From: Hommel, Carolyn - OC
Sent: Thursday, July 06, 2006 7:55 AM
To: '**[Redacted]**'
Subject: RE: 1572 Questions/Clarification
Dear Ms **[Redacted]**:

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

Please refer 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. [As you know, sponsors must obtain a Form FDA-1572 from each investigator before permitting the investigator to begin participation in an investigation (see 21 CFR 312.53(c).]

In answer to your question about other changes to information contained on the 1572 (e.g., an IRB 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.

Please note that sponsors often submit the 1572 to the agency because it conveniently collects in one place the information that is required to be submitted under 21 CFR 312.23(a)(6)(iii)(b), however, there is no requirement to submit the actual form to us.

As for the date on the form--it refers to the Office of Management and Budget's (OMB's) time frame during which FDA may collect information contained in the form. Sites may continue to use the form, even though the OMB date has passed; it has no impact on the utility of the form itself. In addition, FDA does <u>not</u> expect sponsors to ask clinical investigators to routinely "update" forms previously submitted simply because the OMB expiration date has changed.

There is no way to automatically be notified that a new version of the 1572 has been created. I would suggest, however, that at the time a site needs to complete a new form, they visit FDA's Forms Distribution Page (http://www.fda.gov/opacom/morechoices/fdaforms/cder.html) and download the most recent version posted there.

I hope this answers your questions.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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.

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, July 05, 2006 5:02 PM
To: Hommel, Carolyn - OC
Subject: 1572 Questions/Clarification

Carolyn,

Per our conversation earlier today, please confirm that if there is no change on a 1572 that we do not need to create a new 1572 with the latest version.

Also, please confirm that a new 1572 does not need to be generated unless there is a change to the Sub-Investigator's only. Any other changes; such as laboratory, research facility, IRB, etc; needs to be told to the sponsor via correspondence not a new 1572, who in turn is responsible for notifying the FDA.

Thanks in advance,

Kind Regards,
[Redacted]