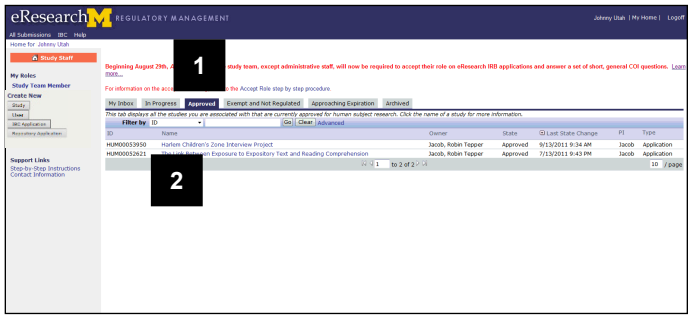
Creating an Amendment

Once a study application has been approved, an amendment must be created to document changes to the study (e.g., changes to study team, sponsors, subject populations, etc.). An amendment can be initiated by any Study Team Member listed on the approved application, but it can only be submitted for review by the UM Principal Investigator. After submission, the amendment application is locked and no further changes can be made unless requested by a reviewer. Only one amendment can be in process at a time for a study.

⚠ Important

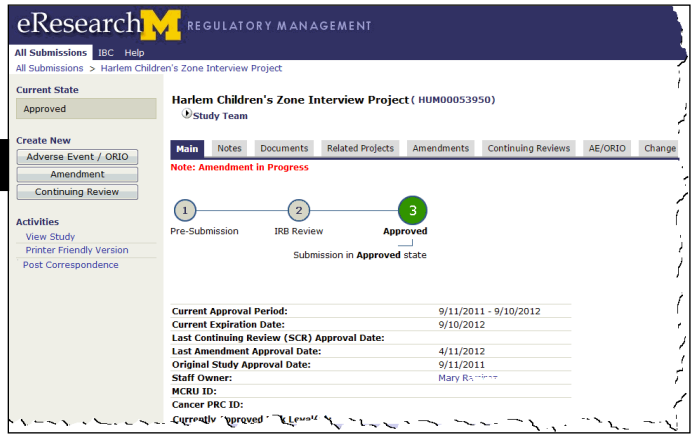
- In addition to any changes related to the amendment, **you must also verify that the required HR appointment information is provided for each study team member listed on the study before submitting the amendment.**
- If the required appointment information is not provided, you will receive an error and will not be able to submit the amendment. For more information regarding study team member appointments, see the Adding a Study Team Member step-by-step procedure.

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

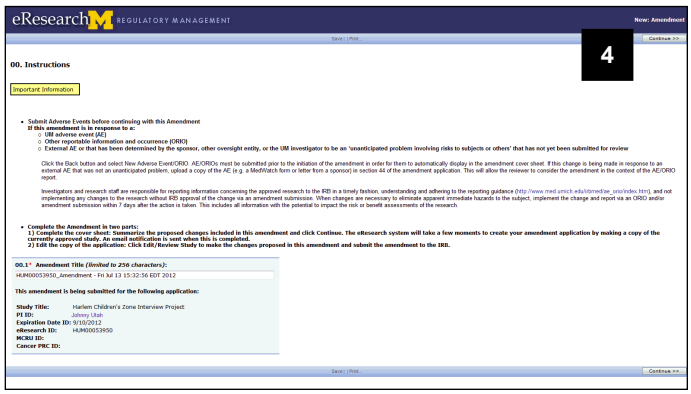


3. Click **Amendment**.

Notes:

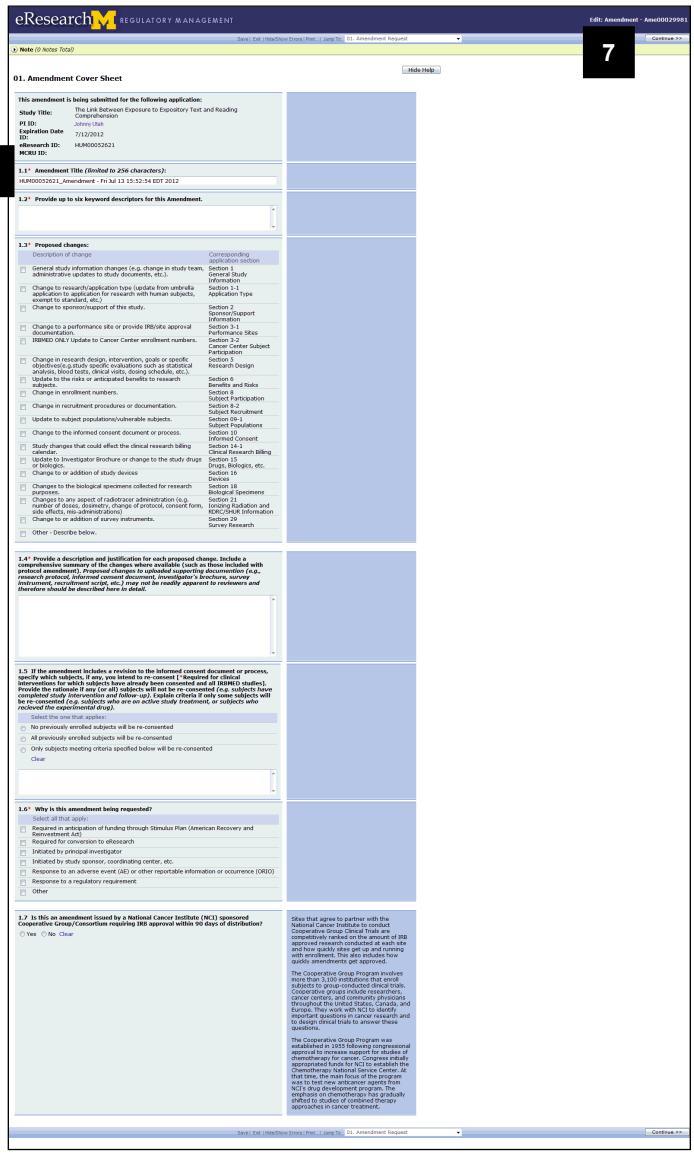
- If the amendment is in response to an *adverse event* (AE) or an *other reportable information and occurrence* (ORIO) that has not yet been submitted for review, click **Adverse Event/ORIO** instead.
- AE/ORIOs must be submitted prior to the initiation of the amendment in order for them to automatically display in the amendment cover sheet. This allows the reviewer to consider the amendment in the context of the AE/ORIO report.

Amendment Instructions



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

Amendment Cover Sheet

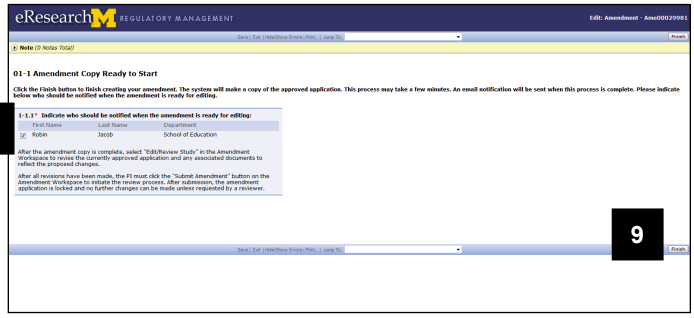


5. **Optional:** Enter a title for your amendment. Leave the original study number in the amendment title unless directed by the IRB to follow a specific naming convention.

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

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

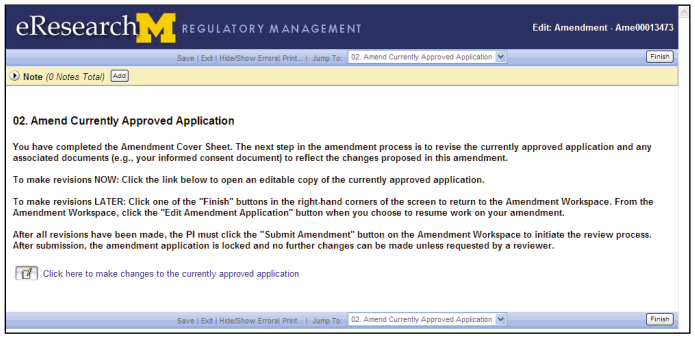
Amendment Copy Ready to Start



Note: This page informs you that the system is currently creating a copy of the approved application. The system notifies the selected study team members via email when the amendment copy process is complete.

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**.

Amend Currently Approved Application



Note: This page only appears 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

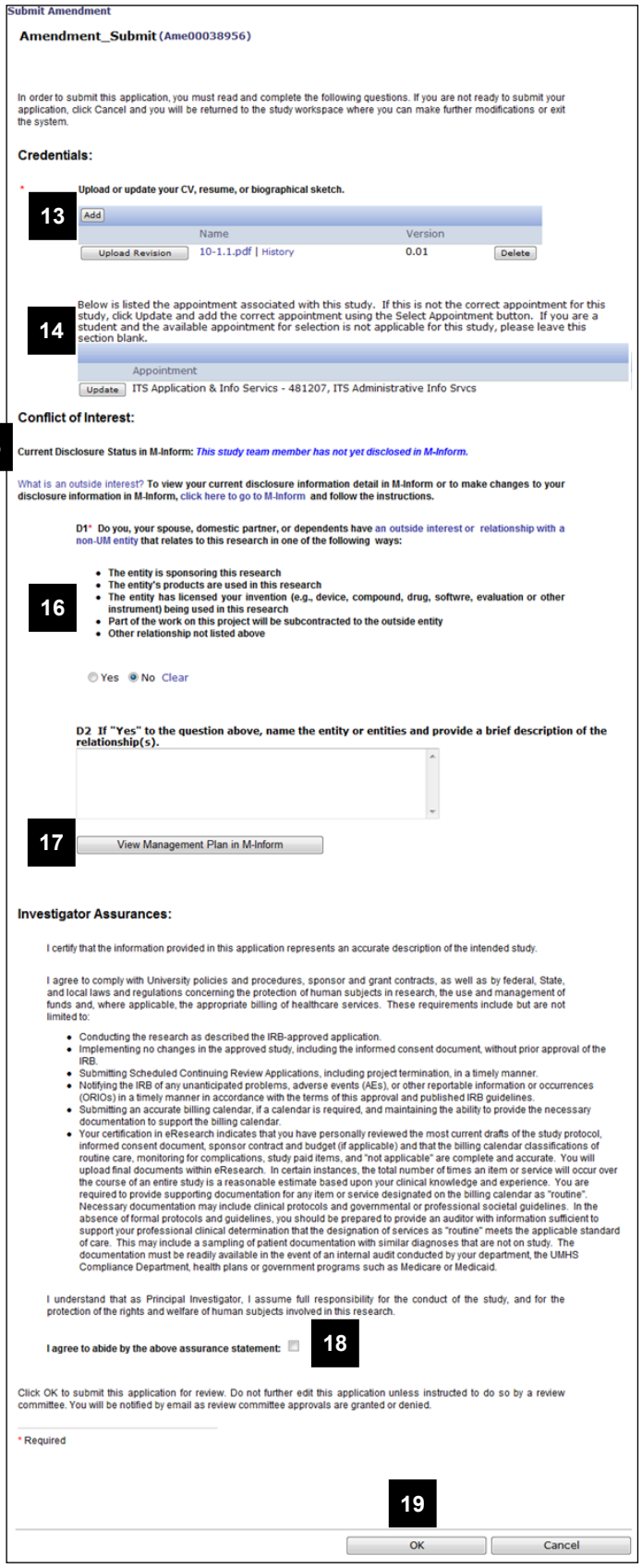
11. Click **Edit Study** to amend the study.

Note: If adding study team members in the amendment, any new 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**.

Note: Only the PI can submit an amendment**.**

Submit Amendment Window



13. (Optional) Click **Upload Revision** to update any documents listed in the **Credentials** section, or click **Add** to upload any new documents to the section
14. (Optional) If applicable, click **Update** if you wish to update the appointment associated with the study. This option only displays if an appointment was previously selected.
15. Note your **Current Disclosure Status in M-Inform**.
16. Read COI question **D1** and respond by clicking the applicable Yes/No radio button. If your answer to D1 is "Yes," complete question **D2**.

Note: Depending on a combination of your current disclosure status and your response to the COI question, you may be required to update your disclosure in M-Inform before submitting.

Disclosure Status / COI Question Response Scenarios

- In ALL cases where you answer "no," you can submit the amendment.
- If you answer "yes" and have not disclosed, you will have to disclose in M-Inform before you can submit.
- If you answer "yes' and have disclosed but have not outside interests, you will have to update your disclosure in M-Inform before you can submit.
- If you answer "yes" and have disclosed and have outside interests, you will be able to submit the amendment but will see a pop-up warning that says if necessary, update your disclosure information.

17. (Optional) Click **View Management Plan in M-Inform** to verify that one exists, or in order to update your current disclosure in M-Inform.
18. Click the checkbox to indicate that you agree to abide by the **Investigator Assurance** statement.
19. Click **OK** to submit the amendment for review by the appropriate committee(s).