4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0847]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Institutional Review Board Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an Investigational New Drug/Investigational Device Exemption is Needed; 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: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed." The guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in fulfilling responsibilities related to reviewing the qualifications of investigators and adequacy of research sites, and determining whether an investigational new drug (IND) application or investigational device exemption (IDE) is required, to protect the rights and welfare of human subjects involved in biomedical research.

DATES: Submit written or electronic 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. 4621, 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 on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Doreen Kezer, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5170, Silver Spring, MD 20993-0002, 301-796-8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is

Needed." This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in determining that the proposed research satisfies the criteria for approval contained in 21 CFR 56.111, that "[r]isks to subjects are minimized…[and] reasonable in relation to anticipated benefits, if any, to subjects..." In particular, the guidance addresses the IRB's role in reviewing: (1) The qualifications of clinical investigators, (2) the adequacy of the research site, and (3) the determination of whether an IND/IDE is required.

Many of the recommendations in this guidance have appeared in other FDA guidance documents. FDA has compiled the recommendations from these various sources into this guidance to ensure that all IRBs have access to it. The guidance also explains how IRBs may efficiently fulfill these important responsibilities.

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

In the Federal Register of November 20, 2012 (77 FR 69631), 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 the final guidance, FDA clarified that IRBs, sponsors, and clinical investigators all have responsibility for ensuring that the research complies with applicable laws and regulations and that risks to subjects are minimized. FDA also made changes to confirm that the recommendations in the guidance may

be fulfilled by any IRB, whether independent or affiliated with an institution, and whether serving as a local IRB or as the central IRB, and made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated November 2012, and replaces Question 56 in FDA's guidance entitled "Institutional Review Boards Frequently Asked Questions--Information Sheet--Guidance for Institutional Review Boards and Clinical Investigators."[1]

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 subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). None of the collections of information referenced in this guidance are new or represent material modifications to previously approved collections of information. The collections of information under 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information under 21 CFR part 56 have been approved under OMB control number 0910-0130.

III. Comments

[1] See http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm#GeneralQuestions.

Interested persons may submit either electronic comments regarding this guidance 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.regulations.gov or http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm

Dated: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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