

From: OC GCP Questions
To: [REDACTED]
Subject: Signatures via smart phone inquiry
Date: Wednesday, August 10, 2016 6:54:00 AM

Good morning –

FDA regulations do not specifically mention smart phone signatures. However I am not sure that the method you describe will work as you say you don't have a Part 11 e-signature validation system. You may wish to review the guidance documents below for further clarification.

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 are 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
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf

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

FDA's Guidance for Industry - Electronic Source Data in Clinical Investigations found at
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf>

Kind regards,

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From: [REDACTED]
Sent: Monday, August 08, 2016 5:20 PM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Signatures via smart phone inquiry

To the FDA Office of Good Clinical Practice
Subject: Signatures presented via smart phones

Good afternoon,

Our institution currently does not have a Part 11 e-signature validated system in place and therefore the clinical research files of record are paper. When our director is on travel, is it adequate to have him send a picture of his signature via his smart phone (perhaps substituting the scan or fax copy of the original? He would then send or hand carry the wet signature original for the files. The picture of his signature would serve as a place holder acknowledgement. Is the picture of his signature enough to validate the approval of the document?

Thank you so much for your guidance.

Respectfully,

Roxana

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