

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Certifying signed consents when entering into electronic Storage Cabinet
Date: Thursday, June 15, 2017 10:22:00 AM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your question. I believe you are asking about the process used to create certified copies of paper study records for electronic archiving purposes. Based on this assumption, I provided some information below that I hope is helpful to you.

We are frequently asked if sites may archive records by converting paper documents into an electronic format; in essence, creating certified copies of source documents. Neither FDA's regulations nor the ICH E6 Good Clinical Practice: Consolidated Guidance found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf> define "certified copy", however, the term is mentioned in the E6 definitions for "source data" and "source documents" as follows:

1.51 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

1.52 Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Although the term "certified copy" is not defined in the FDA regulations or the ICH E6 guidance, FDA attempted to define this term as it is used in the FDA guidance document titled, "Computerized Systems Used in Clinical Investigations" found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf> - see section on Definitions that says:

Certified Copy: 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 in the definition in this guidance document on computerized systems generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. However, 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 as the original, 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. **NOTE:** There may be multiple ways to accomplish this, and the procedures described here are only suggested examples.

This other guidance document may also be of interest to you:

Electronic Source Data in Clinical Investigations – see

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC

Policy Analyst

Office of the Commissioner

Office of Good Clinical Practice

U.S. Food and Drug Administration

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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: Tuesday, June 13, 2017 5:14 PM
To: OC GCP Questions
Subject: Certifying signed consents when entering into electronic Storage Cabinet

Our practice is in the process of switching from off- site storage of study documents to electronic storage after study close out.

I have search for guidance on electronic storage of study documents but cannot find any information. I have heard that patient signed consents require a certified process when scanning to an electronic system.

Can you provide any written processes of how this procedure is to be completed? I want to make sure all the “inked signatures” (ie. Consents, 1572, Financial disclosures, Protocol Signature pages etc) are properly entered prior to disposal of original.

Any guidance would be greatly appreciated.

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