From: OC GCP Questions
Sent: Thursday, March 06, 2014 12:24 PM
To: [redacted]
Subject: RE: MS Word document as source

Dear [Redacted],

For information that might be helpful to you, please see FDA's "Guidance for Industry – Computerized Systems Used in Clinical Investigations" (May 2007), at http://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).

Your inquiry appears to suggest using a computer as a typewriter. 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 http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.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.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,

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WO32/5129
301-796-8346

From: [Redacted]
Sent: Thursday, March 06, 2014 9:13 AM
To: OC GCP Questions
Subject: MS Word document as source

Question:

Does FDA deem acceptable, per current regulation and guidance on electronic documentation, that for a phase III clinical trial a Clinical Investigator types the subject visit information ("source data") into a Microsoft Word document, prints the document, signs and dates it, saves the document in Word for some (undefined) period of time, and then eventually deletes the Microsoft Word document?

Is the electronic record (saved Word document) considered the source because it was the first place the information was recorded?

In this case, is the signature and date of the investigator considered a "certified copy"?

Is it thus a violation for the investigator to delete the Word document? Is the "typewriter exclusion" still in effect, as the more recent guidance documents do not mention it?

[Redacted]