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.

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

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

4. Click **Continue** after reading the Amendment Instructions.

5. **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.

6. Complete the remaining fields on the form.

7. Click **Continue**.

Amendment Cover Sheet

5. 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.

6. Complete the remaining fields on the form.

7. Click **Continue**.

Amendment Copy Currently in Progress

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

9. Click **Finish**.

**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.
Amend Currently Approved Application

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

10. 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.

11. 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.

12. After making all changes to the amended application, click Submit Amendment (PI only).
Submit Amendment Window

13. Complete the **Conflict of Interest** form.

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

15. Click **OK**.

**Note:** Track the progress of the amendment in your Home Workspace under the **In Progress** tab. Once the amendment is approved, the amendment is viewed under the **Approved** tab.