From: Toth-Allen, Jean
Sent: Tuesday, August 15, 2006 2:54 PM
To: **[Redacted]**
Cc:
Subject: Availability of 1572s

Dear Mr. **[Redacted]** :

Dr. Lepay requested that I respond to your inquiry via the GCP query system.

The Form FDA 1572, while an FDA form, is provided for use by the study sponsor. While sponsors often do submit a copy with IND information, that is not required. The purpose of the form is to provide the sponsor, on one document, essential information concerning those involved with the conduct and/or oversight of a study at a particular site. In addition, with the statements included on the second page, the clinical investigator's signature provides the sponsor with a legal agreement that the clinical investigator will comply with the investigational plan and all applicable regulations. Therefore, when completed, this document becomes part of the sponsor's file for the study in question. That is, it is not an FDA document for that study, but the sponsor's study document, and therefore I do not see how we would be able to release it under FOI.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: **[Redacted]**
Sent: Friday, August 11, 2006 8:08 AM
To: **[Redacted]**
Cc: Lepay, David
Subject: RE: 1572 form

[Redacted] —sorry to be slow, I just got back from travel**[Redacted]** . David Lepay is the best person to answer your question. **[Redacted]**

From: **[Redacted]**
Sent: Wednesday, August 09, 2006 3:43 PM
To: **[Redacted]**
Subject: 1572 form

[Redacted] …..Sorry to bother but I figure you would know the answer to my question or point me to someone who does. I assume the 1572 Form is a public document. Is their a way to obtain the names and address of the investigators who sign the forms? Thanks…..**[Redacted]**