

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.

FOR FURTHER INFORMATION CONTACT: Nikunj B. Patel, Clinical Outcome Assessments Staff (formerly Study Endpoints and Labeling Development (SEALD)), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6369, Silver Spring, MD 20993-0002, 240-402-6502, email: COACompendium@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Capturing outcomes that are important to patients in clinical trials is a high priority for FDA. The pilot COA Compendium is part of FDA's efforts to foster patient-focused drug development.¹ The COA Compendium is intended to facilitate communication and to provide clarity and transparency to drug developers and the research community by collating and summarizing clinical outcome assessment information for many different diseases and conditions into a single resource. It can be used as a starting point when considering how certain clinical outcome assessments might be utilized in clinical trials and will likely be most informative in early drug development. The public is referred to the following FDA Web site for additional background information, along with the pilot COA Compendium: <http://www.fda.gov/COACompendium>.

II. Establishment of a Docket and Request for Comments

To help FDA determine the utility of the COA Compendium, develop future iterations of the COA Compendium, and identify best methods for conveying COA Compendium information on FDA's Web site, FDA is launching the pilot COA Compendium and soliciting public suggestions, recommendations, and comments for each aspect of the COA Compendium mentioned on the following FDA Web site: <http://www.fda.gov/COACompendium>.

¹ The term *drug*, as used in this notice, refers to human drugs including biological products.

www.fda.gov/COACompendium. Specifically, FDA welcomes your comments concerning: (1) The utility of the COA Compendium; (2) the best approach for developing future iterations of it, including any suggested expansions of its scope; and (3) COA Compendium-related questions you would like FDA to address in its future communications. FDA will consider all comments submitted but will generally not respond directly to the person or organization submitting the comment.

Dated: January 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-00529 Filed 1-12-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Cancer Genomics Cloud Pilots Survey (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; The quality, utility, and clarity of the information to be collected; and Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: Comments regarding this information collection are best assured

of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Anthony Kerlavage, NCI CBIIT, Program Manager, 9609 Medical Center Drive, Room 1W-436, Rockville, MD 20850 or call non-toll-free number 240-276-5190 or email your request, including your address to: anthony.kerlavage@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Proposed Collection: Cancer Genomics Cloud Pilots Survey, 0925-NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Biomedical Informatics and Information Technology (CBIIT), in collaboration with the Center for Cancer Genomics at the National Cancer Institutes (NCI) in the National Institutes of Health (NIH), is coordinating a program to develop three Cancer Genomics Cloud Pilots to help meet the research community's needs to access and analyze high quality, large-scale cancer genomic data and associated clinical information. The goal of this effort is to develop an innovative, cost-effective model for computational analysis of biological data and provide broader yet secure access to genomic data that NCI generates. Cloud computing will be a valuable tool to support studies related to the mechanisms of cancer. This capability will be equally valuable to other NCI scientific areas, including clinical trials and other types of patient-focused research. In order to understand the utility and value of the tools being developed, the NCI has developed a survey instrument to capture feedback from the cancer research community. The information collected as part of this survey process will be used exclusively by the NCI to determine future funding of cloud technology projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 375.

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
Cloud Pilot Survey	Principal Investigator	1500	1	15/60	375

Dated: January 6, 2016.

Karla Bailey,
Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016-00458 Filed 1-12-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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/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 grant applications/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Purification of Cancer Cell Extracellular Vesicles.

Date: February 10, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Bethesda, MD 20892-9750, 240-276-6371, decluej@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Quantification of Redox.

Date: February 11, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W260, Bethesda, MD 20892-9750, 240-276-5856, nkhann3@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Biomarker Immunoassay Signal Amplification.

Date: February 16-17, 2016.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Bethesda, MD 20892-9750, 240-276-6371, decluej@mail.nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee F—Institutional Training and Education.

Date: February 22-23, 2016.

Time: 7:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road Bethesda, MD 20852.

Contact Person: Timothy C. Meeker, MD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W624, Bethesda, MD 20892-9750, 240-276-6464, meekert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 7, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-00459 Filed 1-12-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 Institute on Deafness and Other Communication Disorders Special Emphasis Panel; P50 Clinical Research Center Vocal Disorders Review Meeting.

Date: January 28, 2016.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Rockville, MD 20850, 301-402-3587, rayk@nidcd.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Clinical Trial Review.

Date: February 2, 2016.

Time: 2:45 p.m. to 4:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute