



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

Title: <u>Source Documents</u>		Version # 1
SOP Number: OCR-ED-002	Effective Date: August 2013	Page 1 of 4

PURPOSE: : Source documentation of the subject's medical history, Informed Consent process and on-going activities during the clinical trial are all considered essential documents within a clinical trial. Detailed and exact records need to be maintained. These records will be made accessible to the Sponsor's representative (Monitor) during regular visits to verify the data that is being entered in the Case Report Forms (CRFs).

Examples of source documentation include, but are not limited to the following:

1. Clinical charts.
2. Laboratory results.
3. Diagnostic procedures.
 - a. E.g. x-ray reports, ECG readings, etc.
4. Physician referral letters.
5. Records of medical history.
 - a. E.g. operating room reports, specialists letters, etc.
6. Records of telephone conversations.
 - a. With the subject.
 - b. With other health care professionals about the subject.
 - c. With the Sponsor about the subject.

POLICIES:

1. There should be "supplemental source documents" developed for each specific clinical trial to document the required procedures at each visit. The Sponsor will frequently supply these forms, but if not supplied, it is advisable that the Center/College develop a series of forms for each study. These forms allow for easy documentation of the required procedures at each visit and also assure that nothing is forgotten at any visit.

Recruitment:

1. Completed forms used for telephone screening should be filed in the subject's clinic chart.

Screening:

1. There needs to be a detailed recording of the consent process which includes:
 - 1.1 That the subject was given ample time to review the ICF and to ask questions.
 - 1.2 The date and time that the ICF was signed by the subject.
 - 1.3 Who was present during the consenting process.
 - 1.3.1 Include staff members.
 - 1.4 That no study-specific procedure was completed prior to the subject giving consent.
 - 1.5 If a procedure that is part of normal medical practice was done prior to consent is to be used in the study, it should be documented that the subject is aware that this information is to be used and give consent for its use.
2. Document what procedures are conducted at the screening visit. These should include the following at a minimum but may include others as determined by the protocol:
 - 2.1 Evidence that the subject meets all of the inclusion criteria for the study.
 - 2.2 Evidence that the subject does not have any of the exclusion criteria for the study.
 - 2.3 Documentation of the disease or condition under study.
 - 2.4 Medical history.
 - 2.4.1 Should include subject recall, referral letters, and documentation of previous diseases or conditions.
 - 2.5 Concurrent conditions.
 - 2.6 Concomitant medications.
 - 2.7 Physical examination.
 - 2.8 Documentation of study-specific procedures and results.
 - 2.9 Documentation the subject is considered eligible for inclusion in the study by the Principal Investigator.
 - 2.9.1 If the subject is not eligible document why he/she is not eligible and what follow-up is to be offered.

Randomization

1. If the subject is found to be eligible a letter should be dictated to the Family or Referring Physician containing the following information:
 - 1.1 That the subject is to be included in a clinical trial.
 - 1.2 Report the medical history and physical findings at screening.
 - 1.3 The nature of the clinical trial.

- 1.3.1 Include the class of drug and action.
 - 1.3.2 Include the length of the trial and number of visits required.
 - 1.3.3 Request that no changes be made to current medications without first notifying the research site.
 - 1.3.4 That the physician will be notified of any significant findings during the course of the trial.
2. Document what the randomization number is (if any) and the amount of study drug (device) dispensed to the subject.
 - 2.1 This should be recorded in the clinic notes and drug accountability log.
3. Any study-specific procedures and the results.
4. Review of medical conditions and concomitant medications prior to randomisation.
5. Next scheduled visit.

Routine Study Visits:

1. Document all study-specific procedures and results.
2. Review with the subject for adverse experiences and document.
 - 2.1 At any visit, all new or continuing adverse experiences which were not present at the Screening Visit must be recorded. Any medical condition present at baseline, which remains unchanged or improves, should not be recorded as an adverse experience at following visits. However, if there is deterioration of a medical condition that was present at the Screening Visit, then this should also be considered a new adverse experience and recorded in the subject's chart and in the Case Report Form.
 - 2.2 If an adverse experience does occur, it is important to document the severity and relation to the study drug/device.
 - 2.3 Determine if any AE constitutes a Serious Adverse Event.
3. Review and document any changes to previous concomitant medication or any new medications.
4. Record amount of study drug (device) returned and amount dispensed at this visit.
 - 4.1 Needs to also be recorded in the drug accountability log.
 - 4.2 Record the subject's compliance.
 - 4.3 Record any unusual events related to the study drug.
 - 4.3.1 E.g. lost drug or container.
5. Record any protocol deviations and reason for deviation.

Termination (Early Withdrawal) Visit:

1. Document if the subject completed the study successfully.
 - 1.1 If the subject did not complete the study record the reason

why not.

1.1.1 E.g. adverse event, withdrew consent, lost to follow-up, administrative reason, etc.

2. Document all study-specific procedures and the results.
3. Review and record any adverse events.
4. Review and record any changes to concomitant medications.
5. Record amount of study drug (device) returned and the subject's compliance.
 - 5.1 Should also be recorded in drug accountability log.
6. dictate a letter to the Family or Referring Physician with the following information:
 - 6.1 The subject did or did not complete the clinical trial.
 - 6.2 Any significant findings.
 - 6.3 Any changes to medical or physical condition during the course of the study.
 - 6.4 What, if any, follow-up care is planned.

Data Transfer:

1. Data that is required for the Case Report Form should be transferred from the source documentation to the appropriate CRF page in a timely manner.

Record Retention:

1. All subject records become part of the study related documents and are required to be maintained for a minimum of 25 years.

References:

21 CFR 312.60 General responsibilities of investigators
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 312.68 Inspection of investigator's records and reports
FDA Information Sheets, October, 1995 Recordkeeping in Clinical Investigations
May 9, 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline