a reduction of toxicity by more than 100,000-fold. Sandwich ELISA analysis indicated that the featured toxoids were two- to three-fold less antigenic than the native neurotoxin compared to commercially available toxoids, which were about 100-fold less antigenic.

Preclinical studies have been performed using the toxoids of the invention. Mice were immunized twice, on Day Zero (0) and Day Fourteen (14). By Day Twenty-Eight (28), relatively high toxin-specific IgG titers were detected in animals that had received any of the in-house toxoids, with greater than 99% being IgG1 and the remainder IgG2. These immunized mice remained asymptomatic after being challenged with Fifty (50) to One Million (1,000,000) median lethal dose (LD50) units of the 900 kDa neurotoxin. In contrast, animals immunized with several different batches of commercially available toxoids did not develop measurable toxin-specific antibody titers; however, these mice did survive neurotoxin challenges with Two (2) LD50 units, but died when challenged with Six (6) LD50 units.

This application claims the formalin-detoxified botulinum compositions described above and an in vitro method for characterizing the toxoids. Also claimed are methods of making the botulinum compositions, and methods of producing antitoxin to botulinum toxin.

Applications: ELISA development, production of equine or human-derived botulinum antitoxin, development of next generation botulism vaccines.

Development Status: Toxoids have been prepared and preclinical studies have been performed. Standard antibody reagents for ELISA assay development have been prepared.

Inventors: James E. Keller (FDA/CBER).

Publication: JE Keller. Characterization of New Formalin Botulinum Neurotoxin Toxoids. Clin Vaccine Immunol. 2008 Jul 30; Epub ahead of print, doi:10.1128/CVI.00117–08.

Patent Status: U.S. Provisional Application No. 61/036,904 filed 14 Mar 2008 (HHS Reference No. E–325–2007/0–US–01).

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

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

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize botulinum toxoids. Please contact Alice Welch, PhD at 301–827–0359 or *Alice.Welch@fda.hhs.gov* for more information.

Magnetic Resonance Imaging Methods and Systems for Estimating Cone of Uncertainty

Description of Technology: In diffusion tensor MRI imaging it is desirable to determine and display the fiber tract dispersion, e.g., the eigenvectors and the associated uncertainties. For example, the unit eigenvector may be displayed with a cone of uncertainty around its tip. This conveys the notion that the direction of fiber is not known precisely. However, the known methods are directed to computation and visualization of a circular cone of uncertainty. These methods are suitable for practical computation and visualization of an elliptical cone of uncertainty. The current invention overcomes this problem by providing (1) a reconstruction procedure to construct the covariance matrix of a major eigenvector for each voxel of a region of interest of a subject, (2) a visualization technique to visualize the elliptical cone of uncertainty of the eigenvector, and (3) two reconstruction procedures to compute the normalized areal and circumferential measures of the elliptical cone of uncertainty. The methods can be used to diagnose medical disorders associated with anomalous changes in water diffusion. The methods can also be used in applications in material science and earth science (geomagnetism).

Applications: Magnetic Resonance Imaging; Diagnostics; Material science; Earth science (Geomagnetism).

Inventor: Cheng Guan Koay (NICHD).

Publications:

1. CG Koay *et al.* The elliptical cone of uncertainty and its normalized measures in diffusion tensor imaging. IEEE Trans Med Imaging. 2008 Jun;27(6):834–846.

2. CG Koay *et al.* Error propagation framework for diffusion tensor imaging via diffusion tensor representations. IEEE Trans Med Imaging. 2007 Aug;26(8):1017–1034.

3. CG Koay *et al.* A unifying theoretical and algorithmic framework for least squares methods of estimation in diffusion tensor imaging. J Magn Reson. 2006 Sep;182(1):115–125.

Patent Status: U.S. Provisional Application No. 60/996,169 filed 05 Nov 2007 (HHS Reference No. E–273–2007/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The NICHD, Section on Tissue Biophysics and Biomimetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Alan E. Hubbs, PhD at 301–594–4263 or *hubbsa@mail.nih.gov* for more information.

Dated: August 18, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–19915 Filed 8–27–08; 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.

Radiotracers for Imaging Cannabinoid Sub-Type1 (CB_1) Receptor

Description of Technology: The present invention relates to novel radiolabeled compounds for imaging cannabinoid sub-type 1 (CB_1) receptors in brains of mammals, particularly humans, using positron emission tomography (PET) or single photon emission computed tomography

(SPECT). These radioligands can be used in clinical research, diagnostics, or drug discovery and development, in that, they permit understanding of the role of CB_1 receptors in neuropsychiatric disorders such as Parkinson's disease, Huntington's disease, Alzheimer's disease, multiple sclerosis, depression, mood disorder, anxiety, schizophrenia, drug addiction, alcohol disorder, obesity and anorexia.

Applications:

• *In vivo* imaging of CB_1 receptor in mammals, particularly humans

• Diagnostic imaging of CB_1 receptors in subjects having a neurological, neuropsychiatric, neurodegenerative or other condition and treatment

• Pharmaceutical composition

• Diagnostic kits

Advantages: The principal radioligand under the claim is effective for imaging CB_1 receptors *in vivo* with PET.

Development Status: Primary radioligand has been evaluated in non-human primates with PET.

Market: Radioligands may be useful for performing drug occupancy studies of CB_1 receptors, and for neuropsychiatric studies and investigations with imaging techniques (*e.g.*, PET or SPECT).

Patent Status: U.S. Provisional Application No. 61/052,581 filed 12 May 2008 (HHS Reference No. E–155–2008/0–US–01).

Inventors: Victor W. Pike (NIMH), Sean R. Donohue (NIMH), *et al.*

Relevant Publications:

1. SR Donohue, C Halldin, VW Pike. Synthesis and structure-activity relationships (SARs) of 1,5-diarylpyrazole cannabinoid type-1 (CB_1) receptor ligands for potential use in molecular imaging. Bioorg Med Chem. 2006 Jun 1;14(11):3712–3720.

2. SR Donohue, VW Pike, SJ Finnema, P Truong, J Andersson, B Gulyás, C Halldin. Discovery and labeling of high affinity 3,4-diarylpyrazolines as candidate radioligands for *in vivo* imaging of cannabinoid subtype-1 (CB_1) receptors. J Med Chem., in press.

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

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

HIV Immunogen and Method of Making and Using Same

Description of Technology: The invention describes composition and methods of preventing HIV infection using a truncated version of the HIV gp41 subunit of *Env* fused to human Fc through a flexible linker as a vaccine immunogen. This immunogen binds several broadly cross-reactive HIV–1 neutralizing human monoclonal antibodies recently identified and developed by the inventor's laboratory, including m44. m44 does not react with self-antigen suggesting that this immunogen may elicit antibodies which are not regulated by tolerance mechanisms, a problem suggested as the cause of failure for some of the gp41-based immunogens previously tested. Rabbits immunized with this fusion construct developed broad-neutralizing antibodies against several HIV-isolates from different clades in a cell line/pseudovirus assay with high titer. Preclinical testing of these novel immunogens in primate models is currently being planned.

Applications: Treatment and prevention of HIV infection.

Advantages:

• Has potential to elicit broad neutralizing antibodies against several HIV isolates from different clades.

• Immunogen is based on the gp41 subunit of the HIV *Env*, a region more conserved than the gp120 subunit of *Env* and fusion to Fc increases the stability and half-life of the immunogen.

• Potentially elicits antibodies that are not regulated by tolerance mechanisms.

Development Status: Data can be provided upon request.

Market: Preventative or treatment for HIV infection.

Inventors: Dimiter S. Dimitrov and Mei-yun Zhang (NCI).

Publications:

1. M–Y Zhang, V Choudhry, IA Sidorov, V Tenev, BK Vu, A Choudhary, H Lu, GM Stiegler, HWD Katinger, S Jiang, CC Broder, DS Dimitrov. Selection of a novel gp41-specific HIV–1 neutralizing human antibody by competitive antigen panning. J Immunol Methods 2006 Dec 20;317(1–2):21–30.

2. M–Y Zhang, DS Dimitrov. Novel approaches for identification of broadly cross-reactive HIV–1 neutralizing human monoclonal antibodies and improvement of their potency. Curr Pharm Des. 2007;13(2):203–212.

3. V Choudhry, M–Y Zhang, IA Sidorov, JM Louis, I Harris, AS Dimitrov, P Bouma, F Cham, A Choudhary, SM Rybak, T Fouts, DC Montefiori, CC Broder, GV Quinnan, DS Dimitrov. Cross-reactive HIV–1 neutralizing monoclonal antibodies selected by screening of an immune human phage library against an envelope glycoprotein (gp140) isolated from a patient (R2) with broadly HIV–1 neutralizing antibodies. Virology 2007 Jun 20;363(1):79–90.

4. M–Y Zhang, BK Vu, A Choudhary, H Lu, M Humbert, H Ong, M Alam, RM Ruprecht, G Quinnan, S Jiang, DC Montefiori, JR Mascola, CC Broder, BF Haynes, DS Dimitrov. Cross-reactive human immunodeficiency virus type 1-neutralizing human monoclonal antibody that recognizes a novel conformational epitope on gp41 and lacks reactivity against self-antigens. J Virol. 2008 Jul;82(14):6869–6879.

Patent Status: U.S. Provisional Application No. 61/126,662 filed 06 May 2008 (HHS Reference No. E–072–2008/0–US–01).

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

Licensing Contact: Sally Hu, Ph.D.; 301–435–5606, *HuS@mail.nih.gov.*

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

Cross-Reactive Neutralizing Human Domain Antibody Against HIV–1

Description of Technology: The invention describes the first identified anti-HIV human domain antibody (m36), which can potentially be used alone or synergistically with other anti-HIV antibodies and antiretroviral drugs as a therapeutic and/or preventative for HIV infection. It targets an epitope whose exposure is enhanced by binding of the HIV receptor CD4 to the HIV envelope glycoprotein (Env). M36 was identified by sequential panning of a newly developed large human VH library against Envs from different HIV–1 isolates. The antibody can neutralize HIV–1 primary isolates from different clades at low (nM) concentrations and due to its small size (14 kDa) is potentially able to efficiently penetrate lymphoid tissues where the virus replicates. The antibody is fairly well characterized and the inventors are generating derivatives of this antibody to improve the half-life and increase its potency and cross-reactivity.

Applications: Treatment and prevention of HIV infections.

Advantages:

• Human monoclonal antibody, thus eliminating some of the issues associated with humanized or murine monoclonal antibodies.

• Potential neutralization of HIV–1 primary isolates from different clades at nM concentrations.

• Relatively small size allows for potential efficient penetration into lymphoid tissues.

Development Status: In vitro data is available.

Market: HIV therapeutics and preventatives.

Inventors: Dimiter Dimitrov and Weizao Chen (NCI).

Publications:

1. MY Zhang *et al.* Identification of a Novel CD4i human monoclonal antibody Fab that neutralizes HIV–1 primary isolates from different clades. Antiviral Res. 2004 Mar;61(3):161–164.

2. MY Zhang *et al.* Improved breath and potency of an HIV–1 neutralizing human single-chain antibody by random mutagenesis and sequential antigen panning. J Mol Biol. 2004 Jan 2;335(1):209–219.

3. CC Huang *et al.* Structure of a V3-containing HIV–1 gp120 core. Science 2005 Nov 11; 310(5750):1025–1028.

4. 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, in press.

5. W Chen *et al.* Human domain antibodies to conserved sterically restricted regions on gp120 as exceptionally potent cross-reactive HIV–1 neutralizers. Proc Natl Acad Sci USA., under review.

Patent Status: U.S. Patent Application No. 61/019,426 filed 07 Jan 2008 (HHS Reference No. E–043–2008/0–US–01).

Licensing Status: This invention is available for exclusive or non-exclusive licensing.

Licensing Contact: Sally Hu, Ph.D.; 301–435–5606, *HuS@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute CCR Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize domain antibodies and nanoantibodies against HIV. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Monodisperse and Modified *Yersinia pestis* Capsular F1–V Antigen Fusion Proteins for Vaccination Against Bubonic and Pneumonic Plague

Description of Technology: An effective plague vaccine against *Yersinia pestis* is currently unavailable in the U.S. The F1–V (fusion of two *Y. pestis* proteins, the Fraction 1 capsular antigen and a second immunogen called the V-antigen) vaccine of this invention is a monodispersed, mutated form of F1–V fusion protein. This is a promising candidate for commercialization.

Features and benefits include:

- The vaccine is substantially monomeric but does not tend to self-associate and form aggregates.
- The antigen fusion proteins retain immunogenicity.
- The associated, new manufacturing process provides an inexpensive means of making an effective vaccine.
- The method eliminates the need for mixing components that is the case with competitive technology.

Applications:

- An effective vaccine is needed where plague is endemic.
- An important biodefense countermeasure against dissemination of weaponized plague is sought.

Inventors: David F. Nellis and Steven L. Giardina (NIAID).

Relevant Publication: JL Goodin et al. Purification and protective efficacy of monomeric and modified *Yersinia pestis* capsular F1–V antigen fusion proteins for vaccination against plague. Protein Expr Purif. 2007 May;53(1):63–79.

Patent Status: U.S. Patent Application No. 11/944,230 filed 21 Nov 2008 (HHS Reference No. E–189–2007/0–US–01).

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

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

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov.*

Collaborative Research Opportunity: The NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this plague vaccine. Please contact Marguerite J. Miller at 301–435–8619 /or *millermarg@niaid.nih.gov* for more information.

Dated: August 18, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–19917 Filed 8–27–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2008–0087]

Data Privacy and Integrity Advisory Committee

AGENCY: Office of the Secretary, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Data Privacy and Integrity Advisory Committee will meet on September 17, 2008 in Las Vegas, NV. This meeting will be open to the public.

DATES: The Data Privacy and Integrity Advisory Committee will meet on Wednesday, September 17, 2008 from 9 a.m. to 12 p.m. and 1 p.m. to 4:20 p.m. Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held in a conference room in the Hampton Inn Tropicana and Southwest Event Center, 4975 Dean Martin Drive, Las Vegas, NV 89118. Send written materials, comments, and requests to make oral presentations to Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528. Written materials, comments, and requests to make oral presentations at the meeting should reach the contact person listed by September 8, 2008. Requests to have a copy of your material distributed to each member of the committee prior to the meeting should reach the persons listed under **FOR FURTHER INFORMATION CONTACT**, below, by September 8, 2008. Persons wishing to make comments or who are unable to attend or speak at the meeting may submit comments at any time. All submissions received must include the docket number DHS–2008–0087 and may be submitted by any one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov*. Follow instructions for submitting comments on the Web site.
- *E-mail: PrivacyCommittee@dhs.gov*. Include docket number in the subject line of the message.
- *Fax:* (866) 466–5370.
- *Mail:* Mr. Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security Data Privacy and Integrity Advisory Committee'' and the docket number: DHS–2008–0087. Comments received will also be posted without alteration at *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Committee, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Hugo Teufel III, Chief Privacy Officer, or Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland