

*Contact Person:* Janet M. Larkin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892, 301-435-1026, [larkinja@csr.nih.gov](mailto:larkinja@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Behavioral and Social HIV/AIDS Review of SBIR Applications.

*Date:* March 28, 2008.

*Time:* 1 p.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:* Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1775, [rubertm@csr.nih.gov](mailto:rubertm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Development of Assays for High Throughput Screening (HTS) in the Molecular Libraries Probe Production Centers Network (MLPCN).

*Date:* April 3, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Suites, 1000 29th Street, NW, Washington, DC 20007.

*Contact Person:* George W. Chacko, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7849, Bethesda, MD 20892, 301-435-1245, [chackoge@csr.nih.gov](mailto:chackoge@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: February 27, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-936 Filed 3-04-08; 8:45 am]

BILLING CODE 4140-01-M

## 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. Appendix 2), 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, Atherosclerotic and Lipid Metabolism.

*Date:* March 11, 2008.

*Time:* 1:30 p.m. to 3 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:* Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@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.

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

Dated: February 27, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-937 Filed 3-4-08; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Environmental Health Sciences Special

Emphasis Panel, Mentored Career Development Award Review Meeting.

*Date:* April 7, 2008.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

*Contact Person:* Linda K. Bass, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307, [bass@niehs.nih.gov](mailto:bass@niehs.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: February 27, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-938 Filed 3-4-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases: Licensing Opportunity and Cooperative Research and Development Agreement ("CRADA") Opportunity; Live Attenuated Vaccine To Prevent Disease Caused by West Nile Virus

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases (NIAID) of the NIH is seeking licensees and/or CRADA partners to further develop, evaluate, and commercialize modified West Nile virus (WNV) chimeras as a live attenuated vaccine against infections of WNV in humans. NIAID is also seeking licensees to commercialize modified WNV chimeras as live attenuated veterinary vaccines against infections of WNV in animals.

**DATES:** Respondents interested in licensing the invention will be required to submit an "Application for License to Public Health Service Inventions" on or

before June 3, 2008 for priority consideration.

Interested CRADA collaborators must submit a confidential proposal summary to the NIAID (attention Percy S. Pan at the address mentioned below) on or before June 3, 2008 for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA and PHS License Applications submitted thereafter may be considered if a suitable CRADA collaborator or Licensee(s) has not been selected.

**ADDRESSES:** Questions about licensing opportunities should be addressed to Peter Soukas, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, Telephone: (301) 435-4646 ; Facsimile: (301) 402-0220; E-mail: [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov). Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondents interested in licensing the invention will be required to submit an "Application for License to Public Health Service Inventions."

Depending upon the mutual interests of the Licensee(s) and the NIAID, a CRADA to collaborate to develop WNV vaccines in humans may also be negotiated. Proposals and questions about this CRADA opportunity should be addressed to Percy S. Pan, Technology Development Associate, Office of Technology Development, NIAID, 6610 Rockledge Drive, Room 4071, Bethesda, MD 20892-6606, Telephone: (301) 451-3523; E-mail: [panp@niaid.nih.gov](mailto:panp@niaid.nih.gov). Respondents interested in submitting a CRADA Proposal should be aware that it may be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.

**SUPPLEMENTARY INFORMATION:** WNV has recently emerged in the U.S. and is considered a significant emerging disease that has embedded itself over a considerable region of the U.S. WNV infections have been recorded in humans as well as in different animals. To date, WNV has killed 294 people in the U.S. and caused severe disease in more than 4222 others. This project is part of NIAID's comprehensive emerging infectious disease program, which supports research on bacterial,

viral, and other types of disease-causing microbes.

The methods and compositions of this invention provide a means for prevention of WNV infection by immunization with attenuated, immunogenic viral vaccines against WNV. The invention involves a chimeric virus form consisting of parts of WNV and Dengue virus. Construction of the hybrids and their properties are described in detail in PNAS, Pletnev AG et al., 2002; 99(5):3036-3041.

The WNV chimeric vaccine does not target the central nervous system, which would be the case in an infection with wild type WNV. The vaccine stimulates strong anti-WNV immune responses, even following a single dose of the vaccine. When injected into mice, the vaccine protected all of the immunized animals from subsequent exposure to the New York WNV strain. The vaccine was also effective in primates. Researchers intend to begin human trials in late 2003.

The WNV vaccine may be used to protect the human population, particularly the elderly people, and domestic animals from WNV infection in the affected regions of the U.S. as well as worldwide.

The invention claimed in HHS Reference No. E-357-2001/1-US-02, "Construction of West Nile Virus and Dengue Virus Chimeras for Use in a Live Virus Vaccine to Prevent Disease Caused by West Nile Virus" AG Pletnev et al.), U.S. Patent Application No. 10/871,775, filed June 18, 2004, is available for exclusive or non-exclusive licensing for developing a vaccine against WNV for humans or veterinary use in accordance with 35 U.S.C. 207 and 37 CFR Part 404. NIAID is also interested in further development of the technology under one or more CRADAs in the human applications described below.

Under the CRADA the production of WNV vaccines for humans will be optimized and the vaccine evaluated in a series of clinical studies in humans as well as initial safety testing in humans. Positive outcomes of these studies will indicate continued clinical development aimed at supporting regulatory approval of a product to be labeled for use in humans. The Public Health Service (PHS) has filed patent applications both in the U.S. and internationally related to this technology. Notice of the availability of the patent application for licensing was first published in the **Federal Register** on May 2, 2002 (67 FR 22093).

NIAID's principal investigator has extensive experience with live attenuated vaccines, their production

and testing, and clinical trials. The Collaborator in this endeavor is expected to assist NIAID in evaluating its current system for producing the WNV chimeras claimed in the patent applications and to develop and optimize an alternative production method, if necessary, to manufacture sufficient quantities of the vaccine for clinical testing in humans and initial safety studies in humans. The Collaborator must have experience in the manufacture of live attenuated vaccines according to applicable FDA guidelines and Points to Consider documents to include Good Manufacturing Procedures (GMP). In addition, it is expected that the Collaborator would provide funds to supplement the LID's research budget for the project and to support the initial human testing.

The capability statement should include detailed descriptions of: (1) Collaborator's expertise in the production of live attenuated vaccines, (2) Collaborator's ability to manufacture sufficient quantities of the vaccine according to FDA guidelines and Points to Consider documents, (3) the technical expertise of the Collaborator's principal investigator and laboratory group in preclinical safety testing (e.g., expertise in *in vitro* and *in vivo* toxicity and pharmacology studies) and initial human safety studies, and (4) Collaborator's ability to provide adequate funding to support initial human safety studies required for marketing approval.

Dated: February 25, 2008.

**Michael Mowatt,**

*Director, Office of Technology Development, National Institute of Allergy and Infectious Diseases, National Institutes of Health.*

Dated: February 26, 2008.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. E8-4193 Filed 3-4-08; 8:45 am]

**BILLING CODE 4140-01-P**

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

### **National Institutes of Health**

#### **Prospective Grant of Exclusive License: The Development of Human Therapeutics for the Treatment of Cancer**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.