From: OC GCP Questions
To: [redacted]
Subject: RE: Questions on Potential Conflict of Interest Related to Investigators of Clinical Trials
Date: Friday, August 22, 2014 2:33:00 PM

Dear [Redacted],

Thank you for your question. The FDA regulations do not specifically address your scenario or what constitutes a conflict of interest. However, FDA's regulations for financial disclosure by clinical investigators (found at 21 CFR part 54 - see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54) require applicants who submit a marketing application for a drug, biological product or device to submit certain information concerning the compensation to, and financial interests and arrangements of, any clinical investigator conducting clinical studies covered by the regulation. The regulation requires applicants to certify the absence of certain financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA, or to disclose those financial interests and arrangements to the agency and identify steps taken to minimize the potential for bias.

FDA has a guidance document titled, "Guidance for Clinical Investigators, Industry, and FDA Staff – Financial Disclosure by Clinical Investigators" (found at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf) that was developed to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators (21 CFR part 54). As stated in this guidance, FDA encourages study sponsors to consult FDA with questions about specific circumstances regarding financial disclosure. The Introduction section of this guidance (page 1) states:

> *FDA encourages applicants and sponsors to contact the agency for advice concerning specific circumstances regarding financial disclosures that may raise concerns as early in the product development process as possible.*

Question B.8. in section IV of the guidance (page 10, Questions and Answers) also says:

> ***B.8. Q: Is clinical investigator financial disclosure information required in IND or IDE applications?***
>
> ***A:*** *No, IND/IDE sponsors are not required to submit information regarding clinical investigator financial interests or arrangements in IND or IDE applications. They are, however, required to collect this information before a clinical investigator participates in a clinical study (see 21 CFR §§ 312.53(c)(4), 812.20(b)(5), and 812.43(c)(5)), and clinical investigators are required to disclose financial information to sponsors (see 21 CFR §§ 312.64(d) and 812.110(d)). The information need not be submitted to FDA until a marketing application is submitted containing the results of the covered clinical study (21 CFR § 54.4).*
>
> ***Study sponsors are encouraged to consult with FDA prior to and during clinical studies about the management of specific situations involving potential bias on the part of a clinical investigator [emphasis added].*** *During these consultations, FDA staff should focus on the protection of research subjects and the minimization of bias from all potential sources.*

The guidance also provides contacts at FDA for questions about the financial disclosure regulations (see section IV.K. copied here for reference):

> ***K. CONTACTS***
>
> ***K.1 Q: Who may be contacted in each FDA Center to answer questions regarding this regulation?***
>
> ***A:*** *The following entities may be contacted Division of Drug Information in the Center for Drug Evaluation and Research, phone 888-463-6332 or 301-796-3400, Division of Small Manufacturers, International and Consumer Assistance in the Center for Devices and Radiological Health, phone 800-638-2041 or 301-796-7100, and the Office of Communication, Outreach and Development in the Center for Biologics Evaluation and Research, phone 800-835-4709 or 301-827-1800.*

I recommend that you reach out to the appropriate center contact noted above (and listed in section K of the guidance). You can determine which center to contact based on the type of product you are developing (e.g., drug, device, biologic).

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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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, August 20, 2014 2:16 PM
To: OC GCP Questions
Subject: RE: Questions on Potential Conflict of Interest Related to Investigators of Clinical Trials

Dear Sir/Madam,

Good afternoon.

We have a question regarding potential conflict of interest related to clinical investigators of clinical trials, and we are hoping that you may be able to guide us to the right FDA guidance documents or the right FDA person to get more information on this issue. Specifically, would there be any conflict of interest if one of the clinical investigators of our covered clinical trial is also a member of our scientific/advisory boards and expert panel, who receives company stocks as payment for being a member of our scientific and advisory boards?

Your help in us seeking an answer to this question would be greatly appreciated.

[Redacted]