products in determining that the proposed research satisfies the criteria for approval contained in 21 CFR 56.111, that ''* * * the risks 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 investigators, (2) the adequacy of the research site, and (3) the determination of whether an IND/IDE is needed. When finalized, this guidance will supersede Question 56 in FDA's January 1998 guidance entitled ''Institutional Review Boards Frequently Asked Questions—Information Sheet Guidance for Institutional Review Boards and Clinical Investigators.'' [1]

FDA is issuing this as a draft guidance. Although many of these recommendations have appeared in other FDA guidance documents, FDA has compiled the information here in order to assure that all IRBs are aware of and have access to it. The guidance also explains how IRBs may efficiently fulfill these important responsibilities.

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services (HHS) 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 addition, FDA acknowledges HHS's publication of the advanced notice of proposed rulemaking (ANPRM), ''Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,'' in the **Federal Register** of July 26, 2011 (76 FR 44512). In the ANPRM, HHS sought comment on whether the Federal human subject protection regulations should be modified in a number of ways. In finalizing this draft guidance, ''IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed,'' FDA intends to consider relevant public comments submitted in response to both the draft guidance and the ANPRM.

The draft guidance is being issued consistent with FDA's Good Guidance Practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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.

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

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collections provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information under 21 CFR Part 312 have been approved under OMB control number 0910–0014; and the collections of information under 21 CFR Part 812 have been approved under OMB control number 0910–0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.

IV. Electronic Access

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

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0643]

Draft Guidance for Industry on Electronic Source Data in Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Electronic Source Data in Clinical Investigations.'' This document revises and updates the draft guidance entitled ''Electronic Source Documentation in Clinical Investigations.'' This revised draft document provides guidance to sponsors, contract research organizations (CROs), data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. The revised draft guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within January 22, 2013.

ADDRESSES: Submit written requests for single copies of the revised draft 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; 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; 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. 4613, Silver Spring, MD 20993–0002; and Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4173, Silver Spring,

MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the guidance 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: Ronald Fitzmartin, Office of Planning and Informatics, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993–0002, 301–796–5333.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Electronic Source Data in Clinical Investigations.'' This document revises and updates the draft guidance entitled ''Electronic Source Documentation in Clinical Investigations.'' This revised draft document provides guidance to sponsors, CROs, data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. The revised draft guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.

With the use of computerized systems for capturing clinical study data, it is common to find at least some source data recorded electronically. Common examples include clinical data initially recorded in electronic health records maintained by hospitals and institutions, electronic laboratory reports, electronic medical images from devices, and electronic diaries provided by study subjects.

Capturing source data electronically should help to: (1) Eliminate unnecessary duplication of data; (2) reduce the possibility for transcription errors; (3) encourage entering source data at the time of a subject's visit; (4) eliminate transcribing source data before entering the data into an electronic data capture system; (5) promote real-time data access for review; and (6) ensure the accuracy and completeness of the data.

In the **Federal Register** of January 7, 2011 (76 FR 1173), FDA announced the availability of the draft guidance entitled ''Electronic Source Documentation in Clinical Investigations.'' Based on public comment, we have revised the January 2011 draft guidance to clarify a number of points made by industry. The Agency is publishing the draft guidance as a revised draft guidance to collect additional public comments. This revised draft guidance addresses source data (from clinical investigations) used to fill the predefined fields in an electronic case report form (eCRF), according to protocol. The draft guidance discusses the following topics related to electronic source data:

- Identifying and specifying authorized source data originators;
- Creating data element identifiers to facilitate sponsors, FDA, and other authorized parties in examining the audit trail of data;
- Capturing source data into the eCRF using either manual or electronic capture methods; and
- Investigator responsibilities with respect to reviewing and retaining electronic data.

The revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CDR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. 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. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

III. Paperwork Reduction Act of 1995

The draft guidance refers to collections of information that 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 draft guidance pertains to sponsors, clinical investigators, contract research organizations, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others, or keep certain records and make them available to FDA inspectors. The information collection discussed in the draft guidance is contained in our investigational new drug regulations (21 CFR 312) and approved under OMB control number 0910–0014, including §§ 312.62(b) and 312.58(a). In addition, the collection of information in 21 CFR part 11, as discussed in the draft guidance, is approved under OMB control number 0910–0303. OMB approval of the information collection in the guidance entitled ''Computerized Systems Used in Clinical Investigations,'' as mentioned in the draft guidance, is discussed in the May 10, 2007 (72 FR 26638), **Federal Register** Notice of Availability of that guidance. The capture, review, and archiving of electronic source data, as described in the draft guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have and are experienced with using the computer-based equipment and software necessary to be consistent with the guidance.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/RegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: November 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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