

<b>SOP: GA 101</b> <b>Version No:</b> <b>Effective Date:</b>	<b>POLICIES AND PROCEDURES</b> <b>MAINTENANCE</b>	<b>Supersedes Document:</b> <b>xx/xx/xx</b>
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## **1. POLICY**

Following regulations and guidance of OHRP, FDA, and the International Conference on Harmonisation (ICH), supported by institutional policies, ensures that the rights and welfare of the human subjects of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. 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.

Standard operating policies and procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research.

### **Specific Policies**

#### **1.1 Review, Revision, Approval of Policies & Procedures**

- 1.1.1 Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of INSTITUTION NAME may require a new SOP or a revision to a previously issued SOP.
- 1.1.2 Policies will be reviewed by the appropriate institutional official(s) at intervals established by the CUSTOM TITLE.
- 1.1.3 Approval of new or revised SOPs is required by the CUSTOM TITLE.
- 1.1.4 Documentation of review and approval is required by signature of the responsible and authorized individuals.

#### **1.2 SOP Dissemination and Training**

- 1.2.1 When new or revised SOPs are approved, they will be disseminated to the appropriate individuals & departments as detailed in form GA 101-F.
- 1.2.2 Training will be provided to all members of the IRB and IRB staff on any new or revised policy and/or procedure. Evidence of training must be documented and filed with the IRB Manager.
- 1.2.3 Each new IRB member or staff employee must review all applicable SOPs prior to undertaking any responsibilities at the IRB. Evidence of training must be documented and filed with the IRB Manager.

### 1.3 Forms

Forms are used to 1) ensure that policies are integrated into the daily operations of research and review throughout the INSTITUTION NAME system, and 2) enable IRB staff to manage review, tracking, and notification functions consistently. Forms are either **controlled** or **non-controlled**.

1.3.1 **Controlled** forms are regulatory documents that become part of the permanent record of IRB review and determination.

Therefore, they must be reviewed and approved as described in sections 1.1 and 1.2.

1.3.2 **Non-controlled** forms are management tools that are not subject to the standards of control cited in sections 1.1 and 1.2.

## 2. SCOPE

These policies and procedures apply to all IRB staff.

## 3. RESPONSIBILITY

Institutional Official is responsible for granting final approval (as appropriate) to new and revised IRB policies.

IRB Manager (or equivalent) is responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.

IRB Chairperson (or designee) is responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.

## 4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113

45 CFR 46.108

## 5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

## 6. ATTACHMENTS

GA 101-A SOP Revision Worksheet

GA 101-B SOP Review Meeting Template

GA 101-C SOP Revision Log

GA 101-D Forms Revision Log

GA 101-E SOP Template

GA 101-F Notification of SOP Change

## 7. PROCESS OVERVIEW

States the IRBs' commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles.

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

<b>Who</b>	<b>Task</b>	<b>Tool</b>
<i>IRB Manager</i>	Using SOP Revision Worksheet, monitor appropriate sources and contacts for policy updates, note policies that may need revisions and indicate priority.	SOP Revision Worksheet
<i>IRB Manager</i> <i>IRB Chairperson</i>	On pre-determined schedule, meet regarding changes to SOPs.	SOP Review Meeting Template
<i>IRB Manager</i> <i>IRB Staff</i>	Discuss changes and determine if additional procedures are required or if forms need revisions.	
<i>IRB Manager</i>	Revise policies and/or procedures. Revise forms if needed. Track changes.	SOP Template SOP Revision Log Forms Revision Log
<i>Institution Official</i>	Sign revised policy, if appropriate.	
<i>IRB Manager</i>	Update policy and archive hard copies of previous policy.	
<i>IRB Manager</i>	Notify Information Technology staff to make changes on electronic system and to archive previous version.	
	Replace & destroy paper copies of obsolete sections.	
	Notify research community & distribute new SOPs & forms as needed.	Notification of SOP Change