UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB
Creating A Human Subjects Research (HSR) Determination Application

Document Overview:

This is a guide to help researchers complete a new submission in the RAP for a Human Subjects Research (HSR) Determination. An 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.

An HSR Determination may also be needed if you or someone else at the UO is planning to do genetic tests or will obtain genetic information from people or along with data/biospecimens. RCS review will be required regardless of identifiability due to Oregon State Genetic Privacy laws. View the Oregon Genetic Privacy Law website for more information.

For more information see the Does your project require IRB review webpage.

Table of Contents

RAP Tips

- For assistance with terminology, see the Human Subject Research Definitions.
- 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 have the authority to "Submit".

Human Subjects Research (HSR) Determination Tips

- Complete one of two Human Subjects Research Determination Worksheets as thoroughly as possible, including the last page:
  - Human Subjects Research Determination Worksheet - RAP is appropriate for projects that do not involve genetic testing or use genetic information as defined on our Genetic Privacy Definitions page.
  - Human Subjects Determination Worksheet (Genetics) - RAP is appropriate for projects that involve genetic testing or using genetic information as defined on our Genetic Privacy Definitions page. See our Oregon Genetic Privacy Law Website and the Corresponding Genetic Privacy Definitions page for more information.
- When completing the Human Subjects Research Determination Worksheet, provide sufficient information for the reviewer to be able to make an independent determination. For example, do not simply state that data will be de-identified as that does not give the reviewer enough information to confirm that assessment is accurate. Instead, provide a list of variables and an explanation of why you do not believe identities will be readily ascertainable to anyone at the UO.

Login and Create New Study

- Go to the Research Administration Portal (RAP) and login using your Duck ID. If you are having issues logging in, email RCS.
- 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.

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 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 project.

4. *What kind of study is this?* Choose "Single-site study".

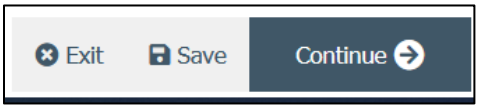
5. Will an external IRB act as IRB of record for this study? Select "no".

6. *Local principal investigator.* Enter the principal investigator (PI). This field will default to the person creating the submission. 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. You can also contact the COI office at COI@uoregon.edu.

8. Upload a completed HSR Determination form. As noted in the HSR Determination Tips section, you will need to complete one of two forms, depending on whether the project includes genetic testing or genetic information.

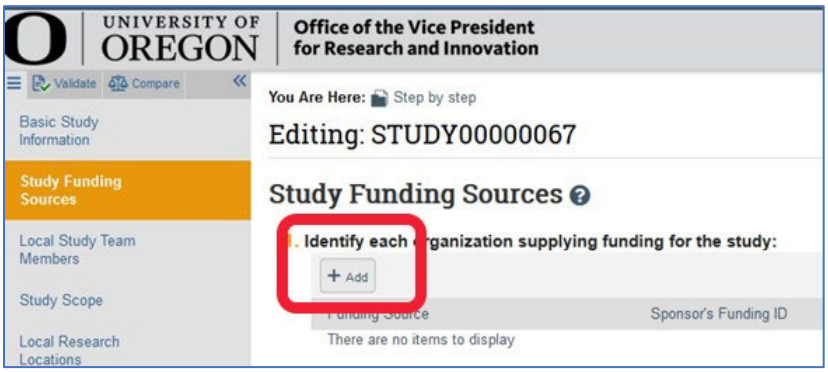
9. Select "Continue" at the lower right side of the screen to access the next smart form. Selecting continue will save your work. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".



Study Funding Sources

- If there is no study funding, skip this section. Otherwise, complete the information on the Study Funding Sources smart form as indicated below.

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. View the RAP Quick Reference - Units (Other Study Information section) for tips on locating departments in the RAP.

3. *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).

4. *Grants office ID* (assigned internally). If Sponsored Project Services (SPS) facilitates the distribution of the award, enter the EPCS number as the Grants office ID.

5. Attach the narrative of the study activities from the grant application or scope of work. 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.

    - 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 UO Study Team members in the Local Study Team Members section. For HSR Determinations, generally no study team members are listed unless a PI Proxy is needed to manage the submission. In that case, the individual who will serve as the PI Proxy needs to be listed.
- Do NOT list the PI in this section.

A. UO affiliated study team members.

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

2. *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.

    - 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 will also serve as a PI Proxy. The person who creates the study in the IRB system is assigned as the primary contact by default and can be changed later. Any team members who will serve as PI Proxy will need to be manually added as a PI Proxy upon submission. See Quick Reference - Primary Contacts and PI Proxies for additional information.

    - 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.

3. *Role in research.* Choose which best describes the team members' role.

4. *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.

5. *Is the team member involved in the consent process?* Answer "yes" or "no". Generally, there is not a consent process for projects that are not human subjects research.

6. *Is the team member interacting with participants and/or identifiable participant information for research purposes?* Answer "yes" or "no". Generally, for projects that do not involve human subjects research, team members are not interacting with participants or identifiable participant information.

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

B. External team member information.

- This section is for external study team members who are engaged in human subjects research activities and are:
    - Not affiliated with an institution with an FWA*; OR
    - Are working on this project independent of any institutional affiliation (Independent Investigator).

Human subjects research determination applications are intended for projects that do not involve human subjects research activities. As a result, these projects generally do not include external study team members. If you have any questions, please contact Research Compliance Services.

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, and consult the help text provided in the smart form. To access the help text, click on the question mark icon that follows the question text.

Screenshot of help text icon:

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 describes 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".

Local Site Documents

- If the project does not include human subjects research activities, there will be nothing to upload in the Local Site Documents section.

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 the project.

2. *Choose from the following which best describes the application type.* Select "Human Subjects Research Determination" from the list.

3. *What is the Principal Investigator's role at the U of O?* Answer which best describes the PI role for this project.

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.

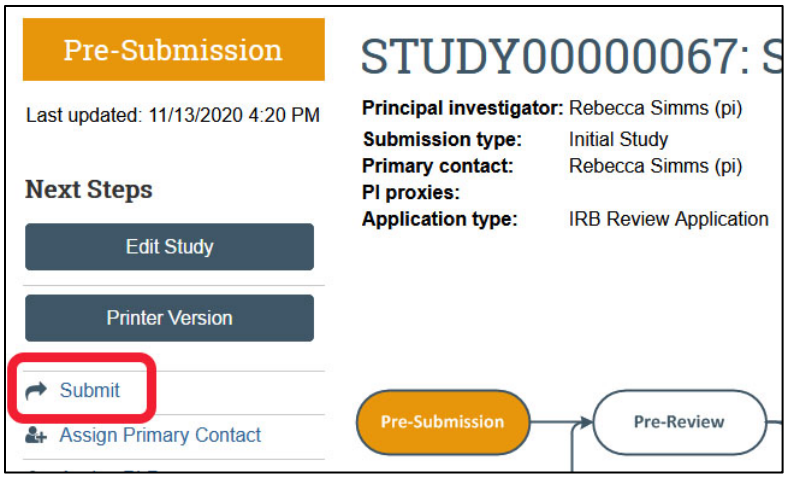
5. Select "Continue" at the lower right side of the screen to access the next section. Selecting continue will save your work. You may also select "Save" and then "Exit" and return at a later time by selecting the study and choosing "Edit Study".

Submit Application

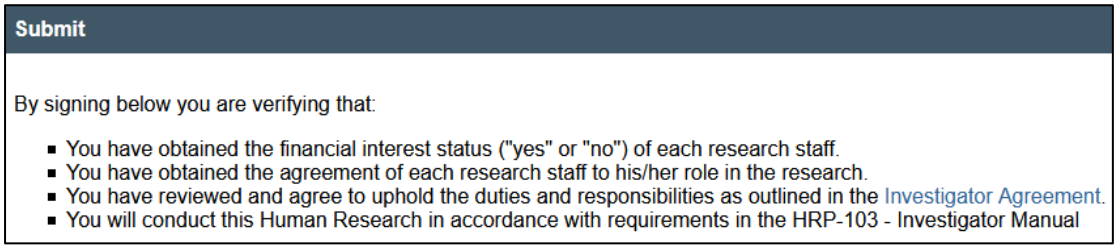
- Only the PI or a PI Proxy can submit the application.

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. View the Submit Study Instructions (RAP) guidance.



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 Human Subjects Research Determination 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. 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 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.

4. *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.

5. *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.

6. *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.

7. *Discard*. Choosing this action will permanently remove the submission.