

## **The Institutional Review Board**

November 2021

As the dawn of the third year of the COVID-19 pandemic approaches, we look back on the past year in awe of all science has helped us accomplish. We now have effective vaccines for ages 5 years and older. We applaud the MUSC research community and all health care workers who have worked tirelessly to help keep us safe amidst all of the uncertainty, and who have provided us with the tools that we need to do our part in protecting each other and helping to put an end to the pandemic. We thank all of you who have given us the ability to reunite with our loved ones this holiday season. Wishing you and yours an abundance of health and happiness now and throughout the New Year.

### **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 for the latest guidance from the MUSC Research Continuity & Planning for COVID-19 website.

See the link below for more information.

MUSC Research Continuity & Planning for COVID 19

#### **2022 IRB Meeting Dates and Deadlines**

We have updated our website with the 2022 Meeting Dates and Deadlines for Full Board IRB submissions.

As a reminder, initial study submissions must be received in the IRB office via eIRB by the posted deadlines.

**IRB Meeting Dates and Deadlines** 

#### How to Follow the Process of Study Approval

The eIRB system is designed to let you know at any point in time where a study application is as it moves through the review process.

Each study application will transition through various stages or "states" as it progresses, from "Pre-Submission" to final states such as "Approved", "Acknowledged", "Withdrawn", and "Completed". A study's "Current State" is viewable within the column called "State" on your homepage, or on the upper left-hand side of the study's workspace.

Users with access to the study application can log into the eIRB system and see in which state the application resides, as well as view the history showing when actions were taken on the application. To see a listing of all the available states and their definitions, go to the "Education & Training" section of eIRB and select the 'States Chart' document.

Cu	rrent State
	Pre Submission
G	Edit Reportable Event

#### **Frequently Asked Question**

# Q: The PI has submitted the study, but it doesn't seem to have gone through to the IRB. What is the hold-up?

A: Studies may require mentor, department, and/or other ancillary reviews before they will route to the IRB for processing. These approvals, if applicable to your study, must be obtained before eIRB will route an application to the IRB. The eIRB system automatically routes each study to the appropriate approving individuals along with a notification email. If required approvals are incomplete, the current "State" of the study shown on the study's main page will be "Department Review." In this case, the required department reviewers may not yet have issued their approval for the study.

You can check which approvals are required by clicking the "Pre-Review Status" tab on the study's home page. An update of pending and received approvals will be displayed. You can also check the study's "History" tab to see who in a department or ancillary group was sent an email with a request to review the study.

The time it takes to obtain departmental approvals must be taken into consideration when trying to meet IRB deadlines. Example: If the submit button was selected but the study has not received all of its required departmental approvals, the study will not have been routed to the IRB; thus, if it is deadline day, a study lacking all of its departmental approvals will not have made the deadline.

The IRB does not have your application until every necessary prior approval has been acquired. Once the prior approvals are in place, the study's state will change to "IRB Staff Review". An application is not complete and deemed received by the IRB until the state changes to "IRB Staff Review".

#### PI Responsibility: Closing or Transferring Studies Prior to Leaving MUSC

Principle Investigators (PI's) who are leaving MUSC are responsible for either closing their study/ies with the IRB or transferring the responsibilities of the study/ies to another qualified MUSC PI prior to leaving.

- To close a study the PI must submit a Continuing Review with "Permanently Closed – All study activities are completed" selected on the Study Status SmartForm to notify the IRB that the study is being closed.
- To transfer the study to another Principal Investigator, the departing (or original) PI must submit a personnel amendment to change the PI of the study.

Note: Exempt studies do not require close-out via continuing review, but if there is a change in PI an amendment must be submitted.

Make sure to review the Research Faculty Off-Boarding Checklist for completion prior to faculty separation.

IRB HRPP 5.1 Principal Investigator Responsibilities Supervision of Staff and Protection of Subjects

MUSC Research Faculty Off Boarding Checklist

#### **Sponsor Commitment Language in Informed Consent Forms**

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

TIP: If you happen to be working on multiple study applications with the same sponsor, it is recommended that the sponsor commitment language in the informed consents be consistent across each of the applications. Similarly, if you are creating a new study application with the same sponsor of an active study, you may want to copy the sponsor commitment language out of the active study's informed consent.

#### **Personnel Amendment Tip**

If you are submitting a personnel amendment to the IRB please note the following:

- Personnel must have completed all required CITI trainings.
- Personnel being added to the study team have their name and role listed in the description of the amendment.
- Personnel being removed from the study team have their name listed in the description of the amendment.
- If you are adding a Co-Investigator or Other Study Team Member to an <u>Exempt</u> <u>Study</u>, the PI or main study coordinator can do this without submitting an amendment to the IRB. eIRB will automatically check the CITI Training of those being added.
  - Note: The above mentioned mechanism is for Exempt Studies only.
  - See "Add Study Team Member" under "My Activities".

#### Helpful Tool for Determining Type of IRB Application to Submit

The Office for Human Research Protections (OHRP) provides Human Subject Regulations Decision Charts to guide IRBs, investigators, and others to decide if an activity is research involving human subjects that requires review by an IRB. The charts address decisions on the following:

- Whether an activity is research that must be reviewed by an IRB
- Whether the review may be performed by expedited procedures, and

• Whether **informed consent** or its documentation may be waived. Please see the link below:

**OHRP Human Subject Regulations Decision Charts** 

#### Commercial IRBs as a Choice for single IRB (sIRB) Review

MUSC offers the use of the commercial IRBs for multi-site corporate-sponsored clinical trials to all departments as long as the following criteria are met:

- The external IRB is currently registered with OHRP/FDA.
- For commercial IRBs: the commercial IRB is AAHRPP-accredited.
- For non-commercial IRBs: the IRB is AAHRPP-accredited or determined as part of the administrative review to meet MUSC standards.
- The external IRB is located within the U.S.

An MUSC external IRB application is still required via eIRB to document local context requirements and the reliance arrangement. Many commercial IRBs are members of SMART IRB and can be used via the SMART IRB platform.

MUSC IRB reserves the right to withhold any new research study from being sent to an external IRB.

For more information about sIRB and External IRB Reliance, see the information locate on the IRB website:

**Reliance Requests** 

FAQs about sIRB Reviews

## About the Staff

#### **Cheryl Green**

Cheryl Green is one of the Coordinators for Board III. She has been with the IRB for 27 years! She started her career with MUSC as a courier for the IRB and ORSP. When she started working for IRB, she started as an Administrative Specialist, became a Coordinator for IRB II, and then finally became one of the Coordinators for IRB III. Cheryl enjoys going on cruises, traveling, watching the Food Network, and spending time with family and friends.

#### 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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