From: OC GCP Questions
To: [redacted]
Subject: Clinical Study Report for Phase 2 and/or 3 - Signatures as per FDA requirement
Date: Friday, October 19, 2018 10:33:35 AM
Attachments: [redacted]
Importance: High

Good morning –

Your email was forwarded to my office for a response.

FDA's regulations do not discuss "clinical study reports" although these are the topic of an FDA recognized guidance document, ICH E3, "Structure and Content of Clinical Study Reports" that you reference.

ICH E-3 -- Structure and Content of Clinical Study Reports - www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073113.pdf which is a recognized guidance for FDA states under 16.1.5 - "Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement."

You will have to determine who can sign the report to meet the recommendation stated above.

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, October 15, 2018 12:25 PM
To: CDER SBIA <CDERSBIA@fda.hhs.gov>
Subject: Clinical Study Report for Phase 2 and/or 3 - Signatures as per FDA requirement

Dear CDER,

A clarification question on FDA' requirement as per the following statement in ICH guidance E3 (page #36) for the signatures on Clinical Study Report (CSR):

16.1.5 Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement.

the Is there a specific FDA guidance document on minimum requirements of a signature of a principal or a

coordinating investigator (s) or sponsor's medical officer, for a Phase 2 and/or Phase 3 CSR? If yes, could you please share the info?

Thank you,

[redacted]