From: OC GCP Questions
To: [redacted]
Subject: IRB Research
Date: Thursday, July 24, 2014 1:23:07 PM

Good morning:

I cannot specifically answer your question as FDA does not deal with malpractice insurance. Also I am unclear if the two physicians are functioning as sponsor-investigators. FDA refers to individuals who initiate clinical trials as sponsor-investigators. As that term implies, they are considered the sponsor and the investigator for the study and thus are responsible for complying with regulations pertinent to both entities. As a sponsor, they would be responsible for obtaining the IND/IDE when necessary, obtaining Form FDA 1572s or investigator agreements for any other investigators who choose to participate in the study, ensuring IRB approval prior to initiate of the study across all sites, submitting progress reports and other required reports to FDA, etc. A 1572 form will need to be signed.

I can give you the following information regarding compensation of subjects during a clinical trial.

Before a clinical trial begins, the study sponsor should define and establish all trial-related responsibilities including compensation of subjects during a trial. Please see below:

Please see page 28, section "5.8 Compensation to Subjects and Investigators" in the "Guidance for Industry – E6 Good Clinical Practice: Consolidated Guidance", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf .

Also, please see section 4.8 of the above-referenced "Guidance for Industry – E6 Good Clinical Practice: Consolidated Guidance". On page 18, paragraph 4.8.10, it states that "[b]oth the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following: . . . (j) The compensation and/or treatment available to the subject in the event of trial-related injury."

Prior to the beginning of the trial, the investigator should have the institutional review board's written approval/favorable opinion of the written informed consent form and any other written information to be provided to subjects. [Emphasis added] If the study is conducted under an IND (investigational new drug) application, the application to FDA will have the IRBs that are participating in the trial. As stated in my original response an FDA-regulated study has safeguards in place (FDA regulations) that allows for safety of all subjects as long as the regulations are followed.

There is no "qualification process" related to IRBs for sponsor and industry according to FDA regulations. However, FDA would expect that the IRB that is chosen would meet the expectations of the IRB regulations that can be found at the link below. Sponsors should perform due diligence by possibly performing a web search to make sure that the IRB is in compliance with FDA regulations and that there is no past regulatory violations.

Please see the FDA regulations link below.
Clinical Trials and Human Subject Protection > Regulations

Also you will find this guidance document helpful. (Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects)
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

I hope this information was 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

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: Wednesday, July 23, 2014 2:39 PM
To: OC GCP Questions
Subject: RE: IRB Research

Just to give you some more detail, we are a physician malpractice insurance company…

Our clients, 2 physicians who are working on a research project approved by an outside IRB wants to conduct the research on patients at [redacted]. They don't have an IRB and want to know that if their policy covers research protocols (which it does), what is their obligation in assuring this research is safe?

Thank you again
[redacted]

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