From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, November 09, 2006 1:14 PM
To: '**[Redacted]**'
Subject: RE:

Dear Dr. **[Redacted]**:

There isn't an easy way to obtain copies of 1572s which you signed or on which you are mentioned.

I checked FDA's Bioresearch Monitoring Information System (BMIS) file, but did not come up with any matches. BMIS, which can be accessed and searched online, contains information about clinical investigators (CIs), contract research organizations (CROs), and institutional review boards (IRBs) involved in the conduct of Investigational New Drug (IND) studies with human investigational drugs. The information has been abstracted from FDA Forms 1571 and 1572 and other pertinent documents contained in IND submissions (e.g., C.V.s, cover letters, investigator lists, etc.). Please note that this file contains a separate entry for each time an investigator, CRO or IRB is identified in a new submission. For example, if an investigator is named in 10 INDs, his/her name will appear 10 times in this file.

Here is the link to the database:
http://www.fda.gov/cder/foi/special/bmis/index.htm .

That database does not include information about subinvestigators (individuals named in block #6 of the 1572), however, so in order for you to obtain copies of any 1572 on which you were listed as a subinvestigator, you would have to know the IND # of the study that you were involved with so that the physical IND file could be searched.

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

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 14-B17
Rockville, MD 20857

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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: Dr. **[Redacted]**
Sent: Thursday, November 09, 2006 11:52 AM
To: OC GCP Questions
Subject:

Hi. My name is **[Redacted]** and I am a primary investigator for pharnaceutical research companies.
My question is ; How would I'll be able to obtain documents (1572) indicating what clinical trials I have either been either a PI or Sub-I of.
Thank you