

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Physician referrals  
**Date:** Thursday, April 03, 2014 10:25:27 AM

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Good morning --

Thank you for your question. FDA's regulations do not specifically address your question of whether it is acceptable for a sponsor to pay investigators. FDA has regulations addressing the reporting to FDA of certain financial interests and relationships of clinical investigators, see 21 CFR 54, found at [CFR - Code of Federal Regulations Title 21](#). Additionally FDA has a guidance document entitled Financial Disclosure by Clinical Investigators found at the link here <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

I recommend that you determine whether the payment for patient referral is a significant payment of other sorts as described in the financial disclosure regulations at 21 CFR 54.2(f). You may also want to reference section IV, question C.4 in the draft guidance document mentioned above.

That being said, there are also concerns that financial relationships and interests in clinical trials may affect the rights and welfare of human subjects. The guidance titled, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" found at <http://www.hhs.gov/ohrp/policy/fguid.pdf>, discusses financial relationships in research and points to consider to ensure that financial interests do not compromise the protection of research subjects. It is also very important to be familiar with any policy requirements regarding bonus payments that an investigator or their institution must follow. For example, there are a number of institutions and IRBs that by policy, do not allow investigators to accept payments from sponsors for activities such as recruitment or enrollment, as they think this may create a potential conflict of interest. Specifically, the institution or IRB may prohibit such payments out of concern that the investigator may be motivated by financial interest to refer a patient when such referral might not be of any benefit to, or in the best interest of the subject.

Some sponsors actually have policies that do not allow clinical study incentives such as enrollment bonuses, patient referrals, finders fees, awards, or gift certificates that are designed to reward the achievement of subject enrollment goals within a specified time period. If you are offering the recruitment bonus, or are in the position of being offered a recruitment bonus, you will want to be sure that you check with your company, institution, IRB, and any other appropriate oversight entities about whether there are any prohibitions.

You may also wish to review our information sheet on recruiting study subjects found at the link below.

[Guidances > Recruiting Study Subjects - Information Sheet](#)

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov).

Kind regards,

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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.

-----Original Message-----

From: [Redacted]

Sent: Wednesday, April 02, 2014 2:40 PM

To: OC GCP Questions

Subject: Physician referrals

I am a clinical QA auditor and would like a response to the following question.

Can a clinical research site give physicians a referral fee for sending patients with a particular indication to their site? How does the FDA view this recruitment procedure?

[Redacted]