Continuing Review for External IRB Study Guidance for Researchers

Use these directions to request an extension of your expiration date in the RAP for a study where the University of Oregon (UO) is not the IRB of record and is relying on another IRB for review and approval. As the UO uses the approval letters from the IRB of record to identify the expiration date, this is a two step process to report the continuing review data and submit a modification with the updated approval memo from the external IRB.

1. Go to the parent study for your external IRB project in the RAP. This is the submission that begins with "STUDY" and then a series of eight numbers (e.g., STUDY00000000).

2. Click "Report Continuing Review Data"
   Note: only the PI and PI proxy will have access to this button. Other study team members will not see it. This is a system limitation that cannot currently be changed.

3. In items 1 and 2, complete the questions about your enrollment numbers. For item 3, check all that apply. Note: please do NOT upload anything into supporting documents.

Report Continuing Review Data

1. Specify enrollment totals at this investigator's sites:

2. Specify enrollment totals at this investigator's sites since last approval:

3. Check the items that are true for this site since the last IRB approval: (initial review or last continuing review)
- [ ] NO subjects experienced unexpected harm
- [ ] Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- [ ] NO subjects withdrew from the study
- [ ] NO unanticipated problems involving risks to subjects or others
- [ ] NO complaints about the study
- [ ] NO publications in the literature relevant to risks or potential benefits
- [ ] NO interim findings
- [ ] NO multi-center trial reports
- [ ] NO data safety monitoring reports
- [ ] NO regulatory actions that could affect safety and risk assessments
- [ ] NO other relevant information regarding this study, especially information about risks
- [ ] In the opinion of the PI, the risks and potential benefits are unchanged
- [ ] All modifications to the protocol have been submitted to the IRB
- [ ] All problems that require prompt reporting to the IRB have been submitted

4. Supporting documents: (include an explanation of each item left unchecked above)

+ Add

Name
There are no items to display

5. Comments:

4. Click ok

5. Click Create Site Modification

Create Site Modification

6. Click Modification/Update

7. Click Other parts of the site then Continue

8. In item 1, describe the enrollment status. In item 2 indicate whether you plan to notify subjects about the changes in the modification. If you are not changing anything that impacts subjects, you can leave those boxes in item 2 blank. In item 3, describe what you are changing (e.g., uploading most recent approval letter from IRB of record, uploading most recent IRB approved documents from main site, updating funding details).

Modification Information

1. Study enrollment status:
- ☐ No subjects have been enrolled to date
- ☐ Subjects are currently enrolled
- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions
- ☐ Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)
- ☐ Current subjects will be notified of these changes
- ☐ Former subjects will be notified of these changes

ⓘ Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Summarize the modifications: ❓

[text box]

9. Click Continue

10. Update the applicable sections of the RAP for your reliance. The approval letter and other approved materials will go in the Local Site Documents section (Other attachments). If you have local UO consent forms or local UO recruitment materials, include them in the corresponding sections as applicable.

11. Click Finish

12. Click Submit   ➔ **Submit**