5 Training and Education 5.3 Research investigators and team members	Effective Date: **7/11/2008** Revised: **2/12/2010, 1/1/12, 7/1/2020**

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 investigators and research team members complete initial and ongoing training appropriate for their role in conducting research involving human participants.

1.0 Training requirement.

Research investigators and team members engaged in human subjects research complete initial training requirements prior to conducting research with human participants; training must be updated every 3 years.

1.1 Engaged in research.

NDSU faculty, staff and students are considered to be engaged in human subjects research, and must complete training when their involvement includes any of the following:

1.1.1. Receive a direct award, grant or contract for human subjects research.

1.1.2. Direct or supervise human subjects research.

1.1.3. Intervene with participants for research purposes by performing invasive or noninvasive procedures, or manipulating the environment. *(Exceptions – when the activities are limited to those described in 1.2.1 – 1.2.4 below, they are not engaged).*

1.1.4. Interact for research purposes with participants. *(Exceptions – when the activities are limited to those described in 1.2.1 – 1.2.4 below, they are not engaged).*

1.1.5. Obtain informed consent of human subjects. *(Exceptions – when the activities are limited to those described in 1.2.3 – 1.2.4 below, they are not engaged).*

1.1.6. Obtain private information or specimens from any source for research purposes. This includes, but is not limited to: observing or recording private behavior, using, studying or analyzing private information or specimens provided by another institution or already in the possession of the investigators.

1.2 Not engaged in research.

The training requirement is not applicable to NDSU faculty, staff and students whose involvement is *limited* to one or more of the following activities (NOT engaged in human subjects research):

1.2.1. Perform commercial or other services for investigators, provided that:

- services do not merit professional recognition or publication privileges,
- services are typically performed for non-research purposes, and

- employees or agents do not administer any research intervention being evaluated under the protocol.

Some examples of services may include: interview transcription performed by a transcription company, blood draw or analysis performed by a hospital lab, data collection or analysis performed by a survey firm.

1.2.2. Permit use of facilities to allow another institution's investigators to intervene or interact with subjects.

1.2.3. Assist with recruitment by informing or providing prospective subjects with information about research (may include a consent document or other IRB-approved materials) or contact information for investigators; provided they do not obtain consent or act as a representative for the research.

1.2.4. Seek or obtain prospective subjects permission for investigators to contact them directly.

1.2.5. Release lists of names/contact information, private information or biological specimens to another institution.

1.2.6. Access or utilize identifiable private information only while visiting an institution engaged in the research (provided that their IRB has approved the study).

1.2.7. Author a paper, journal article, or presentation describing a human subjects research study.

2.0 Initial training.

Research investigators and team members complete training prior to their involvement in a human subjects research project.

2.1 Course options.

Options for meeting the initial training requirement include:

- online courses from Collaborative Institutional Training Initiative (CITI)
    - Social/Behavioral Research Course – Basic Course, or
    - Biomedical Research Course – Basic Course
    - Research Assistants or Team Members
    - Extension Agents

Investigators conducting an NIH-funded clinical trial must also complete training in Good Clinical Practice (GCP). Training on GCP is also offered through the CITI Program website.

Specific instructions and resources to fulfill training requirements are maintained on the IRB website.

2.2 Training content.

The content of the initial 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
- IRB reporting requirements
- FDA requirements for clinical investigations of test articles (as applicable)

Investigators who also serve on the IRB automatically fulfill initial researcher training requirements upon completion of IRB member training course.

3.0 Ongoing training.

Maintaining continuing knowledge of relevant ethical principles, policies and procedures is an important responsibility for investigators and research team members in their role of conducting human subjects research. Investigators and research team members complete continuing education (CE) every 3 years through the online CITI refresher or basic courses on the protection of human subjects.

Consult the IRB website for specific instructions and links to CITI training resources. Investigators who also serve on the IRB automatically fulfill requirements for refresher training upon completion of their online CITI course for IRB Members and Staff.

4.0 Documentation.

Training records must be current within the CITI Program website. Current training must be on file for the Principal Investigator, co-Investigator, and any team member upon submission of new protocols for review or requests for continuing approval.

REFERENCES:

DHHS Office of Human Research Protections
IRB website – training page
CITIProgram.org

RELATED HRPP SECTIONS:

2.1 Human Subjects Research
2.2 NDSU Engagement in Human Subjects Research
5.1 Training and Education – IRB Chair and Members
5.2 Training and Education – HRPP Staff