From: OC GCP Questions
To: [redacted]
Subject: URGENT QUESTION.
Date: Friday, December 18, 2015 9:49:33 AM

Good morning --

This is a difficult question to answer. It is best to ask the sponsor of the study or if the study is under IND please ask the FDA project manager for the IND.

I can give you the following general information --

A conflict of interest in a clinical trial related to a clinical investigator may be considered a conflict between the private interests and official responsibilities of the clinical investigator and the objective design, conduct and reporting of the clinical trial. A risk of such interests is that they may lead to intentional or unintentional bias or errors in the clinical trial and may compromise the well-being of the human research subjects.

I hope this information is helpful.

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 exprssed.

-----Original Message-----
From: [redacted]
Sent: Thursday, December 17, 2015 4:02 PM
To: OC GCP Questions
Subject: URGENT QUESTION.

Dear Madam / Sir,
We are currently about to launch a Phase 1 clinical trial in the US.
We would like to know if the Principal Coordinating Investigator of a multi-center trail can also be a Principal Site Investigator?
This is NOT an Investigator initiated clinical trial.
Thank you in advance for a quick response.
Sincerely,
[redacted]