MUSC
Medical University of South Carolina

The Institutional Review Board

May 2024

Before you start working on a study, be sure to check out our website to familiarize yourself with the Policies and Procedures for Human Subjects Research at MUSC. There are many helpful forms, templates, and language suggestions on our IRB website for you to reference when working on your IRB submissions. Another helpful resource is the SCTR SUCCESS Center, which can offer guidance and other services when preparing an IRB submission.

MUSC IRB Forms **SUCCESS Center**

IRB Updates

HIPAA Violation Auditing Software

NEW: Privacy Management Software implemented to detect inappropriate access.

According to the Office of Civil Rights annual report, in 2023, 171 million patient records were breached, 93% of which were caused by unauthorized access. This represents a 98% increase in large-scale breaches from 2022.

Patent privacy violations are a growing problem for health systems across the country, resulting in increased risk for organizations and, more importantly, their patients. **In response, MUSC is implementing Protenus, the only healthcare privacy solution that utilizes artificial intelligence and advanced analytics to audit up to 100% of system access.**

Starting in May, the Privacy department will utilize Protenus to detect inappropriate access by analyzing the following attributes:

- Patient last name compared to care team member's last name
- Patient address compared to care team member's address
- Departments accessing other departments' records
- Access to High Profile patient records
- Co-workers accessing co-worker records
- Anomalies in access (volume and type by care team member)

IMPORTANT REMINDERS:

- Only access records needed to perform job duties
- Do not access records out of personal interest
- Do not access records out of compassionate curiosity
- Do not access records for information to celebrate birthdays, anniversaries, etc.

INAPPROPRIATE ACCESS WILL RESULT IN DISCIPLINARY ACTION UP TO AND INCLUDING TERMINATION AND, DEPENDING ON THE CIRCUMSTANCES, MAY RESULT IN CIVIL AND CRIMINAL ACTIONS.

For more tips about HIPAA, see University Compliance website.

Updates to Notice of Privacy Practices (NPP)

The MUSC Notice of Privacy Practices has been updated effective February 2024. Please use the link for those studies still using the NPP and update as necessary via amendment in eIRB.

MUSC Notice of Privacy Practices

IRB Education Resource Reminder

If your department needs IRB education, please contact the IRB Administrator for Education and Training. Currently, we offer presentations on IRB Basics, Initial Studies, Amendments, Continuing Reviews/Annual Status Updates, Reportable Events, and Reliance Studies.

IRB Contacts

Locating Stamped Items in eIRB

After a research study or an amendment is approved there may be documents that require the eIRB watermark to be stamped by the IRB, i.e., informed consent form, HIPAA, recruitment materials.

If you are unable to locate the stamped versions of these documents, be sure to go to the main page of the study, then go to the "Attachments" tab, and scroll all the way to the bottom to "Ancillary Documents." In Ancillary Documents, you will find your HIPAAs and recruitment materials. Stamped informed consent forms can be found on a separate tab on the study's main page called, "Stamped ICF."

Audit Submissions and the IRB

If your study is audited, the audit report and a PI response with a corrective action plan, if there are any findings, must be submitted to the IRB. A response to each audit finding should be included with your response. Audit submissions can be submitted to the IRB using the Reportable Event feature in eIRB. For more information on how to create a Reportable Event, please refer to the link below.

eIRB Creating and Submitting Reportable Events video

Faculty Transfers to Different Department

For MUSC faculty members transferring to other MUSC departments, please contact the eIRB Administrators to update your department in eIRB.

eIRB Administrators

Quick tips for speeding up IRB review time

Here are some tips to help speed up IRB review time for study applications:

1. Review the IRB due dates for full board meetings. If the study is not received by the IRB on or before the deadline, it will not be assigned to the specific meeting you might want.
2. Factor in the time it takes for department reviews. Your IRB application is not received by the IRB until all department reviews are completed. When the IRB receives the application, the current state of the study will be: “IRB Staff Review.”
3. Kindly respect the IRB assigned “Changes Requested” deadlines to enable your application’s timely processing for a full board meeting. If the requested changes are not submitted by the IRB assigned deadline, your study application will not go to the next full board meeting.
4. Your informed consent (ICF) should be formatted according to the MUSC IRB approved consent format. Use the ICF templates available on the IRB Forms website. There is also pre-approved, suggested consent language available on the IRB website that can be used in the ICF.
5. The ICF must be understandable at the 8th grade reading level; medical jargon and study procedures must be explained in lay language. The ICF template also has a link with suggested lay terminology that you can utilize.
6. Make sure that there are no discrepancies between the documents uploaded to the study and the study smartforms (i.e., the risks listed in the eIRB smartform must reflect those included in the ICF).
7. If your protocol states you will be using advertisements, make sure to upload the advertisements that you will be using in the eIRB smartforms for approval.
8. Verify that institutionally required CITI training for all study personnel is complete and/or current prior to study submission.
9. Ensure that all IRB comments have been addressed appropriately. If there are question(s) from an IRB Reviewer, respond to the question(s) fully and completely. A missing answer could keep your items from being reviewed according to the expected schedule.
10. When using the eIRB watermark, it should be used as it is formatted in the eIRB watermark template to ensure active data fields are included in the form. Do not alter or convert the watermark to picture format (.jpg); if you do so, the watermark will not be recognized by the eIRB system and will not accept the stamp when approval is released. Refer to the eIRB watermark guidance on our Forms page.

Data Safety Monitoring Board Reports

A Data Safety Monitoring Board (DSMB) is a formal committee that is established specifically to monitor data throughout the life of a study to determine if it is appropriate, from both the scientific and ethical standpoint, to continue the study as planned.

Principal Investigators (PIs) are responsible for submitting the Data Safety Monitoring Board (DSMB) reports as soon as they are available to the Investigator, regardless of the timing of the report in relation to the study's scheduled continuing review. These reports should follow the timeframe as specified in the IRB approved protocol. The PI will submit the DSMB report to the IRB via the eIRB system as a Reportable Event under the type "Other Reports/ Events."

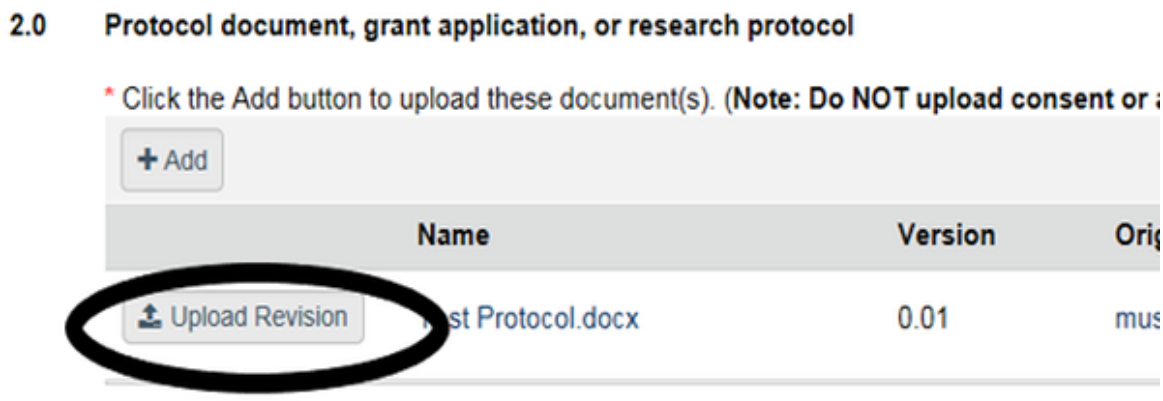
For more information regarding Data Safety Monitoring Plans and Data Safety Monitoring Boards, please see the policy: HRPP 4.10 Data and Safety Monitoring Plans.

For more information on how to submit a Reportable Event to the IRB via the eIRB system, please see the eIRB training video below: eIRB Reportable Events Video.

eIRB Tip: Upload Revision button

At some point when submitting an application or making changes to an ongoing research study via amendment, you may need to revise study documents. When uploading revised documents to the study, be sure to use the "Upload Revision" button. Do not remove the older version(s) of the item(s) from the smartform and then add the revised documents.

The "Upload Revision" button is important for your regulatory records. It creates a history of documents for your study that can be referenced by you, any regulatory or monitoring personnel, and the IRB. The "+ADD" button should only be used the first time a document is uploaded; after that, use only the "Upload Revision" button.



IRB Reliance

IRB Reliance is the process of using a single IRB for review of multiple sites or investigators at multiple institutions. MUSC is willing to review requests for MUSC to rely on an external IRB and requests for MUSC to act as the IRB of Record for institutions participating in a multisite study. In both scenarios, the first step in the reliance process is to complete a reliance intake form.

For information on fees charged for studies where MUSC relies on an external IRB or when MUSC serves as the IRB of record, please view the IRB submission information.

For questions related to reliance, please see the single IRB frequently asked questions (FAQs).

IRB Submissions

Frequently Asked Questions about Single IRB Review

About the Staff

Erin Dawley

Erin Dawley began her career at MUSC in 2013 and has spent the last 11 years as a Research Coordinator in the Department of Pediatrics, coordinating and managing research studies for the South Carolina Pediatric Practice Research Network. She is excited to join the IRB as the Administrator for Education and Training. In her free time, she enjoys shopping, spending time on the boat, and hanging out with her husband and 2 kids!

Catch up on Previous IRB Newsletters

Visit the IRB News & Updates webpage to view past IRB Newsletters with helpful information!

News & Updates

Contact Us

Have feedback or suggestions you would like to share?
Email us at: irb-news@musc.edu

IRB Homepage

IRB Contacts

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