

Service, HHS at: <http://www.dpm.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) the project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the Grants Management Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

Telecommunication for the hearing impaired is available at: TTY (301) 443-6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Mr. Chris Buchanan, Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, email: Chris.Buchanan@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. John Hoffman, Grants Management Specialist, DGM, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852, Telephone: (301) 443-5204, Fax: (301) 443-9602, email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, DGM, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, email: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: August 19, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014-20109 Filed 8-22-14; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

AGENCY: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) hereby announces the Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics for 2014. The BPCA, reauthorized in 2012 as part of the Food and Drug Safety and Innovation Act, seeks to improve the level of information on the safe and effective use of pharmaceuticals used to treat children. The BPCA requires that the NIH identify the drugs of highest priority for study in pediatric

populations and publish a list of drugs/needs in pediatric therapeutics. This notice fulfills the requirement to publish that list.

SUPPLEMENTARY INFORMATION: The pediatric medical community, the public health community, and government agencies have recognized multiple gaps in knowledge regarding the use of therapeutics in children, including the correct dose, appropriate indications, side effects, and safety concerns of pharmaceuticals in the short and long term. These gaps have frequently resulted in inadequate labeling for pediatric use and in wide-spread off-label use of prescription drugs in children. Off-label use of a drug substantially limits the ability to gain clinical information of the drug product, such as appropriate dosing of a drug, changes in drug metabolism and response during growth and development, and important short- and long-term effects.

The NICHD is working with the Food and Drug Administration (FDA), other federal agencies, and various nonprofit and commercial organizations to address the knowledge gaps that exist in pediatric therapeutics and to promote an increase in evidence-based data about medications used in children.

Update on BPCA Prioritization

The BPCA requires that the NIH, in consultation with the FDA and experts in pediatric research, identify the drugs and therapeutic areas of highest priority for study in pediatric populations. The BPCA authorizes the NIH to establish a program for pediatric drug testing and development and to publish a list of drugs/needs in pediatric therapeutics. The BPCA program consists of a series of clinical trials in various therapeutic areas, which may be based on proposed pediatric study requests (PPSRs) submitted to the FDA and/or on written requests (WR) received from the FDA. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents that need further study. It is organized by therapeutic areas, which are general categories of conditions, diseases, settings of care, or populations with multiple therapeutic needs. The first priority list of off-patent drugs needing further study under the 2002 BPCA legislation was published in January 2003 in the **Federal Register** (FR Vol. 68, No. 13; Tuesday, January 21, 2003; 2789-2790). The most recent priority list was published October 24, 2012; all **Federal Register** Notices can be found on the BPCA Web site: <http://bpca.nichd.nih.gov/prioritization/>

status/Pages/status.aspx. The NIH is required by the BPCA to update the priority list every three years. This publication serves as an update to the BPCA priority list of needs in pediatric therapeutics.

The Obstetric and Pediatric Pharmacology and Therapeutics Branch of the NICHD developed a prioritization process for the determination of the needs in pediatric therapeutics. There are two main phases in this process. Phase I of the prioritization process entails identifying therapeutic areas, which are general categories of conditions, diseases, settings of care, or populations with multiple therapeutic needs. The NICHD solicits input from experts in the pediatric research, general pediatric and subspecialty care, and patient advocacy groups to determine these therapeutic areas that need further study. At the beginning of every year, the NICHD revisits the current list of needs in pediatric therapeutics, prioritizes three therapeutic areas of interest for that calendar year, and develops working groups in the prioritized areas. Recommendations from the therapeutic area working groups are then presented to the NICHD and the FDA at the end of the calendar year at the Institute's annual BPCA meeting. Previous meeting minutes can be found on the BPCA Web site: <http://bpca.nichd.nih.gov/prioritization/meetings/Pages/index.aspx>.

Phase II of the prioritization process entails an extensive review and ranking of all nominations received based on key criteria for prioritization, such as relevance, label gaps, affected population, and feasibility. Please visit the BPCA Web site for more details: (http://bpca.nichd.nih.gov/prioritization/priority_list/Pages/priority_list.aspx).

Below is an updated list of therapeutic areas and drugs that have been prioritized for study since the inception of the BPCA and a summary of the NICHD's plans and progress in all of these areas to date. The NICHD welcomes input from the pediatric medical community on additional gaps in pediatric therapeutics for future consideration. All nominations should be submitted to Dr. Perdita Taylor-Zapata (contact information below).

Priority List of Needs in Pediatric Therapeutics 2014

In accordance with the BPCA legislation, the list outlines priority needs in pediatric therapeutics for multiple therapeutic areas listed below. The complete 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*

We would like for you to save the date of December 10, 2014, for our annual BPCA stakeholders meeting. The meeting will be held at the Natcher Auditorium on the NIH campus in Bethesda, Maryland, and will be streamed live via videocast for all non-local attendees.

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata via email at taylorpe@mail.nih.gov; by phone at 301-496-9584; or by fax at 301-480-2897.

Dated: August 18, 2014.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2014-20156 Filed 8-22-14; 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 Cancellation of Meeting

Notice is hereby given of the cancellation of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel, September 10, 2014, 10:00 a.m. to September 10, 2014, 12:00 p.m., National Institutes of Health, 6700B Rockledge Drive, Room 3124, Bethesda, MD 20817 which was published in the **Federal Register** on August 15, 2014, 79FR48173.

The Review Committee will not meet because the application was withdrawn.

Dated: August 19, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-20057 Filed 8-22-14; 8:45 am]

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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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Ancillary Studies to the NIDDK IDBGC.

Date: October 16, 2014.

Time: 1:00 p.m. to 3:00 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: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707, Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-7682, campd@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Panel, Small Grants for New Investigators to Promote Diversity.

Date: October 30, 2014.

Time: 12:00 p.m. to 2:30 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: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 402-7172, woynarowskab@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes,