From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, April 25, 2006 3:33 PM
To: **[Redacted]**
Subject: RE: Query regarding Updating Form FDA 1572

Dear Ms. **[Redacted]**:

You asked about the circumstances in which it would be necessary to update the information contained on the 1572.

I would like to start by referring you to 21 CFR 312.30, Protocol amendments. Under 21 CFR 312.30(c), the sponsor is required to submit a protocol amendment when a new investigator is added to the the study. So, if one investigator leaves and a new one takes his place, FDA would expect the sponsor to (1) submit a protocol amendment to the agency and (2) obtain a 1572 from the new investigator.

In answer to your question about other changes to information contained on the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes and inform the sponsor, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and signed by the investigator.

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 9C24
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: **[Redacted]**
Sent: Thursday, April 13, 2006 2:19 PM
To: OC GCP Questions
Subject: Query regarding Updating Form FDA 1572

To whom it may concern,

Could you inform me whether there are instructions on when a Form FDA 1572 would need to be updated?

It has been my experience that the general rule of thumb is of course when there is a new PI, and when there is a change in IRB or facility location. It has also been my experience that any changes in sub investigators is notified to the FDA via a text letter.

Could you confirm whether the FDA would expect a FDA 1572 to be updated when there is any change to any information currently disclosed on the form?

With Kind Regards,
[Redacted]