

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

Unanticipated Problems, Adverse Event, and IND Safety Reporting
Effective 06/14/2007; Revised 01/02/2008, 01/08/2009, 10/14/2010; 08/29/2011
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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 (non FDA research) 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. For FDA-governed research, the criteria of an unanticipated problem are that the event is
 - Unexpected
 - Serious
 - Would have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure).
3. Serious Adverse Events are defined as follows:
 - Death
 - Congenital Anomaly/Birth Defect
 - Hospitalization Required or Prolongation of a Hospitalization
 - Life Threatening Event
 - 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. Investigators must also report to the IRB any IND safety reports received by the last business day of the month in which the report was received. IND safety reports must be accompanied by investigator attestation that he or she has reviewed the IND safety report.

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 (IND safety reports). The subcommittee will present a summary of any received reports at the next convened meeting of the board and the IRB will discuss the report and, if warranted, request action or additional information.

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.

In instances when there are investigator-initiated (NSU sponsored) studies involving FDA-regulated products, where reporting to the FDA is required, the IRB will report to the FDA adverse events in keeping with FDA requirements.

A subject complaint is to be reported to the IRB if the principal investigator is unable to resolve the complaint, even if it does not meet the definitions of an unanticipated problem or adverse event..

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/Unanticipated Adverse Device Effect for NSU Subjects form (attachment a). Serious adverse events must be reported within 24 hours, all other adverse events and unanticipated problems must be reported within 5 working days. IND safety reports must be submitted, along with the

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attestation (IND Safety Report form) that the principal investigator has reviewed the safety report (attachment b), to the IRB by the last business day of the month in which the IND safety report was received. The AE/SAE/UP reporting form and the attestation form are also available under the Adverse Events/Unanticipated Problems link on the IRB web site (www.nova.edu/irb).

2. Once an Unanticipated Problem/Adverse Event Report/IND Safety Report is received, it is transmitted to the Adverse Events sub-committee in a timely manner by the IRB staff. 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 are presented to the IRB at the next convened meeting of the IRB for discussion, and the subcommittee will provide a written report for inclusion in the meeting minutes. The report will include the principal investigator's name, the title of the study, and the applicable IND safety report number information. The Board will discuss the summary report at the convened meeting in which it is presented by the sub-committee. When applicable the IRB Director and/or Chair will discuss the reported problem/event with the vice-president for institutional effectiveness (VP).
3. The PI will be notified by the IRB if any action is needed on his/her part if any additional information is required. 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.

**Nova Southeastern University
Office of Grants and Contracts
Institutional Review Board
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5. The PI, sponsor, and any applicable regulatory agencies will be notified if the IRB suspends or terminates the study.

Attachment A

Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
Unanticipated Problem/Adverse Event Report/Unanticipated Adverse Device Effect for
NSU Subjects

Please review the IRB's policy on Unanticipated Problems and Adverse Events found at
<http://www.nova.edu/irb/manual/policies.html>.

Date of this Report:	
IRB Protocol #:	NSU Center/College:

Project Title

Principal Investigator Information

Name		Relationship to NSU: Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/>
Home Mailing Address (for students)		
City/State/Zip:		
Office Phone:	Home Phone (for students):	Email:

Study Sponsor:
Has the sponsor been notified? Yes <input type="checkbox"/> No <input type="checkbox"/>
Date of Notification:

Unanticipated Problem/Adverse Event/Unanticipated Adverse Device Effect Information

Submit 1 Adverse Event Report for each subject. You may use additional sheets to describe the nature of the adverse event. If a separate notification is required for sponsored studies and/or regulatory agencies, please include a copy of that notification.

Participant #	Date of Adverse Event	Description of Unanticipated Problem/Adverse Event	Was the Adverse Event Unexpected? Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Adverse Event Serious? Yes <input type="checkbox"/> No <input type="checkbox"/>		Study Related Adverse Event? Yes <input type="checkbox"/> No <input type="checkbox"/>	Does the adverse event suggests that the research places subjects or others at a greater risk of harm? Yes <input type="checkbox"/> No <input type="checkbox"/>
Should the protocol and/or consent forms be revised Yes <input type="checkbox"/> No <input type="checkbox"/>		Will additional information be given to enrolled subjects? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Does the event have implications for the conduct of the study? Yes <input type="checkbox"/> No <input type="checkbox"/>			
If Yes, please submit a copy of the corrected amendment forms with bold changes and a clean copy incorporating the changes.			

Principal Investigator's Signature: _____ Date: _____

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 - Hospitalization Required or Prolongation of a Hospitalization
 - Life Threatening Event
 - Significant or Persistent Disability/Incapacity

IND Safety reports are generated when a serious adverse event which may be related to the study drug and not expected occurs in any protocol using the study drug. IND safety reports must be reported to the IRB in keeping with the Unanticipated Problems and Adverse Event Reporting policy.

Attachment B

DEFINITIONS:

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