From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 07, 2006 4:57 PM
To: [purged]
Cc: Dada, Kavita; Woollen, Stan
Subject: RE: Patient Retention Campaign on a long-term study.
Dear [purged],

If you want to contact me to discuss your retention strategy, you can reach me at home (where I work) at 301-865-3053 or send an email to my address below . However, I am not sure that I would be the best person--my specialty is human subject protection. You might want to contact the FDA review division that is responsible for the particular study. Not knowing the test article, I can't tell you who to contact.

I'm sorry that I can't be more helpful.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Note new email address: Bonnie.Lee@FDA.HHS.GOV
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: Woollen, Stan
Sent: Thursday, March 30, 2006 5:19 PM
To: Dada, Kavita
Cc: Hommel, Carolyn - OC; Lepay, David
Subject: RE:

Name: [purged]

E-Mail: [purged]

Comments:
[purged] wishes to run a patient retention campaign on one of its long-term studies. Although materials will be submitted to IRBs and approved, we would like to be sure that our retention strategy is in alignment with the FDA regulations.

Question: Whom should I contact for advice?

Thank you for your help,

[purged]