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Dated: April 28, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: VHL and MET Mutation Detection Technology: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Joint Evaluation and Development of Methods to Detect Mutation in Both Gene Sequences Using Nucleic Acid Array Technology

The methods may include but are not limited to spectroscopic partitioning techniques and DNA chip technology. The NCI is looking for multiple CRADA Collaborators to develop independently different aspects of this VHL and MET mutation detection technology.

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

ACTION: Notice for CRADA Opportunities.

SUMMARY: Pursuant to 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 detect mutations in both the MET and VHL gene sequences using nucleic acid array technology. 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 publications of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to elect a non-exclusive or exclusive commercialization license to subject inventions arising under the CRADAs that are related to the DNA array technology of the collaborators, which are the subject of the CRADA Research Plan, for diagnostics and research supply and can apply for background licenses to the existing patents listed below, subject to any pre-existing licenses already issued for other fields of use. Licensing by NIH is subject to 35 U.S.C. 207 and 37 CFR Part 404.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Thomas M. Stackhouse, 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).

Scientitific inquiries—Dr. Berton Zbar, Chief, Laboratory of Immunobiology, National Cancer Institute-Frederick Cancer Research & Development Center, P.O. Box B, Building 560, Room 12–68, Frederick MD, 21702–1201 (phone: 301–846–1288 FAX: 301–846–6145).

EFFECTIVE DATE: Inquiries regarding licensing and scientific matters may be forwarded at any time. Confidential CRADA proposals, preferably one page or less, must be submitted to NCI on or before July 6, 1998. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists have identified mutations in the proto-oncogene c-MET, and the von Hippel-Lindau disease (VHL) tumor suppressor gene in human cancers. c-MET is the receptor for hepatocyte growth factor/scatter factor. Germline mutations in the MET gene have been detected in affected members of families with an inherited predisposition to develop papillry renal carcinomas; somatic mutations in the MET gene have been detected in a subset of papillary renal carcinomas. All mutations detected in the MET gene to date were located in the tyrosine kinase domain; all mutations were missense.

The VHL gene is mutated in patients with von Hippel-Lindau disease, and in sporadic clear cell carcinomas of the kidney. Disease-causing mutations include gender deletions (partial or complete), missense and nonsense and frame shift mutations.

About 30,000 individuals develop kidney cancer each year. We anticipate that the novel mutation detection techniques for the MET and VHL genes will be used in patients with sporadic and inherited predispositions to renal cancer. Possible uses would include diagnosis and prognosis of kidney cancer. In addition, these new methods might be applied to the study of other types of human neoplasia.

DHHS now seeks collaborative arrangements for the joint evaluation and development of methods to detect mutations in both gene sequences using nucleic acid array technology. The methods may include but are not limited to spectroscopic partitioning techniques and DNA chip technology. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide equitable distribution of intellectual property rights developed under the CRADA. The successful CRADA partner will collaboratively develop and test known mutations within the genes from samples provided by the government. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

NCI's VHL/MET Patents and Patent Applications

1. Von Hippel-Lindau(VHL) Disease Gene and Corresponding cDNA and Methods for Detecting Carriers of the VHL Disease Gene; United States Patent 5,654,138, issued August 5, 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 samples of the subject gene sequences for evaluation.

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) for 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.

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

9. The agreement to be bound by the appropriate DHHS regulating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

10. 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.

Dated: April 26, 1998.

Kathleen Sybert,

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

[FR Doc. 98–12110 Filed 5–6–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Opportunity for a Cooperative Research and Development Agreement (CRADA) To Develop a Vaccine for Pneumonia

AGENCY: National Institutes of Health (NIH), PHS, DHHSNIA, NIH, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institute on Aging (NIA) is seeking a Collaborator to participate in a Cooperative Research and Development Agreement (CRADA) to develop a vaccine for pneumonia. The term of the CRADA will be up to five (5) years.

ADDRESESS: Inquiries and proposals regarding this opportunity should be addressed to Bruce D. Goldstein, J.D., Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., EPS Suite 450, Rockville, Maryland 20852, telephone number 301–496–0477, FAX number 301–402–2117.

DATES: interested parties are advised to notify this office in writing of their intent to file a formal proposal no later than FIFTEEN (15) days from the date of this advertisement. Formal proposals must be submitted to this office no later than TWENTY (20) days from the date of this notice.

SUPPLEMENTARY INFORMATION: A CRADA is the anticipated joint agreement to be entered into by NIA pursuant to the Federal Technology Transfer Act of 1986, a amended by the National Technology Transfer Act (Pub. L. 104–113 (Mar. 7, 1996)) and by Executive Order 12591 of April 10, 1987. The NCI owns U.S. Patent No. 4,455,032, concerning the use of phosphocholine hapten conjugates in vaccines, which presently is not licensed. NIA is now planning to develop a vaccine for pneumonia utilizing the invention in the NCI patent.

Under the present proposal, the specific goals of the CRADA will be the development of the following technology:

- Development of one or more vaccines utilizing the phosphocholine-hapten technology;
- and preclinical evaluation of the candidate vaccines.

Party Contributions

The role in NIA includes the following:

(1) Develop, in cooperation with the Collaborator, candidate pneumonia vaccines;

(2) Conduct preclinical trials of candidate vaccines in small mammal models;

(3) Provide staff, expertise, & materials for the development and testing of promising vaccines, and provide work space and equipment for testing of the prototype vaccines; and

(4) Jointly evaluate and publish the data generated with Collaborator.

The role of the successful Collaborator will include the following:

(1) Provide an adequate supply of at least one mutually agreeable, GMP-grade carrier system, and provide expertise and assistance in the development and use of its vaccine carrier system(s);

(2) Provide resources, staff, expertise, and funding, as necessary, in support of the research goals; and

(3) Develop and market any promising vaccines.

Selection Criteria

Proposals submitted for consideration should fully address each of the following qualifications:

(1) Expertise:

A. Demonstrated expertise in developing and producing high quality pharamacuetical compositions;

B. Demonstrated ability to secure national and/or international marketing and distribution of pharmaceutical compositions;

C. Demonstrated intellectual ability to guide development of product line which addresses the requirements of NIA;

(2) Reputation: The successful Collaborator must be recognized in the pharmaceutical industry for:

A. Producing quality pharmaceutical products;

B. Indications of satisfaction by industry experts with the Collaborator's products; and

C. Commitment to the research and development of new pharmaceuticals.

(3) Physical Resources:

A. An established headquarters with offices, space, and equipment;

B. Access to the organization during business hours by telephone, mail, e-mail, the Internet, and other evolving technologies; and

C. Sufficient financial resources to support, at a minimum, the current activities of the CRADA to meet the needs of NIA.

Dated: April 26, 1998.

Kathleen Sybert,

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

[FR Doc. 98–12109 Filed 5–6–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 Center for Scientific Review Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: May 12, 1998.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 4182, Telephone Conference.

Contact Person: Dr. William Branche, Scientific Review Administrator, 6701 Rockledge Drive, Room 4182, Bethesda, Maryland 20892, (301) 435–1148.

Name of SEP: Clinical Sciences.

Date: May 13, 1998.