

the program. The plan should address each of the activities under the program area for which the applicant organization is applying and provide a timeline for conducting program activities.

#### 5. Organizational Experience (15 Points)

The extent to which the applicant can demonstrate existing support for partnership activities and collaboration with CDC, other associations and organizations, and official health agencies.

#### 6. Evaluation Plan (15 Points)

The extent to which the applicant presents an evaluation plan to measure the achievement of program objectives and monitor the implementation of proposed activities, or the commitment to implement a collaboratively developed evaluation plan.

#### 7. Budget Justification (not scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

### H. Other Requirements

1. Technical Reporting Requirements  
Provide CDC with original plus two copies of

- a. semiannual progress reports;
- b. financial status report, no more than 90 days after the end of the budget period; and
- c. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

2. The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR-7 Executive Order 12372 Review  
AR-10 Smoke-Free Workplace

Requirements  
AR-11 Healthy People 2010  
AR-12 Lobbying Restrictions

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a), as amended. The Catalog of Federal Domestic Assistance Number is 93.283.

### J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page

Internet address—<http://www.cdc.gov>  
Click on "Funding" then "Grants and Cooperative Agreements." To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Juanita D. Crowder, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3720, 2920 Brandywine Road Atlanta, GA 30341-4146, Telephone Number: (770) 488-2734, Email address: [jdd2@cdc.gov](mailto:jdd2@cdc.gov).

For program technical assistance, contact: R. Gibson Parrish, M.D., CDC Project Officer, 2877 Brandywine Road, Mailstop K74, Atlanta, Georgia 30341-3724, Telephone number: (770) 488-8357, Email address: [rgp1@cdc.gov](mailto:rgp1@cdc.gov).

Dated: July 19, 2000.

**Henry S. Cassell III,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 00-18700 Filed 7-24-00; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

### National Institutes of Health (NIH); National Institute on Drug Abuse (NIDA)

#### Licensing Opportunity and/or Cooperative Research and Development Agreement ("CRADA") Opportunity: Novel Methods and Compositions for Diagnosing, Treating and Monitoring Psychiatric Disease

**AGENCY:** NIDA, NIH, DHHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute on Drug Abuse (NIDA), Cellular Neurobiology Research Branch, is seeking Licensee(s) and/or proposals from potential collaborators for a Cooperative Research and Development Agreement (CRADA) to participate in the exploration of the clinical significance of recent studies in which NIDA has identified variations in the isoforms of neural cell adhesion molecule (N-CAM) associated with neuropsychiatric disorders. Elevations in certain isoforms are associated with specific neuropsychiatric disorders.

These specific variations in the levels of N-CAM suggest that diagnostic techniques or therapeutic interventions could be based on the observed alterations in cell adhesion molecules. A provisional patent application relating to the N-CAM isoforms associated with neuropsychiatric disorders has been filed. Any successful CRADA collaborator may need to negotiate a license to the provisional patent application in order to commercialize developments under the CRADA. Contact information to apply for a license to the provisional patent application appears below.

**DATES:** Interested CRADA applicants should submit written notice of intent to apply within 45 days of the date of this notice. NIDA will consider all written proposals received within 60 days of the date of publication of this notice. CRADA proposals submitted thereafter may be considered if a suitable CRADA collaborator has not been found. There is no specific deadline for licensing applications.

**ADDRESSES:** Scientific questions about this notice may be addressed to Dr. Marquis Vawter, National Institute on Drug Abuse, 5500 Nathan Shock Drive, Baltimore, Maryland 21224, Tel. 410-550-1405; questions concerning the CRADA opportunity may be addressed to Dr. Malka Scher, Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Boulevard, Suite 450, Rockville, Maryland 20852, Tel: 301-496-0477, Fax: 301-402-2117, e-mail: [scherm@mail.nih.gov](mailto:scherm@mail.nih.gov); and questions concerning the patent application should be addressed to Dr. Norbert Pontzer, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, Tel: 301-496-7057 (ext. 284), Fax: 301-402-0220, e-mail: [np59n@nih.gov](mailto:np59n@nih.gov).

#### SUPPLEMENTARY INFORMATION:

Respondee(s) interested in licensing the invention will be required to submit an Application for License to Public Health Service Inventions. Inventions described in the patent application are available for either exclusive or non-exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR Part 404. Information about Patent Application(s) and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement.

A "Cooperative Research and Development Agreement" or "CRADA" is the anticipated joint agreement to be entered into by NIDA and a collaborator pursuant to the Federal Technology

Transfer Act of 1986 as amended by the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113 (Mar. 7, 1996)) and by the Executive Order 12591 of October 10, 1987. The CRADA would pertain to inventions conceived or reduced to practice after the effective date of the CRADA. CRADA applicants should be aware that a license to the above mentioned patent rights may be necessary in order to commercialize products arising from a CRADA.

A CRADA is an agreement designed to enable certain collaborations between Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. The NIDA is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NIDA can contribute facilities, staff, materials, and expertise to the effort. The collaborator may contribute facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator receives an exclusive option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a pre-determined field of use and may qualify as a co-inventor of new technology developed under the CRADA.

NIDA's principal objectives under a License and/or CRADA would be the development and timely commercialization of new diagnostics and/or therapeutics for specific neuropsychiatric disorders and rapid publication of results related to these research projects.

Scientists at NIDA have discovered that distinct isoforms of N-CAM are elevated in the cerebrospinal fluid (CSF) and brains of patients diagnosed with specific neuropsychiatric disorders including schizophrenia, bipolar disorder and depression. A distinct isoform with molecular weight 105-115 kDa is present in elevated levels in both the CSF and brain tissues of patients with schizophrenia. The secreted (SEC) N-CAM isoform was elevated in brain tissue from bipolar disorder patients. Elevation of at least one isoform, the variable alternative spliced exon, or VASE isoform, is correlated significantly with behavioral ratings in patients with schizophrenia but not affective disorders. Thus, patients with neuropsychiatric disorders exhibit variations in N-CAM isoforms which are specific for their particular disorder. The specific association of these variations in N-CAM isoforms with particular neuropsychiatric disorders suggests the potential for development of therapeutic interventions, clinical

trials for monitoring treatment response, and diagnostic methods of schizophrenia, bipolar disorder, depression and related diseases.

Present treatment of schizophrenia, bipolar disorder, depression and related diseases is inadequate. Existing treatments may have serious side effects and do not prevent the progression of schizophrenia. Development of an effective treatment requires a greater understanding of the biological mechanisms underlying the disease conditions. Through NIDA's discovery of an association between clinical abnormalities and alterations in the level of N-CAM, a greater understanding of the disease process is now possible, and this discovery suggests possible therapies.

In addition to inadequate existing treatments, there is presently no definitive diagnostic test for schizophrenia. Determination of the presence of the various criteria characteristic of schizophrenia is made by a trained clinician and is somewhat subjective. NIDA's discovery suggests that altered levels of N-CAM isoforms in the CSF may be the basis of an objective diagnostic test.

N-CAM is a cell recognition molecule with four major isoforms present in the brain. N-CAM isoforms are membrane-associated glycoproteins, either transmembrane glycoproteins or glycosylphosphatidyl inositol-anchored glycoproteins. There is also a secretory isoform. Membrane-associated N-CAM has several roles in cellular organization and development of the central nervous system. An important aspect of N-CAM activity is the regulation of adhesion of brain cells. Adhesion of neural to glial cells is mediated by N-CAM binding. N-CAM is also involved in memory processes, intracellular signal cascades, and neurite outgrowth. N-CAM is thought to be a neuronal protein and is known to be associated with synaptosomes, vesicles recovered from neuronal preparations. Thus, alterations in N-CAM influence brain structure, learning, and psychiatric systems, as shown in the recent research that NIDA is seeking to develop with a collaborator.

The proposed collaboration would include *in vivo* investigations of production of N-CAM isoforms and release of N-CAM isoforms into CSF. Measurements on N-CAM production and release would be correlated with the clinical status of patients. The possibility of using these correlations to develop a diagnostic method will be investigated. Potential therapeutic compounds would be tested for effects on the biochemical parameters and the

clinical status of patients. The collaboration would also involve *in vitro* investigation of N-CAM fragment production and release from brain tissue.

The proposed duration of the CRADA is two (2) years. However, the duration could be as long as five (5) years depending on the nature of the research plan developed by the parties.

The role of NIDA under the proposed CRADA may include the following, and other relevant scientifically appropriate collaborative research projects will be considered:

- (1) Provide further characterization of association between N-CAM variations with neuropsychiatric disorders.
- (2) Perform *in vitro* determinations of N-CAM fragment production and release from brain tissue.
- (3) Provide *in vitro* assessment of possible therapeutic compounds.
- (4) Monitor the efficacy of therapeutic compounds through biochemical methodology.
- (5) Jointly publish results.
- (6) Provide project coordination for the overall development and testing.

The role of the Collaborator under the proposed CRADA may include the following, and other relevant and scientifically appropriate collaborative research projects will be considered:

- (1) Provide significant intellectual, scientific, and technical expertise in developing appropriate methods for a diagnostic assay based on the level of N-CAM isoforms in cerebrospinal fluid.
- (2) Determine whether the variation in level of N-CAM isoforms in cerebrospinal fluid can be used diagnostically.
- (3) Provide compounds which may have therapeutic potential.
- (4) Provide significant intellectual, scientific, and technical expertise in developing a therapeutic protocol based on regulating the level of N-CAM isoforms.
- (5) Perform clinical studies including assessments of patients and collection of samples.
- (6) Monitor the efficacy of therapeutic compounds using clinical determinations of efficacy.
- (7) Jointly publish results.
- (8) Jointly provide project coordination for the overall development and testing.

The following factors will be evaluated in selecting a CRADA collaborator:

- (1) Corporate expertise in the field of development of diagnostic tools.
- (2) Competency in developing and assessing efficacy of therapeutic interventions.

(3) Number and character of possible therapeutic compounds that collaborator may be able to provide.

(4) Ability to provide for staff to perform in vitro studies.

(5) Key staff expertise, qualifications and relevant experience.

(6) Ability to effectively commercialize new technologies.

Dated: July 6, 2000.

**Kathleen Sybert,**

*Director, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.*

Dated: July 14, 2000.

**Jack Spiegel,**

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

[FR Doc. 00-18724 Filed 7-24-00; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; 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 Human Genome Research Institute Special Emphasis Panel ZHG1 HGR P 03.

*Date:* August 10, 2000.

*Time:* 3:00 pm to 4:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Conference Room B2B32/BLDG 31, 31 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Rudy O. Pozzatti, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301-402-0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 14, 2000.

**Anna P. Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 00-18721 Filed 7-24-00; 8:45 am]

**BILLING CODE 4140-01-M**

## 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. 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 on Aging Special Emphasis Panel, Effects on Menopause and Hormone Replacement on Visceral Fat and Insulin Sensitivity.

*Date:* August 7, 2000.

*Time:* 11 am to 3 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Crowne Plaza Washington-National Airport, 1489 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Ramesh Vemuri, Office of Scientific Review, National Institute on Aging, The Bethesda Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892; (301) 496-9666..

(Catalogue of Federal Domestic Assistance Program Nos. 93866, Aging Research, National Institutes of Health, HHS)

Dated: July 18, 2000.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 00-18711 Filed 7-24-00; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-7 O1.

*Date:* August 3-4, 2000.

*Time:* 8:30 pm to 5 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Lakshmanan Sankaran, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 659, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-7799.

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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1, GRB-2(02)S.

*Date:* August 7-8, 2000.

*Time:* 7:30 pm to 5 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Shan S. Wong, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 643, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594-7797.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-3(02).

*Date:* August 9-10, 2000.

*Time:* 8 am to 12 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Michele L. Barnard, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 657, 6707 Democracy