

The Institutional Review Board

February 2020

Welcome to the IRB's first newsletter

With the new year, we are excited to launch our first newsletter, which is specifically designed to keep the research community apprised of the information and changes within the world of the MUSC IRB and Human Subjects Research. We have signed you up for our newsletter in the hope that you will find value in its content and assistance in your future research endeavors. If you ever find that what we offer is not for you, please feel free to use the email at the bottom of the newsletter to unsubscribe. We hope that you stayed tuned for this and many future, quarterly newsletters from the IRB.

The IRB has moved!



With the closing of Harborview Office Tower, the IRB has moved to a new location. We are now located in the Palmetto Park Place, formerly known as South Park Plaza, in Building 1, Suite 401. Even though we've moved, we are still available via phone, WebEx, or even in person by appointment.

sIRB Requirement 2020

The single IRB (sIRB) mandate is a set of federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all participating sites.

The Two Policies:

- 1) The Common Rule's Cooperative Research Provision

- *Effective Date:* January 20, 2020
- *Applies to:* Federally funded cooperative research projects receiving initial IRB approval on or after January 20, 2020. That is, studies that involve more than one institution conducting research with human subjects (regardless if each institution is not carrying out the same human subject research activities).
- *Reviewing IRB:* Will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution (subject to the acceptance of the Federal department or agency supporting the research).
- *Details:* See "The Revised Common Rule's Cooperative Research Provision" below.

1) The NIH Single IRB Policy for Multi-Site Research

- *Effective Date:* January 25, 2018
- *Applies to:* NIH funded studies in which the sites are all using the same research protocol to conduct the same human subject research activities at each site.
- *Details:* See "NIH Single IRB Policy for Multi-site Research" below.

**The Revised Common Rule's
Cooperative Research Provision**

**NIH Single IRB Policy for Multi-site
Research**

2018 Revised Common - Annual Status Updates

What is an Annual Status Update?

One of the changes associated with the 2018 Common Rule had to do with removing the requirement for Continuing Reviews for certain expedited studies approved on or after January 21, 2019.

While a Continuing Review is no longer mandatory for certain expedited studies, MUSC does require the PI to submit an Annual Status Update (ASU) for the study.

ASU's are submitted via the eIRB system and have been designed to collect a very limited amount of information from the study team. It is important to note that a completed annual status report must be received by the IRB 30 days prior to the annual status date of the study. If the researcher does not submit the MUSC required ASU, the IRB may consider this noncompliance.

What is the difference between an Annual Status Update and a Status Change?

It is important to note that an ASU is an abbreviated report that must be submitted to the IRB annually for review. Status Changes are only submitted to the IRB to report an immediate change in study status that is outside of normal study progression.

If the Continuing Review requirement has been removed for a study please make sure to use the status update button to report any changes in the status of the study.

Creating and submitting Annual Status Updates in eIRB can be confusing. Here is why: ASU documentation will be located within the "Continuing Review" tab on the study's home page. Because of the way eIRB works, the ASU's will be assigned a Continuing Review number rather than an ASU number.

New IRB Education Resource

The IRB has added a new resource to our team: The IRB Education and Training Administrator, Jessica Orak. Jessica has been with the IRB for three years and has worked with all three IRB Boards. She is very familiar with the different types of submissions, such as initial studies, amendments, continuing reviews, and reportable events. Jessica is able to provide the MUSC Research Community with assistance to their eIRB applications and also navigating the eIRB system. She is available to set up group or individual sessions with study teams to go over the basics of what the IRB requires. Please feel free to contact her at orakje@musc.edu or (843) 792-9128 to set up a session today.

CITI Training Requirements



MUSC requires all individuals involved in human subjects research to complete the ICH GCP CITI training modules. Many of you know this to be a specific policy issued in 2018 by NIH for NIH-funded trials. MUSC has established that this training is beneficial and necessary for all individuals involved in human subjects research. Study applications submitted to the IRB must have all team members compliant with these training requirements - in addition to the Biomedical or Social/Behavioral training. The IRB will not release the approval of a new study or continuing review approval of an existing study for which research personnel have not completed the required GCP ICH CITI training modules. Please note that the basic course must be completed before a refresher can be accepted, and completion of the refresher modules is required every three years.

See the link below for further information:

[CITI Requirements](#)

Current State

Department Review

 View Study

 Printer Version

 View Differences

Did you know?

Before a study is submitted to the IRB, departmental approvals and a Prospective Reimbursement Analysis (PRA) with the Office of Clinical Research must be obtained. The eIRB system automatically routes the study to the approving individuals along with a notification email. If required approvals are incomplete, the current “State” of the study under the study’s main page will be “Department Review.” In this case, the department reviewers may not have issued approval for the study to move forward. The IRB will not receive your application until all of the necessary prior approvals have been completed. The state of the study will then change to “IRB Staff Review”. An application is not complete and deemed received by the IRB until the state changes to “IRB Staff Review.” Remember to leave time for Department Review and the PRA review when trying to make the deadlines for meeting submissions. Please see the MUSC IRB policy below.

Section 1.7 - Mentor Department and Ancillary Reviews

About the Staff

Kristin Zaks

Kristin Zaks is the IRB Administrator for Board I. Kristin has worked in the Office of Research Integrity since 2015; prior to that she worked as the regulatory coordinator for the Department of Obstetrics and Gynecology. In addition to chasing around her 6-year-old twins, Kristin stays active by running, yoga and surfing.

Contact Us

Have feedback or suggestions you would like to share?

Email us at : irb-news@musc.edu

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