

The Institutional Review Board

August 2021

There are many helpful forms, templates, and suggested language on the IRB website. Be sure to check out our website before you start working on a study to familiarize yourself with the Policies and Procedures for Human Subjects Research at MUSC. Another helpful resource is the SUCCESS Center, which can help by offering guidance and other services when preparing an IRB submission.

MUSC IRB Website

SUCCESS Center Website

IRB Updates

COVID-19 Initial Studies Reminder

All COVID-19 studies submitted to the IRB will need to include "COVID" in the short title of the study application for quick identification and reporting purposes.

Before submitting COVID-19 studies to the IRB, please check with the COVID-19 Research Review Committee for approval of these projects. See the link below for more information.

MUSC Research Continuity & Planning for COVID 19

CITI: Faculty/Staff Transferring from Another Institution to MUSC

As of January 1, 2019, a researcher transferring to MUSC may not affiliate prior completed CITI modules to meet the MUSC training requirements. While some researchers may have taken CITI modules at a previous institution, MUSC requires that anyone transferring to MUSC must complete the MUSC-specific elements of CITI's Basic Biomedical or Social and Behavioral and the Good Clinical Practice modules.

Collaborative Institutional Training Initiative (CITI)

How to Locate eIRB Update Information

eIRB, the electronic IRB protocol tracking system, is occasionally updated with new features. To stay up-to-date with changes in the eIRB system, after logging in, check out the main page. Along with system updates, which are listed after going into effect on the 3rd Wednesday of the month, this page will inform you of scheduled system outages and browser compatibility.

Health Sciences tour to conting to the science of t					
	My Home	elF05	Education and Training	Studies	Committees -
Added Health Method Senter Generatile Health System	Welcome to the Health Sciences South Carolina (HSSC) electronic Institutional Review Board (eIRB), the application to manage IRB reviews and documentation for human research. System outages: eIRB is unavailable during all routine, scheduled times listed below. Users will not be able to Jop in:				
Medical University of South Carolina					
Fainello Health Self Regional Healthcare					
 University of South Carolina 	 DALX_System Maintenance Depinning at 12:30 am each morning, system maintenance is performed on the eIRII system. This process takes up to 2 hours to complete System Updates The next system changes are scheduled for Wednesday, June 16, 2021 from approximately 5:00am - 6:00am. 				
 Announcements 	To ensure content remains in the system, users should save their work before these outsges begin.				
Code of Factors C	Compatibility: If you expenses using Memet Explore or Edge Internet bookses (i.e. pages display incorrectly and/or user input fields appear missing) it is recommended to try using Google Chrome or Modilia Firefox. You may also trying updating your Microsoft broaker to the latest level. Users should generally keep their broaker updated to the latest level.				
	System Changes				
	System Charges Instaline TAE23. effective July 21. 2021. The WRB system updates include changes to a variety of matters associated with the application. Please contact your institution's and administratory with any system questions or concerns. Changes: Question 11. Yame 47450° on the Section 14 Medical DeviceHUD Information Smarthim page Is now a required field. This fail is accessible when the study team indicates a HUD will be used in the study.				
	The HUD defetion on the Section 14 Medical Devices - Humanitarias Use Device HUD) Smarthern page has been apolated. It is new consistent with current FOA pulsance and the defetion presented on the Section 2 Human Subjects Research Smarthern page.				
	The user profile links) for Other Study Team Members on the personnel tab of the study workspace have been evabled				
	(MUSC, Prisme, Self, AnMed) Users now here read only access to the roles specified on their account by access to the roles specified on their account by access the TMy Profile' link by closing on their name in the to split of the access.				
	The Withdraw activity has been removed from Modified Studies associated to amendments. Amendments can sill be withdrawn from the amendment workspace.				
	Beachtan:				
	(NUSC) A fix has been implemented for the Add Study Team member activity. This activity allows study team members to be added to Exempt Approved studes. Previously, this activity add not correctly add the newly specified user to the Access or Edit permission lists.				
	(MUSC) A configuration losse with the Study Panding New P1 Info 3-day inactivity notification has been resolved. This notification was not properly populating links to the project.				
	Previous changes are available in the Anthreed Announcements folder - CLICK-HEIRE.				

Legally Appointed Representative (LAR) Priority List Information

If a study is enrolling cognitively impaired persons, and it is determined that the potential subject cannot consent for themself, a legally appointed representative (LAR) will need to consent for them. According to state law, and also in the IRB policy, there is a prioritized list of persons who are legally eligible to serve as LARs and in what order these individuals can be contacted. When referencing this list, please keep in mind that study teams must make "good faith efforts" to contact persons in specified order of priority before moving down the list. The fact that the listed person is not at the hospital at the time study teams are looking for consent does not make them unavailable. Additionally, study teams need to document any unsuccessful efforts to locate persons with higher statutory priority to provide consent.

Section 8.2 Research Involving Persons with Impaired Decision Making Capability (Cognitively Impaired)

Institutional Engagement - OHRP

When submitting an application to the IRB, you might receive a comment back asking if MUSC is "engaged" in the research. According to OHRP, an institution is considered "*engaged*" in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

For more information on this topic, please see the links below.

Institutional Engagement in Human Subjects Research OHRP video

Engagement of Institutions in Human Subjects Research (2008)

Reliance (External IRB) Studies Reminder

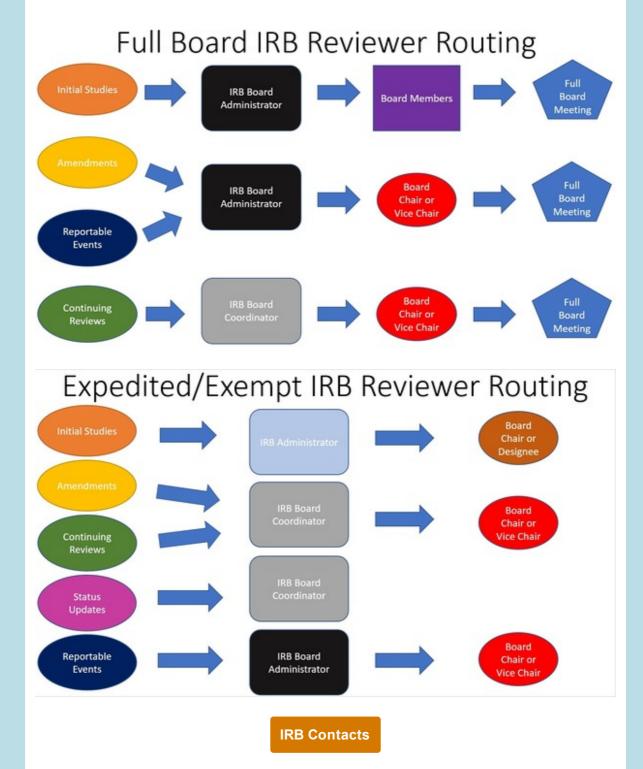
For industry-sponsored External IRB studies, the contract between MUSC and the sponsor of the research must be finalized and executed before the study can be released for review by the External IRB.

MUSC IRB Reliance Requests

MUSC Reliance Intake Form

IRB Submission Routing Processes

When you submit to the IRB, depending on your submission type (i.e., new study or amendment) and/or its required level of review (i.e., full board or expedited), different members of the IRB Staff may review your submissions. Below are charts to show how your submission might route through the IRB Office.



FAQ: How do I register with the IRB?

eIRB registration must occur if you are starting your first eIRB application or adding someone to your study that is new to research. All personnel, no matter the role, working on the study will need to register. To register go to http://eirb.healthsciencessc.org, select the affiliated institution 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 put in eIRB matches your CITI registration information so that both systems will sync. An email will be sent to the eIRB Administrators, who will verify your account, assign user roles as appropriate, and activate your account. You will receive an email notification of account activation.

eIRB Administrators

About the Staff

Brittany Smalls

Brittany Smalls is one of the coordinators for Board III. She recently joined the IRB staff in July, but her MUSC career started in the Department of Surgery back in 2018, and then the Department of Medicine Administration as a Grants Coordinator. Her hobbies include spending time with family, renovating/refurbishing old furniture, meditating/yoga, and traveling to different wine vineyards all over the country.

