



**Nova Southeastern University
Standard Operating Procedure for GCP**

<u>Title: Retention of Research Records</u>		Version # 1
SOP Number: OCR-RDM-002	Effective Date: August 2013	Page 1 of 1

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. 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. 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.