

**Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
Unanticipated Problem and Adverse Event Report**

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 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	NSU Subject? Yes <input type="checkbox"/> No <input type="checkbox"/>
Was the Adverse Event Serious? Yes <input type="checkbox"/> No <input type="checkbox"/>	Was the Adverse Event Unexpected? Yes <input type="checkbox"/> No <input type="checkbox"/>	Was the Adverse Event Unanticipated? Yes <input type="checkbox"/> No <input type="checkbox"/>	Study Related Adverse Event? 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"/>	
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: _____

**Nova Southeastern University
Institutional Review Board
IND Safety Report**

Date	IRB Protocol #
Principal Investigator	NSU Center/ College

Project Title _____

Study Sponsor _____
IND Safety Report dated _____

Serious Adverse Event / Sentinel Event Information

Description of Serious or Sentinel Event	Date of event

I have personally reviewed the IND safety report of a serious adverse event

Principal Investigator Date

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

4. **Sentinel Events** defined by HRPP are:
 - Death
 - Major permanent loss
 - Permanent loss of physical or psychological function not related to natural course of subject's illness or underlying condition

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.

