From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, February 28, 2005 11:06 AM
To: [Redacted]
Subject: RE: Reimbursement to Patient/Subjects
Dear [Redacted], In order to ensure that reimbursement to subjects is not coercive (either in amount or schedule of payment), it is important for the IRB to review what will be offered to all subjects. To ensure that subjects understand what they will be paid, this information should also be clearly contained in the consent form. While there may be some variability in compensation (e.g., compensation for travel may vary from the cost of a bus ride to private transportation and parking), the categories of compensation can be described in the consent form if the actual amounts cannot; a separate sheet might then describe the minimum and maximum in each category (if the IRB believes the latter is needed).

There has been criticism of payments that are too variable based on the principle of justice. That is, if one reimburses individuals for taking time off of work, there ought to be a single level payment for that (similar to what is done for jury members). Generally, it would be inappropriate, for example, to compensate lawyers at their hourly or daily rate, and restaurant workers at theirs, in order to participate in the identical research study.

Please let me know if you need additional information. I hope 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: Thursday, February 24, 2005 9:39 AM
To: gcpquestions@oc.fda.gov
Subject:
Dear sirs,

I am in need of some clear guidance regarding patient reimbursement for participation in research. Is it acceptable that reimbursement for patient inconvenience and travel be reviewed on a case-by-case basis by the appropriate IRB post-hoc or is it required that this reimbursement information be decided prior to the need, included in the informed consent and offered across the board to all patients?

Thank you for your time and assistance.
[Redacted]