NOVA SOUTHEASTERN UNIVERSITY

Nova Southeastern University
Standard Operating Procedure for GCP

Title: Handling Information on Serious Adverse Events from External Sources		Version # 1
SOP Number: OCR-AE-002	**Effective Date: August 2013**	**Page 1 of 3**

PURPOSE: Serious Adverse Experiences often occur with the use of the Investigational Product at other research Center/Colleges or in the worldwide market. This information should be considered in the risk/benefit ratio of any study activity.

POLICIES:

1. The Center/College accepts information from all sources that may have bearing on the safety of the subjects. Most commonly, these come in the form of:
   1.1. IND Safety Reports from the Sponsor (a.k.a. MedWatch Reports)
   1.2. News and Journals

Whenever there is a question on if an adverse event should be reported, error should be made in "over-reporting" as opposed to "under-reporting".

PROCEDURE:

Upon receipt of the IND Safety report/s from the Sponsor, the Principal Investigator (PI) or Study Coordinator (CRC) should:

1. PI/CRC should complete the form titled "IND Safety Report Form" found on the following NSU website http://www.nova.edu/irb/manual/aer.html, click on Unanticipated Problems and Adverse Events Report Form (MS Word document) link and complete page 2 of 4 for each IND Safety Report
2. Attach the completed IND Safety Report Form to the IND Safety Report
3. The PI should review the IND Safety Report
4. PI should acknowledge the report by signing and dating each IND Safety Report Form
5. Do not use staples.

6. CRC should create a submission memo to the Institutional Review Board on College letterhead.
7. PI/CRC should keep a copy of the submission in the Investigator Binder
8. Forward a copy of the submission letter and summary page/s for OCR file
9. Forward the IND Safety Report/s submission to IRB for acknowledgement
10. IRB will send acknowledgement letter via email to distribution

Procedure for Handling Adverse Events in which the subject was administered a pharmaceutical investigational product or devices at NSU

CRITERIA: Any untoward medical occurrence in a patient participating in a clinical trial of an investigational product which does not necessarily have a casual relationship with investigational product or treatment is considered an adverse event. This adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease whether or not related to the investigational product.

1. Detail of documentation of an adverse event should include the following:
    - 1.1 Date/Time of onset
    - 1.2 Description of Adverse event
    - 1.3 Severity
        - 1.3.1 Mild: Experiencing mild discomfort with insignificant changes in daily activity or clinical status.
        - 1.3.2 Moderate: Makes accommodating changes in normal daily activity but can still function relatively well. Noticeable changes in clinical status.
        - 1.3.3 Severe: Makes major changes in (or is prevented from accomplishing) normal daily activity. Major changes in clinical status.
    - 1.4 Date/Time of resolution (if applicable)
    - 1.5 Association with research study as determined by the Principal Investigator
2. Any action or therapy implemented due to unanticipated problem/adverse event
3. Where necessary to eliminate apparent immediate hazards, the protocol may be deviated from for the benefit of the subject.
    a. The Sponsor AND IRB must be notified of the protocol deviation.
    b. The Principal Investigator should determine if the subject should be removed from the protocol.

Procedure for Unblinding Investigational Products

1. CRITERIA: Every effort should be maintained to protect the blind unless there is a medical emergency and:
   1.1. The treating physician needs immediate knowledge to optimize the clinical management
   1.2. The clinical management would be a different course of action depending on the results of the unblinding (example, in an overdose situation, if the course of action would be the same if the subject were on Drug A versus Drug B, unblinding is not necessary).
2. Whenever possible, the sponsor should be notified before the blind is broken.
3. The protocol should dictate the manner in which the blind is able to be broken. In the absence of such explanation, the sponsor's policies should dictate. Examples are as follows:
   3.1. Peal Off Labels
   3.2. Scratch-Off Labels
   3.3. IVRS
4. The blind should only be broken for the individual subject.
5. In the absence of a medical emergency, the code should only be broken in accordance with the protocol.

The investigator should promptly document and explain to the sponsor any premature unblinding of the investigational product(s) with consideration for the criteria above