| Policy Name: **Multi-Site Research Studies Policy and Procedures** | | | |
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# I. POLICY

## A. Introduction

There are times when an investigator or multiple investigators will participate in trials involving several sites that are not affiliated with MUSC.

When an investigator uses a non-MUSC site and the site is engaged in research, under limited circumstances, MUSC may agree to allow the site to rely on the MUSC IRB. If MUSC agrees to allow another site to rely on the MUSC IRB, the non-MUSC site must obtain an FWA if they do not have one.

**B.** The investigator or his/her designee should first consider whether these sites are considered part of the MUSC family of organizations (examples: Carolina Family Care, University Medical Associates & others).

**C.** Sometimes MUSC will be part of a multi-center trial with several sites involving other university medical centers, other clinics, community hospitals and other medical entities.

**D.** Prior to initiation, the principal investigator or his/her designee must consider several issues:

1. Listing the sites for the proposal and determine whether each site has an IRB and a Federal wide assurance;

2. For institutions with no IRB, decision as to MUSC IRB serving as the IRB of record for these institutions (requires identification and addition to MUSC FWA); and

3. For some multi-center studies, the use of the VA Central IRB may be required. The use of central IRBs will be determined by the Associate Provost for Research on a case-by-case basis.

**E.** In addition to MUSC IRB committees, the MUSC FWA includes the use of the National Cancer Institute Central IRB #2 (IRB00004296) 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 being developed.

**F.** It will be useful for the principal investigator or his/her designee to speak with staff from the IRB board that has jurisdiction over their studies (IRB I, II, III).

**G.** It is important to communicate with a member of the staff of the Office of Research and Sponsored Programs. Contractual arrangements among institutions will be required; 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.

**H.** 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 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 actively 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

## II. PROCEDURES

### A. Investigator Responsibilities

1. At the time of initial review, complete and submit to the IRB a human research review application on-line form. Indicate that the research will be conducted at multiple sites not affiliated with MUSC, and provide a thorough and clear description of the type of activities to be conducted at each site.

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."

b) Address and contact information of the non-MUSC site.

3. Submit a formal letter (on letterhead stationary) from the appropriate administrator of the non-MUSC site stating 1) review of the project has been completed by someone 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.

4. Submit an IRB Authorization Agreement signed by the off-site facility official to abide by the decision and determinations of the MUSC IRB in the conduct of research.

5. Provide a description of reporting requirements for non-MUSC sites being used to conduct the research (e.g., revisions/amendments, serious adverse events).

6. Provide information regarding whether the non-MUSC site(s) have an IRB.

7. Submit copies of the IRB approval(s) from other site, if applicable and as soon as they become available.

8. Indicate that (s)he is the principal investigator for the local site or for the coordinating center for a multi-center study, and includes in the application a description of the following:

   a) How human subjects approvals will be obtained or supplied by other sites prior to initiation of the project at the site;

   b) How the human subjects approvals (both initial and continuing) will be maintained; and

   c) The mechanisms/agreements that describe reporting requirements for amendments/revisions, serious adverse event reporting, etc.

9. Indicate in the continuing review, at time of continuing review, that (s)he is collecting and maintaining continuing IRB approval for all sites.

10. Complete the “IRB/IEC Authorization Agreement” or “Individual Investigator Agreement” form depending on which is applicable.

## B. Senior IRB Staff Responsibilities

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

2. Making preliminary determination if the other site(s) is "engaged in research" based on OHRP guidance.

3. Responding to OHRP when requested opinions from OHRP regarding "engagement in research".

4. Determining if the other site engaged in research has an IRB with a Federal wide Assurance (FWA) and, if so, checking for documentation of IRB approval.

5. Communicating with the local PI, performance site PI, and IRB to determine the best review arrangement for the other site engaged in research if other institution does not have a FWA. 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.*

6. Forwarding appropriate review agreement documents to MUSC Institutional Official for signature, as required.

7. Ensuring 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.

8. Inspecting 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.

9. Reviewing the initial protocol review at time of continuing review to insure that the investigator has noted that (s)he is collecting and maintaining IRB approvals from other sites.

10. If the non-MUSC site has an IRB, the IRB Program Manager/IRB Administrator, upon approval from the IRB Chair and/or ORI Director, will correspond in writing (email is sufficient) with the IRB at the non-MUSC site to determine the best review arrangement and scope of review responsibilities.

### C. IRB Administrative Staff Responsibilities

1. Maintains files of agreements with other sites.

2. Mails copies of agreements with other sites to the site and to the PI.

### D. IRB Staff and Board Responsibilities

1. Reviews and approves reliance agreements if satisfied that human subjects protections afforded under the agreement will be appropriate and adequate.

2. Reviews amendment submissions concerning addition of other sites.

3. Checks with Office of Research and Sponsored Programs that proper contractual arrangements are maintained at time of continuing review.

4. Checks with the Regulatory and Compliance Office at the time of continuing review to determine reports of compliance problems, audits and other.

### E. Institutional Officials Responsibilities

1. Makes the final determination as to whether MUSC will serve as the relied-upon IRB.

## III. REFERENCES