

# **The Institutional Review Board**

August 2023

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

### eIRB Upgrade Announcement

We are excited to announce that the eIRB development team successfully applied the software upgrade (Portal 9.0.8) to the eIRB system on Saturday, August 26, 2023. The upgrade includes many enhancements and an updated design for Smartforms and other projects. The functionality of Smartforms, their content, and data <u>did not change</u>, however reviewers' comments are now easier to locate for study teams' responses. To assist with the transition to the new format, the development team has created eIRB education and training material for researchers and staff review. Researchers and staff are strongly encouraged to access the written education documents/materials and corresponding video links below to view the new system changes. Further materials are now available under the eIRB Education and Training tab.

eIRB Education & Training

eIRB Portal 9.0.8 Software Upgrade Document

eIRB Portal 9.0.8 Software Upgrade Video

### 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.

#### elRB

elRB registration must occur for anyone that is new to MUSC and has not previously signed in to elRB. This applies in situations in which a PI is completing their first elRB 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 elRB.

To register go to <u>http://eirb.healthsciencessc.org</u>, 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).

## Industry Sponsored Studies – Sponsor Commitment Language – Process for Harmonization Between the Contract and the Informed Consent Document

For any industry-sponsored study, a contract is required between MUSC and the study sponsor (or LCVR in the case of VAHCS studies). Before the release of IRB approval, the contract must be finalized. The reason for this is because the "Sponsor Commitment" language in the informed consent document must reflect the contractual agreement concerning what will be done in the event of a study-related injury or illness. This portion of the informed consent is reviewed to ensure harmonization of the language between the contract and informed consent document before the IRB will be authorized to release approval of any industry-sponsored research.

The procedures in place for informed consent and contract language harmonization are as follows:

- The IRB administrator contacts the Office of Research and Sponsored Programs (ORSP) to confirm an agreement is in place between our institution and the sponsor and to request the review of the sponsor commitment wording in the consent to ensure its alignment with the contract prior to releasing a study.
- ORSP will review the consent and should any changes be required, have the IRB relay the requested changes to the study team.
- Once the revisions to the consent by the study team are made and the application is returned to the IRB, IRB personnel will review the revisions for accuracy and advise ORSP when the study is ready for ORSP's final review and ancillary approval.
- If the wording in the consent accurately reflects the information in the contract, ORSP will issue ancillary approval and the IRB may release the study approval.

**IRB Administrator Tip:** If you have an IRB-approved study with the same sponsor, use the sponsor commitment language from the approved study. Chances are that the language will be the same (or nearly the same) and this may save you some time.

### **Patient-Outreach Recruitment Information**

If you would like to learn more about Patient-Outreach Recruitment, also known as coldcontact recruitment, the following link provides the most up-to-date information for this type of recruitment as well as items such as a communication script template and guidance for submitting to the IRB.

## **Institutional Biosafety Committee**

The Institutional Biosafety Committee (IBC) is charged with reviewing clinical research involving administration (directly or indirectly) of recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins into human research participants. When a Principal Investigator proposes research, whether it be an initial study application or External IRB application, involving administration of one or more of such agents to human subjects, the PI must submit an application to the IBC and IRB simultaneously for review in eProtocol and eIRB, respectively.

There is a specific section within the eIRB application where selections must be made to ensure that the study will route to the IBC ancillary reviewer. The Application Checklist smartform of the eIRB application has an entry under "Biosafety/Genetics" for

- "Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents or microorganism (including bacteria, fungi, viruses, etc.), or biological toxin (including Botulinum toxins) exposure to human subjects"
- "Vaccine Trials"
- "Transplantation"

If any of these boxes are checked, the IBC manager is notified via eIRB that this study is available for review. The purpose of the ancillary review is to determine if IBC review and approval is needed for the study.

When submitting a study for IBC's eProtocol system, the PI will need to complete the Human Subjects Research (Section 7) and upload copies of the "clinical trial protocol" and "Investigator's Brochure" to the Attachment section.

Amendments should follow the same procedures with updating the necessary eIRB smartforms (Application Checklist) and eProtocol sections so that IBC can conduct their review of the study application.

Annual/Continuing Reviews are required for the IBC, so PIs are reminded to submit both Annual and Continuing Reviews via eProtocol to remain in compliance with IBC Guidelines.

No such research study shall be initiated until IBC approval has been obtained and all applicable regulatory authorization(s) and approvals have been obtained. IRB approval will be held until the IBC review is complete.

#### **Biosafety/Genetics**

- Human Genetic Research
- Human In Vitro Fertilization

Recombinant or synthetic nucleic acid molecules, gene transfer, infectious agents, select agents or microorganism, or biological toxin (including Botulinum toxins)

Transplantation

Vaccines

HRPP 4.11 Human Subjects Exposed to Recombinant Nucleic Acid Molecules, Biological Toxins or Microorganisms Policy and Procedures

## Exempt Studies - Add a Study Team Member Feature and Delete Approved Study Personnel Feature Reminder

The elRB system has been modified to allow PIs and main study coordinators to add Co-Investigators and/or Other Study Team Members to Exempt studies without submitting an amendment. The PI or main study coordinator can also edit the Communication Lead or add to the Guest List. The elRB system will automatically check the CITI training of the personnel being added. If the CITI training is not up to date, the system will not allow the person to be added to the study. Please note, this feature is available for Exempt studies only.

Additionally, the eIRB system is equipped to allow the PIs and main study coordinators to remove Co-Investigators and/or Other Study Team Members from Exempt, Expedited, and Full Board studies with the "Delete Approved Study Personnel" button. This button, located under "My Activities" on the main study page, will only show for PIs and main study coordinators and will not be available if there is an open and active amendment. The button will reappear once the amendment has been approved or withdrawn.

HRPP: 3.2 Exempt Research Review

### **FDA Final Guidance on Informed Consent**

The FDA has issued Final Guidance on Informed Consent. This guidance is meant to assist IRBs, principal investigators, and sponsors involved in clinical investigations of FDA-regulated products with their responsibilities related to informed consent. See the link to the final guidance below.

FDA Informed Consent Guidance

FAQ: What is the difference between a Data and Safety Monitoring Plan and a Data and Safety Monitoring Board?

A Data and Safety Monitoring Plan is intended to assure the safety of the human subjects, and the validity of the data generated. All greater-than-minimal-risk research must have a data and safety monitoring plan. The essential elements of the plan include:

- 1. What data is to be monitored
- 2. Who is responsible for monitoring and how often
- 3. Reporting plan for communicating findings to IRB/Sponsor/Federal Agencies
- 4. Reporting plan for adverse events
- 5. Endpoints Proposed

A Data and Safety Monitoring Plan must appropriately consider several criteria including the potential risks, nature, size, and complexity of the research protocol, as well as the subject population. A DSMP is commensurate with the risks involved with the investigation and can involve the principal investigator submitting an annual safety and adverse event report to the IRB or establishing a formal Data and Safety Monitoring Board (DSMB).

A DSMB is a formal committee that is established specifically to monitor data throughout the life of a study to determine if it is appropriate to continue the study as planned, from both the scientific and ethical standpoints. A DSMB may consist of as few as 3 members, but this number should be large enough to include a representation of all needs/skills and experience. The membership of the DSMB cannot have any actual or perceived conflict of interest associated with the study.

All multi-site clinical trials, all investigator-initiated Investigational New Drug trials, and all investigator-initiated Investigational Device trials involving interventions that entail potential risk to the participants must have a DSMB included in the Data and Safety Monitoring Plan. The IRB will review and approve the adequacy of Data and Safety Monitoring Plans.

### HRPP 4.10: Data and Safety Monitoring Plans

### About the Staff

### Summer Young, JD, MPH, CIP

Summer Young is the Reliance Manager for the MUSC IRB. She started her career at MUSC in the University Compliance office before transferring to the IRB 13 years ago. Prior to joining MUSC, Summer worked as an attorney in Summerville, SC. Summer spends her free time with her husband, Robert, and trying to keep up with her two fabulous girls.

### **Contact Us**

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



**IRB** Contacts

# 🕤 🚯 🎔 💙 🗿 ye

© Medical University of South Carolina

171 Ashley Avenue

Charleston, SC 29425