

From: OC GCP Questions
To: [REDACTED]
Subject: Certified Copies of Source Documents
Date: Wednesday, February 08, 2017 12:23:00 PM
Attachments: [REDACTED]

Good afternoon –

Generally my office does not comment on specific SOPs. However it appears that the scenario that you describe may not conflict with FDA regulations. 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

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>

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>
Please see section 1.51 and 1.52

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: Friday, February 03, 2017 11:02 AM
To: OC GCP Questions
Subject: Certified Copies of Source Documents

Hello. Our site has transitioned from paper medical records to electronic medical records. Our site is engaged in research and we want to ensure we are part 11 compliant.

Our source is going to be made up of the following 3 categories:

Category 1: Data will be entered directly into the EMR during / post patient visit in structured fields within the EMR. For example, vitals, drug administration details are entered directly into the EMR.

Category 2: Data will be documented on paper flowsheets. these are wet ink.

Category 3: Copies of Reports (example: radiology, ECGs) are received by the site and uploaded to our EMR.

Our process is as follows:

1. Category 1: No add'l certification is required because they are entering data directly into the EMR and that is considered source.
2. Category 2: The Paper, wet ink flowsheets are uploaded into the EMR. The upload process involves passing the papers into a scanner which converts the paper into a PDF and then the PDF is uploaded into the EMR to the applicable patient record. During the upload process, the medical records personnel ensures the file is legible, complete, associated with the correct patient and being uploaded to the right category in the EMR. the EMR has an audit trail that indicates signature and date of when the documents were uploaded and by who. Once uploaded, the original paper, wet ink flowsheets are discarded after 90 days of the visit.
3. Category 3: These are uploaded to the EMR following the same process as category 2.

Question:

We understand that 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. We also understand that the use of a certified copy generally applies to situations where original records are copied to a different media (e.g., electronic records such as a pdf file) 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 an 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.

1. Our main concern is categories 2 & 3. We have 1 individual that is obtaining the records and uploading them into the EMR. the verification process is completed on the spot as the document is uploaded to the EMR. Once the verification is completed, the individual saves the screen and the records are available for viewing on the patient's record, date and time stamped including that individual's name via system audit trail. **Does the audit trail meet the requirement of "verification via dated signature"?**
2. **Does the outlined process above suffice for ensuring our EMR has certified copies of categories 2 & 3 source documents or is there supposed to be a secondary independent check that is documented by someone who is checking to ensure ALCOA -attributable, legible, contemporaneous, original and accurate requirements are met and this secondary check should be documented via signature and date?** To be clear, once the documents are uploaded to the EMR, we can't manually sign and date them bc they

are read only documents at that point.

Please advise. Thank you for your assistance.