From: OC GCP Questions
To: [redacted]
Subject: ICF Question
Date: Thursday, March 19, 2020 3:43:00 PM
Attachments: [redacted]

Good afternoon –

Thank you for your email. 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. Several guidance documents do suggest other signatures, but what is in guidance and not regulation cannot be required. (For example, the GCP E6(R2) guidance https://www.fda.gov/media/93884/download-- recommendations signatures and dates on study case report forms. FDA has adopted this document as official guidance.)

In situations where signatures are required/recommended by the sponsor and or IRB (as outlined in your email below), it would be expected that the individual sign the form. Since this appears this is a requirement of the IRB, you will need to ask the IRB if they would consider the sub-investigator (Sub-PI) signature acceptable as the Sub-PI name appears on the 1572 form and the delegation. It appears the Sub-PI is an active member of the study team.

Because FDA does not have many regulations which require signatures, it would be appropriate for sponsors and/or study sites to develop their own procedures on how to appropriately document study-related tasks. An FDA investigator who conducts a BIMO inspection will look at these documents and review any associated documents to ensure that the instructions the protocol and/or plan are followed appropriately. Additionally, the clinical investigator is responsible for supervising the overall activities of a clinical study site which includes study-related tasks that may be delegated to employees or colleagues of the investigator or other third parties and is accountable for any regulatory failures that may have occurred during the conduct of a study. Please see FDA's guidance on Investigator Responsibilities that provides for additional information regarding this matter: https://www.fda.gov/media/77765/download

Kind regards,

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Office of Good Clinical Practice (OGCP)
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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, March 19, 2020 11:10 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: ICF Question

Good day. I have a question regarding signatures on a ICF approved by a central IRB.

In review of an ICF, the signature page of the ICF notes the following

Statement of Study Doctor
I acknowledge my responsibilities for the care and well-being of the subject named above, to respects the rights and wishes o the subject, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations, the study plan, and standard operating procedures.

Date Printed Name of Study Doctor Signature of Study Doctor

In this particular scenario, the study doctor (PI) did not sign the statement of the study doctor. The signature noted was of the Sub-Investigator was is a Nurse Practitioner (NP).

Has the site deviated from the ICF by having the sub-I who is a NP (delegated on the delegation of authority log to consent and noted as a sub-I on the FDA Form 1572) sign the document?

Is there any guidance for this scenario that should be followed?

I look forward to hearing from you.

Thanks,

[redacted]