MUSC
Medical University of South Carolina

I. Policy

The policy describes how the MUSC IRB may rely on an external IRB to serve as the IRB of Record for a nonexempt study in which an MUSC investigator is deemed to be engaged (Per OHRP Guidelines on Engagement in Research). In this situation, the External IRB is the *IRB of Record*, and the MUSC IRB is the *Relying IRB*.

II. Introduction

MUSC may rely on an external IRB, including the IRB of another institution or organization, or an independent (Commercial) IRB, for review and approval of human research if such reliance is a requirement of the research, or if it benefits MUSC, its investigators and/or its research participants.

III. Criteria for Selecting an External IRB

MUSC will apply the following criteria in selecting an external IRB to conduct the review of MUSC protocols:

- 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 will only rely or be the reviewing IRB for studies within the United States at this time.*

<u>Updates/modification of reliance information</u>
Once the reliance request has been accepted and approval obtained from the external IRB, study teams must notify the MUSC IRB of any of the following:

- PI and personnel changes
- Any changes which require revisions to the HIPAA authorization if MUSC is serving as the Privacy office.
- Potential conflicts of interest, including institutional and potential financial interests, which could affect or be affected by the research

• Study closure, when the project is complete and closed with the reviewing IRB . Study teams are also required to notify MUSC of study closure.

IV. IRB AUTHORIZATION AGREEMENT/RELIANCE AGREEMENT

In accordance with OHRP Guidance, when MUSC relies on an external IRB for review and approval of human research, the relationship is documented with an IRB Authorization Agreement (IAA) or other formal reliance agreement. This formal agreement requires each institution to have an FWA and

- Identifies one institution's IRB as the IRB of record, or specifies which institution's IRB will review which components of a study, and includes a description of the regulatory requirements for which each party will assume responsibility.
- The MUSC Institutional Official (IO) or designee has the ultimate authority regarding whether or not to rely on an external IRB. The IO is authorized to execute IAAs / Reliance Agreements on MUSC's behalf and may delegate this authority

V. MUSC PI Responsibilities/Study Team

1. Submit an abbreviated application through the MUSC eIRB system.
    a. Letter of approval from the external IRB
    b. Final approved protocol and informed consent
    c. approved waivers and/or HIPAA authorization
2. Meet MUSC education requirements (e.g. CITI training)
3. Researchers must comply with the determinations and requirements of the IRB of Record, which includes conducting the research in accordance with the reviewing IRB's policies and procedures, the IRB-approved documents and conditions of approval, and any applicable laws and regulations.
4. Researchers and research staff agree to disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.
5. Researchers will report promptly to the IRB of Record any proposed changes in the research. The investigator will not initiate changes in the research (including changes in the consent document) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
6. Researchers will report to the IRB of Record any unanticipated problems involving risks to participants or others according to the IRB's reporting policy.
7. Researchers will report to the IRB of Record any non-compliance or protocol deviations according to the IRB's reporting policy.
8. Researchers will report to the IRB of Record as well as the MUSC IRB any complaints from a subject or other person regarding the research.

VI. Responsibilities MUSC

1. The organization is responsible for ensuring compliance with the IRB of Record's requirements at the research site.
2. Prior to review, provide the IRB of Record with any local context issues relevant to the research protocol.
3. Research may be further reviewed and approved or disapproved by officials of MUSC as the relying institution, but MUSC may not approve the research if it has not been approved by the reviewing IRB.
4. Educate and train its investigators to perform research in compliance with human research protection regulations.
5. MUSC and its researchers acknowledge and agree to cooperate in the IRB or Record's responsibility for initial and continuing review, record keeping and reporting. All information requested by the IRB of Record will be provided in a timely manner.
6. Researchers will not enroll individuals in research prior to review and approval by the IRB of Record.
7. The researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative as stipulated by the IRB of Record.
8. MUSC may conduct post-approval monitoring in addition to, or in cooperation with, the reviewing IRB.

VII. RESPONSIBILITIES OF THE External IRB of Record

1. Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modification to previously approved research.

2. Suspend or terminate IRB approval when determined necessary.

3. Review unanticipated problems involving risks to subjects or others.

4. Review incidents of serious or continuing non-compliance.

5. Notify the researchers and MUSC IRB in writing of its decision.

6. Make available recent IRB minutes to the MUSC IRB upon request.

7. When appropriate, conduct on-site or remote post approval monitoring or audits, unless delegated to MUSC.

8. Specify the contact person and provide contact information to the MUSC IRB.

9. Report to MUSC IRB, regulatory agencies, and sponsors of serious or continuing non-compliance, unanticipated problems involving risks to subjects or

others, suspensions or terminations of IRB approval (unless other provisions have been stipulated in the Reliance agreement).

VII. Roles that may be delegated to either the IRB of Record or MUSC IRB:

1. The IRB Authorization Agreement/Reliance Agreement should stipulate whether the relying organization or IRB of Record performs these responsibilities:
    a. Reporting to organizational officials, regulatory agencies, and sponsors of serious or continuing non-compliance, unanticipated problems involving risks to participants or others, suspension or termination of IRB approval.
    b. Education and continuing education of researcher and research staff. The education requirements followed should be specified in the agreement
    c. Obtaining disclosure and management of financial conflict of interest, although if MUSC maintains responsibility for this issue, any disclosure of management plan(s) will be provided to the IRB if Record in a timely manner prior to the decision by the IRB of Record.
    d. Management of organizational conflict of interest related to the research.