

order to participate in the Medicare program. Specifically, the CoP at § 484.55 requires that each patient receive from an HHA a patient-specific, comprehensive assessment that identifies a patient's continuing need for home care and meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, to evaluate, non-maternity patients. The data collected using OASIS is used for three main purposes: assessing and improving the quality of care provided by an HHA, submitting and paying claims for Medicare home health services, and surveying the HHAs in accordance with Section 1891 of the Social Security Act (the Act).

We have made several modifications to this information collection without increasing the burden. The modifications include but are not limited to the following items. In order for the OASIS to have the information necessary to allow the grouper to price-out the claim, we propose to make the following changes to the OASIS to capture whether an episode is an early or later episode. In addition, for the purposes of payment, we propose to make changes to the OASIS in order to enable agencies to report secondary case mix diagnosis codes. The proposed changes clarify how to appropriately fill out OASIS items M0230 and M0240, using ICD-9-CM sequencing requirements if multiple coding is indicated for any diagnosis. The proposed OASIS revisions also include incorporating previously revised instructions regarding diagnosis coding in items M0190, M0210, and M0230/M0240/M0246 (previously M0245). The burden associated with these proposed changes includes possible training of staff, the time and effort associated with downloading a new form and replacing previously pre-printed versions of the OASIS, and utilizing updated vendor software. However, CMS will be removing or modifying existing questions in the OASIS data set to accommodate the requirements referenced above. Therefore, CMS believes the burden increase associated with these changes is negated by the removal or modification of several current data items. *Frequency:* Recordkeeping and Reporting—upon patient assessment; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 8,277; *Total Annual*

Responses: 10,105,827; *Total Annual Hours:* 11,977,601.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: April 27, 2007.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. E7-8424 Filed 5-3-07; 8:45 am]

BILLING CODE 4120-01-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, 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.

Method for Predicting and Detecting Tumor Metastasis

Description of Technology: Detecting cancer prior to metastasis greatly increases the efficacy of treatment and the chances of patient survival. Although numerous biomarkers have been reported to identify aggressive tumor types and predict prognosis, each biomarker is specific for a particular type of cancer, and no universal marker that can predict metastasis in a number of cancers have been identified. In addition, due to a lack of reliability, several markers are typically required to determine the prognosis and course of therapy.

Available for licensing are carboxypeptidase E (CPE) inhibitor compositions and methods to prognose and treat cancer as well as methods to determine the stage of cancer. The inventors discovered that CPE expression levels increase according to the presence of cancer and metastasis wherein CPE is upregulated in tumors and CPE levels are further increased in metastatic cancer. This data has been demonstrated both in vitro and in vivo experiments and in liver, breast, prostate, colon, and head and neck cancers. Metastatic liver cells treated with CPE siRNA reversed the cells from being metastatic and arrested cells from further metastasis. Thus, CPE as a biomarker for predicting metastasis and its inhibitors have an enormous potential to increase patient survival.

Applications:

1. Method to prognose multiple types of cancer and determine likelihood of metastasis.

2. Compositions that inhibit CPE such as siRNA.

3. Method to prevent and treat cancer with CPE inhibitors.

Market:

1. 600,000 cancer related deaths in 2006;

2. Global cancer market is worth more than eight percent of total global pharmaceutical sales;

3. Cancer industry is predicted to expand to \$85.3 billion by 2010.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Y. Peng Loh (NICHD) *et al.*

Publication: Manuscript in preparation.

Patent Status:

1. U.S. Provisional Application No. 60/885,809 filed 19 Jan 2007 (HHS Reference No. E-096-2007/0-US-01)

2. U.S. Provisional Application No. 60/887,061 filed 29 Jan 2007 (HHS Reference No. E-096-2007/1-US-01)

3. U.S. Provisional Application No. 60/895,912 filed 20 Mar 2007 (HHS Reference No. E-096-2007/2-US-01) *Licensing Status:* Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301/435-4633; wongje@mail.nih.gov.

Collaborative Research Opportunity: The National Institute for Child Health and Human Development, Section on Cellular Neurobiology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize CPE as a biomarker for predicting metastasis. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Novel Diagnostics and Therapeutics for Various Hematologic Malignancies: Monoclonal Antibodies to Members of Fc receptor-like (FCRL) Proteins

Description of Technology: Fc receptor-like (FCRL) is a gene family homologous to Fc receptors (alternative names, FcRH, IRTA, IFGP, SPAP). FCRL1-6 genes are located on human chromosome 1, where translocations and other abnormalities are frequently observed in certain B-cell lymphoma and multiple myeloma. Previous studies suggests that the FCRL proteins are differently expressed on various malignant cells from B-lineage cells as well as normal B cells in different stage of the differentiation in adaptive immunity. Although the natural ligands are not known, FCRL proteins likely play roles in regulation of immunity. The members of the immunoglobulin superfamily receptor translocation associated (IRTA) genes 1-6 encode proteins homologous to Fc receptors. Previous studies suggest that each IRTA may play a different role in B-cell differentiation and immune responses. FCRL1-6 proteins possess 3-9 extracellular immunoglobulin (Ig) domains, each of which exhibits a substantial homology to the same subtypes of Ig domains (up to 86% identity). Consequently there are some epitopes shared by FCRL1-6 extracellular domains evidenced by the presence of many cross-reactive monoclonal antibodies (MAbs) with FCRL1-6. The invention relates to the development of novel MAbs specific to each members of the FCRL proteins, which show no cross-reactivity with other FCRL members. These antibodies could be used for studies on detailed expression studies of FCRLs in different cancer cells and on potential therapeutic use for FCRL-expressing hematological malignancies.

Applications and Modality:

1. Novel monoclonal antibodies to FCRL family members can help diagnose and treat B cell malignancies and RA.

2. The antibodies can be used as research tools to detect cellular expression of FCRLs.

Advantage: Monoclonal antibody clones are available that are specific to one member of the FCRL family with no cross-reactivity to other members.

Development Status: The technology is in pre-clinical stage of development.

Inventors: Ira Pastan (NCI) *et al.*

Publications:

1. A manuscript directly related to this technology will be available as soon as it is accepted for publication.

2. T Ise, H Maeda, K Santora, L Xiang, RJ Kreitman, I Pastan, S Nagata. Immunoglobulin superfamily receptor translocation associated 2 protein on lymphoma cell lines and hairy cell leukemia cells detected by novel monoclonal antibodies. Clin Cancer Res. 2005 Jan 1;11(1):87-96.

3. T Ise, RJ Kreitman, I Pastan, S Nagata. Sandwich ELISAs for soluble immunoglobulin superfamily receptor translocation-associated 2 (IRTA2)/FcRH5 (CD307) proteins in human sera. Clin Chem Lab Med. 2006;44(5):594-602.

4. T Ise, S Nagata, RJ Kreitman, WH Wilson, AS Wayne, M Stetler-Stevenson, MR Bishop, DA Scheinberg, L Rassenti, TJ Kipps, RA Kyle, DF Jelinek, I Pastan. Elevation of soluble CD307 (IRTA2/FcRH5) protein in the blood and expression on malignant cells of patients with multiple myeloma, chronic lymphocytic leukemia, and mantle cell lymphoma. Leukemia. 2007 Jan;21(1):169-174. Epub 2006 Oct 19.

Patent Status:

1. U.S. Provisional Application No. 60/891,434, filed 23 Feb 2007, entitled "Antibodies That Specifically Bind IRTA and Methods of Use" (HHS Reference No. E-016-2006/0-US-01)

2. PCT Application No. PCT/US2005/034444 filed 22 Sep 2005, entitled "IRTA2 Antibodies and Methods of Use," which published as WO 2006/039238 on 25 Jan 2007 (HHS Reference No. E-287-2004/1-PCT-01)

3. U.S. Patent Application filed 28 Mar 2007 (HHS Reference No. E-287-2004/1-US-02)

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Jesse S. Kindra, J.D.; 301-435-5559; kindraj@mail.nih.gov.

High Speed Parallel Molecular Nucleic Acid Sequencing

Description of Technology: Available for licensing and commercial

development is a new system, methods and compositions for DNA sequencing, also known as Two Dye Sequencing (TDS). This invention is based on Fluorescence Resonance Energy Transfer (FRET), a technology increasingly in use for several molecular analysis purposes. In particular, the method consists of:

(1) Attachment of engineered DNA polymerases labeled with a donor fluorophore to the surface (chamber) of a microscope field of view;

(2) Addition to the chamber of DNA with an annealed oligonucleotide primer, which is bound by the polymerase;

(3) Further addition of four nucleotide triphosphates, each labeled on the base with a different fluorescent acceptor dye;

(4) Excitation of the donor fluorophore with light of a wavelength specific for the donor but not for any of the acceptors, resulting in the transfer of the energy associated with the excited state of the donor to the acceptor fluorophore for a given nucleotide, which is then radiated via FRET;

(5) Identification of the nucleotides most recently added to the primer by recording the fluorescent spectrum of the individual dye molecules at specific locations in the microscope field, and

(6) Converting the sequential spectrum into a DNA sequence for each DNA molecule in the microscope field of view.

Application: Sequencing of single nucleic acid molecules on a substrate.

Development Status: Early stage of development.

Inventors: Thomas Schneider and Denise Rubens (NCI).

Patent Status: U.S. Patent No. 6,982,146 issued 03 Jan 2006 (HHS Reference No. E-033-1999/0-US-03); U.S. Patent Application No. 11/204,367 filed 12 Aug 2005 (HHS Reference No. E-033-1999/0-US-04)

Licensing Status: Available for co-exclusive licensing.

Licensing Contact: Cristina Thalhammer-Reyero, PhD, M.B.A.; 301/435-4507; thalhamc@mail.nih.gov.

Collaborative Research Opportunity:

The NCI Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize nanoscale or molecular nucleic acid sequencing. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Peptide Inhibitors of Fibronectin and Related Collagen-Binding Proteins

Description of Technology:

Fibronectin has been implicated in a variety of cell contact processes, including cell attachment and migration. Fibronectin interacts with collagen through its gelatin-binding domain and this interaction is fundamental to the organization of extracellular matrices and the behavior of these cells on substrates. Fibronectin is essential for the attachment and migration of many cells, including various tumor and cancer cells.

The issued patents disclose peptide compositions having binding affinity for fibronectin, as well as methods for binding fibronectin with a fibronectin-binding peptide and methods for inhibiting fibronectin-mediated cell adhesion. The peptides disclosed are derived from the extracellular matrix protein thrombospondin, which is a modular adhesive glycoprotein that binds to the gelatin binding domain of fibronectin. These peptides are strong inhibitors of fibronectin-mediated cell adhesion. As such, they may be applicable to a variety of indications including cancer, wound healing, and connective tissue diseases.

Applications:

1. Potential therapeutic use for applications such as cancer, wound healing, and connective tissue disease.
2. Research tools for study of cell adhesion and migration processes.

Inventors: David D. Roberts *et al.* (NCI)

Related Publications:

1. JM Sipes, N Guo, E Nègre, T Vogel, HC Krutzsch, DD Roberts. Inhibition of fibronectin binding and fibronectin-mediated cell adhesion to collagen by a peptide from the second type I repeat of thrombospondin. *J Cell Biol.* 1993 Apr;121(2):469-477.

2. S Schultz-Cherry, H Chen, DF Mosher, TM Misenheimer, HC Krutzsch, DD Roberts, JE Murphy-Ullrich. Regulation of TGFbeta activity by peptides from the type I repeats of thrombospondin-1. *J Biol Chem.* 1995 Mar 31;270(13):7304-7310.

3. C Daniel, J Wiede, Y Takabatake, M Mizui, Y Isaka, E Imai, H Rupprecht, E Schulze-Lohoff, HC Krutzsch, SMF Ribeiro, DD Roberts, JE Murphy-Ullrich, C Hugo. Thrombospondin-1 is a major activator of TGFbeta in fibrotic renal disease in the rat *in vivo*. *Kidney Int.* 2004 Feb;65(2):459-468.

Patent Status:

1. U.S. Patent No. 5,491,130 issued 13 Feb 1996 (HHS Reference No. E-219-1992/0-US-01).

2. U.S. Patent No. 5,849,701 issued 15 Dec 1998 (HHS Reference No. E-219-1992/0-US-10).

3. Foreign counterparts issued in Australia, Great Britain, France, Germany, and Japan.

Related Technologies:

1. Heparin- and Sulfatide-Binding Peptides From the Type I Repeats of Human Thrombospondin.

a. U.S. Patent No. 5,357,041 issued 18 Oct 1994 (HHS Reference No. E-198-1991/0-US-01);

b. U.S. Patent No. 5,770,563 issued 23 Jun 1998 (HHS Reference No. E-198-1991/2-US-01);

c. U.S. Patent No. 6,051,549 issued 18 Apr 2000 (HHS Reference No. E-198-1991/2-US-03); and

d. foreign counterparts.

2. Compositions for Stimulating TGF Activity.

a. U.S. Patent No. 6,384,189 issued 07 May 2003 (HHS Reference No. E-019-1994/1-US-02)

Licensing Availability: Available for exclusive or non-exclusive licensing.

Licensing Contact: Tara Kirby, PhD; 301/435-4426; tarak@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Pathology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these peptides. Please contact John D. Hewes, Ph.D. at (301) 435-3121 or hewesj@mail.nih.gov for more information.

Dated: April 27, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-8500 Filed 5-3-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 meeting of the President's Cancer Panel.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(9)(b), Title 5 U.S.C., as amended, because the premature disclosure of information and the discussions would likely to significantly frustrate implementation of recommendations.

Name of Committee: President's Cancer Panel.

Date: May 24, 2007.

Time: 12:30 p.m. to 2:30 p.m.

Agenda: The Panel will review the final draft of 2006/2007 Annual Report to the President.

Place: National Cancer Institute, National Institutes of Health, Building 6116, Room 212, 6116 Executive Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Abby Sandler, PhD, Executive Secretary, Chief, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, Building 6116, Room 212, MSC 8349, 6116 Executive Boulevard, Bethesda, MD 20892-8349, 301/451-9399, sandlera@mail.nih.gov.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/pcp/pcp.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 26, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-2190 Filed 5-3-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Diabetes Centers Applications.