From: OC GCP Questions
To: [redacted]
Subject: Certified Copies
Date: Tuesday, November 10, 2015 12:46:59 PM

Good afternoon --

FDA regulations do not specifically state that all copies of study documents need to be signed as certified copies. SOPs are recommended and documentation of training for study staff on newly developed SOPs is also recommended. Clarifying your current SOP might assist your staff in understanding why you want them to certify certain study documents.

That said, I can offer you the following information below.

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 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 below:

"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 bulk. 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.

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,

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From: [redacted]
Sent: Tuesday, November 10, 2015 11:38 AM
To: OC GCP Questions
Subject: Certified Copies

Greetings,

There is a common expectation form CROs when copying a medical record to sign and date them as a "certified copy". A recent debate at our center has us re-visiting this practice and exploring the best way to certify medical records received from another facility. Staff are resistant to sign off such a medical record, objecting because they did not actually make the copies themselves from an original: they received them from another party. However, it seems reasonable to expect that a medical record requested from a clinical provider or healthcare facility is an actual and accurate representation of the original document. If one were to suspect otherwise it would not be logical to use it as a source.

Some staff feel uncomfortable signing their names in general because their impression is that "certifying" a medical record means they are legally attesting to the accuracy of every piece of information within. However, in today's landscape, electronic voice recognition, off-site

transcription methods and automated boiler plate language can leave any medical record with unintended discrepancies or even errors. As such, the addition of a signature can only attest to the accuracy of the reproduction as it was received and the assurance that the record was not altered or falsified while in our possession.

Would you recommend we put language in our SOPs more clearly defining what we attest to when signing off a "certified copy" and, if so, what should we include, or would you recommend not signing them off at all, or is there other advice we should consider?

Thank-you for your time and attention.

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