

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** certified copy question  
**Date:** Wednesday, September 12, 2018 8:38:00 AM  
**Attachments:** [REDACTED]

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Dear [REDACTED],

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 date stamps by clinical investigators and study staff. 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 date or signature stamps, from a practical standpoint, you might wish to consider developing standard operating procedures (SOPs) for their use. If a signature stamp were to be employed as you indicate, 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



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.

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**From:** [REDACTED]  
**Sent:** Monday, September 10, 2018 2:38 PM  
**To:** Kezer, Doreen M <Doreen.Kezer@fda.hhs.gov>  
**Subject:** certified copy question

Hello Doreen,

I was hoping you could provide clarification on the method of sign off for certifying records or perhaps direct me to a more appropriate contact if I've reached you in error.

If our Study Coordinators are to print medical records off of an EMR that does not automatically

apply a date and our name, could we use a stamp that has our name and date on it? We have studies that we pull many pages of records on and to sign and date sometimes 30 pages, can be burdensome. We have found custom stamps that can be made for each of our Study Coordinators in which you simply change the date within. Would this be acceptable to use a custom stamp to expedite the certification process of medical records printed from an EMR?

This is what we would like the stamp to look like:

Certified Copy  
10Sep2018

[REDACTED]

Must it be a manual signature or can we use a custom stamp in which our SOP would explain that there is only one stamp made per coordinator and that is looked within their desk at all times?

Thank you in advance for your time and consideration to my question.

[REDACTED] [REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
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