Nova Southeastern University
Standard Operating Procedure for GCP

Title: ICH Related Guidelines for the Protocol		Version # 1
SOP Number: OCR-PRO -001	Effective Date: August 2013	Page 1 of 1

PURPOSE: The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. The Investigator should conduct the trial in compliance with the designed study. ICH is a program standardize technical requirements for testing and developing new drugs and biologics in the United States, European Union (EU) and Japan

POLICIES:

1. The Investigator/Center/College should conduct the trial in compliance with the protocol agreed by the sponsor, and if required, by the regulatory authority)ies and which have been given approval by NSU's IRB (if applicable). The Investigator/Center/College should sign the protocol, or an alternative contract, to confirm agreement.
2. The Investigator/Center/College should not deviate from or change of the protocol without agreement by the sponsor and prior review and documented approval from NSU's IRB, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involve only logistical or administrative aspects of the trial (eg., change in monitor(s), change of telephone number(s).
3. The investigator or person designated by the investigator, should document and explain any deviation from the approved protocol.
4. The investigator may implement a deviation from, or change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior NSU's IRB approval. As soon as possible, the implemented deviation or change, the reason for it and if appropriate, the proposed protocol amendment(s) should be submitted:
    4.1 To NSU's IRB for review and approval
    4.2 To the sponsor for agreement
    4.3 To the regulatory authority(s)