ACTION: Notice for CRADA opportunities.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to evaluate and develop methods to generate, expand and modify dendritic cells to act in an immunologically specific manner. The Collaboration will focus on the development and evaluation of conditions for specific immunomodulatory maneuvers focused on induction of Th1 and Tc1 biased immune responses by dendritic cells. Additionally, the collaboration will include the characterization of human dendritic cell phenotypic subsets including the generation of subset specific reagents. These research efforts would be directed by our evolving understanding of dendritic cell biology which includes both the characterization of cytokine expression by dendritic cells (production and regulation of production) and the characterization of dendritic cell responses to both known and as yet uncharacterized cytokines.

Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADAs which are the subject of the CRADA Research Plan.

ADDRESSES: Statements of interest, proposals and questions about this CRADA opportunity may be addressed to Gary Cuchural, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820). Scientific inquiries may be addressed to Dr. Edward Nelson, Immunotherapy Laboratory, NCI Clinical Services Program, National Cancer Institute-Frederick Cancer Research & Development Center, phone: 301–846–1491; FAX: 301–846–6022.

EFFECTIVE DATE: Confidential CRADA statements of interest describing the proposed research, preferably one page or less, must be submitted to NCI on or before December 29, 1998. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected on the basis of mutual scientific interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The Immunotherapy Laboratory of the NCI Clinical Services Program at the Frederick Center Research and Development Center has expertise in the following technological areas:

- Experience generating frequent, large dendritic cell (DC) preparations.
- Experience generating in excess of 80 DC preparations, from both normal donors and cancer patients.
- Well established, extensive systems for functional and phenotypic evaluation of dendritic cell preparations and their responses to various immune mediators.
- Access to Good Manufacturing Practice (GMP) monoclonal antibody production facility.
- Established human tumor antigen systems for final functional evaluations of immune response.

NCI's Dendritic Cell Patents and Patent Applications:

1. A Method and Compositions for Making Dentritic Cells from Expanded Populations of Monocytes and for Activating T Cells, filed in the United States Patent and Trademark Office May 21, 1997.

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 data from in-vitro and in-vivo studies.
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. Planning research studies and interpreting research results.
3. Providing technical expertise and/or financial support for (e.g. facilities, personnel and expertise) CRADA related Government activities.
4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
5. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
6. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
8. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the licensing of patent rights to CRADA inventions.

Dated October 21, 1998.

Kathleen Sybert,

Acting Director, Technology Development & Commercialization Branch National Cancer Institute National Institutes of Health.

[FR Doc. 98–29074 Filed 10–29–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Cannabinoids As Neuroprotectants

A Hampson, J Axelrod, M Grimaldi (NIMH)
DHHS Reference Nos. E–287–97/0 filed 21 Apr 98 and E–287–97/1 filed 10 Aug 98
Licensing Contact: Stephen Finley, 301/496–7735 ext. 215

This technology describes the neuroprotective properties of cannabidiol (CBD), 2-[3-Methyl-6-(1-methylethenyl)-2-cyclohexen-1y1]-5-pentyl-1,3-benzenediol. Cannabidiol is a neuroprotective cannabinoid that does not possess the psychoactive qualities which have previously hampered the development of cannabinoid-based therapeutics. Cannabidiol is an effective blood-brain barrier permeable antioxidant, that is more potent than either tocopherol or ascorbate. As reported in PNAS 95, 8268–73 (July 1998), CBD can protect neurons from both glutamate and free radical induced toxicity. It is believed that CBD may present a viable alternative for treatment of ischemia or physical traumas. This technology is currently available for either licensing or collaborative efforts under a Cooperative Research and Development Agreement (CRADA).

Methods and Compositions for Inhibiting Inflammation and Angiogenesis

K Kelly (NCI)
PCT/US97/19772 filed 24 Oct 97 (claiming priority of USSN 60/027,871 filed 25 Oct 96)
Licensing Contact: Charles Maynard, 301/496–7735 ext. 243

The invention provides compositions and methods directed to isolated α subunits of the 7TM protein CD97. CD97 is a heterodimer existing in three isoforms, namely three forms of α subunit and one invariant β subunit. The invention provides compositions and methods for detecting a subunit of CD97, a T-cell protein which is upregulated in activated T-cells and is involved in the onset and maintenance of inflammation and angiogenesis. The invention provides an isolated protein comprising a soluble CD97 α subunit, and an isolated nucleic acid encoding a soluble CD97 α subunit protein. The invention also provides methods for identifying compounds which inhibit soluble CD97 α subunit expression. The invention may be used to inhibit angiogenesis associated with chronic inflammation in a mammal by administering a therapeutically effective amount of a CD97 antagonist. Another application includes determining the degree of inflammation at a site in a mammal with an antibody composition specifically reactive to a soluble CD97 α subunit. Further, it should be noted that these compositions and methods have in vitro utility in the construction of proteins and subsequences thereof for the construction of antibodies, and nucleic acids and subsequences thereof for use as probes.

Genetic Polymorphisms Of Interleukin-1 Alpha And Beta Associated With Early Onset Periodontitis

SR Diehl, HA Schenkein, YF Wang (NIDR)
Serial No. 09/035,220 filed 05 Mar 97
Licensing Contact: Dennis Penn, 301/496–7056 ext. 211

Periodontal disease occurs in 10–20% of adults, and constitutes a major cause of tooth loss. About 0.5% of U.S. adolescents between the ages of 14 to 17 years old (about 70,000) have localized early onset periodontitis and 0.1% (17,000) have the more destructive form known as generalized early onset periodontitis. Both types of early onset periodontitis often lead to tooth loss before the age of 20. Extrapolation of these figures up to age 35 leads to estimates of early onset periodontitis having a major impact on the dental health of 400,000 individuals in the U.S. population. Discovery of genetic polymorphisms at the interleukin 1 alpha and 1 beta genes significantly associated with disease risk allows genetic testing to be used to predict disease prior to onset. This can be used to target clinical efforts for disease prevention to those individuals at greatest risk. The genetic test can also justify more aggressive therapeutic treatments for individuals already affected by the early onset periodontitis who, based on their genetic profile, are predicted to exhibit very rapid disease progression.

Dated: October 24, 1998.

Jack Spiegel,

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

[FR Doc. 98–29072 Filed 10–29–98; 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 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 552(b)(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.

Date: December 7–9, 1998.

Time: December 7, 1998, 7:30 PM to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Durham Hilton, 3800 Hillsborough Road, Durham, NC 27705.

Contact Person: FRANCISCO O. CALVO, PHD, Chief, S.E.P. Section, Chief, Special Emphasis Panel, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37E, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8897.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 26, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–29067 Filed 10–29–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; 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.