From: OC GCP Questions
To: [redacted]
Subject: Original signature vs scanned signature on study document
Date: Thursday, January 23, 2014 10:34:50 AM

Good morning --

FDA regulations do not specifically mention sponsor signatures, therefore, scanning copies of original documents does not conflict with FDA regulatory requirements.

That being said, it is always good to be able to ascribe a report to someone as these will likely be important study data. When FDA regulations on silent on a specific topic, we suggest developing standard operating procedures (SOP). These procedures will assist you in determining how to maintain records and, for those that could depend on the opinion/expertise of a particular person, how best to ensure they will always know who made the diagnosis/decision. Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done. The SOP that you develop might include instructions that documents how the original document with the wet signature will be obtained.

I've listed below a few FDA guidance documents that you may find helpful in answering your questions:

FDA's Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope and Application found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.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: Thursday, January 23, 2014 3:22 AM
To: OC GCP Questions
Subject: Original signature vs scanned signature on study document

Good morning,

Would be kind to give advice on the following question:

As a CRO we often send study document (*not talking here of CSR or protocol but more from Data Management study document*) to sponsor for approval on which they need to sign off. First we initially receive a scanned version of the signature page. Afterwards attempts are made to receive the wet signatures from the sponsor but unfortunately it can happen that we never receive a reply related to this request.

Therefore my question, are scanned version of signature can be considered as acceptable?

Thank you in advance!

Kind regards,
[Redacted]