

POLICY AND PROCEDURE MAINTENANCE

SOP #:	103	VERSION #:	1	EFFECTIVE DATE:	5/1/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:			IRB MEMBERS AND STAFF WITHIN UND				
RESPONSIBILITY FOR EXECUTING POLICY:		IRB STAFF, IRB CHAIRPERSON, IRB MEMBERS, AND INSTITUTIONAL OFFICIALS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	/ /

1. POLICY

Following regulations and guidance of the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the University of North Dakota institutional policies, assures 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 standard operating policies and procedures (SOPs) 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. SOPs provide the framework for the ethical and scientifically sound conduct of human research.

2. SPECIFIC POLICY

2.1 Review, Revision, Approval of Policies and Procedures

2.1.1 Changes to regulations, federal guidelines, or research practice, as well as the policies of the University of North Dakota may require a new policy or a revision to a previously issued SOP. Any new information, identified by the Research Development and Compliance (RD&C) office as being pertinent to the protection of research participants, will be disseminated and will be available on the IRB website.

2.1.2 SOPs will be reviewed by the appropriate institutional official(s) at intervals established by the Associate Vice President for Research and Economic Development. The Associate Vice President for Research and Economic Development approves new or revised SOPs. Documentation of review and approval is required by signature of the responsible and authorized individuals.

2.2 Dissemination and Training of Policies and Procedures

When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and departments via email or mail and will be available on the website. Training will be provided to all members of the Institutional Review Board (IRB) and IRB staff on any new or revised policy and/or procedure. Evidence of training will be documented and filed with the IRB Coordinator.

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 Coordinator.

2.3 Forms

Forms are used to 1) ensure that policies are integrated into the daily operations of research and review throughout the UND system, and 2) enable IRB staff to manage review, tracking, and notification functions consistently.

3. RESPONSIBILITY

The UND Associate Vice President for Research and Economic Development is responsible for granting final approval (as appropriate) to new and revised SOPs for the IRB.

The UND Associate Vice President for Research and Economic Development is responsible for establishing and periodically reviewing and modifying (as appropriate) SOPs.

The IRB Chairperson (or designee) and/or the IRB Coordinator is responsible for periodically reviewing and suggesting modifications as appropriate to the SOPs.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113
 45 CFR 46.108

5. ATTACHMENTS

GA 103-A SOP Policy Revision Worksheet
 GA 103-B SOP Revision Log
 GA 103-C SOP Template
 GA 103-D Notification of SOP Change

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>Associate Vice President for Research and Economic Development, IRB Coordinator</i>	Using SOP Revision Worksheet, monitor appropriate sources and contacts for policy updates, note policies that may need revisions and indicate priority.
<i>Associate Vice President for Research and Economic Development, IRB Chairperson, IRB Coordinator</i>	Annually meet regarding changes to SOPs. Discuss changes and determine if additional procedures are required or if forms need revisions.
<i>IRB Coordinator, IRB Secretary</i>	Revise SOPs. Revise forms if needed. Track changes.

<i>Associate Vice President for Research and Economic Development</i>	Sign revised policy, if appropriate.
<i>IRB Coordinator</i>	Update SOP and archive hard copies of previous SOP for 5 year time period. Delegate changes to be made on electronic system. Replace & destroy paper copies of obsolete sections. Notify research community & distribute new SOPs & forms as needed.