

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 coordinates and presents educational sessions.

1.0 Initial training and orientation:

The initial training requirements for IRB office staff are similar to those for research investigators and IRB members. Options for meeting the initial requirement include:

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

The content of the training will cover:

- 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

Prior to performing independent exempt certifications or IRB reviews or presenting training sessions, new staff must develop sufficient competency in the application and interpretation of relevant federal regulations and institutional policy for protecting research subjects. Obtaining a professional certification, such as a CIP (Certified IRB Professional) is highly encouraged for staff who will have this role.

The IRB staff member listed on the FederalWide Assurance as the 'human subjects administrator', is also required to complete the 'Human Subjects Assurance Training' available on the OHRP website. The assurance training is also required for the IRB chair and the Institutional Official (IO).

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, ongoing education and training is required. Resources include

attendance at national or regional conferences and seminars, professional memberships (ie, Public Responsibility in Medicine and Research, PRIMR), OHRP guidance documents, IRB listservs, and networking with colleagues.

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](#)