

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Question about the FDA1572
Date: Wednesday, July 05, 2017 9:27:00 AM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your question. FDA has guidance titled, "*Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*" that can be found at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>. Section VII provides guidance on listing the names of subinvestigators on the 1572 form for those individuals who will be assisting the investigator in the conduct of the study. Questions 31 and 32 should address your question. The guidance says, in general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572.

The FDA Form 1572 is a form the sponsor is responsible for, so if after reviewing FDA's guidance noted above you have any remaining questions about whether or not to include an individual on the 1572 form, you should consult the sponsor company. I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

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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: Monday, July 03, 2017 7:56 AM
To: OC GCP Questions
Subject: Question about the FDA1572

Hello,

I am wondering if there is the need to include Microbiologists in the FDA1572 if they are performing key microbiology tests for the protocol (but nothing more).

Than you,

Best Regards,

[REDACTED]