

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 for new members:

All IRB members must complete an initial training session and new member orientation prior to reviewing a protocol; ongoing education is also required on an annual basis.

Options for meeting the initial training requirement include:

- online sessions (CITI, NIH)
- attendance at a campus training session conducted by IRB staff or member
- 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

2.0 Orientation for new members:

New members will also take part in an orientation session with the IRB chair or staff, that includes:

- discussion of the IRB review processes of new and continuing protocols
- 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 will be mentored by an experienced IRB chair, current member, or staff until they become comfortable with interpretation of the ethical and regulatory requirements for IRB review and approval of research.

3.0 Ongoing training:

Continuing education is required for IRB members, equivalent to 1 hr each year. A variety of topics relevant to research protections will be presented by the IRB staff, chair or experienced member at each convened meeting as an agenda item. Attending 7 sessions each year will meet the requirement; other options could include online or campus training sessions as mentioned above.

IRB members are also updated with new regulations and guidance from OHRP or FDA, recent news or events related to human research protections, and encouraged to attend regional or national conferences.

4.0 IRB Chair:

In addition to IRB member training and continuing education requirements, OHRP requires that the IRB chair, human subjects administrator (IRB staff) and Institutional Official (IO) complete the 'Human Subjects Assurance Training' available on the OHRP website.

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](#)

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