From: OC GCP Questions
To: [redacted]
Subject: RE: Question Regarding Payment for Services
Date: Tuesday, November 17, 2015 1:07:00 PM

Dear [redacted],
FDA regulations and guidances do not address payments to IRBs for their services, and we don't get involved with contractual issues. The regulations for suspension/termination of research at 21 CFR 56.113 state:

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

You state that [the sponsor] "informed us that they had already reimbursed the site for the IRB related fees." It is not clear whether or not the sponsor intended for the site to pay the IRB fees on their behalf, rather than reimburse the IRB directly. You may want to recommend that this be clarified between the site and the sponsor; the site may not have realized they were supposed to pay the IRB fee from the funds provided by the sponsor, and this was a simple miscommunication.

FDA's regulations and the IRB's SOPs should be followed to determine whether or not to suspend/terminate the study, and how to proceed if the decision is made to suspend/terminate the study. You may also wish to obtain legal counsel regarding appropriate actions to pursue collection of payment.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Friday, November 13, 2015 5:11 PM
To: OC GCP Questions

Subject: Question Regarding Payment for Services

Good Afternoon,

I have a question related to our rights as a for profit business and the continuation of review and oversight of a research study. We have a client who is unwilling to pay for their IRB services. This also leads to concerns that they may not have the funds to adequately oversee and protect the subjects involved in their current research projects. As an IRB we feel that we have an obligation to the subjects involved in the current research study and would like some guidance on whether or not it would be appropriate to suspend/terminate. Our board members do not feel that it would be justified to suspend/terminate for non-payment. However as a business we cannot continue to provide this service free of charge.

In addition, many efforts have been made over the last year to make payment arrangements, etc. We have most recently contacted the sponsor regarding this issue and they informed us that they had already reimbursed the site for the IRB related fees.

In our process to suspend/terminate, safeguards for the subject are put in place to ensure the subjects are safely removed from the research. Should this come from a board or can this decision be made by our Organizational Official?

You guidance is greatly appreciated in this matter.

Sincerely,

[redacted]