

## 5 Training and Education

### 5.1 IRB Chair and members

Effective Date: **7/11/2008**

Revised: **9/09/2011** (effective  
1/01/2012), **7/06/2012**

NDSU has an obligation to ensure that investigators, IRB members and staff maintain continuing knowledge of, and comply with, the relevant ethical principles, federal regulations, OHRP guidance, other applicable guidance, state and local laws and institutional policies for the protection of human subjects. To fulfill this obligation, NDSU IRB Chair and members complete initial and ongoing training, appropriate for their role in the review and oversight of research involving human participants.

#### 1.0 Initial training and orientation:

Within 2 months of appointment, and prior to reviewing a protocol, all new IRB members complete initial training and orientation appropriate for their role in the review of research.

#### 1.1 Training course.

The initial training course for IRB members consists of a series of web-based modules from the Collaborative Institutional Training Initiative (CITI) program. The content of the training includes:

- history of the federal regulations for the protection of human research subjects
- ethical principles of the Belmont Report
- definitions of 'research' and 'human subjects/participants'
- selection of subjects, informed consent
- risk and benefit assessment
- privacy and confidentiality concerns
- IRB review process and criteria for approval
- safeguarding vulnerable populations
- continuing review, protocol amendments
- reporting requirements
- conflict of interest in human subjects research
- other topics relevant to the range of research conducted at NDSU

The content of training for IRB members is more comprehensive than that required for investigators, due to the member's broader role in review and oversight of human subjects research. New IRB members who also conduct research automatically fulfill investigator training requirements upon completion of IRB member training. Refer to SOP 5.3 *Training and Education – Research investigators*.

The initial training course is periodically assessed and updated as necessary to reflect emerging ethical issues, regulatory changes or new NDSU research initiatives.

#### 1.2 New member orientation:

New members complete an orientation session with the IRB chair or HRPP staff, which includes:

- overview of the HRPP Standard Operating Procedures (SOPs)

- discussion of IRB review procedures for new and continuing protocols
- voting and documentation requirements
- criteria for approval of protocols
- informed consent process and elements; review of waiver requests
- additional criteria for review of protocols involving vulnerable groups
- review of protocol amendments, continuations, unanticipated events and potential noncompliance findings

New members are encouraged to seek guidance from the IRB chair, other experienced members or HRPP staff to gain familiarity with the interpretation and application of ethical and regulatory requirements for IRB review and approval of research.

### 2.0 Ongoing training:

Maintaining current knowledge of relevant ethical principles, policies and procedures is an important responsibility for IRB members in their role of oversight for human subjects research. A variety of methods are used to meet this obligation.

Prior to re-appointment (by September 1) members are required to complete the CITI IRB member refresher course (or initial IRB member course) for each 3-year term of membership. The refresher course is periodically assessed and updated as necessary.

HRPP staff, the IRB chair, an experienced member, or invited researcher periodically present brief (5 – 10 minutes) discussions on various topics related to research protections at convened meetings. In addition, various periodicals or newsletters (*Research Ethics Digest*, *IRB Ethics*, *IRB Advisor*), as well as online video or audio-recordings (PRIM&R, OHRP or FDA), seminars or webinars are also available to members.

IRB members who also conduct research automatically fulfill investigator refresher training requirements upon completion of the IRB member refresher course.

### 3.0 Documentation.

The HRPP staff maintain IRB member training records and track completion for each member. A report may be provided periodically to each member and the IRB Chair to assess completion of training requirements.

Should a member be unwilling or unable to fulfill initial or ongoing training requirements for a prolonged period (e.g., over 3 months), they will be asked to resign from the board and a new member will be sought.

## **REFERENCES:**

[DHHS Office of Human Research Protections](#)

[IRB website – training page](#)

[CITI online training sessions](#)

[PRIM&R \(Public Responsibility in Medicine and Research\) organization](#)

**RELATED HRPP STANDARD OPERATING PROCEDURES:**

- 3.2 Roles and Responsibilities – Institutional Official and IRB Members
- 4.2 IRB Meeting Procedures
- 5.2 Training and Education – HRPP Staff
- 5.3 Training and Education – Research investigators and team members