AAH RSPP GUIDANCE

IRB Composition

PURPOSE

To provide guidance on IRB Membership requirements, as well as use of consultants and alternates to supplement membership.

Definitions of *italicized words* can be found in the AAH RSPP Glossary.

What are the requirements for IRB composition?

The IRB must be perceived to be fair and impartial, immune from pressure by the institution’s administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The ethical criteria at 45 CFR 46.107 and 21 CFR 56.107 guide the selection of IRB members. Regulations require that the IRB 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 participants.

1. Common Rule IRB Membership requirements are defined at 45 CFR 46.107 and require:
   a) at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution
   b) a membership sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including 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
   c) persons knowledgeable and able to ascertain 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
   d) if regularly reviewing research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration for including in the IRB membership one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

• NOTE that the Advocate Aurora IRB is not duly constituted to review research that involves prisoners. If such research is to be conducted at AAH, or if an enrolled subject becomes a prisoner while an active participant, the research study will need to be ceded to an external IRB that is constituted to review this type of research.
e) at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas

f) 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.

g) that no 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.

2. FDA requirements for IRB membership are defined at 21 CFR 56.107 and are essentially the same as the Common Rule with the exception of the following, which is anticipated to be harmonized in the near future:

*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.*

3. AAHRP Accreditation Elements II.1.A-E. outline requirements for IRB membership consistent with regulatory requirements but add a requirement for evaluation of IRB chair and member performance.

4. The AAH IRB obtains expertise from outside the IRB when the IRB lacks the experience and knowledge required to review a specific protocol. 21 CFR 56.107 (f) allows for consultants. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

**What are considerations for IRB composition?**

1. **Voting Members.** In addition to membership requirements outlined above, appointment of IRB voting members will consider the following:

   a) Inclusion of at least one physician and one non-physician level scientist.

   b) At least one member who represents the general perspective of research subjects.

   c) Unaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community, able to provide the general perspective of research subjects, and willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the subjects are drawn. The unaffiliated member(s) should not be vulnerable to intimidation by the professionals on the respective IRB.
d) Per Office of Human Research Protection guidance, members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews. Note that at least one nonscientific IRB member must be at each IRB meeting for the quorum requirements to be satisfied.

e) Membership should not include (as either a voting or ex officio member) any individual who is specifically responsible for Aurora research business development including personnel in Finance, Business Services, Marketing, the Enterprise Business Group, and those individuals within Aurora Research Institute who are responsible for obtaining research funding or who have overall responsibility for the research program.

f) Membership should not include a member that also serves on the IRB of an organization which is a competitor of Advocate Aurora Health

2. Nonvoting members.

a) The Institutional Official is an ex-officio attendee of the IRB. In this capacity, the IO receives the meeting agenda, all meeting materials, and minutes from past meetings; can observe the IRB Chairs and IRB members; and becomes aware of any institutional issues related to human subject research.

b) The Institutional Official does not vote on any research proposals or counts toward quorum, and only provides information as requested by IRB members.

c) The IO is documented as a non-voting attendee in the meeting minutes.

What information is included in the IRB roster?

The IRB roster will include the following information for voting IRB members and alternatives. It will be used to determine relevant expertise in making protocol assignments at convened IRB meetings:

- Name of member;
- Earned degree(s);
- Representative capacities;
- Affiliation status (whether the IRB member or an immediate family member of the IRB member is affiliated with the organization)
- Indications of experience sufficient to describe each IRB member’s chief anticipated contributions;
• Employment or other relationship between each IRB member and the organization;
• Alternate members including the primary members or class of primary members for whom each alternate can substitute.

The IRB Rosters are available for review by contacting the RSPP office.

Who are IRB member alternates?
IRB membership includes not only voting members but alternates. The alternates are designated as replacements for specific members with comparable qualifications.

• Alternates may replace designated voting members who are unable to attend the meeting or are recused due to a conflict and the alternate provides necessary expertise.
• When an alternate replaces a regular member, the alternate is provided the same material that the regular member received or would have received.
• Alternates adhere to the same conflict of interest and confidentiality standards as members.
• At times, an alternate member may be asked to serve as Primary Reviewer and provide expertise for a specific protocol. If quorum requirements are met, the alternate member will not count toward quorum and will not vote. This will be reflected in the meeting minutes.
• An alternate member may be considered for quorum and vote even if the regular voting member is present, provided the minutes reflect that the regular member is not voting.
• IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

Are consultants to the IRB allowed?
During initial review (at the time of RCA review, meeting assignment, or Primary Reviewer review) of a proposed research study, it may be determined that the current membership of the IRB does not include appropriate expertise to conduct an adequate study evaluation. The study may be deferred to another IRB committee or the RSPP may invite an individual with competence in specific areas [consultant to the IRB] to assist in the review.

When additional expertise or knowledge of a particular subject population is required and is not available among the IRB membership (regular or alternate member), a consultant may assist in the review. Consultants may be chosen from IRB alternates, past IRB members or an individual with needed expertise that is not directly associated with the IRB. See RSPP Guidance: Convened IRB Meeting Administration for more information on who may serve as a consultant to the IRB.
• Consultants adhere to the same conflict of interest and confidentiality standards as members.

• The consultant will not serve as the Primary Reviewer. Another IRB member will conduct a review of the study in consideration of the regulatory criteria for approval.

• Consultants may attend the meeting to participate in the review and discussion of the research study assigned to him/her; however, s/he may not vote or count towards quorum.

• If the consultant is not able to attend the IRB meeting a written summary/evaluation of the study will be requested in advance of the meeting. The IRB Chair and Primary Reviewer will be provided this summary/evaluation in the absence of the Consultant. The Primary Reviewer will present the consultant’s thoughts/opinions on the research study to the IRB.

• Attendance of the consultant, or provision of written comments will be documented in the IRB meeting minutes.

Is the IRB composition periodically evaluated?
Yes, the IRB Membership assessment tool is completed on a semi-annual basis as part of the RSPP Quality Program (RQP). The evaluation looks at the IRB membership as compared to regulatory requirements. The expertise level of the members as compared to the research studies reviewed is also assessed.

• After review by the RSPP Director, the completed assessment tool will be sent to the IO for review.

• The IO may request comment/opinion from the HRPP Advisory Committee in consideration of whether the IRB membership is sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. If discussed at an HRPP Advisory Committee meeting, the minutes of that meeting will document the discussion.

What is the process for IRB Member/IRB Chair appointment?
Per system policy 2467, the Institutional Official is tasked with the responsibility for ensuring the recruitment and appointment of qualified IRB Chair(s) and members.

Individuals being considered for IRB membership will be requested to provide his/her CV/resume to the RSPP Office. This document will be reviewed by the Institutional Official, and others (RSPP Director, and IRB Chairs) as necessary. The Institutional Official and/or others may interview interested candidates in consideration of appropriateness of filling an open position on the IRB roster.
The RSPP Director or designee will review the individual’s CV to determine member’s status (i.e., scientific versus non-scientific, affiliated vs. non-affiliated) for the IRB roster.

New Members are required to complete the educational and observation requirements as noted in RSPP Guidance: Human Subject Research Training/Education prior to appointment to the IRB.

As needed, a current/experienced IRB member may be assigned to the new member as a mentor.

REQUIREMENTS

- Common Rule Regulations: 45 CFR 46.107
- FDA Regulations: 21 CFR 56. 107
- FDA guidance – Institutional Review Boards Frequently Asked Questions
- AAHRPP Accreditation Standards/Elements: II.1.A-E
- AAHC System Policy: 2467
- RSPP Guidance: Human Subject Research Training/Education