4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0835]

# Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB." The guidance announced in this document discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. The guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 (1-888-463-6332 or 301-796-3400); or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville

Pike, suite 200N, Rockville, MD 20852-1448 (1-800-835-4709 or 301-827-1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4622, Silver Spring, MD 20993 (1-800-638-2041 or 301-796-7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Bridget Foltz, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5174 Silver Spring, MD 20993, 301-796-8340.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB." The guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. In particular, the guidance discusses eight steps to be considered when transferring oversight of a previously approved clinical investigation from one IRB to another IRB. These include identifying those studies for which IRB oversight is being transferred; ensuring availability and retention of pertinent records;

establishing an effective date for the transfer of oversight; conducting a review of the study(ies) by the receiving IRB, where appropriate; confirming or establishing the date for the next continuing review; determining whether the consent form needs to be revised; notifying the key parties; and updating IRB registration information. The IRB transfer process is expected to vary depending on the reasons for the transfer, the parties involved, and the number and risk of the studies being transferred.

To enhance human subject protections and reduce regulatory burden, FDA and the Office for Human Research Protections (OHRP) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. This guidance document was developed as a part of these efforts and in consultation with OHRP.

In the Federal Register of June 12, 2012 (77 FR 34958), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and considered them in preparing the final guidance. In response to the comments, FDA added a recommendation that the receiving IRB notify the sponsor if it decides to suspend or terminate study approval. FDA also clarified both drug and device sponsor's reporting requirements related to such suspensions and terminations. Section III(6) was modified to recommend the use of a letter to provide currently enrolled subjects with any changes in contact information regarding subject rights or research-related injuries from a resulting IRB transfer. In addition, numerous editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2012.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not

create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 56 have been approved under OMB control number 0910-0130.

## III. Comments

Interested persons may submit either electronic comments regarding this document 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.regulations.gov or

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm.

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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