

**Nova Southeastern University
Office of Grants and Contracts
Institutional Review Board
Policies and Procedures**

Unanticipated Problems and Adverse Event Reporting

Effective 06/14/2007; Revised 01/02/2008; 01/08/2009

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Purpose:

To establish policy and procedures for the submission and review of unanticipated problems and adverse events related to approved research.

Definitions:

1. Unanticipated Problems are considered to include any incident, experience, or outcome that meets all of the following criteria:
 - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related outcomes, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
 - Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; **and**
 - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

2. Adverse Events are any unanticipated problems involving risks to subjects or others that do not fall into the different categories under Serious Adverse Events (SAEs). For example:
 - Breach in confidentiality that may present a risk to a subject.
 - A participant's complaint of an unanticipated risk that cannot be resolved by the research staff
 - Change to the research protocol that may result in unanticipated risks
 - Rash

3. Serious Adverse Events are defined as follows:
 - Cancer
 - Death
 - Congenital Anomaly/Birth Defect
 - Hospitalization Required
 - Life Threatening Event
 - Overdose
 - Significant or Persistent Disability/Incapacity

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Policy:

The investigator must promptly report any unanticipated problems or adverse events to the IRB. The investigator must also report the adverse event to a study sponsor (via the sponsor's adverse reporting system) or the Food and Drug Administration, if applicable.

It is the responsibility of the IRB's Adverse Events subcommittee to review all worldwide and local unanticipated problems or adverse events received by the IRB office. The subcommittee will present any issues that may be of concern to the full IRB.

The IRB will report to the Office for Human Research Protections (OHRP), and in the case of funded research the funding agency, an adverse event that is an unanticipated problem if (a) the adverse event is unexpected, (b) the adverse event was related to or possibly related to participation in the research, **and** (c) the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.

References:

45 CFR 46.103(a) and 45 CFR 46.103(b)(5)
21 CFR 56.108(b)(1), (b)(2), and 56.115(a)(1)

Procedures:

1. The Principal Investigator (PI) is responsible for submitting the adverse event/serious adverse event via the Unanticipated Problem/Adverse Event Report Form. Serious adverse events must be reported within 24 hours, all other adverse events and unanticipated problems must be reported within 5 working days.
2. Once an Unanticipated Problem/Adverse Event Report is received, it is transmitted to the Adverse Events sub-committee of the IRB that will review the adverse event in a timely manner. If the problem/adverse event presents possible immediate danger to subjects participating at NSU, the sub-committee will promptly report to the Chair of the IRB its recommendation for addressing the adverse event and action related to the study. All other worldwide and local problems/adverse events reviewed by the sub-committee and considered to be of significance are presented to the IRB at the next convened meeting of the IRB. When applicable the Chair will discuss the reported problem/event with the vice-president for research and technology transfer (VP).

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3. The PI will be notified by the IRB if any action is needed on his/her part. The IRB may request corrective actions or substantive changes including:
 - Changes to the research protocol. Proposed changes must be approved by the IRB prior to implementation except when necessary, to eliminate apparent immediate hazards to subjects;
 - Modification of the inclusion or exclusion criteria to mitigate the newly identified risks;
 - Implementation of additional procedures for monitoring subjects
 - Suspension of enrollment of new subjects;
 - Suspension of research procedures in currently enrolled subjects;
 - Modification of informed consent documents to include a description of newly recognized risks; and
 - Provision of additional information about newly recognized risks to previously enrolled subjects

4. The IRB, via the Chair and/or the VP, will notify any applicable regulatory agency within one month of the IRB's receipt of the report from the investigator of any reported adverse event that is an unanticipated problem.

5. The PI, sponsor, and any applicable regulatory agencies will be notified if the IRB suspends or terminates the study.