From: OC GCP Questions
To: [redacted]
Subject: Scanning paper source data
Date: Wednesday, July 24, 2019 1:23:46 PM
Attachments: [redacted]

Good afternoon –

Thank you for your email. Scanning copies of original documents does 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 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 link 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(R2) Good Clinical Practice: Consolidated Guidance https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf defines "certified copy", however, the term is mentioned in the E6(R2) 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(R20 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 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.

If electronic records are used, you should consult guidance on electronic storage of clinical trial records under part 11, “Computerized Systems Used in Clinical Investigations,” for further information about maintaining scanned documents. See link below.

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Please also see guidance on Part 11 -Electronic Records --

https://www.fda.gov/media/75414/download

Or e-Source Guidance:

https://www.fda.gov/media/85183/download

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general. The regulations do not specifically address signing or dating of documents by the clinical investigator, nor do the regulations prohibit the use of date stamps by clinical investigators. Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done.

We would suggest that if your site is contemplating the use of date or signature stamps, from a practical standpoint, you might wish to consider developing standard operating procedures (SOPs) for their use. If a signature stamp were to be employed, the SOPs should address any necessary controls over the stamp, for example, who is authorized to use the stamp, where the stamp is stored and how access to the stamp is controlled, the type(s) of correspondence on which it may be used, and the circumstances for its use (e.g., cover letters providing routine or general information). If your site subsequently follows the SOPs that you develop, then it would appear to be acceptable and in keeping with good clinical practice.

From a regulatory standpoint, since stampers can be used by anyone who gains access to them, the use of stampers would not be acceptable where verification of who accomplished a task and/or when it was accomplished is information required by regulation. Documentation needs to be provided in a manner that can be verified as unique to the individual who is indicated as "signing" the document.

Again, the rationale for a written date with the signature is matching handwriting. A date stamp can be misused and defeat the purpose for the signature - to testify that the person signing reviewed or witnessed the information and when this was accomplished. While I do not believe we have specifically outlawed the use of a date stamp, since simply adding a written date when signing does not appear burdensome, it would be advisable to go that route.

I hope this information is helpful.

Kind regards,

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From: [redacted]
Sent: Tuesday, July 23, 2019 6:06 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Scanning paper source data

Hello

We are just about to begin transitioning the TMF of a completed study from paper to electronic form. We understand that to do this we must comply with a wide range of regulations and have robust procedure in place to certify that the electronic copies are accurate representations of the original paper doc. The platform that will house the eTMF is CFR21 Part 11 compliant.

We will instruct the person that is making the scanned copies to also sign/date them and stamp them as "true to original" or "certified copy". Do you agree with this approach and should this be done for each and every paper in the TMF? It will be a very long process but we wish to be fully compliant.

Also, when the original paper is scanned how do you propose that it be stamped, signed and dated? can we use an electronic stamp? with electronic signature and date? or should the original be stamped before it is scanned?

Thank you, in advance, for your precious guidance