From: OC GCP Questions
To: [redacted]
Subject: Question on Certified Copies under GCP
Date: Wednesday, November 06, 2019 2:00:24 PM
Attachments: [redacted]

Good afternoon –

Below is what we have stated in the past regarding electronic records in clinical trials.

There is a guidance document that mentions certified copies of source documents in several places as well as electronic source documents, "Electronic Source Data in Clinical Investigations" (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf):

Source data includes all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation. Access to source data is critical to the review of clinical investigations and inspection of clinical investigation sites. Both FDA's and the sponsor's review of source data are important to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the clinical investigation data. It is critical that source data be attributable, legible, contemporaneous, original, and accurately recorded (when they are acquired), and that they meet the regulatory requirements for recordkeeping. Capturing source data electronically should help to:

-Eliminate unnecessary duplication of data

-Reduce the possibility for transcription errors

-Encourage entering source data during a subject's visit

-Eliminate transcribing source data before entering the data into an electronic data capture system

-Promote real-time data access for review

-Ensure the accuracy and completeness of the data

Investigators are required to maintain adequate and accurate case histories that record all observations and other data pertinent to an investigation under 21 CFR 312.62(b) and 21 CFR 812.140(a). Investigators of device studies must maintain the study records during the investigation and for a period of 2 years after the later of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol (21 CFR 812.140(d)). A sponsor shall upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, permit such officer or employee to have access to and copy and verify any records and reports relating to a clinical investigation conducted under this part (21 CFR 312.58(a)). and

III. ELECTRONIC SOURCE DATA

Electronic source data are source data that were initially recorded electronically. They can include information in original records and certified copies of original records of clinical findings, observations, or other activities captured prior to or during a clinical investigation used for reconstructing and evaluating the investigation. Source data recorded electronically, without proper controls, can be copied, transferred to other computerized

systems or devices, changed, or deleted without obvious evidence of these events.

and

c. Transcription of Data from Paper or Electronic Sources to the eCRF

authorized person transcribing the data from the source documents is regarded as the data originator. For these data elements, the electronic or paper documents from which the data elements are transcribed are the source. These data must be maintained and available to an FDA inspector if requested (e.g., an original or certified copy of a laboratory report, instrument printout, progress notes of the physician, the study subject's hospital chart(s), and nurses' notes) (21 CFR 312.62(b), 812.140(a)(3)).

and

C. Retention of Records by Investigator

Access to a signed electronic copy of the eCRF should be controlled by the investigator and made available upon request during a site inspection. When data elements are transcribed from paper sources into an eCRF, the investigator must also retain the paper sources, or certified copies, for FDA review (see 21 CFR 312.62(b) and 812.140(a)). Other records (electronic and paper) required by 21 CFR 312.62(b) and 812.140(a)(3) to corroborate data in the eCRF (see section III.A.2.a) may also be requested by FDA during a site inspection.

Please note that 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. 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 is only a suggested example.)

Please see other guidance documents that 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, please 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 trials.

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: Tuesday, November 05, 2019 10:49 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Question on Certified Copies under GCP

Topic “Certified Copies”

To whom it may concern:

We are a logistics provider for clinical trials and within this context sponsors and investigators do outsource trial related activities to us, for instance IMP shipments to sites and patients. As part of our work we are processing TMF relevant documents that fall under GCP regulations. In order to properly return such documents to the TMF owner we would like to understand if the following process for generating a certified copy of a original document is acceptable:

- The original document is scanned following a defined procedure for generating accurate scans
- The person who scanned the original document checks the scanned version for completeness and accuracy
- The checked scanned version is sent to the investigator via e-mail whereas in the body of the e-mail the person who checked completeness and accuracy of the scanned copy confirms in writing that this is a certified copy of the original
- The e-mail sender and time sent do automatically confirm origin and time of the certified copy being sent
- Because the certified copy is just processed and directly transmitted to the document / TMF owner who will manage the certified copy according to GCP regulations it is not required to store any additional copies of the document in a validated system on our end

Question: Is above mentioned process acceptable under GCP?

Thank you

[redacted]

[redacted]