12 Quality Assurance and Research Compliance: 12.4 Reporting Noncompliance, Suspensions, Terminations and Unanticipated Problems	Effective Date: **6/12/2009** Revised: 7/06/2012

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 Reportable findings.

The following determinations of the IRB require external reporting:

- unanticipated problems involving risks to subjects or others
- serious or continuing noncompliance with federal regulations, NDSU policy, or the requirements or determinations of the IRB
- suspension or termination of IRB approval of research.

2.0 Reporting process.

Within 3 working days of notification from the IRB, the Vice President for Research, Creative Activities & Technology Transfer (IO), with the assistance of HRPP staff, drafts a report 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
- specific or systemic corrective actions that have been, or will be taken to address the problem

A copy of the report is retained in the protocol file, and submitted promptly 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.

The IO and IRB are responsible to address any subsequent requests from OHRP or other entities for additional information, audits, investigations or other corrective actions to prevent recurrence of the problem.

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.

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:

45CFR46.103(b)(5) Reporting Requirement

21CFR56.108(b) Reporting Requirement (FDA)
45CFR46.113 Suspension or termination of IRB approval of research
OHRP FWA Assurance Training
Terms of the FederalWide Assurance
OHRP Guidance on Reporting Incidents to OHRP

RELATEDSTANDARD OPERATING PROCEDURES:
7.7 Unanticipated Problems and Serious Adverse Events
12.2 Directed Audits of Research
12.3 Complaints or Allegations of Noncompliance