



<b>Policy Name: Multi-Site Research Studies Policy and Procedures</b>			
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## I. POLICY

### A. Introduction

Research activities conducted at sites that are not owned or operated by the Medical University of South Carolina and do not fall under the MUSC IRB's authority are subject to special procedures for the coordination of research review.

Off-campus site research is defined as research conducted at a site that is external from MUSC. An off-campus site may be domestic or international and may or may not have its own IRB.

Off-campus site or multi-site research may involve more than one institutional review board responsible for research oversight. In these cases, MUSC has established additional procedures to define the responsibilities of each IRB, coordinate communication among responsible IRBs, and manage information obtained in off-campus site or multi-site research to ensure protection of human subjects.

A determination must be made as to whether the non-MUSC institution is "engaged" in human subject research activity. Research procedures should not be initiated at an off-campus site location prior to IRB review of the appropriate documentation for that site.

If the off-campus site(s) has its own IRB, the MUSC IRB preference is that each site be responsible for reviewing the research activities to be conducted at the respective site. The MUSC investigator should obtain copies of the non-MUSC institution's approval letter and FWA number and submit them to the IRB in the IRB application (or make arrangements to do so when the documents become available). In cases in which research undergoes joint IRB review at MUSC and at the non-MUSC institution, no IRB Authorization Agreement is necessary.

If the off-campus site(s) does not have its own IRB, MUSC policy requires that (except in the limited circumstances described below) the site establish its own IRB (or contract with a "for-hire" IRB) prior to its participation in the research. The cooperative site must register its IRB with the Office of Human Research Protections (OHRP).

Under certain limited circumstances, the MUSC IRB may serve as the relied-upon IRB for the non-MUSC institution. These limited circumstances may include research that is: a) not greater than minimal risk, and b) the non-MUSC institution does not have an IRB and is not the type of institution that would typically establish an IRB. MUSC may also serve as the relied upon IRB if the PI of the study is a MUSC employee and the study is conducted at an off-site facility. In such cases, the off-site facility signs an IRB Authorization Agreement to abide by the decisions and determinations of the MUSC IRB in the conduct of the research. The Associate Provost for Research in consultation with the IRB and, if appropriate, MUSC Legal Counsel, makes the final determination whether the MUSC IRB will serve as the relied-upon IRB.

For some multi-center studies, the use of the VA Central IRB may be required.

In addition to MUSC IRB committees, the MUSC FWA includes the use of the National Cancer Institute Central IRB for pediatric protocols, the NCI Central IRB for Adult Phase III Clinical Trials and Western Institutional Review Board for selected multi-site clinical trials as needed or defined for specific studies. VA studies reviewed by the MUSC IRBs cannot use a central IRB, although a central VA IRB is currently in operations and my mandate the use of their IRB for certain studies).

It is important to communicate with a member of the staff of the Office of Research and Sponsored Programs. Contractual arrangements among institutions may be required or; particularly those institutions that plan to use the MUSC IRB as their IRB of record. Additional information can be obtained from IRB Administrators for each of the IRB's, the IRB Manager and the Director of ORI. It will be useful for the principal investigator or his/her designee to speak with staff from the IRB that has jurisdiction over his/her studies (IRB I, II, III).

MUSC may agree to defer responsibility for IRB review to a non-MUSC institution's IRB under limited circumstances as approved by the Associate Provost for Research. To defer, the non-MUSC IRB must be part of an accredited HRPP (AAHRPP) with an FWA. Circumstances when MUSC may defer IRB review may include:

1. Funding agency requirements (such as NIH-sponsored trials where this is required);
2. MUSC employee role limited to data analysis;
3. Research which began at another institution prior to employment of the investigator at MUSC and remains active only at the other institution (any funds supporting the research remain under control of the non-MUSC institution); and/or
4. Research is not greater than minimal risk.

The Associate Provost for Research in consultation with the IRB and, if appropriate, MUSC Legal Counsel, makes the final determination whether the MUSC IRB will defer review and oversight responsibility to another IRB.

## **II. PROCEDURES**

### **A. Investigator Responsibilities**

1. In either the human research review application on-line form for an initial study or in an amendment to an existing study include:
  - a. That the research will be conducted at a site or multiple sites not affiliated with MUSC;
  - b. A description of the specific research activities to be conducted at the site;
  - c. For each non-MUSC site, submit a formal letter (on letterhead stationery) from the appropriate administrator of the non-MUSC site stating:
    - 1) review of the project has been completed by a properly credentialed individual at the facility with respect to the issue of appropriateness for its human subject population, and adequacy for the facility to perform the procedures as approved by the MUSC IRB;
    - 2) written confirmation that facility personnel have the appropriate expertise to carry out the research procedures and assurance that personnel from the facility who are involved in the research and data collection have appropriate training in human subject research protection (CITI) and;
    - 3) granting permission to allow the research to take place at the facility.
  - d. A (revised) Key Personnel list to reflect the key personnel at the new site(s).
2. Complete the "Off-Campus Study Site Form" indicating the following:
  - a. A determination of whether the site is "engaged" in research using OHRP Guidance Document, "Engagement of Institutions in Research".

The IRB staff may assist the PI in determining whether the non-MUSC employees are actively participating in the

implementation of research procedures or are obtaining individually identifiable private data about human subjects research purposes. If the non-MUSC employees are engaged in the research, then the MUSC human research protection policy applies to those personnel and they must complete the appropriate human subjects protection training (CITI) and be listed as study personnel.

- b. Documentation of whether the off-campus site has an IRB and if so, whether it has approved the research or will request reliance upon the MUSC IRB.
  - c. If the off-campus site has an approved FWA, provide the off-campus site's FWA number.
3. If the off-campus site has an IRB and does not plan to request reliance on the MUSC IRB, the MUSC investigator is responsible for providing documentation of that off-campus site's IRB initial and continuing approval of the investigator's research at that site. In addition, the investigator is responsible for ensuring that the off-campus site's IRB approval is current and for providing documentation of that approval to the MUSC IRB.
  4. If the off-campus site plans to rely on the MUSC IRB, the site may need to obtain an Federal Wide Assurance (FWA) depending on the funding source, and an IRB Authorization Agreement must be established between the site and MUSC prior to the initiation of study activities at the off-campus site. The investigator will be responsible for consulting with the MUSC IRB Program Manager or designee who will oversee the completion of the MUSC IRB Authorization Agreement. The off-campus site will be responsible for updating its FWA to reflect reliance upon the MUSC IRB, as required by OHRP policy. The off-campus site and the MUSC IRB will each maintain one fully executed agreement for inspection by OHRP, as requested.
  5. When the MUSC PI is responsible for conduct of a multi-site study or coordinating center for a multi-site study, (s)he should include in the protocol, a description of how initial and continuing IRB approvals are collected and maintained from off-campus sites and provide a description of reporting requirements for off-campus sites being used to conduct the research (e.g., revisions/amendments, serious adverse events).

## **B. IRB Staff Responsibilities**

1. Review initial, continuing, and amended applications to the IRB to determine if the research is being conducted at other sites.

2. Make preliminary determination if the other site(s) is “engaged in research” based on OHRP guidance.
3. Determine if the other site engaged in research has an IRB with a Federal Wide Assurance (FWA) and, if so, check for documentation of IRB approval.
4. Communicate with the local PI, off-campus site PI and IRB and Institutional Official to determine the best review arrangement for the other site engaged in research. This may include:
  - a) Joint review; or
  - b) Reliance upon the review of another qualified IRB or similar arrangement aimed at avoiding duplication of efforts.

*Note: These types of review arrangements must be in writing and must define the scope of studies subject to review by the IRB.*

5. Forward appropriate review agreement documents to MUSC Institutional Official for signature, as required.
6. Ensure when a MUSC investigator serves as the PI of a coordinating center that the protocol addresses how initial and continuing IRB approvals are collected and maintained from other sites.
7. Inspect files to ensure that, before the initial approval form is issued, all collaborating sites have provided current IRB approval of the protocol. If approvals have not been collected from all collaborating sites, only approval for those sites in which IRB approval is on file will be issued. Approvals for additional sites will be issued as local IRB approval is received by the MUSC IRB through the revision/amendment process.
8. At the time of initial and continuing review, the MUSC IRB will assess the procedures for promptly disseminating protocol information to all participating sites. Assessment of protocol information includes unanticipated problems involving risks to participants or others, protocol modifications and interim findings, or for a specific site, a finding of serious or continuing non-compliance, or the suspension or termination of IRB approval. Any unanticipated problems occurring at the external site(s) that are related to the study must be reported according to the MUSC reporting policy.

### **C. IRB Administrative Staff Responsibilities**

1. Maintain files of agreements with other sites.

2. Mail copies of agreements with other sites to the off-campus site and to the PI.

#### **D. IRB Staff and Board Responsibilities**

1. Review and provides recommendation regarding reliance agreements if satisfied that human subjects protections afforded under the agreement will be appropriate and adequate.
2. Review amendment submissions concerning addition of other sites.

#### **E. Institutional Officials Responsibilities**

1. Make the final determination as to whether MUSC will serve as the relied-upon IRB or whether the MUSC IRB will defer review to another IRB.

### **III. REFERENCES**

**ORHP Guidance Document: “Engagement of Institutions in Human Subjects Research**

**<http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>**