From: OC GCP Questions
To: [redacted]
Subject: EHR to source
Date: Thursday, December 12, 2019 10:48:31 AM

Good morning –

Thank you for your email. FDA permits the interchangeable use of electronic records (EHR) and paper records for the archiving and protection of records provided that recordkeeping and retention requirements are met (see 21 CFR 56.115, 312.57, 312.62, and 812.140). It appears that a certified paper hand signed and dated document is your source document.

The copy of the original record should be verified as having all of the same attributes and information as the original record and it should be certified as indicated by a dated signature. Sponsors and other regulated entities should have written procedures to ensure consistency in the certification process. Part 11 regulations would not apply if you plan to retain your hard copy (i.e., not destroy the paper source data) and rely on the paper hard copy to perform your regulated activities. In such cases certification of an electronic copy would not be necessary because you are retaining and maintaining the paper source data.

Even if there are no applicable predicate rule requirements, it may be important to have computer-generated, time-stamped audit trails or other physical, logical, or procedural security measures to ensure the trustworthiness and reliability of electronic records. We recommend that any decision on whether to apply computer-generated audit trails or other appropriate security measures be based on the need to comply with predicate rule requirements, a justified and documented risk assessment, and a determination of the potential effect on data quality and record integrity. Firms should determine and document the need for audit trails based on a risk assessment that takes into consideration circumstances surrounding system use, the likelihood that information might be compromised, and any system vulnerabilities.

If you determine that audit trails or other appropriate security measures are needed to ensure electronic record integrity, we recommend that personnel who create, modify, or delete electronic records not be able to modify the documents or security measures used to track electronic record changes. We recommend that audit trials or other security methods used to capture electronic record activities document who made the changes, when, and why changes were made to the electronic record.

Some examples of methods for tracking changes to electronic records include:

-Computer-generated, time-stamped electronic audit trails.

-Signed and dated printed versions of electronic records that identify what, when, and by whom changes were made to the electronic record. When using this method, it is important that appropriate controls be utilized that ensure the accuracy of these records (e.g., sight verification that the printed version accurately captures all of the changes made to the electronic record).

-Signed and dated printed standard electronic file formatted versions (e.g., pdf, xml or sgml) of electronic records that identify what, when, and by whom changes were made to the electronic record.

-Procedural controls that preclude unauthorized personnel from creating, modifying, or deleting electronic records or the data contained therein."

Please see a few FDA guidances below.

Electronic Source Data in Clinical Investigations - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

Part 11 -Electronic Records - https://www.fda.gov/media/75414/download

Electronic Signatures - https://www.fda.gov/media/105557/download

Computerized Systems Used in Clinical Investigations - https://www.fda.gov/media/70970/download

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 considered the experts on electronic source documentation.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, December 10, 2019 9:51 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject:

Dear Food and Drug Administration,

If the Medical History of a subject is documented into the EHR as the source, is there any GCP concern with transcribing this to paper documents as a certified copy only for subjects who will meet eligibility and proceed to randomization? Are there any concerns with transcribing this information to then use the paper documents as study data moving forward for subjects who do not screen fail? Would you have any concerns with this mixed source approach?

Thank you so much for your time in advance.

Kind Regards,

[redacted]