MUSC
Medical University of South Carolina

The Institutional Review Board

May 2022

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

IRB Survey

IRB Updates

AAHRPP Re-Accreditation

The Medical University of South Carolina (HRPP) has been accredited by The Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2009 and has recently submitted for re-accreditation. AAHRPP is a non-profit organization founded in 2001 to ensure research compliance and to promote uniform standards for the protection of human research subjects.

The MUSC HRPP includes not only the IRB, but those involved in human subject research across the University: Leadership, Department chairs, investigators, research teams and research support offices, to name a few.

The re-accreditation process includes a virtual site visit which that is scheduled to occur July 13-14, 2022. During the site visit, the AAHRPP team will review records, policies and procedures to ensure the culture of compliance is consistently applied throughout the HRPP. The AAHRPP team will also conduct interviews with stakeholders in the HRPP which may include you! Those selected for interview will be notified prior to the scheduled session.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOS) - HRPP 4.7

MUSC investigators are required to promptly report to the IRB if there are unanticipated problems during the course of the research that involve risks to subjects or to others.

According to federal guidance, an unanticipated problem involving risks to subjects or others (UPIRSOS) refers to any incident, experience, or outcome that:

- is unexpected (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- is related or possibly related to a subject's participation in the research; and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

For additional information, see the link below or the education material located on the IRB website, Additional Education Resources page. Also, HRPP 4.7 outlines specific information regarding reportable external adverse events.

UPIRSOS Education

HRPP 4.7 Unanticipated Problems and Adverse Events

University Compliance Reminder

University faculty, students and staff are responsible for immediately reporting to the University Compliance Office any activity reasonably believed to be a breach of privacy caused by the unauthorized acquisition, access, use or disclosure of any personally identifiable information, including protected health information (PHI). This report must be made in accordance with the MUSC Compliance policy and Privacy/Security Breach Determination and Notification policy. The Compliance Office will work with you to determine whether a breach has occurred and whether any notifications are required. Reporting may be done through any of the following methods:

- Online reporting to the Compliance Reporting and Resource Form
- (musc.edu), Campus mail (MSC 002),
- Email us at univ-compliance@musc.edu,
- Call us at 843.792.8652,
- 24/7 calls to the hotline 1-800-296-0269, or
- In-person visit to the Compliance Office during normal business hours at 49 Bee Street.

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 occurs, in accordance with HRPP 4.13 and HRPP 4.14.

Informed Consent Template Update

The Medical Records section of the Informed Consent template has been updated to help determine which standard language to use if information will or will not be placed in the subject's medical record, if medical monitors will or will not have access to the medical records, if using recruitment tools in the EHR, if utilizing MyChart to communicate with participants, or if the study will utilize any of the Epic Research Functionality. The Informed Consent template can be located on the Forms page of our website.

IRB Forms

Mentor Responsibilities

When a student or trainee is listed as a study's Principal Investigator (PI), a faculty member must also be listed on the protocol submission as a Mentor. Faculty must meet criteria to be considered eligible mentors. The student or trainee PI and their Mentor are both responsible for the conduct of human research, but the Mentor has additional responsibilities to ensure the integrity of the research is maintained.

- The Mentor will review the study protocol prior to submission to the IRB to ensure that the study has a valid research question and the research procedures are sufficient to answer the research question.
- The Mentor will meet with the student/trainee Principal Investigator on a regular basis to monitor study progress.
- If the Mentor will be unavailable for an extended period of time (e.g., on sabbatical or extended leave), they will arrange for an alternate faculty member to assume mentoring responsibility during their absence. The Mentor will advise the MUSC IRB in advance via both by letter and submitting change in personnel amendment of such arrangements.

For further information on PI and Mentor Responsibilities please see the following links:

IRB HRPP 5.1 Principal Investigator Responsibilities Supervision of Staff and Protection of Subjects

Section 5.2 Principal Investigator Responsibilities Recordkeeping and Record Retention Requirements

IRB Reliance

IRB Reliance is the process of using a single IRB for review of multiple sites or investigators at multiple institutions. MUSC is willing to review requests for reliance on an external IRB as well as requests for MUSC to act as the IRB of Record. In both of these scenarios, the first step in the reliance process is to complete a reliance intake form.

For information on fees charged for studies where MUSC relies on an external IRB or when MUSC serves as the IRB of record, please view the IRB submission information.

For general questions related to reliance, please see the single IRB frequently asked questions (FAQs).

Regional Health Network Sites

The eIRB smartforms have been updated to include the recently added Regional Health Network (RHN) sites. If you plan to submit a new study using the RHN site(s), or you are going to add a RHN site(s) to an existing study, make sure you submit the below REDCap form to the MUSC Regional Health Network (RHN) Research Expansion Governance Committee for approval. If RHN(s) are being added to an approved study, an amendment adding the new location(s) must be submitted and approved before any research may be done at the new location(s). For additional information about the RHN sites, please see the links below.

Regional Health Network Research Application REDCap Form

Regional Health Network

Exempt Research Reminder: Are you conducting Exempt Research?

If so, please note that section 3.2 of the Human Research Protection Program (HRPP 3.2) Exempt Research stipulates that Exempt studies are expired by the IRB five years after the initial date of approval unless the study plan specifically describes the duration beyond the five-year expiration, in which case, that will be the end date for the project.

Researchers are responsible for tracking the study's expiration date. Once the Exempt study expires, no further research can be performed on the project. If there is still a need to perform research past the expiration date, another Exempt study will have to be opened in order to continue.

HRPP 3.2 Exempt Research Review Policy and Procedures

New IRB Website Enhancements

The IRB has updated the Education and Training pages on the IRB website to include a focus on CITI, eIRB, and Additional Education Resources available at MUSC. See the links below for more information:

Education & Training CITI

eIRB Training & Guidance

Additional Education Resources

Frequently Asked Question

Q: I completed my CITI training, but my PI cannot find my name in the eIRB system to add me to their study. Can you please help?

A: You need an eIRB account in addition to a CITI account. If you are a first-time user of the eIRB system, you must create an account to get started. Please follow the self-registration steps below:

- Go to https://eirb.healthsciencessc.org/
- Select Medical University of South Carolina as your Institution (MUSC Users)
  - Or MUSC External Affiliate (Affiliated External to MUSC)
- Enter your NetID and Password on the following screen.
- Complete the registration page on the following screen.
  - Important Note: Ensure that your First Name, Last Name and Primary email address are exact matches in both eIRB and CITI so that your CITI training will display within the eIRB study application.
- Once submitted, the registration will be completed and you will be notified via email from the eIRB.
- After receiving the confirmation email from the eIRB, log in again access the Education and Training Tab at the top of the page. This section has many videos including how to submit an initial study. There is also a great FAQ section that might address your questions as you get started.

About the Staff

Jessica Orak

Jessica Orak is the Education and Training Administrator for the IRB. Her MUSC IRB career started over 5 years ago on Board III as a Grants Coordinator II. She graduated from the College of Charleston and previously worked as a Chemist at a chemical manufacturing company in North Charleston. She spends her free time with family and close friends and enjoys gardening, traveling to new places, and playing darts.

Contact Us

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

IRB Homepage

IRB Contacts

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