

form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: [deainfo.nci.nih.gov/advisory/pcp/pcp.htm](http://deainfo.nci.nih.gov/advisory/pcp/pcp.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 9, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-28848 Filed 11-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 materials, 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 Neurological Disorders and Stroke Special Emphasis Panel; Stroke.

*Date:* December 14, 2010.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Room 3204, MSC 9529, Bethesda, MD 20892, 301-594-0635, [Rc218u@nih.gov](mailto:Rc218u@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 9, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## 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; Member Conflict: HIV/AIDS Vaccines.

*Date:* December 1-2, 2010.

*Time:* 8 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Kenneth A. Roebuck, PhD Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, [roebuckk@csr.nih.gov](mailto:roebuckk@csr.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:* Center for Scientific Review Special Emphasis Panel; Neurophysiology.

*Date:* December 6, 2010.

*Time:* 2 p.m. to 4 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:* Toby Behar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435-4433, [behart@csr.nih.gov](mailto:behart@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 9, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Large-Scale Collaborative Projects Awards.

*Date:* December 6-7, 2010.

*Time:* 10 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN-12, Bethesda, MD 20892, (Hybrid Meeting)

*Contact Person:* Arthur L. Zachary, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN12, Bethesda, MD 20892, 301-594-2886, [zacharya@nigms.nih.gov](mailto:zacharya@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 9, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory  
Committee Policy.*

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

### **Food and Drug Administration**

[Docket No. FDA-2010-N-0001]

#### **External Defibrillators; Public Workshop**

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: FDA Public Workshop on External Defibrillators. The purpose of the public workshop is to share FDA's understanding of the risks and benefits of external defibrillators, to clarify FDA's current expectations for how industry should identify, report, and take action on problems observed with these devices, and to promote innovation for next-generation devices that will bring safer, more effective external defibrillators to market.

**Dates and Time:** The public workshop will be held on December 15, 2010, from 8 a.m. to 5:30 p.m., and on December 16, 2010, from 8 a.m. to 2 p.m. Persons interested in attending this public workshop must register by 5 p.m. on December 8, 2010.

**Location:** The public workshop will be held in the Great Room at the Food and Drug Administration, White Oak Campus, Bldg. 31, 10903 New Hampshire Ave., Silver Spring, MD 20903.

**Contact:** Megan Moynahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5404, Silver Spring, MD 20903, 301-796-5435, FAX: 301-847-8510, or e-mail: [Megan.Moynahan@fda.hhs.gov](mailto:Megan.Moynahan@fda.hhs.gov).

**Registration and Requests for Oral Presentations:** Registration is free and will be on a first-come, first-served basis. To register for the public workshop, please visit the following Web site: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm232062.htm> (or go the FDA Medical Devices New & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail,

and telephone number. For those without Internet access, please call the contact person to register. Registration requests should be received by 5 p.m. on December 8, 2010. Early registration is recommended because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

Registrants requesting to present written material or to make oral presentations at the public workshop, please call the contact person by November 29, 2010.

If you need special accommodations due to a disability, please contact Susan Monahan (e-mail: [Susan.Monahan@fda.hhs.gov](mailto:Susan.Monahan@fda.hhs.gov)) at least 7 days in advance.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

External defibrillators (including automated external defibrillators (AEDs)) are life-saving devices designed to restore normal heart rhythms following sudden cardiac arrest. Each year, nearly 300,000 Americans collapse from sudden cardiac arrest. In sudden cardiac arrest, the heart unexpectedly stops pumping blood to the body. When normal heart rhythms are not restored quickly, sudden cardiac arrest can cause death.

External defibrillators are important, life-saving devices. However, over the past 5 years we have seen persistent safety problems with all types of external defibrillators, across all manufacturers of these devices. From January 1, 2005, to July 10, 2010, there were a total of 68 recalls, of which 9 occurred in 2005 increasing to 17 in 2009 (the last complete year for which data are available). During this period, FDA received over 28,000 medical device reports (MDRs), of which 4,210 occurred in 2005 increasing to 7,807 in 2009 (the last complete year for which data are available). FDA conducted multiple inspections of all external defibrillator manufacturers throughout this time period.

Many of the types of problems we have identified are preventable, correctable, and impact patient safety. As part of a comprehensive review, FDA identified several industry practices that have contributed to these persistent safety risks including industry practices for designing and manufacturing defibrillators, handling user complaints, conducting recalls, and communicating with users. In some cases, these practices can contribute to device performance problems, place undue

burden on users, and put patients at risk.

To date, FDA has addressed individual device problems on a case-by-case basis. However, our analysis of MDRs, recalls, and inspections confirms that common problems persist across all types of external defibrillators and all manufacturers. One purpose of the public workshop is to share FDA's understanding of the risks and benefits of external defibrillators and to clarify FDA's current expectations for how industry should identify, report, and take action on problems observed with these devices.

In addition, to promote innovation and to better understand patient outcomes, FDA is collaborating with the University of Colorado's Department of Emergency Medicine and the Centers for Disease Control and Prevention (CDC) to develop a multi-city AED registry that will link with the CDC-funded Cardiac Arrest Registry to Enhance Survival (CARES). The registry will provide the infrastructure to foster the development of innovative AED features such as automated integration into local 9-1-1 systems. FDA will work with multiple stakeholders to facilitate the development of next-generation defibrillators, enhance surveillance of defibrillators in community settings, and improve the rapid delivery of treatment for sudden cardiac arrest patients. One purpose of the public workshop on December 15 and 16, 2010, is to advance these efforts by bringing together government, industry, academia, and users, including clinicians and consumers, to share perspectives.

##### **II. Topics for Discussion at the Public Workshop**

The public workshop will be organized to allow facilitated discussion by industry, academia, clinicians, users, and regulators on the following broad topic areas:

1. What are the nature, scope, and impact of external defibrillator problems that have been observed? What are the root causes of these problems?
2. How should problems with external defibrillators be identified, reported, and acted upon by industry and users?
3. What factors or criteria should be considered when designing external defibrillators for use in different environments (hospital, community, home)?
4. What features of next generation devices can be defined that will increase the diffusion of new technologies, enhance device interoperability, and improve ease of use?