



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

<u>Title: Storage and Destruction of Paper-Based Research Documentation</u>		Version # 1
SOP Number: OCR-RDM-004	Effective Date: August 2013	Page 1 of 3

PURPOSE: Storage and/or destruction of paper-based research records shall adhere to the appropriate conditions and timeframes, respecting sponsor and subject confidentiality as well as consider that the documents may need to be unpacked to recreate the study given relatively short time periods.

POLICIES:

1. In the event shelf-space becomes an issue, research records for closed protocols may be stored or destroyed, but only in accordance with this policy.
2. Storage shall
 - 2.1. Be secure from accidental loss, damage and/or disclosure
 - 2.2. Allow for easy retrieval and recreation of the research activity.
3. The Center/College shall destroy research related documents when they no longer remain useful to the Center/College, the sponsor AND other regulatory agencies. Destruction shall only be done after the required retention period had ended. In the event the Center/College wishes to destroy documents and the time is after the regulatory retention requirements has passed but before the obliged timeframe contractual to the sponsor, the sponsor may be contacted to amend the contracted timeframe or provide for the shipment of documents to the Sponsor or their designee.

Procedures for Storing Paper-Based Research Documentation

1. Storage Boxes shall be provided by IRON MOUNTAIN and durable and labeled on the outside in easily readable markings with:
 - 1.1. "Clinical Research"
 - 1.2. Box number
2. A master log of protocol, records and regulatory binders for each box will be maintained by the college/center

3. If space in the box is an issue, it is acceptable to recycle the binders from CRFs or separate source document binders. It is not preferable to break down the regulatory binders due to the potential of disrupting the integrity of the documents and the order in which they exist.
4. Storage area shall be secure and not conducive to physical harm to the records or unauthorized access. Examples are as follows:
 - 4.1. Adequate prevention from water damage
 - 4.2. Controlled access similar to that of access to patient files must be maintained
5. When records are moved off-Center/College, the storage conditions and security shall be at least similar to those of the Center/College.
 - 5.1. A record of where the boxes are located should be kept.

Procedure for Destruction of Paper-Based Research Documentation

1. The timelines for destruction of documents shall be verified and the longest most distant date shall be used as the destruction date. This includes a review of at least the following:
 - 1.1.1. 21CFR312.62 or its relevant successor or equivalent for non-drug studies
 - 1.1.2. The timeframe specified by the sponsor contractually, whichever is longer.
2. The Center/College shall send a certified letter with return receipt requested to the Sponsor or the Sponsor's successor indicating the intent to destroy the documents within 90 days.
 - 2.1. This letter shall indicate that the timeframes initially set forth by the sponsor have expired.
 - 2.2. This letter shall indicate the one contact person at the Center/College that has the authority to stop the destruction process.
 - 2.3. The letter should specify a date which is a minimum of 90 days from the date of the letter (i.e. "The records will be destroyed on or after October 3rd, 2005").
 - 2.4. The letter shall indicate that a non-response to the letter shall be construed as approval for the process.
 - 2.5. The letter shall be copied to the Vice President Research and Technology Transfer.
3. In the event the Sponsor or Sponsor's successor has received the first correspondence and not responded, a second letter shall be sent via certified mail with return receipt requested indicating the intent to destroy the documents within 30 days.
 - 3.1. This letter shall also indicate the one contact person at the Center/College that has the authority to stop the destruction process.

- 3.2. The letter should specify a date which is a minimum of 30 days from the date of the letter (i.e. "The records will be destroyed on October 3rd, 2005").
- 3.3. The letter shall indicate that the previous letter was not responded to and a non-response to the letter shall be construed as approval for the process.
- 3.4. The letter should indicate that this is the "Final Notice".
- 3.5. The letter shall be copied to the Vice President Research and Technology Transfer.
4. In the event the Sponsor or Sponsor's successor has received the second correspondence and not responded, and the Vice President Research and Technology Transfer gives permission, the records are to be destroyed in accordance with the policies and procedures for destroying confidential documents of the Center/College.
5. In the event the Sponsor or Sponsor's successor requests the records be not be destroyed, the records shall be shipped to the sponsor's designated address, preferably at their expense.