

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 has implemented initial and ongoing training programs; the IRB office maintains all training records and presents educational sessions.

1.0 Initial training

All research investigators must fulfill initial training requirements prior to conducting research with human participants; training must be updated every 3 years.

Investigators include those individuals (NDSU faculty, staff or students, or non-NDSU collaborators or assistants) who will:

- Oversee, direct or supervise research involving human subjects
- Actively recruit potential participants for research
- Seek to obtain the informed consent of volunteers
- Interact or intervene with subjects to obtain data for research
- Perform research procedures
- Obtain private, identifiable information for research

Options for meeting the initial training requirement include:

- online sessions (CITI, NIH)
- attendance at a campus training session conducted by the IRB member or staff
- attendance at a conference for human research protections
- other equivalent option (consult IRB office)

The content of the training will include:

- history of the federal regulations
- ethical principles of the Belmont Report
- definitions of 'research' and 'human subjects/participants'
- selection of subjects, informed consent
- risks to research participants
- privacy and confidentiality concerns
- the IRB review process and criteria for approval
- safeguarding vulnerable populations
- continuing review, protocol amendments
- reporting requirements

Training documentation from another institution's IRB may be accepted, if equivalent. IRB staff or members are also available for presentations to individual groups, departments or classes. Alternative arrangements can be made to facilitate training for large groups of research team members; please consult the IRB office.

2.0 Ongoing training

Refresher training is required for those investigators with continued involvement in human research. A minimum of 1 hr every 3 years is required, and may be fulfilled through online or on-campus presentations, or other equivalent options. Consult the IRB website for updates on campus training sessions, and instructions and links to online modules. In addition, the IRB office maintains an active PI listserv and newsletter for distributing information on new policies, emerging issues of interest, and discussion of relevant subject protections topics.

REFERENCES:

[Terms of the FederalWide Assurance, OHRP \(#13\)](#)

[DHHS Office of Human Research Protections](#)

[IRB website – training page](#)

[CITI online training sessions](#)

[NIH online training sessions](#)

[Certified IRB Professional \(CIP\) Program](#)

[PRIMR \(Public Responsibility in Medicine and Research\) organization](#)