MUSC
Medical University of South Carolina

I. Policy

Purpose

This policy applies to research studies in which research activities are 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.

Policy

Off-campus research that is conducted by an agent of MUSC must be reviewed and approved by the MUSC IRB. The off campus site(s) may require its/their own review. If this is the case, approval from both sites would be required before the investigator initiated research. With an appropriate reliance agreement, single review by one IRB may occur.

Introduction

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

Off-campus 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 research to ensure protection of human subjects.

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

If the off-campus/non-MUSC site(s) has its own IRB, the research may either be reviewed by that institution or a reliance agreement may be established between MUSC-IRB and the off-campus site's IRB. If the off-campus site(s) does not have its own IRB, the MUSC IRB may serve as the

relied-upon IRB for the non-MUSC institution if that institution is considered engaged in research per OHRP guidance.

Memorandum Of Understanding

In situations where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards". For some multi-center studies, the use of the VA Central IRB may be required.

Procedures

Investigator Responsibilities

In either the human research review application on-line form for an initial study or in an amendment to an existing study include:

That the research will be conducted at a site or multiple sites not affiliated with MUSC (non-MUSC site);
A description of the specific research activities to be conducted at the site;
For each non-MUSC site that is not engaged in research, submit a letter of support (on letterhead stationery) from the appropriate administrator of the non-MUSC site stating that the study may occur at the location in question. There may be exceptions to this requirement (e.g. interviews in public restaurants or parks).
For each non-MUSC site that is engaged in research, approval to conduct the study at that site will be documented by either the off-campus site's IRB or through a reliance agreement with MUSC IRB.

The MUSC PI should provide written confirmation that facility personnel have the appropriate expertise to carry out the research procedures and assurance that personnel from the facility who are engaged in the research have appropriate training in human subject research protections (CITI)

Complete the "Off-Campus Study Site Form" for each site non-MUSC site indicating the following:

A determination of whether the site is "engaged" in research using the 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 for research purposes. If the non-MUSC employees are engaged in the research, then the non-MUSC site must also have IRB approval before the study may be conducted there.
Documentation of whether the non-MUSC site has an IRB and if so, whether it has approved the research or will request reliance upon the MUSC IRB.
If the off-campus site has an approved FWA, provide the off-campus site's FWA number.

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 approval of the investigator's research at that site if requested by the MUSC IRB. In addition, the investigator is responsible for ensuring that the off-campus site's IRB approval is current for the duration of that site's involvement.

MUSC IRB Responsibilities

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

Make preliminary determination if the off-campus site(s) is "engaged in research" based on OHRP guidance.

For off-campus sites that are engaged, determine if the off-campus site has an IRB with a Federal Wide Assurance (FWA) and, if so, check for documentation of IRB approval.

VA Research - When following VA regulations and guidance:

The principal researcher, and also the VA PI (if different), must obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.

Research cannot be initiated at any given VA site until the local researcher has obtained written notification that the research can be initiated from the local Research and Development committee.

Institutional Officials Responsibilities – When the off-campus site is engaged in the MUSC PI's research, the Institutional Official is responsible for making 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 (see policies 9.4 and 9.5).

Guidance on Additional Requirements of Federal Funding Agencies
Regardless of where research is conducted, research sponsored by any of the following may have additional regulations that must be followed:
* Department of Defense (DOD),
* Department of Education,
* Department of Energy,
* Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
* Environmental Protection Agency (EPA)

Specific sponsors may have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation - Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

REFERENCES

A. **OHRP Guidance Document: "**Engagement of Institutions in Human Subjects Research**"**
B. **HRPP Policy Guide Section 9.4 –"**MUSC as Single IRB of Record"
C. **HRPP Policy Guide Section 9.5 -** "Relying on an External IRB"