MUSC
Medical University of South Carolina

The Institutional Review Board

August 2020

In these uncertain times, it is encouraging to see everyone at MUSC pulling together to accomplish what is needed. The IRB has been hard at work trying to process all submissions in a timely manner. While the studies that are directly related to research for COVID-19 have been the top priority, the IRB is also processing all other initial studies, continuing reviews, and amendments as efficiently as possible. Together, we can get through these tough times and come out on top to change what's possible.

IRB Updates

New IRB Staff Member

The IRB is happy to announce that we have added a new staff member to the team, Kelsey Shirey. Kelsey is the new Board III Coordinator and can be reached at shireyk@musc.edu or 792-5997. Welcome to the team, Kelsey!

Data Safety Monitoring Plans

The IRB requires review and approval of data and safety monitoring plans (DSMP) for greater than minimal risk research, clinical research, or clinical investigations funded by the National Institute of Health (NIH) or regulated by the Food and Drug Administration (FDA). Investigators are to develop and implement a mechanism to assure the safety of human subjects and human subject research data, the validity of data, and the appropriate termination of studies.

If your study has a formal Data Safety Monitoring Board (DSMB) or Independent Monitoring Committee (IMC), you will need to submit their reports to the IRB for review and acknowledgement. The principal investigator is responsible for submitting the DSMB reports at the time the reports become available to the Investigator, regardless of the timing of the report in relation to the continuing review of the study. These reports should be submitted to the IRB in accordance with the schedule outlined in the IRB approved protocol. DSMB reports must be submitted via the Reportable Events mechanism within eIRB. A video link has been provided below showing how to submit Reportable Events to the IRB.

For more on DSMP's please see the policy below.

HRPP 4.10 Data and Safety Monitoring Plans

MUSC IRB Policy and Procedures

eIRB Creating and Submitting Reportable Events

Sponsor Site Visit Monitoring Letter

After a study sponsor completes a site monitoring visit, it is routine for the study's principal investigator to receive a follow-up letter from the sponsor monitor outlining the visit and any issues found during the visit such as protocol violations, discrepancies, etc.

The IRB no longer requires the principal investigator to submit these sponsor monitoring letters to the IRB for review. However, the principal investigator is still required to submit any protocol deviations that meet MUSC's policy for reporting protocol deviations, or any unanticipated problems that meet MUSC's policy for reporting unanticipated problems.

For more information regarding these reporting requirements, please review:

HRPP 4.14 Protocol Deviations Protocol and Procedures

HRPP 4.7 Unanticipated Problems and Adverse Events Policy and Procedures

Advertisements Policy

If you are looking for new ways to recruit for your study, you might choose to use advertisements. The federal regulations allow advertisements to be used, but the ads must be fair and equitable. IRB review and approval is required for all means of advertising, recruiting, and notifying individuals of research studies across all types of media. To learn more about what information is required for ads, what should not be listed in ads, etc., please see the Advertisements for Research Participants Policy, which can also be found on the IRB Policies and Procedures website.

Please keep in mind that even though the IRB may approve the ad, it does not mean that you do not need other institutional approvals, for instance, from the University's Brand Center.

MUSC IRB Policy and Procedures

HRPP 7.2 Advertisements for Research Participants Policy and Procedures

You Might Have Noticed...

You might have noticed that there is an "Important Note" at the bottom of Initial Study and Amendment approval letters which states:

“Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other MUSC clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.”

This note is to serve as a reminder that just because IRB approval has been issued, it does not mean that other institutional or external agency approvals are not needed. For example, if you are working on an industry-sponsored study, a finalized contract agreement is needed between MUSC and the sponsor before the research may be initiated. These agreements are handled by the Medical University’s Office of Research and Sponsored Programs (ORSP).

Single IRB(sIRB) / Reliance: Commercial IRB's

Q: Are commercial IRBs available as a choice for single IRB review?

A: Yes. The Medical University of South Carolina (MUSC) offers the use of the commercial IRBs for multi-site clinical trials to all departments as long as the following criteria are met:

- The external IRB is currently registered with OHRP/FDA
- For commercial IRBs: the commercial IRB is AAHRPP-accredited
- For non-commercial IRBs: the IRB is AAHRPP-accredited or determined as part of the administrative review to meet MUSC standards
- The external IRB is located within the U.S. (MUSC IRB reserves the right to withhold any new research study from being sent to an external IRB)

An MUSC external application is still required via eIRB to document local context requirements and the reliance arrangement. Many commercial IRBs are members of SMART IRB and can be used via the SmartIRB platform.

The MUSC IRB has also answered many other reliance related questions on the FAQ page:

Frequently Asked Questions about Single IRB Review

eIRB Tip of the Issue

Using the Upload Revision Button

At some point after a study receives IRB approval, it is very likely that an amendment will be needed to revise some part of the study, usually the protocol or informed consent document. When submitting an amendment to revise an already approved document, make sure to use the “Upload Revision” button instead of the “Add” button when uploading the clean copy of the document to the smartform. The "Add" button should only be used when adding a brand new document to the study. It is also important to note that documents should never be “Removed” from a study. By using the “Upload Revision” button, a history of that document is created, which can be accessed to see all the changes that have been made throughout the life of the study. For more information on uploading documents into the eIRB research application, please see the video link below.

eIRB Uploading Documents

About the Staff

Amy Haynes, CIP

Amy Haynes is the IRB Administrator for Board II. Amy has worked at MUSC for 16 years and in the Office of Research Integrity for 8 years. She grew up in Hemingway, SC and went on to graduate from the College of Charleston. In her free time, she enjoys spending time with her family and friends, attending her son's youth ball games and sailing regattas, and traveling.

Contact Us

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

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