From: OC GCP Questions
To: [redacted]
Subject: Comments on Informed Consent Information Sheet."
Date: Tuesday, October 14, 2014 11:07:06 AM

Good morning ---

Your query was forwarded to our GCP queries box.

Regarding re-consenting subjects, the guidance includes the following:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

During the clinical investigation, the investigator may need to revise the consent form to address changes to the protocol or new information, such as significant new findings. The investigator will need to obtain IRB review and approval of the revised form. (21 CFR 56.109.) In addition, because the consent form is being modified to reflect changes to the protocol or new information, either of which may affect the willingness of already enrolled and actively participating subjects to continue in the clinical investigation, the IRB should determine the need to re-consent these enrolled subjects.

Regarding patient compensation (apart from injury) and travel reimbursement, there is a separate information sheet guidance, "Payment to Research Subjects" that may be helpful in responding to the inquiry, http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm. The draft guidance includes the following:

FDA considers payment to subjects for participation in clinical investigations to be compensation for expenses and inconveniences, not a benefit of participation in research. If payments are provided, the consent process should not identify them as benefits.

The IRB must review all information given to subjects describing recruitment incentives, such as payments to reimburse potential subjects for expenses and inconveniences related to their participation (21 CFR 56.109(b)). In addition, the IRB must review the proposed amount and schedule of payments to subjects to ensure payments are appropriate to the time commitment and study procedures, and that subjects will not be unduly influenced by these incentives.

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, October 13, 2014 9:27 AM
To: [redacted]
Subject: RE: Comments on Informed Consent Information Sheet."

Dear Ms Melvin,

Two questions

1) Are there guidelines to applicability of reconsenting (e.g. Under what circumstances; timelines, retroactive reconsenting (e.g. procedure was added or removed but consent not updated by site until after procedure was performed)
2) Patient compensation (apart from subject injury) fee, travel reimbursement (any restrictions? Who oversees this..IRB?).

Thank you in advance,
[redacted]