Nova Southeastern University
Standard Operating Procedure for GCP

Title: Training ,Availability and Interpretation of SOP for GCP		Version # 1
SOP Number: OCR-ADM-002	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: Without the relevant staff being knowledgeable of the policies, the best-written policies are useless. The purpose of this SOP for GCP is to assure that research site employees are qualified to perform their respective duties for the conduction of clinical trials and that there is appropriate documentation of education and training

POLICIES:

1. All Office of Clinical Research staff are to be trained on the most recent version of this manual prior to undertaking their duties.
2. Changes to SOP for GCP are to be communicated to relevant staff with sufficient time prior to their effective date to accomplish the transition to the new procedures.
3. The manual shall be readily available on the Office of Clinical Research website to those that will need it for reminders.
4. The Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research shall be the ultimate authority on the interpretation of and resolution of any ambiguity in this manual.

Procedure for Initial SOP for GCP Training and Routine Review

1. At a minimum, the following staff shall receive a copy of this manual prior to undertaking duties:
    - 1.1.1. Office of Clinical Research staff
    - 1.1.1.1. Principal Investigators
    - 1.1.1.2. Sub-Investigators
    - 1.1.1.3. Center/College Clinical Research Directors, Clinical Research Coordinators, Research Assistants and research staff or students otherwise engaged on behalf of the Center/College.

2. As research involves ancillary staff at the Center/College (e.g. billing, business development, consultants, etc), these staff should be aware of at least the relevant portions pertaining to their duties that are directly involved in the conduct of clinical trials.
3. At initial employment or initial engagement in research activities, the entire manual must be reviewed. Upon completion of reviewing the manual and completing the online form a Certificate of Acknowledgement will be awarded.
4. Certificate of Acknowledgement form confirming SOP for GCP review, shall be forwarded to and maintained by the Office of Clinical Research.

Procedure for Manual Availability

1. At all times, one copy of this manual must be available at the Office of Clinical Research for staff to review. This can be accomplished in one of many ways such as:
   1.1. Nova Southeastern University Office of Clinical Research website.
   1.2. Print Version
2. Office of Clinical Research Staff should be readily able to state where this manual is located
3. This manual should be made accessible to Sponsors or Sponsor's Representatives in the event of Pre-Study Qualifications Visits or Site Audits.

Procedure for Interpretations of SOPs

1. Questions concerning any ambiguities or uncertainties in this manual are to be routed to the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research.
2. The policies shall be interpreted by the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research, in accordance to the spirit of the law, GCPs and the Nova Southeastern University's mission statement.