

The Institutional Review Board

February 2023

There are many helpful forms, templates, and suggestions for approved document language on the IRB website. Be sure to check out our website before you start working on an initial application or amendment to familiarize yourself with the available resources and guidance. Another helpful resource is the SUCCESS Center, which can help by offering guidance and other services when preparing any type of IRB submission.

IRB Forms

SUCCESS Center

IRB Updates

MUSC Informed Consent Template Reminder

The MUSC IRB requires the use of the MUSC informed consent form template unless submitting a request for a waiver of consent. The template can be found on the Forms page of the IRB website. Utilization of the MUSC informed consent template will ensure that all elements of consent, as required by federal regulations, are included as well reduce the number of comments you will receive.



New Education Resource: Researcher Amendment Checklist

The MUSC IRB has developed a Researcher Amendment Checklist as a new resource for study teams when preparing amendment submissions. The Amendment Checklist was created to help reduce the number of IRB comments on amendment submissions by identifying changes being made to the study and what may need to be changed in the eIRB smartforms and associated documents (i.e., informed consent form, protocol, etc.).

Please note that the checklist addresses the most common changes that are seen by the IRB and not every change is addressed in the checklist. The checklist can be found on the "Additional Education Resources" page of the IRB website under "Additional Links."

Researcher Amendment Checklist

Additional Education Resources

What studies qualify for expedited review?

Federal regulations permit expedited review for certain kinds of research involving no more than minimal risk to human subjects and involve only procedures listed in one or more of the categories determined by OHRP and FDA. The expedited review of the proposed research may be conducted by the IRB chair or his or her designee. There are seven categories of expedited research studies, and an expedited study may involve more than one of the qualifying research procedures. You will find additional information on what research is eligible for expedited review at the links below.

HRPP 3.3: Expedited Research Review **OHRP Expedited Research Categories**

Notice of Privacy Practices (NPP) no longer required

The IRB no longer requires the Notice of Privacy Practices (NPP) to be attached to the combined informed consent and HIPAA or the stand-alone HIPAA documents.

If submitting an amendment to remove the NPP from these documents, remember to also remove the following sentences from the end of the HIPAA section:

"Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form."

For more information, please download the original announcement posted by the IRB on August 9, 2022 in the link below. It can also be found on the IRB News & Updates website.

Notice of Privacy Practice - Removed from Research HIPAA Authorization

IRB News & Updates

IRB Fees: Reliance on an External IRB and Single IRB Review (sIRB)

Reliance on an External IRB

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 the MUSC IRB are billable per the amendment fee guidelines, which can be found on the MUSC IRB Submissions website.

MUSC Serving as the IRB of Record for a Multi-Site Trial

The current rates for MUSC serving as the sIRB are: \$4,000.00 Initial Non-MUSC Site Review per site and \$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.

Make sure to consider these fees when preparing your study budgets.

IRB Submissions

IRB Review of a Full Board Initial Protocol: Approval with conditions vs. Tabled

Have you ever wondered what happens to your full board study after you submit the application to the IRB? During the initial review of a study, the first step is a prereview process during which assigned primary reviewers and an IRB administrator evaluate the application to ensure it is complete and addresses regulatory standards. Comments from this review are collected and sent back to the PI via eIRB. The PI then thoroughly addresses each item and resubmits the application to the IRB. Prior to resubmitting the study, researchers should make sure all of the review notes have been addressed. Once received by the IRB, the study will be prepared for review at a convened board meeting where it will be determined whether the study meets all regulatory criteria for approval.

There are four possible outcomes when the study goes to the Board: the IRB will vote to either approve, approve with conditions, table or disapprove the protocol. When a study is tabled, the IRB is often asked why it wasn't approved with conditions. The quick answer is that the information required by federal regulations to approve the study has not been fully provided by the study team. This type of information is known as 'substantive information', and when it is missing the IRB has no choice but to table a protocol. If even only one of the regulatory criteria is missing, the study cannot be approved and will typically be tabled.

If the application has provided all of the required substantive information but is missing details that are not essential to meeting regulatory criteria, the IRB may vote for "approval with conditions" rather than a full approval. The PI will be requested to make specific modifications to the application, and if they are all successfully made, the Chair or their designee may fully approve the research without returning to the Board.

As stipulated by federal regulations, if the IRB cannot determine whether all of the regulatory requirements for research have been satisfied from the application submitted, the IRB cannot approve the research project. Detailed information on what must be included per the regulations at 45 CFR 46.111 and 21 CFR 56.111 can be found in a brief summary below:

- Risks to subjects are minimized by designing research that does not unnecessarily expose subjects to hazards and when appropriate, results from procedures already being performed on subject for diagnostic or treatment purposes are used rather than repeated.
- 2. Risks are reasonable in relation to the anticipated benefit, or to the importance of generalizable knowledge gained. The IRB considers only those risks/benefits that are research-related and only result from the subject participating in the research.
- 3. The selection of subjects is equitable. When evaluating this, the IRB will review the purposes of the research, the setting in which it will be conducted and whether vulnerable populations, if included in the research, are protected from unnecessary risks. Also, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, (examples - children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons) additional safeguards have been included to protect them.
- 4. Informed consent is obtained from the subject or their legally authorized representative (LAR)

- 5. Informed consent is appropriately documented.
- 6. When appropriate, the research plan makes adequate provisions for monitoring the data to ensure subject safety.
- 7. When appropriate, the protocol has adequate provisions to protect subject privacy and maintain data confidentiality.

Please keep in mind that the best mechanism for making sure your study continues to move forward with IRB review and approval is to provide thorough answers to the IRB's questions and comments and to carefully make all requested changes.

Removal of old studies in Pre-Submission from eIRB

The eIRB development team is going to be purging studies remaining in Pre-Submission based on the following criteria to clear up much needed space in the eIRB system:

- Studies which have been in Pre-Submission for more than 5 years,
- Studies where the Principal Investigator has not logged in within the last 3 years,
- Studies which have been copied in the last 12 months will be exempt from the deletion,
- Studies which are marked as a template will be excluded from deletion.

Investigator Responsibility: Study Closure

Principal Investigators (PIs) are responsible for closing their study with the IRB when a protocol is completed. This requirement is for any study that initially underwent full board or expedited review. This process does not apply to exempt studies.

A study is open and active until the investigator notifies the IRB it is complete. To notify the IRB that you are closing a full board or expedited study, you will need to submit a Continuing Review via eIRB or ERMA to permanently close the study.

Mentors for student research have the obligation to ensure that the Continuing Review to close the study is submitted to the IRB in a timely fashion. Pls leaving the institution are responsible for notifying the IRB well in advance of their departure so that they can plan to either close the study or name another appropriately qualified individual currently at the institution to serve as the Pl.

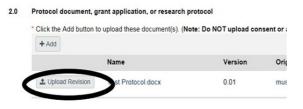
To review the criteria for when a study may be closed with the IRB, please visit our website at the following link.

Research Nexus and Medical Record Language in Informed Consent

If a study team selects Research Nexus as a site on the "Study Identification-Study Sites" page of the application, the study team will need to include the below language from the Informed Consent Template in the Medical Records section of the consent form, even if the study is not being pushed to Epic:

"If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law."

eIRB Tip: Upload Revision Button



At some point when submitting an application or making changes to an ongoing research study via amendment, you may need to revise study documents. When uploading revised documents to the study, be

sure to use the "Upload Revision" button. Do not remove the older version(s) of the item(s) and then add the revised documents. The "Upload Revision" button is important for your regulatory records and allows a history of documents to be created for your study that can be referenced by you and the IRB. The "+ADD" button should only be used the first time a document is uploaded; after that, use only the "Upload Revision" button.

About the Staff

Courtney Hollis

Courtney Hollis joined the IRB in January 2023 as one of the IRB Coordinators for Board III. She graduated from The University of Wisconsin-Milwaukee and previously worked at Froedtert & Medical College of Wisconsin. In her free time, Courtney enjoys spending time with her family, close friends and fur baby and enjoys traveling, dancing, and reading a good book.

Contact Us

Have feedback or suggestions you would like to share? Email us at: <u>irb-news@musc.edu</u>



IRB Contacts

🕄 🚯 У 🔰 🗸 🧿 ye

© Medical University of South Carolina

171 Ashley Avenue

Charleston, SC 29425