From: Lepay, David
Sent: Wednesday, July 07, 2004 7:46 AM
To: [Redacted]
Cc: Alderson, Norris
Subject: Your e-mail and voice-mail query

Dear Mr. [Redacted] :

Your e-mail was forwarded to my office which directs Good Clinical Practice Programs within FDA's Office of the Commissioner and its Office of Science and Health Coordination.

I am not clear on the information you are seeking. However, there are two approaches to obtaining information relating to IRB's and FDA-regulated clinical trials. The first is through FDA's clinical trials/Good Clinical Practice website (www.fda.gov/oc/gcp --- or simply www.fda.gov with a click on "Clinical Trials" from the rightmost menu). I might call your attention to FDA's Information Sheets for IRB's and Clinical Investigators which can be accessed from this site through the further link to "Guidances and Information Sheets" and hence to the Information Sheets. This guidance includes general information on a variety of topics as well as a section that covers frequently asked questions.

A second approach to obtaining information is through our GCP questions mailbox (gcpquestions@oc.fda.gov). From this mailbox, our office can answer queries relating to general clinical trial, Good Clinical Practice, and IRB issues. However, FDA can not provide information about a specific study or investigational product from this box (since such information is generally governed by laws relating to commercial confidential information).

I would encourage you first to visit the GCP website (and FDA regulations/guidances including the Information Sheets). If your question is not answered, please submit per above to the GCP questions mailbox.

I hope this information is helpful.

Sincerely,

David A. Lepay, MD PhD, Senior Advisor for Clinical Science and Director, GCP Programs, OSHC, Office of the Commissioner

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: Tuesday, July 06, 2004 11:11 PM

To: daniel.schultz@fda.hhs.gov; norris.alderson@fda.hhs.gov

Subject: Please assist ...

Dear Mr. Schultz,

Please assist. I went to the CDRH- FDA website researching Corporate IRB and discovered that instead I wanted information about non-Local IRBs. The data referred me to the Office of Science Coordination and Communication. On the CDRH- FDA website there is no identification of this group. I called the DIRECTORS office and Ardian 301 827 7975 advised me that the name was changed to Office of Science & Health Coordination and I should contact Norris Alderson at 301 827 3340.

I went to the FDA web site and there is no Office of Science & Health Coordination. I have lost 1 day trying to identify just who to ask my question to.

Your system should be more responsible than this.

Please direct me to the proper individual so I may advise my client about "non-Local IRBs" without delay.

Sincerely,

[Redacted]