From: OC GCP Questions
To: [redacted]
Subject: [redacted] Dear Investigator Letters
Date: Wednesday, August 22, 2018 9:22:00 AM
Attachments: [redacted]

Good morning –

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general and do not specifically address signing or dating of documents by the clinical investigator.

Again, FDA regulations related to the conduct of clinical trials require very few signatures. Title 21, Code of Federal Regulations (21 CFR) Part 312, which concerns the conduct of studies with investigational drugs and biologics, requires a signature on the FDA Form 1572 [312.53(c)(1)]; 21 CFR Part 812, which covers investigational device studies, requires a signed investigator agreement [812.43(c)]; and 21 CFR Part 50, Protection of Human Subjects, requires an informed consent form signed by the subject [50.27(a)] when documentation is required. Guidance documents do suggest other signatures, but what is in guidance and not regulation cannot be required. (For example, the GCP E6 guidance - - recommendations signatures and dates on study case report forms. FDA has adopted this document as official guidance.)
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

In situations where signatures are required/recommended by the sponsor or per protocol, it would be expected that the individual signing also date the document.

Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done. Developing standard operating procedures for the site would be a good start.

Other guidances that might be helpful to you to review are listed by links below.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

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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: Tuesday, August 21, 2018 9:49 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: [redacted] - Dear Investigator Letters

Good morning!
I moderate the [redacted] Online Community discussion boards and have a question from a member:

Is there any FDA or GCP Guidelines that states that says the PI must have original signatures on any correspondence that says: "Dear Investigator". I currently have a CRA stating per FDA and GCP guidelines, this is a requirement. I have looked briefly, but hoping you might have some insight on this?

I look forward to your answer.

I see the guidance to pharmaceutical companies on creating and tracking effectiveness of DHCP letters, but not the responsibilities of the receiving investigator.

Thank you,

[redacted]