

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Submission of rotational plans for health warning label statements	20	1	20	100	2,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 2, 2010.  
**Leslie Kux**,  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2010-16805 Filed 7-8-10; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control**

Special Emphasis Panel (SEP): Preparedness and Emergency Response Learning Centers (PERLC) Panel, Request for Applications (RFA) TP10-1001, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the aforementioned meeting:

*Times and Dates:* 8:30 a.m.–5 p.m., July 27, 2010 (Closed). 8:30 a.m.–5 p.m., July 28, 2010 (Closed). 8:30 a.m.–5 p.m., July 29, 2010 (Closed).

*Place:* The W Atlanta Hotel-Perimeter, Perimeter Center West, Atlanta, Georgia 30346, Telephone: (770) 396-6800.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Preparedness and Emergency Response Learning Centers (PERLC) Panel, RFA TP10-1001.”

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Shoukat Qari, Senior Scientific Program Official, Extramural Research Program, Office of Public Health Preparedness and Response, 1600 Clifton Road, Mailstop D-44, Atlanta, Georgia 30333, Telephone: (404) 639-7938, E-mail: [SQari@cdc.gov](mailto:SQari@cdc.gov).

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 2, 2010.  
**Elaine L. Baker**,  
*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*  
 [FR Doc. 2010-16741 Filed 7-8-10; 8:45 am]  
**BILLING CODE 4163-18-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.

**Identification of Cancer Stem Cells**

*Description of Invention:* Cancer stem cells (CSC) are thought to be responsible for cancer initiation, maintenance, and therapeutic failure. A hallmark of stem cells is self-renewal via asymmetric cell division (ACD) into daughter stem-cells and cells predestined for differentiation. Demonstration of fundamental stem-cell’s traits such as ACD in cancers is lacking. Label retaining cells are thought to be enriched for stem-like cells. Label retaining cells are thought to be the

results of either very slow cycling cells and/or cells undergoing ACD. This invention is directed to the identification, isolation and purification of cancer stem cells by detecting asymmetrically dividing cells and/or label retaining cells. Detection of asymmetric cell division via non-random chromosomal cosegregation (ACD-NRCC) in various human cancers defines a unique and novel class of universal cancer stem cells, and potentially suggests a novel mechanism of carcinogenesis. The isolation of CSC might be used as a basis for a potential new strategy in cancer therapeutics. The invention also might have some implications in genetics and regenerative medicine.

*Applications*

- This invention may provide a novel way to target various cancers for treatment.
- This invention maybe also useful in regenerative medicine, i.e. spinal cord injury (regeneration of neurons), Alzheimer (regeneration of neurons) and Parkinson’s disease regeneration of neurons).

*Development Status:* Pre-clinical stage of development.

*Market*

- Cancer is the second leading cause of death in the U.S. The National Cancer Institute estimates the overall annual costs for cancer in the U.S. at \$107 billion; \$37 billion for direct medical costs, \$11 billion for morbidity costs (cost of lost productivity), and \$59 billion for mortality costs.

• According to statistics gathered by the National Institutes of Health, more than 10,000 Americans experience spinal cord injuries each year and more than 200,000 are living with permanent paralysis in their arms or legs due to spinal cord injury.

• Parkinson’s disease affects some four million patients worldwide. Approximately 50,000 Americans are diagnosed with Parkinson’s disease each year. Alzheimer Disease is estimated to affect 5.09 million patients by 2010.

*Inventors:* Itzhak Avital, Hong-Wu Xin, Danielle M. Hari (NCI)

*Publication:* Manuscript submitted.

*Patent Status:* U.S. Provisional Application No. 61/342,642 filed 16 Apr 2010 (HHS Reference No. E-122-2010/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Betty B. Tong, Ph.D.; 301-594-6565; [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov).

*Collaborative Research Opportunity:* The Center for Cancer Research, Surgery Branch, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize our unique method for isolating cancer stem cells. We are seeking interested parties who would be interested in collaboration with the goal of developing cancer stem cell cell-lines for personalized targeted therapies, drug testing and finding novel targets for cancer treatments. In addition, we would like to collaborate with parties interested in developing normal (not cancer) adult tissue stem-cell cell-lines for adult tissue regeneration such as Parkinson's disease, liver failure, Alzheimer, etc. Please contact John Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **Human Single-Domain Antibodies (dAbs) Against Insulin-Like Growth Factor 1 Receptor (IGF-1R) or Its Ligands, IGF-1 and IGF-2**

*Description of Invention:* Insulin-like growth factor (IGF) mediated signaling has been implicated in the development of several epithelial cancers, such as prostate, breast, and colorectal cancers. This technology consists of human single domain antibodies (dAbs) that bind to human insulin-like growth factor 1 receptor (IGF-1R) or its ligands, IGF-1 and IGF-2. These dAbs are comprised of only a single variable domain of an antibody with a human framework and three complementarity determining regions (CDRs). Several of these antibodies inhibit the IGF signaling pathway so they may be therapeutic candidates for the treatment of IGF-related cancers.

#### *Applications*

- A cancer therapeutic agent that inhibits the IGF-mediated signaling pathway.
- A diagnostic employing the detection of insulin-like growth factor 1 receptor (IGF-1R) or its ligands, IGF-1 and IGF-2, in a sample.

#### *Advantages*

- dAbs are about 10-fold smaller than IgG antibodies and exhibit dramatically increased penetration into solid tumors.
- dAbs can be produced in high yields at low cost, have favorable biophysical properties, and are well suited to engineering.
- dAbs are bioactive as monomers or can be linked into larger molecules to create drugs with prolonged serum half-lives or other pharmacological activities.
- dAbs can be fused to other polypeptides or other drugs to provide fusion proteins or conjugates.
- Human framework reduces potential for host immune reactions.

#### *Market*

• Cancer is the second most common cause of death in the US, exceeded only by heart disease. Survival varies greatly by cancer type and stage at diagnosis. The most recent estimate of the economic impact of cancer is that it costs the U.S. some \$228.1 billion annually. Hence, there is a need for the development of medical products that can improve the treatment of cancer patients.

• In the U.S., over 2.4 million new cancer cases are diagnosed yearly. A large proportion of these diagnoses are due to carcinomas of the breast, prostate, colon, lung, pancreas, and bladder. Monoclonal antibodies are increasingly being used to treat these cancers leading to sales of \$13.6 billion in 2008 with a market share of 28.6% of total sales.

*Development Status:* Early-stage development.

*Inventors:* Dimiter S. Dimitrov and Weizao Chen (NCI).

*Publications:* Chen W, Zhu Z, Feng Y, Dimitrov DS. A large human domain antibody library combining heavy and light chain CDR3 diversity. *Mol Immunol.* 2010 Jan;47(4):912-921. [PubMed: 19883941].

*Patent Status:* U.S. Provisional Application No. 61/249,476 filed 07 Oct 2009 (HHS Reference No. E-232-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Whitney Hastings; 301-451-7337; [Whitney.Hastings2@nih.gov](mailto:Whitney.Hastings2@nih.gov).

*Collaborative Research Opportunity:* The Center for Cancer Research Nanobiology Program (CCRNP), National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the dAbs that exhibit potent inhibitory activities against the

human IGF signaling pathway. Please contact John Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: July 2, 2010.

**Richard U. Rodriguez,**

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

[FR Doc. 2010-16800 Filed 7-8-10; 8:45 am]

**BILLING CODE 4140-01-P**

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### **National Institutes of Health**

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#### **Diagnostic H5N1 Avian Influenza Virus Peptides**

*Description of Invention:* The recent spread of highly pathogenic H5N1 avian influenza viruses among poultry and transmission of these viruses to humans raises concerns of a potential influenza pandemic. There is a need to track the spread of these viruses both in the animal and human populations to avert or reduce the impact of any potential influenza pandemic as well as to know the actual number (accurate surveillance) of people infected with H5N1, including individuals with subclinical H5N1 infection.

The subject technology is a specific combination of H5N1 peptides useful for assays to detect antibodies generated