Nova Southeastern University
Standard Operating Procedure for GCP

Title: Protocol Deviations		Version # 1
SOP Number: OCR-DEV-001	Effective Date: August 2013	Page 1 of 1

PURPOSE: A Deviation is any procedure, which deviates from which is outlined in the protocol.

POLICIES:

1. Protocol deviations for patient/volunteer entering into the study. Patients that do not meet all the inclusion exclusion criteria must get sponsor approval to be enrolled in the study. A "**Memo to file"** is generated. Once the sponsor determines eligibility, the investigator or coordinator must report the protocol deviation to the IRB.

    1.1. If a patient is entered into a study in error by the investigator the sponsor will be notified immediately. If the sponsor decided to continue the patient in the study a **"Memo to file"** is generated and the Investigator or coordinator must notify the IRB

2. All protocol deviations that occur while a patient is actively enrolled in the study must be captured in the source documents and the sponsor and IRB must be notified. Examples are drug non-compliance, missing safety and efficacy data, failure to document adverse events, not adhering to schedule window for study visits. When there is a protocol deviation a **"Memo to file**" is generated.

The **"Memo to file"** captures and explains any deviation form the protocol. The **"Memo to file"** includes the following information, principal investigator, study protocol, subject identification code (if applicable) date and nature of deviation. The **"Memo to file"** is endorsed by person reporting it and the Principal investigator