First time using the RAP for Legacy Studies
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Making your Study Complete/Whole

The first submission using the RAP for legacy studies will take some extra time and consideration. Some information, but not all, has been migrated to the IRB module of the RAP. In addition to updating study information, all currently approved study materials must be uploaded. **The only way to add/change information to a RAP record and make the study complete/whole is through a modification.**

- ➢ ***Review each smart form page to ensure the information migrated is accurate.***
- ➢ Enter missing information. *Questions marked with a red asterisk (*) are required.*
- ➢ *Ensure **ALL** approved study materials are uploaded.* **See [this table] for guidance on where to upload documents.**
  - o For modifications with no changes to the study (i.e., complete the migration of a legacy study/prep for future submissions), upload the following:
    - ▪ *All previously approved study materials.*
  - o For modifications with proposed changes to the study, upload the following:
    - ▪ *The Amendment Application.*
    - ▪ *Revised materials with the proposed changes tracked highlighted.*
    - ▪ *All other previously approved study materials.*
  - o For continuing reviews, upload the following:
    - ▪ *The Continuing Review Application.*
    - ▪ *All previously approved study materials*
- ➢ In addition to our [FAQs], guidance can be found in the [RAP Help Center] *and* on our [website].
  - o [Guidance for Single-Site Studies.]
  - o [Guidance for Multi-Site Studies where UO is the relying IRB.]
  - o [Guidance for Multi-Site Studies where UO is the reviewing IRB.]

How do I get started?

==With the first follow-on submission, additional information must be entered, and all study documents must be uploaded in order to make your study complete/whole. The only way to upload documents and update information to a RAP record is through a modification. See the steps below to get started.==

1. **Login to the RAP.**

   Go to [irb.rap.uoregon.edu] and login using your Duck ID.

2. **Access your study.**

   Open the study you want to update. See our [guide for help accessing your study].

3. **Create a Modification or a Modification/CR**

   a. Under "Next Steps" select Create Modification/CR

Next Steps

> View Study

> Printer Version

> Create Modification/CR

> Report New Information

> Assign Primary Contact

b. Select "Modification/Update" or "Modification and Continuing Review"

For the first submission to the RAP, DO NOT select "Continuing Review".

Modification / Continuing Review

* **What is the purpose of this submission?** ❓

~~Continuing Review~~

○ Modification / Update

○ Modification and Continuing Review

Clear

  i. Select "Modification/Update" if you want to propose changes to previously approved research or if you are submitting a modification to complete the migration of a legacy study.

  ii. Select "Modification and Continuing Review" if you are submitting a continuing review application as your first RAP submission.

c. Modification Scope.

Select both "study team member information" AND "other parts of the study".

Modification / Continuing Review / Study

* **What is the purpose of this submission?** ❓

○ Continuing Review

○ Modification / Update

● Modification and Continuing Review

Clear

ℹ To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

☑ Study team member information

☑ Other parts of the study

d. Modification Information

  i. Under "Study enrollment status", select which, if any, of the options apply to your study.

  ii. Under "Notification of subjects", select which, if any, of the options apply to your study.

iii. Under "Summarize the modifications", give a brief description of what, if anything, is being modified. I the purpose of the modification is to complete the migration, state this here.

iv. Select "Continue" on the lower right corner.

e. Navigation for each smart form will appear on the left side of the screen. The smart form currently being viewed will be shown highlighted in orange. Some study information has been migrated. Some study information needs to be entered. All approved study materials need to be uploaded.

i. See "What Information was Migrated" below for information on what

was migrated for each study.

ii. See "What information do I need to add/update and what materials do I need to upload?" for details on what information needs to be updated and materials need to be uploaded.

What Information was Migrated?

1. **Basic Study Information Smart Form**

   a. Title of the Study.

   b. Short Title.

   c. What kind of study is this?

   This asks if this study is collaborative. If there are multiple IRBs or individuals engaged not affiliated with University of Oregon, your study is collaborative.

   ➤ If this study is collaborative, there are additional questions that follow. These questions help determine if the study is a single IRB (sIRB) or not. Depending on how these questions are answered, additional smart forms may become available. Please contact *RCS* with any questions.

> ➤ If a study an sIRB, the collaborating sites will have to be established and site PIs will need to be added. RCS will work with you at the time of submission to help with this process.

d. Local Principal Investigator.

University of Oregon PI name.

> ➤ If the study is collaborative, you *may* also be prompted to enter the collaborating investigator depending on how the collaboration question is answered.

e. Does the local Principal Investigator have a financial interest related to this research?

If the answer is "Yes", the PI must complete a COI Form. The COI form for the Local PI can be attached to the final question. If any other investigators have conflicts, their forms will be attached later to the Local Study Team Members smart form.

2. **Study Funding Sources Smart Form.**

For studies funded via Sponsored Project Services, the name of the primary funding source and the EPCS number will populate.

3. **Local Study Team Members Smart Form.**

The names of individuals associated with University of Oregon have been uploaded.

4. **Study Scope Smart Form.**

If the study involves Drugs or Devices, the appropriate questions are marked "yes".

What information do I need to add/update and what materials do I need to upload?

Questions marked with a red asterisk (*) are required.

1. **Assign [Primary Contact and PI Proxy(s)](#) as needed.**

ONLY the PI will receive system notifications until the PI updates the Primary Contact and PI Proxy(ies).

> ➤ If the PI depends on others to track research, it is imperative they update the studies so that the appropriate individuals receive notifications.
> ➤ For student research, the faculty advisor must be assigned as a PI Proxy.

2. **Basic Study Information Smart Form.**

a. Short Title.

You can enter a different title here if you wish.

> ➤ If you use a nickname for your study, you can reference it with the short title here! The short title identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review.

b. Basic Description.

Enter a brief description of the research and explain if it is either greater than minimal risk or no greater than minimal risk.

c. Upload the following to the last question.

The following materials are attached to the last question of the Basic Study Information Smart Form.

- ➢ If you are proposing changes at this time, the uploaded materials will have to be *tracked*. We highly recommend using Word documents whenever applicable.

  i. Modification Application

    A Modification Application only is required if the investigator is proposing changes at this time. If the purpose of submitting an amendment is simply to complete the migration of a legacy study in the RAP and upload previously approved materials, a Modification Application is not required.

  ii. Research Plan and the following applicable Research Plan appendices.

    o Appendix A - Drugs and Other Substances
    o Appendix B - Medical Devices
    o Appendix C - Ionizing Radiation
    o Appendix D - HIPAA (use of PHI)
    o Appendix E - Genetic Materials

  iii. COI Form for Principal investigator.

    Submit only if you have identified a COI for the PI.

3. **Study Funding Sources Smart Form.**

   a. Update internal funding source.

     Add the funding source for research funded internally (i.e., if for research with no EPCS Record associated).

   b. Upload the funding form.

     The funding form associated with each award here.

   c. See the quick reference for details of what to find on the study funding sources smart form.

4. **Local Study Team Members Smart Form.**

   a. Local (UO) Study Team Members.

     i. Add the UO affiliated study team members engaged in human subjects research.

     ii. Answer all required questions for each UO affiliated team member. If an individual team member has identified a conflict, upload the COI their COI form.

   b. External Team Members.

     i. If there are external team members (unaffiliated with University of Oregon) **not covered** under an institutional reliance agreement (e.g., IAA, Smart IRB), complete the external team members/personnel form and attach here.

ii. Individuals with no institutional affiliation must have a completed Individual Investigator Agreement (IIA). The IIA and any other relevant information needs to be attached here.

iii. Do not include information about team members you were able to select under Local Study Team Members. For people listed in the system, the information should be added to their profiles in the system instead.

5. **Study Scope Smart Form.**

   a. Indicate if the study used ionizing radiation, protected health information (HIPAA), or genetic information.

   b. Indicate if recruiting through UO Human Subjects Pools.

   c. Answer whether the study is a clinical trial.

6. **Local Research Locations Smart Form.**

   a. 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.

   b. Will activities take place at non UO campus locations?

   Identify any research locations that are not part of the University of Oregon campus.

7. **Drugs Smart Form.**

   If question 1 under the Study Scope smart form was affirmative, the Drugs smart form will appear.

   a. List all drugs, biologics, foods, and dietary supplements.

   b. Attach related materials.
      o Package insert
      o Investigator brochure
      o Verification of each IND number (one of these)
        ▪ Sponsor protocol with the IND number
        ▪ Communication from the FDA or sponsor with the IND number

8. **Devices Smart Form**

   If question 2 under the Study Scope smart form was affirmative, the Devices smart form will appear.

   a. Select the device.

   b. Answer the device exemptions applicable to the study.

   c. Attach related materials.
      o Product labeling/device instructions

- o Investigator brochure
- o 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

9. **Local Site Documents Smart Form.**

   a. Consent forms.

   If applicable, attach all consent materials.
   - o Informed Consent
   - o Passive Parental Consent (opt-out consent)
   - o Oral consent scripts
   - o Translations and Translated Materials

   b. Recruitment materials.

   If applicable, attach all recruitment materials. Examples of recruitment materials are:
   - o Recruitment flyers
   - o Print media, such as newspaper ads
   - o Verbal/email recruitment and screening scripts
   - o Social media/online advertising/MTurk HIT
   - o Video advertisement

   c. Other attachments.

   Attach any other materials not otherwise solicited.
   - o Research instruments
   - o Debriefing materials
   - o Permissions and approvals (e.g., human subjects pool coordinator, school districts, owner of a bulletin board, listserv, etc.)
   - o Data use agreements
   - o Data safety monitoring plans
   - o Data safety monitoring boars/committee information
   - o Release form for translators and transcribers
   - o All other related study materials documents not otherwise solicited

10. **Other Study Information Smart Form.**

    a. Anticipated Start Date.

    Provide the date you started HSR activities (including recruiting participants) or anticipate you will start HSR activities for continuing review and modifications.

    b. Anticipated End Date.

    Provide the date you anticipate you will no longer be working with participants or identifiable participant information.

    c. Select which application type describes the study.
    - o IRB Review Application. Choose if your research was reviewed as Expedited or Full Board.
    - o Exempt Determination Application. Choose if your research was given an Exempt determination.
    - o Approval in Principle Application. Choose if you have an AIP and your research was previously issued an AIP and is still under development. If you are submitting a modification to apply for IRB approval, select either "IRB Application" or "Exempt Determination Application".

d. What is the Principal Investigator's role at the U of O?

e. Under which unit is the investigator conducting this research?

11. **CITI**

   Current CITI training for individuals affiliated with the University of Oregon will show up in the submission for each person listed on the protocol so long as the CITI profile information is an exact match to what is listed in the RAP.

   - o To integrate properly, the individual's first name in their CITI profile must match the [preferred first name](#) as listed in DuckWeb. The last name and email address as must match what is listed in the University of Oregon database (Banner).
   - o If your CITI account was set up when affiliated with another institution, update your [CITI profile information](#) so that your first name, last name, and email address match what is listed in the RAP.

What can I do to prepare?

1. **Attend a training!**

   See our [training catalog](#) for more information on dates, times, and registration links for the latest sessions.

2. **Locate your most recently approved materials.**

3. **Make sure your CITI profile name and email address match that listed in the RAP.**

   To integrate properly, the individual's first name in their CITI profile must match the [preferred first name](#) as listed in DuckWeb. The last name and email address as must match what is listed in the University of Oregon database (Banner).

4. **Identify who will act as your PI Proxy.**

   See our [quick reference](#) for information on PI Proxies and Primary Contact.

5. **Reach out to RCS with any questions!**

   Email us at [researchcompliance.uoregon.edu](#) and we would be happy to answer any questions!