

Standard Operating Procedures for Clinical Research at USF Health Morsani			
	SOURCE DOCUMENTATION		
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PURPOSE: The purpose of this SOP is to describe a standardized procedure for research personnel to record source data and manage source documents for clinical research studies at the CRC.

SCOPE: This SOP applies to the Investigator and designated research personnel who are responsible for maintaining source documentation at the CRC.

RESPONSIBILITIES: The Investigator and designated research personnel are responsible for clearly identifying the data and documents that will be maintained as source data and documents for the research.

DEFINITIONS:

ALCOA Criteria: Source data that should be attributable, legible, contemporaneous, legible and accurate

Certified Copy: A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject

Source Documents: 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).

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

PROCEDURE:

1. Designated research personnel will prepare source documentation of every visit, conversation, and procedure associated with the clinical trial.
2. Research staff will capture source data for every data point on the case report form (CRF), an important GCP rule.
3. Research staff will ensure that all data is verifiable and all documentation has an audit trail.

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PROCEDURE (cont.):

4. Qualified research personnel will apply the **ALCOA** standard to achieve data quality.
 - **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.
3. Research personnel will ensure that documentation such as study participant diaries are initialed or signed and dated by the person completing the form in order to be considered a source documentation.
4. 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 later entry must be signed/initialed and dated in present time by person making the entry.
5. 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.
6. If it is noted in the research record that data are missing and those data are then obtained/found at a later date, study personnel will ensure that its incorporation in the research record is noted in the research record. The notation must be signed/initialed and dated.
7. With Sponsor approval, study personnel may use Case report forms (CRFs) as source documents if they represent data collected for the study and are where data were initially recorded.
 - 7.1 To ensure consistency, the site should clearly indicate at the start of a monitoring visit or audit, which CRFs are being used as source documentation and maintain a list of the CRFs being used as source documentation.
 - 7.2 If data are obtained at a later date (i.e., after the study visit) and are recorded on the CRF as source documentation, it must be signed/initialed and dated.
 - 7.3 If data are transcribed from another source onto the CRF, the CRF is not considered to be the original source document and it cannot be used as source documentation. Examples include: laboratory results, radiology reports, history from referrals, etc.

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PROCEDURE (cont.):

- 7.4 As a source document, the original CRF must be signed/ initialed and dated by the individual recording the data on the CRF so that there is a clear audit trail of who completed the documentation.
- 8. Study staff will follow any source documentation procedures outlined in the protocol in addition to above procedures.
- 9. The Investigator and his/ her research team are strongly encouraged to perform intermittent internal QAs to identify incomplete/deficient source documentation.
- 10. The Investigator must retain source documents for the required period of time so they are accessible when needed for audits and inspections.

Approval Date	FDA Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance	Effective Date	Review/Revision Date
REF/2015	WHO Harmonized Good Clinical Research Practice (GCP)	01/01/2015	
	SOP 402: Informed Consent Process		
	SOP 405: Study Visits		
	SOP 204: Adverse event Reporting		
	SOP 501: Case Report Form Completion		
	SOP 504: Archiving Study Records		
	SOP 505: Printing and Certifying Medical Records		
RELATED POLICIES:			
APPENDICES:	None		
REVISION HISTORY:	Keep a running history of all revision dates.		