

the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydtt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 30, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health & Human Development (NICHD): Opportunity for Cooperative Research and Development Agreement (CRADA)

SUMMARY: The National Institute of Child Health & Human Development is seeking at least one Collaborator to participate in a CRADA to develop computer software that will assist in the diagnostic and clinical management of amenorrhea.

DATES: On or before August 6, 2001, interested parties should send informal written notice to the Technology Transfer Branch of the National Cancer Institute (NCI TTB), acting on behalf of NICHD, of the intent to file a formal proposal. Formal proposals must be submitted to the NCI TTB on or before September 5, 2001. Proposals submitted after September 5, 2001 will be considered, but only after any and all proposals submitted within the ninety-day period.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to: Bruce D. Goldstein, NCI Technology Transfer Branch, Executive Plaza South, 6120 Executive Blvd., Suite 450, Rockville, Maryland, 20852 (Phone 301-496-0477, Fax # 301-402-2117). Scientific questions should be addressed to: Dr. Lawrence Nelson, Head, NICHD Gynecologic Endocrinology Unit, Developmental Endocrinology Branch, Building 10, Room 10N262, Bethesda, MD 20892-1862 (Phone (direct) 301-402-6608; Phone (office) 301-496-4686; Fax 301-402-0574; email Lawrence_Nelson@nih.gov).

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NICHD and a collaborator pursuant to the Federal Technology Transfer Act of 1986 (15

U.S.C. 3710a), as amended. 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 NICHD is prohibited from transferring funds to a CRADA collaborator.

Under a CRADA, the NICHD can offer the selected collaborator access to facilities, staff, materials, and expertise. The collaborator may contribute facilities, staff, materials, expertise, and funding to the collaboration. A CRADA collaborator may elect an option to an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA, and may qualify as an inventor or co-inventor of new technology developed under the CRADA. Any party is eligible to participate; however, as between two or more sufficient, overlapping research proposals (where the overlap cannot be cured), the NICHD, as specified in 15 U.S.C. 3710a(c)(4), will give special consideration to small businesses, and will give preference to business units located in the U.S. that agree that products either embodying inventions made under the CRADA or produced through the use of such inventions will be manufactured substantially in the United States. In all other respects, the decision whether to begin negotiating a particular CRADA will turn on how well the proposal addresses the selection criteria below and how closely the proposed research matches the research interests of the NICHD.

The NICHD's general objectives for all CRADAs are the rapid publication of research findings, and the timely commercialization of prognostic, diagnostic, or therapeutic products. Specific CRADA research goals will be tailored to the particular needs of the NICHD laboratory, the expertise of the collaborator and NICHD, and any proprietary technology the collaborator and/or NICHD brings to the project. Under the present opportunity, the goals of the CRADA are anticipated to include, but not be limited to, the development of the following technology:

- Development of one or more software packages for analyzing patient data in cases of amenorrhea;
- Examination of possible automated processes for conducting differential diagnoses of conditions causing amenorrhea; and
- Development of improved tools for diagnosing conditions causing amenorrhea, to be used by clinicians in a clinical setting.

The software to be developed will be able to collect standardized data from patients with amenorrhea at the point of care. This system will be used to collect research data that will accurately characterize the clinical presentation of a broad range of disorders that may present with a chief complaint of amenorrhea. As this data is collected and analyzed the findings will be used to update the software. This iterative process will build an effective instrument that eventually can be used by caregivers at the point of patient contact to assist in the diagnosis and management of amenorrhea. After the system has been fully validated in a research setting this "working model" may be modified so as to collect basic screening data from women with amenorrhea in preparation for a visit to their health care provider. Thus, the development of a successful system will depend heavily on insight and experience on how to best meet the needs of the health care consumer as well as the health care provider.

A strategy should be developed to collect the patient data, link it to the pertinent published medical literature across disciplines, and provide a process for guided investigation and clinical decision making. Strategies should also be developed to employ the system for patient education, disease prevention, and health promotion.

The term of the CRADA(s) will be up to five (5) years, depending on the proposal(s). Applicants are encouraged to recommend in the written proposal alternative, additional applications and technologies to be developed.

Anticipated Party Contributions

The role of NICHD may include the following:

- (1) Plan research studies, interpret research results, and jointly publish the conclusions with the collaborator;
- (2) Provide collaborator with access to existing NICHD research data (both already collected and yet to be collected);
- (3) Provide staff, expertise, & materials for the development and testing of promising products; and
- (4) Provide work space and equipment for testing of any prototype systems developed.

The role of the successful collaborator will include the following:

- (1) Provide significant intellectual, scientific, and technical expertise in the development and manufacture of relevant products;
- (2) Plan research studies, interpret research results, and jointly publish the conclusions with NICHD;

(3) As necessary for the project, provide to NICHD any specialized or unusual equipment, access to necessary proprietary technology and/or data; and

(4) As necessary for the project, provide staff and funding in support of the research goals.

Other contributions may be necessary for particular proposals.

Selection Criteria

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following qualifications:

(1) Expertise:

A. Expertise in the research and development of high quality software utilizing artificial intelligence;

B. Experience in determining and meeting the needs of health care consumers; and

C. Demonstrated ability in the production and verification of software products.

(2) Reliability as a research partner:

A. Develops and produces products in a timely manner (for example, as demonstrated by a history of meeting benchmarks in licenses);

B. Indications of high levels of satisfaction by industry with the collaborator's products; and

C. Commitment to supporting the advancement of scientific research, as evidenced by a willingness to publish research results in a prompt manner; and

D. Willingness to be bound, to the extent applicable, by DHHS and PHS policies regarding:

(i) The rapid, public distribution of pure research tools,

(ii) The care and handling of animals, and

(iii) Human subjects research.

(3) Physical Resources:

A. An established headquarters, with office space and basic office equipment;

B. Access to the organization during business hours by telephone, facsimile, courier, U.S. Post, e-mail, the World-Wide-Web, and any evolving communication technologies; and

C. Sufficient financial and material resources to support, at a minimum, the anticipated activities of the CRADA.

Dated: May 31, 2001.

Kathleen Sybert,
Chief, TTB/NCI/NIH.

[FR Doc. 01-14365 Filed 6-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, June 7, 2001, 2:30 p.m. to June 7, 2001, 4 p.m., 7201 Wisconsin Avenue, Bethesda, MD, 20892 which was published in the **Federal Register** on May 24, 2001. 66 FR 28756.

The meeting scheduled for June 7, 2001 will now be held on June 20, 2001. The meeting is closed to the public.

Dated: May 31, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-14359 Filed 6-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel.

Date: July 2-3, 2001.

Time: 8:30 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Governor's House Hotel, 17th & Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Richard E. Weise, PhD., Scientific Review Administrator, National Institute of Mental Health, DEA, National Institutes of Health, 6001 Executive Boulevard, Room 6140, MSC9606, Bethesda, MD 20892-9606, 301-443-1340, rweise@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.

Date: July 12, 2001.

Time: 8 am to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Houmam H. Araj, PhD., Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6150, MSC 9608, Bethesda, MD 20892-9608, 301-443-1340.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: May 31, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-14360 Filed 6-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: July 18, 2001.

Time: 3 pm to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20892.

Contact Person: Aftab A. Ansari, PhD, National Institutes of Health, NIAMS, Natcher Building, 45 Center Drive, Room 5AS25N, Bethesda, MD 20892, 301-594-4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis,