From: Toth-Allen, Jean
Sent: Friday, March 03, 2006 9:41 AM
To: '**[Redacted]**'
Subject: RE: FDA 1572 form

Dear Mr. **[Redacted]**:

Thank you for your inquiry regarding the FDA Form 1572.

The main purpose of the 1572 is to provide information to the study sponsor. Therefore, if a sub-investigator who was originally listed on the 1572 has left the study, this information should be documented in the study records and provided to the sponsor so that the IND is properly updated. However, the 1572 itself does not need to be revised and signed by the investigator.

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: Tuesday, February 21, 2006 2:19 AM
To: OC GCP Questions
Subject: FDA 1572 form

Dear,

Is it necessary to update the 1572 Form when a sub-investigator is no longer working on a trial or in a trial site?

Thanks for your response.

Kind Regards
[Redacted]