From: OC GCP Questions
To: [redacted]
Subject: RE: Informed Consent Inquiry
Date: Thursday, May 01, 2014 2:42:00 PM

Good Afternoon-

Thank you for your question. FDA regulations do not specifically address payment to research subjects for participation in clinical studies. However, FDA does have Information Sheet Guidance on Payment to Research Subjects that can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm. This guidance states that payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive, and that financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither is coercive or present undue influence [21 CFR 50.20].

ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) also addresses payment and compensation available to subjects in section 3.1.2 (as you noted), and in sections 3.1.8, 3.1.9, 4.8.10(k), and 5.11.1(c). You can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf. This guidance essentially says that the IRB should receive information about payments and compensation available to subjects, review this information to assure that neither the amount and method of payment present problems of coercion or undue influence, and ensure that information regarding payments (including methods, amounts and schedules) is set forth in the ICF and any other written information to be provided to subjects.

From the limited information provided in your question, it does not sound like there is any payment (i.e., monies) being provided to subjects participating in the study at the SMO sites. Rather, it sounds like some sites (at least the SMO sites) are providing a transportation service to subjects for study visits. This sounds more like a recruitment incentive or an enrollment incentive.

When I think about your scenario, a couple of questions come to mind:

- Is this a multi-site study?
- Is this transportation being offered at no charge to subjects – is it free transportation?
- Are some sites (e.g., those using the SMO) going to offer this free transportation while other sites will not offer this free transportation?
- Is there an equity issue if this service is offered at some sites but not others?
- Is this transportation service being offered as remuneration/reward for participating in the study?
- Is this transportation service being offered as a recruitment incentive/enrollment incentive for participating?
- What type of study is this?
- What is the intended study population?
- Where is this study being conducted (i.e., geographic regions)?
- Does this recruitment/enrollment incentive create undue influence on a potential subject's decision about participating?

There are likely other questions that I did not include above that should be considered, but I think this provides some insight into how to assess your specific scenario.

Using recruitment/enrollment incentives may be permissible as long as the IRB has determined that, although they may be a factor in a subject's decision to participate, they have not served to unduly influence the subject to participate. In order to make this determination, IRBs should know who the subject population will be, what incentives are being offered, and the conditions under which the offer will be made. The IRB may have written procedures that address such incentives.

For these reasons, information about this transportation service should be provided to the IRB upfront for their consideration. The IRB can provide their assessment as to how they view this transportation service (e.g., as compensation for participation, or as a recruitment/enrollment incentive, or in some other way based on the details of the study) and whether it warrants inclusion in the IRB-approved informed consent form. I recommend you discuss your thoughts and concerns about this with the IRB.

I 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

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Office of Special Medical Programs, Food and Drug Administration

-----Original Message-----
From: [Redacted]
Sent: Tuesday, April 29, 2014 7:57 AM
To: OC GCP Questions
Subject: Informed Consent Inquiry

If the Site Management Organization (SMO) hired a private driver to transport subjects to/from study visits, is this transportation construed as 'payment and compensation' available to study subjects (per ICH GCP 3.1.2), and should the Investigator notify the IRB and include language regarding this transportation in the IRB-approved informed consent form (ICF)? Furthermore, if information regarding this transportation is not required to be disclosed to the IRB (via investigator submission) and to the study subjects (via IRB-approved ICF), how can it be ensured that all subjects are afforded equal consideration (without prejudice) for this study benefit (no-cost transportation)?

Background: The large central IRB does not view sites providing transportation to participants as something that falls under the purview of the IRB. However, if the study subject was receiving reimbursement for their travel expenses, the IRB would typically require review and would require that information to be included the ICF. For example, if a private driver was hired to transport the subjects to/from study visits (no payment/reimbursement made directly to the subjects), the IRB does not advise/require IRB review and disclosure within the ICF. The IRB's standard operating procedures (SOPs) and the IRB's Investigator Handbook do not specifically address when the IRB would require travel/transportation to be disclosed in the ICF.

Thank you.