MUSC
Medical University of South Carolina

I. Policy

A. Introduction

The Institutional Review Boards of MUSC have the responsibilities, Ethical Principles, Authority and Independence as specified in HRPP Guide 2.1.

B. Functions of the IRB

The IRBs are responsible for ensuring the following:

1. subjects are adequately informed of the nature of the study;
2. subjects' participation is voluntary;
3. risks to subjects are minimized and reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the studies;
4. risks and benefits of the study are evenly distributed among the possible subject population;
5. adequate provisions for monitoring research activities are in place to protect the safety of research participants;
6. adequate provisions are in place to protect the privacy of research participants and to maintain the confidentiality of research data;
7. informed consent is sought for prospective participants;
8. initial and continuing review of all human research protocols under the purview of the IRB;
9. written reports conveying the findings and actions of the IRBs are provided to the investigator, the Organizational Officials and the Director -VA Research and Development as appropriate;
10. studies are evaluated to determine if they require review more often than annually;

11. studies are evaluated to determine if they need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

12. changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects and others;

13. prompt reporting of IRB board determinations to appropriate Organizational Officials, OHRP, FDA, and appropriate sponsors or agencies of unanticipated events involving risks to subjects or others, and/or serious or continuing noncompliance with regulations governing research involving human subjects or the requirements of the IRB;

14. IRB approval of studies in violation of policy are suspended or terminated;

15. adequate additional protections are provided for vulnerable populations used as subjects in research;

16. studies are evaluated to determine if an IND is required when drugs are used in research;

17. studies are evaluated to determine if devices meet the definition of a significant risk device or a non-significant risk device according to guidance provided by the FDA; and,

18. consult and monitor the emergency use of an IND and IDE test article.

C. Interaction with Sponsors

MUSC requires a written and signed contract/agreement from all sponsors of proposed research activities conducted by the University and its affiliates. All such contracts and funding agreements include language that obligates MUSC and the investigators to follow the protocol, applicable regulations, and ethical principles and guidelines related to the protection of human subjects in research.

D. 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".