

NDSU is responsible for ensuring compliance with relevant ethical principles, federal and state law and institutional policies for the protection of research participants. NDSU research projects associated with potential noncompliance or concerns related to the rights or welfare of research participants may undergo audits to evaluate the allegation, and implement any appropriate corrective actions or remediation.

The federal regulations provide the IRB with the authority to observe, or have a third party observe the consent process and the research, and to verify that no material changes have occurred in approved projects without IRB approval. In addition, the IRB has the authority to suspend or terminate approval of research not conducted in compliance with federal regulations or requirements of the IRB, or that has been associated with unexpected serious harm to subjects.

#### 1.0 Selection of research for audit.

HRPP staff, IRB chair, or qualified designee may perform directed audits of research when any of the following are identified or received:

- allegations of noncompliance with federal regulations or NDSU policy for research subject protections
- complaints or concerns regarding participants' rights or welfare
- reports of unanticipated problems involving risks to subjects or others
- serious adverse events
- a protocol involving an investigator unresponsive to IRB requests

#### 2.0 Investigator notification.

Where practicable, investigators are contacted in advance to arrange the audit, informed of the process, and the type of records to provide for review. The department Chair/Head or unit supervisor is also notified of the audit. The principal investigator is expected to cooperate in a complete and timely manner to facilitate conduct of the audit.

#### 3.0 Evaluation materials.

Depending on the nature of the issue, the audit may be broad and comprehensive, or limited in scope and may include evaluation of any or all of the following:

##### 3.1 IRB protocol file and other records.

IRB records are evaluated by a non-conflicted HRPP staff, IRB chair, or qualified designee to verify that applicable ethical issues were addressed, the appropriate category of review was utilized, and the relevant determinations required for approval were documented in the initial, as well as ongoing review(s). Using the *Audit Checklist*, any of the following may be evaluated:

- protocol submission materials and timeline of approval process
- documentation of reviews and correspondence with investigator

- relevant approved meeting minutes
- grant proposal, cooperative agreements
- electronic database records and training records

### 3.2 Research documentation.

Using the *Audit Checklist*, research records are evaluated by HRPP staff, IRB Chair or qualified designee to verify compliance with federal regulations, NDSU policy and adherence to the protocol approved by the IRB. The extent of records selected for audit may be broad and comprehensive, or fairly limited in scope. The principal investigator is responsible for making all relevant records available for an evaluation, which may include, but are not limited to:

- records of IRB approvals
- informed consent documentation and recruitment materials
- data records (hard-copy and electronic records)
- records of complaints, problems, or unanticipated events involving risk to participants or others
- any other records relating to a complaint or allegation of noncompliance

### 3.3 Observation of the research and/or consent process.

The audit may include observation of the research procedures, and/or process of obtaining informed consent.

### 4.0 Investigator(s) or research team visit.

HRPP staff, IRB Chair or designee meets with the principal investigator, and/or or members of the research team to discuss the nature of the issue and obtain additional information.

### 5.0 Summary and report.

A summary report of the audit is distributed to the investigator and research team for comment. Once comments from all parties are received and considered, the final report is submitted to the IRB, IRB Chair or designee, IRB subcommittee (as applicable), the investigator, and the applicable department Chair/Head or unit supervisor. The IRB considers the report in accordance with procedures described in *12.3 Complaints or Allegations of Noncompliance*.

## **DEFINITIONS:**

Allegation of noncompliance: an unconfirmed report of noncompliance

Noncompliance: the failure of a person or an organization to act in accordance with the requirements of a law, regulation, policy, or the requirements and/or determinations of the IRB. Noncompliance may be intentional or unintentional, and may range from minor to serious or continuing.

Serious noncompliance: an act or omission that negatively impacts the rights or welfare of research participants, or compromises the integrity or validity of the research or the human research protection program. Examples of serious noncompliance may include, but are not limited to: initiating or conducting nonexempt human subjects research without IRB approval; inappropriate use of the exempt or expedited review categories; failure to obtain legally effective

informed consent from participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data.

Continuing noncompliance: any noncompliance that occurs repeatedly after appropriate remedial education or corrective action. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, repeated failure to obtain prospective exempt determinations, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Minor noncompliance: any noncompliance that is not serious or continuing. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain a prospective exempt determination from the IRB, minor changes in or deviations from an approved protocol, or administrative errors.

Unanticipated problem: any incident, experience, or outcome that meets all the following criteria:

- is unexpected (in terms of nature, severity, or frequency) given the characteristics of the subject population and the research as described in the IRB approved protocol and consent document(s)
- is related, or possibly related to participation in the research
- suggests the research places subjects or others at greater risk of harm (physical, psychological, economic, or social harm) than previously known or recognized

Adverse event: any untoward or unfavorable medical occurrence (physical or psychological) in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to their research participation

Serious adverse event: any adverse event that meets any of the following criteria:

- results in death
- is life-threatening
- requires hospitalization
- results in persistent or significant disability
- results in congenital anomaly
- may jeopardize subject's health and may require medical intervention to prevent any of the other outcomes listed here

Risk: the probability of harm or discomfort; may include physical, psychological, social, economic, legal, or other harms

## **REFERENCES:**

[45CFR46.109\(e\)](#) IRB Review of Research

[21CFR56.109\(f\)](#) IRB Review of Research

[45CFR46.103\(b\)\(4\)](#) Assuring compliance with this policy

[21CFR56.108\(a\)](#) IRB Functions and Operations

[OHRP FWA Assurance Training](#)

[Terms of the FederalWide Assurance](#) #4, Written Procedures

**RELATED [FORMS:](#)**

Audit Checklist

**RELATED STANDARD OPERATING PROCEDURES:**

7.7 Unanticipated Problems and Serious Adverse Events

12.1 Quality Assurance Audits - Random

12.3 Complaints or Allegations of Noncompliance