

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indians Into Medicine Program

AGENCY: Indian Health Service, HHS.

ACTION: Extension of deadlines and change in funds availability for competitive grant applications for the Indians Into Medicine Program.

The Notice of funding availability for competitive grants for the Indians Into Medicine Program was published at 66 FR 27665 on May 18, 2001, and corrected at 66 FR 30219 on June 5, 2001.

The Indian Health Service announces the extension of dates for the following:

1. Application Receipt Date: August 1, 2001.
2. Application Review: August 13, 2001.
3. Applicants Notified of Results (approved, approved unfunded, or disapproved): August 27, 2001.

It is anticipated that approximately \$220,100 will be available for one award. This is a change from the \$400,000 previously announced and published on May 18, 2001. The available funding level of \$220,100 is inclusive of both direct and indirect costs.

Applicants are notified in writing on or about August 27, 2001.

This extension provides applicants approximately five additional weeks to prepare and submit competitive applications.

All other information contained in the **Federal Register** announcements remains unchanged.

Dated: July 16, 2001.

Michel E. Lincoln,

Deputy Director.

[FR Doc. 01-18290 Filed 7-20-01; 8:45 am]

BILLING CODE 4160-16-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute (NCI); Development of Therapeutic Antibodies and Vaccines From Tumor Associated Antigens in Human Lymphoma

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of an opportunity for Cooperative Research and Development Agreement (CRADA).

An opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI intramural Center for Cancer Research (CCR) to develop therapeutic antibodies and vaccines from novel tumor associated antigens in human lymphoma. This collaboration specifically excludes idiotype as the lymphoma antigen. Collaborative projects will focus upon cancer and/or areas of high public health significance and high national and international priority.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA), 15 U.S.C. 3710 as amended; and Executive Order 12591 of April 10, 1987, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Department of Health and Human Services (DHHS) seeks one Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to develop therapeutic antibodies and vaccines from tumor associated antigens in human lymphoma. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, and/or methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are the subject of the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Jeffrey W. Thomas, Ph.D., Technology Transfer Branch, National Cancer Institute, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301-846-5465; fax: 301-846-6820; email: jeffreyt@mail.nih.gov). Scientific inquiries should be submitted to Larry W. Kwak, M.D., Ph.D., CCR, National Cancer Institute, Bldg. 567, Room 205, Frederick MD, 21702-1201 (phone: 301-846-1607; Fax: 301-846-6107; e-mail kwak@mail.ncifcrf.gov).

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential, preliminary CRADA proposals, preferably two pages or less, must be submitted to the NCI on or before August 22, 2001. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have

established sufficient mutual interest. CRADA proposals may be accepted after the initial 30 day period if a CRADA Collaborator is not identified from the initial pool of respondents.

SUPPLEMENTARY INFORMATION:

Technology Available

The intramural CCR NCI is seeking a collaborative partner to develop therapeutic antibodies and vaccines from novel tumor associated antigens (TAAs) in human lymphoma. Identification of novel TAA proteins differentially expressed in human lymphoma samples may be useful targets for the development of such therapeutic antibodies and vaccines. This collaboration specifically excludes idiotype as the lymphoma antigen. The CCR has experience with collection and characterization of primary human lymphomas, understanding of basic lymphoma immunobiology, and unique reagents generated from patients who have undergone immunotherapy. As part of the proposed collaboration, the CCR will utilize its expertise to collect and characterize human lymphoma samples prior to protein and genetic analysis. Also, clinical data from well-characterized vaccinated patients will be available for clinical correlation. CCR is seeking a collaborative partner with experience in proteomics to identify TAAs differentially expressed in lymphoma samples that may have potential as therapeutic or diagnostic targets. For example, the partner may have expertise in liquid chromatography and mass spectrometry to identify proteins differentially expressed in lymphomas, compared to normal B lymphocytes. Additionally, the use of gene expression techniques to confirm the proteomics results is envisioned. Genetic analysis of the identified TAAs will be essential in the development of effective immunotherapies; thus, the collaborative partner must have a strong background in genetic analysis to understand the effects of variations (e.g. polymorphisms) and to recognize genetic components that could be used to develop effect vaccines and therapeutic antibodies. Thus, the potential collaborator must be a leader in proteomics, bioinformatics and genomics and have a demonstrated interest, expertise, or ability in the development of cancer vaccines.

NCI and Collaborator Responsibilities

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Providing the Collaborator with human lymphoma samples suitable for proteomic and genomic analysis.

3. Planning research studies and interpreting research results.

4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Providing essential research materials, such as enzymes or other reagents, extracts, compounds, hardware, software and access to databases.

3. Planning research studies and interpreting research results.

4. Providing technical expertise and/or financial support (e.g. facilities, personnel and expertise) for CRADA-related research as outlined in the CRADA Research Plan.

5. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on research and development of this technology involving the development of lymphoma vaccines. This ability can be demonstrated through experience, expertise, and the ability to contribute intellectually in this or related areas.

2. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology as defined above.

4. The demonstration of expertise in the commercial development, production, marketing and sales of antitumor products.

5. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

6. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, PHS policies relating to the use and care of laboratory animals, and the dissemination of research tools according to NIH policy.

7. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license

for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or non-exclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: July 11, 2001.

Kathleen Sybert,

Chief, Technology Transfer Branch, National Cancer Institute, National Institutes of Health.
[FR Doc. 01-18281 Filed 7-20-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of 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 a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodation, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: September 13, 2001.

Closed: 8:30 am to 1 pm.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Room G, Rockville, MD 20852

Open: 1 pm to 5 pm.

Agenda: Following opening remarks by the Director, NEL, there will be presentations by staff of the Institute and discussions concerning Institute programs and policies.

Place: 6130 Executive Boulevard, Room G, Rockville, MD 20852.

Contact Person: Lore Anne McNicol, Director, Division of Extramural Research,

National Eye Institute, National Institutes of Health, Bethesda, MD 20892, 301-496-9110.

Information is also available on the Institute's/Center's home page: www.nei.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 16, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-18274 Filed 7-20-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of 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 a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: September 6, 2001.

Open: 8:30 am to 2 pm.

Agenda: For discussion of program policies and issues.

Place: National Institutes of Health, Building 31, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: 2 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.