Submitting Amendments and Continuing Reviews in webIRB
Creating Amendments & Continuing Reviews in webIRB

- After approval of a study in webIRB, Amendments (AMs) and Continuing Reviews (CRs) are submitted through webIRB.

- AMs and CRs are created in the approved study workspace using:

  AM  New Amendment
  CR  New Continuing Review
Amendments in webIRB
How many AMs can I submit at the same time?

• Only one amendment can be created at a time.

• When an amendment is submitted, the sections of the application that are being modified are locked to further changes until the amendment is reviewed and approved.
Steps for preparing an AM application

• **Step 1:** Start the AM application by clicking in the approved study workspace of the study you are modifying.

• **Step 2:** Describe the amendment (i.e., proposed changes to the study application).

• **Step 3:** Revise the study application and study documents, if applicable.

• **Step 4:** Submit the Amendment.
Step 1: Create an AM

• In the approved study workspace click on: **AM New Amendment**

• The **Description of Amendment** section will appear.

Warning: Save your work at least every 15 minutes by clicking “Save” or “Continue.”
Step 2: Describe the Amendment

Complete the Description of Amendment section:

- **1.0- Provide a short title**
  The title will appear on the AN.

- **2.0- Indicate whether or not there is change in study staff and/or key personnel**
  New study staff/personnel will have access to the study when the AM is approved.

- **3.0**
  If this amendment includes a change to the Principal investigator and the current person filling this role...

- **4.0**
  *Minor Amendment - Types of change(s) proposed.*
  Check all that apply:
Step 2: Describe the amendment (cont’d)

Select the check box(es) that best describe the proposed change(s).

4.0 * Minor Amendment - Types of change(s) proposed.
   Check all that apply:
   - Clarification or technical change
   - Minor increase/decrease in number of Study participants
   - Narrowing of the inclusion criteria
   - Broadening of the exclusion criteria
   - Changes in the dosage or form (e.g., tablet to liquid) but not the route of administration of an approved drug
   - Increase or decrease in the number of safety monitoring visits provided that there is no impact on subject safety.
   - Addition or deletion of study sites
   - Change in payments to study participants
   - Minor changes to recruitment materials
   - Minor changes to screening procedures
   - Change in funding source(s)
   - Other
   - None of the above

5.0 * Major Amendment - Types of change(s) proposed.
   Check all that apply:
   - Change in study design of a protocol approved by the full board of the IRB
   - Change in status of study participants (e.g., study participant becomes prisoner, ward, or pregnant in a protocol not approved for these populations (Note: This primarily applies to medical or treatment studies.)
   - Addition of a procedure not approvable using expedited review procedures (e.g., ionizing radiation)
   - Changes that increase risk or discomfort to study participants
   - Substantive changes to a consent form or other study documents distributed to subjects.
   - Other
   - None of the above

6.0 If you selected “other” to any of the items above, list the type of change.
Step 2: Describe the amendment (cont’d)

7.0- Provide a description and justification for the changes you selected in Items 2.0, 4.0, and 5.0.
- If applicable, describe procedures for re-consenting subjects.

7.1- If applicable, attach the summary of changes provided by the sponsor.
- Use Item 7.0 to describe the changes that apply to the study.
- Do not attach new or modified study documents.

Note: All other materials - such as consent forms, recruitment flyers, etc. - must be attached to the appropriate section of the application - not here.
Step 2: Describe the amendment (cont’d)

8.0 Indicate whether there are any subjects currently enrolled in the study.
- If applicable describe procedures for re-consenting subjects in Item 7.0.

Addendum Consent Templates are available at http://ora.research.ucla.edu/OHRPP/Pages/ConsentTemplates.aspx#addendum
9.0- Indicate whether you are submitting a Post-Approval Report (PAR) with the Amendment.
- The application will branch with the PAR questions.
- If the PAR has been submitted as a separate application, select “No”.
- Click “Continue” to go to the next section.

Finish
- When you reach Finish click “SmartForm” to go to the study application.
- Section 1.1 of the study application will appear.
Step 3: Modify the study application

• Review all sections of the study application. Use **Jump To** or **Continue** to navigate through the sections.

• Modify **all relevant** sections of the study application.

• Click **Save** after revising each section.

• **DO NOT** modify the response in the CRC sections. Studies converted to webIRB at the time of continuing review contain the CRC sections.
Step 3: Modify the study application (cont’d)

Revised Documents:

- Use **Edit** to replace previous versions of documents with the updated versions.

- Use **Add** to upload new documents in the application.

- Update the document title to distinguish between the marked and clean copy. Include the version date. (e.g., “child assent_marked_010111”, “child assent_clean_010111”).

- To remove documents, click on the checkbox of the document you want to remove. Then click on **Delete**.
Step 3: Modify the study application (cont’d)

Example: The PI is adding a youth assent and revising the HIV consent form in section 20.3.

Modify the consent form and save the marked and clean copy on your desktop. Name them “HIV Consent Form-marked 081211” and “HIV Consent Form-clean 081211”.

Section 20.3 before uploading the youth assent and revised consent forms.

Use Add to upload the youth assent.

Use Edit to upload the updated marked and clean version of the consent form.
Step 3: Modify the study application (cont’d)

Section 20.3 before uploading the youth assent and revised consent form.

Section 20.3 after uploading the new youth assent and revised consent form.

Note document version # of the updated documents.
Step 3: Modify the study application (cont’d)

• Click Exit when you are done updating the study application.

• You will return to the Finish section of the Amendment Smartform.

Click Finish to go to the Amendment workspace to submit.
Step 4: Submit

- The **Submit Amendment** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the Amendment is ready to be submitted.
Continuing Reviews
Steps for preparing a CR application

• **Step 1:** Start the CR application by clicking in the approved study workspace.

• **Step 2:** Complete the CR application.

• **Step 3:** Submit the CR.
  - If you are modifying the study application at the time of continuing review, create and submit a separate amendment.
  - If you are submitting a PAR at the time of continuing review, create a PAR in the approved study workspace. The PAR will be reviewed with the CR.
Step 1: Create a CR application

• In the approved study workspace click on:

   ![CR New Continuing Review](image)

• The **Continuing Review-Type of Study** section will appear:
Step 2: Complete the CR application

• The SmartForm will branch depending on the type of report you are submitting:
  • Progress report for continuing review
  • Study Closure

• Click **Continue** to navigate through the sections.

• Complete the CR by providing a response to all the questions in each section.
Step 2: Complete the CR application (cont’d)

If you have not submitted all the required post-approval reports during the past approval period:

• Go to the approved study workspace and create a PAR.
• The PAR will be reviewed along with the CR.
• Submit the PAR at the same time you submit the CR.
Step 2: Complete the CR application (cont’d)

Click Finish when you reach Section 4.0-Continuing Review or Closure Report to go to the CR workspace.
Step 3: Submit the CR

- The **Submit Continuing Review** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the CR is ready to be submitted.
Submit the CR

Before submitting:
- If you have a faculty sponsor (FS) use **Send Notification to FS for FS Assurances** to obtain your FS assurances.

To submit the CR:
- **Submit Continuing Review** available only to the PI and PI Proxy.
- **Send Ready Notification** - available only to study staff to let the PI/PI Proxy know the CR is ready to be submitted.

After Submitting:
- The activity **[PI Assurances]** will appear.
- The PI must provide his/her assurance by clicking on this activity.
The PI must provide the appropriate PI Assurances.

If **Progress Report for Continuing Review** was selected in Section 1.1/item 2.0, the PI must provide the **Continuing Review Assurances #1-#3**.

If **Study Closure** was selected in Section 1.1/item 2.0, the PI must provide the **Study Closure Assurances**.
Create and complete the PAR

If you are submitting a PAR with the CR, go to the approved study workspace to create the PAR using:

- The PAR application will appear. Complete the application.
- When you complete the application the PAR workspace will appear.
Submit the PAR:

- The **Submit** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the Amendment is ready to be submitted.
Summary

- Amendments and Continuing Reviews are created in the approved study workspace.

- If you are submitting a PAR the time of continuing review, go to the approved study workspace to create the PAR.
Questions?