

From: [REDACTED]
Subject: Paper Copies of Certified Copies of Source Document Questions
Date: Wednesday, May 27, 2020 9:48:42 AM
Attachments: [REDACTED]

Good morning –

Thank you for your inquiry. Creating a SOP addressing removing/destroying of records is good practice. Keep in mind the records should be destroyed in a confidential way, such as shredding so that subject confidentiality is not compromised.

Additionally, we recently received similar questions. Please see the response below from the Center for Drugs (CDER) and the Office of Medical Policy (OMP). CDEROMP@fda.hhs.gov This office is considered the experts on electronic records in clinical investigation.

First, FDA permits the interchangeable use of electronic and paper records for the archiving and protection of records provided that record keeping and retention requirements are met (see §§ 56.115, 312.57, 312.62, and 812.140). You are not required to have paper back-ups of electronic source data. Electronic source data refers to data initially recorded in electronic format. When electronic source data are used, the electronic system and records must comply with 21 CFR part 11.

If you intend use an electronic scanned copy in lieu of the paper source data (i.e., destroy the paper source data), the electronic system and records must comply with 21 CFR part 11. FDA accepts electronic scanned copies of documents without the original paper records, provided that there is a process in place to certify that the electronic copy is an accurate representation of the original paper document. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information, should be the same person who actually made the copy from the original. The person who makes the copy should sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. IRBs, sponsors and other regulated entities should have written procedures to ensure consistency in the certification process.

The guidance documents listed below might be helpful to you.

Part 11 -Electronic Records - <https://www.fda.gov/media/75414/download>

Computerized Systems Used in Clinical Investigations - <https://www.fda.gov/media/70970/download>

Electronic Source Data in Clinical Investigations - <https://www.fda.gov/media/85183/download>

Use of Electronic Informed Consent - <https://www.fda.gov/media/116850/download>

If you have additional questions regarding electronic records in clinical investigations, please consult

CDER OMP at (CDEROMP@fda.hhs.gov).

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Tuesday, May 26, 2020 1:28 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Paper Copies of Certified Copies of Source Document Questions

Hello,

Our research center has implemented the use of RealTime CTMS for maintenance of eRegulatory Files. The system is fully validated and part 11 compliant.

I am writing SOP's for Certified Copies of Documents. What are the FDA's recommendations on keeping paper copies of certified documents?

Does a site need to keep the paper document for a certain amount of time prior to discarding?

If the SOP states that a certified copy of the document can be provided in the event of a regulatory inspection or audit may it be shred after it is uploaded into the system?

I look forward to your reply,



