

newsletter and to assess which audiences are being reached through these channels. This effort involves a telephone survey consisting of 9 questions, which will be asked of 50 percent of all callers, for an annual total of approximately 4,059 respondents; and a newsletter survey consisting of 10 questions, which will be sent as a print survey to all newsletter subscribers, for an annual total of approximately 823

respondents. NCCAM will use the data collected from the surveys to help program staff measure the impact of their communication efforts, tailor services to the public and health care providers, measure service use among special populations, and assess the most effective media and messages to reach these audiences. *Frequency of Response:* Once for the telephone survey, and periodically for the newsletter survey

(to measure any changes in customer satisfaction). *Affected Public:* Individuals and households. *Type of Respondents:* For the telephone survey, patient, spouse/family/friend of patient, health care providers, physicians, CAM practitioners, or other individuals contacting the NCCAM Clearinghouse; for the newsletter survey, subscribers to the NCCAM newsletter. The annual reporting burden is as follows.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
<b>Telephone survey</b>				
Individuals or households .....	4,059	1	0.075	305
<b>Newsletter survey</b>				
Individuals or households .....	823	2	0.050	82
Annualized totals .....	4,882	.....	.....	387

The annualized cost to respondents is estimated at \$5,545 for the telephone survey and \$1,312 for the newsletter survey. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

#### Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

#### Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more

information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475; or fax your request to 301-480-3519; or e-mail [thomsenc@mail.nih.gov](mailto:thomsenc@mail.nih.gov). Ms. Thomsen can be contacted by telephone at 301-451-8876.

#### Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: May 1, 2003.

**Christy Thomsen,**

*Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.*

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**BILLING CODE 4140-01-M**

## 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 August 11, 2003, for priority consideration.

Interested CRADA collaborators must submit a confidential proposal summary to the NIAID (attention Richard K. Williams, Ph.D. at the address mentioned below) on or before August 11, 2003, 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: [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.,