

1: Principles and Purpose

1.3 Maintenance of Procedure Manual

Effective Date: 7/8/11

Revised: 8/14/2015

Standard operating procedures (SOPs) of the human research protection program (HRPP) describe processes for NDSU compliance with federal, state, and institutional requirements in the review, oversight and conduct of all human subjects research in which the institution is engaged. Periodic review of these SOPs ensures that adequate processes are in place to protect the rights and welfare of participants, and NDSU remains in compliance with new and evolving requirements for the protection of human research subjects.

1.0 Periodic review.

Each SOP in the procedure manual is reviewed at regular intervals (approximately every 3 to 5 years) to determine compliance with current federal regulations and guidance, state and local laws, institutional policy and organization, as well as adequacy and clarity of information.

1.2 Review schedule.

HRPP staff track and monitor SOPs in the procedure manual, scheduling review as necessary based on effective date, or date of last revision. SOPs are scheduled for review at a convened meeting, as time allows.

1.3 Documentation of review.

The IRB reviews each SOP at a convened meeting, and may determine that the procedure conforms to current regulations, policies and standards, provides adequate clarity and guidance, and reflects current practices. Alternatively, the IRB may determine that revisions to the procedure manual are required (see 2.0 below).

2.0 Revisions.

Proposals to revise the procedure manual may result from a periodic review or may be initiated at any time. HRPP staff, the IRB Chair, or an IRB member may draft a proposal to create, delete, or change an SOP for various reasons, such as:

- improving subject protections
- complying with new requirements or best practice standards
- providing additional guidance
- streamlining processes to enhance efficiency
- updating institutional information or roles
- adding procedures for new areas of research
- removing procedures or requirements no longer relevant
- re-organizing sections of the manual
- revising text or format for clarity
- correcting errors in text or formatting.

Additional expertise may be solicited from various sources (e.g., federal agencies, General Counsel, other NDSU administrative units or academic departments, other research institutions, etc.) to prepare the revision. A complex issue or highly specialized

topic may also require the assistance of a subcommittee or consultant(s) to prepare the draft for IRB review.

2.1 IRB review.

IRB members are provided with copies of the proposed revision with meeting packets. After review and discussion, the board may:

- vote to approve as proposed;
- vote to approve with minor changes;
- delay voting pending:
 - extensive revisions
 - additional input from expert sources
 - review of peer institution's policies
 - additional time for discussion
 - comments from the research community (see 2.2, below); or
- vote to disapprove the proposed revision.

2.2 Comment period.

The IRB may solicit comments from the research community prior to voting on a proposed revision. HRPP staff may use variety of methods to invite comment from relevant sections of the research community: listserv or website postings, newsletter articles, departmental meetings, etc. After a reasonable period of time, HRPP staff, the IRB Chair or their designee compiles all comments for review at the next available convened meeting.

2.3 Implementation.

Upon approval of the revision, HRPP staff incorporates the change(s) into all published versions of the procedures, and notify the research community through various methods as appropriate: listserv or website postings, newsletter articles, departmental meetings, etc. Training may be provided as necessary to HRPP staff, IRB members, and research investigators.

3.0 Publication.

HRPP staff maintains current versions of the published procedure manual, ensuring accessibility for researchers, IRB members, HRPP staff and other administrative units. In addition, archived versions are maintained for internal and external audit purposes.

REFERENCES:

[FederalWide Assurance](#) of Protection for Human Subjects
[Guidance on Written Procedures](#), Office of Human Research Protections (OHRP)

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

- 1.1 Ethical Principles for Human Research
- 1.2 Regulatory Requirements for Human Research
- 2.2 NDSU Engagement in Human Subjects Research
- 3.2 Roles and Responsibilities – Institutional Official and Institutional Review Board