

1. How to identify patients and their preferences

- What type of information can/should patients provide?
- What types of information do patients use to formulate decisions about their treatment options?
- Where can patient preference information be found?

2. What approaches should be used to collect patient preference information?

- What methods and tools can be used?
- What are the relative strengths and limitations of these methods and tools?
- Who should collect patient preference information?

3. How to validate patient preference data and information

- What methods and tools can be used?
- Who should validate patient preference information?

4. How to incorporate patient preference information in the regulatory process

- How can FDA use patient preference data within the Total Product Life Cycle regulatory paradigm?
- In what ways should it not be used?
- What additional safeguards should FDA consider when including patient preference information into its regulatory decision making?

Dated: July 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the

Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Advanced Education Nursing Traineeship (AENT) Program application.

OMB No. 0915-XXXX—New.

Abstract: The Health Resources and Services Administration (HRSA) provides advanced education nursing training grants to educational institutions to increase the numbers of advanced education nurses through the AENT Program. The AENT Program is governed by Title VIII, Section 811(a)(2) of the Public Health Service Act, (42 U.S.C. 296j(a)(2)), as amended by Section 5308 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148. This new request includes the Project Abstract, Program Narrative, Attachments and Tables. The proposed AENT Tables will include information on program participants such as the projected number of enrollees/trainees receiving traineeship support; projected number of graduates receiving traineeship support for the previous fiscal year; the types of programs they are enrolling into and/or from which enrollees/trainees are graduating; and the distribution of

primary care nurse practitioners and nurse midwives who plan to practice in rural, underserved, or public health practice settings.

Need and Proposed Use of the Information: The Project Abstract is often distributed to provide information to the public and Congress. HRSA will use this information in determining the amount of traineeship support to be awarded per student per institution and to succinctly capture data for the number of projected students for determining eligibility for Special Consideration and Statutory Funding Preference.

Likely Respondents: Eligible applicants are schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit an application and are accredited for the provision of primary care nurse practitioner and nurse midwifery programs accredited by a national nurse education accrediting agency recognized by the Secretary of the U.S. Department of Education. The school must be located in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, Guam, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

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 Information Collection Request 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
AENT Application including the AENT Tables and Attachments	236	1	236	7	1,652
Total	236	1	236	7	1,652

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-18162 Filed 7-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 18-19, 2013.

Closed: September 18, 2013.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, T508, Rockville, MD 20852.

Open: September 19, 2013, 8:45 a.m. to 2:00 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, T508, Rockville, MD 20852.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 2085, Rockville, MD 20852, 301-443-9737, bautista@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: July 22, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-18054 Filed 7-26-13; 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 Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID; AIDS Vaccine Research Subcommittee.

Date: September 18, 2013.

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

Agenda: Presentations by the Vaccine Research Program staff on the preclinical, translational and clinical AIDS vaccine research programs supported by the Division of AIDS for the purpose of obtaining advice and guidance from the AVRS on future vaccine efforts.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: James A. Bradac, Ph.D., Chief, Preclinical Research and Development Branch, Division of AIDS, Room 5134, National Institutes of Health/NIAID, 6700B Rockledge Drive, Bethesda, MD 20892-7628, 301-435-3754, jbradac@mail.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: July 22, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-18055 Filed 7-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review ;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: Center for Scientific Review Special Emphasis Panel; OppNet RFA: Culture, Health and Wellbeing.

Date: August 1, 2013.