

SOP: GA 102 Version No: 06 Effective Date: 12/1/10	TRAINING AND EDUCATION	Supersedes Document Dated: 07/1/08
---	-----------------------------------	---

1. POLICY

Steering Committee approved 1/31/11

All individuals involved in Human Subject Research have an obligation and responsibility to protect the rights and welfare of human subjects. Training of RSPP staff, investigators, research staff, and IRB members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout the research community at Aurora Health Care.

RSPP staff, IRB members, researchers, research staff, and others charged with responsibility for reviewing and overseeing human subject research shall receive training, as appropriate, in the regulations, guidelines, ethics and policies applicable to human subjects research.

Specific Policies

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

1.1. Training

1.1.1. RSPP staff and members of any IRB who are overseeing research on human subjects, will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.

1.1.2. The RSPP Manager establishes the educational and training requirements for IRB members and RSPP staff who review biomedical and behavioral research involving human subjects at Aurora Facilities.

1.1.3. All investigators listed on a research submission form (FO 301-A or FO 302-A) must have completed the online NIH tutorial, and have a copy of the completion certificate on file in the RSPP office prior to issuance of the final IRB approval letter. Training equivalent to the online NIH tutorial may be substituted at the discretion of the RSPP Manager.

1.1.4. Any physician conducting Human Subject Research at any Aurora Mid Market region facility will be required to complete an application for Research Privileging. The application will be completed when the physician is due to renew his/her Aurora Health Care medical staff privileging appointment.

This request for Research Privileging will be reviewed and approved as an “additional” privilege by the Aurora Health Care Metro Inc. Board of Directors (“Metro Board”). The Research Privilege, administered by the Aurora IRB, is valid for two years from the date of the Board’s approval, at which time it will need to be renewed.

1.1.5. Research personnel not employed by Aurora Health Care, Inc. or those Aurora-employed individuals not employed by the Department of Clinical Research but

SOP: GA 102 Version No: 06 Effective Date: 12/1/10	TRAINING AND EDUCATION	Supersedes Document Dated: 07/1/08
---	-----------------------------------	---

who act as a study coordinator on any research study under review by the Aurora IRB are expected to receive appropriate training, germane to their responsibilities as delegated by the Principal Investigator. It is the Principal Investigator’s responsibility to ensure those individuals are appropriately trained. In addition, those individuals are expected to attend the periodic training sessions offered by the RSPP. The training session schedule is communicated via email to all research personnel by the RSPP office. A copy of the completion certificate for the NIH tutorial (or appropriate equivalent) must also be on file in the RSPP office. The link is available on the RSPP website.

1.1.6. Research personnel employed by Aurora’s Department of Clinical Research will follow the training mandates described in that department’s policies and procedures.

1.1.7. Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities. New member orientation will be documented on form GA102-B. Ongoing training will be documented in IRB meeting minutes or through written acknowledgment of materials distributed.

1.1.8. The Institutional Official will complete OHRP’s online Human Subject Assurance training modules. The completion certificates will be kept on file in the RSPP office. The Institutional Official will receive ongoing training in areas germane to his/her responsibilities.

1.1.9. IRB Chairs will receive additional training in areas germane to their additional responsibilities.

1.1.10. RSPP staff will receive initial training and continuing education in the areas germane to their responsibilities, including all SOPs and Human Subject Protection periodicals as noted in GA102-A. New staff orientation will be documented on form GA102-C. Ongoing training will be documented in RSPP staff meeting minutes.

1.1.11. IRB members and RSPP staff will be encouraged to attend workshops and other educational opportunities focused on human subject protections issues and IRB functions. Aurora Health Care will support such activities to the extent possible and as appropriate to the responsibilities of IRB members and RSPP staff.

1.2. Documentation

Training and continuing education shall be documented and the records retained as described in SOP FO 305.

SOP: GA 102 Version No: 06 Effective Date: 12/1/10	TRAINING AND EDUCATION	Supersedes Document Dated: 07/1/08
---	-----------------------------------	---

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 56.107

45 CFR 46.107

OHRP IRB Guidebook

FDA Information Sheets

NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

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

AAHRPP Elements I.1.E and III.2.A.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.