



The Institutional Review Board

February 2024

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 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.

[eIRB FAQs](#)

IRB Updates

Modifying or Amending an Approved IRB Application or Materials

Any changes or modifications to your study must first be submitted and approved by the IRB before being implemented. Exceptions to the process can only be made to eliminate apparent immediate hazards to human subjects. If there are subject safety concerns, contact an IRB Chair immediately.

Examples of modifications that must be submitted include, but are not limited to, changes in:

- a) Study Personnel
- b) Enrollment numbers
- c) Duration of study
- d) Recruitment methods
- e) Consent form
- f) Investigator Brochure or device information
- g) Study design, methods, procedures, or randomization
- h) Adding or dropping an arm of the study
- i) Questionnaires, surveys, interview scripts, advertising
- j) Funding
- k) Data and Safety Monitoring plan
- l) Study instruments

If you need to make changes to your IRB-approved study application, you can submit an amendment to the IRB via the eIRB system.

HRPP 3.6 Modifications to Approved Research

New Technology eIRB Smartform and Information Security Risk Assessment

If you are planning on submitting a new study application or amendment for research that uses new technology that will process subject data (such as a cloud platform, mobile app, on-premise software, wearables, etc.), eIRB will now include a new selection in the Application Checklist for new technology.

When a researcher selects the new technology item in the Application Checklist, a new smartform will open. This New Technology Smartform includes an area for the researcher to upload the MUSC Information Security Risk Assessment for the new technology. This assessment can be done through MUSC Information Security portal, Service-Now. New technology does not include common research technology currently used at MUSC (i.e., REDCap) or cloud-based/sponsor-hosted technology/platforms which do not require installation of software on MUSC devices.

1.0 Will the following be involved in the research study?

Select all that apply

Subject Consent Documentation/Authorization

- Deception (Requires Waiver or Alteration of Informed Consent and debriefing procedures)

- Informed consent document(s)

- Waiver of the Requirement to Obtain Written and Signed Consent

- Waiver or alteration of informed consent procedure or elements

Data Capture/Review/Monitoring/Storage

- Data from the statewide Health Sciences South Carolina (HSSC) Clinical Data Warehouse 

- Data Safety Monitoring Plan

- Medical Record, Chart Review

- The storage of Data (e.g. subject level data, images, scans, recordings, etc.) for potential future, yet undesignated

- The storage of biological specimens (e.g. biological material, tissue, blood, etc.) for potential future, yet undesignated

- Use of survey, questionnaire, focus group, interviews, group discussion

- Research Includes use of New Technology 

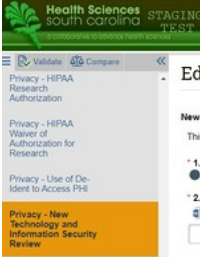
Recruitment

- Advertisements or recruiting materials

Laboratory/Specimens

- Specimens (blood, urine, tissue and other biological materials)

Research includes the use of any new technology (e.g., cloud platforms, mobile apps, on-premise software, wearable) that will process subject data. "New technology" does not include (1) common research technology currently used at HUSC (e.g., RedCap) or (2) cloud-based / sponsor-hosted technology/platforms which do not require installation of software on HUSC devices.



Editing: Pro00134913

New Technology and Information Security Review

This Smartform is in path on the study application as "Research Includes use of New Technology" was selected on the application checklist.

- * 1.0 Has the Information Security Office approved use of such technology and will you be implementing all requirements specified in the review?

Yes No 

- * 2.0 Upload technology approval from information Security Office

 Test Document.docx(0.01) ...

Service-Now

IRB Series – The Belmont Report

The Belmont Report is a set of ethical principles and guidelines created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was tasked with developing this code to help strengthen human subjects' research and ensure it is conducted ethically. The Commission established three basic ethical principles that must be considered when conducting human subjects research: respect for persons, beneficence, and justice.

1. **Respect for persons** describes that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protections.
2. **Beneficence** describes the obligation to maximize possible benefits and minimize possible harms.
3. **Justice** describes how subject selection, and the risks and benefits of research are distributed equitably.

The Belmont Report

Protocol Review Committee Guidelines for Hollings Cancer Center or Cancer-Related Research

In accordance with the operational guidelines involved with Hollings Cancer Center's (HCC) National Cancer Institute (NCI) designation and the HCC Protocol Review and Monitoring System, all MUSC patient-oriented human subjects research must be reviewed by the HCC Protocol Review Committee (PRC). This includes research involving cancer patients or cancer-related aims (including cancer-related epidemiological or diagnostic trials involving healthy patient(s)).

In eIRB, protocols indicating use of either Hollings Cancer Center or cancer-related research will automatically be routed to the PRC. Any prospective cancer-related institutionally-sponsored trial must be PRC reviewed and approved **PRIOR** to IRB review. This includes trials that are led by MUSC and have outside funding or support. All other prospective cancer-related studies may have PRC review and IRB review occur simultaneously. However, the HCC PRC approval must be obtained and submitted in eIRB before an IRB approval is released.

For more information about studies subject to PRC review and the PRC review process, please log into the MUSC Intranet (login required).

[Protocol Review Committee](#)

Tool for Determining IRB Level of Review for Secondary Use of Data and/or Specimens

A new tool, the IRB Level of Review for Secondary Use of Data and/or Specimens Tool, was developed by SCTR to help investigators understand what level of Institutional Review Board (IRB) review may be required for studies in which the only research procedure(s) is secondary use of data and/or specimens. The data/specimens must have already been collected for some other purpose (e.g., clinical care, quality improvement, or another research study) prior to being reviewed and obtained for use in the current study. To access the tool, visit the IRB Submission & Closure Processes website.

[IRB Submission & Closure Processes](#)

Exempt Category 4: eIRB Smartform and Guidance Update

If you will be submitting an Exempt Category 4 study application, you might notice there are changes to the eIRB smartforms. These changes were implemented to streamline the submission process while also allowing enough information to be collected for the IRB reviewers. Sections of the guidance document for Exempt Categories 2 and 4 have also been updated to reflect the Category 4 Smartform changes. See the link to the guidance document below.

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

Did you know you can find out who the Department Approvers are for your study?

After the Principal Investigator submits a study application to the IRB, the application will be routed to the appropriate department approvers. On the main page of the study application, in the study's History Tab, if you click on "Study Submitted for Review," an Activity Details Page will be displayed. Then, click the "Notifications Tab." This tab will list the name and email of the department reviewer for the study application.

This function is helpful if you ever need to reach out to a department reviewer about changes needed to an application or if department review is delayed.

Activity Details (Study Submitted for Review) Use this form to send your Study on to the departments or divisions which must approve the Study. From there it will be forwarded to the IRB Staff for review.

Author:

Logged For (Study):

Activity Date:

6/21/2023 9:51 AM

Activity Form	Property Changes	Documents	Notifications
Job Name	Subject	Recipients	
Study application has moved into Department Review state	Study application has moved into Department Review state		
Department Review Requested	Department Review Requested		

IRB Fees

When submitting a study application to the IRB, be sure to consider the IRB fees when preparing the study's budget. Fees apply to non-sponsored initial protocol review for expedited and full board studies, industry-sponsored submissions (i.e., initial protocol review (regardless of level of review), continuing review, amendment review), and sIRB/Reliance studies.

Submission Type	IRB Fee
------------------------	----------------

No Sponsor Initial Protocol Review	\$100
---	-------

MUSC Faculty

(no fee for student/trainee or VA studies)

Expedited & Full Board Initial Protocols

Industry-Sponsored Studies	IRB Fee
-----------------------------------	----------------

Initial Protocol Review	\$2500
-------------------------	--------

Continuing Review	\$750
-------------------	-------

Amendments*	\$500
-------------	-------

*Does not apply to COI, personnel (except PI), and administrative changes unless requested by sponsor.

Reliance on an External IRB	IRB Fee
------------------------------------	----------------

Initial Protocol Review	\$1000
-------------------------	--------

Amendments*	\$500
-------------	-------

*Does not apply to COI, personnel (except PI), and administrative changes unless requested by sponsor.

MUSC as the Single IRB of Record for multisite trials	IRB Fee
--	----------------

Initial Non-MUSC Site Review per site	\$4000
---------------------------------------	--------

Annual Management per site	\$1664
----------------------------	--------

[IRB Submission](#)

About the Staff

Rebekah Whichard

Rebekah Whichard began her career at MUSC in 2002 as a Research Coordinator with the Digestive Disease Center, coordinating IBD (Inflammatory Bowel Disease) and NIH trials. She remained there until her daughter was born in 2010 and became a stay-at-home mom. She returned to MUSC in 2012 and volunteered as an IRB III reviewer until 2017. In Fall 2017, she began substitute teaching at her children's preschool, eventually becoming a teacher there. She rejoined IRB III in November 2023 as a Coordinator. Rebekah is excited to be back working in clinical research! In her free time, she likes to travel, and hang out with her husband and 3 kids!

Catch up on Previous IRB Newsletters

Visit the IRB News & Updates webpage to view past IRB Newsletters with helpful information!

[News & Updates](#)

Contact Us

Have feedback or suggestions you would like to share?

Email us at: irb-news@musc.edu

[IRB Homepage](#)

[IRB Contacts](#)



© Medical University of South Carolina

171 Ashley Avenue

Charleston, SC 29425