From: OC GCP Questions
To: [redacted]
Subject: Question regarding clinical trial
Date: Friday, January 23, 2015 10:40:46 AM

Good morning –

Sponsors do fund many studies and have an interest in the outcomes of those studies. This may raise concerns about conflicts of interest. Such concerns may be addressed by various means, such as through study design and by ensuring payments to investigators are not based on study outcomes or may otherwise potentially bias the investigator. Although it may be ideal, ensuring the absence of conflicts of interest may not be possible. To the extent possible, however, the potential for bias due to conflicts of interest should be minimized in order to ensure the integrity of the research.

FDA has regulations addressing the reporting to FDA of certain financial interests and relationships of clinical investigators, see 21 CFR 54, Financial Disclosure by Clinical Investigators. Information on expenses paid by the sponsor to a CI or site may need to be collected by sponsors of clinical investigations and reported to FDA by applicants of marketing applications. Most likely, expenses would be reportable as a significant payment of other sorts. However the reportable amount is high, $25,000.

Further information on financial relationships and disclosure is available in the following documents:

FDA's regulations 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

FDA's "Guidance for Industry - Financial Disclosure by Clinical Investigators" available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

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

From: [redacted]
Sent: Thursday, January 22, 2015 2:40 PM
To: OC GCP Questions
Subject: Question regarding clinical trial

Hello,

We are a group physicians' office and have been asked to participate in a research study. We have been offered compensation, an honorarium, for each patient referred

to this study. We are wondering if this is ok to accept.

Thank you,

[redacted]