From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, April 13, 2005 12:03 PM
To: [purged]
Subject: RE: Outdated 1572 form

Dear Ms. [purged]:

Your question about the need update a 1572 simply to use the most recent version of the form was forwarded to me for a response. If the information provided on an earlier version of the form has not changed, there is no need to send in a NEW form simply to use the "most current" version.

The date on the Form FDA 1572 refers to the time period established by the Office of Management and Budget during which the information requested in the form may continue to be collected. An agency may not conduct or sponsor collection of information, and a person is not required to respond to a request for collection of information, unless the form displays a currently valid OMB control number. The OMB expiration dates for the "Investigational New Drug Application (IND)" Form FDA-1571 and the "Statement of Investigator" Form FDA-1572 (found on the FDA Forms Distribution Page) have been extended to Jan. 31, 2006.

A 1572 must be signed as each new investigator joins the study. If there are other changes to information contained on the 1572 (e.g., an IRB address change, the addition of new sub-investigators, 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. While all such changes should be documented, such changes do not necessarily require use of the 1572 to do so.

I hope this is helpful.

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)
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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.

-----Original Message-----
From: [purged]
Sent: Wednesday, April 13, 2005 11:01 AM
To: 'gcpquestions@oc.fda.gov'
Subject: Outdated 1572 form

To whom it may concern:

History of 1572 at site:

Original: [purged]
Updated: [purged] to add 2 sub investigators
Updated [purged] (no changes to information on 1572, just rearranged order of labs, expanded abbreviations) Unfortunately an obsolete FDA 1572 form was used (expired [purged])

Now the site wants to update the 1572 again using the most recent FDA 1572 form (dated [purged]) Is this necessary? Which 1572 should be considered the most recent?

Thanks for your assistance and advice.

[purged]

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