From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, January 06, 2006 12:39 PM
To: **[Redacted]**
Subject: RE: 1572 question
Dear Ms. **[Redacted]**:

Yes, sites may use the form with the January 31, 2006 expiration date.

The date on the form 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. FDA does not expect sponsors to ask clinical investigators to routinely "update" forms previously submitted simply because the OMB expiration date has changed.

Unfortunately there is no way to automatically be notified that a new version of the 1572 has been created. I would suggest 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 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)
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.

-----Original Message-----
From: **[Redacted]**
Sent: Friday, January 06, 2006 9:45 AM
To: gcpquestions@oc.fda.gov
Subject: 1572 question

Hello-

I have a question regarding the 1572 that expires at the end of the month. With the current 1572 expiring on 31 January 2006, do sites that have studies currently running be required to obtain a new 1572 or will the one with the expiration date of 31 January 2006 be satisfactory? I understand that studies that have not begun will use the new version of the 1572.
THank you for your time.
Sincerely,

[Redacted]