

(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 histocompatibility 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**