From: OC GCP Questions
To: [redacted].
Subject: FDA advise requested on maintaining primary source/ records retention at site
Date: Wednesday, March 23, 2016 1:49:06 PM
[redacted] [redacted]

Good afternoon –

We recently received a similar question. 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.

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: Wednesday, March 23, 2016 12:51 AM
To: OC GCP Questions
Subject: FDA advise requested on maintaining primary source/ records retention at site

Dear GCP FDA advisory team,

We have a clinical trial site that plans to scan all the paper source data into an electronic system and

then destroy the primary paper source. They do not agree to archive the primary paper source document at site once they are scanned.

Kindly could you advice if

1. Is this acceptable to the FDA?
2. If yes, what are the requirements that should be met by the system in case the site wants to destroy the primary source after scanning it into an electronic system.

Thanks and best regards,

[redacted]