

NDSU is responsible for ensuring compliance with relevant ethical principles, federal and state law and institutional policies for the protection of research participants. Reports of alleged noncompliance, complaints or concerns related to the rights or welfare of NDSU research participants are investigated to determine validity, and address the issue with corrective actions or remediation as appropriate.

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 Reports of complaints or allegations of noncompliance:

The IRB considers all concerns or complaints regarding the rights and welfare of NDSU research participants, or reports or allegations of noncompliance with subject protection regulations or policies, which may include, but are not limited to:

- unanticipated and/or serious harm to subjects or others
- coercion or undue influence; concerns regarding the consent process
- concerns regarding confidentiality or privacy
- research conducted without prior IRB approval, or during a lapse in approval
- changes in research implemented without prior IRB approval (ie, new or altered research site, subject selection criteria, interventions, data collection or consent process, etc.)

#### 1.1 Reporting procedures:

Any person with knowledge of a complaint, concern, or alleged noncompliance may report (anonymously if desired) to the IRB office, IRB chair or member, Director of Sponsored Programs Administration, or the Institutional Official (IO). Reporters may include:

- investigators, or research team members
- research participants
- parents or guardians of participants
- members of the public
- Institutional Official
- NDSU faculty, staff or students
- IRB chair or members
- HRPP staff

Investigators and research team members are required to report any noncompliance, as well as unanticipated problems, or complaints to the IRB in a prompt manner. When reported by other parties, the reporter's identity will generally not be disclosed.

#### 1.2 Content of report:

The report may be verbal or written, but should include sufficient information to allow for an investigation, such as any of the following:

- detailed information about the alleged noncompliance or complaint, including relevant date(s) if known
- information about any harm to subjects (ie, physical, psychological, social, legal, economic, confidentiality, dignitary, etc.)
- assessment of whether any subjects were placed at risk as a result of the noncompliance
- any corrective action(s) that may already have been taken (if investigator is filing the report)
- contact information for the reporter (unless anonymous)
- any other relevant information

## 2.0 IRB Consideration of Reports:

### 2.1 Review by HRPP staff, IRB Chair or designee:

HRPP staff conduct an initial review to determine if the report can be substantiated. This review may include requests for additional information from the investigator and research team, and/or a directed audit, and/or consultation with the IRB chair, designee or others. The initial review and all communications are documented in writing.

#### 2.1.1 No basis for complaint or allegation of noncompliance:

HRPP staff or the IRB Chair or designee, may determine that the complaint/concern or allegation of noncompliance cannot be substantiated, or does not appear related to an issue of subject protections. The case is closed with a response to the reporter, if known; and may be forwarded to another NDSU office, ie, General Counsel or Provost, as applicable.

#### 2.1.2 Minor noncompliance:

HRPP staff, in consultation with the IRB Chair or designee, may determine that the complaint/concern or allegation does constitute noncompliance, although of a minor nature. Applicable corrective actions to prevent recurrence may be required, which could include:

- additional education or training
- revision of recruitment or consent process or documents
- revision of data collection instruments
- revision to data safeguarding procedures
- revision to review process or procedures
- notification to present or past participants
- notification to publishers
- any other action as applicable

As applicable, the investigator and research team and Department Chair/Head are notified in writing of required actions or requested to draft their own correction action plan, with a due date for completion. The IRB is notified at the next convened meeting.

#### 2.1.3 Potentially serious or continuing noncompliance:

HRPP staff, and/or the IRB Chair or designee, may determine that the complaint/concern or allegation of noncompliance could represent an issue of serious or continuing noncompliance. The IRB Chair or designee may elect to convene a subcommittee (as described in 2.2) for an initial investigation, or may forward the issue directly to the IRB for consideration at the next convened meeting.

#### 2.1.4 Suspension of research:

The IRB Chair or designee may immediately suspend approval for the research if the report suggests subjects have experienced unexpected serious harm, and the investigator has not already voluntarily suspended research activities. Suspension may also be warranted if the research was conducted without IRB approval, or may negatively impact rights or welfare of subjects. Unless already voluntarily halted by the investigator, HRPP staff will promptly notify in writing the following:

- investigator and research team
- NDSU Department Chair/Head
- IO
- Sponsored Programs Administration, if funded

#### 2.2 Review by IRB subcommittee:

Where an issue of potentially serious or continuing noncompliance may be complex, and/or require additional fact-finding, the IRB, IRB Chair or designee may direct that a subcommittee review the issue prior to consideration by the full board. A subcommittee comprised of at least 3 members, including the IRB Chair or designee, selected members, and HRPP staff may obtain additional information through directed audits of research, as well as meetings with the investigator, research team members, or any other parties as appropriate. All communications are documented in writing, and the subcommittee provides a written recommendation to the board as to whether the noncompliance is serious and/or continuing, appropriate corrective actions(s), and whether a report will be required to federal agencies. The subcommittee may also immediately suspend the research if subjects have experienced serious harm, the research negatively impacts the rights or welfare of subjects, or has been initiated without IRB approval. The suspension is reported promptly, as described above.

#### 2.3 Review at convened meeting of IRB:

At a convened meeting, the IRB considers issues of potentially serious or continuing noncompliance, as well as suspensions of IRB approval referred from the IRB Chair or subcommittee.

##### 2.3.1 Materials for review:

HRPP staff prepare a written summary containing the initial report, any additional information, including subcommittee report and recommendations, as applicable. IRB Chair or designee and another member are assigned as primary reviewers; the information is provided to board members at least one week prior to a convened meeting.

##### 2.3.2 Consultation with investigator and research team:

The IRB provides the investigator and members of the research team an opportunity to either attend the meeting, or provide additional information or refute the complaint or allegation of noncompliance.

#### 2.3.3 Determination regarding suspension or termination of IRB approval:

The IRB may determine that research must be suspended or terminated in order to protect the rights, safety and welfare of research participants. If the IRB Chair, designee or subcommittee has already suspended approval for the project, the IRB determines whether to lift, or continue the suspension, or terminate the project to protect subject safety.

#### 2.3.4 Determination regarding noncompliance:

The IRB makes a determination regarding the complaint or issue of noncompliance:

2.3.4.1 No evidence of noncompliance. The IRB may disagree with the original determination, and find that noncompliance did not occur. The determination is communicated in writing to the investigator, Department Chair/Head, and reporter, if requested; the case is closed.

2.3.4.2 Noncompliance is minor. The IRB may find that the issue of noncompliance is neither serious nor continuing. Suitable corrective actions will be required, as described above, and communicated in writing to the investigator, Department Chair/Head, and reporter, if requested.

2.3.4.3 Noncompliance is serious or continuing. The IRB may find that the issue of noncompliance constitutes either serious noncompliance or continuing noncompliance. In addition to any of the corrective actions listed under minor noncompliance, the IRB may also require:

- re-consent of prior or current research subjects
- modification of data collection, or privacy and confidentiality procedures
- continued monitoring of the research or consent process
- more frequent continuing review of research
- restriction of use of data for research
- enrollment of additional participants suspended
- audits of other related research
- restriction of investigator's ability to conduct human subjects research
- systemic corrective actions to HRPP policies or procedures
- any other action that may be applicable to protect the rights and welfare of subjects
- referral to other NDSU officials (ie, Provost, General Counsel)

HRPP staff and the IRB Chair or designee prepare a written report to promptly notify:

- investigator and research team
- NDSU Department Chair/Head
- IO
- Sponsored Programs Administration, if funded

### 3.0 Review by Institutional Official:

The IO is promptly notified when the IRB has suspended or terminated research, and/or made a determination of serious or continuing noncompliance. The IO may:

- accept the determination of the IRB and promptly report to external entities
- accept the determination, but require additional corrective actions
- require additional investigation
- suspend or terminate the research, unless already suspended or terminated

The IO, with the assistance of HRPP staff, submits required reports to OHRP, any applicable funding sponsors, and other applicable federal agencies (ie, FDA). Refer to *12.4 Reporting Noncompliance, Suspensions, Terminations and Unanticipated Problems*.

### 4.0 Appeals process:

The investigator may appeal a determination of the IRB only if new information becomes available, or evidence is provided that the IRB has failed to follow their own procedures, or incorrectly applied federal regulations, state law, or NDSU policy for the protection of research participants. A written appeal, citing specific federal regulations, NDSU policy or procedures, may be made to the IRB office or the IO within 10 business days after receipt of communication from the IRB.

Upon receipt of the appeal, HRPP staff notify the IRB and the IO. The IRB Chair or designee makes an initial assessment, and forwards to the IRB for consideration at the next convened meeting. In consultation with the IO, a final determination is made, and communicated in writing to the investigator and other entities as applicable.

### **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
- enrollment of subjects or continued data collection during a lapse in protocol approval
- failure to report or review serious adverse events, unanticipated problems, or substantive changes in research
- 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 failure to provide or review progress reports resulting in lapses of IRB approval
- repeated failure to obtain prospective exempt determinations
- inadequate oversight of ongoing research
- 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:

- lapse in continuing IRB approval
- failure to obtain a prospective exempt determination from the IRB
- minor changes in or deviations from an approved protocol
- administrative errors

**Suspension or termination of research:** a temporary or permanent halt of some or all research activities involving human subjects, including recruitment, enrollment, research interventions or interactions, data collection from currently enrolled participants, or data analysis. Under some circumstances, it may be necessary to continue follow-up procedures for currently enrolled participants to protect their safety.

**REFERENCES:**

- [45CFR46.109\(e\)](#) IRB Review of Research
- [21CFR56.109\(f\)](#) IRB Review of Research
- [45CFR46.103\(b\)\(4\)](#) Written procedures
- [45CFR46.103\(b\)\(5\)](#) Written procedures
- [21CFR56.108\(a\)](#) IRB Functions and Operations
- [45CFR46.113](#) Suspension or termination of IRB approval of research
- [21CFR56.113](#) Suspension or termination of IRB approval of research
- [OHRP Guidance on Written Procedures, January 2007](#)
- [OHRP FWA Assurance Training](#)
- [Terms of the FederalWide Assurance](#) #4, Written Procedures

**RELATED FORMS:**

Audit Checklist

**RELATED HRPP SECTIONS:**

- 7.7 Reports of Unanticipated Problems or Events involving Risks to Participants or Others
- 12.1 Quality Assurance Audits
- 12.2 Directed Audits of Research
- 12.4 Reporting Noncompliance, Suspensions, Terminations and Unanticipated Problems