Composition of Institutional Review Boards

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

This policy describes the composition of Mayo Clinic's IRBs, the elements of the IRB roster, and the responsibilities of IRB administration in maintaining rosters, and identifying new members for approval by the Mayo Clinic Board of Governors.

The IRB roster is submitted to OHRP to fulfill a requirement of Mayo Clinic's Federalwide Assurance.

Federal regulations (45 CFR 46.107 and 21 CFR 56.107) describe the requirements for membership of a duly constituted IRB.

IRB Composition

1. Each Mayo Clinic IRB has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted at Mayo Clinic in Rochester, Arizona, Florida, and the Mayo Clinic Health System (MCHS).
2. Each Mayo Clinic IRB includes at least one Registered Nurse (RN) with voting privileges to meet the requirements of the American Nurses Association (ANA) Magnet Recognition Program.
3. Each IRB is sufficiently qualified through the experience and expertise of its members, and 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 in safeguarding the rights and welfare of human subjects.
4. Every nondiscriminatory effort is made to ensure that no IRB consists entirely of men or entirely of women.
5. No IRB consists entirely of members of one profession.
6. Individuals responsible for Institutional business development are prohibited from serving as members of the IRB and do not carry out the daily operations of the review process.
7. Each IRB includes at least one member whose primary concerns are in scientific areas (scientific member).
8. Each IRB includes at least one member whose primary concerns are in nonscientific areas (non-scientific member).
9. Each IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution (non-affiliated member). This member represents the perspective of research subjects.

10. No IRB has a member participate in the IRB's initial or continuing review of any research project in which the member has a conflicting interest, except to provide information requested by the IRB.
11. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals do not vote with the IRB.
12. Each IRB is able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
13. For each IRB that reviews research involving vulnerable subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration is given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those human subjects.
14. For all research projects that involve prisoners as a vulnerable category, at least one member who is a prisoner representative is required to participate in the review of any research involving prisoners as subjects.
15. Each IRB member serves as an alternate for other members. The list of IRB members must identify the member(s) for whom each alternate member may substitute.

IRB Roster

1. IRB Administration is responsible for maintaining a current roster of all members serving on the IRBs. Current rosters are accessible on the IRB website.
2. The IRB roster shall include, at a minimum, the following:
    a. Name of member
    b. Gender
    c. Earned degree(s)
    d. Scientific or nonscientific status
    e. Primary area of expertise or specialty
    f. Affiliation status with the institution
    g. Alternate status and which member(s) or class of primary members the alternate may replace

IRB Administration Responsibilities

IRB Administration identifies new replacement members for existing members who rotate off the IRB Committees, and submits the names of the members comprising the IRB Committees to the Mayo Clinic Board of Governors for review and approval.

Related Documents

IRB Rosters: http://intranet.mayo.edu/charlie/irb/committees/convened-irb/

References

Association for the Accreditation of Human Research Protection Programs (AAHRPP) version 1/2012

45 CFR Part 46 Protection of Human Subjects

21 CFR Part 56 Institutional Review Boards

Effective Date

January 14, 2016

Revision History

Date	Synopsis of Change
12-30-15	Scheduled review. No changes.