

The Institutional Review Board

August 2022

While we always try to highlight the latest information with the IRB newsletter, we also want to use it to remind you of different resources that are available to you. Built within our electronic protocol tracking system, eIRB, we have a frequently asked questions (FAQs) section that may be helpful to you when working on different types of eIRB submissions. In eIRB, you can access this through the Education and Training tab at the top of your home page. Below is a quick link to the eIRB FAQs.

IRB Updates

Top 10 Pitfalls of Initial Study Applications

Through an IRB survey in the May 2022 quarterly IRB newsletter, we asked for your feedback on how we can best assist you. We greatly appreciate the time you took to complete the survey and provide meaningful comments. We are excited to have your feedback to use as our guide in developing education and useful information for the MUSC research community. The survey results suggested that supplying tips that might help make the IRB process move faster could be helpful. We have developed a list of the Top 10 Pitfalls of Initial Study Applications and hope this information will provide useful tips that will help move the review process forward as quickly as possible.

- 1. Pay attention to the IRB <u>due dates</u> for full board meetings. If the study is not received by the IRB on or before the deadline, it will not be assigned to a specific meeting you might want.
- 2. Factor in the time it takes for department reviews. Your IRB application is not received by the IRB until ALL department reviews are completed. Your application won't be delivered to the IRB's inbox until these approvals are in place. When we do have the application available for review, the current state of the study will be: "IRB Staff Review."
- 3. Kindly respect the IRB assigned "Changes Requested" deadlines to enable your application's timely processing for a full board meeting. If the requested changes are not submitted by the IRB assigned deadline, your study application will not go to the full board meeting.
- 4. Use the informed consent form (ICF) templates available on the <u>IRB Forms</u> website. There is also pre-approved, suggested consent language available on the IRB website that can be used in the ICF.
- 5. The ICF must be understandable at the 8th grade reading level; medical jargon and study procedures must be explained in lay language. The ICF template also has a link with suggested lay terminology that you can utilize.
- 6. Make sure that there are no discrepancies between the documents uploaded to the study and the study smartforms (i.e., the risks listed in the eIRB smartform must reflect those included in the ICF).
- 7. If your protocol states you will be using advertisements, make sure to upload the advertisements that you will be using in the elRB smartforms for approval.
- 8. Institutionally-required <u>CITI training</u> for all study personnel must be completed and/or current prior to study submission.
- If recruiting Veterans, your study will require IRB approval prior to going to the VAMC R&D Committee and cannot start until it has been reviewed by the VAMC R&D Committee.
- 10. When using the eIRB watermark, it should be used as it is formatted in the eIRB watermark template to ensure active data fields are included in the form. Do not alter or convert the watermark to picture format (.jpg); if you do so, the watermark will not be recognized by the eIRB system and will not accept the stamp when approval is released. Refer to the eIRB watermark guidance on our Forms page.

Data Safety Monitoring Board Reports

A Data Safety Monitoring Board (DSMB) is a formal committee that is established specifically to monitor data throughout the life of a study to determine if it is appropriate, from both the scientific and ethical standpoint, to continue the study as planned.

Principal Investigators (Pls) are responsible for submitting the Data Safety Monitoring Board (DSMB) reports as soon as they are available to the Investigator, regardless of the timing of the report in relation to the study's scheduled continuing review. These reports should follow the timeframe as specified in the IRB approved protocol. The PI will submit the DSMB report to the IRB via the eIRB system as a Reportable Event under the type "Other Reports/ Events."

For more information regarding Data Safety Monitoring Plans and Data Safety Monitoring Boards, please see the policy:

HRPP 4.10 Data and Safety Monitoring Plans

For more information on how to submit a Reportable Event to the IRB via the eIRB system, please see the eIRB training video below:

elRB Reportable Events Video

Exempt Research Guidance

The IRB guidance document for the most common Exempt research categories at MUSC, Guidance for Exempt Review - Categories 2 and 4, can be found on our IRB Forms website. We also highly recommend using the Office for Human Research Protections (OHRP) decision charts, which can help you decide if an activity is human subjects research that must be reviewed by an IRB, if exemptions apply, or if consent or documentation of consent can be waived.

Guidance for Exempt Review Categories 2 and 4

Human Subject Regulations Decision Charts: 2018 Requirements

Continuing Review/Annual Status Update Deadlines

The deadline to submit your Continuing Review (CR) or Annual Status Update (ASU) to the IRB is 1 month prior to the expiration date. The eIRB system will send you automated reminders at 8 weeks, 6 weeks, 4 weeks, and the day before study expiration to remind you to submit your CR or ASU to the IRB. For more information on CRs and ASUs, see our policy below:

HRPP 3.5 Continuing Review and Annual Status Update Policy and Procedures

Optional Research HIPAA Language

If a study includes optional research that subjects may choose to opt in or out of, the HIPAA Authorization must contain corresponding optional research language, whether the combined or free-standing HIPAA is used. Make sure to add this language to the HIPAA, if applicable, and to briefly describe the optional research where it says "(insert the optional types of research that may be performed)."

OPTIONAL LANGUAGE- to be included in the consent if the participant is being asked to participate in optional research.

In addition to the main study, you have the option of participating in (insert the optional types of research that may be performed). Your protected health information may be used or shared with others outside of MUSC for this research as well. Please initial below if we may use/disclose your protected health information for the optional research portion/s of this study.

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____No, you may not use my protected health information for the optional research portions of this study.

sIRB/Reliance Fees

The MUSC IRB charges a fee of \$1000.00 for the processing of industry-sponsored protocols submitted to an external IRB for review. Amendments submitted to MUSC IRB are billable per the amendment fee guidelines which can be found on the MUSC IRB Submissions website. For more guidance regarding submission of amendments for a study reviewed by an external IRB, see the External IRB Reliance link below.

The current rates for MUSC serving as the sIRB are:

\$4,000.00 Initial Non-MUSC Site Review per site \$1,664.00 Annual Management per site

sIRB fees may increase or decrease due to future rate adjustments. It is always best to check for the most up to date fees.

IRB Submissions Website

External IRB Reliance

Frequently Asked Question

Q: Where is a copy of my stamped approved documents such as informed consent, assent forms, HIPAA authorization, advertisements, etc.?

A: Stamped copies of informed consent/assent are found under a separate study tab labeled "Stamped ICF." The currently approved versions of consent forms are listed here. Previously approved/obsolete versions are also located under this tab and can be accessed by clicking on the small "History" icon next to the consent's name. The draft versions of these document are located under the 'Attachments' tab on the study's main page, within the Consent Process section.

Stamped copies of separate HIPAA authorizations, as well as other stamped documents (such as recruitment materials) are found by scrolling to the bottom to the section labeled "Ancillary Documents" under the study's "Attachments" tab. The previously approved versions of these documents may be accessed by clicking on the small "History" icon next to the documents' names. Draft versions of these documents are also located under the 'Attachments' tab, within the study Smartform section of the document.

About the Staff

Jocelyn Reddix

Jocelyn Reddix joined the IRB in June 2022 as one of the IRB Coordinators for IRB III. Jocelyn has been with MUSC since 2019, where she worked in clinical research in the Department of Psychiatry and Behavioral Sciences. She earned her Bachelor's of Public Health from the University of South Carolina and her MPH from Kent State University. In her free time, Jocelyn enjoys spending time with her family and fur babies, traveling, cooking, and binge-watching crime documentaries.

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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