OFFICE OF
RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

Guidance for Creating Certified Electronic Copies of Research Documents

Overview

When conducting human subjects research, investigators are required to retain research records in compliance with applicable laws, regulations, institutional policies, and agreements. Investigators may maintain electronic copies of their research records as long as procedures are in accordance with University of Michigan, FDA, and sponsor policies. A Standard Operating Procedure (SOP) for certifying electronic files and securely storing source documents should be documented by individual departments and study teams prior to electronic archiving. The following document intends to provide guidance in producing study or unit-specific SOPs for electronic storage.

As study and sponsor requirements will vary, it is the responsibility of the principal investigator (PI) to ensure SOPs are being used in compliance with the University, FDA, and sponsor instructions. The PI should request and document sponsor approval for electronic storage of source documents prior to implementation.

Definitions

- Certified Copies: A copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original.
- Source Documents: 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 and complete, 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).

Recommended Procedures

I. Creating electronic files
   a. Scanning best practices
      i. Source documents should be scanned and saved as PDF files.
      ii. Scanning procedures should consider source type (e.g., hand-written notes, photographs, or print), resolution quality, and file size (e.g., documents scanned in color render larger file sizes).
      iii. In general, source documents should be scanned under parameters that would generate the best replication of the original document.
   b. File naming convention
      i. When provided and applicable, use FDA specific naming conventions for saving electronic files.
      ii. Consider including study's IRB approval number, assigned subject ID, date of source document, and a word or two that describes the source document (e.g., "consent", "lab notes", etc.) (For example: HUM00123456_A001_Consent_20180615).

iii. In general, keep naming conventions consistent, indicate method in SOPs, and use a method that makes source documents easy to find for the study team, sponsors, and reviewers.

II. Certifying electronic files
   a. Copies should be certified by the same person who created the electronic copy from the original.
   b. Certifiers do not have to be the PI; however, the integrity and compliance of the certification process is the responsibility of the PI.
   c. The certifying study team member will review original records and complete a Certified Copy Cover Sheet (example in Appendix 1). The cover sheet and original records will be scanned into an electronic PDF.
   d. Certifiers should ensure the copy has the same attributes and information as the original; thus, meeting the FDA definition deeming certified copies as exact copies of the original source document.
      i. In ensuring that certified copies are exact, certifiers should verify scanned copies are legible and facing in the appropriate direction, hand-written notes and/or signatures are readable, and pages are fully copied and not cut off.

III. Storing electronic files
   a. A storage process for the original source documents should be in place and described in the SOPs prior to converting all documents to electronic files.
      i. SOPs should clearly indicate how study team members, sponsors, and reviewers find stored documents and files.
   b. Electronic files and original source documents should be stored securely and in compliance with U-M Standard Practice Guides. The U-M Sensitive Data Guide to IT Services can help with determining how security can be assured (see resources).
   c. If the research is FDA regulated, the systems and procedures must be FDA compliant (including 21 CFR Part 11, see resources).
   d. Storage procedures should incorporate contingency plans, such as data back-ups, in case documents are compromised.

Resources

U-M HRPP Operations Manual Record Retention Policy (see Part 11, section II.F)

U-M IRB Record Keeping Guidelines (provided by IRBMED)

FDA Guidance "Use of Electronic Record and Electronic Signatures in Clinical Investigations". June 2017

FDA Guidance "Part 11, Electronic Records; Electronic signature – Scope and Application. September 2003

U-M SPG 601.12: Institutional Data Resource Management Policy

U-M Information and Technology Services Sensitive Data Guide to IT Services

Appendix 1

Certified Copy Cover Sheet

The following (insert number) pages are a copy of the original document which has been scanned into the ADOBE® portable document file format and verified by me as a true and accurate copy, according to Standard Operating Procedure ___ (specify).

_____ _____

Signature Date