Step-by-Step Follow-On Study Submission Guide
eIRB User Guide – Modifications, Continuing Review, and study closure

Purpose: The purpose of this guidance document is to provide step-by-step instructions to modify, renew, or close your project in the eIRB. See the table below for a summary of the actions that can be accomplished with each type of submission.

<table>
<thead>
<tr>
<th>Follow-on Submission Type</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Modification</strong></td>
<td><strong>Modification Scope:</strong></td>
</tr>
<tr>
<td></td>
<td>• Study Team Member Information</td>
</tr>
<tr>
<td></td>
<td>o Add or Remove Study Staff</td>
</tr>
<tr>
<td></td>
<td>o Assign/change Study Staff Roles</td>
</tr>
<tr>
<td></td>
<td>o Upload External Study Staff Documentation (Training Certificates, IIAs, IAAs)</td>
</tr>
<tr>
<td></td>
<td>• Other Parts of the Study</td>
</tr>
<tr>
<td></td>
<td>o Change the PI</td>
</tr>
<tr>
<td></td>
<td>o Add/remove study documents</td>
</tr>
<tr>
<td></td>
<td>o Update the IRQ (basic information, funding sources, study scope, recruitment/consent, study details, ancillary reviews)</td>
</tr>
<tr>
<td><strong>Modification &amp; Continuing Review</strong></td>
<td><strong>Modification:</strong></td>
</tr>
<tr>
<td></td>
<td>• Modification Scope: see options above</td>
</tr>
<tr>
<td></td>
<td><strong>Continuing Review:</strong></td>
</tr>
<tr>
<td></td>
<td>• Renew IRB approval</td>
</tr>
<tr>
<td></td>
<td>• Close a study</td>
</tr>
</tbody>
</table>

Contents

How to modify an existing project in the eIRB................................................................. 3
How to prepare a combined Modification and Continuing Review for an existing project in the eIRB... 7
How to prepare a study closure submission ........................................................................ 11
How to modify an existing project in the eIRB

If you find that your project requires changes to documents or study staff, you should submit a modification in the eIRB system.

Notes:

- Once the pathway for the modification is selected and you click “continue,” it cannot be changed. If you make an error in the creation of your modification, please contact the eIRB at 503-494-7887, option 1 and ask to have the modification discarded.
- The system only allows 1 type of modification (“study staff” vs “other parts”) to be active at any one time in the system.

1) Click the “create modification/CR” action from the main page of your study as seen below:

2) On the next screen you will select “modification”:

3) Next, select what you plan to modify. Choose “Study team member information” and/or “Other parts of the study” by selecting the appropriate check box. **Note: the system defaults to select both of the below options.**
   
a. Study team member information – use this function to add/remove study staff, change the role of a member of the study staff (i.e. staff member, obtaining consent, data analysis, etc.)
   
b. Other parts of the study – use this function to add/revise study documents, change the PI, or update funding information.

Click the “Continue” button in the upper right-hand corner to advance to the next page.
4) Provide information about the modification you wish to make using the “Modification Information” page of the eIRB including:
   a. **Title** - Provide a title for the modification that makes clear the main reason for the modification.
   b. **Study enrollment status** - Indicate the study enrollment status(es) that most closely match that of your study. If you feel that none of the options adequately reflect your study status, select the one that’s closest and provide clarification in question 5 of the Modification Information page.
   c. **Notification of subjects** - Indicate if current and/or former subjects will need to be notified of the change.
      i. “Current subjects will be notified of these changes” – Check this box for changes to risks and/or procedures.
      ii. “Former subjects will be notified of these changes” – Check this box if you are adding/changing information about risks that may present after the end of the study.
   d. **Summarize the modifications** - Provide a brief summary of the changes you wish to make, including documents revised, any new documents, and any changes to study staff.
      i. Note: if a protocol and/or Investigator Brochure summary of changes is not provided by your study sponsor, you will be expected to provide one here.
   e. **Subject Status** - Provide a brief summary of subjects’ status including the total number enrolled (i.e. consented) into the study, the number still active on study, and the number in follow up. If the study involves an experimental medication or device, state the last date that the subject received the experimental treatment.
   f. **Does this modification add or change radiation for this study?** – Indicate if any of the changes to your study will result in a change in exposure to radiation. If yes, be sure to update your radiation form on the ancillary reviews page of the eIRB.

5) Advance through the rest of the submission using the continue button or the “Jump to:” drop down menu.

6) To revise a previously approved document:
   a. Download the draft version of the document from the documents tab of your main study space in the eIRB.
   b. Using the track changes function in Microsoft Word, make changes to your desired documents and save your document to your desktop.
   c. Upload your revised document to the eIRB using the “update” function next to the previously approved document. **Note:** Do not upload a revised document using the “Add” function; your project will be returned for corrections.
d. After clicking “update”, click “choose file” and find your revised document on your computer desktop. Double click on your document, and click “OK”.

e. Repeat for all revised documents.

7) To add a new document to the study:
   a. Navigate to the page where the document you wish to add fits best (i.e. protocol, consent, recruitment, etc.)
   b. Click the “Add” action at the top of the appropriate field to bring up the upload dialogue box as seen above in 6d. Click “Choose File,” locate your document and double click on it, and click “OK”.

8) To change the PI:
   a. From the Basic Information page in the eIRB, click the “Select” button under question #4.
   b. Search for your new PI and select the appropriate radio button to indicate the person to assume PI responsibilities.
   c. Obtain a memo/email from the PI stating that s/he is willing to assume study oversight responsibilities for the current PI. Upload this document under “Supporting Documents”.

9) To change/add funding:
   a. Navigate to the “Funding Sources” page in the eIRB.
   b. Click the appropriate radio button to indicate if the study is funded, unfunded with external, non-monetary support, or unfunded.
   c. To add a new funding source:
      i. Click the “Add” action to bring up the funding dialogue box.
      ii. **Funding organization** - Click the “Select” action to search for your funding agency.
      iii. If you cannot locate your funding agency in the list, contact awards@ohsu.edu or 503-494-0355 for assistance. If it is a new funding agency, it may take up to 2 days for OPAM to set up. You will be notified when the funding agency is available.
      iv. **Sponsor’s funding ID** - Provide the sponsor’s funding ID (if applicable).
v. **PPQ#** - Provide your PPQ/ePPQ# (if applicable). You may enter “n/a” if your study does not have a PPQ#.

vi. **Note** – Any supporters (i.e. companies providing free drug only) should also be added as a funder.

vii. **Attach files** – Attach your full grant application if grant funded.

d. **To change the funding source:**
   
i. Click the underlined link under “Funding source” on the funding page.
   
ii. Revise all applicable information as indicated under 10c.
How to prepare a combined Modification and Continuing Review for an existing project in the eIRB

If you wish to alter the eIRB, documents or study staff with your continuing review submission, you can create a combined “Modification and Continuation Review” submission.

1) Click the “create modification/CR” action from the main page of your study as seen below:

2) On the next screen you will select “Modification and Continuing Review”:

   * What is the purpose of this submission?

   - [ ] Modification
   - [x] Modification and Continuing Review
   - [ ] Clear

   Click the “Continue” button in the upper right-hand corner to advance to the next page.
3) Provide the following current enrollment numbers for the study:
   a. At all sites
   b. At OHSU
   c. At OHSU since last Continuing Review (CR)
   d. Subject withdrawals
   e. Include VA enrollment if applicable (check box labeled “VA subjects not included in project” if not applicable)

   1. Total subjects to date:

<table>
<thead>
<tr>
<th>Subjects to Date</th>
<th>Total</th>
<th>Since Initial or Continuing Review Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At all sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At this Investigator's sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject withdrawals at this Investigator's sites</td>
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</tbody>
</table>

   Additional Details on VA Subjects:
   - [ ] VA subjects not included in project

   Total Number VA Subjects: __________________________
   VA Subjects withdrawn to date: ______________________
   VA - Prisoners: __________________________
   VA - Subjects lacking decision-making capacity: ______
   VA - Minors: __________________________
   VA - Premature: __________________________
   VA - Failed: __________________________

4) Indicate the status of your study by checking the appropriate “Research Milestones” (check all that apply):

   - [ ] Study is permanently closed to enrollment.
   - [ ] All subjects have completed all study-related interventions.
   - [ ] Collection of private identifiable information is complete.
   - [ ] Analysis of private identifiable information is complete.
   - [ ] Study remains active only for long-term follow-up of subjects (No research-only procedures)
   - [ ] Remaining study activities are limited to data analysis

   **Note:** Checking all four of the first milestones will signal the IRB to close your study in the eIRB.

5) Upload the appropriate “Continuing Review Form” (OHSU or VA/Joint). Links to both forms are available from within the eIRB smart form:

   3. * REQUIRED: For all studies, complete and upload the OHSU Continuing Review Form or VA/Joint Continuing Review Form.
   
   Name: __________________________
   Version: __________________________

   There are no items to display

   f. Continuing review form questions
      i. Describe the circumstances behind any subject withdrawals that occurred since the last CR.
      ii. Summarize the unreportable events (usually SAE reports or protocol violations that did not rise to the level of requiring RNI reporting) that occurred since last CR. This can be a list typed into the CR form, or a spreadsheet uploaded under
Industry sponsors will often be able to provide you with a list for your study.

iii. Reportable events that qualify as an RNI (see RNI quick guide) should be summarized here and submitted in the eIRB as an RNI.

iv. Summarize any new information such as change in funding, DSMB/C reports, interim analysis, etc.

v. Provide a brief statement about the status of subjects enrolled in the trial. Ideally, we are looking for the number of subjects actively receiving study drug, the number in study follow-up, and if all subjects are off study drug, when the last dose was given.

vi. List any documents that you have archived (only an option if you are doing a combined mod/CR).

vii. If the study has lapsed prior to submitting your MODCR:
   1. You’ll need to fill out #s 7 and 8 indicating any need to continue with study procedures or treatment, as well as the study team’s plan to prevent the study from lapsing again in the future.

6) Upload any additional documentation you wish to submit with your MODCR. This could include, but is not limited to, the following:
   g. DSMB/C reports
   h. Audit reports
   i. Lists of unreportable events
      i. AEs that are not UPs
      ii. PDs that were not reported as RNIs
   j. Repository tracking sheets – Note: The study’s repository tracking sheet must be updated and uploaded at every continuing review to document the collection and distribution of all data/samples over the life of the study. Each year, you will go back to the MODCR project from the year before to find the most recent version of the study’s tracking sheet.
   k. Sponsor correspondence (including study closure notification)

7) For VA studies, describe any subject injuries reported to the study team.

8) Click “Continue” to advance to the final page.

9) Complete the submission by clicking the “Finish” button in the upper right-hand corner of the screen. You will be taken out of the submission to the MODCR workspace.
10) Submit your MODCR by clicking the “Submit” action under “My Current Actions” on the left side of the screen. If you are not the PI, the action will say “Notify PI”. The PI will then receive an automated notification from the eIRB prompting them to submit the study.

Note to PIs: If you are returning a submission after receiving a “clarification request” from your IRB Coordinator, the action will read “Submit Response”.
How to prepare a study closure submission

When all study activities have been completed, the study no longer requires IRB oversight. A modification/continuing review should be submitted to end IRB oversight.

**When can I close my study?** – In order to cease IRB oversight for your study, the following conditions must be satisfied here at OHSU:

- Enrollment of study subjects has ended
- All study subjects have completed trial related interventions/procedures
- Collection of private identifiable information has been completed
- Analysis or private identifiable information has been completed.

If any of the above tasks has not been completed, the study is not ready to be closed.

1) Click the “create modification/CR” action from the main page of your study as seen below:

![Create Modification/CR button]

2) Click the radio button for the combined “Modification/CR” option, and click continue:

![Modification and Continuing Review]

3) Provide all enrollment information, including the number of subjects enrolled since the last continuing review approval
   a. If the study did not enroll any VA subjects, check the box to the left of these fields

   **Additional Detail on VA Subjects:**

   - VA subjects not included in project

4) Mark the first four research milestones to indicate that the study is ready to end IRB oversight:
5) Prepare and upload the OHSU Continuing Review Form or VA/Joint Continuing Review Form as applicable (required even for studies closing to IRB oversight) using the “Add” function:

3. **REQUIRED:** For all studies, complete and upload the [OHSU Continuing Review Form or VA/Joint Continuing Review Form](https://ohsuforms.ohsu.edu/forms/Continuing-Review-Form).

   - Name: [Add]
   - Version: [Add]

   There are no items to display

6) Upload any documentation needing review prior to closure using the “Add” function. Examples include (but are not limited to) DSMB reports, audit reports (that do not require submission via RNI), list of unreportable events, repository tracking sheets, sponsor closure notification.

   - Industry sponsored projects are required to submit correspondence indicating site closure

7) For VA studies, describe any claims of subject injury.

5. **For VA Studies only:**

   **Describe if any subjects claimed injury for participating at the VAPORHCS:**