MUSC
Medical University of South Carolina

The Institutional Review Board

November 2025

The holidays are fast approaching and with that, the start of a new year is on the horizon. We look forward to seeing all the innovative projects that will be coming our way in 2026. The hard work and dedication to the protection of human subjects in research at MUSC is both admirable and impressive. You and your study teams are at the core of what makes change possible for South Carolina communities and beyond. We wish you and yours the happiest of holidays and all the best for the New Year!

IRB Updates

2026 IRB Meeting Dates and Deadlines

The IRB website has been updated with the 2026 Meeting Dates and Deadlines for Full Board IRB submissions. As a reminder, initial study submissions must be received by the IRB via eIRB by the posted deadlines.

Meeting Dates & Deadlines

Electronic Informed Consent Guidance

A growing number of researchers are either conducting research at a distance or are moving to entirely computer-based models where all data and correspondence are collected and stored electronically.

The MUSC IRB has prepared guidance along with policy wording to clarify the various approaches available to electronically obtain and document consent to participate in a research study. This guidance was developed to aid researchers who want to use an electronic process to document consent either as an alternative to or replacement of a paper-based consent process.

NOTE: This guidance will not be available on the IRB website until the website migration is complete.

HRPP 6.1 Informed Consent to Participate in Research

Remote Consent Guidance

The IRB supports the use of remote consent and remote study procedures, when appropriate.

The use of remote methods must be outlined for prospective IRB review and approval to ensure that risks to subjects continue to be minimized, and the data integrity of the study can be maintained. This guidance is meant to serve as a resource to guide research teams considering the use of remote procedures for research.

There are multiple methods that can be used to obtain consent from research participants when the research team is unable to have an in-person meeting. Many use the term “Remote Consenting” to describe the different methods that can be used to obtain consent outside of an in-person meeting.

The most used methods of Remote consenting include:

1. Waiver of Documentation of Signed Consent
2. Teleconsent
3. Remote consent via paper consent
4. Remote consent using electronic consent

Any method used to obtain informed consent must allow for an adequate exchange of information and documentation and ensure that the signer of the consent form is the person who plans to enroll as a subject in the research study or is the legally authorized representative (LAR) of the subject.

NOTE: This guidance will not be available on the IRB website until the website migration is complete.

HRPP 6.1 Informed Consent to Participate in Research

VA Researchers: Updated VA Form 10-0493 (HIPAA Authorization)

The VA Office of Research and Development (ORD) has implemented a new HIPAA Authorization Form, **effective November 3, 2025**. Only study teams with a new/initial study after 11/3/2025, or teams requiring a change to their HIPAA Authorization Form, will be required to utilize the new VA Form 10-0493. All others will be grandfathered in.

ORD recommends retrieving the HIPAA Authorization Form directly from the VA Forms page by typing in "10-0493". Summary of changes can be found in IRBNet, and the webinar recording can be found here.

If you have any questions, please contact the VA's Privacy Officer, David Stine (David.Stine@va.gov, 843-789-7767 x 207767), or HRPP Administrator, Dr. Jocelyn Reddix (Jocelyn.Reddix@va.gov).

IRB Reminders - eIRB Application Tips!

Study Personnel

Any study team member added to the eIRB application on the "Guest List" is given view only rights.

CITI Training Requirements

All Study team members listed on the humans subjects research application must have completed the following MUSC CITI Training:

Human Subjects Research:

Group 1. Biomedical Investigators and Key Personnel **OR**

Group 2. Social/Behavioral Investigators and Key Personnel

AND

Good Clinical Practices (GCP):

GCP for Clinical Trials with Investigational Drugs and Biologics **OR**

GCP-Social and Behavioral Research Best Practices for Clinical Research **OR**

GCP for Clinical Investigators for Devices

A Basic Course must be taken before a Refresher will be accepted! The eIRB application will not be approved until all study personnel have complete and up to date CITI training showing in the eIRB system.

Education & Training - CITI

eIRB Registration

All Study team members listed on the application must register in eIRB

To register in eIRB, you must log in to eIRB using your Net ID and password then enter your fist name, last name and primary email address (MUSC email address).

Make sure this information exactly matches your CITI Database profile!

eIRB Registration

Study Personnel/CITI Training not showing in eIRB

If study personnel/CITI Training are not populating in the eIRB system, some questions to ask may be:

1. Has the study team member completed their MUSC CITI training?
2. Has the study team member registered in eIRB?
3. Was the study team member assigned the correct role in eIRB at registration? (Check registration confirmation email)
4. Do names and primary email match both CITI and eIRB databases?

CITI Training and eIRB registration are two, distinctly separate systems. CITI training needs to be completed for CITI training to populate in eIRB and eIRB registration needs to be completed for study personnel to populate.

First name, Last name, and primary email address need to match exactly in both systems!

What needs to be included with Reportable Events?

When filing a Reportable Event, please be sure to include and upload all appropriate documents with the Reportable Event submission.

Reportable Event	Things to include with submission (if applicable)

Adverse Events (AE) & Unanticipated Problems	• Determine if the AE is: Unexpected; Related/Possibly Related; and/or Serious
	  ○ If all 3 conditions are not met, then the AE does not need to be reported to the IRB
	• Describe the event and the impact the event had on the subject(s)
	  ○ Be as detailed as possible!
	• Confirm if any changes need to be made to the Protocol, ICF, and/or the Investigator's Brochure
	  ○ If so, an Amendment is needed
	• Include any other documents that will assist in the review of the Reportable Event

Unanticipated Problem Involving Risks to Subjects or Others (UPIRSOs)	• Describe the problem and any risks that have changed for the study and the actions taken by the study team in response to the unanticipated problem
	  ○ Be as detailed as possible!
	• Confirm if any changes need to be made to the Protocol, ICF, and/or the Investigator's Brochure
	  ○ If so, an Amendment is needed
	• Include any other documents that will assist in the review of the Reportable Event

Protocol Deviation	• Describe the Protocol Deviation • Confirm if changes need to be made to the Protocol, ICF, and/or Investigator's Brochure. ○ If so, an Amendment is needed • Describe the corrective action plan to ensure that the same protocol deviation(s) are not repeated • Include any other documents that will assist in the review of the Reportable Event
Other Reports – Data Safety Monitoring Board Report & Audits	• Indicate the other type of event/information being reported • Upload supporting documents ○ DSMB Reports need to include the document stating the Board's recommendation

	○ Audit Reports must include the Audit documents and the PI Response to any audit finding.

HRPP 4.7 Unanticipated Problems and Adverse Events

HRPP 4.14 Protocol Deviation

Following the State of your study!

Check the current “State” of your study under the study’s main page. The IRB does not have the study until the “State” is “IRB Staff Review.”

Be sure to follow the state of your study to avoid delays.

Other common states are:

In Review

Assigned to IRB Meeting

Changes Required per IRB Staff

Changes Required per IRB Reviewer

Awaiting Correspondence

IRB Review Request Smartform

This smartform requests either a Single IRB Review (sIRB) or an External IRB Review for multi-site Studies.

If the research is being conducted at MUSC, no other sites are engaged in the research, and MUSC is not planning to rely on another institutions IRB, the responses to 1.0 & 2.0 should both be “No”.

sIRB review is reserved for when the MUSC IRB is serving as the IRB of record for a multi-site study.

IRB Education & Training

Schedule an Education & Training Session!

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, Reliance Studies and More!

IRB Education & Training Session Request Form

Updates on ICH E6 (R3) GCP

The International Council for Harmonisation (ICH) released the revised Good Clinical Practice guideline **ICH E6(R3)** in January 2025. These revisions reflect current approaches to clinical research, including decentralized models, electronic data capture, and risk-based oversight.

MUSC's Approach

MUSC will integrate these updates into our existing training process without requiring additional or early training for staff.

- **Training Requirements:** Researchers are **not required to retake GCP training early** solely due to ICH E6(R3).
- **Renewal Cycle:** NIH-funded investigators and clinical trial staff must continue to complete GCP training **every 3 years.**
- **Updated Content:** Beginning with upcoming renewals, all GCP training completed through the **CITI Program** will reflect the ICH E6(R3) updates.
- **Optional Early Access:** Staff who wish to familiarize themselves with the new content may voluntarily re-enroll in the updated CITI modules at any time.

Next Steps

- No immediate action is required for staff who are current with their GCP training.
- MUSC will continue monitoring sponsors and federal guidance related to E6(R3).
- Additional resources and instructions will be shared as implementation progresses.

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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