

<b>SOP: GA 105</b> <b>Version No: 03</b> <b>Effective Date: 12/1/10</b>	<b>SIGNATORY AUTHORITY</b>	<b>Supersedes Document Dated: 01/23/06</b>
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## 1. POLICY

Steering Committee approved 2/25/11

The IRB Chairs are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects that have been reviewed and approved pursuant to Aurora Health Care policies and procedures. This policy applies to all staff of the RSPP.

### Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in Form GA 105-A or the Glossary.

#### 1.1. Revisions, Corrections, Additions to Documents Submitted to the IRB

Any revisions, correction, or additions to any document submitted to the IRB may be made by the RSPP staff or RSPP manager with oral or written communication from the investigator or study coordinator. Such revisions, corrections or additions shall be initialed and dated by the person making such changes.

#### 1.2. Results of Reviews, Actions and Decisions (Approval, Tabled or Disapproval Letters)

The results of reviews and actions taken by the IRB, either by the full IRB or by expedited review, that grant or may appear to grant investigators with initial or continuing approval of research, training or educational projects involving human subjects; may be signed by designated RSPP staff members who are members of the IRB. In all cases individuals must sign their own name and no other and indicate their title under their signature.

#### 1.3. Routine Internal Correspondence

Any action, letters, memoranda or emails between IRB members and/or members of the staff of any Facility providing information concerning the review of research by the IRB or RSPP staff do not imply or appear to imply approval of such activity; may be signed or initialed by designated RSPP staff members.

#### 1.4. Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the applicable IRB Chair, or RSPP Manager.

#### 1.5. Decisions Made by IRB Chairs

Any letters, memoranda or emails sent representing the decision or opinions of the applicable IRB Chair or his/her respective designees, as long as such correspondence does not

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imply review and approval of research projects, may be signed by designated RSPP staff. For Examples of such correspondence include letters requesting continuing review, correspondence requesting additional information related to a study or any inquiry thereof, correspondence with sponsors related to IRB operations or policies, and correspondence with outside accrediting agencies or governmental agencies for guidance.

#### **1.6. IRB Chair Signature Stamp/Electronic Signature**

The RSPP Manager or his/her designee is authorized to use the signature stamp or electronic signature of any IRB Chair only when that IRB Chair has confirmed use of such device/mechanism.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, all electronic signatures executed by the RSPP Manager or his/her designee are the legally binding equivalent of traditional handwritten signatures.

#### **2. SCOPE**

These policies and procedures apply to all RSPP staff.

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

45 CFR 46.103, 46.115

#### **4. REFERENCES TO OTHER APPLICABLE SOPS**

This policy affects all other SOPs.