Policy Name: MUSC as Single IRB of Record		
Approved:		
Effective Date: 02/23/2018	Page 1 of 3	Section: HRPP 9.4
Replaced Policy: 09/15/2016		

I. POLICY

The policy describes how the MUSC IRB may serve as the Single IRB of Record for a nonexempt multi-site study in which an MUSC investigator will serve as the Lead PI. In this situation, the MUSC IRB is the *IRB of Record*, and the non-MUSC (Relying) sites' IRB is/are the *Relying IRBs*.

II. INTRODUCTION

MUSC will typically only serve as the Single IRB of Record for a multi-site trial if the MUSC PI is either the Lead Investigator or serves as the Coordinating Center for the multi-site trial. There may be other circumstances for which MUSC IRB would serve as the Single IRB or Record, which will be determined on a case-by-case basis.

Criteria for Relying Institutions to use MUSC as the Single IRB of Record:

MUSC will apply the following criteria when deciding whether MUSC IRB will serve as Single IRB for a given site:

- The Relying site currently has a valid FWA.
- The Relying site has the ability to perform post-approval monitoring of the research.
- The Relying site is located within the U.S.

III. IRB Authorization Agreement/Reliance Agreement

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

- Identifies MUSC's IRB as the IRB of record, 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 MUSC will serve as the Single IRB of Record. The

IO is authorized to execute IAAs / Reliance Agreements on MUSC's behalf and may delegate this authority

IV. MUSC PI Responsibilities

1. The MUSC PI will serve as either the Lead Investigator of the multi-site trial or as the Coordinating Center (unless as determined different on a case by case basis as stipulated in agreement).
2. The PI will work with the MUSC IRB to disseminate Reliance Agreements to the sites interested in relying on MUSC IRB.
3. The PI will submit appropriate documents for MUSC IRB approval including protocol, consent form for local site, as well as consent template for the Relying Sites.
4. Once the PI has initial approval, the PI will be responsible for adding each Relying site in the MUSC eIRB system. This will include adding Relying site staff, local context information, and appropriate site-specific documents.
5. The MUSC PI is responsible for ensuring appropriate communication regarding MUSC IRB approvals/requirements with the Relying Sites (e.g. IRB approved documents).
6. After Relying Site approval, the MUSC PI is responsible for:
    - coordinating the submission of any amendments for Relying Sites
    - coordinating the submission of information for continuing review from each site for review and approval by MUSC IRB
    - reviewing all Relying Site regulatory documents/reports and submitting them for IRB review.

V. Responsibilities of Relying Sites

1. The Relying Site is responsible for ensuring compliance with the MUSC IRB's requirements at the research site.
2. Prior to review, provide the MUSC IRB with any local context issues relevant to the research protocol.
3. Research may be further reviewed and approved or disapproved by officials of the Relying Site as the relying institution, but the Relying Site IRB may not approve the research if it has not been approved by the MUSC IRB.
4. Educate and train its research staff to perform research in compliance with human research protection regulations. If Relying Site does not have a human subjects' protection educational requirement, the Relying Site research staff must follow MUSC training requirements (CITI course)
5. The Relying Site and its researchers acknowledge and agree to cooperate in MUSC IRB's responsibility for initial and continuing review, record keeping and reporting. All information requested by the MUSC IRB will be provided in a timely manner.
6. Researchers will not enroll individuals in research prior to review and approval by the MUSC IRB.

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 MUSC IRB.
8. The Relying Site must have the capacity to conduct post-approval monitoring in addition to, or in cooperation with, the MUSC IRB.
9. The Relying Site will identify local Conflict of Interest(s) and provide a management plan to MUSC IRB.
10. Researchers will report to the MUSC IRB any unanticipated problems involving risks to participants or others according to the MUSC IRB's reporting policy.
11. Researchers will report to the MUSC IRB any non-compliance or protocol deviations according to MUSC IRB's reporting policy.
12. Researchers will report to the MUSC IRB any complaints from a subject or other person regarding the research.
13. The Relying site PI will also need to provide any necessary documents or reports that the Relying site IRB deems necessary to be in compliance with Relying site policies.

VI. Responsibilities of the MUSC 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 Relying Site IRB in writing of any determinations.
6. Make available relevant IRB minutes to the Relying Site IRB upon request.
7. When appropriate, request post approval monitoring or audits, by the Relying Site's institution.
8. Specify the contact person and provide contact information to the Relying Site IRB.
9. Report to Relying Site 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).
10. Review and approve Conflict of Interest management plans for Relying Sites.

VI. Roles that may be delegated to either the Relying Site IRB or MUSC IRB or Record:

The above roles and responsibilities represent what would typically be in a standard reliance agreement between MUSC and another institution. However, there may be different arrangements on which institution will be responsible for what part of study oversight as long as it is stipulated in the Reliance Agreement and both parties agree.