From: OC GCP Questions
To: [redacted]
Subject: Question on Insurance for Sponsors
Date: Friday, November 28, 2014 2:18:49 PM

Good afternoon –

As far as I am aware there is no FDA requirement that sponsors purchase indemnity insurance. That said, I cannot advise you on legal issues.

Kind regards,

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

From: [redacted]
Sent: Friday, November 28, 2014 11:03 AM
To: OC GCP Questions
Subject: Question on Insurance for Sponsors

Dear FDA,

A few years ago I retired as a GCP Clinical Auditor working for a major pharmaceutical company. Recently a former colleague of mine located in Switzerland reached out to me with a question regarding insurance and indemnity requirements for US sponsors. He has referenced the point that both ICH and the Declaration of Helsinki require sponsors to take out insurance. He would like to know if this is this also enforced in the US or if alternative schemes of indemnification can be used.

As per ICH:

5.8 Compensation to Subjects and Investigators

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.

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

5.8.3 When trial subjects receive compensation, the method and manner of compensation should

comply with applicable regulatory requirement(s).

The item in question is 5.8.1 as this applies to US sponsors.

According to my research, in the US sponsors are not required to have insurance/indemnity policies, nor are research institutions required to provide compensation for clinical trials. The only requirements are as per ICH 5.8.2 and 5.8.3, and the fact that subjects must be informed of the type of compensation, if any. If no compensation is provided this must be clearly stated in the informed consent document.

Therefore my response to him will be that, currently, US regulatory authorities do not require the sponsor to provide insurance or to indemnify the investigator/institution against claims arising from a clinical trial.

Before submitting this answer, I wanted to double check with the Agency to make sure that there are no recent FDA regulations requiring this that I am unaware of.

Thank you very much.

Kind regards,
[redacted]