

**Background and Brief Description**

Tobacco use remains the leading preventable cause of disease and death in the United States, resulting in approximately 440,000 deaths annually. Smokers die an average of 14 years earlier than non-smokers. Moreover, cigarette smoking costs more than \$193 billion; \$97 billion in lost productivity plus \$96 billion in health care expenditures. Although the prevalence of current smoking among adults in the United States has declined significantly since 1964, in more recent years (2004 to 2010) these declines have slowed or stalled with 1 in 5 adults reporting current smoking. In addition, promotion of non-cigarette tobacco products is leading to increased diversity of tobacco product usage, including the use of multiple products.

With passage of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in 2009, the Food and Drug Administration is legally mandated to regulate tobacco products for the protection of public health. Congress passed the FSPTCA to discourage tobacco use among minors and young adults, to encourage cessation among adult smokers and to reduce the public health burden of tobacco related disease in the U.S. Under the Tobacco Control Act, FDA has been granted broad authority to use the best available science to develop and implement effective strategies to protect the public's health. FDA authority includes setting and enforcing standards for

tobacco product ingredients and design, establishing good manufacturing practices, instituting tobacco product labeling and health warnings; prohibiting marketing that is misleading to consumers and developing enforcement authorities to act quickly and effectively to remove violating products. In addition, the FSPTCA gives FDA the authority to assert jurisdiction over cigars and other currently unregulated tobacco products. Finally, FDA's regulatory authority involves considering whether the marketing of tobacco products might encourage people who don't use tobacco products to begin using them, encourage people who might otherwise quit to continue using tobacco, or encourage former users to relapse.

In order to ensure that FDA is in compliance with the Tobacco Control Act's mandate to protect the public health, annual data collection is needed at least initially to monitor the benefits and potential adverse consequences of FDA's regulatory actions, as the regulatory framework is being established. The FDA must regularly monitor patterns of tobacco product usage—novel tobacco products as well as cigarettes—to identify changes in susceptibility and rates of tobacco use initiation, perceptions regarding tobacco use, and rates of tobacco use cessation. Rather than develop a completely new system to monitor measures critical to FDA, and thereby increasing burden to the population, FDA has partnered with CDC to leverage the existing NATS

system. While NATS has been re-designed to meet the critical data needs of the FDA, many of the measures are relevant to CDC's National Tobacco Control Program (NTCP), and CDC also will use the NATS data to evaluate the NTCP. Many of the NATS questions reflect CDC's key outcome indicators for evaluating tobacco control programs.

CDC proposes to conduct three annual cycles of the National Adult Tobacco Survey (NATS) to collect data necessary to evaluate the effectiveness of FDA's initial regulatory actions. The NATS will be a stratified, random-digit dialed telephone survey of non-institutionalized adults 18 years of age and older. To yield results that are representative nationally, information will be collected from 56,250 landline respondents. In addition, to include the growing population of households that exclusively use cell phones and would be missed in a survey relying only on land-lines, information will be collected from 18,750 cell phone respondents who do not have a landline. To obtain the target number of completed telephone interviews, approximately 166,000 respondents will be contacted for initial eligibility screening.

Response is voluntary. Study results will have significant implications for the development and periodic adjustment of policies and programs aimed at preventing and reducing tobacco use in the United States. There are no costs to respondents except their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondent            | Form name   | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|-------------------------------|---|-----------------------|------------------------------------|--|-------------------------|
| Adults ages 18 or older ..... | Screener for land-line users (pp 67–78 of the NATS).            | 125,000               | 1                                  | 2/60                                   | 4,167                   |
|                               | Screener for cell phone users (pp 79–86 of the NATS).           | 41,000                | 1                                  | 1/60                                   | 683                     |
|                               | National Adult Tobacco Survey (pp 5–66 of the NATS)—landline.   | 56,250                | 1                                  | 20/60                                  | 18,750                  |
|                               | National Adult Tobacco Survey (pp 5–66 of the NATS)—cell phone. | 18,750                | 1                                  | 20/60                                  | 6,250                   |
| Total .....                   | .....   | .....                 | .....                              | .....                                  | 29,850                  |

Dated: January 6, 2012.

**Kimberly Lane,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; Strategies for the protection of Pregnant Women and Infants Against Infectious Diseases (R01)

*Date:* February 2–3, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Washington DC–Silver Spring, Silver Spring, MD 20910.

*Contact Person:* B. Duane Price, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, Room 3139, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 451–2592, [pricebd@niaid.nih.gov](mailto:pricebd@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

*Date:* February 3, 2012.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call)

*Contact Person:* Raymond Richard Schleef, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 451–3679, [schleefrr@niaid.nih.gov](mailto:schleefrr@niaid.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: January 5, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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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 Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Studies of CAM Therapies.

*Date:* January 30, 2012.

*Time:* 1:30 p.m. to 5 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:* Hungyi Shau, Ph.D., Scientific Review Officer, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, (301) 402–1030, [Hungyi.Shau@nih.gov](mailto:Hungyi.Shau@nih.gov).

*Name of Committee:* National Center for Complementary and Alternative Medicine Special Emphasis Panel.

*Date:* February 24, 2012.

*Time:* 7 a.m. to 7 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Peter Kozel, Ph.D., Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–5475, (301) 496–8004, [kozelp@mail.nih.gov](mailto:kozelp@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 5, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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 review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, 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, Lister Hill Center for Biomedical Communications.

*Date:* April 5–6, 2012.

*Open:* April 5, 2012, 9 a.m. to 11:30 a.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Closed:* April 5, 2012, 11:30 p.m. to 4:30 p.m.

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

*Place:* National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Closed:* April 6, 2012, 8:30 a.m. to 10 a.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Karen Steely, Program Assistant, Lister Hill Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S709, Bethesda, MD 20892, (301) 435–3137, [ksteely@mail.nih.gov](mailto:ksteely@mail.nih.gov).

*Open:* April 6, 2012, 10 a.m. to 11:30 a.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Karen Steely, Program Assistant, Lister Hill Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S709, Bethesda, MD 20892, (301) 435–3137, [ksteely@mail.nih.gov](mailto:ksteely@mail.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.

In the interest of security, NIH has instituted stringent procedures for entrance

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary and Alternative Medicine; 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.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Library of Medicine; Notice of Meetings

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, Lister Hill Center for Biomedical Communications.

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