DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB NO. 0930–0158)—Extension

SAMHSA's Mandatory Guidelines for Federal Workplace Drug Testing Programs will request OMB approval for the Federal Drug Testing Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644) dated April 13, 2004, and for the information provided by laboratories for the National Laboratory Certification Program (NLCP).

The Federal Drug Testing Custody and Control Form is used by all Federal agencies and employers regulated by the Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination. The Federal Drug Testing Custody and Control Form approved by OMB three years ago is being resubmitted for OMB approval without any revision.

Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the laboratory's testing procedures before arriving at the laboratory.

The NLCP application form has not been revised compared to the previous form.

The annual total burden estimates for the Federal Drug Testing Custody and Control Form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Burden/ response (hrs.)	Number of responses	Total annual burden (hrs.)
Custody and Control Form			
Donor	.08	7,096,000	567,680
Collector	.07	7,096,000	496,720
Laboratory	.05	7,096,000	354,800
Medical Review Officer	.05	7,096,000	354,800
Laboratory Application	3.00	3	9
Laboratory Inspection Checklist	3.00	100	300
Laboratory Recordkeeping	250.00	50	12,500
Total			1,786,809

Written comments and recommendations concerning the proposed information collection should be sent by August 21, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: July 15, 2009.

Dennis O. Romero,

Deputy Executive Officer and Deputy Director, Office of Program Services.

[FR Doc. E9–17377 Filed 7–21–09; 8:45 am]

BILLING CODE 4162–20–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.

High Diversity/High Affinity Domain Antibody Library

Description of Invention: Available for licensing and commercial development is a highly diverse domain antibody (dAb) library providing antibodies that bind with high affinity to a variety of antigen targets. Antibody diversity is inherently limited by using only three CDRs of either light chain variable domain (LCDRs) or heavy chain variable domain (HCDRs). This novel dAb library is designed using light chain variable domain 3 (LCDR3) and heavy chain variable domain (HCDR3), which are of primary importance for creating binding site diversity in the human immune system. The library contains 2.5×10^{10} dAbs. Human naturally occurring LCDR3s were grafted onto HCDR1 of m0. These antibodies are of very small size (15–17 kDa), high

stability and can be expressed at high levels as monomers. The library can be used for the selection of antibodies to any antigen including cancer and viral antigens and exhibit such properties as good penetration, stability, solubility, high levels of expression (at potentially low cost), and low level of immunogenicity or toxicity.

Applications: Cancer; Infectious disease; Therapeutics; Diagnostics; Research reagents; Research tools; Library panning.

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

Relevant Publications:

1. P Jirholt et al. Exploiting sequence space: shuffling in vivo formed complementarity determining regions into a master framework. Gene 1998 Jul 30;215(2):471–476.

2. Y Reiter et al. An antibody single-domain phage display library of a native heavy chain variable region: isolation of functional single-domain VH molecules with a unique interface. J Mol Biol. 1999 Jul 16;290(3):685–698.

3. L Riechmann and S Muyldermans. Single domain antibodies: comparison of camel VH and camelised human VH domains. J Immunol Methods 1999 Dec 10;231(1–2):25–38.

4. E Söderlind et al. Recombining germline-derived CDR sequences for creating diverse single-framework antibody libraries. Nat Biotechnol. 2000 Aug;18(8): 852–856.

5. LJ Holt et al. Domain antibodies: proteins for therapy. Trends Biotechnol. 2003 Nov;21(11): 484–490.

6. W Chen et al. Construction of a large phage-displayed human antibody domain library with a scaffold based on a newly identified highly soluble, stable heavy chain variable domain. J Mol Biol. 2008 Oct 10;382(3):779–789.

Patent Status: HHS Reference No. E–216–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, CCR, CCRNP is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this domain antibody library. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Mouse Monoclonal Antibody Targeting Tetanus Toxin Heavy Chain Fragment C

Description of Invention: The FDA is pleased to announce as available for licensing a murine monoclonal antibody that specifically binds to Fragment C of tetanus toxin. Tetanus toxin is one of the most potent neurotoxins known. It is a complex molecule, composed of a linked heavy chain and light chain, each having different domains serving different functions. One domain of the heavy chain, known as ''Fragment C,'' is known to bind the toxin to neurons. Fragment C is the focus of much research, including: analysis of the subtle differences between neuronal uptake of tetanus toxin and the related botulinum toxin, the design of compounds that block the uptake of tetanus toxin, and design of drugs that target the same cellular mechanism to enhance uptake.

Applications: Cell-based imaging agents; New drug development, including antitoxins.

Advantages: Toxin specific-site antibodies.

Development Status: Cell line (mouse-spleen hybridoma) established to produce antibodies.

Inventors: Marjorie A. Shapiro, PhD, and Sean P. Fitzsimmons, PhD (FDA).

Relevant Publication: SP Fitzsimmons, KJ Clark, R Wilkerson, MA Shapiro. Inhibition of tetanus toxin fragment C binding to ganglioside G(T1b) by monoclonal antibodies recognizing different fragment C epitopes. Vaccine 2000 Aug 15;19(1):114–121.

Patent Status: HHS Reference No. E–061–2009/0—Research Materials. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive Biological Materials Licensing.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301–435–5470; *goldsteb@mail.nih.gov*.

Collaborative Research Opportunity: The FDA's Office of Biotechnology Products in the Center for Drug Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize antibodies directed against tetanus toxin. Please contact Alice Welch, PhD at (301) 827–0359 or *Alice.Welch@fda.hhs.gov* for more information.

Membrane Proximal Region of HIV gp41 Anchored to the Lipid Layer of a Virus-Like Particle Vaccine

Description of Invention: The HIV–1 envelope glycoproteins (gp120–gp41), which mediate receptor binding and entry, are the major targets for neutralizing antibodies. Although the envelope glycoproteins are immunogenic and induce a variety of antibodies, the neutralizing antibodies that are induced are strain-specific and the majority of the immune response is diverted to non-neutralizing determinants. Broadly neutralizing antibodies have been isolated only from natural HIV infection, and rarely, as only five broadly-neutralizing antibodies have been identified to date. Three are gp41-directed (2F5, 4E10 and Z13) and the other two (b12 and 2G12) are gp120-directed. The three gp41 neutralizing antibodies recognize the membrane proximal region (MPR) of the HIV–1 gp41 glycoprotein. The MPR region includes a series of amino acids that lie on the HIV virus surface, just before gp41 crosses the viral membrane. The MPR is highly hydrophobic (fifty percent of its residues are hydrophobic) and is highly conserved across many HIV clades. Recently, the hydrophobic context of MPR and the presence of lipid membrane were shown to be important for the optimal binding of 2F5 and 4E10 antibodies. To date, immunization with conserved membrane proximal elements or the core 2F5 epitope in a number of contexts has failed to elicit broadly neutralizing antibodies.

Available for licensing is a technology that uses the immunogenic hepatitis B surface antigen (HBsAg) platform to array epitopes from the conserved, neutralization-sensitive MPR of HIV–1, and use of these constructs to induce an immune response to HIV–1. The replacement of a membrane spanning domain of HBsAg with a membrane spanning domain of gp41 anchors gp41 into HBsAg in virtually the identical orientation as on HIV virions and correctly orients the nearby MPR on the lipid layer. More specifically, HBsAg variant compositions with one or more transmembrane domains of the HBsAg replaced with a gp41 transmembrane domain and one or more gp41 MPRs are available for licensing.

Application: Development of Human Immunodeficiency Virus (HIV) vaccines, therapeutics and diagnostics.

Development Status: Vaccine candidates have been synthesized and preclinical studies have been performed.

Inventors: Ira Berkower (FDA).

Patent Status: U.S. Provisional Application No. 61/086,098 filed 04 Aug 2008 (HHS Reference No. E–291–2008/0–US–01).

Licensing Status: Available for licensing.

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

A Unique Infectious Hepatitis C Virus Clone, Strain HC–TN (genotype 1a)

Description of Invention: It is anticipated that this infectious clone of hepatitis C virus (HCV) strain HC–TN (genotype 1a) will be useful for the development of vaccines and antiviral drugs that target HCV, genotype 1a. The HC–TN strain is unique because it has been shown to cause fulminant hepatitis. To date, only one other HCV strain, JFH1 (genotype 1b), has been isolated that is known to cause fulminant hepatitis. Additionally, little is known about the etiology of fulminant hepatitis C disease. Therefore, the HC–TN strain may be useful as a tool for studying the etiology of fulminant hepatitis. This invention includes the infectious clone, nucleotide sequences of the clone, and polypeptides encoded by the HC–TN clone. Methods are included for producing attenuated HCV, and for screening therapeutics against HCV and developing vaccines and diagnostics.

Apparently, no companies or other laboratories have this HC–TN strain. The availability of the pHC–TN clone will be highly useful to pharmaceutical companies since no further research is required for its commercialization into, e.g., assays for testing antiviral compounds targeting HCV.

Applications:

- Production of attenuated viruses and polypeptides.
- HCV vaccines, diagnostics, therapeutics and screening tool for anti-HCV compounds.

Advantages: There is no universally effective therapy against HCV infection. This invention enables development of vaccines, diagnostics and therapeutics that are specific for the HC–TN strain or HCV genotype 1a.

Development Status: The technology is currently in the preclinical stage of development.

Market: More than 80% of the HCV infections in North and South America, Europe, Russia, China, Japan and Australia are genotype 1. The instant technology may be transferred through biological materials licenses for territories in which no patent rights exist.

Inventors: Jens Bukh, Robert H. Purcell, Suzanne U. Emerson, Akito Sakai, Patrizia Farci (NIAID).

Publication: A Sakai et al. In vivo study of the HC–TN strain of hepatitis C virus recovered from a patient with fulminant hepatitis: RNA transcripts of a molecular clone (pHC–TN) are infectious in chimpanzees but not in Huh7.5 cells. J Virol. 2007 July;81(13):7208–7219.

Patent Status: U.S. Patent Application No. 12/061,504 filed 02 April 2008 (HHS Reference No. E–249–2007/0–US–01); No foreign rights available.

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov*.

Dated: July 13, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–17319 Filed 7–21–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Environmental Health Sciences Special Emphasis Panel. Formative Children's Center Review 2.

Date: July 24, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P. O. Box 12233, MD EC–30, Research Triangle Park, NC 27709. (919) 541–1307. *malone@niehs.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–17303 Filed 7–21–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

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 following meeting for the aforementioned committee:

Time and Date: 11 a.m.–12 p.m., July 23, 2009.

Place: The teleconference call will originate at the CDC.

Status: Open to the public. Teleconference access limited only by availability of telephone ports. To participate in the teleconference please dial 1 (800) 779–6036 and enter conference code 6417394.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and the Director, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), regarding: (1) The practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (*e.g.,* nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: The agenda will include a follow up discussion of CDC's *Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting.*

Agenda items are subject to change as priorities dictate. This notice is being published less than 15 days prior to the meeting due to the public health emergency declared on April 26, 2009. There is a critical need for this committee to deliberate and discuss urgent matters related to the H1N1 virus, and be actively engaged in the national preparedness and response efforts as dictated by circumstances and events.