document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 9, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–08620 Filed 4–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1083]

Innovations in Medical Evidence Development and Surveillance-Methods Research Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of Center for Drug Evaluation and Research (CDER). The goal of the CDER is to support the development of appropriate methodologies to conduct medical product safety surveillance in large electronic databases. Innovations in Medical Evidence Development and Surveillance (IMEDS)-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases.

DATES: 1. The application due date is June 15, 2015.

2. The anticipated start date is July 15, 2015.

3. The opening date is April 13, 2015.

4. The expiration date is June 16, 2015.

ADDRESSES: Submit the electronic application to: *http://www.grants.gov*. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Patrick Archdeacon, Food and Drug Administration, Bldg. 51 Rm.6314, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3952; or Vieda Hubbard, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240–402–7588.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: *http://www.grants.gov/*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–15–010 93.103

A. Background

Section 905 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) mandates FDA to develop an enhanced ability to monitor the safety of drugs after these products reach the market. In response to this mandate, FDA launched its Sentinel Initiative, a long-term program designed to build and implement an electronic system for monitoring the safety of medical products in the post market setting. FDA has already created significant infrastructure on which to operate such a system: Through its Mini-Sentinel pilot, a distributed database with access to more than 150 million patient records has been created (the Sentinel Distributed Database). In order to optimally leverage these data, however, new analytic methodologies will be required. IMEDS-Methods is a program within the Reagan-Udall Foundation that supports FDA's scientific mission of serving public health needs by initiating and facilitating research into the methods of safety evaluation in large databases. IMEDS-Methods aims to improve the tools for conducting post-marketing safety surveillance using automated healthcare data and to foster their adoption.

B. Research Objectives

IMEDS plans to conduct methods research in five core areas: (1) Addressing bias in estimates from observational studies; (2) better understanding uses and limitations of the data; (3) applying lessons learned from earlier IMEDS projects to FDA surveillance activities; (4) expanding the surveillance question to continuous risk/benefit assessment; and (5) continuing to support qualified investigators in industry, government, and academic settings by providing access to de-identified electronic healthcare data and computing resources through the IMEDS Research Laboratory.

C. Eligibility Information

Eligibility is limited to the Reagan-Udall Foundation. The Reagan-Udall Foundation has established the IMEDS-Methods program, which is uniquely positioned to develop the new methodologies required for FDA to conduct effective active post market safety surveillance of medical products using large electronic health care data. The IMEDS organization has developed a network of statisticians, epidemiologists, data scientists, and clinicians who have experience operating in both the IMEDS research laboratory and also familiarity with the Sentinel Distributed Database. In addition, through the Reagan-Udall Foundation public-private partnership, the IMEDS-Methods program has a unique ability to convene FDA, patients, academics, government, and industry so that the findings and tools developed through its research agenda will be promulgated and adopted.

II. Award Information/Funds Available

A. Award Amount

FDA/CDER intends to fund up to $1,000,000 in fiscal year 2015 in support of this program project. It is anticipated that only one award will be made, not to exceed $1,000,000 (direct plus indirect) for total costs.

B. Length of Support

There is a one year period of performance beginning on June 15, 2015 or the date of award.

III. Electronic Application, Registration, and Submission

Only one electronic application will be accepted. To submit an electronic application in response to this FOA, the applicant should first review the full announcement located at *http://www.grants.gov/*. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

For the electronically submitted application, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password

- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit the electronic application to: *http://www.grants.gov*.

Dated: *April 8, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08613 Filed 4–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0382-30–D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0382, scheduled to expire on May 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before May 15, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0382 and document identifier HHS–OS–30D for reference.

Information Collection Request Title: Evaluation of Pregnancy Prevention Approaches—First Follow-up

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting an extension without change of a currently approved information collection request by OMB. The purpose of the extension is to complete the ongoing follow-up data collection for the Evaluation of Adolescent Pregnancy Prevention Approaches (PPA), a multi-site random assignment evaluation of promising approaches to teen pregnancy prevention.

Need and Proposed Use of the Information: The PPA study is being conducted in seven program sites around the country. The proposed extension is necessary to complete ongoing follow-up data collection in five of the seven study sites. The resulting data will be used in a rigorous program impact analysis to assess the effectiveness of each program in reducing rates of teen pregnancy and associated sexual risk behaviors.

Likely Respondents: The 1484 youth participants who agreed to participate in the study upon sample enrollment in 5 impact study sites.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Oklahoma Institute for Child Advocacy (OICA)	294	2	42/60	412
Ohio Health	148	3	42/60	310
Children's Hospital Los Angeles	254	2	36/60	305
EngenderHealth	240	2	36/60	288
Princeton Center for Leadership Training	548	2	36/60	658
Total				1,973

Terry S. Clark,

Assistant Information Collection Clearance Officer.

[FR Doc. 2015–08541 Filed 4–14–15; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development Notice of Closed Meeting

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 meeting.

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

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel PDB–P2C_Infrastructure/Center Grants.

Date: June 29, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.