From: OC GCP Questions
To: [redacted]
Subject: Re legality, validity and compliance of electronic signatures
Date: Tuesday, June 03, 2014 3:34:45 PM

Good afternoon,

We consulted our IT specialists in the Center for Drugs (CDER). They have given the following information below.

Based on the limited information provided in your e-mail below, in response to your inquiry, it does not appear as if you have overlooked aspects of the regulatory requirements found in 21 CFR Part 11.

Kind regards,

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

From: [Redacted]
Sent: Monday, June 02, 2014 5:22 PM
To: OC GCP Questions
Subject: Re legality, validity and compliance of electronic signatures

Good afternoon,

Our office has instituted an electronic regulatory document management system, including the use of 21 CFR part 11 compliant electronic signatures.

One of our CROs is telling us they cannot accept these signatures for the following reasons:
We don't have the software equipped to recognize and verify the validity of the e-signatures on the documents. If we were to take them as they are for use on this study there isn't a way for us to get them to the sponsor as still valid documents.

We are submitting the standard essential documents (1572, financial disclosure forms and protocol/IB signature pages) to the CRO. I believe the responsibility falls on our institution to meet the regulatory criteria, and I do not see that special software is required for the sponsor to recognized and verify the e-signatures.

§11.2 Implementation
(a) For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.

The regulation also states that the agency will accept copies. Our system allows the CRO the capability to print the documents if they wish.

§11.10 Controls for closed systems

(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

Can you please advise if there is something that I have overlooked here? Most of our sponsors have had no problem with this new process and have, in fact, embraced it.

Thank you for your assistance,
[Redacted]