1. POLICY

On-going assessment and evaluation of the IRB committee composition and individual IRB members, is critical to the proper functioning of the IRB. Assessment/evaluation of the IRB is authorized by the IRB Steering Committee Charter. The goal of the quality assurance activities surrounding this on-going assessment/evaluation is to ensure ethical and regulatory review of research and identify areas for improvement within the IRB. The Aurora IRB consists of three fully functional teams. Each team is evaluated relative to the criteria established within this policy.

Specific Policies

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

1.1. Aurora IRB Evaluation

The operation of the Aurora IRB will be assessed to ensure that the IRB is performing in compliance with the regulatory criteria for approval. Such evaluation shall occur at least annually, and shall be documented in the Steering Committee meeting minutes. The evaluation shall minimally consider the following:

1.1.1. Composition of the Aurora IRB to ensure that each possesses sufficient skills, experience, expertise, and diversity to competently review the types of research conducted, and issues related to vulnerable populations. Review of individual IRB member performance will be conducted prior to term reappointment (see section 1.3).

1.1.2. The size of the Aurora IRB is sufficient to competently and thoroughly perform its review functions in light of the amount and volume of research being conducted;

1.1.3. The Aurora IRB is composed of and includes, either as members or ad hoc consultants, representatives interested in or who have experience with vulnerable populations involved in research;

1.1.4. The Aurora IRB is operated in compliance with Aurora IRB’s Conflict of Interest Policy (GA 104) and that IRB members refrain from participation in deliberation and voting on protocols for which they have a conflict of interest as defined by this policy.

1.1.5. The efficiency of the IRB review function assessed as a measure of IRB turn-around time (measured from date of initial submission to IRB approval – does not include the time necessary to obtain administrative authorization/clearance of the
research, completion of key personnel training or conflict of interest disclosure/management).

1.1.6. The general performance of the IRB including feedback from investigators, research staff, sponsors, and subjects; results of continuous improvement activities; compliance with policies and procedures; compliance with regulatory requirements, etc.

1.2. IRB Evaluation Outcome

Any suggestions for individual or programmatic improvement or continuing education will be addressed by the RSPP Director, and/or the IRB Steering Committee as needed. A follow-up report will be provided to the IRB Steering Committee at the next scheduled meeting.

1.3. Voting IRB Member Assessment and Evaluation

1.3.1. Self-evaluation tool

Voting IRB members (including IRB Chairs) will be requested to complete a self-evaluation tool (form QA 903-A) prior to the completion of their three year IRB member term. The goal of this evaluation 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 IRB policies; IRB review criteria and procedures; etc. Individual members may suggest areas for individual or programmatic improvement or continuing education.

Voting IRB members (including IRB Chairs) will be requested to complete a self-evaluation tool (form QA 903-A) once per member term. The goal of this evaluation 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 IRB policies; IRB review criteria and procedures; etc. Individual members may suggest areas for individual or programmatic improvement or continuing education.

1.3.2. Evaluation review

The submitted-completed self-evaluation tool is reviewed by the IRB Chair (IRB regular or alternate members) or the Institutional Official (IRB Chairs). The Reviewer shall consider:
1.3.3. **Review outcome**

(i) 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.

(ii) The document also allows the reviewer the opportunity to provide written comments relative to member preparedness, meeting contribution, and knowledge of regulatory criteria and local policy. During the review, the Reviewer Chair/IO may make a “needs assessment” relative to the member’s continuing education. Comments on the member’s continuing education level may be added to the self-evaluation tool as necessary. The IRB Chair/IO will provide comments or feedback as needed, or concur with the individual’s self-evaluation.

(iii) The IRB Chair/IO will provide a report of the member’s evaluation to the IRB Steering Committee. The Steering Committee will consider the member’s understanding of their role in human subject protection when making decisions about the individual’s reappointment for continued service on the IRB. The Steering Committee will vote for reappointment of the individual at a convened meeting or via e-mail vote.

(iv) The completed self-evaluation tool, with Reviewer comment, will be returned to the IRB member. If reappointed by the Steering Committee, the member will also 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, if reappointed. If necessary, the Reviewer may request to meet with the IRB member to discuss any issues or concerns.
2. Any suggestions made for individual or programmatic improvement or continuing education will be addressed by the RSPP manager, and also by the IRB steering committee when necessary.

3. IRB meeting evaluation

4. IRB meeting evaluations relative to appropriate member expertise and overall composition are completed by the IRB steering committee on a quarterly basis and no less than semi-annually. Individual issues are discussed as needed.

5.2 SCOPE

These policies and procedures apply to all Aurora IRB approved protocols.

6.3 APPLICABLE REGULATIONS, GUIDELINES, AND STANDARDS

AAHRPP Elements II.1.B

7.4 REFERENCES TO OTHER APPLICABLE SOPS

None