

PURPOSE(S):

The sole purpose of the system is to support the Application Submission and Processing System electronic application for the development, submission, and review of applications for HPSAs and MUPs. The most critical requirement for accurate designation determinations is reliable data on the location of primary care providers relative to the population. To this end, SDB continually tries to obtain the latest data on primary care providers and their practice location(s) at the lowest geographical level possible for use in the designation process, with the objective of minimizing the level of effort required on the part of States and communities seeking designations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HRSA employees in order to accomplish the purposes for which the records are collected. The users are required to comply with the requirements of the Privacy Act with respect to such records.
2. Each state Primary Care Office (and a few Primary Care Associations) may have access to provider data within their own state. These users will also have access to bordering states' data (one county-deep) at an aggregate level only.
3. Disclosure may be made to contractors engaged by the Department to geocode the physicians' address so that it may be seen on a computerized map, or to load the provider data into the Application Submission and Processing Systems. All such contractors shall be required to maintain Privacy Act safeguards with respect to such records and return all records to HRSA.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

Records are maintained in file folders and in computer data files.

RETRIEVABILITY:

Retrieval of physician records is by use of personal identifiers used when entering the system.

SAFEGUARDS:

1. *Authorized users:* Access to records is limited to designated HRSA and PCO/A staff. These employees are the only authorized users. HRSA maintains current lists of authorized users.
2. *Physical Safeguards:* All computer equipment and files are stored in areas

where fire and life safety codes are strictly enforced. All automated and non-automated documents are protected on a 24-hour basis. Perimeter security includes intrusion alarms, on-site guard force, random guard patrol, key/passcard/combination controls, and receptionist controlled area. Hard copy files are maintained in a file room used solely for this purpose with access limited by combination lock to authorized users identified above. Computer files are password protected and are accessible only by use of computers which are password protected.

3. *Procedural Safeguards:* A password is required to access computer files. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised area. All authorized users sign a "Rules of Behavior" document. All passwords, keys and/or combinations are changed when a person leaves or no longer has authorized duties. Access to records is limited to those authorized personnel trained in accordance with the Privacy Act and ADP security procedures. The safeguards described above were established in accordance with DHHS Chapter 45-13 and supplementary chapter PHS hf:45-13 of the General Administration Manual; and the DHHS Information Resources Management Manual, Part 6, "ADP Systems Security."

RETENTION AND DISPOSAL:

Retention and disposal is in accordance with the HRSA records retention schedule. Contact the System Manager at the following address for further information.

SYSTEM MANAGER(S) AND ADDRESS:

Debra Small, ASAPS System Manager, Public Health Analyst, Shortage Designation Branch, Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C-26, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a

criminal offense under the Act, subject to a fine.

RECORD ACCESS PROCEDURE:

To obtain access to a record, contact the System Manager at the above specific address. Requesters should provide the same information as is required under the Notification Procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under Notification Procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, incorrect, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Data are collected from the State Primary Care Offices and a few State Primary Care Associations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05-447 Filed 1-7-05; 8:45 am]

BILLING CODE 4165-15-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, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

Methods and Composition for Development of Preclinical Testing of Anticancer Therapies Using Transgenic Animals

Lyuba Varticovski (NCI), DHHS Reference No. E-017-2005/0—Research Tool

Licensing Contact: John Stansberry; 301-435-5236; stansbej@mail.nih.gov.

Mouse models are valuable tools for screening anticancer agents during the preclinical stage of drug development. The methods and composition described here provide a versatile system for testing drug therapies in an *in vivo* setting. This invention combines a unique flexibility for testing therapeutic interventions for tumor prevention, progression, and development of metastasis in tumors with specific genetically defined backgrounds. Because these tumors can be transplanted into immuno-compromised recipients, this invention provides an opportunity for testing the role of host immune system, angiogenesis and stromal cells in tumor development, progression, and metastasis. The tumors that develop in this model system mimic the heterogeneity of human disease and genetic instability associated with tumor progression and metastasis. The combination of these applications makes this method of testing anticancer therapies superior to any currently available *in vivo* preclinical models.

Mabs to IRTA2 for Use in Diagnosis and Therapy of IRTA-Expressing Cancers

Ira Pastan (NCI), U.S. Provisional Application No. 60/615,406 filed 30 Sep 2004 (DHHS Reference No. E-287-2004/0-US-01)

Licensing Contact: Brenda Hefti; 301-435-4632; heftib@mail.nih.gov.

Immunoglobulin superfamily receptor translocation associated 2 (IRTA2) is a cell surface receptor that is normally expressed in mature B cells. IRTA2 expression is deregulated in multiple myeloma and Burkitt lymphoma cell lines. The invention discloses monoclonal antibodies specific for the extracellular domain of IRTA2 and their use in diagnostic and therapeutic applications. The antibodies can detect IRTA2 expression on non-Hodgkin's B-cell lymphoma cell lines and can detect hairy cell leukemia cells in blood

samples taken from patients. The antibodies are specific for IRTA2, and can detect formalin-fixed antigen and SDS-denatured antigen.

These antibodies could be used for detailed expression studies of IRTA2 in different cancer cells lines. The antibodies could be also be used to treat B cell malignancies. In a diagnostic application the antibodies could be employed to investigate the presence of a residual number of malignant cells following a therapeutic regimen. The IRTA2 gene is known to produce alternative spliced products that encode soluble forms of IRTA2. The antibodies could be used to construct immunoassays to detect soluble IRTA2s in patients' sera as a useful diagnostic maker for B-cell malignancies.

The UBE2G2 Binding Domain in the Ubiquitin Ligase GP78 and Methods of Use Thereof

Allan Weissman *et al.* (NCI), U.S. Provisional Application No. 60/583,263 filed 26 Jun 2004 (DHHS Reference No. E-244-2004/0-US-01)

Licensing Contact: Thomas Clouse; 301-435-4076; clouset@mail.nih.gov.

Cytosolic and nuclear proteins are targeted for proteosomal degradation by the addition of multiubiquitin chains. The specificity of this process is largely conferred by ubiquitin protein ligases (E3s) that interact with specific ubiquitin conjugating enzymes (E2s). One important role for ubiquitylation is in quality control in the secretory pathway, targeting proteins for degradation through a set of processes known as endoplasmic reticulum (ER)-associated degradation (ERAD). ERAD is important in many diseases including cystic fibrosis, neurodegenerative disorders, alpha-1 antitrypsin deficiency, tyrosinase deficiency and cancer. ERAD is also important in controlling levels of cell surface receptors and in regulation crucial enzymes involved in cholesterol metabolism. gp78, also known as the autocrine motility factor receptor, is an E3 implicated in ERAD. This invention relates to the identification of a discrete domain within gp78 that encodes a binding site specific for gp78's cognate E2, Ube2g2. Ube2g2 is the most widely implicated E2 in ERAD. Expression of the Ube2g2 binding region provides a means of blocking ERAD by preventing interactions between gp78 and Ube2g2 and has the potential to provide diagnostic and therapeutic methods of intervening in modulating ERAD with consequences for disease processes and for generating recombinant secreted proteins in mammalian cells.

Composition for Detecting the Response of Rectal Adenocarcinomas to Radiochemotherapy

Thomas Ried *et al.* (NCI), U.S. Provisional Application No. 60/535,491 filed 12 Jan 2004 (DHHS Reference No. E-269-2003/0-US-01)

Licensing Contact: Thomas Clouse; 301-435-4076; clouset@mail.nih.gov.

Rectal adenocarcinomas are among the most frequent malignant tumors. Surgery, including total mesorectal resection, is the primary treatment. Radiation or combined radiochemotherapy can be necessary before or after resection of the primary tumor. However, the response of individual tumors to radiochemotherapy is not uniform, and patients with radiochemotherapy resistant tumors are needlessly exposed to radiation, chemotherapy drugs, and the associated side effects thereof. The invention discloses the identification of genes and gene products, *e.g.*, molecular markers or molecular signatures that are differentially expressed in responders and non-responders to radiochemotherapy treatment of rectal adenocarcinoma. The detection of differential expression levels of these genes can serve as a basis for diagnostic assays to predict the response to radiochemotherapy and can be used to identify the appropriate agent to be administered to enhance the effectiveness of the radiochemotherapy.

Peptide Agonists of Prostate-Specific Antigen and Uses Thereof

Kwong-yok Tsang and Jeffrey Schlom (NCI), U.S. Provisional Application No. 60/334,575 filed 30 Nov 2001 (DHHS Reference No. E-123-2001/0-US-01); PCT Application No. PCT/US02/37805 filed 26 Nov 2003 (DHHS Reference No. E-124-2001/1-PCT-01); and subsequent National Stage filings in the United States, Europe, Canada, Australia, and Japan

Licensing Contact: Jeff Walenta; 301-435-4633; walentaj@mail.nih.gov.

Current treatment for prostate cancer involves surgery, radiation, chemotherapy, and/or hormonal therapy. In spite of these treatments, over 40,000 men die of prostate cancer each year in the United States alone. A promising new treatment modality for prostate cancer involves harnessing the body's own immune response to eliminate a cancer. Traditional and non-traditional vaccine therapies have been shown to stimulate an immune response against commonly expressed tumor-associated antigens. One such common tumor-associated antigen expressed on a

majority of prostate cancer cells is Prostate Specific Antigen (PSA).

The present invention relates to isolated peptides comprising immunogenic peptides derived from PSA. These immunogenic peptides are considered agonist epitopes of the wild-type PSA-3 cytotoxic T lymphocyte (CTL) epitope: an agonist epitope is modified from the wild type epitope and shows greater immune stimulating characteristics. This invention claims the physical composition and use of the PSA-3 agonist epitopes, including peptide, nucleic acid, pharmaceutical composition, and method of treatment. The PSA-3 agonist epitopes would have application in a number of traditional and non-traditional vaccine delivery systems for the treatment of cancer.

Some vaccine delivery fields of use for the PSA-3 epitope have been exclusively licensed. However, a number of fields are available for other traditional and non-traditional vaccine delivery systems. This invention has been published in Schlom, *et al.*, "Identification and Characterization of a Human Agonist Cytotoxic T-Lymphocyte Epitope of Human Prostate-specific Antigen." Clinical Cancer Research, Vol. 8, 41-53, January 2002.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Dated: December 29, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05-391 Filed 1-7-05; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel Clinical Science.

Date: February 23-24, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriot Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jeanette M. Hosseini, Scientific Review Administrator, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd, Suite 401, Bethesda, MD 20892. (301) 594-9098.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel Basic Science.

Date: March 3-4, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Dale L. Birkle, PhD, Scientific Review Administrator, NIH/NCCAM, 6707 Democracy Blvd, Suite 401, Bethesda, MD 20892. (301) 451-6570. birkled@mail.nih.gov.

Dated: January 3, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-386 Filed 1-7-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 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.

Name of Committee: National Center for Research Resources Special Emphasis Panel.

Date: February 10-11, 2005.

Time: February 10, 2005, 8 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Linda C. Duffy, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd. Room 1082, Bethesda, MD 20892, (301) 435-0810. duffy1@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS.)

Dated: January 3, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-389 Filed 1-7-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Conference Grant Applications.

Date: January 12, 2005.

Time: 9:30 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, NEI Conference Room, Bethesda, MD 20892.

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892-9602. 301-451-2020. haraj@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS.)