



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

Title: <u>ICH Guidelines for Source Documents and Records</u>		Version # 1
SOP Number: OCR-ED-005	Effective Date: August 2013	Page 1 of 3

PURPOSE: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

POLICIES:

1. Completion of case report forms (CRFs and e-CRFs)

The investigator(s)/ Center/College should:

- 1.1 Ensure the accuracy, completeness, legibility, and timeliness of data collection is adhered to according to the protocol.
- 1.2 Ensure the accuracy, completeness, legibility, and timeliness of data collected in the CRFs or e-CRFs and other required documents submitted to the sponsor or Coordinating Investigator is adhered to according to the protocol.
- 1.3 Ensure that data reported on the CRF or e-CRFs, which is derived from source documents, is consistent with the source documents. Any discrepancies should be explained.
- 1.4 Ensure that any change or correction to a paper CRF is made with a single stroke through the incorrect information, dated, initialled, and explained (if necessary). The original entry should not be obscured (i.e. an audit trail should be maintained). eCRF's are required to have

an inbuilt correction and audit process. However, if there is no inbuilt audit trail, see below.

- 1.5 Retain records of the changes and corrections (eg data queries) to demonstrate an audit trail.

2. Source documents, record keeping and archiving

The investigator(s) should:

- 2.1 Keep original source documents (where the data was first recorded) and take measures to prevent accidental or premature destruction of these documents.
- 2.2 Ensure that any change or correction to any source data is made with a single stroke through the incorrect information, dated, initialled, and explained (if necessary). The original entry should be not obscured (i.e. an audit trail should be maintained). This applies to written changes or corrections.
- 2.3 Where an investigator is using their own electronic CRF documents, changes and amendments should be tracked, and version dates (and numbers, depending on the degree of change) should be altered to reflect the changed data. An explanation of the changes should be added in the footer, or noted in a record of changes.
- 2.4 Ensure that a copy of the signed and completed Participant Information Sheet and Consent form has been filed in the appropriate place in the Center/College chart
- 2.5 Maintain the trial documents as specified by Center/ College - The Study Site Master File and Essential Documents and as required by the applicable regulatory requirement(s) and take measures to prevent accidental or premature destruction of these documents. 4
- 2.6 Ensure that upon request of the monitor, auditor, FDA or regulatory authority, make available for direct access, all requested project related records as outlined in the Clinical Trial Agreement and Patient Information Sheet and Informed Consent Form.
- 2.7 Ensure that in those instances where a study participant does not have a medical record for that Center/College , that a medical

record is created in accordance with local Center/College requirements.