From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: [redacted] - please help
Date: Wednesday, December 12, 2018 1:19:38 PM
Attachments: [redacted]

Good afternoon –

Your email was forwarded to my office for a reply. I have discussed your three questions with my OGCP colleagues. Please see our answers below.

Question 1 – We don't think the postcard letters handed to the subjects meet the definition of doctor/doctor letters as mentioned in the guidance that you site. We feel the subject postcards may need IRB review because they fall within recruitment of research subjects.

Question 2 - You appear to be asking whether there are any FDA regulations that address paying fees to physicians for referring patients to clinical trials. FDA's regulations do not specifically address your question. 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. I have provided some information below that I hope is helpful to you as you explore this issue at your organization.

You may be referring to a scenario where physicians, who are not investigators on a given study, are paid a fee simply for referring the names of any of their patients who may be eligible for inclusion in a study that the investigator is conducting; or, a scenario where physicians, who are not investigators on a given study, are paid a fee for performing a service to identify any of their 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 described above 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 who might eligible to the investigator vs. the physician who actually performs a service to identify potentially eligible patients by reviewing their patient charts, assessing patients in accordance with the inclusion/exclusion criteria of the study protocol, contacting a patient/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 patients who might be potential subjects in this detailed manner.

You may want to check with your institution and IRB on whether or not they have a policy on this topic of paying referral fees or finder's fees. If your institution does not have a policy, they may want to explore this topic and then determine whether or not to develop an institutional policy. I suggest that you take a look in the literature as you will find that there is a fair amount of information on this topic and discuss this information with the appropriate institutional officials, including your legal counsel. 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 ethical statements or ethical codes that prohibit the use of such fees as they are viewed by such groups as being 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 might add, that most IRBs do not permit the scenario that you describe in question 2.

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Question 3 – With the limited information provided, OGCP is unsure why this scenario (using equipment given by the sponsor) is necessary as most physician offices already have the equipment that your site in your email. OGCP believes you should discuss this situation with the FDA review division that is handling your clinical trial. It is also unclear to OGCP whether you are using this equipment for screening purposes.

As references, I am suppling you with FDA's Financial Disclosure guidance as well as our screening and recruiting information sheets. Please see the links below.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

Search for FDA Guidance Documents > Screening Tests Prior to Study Enrollment - Information Sheet

Search for FDA Guidance Documents > Recruiting Study Subjects - Information Sheet

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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.

From: CDER DRUG INFO
Sent: Monday, December 10, 2018 9:48 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: [redacted] - please help

Dear Office of GCP,

We received the inquiry below regarding study materials that are handed to the investigators and we defer to you for guidance.

Please let us know if you can assist.

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U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, December 07, 2018 2:53 PM
To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: [redacted] - please help

Dear FDA,

I have 2 questions regarding IRB clearance:

I am working with a client that wishes to send out dear doctor letters to reach out to physician offices nearby study investigator sites to refer patients who present at the office to be referred into a clinical study that they are running. The Dear doctor letters will be in compliance with FDA guidance "Recruiting Study Subjects Information Sheet" last updated 7/12/2018 that states regarding IRB clearance that--- ***Not included*** *are: (1) communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects)*

Please note: No communication will be provided as directly to patients by the sponsor and should not be considered as advertising according to the same guidance as: *advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study.*

1. Can the sponsor provide a postcard to be handed by the referring physician to a patient regarding a study the sponsor is conducting. These postcards will have solely the following information:

the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. This information was selected to be in accordance with FDA guidance "Recruiting Study Subjects Information Sheet" last updated 7/12/2018

2. Can the sponsor reimburse these referring (non-study physicians) monies that are less than (or equal to) usual customary and reasonable costs for losing the opportunity to treat these patients. If there are any other possible restrictions that

may need to be addressed please let me know.

I have one question regarding supplying investigator sites with a device to aid in identification of potential study patients.
1.The sponsor would like to provide FDA approved or CLIA Cleared commercially available to the general public some equipment that can be used to aid the Investigator Clinical staff to identify potential patients who **may be eligible** for inclusion in the study. These devices will be used as part of a patient's current history of disease to ensure only qualified patients are placed on the study and reduce the number of patients exposed to treatment unnecessarily. This equipment will be returned to the sponsor at the end of the study to be re-deployed at a later time. This equipment will be non-invasive and may be instruments such as electronic thermometers to determine fever levels, pulse-ox readers to identify respiratory distress levels etc. that are in a range suitable for a patient to be considered for enrollment. These instruments **will not** need to be used by a physician.

If provisioning this equipment must meet any specific criteria or be handled in any special way, please let me know.

Thanks in advance for your response.

[redacted]