



<b>Policy Name: Scientific/Scholarly Review of Protocols Policy and Procedures</b>		
Approved		
Effective Date: <b>01/27/2012</b>	Page 1 of 2	Section: HRPP 1.4
Replaces Policy: 02/20/2009		

## **I. POLICY**

### **A. Introduction**

Each department chairman or center director is ultimately responsible for the review and scientific integrity of any proposal that will be sent to the IRB. In the case of most centers, such as the Hollings Cancer Center, Clinical and Translational Research Center (CTRC), and the Alcohol Research Center, there are standing committees of scientists, physicians, statisticians, and other health professionals that review protocols for scientific integrity prior to review by the director or chairman's office. The evaluation of the available non-clinical and clinical information on an investigational product is adequate to support the proposed clinical trial.

### **B. Large Clinical Research Departments**

Some large clinical research departments, such as Medicine and Psychiatry, have a vice-chair designated to review scientific integrity and merits of research protocols. Vice-chairman for research review research documents personally or delegate them to individuals with greater scientific expertise in the area of the proposed research topic.

### **C. Routing**

There is a system of electronic routing tracts within departments and centers that ensures that proposals are reviewed and signed off by a consistent and appropriate group of faculty and staff responsible for oversight. Within departments and centers, fellows and junior faculty are usually assigned a senior faculty mentor to guide scientific literature review, research methodology design, statistical analytical procedures, discussion of best clinical practices and the bioethics of human scientific research. Other resources for scientific review available to investigators include the statistical clinical trials group in the Biometry & Epidemiology Division of the Department of Medicine, the Master in Clinical Science Research faculty, and the recently developed Research Navigation Services in the SC Clinical and Translational Research Center. All of these divisions are available for consultation on design, methodology, statistics, and ethical issues.

#### **D. VAMC**

If the Ralph H. Johnson VA Medical Center's Research and Development Committee conducts scientific review, the review is communicated to the Medical University of South Carolina's IRB.

1. The Research and Development Committee may delegate scientific review to the affiliate IRB.
2. The Research and Development Committee may delegate scientific review to a different process at the VA or affiliate, and the review is communicated to the affiliate IRB.

#### **E. Guidance on Additional Requirements of Federal 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. 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) (<<http://research.musc.edu/ori/irb/resources.html>> ).

#### **F. IRB Responsibilities for Minimizing Risk**

1. The IRB is responsible for determining that risks to subjects are minimized by:
  - a) Using procedures which are consistent with sound research and design and which do not unnecessarily expose subjects to risks,
  - b) Using procedures, whenever appropriate, already being performed on subjects for diagnostic or treatment purposes,
  - c) The IRB Chair, in consultation with the IRB Administrator, assigns studies to Primary Review Groups relative to expertise of the members, and

- d) If vulnerable populations are involved, the IRB Chair, in consultation with the IRB Administrator, assigns one or more IRB members experienced in working with the specific vulnerable population.
- 2. When appropriate expertise is not available among members of the IRB assigned to review the proposed research activities, the IRB will obtain consultation from experts with relevant expertise and knowledge to assist in further evaluation of the scientific design and to provide an in-depth review of the study. If appropriate expertise is unavailable at a meeting, discussion of the protocol will be deferred until such time as appropriate expertise may be obtained.
- 3. The IRB will defer review until necessary expertise and in-depth review can be obtained through the current membership or consultation.

## II. PROCEDURES

- A. An initial application submitted for either full board or expedited review by the IRB must provide adequate documentation to demonstrate the methodology and procedures are consistent with generally accepted scientific principles in the discipline.
- B. Each application must also include a Statement of Assurance which includes the electronic signature of the Principal Investigator's department chair or his/her designee indicating concurrence with the scientific merit of the proposal.
- C. The application will be assigned to an appropriate member of the IRB for primary review of the Chair will seek outside consultation to provide an in-depth review.
- D. In addition, if a member of the primary review team cannot adequately evaluate the scientific merit and scholarly validity of an assigned protocol, (s)he will notify the Chair to discuss the use of another member of the IRB or whether it is necessary to obtain a consultant to assist in the review or request that the investigator provide additional information and/or be present for IRB discussion.

## III. REFERENCES

- A. [Master in Clinical Science Research](#)
- B. [Research Navigation Services in the SC Clinical and Translational Research Center \(SCTR\)](#)