From: Toth-Allen, Jean
Sent: Friday, January 27, 2006 7:44 AM
To: '**[Redacted]**
Cc: **[Redacted]**
Subject: RE: FDA Form 1572 expiring 01/31/2006

Dear Mr. **[Redacted]** :

Thank you for your inquiry regarding the expiration date on the FDA Form 1572.

The date on the form refers to the Office of Management and Budget's (OMB's) approval period 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. Furthermore, FDA does not expect sponsors to ask clinical investigators to routinely "update" forms previously submitted simply because the OMB expiration date has changed.

If and when a site needs to complete a new 1572, they should visit FDA's Forms Distribution Page (http://www.fda.gov/opacom/morechoices/fdaforms/cder.html) and download the most recent version posted there. It is doubtful that there will be any significant changes to the new version, merely an updated OMB expiration date.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Thursday, January 26, 2006 2:06 PM
To: **[Redacted]** ; OC GCP Questions
Subject: RE: FDA Form 1572 expiring 01/31/2006

> Hello **[Redacted]** :
> We are looking for guidance regarding the 3/05 version of FDA form 1572 which indicates an expiration date of January 31, 2006. What is the best Good Clinical Practice to handle 1572 that have been executed and submitted to an IRB that have this version date of the 3/05 FDA form 1572? Once the new version is released, will previously executed 1572 bearing this date need to be revised? Will there be significant changes to the new 1572? Please advise.
> Thank you,
> **[Redacted]**

From: **[Redacted]**
Sent: Thursday, January 19, 2006 10:33 AM
To: '**[Redacted]** '
Subject: RE: FDA Form 1572 expiring 01/31/2006

Thank you,
Please advise if 1572s executed with the January 31, 2006 date will need to be re-generated.
Thank you again,
[Redacted]

From: **[Redacted]**
Sent: Thursday, January 19, 2006 8:47 AM
To: **[Redacted]**
Subject: RE: FDA Form 1572 expiring 01/31/2006

Mr. **[Redacted]**,
The FDA Forms Officer says Form FDA 1572 will be revised once there's new approval which normally happens somewhere close to the expiration date; any overlap will be covered by a 30 day extension which will not show on the form. I hope this helps.

> -----Original Message-----
> **From:** **[Redacted]**
> **Sent:** Wednesday, January 18, 2006 5:47 PM
> **To:** **[Redacted]**
> **Subject:** FDA Form 1572 expiring 01/31/2006
>
> Hello **[Redacted]** :
> Please advise regarding expiration date of 1572 version 3/05 posted on the FDAs web site. The top right corner states "Expiration Date of January 31, 2006", will all 1572 generated stating this date need to be re-generated etc...?
> When will the FDA post a newer version of the 1572?
> Thank you,
>
> *[Redacted]*