Title: Core Standard Operating Procedure for Source Documentation

I. Procedure Statement

To describe procedures for the use of source documentation in clinical trials.

II. Definitions

1. Source Document: The original document, data, and record, 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 clinical trial (ICH GCP 1.52).

2. Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the information required to be reported by the protocol to the sponsor for each trial subject (ICH GCP 1.11). A CRF is also considered a source document if it is the place that data is originally recorded.

III. Procedure/Content/Scope

This SOP will apply to all clinical trials research within MU Health including the School of Medicine, School of Health Professions, School of Nursing, and MU Healthcare to provide guidance to research personnel on the creation of source documentation. Source documentation serves to verify the integrity of trial data, and confirm findings for the reconstruction and evaluation of the investigation. This SOP also serves to ensure data quality by creating audit trails and enabling verification of the presence, completion, and accuracy of data.

1. General Rules for Source Documentation:

a. Source documentation must be:
   i. Attributable
   ii. Legible
   iii. Contemporaneous
   iv. Original
   v. Accurate
   vi. Complete
   vii. Dated

b. The original data can be in electronic or paper form, or a combination of both.

c. The goal is to collect concise, complete, accurate, and consistent data that covers all the data and information needed for the study using the fewest and simplest documents.
d. Source documents are most successful when they are in a format that is logical and chronological for a study visit.
e. Lab reports, radiology reports, EKGs, films, etc. are considered source documents and do not need to be recopied unless specified by a sponsor.
f. All entries on paper source must be in nonerasable ink.
g. The person creating paper source will sign and date the record, just as the person creating the record signs electronic records.
h. A qualified person, designated by the Principal Investigator (PI), must create source documentation.
i. If a report is to be interpreted for clinical significance, the determination must be signed and dated by a qualified member of the research staff, designated by the PI.
j. If applicable, note why a scheduled activity did not occur, why it was outside a defined time window in the protocol, and why and how the error occurred.
k. Do not use abbreviations unless they are of a universally accepted standard.
l. Record all data, even if the results are unexpected or undesirable.

2. Late Entries, Corrections, and Modifications

a. Source documentation must be timely. When using narrative notes**,** late entries must be written at the end of the text. Late entries must be identified as such by indicating the date of the event being clarified. The narrative will then be signed and dated with the date that the late entry is written.
b. Data must be reviewed in a timely fashion so corrections can be made in real time.
c. Errors must be crossed out with a single line, and corrections initialed and dated with the date of correction.
d. White out, erasing or covering the error in any way is not acceptable.
e. Source documents must not be recopied, even for the sake of neatness or legibility. An untidy source document is acceptable as long as it is legible. If an entry is illegible, the person who made the entry may write a clarifying note (initialed and dated) in the margin, but the original entry MUST remain visible and unchanged.
f. Source documents must not be discarded prior to the approved date for the destruction of all study related data.
g. Forms completed by subjects, such as surveys or diaries, must be corrected by the subject. Subjects should make corrections by crossing out the error with a single line, entering the correct information, and then initialing and dating the new entry.

IV. REFERENCES:

1. Title 21 CFR Part 11, Electronic Records; Electronic Signatures – Scope and Application.
2. Title 21 CFR Part 50, Protection of Human Subjects, and Part 56, Institutional Review Boards.
3. Title 21 CFR Part 312, Investigational New Drug Application, and Part 312.62, Investigator

Record Keeping and Record Retention.

4. Title 21 CFR Part 812, Investigational Device Exemptions, and Part 812.140, Records and Reports.
5. ICH GCP Consolidated Guideline Part 4.9 Investigator: Records and Reports.
6. ICH GCP Consolidated Guideline Part 5.15 Sponsor: Record Access.
7. ICH GCP Consolidated Guideline Part 5.18.4 Sponsor: Monitor's Responsibilities.
8. Title 45 CFR part 170, Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology.
9. Food and Drug Administration Guidance for Industry, Computerized Systems Used in Clinical Investigations, available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm070266.pdf