From: OC GCP Questions
To: [redacted]
Subject: Question re: electronic signatures within traditional paper-based system
Date: Tuesday, January 16, 2018 10:17:00 AM
Attachments: [redacted]

Good morning –

Sorry for the delay in responding. I had to send your email to the Center for Drugs (CDER) Office of Medical Policy (OMP). Please see their cleared response below.

Kind regards

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

Hi Doreen,

Here is our cleared response:

Yes, if the sponsor is using electronic signatures (e.g., flattened digital signatures) to sign documents such as clinical protocols and investigator's brochures, then the sponsor is required to certify to FDA (as described in 21 CFR 11.100) that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures.

OMP

From: [redacted]
Sent: Tuesday, January 09, 2018 2:31 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Cc: [redacted]
Subject: Question re: electronic signatures within traditional paper-based system

Hello.

I have a question regarding the use of electronic signatures within the framework of a traditional paper-based system.

A U.S.-based sponsor/applicant uses traditional paper-based system for their records and does not maintain electronic records that would be subject to Part 11 Electronic Records requirements.

If the sponsor uses a traditional paper-based system for their records and the sponsor starts to use electronic signatures (e.g., flattened digital signatures) to sign documents such as clinical protocols and investigator's brochures, is the sponsor still required to certify to the agency (as described in 21 CFR 11.100) that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures?

Thank you in advance for your reply.

Regards,

[redacted]