From: OC GCP Questions
To: [redacted]
Subject: PI and Medical monitor / Project Manager
Date: Wednesday, May 23, 2018 11:40:00 AM
Attachments: [redacted]

Good morning –

Sponsors do fund many studies and have an interest in the outcomes of those studies as do clinical investigators. The scenario you describe may raise concerns about conflicts of interest.

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. That said, it is best to check with your institutional ethics office for specific advice related to your situation.

Also, you should check with your local and national laws and policies to see if there are any requirements related to conflict of interest and clinical trials. The U.S. has regulations related to federally funded studies and ensuring objectivity ("Responsibility of Applicants for Promoting Objectivity in Research for which Funding is Sought" and "Responsible Prospective Contractors" available at www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf).

You may want to review FDA's guidance on monitoring. Please see the link below.
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf
Please see Section III. OVERVIEW OF MONITORING METHODS.

As stated above, you may also discuss your situation with your reviewing IRB/IEC.

Generally, study monitoring is performed by the sponsor not the clinical investigator (PI) because of the possible introduction of bias into the study.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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: Wednesday, May 23, 2018 9:13 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: PI and Medical monitor / Project Manager

Dear FDA
Can the PI and the medical monitor / project manager in a phase 1 unit be the same
Can they perform same activities

[redacted]

[redacted]

[redacted]

[redacted]