From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, March 03, 2006 10:37 AM
To: '**[Redacted]** '
Subject: RE: FDA form 1572

Dear Ms. **[Redacted]**,

There is no need to revise the 1572 when a subinvestigator leaves a study or no longer has responsibility for the conduct of a clinical study. Instead, his/her termination date and an explanation of the reasons for his/her termination should be documented in writing. This documentation should kept with other study records. Oh, one last thing- the sponsor should be made aware of all of this and sent a copy of the documentation.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 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: **[Redacted]**
Sent: Tuesday, February 28, 2006 2:14 PM
To: OC GCP Questions
Subject: FDA form 1572

If a sub-investigator leaves the clinical site (and therefore is no longer involved in the clinical trial), should their name be removed from box 6 of the FDA form 1572, or should it remain? I remember reading somewhere that all sub-investigators should remain on the 1572, even if they are no longer involved in the trial. If they were involved in any part of the trial, their name should remain. Is this true?

Thank you,

[Redacted]