

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

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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Use of Electronic Health Record Data in Clinical Investigations; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Use of Electronic Health Record Data in Clinical Investigations." The draft guidance is intended to assist sponsors, clinical investigators, contract research organizations, institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft 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; the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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; 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; or Irfan Khan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3563, Silver Spring, MD 20993-0002, 301-796-7100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Use of Electronic Health Record Data in Clinical Investigations." The draft guidance is intended to assist sponsors, clinical investigators, contract research organizations, IRBs, and other interested parties on the use of EHR data in FDA-

regulated clinical investigations. In particular, the draft guidance provides recommendations on the following: (1) Deciding whether and how to use EHRs as a source of data in clinical investigations; (2) using EHRs that are interoperable with electronic systems supporting clinical investigations; (3) ensuring the quality and the integrity of EHR data that are collected and used as electronic source data in clinical investigations; and (4) ensuring that the use of EHR data collected and used as electronic source data in clinical investigations meet FDA's inspection, recordkeeping, and record retention requirements. In an effort to modernize and streamline clinical investigations, the goals of the draft guidance are to facilitate use of EHR data in clinical investigations and to promote the interoperability of EHRs and electronic systems supporting the clinical investigation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the use of EHR 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.

II. Paperwork Reduction Act of 1995

This 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, IRBs, and other interested parties who use EHR systems 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 discussed in the draft guidance are contained in our investigational new drug regulations in part 312 (21 CFR part 312), approved under OMB control number 0910–0014, including §§ 312.58(a) and 312.62(b); investigational device exemption regulations in § 812.140 (21 CFR 812.140) approved under OMB control number 0910–0078; and electronic records; electronic signatures regulations in 21 CFR part 11, approved under OMB control number 0910–0303. The use of EHR systems as a source of 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 computer-based equipment and software necessary to be consistent with the draft guidance.

III. Electronic Access

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

Dated: May 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11564 Filed 5–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, NIAID Peer Review Meeting.

Date: June 9, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 3G61, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Travis J Taylor, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G62B 5601 Fishers Lane, MSC 9823,

Bethesda, MD 20892–9823, (240) 669–5082, Travis.Taylor@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: June 14, 2016.

Time: 12:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 3F100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834 Rockville, MD 20852, 301–496–2550, amir.zeituni@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 11, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11554 Filed 5–16–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institutes of Health (NIH) Loan Repayment Programs; Office of the Director (OD)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Division of Loan Repayment (DLR), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2016, and page numbers 8514–8516, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office