Nova Southeastern University
Standard Operating Procedure for GCP

Title: PRINCIPAL INVESTIGATOR RESPONSIBILITIES		Version # 1
SOP Number: OCR-PRI-001	Effective Date: August 2013	Page 1 of 2

PURPOSE: SOP for GCP to set standards for which Principal Investigators, Sub-Investigators and Co-Investigators conduct Clinical research trials.

POLICY:

1. Agree to conduct the study according to Declaration of Helsinski.
2. Follow the following commitments outlined in FDA form 1572.
3. Agree to conduct the study(ies) in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
4. Agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approved in 21 CFR Part 56 are met.
5. Agree to report to the sponsor adverse events that occur in the course of the investigation(s) in accordance with 21 CFR 312.64
6. Have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.
7. Agree to insure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
8. Agree to maintain adequate a accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance wit 21CFR 312.68.
9. Will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. They also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or other. Additionally, they will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazard to human subjects.

10. Agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312

- Statement Of Investigator (Title 21, Code Federal Regulations (CFR) Part 312) Form 1572