

Amendments

Medical University of South Carolina

What is the purpose of an Amendment?

To make changes to the currently approved study, including:

- Informed Consent Form (ICF)
 - Protocol
 - HIPAA
 - Investigator Brochures (IB)
 - Recruitment/Subject Materials
 - Conflict of Interest (COI)
 - Risks
 - Enrollment Goals
 - Procedures/Populations
 - Study Personnel
 - Other Changes
- All changes to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects.

Full Board vs. Expedited Amendments

Full Board

- Significant changes to the study such as:
 - Updated risks
 - Major changes to the protocol

Expedited

- Minor changes to the study, such as:
 - Personnel
 - Advertisements
 - Administrative changes as defined in IRB policy

Two parts of Amendments in eIRB:

Amendment Workspace

- Explain all the changes being made to the study.
- Upload tracked change versions



Modified Study

- Upload Clean Versions and update all applicable smartforms

***Use "Upload Revision" button NOT "Add/Remove"**

Instructions for Completing Amendments

An amendment requires two parts: the Amendment summary form and edits to the IRB study application pages.

Step 1: So far, you have filled out the Amendment summary form.

Step 2: You will now begin to make changes to the IRB study application pages (see [CLICK HERE](#) link below).

Step 3: Documents uploaded in the Amendment summary form must also be uploaded in the IRB study application.

Step 4: Once all changes have been made to the IRB study application, click Finish.

Step 5: After returning to this Amendment instructions page, click Continue for next steps to submit the Amendment for IRB review.

[CLICK HERE](#) to edit the IRB study application, as described in Steps 2-4 above.

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Getting Started

- In your inbox, select the study that needs revisions.
- Under “My Activities” select “New Amendment”

NOTE: Only one amendment can be open at a time.



Amendment Workspace: Category

- Determine if the changes are significant
- Select if risks and/or benefits are being affected by the changes
- If there is an increase in risk, the changes are significant

Amendment - Category

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Amendment – Change(s) in previously approved research. An amendment request includes two parts in the eIRB portal: the **Amendment Smartforms** and the modifications to the Amendment copy of the **Study Smartforms**. Only one amendment request is allowed at any given time, i.e.: Amendment 1 must be approved, denied or withdrawn before Amendment 2 can be created.

1.0 * Category of amendment:

- Minor change(s), Minimal risk change(s)
- Significant Change(s), Greater than minimal risk change(s)
- Clear

2.0

* Are the risks to subjects affected by the amendment?

- Increased Risk
- Decreased Risk
- No effect to Risk
- Clear

If affected, explain:

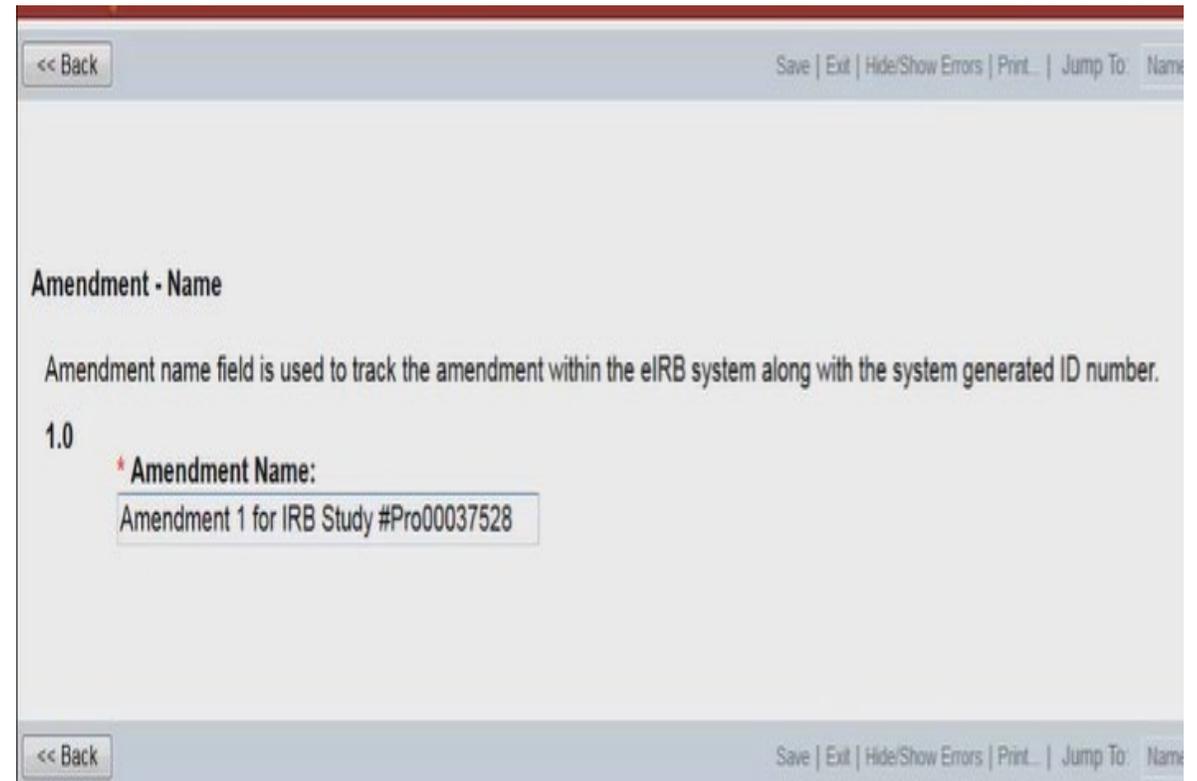
3.0

* Are the benefits to subjects affected by the amendment?

- Increased Benefit
- Decreased Benefit
- No effect to Benefit
- Clear

Amendment Workspace: Name

- Provide a name for the amendment.
- The name created here will appear on the approval letter.



The screenshot shows a web application interface for entering an amendment name. At the top, there is a navigation bar with a "<< Back" button on the left and "Save | Exit | Hide/Show Errors | Print... | Jump To: Name" on the right. The main content area is titled "Amendment - Name" and contains the following text: "Amendment name field is used to track the amendment within the eIRB system along with the system generated ID number." Below this, there is a version indicator "1.0" and a required field label "* Amendment Name:". The text "Amendment 1 for IRB Study #Pro00037528" is entered into the text box. At the bottom, there is another navigation bar with a "<< Back" button on the left and "Save | Exit | Hide/Show Errors | Print... | Jump To: Name" on the right.

Amendment Workspace: Request

- Select all aspects of the study that will be updated.
- In the description, briefly address all changes being made.

NOTE: Multiple changes can be made to the study!

Amendment - Request

1.0 * Type of change(s) this amendment is requesting:

Check all that apply. *Note: Checking any of these options requires revisions to the applicable 'Instructions for Completing Amendments' page).*

- Study Personnel
- Advertisements/Study Recruitment Materials
- Informed Consent Document/Procedures
- Protocol Document(s)
- Investigator's brochure
- Editorial/Administrative Changes
- Additional Sites for Treatment/Follow-up
- Modification In Subject Enrollment Goals
- Location of Program Activities
- Questionnaires & Assessment Tools
- Risk Change(s)
- Study Procedure(s)
- Subject Confidentiality/Anonymity
- Subject Population
- Other Changes
- HIPAA Authorization
- Study Funding Source/Sponsorship
- Conflict of Interest (COI)

2.0 * Change Description

Briefly summarize changes:

Amendment Workspace: Study Personnel

- Select the category where the study personnel changes will be made in the study.

NOTE: In order for someone to be added to the study, make sure they have created an eIRB profile.

Amendment - Study Personnel Changes

1.0

* Principal Investigator

Is there a change in the principal investigator for this study? If yes, please upload PI Statement of assurance, COI, CV, as applicable.

Yes No [Clear](#)

2.0

* Co-Investigator(s)

Is there a change in the co-investigator(s) for this study?

Yes No [Clear](#)

3.0

* Study Coordinator

Is there a change in the study coordinator for this study?

Yes No [Clear](#)

4.0 Other Study Team Members

Is there a change in the study team members for this study?

Yes No [Clear](#)

Note: Changes to personnel require a review of the Conflict of Interest section of the Amendment copy of the Study Smartform.

Delete Approved Study Personnel Button

- The PI and main study coordinator can remove Co-Investigators and Other Study Team Members without an amendment.
- The Delete Study Personnel button will appear under “My Activities” on the main page of the study.

NOTE: If there is an open amendment the button will not appear.



Amendment Workspace: General Comments

- Upload any other relevant documents that need to be reviewed here!
- Documents that should not be uploaded to the General Comments page:
 - Investigator's Brochure
 - ICF
 - HIPAA
 - Protocol

Amendment Workspace to the Modified Study

- Select “Click Here” to make edits to the Modified Study
- Upload all clean copies of documents that are being amended.
- Update all smartform content to harmonize with the changes being made.

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FINISH

The PI will submit
the completed
application!

