Policy Name: **Approval of Research Activities by the IRB**			
Approved			**Date: 11/01/08**
Effective Date: 02/20/09	**Page 1 of 3**	**Section: HRPP 2.4**	**Policy Number: N/A**
Replaces Policy: N/A			**Dated: N/A**

I. POLICY

A. Introduction

The Institutional Review Boards of MUSC have the responsibilities, Ethical Principles, Authority and Independence as specified in HRPP Guide Section 2.1, function as specified in HRPP Guide Section 2.2 and are comprised of a membership as specified in HRPP Guide Section 2.3.

B. Approval of Research Activities

In order for the IRB to approve research, all of the following requirements below must be satisfied (46.111 and 21 CFR 56.111) These review criteria are used for initial, continuing review, and review of modifications

1. Risks to subjects have been minimized by using sound research design, or, whenever appropriate, using procedures already being performed on the subject for diagnostic or treatment purposes.

2. Risks, physical, psychological, social and economic, are reasonable relative to anticipated benefits.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Compliance with all requirements (MUSC policies and to the extent required by §46.116) for informed consent, including seeking consent only under conditions that allow the subject or the subject's legally authorized representative sufficient opportunity to consider whether or not to participate, and that minimize the opportunity for coercion or undue influence.

5. Documentation of informed consent is required, in accordance with, and to the extent required by MUSC policies and §46.117.

6. A Data and Safety Monitoring Plan, when appropriate, is included to assure the safety of the human subjects, and the validity of the data generated.

7. If the research subjects include a vulnerable group, additional safeguards have been included to protect the rights and welfare of these subjects and that all special requirements for the populations have been adequately addressed.

8. Provisions are adequate to protect the privacy of subjects and maintain confidentiality of the data.

9. Research deemed to be greater than minimal risk will undergo full board IRB review and approval. Research deemed to be minimal risk may be reviewed by the expedited review or may be exempt from IRB approval.

In addition, for a study to be approved by the MUSC IRB, the study must be scientifically sound, ethically appropriate and meet the federal regulatory criteria for approval.

II. PROCEDURES

A. Duration of Approval

1. Unless renewed, a protocol is active for one year. The expiration date, the last day the protocol is approved, is calculated as 365 days after approval. The calculation of the approval period is based on the date of the convened meeting at which the IRB approves the protocol and not on the date when the reviewer approves any requested modifications.

2. For all approved research protocols, including initial reviews, continuing renewals and amendments, the IRB may determine that the research risk is of significant magnitude meriting review more frequently than on an annual basis. Examples of increased risk include sensitive issues (HIV and AIDS), vulnerable populations (school children) and safety (protocol deviations and AEs).

B. Notification of Investigators

The IRB provides the investigator with written notification of decisions to approve or disapprove research and of modifications required to secure IRB approval of the research activity; the written notification includes rationale for the decision and the investigator is given an opportunity to respond in person or in writing. If the research protocol is approved, the investigator is notified in writing of the following requirements: 1) only IRB

approved copies of consent document(s), questionnaire(s), letter(s), and advertisement(s) may be used; 2) IRB approval must be obtained if any modifications or changes to the protocol and consent document(s) prior to initiation of the proposed changes; 3) reporting requirements for any unanticipated problems experienced; and, 4) expiration date of IRB approval.

C. Notification of the Institution

The MUSC Organizational Officials receive copies of the IRB meeting minutes, as do the VA Associate Chief of Staff for Research and the VA Research and Development Committee.

D. Review and Approval by Other Committees/Departments

When the research protocol involves the use of investigational drugs, biologics, exposure to ionizing or non-ionizing radiation, cancer patients, use of the General Clinical Research Center, or inclusion of VAMC patients, the approval of the relevant ancillary committee is required prior to activation of the study or enrollment of subjects.

The committees involved include the:

1. Institutional Biosafety Committee;
2. Radiation Safety Committee;
3. Investigational Drug Pharmacy;
4. Hollings Cancer Center Protocol Review Committee;
5. General Clinical Research Center Advisory Committee; and,
6. VAMC Research and Development Committee.

E. HIPAA Privacy Review

MUSC IRBs are designated by MUSC to review authorization for use and disclosure of protected health information involved in research protocols and to grant waivers of, or alteration to, such authorizations using the standards and procedures specified in the HIPAA Privacy regulations (45 CFR Parts 160, 164 – specifically 45 CFR 164.508 and 164.512).