

*For devices regulated by CBER:*  
Stephen Ripley, Center for Biologics  
Evaluation and Research (HFM-17),  
Food and Drug Administration, 1401  
Rockville Pike, suite 200N, Rockville,  
MD 20852, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background**

This draft guidance document is intended to provide guidance to those involved in designing clinical studies intended to support premarket submissions for medical devices and for FDA staff who review those submissions. Although the Agency has articulated policies related to design of studies intended to support specific device types, and a general policy of tailoring the evidentiary burden to the regulatory requirement, the Agency has not attempted to describe the different clinical study designs that may be appropriate to support a device premarket submission or to define how a sponsor should decide which pivotal clinical study design should be used to support a submission for a particular device. The draft guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements. The draft guidance is not intended to provide a comprehensive tutorial on the best clinical and statistical practices for investigational medical device studies.

A medical device pivotal study is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Evidence from one or more pivotal clinical studies generally serves as the primary basis for the determination of reasonable assurance of safety and effectiveness of the medical device of a premarket approval application (PMA) and FDA's overall risk-benefit assessment. In some cases, a PMA may include multiple studies designed to answer different scientific questions.

The draft guidance describes principles that should be followed for the design of premarket clinical studies that are pivotal in establishing the safety and effectiveness of a medical device. Practical issues and pitfalls in pivotal clinical study design are discussed, along with their effects on the conclusions that can be drawn from the studies concerning safety and effectiveness.

### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the Agency's current thinking on design considerations for pivotal clinical investigations for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or on the Division of Dockets Management Internet site at <http://www.regulations.gov>. To receive "Design Considerations for Pivotal Clinical Investigations for Medical Devices," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1776 to identify the guidance you are requesting.

### **IV. Paperwork Reduction Act of 1995**

This draft 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 have been approved under OMB control number 0910-0231.

### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 9, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-20603 Filed 8-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

### **Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of July 14, 2011 (76 FR 41507). The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

#### **FOR FURTHER INFORMATION CONTACT:**

Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993-0002, 301-796-6639, [Shanika.Craig@fda.hhs.gov](mailto:Shanika.Craig@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 14, 2011, FDA announced that a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee would be held on September 8 and 9, 2011. On page 41508, in the first column, the *Procedure* section is changed to add, directly after the first full paragraph, the following paragraph:

FDA will work with the manufacturers of surgical mesh products who wish to make presentations to ensure that adequate time, separate from the 10 a.m. to 11 a.m. time slots from the general open public hearing, is provided. Manufacturers interested in making formal presentations to the committee should notify the contact person on or

before August 22, 2011. Manufacturers with common interest are urged to coordinate their oral presentations.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-20644 Filed 8-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; 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:* Center for Inherited Disease Research Access Committee.

*Date:* September 9, 2011.

*Time:* 11:30 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Camilla E. Day, PhD, Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, 301-402-8837, [camilla.day@nih.gov](mailto:camilla.day@nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 9, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-20688 Filed 8-12-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; 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 a meeting of the Board of Scientific Counselors, National Human Genome Research Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Human Genome Research Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Human Genome Research Institute.

*Date:* September 26-27, 2011.

*Time:* September 26, 2011, 8 a.m. to 7 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 50, Fifth Floor Conference Room, 50 Center Drive, Bethesda, MD 20892.

*Time:* September 27, 2011, 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 50, Fifth Floor Conference Room, 50 Center Drive, Bethesda, MD 20892.

*Contact Person:* Claire Kelso, Intramural Program Specialist, Division of Intramural Research, Office of the Scientific Director, National Human Genome Research Institute, 50 South Drive, Building 50, Room 5222, Bethesda, MD 20892-8002, 301 435-5802, [claire@nhgri.nih.gov](mailto:claire@nhgri.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 9, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-20687 Filed 8-12-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review 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:* Center for Scientific Review Special Emphasis Panel; Oncology AREA Review.

*Date:* September 15-16, 2011.

*Time:* 9 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Manzoor Zarger, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435-2477, [zargerma@csr.nih.gov](mailto:zargerma@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* September 19-20, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin Seattle, 1900 Fifth Avenue, Seattle, WA 98101.

*Contact Person:* Suzan Nadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301-435-1259, [nadis@csr.nih.gov](mailto:nadis@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

*Date:* September 26-27, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* W Chicago Lakeshore, 644 North Lakeshore Drive, Chicago, IL 60611.

*Contact Person:* Lee S. Mann, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301-435-0677, [mannl@csr.nih.gov](mailto:mannl@csr.nih.gov).