Nova Southeastern University
Standard Operating Procedure for GCP

Title: Retention of Research Records		Version # 2
SOP Number: OCR-RDM-002.1	**Effective Date: July 2016**	**Page 1 of 2**

PURPOSE: The Center/College recognizes the difference between the medical/health record and other source documents/Case Report Forms used exclusively for research. There are also other essential documents that pertain to research protocols that are not patient related such as regulatory documents.

POLICIES:

1. The Center/College will retain the research records of the patient a minimum of 12 years according to the longer of the relevant Policies and Procedures of the Center/College OR the time frames specified for research documents below.
2. For the Case Report Forms, Regulatory Documents and other research related documents, the Center/College shall retain the documents for the longer of the following timeframes:
   2.1. U.S FDA IND as specified in 21CFR 312.62(c) or it's relevant successors which currently states "2 years following the date a marketing application is approved for the **drug** for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified." OR
   2.2. U.S.FDA IDE as specified in 31CFR 812.140 or it's relevant successors which currently states "2 years after the date on which the investigation is terminated or completed; or the date the records are no longer required for the purposes of supporting a premarket approval or a notice of completion of a product development protocol ." OR
   2.3. As otherwise agreed to with the Sponsor in writing (i.e. in the Clinical Study Agreement).
3. The Center/College shall take the necessary precautions to prevent accidental or premature destruction of the research documents.

4. The location of the research records must be listed and accessible within a reasonable timeframe.