

SOP: OR 202 Version No.: 07 Effective Date: 12/1/10	RESPONSIBILITIES OF IRB MEMBERS	Supersedes Document Dated: 7/1/08
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Steering Committee approved 4/6/11

1. POLICY

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. 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. In order to fulfill their duties, IRB members are expected to be knowledgeable in regulations governing human subjects protection, biomedical and behavioral research ethics, and the policies of Aurora Health Care and the Aurora Facilities germane to human subjects protection.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Duty to Aurora Health Care

1.1.1. The IRBs are appointed as Institutional Committees. As such, the IRB members serve Aurora Health Care as a whole, rather than a particular department. Therefore, members must not allow their own interest, or that of their department to supersede their duty to protect the rights and welfare of research subjects.

1.1.2. The IRB must act as an independent committee within the organization with its focus on protecting the rights and welfare of human subjects. Per the general standards of Aurora’s Code of Ethical Conduct, IRB members are expected to promptly report to the Senior IRB Chair, IRB Chair, RSPP Manager, or the Institutional Official any unethical activities, including any attempt by others to unduly influence an IRB member’s decision(s). The Senior IRB Chair, in consultation with the Institutional Official and RSPP Manager, will investigate any suspected unethical activities related to influence of IRB members.

1.1.3. IRB members who are physicians or Allied Health Professionals on the medical staff should notify the RSPP Manager if their privileges on the medical staff at any Aurora Facility are suspended, terminated or are otherwise restricted. A suspension or termination in privileges may result in immediate removal from the IRB (Policy OR 201, sub-section 1.1.5). However, 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

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removal from the IRB. The RSPP staff also verify and document IRB physician member privileges are not suspended or terminated prior to each IRB meeting.

1.2. Term of Duty

Regular and alternate IRB members and IRB Chairs are expected to commit to a 3-year term and, during that time, to fulfill certain duties. These duties will be described prior to appointment, and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member.

1.3. Scheduled IRB Attendance

All IRB members, including the IRB Chairs, are expected to attend a majority of the meetings to which they are scheduled. Meeting schedules are disseminated annually or upon revision. Failure to meet this requirement may result in immediate removal. The Senior IRB Chair can make exceptions in extenuating circumstances.

1.4. Specific Duties

1.4.1. Regular Members:

- **Unaffiliated member(s):** Unaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- **Non-scientific members:** Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
- **Scientific members:** Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess -whether the protocol adequately protects the rights and welfare of subjects.
- **IRB Chairs:** In addition to the above responsibilities (germane to the member's capacity), the IRB Chairs preside over meetings of the IRB. IRB Chairs perform or delegate to an appropriate voting IRB

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member expedited review when appropriate. They are empowered to suspend the conduct of a research study deemed to place individuals at unacceptable risk, pending IRB review. The IRB Chair is also empowered, pending review by the full IRB, to suspend the conduct of a study if he/she determines that an investigator is not following the -IRB's requirements. The IRB Chair alone cannot disapprove research.

- The IRB Chair shall be responsible for alerting the IRB to any issues related to compliance with the privacy standards under HIPAA.
- The IRB Chair may request/assign a consultant to review any study he/she believes requires expertise not available through the IRB membership.
- **Senior IRB Chair:** The Senior IRB Chair is responsible for making Primary Reviewer assignments, conducting exempt and expedited review of qualifying actions (or delegating to an appropriate IRB member), making Human Subject Research determinations, conducting preliminary assessment of items submitted to the RSPF office for action, conducting Research Misconduct investigations, conducting Facilitated Reviews, and issuing approval letters, as well as other duties identified in Aurora IRB SOPs.
- **Alternate Members.** Alternate members are expected to contribute to the meetings as if they were-regular members.

1.4.2. Primary and Secondary Reviewers.

In addition to the duties described in section 1.4.1, each member will be expected to serve as a Primary Reviewer for assigned studies at convened meetings. Research Compliance Analysts typically serve as a Secondary Reviewers, and additional Secondary Reviewers may also be assigned. The Primary Reviewer presents his or her findings resulting from review of the application materials, provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB (see sections 1.1 and 1.2 of policy RR 402). He or she leads the IRB discussion of the study and takes the IRB through the determinations in RR 402-A to determine whether the research can be approved. The Primary Reviewers may be required to review additional material requested by the IRB for the purpose of study approval. The Secondary Reviewer, if assigned, adds to the discussion, as necessary.

Should a Primary Reviewer be unable to attend the IRB meeting in person, he/she may present their review via telephone conference call. If this is not

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possible, the reviewer will be asked to submit his/her review/recommendations in writing to the RSPP office and the IRB Chair prior to the scheduled meeting, however this is not required. This will allow the IRB Chair or RSPP staff to clarify any issues related to the written comments prior to such meeting. The IRB Chair is responsible for presenting any written review at the IRB meeting. If the IRB Chair does not feel that there is enough information available from the Primary Reviewer to review the research protocol, it is his/her discretion as to whether the study will be deferred to another IRB meeting.

The Primary Reviewer is required to complete the Reviewer Checklist and submit it to the RSPP office for placement in the study file. The checklist is expected to be completed prior to the approval of the protocol.

1.5. Outside Consultant

If a Primary Reviewer feels a consultant to the IRB (who has additional expertise) is needed for a particular study, he/she will make the RSPP office aware of this request prior to review of the protocol at an IRB meeting .

1.6. Formal IRB Evaluation

Prior to term expiration, the IRB Steering Committee will formally evaluate (see SOP AQ 903 and document QA 903-A) the performance of each IRB member and each IRB Chairs according to the responsibilities listed on the IRB Member Agreement/Confidentiality Statement (form OR 201-C). If the member's performance is satisfactory, the member will be reappointed and notified of the reappointment. The IRB Steering Committee Chair will provide feedback to an IRB Chair on his/her performance. The IRB Chair will provide specific feedback to individual IRB members as needed. The IRB Chair will provide a general overview of committee performance to the IRB on a routine basis.

2. SCOPE

These policies and procedures apply to all IRB Members.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

OHRP IRB Guidebook

OHRP Guidance on Written IRB Procedures (January 15, 2007)

FDA Information Sheets, IRB FAQ, Question #17

Aurora General Standards of Conduct from Aurora's Code of Excellence —Compliance Plan

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AAHRPP Element II.1.E.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.