From: OC GCP Questions
To: [redacted]
Subject: Document management
Date: Wednesday, May 01, 2019 8:56:45 AM
Attachments: [redacted]

Good morning –

Please see the information below from a previous question. This information should answer your questions.

Question 1:

I have a question in regards to electronic records.

Our site is interested in an electronic regulatory system and have a couple of questions in regards to the study documents.

Can sites destroy original paper records after scanning them to electronic format as certified copies? Is there any recommended time-frame that the site should employ before destroying the original paper records after certified copies have been made (e.g. 1 month, 4 months, 6 months)?

Can certified copies be used in place of original paper records during an inspection?

Answer 1:

The answer to both questions is yes. Also, there is no specific time frame for saving or destroying the original paper records. It is best to ask the sponsor of the studies in which you are converting to electronic records.

Additionally, we recently received similar questions. Please see the response below from the Center for Drugs (CDER) and the Office of Medical Policy (OMP).

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 guidances listed below might be helpful to you.

Part 11 -Electronic Records - www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations - www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations -
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 30, 2019 3:50 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Document management

Dear FDA helpdesk

According to ICH-GCP, there is a list of essential documents to be filed at an investigational site and a sponsor.
My question is that if sponsor can file all documents as electronic document except for mandatory original documents(CRF/DCF) required GCP, is it acceptable to destroy original wet-ink document after scaaning file?
In this situation, sponsor will destroy collected original documents(wet-ink signature) like CV and training records and only keep electronical TMF management. In the result, there will be no existing original documents(wet-ink signature) in sponsor and site too.
But I understood that this make senses. Could you please confirm this situation is acceptable?
And if it's not acceptable, please let me know the rational of ICH-GCP.

Kind regards,
[redacted]