Nova Southeastern University
Standard Operating Procedure for GCP

Title: Required Information in Medical Records		Version # 1
SOP Number: OCR-RDM-001	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: The information in the medical record should support the documentation for research purposes as well as adhere to relevant laws and accreditation agencies.

POLICIES:

1. In the event a patient is enrolled to a research protocol, the records of research activities shall be collected. This maximizes the integrity of the research documentation.
2. In the event of hospitalization of the research patient, the medical record from the inpatient facility should be obtained and included in a Source Document.
3. Whenever possible, any oral history from the subject/significant other shall be supported by observable medical records.
4. Unless waived by the IRB, a copy of the following information shall be in the research record
   4.1. informed consent document(s)
   4.2. any additional authorizations to release protected health information (if not combined with the Informed Consent Document)
5. Documentation that the patient met the Inclusion/Exclusion criteria to be admitted to the study shall be substantiated in the research record.
   5.1. In the event the portions of the criteria are based on historical data, the record shall specify whether the data was gathered by report from the subject/significant other or from past medical data.
   5.2. In the event the Center/College does not have documented medical data that supports the subject's meeting the Inclusion/Exclusion criteria and such documentation is reasonably believed to exist, the Center/College will pursue the obtainment of said documentation from external agencies through obtaining proper release of this information from the subject or subject's legally authorized representative.

5.2.1. Any and all efforts of retrieval of such documentation shall be documented and/or attached on the checklist.

5.2.2. In the event such documentation is not obtained but is verbally verified by a third party, this shall also be documented on the checklist.

5.3. It is the ultimate judgment of the Principal Investigator to validate any historical reports as accurate.