

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP Question regarding source documents
Date: Wednesday, December 06, 2017 8:12:00 AM
Attachments: [REDACTED]

Good morning –

FDA permits the interchangeable use of electronic records 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 your 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 trails 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."

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



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: Wednesday, December 06, 2017 6:19 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: GCP Question regarding source documents

Dear FDA,

I have a question regarding source document.

When an investigator wrote a physician note (one type of source document), he/she wrote it using his/her desktop computer instead of hand-writing, then printed it out and hand-written signed and dated as a certified copy.

As His/her computer was not compliant with PART 11, he/she only used desktop computer for typing purposes.

As per the source document identification log list, these certified copies are primary source documents for this clinical trial, so these certified copies are archived as primary source documents and the investigator deleted word files from computer.

In this case, I wonder if there is any GCP compliance issue.

In addition, we found the below guideline (Guidance for Industry Part 11, Electronic Records; Electronic Signatures), "5. Record Retention, FDA does not intend to object if you decide to archive required records in electronic format to nonelectronic media such as microfilm, microfiche, and paper, or to a standard electronic file format (examples of such formats include, but are not limited to, PDF, XML, or SGML). Persons must still comply with all predicate rule requirements, and the records themselves and any copies of the required records should preserve their content and meaning. As long as predicate rule requirements are fully satisfied and the content and meaning of the records are preserved and archived, you can delete the electronic version of the records. In addition, paper and electronic record and signature components can co-exist (i.e., a hybrid⁸ situation) as long as predicate rule requirements are met and the content and meaning of those records are preserved."

Best regards,

