

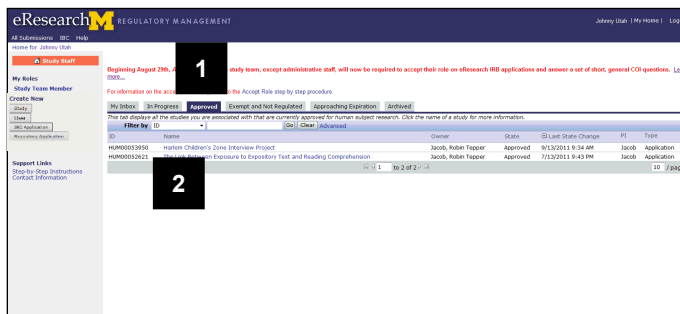
Creating an Amendment

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

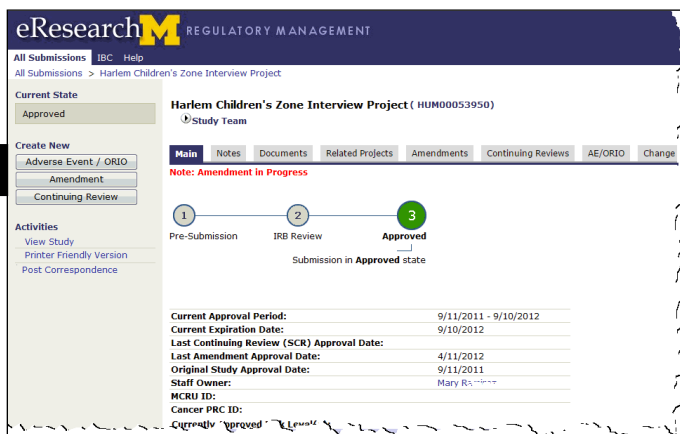
- In addition to any changes related to the amendment, **you must also verify that the required HR appointment information is provided for each study team member listed on the study before submitting the amendment.**
- If the required appointment information is not provided, you will receive an error 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

00. Instructions

Important information

- Submit Adverse Events before continuing with this Amendment
- If this amendment is in response to a:
 - 1. USI adverse event (AE)
 - 2. Other reportable information and occurrence (ORIO)
- 1. Except for AEs that have been determined by the sponsor, other oversight entity, or the IRB investigator to be an "unanticipated problem involving risks to subjects or others" that has not yet been submitted for review

Click the Check button and select New Adverse Event (ORIO, AE/ORIO) must be submitted prior to the initiation of the amendment in order for them to automatically display in the amendment cover sheet. If this change is being made in response to an external AE that was an unanticipated problem, upload a copy of the AE (e.g. a MedWatch form or letter from a sponsor) in section 4.4 of the amendment application. This will allow the reviewer to consider the amendment in the context of the AE/ORIO report.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.fda.gov/oc/ohrt/030708a101.pdf) and not implementing any changes to the research without IRB approval of the change as an amendment submission. When changes are necessary to address apparent credible hazards to the subject, implement the change and report as an ORIO adverse amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

Complete the Amendment in two parts:

1. Complete the cover sheet. 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 will be sent when this is completed.
2. Click the view of the application. Click edit/revise Study to make the changes proposed in this amendment and submit the amendment to the IRB.

00.1* Amendment Title (limited to 256 characters):
H4M0003950_Amendment - F4 Jul 13 13:52:54 EDT 2012

This amendment is being submitted for the following application:

Study Title: Harlem Children's Zone Interview Project
PI ID: J00001326
Application Date (IRB): 01/03/2012
Research ID: H4M0003950
NCRI ID: [Blank]
Cancer PNC ID: [Blank]

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

Amendment Cover Sheet

01. Amendment Cover Sheet

This amendment is being submitted for the following application:

Study Title: The Link Between Exposure to Expository Text and Reading Comprehension
PI ID: J00001326
Application Date (IRB): 01/03/2012
Research ID: H4M0003950
NCRI ID: [Blank]

1.1* Amendment Title (limited to 256 characters):
H4M0003950_Amendment - F4 Jul 13 13:52:54 EDT 2012

1.2* Provide up to six keyword descriptors for this Amendment.

1.3* Proposed changes:

Description of change	Corresponding Section/Information
<input type="checkbox"/> General study information changes (e.g., change in study team, administrative updates to study documents, etc.)	Section 1.4, Information
<input type="checkbox"/> Change to research/application topic (update from umbrella application for research with human subjects, element to standard, etc.)	Section 1.4, Application Type
<input type="checkbox"/> Change to sponsor/recipient of this study.	Section 2, Sponsor/Support Information
<input type="checkbox"/> Change to a performance site or provide IRB/IEC approval documentation.	Section 3.1, Performance Sites
<input type="checkbox"/> IRB/IEC ORIO for Cancer Center enrollment numbers.	Section 3.2, Cancer Center Subject Participation
<input type="checkbox"/> Change in research design, intervention, goals or specific objectives (e.g., study specific evaluations such as statistical analysis, blood tests, final study, quality checks, etc.)	Section 3, Research Design
<input type="checkbox"/> Update to the risks or anticipated benefits to research subjects.	Section 6, Benefits and Risks
<input type="checkbox"/> Change in enrollment numbers.	Section 4, Subject Participation
<input type="checkbox"/> Change in recruitment procedures or documentation.	Section 4.1, Subject Recruitment
<input type="checkbox"/> Update to subject populations/vulnerable subjects.	Section 4.1, Subject Populations
<input type="checkbox"/> Change to the informed consent document or process.	Section 4.2, Informed Consent
<input type="checkbox"/> Study changes that could affect the clinical research billing contract.	Section 4.3, Billing
<input type="checkbox"/> Update to Investigator Brochure or change to the study drug or biologics.	Section 15, Drug, Biologics, etc.
<input type="checkbox"/> Change to or addition of study devices.	Section 16, Devices
<input type="checkbox"/> Changes to the biological specimens submitted for research purposes.	Section 18, Biological Specimens
<input type="checkbox"/> Changes to any aspect of radiopharmaceutical administration (e.g., number of doses, dosimetry, change of protocol, consent form and site effects, etc.)	Section 19, Radiopharmaceutical Administration
<input type="checkbox"/> Change to or addition of survey instruments.	Section 20, Survey Research

Other - describe below.

1.4* Provide a description and justification for each proposed change. Include a comprehensive summary of the changes where available (such as those included with protocol amendments). Proposed changes to umbrella supporting documentation (i.e., protocol amendments, informed consent, investigator's brochure, survey instruments, recruitment materials, etc.) may not be readily apparent to reviewers and therefore should be described here in detail.

1.5. If the amendment includes a revision to the informed consent document or process, identify which subjects, if any, are believed to be impacted. Required for clinical interventions for which subjects have already been consented and all IRB/IEC studies. Provide a list of the names of all subjects who will be re-consented. Have re-consented study instruments and adhere to all applicable IRB rules on subjects who are re-consented (e.g., subjects who are an active study treatment, or subjects who received the experimental drug).

Select the one that applies:

- No previously enrolled subjects will be re-consented
- All previously enrolled subjects will be re-consented
- Only subjects meeting criteria specified below will be re-consented

Clear

1.6* Why is this amendment being requested?

- Required in anticipation of funding through Stimulus Plan (American Recovery and Reinvestment Act)
- Required for conversion to efficacy trial
- Initiated by principal investigator
- Initiated by study sponsor, coordinating center, etc.
- Response to an adverse event (AE) or other reportable information or occurrence (ORIO)
- Response to a regulatory requirement
- Other

1.7. Is this an amendment issued by a National Cancer Institute (NCI) sponsored Cooperative Group/Consortium requiring IRB approval within 90 days of distribution?

Yes No Clear

Study that agrees to partner with the National Cancer Institute to conduct Cooperative Group Clinical Trials and is comprehensively ranked on the amount of IRB approved research conducted at each site will be given priority in site opening with enrollment. This also includes low-income investigators per approved.

The Cooperative Group Program involves more than 1,500 institutions that enroll subjects to group-conducted clinical trials. Cooperative groups include researchers, clinicians, and other professionals throughout the United States, Canada, and Europe. The work with NCI to identify important questions in cancer research and to design clinical trials to answer these questions.

The Cooperative Group Program was established in 1957 following congressional approval of its creation to provide support for studies of chemotherapy for cancer. Congress established the National Cancer Institute's Cooperative Group Program to establish the character of the most rigorous drug trials, and to test new anticancer agents from NCI's drug development program. The program has demonstrated that it is possible to study the use of combined therapy approaches to cancer treatment.

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

8

9

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

10

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

12

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

Submit Amendment

Amendment_Submit (Ame00038956)

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.

13

Name	Version
10-1.1.pdf History	0.01

14 Below is listed the appointment associated with this study. If this is not the correct appointment for this study, click Update and add the correct appointment using the Select Appointment button. If you are a student and the available appointment for selection is not applicable for this study, please leave this section blank.

Appointment: ITS Application & Info Services - 481207, ITS Administrative Info Svcs

15 **Conflict of Interest:**

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

What is an outside interest? To view your current disclosure information detail in M-Inform or to make changes to your disclosure information in M-Inform, click here to go to M-Inform and follow the instructions.

D1* Do you, your spouse, domestic partner, or dependents have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

16

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g., device, compound, drug, software, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

Yes No

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

17

Investigator Assurances:

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

I agree to comply with University policies and procedures, sponsor and grant contracts, as well as by federal, State, and local laws and regulations concerning the protection of human subjects in research, the use and management of funds and, where applicable, the appropriate billing of healthcare services. These requirements include but are 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 unanticipated problems, adverse events (AEs), or other reportable information or occurrences (ORIOs) in a timely manner in accordance with the terms of this approval and published IRB guidelines.
- Submitting an accurate billing calendar, if a calendar is required, and maintaining the ability to provide the necessary documentation to support the billing calendar.
- Your certification in eResearch indicates that you have personally reviewed the most current drafts of the study protocol, informed consent document, sponsor contract and budget (if applicable) and that the billing calendar classifications of routine care, monitoring for complications, study paid items, and "not applicable" are complete and accurate. You will upload final documents within eResearch. In certain instances, the total number of times an item or service will occur over the course of an entire study is a reasonable estimate based upon your clinical knowledge and experience. You are required to provide supporting documentation for any item or service designated on the billing calendar as "routine". Necessary documentation may include clinical protocols and governmental or professional societal guidelines. In the absence of formal protocols and guidelines, you should be prepared to provide an auditor with information sufficient to support your professional clinical determination that the designation of services as "routine" meets the applicable standard of care. This may include a sampling of patient documentation with similar diagnoses that are not on study. The documentation must be readily available in the event of an internal audit conducted by your department, the UMHS Compliance Department, health plans or government programs such as Medicare or Medicaid.

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.

I agree to abide by the above assurance statement: **18**

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

19

- (Optional) Click **Upload Revision** to update any documents listed in the **Credentials** section, or click **Add** to upload any new documents to the section
- (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.
- Note your **Current Disclosure Status in M-Inform**.
- 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.

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