From: OC GCP Questions
To: [redacted]
Subject: Question for reimbursement of study drugs
Date: Tuesday, January 02, 2018 12:01:00 PM
Attachments: [redacted]

Good afternoon –

I can't specifically answer your question from a GCP standpoint. It is best to ask the FDA regulatory project manager of the IND for guidance. I can offer you information below regarding subject reimbursement and compensation.

Generally in the guidance below, it states in part -"…payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive.

Guidances>Payment to Research Subjects - Information Sheet

www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm

It is best to have IRB approval first, however, if the subject needs to be seen sooner than IRB approval is given a note to file as well as notifying the reviewing IRB and sponsor as soon as possible would be appropriate.

Please note that routine reimbursement to subjects should have IRB oversight and approval and also should be explained in the informed consent document.

Subject compensation is not a regulatory requirement. In fact, both FDA and reviewing IRBs take a careful look at such provisions when reviewing study protocols, as they can be a source of "undue influence" if inappropriate. Reimbursement for expenses incurred are usually allowed, which you are likely referencing here given your terminology. If a subject waives any reimbursement, that should be documented for the site's protection should the individual have different thoughts about study participation in the future and attempt to falsely accuse the site of refusing just compensation.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional GCP questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [redacted]
Sent: Tuesday, January 02, 2018 3:45 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>

Subject: Question for reimbursement of study drugs

Dear Sir,

I would like to inquire a reimbursement of chemotherapy drugs for clinical trials.
Basically, it should be supplied by sponsor however due to technical reasons, site's own drugs were used for patient treatment.
According to the CSA, the reimbursement was not agreed since it was already defined as one of essential materials.
It was only identified that sponsor has the obligation of chemotherapy drugs supply.
So now, the investigator asked sponsor to additionally supply drugs as much as used. But it cannot be investigator's fee since it was not initially contracted.
Thus, my question is... is there any concerns about sponsor provides real drugs (instead of investigator's fee)?
It would be a GCP violation?

Please let me have your advice for above matter.

Thank you.

[redacted]