From: OC GCP Questions
To: [redacted]
Subject: Archived Study records
Date: Wednesday, March 05, 2014 9:59:24 AM

Good morning --

Scanning copies of original documents do not conflict with FDA regulatory requirements; such scanned copies may be considered "Certified Copies." The term "Certified Copy" is defined in FDA's Final Guidance Computerized Systems Used in Clinical Investigations (the one you referenced) as: "A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original." See: http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gd 0002.pdf

We are frequently asked if sites may archive records by converting paper documents into an electronic format--in essence, creating certified copies of source documents. Neither FDA's regulations nor the ICH E-6 Good Clinical Practice: Consolidated Guidance http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf defines "certified copy", however, the term is mentioned in the E6 definitions for "source data" and "source document":

"1.51 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."

"1.52 Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial)."

Although the term "certified copy" is not defined in the ICH E6 guidance, we attempted to define this term in the CCT Guidance referenced above:

"Certified Copy means a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original."

The use of certified copies as described above generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. However, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. 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. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bu k. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

Burning a CD at the end of the study, converting e-mails into a PDF format or adopting a procedure to make certified copies are all acceptable methods to achieve study related documents. (FDA does not have any regulatory requirements as to the type of CD or DVD that might be used to preserve information (presumably to meet the regulatory requirements concerning clinical data/records). A company just needs to make certain that whatever media it uses does so in a manner that preserves the integrity of the original data/information.

Please also see guidance on Part 11 –Electronic Records -- http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Or draft e-Source Guidance: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf

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

Kind regards,

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Office of the Commissioner, FDA

From: [Redacted]
Sent: Tuesday, March 04, 2014 4:12 PM
To: OC GCP Questions
Subject: Archived Study records

Good afternoon,
I have a question regarding record retention of study records. One of our sites has asked the question "if retaining scanned study records (of original study documents) stored electronically will suffice for meeting FDA's requirements for keeping study records 2 years after marketing approval" and would this include informed consents? Would the site be able to destroy the original paper copy, maintaining only the scanned document now serving as the original?

Thanks.

[Redacted]