Nova Southeastern University
Standard Operating Procedure for GCP

Title: Prescreening of Subjects		Version # 1
SOP Number: OCR-RR-006	**Effective Date: August 2013**	**Page 1 of 2**

1. When communicating with individuals as potential subjects for a research protocol, the needs of an individual as a patient supercede the need for enrollment.
2. When Pre-screening a subject, no research procedures shall be performed without the subject's completing the informed consent process. Only procedures that would be done to the subject as a patient (i.e. absent a study) are allowed. For example, if a protocol calls for patients diagnosed with schizophrenia and have a negative HIV test, if the potential subject shows for triage and the normal course of action (absent a study) would be a diagnostic interview but not any blood draws, the diagnosis confirmation can be done as part of prescreening but the HIV lab draw may not be done until after the subject has completed the initial informed consent process.
3. In the event that potential subjects meet the criteria for more than one study being performed at a Center/College, they will be informed of all studies for which they are eligible to participate, without any coercion or preference toward a particular study.

Procedure for Pre-Screening

1. The Principal Investigator should follow their usual policies to determine the medical necessity of treatment and risk factors.
2. Give appropriate recommendations for immediate treatment of presenting problems before discussing research opportunities.
3. If the patient meets the written profile for suitable research subject candidacy, give brief information concerning the clinical study to the client. Referral to research opportunities shall not be offered to any individual who clearly is incapable of providing informed consent. This includes but is not limited to: acutely suicidal persons, acutely agitated

individuals, acutely psychotic individuals, the mentally retarded or minors (prior to reviewing with their legal guardian).

4. If applicable, give the client an IRB approved written handout containing a description of the clinical study. If study personnel are not readily available, inform the client on how to contact alternative study personnel. (Usually the Principal Investigator or the Study Coordinator but may also include Sub-Investigators as well). Recruitment that has been IRB approved maybe distributed or displayed to potential subjects at NSU locations and events by NSU's representatives