

office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the TA Project Plan.

Submit electronic comments on the TA Project Plan 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:**

Colleen Ratliffe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1158, Silver Spring, MD 20993, email: [CDERDataStandards@fda.hhs.gov](mailto:CDERDataStandards@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of the TA Project Plan. This TA Project Plan will be the primary document for guiding all major aspects of FDA's multi-year initiative to develop and implement TA standards to support the regulatory review process for drugs and biologics. Updated annually and made available for public comment, the plan will provide the overall management framework for addressing and accomplishing the PDUFA V objectives to develop and adopt clinical terminology standards for TAs.

Standardized data elements and terminologies enable data from multiple trials to be grouped for analysis, and meta-analyses within and across drug classes. In 2011, in response to an urgent need to further standardize study data terminologies and concepts for efficacy analysis, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) compiled a prioritized list of disease and TAs and made it available on FDA's Web site.<sup>1</sup> Several factors were considered in the identification and prioritization of these TAs: (1) Active investigational new drug applications (INDs), (2) existing standardization projects underway, and (3) industry input on drug development pipeline activity.

The Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the Prescription Drug User Fee Act (PDUFA V) in July 2012. The PDUFA V Reauthorization Performance

Goals and Procedures (Section XII)<sup>2</sup> states that FDA will prepare a project plan for developing distinct TA terminology standards, using a public process that allows for stakeholder input through open standards development organizations.

In November 2012, FDA requested public input relevant to study data standards by: (1) Convening a public meeting on November 5, 2012, entitled "Regulatory New Drug Review: Solutions for Study Data Exchange Standards" to receive input from stakeholders on the advantages and disadvantages of current and emerging alternatives for the exchange of regulated study data, and (2) issuing a notice in the August 14, 2012 **Federal Register** (77 FR 48491), informing the public of FDA's intent to prioritize and develop study data standards for identified TAs, and requesting public comment on the TA roadmap as well as recommendations on how the effort could be accomplished most efficiently. The TA Project Plan was developed based upon information from the November 5, 2012, public meeting and public comments submitted in response to the November 20, 2012, **Federal Register** notice on the prioritization of TAs.

The TA standards should enable and enhance the ability to integrate, analyze, report, and share study data. As described in the TA Project Plan, CBER and CDER are actively collaborating with external stakeholders to support the development of these TA standards. Stakeholders are encouraged to engage in and support these data standardization efforts where possible, including providing feedback on the TA Project Plan.

**II. Comments**

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

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/>

[DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm), <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>.

Dated: October 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-24909 Filed 10-23-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request; Application for the Postdoctoral Research Associate Program**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 July 23, 2013, pages 44135-44136, 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 National Institute of General Medical Sciences (NIGMS), National Institutes of Health 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 of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Ms. Tammy Dean-Maxwell, NIGMS, NIH, Natcher Building, Room 3AN-44, 45 Center Drive, MSC 6200,

<sup>1</sup> <http://www.fda.gov/TherapeuticAreaStandards>.

<sup>2</sup> <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

Bethesda, MD 20892–6200, or call non-toll-free number 301–594–2755 or Email your request, including your address to [deanmat@mail.nih.gov](mailto:deanmat@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* The Postdoctoral Research Associate Program is an Reinstatement without change for the currently approved collection, OMB No. 0925–0378, National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The Postdoctoral Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in an NIGMS designated emerging area of research or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of

Health or the Food and Drug Administration. The goal of the program is to develop leaders in designated emerging areas of research for key positions in academic, industrial, and Federal research laboratories.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 331.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
PRAT Primary Application (NIH 2721–1)	Applicants	25	1	8	200
PRAT Request for Evaluation Form (NIH 2721–2)	Referee	75	1	105/60	131

Dated: September 27, 2013.

**Sally Lee,**

*Executive Officer, National Institute of General Medical Sciences, National Institutes of Health.*

[FR Doc. 2013–24997 Filed 10–23–13; 8:45 am]

**BILLING CODE 4140–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Heart, Lung, and Blood Institute; 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Atlas of Lung Development Research Centers and Tissue Core.

*Date:* November 7, 2013.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Stephanie L Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, [constantsl@nhlbi.nih.gov](mailto:constantsl@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Atlas of Lung Development Data Coordinating Center.

*Date:* November 7, 2013.

*Time:* 2:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, [constantsl@nhlbi.nih.gov](mailto:constantsl@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; SBIR Phase IIB Bridge Awards.

*Date:* November 8, 2013.

*Time:* 8:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Crystal City at Washington Reagan National, 2399 Jefferson Davis Hwy, Arlington, VA 22202.

*Contact Person:* Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, [creazzotl@mail.nih.gov](mailto:creazzotl@mail.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; SBIR Phase IIB Small Market Awards.

*Date:* November 8, 2013.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Crystal City at Washington Reagan National, 2399 Jefferson Davis Hwy, Arlington, VA 22202.

*Contact Person:* Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, [creazzotl@mail.nih.gov](mailto:creazzotl@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 18, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013–24874 Filed 10–23–13; 8:45 am]

**BILLING CODE 4140–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Alcohol Abuse and Alcoholism; 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 sections 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