MUSC
Medical University of South Carolina

The Institutional Review Board

August 2025

While we do our best to highlight the latest information with the IRB newsletter, we also want to use it to remind you of different resources that are available to you. Built within our electronic protocol tracking system, eIRB, we have a frequently asked questions (FAQs) section that may be helpful to you when working on different types of eIRB submissions. In eIRB, you can access this through the Education and Training tab at the top of your home page. Below is a quick link to the eIRB FAQs.

eIRB FAQs

IRB Updates

New Privacy Policy

MUSC is committed to safeguarding sensitive, confidential, and restricted information and being transparent about how we use it. To support this commitment, we are introducing a new privacy policy, **U-COMP-003 *Privacy and Protection of MUSC Data and Information***, effective May 23, 2025. You can view the policy here: https://musc.policytech.com/dotnet/documents/?docid=22202

Our policy reflects MUSC's ongoing commitment to transparency, accountability, and the protection of sensitive, confidential, and restricted data across the university and provides:

- **Clarity** to help you better understand individual rights and our institutional responsibilities.
- **Consistency** on how we collect, use, and protect sensitive, confidential, and restricted data.
- **Resources** to summarize relevant privacy laws and best practices in higher education and research.

We encourage all members of our university community to review the policy. Understanding how data is managed helps us maintain a secure and integrity-driven academic environment.

If you have any questions or concerns, don't hesitate to reach out to the **University Compliance Office** at **univ-compliance@musc.edu** or via our website at https://horseshoe.musc.edu/everyone/compliance/univ-compliance.

Thank you for helping us maintain a confidential workplace.

— The University Compliance Team

Is your research data Coded or De-identified?

When talking about research data, often the terms ‘coded’ and ‘de-identified’ are used synonymously. While both terms relate to subject data privacy, there is a difference in definition, which affects an exempt research application.

Coded data is when you use a code (i.e. study identification number/random number) to replace direct identifiers.

When collecting data for a chart review, most research teams will create a linking document. This document will usually have the MRN and link it to a random study identification number. This helps prevent data duplications and allows for the study team to re-enter a subject chart if there is missing data or additional data is needed. A ‘code’ has been created by creating this linking document. This code, or linking document, must also be kept separate from research data.

De-identified data is data that is collected that does not contain any of the eighteen PHI identifiers, nor would there be a master identification log available to the researchers. De-identified data cannot be used to identify individuals or provide a reasonable basis to believe it could be used to identify individuals. There are no codes or links with de-identified data which could re-identify a subject.

If research data that does not include any of the eighteen PHI identifiers is received from another entity, that would be considered de-identified data.

We have had a few exempt applications where research data is gathered from previously completed exempt study databases (at MUSC). Would data that is gathered from previously completed exempt studies be considered coded or de-identified? It would depend on a couple of different factors.

First, is there an existing linking document for the completed exempt study? If so, does the staff working on the new exempt study have access to this linking document? If so, the data would be considered ‘coded’.

If the staff does **not** have access to this linking document, then the data would be considered ‘de-identified’ as long as it does not contain any of the eighteen PHI identifiers. If the linking document for the previously completed exempt study has been destroyed, the data would also be considered ‘de-identified’.

Identifiers may end up being stripped at the end of a research project. That would ultimately make the data ‘de-identified’. However, the use of PHI or other identifiers during the data collection process and having a linking document, deems the study data as coded.

Protecting participant identity, protected health information, and data are essential

Protecting participant identity, protected health information, and data are essential for researchers conducting exempt research trials. A clear understanding of these two terms, as well as documentation of how identifying data elements will be protected is vital when completing exempt research applications.

New ICF language and signature blocks

The IRB has made changes to the informed consent form (ICF) template. The Standard Paragraph examples have been reduced to one and it is now placed within the ICF template. Any edits made to the Standard Paragraphs will still require review and approval from MUSC General Counsel. The only exception, without prior approval of General Counsel, is the addition of “your child” and/or “you and your child” (see the instructions in the ICF template on the IRB Forms website).

The other change is to the signature blocks. The Person Obtaining Consent signature line has been moved so that the Participant or Legally Authorized Representative (LAR) signs the ICF first. There are also different signature block examples to choose from. Please review the signature block examples to ensure that applicable signature lines are in place for your study, then delete the other examples.

For studies already approved or submitted in eIRB with the previous versions of the Standard Paragraphs, amendments are not necessary. This is a change that can be implemented moving forward with new studies.

IRB Forms

IRB Contacts

Do I need to wait for a Just in Time request to submit my study?

If you have been informed by NIH or other funding agency that your application is likely to be funded, you can submit your research to the IRB prior to receipt of a “formal” Just in Time request, as these requests often have a short turnaround time.

sIRB Fees Update Reminder

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 went into effect on **7/1/2025**.

For planning purposes, the new rates are 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.

Board III Submission Dates

Beginning July 2025, IRB Board III will only meet once a month. The meeting will take place on the second Tuesday of each month.

The IRB website has been updated with the 2025 Meeting Dates and Deadlines for Full Board IRB submissions through December 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”.

Meeting Dates & Deadlines

New Approval Requirement for Studies at MUSC Health/RHN Sites

All eIRB applications (initial submissions and amendments) that involve MUSC Health/Regional Health Network (RHN) sites must now receive departmental approval from the MUSC Health/RHN Research Expansion Governance Committee after eIRB submission. If RHN Governance Committee approval has not been secured, study teams will be contacted by the RHN Governance Committee Coordinator with instructions and timelines for committee review. A Request for Changes will also be submitted in eIRB until approval is obtained.

Investigators planning to engage RHN sites should plan accordingly—the committee meets on the 2nd Wednesday of each month, and feasibility evaluations must be completed at least one week prior. These evaluations are coordinated by the RHN Research Expansion team and include consultations and site-specific feasibility reviews. For questions, email researchexpansion@musc.edu.

The Road to IRB Approval

SCTR has developed the MUSC Approval Plan for Research (MAP-R) tool, linked below, which provides tips to help you understand the Regulatory and Institutional approvals needed before you begin your study!

MAP-R

New Educational Materials available on the IRB Website!

There are several new educational materials available on our IRB website. New materials can be found under the Education and Training – CITI tab and by clicking on the “Additional Education” button. The resources are available at the bottom of the page and include presentations on “Overview of the IRB”, “Navigating eIRB”, "Quality Improvement vs. Research” and much more!

We have also included Tip Sheets for completing Exempt and Expedited applications. Those can be found on the IRB Forms page.

REMINDER: If your department needs IRB education for new faculty or staff members, small study teams or large department groups, 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.

Tell us how we are doing!

The IRB wants to hear from you and see how we can help! Please fill out our survey below:

Survey

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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