copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Adaptive Designs for Medical Device Clinical Studies'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Gerry Gray, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2112, Silver Spring, MD 20993–0002, 301–796–6012; or the Division of Biostatistics, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–5750; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. This document addresses adaptive designs for medical device clinical trials and is applicable to premarket medical device submissions including premarket approval applications (PMA), premarket notification (510(k)) submissions, de novo submissions (evaluation of automatic class III designation), humanitarian device exemption (HDE) applications, and investigational device exemption (IDE) submissions. This guidance can be applied throughout the clinical development program of a medical device, from feasibility studies to pivotal clinical trials. This guidance does not apply to clinical studies of combination products or codevelopment of a pharmaceutical product with an unapproved diagnostic test. The draft guidance was available from May 18, 2015, to August 17, 2015. FDA received 151 comments from seven entities and has incorporated most of them in this final guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Adaptive Designs for Medical Device Clinical Studies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Adaptive Designs for Medical Device Clinical Studies'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUD1500005 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812, have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814,subpart H, have been approved under OMB control number 0910–0332; and the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17651 Filed 7–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

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.blsmeetings.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.blsmeetings.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.

[FR Doc. 2016–17724 Filed 7–26–16; 8:45 am]

BILLING CODE 4165–15–P

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.

[FR Doc. 2016–17655 Filed 7–26–16; 8:45 am]

BILLING CODE 4140–01–P