

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 In particular, the draft guidance provides recommendations on the following: (1) Deciding whether and how to use EHRs as a source of data in clinical investigations; (2) using EHRs that are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 In an effort to modernize and streamline clinical investigations, the goals of the draft guidance are to facilitate use of EHR data in clinical investigations and to promote the interoperability of EHRs and electronic systems supporting the clinical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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the use of EHR data in clinical investigations.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This draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44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 The draft guidance pertains to sponsors, clinical investigators, contract research organizations, IRBs, and other interested parties who use EHR systems as electronic source data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 The collections of information discussed in the draft guidance are contained in our investigational new drug regulations in part 312 (21 CFR part 312), approved under OMB control number 0910–0014, including §§ 312.58(a)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 The use of EHR systems as a source of data, as described in the draft guidance, would not result in any new costs,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.*

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**BILLING CODE 4164–01–P**

## 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](mailto: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](mailto: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.*

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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