Source Documentation and Case Report Forms

PRO-018
Effective date: 01 JUL 2020

I. SCOPE

This SOP applies to all research studies involving human subjects. Source documents are used to collect information or observations in order to validate clinical findings in a clinical trial. These documents serve to substantiate the integrity of the data and provide an audit trail and verification process for what is recorded in the case report form.

This procedure applies to Loyola University of Chicago employees and students who are working on clinical research at the Health Sciences Campus.

II. DEFINITIONS

A. Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken. (ICH GCP 1.22)

B. Source Data: 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). (ICH GCP 1.51)

C. Source Document: Original documents, data, and records (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).

D. Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. (ICH GCP 1.11).

III. PROCEDURES

A. Content of a Source Document
   a. A source document serves is a tool to document data points in the trial and confirm the accuracy of the data.
   b. The source document starts with the consenting of the participant through completion of trial.
   c. Source documents must be:
      i. Attributable: clear on who has documented the data
      ii. Legible: readable and signature identifiable
      iii. Contemporaneous: Information should be recorded at the time of the activity.
      iv. Original: Original record or certified copy.
      v. Accurate: exact, truthful, correct and verifiable
      vi. Complete: Capture all required data. 21 CFR part 11
   d. Lab reports, radiology, EKGs, films, etc are source documents.
   e. All entries in a source document must be in ink.
   f. Source documents need to be signed and dated.
   g. If a document is to be interpreted for clinical significance, the determination must be signed and dated by the Principal Investigator or a qualified designated member of the study team.

h. Only approved abbreviations, please refer to website below with acceptable abbreviations.Record all data even if the results are undesirable.
i. To make a correction, cross out the erroneous data with a single line, write the correct data next to it, and sign and date next to the correct data. White out, erasing and covering the error are not permitted.

B. Content of a CRF:
a. A CRF is a document that is protocol-driven to collect study-specific data. The goal of the CRF is to collect meaningful data to analyze.
b. The CRF document design should enable the researcher to be able to answer the main goal in the protocol.
c. CRF can be paper or electronic.
d. A validation process must be in place when designing a CRF. The questions should be clear, concise and provide instruction on how to complete the form.
e. Consistent format is best (font, dates, and check boxes).
f. All Source documents must be securely locked stored.

C. Title 21 CRF Part 11
a. Title 21 CRF Part 11 of the federal regulations provides guidance for electronic records, electronic signature scope and applications.
b. RedCap is the preferred CRFs software for non-externally sponsored research at LUMC/LUC.
c. Source Documents must be kept secure on institutionally supported servers if electronically stored.

IV. REFERENCES:

A. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1) Guidance for Industry. OMB Control No. 0910-0843 Expiration Date 09/30/2020
B. Perspective in Clinical Research 2011 Apr-Jun; (2):59-63
C. Perspective in Clinical Research 2014 Oct-Dec; (4):159-166
D. http://www.lumen.luc.edu/lumen/meded/unaccept_abbreviations.pdf

V. APPROVALS

Katherine van Meurs 6/8/2020
LUMC Manager, Research Operations Office (or designee) Date

Jessica Shore
Digitally signed by Jessica Shore
DN: cn=Jessica Shore, o, ou, email=jshore@luc.edu, c=US
Date: 2020.06.05 13:53:54 -05'00'
LUC Senior Director, Clinical Research Office (or designee) Date