MUSC
Medical University of South Carolina

The Institutional Review Board

May 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 SCTR 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

Updated Exempt Study Guidance

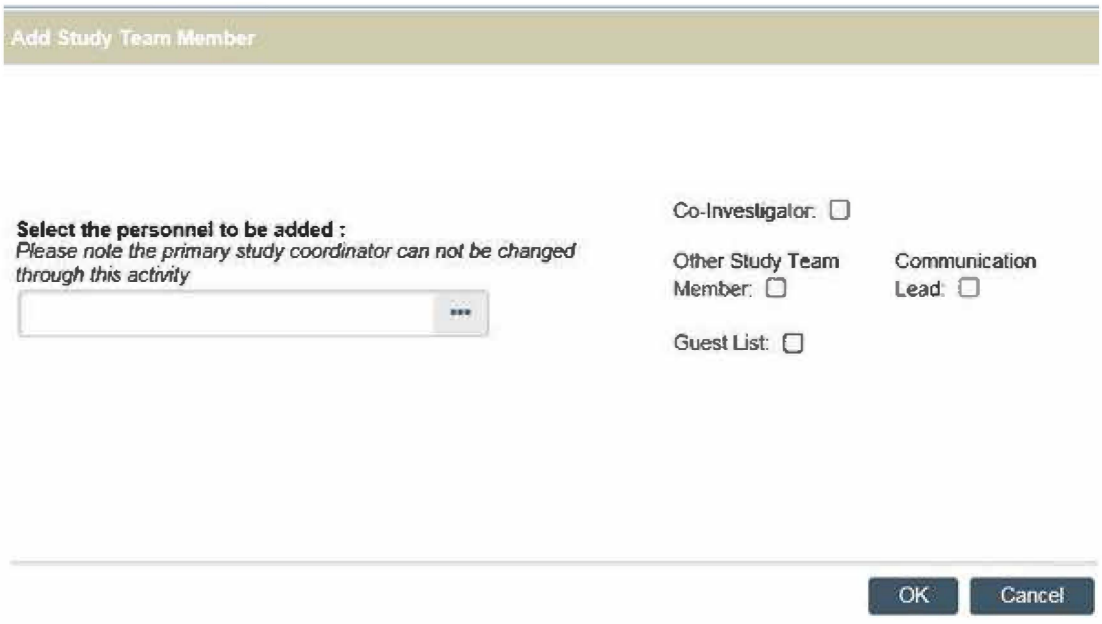
The IRB has updated the Exempt Categories 2 and 4 Guidance Document. This update differentiates and clarifies the types of research that fit under each category. The update also lists the information that must be included with an Exempt Study application. See the links below for direct access to this information.

IRB Forms Page

Guidance for Exempt Review – Categories 2 and 4

New Exempt Study Feature – Adding Study Personnel

Effective April 21, 2021, the eIRB 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 eIRB 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. This new feature is available for Exempt studies only.



Doxy.me Teleconsent at MUSC

Teleconsent is a way to obtain informed consent for research without requiring in-person contact with prospective subjects. It is completed using the Doxy.me telemedicine platform. Doxy.me is a browser based, HIPAA compliant, video call platform available to all MUSC faculty and research staff. It is one of two methods approved by MUSC's IRB for e-consenting. The Doxy.me platform is free to use; however, studies will incur a charge for initial document development and updates.

IRB approval is required to use Doxy.me teleconsent for your study. If your study is locally reviewed, this can be done via eIRB either during the initial study approval process or through an amendment to an already approved study. Toobtain clearance to use Doxy.me, you will need to provide specific information on the Consent Process Part 1 Smartform:

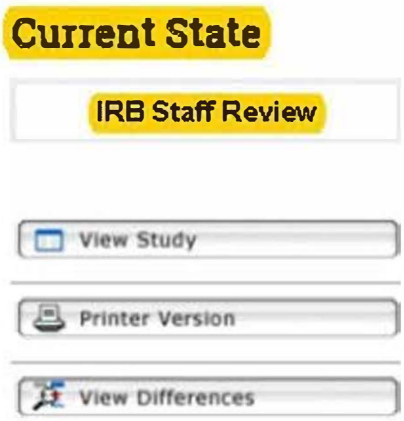
- Question 5.0: Respond "Yes" to this question – "Will electronic consent be used for this study?"
- Question 6.0: Describe the process you will be using for teleconsenting here – "Describe the consent process (where, when and how a written copy of the consent form will be provided)."
- Relevant information may include details about the location where subjects will be consented (i.e.,will it be a private location, etc.), what device the subject will use (whether it will be provided by the study or use the subject's own computer/ mobile device), how the consent session will be scheduled, and how the subject will be provided with a copy of the signed consent.

*Additional Note: There is not a different format for electronic ICFs. No specific language or changes are required to the ICF for teleconsent – consent documents used with Doxy.me are developed the same way standard in-person consents are created. The changes enabling the ICF to be used electronically are not made until after the consent receives IRB approval.

- After IRB approval, request the Teleconsent service via SPARC to convert your document into the specified electronic format that enables teleconsenting.
- SPARC will send you a follow-up form to assist with the intake of your documents, approvals, and create Doxy.me accounts for the study team members who will need access to the electronic documents.

If you have any questions or would like to schedule a consult, please contact Trevor Faith at faitht@musc.edu.

SPARCRequest



New VAMC Requirement -VAMC Blocking Ancillary Approval

If you have recently submitted an application for a study being conducted at the VAMC, you might have noticed that the VAMC is now a Blocking Ancillary reviewer. This means that before the IRB will receive the study application, it will be routed via eIRB to the VA Privacy Officer for ancillary approval. Please make sure that you factor in additional time this may require to meet any deadlines you may have. You can follow the application's progress by observing the study's status (see the upper left corner of the study' s front page under "Current State"). Reminder: The IRB does not have a study application until the current state is "IRB Staff Review."

Compliance Reporting

University faculty, students and staff are responsible for reporting any known or suspected breach of privacy caused by the unauthorized acquisition, access, use or disclosure of Protected Health Information to the University Compliance Office **immediately**. Reporting may be done through 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
- Visit us in person 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.

HRPP 4.13 - Privacy and Confidentiality

SMART IRB for Reliance (External IRB) Studies

Smart IRB is a Master Reliance Agreement and platform used to assists in streamlining IRB review and oversight of multisite studies and supports small and large studies, regardless of funding status. Currently, SMART IRB has over 800 participating institutions. In addition to the agreement, SMART IRB provides an Online Reliance System which allows investigators and institutions to request, track and document reliance arrangements on a study by study basis, as well as, numerous resources to assist study teams as they navigate single IRB review.

MUSC investigators interested in using SMART IRB should begin the process at MUSC by submitting a Reliance Intake Form to the MUSC IRB.

Note: Smart IRB is only a platform to streamline the reliance agreement process. Even when relying on another IRB, local institutional requirements must still be met and MUSC investigators are required to submit an abbreviated eIRB application.

SMART IRB

MUSC IRB Reliance Requests

MUSC Reliance Intake Form

eIRB Stamped Documents

There are certain documents that require an eIRB watermark to show that they have been IRB-approved. These documents will be “stamped” by the IRB with the study’s Protocol Number (Pro#) and the Approval Date. It is important to note that the watermark template should not be edited in any way so that the eIRB system can place the study number and date in the correct fields. There are only certain documents that need to be stamped and are listed as follows:

- Consent form(s)
- HIPAA document(s) (if separate from consent)
- Recruitment Materials (such as advertisements, brochures, phone scripts, etc.)

When it comes to recruitment materials, MUSC does not require posted/ published advertisements to be displayed with the stamp; however, the stamped copies of documents must be kept in your regulatory binder.
On the other hand, if you are displaying an advertisement or brochure for a VAMC study, the VAMC requires you to have the stamp visible on those materials.

About the Staff

Paul Kelly, CIP

Paul Kelly is one of the administrators for Board III. His MUSC career started as a study coordinator with the Institute of Psychiatry. He was the Research Compliance Officer for the Ralph H. Johnson VA Medical Center before making the move to the IRB. He has been with the IRB for 9 years. He spends spare time with family and close friends and enjoys fishing, boating, and DIY around the house.

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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