

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question on Data Integrity of clinical trial_ using Word software to enter the source data
Date: Wednesday, November 15, 2017 11:22:00 AM
Attachments: [REDACTED]

Good morning --

For information that might be helpful to you, please see FDA's "Guidance for Industry - Computerized Systems Used in Clinical Investigations" (May 2007), at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf. In particular, Section IV. C. of this guidance document states the following:

When original observations are entered directly into a computerized system, the electronic record is the source document. Under 21 CFR 312.62, 511.1(b)(7)(ii) and 812.140, the clinical investigator must retain records required to be maintained under part 312, § 511.1(b), and part 812, for a period of time specified in these regulations. This requirement applies to the retention of the original source document, or a copy of the source document.

A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original. The use of certified copies (as described) 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. 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 and ensure that the integrity of the original records is preserved. (There are many ways to accomplish this, and the procedures described above are only suggested examples).

For additional information in this regard, please see FDA's Guidance for Industry - Part 11, Electronic Records; Electronic Signatures - Scope and Application (August 2003), at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf> When persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11.

You might be also be interested in FDA guidance on Electronic Source Data in Clinical Investigations - www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst



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, November 15, 2017 4:57 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question on Data Integrity of clinical trial_ using Word software to enter the source data

Hope this email finds you well.

I have questions on data integrity for source document.

One investigator used the "Word" to record the study processes/relevant information, e.g. obtaining the ICF process, at screen visit and print it out as the source document for CRA to monitor, which was also signed and dated by the investigator.

It is asked to verify the original "word" file from the investigator's computer; however, she could only find some subjects' data. Some might be deleted from her computer as this is a long-term study. Is it allowed to delete the subject's data from her computer and just kept the certificated copies as source data?

And, it's claimed that this is no system, validated or not, there is a laptop or even a mobile storage drive where investigator type their visit records in Word before they print them out, sign and date; hence, these Word files can't be source data. Is it correct?

Could you please kindly help to address my questions. Many thanks in advance.

BR,

[REDACTED]