From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Clinical research site question
Date: Monday, October 01, 2018 1:05:00 PM
Attachments: [redacted]

Good afternoon –

FDA does not have regulations or guidance that address gifts to sites in terms of maximum amount, type of gift, etc. As you state, FDA has regulations addressing the reporting to FDA of certain financial interests and relationships of clinical investigators, 21 CFR 54, Financial Disclosure by Clinical Investigators. Information on gifts to a site may need to be collected by sponsors of clinical investigations and reported to FDA by applicants of marketing applications. Most likely, a gift to a site would be reportable as a significant payment of other sorts.

Sponsors do fund many studies and have an interest in the outcomes of those studies. This may raise concerns about conflicts of interest. Such concerns may be addressed by various means, such as through study design and by ensuring payments to investigators or sites are not based on study outcomes or may otherwise potentially bias the investigator and or the site. Although it may be ideal, ensuring the absence of conflicts of interest may not be possible. To the extent possible, however, the potential for bias due to conflicts of interest should be minimized in order to ensure the integrity of the research.

FDA's "Guidance for Industry - Financial Disclosure by Clinical Investigators" available at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf

The scenario you have described does not appear to fall under the definition of SPOOS. By definition, significant payments of other sorts (SPOOS) are payments that have a cumulative monetary value of $25,000 or more made by any sponsor of a covered study to the investigator or the investigator's institution, during the time the clinical investigator is carrying out the study and for one year following completion of the study, to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies (e.g., a grant to the investigator or to the institution to fund the investigator's ongoing research or compensation in the form of equipment), or to provide other reimbursements such as retainers for ongoing consultation or honoraria. The term "significant payments of other sorts" was intended to capture substantial payments or other support that has a value of more than $25,000 provided to an investigator or institution that could create a sense of obligation to the sponsor. These payments do not include payments for the cost of conducting the clinical study of the product under consideration or clinical studies of other products, under a contractual arrangement, but do include other payments made directly to the investigator or to an institution for direct support of the investigator.

Some sponsors actually have policies that do not allow clinical study incentives such as enrollment bonuses, finder's 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 consult your legal department for additional advice. You would want to avoid any appearance of coercion or undue influence.

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: [redacted]
Sent: Monday, October 01, 2018 9:25 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Clinical research site question

Hello,

I have a few clinical sites participating in my Ph2 study who have been very diligent in their data entry to date. I wanted to thank them by sending each study coordinator a $5 Starbucks gift card. I have received various CRO/internal feedback that FDA regulation does not allow this, but I am unable to find information relating to this other than 21CRF Part 54.2f (Financial Disclosure), but this relates to amounts >$25,000 exclusive of study related conduct costs. I am following up directly to determine if there is a definable regulation or guidance in such cases. Typically such feedback I've received, when I inquire, notes that the agency will disagree or frown upon such things, but I'd like to follow up directly to ensure I am receiving proper feedback. My company also does not have any marketed products at this time.

Your feedback is greatly appreciated. If this feedback request is best suited to another department, I would also appreciate if you could please connect me appropriately.

Best Regards,
[redacted]

[redacted]

[redacted]