From: OC GCP Questions
To: [redacted]
Subject: Question about signatures on source documentation
Date: Monday, July 27, 2015 10:55:34 AM

Good morning –

FDA 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. That said, 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.

However we would suggest that if your site is contemplating the use of date or signature stamps for other trial documents, 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 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf.

It might be helpful to review the guidance link below that discusses Investigator Responsibilities in Protecting the Rights, Safety, and Welfare of Research Subjects.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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

From: [redacted]
Sent: Monday, July 27, 2015 8:52 AM
To: OC GCP Questions
Subject: Question about signatures on source documentation

Good morning,
I manage several clinical trials for NCI, Division of Cancer Prevention consortia program. A question has arisen for which we'd like guidance. Specifically, we know that most documents used as source documents for a given person's participation in a clinical trial require a signature and date.

Is it acceptable for a study coordinator to purchase and utilize a signature stamp, an inked rubber stamp, with her/his signature and a line for the date? The purpose would be to save time by using the stamp and a manually-entered date for all source documentation.

Thanks for your guidance.
[redacted]