

PI & Study Team Quick Reference Guide #4: Amendments, Continuing Reviews (& Study Closures) & PARs (7/30/2013)

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**.