goal of 10 percent of eligible households, ATSDR/NCEH will consent and collect samples from approximately 15 households per EA or households annually (152*10/100*5). The average time burden is estimated as 15 minutes per response, or 19 hours annually.

ATSDR estimates the total annualized time burden is 961 hours. Participation is voluntary, and there are no costs to respondents other than their time.

Public health professionals, environmental risk managers, and other decision makers can use EA results to make informed decisions about the sources and impact of PFAS contamination in environmental media within their own community and jurisdiction. The data will support their recommendations for public health actions to reduce or eliminate harmful levels of PFAS in the local environment. These EAs are not intended to yield information about PFAS exposure that will be generalized beyond the defined boundaries of each investigation; however, ATSDR/NCEH will use these EA findings to inform a future national PFAS health study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Potential EA Heads-of-Households	Household Eligibility Screener	1,170	1	5/60	98
EA Adults	*Exposure Questionnaire for Biological and Environmental Testing (Adults).*	1,440	1	30/60	720
EA Parents	EA Questionnaire for Biological Testing (Child).	264	1	15/60	66
EA Children	EA Questionnaire for Biological Testing (Child).	191	1	15/60	48
EA Heads-of-Households	*Household Recruitment Script for Environmental Sampling.*	117	1	5/60	10
	Environmental Sample Collection Form.	76	1	15/60	19
Total					961

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1224]

Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Use of Electronic Health Record Data in Clinical Investigations.'' The guidance provides recommendations for sponsors, clinical investigators, contract research organizations (CROs), institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations. The guidance finalizes the draft guidance issued in May 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on July 19, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1224 for ''Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. 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.

FOR FURTHER INFORMATION CONTACT: Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3348, Silver Spring, MD 20993–0002, 301–796–2500, *cheryl.grandinetti@fda.hhs.gov;* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *ocod@fda.hhs.gov;* or Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 1–800–638–2041 or 301–796–5528, *bakul.patel@fda.hhs.gov* or *DigitalHealth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Use of Electronic Health Record Data in Clinical Investigations.'' The guidance is intended to assist sponsors, clinical investigators, CROs, IRBs, and other interested parties on the use of EHR data in FDA-regulated clinical investigations. In an effort to modernize and streamline clinical investigations, the goals of the guidance are to facilitate the use of EHR data in clinical investigations and to promote the interoperability of EHR and EDC systems.

In the **Federal Register** of May 17, 2016 (81 FR 30540), FDA announced the availability of the draft guidance. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. A summary of changes includes clarifying the following: (1) The types of clinical investigations using EHR data as source data that fall under the scope of the guidance; (2) recommendations on the use of EHR and EDC systems that are interoperable or fully integrated; (3) recommendations on the use of certified and noncertified EHR technology; (4) how electronic source data principles apply to EHR data used as source data; and (5) inspection, recordkeeping, and record retention requirements. This guidance finalizes the draft guidance issued in May 2016.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Use of Electronic Health Record Data in Clinical Investigations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. 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 guidance pertains to sponsors, clinical investigators, CROs, IRBs, and other interested parties who use EHR data as electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others or who keep certain records and make them available to FDA inspectors. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR 812.140 have been approved under OMB control number 0910–0078. The use of EHRs as a source of data, as described in the guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have experience and are experienced with using computer-based equipment and software necessary to be consistent with the guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *https://www.regulations.gov*.

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15390 Filed 7–18–18; 8:45 am]

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