Procedure Name: Source Documentation Procedure	**Number:** SOP 6 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure for developing, completing and maintaining Source Documentation.

SCOPE:

This standard operating procedure ("SOP") applies to all research team members responsible for developing, completing and maintaining source documentation.

RESPONSIBILITY:

This SOP sets forth responsibilities of research team members involved with completing and maintaining Source Documentation. The Principal Investigator ("PI") retains source documentation responsibility unless the investigator has specifically delegated this duty to another research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

General Practice Procedures

1. Source Documentation also known as Case Report Forms (CRFs) are to be completed at every visit for every patient. At a minimum, source documents should include:
    - The diagnosis for which the subject is receiving the study intervention/interaction;
    - A statement specifying the study and the subject's enrollment;
    - A statement that consent was obtained; and
    - The results of the subject's protocol required evaluations.
2. Record "adequate and accurate case histories" for all subjects enrolled in (signed a study-specific informed consent form), randomized (given a study intervention/interaction), withdrawn from (voluntarily or involuntarily), and those who completed the clinical research study. Case histories include patient medical history, date of diagnosis, eligibility based on inclusion/exclusion, medication history, etc. This is all information that is recorded in the patient CRF and becomes known as the source documentation.
3. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification, while maintaining the security and confidentiality. This applies to all records, irrespective of the type of media used.

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4. Apply **ALCOA** to ensure data quality and integrity:

   A: attributable – is it obvious who wrote it.
   L: Legible-can it be read.
   C: Contemporaneous-is the information current and in the correct timeframe.
   O: Original-is this a copy or is the form in its original format or has it been altered. **A**: Accurate – ensure there is not conflicting data recorded elsewhere.

Documentation of Protocol Violations/Deviations

1. Document any protocol violations/deviations and provide an explanation.
2. Report all protocol violations to the sponsor or sponsor representative, monitor, if applicable.
3. Report all protocol violations/deviations to the IRB (GWIRB or WIRB) in accordance with the Promptly Reportable Events Policy of the IRB responsible for the oversight of the study.

Creation of Source Documentation

1. If provided, review source documents provided by the Sponsor. If all relevant information can be captured on these documents, the source documents may be used or they may be used to develop MFA specific source documents.
2. For studies with no sponsor source documentation, review the protocol to determine what documentation is needed. When drafting source documentation, the layout should have a logical, systematic flow that is consistent from visit to visit, does not cause confusion and is easily completed.
3. Each page of the source document should provide space to identify the protocol, visit and date of visit, subject initials (if being recorded) and study identification number/participant ID number.
4. Source documentation can also be captured as part of Epic Encounter Note. You may only access the encounter notes for those participants already approved by the IRB for the clinical trial.

   a. The encounter can include all aspects required for the protocol visit. At minimum it needs to note that the visit occurred and that remaining information will be capture on paper source and filed in subject binder.

Source Documentation Completion and Maintenance

1. All Source Documentation should be attributable, legible, contemporaneous, original, accurate, and complete.

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2. All source material should contain a subject identifier. A subject identifier is a unique Id assigned to a clinical trial participant at the time of screening and enrollment in order to maintain their confidentiality. For as long as the participant is in the study, their information will only be identified using this unique ID.
3. Source documents should document that informed consent was obtained prior to participation in the study (where applicable).
4. Contemporaneous: Complete all source documents at the time of each study subject visit or within 24 hours of the visit.
5. Complete: Complete all source document data fields. If information is not available or needed enter "NA." If a procedure/test is not done, enter "ND."
6. Review all subject charts for relevant historical findings and include this information in the source document(s).

    a. If necessary, request records from previous physicians to supplement current records.
    b. Make every effort to obtain primary medical records for individuals that are not GWU MFA patients (referred through advertising, friends, etc.). Document these efforts in the source record.

7. Review all peripherals (i.e. ECGs, PFTs, lab reports, x-rays, MRI, etc.) as they are all considered source documentation.

    a. Have PI sign all peripherals as soon as possible after receipt.
    b. Keep original copies of these findings in the subject's study chart;
    c. Copies of source documents may be placed in the medical record if requested and allowed.

8. Attributable: The research team member who writes the information on the source document should sign and date at the time the source document was completed.
9. Changes made to the source documents:

    a. Should not obscure the original entry (single strike/line through the incorrect information) and should be explained if necessary.
    b. Changes should be traceable, meaning initialed and dated by the research team member making the correction (if source is a paper document) or the change should be recorded in an audit trail (electronic source document).

10. Any research notes documented in Epic need to be co-signed electronically by the PI.

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Certified Copies as Source Documents

1. A copy of an original document may be used as a source document if the copy is certified and verified to be an exact copy of the original.
2. Verify a certified copy by obtaining a dated signature (or initials) and certification statement stating that the document is an exact copy having all of the same attributes and information as the original. The person making the copy or the person verifying the copy may do verification. The statement may be a stamp but must have an original signature or initials and date.

Epic Encounter Note

1. All encounter entries must be signed and dated by the person making the entry and co-signed by the PI.
2. Notes can include a complete listing of all assessments that occurred during that visit or can be written as a note that the patient was seen that day and refer to the paper source documentation. This is left to PI and research staff discretion.
3. All encounters must follow appropriate confidentiality guidelines.

Addenda to Source Documentation (SD)

1. Incomplete or missing Source Documentation may be added to a subject's research record by documenting the deficiency in a chart note, signing and dating the note, and ensuring that the note is situated in real-time.
2. Past-dated research records may not be modified to resolve deficiencies without noting the reason for the addenda, signing and dating the note.
3. If a correction needs to be made to data entered on paper, the incorrect information needs to be lined through, and initialed and dated by the individual making the correction. The correct information can be added directly on to the source document.
4. If a correction is to be made to the electronic encounter, a correction to the note can be made and it is timestamped by Epic to note when the correction was added and by whom.
5. The clinician responsible for the study subject, or designated study staff member, should make all addenda.

Retention of Records

All records pertaining to a clinical trial must be retained on site for all clinical trials.

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1. FDA regulated trials:

• Two (2) years following the date a marketing application is approved for the drug/device for the indications for which it is being investigated;
Or, if no application is to be filed, or if the application is not approved for such indications, until 2 years after the investigation is discontinued and the FDA is notified; **Or,** the length of time as indicated in the contract (CTA) with the sponsor, or sponsor representatives, whichever is longer.

2. Non-FDA regulated trials:

- For 6 years if PHI is involved (ie. HIPAA Authorization signed), or the length of time indicated in the contract with the sponsor, when applicable, whichever is longer.
- For 3 years if PHI is not involved (no HIPAA Authorization), or the length of time indicated in the contract with the sponsor, when applicable, whichever is longer.

All records must be stored at MFA, or if on-site storage is impractical, in a secure off-site facility where they may be readily accessed in the event of an audit. Based on negotiated clinical trial agreement, some records may need to be retained between 15-20 years or until FDA approval is obtained. Always refer to clinical trial agreement and obtain approval from sponsor prior to destroying any clinical trial information or papers. Alternatively, with IRB approval, study records may be sent to Sponsor headquarters for storage on-site or at a secure off-site facility. All electronic research encounters will be archived electronically.

Definitions:

Case Report Forms - paper or electronic document that is used to record clinical trial visit information for each subject. There is a different CRF for each patient for each visit. CRFs are also known as source documentation and often can be used interchangeably.

Epic Encounter Note - Refers to all notes related to a study visit that are entered as part of the research encounter entered in the research record by site staff (includes but not limited to: progress note, telephone note, clinic note) if the Epic encounter is where a coordinator documents details about the visit, then the encounter becomes the source documentation or electronic CRF.

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Review and Revision

This procedure shall be reviewed every 2 years. This procedure may be reviewed more frequently if it does not reflect current operations.

REFERENCES:

21 CFR 312.60	General Responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.68	Inspection of investigator's. records and reports
21 CFR 812.100	Specific responsibilities of investigators.
21 CFR 812.140	Records.
21 CFR 812.150	Reports.
MFA SOPs	SOP 4- Research Team Communications/Interactions with IRB SOP 5- CRF Completion and Query Resolution SOP 13- Informed Consent and Research Subject Authorization
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)