From: OC GCP Questions
To: [redacted]
Subject: ICH/GCP #5.8.1 - Request for clarification
Date: Friday, October 16, 2015 1:16:59 PM
Importance: High

Good afternoon --

As far as I am aware there is no FDA requirement that sponsors purchase indemnity insurance. Your citation is from ICH GCP E6 guidance (which is recognized as official FDA guidance) but not a requirement.

That said regarding patient compensation (apart from injury), 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that may be helpful in responding to the inquiry, http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm The draft guidance includes the following: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.

Additionally FDA would expect institutions to follow state and local laws. It might be best to consult your legal department in the institution in which the research is being conducted to obtain advice on indemnity claims and/or insurance.

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, October 16, 2015 10:22 AM
To: OC GCP Questions
Subject: ICH/GCP #5.8.1 - Request for clarification
Importance: High

Good morning….. in trying to determine exactly what a sponsor is required to provide to a site, this

section is unclear. If you could, please provide the specific regulation as referenced in the wording below:

5.8.1. If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage)the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

Any assistance you can provide would be greatly appreciated. Thank you…sandi