From: OC GCP Questions
To: [redacted]
Subject: assistance on a question concerning potential conflict of interest
Date: Tuesday, February 27, 2018 11:22:00 AM
Attachments: [redacted]

Good morning –

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.

For example, an investigator who is a part owner of the CRO managing the trial could be considered to have a conflict of interest. The CRO operates on behalf of the trial sponsor and may have an interest in the sponsor (either through an equity interest or an interest in maintaining a business relationship with the sponsor). As a part owner of the CRO, the investigator's interests in the CRO may create a conflict of interest with the conduct of the clinical trial. For example, the CRO has an interest in the timely completion of the clinical trial in order to meet the sponsor expectations and maintain the business relationship with the sponsor that would lead to more business for the CRO. The investigator's interest in the CRO may conflict with the investigator's objective conduct of the study, such as influencing (intentionally or unintentionally) his/her selection of human subjects in order to ensure timely trial completion.

You may be interested in the U.S. Department of Health and Human Services (HHS) guidance document, "Financial Relationships and Interests in Research Involving Human Subjects" (available at www.hhs.gov/ohrp/policy/fguid.pdf), which raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and, if so, what actions could be considered to protect those subjects.

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).

For studies that will be submitted to FDA to support marketing applications, there are requirements that clinical investigators report their financial interests and arrangements to the study sponsor (see 21 CFR part 54, Financial Disclosure by Clinical Investigators, available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1). The clinical investigator financial disclosure information, along with the steps taken to minimize bias in the study, is submitted to FDA in a marketing application supported by the clinical trial and is used in the evaluation of the conduct of the study and the integrity of the study data.

FDA would not comment on a specific conflict of interest. Please review the information provided above and consult your legal department if necessary.

It also might be helpful to review the Orphan Product Development webpage. Office of Special Medical Programs > Office of Orphan Products Development

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: Tuesday, February 27, 2018 4:52 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: assistance on a question concerning potential conflict of interest

Dear Ma'am/ Sir,

I represent a company that is preparing for a clinical study on a therapy being developed in the framework of Orphan Drug Designation. Please provide me the name and phone number of a person in the Office of Good Clinical Practice, who can clarify the Office's position regarding a prospective Investigator, who is a subordinate of an individual with a conflict of interest.

Thank you for your assistance on this matter.

Sincerely,

[redacted]

[redacted]

[redacted]

[redacted]