

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 14, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**National Institutes of Health**
**Proposed Collection; 60-Day Comment  
Request; A Generic Submission for  
Formative Research, Pre-Testing,  
Stakeholder Measures and Advocate  
Forms at 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 (NCI), 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 on one or more of the following points: (1) 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; (2) 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; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Kelley Landy, Acting Director of the Office of Advocacy Relations (OAR), NCI, NIH, 31 Center Drive, Bldg. 31, Room 10A28, MSC 2580, Bethesda, MD 20892, call non-toll-free number 301-594-3194, or email your request, including your address, to [kelly.landy@mail.nih.gov](mailto:kelly.landy@mail.nih.gov).

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection:* A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI, 0925-0641, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and feedback, and facilitates collaboration to advance NCI's authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities

and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Pre-testing, or formative evaluation, helps ensure that the products and services developed by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. The OAR will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this research, allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective strategies, concepts, activities; (2) use a feedback loop to help refine, revise, and enhance OAR's efforts—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. The anticipated individual respondents will consist of: Adult cancer research advocates, members of the public, health care professionals, and organizational representatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,025.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondent type	Form name	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Individuals .....	Self-Administered Questionnaires .....	800	1	1	800
	Individual In-Depth Interviews .....	75	1	1	75
	Focus Group Interviews .....	100	1	90/60	150

Dated: July 14, 2014.

**Karla Bailey,**

*NCI Project Clearance Liaison, National Institutes of Health.*

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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 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 Cancer Institute Special Emphasis Panel Small Grants Program for Epidemiology.

*Date:* July 23, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2E032, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Gerald G. Lovinger, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W266, Bethesda, MD 20892-8329, 240-276-6385.

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 Cancer Institute Special Emphasis Panel, NCI U01 Review.

*Date:* August 26, 2014.

*Time:* 8:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 3W032/034, Rockville, MD 20850.

*Contact Person:* Ben Prickril, Ph.D., Scientific Review Officer, Research Program and Review Branch, DEA, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W634, Rockville, MD 20850, 240-276-5794, [prickril@mail.nih.gov](mailto:prickril@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel NCI Program Project Meeting II (P01).

*Date:* September 30–October 1, 2014.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Majed M. Hamawy, Ph.D., MBA, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W120, Rockville, MD 20850, 240-276-6457, [mh101v@nih.gov](mailto:mh101v@nih.gov).

*Name of Committee:* National Cancer Institute Initial Review Group Subcommittee J—Career Development.

*Date:* October 29, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Ilda F. S. Melo, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of

Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Rockville, MD 20850, 240-276-6468, [ilda.melo@mail.nih.gov](mailto:ilda.melo@mail.nih.gov).

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(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:* July 14, 2014.

**Melanie J. Gray,**

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

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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(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.); notice is hereby given of a meeting of the Board of Scientific Counselors, NIAAA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Alcohol Abuse and Alcoholism, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIAAA.

*Date:* August 26–27, 2014.

*Time:* 7:45 a.m. to 5:15 p.m.

*Agenda:* To review and evaluate personal qualifications and performance; and competence of individual investigators.

*Place:* National Institute of Health, 5635 Fisher Lane, Terrace Conference Center, Bethesda, MD 20892.

*Contact Person:* George Kunos, M.D., Ph.D., Director, Division of Intramural Clinical and Biological Research, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5625 Fishers Lane, Room

2S-24A, Bethesda, MD 20892, 301-443-2069, [gkunos@mail.nih.gov](mailto:gkunos@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS).

*Dated:* July 14, 2014.

**Melanie J. Gray,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Advisory Council.

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.

*Name of Committee:* National Heart, Lung, and Blood Advisory Council.

*Date:* September 9, 2014.

*Open:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To discuss program policies and issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

*Date:* September 10, 2014.

*Open:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To discuss program policies and issues.

*Place:* National Institutes of Health, Building 35A, Porter Building, Room 640, 35A Convent Drive, Bethesda, MD 20892.

*Contact Person:* Stephen C. Mockrin, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435-0260, [mockrins@nhlbi.nih.gov](mailto:mockrins@nhlbi.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.