From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Ethical Inquiry- #2
Date: Wednesday, October 08, 2014 2:05:00 PM

Dear [Redacted]-

Thank you for both of your questions. Your first question asks whether there are any FDA regulations in place regarding reimbursement for doctors who refer patients to clinical trials, and your second question is whether there are any FDA regulations in place regarding fee for service programs in clinical trials. It is unclear what you mean by "fee for service programs in clinical trials", so I will assume that the two questions are closely related and will try to address both in this response.

Your first question seems to be addressing a scenario where physicians, who are not investigators on a given study, are paid a fee **simply for referring the names of any patients who may be eligible for inclusion in a study** that the investigator is conducting. Your second question seems to be addressing a scenario where physicians, who are not investigators on a given study, are paid a fee **for performing a service to identify any patients who may be eligible for inclusion in a study** that the investigator is conducting. These fees are sometimes called "referral fees" or "finder's fees", however, these terms may be defined differently by varying parties (e.g., institutions, sponsors, investigators, IRBs).

The difference between the two scenarios you describe is the amount of resources (e.g., time, staff effort, and cost) involved in identifying a patient who may be a potential subject. For example, there is a difference between the amount of resources it takes for a physician to simply refer the name of a patient to the investigator vs. the physician who actually performs a service that involves the review of patient charts, assessment of patients in accordance with the inclusion/exclusion criteria of the study protocol to identify potentially eligible subjects, contacting a potential subject to discuss the study and assessing that patient's interest in being referred to the investigator for more information on the proposed study. The thought being that in the second scenario, the fee is being paid as a form of reimbursement for the amount of work it takes for a physician to identify potential subjects in this manner.

FDA's regulations do not specifically address either of your questions. When the regulations are silent, institutions, IRBs, investigators and sponsors are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

You may want to check with your institution on whether or not they have a policy on this topic. If your institution does not, they may want to be educated on this topic and then determine what your institutional policy is regarding the payment of fees to physicians for referring potential study subjects. I suggest that you take a look in the literature as you will find that there is a good amount of information on this topic and discuss this information with the appropriate institutional officials. You may also want to take a look at the policies that other institutions and IRBs have adopted. There are various organizations who have issued ethics statements or ethics codes that prohibit the use of such fees as they are viewed as unethical. There are other organizations that may support the payment of such fees, or varying degrees of payment to physicians based on the amount of work they do to identify potential subjects. I recommend that you discuss this topic internally at your institution with all of the appropriate institutional officials.

I'm sorry I can't be more helpful, but I do 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

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Thursday, October 02, 2014 11:26 AM
To: OC GCP Questions
Subject: IRB Ethical Inquiry- #2

To Whom This May Concern:

The Institutional Review Board of [Redacted] is also in need of FDA guidance related to the following inquiry: Are there FDA regulations in place regarding fee for service programs in clinical trials?

Thank you!

[Redacted]

From: [Redacted]
Sent: Thursday, October 02, 2014 10:11 AM
To: 'gcp.questions@fda.hhs.gov'
Cc: [Redacted]
Subject: IRB Ethical Inquiry

To Whom This May Concern:

The Institutional Review Board of [Redacted] is in need of FDA guidance related to the following inquiry: Are there FDA regulations in place regarding reimbursement for doctors who refer patients to clinical trials? If you could provide us with any documentation regarding the FDA's stance on this issue, it would be much appreciated!

Thank you in advance for your assistance in this matter!

Best Regards,

[Redacted]