

disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples or John Lauttman at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 22, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8-9549 Filed 4-30-08; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources And Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the

Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Health Centers Patient Survey—Pretest (NEW)**

The Health Center program supports Community Health Centers (CHCs), Migrant Health Centers (MHCs), Health Care for the Homeless (HCH) projects, and Public Housing Primary Care (PHPC) programs. Health Centers (HCs) receive grants from HRSA to provide primary and preventive health care services to medically underserved populations.

The proposed Patient Survey will collect in-depth information about HC patients, their health status, the reasons they seek care at HCs, their diagnoses, the services they utilize at HCs and elsewhere, the quality of those services, and their satisfaction with the care they

receive, through personal interviews of a stratified random sample of HC patients. The survey pre-test, which is the subject of this Notice, will serve as a pilot test of the survey instrument, survey sampling methodologies and procedures. This pre-test will also include cognitive interviews to ensure that the questions are being understood as was intended; as a result, it is estimated that each pre-test patient interview will take 2 hours.

The Patient Survey being pre-tested builds on previous periodic User-Visit Surveys which were conducted to learn about the process and outcomes of care in CHCs and HCH programs. The original questionnaires were derived from the National Health Interview Survey (NHIS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) conducted by the National Center for Health Statistics (NCHS). Conformance with the NHIS and NHAMCS allowed comparisons between these NCHS surveys and the previous CHC and HCH User-Visit Surveys. The new Patient Survey was developed using a questionnaire methodology similar to that used in the past, and so will allow some longitudinal comparisons for CHCs and HCH programs with the previous User-Visit survey data, including monitoring of process outcomes over time. In addition, this survey will include interviews of patients drawn from migrant populations and from residents of public housing, populations not included in the previous surveys.

The estimated response burden for the pilot test is as follows:

**PRETEST**

Type of respondent; activity involved	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Total hour burden
Grantee/Site Recruitment .....	2	3	6	3.75	22.5
Patient Recruitment .....	90	1	90	.167	15
Patient Survey .....	70	1	70	2	140
Total—Pretest .....	92	.....	166	.....	177.5

Send comments to Susan G. Queen, PhD., HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 24, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E8-9517 Filed 4-25-08; 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.

#### **Human and Improved Murine Monoclonal Antibodies Against CD22**

*Description of Technology:* CD22 is a cell surface protein that is highly expressed in a number of B cell lymphomas, such as hairy cell leukemia (HCL), non-Hodgkins lymphoma (NHL) and chronic lymphocytic leukemia (CLL). Several clinical trials using anti-CD22 antibodies are ongoing. However, all of these antibodies are murine in nature, and have the potential to elicit immune responses in patients. The immunogenicity may adversely affect the ability to provide patients with repeated doses of a therapeutic comprising the antibody, limiting the clinical application of those therapeutics.

In order to address the issue of immunogenicity in a patient, NIH inventors have generated two anti-CD22 antibodies of human origin. Each antibody has the ability to recognize CD22 on the surface of Raji cells. Thus, these antibodies represent an attractive alternative to the murine anti-CD22 antibodies currently being tested in clinical trials.

Additionally, the inventors have generated a modified murine anti-CD22 antibody with increased binding affinity and solubility. This antibody could also be a suitable alternative for the murine antibodies currently available.

##### *Applications:*

Use as an antibody therapeutic for B cell lymphomas.

Use in an immunotoxin therapeutic for B cell lymphomas.

Diagnostic for the detection of CD22 positive tumors.

##### *Advantages:*

Antibody against a proven target for immunotherapy.

Fully human antibody reduces potential immunogenicity, thereby allowing repeated dosing.

Murine antibody has increased binding affinity and solubility relative to current murine anti-CD22 antibodies.

*Benefits:* The antibody based therapeutic market is likely to grow steadily in the next decade, with the present estimate of the market at more than ten billion U.S. dollars. Approximately five billion U.S. dollars are spent annually for treatment of lymphoma. The development of a

successful antibody therapeutic for B cell lymphomas would occupy a significant portion of that market as approximately eighty-five percent of all lymphomas are B cell-linked.

*Inventors:* Dimiter S. Dimitrov *et al.* (NCI).

*Patent Status:* U.S. Provisional Application No. 61/042,329 filed 04 Apr 2008 (HHS Reference No. E-080-2008/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* David A. Lambertson, PhD; 301-435-4632; [lambertsond@mail.nih.gov](mailto:lambertsond@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI CCR Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-CD22 human monoclonal antibodies. Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **Human Monoclonal Antibody Against Mesothelin**

*Description of Technology:* Mesothelin is a cell surface protein that is naturally expressed at very low levels. However, the expression of mesothelin is significantly increased in aggressive tumors, such as mesotheliomas and pancreatic and ovarian tumors. As a result, mesothelin is an excellent candidate for tumor targeted immunotherapeutics.

Currently, the only antibodies against mesothelin that are available for clinical trials are of murine origin. These antibodies have the potential to elicit immune responses in patients, which may adversely affect the ability to provide patients with repeated doses. As a result, the clinical application of the antibodies may be limited.

In order to address the issue of immunogenicity in patients, NIH inventors have generated an anti-mesothelin antibody of human origin. The antibody has the ability to efficiently recognize mesothelin on the surface of cells, and induce ADCC in mesothelin-positive cells. Thus, this antibody represents an attractive alternative to the murine anti-mesothelin antibodies currently available.

##### *Applications:*

Use as an antibody therapeutic for mesotheliomas and pancreatic and ovarian tumors.

Use in an immunotoxin therapeutic for mesotheliomas and pancreatic and ovarian tumors.

Diagnostic for the detection of mesothelin positive tumors.

Research agent for the detection of mesothelin.

##### *Advantages:*

Fully human antibody reduces potential immunogenicity, thereby allowing repeated dosing.

First human antibody against mesothelin.

*Benefits:* The antibody based therapeutic market is likely to grow steadily in the next decade, with the present estimate of the market at more than ten billion U.S. dollars. The development of a successful antibody therapeutic for mesotheliomas and pancreatic and ovarian cancers would occupy a significant portion of that market.

*Inventors:* Dimiter S. Dimitrov *et al.* (NCI).

*Patent Status:* U.S. Provisional Application filed 27 Mar 2008 (HHS Reference No. E-079-2008/0-US-01)

*Licensing Status:* Available for licensing.

*Licensing Contact:* David A. Lambertson, PhD; 301-435-4632; [lambertsond@mail.nih.gov](mailto:lambertsond@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI CCR Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the antibody. Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **New Insect SF-9ET Cell Line for Determining Baculovirus Titers**

*Description of Technology:* The baculovirus based protein expression system has gained increased prominence as a method for expressing recombinant proteins that are used in a wide range of biomedical applications. An important step in the use of this system is the ability to determine the virus infectious titer, i.e., the number of active baculovirus particles produced during an infection of the insect host cell. The current "gold standard" methods used for determining baculovirus titers, such as the plaque and end point dilution assays, can be costly, take a long time to complete (up to 7-8 days), and are sometimes difficult to interpret as they involve observing the cytopathic effects (CPE) that baculovirus infection has on the infected insect host cell. To solve these problems, a modified insect cell line, SF-9ET, was developed to genetically express the green fluorescent protein (GFP) when infected with baculovirus. In these cells, the gene for GFP is placed

under the control of a baculovirus promoter so that the cells express GFP when they are infected with the virus. The baculovirus titer can then be quantitated from the level of GFP expression in the insect host cell. The results are obtained within 3 days compared to the 7–8 day period typical of the traditional CPE based methods.

The GFP based system is capable of replacing the traditional methods as it is faster, more accurate and may be less expensive than the currently used systems. This proprietary technology can become an indispensable tool for the quantitation of baculovirus titers; a step that is important in the production of recombinant proteins and vaccine like particles (VLPs) for academic and commercial purposes.

**Applications:** Baculovirus based recombinant protein expression.

**Advantages:** Fast, accurate, and inexpensive determination of baculovirus titers for protein expression.

**Inventors:** Ralph F. Hopkins III and Dominic Esposito (SAIC/NCI).

**Patent Status:** U.S. Provisional Application No. 61/019,562 filed 07 Jan 2008 (HHS Reference No. E-009-2008/0-US-01).

**Licensing Status:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Jasbir (Jesse) S. Kindra, J.D., M.S.; 301-435-5170; [kindraj@mail.nih.gov](mailto:kindraj@mail.nih.gov).

#### **A Molecular Grading System for Ductal Carcinoma In Situ (DCIS) of the Breast: A New Molecular Diagnostic To Determine Disease Stages of DCIS**

**Description of Technology:** The technology describes the comprehensive profiling of Ductal Carcinoma in situ (DCIS) in breast cancer patients. The inventors have developed a molecular grading system for DCIS utilizing both gene expression profiling and genomic change profiling. The inventors have identified molecular profiles that identify early stage patients at risk of disease progression requiring more aggressive therapy. These observations suggest that a clinical assay could be developed for the grading of DCIS. Furthermore, the invention demonstrates that the profiles correlate with the molecular grade and with cell proliferation, suggesting that a clinical assay using routine methods, based on the nuclear grade and staining for Ki67 as a measure of proliferation, could also potentially be developed.

**Advantages and Applications:**

The technology has the potential of being developed into an accurate diagnostic test for DCIS patients according to their risk of tumor progression.

The diagnostic profiling can assist physicians in making clinically informed and personalized therapy decisions for DCIS patients.

In the studies, tissue samples collected via laser capture microdissection from in situ breast cancer patients were used, which validate and authenticate the relevance of the study.

**Development Status:** Larger clinical study is currently being planned.

**Inventors:** Paul S. Meltzer *et al.* (NCI).

**Patent Status:** U.S. Provisional Application No. 60/936,526 filed 20 Jun 2007 (HHS Reference No. E-192-2007/0-US-01).

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

**Licensing Contact:** Mojdeh Bahar, J.D.; 301-435-2950; [baharm@mail.nih.gov](mailto:baharm@mail.nih.gov).

**Collaborative Research Opportunity:** The National Cancer Institute, Genetics Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize molecular grading of DCIS. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

April 24, 2008.

**David Sadowski,**

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

[FR Doc. E8-9535 Filed 4-30-08; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Dental & Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel.

**Date:** June 19, 2008.

**Time:** 2 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Sooyoun (Sonia) Kim, MS, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NIDCR/NIH, 6701 Democracy Blvd, Rm 675, Bethesda, MD 20892-4878, (301) 594-4827, [kims@email.nidcr.nih.gov](mailto:kims@email.nidcr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 23, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-9404 Filed 4-30-08; 8:45 am]

**BILLING CODE 4140-01-M**

## **DEPARTMENT OF HOMELAND SECURITY**

### **Office of the Secretary**

#### **Public Workshop: Privacy Compliance Fundamentals—PTAs, PIAs, and SORNs**

**AGENCY:** Privacy Office, Department of Homeland Security (DHS).

**ACTION:** Notice announcing public workshop.

**SUMMARY:** The Department of Homeland Security Privacy Office will host a public workshop, "Privacy Compliance Fundamentals—PTAs, PIAs, and SORNs."

**DATES:** The workshop will be held on May 23, 2008, from 9 a.m. to 4:30 p.m.

**ADDRESSES:** The workshop will be held in the auditorium at the DHS Offices at the GSA Regional Headquarters Building located at 7th and D Streets, SW., Washington, DC, 20024.

**FOR FURTHER INFORMATION CONTACT:**

Tamara Baker, Privacy Office, Department of Homeland Security, Washington, DC 20528; by telephone 703-235-0780; by facsimile 703-235-0442; or by e-mail at [privacyworkshop@dhs.gov](mailto:privacyworkshop@dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Department of Homeland Security (DHS) Privacy Office is holding a public workshop that will provide in-depth training on the privacy compliance process at DHS, and specifically how to write privacy impact assessments (PIAs)