

TRAINING AND EDUCATION

SOP #:	104	VERSION #:	1	EFFECTIVE DATE:	6/1/14	SUPERSEDES DOCUMENT:	5/1/09
THIS POLICY PERTAINS TO:			IRB STAFF AND MEMBERS WITHIN THE UNIVERSITY OF NORTH DAKOTA				
RESPONSIBILITY FOR EXECUTING POLICY:		IRB STAFF, IRB MEMBERS, IRB CHAIRPERSON, INSTITUTIONAL OFFICIALS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:					DATE:	3/1/14	

1. POLICY

Training IRB 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 University of North Dakota research community.

IRB members, staff, and others charged with responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics and policies applicable to human subject research. Such training is fully supported by the Research Development and Compliance office.

2. SPECIFIC POLICIES

2.1 Training

2.1.1 IRB Members and IRB Staff who are overseeing research on human subjects, as defined in [45 CFR 46.102 \(f\)](#) and/or [21 CFR 56.102\(e\)](#), that is managed, funded, or taking place in an entity under the jurisdiction of the University of North Dakota will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.

2.1.2 The IRB Chairperson and IRB members, under the direction of the Associate Vice President for Research and Economic Development, establishes the educational and training requirements for IRB members and IRB Staff who review biomedical and behavioral research involving human subjects and/or who perform related administrative duties. Initial and ongoing training is provided and documented by this institution through the Research Development and Compliance office.

2.1.3 New members of the IRB will be assigned a mentor from among those IRB members who have served on the Board for at least one year. Mentors will assist in the review of proposals by new members and are available to discuss the regulations and policies with the new members.

2.1.4 Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities.

2.1.5 The IRB Chairperson and IRB Vice Chairperson will receive additional training in areas germane to their additional responsibilities.

2.1.6 IRB Staff will receive initial and continuing training in the areas germane to their responsibilities.

2.1.7 IRB members and IRB Staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. The University of North Dakota will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

2.2 Documentation

Training and continuing education will be documented and added to the records of the IRB as described in these policies and procedures.

2.3 Community Outreach

The University of North Dakota Institutional Review Board provides information to the research community regarding the rights of a research participant as a volunteer. The IRB encourages and promotes community outreach efforts through feedback materials, surveys and presentations on campus whenever possible.

2.3.1 Procedure for Maintaining Community Outreach Efforts Offered

The IRB provides resources for research participants, prospective participants, researchers and community.

The IRB maintains a section of the IRB web site entitled “Information for Research Participants” which includes links to: information about becoming a research participant; ethical codes pertaining to research with human subjects; and federal regulations governing research with human subjects. Included on this page is a section specific to community-based participatory research. The IRB will provide hard copies of these as well.

The IRB members or staff conduct trainings or make presentations upon request regarding the rights of research participants.

The IRB Coordinator will evaluate, make changes, and implement changes to the outreach program as needed and will consider any complaints, concerns, suggestions and other input from participants or others within the research community, and consider other departmental outreach efforts on the University campus.

Periodic assessments of outreach efforts and the outreach program are done at least annually, and more frequently, if needed, as determined by the Associate Vice President for Research and Economic Development, the IRB Coordinator, or the IRB Chairperson.

3. RESPONSIBILITY

The Associate Vice President for Research and Economic Development and/or the IRB Coordinator is responsible for establishing, conducting and/or supervising all relevant training programs for IRB members and IRB Staff.

The IRB Chairperson and IRB Coordinator are responsible for guiding the development of IRB member training programs in collaboration with the Associate Vice President for Research and Economic Development.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107

45 CFR 46.107

[OHRP IRB Guidebook](#)

[NIH NOTICE: OD-00-039](#) Required Education in the Protection of Human Research Participants

5. ATTACHMENTS

GA 104-A Checklist and Documentation – IRB Members

GA 104-B Checklist and Documentation – Staff

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>Associate Vice President for Research and Economic Development, IRB Coordinator</i>	Establish training, educational requirements and content for IRB members and IRB Staff. Set annual budget.
<i>Associate Vice President for Research and Economic Development, IRB Coordinator</i>	Based on requirements and budget, determine training & education schedule. Schedule speakers, acquire outside publications, schedule attendance at PRIM&R and seminars as budget allows. Notify Secretary regarding contacting IRB members with training/education schedule. Notify IRB members of available training materials & schedule.
<i>Associate Vice President for Research and Economic Development</i>	Review (annually) the IRB Chairperson’s and IRB Vice Chairperson’s knowledge, understanding, and experience relevant to his/her role.
<i>IRB Chairperson, IRB Coordinator</i>	Review (annually) IRB member’s knowledge, understanding, and experience relevant to their roles.
<i>IRB Secretary</i>	Maintain documentation of all training and education completed.