MUSC
Medical University of South Carolina

The Institutional Review Board

November 2022

With the holiday season fast approaching, it's beginning to look a lot like normal because of your hard work and dedication to excellence in human subjects' research. While everyone struggled with the various barriers Covid-19 created, the MUSC research community managed to overcome difficult challenges. Thanks to you, we can get back to our usual lives and celebrate with our loved ones this holiday season. We wish you and yours the happiest of holidays and the healthiest New Year!

IRB Updates

We are pleased to announce that the Medical University of South Carolina Human Research Protection Program (HRPP) was awarded full reaccreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in September 2022. The accreditation process involves careful evaluation of all components of the HRPP. These components include: Institutional Leadership, Institutional Review Boards, Office of Research and

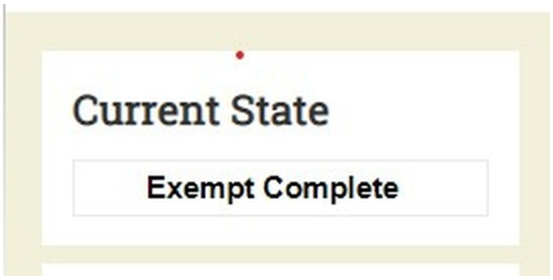
Sponsored Programs, Investigators and Research Staff, University Compliance and Various Other Institutions, Committees and Offices. We would like to thank all who were involved in providing support and participating in the AAHRPP site visit in July 2022.

An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for research quality and human subject protection. To earn accreditation, organizations must provide tangible evidence of their commitment to scientifically and ethically sound research and to continuous improvement through policies, procedures and practices. As the "gold seal," AAHRPP accreditation offers assurances to research participants, researchers, sponsors, government regulators, and the general public that an HRPP is focused first and foremost on excellence. The MUSC HRPP was first accredited in September 2009 and has maintained accreditation since then.

Thank you all for your dedication to protecting the rights and welfare of research participants.

Have questions or need assistance with CITI training?

If you have any questions regarding CITI training or need assistance with a CITI related item, please email: citi@musc.edu



New Study State: Exempt Complete

For exempt research, the MUSC policy (HRPP 3.2 - Human Research Protection Program Exempt Research) stipulates that Exempt studies are expired by the IRB five years after the initial date of approval. The only exception to this would be for studies whose plans specifically describe a duration beyond the five-year expiration, in which case that would be the end date for the project. While researchers are responsible for tracking the study's expiration date, the eIRB system has now been updated to automatically designate the completion of the study. Researchers will now see the current state in eIRB once the study has reached the five-year expiration updated to "Exempt Complete."

Reminder: Once the Exempt study expires, no further research can be performed on the project. If there is still a need to perform research past the expiration date, another Exempt study will have to be opened in order to continue.

HRPP 3.2 Exempt Research Review

Recruitment Method: New Question Added to eIRB Smartform

There is a new question on the study subjects smartform which asks whether cold contact will be used as a recruitment method. If yes is selected to this question, a new Cold Contact Recruitment Smartform will appear to be completed to describe the cold contact recruitment plan, provide justification for using this strategy, list the methods of communication to be employed and upload any scripts or messages that will be used. The question and new smartform also appear in the external IRB review pathway and should still be answered accordingly when the research study is being reviewed as an external IRB.

For more information about cold calling recruitment, please see policy HRPP 7.8 Recruitment of Research Participants.

HRPP 7.8 Recruitment of Research Participants

Updates: Non-English Speaking Subjects Policy and Guidance

Federal regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing. Subjects who do not speak English should be presented with a consent document written in a language understandable to them.

Alternatively, federal regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally (usually the existing English version of the ICF). A witness to the oral presentation is required, and the subject must be given copies of the short form document and the written summary.

The policy HRPP 7.5: Research Involving Non-English Speaking Subjects has been revised. In addition to the policy revisions, the guidance document Guidance for Short Form Consent has also been updated to clarify the processes to use when enrolling non-English-speaking participants.

See the revised policy and updated guidance for short form consent located on the IRB website.

HRPP 7.5 Research Involving Non-English Speaking Subjects

Guidance for Short Form Consent

2023 Meeting Dates and Deadlines

The IRB website has been updated with the 2023 Meeting Dates and Deadlines for Full Board IRB submissions. As a reminder, initial study submissions must be received by the IRB via eIRB by the posted deadlines. Tip: An easy way to know if the IRB has received the study, check the State of the study to make sure it is in "IRB Staff Review."

IRB Meeting Dates & Deadlines

Breakdown of the Different IRBs

The MUSC IRB is comprised of three different boards: IRB-I, IRB-II, and IRB-III. IRB III reviews all industry-sponsored research (regardless of the department for which the PI is appointed).

IRB-I and IRB-II review all other research, including federally or institutionally funded studies. The PI's department assignment will determine whether the research will be reviewed by IRB-I or IRB-II, as these IRBs are separated by department. For information regarding to which IRB a PI should submit a study, please check the IRB Meeting Dates & Deadlines link on the IRB website.

Note: For studies being reviewed by an external IRB, the PI will follow the above logic and still select either IRB-I, -II or -III on the appropriate eIRB smartform.

IRB Meeting Dates & Deadlines

Ralph H. Johnson VA Health Care System (VAHCS) – Name Update

The below message is from the Ralph H. Johnson VA Health Care System (VAHCS) regarding human subjects' research conducted at their site:

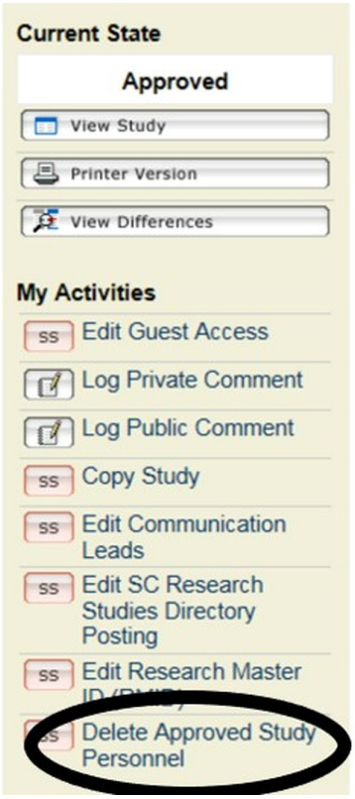
In April 2021, our facility name changed to Ralph H. Johnson VA Health Care System (VAHCS).

Effective Immediately the below guidance must be followed: Ensure all study documents include consents and HIPAAs reflect our new name, Ralph H. Johnson VA Health Care System (VAHCS).

- For IRB-approved studies, revise the study consent and HIPAA and all other study documents with the facility name on it when the next IRB amendment is submitted
- If an investigator is submitting a continuing review without having submitted an amendment (that would include the name change), the investigator is to also submit an amendment for the name change, as a separate review
- For new submissions, we anticipate our investigators will submit correct documents. If not, our Privacy Officer, during his Ancillary Committee review, will require the investigator to make the changes prior to completing his review. There is a hard-stop in place in eIRB for VA studies to receive PO approval before the study is routed for IRB review. Any study documents not reviewed by the IRB and/or PO pre-review will be reviewed during the R&DC review process for the correct facility name
- The VA consent template was revised and is located in the IRBNet forms and templates.
- The HIPAA template does not require revision to the header, but to be consistent with the consent, please update the HIPAA to include our new name in the “VA Facility” section on page 1 (and page 5 if applicable) and in the “REVOCATION” section on page 3

Please reach out to Patricia Tuohy, Patricia.Tuohy@va.gov, for any IRB related questions and Judy Stine, Judy.Stine@va.gov, for any R&D related questions.

Did you know certain study personnel may be deleted without an amendment?



The eIRB system has the capability that allows the Principal Investigator (PI) or main study coordinator to remove study personnel listed under the roles of Co-Investigator (Co-I) or Other Study Team members from the study without submitting an amendment to the IRB; this is done by using the "Delete Approved Study Personnel" button listed under "My Activities."

The "Delete Approved Study Personnel" button can only be seen under the following conditions:

- you are listed as PI or the main study coordinator,
- there is no open amendment
- If there is an open amendment, that amendment needs to be withdrawn or approved before the button appears.

If you are submitting an amendment to the IRB to just remove study staff, it is likely it will be returned to you to use the "Delete Approved Study Personnel" button, to reduce amendment burden.

About the Staff

Kaye Roberts

Kaye Roberts is the IRB Administrator for initial exempt and expedited studies across all boards. She started at MUSC in 1990 and was a coordinator conducting clinical trials for most of her research career. She has been with the IRB for 12 years. Kaye is a graduate of Auburn University and is an avid college sports fan. She also loves spending time outdoors and enjoys gardening, fishing, boating, and parking herself on the porch with her family, pup, and a pinot.

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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