**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Monitor access to electronic medical records
**Date:** Thursday, May 04, 2017 7:30:00 AM
**Attachments:** [redacted]

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Good morning –

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)

Some helpful links are below--

General Guidance on Good Clinical Practice - ICH E6
(www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf )

ICH E-6 Good Clinical Practice: Consolidated Guidance defines "certified copy", however, the term is mentioned in the E6 definitions for "source data" and "source document":

"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)."

Guidance on Computerized System 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."

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general. The regulations do not specifically address signing or dating of documents by the clinical investigator, nor do the regulations prohibit the use of stamps by clinical investigators. Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done.

I would suggest that if your site is contemplating the use of stamps, from a practical standpoint, you might wish to consider developing standard operating procedures (SOPs) for their use. If a stamp were to be employed, the SOPs should address any necessary controls over the stamp, for example, who is authorized to use the stamp, where the stamp is stored and how access to the stamp is controlled, the type(s) of correspondence on which it may be used, and the circumstances for its use (e.g., cover letters providing routine or general information) . If your site subsequently follows the SOPs that you develop, then it would appear to be acceptable and in keeping with good clinical practice.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA




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**From:** [redacted]
**Sent:** Tuesday, May 02, 2017 8:31 AM
**To:** OC GCP Questions
**Subject:** Re: Monitor access to electronic medical records

Ms. Kezer,

Thanks for the update. Many sites still do not understand what a certified copy constitutes. Can you please advise the method(s) a site may use to document a copy as "certified" and acceptable as such for reviewers including FDA. It is my experience that a site could use a rubber stamp marked "certified copy" and the person making the copy would then initial & date the page(s).

[redacted]