

resources and scientific expertise to a project aimed at identifying mechanisms responsible for abnormal melanocyte function in clinical hyperpigmentary conditions. Little is known about the level of abnormal function of melanocytes in a number of clinical conditions of hyperpigmentation, such as occurs in postinflammation, wound healing and/or photodamaged/age pigmented lesions. This proposed study will employ a number of antibodies specific for melanogenic proteins to examine melanocyte function, and thus levels of melanogenic protein expression, in such lesions. DNA probes specific for the encoding genes will be used to characterize the level of abnormal regulation of any gene products so identified. Approaches will be designed to attempt to correct abnormal expression of such genes, or the function of their encoded proteins and thus down-regulate pigmentation *in vitro*, with the ultimate goal of developing commercially useful therapeutic agents to treat conditions of epidermal hyperpigmentation. Since pigment production is inherently associated with photoprotection against UV-induced carcinogenesis, further benefit of these studies towards photoprotection may evolve. The CRADA will allow the selected partner to provide expertise and resources, in collaboration with NCI, for the preclinical development of agents useful in the treatment of epidermal hyperpigmentary conditions. Further clinical development of such agents may also be made subject to this agreement, or a separate agreement at a later date, and upon mutual agreement of the parties.

The expected duration of the CRADA will be three (3) to five (5) years.

The role of the National Cancer Institute, the Division of Cancer Biology, Diagnosis and Centers includes:

1. NCI will provide specific antibodies and probes useful to examine expression of pigmentary genes in hyperpigmented tissues.
2. NCI will perform enzymatic assays that measure melanogenic protein function in hyperpigmented tissues.
3. NCI will examine melanocyte function via expression of pigmentary genes in hyperpigmentary lesions.
4. NCI will screen potential inhibitors or down-regulators of melanogenic activity using *in vitro* techniques with melanocytes in culture.
5. NCI will collaborate with the corporate partner on the design of experiments and evaluation of results.

The role of the successful corporate partner will include:

1. Supply expertise in melanocyte function in hyperpigmentary disorders.
2. Supply potential melanogenic inhibitors or down-regulators of melanogenic activity for testing.
3. Provide funds to support a postdoctoral fellow and associated expenses of the study.
4. The corporate partner will collaborate with the NCI on the design of experiments and the evaluation of results.

Criteria for choosing the collaborating company will include:

1. Experience in the study of hyperpigmentary disorders.
2. Ability to provide adequate amounts of potential melanogenic inhibitors or down regulators of melanogenic activity for the preclinical studies which are subject to the research plan.
3. Experience and ability to produce, package, market and distribute pharmaceutical and/or cosmetic products, including experience with the regulatory approval process and with the FDA.
4. Willingness to cooperate with the NCI in the collection, evaluation, maintenance and publication of data from the investigation.
5. Willingness to share costs of the laboratory studies.
6. An agreement to be bound by DHHS rules involving the use of human and animal subjects, and human tissue.
7. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor or where a joint invention arises)

Thomas Mays,

*Director, Office of Technology Development,
National Cancer Institute.*

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BILLING CODE 4140-01-P

National Institute of Environmental Health Sciences: Opportunity for a Cooperative Research and Development Agreement (CRADA) and/or Licensing Opportunity for Preparative Two Dimensional Gel Electrophoresis System

AGENCY: National Institute of Environmental Health Sciences, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is seeking CRADA partners and/or licensees for the further development, evaluation, and commercialization of a Preparative Two Dimensional Gel Electrophoresis System (U.S. Patent Application Serial No. 08/243,643, filed May 16, 1994) for protein analysis and characterization. The National Institute of Environmental Health Sciences has also determined that the developed technology can be utilized in other scientific areas. The invention claimed in the above-referenced patent application is available for either further development under a CRADA and/or exclusive or non-exclusive licensing (in accordance with 35 U.S.C 207 and 37 CFR part 404) for the applications described below under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: CRADA proposals and questions about this opportunity may be addressed to Dr. B. Alex Merrick, NIEHS, Mail Drop D4-03, P.O. Box 12233, Research Triangle Park, NC 27709 (Telephone: 919/541-1531; Fax: 919/541-4704; Email: MERRICK@NIEHS.NIH.GOV). CRADA proposals must be received by the date specified below.

Licensing proposals and questions about this opportunity should be addressed to: David Sadowski, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Rockville, MD 20852 (Telephone: 301/496-7735 ext. 288; Fax: 301/402-0220).

Information on the patent application and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondee interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondee interested in submitting a CRADA proposal should be aware that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA agreement.

DATES: Capability statements/CRADA proposals must be received by NIH on or before May 22, 1995. There is no

deadline by which license applications must be received.

SUPPLEMENTARY INFORMATION:

The National Institute of Environmental Health Sciences has developed procedures and a prototype device for isolation of proteins from complex mixtures for protein sequencing. The system serves as a one-step purification method for isolation of biologically relevant proteins affected by disease or experimental treatment and has been described in *Electrophoresis* 15,535-545,1994. The system includes a preparative isoelectric focusing device for separation of proteins by charge, a glass mold for preparative polyacrylamide gel separation by mass and a protocol for use.

The commercial advantage of the Preparative Two Dimensional Gel Electrophoresis system is to separate and isolate sufficient amounts of individual protein for sequencing in a powerful one-step purification method. The Preparative Two Dimensional Gel Electrophoresis system can resolve individual proteins by charge and mass from up to 1 to 2 mg of unpurified starting material from protein mixtures. Current devices for two dimensional gel electrophoresis are generally for analytical scale work and are not physically or procedurally adapted to accommodate preparative sample loads. Although other preparative electrophoresis devices do exist, they separate by either mass or charge alone and function as stand-alone units without ready integration into additional systems for resolution of individual proteins.

The developed technology has applications for protein sequencing, protein immunization for antibody production, immunostaining and other modes of protein characterization. Although the system has been tested and is operational, some refinements in protein resolution are still possible which may involve procedural, reagent or equipment modifications.

The CRADA awardees will have an option to negotiate for an exclusive license to market and commercialize any new technology developed within the scope of the CRADA research plan for the Preparative Two Dimensional Gel Electrophoresis System. This CRADA may be directed toward the co-development of improved preparative electrophoresis equipment and pertinent procedures.

Roles of NIEHS

1. Provide design and specifications of an operating prototype device, provide a protocol for prototype

operation, provide user expertise, and assist in beta testing.

2. Work cooperatively with the company(s) to determine the market potential for the Preparative Two Dimensional Gel Electrophoresis system and to refine the prototype system.

Roles of the CRADA Partner

1. Provide expertise in application and commercial-oriented separation systems.

2. Develop plan for production, testing and commercialization of Preparative Two Dimensional Gel Electrophoresis system.

Selection criteria for choosing the CRADA partner(s) will include, but will not be limited to the following:

1. Experience in manufacturing electrophoresis devices or related separation technologies.

2. Capability to develop, implement and manage the product commercialization so as to ensure the dissemination of the technology(s) to research or health care services.

3. Ability to cost share for production and testing of a preparative two-dimensional gel electrophoresis device.

Dated: March 13, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

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National Heart, Lung, and Blood Institute; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Panel: NHLBI SEP on Blood Diseases.

Dates of Meeting: April 27-28, 1995.

Time of Meeting: 9 a.m.

Place of Meeting: National Institutes of Health, Natcher Building, Building 45, Lower Level Room D, Bethesda, Maryland.

Agenda: The panel will review the current status of research in the designated areas, identify gaps and make recommendations regarding opportunities and priorities for future contract or grant solicitations.

Contact Person: Dr. Fann Harding, 7550 Wisconsin Avenue, Room 5A08, Bethesda, Maryland 20892, (301) 496-1817.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: March 14, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, National Institutes of Health.

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National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Response and Adaptation to Exercise-Unit II (Telephone Conference Call).

Date: April 6, 1995.

Time: 1 p.m.

Place: 5333 Westbard Avenue, Room 552, Bethesda, Maryland.

Contact Person: S. Charles Selden, Ph.D., 5333 Westbard Avenue, Room 552, Bethesda, Maryland 20892, (301) 594-7476.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: The Insulin in Resistance Atherosclerosis Study (IRAS).

Date: April 18, 1995.

Time: 12:30 p.m.

Place: Crystal Gateway Marriott, Arlington, Virginia.

Contact Person: David Monsees, Jr., Ph.D., 5333 Westbard Avenue, Room 550, Bethesda, Maryland 20892, (301) 594-7450.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: March 14, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, National Institutes of Health.

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