From: OC GCP Questions

To: Subject: Date:

? re 1572_is a new version being generated Thursday, June 11, 2015 10:26:41 AM

Good morning -

The Center for Drugs (CDER) updates the form and they tell me they don't know when the new form will be completed. You can however use the expired form. You can email CDER directly to check in the future at druginfo@fda.hhs.gov

Kind regards

Doreen M. Kezer, MSN Senior Health Policy Analyst Office of Good Clinical Practice Office of the Commissioner, 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.

From:

Sent: Wednesday, June 10, 2015 3:02 PM

To: OC GCP Questions

Subject: ? re 1572 is a new version being generated

Good afternoon,

The 1572 found on the NCI Investigator Registration website has an OMB expiration date of 2016.

Form Approved: OMB No. 0925-0613

Expiration Date: 03/31/2016

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

The 1572 found on the FDA Forms website still references an OMB date of 2015.

Form Approved: OMB No. 0910-0014

Expiration Date: April 30, 2015 See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

Can you tell me if the FDA document is being updated?

Thank you,