MUSC
Medical University of South Carolina

I. Policy

A. Introduction

MUSC investigators are granted the privilege of conducting studies in human subjects under assurance to the government that research conducted at MUSC complies with regulations protecting human subjects. Therefore, the Principal Investigator (PI) is fully responsible for the human-subjects research under his/her direction. This responsibility includes the protection of human subjects and ensuring the research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies, and requirements or determinations of the MUSC IRB. The Principal Investigator may delegate study tasks to other research team members but still maintains ultimate responsibility for the conduct of the study

Additional requirements of sponsors including Veterans Administration, Department of Energy, Department of Education, Department of Defense, Department of Justice may also apply.

All Principal Investigators and their staff involved with the human research protection program are expected to understand and apply their obligation to protect the rights and welfare of research participants.

B. PI Responsibilities for Supervision

When supervising the conduct of human subjects research, the PI is responsible for ensuring the following points:

1. Study personnel will have completed the mandatory educational compliance training on human research.

2. Study personnel have been appropriately trained to fulfill their role on the study including but not limited to obtaining informed consent, and conducting study procedures.

3. Study personnel follow the IRB-approved protocol.

4. A plan is developed and implemented for supervision and oversight of the research ensuring that there are sufficient study personnel and

resources for the study and that the degree of supervision is commensurate with the subject population and the type of research. Research should not begin unless adequate resources are in place to protect research subjects and should stop if the resources necessary to protect subjects become unavailable.

5. The protection of the rights, safety, and welfare of research subjects are addressed. Special attention must be given to vulnerable populations. Such protection includes the following:

   a) The Principal Investigator must assure reasonable medical care is provided to a subject for any adverse event(s) that occur during the trial or within 30 days of the subject's completion of the trail if the adverse event is thought to be related to study participation.

   b) The Principal Investigator must provide a plan for data and safety monitoring for any study that is greater than minimal risk.

   c) Depending upon the type of research and the risk involved, the Principal Investigator should inform, (if agreed to by the participant) the subject's primary care physician about the subject's participation in the study.

   d) Research subjects have access to qualified individuals to answer questions or provide care during the conduct of the research.

   e) All members of the research team conducting the study adhere to the IRB-approved research plan.

C. Qualifications for Principal Investigator and/or Mentor designation

1. Full time faculty may serve as Principal Investigators and mentors.

2. Faculty, who do not meet the qualifications stated above, may serve as co-investigators but not as Principal Investigators. In unique situations, the Provost, may waive this constraint provided a mentor is added to the study.

3. MUSC trainees in good academic standing may function as Principal Investigators with the inclusion of a faculty mentor.

4. Non-faculty MUSC employees may function as Principal Investigators with the inclusion of a faculty mentor.

5. A Principal Investigator and the mentor are both responsible for the conduct of the human research. For studies in the ERMA system (HR#), these responsibilities are outlined in the IRB documents signed by the Principal Investigator and mentor. For studies in the eIRB system (PRO#), these responsibilities are on the Principal Investigator Assurance SmartForm page electronically signed by the Principal Investigator.

Mentor Responsibilities

1. The Mentor will review the study protocol prior to submission to the IRB to ensure that the study has a valid research question and the research procedures are sufficient to answer the research question.

2. The Mentor will meet with the Principal Investigator on a regular basis to monitor study progress.

3. If the Mentor will be unavailable for an extended period of time (e.g. on sabbatical or extended leave), s/he will arrange for an alternate faculty Mentor to assume responsibility during the absence. The Mentor will advise the MUSC IRB in advance by letter and change in personnel amendment of such arrangements.

D. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the 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)

have additional operational and review requirements. Researchers are responsible for communicating with the Program Officer of the Federal Funding Agency to ensure that all requirements of the Federal Funding Agency are met prior to starting an IRB approved study. Information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>) includes links to the regulations for the Federal Funding Agencies.

E. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. GCP

standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUSC polices, procedures and forms require investigators to comply with most ICH-GCP guidance. 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>).

II. Memorandum of Understanding

In aspects 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".

III. Procedures

A. No research will be initiated without prospective IRB review and approval.

B. The study protocol conforms to DHHS and where applicable, FDA regulations ([21 CRF 312] and [21 CFR 812) and institutional policy for investigational drugs, biologics and devices.

C. Principal Investigators must certify to the IRB that any changes in the approved research will not be initiated until the IRB has reviewed and approved these changes.

D. Informed consent is obtained, when applicable, in accordance with IRB-approval.

E. Promptly report to the IRB any serious or recurring problems, unanticipated problems involving risk to participants or others, or adverse reactions experienced by a subject.

F. Promptly report to the IRB any problems related to the conduct of a study or subject participation (including those in the recruitment or consent process).

G. Data and Safety Monitoring Board/Data Monitoring Committee or other monitoring group reports are submitted promptly to the IRB for review.

H. The Principal Investigator must submit a continuing review application 30 days prior to expiration of IRB approval in accordance with IRB Policy.

I. The Principal Investigator will report premature completion of a study to the IRB.

J. A final continuing review report is submitted to the IRB when the research is completed or terminated prior to completion.

K. The Principal Investigator must maintain an accurate and complete accounting of all investigational drug/device records, and clinical study materials received, dispensed, and returned to the Sponsor as required by the IRB, and when applicable, the sponsor or FDA. These records must be maintained in the study site regulatory binder for the required retention time.

L. All records must be accessible for inspection and copying by authorized MUSC officials and federal representatives (including HHS, FDA, and VA) upon request.

IV. References

A. Guidance based on United States. U.S. Dept. of Health and Human Services, Food and Drug Administration, et al. Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators. Draft Guidance May 2007