Clinical Research Standard Operating Procedure

SOP 108-ADM Identification of Essential Source Documentation and Source Data

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Purpose:
This SOP describes essential source documentation required for the conduct of clinical research according to local, state and federal regulations and GCP and ICH guidelines.

References:
- 21 CFR 312.57 Recordkeeping and record retention
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.62 Investigator record keeping and record retention
- 21 CFR 312.64 Investigator reports
- 21 CFR 11 Electronic records; Electronic signatures
- ICH section, 4.9 Records and reports
- ICH section, 6.4.9 Trial design, identification of any data to be recorded directly onto case report forms and to be considered the source data.
- ICH section, 8.0 Essential Documents for the conduct of a clinical trial
- Oncology Nursing Society Manual of Clinical Trials Nursing, Oncology Nursing Press, Inc. copyright 2000, Pittsburgh, PA.
- The University of Arizona Human Subjects Protection Program Manual of Procedures
- All SOPs are applicable to this SOP.

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Target Audience or Responsibilities:
All University of Arizona Cancer Center clinical research personnel involved in clinical trials.

Tools:
- Listing of types of source documentation or source data, examples (Attachment 1).

Definition of Terms:
SOP 108-ADM Identification of Essential Source Documentation and Source Data

- **Clinical trial:** Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

- **Computerized system:** For the purpose of the guidance, computer hardware, software and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve or transmit in digital form, information related to the conduct of a clinical trial.

- **Documentation:** All records, in any form (including, but not limited to, written, electronic, magnetic and optical records; scans, x-rays and electrocardiograms) that describe or records the methods, conduct and/or results of a trial, the factors affecting a trial and the actions taken.

- **Drug Accountability Record Form (DARF):** Specifically formatted record of transactions used for drug accountability.
  - **Investigational Agent Accountability Record (IAAR):** Record used at AZCC for the drug accountability.

- **Electronic record:** Any combination of text, graphics, data, audio, pictorial or any other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.

- **Source data:** All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

- **Source documents:** Original documents, data and records including but are not limited to, hospital records, clinic and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographs, negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, at the laboratories and at medical-technical departments involved in the clinical trial.

- **Transmit:** To transfer data within or among clinical study sites, contract research organizations, data management centers, sponsors or other entities as appropriate.

**Safety Issues:**

Confidentiality: Research subjects have both a legal and moral right to protection from breaches of confidentiality or from unwarranted invasion of privacy.

**Process Steps:**

1) Source documentation and data should be attributable, concise, legible, current, accurate, complete, easy to access, organized and verifiable.
2) Source documentation includes relevant patient histories, all the events that transpire while the subject is enrolled in the clinical study including any follow-up specified by the clinical research protocol.

3) Source documentation must be signed and dated by the person obtaining the information as appropriate.

4) Source documents, source data and case report forms are typically not contained on, or used as the same document. Patient diaries and questionnaires, as applicable completed by the study subject may be considered both the source document and case report form.

5) Photocopies of the case report form should not be used to capture the source data.

6) Drug accountability records should be accurate and complete.

7) Source documentation must include the research subject's name and medical record number (MRN).

8) Essential documents will be retained and stored as required by all regulatory authorities and study sponsors including but not limited to the IRB, FDA and NIH.

Note: Destruction of original or any other source documentation is not permitted.
Examples of Source Data and Documentation may include:

- Adverse event flow sheets
- Case histories
- Concomitant medications flow sheets
- Copies of transcriptions certified after verification as accurate and complete
- Drug dispensing records
- EKG
- Electronic records
- Flow sheets and work sheets
- Hospital records
- Information from outside sources
- Informed consent forms
- IRB correspondence
- Laboratory results and notes
- Memoranda
- Microfiches, photo negatives, microfilm or magnetic media
- Non-study clinic visits
- Non-study hospitalizations
- Notes to file
- Patient medical record number (MRN)
- Pharmacy records, Drug Accountability Record Form (DARF)
- Physician and nurse notes
- QA records
- Randomization and/or registration forms
- Recorded data from automated instruments
- Records kept in the pharmacy, laboratory or medical-technical departments
- Research patient questionnaires
- Sponsor correspondence
- Subject study identification number
- Subject diaries
- Subject medical or study records
- Telephone logs
- X-rays