NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: SOURCE DOCUMENTS FOR CLINICAL TRIALS	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT - OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-7
EFFECTIVE DATE: July 01, 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE:	

I. DEFINITIONS

Office of Clinical Research ("OCR"): The office responsible for coordinating the review, approval, and administration of industry sponsored clinical trials and clinical research.

Case Report Forms ("CRF"): A printed, optical, or electronic document designed to record all of the protocol required information [e.g., study data] to be reported to the sponsor on each trial subject. CRFs standardize the collection of study data and help to ensure that the medical, statistical, regulatory and data management needs of the study are met.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Protocol: The document that describes the objectives, design, methodology, statistical considerations, and plan for the conduct of the study. A protocol for an industry-sponsored study is usually prepared by the sponsor and ensures the safety of the trial subjects and integrity of the data collected.

Source Data: original records where a data point is recorded.

Source Documentation: All information contained in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the evaluation of the trial. Source Documents may include: clinical charts, hospital records, subject diaries, pharmacy dispensing lists, test results, x-rays, lab records, etc. Examples of source documentation include but are not limited to the following: Clinical charts; Laboratory results; Diagnostic procedures (*e.g. x-ray reports, ECG readings, etc.*); Physician referral letters; Records of medical history (*e.g. operating room reports, specialists' letters, etc.*); and Records of telephone conversations.

II. POLICY

The Investigator and designated research personnel are responsible for clearly identifying the data and documents that will be maintained as source data and documentation for the research at the start of and throughout the trial.

Source documentation should meet ALCOA-C standards. Source data should be attributable, legible, contemporaneous, original, accurate, and complete.

Attributable: It should be obvious who wrote or did what.

Legible: Can it be read? Never use pencils to record source documents, use dark colored ink. Avoid abbreviations.

Contemporaneous: The information should be current and documented in the correct time frame.

Original: Original or a certified copy or a printout from an electronic data source.

Accurate: Are conflicting data recorded elsewhere? Content should precisely reflect the event being recorded.

Complete: Source documents should be complete and not missing any information.

If source documentation is incorrect, incomplete, or otherwise deficient, research personnel may correct and/or complete by making an additional entry or addendum to the source documentation. The late entry must be signed or initialed and dated in present time by the person making the entry.

Research personnel must NOT modify past-dated source documentation in research records in an attempt to resolve deficiencies. Altering past-dated records is potentially fraudulent.

If it is noted in the research record that data is missing and those data are then obtained or found at a later date, study personnel will ensure that its incorporation in the research record is noted. The notation must be signed or initialed and dated.

With Sponsor approval, study personnel may use Case Report Forms (CRFs) as source documents if they were used to initially record data and they accurately represent data collected for the study.

III. PROCEDURES

Source documentation of a clinical trial 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).

A. Supplemental Source Documents

There should be "supplemental source documents" (e.g. Case Report Forms (CRF)) 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 PI develop a series of forms for each study. These forms allow for easy documentation of the required

procedures at each visit and assure that nothing is forgotten at any visit. Data should be transferred from the source documentation to the appropriate CRF page in a timely manner.

B. Recruitment & Informed Consent Source Documents

Any completed forms used for telephone screening should be filed in the subject's clinic chart. Additionally, there needs to be a detailed recording of the consent process which includes:

- That the subject was given ample time to review the ICF and to ask questions.
- The date and time that the ICF was signed by the subject.
- Who was present during the consenting process, including staff members.
- That no study-specific procedure was completed prior to the subject giving consent.
- If a procedure that is part of normal medical practice was done prior to consent and is used in the study, it should be documented that the subject is aware that this information is to be used and gives consent for its use.

Source Documents shall also include 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:

- Evidence that the subject meets all the inclusion criteria for the study.
- Evidence that the subject does not have any of the exclusion criteria for the study.
- Documentation of the disease or condition under study.
- Medical history, which should include subject recall, referral letters, and documentation of previous diseases or conditions.
- Concurrent conditions.
- Concomitant medications.
- Physical examination.
- Documentation of study-specific procedures and results.
- Documentation that the subject is considered eligible for inclusion in the study by the Principal Investigator. If the subject is not eligible, document why he/she is not eligible and what follow-up is to be offered.

C. Source Documents of Investigational Product Randomization

If the subject is found to be eligible, it is recommended a letter should be dictated to the Family or Referring Physician containing the following information:

- That the subject is to be included in a clinical trial.
- Report the medical history and physical findings at screening.
- The nature of the clinical trial.
    - Include the class of drug and action, the length of the trial and number of visits required. Request that no changes be made to current medications without first notifying the research site and that the physician shall be notified of any

significant findings during the trial.

The randomization number (if any) and the amount of study drug/device dispensed to the subject should be recorded in the clinic notes and drug/device accountability log. Other source documents include any study-specific procedures and the results; review of medical conditions and concomitant medications prior to randomization; and the next scheduled visit.

D. Source Documents for Routine Study Visits

Document all study-specific procedures and results and review with the subject for adverse experiences and document. 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.

If an adverse experience does occur, it is important to document the severity and relation to the study drug/device and to determine if any AE constitutes a Serious Adverse Event. At routine study visits:

- Review and document any changes to previous concomitant medication or any new medications.
- Record amount of study drug (device) returned and amount dispensed at this visit.
    - This needs to also be recorded in the drug accountability log.
- Record the subject's compliance.
- Record any unusual events related to the study drug (*e.g. lost drug or container*).
- Record any protocol deviations and reason for deviation.

E. Source Documentation of Termination (Early Withdrawal) Visit

During the termination visit:

- Document if the subject completed the study successfully.
    - If the subject did not complete the study record the reason why not (*e.g. adverse event, withdrew consent, lost to follow-up, administrative reason, etc*.)
- Document all study-specific procedures and the results.
- Review and record any adverse events.
- Review and record any changes to concomitant medications.
- Record amount of study drug (device) returned and the subject's compliance.

The amount of study drug (device) returned and the subject's compliance should also be recorded in the drug/device accountability log. Following the termination visit, it is suggested to dictate a letter to the Family or Referring Physician with the following information:

- The subject did or did not complete the clinical trial.

- Any significant findings.
- Any changes to medical or physical condition during the study.
- What, if any, follow-up care is planned

REFERENCES

- Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act (21 CFR)
- The International Conference on Harmonization ("ICH") Guideline for Good Clinical Practice (GCP)
- US Food and Drug Administration ("FDA") Form 1572