Source Documentation in Clinical Research

I. Purpose
This policy establishes guidelines for source documentation in order to provide verifiable data for the trial and to maintain adequate accessibility of individuals’ medical history.

II. Scope
This policy applies to individuals at OHS whom are engaged in Human Subject Research including but not limited to any person paid by, under the control of or affiliated with the institution such as scientists, investigators, research coordinators, medical education, medical staff, guest researchers and collaborators.

III. Definitions
A. Human Subject Research- A systematic investigation conducted to obtain data through intervention or interaction with a living individual or using identifiable private information. Human Subject Research and Clinical Research are synonymous.

B. Principal Investigator (PI)- An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is dispensed, or, in the case of an investigation conducted by a team of individuals, is the responsible leader of that team. An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is dispensed, or, in the case of an investigation conducted by a team of individuals, is the responsible leader of that team. This term is synonymous with investigator.

C. Source Document- 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 and complete, 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). Any original document relating to the assessment, care and treatment of patients enrolled in clinical research studies. Source documents include, but are not limited to, history and physical assessment findings, procedural or operative notes, test results, progress notes, medication records, flow sheets, and nurses’ notes.

IV. Policy Statements
A. The PI shall maintain adequate and accurate original documents, data, and records which capture all observations and other data pertinent to the investigation on each individual participating in a clinical trial.
B. OHS requires an individual’s medical information to be stored in the Ochsner medical record.

C. Study specific documents and source documents shall be stored for a minimum of ten years after the completion of the study or as specified by the clinical trial agreement (whichever is longer).

D. The preservation of documents shall adhere to OHS policies on the privacy and security of protected health information.

V. Procedures/Standards and Roles & Responsibilities

A. Study documentation pertinent to medical care is found in the subject’s Ochsner medical record.

1. Source Documents generated in the medical record include, but are not limited to:
   a. Subject history;
   b. Subject assessments;
   c. Test results;
   d. Procedures;
   e. Progress notes;
   f. Flow sheets;
   g. Medications;
   h. Treatments;
   i. Referrals; and
   j. Communications between medical personnel and the subject.

2. Copies of Source Documents that should be scanned into the Ochsner medical record include, but are not limited to:
   a. Signed informed consent;
   b. Outside test results (Central lab reports, etc); and
   c. Outside physician reports.

B. Study specific Source Documents, not directly related to patient care, and copies of the subject’s medical records should be maintained in a research chart or study file.

1. Source Documents to be filed in the research chart include, but are not limited to:
Source Documentation in Clinical Research

1. Source documentation in clinical research includes:
   a. The subject’s original informed consent;
   b. Subject diaries, questionnaires and surveys;
   c. Study specific central lab test results with the PI’s assignment of clinical significance and signature;
   d. Inclusion/exclusion checklists;
   e. Worksheets (i.e. dose calculations, drug compliance calculations, lab value calculations, or checklist of study visit procedures); and
   f. Observation notes on a post it or scrap of paper. These documents must be retained if it is where the data was first recorded.

2. Other study specific data that should be in the research chart or study files include but are not limited to:
   a. Shipping of receipts lab or pathology samples;
   b. Randomization/registration acknowledgements;
   c. Copies of the legal health records that verify the subject’s eligibility or study specific procedures;
   d. Adverse event logs and/or deviation logs; and
   e. Study schema.

3. Source Documents maintained in the research chart should be signed and dated to verify the date of collection.

C. Compliance with this policy is verified during Research Administration’s Quality Assurance Clinical Trial Reviews.

D. Any questions regarding the retention of a document in the medical record or the research chart should be referred to the Human Research Protection Program Manager.

VI. Enforcement and Exceptions
Failure to comply with this policy may result in progressive discipline up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers.

VII. Internal References
OHS.RES.014 HIPPA Research Policy
Guidance: Source Documentation
Guidance: Research Data Retention
VIII. External References
21 CFR 312.3
21 CFR 312.62(b)
21 CFR 812.140

IX. Policy History
OHS.ACR.014 Source Documentation in Clinical Research

X. Approved

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