MUSC
Medical University of South Carolina

The Institutional Review Board

November 2024

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 2025. 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

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. As a reminder, initial study 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”.

2025 Meeting Dates & Deadlines

Retiring the ERMA system

The IRB will be retiring the ERMA system soon and we are ready for all ERMA studies to be converted 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 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 criteria on the IRB website for study closure 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.

IRB Submissions

ERMA to eIRB Conversion Guidance

Recruitment of Research Participants Policy Update

The policy IRB HRPP 7.8 Recruitment of Research Participants has been updated to further clarify contacting prospective participants who are identified via medical records. The updated policy also provides clarification on when cold calling is and is not approved for a study. For further information, please see the following link below.

IRB HRPP 7.8 Recruitment of Research Participants

Patient Outreach Recruitment (POR)

Patient Outreach Recruitment (POR) is the formal process that allows investigators to invite potentially eligible patients to participate in research studies when neither the Principal Investigator nor Co-Investigator is a member of the patient's clinical care team. This increasingly popular approach amongst academic medical centers is borrowed from commercial settings and is known as cold contact recruitment.

Patients are identified through a query of EMRs, and outreach is facilitated via phone, email, post mail, and MyChart® message. With IRB approval, any patient is eligible for cold contact if they have not previously documented a preference opting out of such contact.

POR is beneficial for investigators and patients alike, as it may expedite recruitment, and presents investigators with greater access to patients; and MUSC patients with access to study opportunities. Combined, these are likely to yield more representative samples and generalizable findings.

If you are planning to submit a new study application or an amendment for cold contact, eIRB includes selections for this form of recruitment. The application includes areas for the researcher to detail their proposed plans, methods of outreach, and sections to upload the proposed cold contact scripts.

For additional guidance on preparing your application for Patient Outreach Recruitment at MUSC, or a consultation with the POR Team, please visit: https://research.musc.edu/resources/sctr/about/success/recruitment/patient-outreach

Conducting Research at a MUSC Regional Health Network Site (RHN)?

All clinical research studies and activities to occur at MUSC Health/Regional Health Network (RHN) sites, including Humanitarian Use Device (HUD) and registry studies, must be submitted to the MUSC Health/RHN Research Expansion Governance Committee for scientific and feasibility review and approval prior to the start of any study activities. The committee meets on the 2nd Wednesday of each month. The PI and/or study team member should plan to attend the meeting to present an overview of the study and the resources that will be needed. To be placed on the meeting agenda, please submit a SPARCRequest (https://sparc.musc.edu/) for "Regional Health Network (RHN) Clinical Research Governance" for each MUSC Health/RHN site location where study activities will be conducted and complete the "MUSC Health/Regional Health Network (RHN) Research Application" in REDCap. For more information contact the MUSC Health/RHN Research Expansion team at researchexpansion@musc.edu or, to access the RHN Research Application visit the link below.

RHN Research Application

IBC/IACUC Updates

After 10 years with the current research management system used by IACUC, IBC, and DLAR, we are excited to transition to the tick@lab system for IACUC, IBC, and lab animal management through DLAR. There are “blackout” dates for making changes (new protocols, amendments, animal orders) in the current system. Details are available on the current eProtocol Investigator Home pages.

On the IACUC side we are working on prepopulated standardized procedure descriptions that can be added and modified by the PIs as needed. IBC will have SCRO and DURC processes as part of the IBC form. There are also significant animal management improvements including animal health records, a bulletin board feature for sharing unneeded animals with other PIs, and a Transnetyx integration for genotyping results. Basic features will be immediately accessible when we go live in December and extended features will be rolled out as quickly as possible. If you have active animal or biosafety work, please be on the lookout for communications from the respective teams.

*****eProtocol will be replaced by tick@lab in December. Demos of the new system will be available soon and an open Q&A session is planned for early November. Please monitor your inbox for emails from IACUC, IBC, DLAR, and the VPR’s office on required PI actions as we ramp up for the transition.*****

Amendments for External IRB Applications

Not all amendments are required to be submitted to the MUSC IRB for externally reviewed studies. Changes to the study that require an MUSC IRB amendment submission include:

- MUSC Study personnel changes
- Revisions to the HIPAA Authorization
- Changes to Conflict of Interest
- Changes that affect MUSC local context language, institutional policy, or state law requirements
- Changes to study procedures that would require ancillary approval
    - i.e. radiation safety committee approval
- Changes to recruitment activity and potential patient populations
    - i.e. the study was only approved for adults but has been amended to include minors
- Amendments requested to be submitted to the local IRB by the sponsor

If you are unsure if an amendment for your study needs to be submitted to the MUSC IRB, please reach out to the Reliance Manager, Monica Baczko Pearl at baczko@musc.edu.

External Collaborator Form

The External Collaborator Form should be completed when considering the addition of an External Collaborator as a study team member and prior to the request for an external NetID. This form should not be used if the individual is affiliated with an organization that has an IRB. If so, the individual must submit to their institution/organization's IRB. The External Collaborator Form can be found on the IRB website Forms page linked below.

NOTE: If research activities are collaborative or multi-site and request MUSC IRB review/single IRB review please email the MUSC Reliance team at baczko@musc.edu with details on the study, activities and external organization's personnel involvement.

IRB Forms

Upcoming Group Education Sessions:

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

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

SCTR Lunch & Learn Registration

About the Staff

A Fond Farewell to Jackie Shedrow

After 17 years of wonderful IRB service, we want to thank Jackie and wish her all the best in her upcoming retirement.

Prior to coming to MUSC, Jackie had a career in marketing design and construction services, however, she'd always had an interest in science and healthcare.

Jackie began working at MUSC as a transcriptionist for Pediatric Cardiology. She spent about 18 months in that role before joining the IRB in 2007 as a Coordinator for Board I. In 2009, she earned her CIP certification and moved to Board III where she became an Administrator for industry-sponsored studies.

Jackie has always valued ensuring subject safety and being up to date with cutting-edge medical advances, but she is ready to enjoy a life change.

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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