MUSC
Medical University of South Carolina

The Institutional Review Board

August 2024

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

IRB Feedback

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

IRB Survey

Research Privacy - MUSC Compliance

Federal HIPAA regulations define “breach” as the acquisition, access, use, or disclosure of protected health information (PHI) in a manner not permitted under HIPAA which compromises the security or privacy of the PHI. Some examples of HIPAA breaches are listed below.

- Using EPIC to look up a co-worker (unless a study subject) for any reason other than treatment/payment/operations purposes, such as to obtain an address for a birthday/get well card, etc.
- Emailing spreadsheets of screened (screening logs) unconsented patients to sponsors. Many times, subjects’ consent to PHI sharing with sponsors when they are consented.
- Emailing of study communications and mistakenly copying other study participants or forgetting to blind copy on group emails. Blind copying is not considered a best practice when emailing sensitive information such as PHI.
- Study drug mistakenly thrown in the trash bin with PHI on the label.
- Using EPIC to look up patients to see why they are at MUSC out of curiosity and not for approved job-related duties.
- Paper records left in unsecure locations, such as on a public printer, left in a public room, etc.

University faculty, students and staff are responsible for reporting any suspected breach of privacy caused by the unauthorized acquisition, access, use or disclosure of PHI to the University Compliance Office (UCO) **immediately**, even when you are unsure if it is a violation. Under federal regulations and in accordance with MUSC policy A-098, the UCO will determine whether a breach has occurred after conducting a risk assessment using specific criteria. Please refrain from labeling any incident as a “breach,” regardless how obvious it may be, until the UCO has made a final determination. Reports may be made to the UCO through the following methods:

- **Call us at 843.792.8652,**
- **Email us at univ-compliance@musc.edu,**
- **Online reporting** via the Compliance Reporting and Resource Form (musc.edu)
- 24/7 calls to the Confidential Hotline 1-800-296-0269, or
- Campus mail (MSC 002).

If a breach occurred in the scope of a research project, this information should also be reported to the Institutional Review Board no later than 10 working days after it occurred in accordance with HRPP 4.13.

Thinking about conducting Medical Education Research in the College of Medicine (COM)?

All projects involving the MD Degree program and/or MD students, in which data is collected by or about the program or students, require review and approval by the COM Dean's Office prior to the project being submitted to the IRB or the IRB's QI Program Evaluation Self-Certification Tool. The Dean's Office review is to ensure both the feasibility of the project and compliance with standards regarding data use (e.g., confidentiality). Members of the Dean's Office with expertise in medical education research are available for consultation to move your ideas forward!

The following are examples of project work that requires review before submission to the IRB:

- Data collection requiring dissemination of questionnaires to MD students;
- Data collection using focus groups or interviews with MD students;
- Data collection/analyses related to MD students' satisfaction/preferences, performance outcomes, and life experiences;
- Analyses/use of data regarding student outcomes, course outcomes and/or program outcomes.

To submit a project for review by the COM Dean's Office and/or and for consultation on your project, complete the **COM Project Planning Research Form** link here.

Who you gonna call?

If you have a specific study related, IRB/eIRB question, please contact the appropriate IRB Administrator and/or Coordinator for help. In general, the Administrators for each of the Boards work on Initial Studies, Reportable Events, and Full Board Amendments. The Coordinators work on Continuing Reviews and Expedited Amendments. Please be sure to include your study's "Pro" number in any correspondence.

- Reliance
  - Monica Baczko (Reliance Manager)
  - Maggi LeJeune (Administrator)
- Exempt and Expedited Studies
  - Kaye Roberts (Administrator)
- Board I
  - Kristin Zaks (Administrator)
  - Brea Roy (Coordinator)
- Board II
  - Amy Haynes (Administrator)
  - Ashley May (Coordinator)
- Board III
  - Paul Kelly and Jackie Shedrow (Administrators)
  - Rebekah Whichard and Courtney Hollis (Coordinators)
- Quality Assurance
  - Jessica Orak (Administrator)
- IRB Education and Training
  - Erin Dawley (Administrator)

IRB Contacts

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.

Upcoming Group Education Sessions:

11/6/24 – SCTR Lunch n' Learn via Teams
Time: 12pm-1pm
Topic: IRB

11/20/24 – SCTR Lunch n' Learn via Teams
Time: 12pm-1pm
Topic: Deep dive into eIRB

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

CITI Training and eIRB

eIRB Registration and CITI Courses Information

Completing CITI training does not automatically register you in eIRB (the system which is used to submit research protocols for IRB review). CITI and eIRB are two separate systems. You may submit an eIRB application to the IRB for review while working on the CITI training. However, IRB approval for a new study or continuing review of an existing study will not be given until the CITI training has been successfully completed by each member of the study team. The IRB staff will verify that training requirements for study team members are current.

eIRB

eIRB registration must occur for anyone that is new to MUSC and has not previously signed in to eIRB. This applies in situations in which a PI is completing their first eIRB application or adding someone to a study that is new to research at MUSC. All study personnel, no matter their role, working on the study will need to first register in eIRB. To register, go to https://eirb.screserach.org, select the affiliated institution (Medical University of South Carolina) from the drop-down screen, and login with your current and active credentials (Net ID and password). The first time you log into the system, a registration screen will be displayed. Fully complete the requested information and submit the registration form. Make sure the information you enter in eIRB exactly matches your CITI registration information so that both systems will sync and display your CITI training in the eIRB application. An email will be sent to the eIRB System Administrators, who will verify your account, assign user roles as appropriate, and activate your account. You will receive an email notification of account activation.

CITI

All investigators and study team members who participate in the design, conduct, or reporting of human subjects' research (including exempt research) must be appropriately trained in the protection of human subjects. MUSC uses the Collaborative Institutional Training Initiative (CITI) web-based human research courses to satisfy this institutional requirement. Basic-level courses for each group of required trainings must be completed before Refresher-level Courses will be accepted. All required groups of CITI Training will need to be renewed every 3 years. All study personnel must have current CITI certification prior to approval of the study. This also applies to amendments and continuing reviews. ***While some researchers may have taken CITI modules at a previous institution, MUSC requires that anyone transferring to MUSC must complete the MUSC Basic Biomedical or Social and Behavioral modules and Good Clinical Practice Basic modules prior to beginning research activities (even if the course was completed at a previous institution).***

eIRB Training & Guidance

Education & Training - CITI

About the Staff

Monica Baczko Pearl

Monica Baczko Pearl is very excited to be joining the MUSC IRB as the Reliance Manager. She began her research career as a data entry specialist in 2010 at UMass Medical School. In 2013 she accepted a Research Coordinator position at MUSC in the Rheumatology department and relocated to Charleston. She has spent the last 9 years as the Program Manager and IRB Liaison of the PEPPER trial, a national multi-site trial within the Department of Orthopaedics. She enjoys traveling, reading, and cooking.

Contact Us

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

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