MUSC
Medical University of South Carolina

The Institutional Review Board

May 2025

As research continues to flourish across the MUSC campus, the IRB is thankful for all the hard-working research teams and your dedication to providing quality human subject research.

IRB Updates

Changes to IRB Board III Meeting Dates & Deadlines

Effective July 1, 2025, IRB Board III will convene on a once-a-month basis, consistent with Boards I and II.

The IRB website has been updated with the complete list of 2025 Meeting Dates and Deadlines for Full Board IRB submissions for all Boards. Please keep in mind that initial submissions must be received by the IRB via eIRB by 5pm on the posted deadlines.

***Please note:** The IRB has not received the IRB application unless the state of the study says IRB Staff Review. Make sure to keep track of your study with department and ancillary reviews.

Meeting Dates & Deadlines

University Compliance Office Survey

As part of our ongoing efforts to improve our services and ensure we meet your needs effectively, we are conducting a brief survey about our University Compliance Office. Your feedback is invaluable to us and will help us enhance our processes and support. The survey should take no more than 1 minute to complete.

Your responses will be kept confidential and will only be used for the purposes of improving our services.

Survey

Retiring the ERMA system - Update

The IRB has retired the ERMA system and is working to convert all active ERMA studies over to the eIRB system. As of May 1, 2025, ERMA (erma.musc.edu) will only be able to be accessed from an onsite computer or by Citrix or VPN. It is imperative that all active ERMA studies be converted over to the eIRB system for continued monitoring. 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 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.

sIRB Fees updates

The MUSC Institutional Review Board is committed to providing research services at the lowest possible rate and in line with charges across the university. Bi-annually, our fees and expenses are reviewed when MUSC serves as the IRB of record for a multi-site study. MUSC Grants and Contracts Accounting reviews our service center expenses to provide our approved rate. The updated rates will go into effect **7/1/2025**.

For planning purposes, the new rates will be as follows:

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

$1,825.00 - Annual Management per site

Please note that we are committed to providing the highest quality research services at the lowest possible rates to support our investigators.

2025 sIRB Rate Increase Letter

Adverse Events

An **Adverse Event (AE)** is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporarily associated with the subject's participation in the research, whether it is considered related to the subject's participation in the research.

AEs encompass both physical and psychological harms and occur most frequently in the context of biomedical research, however, AEs can occur in the context of social and behavioral research too.

Examples of Adverse Events

- An upper respiratory tract infection
- A broken wrist
- Nausea and vomiting
- Nightmares
- Abnormal physical exam/laboratory finding

A **Serious Adverse Event (SAE)** is any AE associated with the subject's participation in research that meets any of the following:

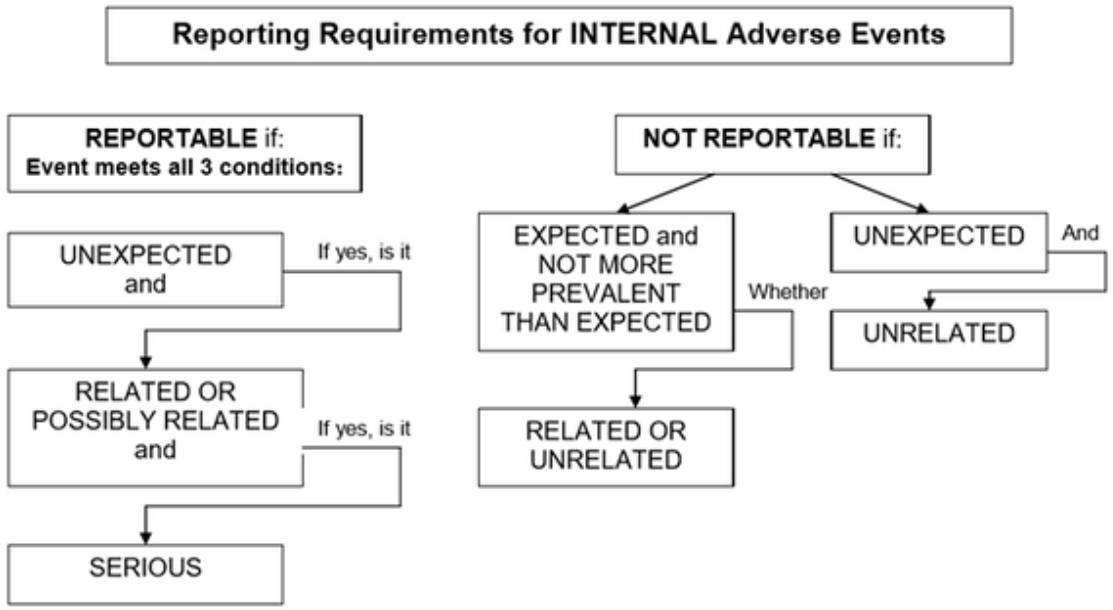
- Death
- Life-threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Disability/incapacity
- Congenital anomaly/birth defect
- Any other AE that may jeopardize the subject's health and require medical/surgical intervention to prevent one of the other outcomes on the list

An **Unexpected Adverse Event** is any AE, the specificity or severity of which is not consistent with the current Investigator's Brochure or, if any Investigator Brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application.

NOTE: The IRB doesn't want to know about every cold a child catches or every minor injury! The IRB is interested in serious problems that are unexpected and therefore might affect the IRB's prior risk-benefit assessment.

Adverse Event Reporting for External Studies:

Study teams only need to submit reportable events to MUSC if they involve complaints regarding the research. Anything else should be submitted to the external IRB. However, they will need to be submitted to MUSC if the external IRB or sponsor requests that the reportable event also be submitted locally.



Standard Paragraph Updates for Informed Consents - Starting June 2025

Based on feedback from the research community, the IRB has made the following revisions to the informed consent template:

-Reducing standard paragraph examples to one, as most consents are sufficiently concise and not enhanced by multiple versions that merely duplicate information. Instructions on proper grammar formatting can be found in the template.

- Amendments are not required to update to the latest version of the standard paragraphs. Older versions, in already IRB-approved consent forms, can still be used.

IRB Forms

IRB Group Education

Please contact Erin Dawley, IRB Administrator for Education and Training, if your department and/or research team need(s) IRB education/training.

We offer presentations on:
- IRB Basics
- Initial Studies
- Amendments
- Continuing Reviews/Annual Status Updates
- Reportable Events
- Reliance Studies
- And more!

- And more!

About the Staff

A Fond Farewell to Kaye Roberts

After 15 years of wonderful IRB service, we want to thank Kaye and wish her all the best in her upcoming retirement. Kaye came to work at MUSC in 1990. She was a research coordinator within the department of psychiatry for 10 years and then continued to coordinate clinical trials in various private practices before returning to MUSC.

Kaye has found it very rewarding not only to follow the progress of testing and approving new medications, but also to work closely with the subjects that make it all possible. As a breast cancer survivor, Kaye has personally experienced the rewards of how continued research can provide new treatments and improve outcomes.

In her retirement, Kaye is looking forward to spending time with her family, grandchildren, and friends.

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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