Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: VII.A
Section: Committee Roles and Responsibilities
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Composition of IRB Committees

Policy:
It is the policy of the Human Research Protections Program (HRPP) that the composition of IRB Committees is in accordance with federal regulations.

I. Each IRB Committee must include at least one regularly attending member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and one member who is not affiliated with VU or VUMC (i.e. not a family member or spouse of an employee, not an active alumnus). The non-scientist and non-affiliated member may be the same individual.

II. Ex Officio and Administrative Members. Selections for Ex Officio and Administrative Member positions are approved by the HRPP Director based upon the specific needs of the Committees.
   A. Ex officio members, administrative members, invited guests or expert consultants do not have voting privileges.
   B. Ex officio and administrative members on the IRB Committees may include the following
      1. Persons who are automatically members by virtue of the position held and
      2. Persons invited to the Committee by virtue of special knowledge or area of expertise (e.g., the Investigational Drug Service, expert consultant).
   C. Ex officio and administrative members may be replaced on the Committee at the discretion of the HRPP Director, the HRPP Medical Director, the Associate Vice Chancellor for Research, and/or the Vice Provost for Research, Faculty, and International Affairs based upon the Committee needs for specific areas of expertise or performance issues such as a breach of confidentiality, excessive absences, etc.

III. Membership Selection. Selections for IRB Committee member voting positions and Chairpersons for the IRB Committees are made by the HRPP Director to the HRPP Medical Director, the Associate Vice Chancellor for Research and/or the Vice Provost for Research, Faculty, and International Affairs based upon the specific needs of the IRB Committee, e.g. medical specialty, diversity, non-scientist, non-affiliated, etc.
   A. The IRB Committee requests faculty volunteers each year and also seeks the advice of IRB Committee Chairs IRB Committee Members, Division Chiefs, Department Chairs, and Deans in making its recommendations.
   B. Decisions for selecting Committee members are made to assure that the IRB Committees retain diversity while maintaining regulations for required individuals to serve on the Committee.
   C. Committee Chairs and Vice Chairs are selected as highly respected individuals from within or outside the institution, fully capable of managing the IRB and matters brought before it with fairness and impartiality.
   D. The IRB Committee Rosters are posted on the HRPP website at http://www.mc.vanderbilt.edu/irb.
IV. **Number of Members.** The IRB Committees are required to have a minimum of five members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Institution.

V. **Alternates.** Trained alternates formally listed on the IRB roster may vote in place of an absent voting member. Alternates are assigned according to their scientific or non-scientific status, i.e. PS, SS, OS, NS, as indicated on the Committee member rosters, and in accordance with the area of expertise required for adequate review. Meeting minutes must document when an alternate member replaces a voting member.

VI. **Qualifications of IRB Members.**

A. The IRB Committee membership must be:

1. Sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel and
2. Able to ascertain the acceptability of proposed research in terms of institutional commitment, regulations, applicable law, and standards of professional conduct and practice;

B. **Additional Qualities of IRB Committee Members and Chairpersons.**

1. Needs to be committed to the workload;
2. Understand time commitment;
3. Come to meetings prepared for discussion;
4. Commitment to institutional goals for human research protections;
5. Good communication skills;
6. Ability to act as a facilitator;
7. Willing to contact Investigators to discuss issues and initiate solutions prior to the meeting and
8. When applicable,
   a) Strong clinical expertise; and/or
   b) Research experience.

C. **Composition of the membership of the IRB Committees is adequate in light of the anticipated scope and complexity of VU and VUMC’s research activities, the types of subject populations likely to be involved, and the size and available resources of the Institution. The HRPP Administration conducts an annual review of IRB membership for composition and accuracy.**

D. **Term of Service.**

1. **Committee Members.**
   a) Committee members are requested to serve a minimum of two years.
   b) Committee members are requested to serve as an alternate member at the completion of their term
2. **IRB Chairs.**
   a) Chairs are required to serve one year as a Committee member prior to assuming the role of Chair.
   b) Chairs are requested to serve a minimum of three years including a minimum of one year as Chair.
   c) Chairs are requested to serve an additional year as a Committee member at the completion of their term to serve as a mentor for the newly selected Chair to promote consistency and continuity. In addition, this will provide a resource for the newly selected Chair and Committee members on historical perspectives rationale for decisions made regarding policy, and meeting facilitation skills.
   d) Chairs are requested to serve as an alternate member at the completion of their term

E. **Child Representative.** An IRB Committee considering a protocol involving children as participants should

1. Assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities and
2. Consider inclusion of one or more individuals who are knowledgeable
about and experienced in working with children. To fulfill this requirement, the IRB Committee may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members (See HRPP Policy IX.A).

3. When reviewing proposed research on handicapped children or mentally disabled persons sponsored by the Department of Education, the IRB must also include a member with the expertise in the area of this population as described in the Department of Education’s regulations at 34 CFR 350 and 356.

F. Prisoner Representative. Federal regulations require that the IRB Committee membership be modified if it is to review research involving prisoners. Therefore, if any IRB Committee will review research involving prisoners, at least one member of the IRB Committee shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity (See HRPP Policy IX.B).

G. Pregnant Women, Human Fetuses and Neonates. The IRB Committee considers all applicable federal regulations regarding research with this population and requests review by an expert as needed (See HRPP Policy IX.C).

H. Cognitively Impaired. The IRB Committee may include, if necessary, at least one member with expertise in the area of the cognitively impaired population when reviewing studies with this population or studies in which the participants may become cognitively impaired throughout the course of the research (See HRPP Policy IX.D).

I. Expert Consultants. On a case-by-case basis, the IRB Committee may request review by an individual with competence in an area not represented by the Committee membership.

J. Investigational Drug Services Representatives. The IRB Committees may include one ex officio representative from the investigational drug services. The role of the IDS ex officio representative is to provide comments to the Committee regarding the side effect profile of the investigational agent as a part of the riskbenefit assessment. In addition, the IDS representative is responsible for assuring that the proposed storage handling, and dispensing of investigational agents are in accordance with hospital policy and make recommendations as appropriate.

K. Community Members. Each Committee’s membership is composed of 2 dedicated Community Members who represent the community at large. The Community Members are non-scientists whose backgrounds are representative of the general population. Additionally, it is desirable that Community Members not be affiliated with the institution.

VII. IRB Committee Member and Chair Performance Evaluations

A. Committee members and Chairs complete a self-evaluation annually which includes the following:

1. Knowledge and application of the federal regulations;
2. Knowledge and application of HRPP policies and procedures;
3. Participation in Committee meeting discussions;
4. Interaction with Investigators and study contacts; and
5. Completion of educational requirements.

B. The Regulatory Compliance Analyst Team Leader performs an ongoing assessment of the IRB Committee members and Chairs based on observations made during the IRB Committee meetings and provide feedback individually to the member to enhance and promote growth in their performance as an IRB Committee member.

C. The RCA Team Leaders and HRPP Administration meet annually to assess the annual selfevaluations along with additional feedback provided during the course of the year through Committee observations and RCA Team Leader meetings. Feedback from these meetings are provided to the Chair and Committee Members verbally. Written documentation may be provided in aggregate to the Committee and Chairs if applicable.

D. IRB Committee Members and Chairs may be replaced on the Committee at the discretion of the HRPP Director and HRPP Medical Director based upon the Committee needs for specific areas of expertise or performance issues such as a breach of confidentiality, excessive absences (less than 80% of meetings/quarter over two consecutive quarters), etc.
VIII. The HRPP Administration is responsible for reporting any amendments or changes to the IRB roster to OHRP prior to the initiation of such changes.

References:
45 CFR 46.107
34 CFR 350 and 356
OHRP IRB Guidebook
OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002