From: OC GCP Questions
Sent: Wednesday, March 05, 2014 1:48 PM
To: [redacted]
Subject: RE: Question related to finder's fees

Dear [Redacted],

From previous FDA responses to questions about finder's fees, I found that the practice is discouraged as "unacceptable" and "unethical". However, I could not find any FDA regulations specifically prohibiting "finder's fees".

FDA regards recruitment as the first step in the informed consent process. An IRB should review the methods and materials that investigators propose to use to recruit subjects, as stated in FDA's Information Sheet Guidance document at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.

FDA regulations require reporting of certain clinical investigator financial interests and relationships. See 21 CFR part 54, Financial Disclosure by Clinical Investigators, at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54. In February 2013, FDA issued the guidance document "Financial Disclosure by Clinical Investigators" (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf). In this document, see in particular, section IV., question and answer C.4., regarding significant payments of other sorts (defined in 21 CFR 54.2(f)).

In May 2004, the Department of Health and Human Services issued a guidance document, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" (http://www.hhs.gov/ohrp/policy/fguid.pdf). This document discusses financial relationships in research and points to consider to ensure that financial interests do not compromise the protection of research subjects.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
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WO32/5129
301-796-8346

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, March 05, 2014 11:06 AM
To: OC GCP Questions
Subject: Question related to finder's fees

Good Morning,

[Redacted] currently does not allow finder's fees, however we are exploring developing a process to review these types of fees, with some stipulations. What is the FDA's current guidelines on this practice? Your guidance is greatly appreciated and will aid us in ensuring our revised policy is in line with current regulations.

Thank you,

[Redacted]