



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: ICH Guidelines for Principal Investigator		Version # 1
SOP Number: OCR-PRI-002	Effective Date: August 2013	Page 1 of 2

Purpose: ICH – International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH is a program to standardize technical requirements for testing and developing new drugs and biologics in the United States, European Union (EU), and Japan

Policies:

1. The Center / College has the following SOP for GCP manual in place, which govern the conduct of the best practice in the Center / College

Procedure:

1. The investigator(s) should be qualified by education training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).
2. The investigator should be aware of, and should comply with GCP and the applicable regulatory requirements.
3. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
4. The investigator should have available and adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
5. During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically

significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

6. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.
7. The sponsor should obtain the investigator's/intuition's agreement:
 - 7.1. To conduct the trial in compliance with GCP, with the applicable regulatory requirement(s), and with the protocol agreed to by the sponsor and given approval/favorable opinion by the IRB/IEC;
 - 7.2. To comply with procedures for data recording/reporting;
 - 7.3. To permit monitoring, auditing and inspection and
 - 7.4. To retain the trial related essential documents until the sponsor informs the investigator/institution these documents are no longer needed.