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1. Overview

Purpose

The purpose of these guidelines is to define the requirements and best practices for maintaining documentation in compliance with Good Clinical Practice (GCP) and according to the ALCOA-C principles (Attributable, Legible, Contemporaneous, Original, Accurate, and Complete), ensuring data integrity, accuracy, and consistency in all documentation related to clinical research activities.

2. Definitions

Note-to-File: a document written by a research team member to provide additional information or clarification about a research study. Examples include the explanation of the location of a study document, documentation of a discrepancy or problem and the actions taken to address it, or clarification of unclear protocol instructions.

Source Documents: original documents, data, and records that document the existence of a research participant and the integrity of the research data collected.

3. ALCOA-C Documentation Practices

3.1 Attributable

Each record must clearly identify who created or modified the information with a signature or initials; all recorded information must be traceable to a person, date, and time (if applicable).

All individuals who create and modify data electronically must have a unique user log-in identification and password to ensure accountability and traceability. Physical, or paper records must include signatures or initials in addition to the date.

Data or source documentation must be marked with appropriate identifiers such as participant number, protocol number, sample identification number.

Questions to verify attribution:

- Is it obvious who documented the information?
- If changes were made, it is obvious who, when, and why the changes were made?
- Is the signature or initials unique to the individual responsible for creating or modifying the documentation, and are they consistent across documents?
- Is it possible to identify the signature or initials to those on the Delegation of Authority log when signatures or initials are not legible?
- Are applicable identifiers (e.g., protocol number, participant number, sample identification number) present in the record?

3.2 Legible

The record should be easy to read and signatures identifiable. Records must be created using legible writing or electronic systems where data cannot be altered once entered (e.g., passwords, electronic signatures). Handwritten entries must be written in permanent, dark-colored ink to prevent fading or erasing without tracking the change.

If a record is illegible or unclear, it must be corrected promptly, and a note-to-file should be created describing who made the change and for what reason. For physical records, corrections must be made in a way so that the original entry is still legible (e.g., using a single strike-through with initials and date).

Questions to verify the record is legible:

- Can the handwritten or typed documentation be read?
- Was paper or ink used that is permanent and appropriate for longtime storage? Is paper likely to fade over time (e.g., thermal paper)? Is the ink permanent?
- Will the system used to store the documents be accessible through the course of the research and after the completion of the research? Will the format still be readable in future years?

3.3 Contemporaneous

Information must be recorded in real time as an event or observation occurs, with a signature/initial and date and time stamp showing that the documentation was performed in real time. If there is a delay in recording, the data should be recorded as soon as possible, and the reason for the delay defined and justified. Records and documentation must never be back-dated. If a record or documentation is created late, the documentation should show the date of the entry and include an explanation for any date discrepancies.

Questions to verify the documentation is contemporaneous:

- Does the record clearly identify the date and time the data were collected and/or entered?
- Is the information recorded in the correct timeframe?
- Is the entry late? If so, has it been appropriately identified and does it have the correct date, i.e., the date of entry?

3.4 Original

The original document is the first record of the information, making it the most accurate and reliable. Any paper or electronic system used to create/record data or information for the first time is considered the source or raw data; this might include medical notes, participant diaries, checklists, emails, scraps of paper or other notes if they are the original form on which pertinent data was recorded. If data was transcribed from another source to the participant record, the participant record is not considered the original source document since it was not the first place the data was recorded.

Any copies of the original document must be clearly labeled as copies, and the original must always be retained. In the case of electronic records, ensure the original document is stored securely and is not altered or deleted, and copies or modifications are properly controlled and documented. Changes or corrections to physical records must be made in a way so that the original entry is still legible (e.g., using a single strike-through with initials and date). Never use white-out or otherwise obscure original source.

Questions to verify whether the documentation is original:

- Is this document the first location where the information was recorded?
- Was the information transcribed from another source where it was recorded first?
- Is this document a copy?
- Has this document been modified?

3.5 Accurate

All recorded information must be consistent, a true representation of facts, and be free of errors throughout the document. If any errors are made, they should be corrected promptly and appropriately (e.g., single strike-through with initials and date for manual records, or system-controlled error correction in electronic records).

Questions to verify source accuracy:

- Has any conflicting information been recorded in another location?
- Have any corrections been properly identified, documented and supported with alternate records?

3.6 Complete

The information should be final and include all necessary information for a full understanding of the activity or observation – answering who, what when, where, why, and how – with no missing information. All relevant observations, calculations, conclusions, and actions taken should be recorded; all fields in forms or logs should be completed in entirety. If any part of the documentation is missing or incomplete, a clear reason must be provided, along with corrective actions if needed.

Questions to verify whether documentation is complete:

- Is the information complete per protocol requirements?
- Are there any missing pages, fields, procedures, or elements?

4. Changes and Corrections to Documentation

4.1 Error Corrections

Common errors in documentation include:

- Missing data
- Missing documentation
- Missing dates
- Missing signature/initials
- Illegible documentation
- Removed information (e.g., erased, scribbled, covered with white-out)
- No documented reason for changes

Errors must be corrected as soon as they are identified. If possible, corrections must be made in real time to avoid any further resulting errors or discrepancies in the record or any additional

records. Errors should be corrected by the individual who created the original entry; if not, by an authorized individual. Any modification or correction to a document must be documented and should not obscure or remove the original entry.

Manual corrections must include a single line strikethrough of the incorrect information, with the correct information added nearby. Nothing should be erased or covered (e.g., with white-out). The individual who made the correction must sign or initial and date the change, and document the reason for the change. Reasons for corrections include, but are not limited to:

- Recording error
- Late entry
- Technical error
- Calculation error
- Erroneous entry
- Wrong date
- Transcription error
- Repeated data
- Spelling error
- Dosing error
- Malfunctioning equipment
- Clarity
- Not legible

For electronic records, changes must be logged with timestamps and include an audit trail showing who made the change, the time, and the nature of the change.

Documentation should include what happened, why it happened, and how to prevent the same error from occurring again, if applicable. Investigators should identify and implement any necessary changes to prevent a recurrence of the error and educate staff about the error and resulting changes, if applicable.

If the error is a protocol deviation, document and report the deviation as appropriate.

4.2 Late Entry and Additional Changes

In some instances, new information must be added after the creation of the original record. Any changes or addenda must be signed/initialed and dated using the correct date on which the changes were made. If documents needed to be amended, the reason should be documented. Data entered on previous dates should not be modified; modifying, replacing, or deleting previously signed and dated documentation may be considered fraudulent. Original documents must never be destroyed or replaced when being updated through a late entry. Electronic systems used during a study should have proper controls and logging to show what information has been added or changed. Late entries to paper records should be documented by including the signature of the individual adding the information and the date of the addition without altering previously documented information.

5. General Practices

5.1 Documentation Format

To ensure consistency in documentation, utilize standard forms, templates, and processes. Sponsors may provide data entry guidelines for specific projects.

5.2 Common Do's and Don'ts of Documentation

Do:	Don't:
• Verify that you have the correct chart before documenting • Write legibly • Ensure documentation is professional and reflects your professional capabilities • Document the time you administered an injection or drew blood, the administration route or phlebotomy site, and the participant's response • Document procedures at the time completed • Record each phone call you make; include time, message, and response • Only complete your own documentation • Begin each entry with date and time, and end with signature and title • If you remember additional information you need to add after completing documentation, add the information with a notation that it's a late entry and include the time and date. • Ensure documentation is frequent and includes sufficient detail to be clearly interpreted by an individual not directly involved in the activity • Ensure units of measure are identified if applicable • Use consistent date and time formats across all documentation	• Document a symptom, event, etc. without also documenting what you did or will be doing about it • Modify a participant record • Use non-standard abbreviations or shorthand • Use imprecise descriptions (e.g., "a long time", "multiple attempts") • Document what someone else did, said, heard, felt, etc. unless that information is critical, in which case quotations should be used. Thoughts, feelings, or intentions should also not be attributed to any individual, including participants, providers, family, etc. • Write any critical or retaliatory comments about participants or other professionals. • Document actions in advance. It is considered fraudulent to document actions that were not completed. • Sign someone else's name on any documentation

Examples of Don'ts:

- "Participant angry because of long wait and decided to leave"
- "Blood draw not done because husband would not let us"
- "Monitor didn't tell us until today that existing participants have to sign new consents"

Better Alternatives:

- 11 Nov 2011 1930 "Participant left the office prior to completion of 30 minute wait time. Participant verbalized understanding of protocol and states that she is unable to comply due to personal commitments." [and then state what, if any, action is taken as a result].
- 11 Nov 2011 1930 "Venipuncture attempt x1 in left arm and x1 in right arm without success. Participant's husband refuses additional attempts." [and then state what, if any, action is taken as a result].
- 11 Nov 2011 1930 "Site informed by monitor of process for updating participant consents; participant currently out of compliance according to this protocol and will sign the updated consent according to process as outlined per monitor".

Or in other words:

- "Participant anxious about ... " should be "Participant states: 'I worry that…'"
- "Participant doing fine ... " should be "Husband states that participant is doing well per baseline and without AEs or SAEs except where noted."
- "Left another message for participant ... " should be "11 Nov 2011 1930 Left message #3 on participant's cell#, explained that participant is now one day out of window per protocol and requested return phone call urgently."

6. Documentation Storage and Retention

Records must be stored in a manner that ensures they remain legible, easily retrievable, and protected from damage, degradation, or loss. Paper records should be stored in a secure, controlled environment (e.g., locked cabinets or filing rooms). Electronic records must be stored on secure servers with appropriate access controls and backups to prevent data loss. Consider who has access to data, especially during changes in personnel.

Documentation must be retained for the duration required by applicable regulatory standards and institutional policies.

7. Responsibilities

7.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

7.2 Principal Investigator Responsibilities

The PI retains overall responsibility for the study and delegating study tasks as appropriate. The PI is responsible for ensuring that study personnel are appropriately trained on good documentation practices and delegated tasks for data collection and data entry, as applicable and in accordance with the sponsor, protocol, applicable regulations and institutional requirements. In addition, the PI is responsible for the requirements as described in ORI-002 Procedures for Principal Investigator Eligibility and Responsibilities and HRP-070 Investigator Responsibilities.

8. Resources

- ICH E6 R2 Guidance for Industry Good Clinical Practice
- ICH E6 R3 Guidance for Industry Good Clinical Practice
- ORI-621 Note-to-File Template

9. Revision and Workgroup Members

9.1 Revision

Version 001/Effective Date 03/13/2025 - Original Document – Guidelines for Good Documentation Practices (ALCOA-C)

9.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

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