NOVA SOUTHEASTERN UNIVERSITY

Nova Southeastern University
Standard Operating Procedure for GCP

Title: Access of Records by Auditors		**Version # 1**
SOP Number: OCR-RDM-003	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: The integrity of the research data as well as evidence of protection of the human subjects shall be available for verification by research sponsors, regulators and the IRB.

POLICIES:

1. The Center/College shall provide to relevant agencies access to the documentation necessary to assure that the research was conducted properly and that the rights of the subjects were protected. In doing so, all necessary provisions to protect the confidentiality of the subject shall be undertaken.

Procedure for Outside Parties Accessing Research Records

1. The Center/College shall provide certain parties access to the Case Report Forms, medical records (or other source documents) and any other documents related to the research process at reasonable times.
2. Relevant agencies include but are not limited to:
   2.1. Food and Drug Administration representatives
   2.2. Office of Human Research Protections
   2.3. Monitors/Auditors of the sponsor or the sponsor's designee.
   2.4. IRB
3. The Center/College shall verify that the individual requesting access to the medical record has the proper authority to do so.
4. Whenever appropriate, subject identifying information shall be eliminated from the review unless the criteria for disclosure as stated below has been met:
   4.1. Records of particular individuals require a more detailed study of the case.
      4.1.1. This may be for scientific purposes.

4.1.2. This may be for purposes of protection of rights or investigation in the potential breaking of their rights.

4.2. The reviewing agency provides reasonable doubt that the records do not represent actual cases.

4.3. The reviewing agency provides reasonable doubt that results reported are not reflected in the medical record.

4.4. The criteria for federal/state/local law that mandates breach of confidentiality (e.g. to prevent imminent harm to the subject or others) has been met.

4.5. The individual has given appropriate written authorization for such release.

5. Although scanning and/or copying is permitted, identifying information on the medical record or other relevant document(s) must be extracted.
6. The policies protecting patient confidentiality must also be met as well.