

The Institutional Review Board

May 2020

"It is not the load that breaks you down. It's the way you carry it." - Lena Horne

The MUSC family has been inspiring in the selfless way it has stepped up to meet the stress and hardships that the COVID-19 response has required from so many. From the first responders, faculty and health care workers directly involved with patient care, administrative and IT workers, support staff keeping our hospitals and facilities safe and operational, to the hundreds of our friends and colleagues who have been furloughed, MUSC's response to the Tri-County area and State of South Carolina is something we can be proud of. As a small token of the deep appreciation we feel, the IRB is honored to dedicate this issue of our newsletter to each of you who have, and continue to risk so much and make such a difference each day. You are changing what is possible and for that, we thank you.

IRB Updates

HIPAA Compliant Technology during COVID-19

Due to the COVID-19 Pandemic and with guidance from the Department of Health and Human Services Office of Civil Rights (OCR), MUSC has temporarily authorized the use of some remote communication apps, previously unapproved, if approved apps are unavailable. Please see the link below for the latest updates on remote patient care solutions.

[MUSC Guidance on COVID 19 Technology](#)

Electronic or Remote Consent

During the COVID-19 Pandemic, you might be considering the electronic or remote consent process for your studies. To conduct consent remotely, you will need to submit an amendment in eIRB to update the consent process. The consent process should include an informed consent discussion with the potential subject and have the subject sign and return the informed consent document to the researcher. This process can occur over the phone or by an MUSC approved, HIPAA compliant video conferencing platform and has to be done prior to any study procedures. The informed consent document can be sent back to the researcher by mail or by using an IRB approved electronic consent mechanism. Please see the link below for guidance on Electronic Consent.

[Electronic Consent Guidance](#)

Drug Management Plan

As of January 22, 2020, if you are working on an outpatient study at MUSC in which study medications are dispensed or administered, you will be asked to complete a Drug Management Plan, unless you are using Investigational Drug Services (IDS). This plan provides institutional acknowledgement to ensure that study drugs are being handled appropriately, and describes how the study drugs will be prepared and dispensed for outpatient studies. Study drugs for inpatient studies must be facilitated by IDS.

The Drug Management Plan review is now a blocking ancillary for all drug studies. This means that the study will have to go through this review and be approved before it reaches the IRB.

You will need to fill out a REDCap form, which details your plan for the study drugs, and then upload this into the eIRB smartforms under the Drug Management Plan. A link to this form is in the eIRB Drugs smartform, but is also provided below.

If you submit your REDCap form and your plan is deemed not acceptable from the message you receive, you should make sure the form is filled out correctly with ample detail and submit a SPARC Request for a Drug Management Services consultation.

[REDCap Drug Management Form](#)

Exempt Studies Guidance

The 2018 Common Rule revision brought about several changes to the Exempt Categories. There are updated guidance documents on the IRB website to help understand some of these changes. For example, retrospective chart reviews may now be eligible for exempt review under Category 4. For more information, please see the links below.

[Exempt Category 4 Review Supporting Information](#)

[Guidance for Exempt Review Categories 2 & 4](#)

[OHRP Exemption Guidance](#)

sIRB/Reliance: Reliance Intake Form

Reliance is the process of using a single IRB for review of multiple sites or investigators at multiple institutions. Reliance and single IRB review is now required by several federal initiatives.

MUSC is willing to review requests for reliance on an external IRB as well as requests for MUSC to serve as the IRB of Record. The MUSC IRB charges a fee of \$1000.00 for the processing of industry-sponsored protocols submitted to an external IRB for review. If MUSC serves as the IRB of Record for a multi-site trial, the MUSC IRB charges a fee of \$2408.00 for initial non-MUSC site review per site and \$1515.00 annual management per site. Please note, single IRB fees may increase or decrease due to future rate adjustments.

The first step in the reliance process is to complete a reliance intake form via the REDCap system located in the link below. The MUSC IRB Reliance Manager will review the information provided in the reliance request and will contact the individual who completed the form with the next steps.

For more information about reliance requests, please see the link to the MUSC IRB website below.

[REDCap Reliance Intake Form](#)

[MUSC IRB Reliance Requests](#)

CITI and eIRB: Why are my training courses not showing?

CITI and eIRB go through a nightly sync in order for all CITI Trainings to show in your applications on the CITI Training Records Smartform. There are times that CITI Training is not displayed in the eIRB smartforms. If research training records are not displayed in the eIRB smartform for particular personnel, here are a few suggestions for resolution.

- Make sure the personnel's first name, last name, and email addresses are exact matches in eIRB and CITI. Updates will appear for successful matches after system nightly data synchronization.
- Required CITI training courses may not have been completed in affiliation with one of the HSSC sites. The user should log into CITI to make sure the CITI profile has been associated to the correct institutions (i.e., MUSC) and required training has been completed.
- The personnel may have multiple eIRB and/or CITI accounts interfering with the matching process.
- The personnel's eIRB profile may not be completely filled out to associate the user with an institutional department.

For additional information, access troubleshooting and other resources in the Education and Training->Researchers and Staff->CITI Training Records section of eIRB, or otherwise contact your institutional eIRB administrator for assistance.

MUSC eIRB Administrators

eIRB Tip of the Issue



Trouble adding Personnel in eIRB?

When trying to add personnel in eIRB, sometimes the person cannot be located in the system. If this occurs, make sure that the person being added to the study has created a profile in eIRB. When new users create an eIRB account, have them log in with their Net ID and password. Then, they can add their name and email address under their profile. If any updates are needed to the already created profile for name or email address changes, personnel can update their eIRB profile, which can be located on the top right corner of the screen.

Personnel must have an eIRB account and been assigned appropriate roles in the system to appear in pick lists.

Contact your MUSC eIRB administrator to discuss the personnel's eIRB account and update role assignments, if needed.

[MUSC eIRB Administrators](#)

About the Staff

Ashley May

Ashley May is the IRB Coordinator for Board I. Ashley has worked in the Office of Research Integrity since 2018. She grew up in the Lowcountry and went on to graduate from the College of Charleston. In her free time, she enjoys spending time at the gym or being outdoors with her friends and husband who serves in the United States Air Force.

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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