From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, June 26, 2006 10:41 AM
To: [purged]
Subject: RE: GCP questions

Dear [purged],

Let me try to answer each of your questions in turn.

1. In my view, if an investigator did not actually participate in the trial (that is, did not include any patients in the trial) then simply noting that fact ought to be sufficient and unless required by some other entity, the financial disclosure form would not need to be filled out.

2. I have never heard anyone propose to send documents that need IEC approval to the individual members rather than to the secretary of the EC. The IEC/IRB is a committee that needs to have sufficient to staff to help it carry out its review responsibilities. To send documents to individual members seems to subvert that function.

3. Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When properly worded, the advertisement may include (but is not required to include) the following items.

· The name and address of the clinical investigator(s) or research facility;
· The condition under study or the purpose of the research;
· A brief summary of the criteria that will be used to determine eligibility for the study;
· A brief list of benefits, if any (for example, a no-cost health examination);
· The time or other commitment needed of the subjects; and
· The location of the research and the person or office to contact for further information.

FDA does not require IEC/IRB review and approval of listings of clinical trials on the Internet when the system format limits the information provided to basic trial information. Basic trial information is: the study title; purpose of the study; protocol summary; basic eligibility criteria; study site locations; and how to contact the site for further information. Examples of clinical trial listing services that do not need prospective IEC/IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the

government-sponsored AIDS Clinical Trials Information Service (ACTIS). Any clinical trial Internet listing that provides more than basic trial information is subject to IEC/IRB review. IECs/IRBs should pay particular attention to risk and benefit information to ensure it is presented in a balanced and fair manner.

I hope this information is helpful to you.

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.

From: [purged]
Sent: Tuesday, June 20, 2006 9:45 AM
To: OC GCP Questions
Subject: GCP questions

Dear,

I do have 3 questions that I like to have your opinion on:

1. Is it necessary that for investigators that did not include any patients during a clinical trial, the financial disclosure form is completed again at the end of the trial and 1 year after?

2. Is it allowed to send the documents that need IEC/IRB approval to the private addresses of the EC members rather than to the secretary of the EC? If yes, is there a need for an individual confidentiality agreement or confirmation of receipt per EC member?

3. Does all Website advertisements have to be approved by IEC/IRB, also if they only refer to the names of the investigators where studies are performed?

Thanks for your input.

kind regards

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