From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, August 30, 2005 2:59 PM
To: [purged]
Subject: RE: FDA question

Dear Ms. [purged],

Your inquiry was referred to our office for a direct reply. As I understand it, you are looking for a list of investigators who have participated as clinical researchers for FDA regulated products. Such a list does not exist. Each sponsor hires its own investigators to conduct studies; the investigator, in turn prepares and signs a "Statement of the Investigator" , Form FDA-1572 that he/she provides to the sponsor. The sponsor uses the information from the 1572 to prepare its IND submission. By regulation (see 21 CFR 312.130), FDA is not permitted to disclose information contained in an IND.

If you are interested in information about clinical investigators who have been inspected by FDA, that information is readily available from our Good Clinical Practice Program website. You can find this information by visiting the following web page:
http://www.fda.gov/oc/gcp/clinenforce.html. The first entry on this page links you to inspectional information about investigators who have conducted studies that where submitted/reviewed by our Center for Biologics Evaluation and Research. The third entry on this page links to you inspectional information about investigators who have conducted studies that were reviewed by our Center for Drug Evaluation and Research.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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: [purged]
Sent: Monday, August 29, 2005 4:30 PM
To: Beers Block, Patricia
Subject: FW: FDA question

-----Original Message-----
From: [purged]
Sent: Monday, August 29, 2005 4:20 PM
To: 'OC Webmail'
Subject: RE: FDA question

Thank you for responding to my email. I am looking for filled out forms from the sponsor that the investigators have completed. My guess is that it would be a scanned one. I am really looking for a form to complete. I need the names of the investigators that have been on clinical trials.

Sincerely,

[purged]

-----Original Message-----
From: OC Webmail [mailto:wmail@OC.FDA.GOV]
Sent: Monday, August 29, 2005 4:03 PM
To: [purged]
Subject: RE: FDA question

Are you looking for Form 1572? If so, scroll down until you come to it on the following page. http://www.fda.gov/opacom/morechoices/fdaforms/default.html

-----Original Message-----
From:[purged]
Sent: Monday, August 29, 2005 3:27 PM
To: wmail@oc.fda.gov
Subject: FDA question

Name: [purged]

E-Mail: [purged]

URL:

Comments: We would like to purchase your listing of 1572 (title 21 Dept of Health and Human Services). The document that an investigator must fill out to participate on a study.

Sincerely,
[purged]