From: OC GCP Questions
To: [redacted]
Subject: Question regarding e-signature and e-signature statements
Date: Tuesday, May 29, 2018 10:50:00 AM
Attachments: [redacted]

Good morning –

The word “reviewed” is not required when certifying a study document. When the regulations are silent, site and institutions are encouraged to develop standard operating procedures to address certain situations or issues.

FDA's current regulations and guidances permit the interchangeable use of electronic and paper records for the archiving and protection of records provided records are maintained in a manner such that all regulatory requirements are met (e.g., records are maintained for 2 years after approval of the investigational drug product as required by 21 CFR Part 312, for drugs and biologics, and Part 812, for devices) the copies of required records preserve their content and meaning.

Source documents are considered to be the original records or certified copies. Use of a certified copy generally assumes that the 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 is recommended that you develop 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. 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 actually are number of ways to accomplish this, and the procedures described above are only suggested examples)

There is increasing use of digital (also referred to as electronic) data capture in clinical trials. This is usually attributed to efforts to increase the efficiency and reduce the costs of conducting clinical trials. For information on electronic data capture (EDC), you may want to review FDA's guidance, "Electronic Source Data in Clinical Investigations" (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf).

Some other guidance documents from FDA that may be of interest to you are:

"Computerized Systems Used in Clinical Investigations"
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf
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."

"Part 11, Electronic Records; Electronic Signatures - Scope and Application"
www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

4. Copies of Records The Agency intends to exercise enforcement discretion with regard to specific part 11 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in §11.30). You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules (e.g., §§ 211.180(c), (d), and 108.35(c)(3)(ii)). We recommend that you supply copies of electronic records by:

- Producing copies of records held in common portable formats when records are maintained in these formats

- Using established automated conversion or export methods, where available, to make copies in a more common format (examples of such formats include, but are not limited to, PDF, XML, or SGML)

In each case, we recommend that the copying process used produces copies that preserve the content and meaning of the record. If you have the ability to search, sort, or trend part 11 records, copies given to the Agency should provide the same capability if it is reasonable and technically feasible. You should allow inspection, review, and copying of records in a human readable form at your site using your hardware and following your established procedures and techniques for accessing records.

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

Kind regards,

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From: [redacted]
Sent: Wednesday, May 23, 2018 7:47 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question regarding e-signature and e-signature statements

Keeping the revision of E6R2 guidelines in mind, and electronic signatures (for e-source).. do the signature statement(s) “I certify this is a true and correct copy” or “I certify this is an original document” imply (enough) that the document was reviewed, or would you need the wording “reviewed” added as a comment to confirm reviewed? One side of our office thinks the e-signature is no different than a wet ink signature, representative of your review of the document (as you don’t write “reviewed” every time you wet ink sign an ECG- you simply sign, and review of the ECG is implied). The other half think the physical wording “reviewed” must be present, in addition to the certified comment that comes with your e-signature.

Thanks in advance for any guidance!

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