5 Training and Education 5.2 Human Research Protection Program staff	Effective Date: **7/11/2008** Revised: **9/09/2011** (effective 1/01/2012)

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, staff of the Human Research Protection Program (HRPP) complete initial and ongoing training, appropriate for their role in administration and oversight of NDSU research involving human participants.

1.0 Initial training and orientation:

Within 2 months of hire, and prior to performing independent exempt certifications, review of protocols or presentation of training sessions, HRPP staff complete comprehensive initial training. Options for meeting the initial requirement include:

- Collaborative Institutional Training Initiative (CITI) online course (IRB member and staff modules) or
- attendance at a conference for human research protections, as funds allow

The content of the training will cover:

- 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
- other topics relevant to specific research methods
- conflict of interest in human subjects research

The initial training is periodically assessed and updated as necessary to reflect emerging ethical issues, regulatory changes or new NDSU research initiatives. Obtaining a professional certification, such as the CIP (Certified IRB Professional) may be a requirement for HRPP staff responsible for independent exempt certifications, review of protocols or presentation of training sessions. HRPP staff may take up to 2 years to establish eligibility requirements for the CIP, currently listed as:

- B.S., plus 2 years relevant IRB experience within the last 7 years
- 4 years of relevant IRB experience within the last 10 years

2.0 Continuing education:

IRB staff have a responsibility to maintain extensive and current knowledge of all aspects of human subjects protections. To achieve this goal, and remain aware of current national best practice standards, a minimum of 30 hours continuing education (CE) is required every 3 years. Options include:

- CITI IRB Member and Staff initial or refresher course
- attendance at IRB meetings or training sessions where another person presents a CE topic
- attendance at national or regional conferences, seminars or webinars, as funds allow
- periodicals or newsletters (*Research Ethics Digest, IRB Ethics, IRB Advisor*)
- online video or audio recorded sessions (available through OHRP, FDA or other sources), or
- resources available through professional memberships (Public Responsibility in Medicine and Research, PRIM&R)

Options may provide various amounts of contact hours; HRPP staff track and record appropriate CE hours for each activity.

3.0 Documentation.

On an individual basis, HRPP staff document completion of initial training and CE, making records available for inspection on request. Additional or more specific CE requirements may apply to maintain CIP certification; consult applicable program requirements.

HRPP staff undergo annual performance reviews, in which completion of training requirements are assessed. A lapse in completion of initial or ongoing training requirements may be addressed through appropriate corrective actions as a result of the review.

REFERENCES:

DHHS Office of Human Research Protections
IRB website – training page
CITI online training sessions
Certified IRB Professional (CIP) Program
PRIM&R (Public Responsibility in Medicine and Research) organization

RELATED HRPP STANDARD OPERATING PROCEDURES:

3.2 Roles and Responsibilities – Institutional Official and IRB members
5.1 Training and Education – IRB Chair and members
5.3 Training and Education – Research investigators and team members