From: OC GCP Questions
To: [redacted]
Subject: Can date be written by a research staff on PI "s behalf or a date stamp can be used?
Date: Wednesday, October 28, 2015 8:17:22 AM

Good morning –

We are a small office and we are unable to accommodate your request. However I can offer you the following information.

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.

In addition, the ICH E-6 Good Clinical Practice: Consolidated Guidance (FDA's official guidance related to GCP) contains a few references to signatures and endorsing documents (4.5.1; 4.9.3) but no specific discussion of signing and dating documents other than Section 4.8.8, which recommends that the informed consent form be signed and dated by the subject or the subject's legally authorized representative, AND by the person who conducted the informed consent discussion.

If you would like to review the ICH guidance in its entirety, it (and many other helpful references) can be viewed on FDA's GCP website at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf.

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.

That said 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. Clearly, nothing prevents back-dating even when the date is handwritten. 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.

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

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.

From: [redacted]
Sent: Tuesday, October 27, 2015 1:48 PM
To: OC GCP Questions
Subject: Fwd: FW: Can date be written by a research staff on PI 's behalf or a date stamp can be used?

Hello FDA,
I asked a question regarding the use of stamp dates by the investigators a few years ago. Kindly see the emails below. Since then I have clarified this question to hundreds of my students of clinical research. (Thanks for your help)
I have launched a clinical research educational webinar system.
Please visit [redacted] The purpose is not only to promote clinical research awareness but also to promote every possible business, industry, academia, regulatory body too so that people get their answers at one platform. Everyone is welcome to sponsor a webinar promoting their business in clinical research. If not webinar then just a company logo or events can be posted that will lead the registrants to their company website in one click.
I understand FDA does not sponsor webinars nor the speakers are paid. I requested CDER for a speaker request however I think they did not understand. I would like to request a speaker from FDA to clarify the question I asked earlier to everyone.
The question was **why date stamps cannot be used with signatures in clinical research, they must be handwritten**. It would be great for everyone to listen from FDAs perspective. Since I am an instructor of clinical research I have many student registrants who want to learn about FDA as well. It will be beneficial for them too. Please advise if this can be a possibility?
Thank you and looking forward to hearing from you soon.
With Gratitude,
[redacted]