AAH RSPP GUIDANCE

IRB Member Qualifications and Responsibilities

PURPOSE

The purpose of this guidance document is to outline the qualifications and responsibilities of the IRB Members.

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

GUIDANCE

**What are the responsibilities of an AAH IRB Member?**

Each IRB member’s primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of that research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the investigator and the research subjects.

IRB members should report any attempt at undue influence to the Institutional Official.

General Responsibilities of IRB members include, but may not be limited to the following:

- Being knowledgeable in regulations governing human subject protection and accreditation standards, biomedical and behavioral research ethics, and the policies of Advocate Aurora Health germane to human subject protection;
- Being willing to serve as a Primary Reviewer for any IRB action conducted at a convened board meeting or as an Expedited Reviewer in the expedited review process (see RSPP Guidance: Convened IRB Meeting Administration or Expedited Review);
- Reviewing research study proposals and evaluating them in accordance with the regulatory criteria for approval (45 CFR 46.111 and 21 CFR 56.111 (if applicable)); and any other relevant ethical, scientific or compliance considerations;
- Assisting in the evaluation of the risk level (i.e., minimal or greater than minimal) of the proposed research.
- Assisting in the evaluation, for research studies involving an unapproved device, whether the device and its proposed use constitutes a non-significant or significant risk to research subjects;
- Reviewing informed consent documents and evaluating them from the perspective of addressing the required and additional elements of informed consent (45 CFR 46.116, and 21 CFR 50.20 (if applicable)) and any other relevant ethical or compliance considerations;
- Participating in deliberations of the IRB actions;
• Making it known to the RSPP Office, IRB Chair and/or IRB when having a conflict of interest with proposed research, and recusing oneself during deliberation and voting at convened board meetings;

• Voting on IRB actions unless holding a conflict of interest with that research study.

• Assisting in the evaluation of need for additional monitoring for research studies under the IRB’s oversight. For example, in studies of greater than minimal risk, if IRB continuing review of the research is warranted, determining whether review is needed on a more frequent basis than the requisite annual review; or if the informed consent process and/or other aspects of the research study should be monitored by groups outside of the IRB (e.g. Research Compliance, Research Quality, etc).

• Provide consideration, for research studies subject to IRB continuing review, if verification is required from sources other than the investigator that no material changes have occurred since previous IRB review.

• Recommending improvements to IRB policies and procedures so as to enhance the IRB review process and/or human subject protections.

• Informing the IRB Chair or RSPP Director of human subject research noncompliance problems or ethical issues of which they become aware.

• Maintaining confidentiality/non-disclosure of human subject research submitted for IRB review and approval, and good faith participation in IRB deliberations without appearance of discrimination or conflict-of-interest.

In general, what qualifications are necessary in an individual serving on the IRB?

The IRB member must:

• be immune to pressures by the organization’s administration, and by researchers whose protocols come before the IRB;

• be willing to voice opinions and concerns to other members during deliberation of IRB actions;

• be in good standing with the organization.
  o IRB members who are physicians or Allied Health Professionals must notify the RSPP Director if their privileges on the medical staff are suspended, terminated or are otherwise restricted. A suspension or termination in privileges will be reviewed by the Institutional Official, and may result in immediate, temporary removal from the IRB. Such individuals will be eligible for reappointment to the IRB when full medical staff privileges are reinstated. Failure to disclose a suspension or termination of medical staff privileges in a timely manner may result in permanent removal from the IRB. RSPP staff verifies and documents that voting IRB physician member privileges are not suspended or terminated prior to each IRB meeting.
Who appoints the IRB Members?
- IRB members are appointed by the Institutional Official.
- Periodic evaluation of the IRB Member is conducted by the Institutional Official.

What is the IRB Member’s term of service?
- A term of service will be a maximum of three calendar years.
- Service terms are renewable. There is no limit to the number of terms an individual can serve.
- The IRB member may resign before the conclusion of his/her term. Written resignation to the RSPP Office is required.
- The Institutional Official may remove other IRB members at any time with or without cause.

What are IRB member expectations/requirements?
An IRB member:
- is expected to attend an IRB meeting to which s/he is scheduled so that quorum can be established and maintained. If the member is unable to attend a meeting in which s/he is scheduled, the individual is expected to notify the RSPP Office well in advance of the meeting so that an alternate IRB member may be found.
- attend a majority of the meetings to which s/he is scheduled. Attendance of the members will be monitored by the RSPP Office. Issues related to non-attendance will be discussed with the IRB Chair and institutional Official to determine whether action is necessary.
- must maintain current Human Subject’s Protection certification through CITI Program for the duration of his/her appointment (see RSPP Guidance: Human Subject Research Training/Education).
- Is expected to complete eighteen units of continuing education during each three year appointment term.
- must disclose annual significant interest disclosures per AAH System Policy 2302 [Conflict of Interest in Research -Individual]. S/he must recuse her/himself from the review of any research study in which there is a potential conflict except if providing information at the request of the IRB.

Are IRB member paid for service?
- An IRB member who is affiliated with the organization is not compensated for his/her service.
• Unaffiliated IRB members receive a stipend for attendance at convened board meetings. Provision of the stipend is not related to or dependent upon a favorable decision or vote on a protocol.

The IO shall have the discretion to reimburse IRB members for expenses associated with their membership including expenses incurred for continuing education.

**Is an IRB member’s performance evaluated?**
As indicated in system policy 2467, it is the Institutional Official’s responsibility to ensure that an IRB member’s performance is periodically evaluated.

**How and when is an IRB member’s performance evaluated?**
Prior to term expiration, a voting IRB member (regular and alternate member) is requested to complete the IRB Member/Chair Self Assessment. The goal of this self-assessment is to document the individual member’s thoughtful evaluation of their performance and expertise as an IRB member, and to identify any areas for improvement.

Areas of self-evaluation include: knowledge and application of federal and ethical principles surrounding human subject research; knowledge and application of RSPP policies; IRB review criteria and procedures; etc. The individual is requested to suggest areas for individual or programmatic improvement or continuing education.

Prior to providing the completed self-evaluation to the Reviewer, the RSPP Office includes attendance statistics.

The completed self-evaluation tool is reviewed by the IRB Chair(s) and/or the IO. The Reviewer shall consider:
- knowledge and performance of the member;
- attendance of the IRB member at scheduled meetings;
- completion of required IRB member continuing education requirements.

The Reviewer shall provide written comments/feedback relative to member preparedness, meeting contribution, knowledge of regulatory criteria and local policy on the self-evaluation tool. The reviewer may provide a ‘needs assessment’ statement regarding the members’ continuing education level.

The completed self-evaluation tool, with Reviewer comment, will be returned to the IRB member. If necessary, the Reviewer may request to meet with the IRB member to discuss any issues or concerns.

Satisfactory performance, and the member’s willingness to continue service on the IRB will be taken under advisement by the IO in considering reappointment to the IRB.
If reappointed, the member will receive an IRB member reappointment letter from the RSPP Office. If service of the individual on the IRB is no longer required, a ‘thank you’ letter will be generated and sent to the individual.

**REQUIREMENTS**

- AAHC System Policy: 2302, 2467
- RSPP Guidance: Human Subject Research Training/Education; IRB Composition