

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: AIDS and Related Research Integrated Review Group, NeuroAIDS and other End-Organ Diseases Study Section.

Date: March 15, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168, montalve@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Extracellular RNA Biomarkers.

Date: March 15, 2013.

Time: 8:30 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: Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301-435-4511, ronald.adkins@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Proteomic and Imaging Biomarkers of Brain Diseases.

Date: March 15, 2013.

Time: 1:00 p.m. to 3:00 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: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Biology of Neurodegeneration.

Date: March 15, 2013.

Time: 12:00 p.m. to 2:00 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: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Cancer Health Disparities/Diversity in Basic Cancer Research.

Date: March 18-19, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, riverase@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopedic and Skeletal Biology.

Date: March 18, 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: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301-435-1777, moongabs@mail.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: February 14, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-03858 Filed 2-20-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 Scientific Review Special Emphasis Panel; PAR 12-048

Prevention and Treatment of Chronic Diseases in Military Populations.

Date: March 6, 2013.

Time: 10:00 p.m. to 11:30 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: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301-408-9436, fungai.chanetsa@nih.hhs.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: February 14, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-03860 Filed 2-20-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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: National Heart, Lung, and Blood Institute Special Emphasis Panel Clinical Trials SEP Review.

Date: March 8, 2013.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892-7924, 301-435-0287, carolko@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for

Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 14, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-03857 Filed 2-20-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of changes to the *NIH Guidelines*.

SUMMARY: Concerns about the emergence of a pandemic influenza virus have spurred research with influenza viruses that have the potential to cause a pandemic, such as highly pathogenic avian influenza (HPAI) H5N1 viruses. In 2012, two published studies funded by the National Institutes of Health (NIH) examined genetic changes that would allow HPAI H5N1 viruses to transmit by respiratory droplets among ferrets, an animal model that is often used to predict transmission and pathogenicity of influenza viruses in humans. This research raised concerns regarding the potential for HPAI H5N1 viruses to evolve and lead to a global pandemic. If transmission of a genetically engineered HPAI H5N1 virus among ferrets by respiratory droplets indicates that HPAI H5N1 viruses could evolve to transmit efficiently among humans by respiratory droplets, the public health risk of such a virus would be greater than that of the HPAI H5N1 virus currently circulating in poultry and wild birds, which does not easily transmit among humans. The NIH Recombinant DNA Advisory Committee (RAC) was asked to review the biosafety requirements for recombinant research with HPAI H5N1 virus contained in the October 2011 *NIH Guidelines* and determine whether these conditions and practices are adequate to address research with HPAI H5N1 viruses that transmit among mammals by respiratory droplets, as demonstrated in an appropriate animal model or clinically in humans (referred

throughout this document as mammalian-transmissible HPAI H5N1). On January 24, 2013, the RAC held a public meeting, together with influenza experts, as well as experts from the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority (BARDA), HHS, the Food and Drug Administration (FDA), the World Health Organization (WHO), and the U.S. Department of Agriculture (USDA). The RAC recommended additional enhancements for research on mammalian-transmissible HPAI H5N1 virus to supplement the biosafety requirements for HPAI H5N1 that are already delineated in the *NIH Guidelines*. These enhancements include changes to the facility and biosafety equipment and practices, including occupational health practices. Based on the recommendations of the RAC, the NIH Office of Biotechnology Activities (OBA) concluded that more specific guidance regarding recombinant research with mammalian-transmissible HPAI H5N1 virus is warranted.

The resulting amendments to the *NIH Guidelines* are "Minor Actions" under Section IV-C-1-(b)-2 of the *NIH Guidelines*, and therefore, will be implemented immediately upon publication in the **Federal Register**. While a Minor Action only requires consultation with the RAC chair and one or more RAC members, as necessary, as noted above, these changes were developed after extensive consultation with the full RAC and other experts and were discussed at a public RAC meeting. Publication in the **Federal Register** will inform the scientific and biosafety communities, as well as solicit continued scientific input should revisions be needed in the future.

DATES: The public is encouraged to submit written comments on this action. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and email addresses shown below under the heading **FOR FURTHER INFORMATION**. All comments should be submitted by March 25, 2013. All written comments received in response to this notice will be available for public inspection in the NIH OBA, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted to the OBA's Web site.

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

301-496-9838. Comments may be submitted to the same email address or by fax at 301-496-9839 or by mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985. Background information may be obtained by contacting NIH OBA by email at oba@od.nih.gov.

SUPPLEMENTARY INFORMATION

Background

The NIH is a major funder of research on influenza viruses, much of which involves recombinant DNA technology. One important area of research is focused on currently circulating HPAI H5N1 influenza viruses. These avian influenza viruses primarily infect and kill poultry and other susceptible species. Currently, almost all HPAI H5N1 infections in humans have been linked to a person having close contact with infected poultry; the virus does not seem to transmit readily among humans. In the approximately 600 human cases of infection with HPAI H5N1 virus reported to the WHO to date, apparent human-to-human transmission is limited to small, familial clusters (see e.g., Kandun, I.N. *et al.* Three Indonesian Clusters of H5N1 Virus Infection in 2005, *N Engl. J. M.* 355: 2186-94 (2006)), without sustained chains of transmission in the community. However, the mortality rate for the human infections reported to WHO is almost 60% [http://www.who.int/influenza/human_animal_interface/EN_GIP_20130201CumulativeNumberH5N1cases.pdf]. The high mortality rate for these clinical infections is of great concern, especially if such a virus developed the ability to transmit efficiently among humans.

The public health benefits of research on potentially pandemic influenza viruses include identification of genetic changes that contribute to host adaptation, transmissibility, and virulence. Such information can be used to enhance surveillance as well as contribute to the development of vaccine candidates, and identification of targets for antiviral drugs. While research into influenza viral virulence mechanisms and the development of vaccines and antiviral drugs are public health priorities, it is equally important that the research be performed under appropriate biocontainment to protect the health of laboratory personnel and the public.

In 2009, the *NIH Guidelines* were amended to address research with certain influenza viruses with increased pandemic potential, including the reconstructed 1918 H1N1 virus and