

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Jacinta Bronte-Tinkew, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806-0009, brontetinkewjm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; OppNet RFA: Culture, Health and Wellbeing.

Date: June 11, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Tremont Suites Hotel and Grand Historic Venue, 222 St. Paul Place, Baltimore, MD 21202.

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301-254-9975, helmersk@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: June 11, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Baltimore, 300 Light Street, Baltimore, MD 21202.

Contact Person: Michael Knecht, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, knechtm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Systemic Injury By Environmental Exposure.

Date: June 11, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member conflict: Lung Diseases.

Date: June 11-12, 2013.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: George M Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, barnasg@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

Date: June 12, 2013.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Janet M Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-806-2765, larkinja@csr.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Development—1 Study Section.

Date: June 12, 2013.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301-435-2406, ariasj@csr.nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; International and Cooperative Projects—1 Study Section.

Date: June 12, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Hilary D Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594-6377, sigmonh@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: May 7, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-11208 Filed 5-10-13; 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; Leadership Group for a Clinical Research Network on Integrated Strategies to Prevent HIV Infection.

Date: May 29-30, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Tracy A. Shahan, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-496-2606, tshahan@niaid.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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: June 4, 2013.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Room 3128, Bethesda, MD 20892-7616, 301-451-2744, battlesja@mail.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Units for NIAID Network.

Date: June 6, 2013.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Vasundhara Varthakavi, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700-B Rockledge Drive, Bethesda, MD 20892-7616, 301-496-2550, varthakaviv@niaid.nih.gov.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Subcommittee.

Date: June 10, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nancy Lewis Ernst, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-451-7383, nancy.ernst@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: May 7, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-11210 Filed 5-10-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Initial Review Group; Behavior and Social Science of Aging Review Committee NIA-S.

Date: June 12-13, 2013.

Time: 4:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Long Beach Downtown, 500 East First Street, Long Beach, CA 90802.

Contact Person: Rebecca Jo Ferrell, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7703, rebecca.ferrell@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-11209 Filed 5-10-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

SUMMARY: The NIH Office of Biotechnology Activities (NIH OBA) proposes to revise the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to streamline review of certain human gene transfer trials that present a low biosafety risk. Specifically, the NIH OBA proposes to remove the requirement that institutional biosafety committees (IBCs) review and approve certain human gene transfer clinical trials that use plasmids and certain attenuated, non-integrating viral vectors, provided the clinical trial follows an initial study in humans that was previously approved by an IBC registered with the OBA. This initial trial will have established the safety of the proposed dose of the gene transfer product (vector and transgene) in a comparable population (adults or children). The initial study should have been conducted in the same country as the proposed study to control for potential variability in infectious disease backgrounds of the participants.

An initial IBC review is important to evaluate the safety of the product and to set standards for administration; however, for well-characterized vectors, in the absence of any unexpected toxicities in the initial study, subsequent biosafety assessments may not provide any additional information. While a single IBC review does not pose an undue burden, as the gene transfer field advances and more Phase II and Phase III multisite trials are developed, the time, effort and expense associated with multiple IBC reviews can be significant without adding commensurate value in the form of additional recommendations to protect the health and safety of the subject, health care worker, and community.

IBCs play a critical role in the evaluation of new products and their review can inform other oversight

bodies, such as Institutional Review Boards. However, given the competing demands on IBCs, this change will provide IBCs with the option of focusing their efforts on those clinical trials where review will be most productive. While IBCs will no longer be *required* to review all clinical trials using the same product, each institution can implement its own policies regarding the need to review such trials and the information that a principal investigator (PI) should submit regarding the safety of the previous trial. For example, an institution may designate the Biological Safety Officer and the IBC Chair to review data from the initial trial and determine whether a subsequent trial using the same agent meets the exemption criteria outlined herein. The institution may also set its own policies regarding the need for the PI to inform the IBC about enrollment, any relevant new biosafety findings, and completion of the trial.

This policy will only exempt human gene transfer clinical trials from IBC review under Section III-C-1. It does not apply to basic, nonclinical research. In addition, it does not create an exemption from registration of the trial with the NIH OBA or the Recombinant DNA Advisory Committee (RAC) review and reporting requirements. By continuing to require registration and reporting on these trials, the NIH OBA will be able to continue to monitor adverse events or incident reports of accidental exposures by health care workers delivering these agents and, if necessary, provide information regarding these events to investigators, IBCs, and the public. The NIH OBA will also be able to assess whether this change in policy has any adverse impact on the biosafety of gene transfer trials.

DATES: All comments should be submitted by June 12, 2013.

ADDRESSES: Comments may be submitted to the NIH OBA by email at oba@od.nih.gov; by fax to 301-496-9839; or by mail to the NIH Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985. All written comments received in response to this notice will be available for public inspection in the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, weekdays between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these proposed changes, please contact the NIH OBA by email at oba@od.nih.gov or telephone at 301-496-9838. Comments