

From: OC GCP Questions
To: [REDACTED]
Subject: sponsor/sub-investigator
Date: Thursday, April 27, 2017 6:42:00 AM

Good morning --

FDA regulations (Part 312) does not define a sub-investigator - or co-investigator, or any similar terms - merely investigator, sponsor, and sponsor-investigator. The ICH GCP document, with which FDA concurs as guidance, available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>, does define at 1.56 a sub-investigator as "Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows)." If an individual chooses to submit an IND for a study and will not consider himself/herself as the clinical investigator of the resulting study, but merely a support person or sub-investigator as defined above, that information would need to be included in the submission materials. The regulations do not prohibit such a person from acting as a sponsor and it would be the decision of the reviewing division as to whether his/her role in the resulting study appeared appropriate or not.

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.

-----Original Message-----

From: [REDACTED]

Sent: Wednesday, April 26, 2017 6:19 PM

To: OC GCP Questions

Subject: sponsor/sub-investigator

Dear GCP Questions,

Is there any reason why an academic researcher could not function as a Sponsor and then assist on the study as a sub-investigator listed on the Form FDA 1572? The investigator is a different person.

Thank you,

[REDACTED]