

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Ruth Barratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4540, Silver Spring, MD 20993-0002, 301-796-2600.

SUPPLEMENTARY INFORMATION:

I. Background

Since publication of the 2011 "Identifying CDER's Science and Research Needs" report, FDA has been engaged in efforts to further assess and prioritize the needs articulated therein. As part of these efforts, CDER's Safety Research Interest Group (SRIG), a subcommittee of the Science Prioritization and Review Committee, assessed CDER's overall drug safety-related regulatory science needs in view of FDA's ongoing research efforts and highlighted areas that would benefit from additional resources and collaboration.

The SRIG identified the following seven overall needs for drug safety-related regulatory science:

1. Improve access to postmarket data sources and explore the feasibility of their use in safety signal analyses
2. Improve risk assessment and management strategies to reinforce the safe use of drugs
3. Evaluate the effectiveness of risk communications of drug safety information to health care providers and the public
4. Improve product quality and design, manufacturing processes, and product performance relating to safety
5. Develop and improve predictive models of safety in humans, including nonclinical biomarkers
6. Improve clinical trial statistical analyses for safety, including benefit-risk assessment
7. Investigate clinical biomarkers of safety, including standards for qualification.

Particular priorities within the seven overall needs requiring further resources and outside participation were also identified. FDA seeks to stimulate collaborations with external partners and stakeholders to address these needs by asking them to: (1) Submit descriptions of their ongoing research and initiatives related to the seven overall needs, especially the identified priorities, and (2) indicate their interest in working with FDA to address these needs. Outside parties are being asked to submit comments to the docket and

email address CDER_Science_Needs@fda.hhs.gov.

II. Comments

Interested persons may submit either electronic comments regarding the report to <http://www.regulations.gov> and email address CDER_Science_Needs@fda.hhs.gov, or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the report at <http://www.regulations.gov>.

Dated: March 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-06288 Filed 3-18-15; 8:45 am]

BILLING CODE 4164-01-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 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; NIDDK Ancillary R01 Telephone Review SEP.

Date: April 3, 2015

Time: 2:30 p.m. to 3:30 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: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.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.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Interdisciplinary Team Science in Diabetes and Obesity (R24).

Date: April 6, 2015.

Time: 2:30 p.m. to 4:30 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: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, jerkinsa@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-06266 Filed 3-18-15; 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; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, March 31, 2015, 04:00 p.m. to April 01, 2015, 05:00 p.m., Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC, 20009 which was published in the **Federal Register** on March 09, 2015, 80 FR 12494.

The meeting is being amended to reflect location change. The new meeting location is the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. The meeting is closed to the public.

Dated: March 13, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-06270 Filed 3-18-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; 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 Advisory Committee on Research on Women's Health.

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: Advisory Committee on Research on Women's Health.

Date: April 10, 2014.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: The Committee serves to advise and make recommendations to the Director, Office of Research on Women's Health (ORWH) on a broad range of topics including, the current scope of research on women's health and the influence of sex and gender on human health, efforts to understand the issues related to women in biomedical careers and their needs, and the current status of inclusion of women in clinical trials research.

Place: National Institutes of Health, Building 35, Room 620/630, 35 Convent Drive, Bethesda, MD 20892.

Contact Person: Susan E Maier, Ph.D., NIH/OD, 6707 Democracy Blvd., Room 400, Bethesda, MD 20852, 301-435-1573, maiers@mail.nih.gov.

Any interested person may file written comments for the public record by submitting their comments to the following email address ACRWHComments@sp10mail.nih.gov. Written comments for the public record must not exceed two single-spaced, typed pages, using a 12-point typeface and 1 inch margins; it is preferred that the document be prepared in the MS Word® format. Only testimony submitted to this Web site and received in advance of the meeting are part of the official meeting record.

Supplementary Information: A draft agenda for this meeting is posted at <http://orwh.od.nih.gov/about/acrwh/index.asp>. The meeting will be live-video streamed at <http://videocast.nih.gov/>.

Individuals who plan to attend the meeting in person should contact Faith Zeff at faith.zeff@nih.gov. Members of the media

will also need to register. 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: March 13, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-06267 Filed 3-18-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers

Lane, Room 11C-26, Rockville, MD 20857; (301) 443-6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**." Set forth below is a list of petitions received by HRSA on February 1, 2015, through February 28, 2015. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the