Creating an Amendment

Important Information

- Amendments can be submitted on approved studies only.
- Only one amendment can be in process at a time for each study.

eResearch Home Workspace

1. Click **Approved** to display approved studies.
2. Click the **Name** of the study to view the approved study workspace.

Study Workspace

3. Click **New Amendment**.
Amendment Instructions

Click Continue >> after reading the Amendment Instructions.

Note: If this amendment is in response to an adverse event (AE) or other reportable information and occurrence (ORIO) that has not yet been submitted for review, click the Back button and select New Adverse Event/ORIO. AE/ORIOs must be submitted prior to the initiation of the amendment in order for them to automatically display in the amendment cover sheet. This will allow the reviewer to consider the amendment in the context of the AE/ORIO report.

Amendment Cover Sheet

4. Optional: Enter a title for your amendment. Leave the original study number in the amendment title unless directed by the IRB to follow a specific naming convention.

Note: Once approved, the amendment is accessed through the original study.

5. Complete the remaining fields on the form.

6. Click Continue >>.
Amendment Copy Currently in Progress

Note: This screen informs you that the system is currently creating a copy of the approved application. The system will notify the study team members selected in section one via email when the amendment copy process is complete.

7. Verify that the check boxes are selected next to the names of the study team members who should receive email notification.

8. Click Finish.

Amend Currently Approved Application

Note: This screen will only appear if the amendment copy process has completed before step 9.

9. Click the Click here to make changes to the currently approved application link or Finish to navigate to the amendment workspace.

Amendment Workspace

Note: Click the link supplied in the email notification to navigate to the amendment workspace.

10. Click Edit/Review Study to make changes to the amendment.

Note: If the amendment includes changes to the study team members, please note that newly added Co-Investigators and Faculty Advisors will need to accept their role prior to submission.

11. After making all changes to the amended application, click Submit Amendment.

Note: Only the PI can submit an amendment.
12. Complete the **Conflict of Interest** form.

13. Select the checkbox to indicate that you will abide by the **Investigator Assurances**.

14. Click **OK**.

**Note:**
Track the progress of the amendment using your Home Workspace in **In Progress**.

Once the amendment is approved, the amendment is viewed under the Study. Use the **Amendments** tab in the Study Workspace to view the amendment.