MUSC
Medical University of South Carolina

The Institutional Review Board

February 2022

The IRB Newsletter is marking its Second Anniversary, and we would like to thank all of you who work diligently to provide research opportunities to the community. Please keep in mind that the IRB website is always accessible as a resource and has many forms, templates, and guidance available to help ease the burden of creating study documents. If you have any questions, concerns, or suggestions about the Human Research Protection Program (HRPP) at MUSC, please call our office at 843-792-4148 or directly contact any of the IRB Staff.

IRB Forms and Guidance

IRB Contacts

IRB Updates

FDA Form 1571/1572

The IRB will no longer require that the FDA Form 1571/1572 be provided with submissions for investigational drug studies. This applies to new study applications as well as amendments, continuing reviews and report form submissions. Investigators must maintain a completed and up-to-date version of the applicable forms in their research records, as well as any previous versions. Completed 1571/1572 Forms must be submitted to the FDA and IND sponsors as per normal process.

Continuing Reviews

A Continuing Review (CR) is a renewal of the study protocol required by federal mandate. The IRB will conduct a CR of research at intervals appropriate to the degree of risk, but not less than once per year. The same criteria used for initial review of protocols will be followed during protocol renewals. If a CR is required for your study, you will get automated reminders from the eIRB system at 60 days, 45 days, 30 days, and the day before study expiration. You may also get reminders from the IRB Staff. CR's are due to the IRB one month prior to study expiration. If the CR is not submitted prior to the IRB deadline, the study may expire, causing all study related activity to cease, notification of study expiration will be sent to the Department Chair, and the study will have to undergo a re-opening process.

Please see the link to the CR policy below:

IRB HRPP 3.5 Continuing Review and Annual Status Update Policy and Procedures

IRB Study Closure Guidance

The IRB has created a guidance document which details criteria for when studies can be permanently closed with the IRB by submitting a Continuing Review in eIRB or ERMA. A study may be closed when **all** of the following have occurred:

- All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing); for chart review studies, this means no more charts will be reviewed.
- All subject records, data, and/or specimens have been obtained (i.e., no further collection of data/information from or about living individuals will be performed).
- No further contact with enrolled subjects will occur (i.e., all interactions or interventions are complete and all contact with subjects is complete)
- Analyses of subject **identifiable** data, records, and/or specimens are complete (i.e., use or access to subject identifiable data is no longer necessary. Note: this includes review of source documents by study monitors.).
- The database is locked, and there is no plan to add additional data.
- There are no outstanding amendments or reportable events.

For more information on study closure, please see the link below:

IRB Submission and Closure Processes

CITI Training

All investigators and study team members who participate in the design, conduct, or reporting of human subjects' research (including exempt research) must be appropriately trained in the protection of human subjects. MUSC uses the Collaborative Institutional Training Initiative (CITI) web-based human research courses to satisfy this institutional requirement. Basic-level courses for each group of required trainings must be completed before Refresher-level Courses will be accepted. All required groups of CITI Training will need to be renewed every 3 years. Any personnel assigned to studies for initial or continuing review and amendments must have current CITI certification prior to the study receiving approval.

A researcher transferring to MUSC may not affiliate prior completed CITI modules to meet the MUSC training requirements; but must complete new training in accordance with institutional guidelines.

Please note there is a new link to access CITI training for External Affiliates. Please be sure to update any bookmarks. The new link is also available from the ORI Website. There is no change to the CITI link for MUSC users.

For more information on CITI training, please see the links below:

Human & Animal Subjects Research Training (CITI Program)

ORI Website CITI Training for External Affiliates

New MUSC IRB Watermark Guidance

We have updated the Forms page on our website to include new usage guidance for the IRB Watermark. It provides information about which study documents need the IRB Watermark, if the study documents need to be displayed with the IRB-stamped watermark (e.g., ads posted in clinics), and instructions for how to place the watermark on your documents based on the type of format used, i.e., Word document or PDF.

Please see the link below:

Instructions for use of Watermark

Remote Site Document (RSD) Watermark

A new Remote Site Document (RSD) watermark is now available. This watermark is to be used on the documents associated with the sites relying on the MUSC IRB as the single IRB of record (sIRB) for multi-site studies. The template for the new watermark has been added to the Forms page of the IRB website. Please note that the RSD watermark is different from the MUSC IRB watermark and must be used for sIRB studies only.

Please see the link below:

MUSC Watermark for All Remote/Relying Site Documents

sIRB Fee Increase

While the IRB is committed to providing the highest quality research services at the lowest rate, the fees for sIRB studies has been increased. The updated rates will go into effect April 1, 2022. For more information on this, please see “IRB Fees” on the website below:

IRB Submissions

Principal Investigator Responsibilities Policy Update

The policy, IRB HRPP 5.1 Principal Investigator Responsibilities – Supervision of Staff and Protection of Subjects, has been updated to further clarify who can serve as a Principal Investigator (PI) at MUSC and at Ralph H. Johnson VAMC.

For further information on PI Responsibilities please see the following links:

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

IRB HRPP 5.2 Principal Investigator Responsibilities Recordkeeping and Record Retention Requirements

Research Sponsored or Funded by Department of Defense

A new policy is now available for research that is funded by the Department of Defense. For more information, please see HRPP 4.16 at located at the below link:

IRB HRPP 4.16 Department of Defense Research Policy and Procedures

About the Staff

Julia Jones

Julia Jones is the IRB Coordinator for IRB II. She joined the team in July 2021, after previously working in administrative roles for other institutions in export compliance and grants and sponsored programs. Julia earned her BA in Political Science and her MA in Minority and Urban Education. In her spare time, Julia enjoys weight lifting, training her dog, and traveling to new places.

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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