MUSC
Medical University of South Carolina

The Institutional Review Board

February 2025

Happy New Year! As a reminder, there are many helpful forms, templates, and suggestions for IRB-approved document language on the IRB website. Be sure to check out our website before you start working on an initial application or amendment to familiarize yourself with the available resources and guidance. Another helpful resource is the SUCCESS Center, which can help by offering guidance and other services when preparing any type of IRB submission.

IRB Forms **SUCCESS Center**

IRB Updates

Retiring the ERMA System

The IRB has retired the ERMA system and is working to convert all ERMA studies over to the eIRB system. After conversion to eIRB, your study will be provided with easier tracking and submissions of continuing reviews and/or amendments. You will still have access to the information and documents in ERMA but will be uploading the most recently IRB-approved documents into the eIRB system. During the conversion process, the eIRB study will be checked to make sure that study documentation and information is consistent between ERMA and eIRB and all required smartforms are completed based on the study information.

If your study can be closed with the IRB, please be sure to review the IRB Submissions and Closure Processes website for study closure criteria and submit a continuing review to permanently close your study in the ERMA system.

For more information, questions, or to get started with this process, please email Jessica Orak, the IRB Quality Assurance Administrator, at orakje@musc.edu.

2025 IRB Meeting Dates and Deadlines

The IRB website has been updated with the 2025 Meeting Dates and Deadlines for Full Board IRB submissions through June 2025. Please keep in mind that initial submissions must be received by the IRB via eIRB by the posted deadlines.

Tip: An easy way to know if the IRB has received the study – check the State of the study to make sure it is in "IRB Staff Review".

IRB Meeting Dates & Deadlines

List of Policies updated in 2024

Over the past year, the MUSC IRB has updated several policies. The following policies have been updated:

Section 1.2 - Organizational Charts (PDF) (Effective 09/11/2024)
Section 1.3 - Definitions of Terms (Effective 08/08/2024)
Section 1.6 - Communicating Conflict of Interest (COI) among IRB, ORSP, and University COI Committees (Effective 12/23/2024)
Section 2.7 - Management of the IRBs (Effective 07/16/2024)
Section 3.5 - Continuing Review and Annual Status Update Policy and Procedures (Effective 10/10/2024)
Section 4.1 - Review of Research Involving Drugs or Biological Drug Products Policy and Procedures (Effective 01/13/2025)
Section 4.2 - Single Emergency Use of an Investigational Drug Policy and Procedures (Effective 10/28/2024)
Section 4.5 - Emergency Use of an Investigational Device Policy and Procedures (Effective 10/28/2024)
Section 4.6 - Humanitarian Use Device Policy and Procedures (Effective 01/29/2024)
Section 5.1 - Principal Investigator Responsibilities - Supervision of Staff and Protection of Subjects (Effective 02/11/2025)
Section 6.2 - Waiver or Alteration of the Consent Process and Waiver of Consent Documentation - Policy and Procedures (Effective 10/28/2024)
Section 7.8 - Recruitment of Research Participants (Effective 08/19/2024)
Section 9.4 - MUSC as Single IRB of Record (Effective 11/27/2024)
Section 9.5 - Relying on an External IRB (Effective 11/27/2024)
Section 10.1 - Human Research Audit Policy and Procedures (Effective 12/23/2024)
Section 10.3 - Quality Improvement Initiatives (Effective 10/01/2024)

Please see the link below to review the policies and procedures of the IRB and reach out to IRB Staff with any questions.

Policies & Procedures

Update to Cost Language in the Informed Consent Template

Cost Language included in the Informed Consent Template has been revised. Please be sure to visit the Forms page on the IRB website to access the updated Informed Consent Template.

G. COSTS

If your study is subject to PRA review, please insert the following language. (If you receive a PRA summary memo with consent language that differs from the language below, please defer to the PRA memo language.):

The study drug/device, (DRUG/DEVICE NAME), will be provided to you at no cost. There will be no additional cost to you for procedures required in this research study that are for research purposes only. All routine clinical care that the Sponsor is not paying for that you would have undergone without participation in the study will be billed to you/your insurance company.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

Please ask _____ (PI's Name) if you would like to know more about which tests and studies are being done solely for research purposes.

If the study is PRA exempt and there is no cost to the study participant, please insert the following language:*There will be no cost to you as a result of participation in this study.*

In addition to the above language please add a description of other potential costs that would be specific to your study (e.g. cell phone data costs, travel costs, etc.).

IRB Forms

Working with the VA?

The VA Informed Consent Template and the VA HIPAA have been added to the IRB Forms page.

The Working with the VA page has been updated with helpful information for researchers and includes a link to the ORD policies and procedures.

HIPAA Waiver of Authorization

To approve a HIPAA Waiver of Authorization for research purposes, three criteria must be met:

- The use or disclosure of PHI must involve no more than minimal risk to the

privacy of individuals.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the protected health information.
    - Confirm that the PHI will remain confidential and that only the PI/study team will have access to the PHI.

If you are requesting a HIPAA Waiver of Authorization for your Research Study, please make the applicable selection in eIRB on the "Privacy – Access to Protected Health Information (PHI) for Research" smartform and then complete the "Privacy – HIPAA Waiver of Authorization for Research" smartform that populates afterwards

Helpful Tips!

- If coding will be used – describe the coding system and ensure that the linking document will be stored separately from the research data and on MUSC secure network storage.
- For a waiver of HIPAA to be approved, identifiers should be removed as soon as possible after the study is over. Your ID log may be deleted after analysis, research data needs to be stored for a minimum of 6 years.
- Describe how it would be impracticable to obtain authorization from each subject. (ex. Contacting a large number of patients and contact information recorded may be obsolete, data exists in medical records and was collected for clinical purposes and contacting patient to obtain authorization would increase loss of confidentiality, etc.)
- Thoroughly explain why you need the PHI to answer your research question.
- You should have the least number of identifiers needed to answer your research question. It is the identifiers + the health information that = PHI.
- Include all of the health information that will be abstracted for research purposes as well as the identifiers. (What is entered should match the elements that you have selected on the Access to PHI for Research smartform. ex. MRN, address, email, etc.)
- Explain why those PHI elements are needed.
- Describe the measures in place to protect privacy and confidentiality. (ex. Coding system, storage of data on the MUSC secure network storage, etc.).

Reliance Requests and sIRB Fees

Effective April 1, 2025, the Reliance on an External IRB fee will increase from $1,000.00 to $2,000.00. This fee increase is intended to meet the university's need to keep revenue in line with expenditures while aligning with other academic medical centers and universities.

External Rates Increase Letter 2024 (PDF)

Reliance on an External IRB

The MUSC IRB charges a fee of **$1000.00** for the processing of industry-sponsored protocols submitted to an external IRB for review.

- For more guidance regarding submission of amendments for a study reviewed

by an external IRB, visit Process for Reliance on an External IRB.

MUSC Serving the as the IRB of Record for a multi-site trial.

$4,000.00 Initial Non-MUSC Site Review per site

$1,664.00 Annual Management per site

*Please note sIRB fees may increase or decrease due to future rate adjustments. Bi-Annually, the prices and expenses are reviewed for when MUSC serves as the IRB of record for a multi-site study.

Group Education

REMINDER: If your department needs IRB education for a small study team or large department, please contact the IRB Administrator for Education and Training, at hintone@musc.edu. Currently, we offer presentations on IRB Basics, Initial Studies, Amendments, Continuing Reviews/Annual Status Updates, Reportable Events, and Reliance Studies.

About the Staff

Kaylee Moye

Kaylee Moye is excited to be joining the MUSC IRB as one of the coordinators for IRB III. She earned her undergraduate degree in Public Health in 2021 and subsequently joined UAB's Institute for Cancer Outcomes and Survivorship as a clinical research coordinator. She worked in both pediatric and AYA oncology populations conducting health and material hardship research observing the HMH relation to cancer outcomes. Earlier this year, she joined the newly established Mobile Infirmary Cancer Care CTO where she played an integral role in maintaining regulatory compliance, training staff, and preparing IRB submissions. In her spare time, she enjoys travelling with her husband and son. Her 2025 bucket list trip is the Washington D.C. Cherry Blossom Festival in April!

Contact Us

Have feedback or suggestions you would like to share?

Email us at: irb-news@musc.edu

171 Ashley Avenue

Charleston, SC 29425