



FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: IRB Organization
Division: IRB
Date: March 1, 2012

IRB Policy 103.1: COMPOSITION OF THE IRB

Policy

1. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
2. The IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both genders shall be considered for membership. IRB membership shall not consist entirely of men or of women.
3. FRI will make every effort to have a diverse membership appointed to the IRB, with available expertise needed to conduct its functions.

Membership Selection Criteria

1. The members of the IRB shall be sufficiently qualified through experience and expertise to review research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. The IRB shall include persons knowledgeable in these areas.
2. The membership shall be diverse, and shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review.
3. There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution, either self or family member.

Composition of the Board

1. Regular members: The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:
 - a) Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective.

- b) Scientific members: Most IRBs include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When the IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f).
 - c) Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.
2. Alternate members: An alternate member(s) may be designated, as needed, for a regular voting member(s). The appointment of alternate member(s) will be based on expertise similar to that of the regular voting member(s). An alternate member may vote only when the regular voting member is absent.
 3. Representatives of special groups of subjects: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups or types of research may be required. In addition, FRI's IRB will have at least one children's advocate and one prisoners' advocate on the IRB to deliberate on issues of these vulnerable populations.
 4. Chairperson: The individual IRB Chairperson should be a highly respected individual, from within or outside FRI, fully capable of managing his/her IRB obligations and the matters brought before it with fairness and impartiality.
 5. Consultants: The 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 may not vote with the IRB.

Responsibility

FRI is responsible for ensuring that the IRB has adequate resources to identify and recruit qualified potential members. The Institutional Official is responsible for appointing new members.

IRB Staff (or equivalent) is responsible for educating new IRB members.

IRB Staff and Chairperson are responsible for determining when consultants are needed. When consultants are needed, it is the responsibility of the IRB staff to find the appropriate consultants, provide him/her with all of the necessary information (the same information provided to the members), and present his/her report to the IRB or schedule him/her to attend the meeting.

Applicable Regulations and Guidelines

45 CFR 46.107

21 CFR 56.107

FDA Information Sheets, FAQ section II