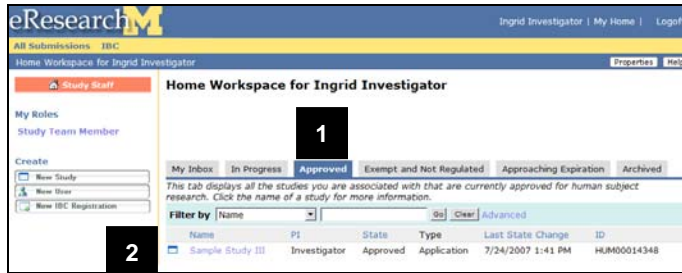


## Creating an Amendment

### Important Information

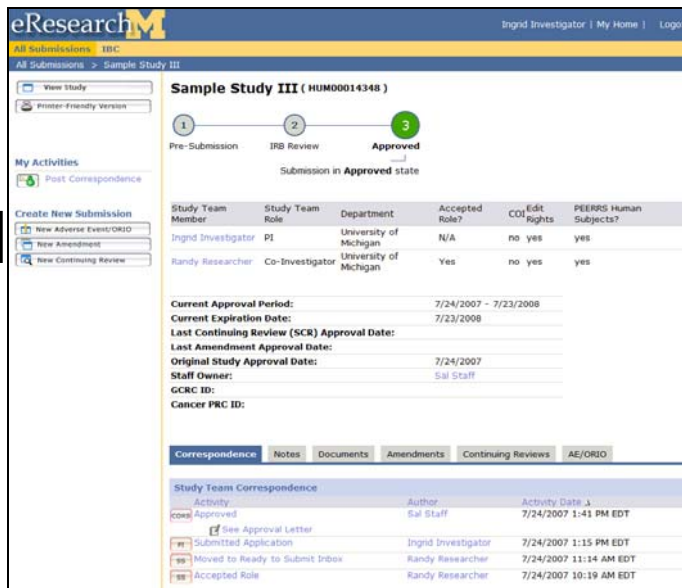
- Amendments can be submitted on approved studies only.
- Only one amendment can be in process at a time for each study.

### 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

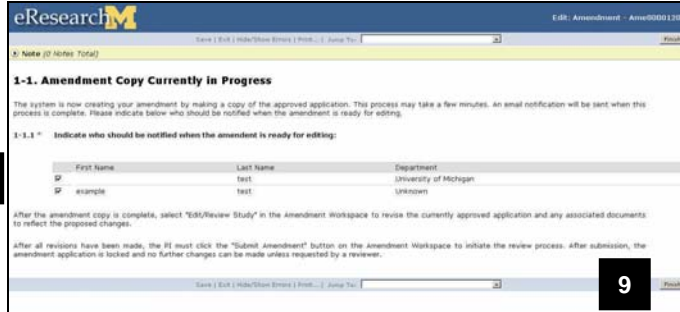
4. **Optional:** Enter a title for your amendment. Leave the original study number in the amendment title unless directed by the IRB to follow a specific naming convention.

**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



8

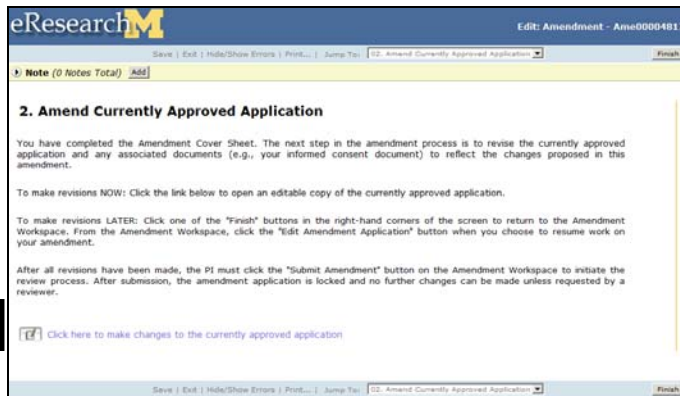
9

**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

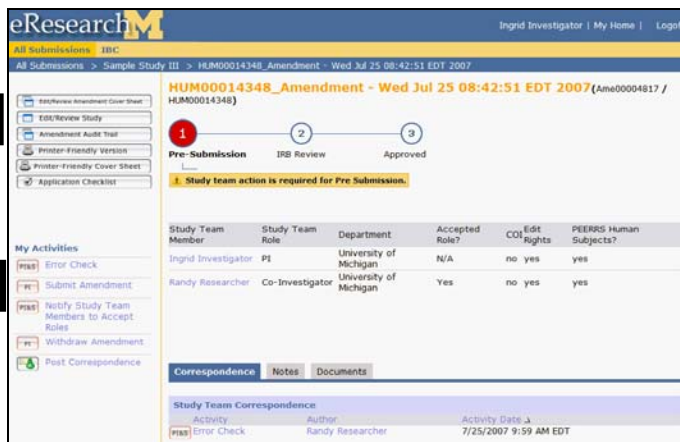


10

**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.

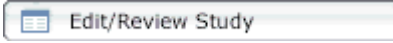
### Amendment Workspace



11

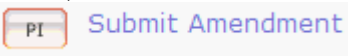
12

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

10. Click  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 

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

Submit Amendment Window

**Submit Amendment**

**HUM00014348\_Amendment - Wed Jul 25 08:42:51 EDT (Ame00004817) 2007**

In order to submit this application, you must read and complete the following questions. If you are not ready to submit your application, click Cancel and you will be returned to the study workspace where you can make further modifications or exit the system.

**Credentials:**

Upload or update your CV, resume, or biographical sketch.

Add	Delete	Name	Version
<input type="checkbox"/>	[Edit]	Investigator_CV	0.01

**Conflict of Interest:**

**C1** Do you receive income greater than \$10,000/year or have any other significant financial interest (stock, stock options, debt, security, or capital holdings, etc.) in or manage:

- a business commercializing a product that the research is intended to evaluate or further develop, or
- a party whose financial interests would be directly and significantly affected by the research?

Yes  No

If yes, answer the following questions. If no, scroll down to **Investigator Assurances**.

**C1.1 Where have you submitted a disclosure of Conflict of Interest?**

Select one:

UM Medical School Conflict of Interest Committee

UM OVPR Conflict of Interest Committee

Have not submitted disclosure

**C1.2 Has a management plan been formalized?**

Yes  No

**C1.2.1 If yes, attach the management plan here.**

Add	Name	Version
There are no items to display		

**C1.2.2 If no, describe the financial interest in sufficient detail to permit the IRB to determine if such involvement represents a potential conflict of interest and/or should be disclosed to potential research subjects in the informed consent form.**

**Investigator Assurances:**

I certify that the information provided in this application represents an accurate description of the intended study.

I agree to follow and abide by University policies and procedures, as well as by federal, State, and local regulations concerning the protection of human subjects in research, including, but not limited to:

- Conducting the research as described the IRB-approved application.
- Implementing no changes in the approved study, including the informed consent document, without prior approval of the IRB.
- Submitting Scheduled Continuing Review Applications, including project termination, in a timely manner.
- Notifying the IRB of any adverse events (AEs) or other reportable information or occurrences (ORIOs) in accordance with the terms of this approval and published IRB guidelines.

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects involved in this research.

**14** I agree to abide by the above assurance statement:

Click OK to submit this application for review. Do not further edit this application unless instructed to do so by a review committee. You will be notified by email as review committee approvals are granted or denied.

\* Required

**15**

- Complete the **Conflict of Interest** form.
- Select the checkbox to indicate that you will abide by the **Investigator Assurances**.
- Click .

**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.