4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0031]

Draft Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance document entitled "Informed Consent Information Sheet." A notice of availability requesting comments on the draft guidance document appeared in the Federal Register of July 15, 2014. The Agency is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Building 32, Silver Spring, MD 20993, marsha.melvin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 15, 2014 (79 FR 41291), FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance document entitled "Informed Consent Information Sheet."

The Agency has received a request for a 30-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA is reopening the comment period for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: September 19, 2014

Leslie Kux,

Assistant Commissioner for Policy.

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