

<b>SOP: GA 105</b> <b>Version No: 1</b> <b>Effective Date: 8/1/07</b>	<b>SIGNATORY AUTHORITY</b>	<b>Supersedes Document:</b> <b>10/11/04; 1/6/06</b>
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## 1. POLICY

Except where the Institutional Official is required by Federal Regulations to be the signatory, the IRB Chairperson is authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as subjects, which have been reviewed and approved pursuant to Sparrow Health System's policies and procedures. The IRB Administrator will have the authority to sign the IRB Chairperson's name as long as the IRB Administrator's initials immediately follow the signature.

### Electronic Signature:

For all correspondence regarding IRB formal actions relating to research projects submitted through the IRB's online, electronic submission/tracking system, the letters will be signed by the IRB Chairperson (or designee) and include a statement that the letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

### **Specific Policies**

#### **1.1 Authorization for Signatory Authority**

Authorization to sign documents not described in this policy may be made in writing by the IRB Chairperson.

#### **1.2 Results of Reviews, Actions and Decisions**

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 the IRB Administrator using the IRB Chairperson's name but initialing thereafter, or will be signed "electronically" through the online, electronic submissions/tracking system.

In the absence of the IRB Chairperson, the IRB Co-Chairperson, or designed IRB member chairing the IRB meeting, has the authority to sign under their name for IRB reviews and actions, as described above. The signature will indicate that the signer is acting on behalf of the IRB Chair.

#### **1.3 Routine Internal Correspondence**

Any action, letters, memos or emails between the IRB or OROC staff of the Sparrow Health System that provide information concerning the review of research protocols by the OROC staff which do not imply or appear to imply approval of this activity, may be signed by the IRB Administrator.

#### **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 IRB Chairperson. The Vice President of Medical Affairs will sign any correspondence requiring the signature of the IO.

**1.5 Decisions Made by Chairperson**

All letters, memos or email representing the decision or opinions of the IRB Chairperson or his/her respective designees, as long as such correspondence does not imply review and approval of research projects, may be signed by the OROC staff.

**2. SCOPE**

These policies and procedures apply to all IRB members and OROC staff.

**3. RESPONSIBILITY**

Institutional Official is responsible for establishing the overall procedure for delegating signatory authority.

IRB Administrator is responsible for implementing and controlling signatory authority delegations.

IRB Chairperson, IRB members and OROC staff are responsible for adhering to institutional signatory authority policies.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103, 46.115

**5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

**6. ATTACHMENTS**

None

**7. PROCESS OVERVIEW**

Circumstances may warrant signatory authority to be delegated to another party. Signatory authority may be granted in writing by the IO and/or the IRB Chairperson.

**8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

Who	Task	Tool
<i>IRB Administrator</i>	Establish signature authority delegation based on nature of documents being signed.	
<i>IRB Chairperson</i>	Sign all documents related to the review and approval of research projects and correspondence with external agencies. In the absence of the IRB Chairperson (or designee) the Institutional Official must sign such documents.	
<i>IRB Administrator</i>	Sign routine internal correspondence or actions taken by an IRB Chairperson if authorized to do so by the Chairperson.	
<i>IRB Administrator</i>	Authorized to use the IRB Chairperson’s signature stamp by initialing thereafter. In no case is any staff to sign the name of the IRB Chairperson.	