

eIRB Quick Reference Guide for Investigators and Study Staff

Logging in

1. Go to [eIRB site](#).
2. Select MUSC from the list of institutions
3. Enter your username and password. *This is your MUSC MNA/netID and password.*

Your Personal Workspace

- Your Personal Workspace, otherwise known as *My Home*, displays all the eIRB study submissions associated to you.
- If you are not already at your home page, click *My Home* at the top right of your screen.

The Study Workspace

- When you open an existing study application, amendment, or continuing review from your Personal Workspace, you will be taken to the study's workspace.
- The Study Workspace is the area where all activities associated with the study will be performed.

Creating a New Application

- Applications for new research studies can only be submitted by the Principal Investigator (PI). Study coordinators, contacts and/or Co-Investigators (Co-Is) may complete, but not submit applications.
 - Click the *Create New Study* button to initiate a new IRB Application.
 - Begin by filling out the first page of the application.
 - Click *Continue* to advance to the next page
 - When finished, click *Save* to save your changes and then *Exit* to exit the application form and return to the Protocol Workspace.
 - Study is not forwarded to IRB until PI clicks "Submit Study" in study workspace

Adding Key Study Personnel

1. Start a new application or create an amendment for an already approved study.
2. Search for the member
 - a. Begin typing in a name *or*
 - b. Click the *Select (or Add)* button beside the study role
 - i. If needed, filter the list to find the team member you want to add.
 - ii. Select the team member to be added by clicking beside his/her name. *If adding 'other' personnel, select whether you are giving edit or read only access.*
 - iii. Click *OK*
 - c. On the next screen indicate the primary IRB contact(s) (who receives IRB correspondences).

How to Add Study Team Members not in the Pick List

- The member may need to self-register first by logging into eIRB, may not have been assigned this role in eIRB or are not affiliated with MUSC. Contact the eIRB Systems Administrator at 843-792-3247 or veatchlm@musc.edu

CITI Certification

- IRB approval cannot be released until all study team members have current Human Subjects Protection Education (CITI) certification.
- If a study team member has not yet completed the CITI training requirements, a reference guide can be found under Human Subjects Research on academicdepartments.musc.edu/uco/training.htm
- The CITI module website is <http://www.musc.edu/citi>.
- Completed CITI training shows up on the eIRB application for personnel added on a study. ***In order for training to appear, the personnel's First Name, Last Name and email address must be exact matches in eIRB and CITI.***

Uploading New Documents

- 1 Click the *Add* button and a new window will appear.
- 2 Enter a *title* for the document you are uploading.
- 3 Click *Browse...* and select the file you want to attach.
- 4 Click *Open*.
- 5 Click *OK*.

Attaching Curriculum Vitae (CV)

- The PI must have a CV included for studies using investigational drugs/devices or upon IRB request.
 1. At the end of creating the new application in the *General Comments* section you can upload any additional forms to the application.
 2. Click the *Upload Files* button.
 3. Click *Browse...* and select the file you want to attach.
 4. Click the *Add* button to upload a new CV document for the PI.

Editing and Deleting Uploaded Documents

Edit documents previously uploaded.

An application cannot be edited when it's under review by IRB.

1. Open the document from eIRB or the saved location
2. Make the necessary changes, using the track changes feature in Microsoft Word.
3. Save the document
4. Back in the eIRB application, locate the study and navigate to the section of the application requiring the edited document.
5. *Use the [Upload Revision] button to upload the revised copy. DO NOT use the 'Add' button as this will not revise the current document. Retain the document name so that version dates are consistent.*

Delete documents previously uploaded. *This option should only be used when a document has been uploaded in error AND when it was never approved by or submitted to IRB OR upon request by IRB.*

1. Locate the section of the document to be deleted.
2. Click the *Delete* button and confirm deletion.

Informed Consent Documents

Locate the MUSC Informed Consent and HIPAA template by clicking [here](#). The consent template also includes links for the standard paragraphs to be used as the last page of the Informed Consent.

Original informed consent

1. Create your draft document. Documents requiring stamped approvals cannot be uploaded and accepted until this task has been performed. *You must leave a 1 inch header/footer margin free of formatting (no text in the footer) at the bottom of each page for the date-stamp watermark.* You may also use stamped template versions to create your draft document. If doing this, you do not need to complete step #2 below.
2. If needed, access instructions to *watermark* your template form(s) on the [IRB Forms Website](#).
3. Save the document

How to upload an original informed consent/HIPAA

1. In the eIRB application use the *Add* button to attach the original Informed Consent [HIPAA] in the *Consent Forms [HIPAA]* section.

How to view current (un-stamped) consent/HIPAA form in eIRB

1. Locate study
2. Go to 'Attachments' tab and locate the Consent Process [HIPAA] section
3. Click on the name of the consent/assent document to open it up. *The document should have the shell of the date-stamped watermark.*

How to edit informed consent/HIPAA documents

An application cannot be edited when it's under review by IRB.

1. Re-open the original document from your saved location or from the eIRB application.
2. Turn on change tracking and modify the body of the document as needed.
3. Save the redlined, tracked changes copy.
4. Turn off change tracking, accept all changes, and save a clean copy of the document.
5. Once back in the eIRB application, upload the tracked changed version when summarizing the amendment and use the *[Upload Revision]* button to attach the revised clean copy in the Consent Forms [HIPAA] section of the study application. *Retain the document name so that version dates are consistent.*

Submitting an Application

- **The Submit activity can only be performed by the PI.** The Submit Application activity is performed from the Protocol Workspace.
 - From the Protocol Workspace, click the Submit Application button.
 - Complete all questions on the pop up screen.
 - Click *OK* at the bottom of the pop up screen.
- After submission, the study team will not have access to edit the application unless it is returned with changes requested by eIRB.

Viewing Application Completion Progress

SmartForm Progress:

1. Locate & select the study
2. Select View Smartform Progress button from the left side of the Protocol Workspace screen
3. In the pop-up screen, view sections that are incomplete
4. Select *Edit Study* and use the *Jump To* drop down feature to navigate to the section to edit.

Hide/Show Errors:

1. Locate & select the study
2. Select *Edit Study* button from the left side of the Protocol Workspace screen
3. Click on *Hide/Show Errors* link at the top of the screen
4. In the bottom portion of the screen:
 - a. View sections that still require information
 - b. Click on the hyperlink name of the required section to navigate to that section to make edits
 - c. Select *Refresh* button to update the list of remaining sections to be edited.

Viewing Reviewers Comments

1. An email will be sent to the MUSC e-mail addresses of the indicated IRB contact that IRB comments require a response
2. The study will appear in the eIRB Personal Workspace ('My Home') inbox with a state of 'Changes Required'
3. **To view the comments:**
 - a. Click on the study's name
 - b. Go to the 'Reviewer Comments' tab or click the 'Edit Study' button

Responding to Reviewers Comments

1. From the 'Reviewer Notes' tab, use the '*Jump To:*' link to go to the section of the application where concerns have been added.
2. Make the necessary changes to the Smartform.
3. Once the changes have been made on the application, use the *Click here to respond* link at the top of the page to summarize your response to the reviewer.
4. Select the appropriate category and give your response.
5. Click *OK*.
6. Answer additional questions by selecting the 'Next' or 'Previous' buttons at the top of the page.
7. When finished, *Save* and *Exit* the application form and return to the Protocol Workspace.
8. Click the *Submit Changes* button to return the application to the IRB

Amendments

- Amendments can be submitted for approved, active studies only.
- Only one amendment request can be in process at a time for each study. However, several amendment types can be combined into one request
- *Tip: review the currently IRB approved application & note which sections need to be revised (the application will be revised in Step #5 below).*

- To create/submit an amendment:
 1. Navigate to the Protocol Workspace of the approved active study.
 2. Click the *New Amendment* button on the left to start a new amendment submission.
 3. As step #1 of this process, complete the required information on each page of the Amendment Request form.
 4. When you reach the *Summary of Amendment Changes* screen, click the 'CLICK HERE' link.
 5. As step #2 of this process, navigate to the appropriate section within the study application that requires changes.
 6. After making all changes to the amended study click *Save*.
 7. Click *Exit* to return to Amendment Summary.
 8. Back in the Amendment summary, click *Continue*.
 9. Click *Finish* to return to the Amendment Workspace.

Only the PI can submit an amendment:

10. Click the *Submit Amendment* button on the left navigation column.
11. Click *OK* in the pop up window.

Continuing Review

- The indicated study contacts will receive an email reminder that the application is due for a continuing review 60 and 45 days prior to the study expiration date and after the deadline for submitting a renewal application, if one has not been sent to IRB.
- Continuing reviews can be submitted for approved active studies only.
- Only one continuing review request can be in process at a time for each study.
- A continuing review cannot be created while an amendment is pending IRB submission (i.e., the amendment is in the Pre-Submission state).
- Scheduled continuing review applications should be submitted at least twenty-one days before the approval is to expire.
- Only IRB-requested changes can be made at the time of continuing review. Study team initiated changes must be filed before or after the continuing review via an amendment.
- If you would like to terminate a study, a continuing review must be submitted. *Note: submitting a study status change will NOT terminate a study*
 1. Navigate to the Study Workspace of the approved active study.
 2. Click the *New Continuing Review* button on the left to start a new continuing review submission.
 3. Complete the required information on each page.
 4. Click *Finish* at the end of the continuing review.

Only the PI can submit a continuing review to IRB:

5. Click *Submit Continuing Review* button on the left.
6. Click *OK*.

Reportable Events

- Reportable events can be submitted for approved active studies only.
- Types of reportable events include: adverse events, unanticipated problems, deviations and other reportable events (e.g., monitoring/auditing/committee reports)
- To create/submit a reportable event:
 1. Navigate to the Study Workspace of the approved active study.
 2. Click the *New Reportable Event* button on the left to start a new reportable event submission.
 3. Complete the required information on each page of the Reportable Request form.
 4. After completing the information, click *Finish* at the end of the reportable event.

Only the PI can submit a reportable event to IRB:

5. Click *Submit Reportable Event* button on the left.
6. Click *OK*.

Printing an Application

- The print version of the study includes only the required application sections. Detailed information is printed at the end of the document.

 1. Navigate to the Study Workspace.
 2. Click the *Print-Friendly Application* button. You also open the study application and click the *Print* button at the top of the screen to print specific pages of the application.
 3. Click *Print* to open the Print dialog box.
 4. Select a printer and click *Print*.

Viewing Approved Documents

1. Locate & select the study
2. The study summary section of the Protocol Workspace, locate the *Letter of Approval* line
3. Click on the 'View' link

Viewing Summary of Amendment Changes

1. Locate & select the study
2. Select the *Amendments* tab from the Protocol Workspace
3. Select the Amendment
4. Select the *View Study History* button from the left side of the Amendment workspace screen
5. Select the *View Differences* button from the left side of the screen
6. Revised information will be located in a highlighted section.
7. Navigate to additional revised sections by using the drop down arrow in the *Changed Steps* section.
8. Select *Close* when done.

Adding study to [S.C. Research Studies Online Directory](#)

New study applications (before IRB submission):

1. On Smartform, ensure box is checked to post online
2. Enter all information for contact & keywords
3. Verify information that will appear online

Study applications post IRB submission/approval:

1. Select 'Edit SC Studies Directory' from main protocol page
2. Check the box to post online & enter all information for contact & keywords