From: OC GCP Questions
To: [redacted]
Subject: Investigator Reviewing and Signing eCRFs
Date: Thursday, January 08, 2015 11:01:33 AM

Good morning –

I don't see how the clinical investigator (PI) and/or the sub-PIs can sign off on data (either paper or electronic) for which they have not seen or reviewed. If you are using eCRFs all parties should be trained as the guidance outlines.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, January 07, 2015 1:22 PM
To: OC GCP Questions
Subject: Investigator Reviewing and Signing eCRFs

Hi,

I'm working on a phase I/II clinical trial and have a question regarding the need for Investigators (principal or sub) to review and sign off on study subjects' eCRFs.

We have PI who does not want to do the training required to access the Part 11 compliant eCRF system so that he can review and sign off on the eCRF.

In reviewing in the applicable guidance, that would appear to be a requirement:

a. Clinical Investigator(s) Review and Electronic Signature
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. Use of electronic signatures must comply with part 11 (21 CFR part 11).

Would it be acceptable to have the PI and none of the Sub-Investigators do the training and therefore never have access to the eCRFs for the purpose of reviewing them. Instead of actually reviewing the eCRF and signing off within the electronic system, the PI would like to sign a paper document that states the source data given to data entry was accurate.

Would that suffice and meet the regulatory requirements concerning the Investigator's review and signing off of subjects' eCRFs?

Thanks so much for your input.

[redacted]