From: OC GCP Questions
To: [redacted]
Subject: GCP question
Date: Monday, May 05, 2014 3:41:30 PM

Dear [redacted],

Thanks for your e-mail to OC GCP Questions. We consulted our IT specialists in the Center for Drugs (CDER). In regards to your inquiry below, FDA guidances represent current thinking on a topic and recommendations to regulated industry. As such, the guidance referenced below Electronic Source Data in Clinical Investigations is not intended to impose any requirements beyond those specified in 21 CFR. Further, Sponsors and Sponsor representatives (i.e.-CROs) should assure that all applicable regulatory requirements in 21 CFR can be fulfilled; specifically, for the predicate rules, the recordkeeping requirements found in 21 CFR Parts 312 & 812.

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: Monday, May 05, 2014 1:24 PM
To: OC GCP Questions
Subject: GCP question

Dear Sir or Madam,

The recently issued “guidance on electronic source data in clinical investigations” in Sep to2013 stated that “FDA does not intend to assess EHR (Electronic Health records) for Part 11 compliance (page 8, line 23).

Does this mean that sponsor or sponsor representative, i.e. CRO, is not required to ensure the HER system used to collect source data is validated or meeting the Part 11 requirements?

Kindest Regards,

[Redacted]