From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, July 10, 2006 5:52 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [purged]

Your question about payments to subjects who participate in clinical trials was forwarded to my office for a response.

Any such payments and payment schedules should be reviewed by the Institutional Review Board that is responsible for the review and approval of the study at your site, to ensure that the amount(s) and the proposed method(s) of payment/timing of payments are neither coercive or present undue influence.

I have pasted the text of FDA's Information Sheet Guidance on this topic into this e-mail for your convenience.

Payment to Research Subjects

The Institutional Review Board (IRB) should determine that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)]. It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. 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 are coercive or present undue influence [21 CFR 50.20].

Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

Also see these FDA Information Sheets, available on FDA's Good Clinical Practice website (http://www.fda.gov/oc/gcp/): "A Guide to Informed Consent Documents," and "Recruiting Study Subjects." (Once at the home page, click on "Guidances and Information Sheets" in the middle column, and then click on "FDA Information Sheet Guidances...")

I hope this is helpful..

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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: [purged]
Sent: Monday, July 10, 2006 12:14 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: I am a monitor currently involved in an early phase
development trial sponsored by a Pharma company.
The objective of the trial is to evaluate the function of a specific
body system and there is no investigational product involved. The study
subjects (patients of [purged]) are treated with approved generic drugs
and the decision for the treatment of a novel drug will be based on
the results of this trial in humans.
Please advise if there are any restrictions regarding payment of
patients who participate in such clinical trial which is an early
development stage.
The trial is not a phase 1 trial and the patients are not healthy.
With kind regards,
[purged]