**Electronic Maintenance of Clinical Trial Documents**

*The following provides guidance for creating and maintaining electronic documents.* *For more information, see FDA Guidance:* [Computerized Systems Used in Clinical Investigations](https://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf)

**Does FDA require investigators to maintain all required documents in paper?**

No. FDA allows required documents to be maintained as original paper documents or as a certified copies.

**What is the FDA definition of a certified copy?**

A *certified copy* is a copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

**Is a certified copy considered to be original data?**

Yes. *Original data* are those values that represent the first recording of study data. FDA allows original documents and the original data recorded on those documents to be replaced by copies provided the copies are identical and have been verified as such. This means that a certified copy will become original data after proper certification.

**When can a certified copy be used for source documentation?**

Source documents include original documents, data, and records and copies or transcriptions certified after verification as accurate and complete. A certified copy will become source documentation after proper certification.

**What is the process for creating a certified copy?**

1. A designated study staff member will review original study records and complete and sign a Certified Copy Cover Sheet (see Appendix 1 as an example), noting the number of pages. The study staff member will scan the Certified Copy Cover Sheet and original study records into Adobe® portable document file (PDF) electronic format.
2. The staff member will ensure that the scanned PDF version appears as the original paper version; verification must include the following: legibility of the scanned document, intact header and footer, and all pages appear "in total."
3. Following the review of the scanned documents, the staff member will upload the PDF, which includes the Certified Copy Cover Sheet and original documents, into a designated HIPAA secure location. For FDA-regulated studies, the data will need to be placed into an electronic system that is Part 11 compliant. If the scanned documents do not meet the requirements of a certified copy (an exact copy having all of the same attributes and information as the original), the staff member will scan again before uploading.
4. Scanned and certified documents will be named in such a manner that they clearly reference the document content. Examples of this could be: "Protocol version 1.02 dated 12-4-2014".
5. Each scanned file will only contain one document.
6. Electronic documents provided by the sponsor or from secure electronic systems will be renamed and placed in the designated secure drive directly without any conversion. The designated study staff member will name these documents so that they reference their original content.
7. Paper documents scanned, certified, and placed into the designated location (HIPAA secure & Part 11 compliant if required) can be returned to the sponsor if requested or destroyed by shredding the document.

**Is an SOP required?**

Yes. Written procedures should be in place to ensure consistency in the certification process. This should include methods for naming, scanning, and storing electronically certified documents.

**Do sponsors need to be notified?**

Yes. External study sponsors/ monitors should be informed during the study start-up (site-selection or the site initiation visit) that the essential regulatory documents are kept and maintained electronically, with records not originally electronic transferred into PDFs as certified copies. Monitors will be able to review certified electronic documents either by assigning the monitor a study-specific "log in" and/or via a flash drive.

**What is the retention requirement for electronic records?**

Electronically certified documents stored on a secure network drive will be maintained for the period specified in the study protocol, study contract, institutional policies, cooperative study group policies, and/or research regulation for whichever period is longer.

Sources:

* Guidance For Industry*:* [Computerized Systems Used in Clinical Investigations](https://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf) May 2007
* Guidance For Industry*:* E6 [Good Clinical Practice: Consolidated Guidance](http://www.cc.nih.gov/ccc/clinicalresearch/guidance.pdf) April 1996
* 21 CFR Part 11
* Florence Library of FDA eSource and eRegulatory Guidance, [Certified Copies](https://florencehc.com/library-fda-esource-eregulatory-guidance/certified-copies/).

**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