From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, July 24, 2003 7:36 AM
To: [Redacted]
Subject: RE: Payment of clinical trials subjects

Dear Ms. [Redacted] :

Your question about payments to subjects who participate in clinical trials was referred to me for a response. I have pasted the text of FDA's "Information Sheet" on payment to research subjects for your convenience and information. The policy is the same regardless of the phase of the clinical study.

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the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.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: "A Guide to Informed Consent Documents", "Recruiting Study Subjects."

If you would like to review FDA's other information sheets, such as the ones listed at the end of the "Payment to Research Subjects" information sheet, you may view them on line by cutting and pasting the following URL into your browser: http://www.fda.gov/oc/ohrt/irbs/default.htm

Other helpful FDA regulations and guidance related to good clinical practice and the conduct of clinical research can be found on my office's website: http://www.fda.gov/oc/gcp

I hope this information 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: [Redacted]
Sent: Monday, July 21, 2003 11:59 PM
To: gcpquestions@oc.fda.gov
Subject: Payment of clinicial trials subjects

Dear GCP staff:
Can you point me to a guidance or regulation document that tells me what the FDA's policy on the payment of clinical trails subjects is? This would be payment for participation, not just covering transport and examination/tests costs. Is the policy different for healthy subjects in Phase 1 trials than for affected subjects in Phase 2 or 3 trials?
Thank you,
[Redacted]