AAH RSPP GUIDANCE
IRB Chair Qualifications and Responsibilities

PURPOSE
The purpose of this guidance document is to outline the qualifications and responsibilities of the AAH IRB Chairperson (“Chair”).

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

GUIDANCE
What are the responsibilities of an AAH IRB Chair?
The IRB Chair has a critical role in the organization’s overall human research protection program. In general, the Chair serves as the leader of the IRB, and as a liaison between researchers and the IRB.

In addition to other IRB members, the IRB Chair’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 Chair 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.

Any attempts to unduly influence the IRB Chair should be reported to the Institutional Official.

The Chair shall:
- maintain a thorough understanding of the federal regulations pertaining to human subject protections, RSPP SOPs, and institutional policies, state and local laws that affect human subject research;
- assist, as necessary, in determinations of whether a project is considered human subject research per 45 CFR 46 and 21 CFR 56;
- appoint qualified members of the RSPP or IRB as designees with review and signature authority. Delegation must be documented in writing;
- review and approve, as needed, expedited research submissions in accordance with regulatory requirements under 45 CFR 46.110 and 21 CFR 56.111;
- review and determine, as necessary, research as ‘exempt’ from regulatory requirements under 45 CFR 46.104;
- review as needed, emergency use requests and outcome reports;
- determine the course of immediate action to address the safety of subjects or others.
  - The Chair is empowered to take immediate action to suspend the approval of any or all research activities prior to convened board action in order to protect the rights and welfare of research subjects deemed to be at unacceptable harm/risk, or in situations where an investigator is not following the IRB’s requirements/IRB approved study protocol. Any suspension of research by the IRB Chair is placed on the agenda and reviewed and upheld, overturned or supplemented by the
convened IRB at their next meeting. The Chair alone cannot disapprove research.

- if requested, provide guidance on the assignment of a Primary Reviewer(s) to studies requiring convened IRB review or consider whether a protocol requires expert consultation;
- act as a Primary Reviewer/Expedited Reviewer of IRB actions as needed;
- review all submitted meeting materials, and assist the reviewers or other IRB members with concerns prior to the meeting;
- present to the convened IRB any written review provided by the Primary Reviewer or consultant;
- vote as a member of the IRB on the proposed research applications at the convened board meetings unless conflicted;
- preside over the convened IRB meeting. Responsibilities include:
  - assisting assigned reviewers in presenting a clear and concise review of study materials;
  - ensuring that appropriate numbers/types of members are present, such that the meetings are appropriately assembled and remain appropriately convened – done with the assistance of an RSPP office member;
  - reminding IRB members of the importance of conflict of interest disclosures at the start of each IRB meeting, and at any other time as needed;
  - ensuring that meetings are conducted in an efficient, orderly and fair manner with respect given to the opinions of all members;
  - directing discussion by the IRB on research studies under review;
  - ensuring that all regulatory-required elements of review (including those required when there is involvement of vulnerable populations) are addressed during the meeting, and there is meaningful and substantive discussion of relevant matters and/or questions;
  - helping to compose conditions of approval that meet the regulatory requirements and are clear to the members prior to their vote on a study;
  - ensuring that IRB decisions are made and applied in accordance with federal, state and local regulations with a commitment to foster ethically and scientifically sound human subject research;
- review responsive materials to conditions of approval, as needed;
- consult with investigators and research staff as necessary;
- uphold the confidentiality of the materials presented and discussions at an IRB meeting;
- review the meeting minutes (including voting records) to ensure that they accurately reflect discussions and IRB actions;
- respect the diverse backgrounds, perspectives and sources of expertise of all IRB members;
- provide to the Institutional Official, as requested, a general overview of the committee's performance;
- perform periodic evaluations of an IRB member's performance;
- uphold IRB decisions to Principal Investigators or institutional leaders;
• foster an atmosphere of respect between the IRB and the institutional community. The IRB must be, and must be perceived to be, fair and impartial, immune from pressure either by the institution’s administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

What are the qualifications of a person serving as an AAH IRB Chair?
The IRB Chair:
• should be a highly respected individual, affiliated with the organization.
• must be capable of managing the IRB, its members, and the matters brought before it with fairness and impartiality.
• must be immune to pressures by the organization’s administration, and by researchers whose protocols come before the IRB.
• should have strong leadership and management skills.
• must be able and willing to guide substantive discussions of research protocols, adequately and concisely summarize the issues raised by the IRB members, apply the ethical and regulatory criteria, and manage the diverse personalities on the IRB and mediate any conflicts that may arise in opinions among the members.
• Must be in good standing with the organization.
  o IRB Chairs 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 the Chair’s privileges are not suspended or terminated prior to each IRB meeting.

Who appoints the IRB Chair?
• The IRB Chair is appointed by the Institutional Official.
• Periodic evaluation of the IRB Chair’s performance is conducted by the Institutional Official.

What is the IRB Chair’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 Chair may resign before the conclusion of his/her term. Written resignation to the RSPP Office is required.
• The Institutional Official may remove IRB Chairs at any time with or without cause.
What are IRB Chair expectations/requirements?

An IRB Chair:

• is expected to attend an IRB meeting to which s/he is scheduled. If the Chair 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 may be found.

• is expected to attend a majority of the meetings to which s/he is scheduled. Failure to meet this requirement may result in immediate removal. Exceptions may be made in extenuating circumstances.

• 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.

• becomes a member of the Human Research Protection Program Advisory Committee (HRPP AC). HRPP AC meetings shall be held not less than semi-annually at the call of the Chair (IO). Attendance is recommended but not required.

• is not compensated for his/her service.

How and when is an IRB Chair’s performance evaluated?

Prior to term expiration, the IRB Chair 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 Chair, 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 IO. The Reviewer shall consider:

• knowledge and performance of the individual;
• attendance of the IRB Chair 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 Chair. If necessary, the Reviewer may request to meet with the IRB Chair to discuss any issues or concerns.

Satisfactory performance, and the individual’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 Chair 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
Include the regulations/requirements related to the guidance document. To include, but not limited to:

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