Department: UAMS Institutional Review Board
Policy Number: 3.6
Section: Committee Membership
Effective Date: July 31, 2002
Revision Date: January 25, 2005; June 1, 2005; January 24, 2011; August 6, 2015; February 15, 2016; May 12, 2020

SUBJECT: IRB Reviewers and Alternates

POLICY
Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of human subject research under its purview. Each IRB's members will, as a group, be sufficiently qualified through experience and expertise, and sufficiently diverse to promote respect for its advice and counsel regarding the protection and promotion of human subjects' rights and welfare. The IRB will be constituted such that its members can assess the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. When the IRB reviews research involving populations potentially vulnerable to coercion or undue influence, such as children, prisoners, people with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB shall include members knowledgeable about these areas as appropriate and/or required by policy or regulation.

Consultants with expertise beyond that represented on the IRB may assist in reviews of particular studies if invited to do so, but will not vote.

Each IRB shall include at least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, and one member who is not otherwise affiliated with the institution and who is not part of the immediate family of someone affiliated with the institution. A single person may meet two of these criteria.

IRB members shall be recruited, trained, and appointed to committees as described below.

PROCEDURES

A. Reviewer Recruitment
1. Anyone wishing to serve as an IRB Reviewer may contact the Institutional Official, IRB Director, IRB Chair, or office staff. Potential reviewers will be asked to submit a CV or resume for consideration.
2. The Vice Chancellor for Research may ask Deans, Division Chiefs, and Department heads to identify reviewers from their respective departments. Such recruitment may facilitate maintaining a balance between the number of reviews submitted by that department and adequate departmental representation on the IRB.
3. Reviewers may also be referred from current reviewers or recruited from local civic clubs, professional organizations, or other institutions.
4. The IRB director, chair, and vice-chair, in consultation with the Institutional Official, will assess the need to assign or reassign reviewers to particular committees.

B. **Reviewer Training**
1. Before serving independently on the IRB, all reviewers shall:
    a) Complete orientation training, either in person and/or online by viewing a taped in-person session, covering IRB role and function; regulatory and policy requirements; reviewing submissions; determination checklists; the IRB e-system; IRB meetings, and resources
    b) Attend at least two meetings as an observer.
    c) Review some assignments with the assistance of an experienced mentor.
2. Continuing education shall be made available by:
    a) Providing education at IRB meetings
    b) Addressing pertinent topics on the IRB blogs
    c) Promoting reviewer attendance at human research protection courses on the UAMS

and AC campuses and remotely.

3. Reviewers are to complete the IRB Member course or an equivalent training course (Basic Biomedical or Social/Behavioral) at citiprogram.org at the beginning of their service. Taking a refresher course when the initial training expires is strongly encouraged.

C. **Alternate Members**

1. Regular members with appropriate qualifications may serve in place of any other regular member if necessary to achieve quorum. Alternates' qualifications must be sufficient to maintain an appropriate quorum in the absence of the member they replace and to ensure the board maintains appropriate expertise to review research.
2. The IRB chair or staff present will note that an appropriate quorum is maintained when there are substitutions.
3. Alternate members will have voting rights when requested to attend or participate for the purpose of establishing or maintaining quorum.

D. **Reviewer Assignment**

1. Reviewers will be assigned to one or more particular committee, with the committee's needs and the particular reviewer's background taken into account.
2. Assignments will be made for 3 years and may be renewed if all parties agree.
3. Reviewers serve at the will of the IRB Chair, IRB Director, and/or the Vice Chancellor for Research, and may be removed from a committee if the IRBs' needs change or the reviewer is unable to fulfill their commitment.

E. **Reviewer Assessment**

1. Reviewers will be asked to participate in periodic self-assessments of the IRB's functioning and their ability to meet their requirements.
2. The IRB Chair, IRB Director, and/or Vice Chancellor for Research, in consultation with the IRB Advisory Committee (see IRB policy 1.7), will consider whether IRB representation is adequate or whether adjustments should be mad

F. **Reviewer Responsibilities**

1. Reviewers are to review new and ongoing research within the framework described in the regulatory and policy-described criteria for approval. Checklists, other IRB policies, and their own experience and knowledge of human subject protections are to guide these reviews.
2. Study reviews require access to an online system. Reviewers should bring their laptops or tablets to meetings.
3. Study reviews should be completed by noon the day before the meeting at which the study is to be discussed. Reviewers should allow themselves enough time to contact the IRB office, chair, or the study team with any questions or concerns.
4. Reviewers are to ensure the contingencies, comments, and motions and recorded votes accurately reflect committee actions.

REFERENCES

45 CFR 46.107

21 CFR 56.107

FDA Guidance titled "Institutional Review Boards Frequently Asked Questions"

AAHRPP Elements I.1.E and II.1.B