



# **Stratton VA Medical Center IRB Standard Operating Procedure: Membership & Management**

## **POLICY**

It is Stratton VA Medical Center's policy to comply with all applicable federal, state and local regulations, and ICH guidelines in the conduct of human subject research studies. Written procedures are required to detail the membership and management of the IRB for review of research.

## **REFERENCE DOCUMENTS**

45 CFR 46

21 CFR 50, 56

38 CFR 16

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

## **PROCEDURE**

All CV's of potential IRB Chairs, Vice-Chairs, or members are reviewed by the ACOS R&D to ascertain the background and qualifications of the potential member.

At the discretion of the ACOS R&D, CV's of potential members may be forwarded to the IRB for review and approval.

The Medical Center Director appoints the Chair and Vice-Chair of the IRB in writing.

The appointments are for one year and may be re-appointed indefinitely in writing.

Qualification for the IRB Chair and/or Vice Chair:

Served on an IRB for at least one year (in capacity as a member, Chair or Vice Chair.)

Have professional competence to review research activities.

Qualified through scientific or scholarly expertise.

Knowledgeable of institutional commitments and regulations, applicable law and standards of professional conduct and practice so as to be able to ascertain the acceptability of proposed research in terms of these issues.

### **Appointments by Director**

The Medical Center Director appoints IRB members in writing.

Recommendations for IRB membership are made by IRB members and R&D Committee members according to the needs of the IRB. Members are selected based on background, qualifications, and the diverse needs of the IRB. Potential conflicts of interest are taken into consideration in the selection of new members.

Other VA personnel may submit names to the IRB or R&D Committee to be forwarded to the committees or Medical Center Director for consideration.

Members of the VA IRB must be appointed by the Medical Center Director for a period of 3 years, and may be re-appointed indefinitely. Members may resign from the IRB at any time.

IRB members are voting or non-voting members.

The ACOS R&D, AO for R&D, the Research Compliance Officer, the ISO and the PO serve as ex-officio non-voting members of the IRB. R&D administration officials may not serve as voting members of the IRB.

All other members are voting members.

### **IRB Appointment Assurances**

The Medical Center Director appoints IRB members to ensure that:

The IRB has at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The members of the IRB are qualified through scientific or scholarly expertise and diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, and promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB includes persons with the professional competence necessary to review research activities regularly reviewed by the IRB.

The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice so as to be able to ascertain the acceptability of proposed research in terms of these issues.

The IRB includes one or more individuals who are knowledgeable about and experienced in working with categories of vulnerable subjects involved in research regularly reviewed by the IRB such as handicapped or mentally disabled persons.

In a non-discriminatory manner, the IRB does not consist entirely of men or entirely of women, or consist entirely of individuals from one profession. No member will be selected to serve on the IRB merely on the basis of gender.

The IRB includes at least one member whose primary expertise is in scientific areas, and one member whose primary expertise is in non-scientific areas.

The IRB includes at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB includes one member who is a licensed physician when research involving FDA regulated articles is being reviewed.

The IRB cannot have a member participate in the review of research in which the member has a Conflict of Interest, except to provide information requested by the IRB.

### **Scientific and other Specialized Reviews**

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that available on the IRB.

Consultants are not considered IRB members and do not vote.

Any IRB member may request a consultant by making a verbal or written request to the IRB Chair or designee.

The IRB Chair or designee will review the qualifications of the consultant prior to the consultant's participation in the review of the research and have them declare on the Primary Reviewer Form whether or not they have a conflict of interest. Essentially, conflict of interest is self-reported.

Consultants will be identified on agendas and minutes as "outside reviewers."

If a consultant is identified as having a conflict of interest, then the conflict of interest administrator (COI), which is the ACOS/R at Stratton VAMC, will consider how serious the conflict is. If the ACOS/R determines that the conflict is significant, then the consultant will not be allowed to provide information to the IRB. If a non-significant conflict of interest is identified, then:

- They disclose their conflicts of interest to IRB members reviewing the research.
- They are excluded from discussion except to provide information requested by the IRB.
- They leave the meeting room for discussion and voting.

Examples of Significant COI are:

- Ownership of stock or other financial interest greater than \$10,000, related to a project
- Immediate family member/s who have a role in the project
- A competitive interest in similar projects

IRB members review proposed research at convened meetings at which a majority of the voting members of the IRB are present, including at least one voting member whose primary expertise is in nonscientific areas and a licensed physician if the research involves an FDA regulated article, and that quorum is met and maintained.

In order for research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

Conference calls or video-conference procedures may be used at a convened meeting, if a member has received copies of the documents that are to be reviewed at the meeting. The member may vote and be considered as part of the quorum.

IRB members may not participate in the review of any research in which the member has a conflict of interest, except to provide information requested by the IRB. The research will not be voted upon should quorum be lost due to the absence of the member(s) with a conflict of interest.

IRB members with a conflict of interest in the research are expected to declare the basis of the conflict to the IRB prior to the review of research. At the start of each IRB meeting, the Chair polls the members of the IRB to determine if any have a conflict of interest associated with any of the items noted on the agenda, which was provided to them approximately one week in advance. Any conflicts that are declared are noted in the meeting minutes; negative responses are noted as well. If a conflict of interest is identified, then the individual member is asked to leave the room and recuses themselves during any discussion or voting on the related items.

The IRB may consider the comments of members who cannot attend the convened meeting. Absent members are not considered in the quorum or voting of IRB meetings.

### **Alternate IRB Members**

The Stratton VA may use alternate members for the IRB.

The Medical Center Director appoints alternate IRB members in writing.

The term of appointment is the same as the term of the primary member.

The IRB roster will identify the primary IRB member for whom the alternate member may substitute.

The alternate member's qualifications must be comparable to those of the primary member to be replaced.

When an alternate member replaces the primary member at a convened meeting, the primary member must assure the alternate member receives and reviews the meeting materials in advance of the meeting.

The alternate member has the same privileges as the primary member, i.e. reviews and votes on protocols at a convened IRB meeting.

The alternate member should receive the same IRB training as primary members.

The alternate should attend as many IRB meetings as possible, even when not required to be present as a formal alternate.

The IRB meeting may not be conducted if alternates constitute the majority of the members present.

The IRB minutes must document when an alternate member replaces a primary member.

### **Periodic Evaluations and Reporting of IRB Activity is conducted by reviewing the following:**

#### **Periodic evaluation of performance of the IRB Chair and members**

All IRB members are required to attend at least 6 out of 12 IRB meetings per calendar year, with the exception of those members covered under a Memorandum of Understanding (MOU).

CV's are reviewed annually by the Chair of the IRB and the ACOS of R&D

Number and type of reviews done by the Chair and members are reviewed by the ACOS/R and HRPP Coordinator

Conflict of Interest disclosure are reviewed

The Chair will evaluate the performance of the IRB members and the Vice-chair or ACOS/R&D will evaluate the performance of the Chair.

***The certification by the Chair of the IRB of the review of the IRB Committee members, and the evaluation of the Chair by the Vice Chair or ACOS/R (evaluation of attendance record, CV, brief narrative of participatory performance) will be provided to the R&D Committee at least once per year as part of an annual review of subcommittees of the R&D Committee.***

In the absence of the Chair, the Vice-Chair or designee is the acting Chair.

The Stratton VA liability Federal Tort Claims Act (FTCA) covers authorized actions of IRB members taken in their official capacity as IRB members.

The IRB staff maintains a file of the current curricula vitae of IRB members which is periodically reviewed by the Chair or designee.

Any change in IRB membership is reported to Office of Human Research Protections (OHRP) and the Office of Research Oversight (ORO) by the Research Office.

The Medical Center Director, at his or her discretion, may remove IRB members, the Chair or Vice-Chair for cause only after an administrative investigation or other disciplinary action is completed.

A list of scheduled IRB meetings and the membership roster is available on the research website.

A demographic report of the population served by the Stratton VAMC will be reviewed by the committee annually to assure membership and composition of the IRB is appropriate and adequate.

### **IRB Staff Management**

Position description for the HRPP Coordinator is posted through the VA Human Resources (HR) department for qualified candidates; qualifications are determined by trained HR staff.

Qualified candidates are interviewed by a Performance Based Interview (PBI) team

Final selection is done by the ACOS and AO for R&D, taking into consideration the recommendations of the PBI team.

Yearly performance appraisals are done by the AO/R&D (supervisor)

On-site training is done with attention to local policies/procedures and all applicable regulatory documents and guidelines.