From: OC GCP Questions
To: [redacted]
Subject: Signature
Date: Thursday, December 13, 2018 12:24:32 PM
Attachments: [redacted]

Good afternoon –

FDA's regulations do not require that investigators, sub-investigators, and study staff sign and date their CVs. When the regulations are silent, sponsors and sites have the flexibility to adopt procedures that make the most sense to them and their existing business practices.

Please see FDA's Financial Disclosure Guidance.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

B.6.Q: Who, specifically, is responsible for signing the financial certification/disclosure forms?
A: The forms are to be signed and dated by the chief financial officer or other responsible corporate official or representative of the applicant. FDA recommends that the "other responsible corporate official or representative" be a senior official who has the authority to ensure the information is collected and reported accurately. Depending on company structure, such an individual could be the person in charge of regulatory or clinical affairs.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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: Thursday, December 13, 2018 11:09 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Signature

What is the agency position if the site Study Coordinator add/sign date for each study team CV and financial disclosures? The study team will sign their CVs and Financial disclosures, but the study coordinator will add the date of signature.