

current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02139 Filed 2-12-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at <https://www.hrsa.gov/advisory-committees/rural-health/index.html>.

DATES:

April 3, 2019, 8:30 a.m.–5:15 p.m. Pacific Time (PT).

April 4, 2019, 8:30 a.m.–5:15 p.m. PT.

April 5, 2019, 8:30 a.m.–11:15 a.m. PT.

ADDRESSES: The meeting will be held in person. On April 3, the meeting will be held at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

On the morning of April 4, NACRHHS will break into subcommittees. One subcommittee will travel to Northern Valley Indian Health Clinic, 207 N Butte St., Willows, California 95988. The other subcommittee will travel to Sierra Nevada Memorial Hospital, 155 Glasson Way, Grass Valley, California 95945. In the afternoon at approximately 4:00 p.m. PT, NACRHHS will reconvene at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

On April 5, the meeting will be held at The Residence Inn, Sacramento Downtown, 1121 15th Street, Sacramento, California 95814.

FOR FURTHER INFORMATION CONTACT:

Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; 301-443-7322; or shirsch@hrsa.gov.

SUPPLEMENTARY INFORMATION:

NACRHHS provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning both rural health and rural human services.

During the April 2019 meeting, NACRHHS will discuss the issues of Cancer Prevention and Control in Rural America along with Supportive Services and Caregiving for the Rural Elderly. Agenda items are subject to change as priorities dictate. Refer to the NACRHHS website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACRHHS should be sent to Steven Hirsch, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

John R. Womack,

Acting Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2019-02207 Filed 2-12-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: March 22, 2019, 10:00 a.m.–3:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is

required. Please visit the ACHDNC website for information on registration: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. The deadline for online registration is 5:00 p.m. ET on March 20, 2019. Instructions on how to access the meeting via webinar will be provided upon registration.

FOR FURTHER INFORMATION CONTACT:

Alaina Harris, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or AHarris@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the March 2019 meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Tentative agenda topics include: (1) The condition nomination and evidence review process, (2) rare disease registries, and (3) implementation of conditions on the RUSP. Agenda items are subject to change as priorities dictate and the final meeting agenda will be available on ACHDNC's website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. Information about ACHDNC, a roster of members, as well as past meeting summaries are also available on the ACHDNC website.

Members of the public will have the opportunity to provide comments, which are part of the official committee record. To submit written comments or

request time for an oral comment during the meeting, please register online by 12:00 p.m. ET on March 18, 2019. Visit the ACHDNC website for information on registration at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.*, parent, family member, researcher, clinician, public health, etc.), and the topic/subject matter.

John R. Womack,

Acting Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2019-02208 Filed 2-12-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Mental Health Special Emphasis Panel; NIMH Clinical Trials: Effectiveness of Treatment, Preventive, and Services Interventions.

Date: April 1, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco, 700 F Street NW, Washington, DC 20001.

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301-451-2356, gavinevanskm@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Computational Approaches for Validating Dimensional Constructs of Relevance to Psychopathology (R01).

Date: April 2, 2019.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 0852, (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892, 301-443-4525, steinerr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-02121 Filed 2-12-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 1, 2019, 11:00 a.m. to March 1, 2019, 2:00 p.m., National Cancer Institute Shady Grove Campus, Rockville, MD 20850 which was published in the **Federal Register** on February 5, 2019, 84 FR 1768.

This meeting notice is amended to change the meeting time on March 1, 2019 to 10:00 a.m. to 1:00 p.m. The meeting is closed to the public.

Dated: February 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-02128 Filed 2-12-19; 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 Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: March 27, 2019.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ross D Shonat, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6196, MSC 7804, Bethesda, MD 20892, 301-435-2786, ross.shonat@nih.gov.

(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: February 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-02123 Filed 2-12-19; 8:45 am]

BILLING CODE 4140-01-P