Post-Approval Activities

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

Amendments

1. To create an amendment, click **New Amendment**.
2. Complete the form.
3. After you complete the amendment cover page, click the link to the Application SmartForm. This will take you to application.
4. Make and save the needed changes to the application.
5. Click **Exit** – you will be returned to the Amendment Application.
6. Click **Finish**.
7. If you are the PI/PI Proxy, click **Submit Amendment**.
8. To notify the PI that the amendment is ready for review and submission, click **Send Ready Notification**.

Continuing Review (and study closures)

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

Post Approval Reports or Single Subject Exception

Post-Approval Reports or Single Subject Exceptions include:

- 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

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