From: OC GCP Questions
To: [redacted]
Subject: GCP_Payment to Subject
Date: Monday, January 09, 2017 7:29:00 AM
Attachments: [redacted]

Good morning –

FDA's Information Sheet Guidance addresses payments made to subjects who participate in research. As stated in the guidance, payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive.

Search for FDA Guidance Documents > Payment to Research Subjects - Information Sheet

ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) also addresses payment to subjects in sections 3.1.8 and 3.1.9.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

With regard to how this information is disclosed in the informed consent form, the IRB should decide the best way to convey this information. It is not uncommon for IRBs to have their own requirements/limitations and/or restrictions regarding monetary compensation paid to subjects on study and/or gifts provided to subjects as either a recruitment or retention incentive.

Please note that for international studies, the IRB/IEC should also consider the local laws of the country as well as the policies of any institution where the study is conducted.

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

Kind regards,

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

From: [redacted]
Sent: Monday, January 09, 2017 3:09 AM
To: OC GCP Questions
Subject: GCP_Payment to Subject

Hello,

a general statement in ICF saying that "reasonable amount will be payed at each site visit for travel bills", would this be enough if in case no concern raised by the EC. How the information will go to subject in this case about the maximum amount he/she may get for travel.

Regards,

[redacted]