

3804, Telephone: (301) 435-4646; Facsimile: (301) 402-0220; E-mail: [ps193c@nih.gov](mailto:ps193c@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 Richard K. Williams, Ph.D., Technology Development Associate, Office of Technology Development, NIAID, 6610 Rockledge Drive, Room 4071, Bethesda, MD 20892-6606, Telephone: (301) 402-0960; E-mail: [rwilliams@niaid.nih.gov](mailto:rwilliams@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 DHHS Reference No. E-357-01/0, "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.*), PCT/US03/00594 filed Jan 09, 2003, 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: April 25, 2003.

**Michael Mowatt,**

*Director, Office of Technology Development, NIAID.*

Dated: May 1, 2003.

**Steven M. Ferguson,**

*Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; 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 552(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 Special Emphasis Panel, Mathematics Cognition and Specific Learning Disabilities.

*Date:* May 29-30, 2003.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Hotel George, 15 E Street NW., Washington, DC 20001.

*Contact Person:* Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd.,