From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 14, 2005 3:04 PM
To: [Redacted]
Subject: RE: financial question

Dear [Redacted], FDA does not deal with financial aspects of research activities. That being said, I believe that most IRBs use the fees to help to support and improve the IRB's activities and staffing. To the extend that the IRB believes these fees ought to be used for compliance or educational activities related to human subjects protection, that would seem appropriate to me as well. I think I'd be concerned if the fees collected were used for activities totally unrelated to the IRB's responsibilities--that is diverted by the institution for a totally unrelated activity. I also would be concerned if an IRB's staffing and support had to totally rely on such fees--personally, I think the fees ought to be supplemental to the IRB's budget. I don't know if this is the information you were seeking. If not, please let me know and I can try again.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [Redacted]
Sent: Friday, October 14, 2005 1:43 PM
To: gcpquestions@oc.fda.gov
Subject: financial question

I am seeking information about best practices for the use of fees that institutions charge to industry sponsors for IRB review - IRB review fees. Are these fees used for salaries, education, compliance, etc?
Thank you for your assistance.

[Redacted]

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