From: OC GCP Questions
To: [redacted]
Subject: RE: Informed Consent: visit compensation amount
Date: Monday, June 23, 2014 12:09:00 PM
Attachments: [redacted]

Dear [Redacted]-

Thank you for your question. As you know, the FDA regulations do not address subject compensation, however, as you said, this topic is covered in the ICH GCP E6 guidance (which is recognized as official FDA guidance). As you mentioned, section 4.8.10(k) says that the informed consent form (ICF) and discussion should include an explanation of the anticipated prorated payment, if any, to the subject for participating in the trial. Also, sections 3.1.8 and 3.1.9 state:

> 3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.
>
> 3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

So this guidance suggests a few things:

- That the IRB review the amount and method of payment to study subjects to assure it is not coercive or presents undue influence;
- Payments should be prorated and not wholly contingent on a subject completing the study;
- That the ICF and any other written information given to subjects should include information about the method, amount and schedule of payment to subjects;
- The way payment will be prorated should be specified in the ICF or any other written information given to subjects.

FDA also has Information Sheet guidance on payment to subjects that can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm.

Have you asked your IRB why they did not include a description of the way payment will be prorated in the ICF? As suggested by both guidance documents listed above, ideally, the ICF should include information about the way payment will be prorated. Since the intention is to provide potential subjects with as much information as possible so that they can make an informed decision as to whether or not they want to participate in a study, you may want to share the guidance information with your IRB and ask them to consider your request to include a description of the way payment will be prorated in the ICF.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Thursday, June 19, 2014 9:37 AM
To: OC GCP Questions
Subject: Informed Consent: visit compensation amount

Hello.

We had an IRB that changed our ICF template text in the ICF for ICH 4 8.10(k).

Our ICF template language for visit compensation:

- You will be paid [insert amount per study visit] to reimburse you for [transportation, parking, meal, or others] expenses related to your participation in this study. If you withdraw from the study early, you will be paid for these expenses for the portion of the study that you did complete.

[or]

- You will be paid [insert amount per study visit] for your participation in this study. If you withdraw from the study early, you will be paid for the portion of the study that you completed.

IRB template language for visit compensation:
If you agree to take part in this research study, we will compensate you _____ ***[indicate amount]*** for your time and effort. ***[Indicate if the amount is pro-rated for research visit completion.]***

The IRB does not require a "per study visit compensation amount" and simply requires that it is mentioned that the amount is prorated. There is no calculation provided for the proration (such as amount per study visit). Is the IRB template language sufficient? Thank you.

[Redacted]