

projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Quality of Life Outcomes in Neurological Disorders; *Type of Information Collection Request:* New; *Form Number:* NA; *Need and Use of Information Collection:* In order to improve outcome measurement in clinical trials of neurological conditions, NINDS is developing a health-related quality of

life (HRQL) measurement system for major neurological diseases that affect the United States population. This measurement system must be consistent enough across the selected conditions to allow for cross-disease comparison, and yet flexible enough to capture condition-specific HRQL issues. The primary end users of this measurement system will be clinical trialists and other clinical neurology researchers; however the measurement system will

also be appropriate for clinical practice. The proposed information collection will support psychometric testing of HRQL item banks and testing of Spanish translation of the final questionnaires. *Frequency of Response:* Once; *Affected Public:* Individuals; *Type of Respondent:* Adults and children. The annual reporting burden is shown in the following table. There are no Capital Costs, Operating Costs or Maintenance Costs to report.

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Adults	6000	1	0.5	3,000
Children	3000	1	0.5	1,500
Totals	9000	4,500

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Claudia Moy, Program Director, Clinical Trials Group, NINDS, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 2214, Bethesda, MD 20892, or call non-toll-free number 301-496-2789 or e-mail your request, including your address to: moyc@ninds.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: September 6, 2007.

Joellen Harper Austin,

Executive Officer, NINDS, National Institutes of Health.

[FR Doc. E7-18772 Filed 9-21-07; 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, 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: Method to prognose multiple types of cancer and determine likelihood of metastasis; Compositions that inhibit CPE such as siRNA; Method to prevent and treat cancer with CPE inhibitors.

Market: 600,000 cancer related deaths in 2006; Global cancer market is worth more than eight percent of total global pharmaceutical sales; 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: U.S. Provisional Application No. 60/885,809 filed 19 Jan

2007 (HHS Reference No. E-096-2007/0-US-01); U.S. Provisional Application No. 60/887,061 filed 29 Jan 2007 (HHS Reference No. E-096-2007/1-US-01); 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.

Methods of Determining the Prognosis of Hepatocellular Carcinoma

Description of Technology: Hepatocellular carcinoma (HCC) represents an extremely poor prognostic cancer that remains one of the most common and aggressive malignancies worldwide. A major hallmark of HCC is intrahepatic metastasis and post-surgical reoccurrence. With current diagnostic methods, HCC patients are often diagnosed with end-stage cancer and have poor survival. Thus, there is a need for an accurate method to identify HCC and its proclivity for metastases/relapse, particularly at early stages of this disease.

The inventors have discovered a unique set of microRNA (miRNA) biomarkers that are associated with HCC metastasis/recurrence. This miRNA signature was validated in an independent cohort of 110 HCC samples as an independent predictor of HCC prognosis and likelihood of metastasis and relapse. In particular, the inventors provide evidence that these miRNA markers can predict HCC metastasis in the early stages of cancer. This methodology may enable clinicians to effectively stratify patients for appropriate cancer treatment and prioritize liver transplantation candidates.

Applications: Method to prognose HCC, patient survival and likelihood of HCC metastasis/relapse; Diagnostic tool to aid clinicians in determining appropriate cancer treatment; Compositions that inhibit miRNA HCC biomarkers such as siRNA; Method to treat HCC patients with inhibitory miRNA compositions.

Market: Primary liver cancer accounts for about 2% of cancers in the U.S., but

up to half of all cancers in some undeveloped countries; Post-operative five year survival rate of HCC patients is 30-40%.

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

Inventors: Xin Wei Wang *et al.* (NCI).

Publication: Budhu *et al.* A Unique Metastasis-related MicroRNA Expression Signature Predicts Survival and Recurrence in Hepatocellular Carcinoma, manuscript in preparation.

Patent Status: U.S. Provisional Application No. 60/884,052 filed 09 Jan 2007 (HHS Reference No. E-050-2007/0-US-01).

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

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

Mutant Alleles of Hsp90 That Modulates the Lifespan of Yeast

Description of Technology: Heat shock protein 90 (Hsp90) are a class of chaperone proteins that are up-regulated in response to elevated temperature and other environmental stresses. They act as chaperones to other cellular proteins and facilitate their proper folding and repair, and aid in the refolding of misfolded client proteins.

This invention identifies Hsp90 mutant residues that affect the chronological lifespan of yeast. These mutations in addition to a deletion in the *sch9* allele, the yeast homolog to human kinase AKT, can increase yeast lifespan from 45 to 57 days, approximately 20% longer than the wildtype strain. These genetically engineered yeast strains may have the longest chronological lifespan reported to date.

Applications: Model to study aging and longevity factors; Model to screen compounds that affect lifespan; A long-lived yeast strain could be used to ferment alcohol in a more efficient and cost effective as an alternative fuel source; Method to extend lifespan of transgenic farm animals.

Market: Anti-aging and alternative fuel industries are worth billions of dollars.

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

Inventors: Bradley T. Scroggins (NCI) *et al.*

Related Publication: BT Scroggins *et al.* An acetylation site in the middle domain of Hsp90 regulates chaperone function. *Mol Cell*. 2007 Jan 12;25(1):151-159.

Patent Status: U.S. Provisional Application No. 60/848,346 filed 09 Sep

2006 (HHS Reference No. E-319-2006/0-US-01).

Licensing Status: Available for non-exclusive licensing.

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

Collaborative Research Opportunity: The National Cancer Institute's Urologic Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize models to study aging and longevity factors. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Biomarkers for Tissue Status

Description of Technology: Tissue regeneration and tumorigenesis are complex, adaptive processes controlled by cues from the tissue microenvironment. There are complex processes both characterized by cell proliferation, migration, and angiogenesis suggesting that wounds and cancer share a number of phenotypic similarities including cellular behavior, signaling molecules, and gene expression.

Utilizing the kidneys as a model to compare renal regeneration and repair (RRR) from ischemically-injured tissues and renal cellular carcinoma (RCC), the inventors have identified biomarkers which are differentially expressed. The invention relates to methods of quickly and accurately diagnosing RCC and monitoring renal tissue health as well as RCC treatment.

Applications: Method to accurately diagnose RCC; RCC biomarker inhibitors such siRNA; Method to treat RCC; Method to determine and monitor renal tissue health status; Method for improving renal ischemia recovery without promoting RCC; Biomarkers for immunotherapy, drug targeting and drug screening, for targeting tumors and not normal regenerating tissue; Biomarkers for immunotherapy, drug targeting and drug screening, for targeting ischemic tissue and not tumors.

Market: Kidney cancer is one of the top ten most prevalent cancers in the U.S. and it accounts for 12,200 deaths annually; Approximately 35,000 new cases of kidney cancer are diagnosed annually; 50% survival rate after five years of diagnosis; Renal cancer accounts for 3% of all adult male malignancies.

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

Inventors: Joseph Riss (NCI) *et al.*
Publications:

1. FF Marshall. Urological Survey. Urological Oncology: Renal, Ureteral and Retroperitoneal Tumors. J Urol. 2007 May;177(5):1732-1734.

2. J Riss *et al.* Cancers as wounds that do not heal: Differences and similarities between renal regeneration/repair and renal cell carcinoma. Cancer Res. 2006 July 15;66(14):7216-7224.

Patent Status: U.S. Provisional Application No. 60/649,208 filed 01 Feb 2005 (HHS Reference No. E-064-2005/0-US-01); PCT Application No. PCT/US2006/003611 filed 01 Feb 2006 (HHS Reference No. E-064-2005/0-PCT-02).

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 Cancer Institute, Center for Cancer Research, Laboratory of Cancer Biology and Genetics, Wound Healing and Oncogenesis (NCI/CCR/LCBG), is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize topics of invention or related to cancer biology, metastasis, wound healing, bioinformatics, pharmacogenomics and therapeutic. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: September 18, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-18774 Filed 9-21-07; 8:45 am]

BILLING CODE 4140-01-P

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A Transgenic Mouse Expressing Reverse Tetracycline-Controlled Transactivator in Melanocytes

Description of Technology: Available for licensing are transgenic mice that allow for specific and inducible expression of proteins in melanocytes. Melanocytes are difficult to study because of their paucity in mammalian skin, and these mice present a readily available source of these cells and model to study melanocyte diseases such as melanoma of the skin and eye. The mice can be crossed with transgenic mice that harbor the green fluorescent protein (GFP) gene, resulting in melanocyte-specific GFP labeling. GFP labeling can aid in imaging and/or isolation of melanocytes via fluorescence activated cell sorting, and it can be used to study melanocytes at both the cellular and molecular level.

Applications: Research tool to study melanocytes and melanocyte related diseases such as melanoma of the skin and eye.

Model to develop and test cosmetic dermatology products such as skin tanners.

Advantages: Research tool to study melanocytes at the cellular and molecular level.

Melanocytes compose a minute fraction of mammalian skin. These mice present a significant advantage in labeling, imaging and isolating these cells.

Market: An estimated 59,940 Americans will be diagnosed with skin cancer in 2007.

An estimated 8,110 Americans will die of skin cancer in 2007.

Intraocular melanoma is a rare disease. For every 100,000 Americans, there are approximately 17.7 new cases of intraocular melanoma.

Cosmetic dermatology industry is worth billions of dollars.

Inventors: Glenn T. Merlino, M. Raza Zaidi, *et al.* (NCI)

Publication: Planned oral presentation at the Fourth International Congress on Melanoma in New York City, November 1-4, 2007. The technology is mentioned in the Abstract for this meeting.

Patent Status: HHS Reference No. E-308-2007/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for non-exclusive licensing.

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

Collaborative Research Opportunity: The Laboratory of Cancer Biology and Genetics of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize use of transgenic mice that allow for specific and inducible expression of proteins in melanocytes. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Chimeric Peptide Antigen Library: A Novel Tool for the Development of Vaccines Against Variable Pathogens Such as HIV, Tuberculosis, Hepatitis C and Malaria

Description of Technology: Many pathogens of dangerous human diseases such as HIV-1, HIV-2, viruses of hepatitis B and C, virus of influenza, viruses of dengue fever of types 1-4, pathogens of malaria and tuberculosis all possess significant variability.

Libraries of chimeric peptides, which imitate the genetic variability of the variable sections of the pathogenic protein, can cause a defensive immune response to the wide spectrum of the pathogen diversity. The immunogenic collections of chimeric peptides (libraries of variable chimeric peptides) in total reflect the natural and potential variability of the sections which determine antigenic activity.

The present invention relates to antigenic peptides, the methods of their preparation and their peptide libraries and it can be used for preparation of vaccines and medicine diagnostics. More specifically, the invention describes that the number of sequences in the library (size of library) is equal to the product of the number of possible residues in each position of peptide. The size of library can be reduced by sequential removal of residues which have the lowest frequency until the size will reach the required value.

Applications: Variable chimeric peptide libraries (VPCLs) can help construct effective vaccines capable of treating variable infectious agents such as HIV, TB, and Malaria.

Advantages: VPCLs represent naturally occurring and potential variability of antigenically active regions in one vaccine.