From: OC GCP Questions
To: [redacted]
Subject: Electronic Signature Certification
Date: Thursday, December 03, 2015 1:12:07 PM

Good afternoon –

Sorry for the delay in responding. I contacted our Office of Medical Policy (OMP). Please see their response below.

FDA does not intend to assess EHRs for compliance of part 11 when data from these systems are used in clinical investigations. However, for electronic records that do not originate from the sponsor (such as EHRs) but are ultimately integrated into the sponsor's electronic system, the point at which data from a record enters an electronic system under the control of the sponsor is when part 11 applies (e.g., when data from such records are incorporated into the EDC system or eCRF).

While EHRs will not be assessed for part 11 compliance, the sponsor should have adequate controls in place to ensure confidence in the reliability, quality, and integrity of the data/record. In addition, part 11 requirements for electronic signatures would also not be assessed when the EHR is used to obtain the electronic signature. However, all other electronic signatures required for clinical investigations must comply with all relevant requirements under 21 CFR part 11, including the general requirements found in 21 CFR 11.100.

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: Tuesday, November 17, 2015 8:47 AM
To: OC GCP Questions
Subject: Electronic Signature Certification

Dear Sir/Madame

Can you kindly clarify if theGuidance on Electronic Source Data in Clinical Investigations (Sep 2013) including the statement: "FDA does not intend to assess EHRs for Part 11 compliance." (page 8, line 23), supports the elimination of Part 11 Representation Forms as wells as electronic signature certifications? The representation form supports

source data compliance while the electronic signature certification would support only e signature on an eCRF.

Thank you in advance for you assistance.

Regards,
[redacted]