

over the last year in refining the prioritization process. These include the need for more preliminary information on candidate drugs (for example, information on frequency of use and frequency of condition) as well as expert input, a better approach for mass outreach, enhancement of NIH interagency collaborations, and improvement in the overall prioritization process.

The revised process includes:

- A Well-defined process, using a systematic approach with clear objectives and outcomes;
- Well-defined objective criteria that are mutually exclusive and of a manageable number;
- A dynamic process, including transparency, stakeholder input, and leadership; and
- Expert involvement to inform and contribute to the process.

For 2010, NIH solicited nominations for the BPCA Priority List of Needs in Pediatric Therapeutics through a "Request for Information" (RFI) announcement as part of NIH's authority and responsibility to establish the program for pediatric drug testing and development outlined in the BPCA legislation. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents. The list is organized by Therapeutic Area, which can be a group of conditions, a subgroup of the population, or a setting of care. Each calendar year, a few Therapeutic Areas are selected for discussion and further prioritization. Below is a summary of the revised BPCA prioritization process:

- In early 2010, the RFI was issued to solicit nominations for future studies of pediatric therapeutics under the BPCA.
- The Obstetric and Pediatric Pharmacology Branch of the NICHD received 107 nominations, 67 of which met the criteria for review.
- All nominations were reviewed and evaluated on six key criteria, as follows:
 - Relevance to BPCA Mission and Goals
 - No disqualifying ethical concerns
 - Evidence: consideration of the level of evidence available and current gaps
 - Impact: potential effect on children, society, and delivery of care
 - Population: consideration of the different populations that may benefit from the research
 - Feasibility: consideration of the resources available to conduct the study
 - Twenty-two volunteer health professional evaluators scored the 67 nominations according to evidence, impact, and the pediatric population affected. Each nomination was reviewed by a panel of three evaluators.

- Therapeutic Area working groups (several Therapeutic Areas are determined annually) were developed and met through the 2010 year to discuss the gaps in knowledge in the therapeutic approaches to diseases in gastroenterology, endocrinology, and neurology.

- Minutes of all working group meetings conducted under the BPCA can be found on the BPCA Web site, <http://bpca.nichd.nih.gov>.

- As a final step in the process, the NICHD, with input from the FDA, ranked the nominations based on the evaluators' scores, quality and quantity of existing studies, and feasibility of the proposed study. The result was a tiered list of nominations considered for listing. Tier One represents the highest percentage of scores: nominations of interest to the NICHD for prioritization. Tier Two represents the average percentage of scores: nominations of possible interest to the NICHD at a later time. Tier Three represents the lowest percentage of scores: Nominations of least interest to the NICHD at this time for prioritization.

The NICHD sponsored the annual BPCA prioritization meeting, held November 9–10, 2010, with stakeholders from the NIH, the FDA, the American Academy of Pediatrics, other pediatric organizations and societies, and patient advocates. The meeting allowed the NICHD to review the present progress from ongoing research and to discuss the proposed Therapeutic Areas from the 2010 nominations to be prioritized for future study under the BPCA and added to the existing BPCA priority list.

Below is an updated list of Therapeutic Areas and drugs that have been prioritized for study since the inception of the BPCA. It includes new areas of prioritization from Tier One nominations of the 2010 outreach and a summary of the NICHD's plans and progress in all these areas.

Priority List of Needs in Pediatric Therapeutics 2011

In accordance with the BPCA legislation, the list outlines priority needs in pediatric therapeutics for multiple Therapeutic Areas listed below. The priority list can be found on the BPCA Web site at the following address: <http://bpca.nichd.nih.gov>

- *Table 1: Infectious Disease Priorities*
- *Table 2: Cardiovascular Disease Priorities*
- *Table 3: Respiratory Disease Priorities*
- *Table 4: Intensive Care Priorities*

- *Table 5: Bio-defense Research Priorities*

- *Table 6: Pediatric Cancer Priorities*
- *Table 7: Psychiatric Disorder Priorities*

- *Table 8: Neurological Disease Priorities*

- *Table 9: Neonatal Research Priorities*

- *Table 10: Adolescent Research Priorities*

- *Table 11: Hematologic Disease Priorities*

- *Table 12: Endocrine Disease Priorities and Diseases with Limited Alternative Therapies*

- *Table 13: Dermatologic Disease Priorities*

- *Table 14: Gastrointestinal Disease Priorities*

- *Table 15: Renal Disease Priorities*
- *Table 16: Rheumatologic Disease Priorities*

- *Table 17: Special Considerations*

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata via e-mail at taylorpe@mail.nih.gov or by telephone at 301-496-9584 (not a toll-free number).

Dated: March 24, 2011.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2011-7673 Filed 3-31-11; 8:45 am]

BILLING CODE 4140-01-P

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; Cell Signaling and Guidance.

Date: April 7–11, 2011.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Joanne T Fujii, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435-1178, fujij@csr.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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-7818 Filed 3-31-11; 8:45 am]

BILLING CODE 4140-01-P

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; Loan Repayment Program.

Date: April 25-29, 2011.

Time: 8 a.m. to 5 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: Nancy Lewis Ernst, PhD, Scientific Review Official, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-451-7383, nancy.ernst@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special

Emphasis Panel; Targeted Clinical Research to Address Select Viral Infections.

Date: April 25-26, 2011.

Time: 8 p.m. to 6 p.m.

Agenda: To review and evaluate contract proposals.

Place: Crowne Plaza Hotel—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Eleazar Cohen, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, 6700 B Rockledge Drive, Room 3129, Bethesda, MD 20892, 301-435-3564, ec17w@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Immune Response to Infection Meeting I.

Date: April 25-26, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Quirijn Vos, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-451-2666, qvoss@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Immune Response to Infection Meeting II.

Date: April 26, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Quirijn Vos, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-451-2666, qvoss@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: March 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-7817 Filed 3-31-11; 8:45 am]

BILLING CODE 4140-01-P

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; "HIV Vaccine Design".

Date: April 27, 2011.

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 R. Schleef, PhD, 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, schleefr@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: March 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-7816 Filed 3-31-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.