

submissions may be made to the contact person on or before January 27, 2010. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 19, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 20, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-29989 Filed 12-16-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92-463, notice is hereby given of the twenty-first meeting of the Secretary's Advisory

Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 5:30 p.m. on Thursday, February 4, 2010, and from 8 a.m. to approximately 3 p.m. on Friday, February 5, 2010, at the Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC 20008. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The main agenda items involve the review of a revised report on gene patents and licensing practices, the review of a public consultation draft report on genetics education and training, and an information-gathering session on the mechanisms and policies related to genomic data sharing. Other agenda items include a preliminary discussion to help plan a future session on implications of an affordable genome; a report on activities of the Clinical Utility and Comparative Effectiveness Task Force; and updates from Federal agencies on activities related to the implementation of the Genetic Information Nondiscrimination Act, the coverage and reimbursement of genetic tests, the oversight of genetic testing, and the retention and use of residual dried blood spot specimens after newborn screening.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health, and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at carrs@od.nih.gov. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: http://oba.od.nih.gov/SACGHS/sacghs_meetings.html.

Dated: December 10, 2009.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

[FR Doc. E9-30023 Filed 12-16-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel, Transplant and Viruses.

Date: January 11, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call.)

Contact Person: Priti Mehrotra, PhD, Chief, Immunology Review Branch, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3138, Bethesda, MD 20892-7616, 301-435-9369, pm158b@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, "B Lymphocyte Responses."

Date: January 12, 2010.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call.)

Contact Person: Wendy F. Davidson, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-402-8399, davidsonw@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-30022 Filed 12-16-09; 8:45 am]

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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: Auditory Neuroscience.

Date: January 19–20, 2010.

Time: 8 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: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408-9664, bishopj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR-07-420: Lymphatic Biology in Health and Disease.

Date: January 27–28, 2010.

Time: 8 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: Maqsood A. Wani, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7814, Bethesda, MD 20892. 301-435-2270, wanimags@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: December 10, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-30021 Filed 12-16-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance and Good Clinical Practices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Florida District, in cosponsorship with The Society of Clinical Research Associates, Inc. (SoCRA), is announcing a public workshop entitled “FDA Clinical Trial Requirements, Regulations, Compliance and GCP.” This 2-day public workshop is intended to provide information about FDA clinical trial requirements to the regulated industry.

Date and Time: The public workshop will be held on Wednesday, March 3, 2010, from 8 a.m. to 5 p.m., and Thursday, March 4, 2010, from 8 a.m. to 4:35 p.m.

Location: The public workshop will be held at The Wyndham Orlando Resort, 8001 International Dr., Orlando, FL 32819, 407-351-2420.

Attendees are responsible for their own accommodations. To make reservations at the Wyndham Orlando Resort, at the discounted rate of \$149 per night (plus applicable taxes), contact the hotel before February 10, 2010, citing “SoCRA”. The hotel’s Web site is: <http://www.wyndham.com/hotels/MCOWD/main.wnt>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contacts:

For FDA: C. Stewart Watson, Food and Drug Administration, 555 Winderley Pl., suite 200, Maitland, FL 32751, 407-475-4756, FAX: 407-475-4768, e-mail: charles.watson@fda.hhs.gov.

For SoCRA: SoCRA Administrative Office, 530 West Butler Ave., suite 109, Chalfont, PA 18914, 1-800-762-7292 or 215-822-8644, FAX: 215-822-8633, e-mail: SoCRAmail@aol.com.

Registration: You are encouraged to register by February 26, 2010. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Registration will close when the workshop is filled. Those accepted into the workshop will receive confirmation. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The SoCRA registration fees cover the cost of the workshop facilities, materials, breaks, and lunches. The cost of registration is as follows:

COST OF REGISTRATION

Affiliation	Fee
FDA Employee	Fee waived
Federal Government (SoCRA Member)	\$450.00
Federal Government (Non-SoCRA Member)	\$525.00
Non-Federal Government (SoCRA Member)	\$575.00
Non-Federal Government (Non-SoCRA Member)	\$650.00

If you need special accommodations due to a disability, please contact C.

Stewart Watson at least 7 days in advance of the meeting.

Registration instructions: To register, please submit your name, affiliation,