From: [redacted]
To: [redacted]
Subject: Question regarding use of digital signatures.
Date: Thursday, July 02, 2020 10:55:00 AM
Attachments: [redacted]

Dear [redacted] –

Thank you for your inquiry. I forwarded your email to FDA's Office of Regulatory Affairs (ORA). ORA perform FDA site inspections. Please see their answer below.

Have a safe holiday.

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted], [redacted]
Sent: Thursday, July 02, 2020 10:09 AM
To: [redacted]
Subject: RE: Question regarding use of digital signatures.

Hi, Doreen!

In this situation, the investigator will likely ask to see the electronic record of the document and the electronic files containing the digital signature to validate the signature. The significance of the document will also come into play. If the document has no real bearing on the conduct of the study or safety of research subjects, they may not seek such validation. If, however, the document is a critical record, I would expect such validation activities.

Hope this helps!

David K. Glasgow

Deputy Program Director, Office of Bioresearch Monitoring Operations

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OBIMO's highly skilled, collaborative, and agile workforce ensures research subjects are protected and the data used to support FDA decisions is reliable.

From: [redacted]
Sent: Friday, June 26, 2020 12:37 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question regarding use of digital signatures.

Hello,

I had a question I was hoping to get some guidance on – if there is a better contact to ask this question please let me know and I can direct my question there.

We are starting to use some part 11 compliant digital signatures for digitally signing FDA regulated clinical research documents. We still, however, operate primarily on a physical paper record keeping system for maintaining trial records.

The question I have, is in the event of an FDA audit where the records are all maintained in paper, when a printed document that is digitally signed is encountered, how is that handled during the auditing process? Will they typically request to see and/or be provided with copies of the files that contain the digital signature in order to validate it, or is a printed copy of the digitally signed document typically sufficient?

We want to be sure we are prepared for any future reviews of clinical trials, so any insight you could provide would be greatly appreciated.

Thanks so much.

[redacted]