

3 Roles and Responsibilities:

3.1 Investigator and research team

Effective Date: **3/11/2011**

Revised:

NDSU's responsibility to protect the rights, safety and welfare of research participants is shared among investigators and their research team, Institutional Review Board (IRB) members, the Institutional Official (IO) and various departments and offices, as well as federal agencies and sponsors.

1.0 Principal investigator.

As the individual with supervisory authority for a project, the principal investigator (PI) bears ultimate responsibility for protection of subjects, and is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the research. An NDSU faculty or staff member may serve as PI. The faculty advisor must serve as PI for any research conducted for a graduate thesis or dissertation. In this role, the PI is required to:

- possess qualifications and/or licensure appropriate for the project
- ensure facilities and equipment are adequate to conduct the research with acceptable risk
- maintain current knowledge and awareness of federal regulations, state laws, and institutional policies regarding subject protections
- complete all required subject protections training and continuing education
- ensure any co-investigators and other members of the research team are appropriately qualified for their role and complete required training
- obtain IRB approval in accordance with regulations and policy for new and continuing research, as well as proposed changes to research
- disclose any protocol-related conflicts of interest having the potential to bias decisions relating to subject protections
- ensure that the research is conducted in accordance with the protocol approved by the IRB
- comply with determinations of the IRB
- submit reports as required, including incidents of research related injuries, adverse events, unanticipated problems involving risks to subjects or others, significant new findings affecting risks to participation, and any noncompliance with federal regulations, NDSU policy, or the determinations of the IRB
- cooperate fully with requests for random or directed audits of the research

Details regarding specific responsibilities are described throughout various sections of the Operating Procedures. Additional responsibilities apply for research subject to requirements of the Food and Drug Administration (FDA); refer to *SOP 11.6 Review of FDA Regulated Research* for more information.

2.0 Co-investigators and research team members.

NDSU faculty, staff, students, or unaffiliated investigators involved as co-investigators or other members of the research team also share in the responsibility to protect research participants. This role may involve interaction or intervention with research participants, or analysis of

identifiable data or specimens. In this role, co-investigators and research team members are required to:

- possess qualifications and training appropriate for role in the project
- maintain current knowledge and awareness of federal regulations, state laws, and institutional policies regarding subject protections
- complete all required subject protections training and continuing education
- disclose to the PI any conflicts of interest having the potential to bias decisions relating to subject protections
- conduct research in accordance with protocol approved by the IRB
- maintain appropriate records in a secure fashion
- comply with determinations of the IRB
- submit reports as required, including incidents of research related injuries, adverse events, unanticipated problems involving risks to subjects or others, significant new findings affecting risks to participation, and any noncompliance with federal regulations, NDSU policy, or the determinations of the IRB
- cooperate fully with requests for random or directed audits of the research
- (for unaffiliated investigators) abide by an agreement to comply with NDSU policies and procedures for subject protections

Details regarding specific responsibilities are described throughout various sections of the Operating Procedures.

DEFINITIONS:

Principal investigator (PI): an NDSU faculty or staff member who has primary responsibility for the research. When graduate students will conduct research, their faculty advisor is considered the PI.

Investigator: anyone involved in conducting the research; ie, study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining coded private information or specimens, analyzing data.

REFERENCES:

[45 CFR 46.111](#) and [21 CFR 56.111](#) Criteria for IRB approval
[FederalWideAssurance \(FWA\) for the Protection of Human Subjects](#)

RELATED FORMS AND LETTERS:

IRB Approval Letters

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

- 2.2 NDSU Engagement in Human Subjects Research
- 3.2 Roles and Responsibilities: Institutional Official and Institutional Review Board
- 3.3 Roles and Responsibilities: Other Institutional Units
- 5.3 Training, Education and Outreach: Research investigators and team
- Section 6 Conflicts of Interest
- 7.6 Criteria for IRB Approval
- 11.6 Review of FDA Regulated Research