

Creating an Amendment

Important Information

- Amendments can be created and submitted for approved studies only.
- Only one amendment can be in process at a time for any approved study.

eResearch Home Workspace



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

eResearch Study Workspace



3. Click New Amendment.

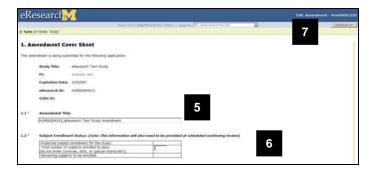
Amendment Instructions



4. Click **Continue** after reading the instructions.



Amendment Cover Sheet

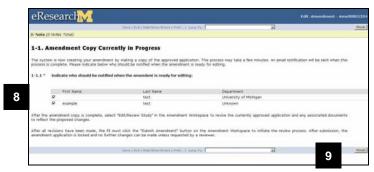


5. Optional: Enter a title for your amendment. Leave the original study number in the amendment title unless directed by the IRB to follow a specific naming convention.

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

- 6. Complete the remaining fields on the form.
- 7. Click Continue.

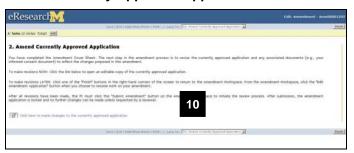
Amendment Copy Currently in Progress



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 1-1.1 via email when the amendment copy process is complete.

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

Amend Currently Approved Application



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

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

Amendment Copy Currently in Progress



Note: This screen will only appear if the amendment copy process has not completed before step 9.

Click My Home to continue with other work in eResearch.



Amendment Workspace



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

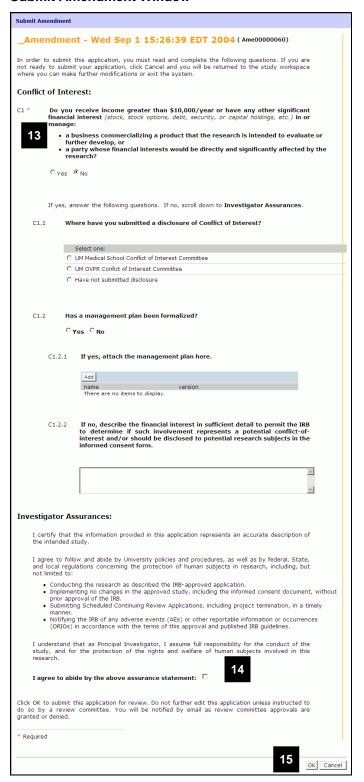
11. Click **Edit/Review Study** to make changes to the amendment.

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.

 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 **My Home** on **Applications In Progress** tab. Once the amendment is approved, the amendment is viewed within the parent study workspace in the **Amendments** tab.