Good Documentation Practices for Human Subject Research

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Outline

• Identify the importance of good documentation
• Understand what is to document
• Become familiar with standard documentation practices, including error correction
• Document/Record retention and storage requirements and best practice
Importance of Documentation

• One of the most common inspection findings in investigator site inspections is lack of reliable, accurate and adequate source documentation.

• Documentation is critical to the validity of a study because it ensures that the study results are built on the foundation of credible and valid data.

• Documentation is the only way in which our work is supported.

*If it isn’t documented- it didn’t happen.*
Source Documentation

• The original documented information to support research data

• ICH GCP Guideline 1.51:
  • “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).”
Purpose of Source Documentation

• enable an independent observer to reconfirm the data

• provide and audit trail to permit investigation when required

• the tool which confirms the eligibility criteria of the subject in the given trial

• records the accountability of the investigational product dispensed, consumed and returned by the subject

• forms a strong foundation for the data that gets transcribed into a CRF, and ultimately translated into a clinical study report

• accurate documentation supports the fundamental principle of protecting subject’s rights, safety and well-being
Examples of Source Documentation

• Informed Consent Forms
• HIPAA Authorization Forms
• Visit/Contact notes
• E-Mail
• IRB correspondence
• Sponsor correspondence
• Laboratory results
• Test results (X-ray, MRI etc.)
• Medical records supplied by the subject
• Medical records created throughout the study
• Questionnaires
• Surveys
• Assessments
• Case Report Forms (CRFs) – only if data are entered directly
What to Document

• Pre-study: site selection communication, feasibility, Site initiation, Delegation of Authority/responsibilities, review of protocol, training, etc.

• Training activities: initial and ongoing research training, protocol-specific training, SOPs, etc.

• All Communication with Sponsor, IRB and FDA

• IC process: individual documentation for all subjects

• Protocol activities: demonstrate protocol compliance

• Adverse events, serious adverse event, unanticipated problems

• Deviations: Protocol, SOP & regulatory deviations
  • PI needs to assess reason for deviation, need for modifications, impact on subject rights or safety and integrity of the study
  • Provide Corrective Action plan to prevent re-occurrence
What to Document

• Documentation to demonstrate PI oversight:
  • Review and assessment of AEs, SAEs and UPs
  • Review of eligibility criteria
  • Review of lab or other protocol procedures/results
  • Subject accountability (enrollment logs)
  • Progress notes
  • Review of Case Report Forms, etc.

• Additional documentation to demonstrate Sponsor-Investigator oversight:
  • Monitoring responsibilities
  • Communication with other sites, FDA, etc.
Documentation Standards

- Information on when, where, who, why and how to complete tasks
- Evidence proving that the tasks have been completed as they should be.
- Use the Acronym ALCOA to remember that source documentation should always be:
  - Attributable
  - Legible
  - Contemporaneous
  - Original
  - Accurate
Documentation Standards

• **ALL** records should be:
  • Dated
  • Signed/Attributed
  • Secured

• Sign/initial and date entries at the time they are made.
• Data entries must be dated on the date of entry.
• Data entries must be signed or initialed by the person entering the data – attribution.
• Never sign anybody else’s name – falsification.
• Do not post- or pre-date.
Correcting Documentation Errors

• Do not try to eradicate the erroneous previous entry
• Date the change
• Make it clear that the entry to correct a mistake in a previous entry
• Identify the person making the change
• Include a reason for the change
• Enter the corrected data or explanation
• Do not use whiteout
• Do not change data without knowing the change is correct
Documentation Problems

- Missing data/documentation
- Missing dates
- No attribution
- Missing subject identifiers
- Little or no organization
- White out / scribbled out
- Illegible
- Use of checklists (in place of notes)
How to Improve Documentation

• PI should delegate responsibilities to staff adequately trained in protocol, GCP and good documentation practice requirements.
• Training of site staff should be repeated at defined frequency. New hires should be adequately trained before trial participation.
• Site should develop a SOP for good documentation.
• Sponsor/CRO should assess the site’s documentation practice during pre-study visit and during the study; provide training to the site staff to reinforce expectations.
# Document/Record Retention

<table>
<thead>
<tr>
<th>Regulation/Policy</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA Privacy Rule</td>
<td>6 years if research involves Protected Health Information (PHI); the study team must retain permission to use the PHI for 6 years beyond the expiration date of the authorization (i.e., the consent form/authorization or waiver)</td>
</tr>
<tr>
<td>FDA regulated studies</td>
<td>2 years after the data has been submitted to FDA or the study is closed (not site specific)</td>
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<tr>
<td>HHS (the Common Rule)</td>
<td>3 years after research has been completed</td>
</tr>
<tr>
<td>ICH-GCP</td>
<td>2 years after last approval of an marketing application in an ICH region (a very long time)</td>
</tr>
<tr>
<td>Sponsor requirements</td>
<td>Can vary- check with the Sponsor</td>
</tr>
<tr>
<td>Local Policy</td>
<td>Check local record retention policy. WFH Policy includes: If FDA-regulated, study coordinator must obtain written permission from the sponsor prior to destroying any research records</td>
</tr>
</tbody>
</table>
Storing Documents/Records - Paper Records

- Easily accessible to the Investigator
  - locked cabinet, limited access
- Keep safe from
  - Fire
  - Water/humidity
  - Other threats
- Original Consent document in the Research record
  - Copy of Consent Document in Medical Record per local policy
- Confidential study documentation should **NOT** be kept in MR (example: Grants, Sponsor Info., etc.)
- Consider HIPAA/Confidentiality requirements
Storing Documents/Records-
Electronic Records

• At least as secure as paper records
• Maintain data security and integrity
• Reliable / Validated Software
• Ability to copy and retrieve
• Controlled access
• Time stamped audit trails
• Training
• SOPs
Storing Documents/Records-Electronic Records

- 21 CFR 11 Electronic Records and Electronic Signatures

**Section 11.1 Scope.**

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations.
Safeguards for Records with PHI

• WFH Corporate HIPAA Policy on TauNet
  • [WFH: Safeguards for Protected Health Information](#)

• Physical Safeguards
  • “Wheaton will use courier bags with a closure mechanism when paper records with PHI are transported. A mechanism must be in place to document when any record with PHI has left the facility.”
  • “Portable computers within the facility are secured, per risk analysis, to prevent theft, manipulation or tampering. Laptop computers outside of the facility are secured per the Wheaton IS-6 Policy: Remote Access.”
  • “Computer and network gear may not be removed from system premises unless the involved person has approval from his or her manager.”

• Technical Safeguards
  • The information system is protected by a variety of technical safeguards to protect the confidentiality, integrity, and availability of PHI, based on the risk analysis.

• These safeguards should be outlined in the IRB application.
Summary

• If it isn’t documented- it didn’t happen.
• All documentation should be organized, complete and accurate.
• Research records should be adequate to provide complete recreation of the study activity and support the research data- without the need for additional explanation.
Resources & Tools from the WFH Quality Improvement Unit

• Services: Study Start Up Meeting, Study Consultation or Review

• Templates including:
  • Study Site Signature & Delegation of Responsibility log
  • Enrollment log
  • Deviation and adverse event logs
  • Device and Drug Accountability logs
  • Note to File & Research Consent Note

• QIU website: http://www.wfhealthcare.org/wfhealthcare/irb/research-quality-improvement-unit/

Presentation References:


