Nova Southeastern University
Standard Operating Procedure for GCP

Title: Identifying, Handling and Reporting Unanticipated problems/AEs at NSU Centers/Colleges		Version # 1
SOP Number: OCR-AE-001	**Effective Date: August 2013**	**Page 1 of 3**

PURPOSE: Information on any unanticipated problems/adverse experiences of subjects should be identified, included as a study finding and evaluated as part of the risk/benefit ratio for the continuance of the study. Throughout this process, the subject's well-being should be maintained.

POLICIES:

1. Investigators and CRCs should gather information from subjects about unanticipated problems/adverse subject experiences during and between visits.
2. Investigators and CRCs should actively gather information from other reliable and available sources about any potential unanticipated problems/adverse subject experiences during and between visits.
3. Any Unanticipated Problem/ Adverse Event should be documented consistently in research chart and the IRB report.
4. The principal investigator must report according to the NSU IRB policies and procedures available on http://www.nova.edu/irb/manual/aer.html
5. Serious Adverse events, Unanticipated Problems/Adverse Events are reported to the Sponsor and IRB according to their accelerated timeframe .
   - 5.1. Serious Adverse Events
     - 5.1.1. To the Sponsor: Within 24 Hours of Being Notified
     - 5.1.2. To the IRB: Within 24 hours of Being Notified
   - 5.2. Unanticipated Problems/Adverse Events:
     - 5.2.1. To the IRB: within 5 working days

DEFINITION: An Internal Unanticipated Problem/Adverse Event and Serious Adverse Event is one occurring to a subject enrolled at a NSU study center

Procedure for Identifying / Unanticipated Problems/ Adverse Events

1. At each study visit, the subject should be sufficiently asked if they have or have had any unanticipated problem/adverse events since prior visit. Documentation of this discussion should be in the research chart.
2. Additional sources of unanticipated problem/adverse events should be sought when available. Examples include:
   2.1. Significant others should be consulted when available.
   2.2. Clinical Observations
   2.3. Subject Diaries that may conflict with oral statements
3. Detail of documentation of an unanticipated problem/adverse event should include the following:
   3.1. Date/Time of onset
   3.2. Description of Unanticipated problem/ adverse event
   3.3. Severity
      3.3.1. Mild: Experiencing mild discomfort with insignificant changes in daily activity or clinical status.
      3.3.2. Moderate: Makes accommodating changes in normal daily activity but can still function relatively well. Noticeable changes in clinical status.
      3.3.3. Severe: Makes major changes in (or is prevented from accomplishing) normal daily activity. Major changes in clinical status.
   3.4. Date/Time of resolution (if applicable)
   3.5. Association with research study as determined by the Principal Investigator
   3.6. Any action or therapy implemented due to unanticipated problem/adverse event.

Procedure for Handling Unanticipated Problems/Adverse Events with the Subject

1. Upon identification of an unanticipated problem/adverse event:
   1.1. The medically necessary treatment should be determined with the subject's best interest in mind.
   1.2. The determination as to suspend or halt the research investigation should be determined.
2. The subject should be informed when medical care is needed for intercurrent illness(es).

3. Whenever appropriate, treatment within the limitations of the protocol should be exhausted first, unless the subject wishes to withdraw from the protocol.
4. All unanticipated problems/AEs should be followed until resolved, referred or determined permanent, or it is determined that there is no resolution.

Procedure for Reporting Unanticipated Problems/AEs and SAEs

1. The PI must determine if the event is classified as an Unanticipated Problem / Adverse Event or Serious Adverse Event (defined in this policy).

2. If a Serious Adverse Event:
    2.1. The immediate report (Note: a more detailed report will promptly follow) is sent to the Sponsor and the IRB within 24 hours of becoming aware of the serious adverse event.
    2.2. The more detailed report shall follow upon resolution of the event or as requested by the sponsor/IRB
3. If the Unanticipated Problem/AE is not SAE, then the information must be reported to the IRB within 5 working days and according to the Sponsor policy (usually just documentation on the CRFs).
4. The mechanism for reporting to the Sponsor may vary according to Sponsor's policy.
5. Subject information reported to the IRB and sponsor should only be identified by their code or other de-identified manner.