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 will have access to this button. The PI proxy and 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.
4. Click ok

5. Click 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).

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