Policy Name: **Principal Investigator Responsibilities – Supervision of Staff and Protection of Subjects**			
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I. POLICY

A. Introduction

MUSC investigators are granted the privilege of using 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 their 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.

All 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 understand the research being conducted.

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 PI or other identified qualified individual(s) must assure that during and following a subject's participation in a trial reasonable medical care is provided to a subject for any adverse events related to the trial.

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

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

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

II. PROCEDURES

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

B. The protocol study 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. 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 patient 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 PI must submit a continuing review form 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 PI and/or study coordinator 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.

III. 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