

NDSU retains documentation of IRB activities in a secure location, accessible for inspection and copying by representatives of federal oversight agencies (e.g. the Office of Human Research Protections, the Food and Drug Administration). In accordance with federal requirements and NDSU records management policy, hard-copy and/or electronic records of IRB activities are retained for at least 3 years. Records pertaining to research that has been conducted are retained for at least 3 years following completion, unless contractual obligations require a longer retention period.

1.0 Protocol records.

Protocol submissions to the IRB are recorded in logs and database records in an organized and secure fashion; reports and queries are generated from these records. Protocol submissions are retained in hard copy for a period of 3 years following completion of the research.

The hard copy protocol file includes the following documentation, as applicable:

- all versions of protocol form(s), including consent document(s) and attachments reviewed by the IRB,
- review guides and pre-screening forms,
- documentation of expedited review,
- correspondence between the IRB and investigator(s),
- federal grant applications and reports
- reports of continuing review, amendments, unanticipated events,
- statement(s) of significant new findings provided to subjects,
- IRB Authorization Agreements or Independent Investigator Agreements,
- audit records and results.

Electronic records of approved protocols may also be retained, but may not include complete documentation as described above. Protocol submissions that are later withdrawn, or determined to not involve human subjects research are retained for a period of one year.

2.0 IRB meeting minutes.

Proceedings of convened IRB meetings are retained for at least 3 years, or 3 years after completion of any research reviewed at the meeting. However, these records may be retained in hard-copy or electronic format for an indefinite period. Although any remarks made during a meeting are eligible to become part of the official record, the minutes are intended as a summary, rather than a verbatim transcript, of the meeting. IRB meeting minutes are recorded in sufficient detail to show:

- presence/absence of members at any time during the meeting,
- representative capacity of any alternates in attendance,
- actions taken by the IRB, including protocol-specific actions,
- vote on these actions, including the number of members voting for, against, abstaining or recusing (including the name and reason for recusal),
- basis for requiring changes in or disapproving research,

- written summary of the discussion of controverted issues and their resolution.
- documentation of risk level and approval period,
- protocol-specific documentation for determinations of:
 - waiver or alteration of the consent process,
 - research involving children, prisoners, pregnant women, human fetuses or neonates,
 - significant or non-significant risk determinations for medical devices.

3.0 Administrative records.

IRB administrative records are retained for at least 3 years; however, hard-copy or electronic records may be retained for an indefinite period.

3.1 IRB membership rosters.

Records of current and previous IRB members and alternates include a list of members including:

- name,
- earned degrees,
- experience, such as board certifications, licenses, etc., sufficient to describe their chief contributions to IRB deliberations,
- employment or other relationship with the institution.

3.2 Training records.

Records of training in human subjects protections for HRPP staff, IRB members, and research investigators are retained in hard-copy (for three years) and electronic format (indefinitely).

3.3 Written procedures

Current operating procedures for the human research protection program are retained in electronic format and available to the research community via the IRB website. Records of prior versions of the procedures are also retained in the IRB office for an indefinite period.

3.4 Assurance documents.

Records of current and previous FederalWide Assurance (FWA) and other assurance documents, as well as IRB registration documents are retained in the IRB office for an indefinite period.

REFERENCES:

45 CFR 46.103 Assuring compliance
 45 CFR 46.115 and 21 CFR 56.115 IRB records
 OHRP guidance on Written Procedures
 AAHRPP Guidance: Documenting Discussions and Decisions on Research Studies and Activities
 NDSU Policy 713: Records Management

RELATED HRPP SECTIONS:

4.1 IRB Membership

4.2 IRB Meeting Procedures

Section 5 – Training, Education and Outreach

Section 7 - IRB Review Process