From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, June 27, 2005 3:54 PM
To: [Redacted]
Subject: RE: Question on GCP policy
Dear [Redacted],

FDA has an information sheet on Payment to Research Subjects. The information sheets can be found on the internet at: http://www.fda.gov/oc/ohrt/irbs/default.htm. The information sheet on Payment is at: http://www.fda.gov/oc/ohrt/irbs/toc4.html#payment. It states:

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the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.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is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.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."
I hope that this information is helpful to you.

Sincerely,
Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: Friday, June 24, 2005 5:23 PM
To: gcpquestions@oc.fda.gov
Subject: Question on GCP policy
Hello,

I am inquiring were to find the policy on offering incentives to clinical trial subjects. I was wondering were to find the statement or policy that prohibits increased incentives over time during a trial so the subject does not feel coerced into completing the trial so they can get the greater incentive than if they were to withdraw from the study before.

Thank you,
[Redacted]