

From: OC GCP Questions
To: [REDACTED]
Subject: Clinical Trial Electronic Storage of Correspondence
Date: Friday, February 03, 2017 11:47:00 AM
Attachments: [REDACTED]

Good morning –

The scenario you describe may not conflict with FDA regulations. The electronic records appear to be your source documents. Below is information on electronic records which we have stated in the past.

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

Data elements can be transcribed into the eCRF from paper or electronic source documents. The 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 her guidance other guidance documents that might be helpful to you.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf>

<http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.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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Office of Good Clinical Practice
Office of the Commissioner, FDA



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: Friday, February 03, 2017 10:19 AM
To: OC GCP Questions
Subject: Clinical Trial Electronic Storage of Correspondence

Good day. In my recent visits to my sites, there seems to be a trend that the SC's are not printing off study related correspondence; however, they are filing them electronically and documenting that information as such in the regulatory binder.

Is there any GCP guidance that I can reference regarding the electronic storage of study related correspondence?

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Best Regards,

A large black rectangular redaction box covering the signature and name of the sender.