

From: [OC GCP Questions](#)
To: [REDACTED]
Bcc: [REDACTED]
Subject: ICF and eSource systems
Date: Friday, May 08, 2020 10:34:57 AM

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 the 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>

Kind regards

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Office of Good Clinical Practice (OGCP)

U.S. Food and Drug Administration

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-----Original Message-----

From: [REDACTED]
Sent: Wednesday, May 06, 2020 11:34 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: ICF and eSource systems

Hello,

I wanted to see if there was guidance regarding our ICF question.

We recently went to an eDOC and eSource system which is 25 cfr part 11 compliant. We were advised to write an SOP about electronic signature and also about certified copies of source documents. That SOP outlines our procedure for scanning in original documents signing them as certified copy of the original and then holding the actual document for 6 months and allowing for that true paper original to be destroyed after 6 months. I wanted to inquire if the fda would feel this would be acceptable for signed ICF. The process for the ICF is documented in the eSource but our ICFs are still paper format. So, after signature we upload the Wet signed ICF and mark it as a certified copy of the original. Would our SOP cover the ICF or should we hold those wet ink signatures for the lifetime of the storage requirements?

Kind Regards,

[REDACTED]

[REDACTED]