

discussion. As described previously in this document, individuals who are interested in making an oral presentation during any of the open comment sessions must indicate this at the time of registration, must identify which discussion topic they intend to address (*see Registration and Requests for Oral Presentations*), and must submit their presentations in advance. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. Commenters are free to submit comments on any discussion topic(s) to the open docket (*see* II. Comments). FDA will schedule speakers for each open session as time permits.

After each of the open comment sessions, there will be a panel discussion between FDA staff and selected participants representing a range of constituencies. The participants in the panel discussions will reflect on the presentations and comments, engage in a dialogue with each other and FDA staff, and provide closing thoughts for each session. The participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to the panel discussions.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each open comment session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm241095.htm>.

II. Comments

FDA is holding this public meeting to obtain information on a number of questions regarding medical device innovation. The deadline for submitting comments related to this public meeting is March 15, 2011.

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments. 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. In addition, when responding to specific questions as outlined in this document, please

identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6-30, Rockville, MD 20857.

Dated: February 4, 2011.

Nancy K. Stade,

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

[FR Doc. 2011-2915 Filed 2-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Organ Transplantation.

Date and Times: March 8, 2011, 7:30 a.m. to 5 p.m.

Place: Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

Status: The meeting will be open to the public.

Purpose: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government

Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

Agenda: The Committee will hear reports from two ACOT Work Groups: Declining Rates of Donation/Geographical and Other Variations in Organ Distribution and Alignment of CMS Regulatory Requirements with OPTN. ACOT also will hear presentations on disease transmission and informed consent, transplant tourism, organ donation and transplantation alliance, a report on an intensive DMV outreach project demonstrating significant increases in Michigan donor registration, and OPO performance metrics for quality improvement. Agenda items are subject to change as priorities indicate.

After the presentations and Committee discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be made available on the Department's donation Web site at <http://www.organdonor.gov/acot.html>.

The draft meeting agenda is available on the Department's donation Web site at <http://www.organdonor.gov/acot.html> and at <http://www.team-psa.com/dot/spring2011/ACOT/>.

Registration can be completed electronically at <http://www.team-psa.com/dot/spring2011/ACOT/> or submitted by facsimile to HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234-1701 ATTN: Brittany Carey. Individuals without access to the Internet who wish to register may call Brittany Carey with HRM/PSA at (703) 889-9033.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12-105, Rockville, Maryland 20857; telephone (301) 443-1127 or e-mail to pstroup@hrsa.gov.

Dated: February 2, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-2839 Filed 2-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Initial Review Group; Population Sciences Subcommittee.

Date: March 3, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Carla T. Walls, PhD, Scientific Review Officer, Division Of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6898, wallsc@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 3, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-2858 Filed 2-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Recombinant DNA Advisory Committee.

Date: March 8, 2011.

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

Agenda: The NIH Recombinant DNA Advisory Committee (RAC) will review and discuss selected human gene transfer protocols and discuss related data management activities. Please check the meeting agenda at http://oba.od.nih.gov/rdna_rac/rac_meetings.html for more information.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Chezelle George, Office of Biotechnology Activities, Office of Science Policy/OD, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892, 301-496-9838, georgec@od.nih.gov.

Information is also available on the Institute's/Center's home page: <http://oba.od.nih.gov/rdna/rdna.html>, where an agenda and any additional information for the meeting will be posted when available.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(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 3, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-2857 Filed 2-8-11; 8:45 am]

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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 (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: National Institute of Mental Health Special Emphasis Panel; Biobehavioral Research Awards for Innovative New Scientists (BRAINS).

Date: March 1, 2011.

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

Agenda: To review and evaluate grant applications.

Place: The Westin Arlington Gateway, 801 N. Glebe Road, Arlington, VA 22203.

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, libbeym@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Scalable Assays for Unbiased Analysis of Neurobiological Function.

Date: March 7, 2011.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Mandarin Oriental, 1330 Maryland Avenue, SW., Washington, DC 20024.