your study is multisite/collaborative and will involve external institutions and/or independent investigators, they will be added to the project later when you are submitting the documents and details for human subjects research.

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 later.

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 (e.g., recruitment, consent forms) will need to be submitted when you prepare a MOD/CR or a new submission for your human subjects research activities later.

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. These answers will have to be reviewed later for accuracy when you are submitting the details/documents for HSR.

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 "Approval in Principle Application"

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 RAP Quick Reference - Units (Other Study Information section).pdf

Student Research

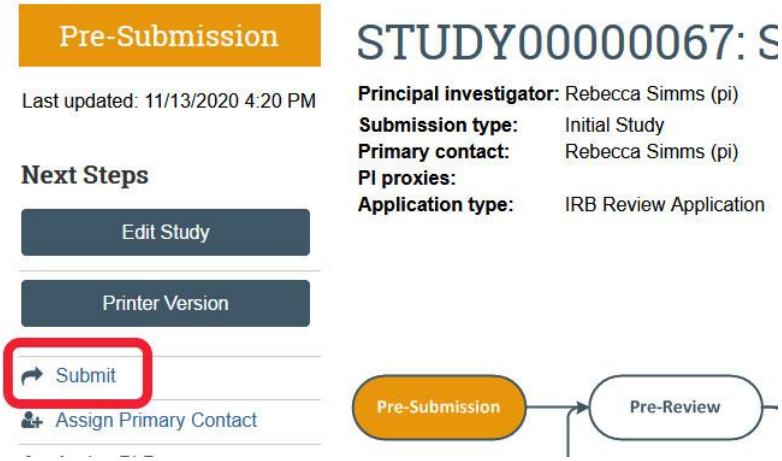
1. Your faculty advisor must be listed in the study under **Local Study Team Members**.
2. You must assign your faculty advisor as a *PI Proxy*.
3. To confirm your faculty advisor's approval for your project, he/she must complete an ancillary review.
4. For instructions on how to add your faculty advisor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

Submit Application

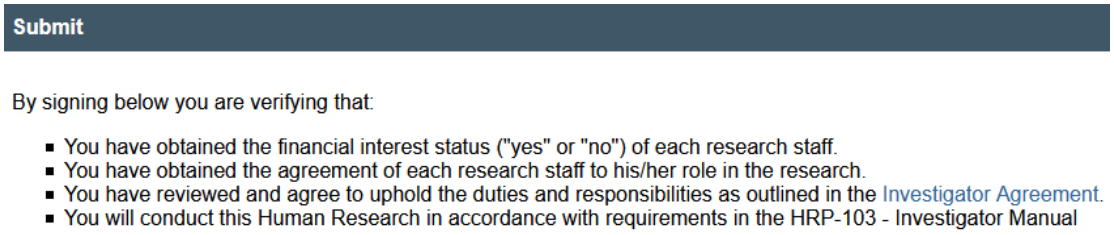
- Only the PI or a PI Proxy can "Submit".

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.



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.