

From: [OC GCP Questions](#)
To: [redacted]
Subject: Reimbursement for patient expenses
Date: Friday, December 12, 2014 12:45:47 PM

Good afternoon --

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](#)

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

That said, FDA regulations do not address the timeliness of subject reimbursements. It might be best to consult the reviewing IRB for some guidance. The informed consent should have their contact information.

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

Kind regards,

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Office of Good Clinical Practice
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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.

From: [redacted]
Sent: Thursday, December 11, 2014 6:28 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Reimbursement for patient expenses

I am enrolled in a clinical trial for cancer immunotherapy drugs, and must travel RT about 900 miles to participate. For the first two months, this was weekly with overnight stays. From that point forward, it is monthly with overnight stays.

The sponsor of the trials has agreed to reimbursement, but its history has been exceedingly slow. According to some people at the clinic, it has taken as long as 8 months. So far I am out of pocket well over \$2000 and counting for airline, lodging and associated expenses. Is there a requirement for pharmaceutical companies to pay travel expenses? If so, is there a requirement for timely restitution?

Thanks you,
[redacted]