


Source Documentation		
 VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-565.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure establishes the standards for quality of data collected during the conduct of a clinical research study and verification of reliability, completeness, accuracy, and traceability of data. This SOP is applicable to all delegated personnel who have responsibility for documentation and acquisition of data collected during the conduct of a research study.

2. REQUIREMENTS

Documentation of source data is necessary to ensure the reliability, quality, and integrity of research and/or clinical findings, observations, and other activities during the conduct of a research study. Source documentation provides evidence of the existence of the research participant, substantiates compliance with protocol requirements, and serves as supporting evidence that facilitates replication of the progression of the research study.

The initial documentation of data is considered source documentation. Documentation may take the form of paper (ex, signed consent form or questionnaire) or electronic data entry directly into a computerized system, including, but not limited to, electronic medical records, electronic case report forms, electronically generated laboratory reports, and electronic medical images.

Source documentation may originate from, but is not limited to, the following:

- Investigators and delegated clinical study staff
- Non-research clinical personnel ([consulting services](#), ex, radiologist reading a CT scan)
- Medical devices (ex: electrocardiogram)
- Imaging facilities
- Automated laboratory reporting systems
- Research participants

3. DEFINITIONS

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

Data Element - a single data point associated with a participant enrolled in a research study.

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 research study. Source data are contained in source documents (original records or certified copies).

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 copies, 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 research study).

4. PROCESS

Each participant encounter including, but not limited to, conversations, visits, and/or procedures associated with a research participant, potential or enrolled, must be documented.

A. To achieve data quality and facilitate replication, the principles of ALCOA+ must be applied to all source documentation.

- **Attributable:** The author of the source data must be readily apparent
- **Legible:** The information must be readable
- **Contemporaneous:** The information is current and documented in a timely manner
- **Original:** Data are unaltered or on a certified copy of paper source data or a printout from an electronic data source
- **Accurate:** Content precisely reflects the event being recorded and does not contradict data recorded elsewhere
- **+**:
 - **Complete:** Controls should be in place, ensuring that all data is present with an audit trail maintained. All reanalyses performed should be included, and nothing must be deleted or removed from the date of documenting.
 - **Consistent:** Data must be able to prove the sequence of events. Data should be arranged chronologically and must be dated and time-stamped in the expected sequence.

- **Enduring:** To ensure the data is accessible long after it is recorded, the material used to record that data should be long-lasting and durable.
 - **Available:** Data should be accessible for review, audit, or inspection whenever needed. It should be easily retrievable over the lifetime of the record.
- B. Research study start-up includes the development of source document templates, as applicable, if the sponsor does not provide them. These templates are inclusive of all data needed to be collected at each study visit, unless certain data elements are entered directly into an electronic source. The original data is then transcribed into the electronic data capture (EDC) system, as applicable. All source documents should be stored in the participant's study file and used to support the data entered into the EDC.
- C. Source documents require evidence of their review by the appropriately delegated study personnel. Source documentation must be initialed or signed and dated by the individual generating the data or completing the form by initialing and dating a generated document certifying copies in bulk. For source documentation generated external to the study team, the PI or sub-I is required to review the results for clinical or non-clinical significance. All signatures or initials must match the signature and initials used on the delegation of authority (or signatures and initials) log.
- D. For hard copy source documentation, indelible ink (preferably black or blue) should always be used. Pencil and erasable ink are never acceptable instruments for documentation.
- E. Case report forms (CRFs) may serve as a source document if data elements are newly created and not transcribed from other sources. However, if data is transcribed from another source onto the CRF, the CRF is not considered to be the original source document and cannot be used as source documentation.
- F. When data is entered directly into a computer system, the electronic data in the computer system is the original source documentation.
- G. A paper record (printout or hard copy) of the electronic data is considered to be a copy and not original source documentation unless certified. A direct printout from the electronic medical record (EMR) containing the electronic signature of a delegated study team member and time and date stamp is considered an original document. Documentation received via fax is considered a copy and not an original.
- H. The actual data on a participant's completed document, such as a questionnaire or diary, is considered original data and does not need supporting source documentation. However, documentation (such as entry into an activity log or visit note) is required to

show that the required participant completed document was provided to the participant in accordance with protocol requirements.

- I. Should source documentation be found incorrect or incomplete, the documentation may be corrected or completed by making an additional entry or an addendum.
 - Corrections should be stricken through with a single line, initialed, and dated. Addendums should include an explanation of the circumstances requiring the addendum and should be signed and dated by the author of the addendum.
 - Any form of erasure, including correction fluid, should never be used on source documentation.
 - Original documents requiring error correction should never be destroyed.
- J. The use of sticky notes and similar temporary notes to record source documentation should be avoided. If they are used inadvertently, they must be maintained as source documentation and kept with all other source documents for the applicable study participant.

5. REFERENCES

- A. US Code of Federal Regulations
 - [312.62 - Investigator Recordkeeping and Record Retention](#)
 - [812.140 - Records](#)
- B. US Food and Drug Administration
 - [Guidance for Industry: Electronic Source Data in Clinical Investigations](#)
- C. Good Clinical Practice
 - [ICH Harmonised Guideline Guideline For Good Clinical Practice E6\(R3\)](#)
 - Section 2.5 - Compliance with Protocol
 - Section 2.12 - Records
 - Section 2.13 - Reports
 - Appendix C - Essential Records for the Conduct of a Clinical Trial
- D. [VCU Health policies](#)
 - Documentation - Entries in the Medical Record
- E. VCU Policies
 - [CR- CO- 525: Delegation of Authority](#)

Review/Revision History CR-CO-565		
Version No.	Effective Date	Description
CR-CO-565.3	08/04/2025	<ul style="list-style-type: none"> ● Revised definitions of source data and source document for clarity and alignment with current GCP guidance ● Expanded description of originators of data and examples of documentation types ● Updated ALCOA to ALCOA+ with full definitions for “+” attributes ● Clarified use of CRFs, EMRs, and participant-completed documents as source documentation ● Standardized language on certified copies, corrections, and acceptable ink types ● Clarified delegation, review, and signature requirements for source documents ● Aligned with ICH E6(R3) ● Aligned with HRPP Toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-565.2	06-01-2021	<ul style="list-style-type: none"> ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-565.1	06-01-2018	<ul style="list-style-type: none"> ● Original