- The adequacy of staff and other resources, and its financial viability.
- The organization's ability to provide adequate funding for performing required surveys.
- The organization's policies with respect to whether surveys are announced or unannounced.
- The accreditation organization's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation.

V. Responses to Public Comments

Because of the large number of comments we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble and will respond to them in a forthcoming rulemaking document.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 2, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01–6311 Filed 3–13–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health, National Institute on Child Health and Human Development; Opportunity for Cooperative Research and Development Agreement

SUMMARY: The National Institute of Child Health and Human Development (NICHD) is seeking research statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA). The purpose of the CRADA is to develop diagnostic and therapeutic uses of the newly identified human MATER (Maternal Effect Gene) gene and protein that are critical for normal oocyte function and fertility. The project is part of the ongoing activities of the Developmental Endocrinology Branch (DEB), Division of Intramural Research, NICHD. The term of the CRADA will be up to five (5) years.

DATES: Interested parties should notify this office in writing of their intent to file a formal proposal no later than April 13, 2001. Formal proposals must be submitted to this office no later than May 14, 2001.

ADDRESSES: Research Statements should be submitted to Kate Sinclair Dunn, Technology Development Specialist, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health, Executive Plaza South, Room 450, 6120 Executive Blvd., MSC 7182, Bethesda, MD 20892–7182, Phone: 301–496–0477, Fax: 301–402–2117, e-mail *sinclaik@otd.nci.nih.gov.* Scientific questions should be addressed to Lawrence M. Nelson, M.D., Head, Gynecological Endocrinology Unit Developmental Endocrinology Branch, NICHD, NIH, Building 10, Room 10N262, Bethesda, MD 20892–1862; Phone (direct): 301–402–6608, Office: 301–496–4686; Fax: 301–402–0574, e-mail: *Lawrence Nelson@nih.gov.* Inquiries directed to obtaining patent license(s) related to participation in the CRADA opportunity should be addressed to Dennis Penn, Pharm.D., MPH, Senior Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852–3804, Phone: 301–496–7735, Fax: 301–402–0220, e-mail: *pennd@od.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. 3710 a), 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 patent rights arising under the CRADA, and may qualify as a co-inventor of new technology developed under the CRADA. 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 to manufacture CRADA products in the U.S.

The CRADA will employ a MATER null mouse line to examine the role of MATER in maintaining oocyte quality so as to support healthy early embryonic development. The project goal is to determine if abnormalities in the amount or quality of oocyte MATER content play a role in some cases of human infertility that is generally ascribed to ''poor egg quality'' or a failure of early embryonic development. A strategy should be developed to measure MATER's biologic activity, to determine the MATER content of human oocytes, and to detect MATER gene mutations. Preimplantation mouse oocytes and embryos may be used for protein analysis and profiling. Basic science expertise as applied to oocyte function in animal models and in the clinical setting will be required.

The described methods are the subject of a U.S. provisional patent application filed October 18, 2000 by the Public Health Service on behalf of the Federal Government. Furthermore, the initial report and characterization of the invention is described in: Tong et al., Mamm. Genome 11:281–287, 2000. Commercialization of new CRADA technology may require obtaining an appropriate PHS license.

The collaborator in this endeavor is expected to commit scientific personnel commensurate with the level of research activities defined by the CRADA Research Plan. It is anticipated that PHS laboratories and/or those of the collaborator will be utilized, as appropriate, for the research activities as defined by the Research Plan. NICHD anticipates, in addition, that the Collaborator, as appropriate, will provide funding for the project.

Party Contributions: The NICHD anticipates that its role may include, but not be limited to, the following:

(1) Plan research studies, interpret research results, and, as appropriate, 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, and materials for the development and testing of promising products;

(4) Provide work space and equipment for testing of any prototype compositions developed.

The NICHD anticipates that 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, as appropriate, jointly publish the conclusions; and

(3) Provide NICHD a supply of necessary materials, access to necessary proprietary technology and/or data, and as necessary for the project, 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:

(1) Expertise:

A. Scientific advisors and staff with a demonstrated record of research success related to diagnostic and therapeutic interventions associated with human fertility.

(i) The technical expertise of the Collaborator's Principal Investigator and laboratory group in the technology described above,

(2) Reliability as a research partner:

A. Willingness to commit best effort and to provide adequate and sustained resources and/or funding, as appropriate, to support the CRADA studies, and

B. Development of this technology, as outlined in the CRADA Collaborator's proposal, and

C. Ability to develop and produce products in a timely manner, as applicable (for example, as demonstrated by a history of meeting benchmarks in licenses), and

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

E. Willingness to be bound by DHHS and PHS policies regarding:

(i) The public distribution of unmodified genetic sequences and research tools,

(ii) The care and handling of animals, and

(iii) Testing in human subjects.

(3) Physical Resources:

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

B. Access to the organization during business hours by telephone, facsimile, courier, U.S. Post, e-mail, the World-Wide-Web, and, as appropriate, other evolving information technologies, and

C. Sufficient financial and material resources to support, at a minimum, the anticipated activities of the CRADA to meet the needs of NICHD under the proposal.

The collaborator is encouraged to propose, in the written research statement, related applications and technologies other than those specifically described herein.

Dated: February 26, 2001.

Kathleen Sybert,

Chief, TDCB/NCI/NIH.

[FR Doc. 01–6274 Filed 3–13–01; 8:45 am]

BILLING CODE 4140–01–P

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 invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting Richard U. Rodriguez, M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 287; fax 301/402–0220; e-mail rodrigur@od.nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

Entitled: ''GHEP, A Gene Highly Expressed in Normal and Neoplastic Prostate, and Uses Therefor.''

Inventors: Drs. Ira H. Pastan (NCI), Par Olsson (NCI), Tapan K. Bera (NCI), Magnus Essand (NCI), and Byungkook Lee (NCI).

DHHS Ref. No. E–144–00/0 Filed: October 10, 2000.

Two types of immunotherapy are currently being intensively pursued for the treatment of cancer. One is the development of antibodies that recognize cell surface antigens. These antibodies can be useful by themselves or can be armed with radioisotopes, drugs or toxins to kill cancer cells. The second approach is to develop vaccines that target intracellular proteins presented as peptides on the cell surface bound to the major histocompatability complex. For these therapies to be effective it is important that the antigen is present on tumor cells and is not expressed in substantial amounts on essential normal cells such as liver, heart, brain or kidney. Recent work has focused on the identification of new differentiation antigens that are present in normal prostate and continue to be expressed in prostate cancer.

The claimed invention provides a Gene Highly Expressed in Prostate (''GHEP''). The gene is found in normal and neoplastic prostate, and encodes two short proteins, one 34 amino acids (''ghep34'') in length and one 35 amino acids in length (''ghep35''). Detection of the transcript or of the proteins in tissues other than the prostate is indicative of prostate cancer. The nucleic acids, proteins, and immunogenic fragments thereof can be used to raise an immune response, for example, via a vaccine, to prostate cancer. This approach could involve active in vivo treatments as well as passive ex vivo approaches to slow or inhibit the growth of GHEP-expressing cancers.

The invention further provides methods of detecting the proteins or the gene transcript in a biological sample. If the biological sample is from a tissue other than the prostate, detection of either of the protein or of the gene transcript is indicative of the presence of prostate cancer in the subject from whom the sample was taken. The invention further provides antibodies that specifically recognize ghep34 and antibodies that specifically recognize ghep35, as well as kits for the detection of one or both of the proteins in a sample.

The above mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: March 6, 2001.

Jack Spiegel,

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

[FR Doc. 01–6271 Filed 3–13–01; 8:45 am]

BILLING CODE 4140–01–P