



## **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 and function as specified in HRPP Guide Section 2.2.

### **B. Membership – General**

Each MUSC IRB is composed of at least five members with varying backgrounds to ensure complete and adequate review of research activities commonly done at the institution. The IRB composition may not consist entirely of one profession. The IRB must have at least one member whose primary interest is scientific, one member whose primary interest is in a non-scientific area, and at least one member who has no affiliation with MUSC and has no immediate family member affiliated with MUSC. Each IRB has at least one member who represents the perspective of the research subjects. In order to ensure that the integrity of the review process is not compromised by competing business interests, individuals involved in research development do not serve as members of the IRB.

### **C. Ethnic Diversity and Appropriate Expertise**

Members include both men and women and members of various ethnic groups. The membership includes individuals with the expertise to review the breadth of research conducted at MUSC including vulnerable subjects, research involving neonates, children, pregnant women, mentally disabled individuals, and persons with impaired decision-making capacity. A qualified member is available to serve as the “prisoner representative” as needed.

### **D. Designated and Alternate Members**

Designated and trained alternates are used to supplement membership. The IRB roster will list the regular member and specify alternate(s) who are authorized to substitute for each regulator member. Alternate members will have qualifications comparable to those of the regular members and will serve in the same representative capacity as the member for whom they

substitute. Alternates may attend any IRB meeting, but their vote will only count when serving as the substitute for the regular member.

#### **E. Documentation of IRB Membership**

The IRB minutes will document each alternate's status, vote, and attendance as they relate to IRB actions and quorum requirements. When an alternate attends a meeting as a substitute for a regular member, the alternate's participation counts toward the quorum requirements.

#### **F. MUSC IRB and the Ralph H. Johnson VA Medical Center**

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".

The MUSC IRBs serve as the IRBs for the Ralph H. Johnson VA Medical Center. Furthermore,

1. Each IRB includes two or more VA employees who hold a minimum of 5/8<sup>th</sup> VA-compensated appoints to serve as voting members unless a waiver is obtained from the chief research and development officer. These individuals serve as full members of the IRB and review non-VA research and all research matters brought to the Boards. At least one VA member must be present during full board review of VAMC human subjects research. These representatives are appointed to the IRB board by the VAMC Medical Center Director following VA Handbook 1200.05.
2. The VA IRB Liaison and/or research compliance officer serves as a non-voting consultant to all the boards and attends every IRB meeting to provide guidance regarding VA regulations. The VA IRB Liaison and/or research compliance officer may not serve as a voting or non-voting member of the IRB.

## **II. Procedures**

### **A. Recruitment and Selection of Members**

0. Affiliated physician, scientist and nonscientist members shall be recruited by the Vice President for Research and the ORI Director

through the departmental chairs or units or through current IRB members.

1. Persons not affiliated with MUSC shall be recruited through current members or the volunteer department of various community agencies or groups. These may be physicians, scientists, and nonscientist representing the local community.
2. New members shall be recruited as needed to ensure that the memberships of the IRBs continues to include individuals with varying backgrounds and the necessary experience or expertise to review the scope of the biomedical and behavior research conducted by MUSC and VAMC

## **B. Member Designations**

Members shall be designated as either: (1) physician-scientists, other scientist or nonscientists; (2) affiliated or unaffiliated; and, (3) voting member or alternate voting member.

1. Physician-Scientists are members who have a medical degree. Other Scientists are members who have substantive training or experience in a scientific discipline or a scientific method, while nonscientists are those members without substantive training or experience in these areas.
2. Affiliated
  - a) members, or their immediate family members, who are affiliated with any component of the Medical University of South Carolina. "Immediate family member" is defined as spouse, domestic partner, child, parent or sibling. "Affiliated" is defined as having an employment relationship with, a professional relationship with, a paid consultant relationship with, a trustee/governing board member relationship with, or being a student of the entity or component.
  - b) Unaffiliated refers to members, or their immediate family members, who are not affiliated with any component of the Medical University of South Carolina.
3. Voting Members
  - a) those who are required to vote or abstain from voting on each research activity considered by the IRB panel when they are present for the discussion and vote.

- b) Alternate Voting Members are those who are required to vote or abstain from voting on each research activity considered by the IRB panel when they are present for the discussion and are substituting for a regular member.
4. Ex-officio Members are those who may be appointed to the IRB depending on the relevance of their office and their expertise and experience. Ex-officio members are not voting members of the IRB

### **C. Appointment and Reappointment**

1. **The IRB Chairs, Co-chairs, Vice- Chairs, and members will be appointed by the Vice President for Research for three year terms. They may serve consecutive terms.**
2. The IRB Chair must have been a member of the MUSC IRB for at least two years and participated in research as an investigator. The Vice President for Research is responsible for appointing a replacement if a Chair cannot complete the three year term for any reason. The Chairs are familiar with regulatory requirements and ethical considerations related to human research. When appointing an IRB Chair or Vice-Chair the Vice President considers the following factors: academic appointment and position of leadership; experience with IRB and human subjects research protection issues; clinical expertise; willingness to commit the time required; and skills involved in presiding over committee affairs. The competency of the Chairs is supplemented by educational opportunities such as attending the annual national PRIM&R human research protections conference and workshops, participating in MUSC IRB related workshops, and other opportunities as designated in the Quality Improvement Initiatives within the Human Research Protection Program of MUSC HRPP Guide Section 10.3.
3. An IRB Chair or Vice-Chair may be compensated for his/her duties.
4. VA representatives to the IRB are appointed by the Ralph H. Johnson VAMC Medical Center Director at least every three years. The appointment letters are retained by the Research & Development (R&D) committee of the VAMC

### **D. Resignation**

Any member of the IRB may resign through a written resignation submitted to the ORI Director and Chair of that IRB.

### **E. Suspension or Removal of Members**

Any member of the IRB can be removed by the ORI Director or Chair of the IRB for failure to perform functions and responsibilities, provided that such member is given reasonable notice of the grounds for the suspension or removal and an opportunity to be heard.

**F. Periodic Review of Membership**

The membership shall be reviewed at least annually to determine 1) if the membership continues to include individuals with varying backgrounds, experience and scientific/scholarly expertise needed to review the scope of the research conducted by MUSC and VAMC and 2) if members are able to fulfill the responsibilities of the IRB.

MUSC recognizes that membership on the IRB boards is voluntary and the members provide an essential service to MUSC. With this in mind, it is the intent of MUSC that the reviews of IRB membership serve multiple purposes. In addition to those 2 goals above, the review provides a platform for members to assess their ability to fulfill their responsibilities and identify how MUSC can strengthen the skills and abilities of our members to fulfill their responsibilities.

Annually, each IRB Chair and Vice-Chair will complete a self-evaluation of his/her performance and provide this to the IRB Program Manager. This evaluation covers the following areas: leadership, preparedness, knowledge of regulations and regulation procedures, and identification of areas for improvement. The Director of ORI and the IRB Program Manager will review these self-evaluations and then meet individually with each IRB Chair and Vice-Chair in order to provide performance feedback and evaluation of Board effectiveness. Such feedback and discussion will include Board metrics, attendance, Board composition, member performance, administrative support, and other issues as appropriate. This process will also provide an additional mechanism for the Chair and Vice-Chair to provide input on overall operations and suggestions for continuing education and quality improvement. Each Chair and Vice-Chair will receive a letter summarizing the overall discussion and feedback.

Annually, each Board member will complete a self-evaluation of his/her performance and provide this to the IRB Program Manager. This evaluation covers the following areas: preparedness, knowledge of regulations and regulation procedures, attendance, identification of areas for improvement, and timeliness of receipt of meeting materials. The Director of ORI and the IRB Program Manager will discuss these self-evaluations with the relevant Administrator, Chair, and Vice-Chair from each IRB. Based on these discussions and member self-evaluations, the Director of ORI and IRB Program Manager may schedule meetings with any members if concerns

come to light. This process also provides an additional mechanism for the IRB members to provide input on overall operations and suggestions for continuing education and quality improvement. All members receive a letter summarizing the evaluation, comments, suggestions and feedback.

After completion of each review, the ORI Director will convey in writing to the Vice President for Research a summary of the IRB Membership Review.

#### **G. Liability of IRB Members**

IRB members and alternates fulfill their administrative and institutional service responsibilities to the University, in part, by serving on an IRB committee. Accordingly, the University will indemnify IRB members in the event of a legal dispute relating to the actions of the committee, provided that the IRB member has acted in good faith and in accordance with federal requirements, state and local laws and University policy.

#### **H. Membership Records**

Information on membership for each IRB panel is maintained by the Office of Research Integrity and includes:

1. Name;
2. Degrees;
3. Status (i.e., physician-scientist, other scientist or non-scientist);
4. Expertise
5. Affiliation with the Medical University of South Carolina or the VAMC, if any, by the member or immediate family member.
6. Contact information
7. Position on IRB
8. Membership status
9. Representative capacity
10. Alternate members and the primary members or class of primary members for whom each alternate member could substitute.

The Office of Research Integrity shall be responsible for updating the membership roster and IRB registration information as needed when membership changes and submitting the updated information to OHRP as required by the Institutions' FWAs. IRB rosters shall be retained a minimum

of five (5) years and shall be made available upon request when applicable to the NIH and FDA for inspection and copying onsite during normal business hours. Individual membership records shall be retained by the Office of Research Integrity a minimum of five (5) years from date of last service.

Curriculum vitae/resumes are on file for all members and alternates.

## **I. Use of Consultants**

The IRB administrator, the IRB chair, and/or any voting member may request that additional expertise be made available to supplement the expertise of the Board members. The decision to use a consultant will be documented on the IRB administrator checklist. The Chair and Director of the IRB are responsible for securing this expertise. The required expertise will be sought among the MUSC faculty if available and without a conflict of interest in accordance with *IRB Member and IRB Consultant Conflict of Interest Policy (Section II.L below)*. If the expertise is not available within the MUSC, external consultants will be secured. The Chair or designee will specify the concerns/questions requiring expert review and will notify the principal investigator that additional expertise has been secured to review the protocol and/or related documents. The IRB Administrator will ensure the expert has all the materials required to review and address the concerns/questions. Depending on the request and need for the additional expertise, the chair will ask the expert(s) to discuss concerns/questions with a Board member, document his/her review, and/or attend the relevant convened Board meeting, but will not be allowed a vote.

## **J. Member Orientation, Education and Training**

### **1. Orientation**

The Office of Research Integrity shall provide new members with the MUSC IRB Governance and Operating Procedures, all IRB policies and relevant Federal and State regulations.

### **2. Education and Training**

IRB Chairs, IRB members, IRB staff involved in the review of human subjects' research applications are required to successfully complete the CITI University of Miami on-line tutorial prior to reviewing applications.

#### **Continuing Education and Training**

Members are required to take Refresher course 101 of the Collaborative IRB Training Initiative (CITI) program for biomedical or

social and behavioral research every three years. All members shall receive copies of various IRB-related publications and new and updated guidance documents from the FDA, OHRP or other governing agencies. Additional education and training opportunities are available as designated in the HRPP Program Guide Section 10.3 "Quality Improvement Initiatives within the Human Research Protection Program of MUSC".

## **K. Responsibilities of Members**

### **1. Chair(s) and Co-Chair(s)**

The responsibilities of the Chair(s) and Co-Chair(s) include but are not limited to the following:

- a) Preside over convened meetings of the IRB;
- b) Call special meetings when necessary;
- c) Assure appropriate assignment of reviews to IRB reviewers;
- d) Review of exempt or expedited submissions and determination of appropriate review levels;
- e) Review of reported problems and determining whether they are unanticipated problems involving risks to subjects or to others;
- f) Advise investigators and study team members;
- g) Recommend committee members for appointment to the IRB;
- h) Make decisions in emergency situations to protect subjects and remain in compliance with regulations;
- i) Inform IRB and University Officials of developing problems;
- j) Designate Vice-Chair or experienced IRB members to perform expedited review procedures either by permanent assignment or on an ad hoc basis;
- k) Appoint subcommittees of the IRB;
- l) Relate concerns of the IRB staff and members to administration regarding issues in human research review;
- m) Serve as liaisons with the University Committees;
- n) Perform all regulatory duties;

- o) Educate the University community regarding human research protections; and
- p) Maintain a working knowledge of federal human subjects regulations through continued education and training.

2. Vice-Chair(s)

The responsibilities of the Vice-Chair(s) are to:

- a) Preside convened meetings of the IRB in the Chair's absence;
- b) Assist the Chair with review procedures as delegated;
- c) Chair Subcommittees;
- d) Perform all duties of the Chair in the Chair's absence; and
- e) Maintain a working knowledge of federal human subjects regulations through continued education and training.

3. Members

The responsibilities of the Members are to:

- a) Attend meetings and plan to be present for the entire meeting;
- b) Contact the IRB Administrator if unable to review for a meeting and arrange their replacement from the alternate reviewer list;
- c) Examine all review materials in preparation for the convened meeting to which they are assigned;
- d) Contact investigators as necessary to resolve questions and concerns and notify the IRB Administrator of these discussions and outcomes;
- e) Present primary reviewed protocols to the Board as requested;
- f) Advise the IRB Administrator and the Board of any conflict or perceived conflict of interest with any business of the IRB and to refrain from reviewing materials, participating in the discussion and voting when a conflict of interest is identified;
- g) Participate in subcommittee activities;
- h) Protect the confidentiality of all materials provided and all business conducted;

- i) Acquire and maintain a working knowledge of federal human subjects regulations through education and training requirements for IRB members; and,
- j) Act as the Chair's designee as required.

#### **L. IRB Member and IRB Consultant Conflict of Interest Policy**

Federal regulations prohibit a member of the institutional review board (IRB) or consultant to the IRB from participating in the initial or continuing review of any project in which the member or consultant has a "conflicting interest," except to provide information at the IRB's request in accordance with 45 CFR 46.107(e)

Definitions for the following terms may be found in HRPP Guide Section 1.3 – Definitions of terms:

- **Conflict of interest in science**
- **Financial conflict of interest**

IRB members complete the **IRB Member Conflict of Interest Statement** annually. At the start of every Board meeting, Board members will be asked to disclose any conflict of interest they may have with the business before the Board. This discussion will be documented in Board meeting minutes and as well as actions taken to minimize the impact of this conflict.

Any Board member who is a member of the research team of a study presented to the IRB for initial review, continuing review and/or modification will leave the Board room during discussion of the study and during the Board members voting process. This includes the roles of principal investigator, co-investigator, mentor and consultant. IRB members with a conflict of interest will not be counted toward quorum during discussion of the conflicted item. This action will be documented in the Board meeting minutes.

**IRB Consultants** complete the **IRB Consultant Conflict of Interest Statement** upon acceptance of the request for providing consultant services. If, upon review of the **IRB Consultant Conflict of Interest Statement**, the IRB Administrator and/or Chair, an actual or perceived conflict is identified, the consultant will be replaced with an alternate consultant. At the start of the board meeting in which the individual is providing consulting services, the consultant will disclose any conflict of interest they may have with the protocol before the board for which the IRB consultant is providing services.

Individuals who are responsible for business development at the Medical University of South Carolina are prohibited from:

- Serving as members or ex-officio members on the IRB.
- Carrying out day-to-day operations of the review process.