Good Documentation Practices

Clinical Research Operations & Regulatory Support

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Objectives

- Recognize the importance of methodical and organized documentation in research

- Become familiar with record retention requirements

- Implement learned knowledge by establishing if your documentation and record retention practices are in accordance with federal and local regulations

Documentation Practices

- In research, the only thing that remains to attest to our efforts is the documentation.

- If it is not documented, it did not happen

Source Documentation

All study data should be supported by "Source Documentation."

As defined in the ICH GCP Guideline 1.51, source documentation is:

"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)."

Documentation Practices

Source documentation should always be:

- – Attributable
- – Legible
- – Contemporaneous
- – Original
- – Accurate

ALCOA

Examples of Source Documents

- 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 Should be Documented?

- Pre-study activities: site selection communication, feasability, meeting minutes, etc.

- Study 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
  - ✓ FDA

- IC process: individual documentation for all subjects

- Protocol activities: demonstrate protocol compliance

What Should be Documented?

- Adverse events, Serious adverse event, unanticipated problems

- Deviations:

  o Submit to IRB in timely manner

  o Protocol, SOP & regulatory deviations

  o PI needs to assess reason for deviation:

    » Should protocol be amended?

    » Should SOP be revised?

- Provide Corrective and Preventive Action (CAPA) plan to prevent deviation from re-occurring

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What Should be Documented?

- To demonstrate PI oversight:
  - o Documentation for :
    - ➤ 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.
- To demonstrate Sponsor- Investigator oversight:
  - o Documentation for :
    - ➤ Monitoring responsibilities
    - ➤ communication with other sites, etc.

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)

Signing/Initialing/Dating

ALL records should be:

- Dated

- Signed/Attributed

- Secured

Signing/Initialing/Dating

- Sign/initial and date entries at the time they are made.

- Data entries must be dated on the date of entry – <u>contemporaneous</u>.

- Data entries must be signed or initialed by the person entering the data – <u>attribution</u>.

- Never sign anybody else's name – <u>falsification</u>.

- Do not post- or pre-date.

Documentation Corrections

When records need correction

- Do not obliterate previous data

- Date the change

- Identify the person making the change

- State reason for the change

- Do not use whiteout

- Do not change data without knowledge that the change is correct

Correction Sample

Visit	Date	Questionnaire I	Questionnaire II	Questionnaire III
# 5	11 Dec 2009	0 ~~80~~ % completed JS 11 Dec 2009	100 % completed	75% completed

Document Your Organization

- Have a system - regulatory binder, source documentation, drug/device accountability, copy of ICF in MR, etc.

- Document the system – establish Standard Operating Procedures

- Use the system as documented

Research Records/Retention

- Six years if HIPAA Authorizations are obtained (HIPAA requirement).

- FDA related studies - 2 years after the data has been submitted to FDA or the study is closed. Data from your study may be submitted several times.

- HHS 45 CFR 46 – 3 years after research has been completed

- ICH-GCP – 2 years after last approval of an marketing application in an ICH region (for a very long time ☺)

- Sponsor requirements

Record Storage

Store research records:

- "Close" to the Investigator

  o locked cabinet, limited access

- <u>Copy</u> of ICF in Medical Record

- Confidential study documentation should **NOT** be kept in MR (example: Grants, Sponsor Info., etc.)

- Consider HIPAA/Confidentiality requirements

Record Storage

Away from:

- Fire

- Water / Humidity

- Other threats

Consider:

- UM Archives – Iron Mountain

E-Records

Not a problem – we keep everything on the computer. Requirements for E-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

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E-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 <u>equivalent to paper records</u> and handwritten signatures executed on paper.

(b) <u>This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted</u>, 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.

Final Words

- All study related documentation, paper and electronic, should be organized, identified and retained so that it can be accurately interpreted without benefit of an interpreter.

- Can I reconstruct what happened?

- Can I identify who did what and when?

- Am I confident in the accuracy and authenticity of the research data?

- Without the documentation, there is no research.

- Your records should be able to tell the complete story of the study on their own.

Good Documentation Practices

How to Contact us

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