

12 Quality Assurance and Research Compliance:

12.4 Reporting Noncompliance, Suspensions, Terminations and Unanticipated Problems

Effective Date: **6/12/2009**

Revised:

NDSU is responsible for ensuring compliance with relevant ethical principles, federal and state law and institutional policies for the protection of research participants. Federal regulations require NDSU to promptly report to federal agencies: instances of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance, and suspension or termination of IRB approval.

1.0 Unanticipated problems:

Within 3 working days of notification from the IRB, the Vice President for Research, Creative Activities & Technology Transfer (IO) reports incidents of unanticipated problems involving risks to subjects or others to:

- Office of Human Research Protections (OHRP)
- Funding sponsors, as applicable
- Food and Drug Administration, as applicable
- Other federal departments or agency heads, as applicable
- Other outside entities, as applicable

A report is drafted, with assistance from HRPP staff, including the following information:

- Title of research, name of principal investigator, NDSU protocol #
- Funding sponsor and # of applicable award, grant, contract, or cooperative agreement
- Detailed description of the problem
- Actions that have been, or will be taken to address the problem

2.0 Serious or continuing noncompliance:

Within 3 working days of notification from the IRB, the Vice President for Research, Creative Activities & Technology Transfer (IO) reports determinations of serious or continuing noncompliance with federal regulations, NDSU policy, or the requirements or determinations of the IRB to:

- Office of Human Research Protections (OHRP)
- Funding sponsors, as applicable
- Food and Drug Administration, as applicable
- Other federal departments or agency heads, as applicable
- Other outside entities, as applicable

A report is drafted, with assistance from HRPP staff, including the following information:

- Title of research, name of principal investigator, NDSU protocol #
- Funding sponsor and # of applicable award, grant, contract, or cooperative agreement
- Detailed description of the noncompliance
- Actions that have been, or will be taken to address the noncompliance

If an issue of noncompliance is expected to take considerable time to investigate or resolve, an initial report should be made promptly, followed by a final report.

3.0 Suspension or termination:

Within 3 working days of notification from the IRB, the Vice President for Research, Creative Activities & Technology Transfer (IO) reports suspension or termination of IRB approval of research to:

- Office of Human Research Protections (OHRP)
- Funding sponsors, as applicable
- Food and Drug Administration, as applicable
- Other federal departments or agency heads, as applicable
- Other outside entities, as applicable

A report is drafted, with assistance from HRPP staff, including the following information:

- Title of research, name of principal investigator, NDSU protocol #
- Funding sponsor and # of applicable award, grant, contract, or cooperative agreement
- Detailed description of the reason for the suspension or termination
- Actions that have been, or will be taken to address the suspension or termination

DEFINITIONS:

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.

REFERENCES:

[45CFR46.103\(b\)\(5\)](#) Reporting Requirement

[21CFR56.108\(b\)](#) Reporting Requirement (FDA)

[45CFR46.113](#) 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

[OHRP Guidance on Reporting Incidents to OHRP](#)

RELATED FORMS:**RELATED HRPP SECTIONS:**

7.7 Unanticipated Problems

12.2 Directed Audits of Research

12.3 Complaints or Allegations of Noncompliance