MUSC
Medical University of South Carolina

I. Policy

A. Introduction

Human research protection activities are overseen by the Program Director of the MUSC IRB who reports to the Director of the Office of Research Integrity and the MUSC Associate Provost for Research.

B. Appropriate Number of IRBs

MUSC will maintain an appropriate number of IRBs to accomplish timely and thorough review of MUSC's human subjects research activities. Establishment of IRBs will be based on the volume and types of research activities engaged in by MUSC.

II. Procedures

Each IRB is supported by qualified and dedicated staff possessing the skills required to support the research activities assigned to their Board.

A. IRB Program Director

The IRB Program Director will be appointed by the Director of the Office of Research Integrity. The responsibilities of the Program Director include but are not limited to:

1. Manage the IRB Staff;

2. Ensure there are necessary resources required to perform regulatory functions;

3. Supervise orientation and training of all new members and ensure appropriate continued training is provided to IRB staff and members;

4. Act as the liaison with all University/ Medical Center departments/ divisions;

5. Coordinate with the University Compliance Office, the Office of Research and Sponsored Programs, and the Office of Grants Accounting regarding compliance on regulations and policies associated with new, continuing, and competing proposals involving human subjects;

6. Provide advice on regulatory compliance to University Officials and Committees;

7. Administer policy on the protection of human subjects and advise on appropriate revisions in policy and procedures;

8. Advise IRB member on review requirements and criteria for approval;

9. Advise investigators and study team members on all matters related to compliance with the protection of human subjects related to IRB requirements; and,

10. Educate the University community regarding human research protections.

B. IRB Administrators

The responsibilities of the IRB Administrators include but are not limited to:

1. Review IRB submissions and keep IRB members aware of current regulations and policies/procedures;

2. Interpret and apply federal and state laws, regulations, policies, and guidelines related to human subjects research;

3. Prepare correspondence on IRB deliberations and contingencies for approval of research activities;

4. Develop and present materials and training materials for IRB members and research teams;

5. Provide orientation and training to new staff members and IRB members;

6. Prepare and distribute Board meeting agenda and attend meetings of the IRB; and,

7. Prepare minutes within the time frame specified.

The competency of all the staff is supplemented by educational opportunities as designated in the HRPP Program Guide Section 10.3 “Quality Improvement Initiatives within the Human Research Protection Program of MUSC.”

C. Review of Resources

During the annual assessment of budgets and fiscal needs, the Director of the Office of Research Integrity and the Associate Provost for Research meet with the Program Director of the MUSC IRB to discuss resource requirements. At that time a formal assessment of the upcoming fiscal year is made. Issues are addressed regarding staffing and financial resources for the support of the IRB chairs, education and training, office operations, and new initiatives.

The volume of materials processed by the IRB is reviewed annually and as required to determine need for additional staffing or changes in procedures to increase efficiency and maintain an adequate level of support for all Boards and human research activities conducted at the University. This allows the Associate Provost for Research to maintain an accurate understanding of the level of work and resource requirements of the IRB and the IRB chairs.