From: OC GCP Questions
To: [redacted]
Subject: Contract Physician as Principal Investigator
Date: Monday, January 27, 2014 1:38:31 PM

Good afternoon –

Based on the limited information in your email, I cannot specifically answer your question. Conflict of interest can be both financial and contractual. You may wish to consult your legal department in your company.

That being said, 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.

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 http://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 http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). The FAQ for this rule is linked below.
Frequently Asked Questions - Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulation)

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 http://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.

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Monday, January 27, 2014 12:38 PM
To: OC GCP Questions
Subject: Contract Physician as Principal Investigator

Dear Office of GCP Compliance,

We have a physician who is contracted as a medical monitor on one of our Phase 2 clinical trials. We have another Phase 3 clinical trial that is starting up, and our contract physician would like to participate as a Principal Investigator (PI) on the new trial. The contract physician is qualified to be a PI on the new trial, but wanted to understand any compliance or conflict-of-interest concerns posed by this scenario. Thank you.

Regards,
[Redacted]