

SOP: Number GA 101 Version No: 06 Effective Date: 12/1/10	POLICIES AND PROCEDURES MAINTENANCE	Supersedes Document Dated: 7/1/08
--	--	--

Steering Committee approved 2/25/11

1. POLICY

The regulations and guidance provided by OHRP, FDA, HIPAA and ICH GCPs, as supported by Aurora's institutional policies, ensure the rights and welfare of the human subjects enrolled in research studies will be overseen and protected in a uniform manner, regardless of changes in personnel or IRB membership. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for the adequate documentation of such oversight.

The RSPP will take steps to ensure that Standard Operating Policies And Procedures (SOPs) are maintained to provide the framework for the ethical and scientifically sound conduct of research on human subjects in accordance with federal and state regulations.

Specific Policies

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

1.1. Review, Revision, Approval of Policies & Procedures

1.1.1. Changes to regulations, federal guidelines, state law, accreditation standards or research practice, as well as the policies and procedures of Aurora Health Care or any Aurora Facility, may require a new SOP or a revision to a previously issued SOP.

1.1.2. The RSPP Manager is ultimately responsible for promptly revising or drafting IRB SOPs when any such changes arise. Legal counsel will be consulted as appropriate.

1.1.3. The IRB Steering Committee shall review and approve all new or revised SOPs prior to their implementation, and has the authority to require revisions to existing SOPs or the creation of new SOPs. Approval is documented in Steering Committee minutes.

1.1.4. Final documentation of review and approval by the IRB Steering Committee of any new or revised SOP is accomplished by signature of the RSPP Manager on the revised or new SOP.

1.2. SOP Dissemination and Training

1.2.1. When new SOPs are approved or major revisions are approved to existing SOPs, these documents will be disseminated to the RSPP staff, IRB members, research staff, investigators, and any applicable departments or institutions deemed appropriate by the IRB Steering Committee via the RSPP web site.

SOP: Number GA 101 Version No: 06 Effective Date: 12/1/10	POLICIES AND PROCEDURES MAINTENANCE	Supersedes Document Dated: 7/1/08
--	--	--

1.2.2. Paper copies of SOPs will be provided to investigators, IRB members and regulatory agencies when requested or as necessary.

1.2.3. Training will be provided to all members of the IRB and RSPP staff on any new or revised policy and/or procedure whenever necessary. Evidence of training must be documented in the IRB meeting minutes, the RSPP staff meeting minutes, or the IRB Steering Committee meeting minutes (or e-mail correspondence).

1.2.4. Each new IRB member or employee of the RSPP office must review all applicable SOPs prior to undertaking any responsibilities involving human subject protection at the RSPP. Evidence of training must be documented and filed in the RSPP office.

1.3. **Forms**

Forms are used to: (1) ensure that policies are integrated into the daily operations of research and review throughout the Aurora Health Care system, and (2) enable RSPP staff to manage review, tracking, and notification functions consistently.

2. **SCOPE**

These policies and procedures apply to all RSPP staff, investigators, research staff, and IRB members.

3. **APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS**

21 CFR 56.108, 56.109, 56.113
 45 CFR 46.103, 46.108
 AAHRPP Element I.1.D.

4. **REFERENCES TO OTHER APPLICABLE SOPS**

This SOP affects all other IRB SOPs.