3. What additional information, if any, that is written in nontechnical, understandable language for patients should be required to be submitted to the data bank or should be provided in the data bank to assist patients in understanding and interpreting the information available in the data bank. Please consider the types of information that would best assist patients and other members of the public in understanding and interpreting results information in the data bank, including information on adverse events. Comment on issues such as the types of information that might assist patients and the public in understanding the results of individual clinical trials and of clinical trials in general. Identify existing sources of explanatory information that are oriented toward patients and the public and could be included in or linked to the data bank.

4. Whether to require submission of the full clinical trial protocol or only such information on the protocol as may be necessary to help evaluate the results of the trial. Comment on the value of the full clinical trial protocol versus partial information from the protocol in evaluating the results of a trial and the completeness of results data submission.

5. Procedures the agency might consider for quality control, with respect to completeness and content of clinical trial information, to help ensure that data elements are not false or misleading and are nonpromotional. Consider the effect of different approaches on the workload of both data submitters and the agency and on the quality of data available to the public, as well as suitable means for the agency to communicate information about its quality assurance processes to data submitters and the public.

6. Whether the 1-year period for submission of basic results information should be increased to a period not to exceed 18 months. Comment on the advantages and disadvantages of increasing the period for submission of clinical trial information from 1-year after the completion date to a period not to exceed 18 months. Consider the implications for all stakeholders, including governmental bodies, data submitters, and users of ClinicalTrials.gov; the extent to which such a change would affect public health or the utility of the data bank; the possible effect on the number of requests that responsible parties would submit to the NIH requesting an extension of the results reporting deadline; and the possible improvements to the quality and or completeness of initial submissions of results data to the NIH. Consider the implications of delay periods of different lengths between 12 and 18 months.

7. Whether the clinical trial information required by the regulation should be required to be submitted for applicable clinical trials for which ''basic results'' information is submitted before the effective date of the regulation. Consider the advantages and disadvantages to data submitters and users of the data bank, including patients, prospective human subjects, care providers, and researchers.

8. The appropriate timing and requirements for updates of clinical trial information and procedures for tracking such updates. Please comment on the advantages and disadvantages of requiring more frequent updating of information submitted to the clinical trial registry and results data bank, which elements (if any) would benefit from more frequent updating, and what would be the optimal frequency of such updates.

9. The standard format for the submission of clinical trial information required by the regulation, including adverse event information, and additions or modifications to the manner of reporting of the data elements established under the basic results reporting provisions of the FDAAA.

10. A statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted as a ''voluntary submission'' after the date specified in the FDAAA for submission of such information.

11. Other issues associated with Section 801 of the FDAAA that will inform rulemaking.

## IV. Request for Comments

As described previously in this Notice, participants wishing to make an oral statement at the Public Meeting are requested to notify the NIH and to submit to the meeting docket or the Contact Person a written version of their remarks on the topics identified in Section IV by 5 p.m. on Monday, April 13, 2009. The docket will remain open after the meeting, and, regardless of attendance at the public meeting, interested persons may submit written or electronic comments to the docket so that they may be considered by the agency during the subsequent rulemaking. To ensure consideration, written comments should be submitted to the docket by Monday, June 22, 2009. Submit electronic comments to Docket No. NIH–2009–0002 at *http://www.regulations.gov*. The site contains instructions for submitting comments.

## V. Transcripts

A transcript of the public meeting will be submitted to the docket and posted to *http://prsinfo.clinicaltrials.gov/public-meeting-april09.html* approximately 15 working days after the public meeting.

Dated: March 16, 2009.

**Raynard S. Kington,**

*Acting Director, National Institutes of Health.*

[FR Doc. E9–6198 Filed 3–20–09; 8:45 am]

**BILLING CODE 4140–01–P**

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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. Appendix 2), notice is hereby given of a meeting of the National Advisory Allergy and Infectious Diseases Council.

The meeting will be open to the public. Individuals who wish to listen to the meeting should register with Jemma Long at the phone number of the contact person listed below at least two days in advance of the meeting.

*Name of Committee:* National Advisory Allergy and Infectious Diseases Council; Allergy, Immunology and Transplantation Subcommittee.

*Date:* March 31, 2009.

*Time:* 1 p.m. to 1:30 p.m.

*Agenda:* The subcommittee will be discussing a concept clearance for the Human Immunology Profiling Centers of Excellence (U01/U19).

*Place:* National Institutes of Health, 6610 Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Daniel Rotrosen, PhD, Director, Division of Allergy, Immunology & Transplantation, National Institutes of Health/NIAID, 6610 Rockledge Drive, MSC 6601, Bethesda, MD 20892–6601, 301–496–1886, *drotrosen@niaid.nih.gov*.

This notice is being published less than 15 days prior to the meeting date due to timing limitations created by the Economic Recovery Act.

Information is also available on the Institute's/Center's home page: *http://www.niaid.nih.gov/facts/facts.htm*, where an agenda and any additional information for the meeting will be posted when available.

(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 16, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9–6199 Filed 3–20–09; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); 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 Cancer Institute Special Emphasis Panel; ''Improved Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations''.

*Date:* April 2–3, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Courtyard Gaithersburg Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD.

*Contact Person:* Gerald G. Lovinger, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329, 301–496–7987, *lovingeg@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: March 17, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9–6339 Filed 3–20–09; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Sleep Disorders Research Advisory Board.

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:* Sleep Disorders Research Advisory Board.

*Date:* April 14, 2009.

*Time:* 12 p.m. to 4:30 p.m.

*Agenda:* To discuss sleep research, education priorities, and programs.

*Place:* National Institutes of Health, Building 45, 45 Center Drive, Natcher Auditorium, Bethesda, MD 20892.

*Contact Person:* Michael J Twery, PhD, Director, National Center on Sleep Disorders Research, Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 10038, Bethesda, MD 20892–7952, 301–435–0199, *twerym@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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 16, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9–6205 Filed 3–20–09; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Conference Grants (R13's).

*Date:* March 31–April 1, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* David A Wilson, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7204, Bethesda, MD 20892–7924, 301–435–0299, *wilsonda2@nhlbi.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 16, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9–6207 Filed 3–20–09; 8:45 am]

**BILLING CODE 4140–01–P**

## 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