From: Hommel, Carolyn - OC
Sent: Tuesday, May 04, 2004 2:29 PM
To: [Redacted]
Subject: RE: 5 GCP questions - Response to Question #5

Dear [Redacted],

In our telephone conversation several weeks ago, you asked my office to address questions 4, 5, and 8 from the original six questions that you sent. I'll be replying in separate e-mails for each. I apologize for the delay in getting back to you.

In question #5, you asked:

Can a site reimburse a study subject for financial hardship over and above the dollar amount specified in the informed consent? **[Sent to FDA]**

A. Here are some examples of items whose costs could be reimbursed even though the informed consent form does not mention them or specify $ amounts that would cover them:

- a medication or procedure required in the protocol if the subject experiences a "protocol specified clinical event or symptom" while on study (e.g., a protocol that requires a subject have an echocardiogram if he/she develops an abnormal EKG)
- the cost of travel to keep a scheduled study visit even though the subject has moved away from the area or is away on holiday
- the cost of reasonable day care for the time of the study visit
- the additional costs of travel incurred by handicapped/disabled study subjects

In general, subjects may be reimbursed for costs in excess of stipends if those costs are for items that do not benefit the subject. These items should meet the following test: would the subject, in the absence of this item, be unable to meet study requirements and/or be out of study compliance.

FDA's informed consent regulations require certain basic information to be provided to each study subject, including a description of "the procedures to be followed" during the study [See 21 CFR 50.25(a)(1)]. If the approved study protocol requires subjects who experience specific clinical events or symptoms to undergo additional tests, then the additional tests should be identified in the informed consent document. In addition, 21 CFR 50.25(b)(3) requires the informed consent to include "Any additional costs to the subject that ***may*** (emphasis added) result from participation in the research."

Thus, FDA would expect the IRB to be informed about, and the informed consent form to describe, any costs for which subjects will ***not*** be reimbursed. If the subjects may incur an additional expense because they are participating in the research, the costs should be explained. If the subjects will not be reimbursed, it may affect the subjects' decisions about participation in the study. IRBs should consider that some insurance and/or other reimbursement mechanisms may not fund tests or care that is delivered in a research context.

Likewise, if subjects will be reimbursed for study-related tests, then the informed consent should state this. Even if all the subjects will not undergo all of the

study tests described in the study protocol (because only some of the subjects experience "specific clinical events or symptoms"), the informed consent document could include a general statement about the test or tests and any reimbursement that may be provided to subjects so that subjects know what to expect (e.g., "Should you experience any of the following clinical events or symptoms, you will be required to have the following tests [which should be listed and explained]. You will be reimbursed for the costs of these tests."

The other examples you provided could also be handled with general statements in the informed consent document, e.g., "You will be reimbursed for any day care costs for children under 12 on days when you are required to visit the clinic"; "You will be reimbursed for any additional transportation costs to keep scheduled appointments, should you move away or go on vacation;" "If you are disabled and require special transportation to bring you to and from the study site, you will be reimbursed for this expense," etc.).

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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: Wednesday, April 07, 2004 2:37 PM
To: Carolyn.Hommel@OC.FDA.GOV
Subject: Re: 5 GCP questions

Dear Ms. Hommel,
Thanks for getting back to us. I'm sending you the Q&As below (with one extra Q&A). We would greatly appreciate your comments. The GCP website does not cover these issues. Our phone # is [Redacted] if you would prefer to talk these over by phone.
Best wishes,
[Redacted]

5. Q. Can a site reimburse a study subject for financial hardship over and above the dollar amount specified in the informed consent? **[Sent to FDA]**

A. Here are some examples of items whose costs could be reimbursed even though the informed consent form does not mention them or specify $ amounts that would cover them:

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[Redacted]