3 Roles and Responsibilities: 3.2 Institutional Official and Institutional Review Board	Effective Date: **05/06/2011** Revised: 11/8/2013

NDSU's responsibility to protect the rights, safety and welfare of research participants is shared among investigators, 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 Institutional Official.

The Vice President of Research and Creative Activity serves as the Institutional Official (IO) for oversight of the Human Research Protection Program (HRPP) at NDSU. In this role, the IO is responsible to ensure:

- a culture of ethical conduct, review and oversight of human subjects research
- independent functioning of the IRB, free from coercion and undue influence
- adequate resources to support the IRB and HRPP

In addition, the IO:

- serves as signatory authority for assurances or agreements involving human research projects
- appoints members to the IRB, including appointment of a Chair, based on recommendations from College Deans, VP for Student Affairs, and HRPP staff
- removes members from the IRB, in consultation with IRB Chair, other members, and HRPP staff
- reports issues of serious noncompliance and unanticipated problems to federal agencies and sponsors with the assistance of HRPP staff
- may disapprove, suspend or terminate IRB approval of human research projects
- is prohibited from approving a project previously disapproved, suspended or terminated by the IRB
- may require additional investigation or corrective actions for any issue of noncompliance or unanticipated problems involving risks to participants or others reviewed by the board

2.0 Institutional Review Board.

Faculty, student and unaffiliated individuals appointed as members of the IRB serve an important oversight role for proposed and ongoing human research projects at NDSU. In this review and oversight role, IRB members:

- possess diverse qualifications and backgrounds relating to human subjects research, familiarity with vulnerable groups or the community,
- maintain a good working knowledge of federal regulations, NDSU policy, and state and local laws pertaining to the protection of research participants,
- complete orientation, training, and continuing education for their role in protocol review
- review proposed and ongoing research in which NDSU is engaged,

- suspend or terminate human research projects in which participants are at potential risk, and/or not being conducted in compliance with federal regulations or NDSU policies,
- disclose any protocol-related conflict of interest which has the potential to impact their consideration of the rights and welfare of participants,
- function independently in the review and oversight of human subjects research, free of coercion and undue influence from other entities
- may observe, or direct another party to observe the consent process or any part of the research.

More specific responsibilities are described in SOP *4.1 IRB Membership* and elsewhere throughout the Operating Procedures.

3.0 HRPP staff.

Qualified staff members within Sponsored Programs Administration (SPA) are charged with supporting the functions of the IRB and HRPP. In their role, HRPP staff serve as a communication link between IRB members, investigators and the Institutional Official (IO), and are responsible to:

- maintain a thorough knowledge of federal regulations, NDSU policy, state and local laws, including best practice standards pertaining to the protection of research participants,
- complete orientation, training, and continuing education appropriate for their role,
- receive and process submissions for proposed and ongoing human subjects research
- serve as a resource for investigators and members with questions about IRB procedures,
- certify protocols eligible for exempt status; ensure appropriate review of protocol submissions,
- disclose any protocol-related conflict of interest having the potential to bias decisions relating to subject protections,
- communicate review determinations to investigators and issue approval notices as appropriate,
- maintain appropriate IRB membership composition, in conjunction with Chair and IO,
- maintain records of all IRB activities and approved protocols,
- maintain required federal and sponsor assurances and registrations,
- maintain a program for initial and continuing education of IRB members and investigators,
- conduct random and directed audits of research,
- maintain manual of HRPP procedures,
- participate in review of noncompliance and reports of unanticipated problems,
- receive and address any complaints, in conjunction with IRB Chair and other members as appropriate,
- ensure research community is kept informed of policies and procedures regarding research subject protections,
- support evaluation of the effectiveness of the HRPP,
- ensure review and certification of funding proposals involving human research,
- serve as point of contact for auditors and inspectors from internal or external entities.

More specific responsibilities are described elsewhere throughout the Operating Procedures.

DEFINITIONS:
Institutional Official (IO): individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance

REFERENCES:
FederalWide Assurance (FWA) for the Protection of Human Subjects Office of Human Research Protections
45 CFR 46.103(c) Assuring compliance with this policy
45 CFR 46.108 and 21 CFR 56 Subpart C IRB functions and operations
45 CFR 46.113 and 21 CFR 56.113 Suspension or termination of IRB approval of research
45 CFR 46.115 and 21 CFR 56.115 IRB records
Assurance Training Modules, Office of Human Research Protections

RELATED FORMS AND LETTERS:
IRB Membership Appointment Letters

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:
2.2 NDSU Engagement in Human Subjects Research
3.1 Roles and Responsibilities: Investigator and Research Team
4.1 IRB Structure and Administration: IRB Membership
Section 7 IRB Review Process