

## 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

The screenshot shows the 'Home Ingrid Investigator' workspace. The 'Approved' tab is selected, indicated by a red box with the number '1'. Below the tabs is a table of approved studies. The first study entry is highlighted with a red box and the number '2'.

ID	Name	Date Modified	Type	Owner	State	Last State Change	PI
HUM000544	Test study for eResearch PI new application	11/29/2006 8:55 AM	Application	Cindango, Mary	Approved	11/29/2006 8:55 AM	Investigator
HUM000546	Test Study for Core Staff Expedited Review	11/11/2006 2:15 AM	Application	Cindango, Mary	Approved	11/10/2006 3:11 PM	Investigator

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

The screenshot shows the 'Test study for eResearch PI new application (HUM000544)' workspace. The 'Approved' status is shown at the top. In the left sidebar, the 'New Amendment' button is highlighted with a red box and the number '3'.

3. Click **New Amendment**.

## Amendment Instructions

**Amendment Instructions**

**Important Information**

- Submit Adverse Events before continuing with this Amendment**  
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.
- Complete the Amendment in two parts:**  
1) **Complete the cover sheet.** Summarize the proposed changes included in this amendment and click Continue. The eResearch system will take a few moments to create your amendment application by making a copy of the currently approved study. An email notification is sent when this is completed.  
2) **Edit the copy of the application:** Click Edit/Review Study to make the changes proposed in this amendment and submit the amendment to the IRB.

0.1 \* **Amendment Title (limited to 256 characters):**

HUM0005441\_Amendment - Wed Nov 29 09:03:48 EST 2006

This amendment is being submitted for the following application:

**Study Title:** Test study for eResearch P1 new application  
**PI:** Ingrid Investigator  
**Expiration Date:** 12/6/2007  
**eResearch ID:** HUM0005441  
**GCRC ID:**  
**Cancer PRC ID:**

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

## Amendment Cover Sheet

**1. Amendment Cover Sheet**

This amendment is being submitted for the following application:

**Study Title:** Test study for eResearch P1 new application  
**PI:** Ingrid Investigator  
**Expiration Date:** 12/6/2007  
**eResearch ID:** HUM0005441  
**GCRC ID:**

1.1 \* **Amendment Title (limited to 256 characters):**

HUM0005441\_Amendment - Wed Nov 29 09:03:48 EST 2006

1.2 \* **Subject Enrollment Status: (Note: This information will also need to be provided at scheduled continuing review)**

Projected subject enrollment for the study:	125
Total number of subjects enrolled to date: (do not enter commas, dots, or special characters)	
Remaining subjects to be enrolled:	

1.3 \* **Provide up to six keyword descriptors for this Amendment.**

1.4 \* **Proposed changes:**

Select all that apply:

Description of change	Corresponding application section
<input type="checkbox"/> Change to the risk level or anticipated benefits to research subjects.	Section 6 - Benefits and Risks
<input type="checkbox"/> Change to the informed consent document or process.	Section 10 - Informed Consent

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

**1-1. Amendment Copy Currently in Progress**

The system is now creating your amendment by making a copy of the approved application. This process may take a few minutes; an email notification will be sent when this process is complete. Please indicate below who should be notified when the amendment is ready for editing.

1-1.1 \* **Indicate who should be notified when the amendment is ready for editing:**

First Name	Last Name	Department
<input type="checkbox"/> test	test	University of Michigan
<input type="checkbox"/> example	test	Unknown

After the amendment copy is complete, select "Edit/Review Study" in the Amendment Workspace to revise the currently approved application and any associated documents to reflect the proposed changes.

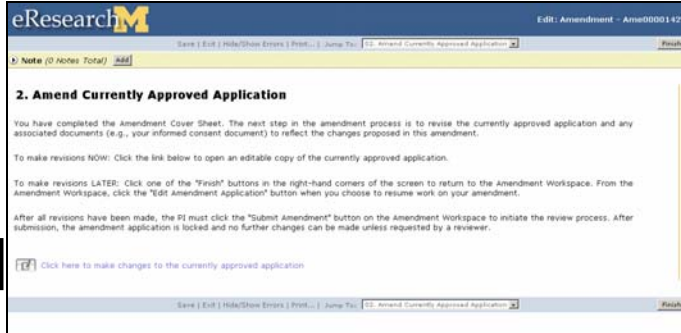
After all revisions have been made, the PI must click the "Submit Amendment" button on the Amendment Workspace to initiate the review process. After submission, the amendment application is locked and no further changes can be made unless requested by a reviewer.

**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.

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

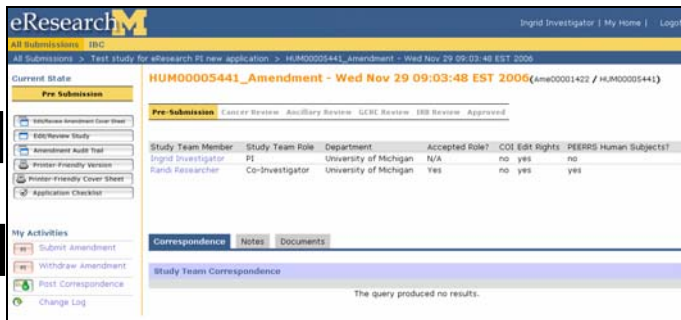


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**Note:** This screen will only appear if the amendment copy process has completed before step 9.

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

## Amendment Workspace



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

- 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

Submit Amendment

**HUM00005441\_Amendment - Wed Nov 29 09:03:48 EST** (Ame00001422)  
**2006**

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"/>	<input type="checkbox"/>	CV.doc	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 [Clear](#)

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

[Clear](#)

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

Yes  No [Clear](#)

**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

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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.