From: OC GCP Questions
To: [redacted]
Subject: Certified copies for Sponsor TMF filing
Date: Thursday, February 14, 2019 9:51:23 AM
Attachments: [redacted]

Good morning –

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(R2) Good Clinical Practice: Consolidated Guidance defines certified copy", https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf 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 medicotechnical 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.

It is my understanding that you don't need to certify original documents.

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

If I have not adequately answered your question, You may contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on electronic records in clinical investigations.

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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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, February 13, 2019 12:49 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Certified copies for Sponsor TMF filing

Hello,

Good Day! We are currently establishing our process for certifying copies of clinical trial documents that gets filed into the Sponsor TMF.
One of the things we are flushing out is if we need to certify copies of everything that goes into the TMF, for example do we need to certify the copies of documents that the CRAs get during monitoring visits (Site staff CVs, medical licenses, etc.) or documents collected for regulatory green light (IP release).

I understand from R2 and recent EMA guidance that we would only need certified copies if it replaces an original. So if the original is present at the site, there is no need to certify that copy? Is this correct?

We would like to get FDA's position on this.

Thank you and looking forward to your response.

Many Thanks and Regards,

[redacted]

[redacted]