

Name: Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: August 25, 2016, 9:00 a.m. to 5:00 p.m. (Meeting time is tentative.)

August 26, 2016, 9:00 a.m. to 3:00 p.m. (Meeting time is tentative.)

Place: Webcast and In-Person, 5635 Fishers Lane, Rockville, MD 20852.

Status: The meeting will be open to the public with attendance limited to space availability. Attendees and participants also have the option of viewing the meeting via webcast. Whether attending in-person or via webcast, all attendees and participants must register for the meeting. The registration link is <https://www.blsmmeetings.net/ACHDNCAugust2016>. The registration deadline is Friday, August 19, 2016, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, Title XI, § 1111, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240) (42 U.S.C. 300b–10), was established to advise the Secretary of the Department of Health and Human Services about 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. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The Committee will hear presentations and discussions on topics including an introduction on sequencing and potential impact on newborn screening and public health, screening for Lysosomal Storage Disorders, newborn screening

timeliness, pilot studies for future nominated conditions, and the National Contingency Plan for Newborn Screening. The Committee will hear updates from the Laboratory Standards and Procedures workgroup, Follow-up and Treatment workgroup, and Education and Training workgroup, Timeliness workgroup, and the Cost Analysis workgroup. Agenda items are subject to changes as priorities indicate. Tentatively, the Committee is expected to review and/or vote on the recommendations regarding the information needed from pilot studies for future nominated conditions. This vote does not involve a proposed addition of a condition to the RUSP. The meeting agenda will be available 2 days prior to the meeting on the Committee's Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Registration information is at <https://www.blsmmeetings.net/ACHDNCAugust2016>. The registration deadline for public comments is Friday, August 19, 2016, 11:59 p.m. Eastern Time. Written comments must be received by the deadline of Friday, August 5, 2016, 11:59 p.m. Eastern Time to be included in the August meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.*, parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Alaina Harris, Maternal and Child Health Bureau, Health Resources and Services Administration; email: aharris@hrsa.gov.

Contact Person: Anyone interested in obtaining other relevant information should contact Alaina Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W66, 5600 Fishers Lane,

Rockville, Maryland 20857; email: aharris@hrsa.gov.

More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering, Special Emphasis Panel, Center for Complex Tissues (2017/01).

Date: October 24, 2016.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, (240) 451–3398, hayesj@mail.nih.gov.

Dated: July 20, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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