

Abstract: The Rural Health Care Services Outreach (Outreach) Program is authorized by section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), as amended, to “promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.” The goals for the Outreach Program are the following: (1) Expand the delivery of health care services to include new and enhanced services exclusively in rural communities; (2) deliver health care services through a strong consortium, in which every consortium member organization is actively involved and engaged in the planning and delivery of services; (3) utilize and/or adapt an evidence-based or promising practice model(s) in the delivery of health care services; and (4) improve population health and demonstrate health outcomes and sustainability.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. Several measures will be used for the Outreach Program. All measures will speak to FORHP’s progress toward meeting the goals.

A 60-day **Federal Register** Notice was published in the **Federal Register** on December 22, 2014, (79 FR 76334). There were no comments.

Likely Respondents: The respondents would be recipients of the Rural Health Care Services Outreach grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. 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	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Grant Program Measures	50	1	50	3	150
Total	50	1	50	3	150

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015-05414 Filed 3-6-15; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 5, 2015, 10:00 a.m. to 4:00 p.m. EDT.

Place: Audio Conference Call and Adobe Connect Pro.

The ACCV will meet on Thursday, March 5, 2015, from 10:00 a.m. to 4:00 p.m. (EDT). The public can join the meeting by:

1. (Audio Portion) Calling the conference Phone Number 877-917-4913 and providing the following information:

Leader’s Name: Dr. A. Melissa Houston.

Password: ACCV.

2. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: <https://hrsa.connectsolutions.com/accv/> (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview. Call (301) 443-6634 or send an email to aherzog@hrsa.gov if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the March 2015 meeting will include, but are not limited to: updates from the Division of Injury Compensation Programs (DICP), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases

(National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DICP, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DICP will notify each presenter by email, mail, or telephone of their assigned presentation

time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

The logistical challenges of scheduling this meeting delayed an earlier publication of this notice.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-6593, or email: aherzog@hrsa.gov.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015-05200 Filed 3-6-15; 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 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "NIAID Resource-Related Research Projects (R24): Fecal Microbiome Transplant National Registry".

Date: April 2, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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 Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, Rockville, MD 20892, 240-669-5082, Travis.Taylor@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: March 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05309 Filed 3-6-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Meeting.

Date: March 26, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, barnardm@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK—Planning Grant in Chronic Kidney Disease (U34).

Date: April 8, 2015.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05308 Filed 3-6-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0390]

Use of an Electronic Informed Consent in Clinical Investigations: Questions and Answers; Draft Guidance for Industry, Clinical Investigators, and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry, clinical investigators, and institutional review boards entitled "Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers." The guidance provides recommendations for clinical investigators, sponsors, and institutional review boards (IRBs) on the use of electronic media and processes to obtain informed consent for FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof.

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 May 8, 2015.

ADDRESSES: 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; or Office of Good Clinical Practice, Office of Special Medical Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire