From: OC GCP Questions
To: [redacted]
Subject: Is a PI e-Signature required on electronic ClinRO records
Date: Friday, January 31, 2014 9:45:16 AM

Good morning –

I believe you sent the same question to us in November 2013. Please see the attached answer. If the answer that we supplied is not sufficient, I suggest emailing one of the contact names on the 2013 final guidance.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [Redacted]
Sent: Thursday, January 30, 2014 5:11 PM
To: OC GCP Questions
Subject: Is a PI e-Signature required on electronic ClinRO records

To GCP Questions At FDA:

In the September, 2013 Final Guidance for Electronic Source Data in Clinical Investigations, section III.B.1.a it states *"To comply with the requirement to maintain accurate case histories clinical investigator(s) should review and electronically sign the completed eCRF for each subject before the data are archived or submitted to FDA."*

Would the same statement apply to the clinical investigator also electronically signing his/her clinician recorded assessments (ClinROs) captured in an eDiary review or electronic questionnaire? Would FDA consider the ClinROs as equivalent to an eCRF and require that the ePRO or ClinRO records be electronically signed?

Thank you for your assistance. [redacted]