

Department: UAMS Institutional Review Board
Policy Number: 3.1
Section: Committee Membership
Effective Date: July 31, 2002
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SUBJECT: Qualifications of Committees

Diversity. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession (45CFR46.107; 21CFR56.107; 38CFR16.107(a-d)).

Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas

Each IRB shall include 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.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

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 may not vote with the IRB. The IRB Committee membership must be 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.

Number of Members. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be 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. In addition to possessing the professional competence necessary to review specific research activities, 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 shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

Composition. The list of IRB members identifies each member by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Office for Human Research Protections (OHRP) [45CFR46.103; 38CFR16.103].

Composition of the membership of the IRB Committees must be adequate in light of the anticipated scope of the UAMS research activities, and the types of subject populations likely to be involved. The IRB Committee must also 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 [45CFR46.107 (a); 21CFR56.107(a)].

Member's Primary Interest. Each IRB Committee must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area (45CFR46.107; 21CFR56.107c), an adequate VA representative, and one member who is not affiliated with the UAMS (*i.e.* not a family member or spouse of an employee, not an alumnus). Although 21CFR56.107(c) does not specifically require the presence of a member not otherwise affiliated with the institution to constitute a quorum, FDA considers the presence of such members an important element. Therefore, frequent absence of all non-affiliated members is not acceptable.

The intent of the requirement for diversity of disciplines was to include members who had little or no scientific or medical training or experience. Therefore, nurses, pharmacists and other biomedical health professionals should not be regarded to have "primary concerns in the non-scientific area". In the past, lawyers, clergy and ethicists have been cited as examples of persons whose primary concerns would be in non-scientific areas. Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. While such members are of great value to an IRB, other members who are unambiguously non-scientific should be appointed to satisfy the non-scientist requirement.

Child Representative. A IRB Committee considering a protocol involving children as subjects should (A) 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 (B) 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 [45CFR46.107(f); 21CFR56.107(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 [45CFR46.304].

If a prisoner representative is selected to serve on the IRB Committee, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

In situations where a protocol is reviewed by more than one board, only one board needs to satisfy the requirement that at least one member of the board be a prisoner, or a prisoner representative.

A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

CAVHS R & D Representative. Because the Central Arkansas Veterans Healthcare System (CAVHS) uses the UAMS IRB to review its research involving human subjects, the IRB Committee must also contain a member from the CAVHS Research & Development Committee

when reviewing VA research. This person may serve as a voting IRB member or as a non-voting ex-officio member.