SUMMARY: The Office of Inspector General (OIG) is announcing the availability of a Proactive Disclosure Service (PDS) Prototype for customers of the Healthcare Integrity and Protection Data Bank (HIPDB). The PDS was developed for the National Practitioner Data Bank (NPDB) in response to customers’ interest in real-time monitoring of practitioner credentials. As a result of the technical interoperability of the NPDB and HIPDB, the PDS feature is also being made available to HIPDB customers.

DATES: This fee will be effective June 11, 2007.

FOR FURTHER INFORMATION CONTACT: Joel Schaefer, OIG Office of External Affairs, (202) 619–0089, or Mark Pincus, HRSA, Bureau of Health Professions, (301) 443–2300.

SUPPLEMENTARY INFORMATION: The PDS has been initially offered as a prototype to authorized NPDB entities, as set forth in a HRSA notice published in the Federal Register on March 7, 2007 (72 FR 10227). In accordance with implementation of the PDS prototype, authorized HIPDB customers can also now choose to enroll all of their practitioners, providers, and suppliers in PDS, or enroll some of their practitioners, providers, and suppliers while continuing to periodically query on others using the regular query methods. Customers with PDS-enrolled subjects will be notified within one business day of the HIPDB’s receipt of a report on any of their enrollees. While customers can expect to receive reports sooner with PDS, the format of and information contained in a report will remain the same.

The annual subscription fee during the prototype period will be $3.25 per practitioner, provider, or supplier. The rate is subject to change after the prototype period is complete. The query fee for periodic queries will continue to remain at $4.75 per name.

PDS Enrollment Availability

The PDS prototype became available to NPDB queries effective April 30, 2007. An invitation to participate in this prototype was extended first to organizations that assisted HRSA with designing and pricing, which occurred between 2003 and 2005. All entities registered with the HIPDB and/or the NPDB have been invited to participate to meet a predetermined number for subjects to be monitored. Once this number is achieved, enrollment in the prototype will close. It is anticipated that the PDS prototype period will last approximately 18 to 24 months before it is opened to all authorized Data Bank entities.

User Fee Amount

An annual subscription fee of $3.25 per subject will be charged upon enrollment. This fee includes the cost of an initial query, which automatically will be incurred when a subject is first enrolled, and all reports received on the enrolled subject over the course of the one-year subscription period. The fee was determined through economic analysis of the average annual rate of queries performed by health care entities in relationship to the current query fee that is based on the actual cost for services. The Department will accept payment for the subscription fee from entities via credit card or electronic funds transfer. When the prototype period concludes, the Department may change the subscription fee. Any changes will be announced through notice in the Federal Register.


Daniel R. Levinson, Inspector General.

[FR Doc. E7–11220 Filed 6–8–07; 8:45 am] 

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.
A Sensitive, High Throughput Pseudovirus-Based Papillomavirus Neutralization Assay for HPV 16 and HPV 18

Description of Technology: This invention is a research tool for measuring protective antibody responses against Human Papilloma Viruses (HPV). Sensitive high-throughput neutralization assays, based upon pseudoviruses carrying a secreted alkaline phosphatase (SEAP) reporter gene, were developed and validated by the inventors for HPV 16, HPV 18, and bovine papillomavirus 1 (BPV1). In a 96-well plate format, the assay was reproducible and appears to be as sensitive as, but more type-specific than, a standard papillomavirus-like particle (VLP)-based enzyme-linked immunosorbent assay (ELISA). The SEAP pseudovirus-based neutralization assay should be a practical method for quantifying potentially protective antibody responses in HPV natural history and prophylactic vaccine studies.

Inventors: John T. Schiller (NCI), Douglas R. Lowy (NCI), Christopher Buck (NCI), Diana V. Pastrana (NCI), et al.


Licensing Status: This assay is available nonexclusively through a biological materials license.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukas@mail.nih.gov.

Development of a Novel High Throughput Assay To Measure Cell-Infection With Vaccinia Strains Expressing Reporter Genes

Description of Technology: Critical to developing a vaccine against viral infections is an assay to measure the neutralizing antibody present in blood of vaccine recipients. The currently available tests are labor intensive and require 5–6 days to complete. The inventors have designed a high throughput vaccinia neutralization assay, which offers several advantages over the assays that are currently used. It is completed in as little as 24 hours, it is sensitive, highly reproducible, requires only 50 μl of plasma and uses automated readout. This assay is based on the use of recombinant vaccinia virus (vSC56) expressing a bacterial gene coding for the enzyme β-galactosidase (β-Gal) under the control of a synthetic early/late promoter. Another recombinant virus expressing an inducible reporter gene (Luciferase) is also being tested in neutralization assay. These assays may be of value in the clinical trials of new smallpox vaccines, for evaluations of new vaccinia immunoglobulin (VIG) and anti-viral agents under development. The technology itself may be adapted for construction of neutralization assays for other viruses and intracellular pathogens.

Inventor: Hana Golding (FDA).

Publications:


Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukas@mail.nih.gov.

Collaborative Research Opportunity: The CBER/FDA Laboratory of Retrovirus Research is seeking statements of capability or interest from parties interested in collaborative research to further develop or evaluate novel antivaccinia agents including monoclonal antibodies and vaccines. Please contact Hana Golding at Tel: 301–827–0784 or E-mail: hana.golding@fda.hhs.gov for more information.

Vectors for Delivering Viral and Oncogenic Inhibitors

Description of Technology: The invention concerns cell transduction vectors which are capable of inhibiting viral replication in cells transduced with these vectors, and which also are capable of inhibiting the growth of cancer cells. Specifically, these vectors produce protective genes which interfere with viral replication. These genes are tightly regulated by HIV–1 Tat and Rev proteins, which if produced after infection can induce expression of the protective genes. The vectors contain either a single gene (delta-gag), or a combination of two different genes (delta-gag and RNAses) which interfere with HIV–1 replication at different stages of the HIV–1 life cycle. Following transduction of target cells, the mRNA for the protective genes is incorporated into the newly budding virion along with the viral genomic mRNA. Following infection of neighboring cells, the mRNA for the protective gene can be reverse transcribed and integrated into these cells, thereby increasing the proportion of cells containing the protective gene.

In providing protection against viral replication, the vectors embodied in this invention could be used in gene therapy against HIV and against other viral diseases. In addition, the vectors could be used for introducing specific genes into neoplastic cells and thereby be effective in treating cancer and other diseases.

Inventors: Susanna M. Rybak, Andrea Cara, Gabriella L. Gusella, Dianne L. Newton (NCI).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Cancer Institute Board of Scientific Advisors.

The meetings will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors; TARGET Ad Hoc Subcommittee Meeting.

Date: June 27, 2007.

Time: 7 p.m. to 9:30 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Malcolm M. Smith, PhD, MD, Executive Secretary, Associate Branch Chief, Pediatric Section, Clinical Investigation Branch, Clinical Therapy Evaluation Program, NCI, 6130 Executive Blvd, EPN, 7th Floor, Rm. 7025, Bethesda, MD 20892, 301–496–2522, smithm@ctep.nci.nih.gov.

Name of Committee: National Cancer Institute Board of Scientific Advisors; TARGET Ad Hoc Subcommittee Meeting.

Date: June 28, 2007.

Time: 8 a.m. to 6 p.m.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Time: June 29, 2007.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Time: June 29, 2007.

Agenda: To discuss activities related to the BSA TARGET Ad Hoc Subcommittee.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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.


Date: July 16, 2007.

Time: 1 p.m. to 4 p.m.

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

Contact Person: Beata Buzas, PhD, Scientific Review Administrator, National Institutes on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, RM 3041, Rockville, MD 20852, 301–443–0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: June 1, 2007.

Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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 on Deafness and Other Communication Disorders Special Emphasis Panel; Chemical Senses.

Date: June 27, 2007.

Time: 12 p.m. to 1:30 p.m.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health