

From: OC GCP Questions
To: [REDACTED]
Subject: Question - Date Stamp on 1572
Date: Thursday, November 03, 2016 9:04:00 AM
Attachments: [REDACTED]
Importance: High

Good morning –

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. Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done.

We 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, 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.

From a regulatory standpoint, since stampers can be used by anyone who gains access to them, the use of stampers would not be acceptable where verification of who accomplished a task and/or when it was accomplished is information required by regulation. Documentation needs to be provided in a manner that can be verified as unique to the individual who is indicated as "signing" the document.

Again the rationale for a written date with the signature is matching handwriting. A date stamp can be misused and defeat the purpose for the signature - to testify that the person signing reviewed or witnessed the information and when this was accomplished. While I do not believe we have specifically outlawed the use of a date stamp, since simply adding a written date when signing does not appear burdensome, it would be advisable to go that route.

You may wish to review FDA's 1572 guidance
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> It states --

18. How should the 1572 be completed?

The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).

It is advisable that you consult the sponsor for further guidance as the completed 1572 form is considered a sponsor requirement.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst



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: Wednesday, November 02, 2016 6:21 PM
To: OC GCP Questions
Subject: Question - Date Stamp on 1572
Importance: High

Good Afternoon:

We have a Clinical Investigator at our site that uses a Date Stamp in lieu of a hand written date due to severe tremors in his hands. Often times, the tremors create an illegible date when hand written. The Date Stamp includes his signature and he would use this along with his hand written signature on the documents as proof that the date was applied to the document by the investigator.

The investigator will be in control of the Date Stamp at all times and when not in use, the stamp will be placed in a secure location accessed only by the investigator. It will only be used by the investigator whose signature is on the stamp.

Is it acceptable for the Investigator to utilize this Date Stamp in Box 11 of the Form 1572 given the above information?

Warm Regards,

[REDACTED]