## Post-Approval Activities

After study approval, Post-Approval Reports, Amendments, and Continuing Reviews (and study closures) are submitted through webIRB. These functions are available from the study workspace.

### Post Approval Reports or Single Subject Exception

1. **Post-Approval Reports or Single Subject Exception**
   - Serious, unexpected adverse events related to the study
   - Updated Safety information
   - Protocol Violations, Incidents or Deviations
   - Complaints about the Study
   - Request for Single Subject Exceptions
   - Sponsor Clarifications that do not amend the study

2. To start a report, click **Post Approval Reports or Single Subject Exception**
3. To notify the PI that the report is ready for review and submission, click **Send Ready Notification**
4. If you are the PI/PI Proxy, click **Submit**

### Amendments

1. **Tip Plan ahead.** You can only submit two “non-overlapping” amendments at a time.
2. To create an amendment, click **New Amendment**
3. Complete the form
4. When you get to Amendment Section 5 – click the link to the Application SmartForm. This will take you to the application
5. Make and save the needed changes to the application.
6. Click **Exit** – you will be returned to the Amendment Application.
7. Click **Finish**
8. To notify the PI that the amendment is ready for review, click **Send Ready Notification**.
9. If you are the PI/PI Proxy, click **Submit Amendment**

### Continuing Review (and study closures)

1. To initiate a **continuing review report or study closure** report, click **New Continuing Review**
2. Complete the form
3. To notify the PI that the report is ready for review and submission, click **Send Ready Notification**

If you are the **PI/PI Proxy**, click **Submit Continuing Review**

## Linked Amendments

The activity of **Create Linked Amendment** provides a way for you to let the IRB know that you are submitting an amendment associated with a Continuing Review or Post-Approval Report.

### Linked Amendment with Continuing Review – Pre Submission

1. When you are in the Continuing Review workspace, click **Create Linked Amendment**

2. An activity form will open.
   - Type in an amendment title and description.
   - Click OK
   - There will be a small delay as the program sets up the amendment

3. Look under the **History** tab. There will be a link to the amendment workspace.
   - Click on it

4. You will be taken to the amendment workspace.
   - Click **Edit Amendment**
   - An amendment smartform will open. Complete it.
   - Click **Edit Modified Study**

   - Returning to the amendment workspace and clicking **Edit Modified Study**
### Linked Amendments (continued)

5. You will be taken to the amendment workspace.
   - Click **Edit Amendment**
     - An amendment smartform will open. Complete it.
     - Make changes to the application by either:
       - Clicking on the link to the Smartform application from Section 5 of the amendment, or
       - Returning to the amendment workspace and clicking **Edit Modified Study**

6. To notify the PI that the amendment is ready for review, click **Send Ready Notification**.

7. If you are the PI/PI Proxy Click **Submit Amendment**

8. Return to the **Continuing Review** workspace to separately submit the continuing review.

- **Linked Amendment with Post Approval Report – Pre Submission**

When you submit an amendment with a Post-Approval Report, you will be asked within the PAR application to identify the IRB# for the related amendment, instead of creating a linked amendment as with the CR.

- **Linked Amendment with Post Approval Report – After review by the IRB**

After the IRB reviews a PAR, you may get feedback that an amendment is required.

1. If you already have submitted an amendment that addresses the IRB’s request, click **Link to Existing Amendment**.
   - When the activity form appears, identify the amendment that should be associated with the PAR.

2. If you need to create an amendment, click **Create Linked Amendment**.
   - Follow steps 2 – 7 as described in the Linked Amendment with Continuing Review – Pre Submission.