

## Nova Southeastern University Standard Operating Procedure for GCP

Title: <u>Screening/Enrollment Logs</u>		Version # 1
SOP Number: OCR-RR-007	Effective Date: August 2013	Page 1 of 1

**PURPOSE:** Prescreening and Screening logs should be kept to reflect study activity by demonstrating that active recruitment efforts are being made as well as provide evidence that we are screening out individuals that do not fit the criteria of the study. These logs can also provide useful feedback to the sponsor and/or the institution on common reasons why people are not enrolling in the study.

## **POLICIES:**

- Screening/Enrollment logs are kept once individuals consent to reflect those that either screen-failed or otherwise progress through the protocol. They usually contain information such as:
  - 1.1. Subject Name or Initials
  - 1.2. Subject contact information
  - 1.3. Date of screening
  - 1.4. Date of Consent
  - 1.5 Inclusion/exclusion criteria prior to enrollment to the research.
- Privacy policies apply to information contained in the Screening/Enrollment Logs. The Center/College may either create their own logs or use a sponsor supplied log.