IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: February 27, 2014.

Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2014–04811 Filed 3–4–14; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, 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. 209 and 37 CFR Part 404 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.

FOR FURTHER INFORMATION CONTACT: 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.

Software for 3D Spectral Fingerprint Based Consensus Modeling Using Orthogonal PLS and Tanimoto Similarity KNN Techniques

Description of Technology: This technology is a software tool for improving molecular modeling. The software addresses data matrices processed in rows instead of columns and the result of these approaches are combined. To process data in rows, the technique uses a measure of similarity known as “Tanimoto Similarity” operating on pairs of objects. The property values of the top most similar objects are normalized and used as coefficients to predict the property of interest. These predictions can then be used in combination with the predictions obtained by multivariate techniques to improve the quality of the consensus model in comparison to the individual predictions. Since, in the case of multivariate techniques, the information is accessed in columns, while for the similarity based technique it is accessed in rows, the two types of techniques provide complementary information. Thus, more useful information can be extracted from the same data matrix. Also contemplated is the use of consensus modeling by letting two algorithms (PLS and KNN) operate on descriptor matrices of different size. If each of these matrices is processed by a different model building algorithm and a consensus model between two or more such individual models is built, the resulting model would benefit from both: i) the partial orthogonality of the modeling techniques and ii) the complementarity of the information contained in 3D–QSAR matrices of different granularity.

Potential Commercial Applications:
• Drug Design
• Drug Development

Competitive Advantages:
• Matrix processing of molecules of biological interest
• High Fit-Activity Prediction capacity

Development Stage:
• Early-stage
• In vitro data available

Inventors: Svetoslav H. Slavov, Jon G. Wilkes, Rick Beger, Dan A. Buzatu, Bruce A. Pearce (all of FDA)

Publications:

Collaborative Research Opportunity: The Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Molecular Modeling/Drug Design. For collaboration opportunities, please contact Ashley Groves at 870–543–7956.

Multivalent, Multiple-Antigenic-Peptides for Serological Detection of HIV–1 Groups M, N, O, and HIV–2

Description of Technology: This CDC-developed invention pertains to multivalent antigenic peptides (MAPs) that can be used in a variety of HIV/AIDs diagnostics. There are two types of HIV: HIV–1 and HIV–2; HIV–1 is subdivided into groups M, N, O, and HIV–2 is subdivided into subtypes A and B. Within HIV–1 group M, several different subtypes and numerous forms of recombinant viruses exist. To detect all types, groups, and subtypes of HIV by serological methods, a mixture of antigens derived from different viral strains representing different HIV types and subtypes is needed. However, due to the competition and dilution effect, mixing multiple antigens may reduce the amount of individual antigen bound to the solid phase and lead to a reduction in assay sensitivity. It is known that MAPs, which contain multiple branches of an oligopeptide sequence, are more antigenic than the corresponding single chain linear peptides. The MAPs encompassed by this technology contain multiple branches of oligopeptides of different sequences, derived from HIV–1 group M, N, O, and HIV–2. Thus, depending on the peptide sequences incorporated, a single MAP can be used to detect HIV–1 group M alone, HIV–2 alone, or to simultaneously detect HIV–1 groups M, N, O, and HIV–2 with high sensitivity and specificity.

Potential Commercial Applications:
• Diagnostic test for HIV–1 and/or HIV–2 infection
• Blood and plasma donation screening
• HIV/AIDS surveillance and monitoring programs

Competitive Advantages:
• Lateral flow assays for HIV detection and discrimination
• On-site, point-of-care testing and diagnosis
• Easily formulated as an ELISA kit for commercial or research applications
• Technology can be used to develop a rapid, low-cost method of determining HIV status for home-use or low-resource settings

Development Stage: In vitro data available
Inventor: Chou-Pong Pau (CDC)

Publications:

**Intellectual Property:** HHS Reference No. E–064–2013/0—Research Tool. Patent protection is not being pursued for this technology.

**Related Technologies:**
- HHS Reference No. E–052–2013/0
- HHS Reference No. E–053–2013/0
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–259–2013/0
- HHS Reference No. E–294–2013/0
- HHS Reference No. E–357–2013/0
- HHS Reference No. E–358–2013/0
- HHS Reference No. E–522–2013/0
- HHS Reference No. E–535–2013/0
- HHS Reference No. E–638–2013/0

**Licensing Contact:** Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov.

**Potential Commercial Applications:**
- Targeted therapies for ABC DLBCL.
- Combination cytotoxic chemotherapies for ABC DLBCL.
- Treatment for other cancers or autoimmune/inflammatory diseases that depend upon the function of RNFL31 and RBCK1 combination.

**Competitive Advantages:**
- Novel composition of inhibitors for ABC DLBCL.
- Novel targeted drug to ABC DLBCL.
- Effective therapies targeting at NF-kB pathway.

**Development Stage:**
- Early-stage
- In vitro data available

**Inventors:** Louis M. Staudt, Yibin Yang, Federico Bernal (all of NCI)


**Licensing Contact:** Sabarni Chatterjee, Ph.D., MBA; 301–435–5587; chatterjees@mail.nih.gov.

**Collaborative Research Opportunity:** The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the inhibitors of the LUBAC ubiquitin ligase for the therapy of lymphoma and autoimmune diseases. For collaboration
opportunity, please contact John D. Hewes, Ph.D. at hewes@mail.nih.gov.

**Mutation Based Control Plasmids for Standardizing Cancer Genomic Diagnostic Assays**

**Description of Technology:** To date, there are no widely accepted standards and controls for multi-analyte based diagnostic assays. The ability to compare the accuracy of different types of assay results and to utilize in process controls is hampered by the lack of availability of such standards/controls. Variations resulting from different platforms, methodologies, and bioinformatics analyses therefore create error in the interpretation of assay results and different results may occur when testing for the presence or absence of specific gene mutations or biomarkers.

This technology includes a library of plasmids that can be used to test for and control for accuracy, sensitivity, and specificity and reproducibility within an assay and across different assays or laboratories and platforms. These standards consist of normal human reference genomic DNA that have engineered to contain known sequence variations representing somatic mutations of interest to cancer management. The plasmids contain approximately 1000 bases of human sequence. Each inserted sequence carries a specific mutation of interest within the appropriate genomic locus and a mutation adjacent alien barcode. The plasmids can be mixed with non-mutant genomes to create exact variant to normal allele frequencies for limit of detection studies. The alien barcode unequivocally indicates the detected mutation is from the plasmid spliced into a test human specimen. If needed for certain applications the barcode can be left out of design.

**Potential Commercial Applications:**
- Quantified standards for scientists to compare, optimize and/or validate assays
- Assess specificity, sensitivity, accuracy and limit detection of artifacts during assay development
- Internal in process runs controls to monitor assay performance

**Competitive Advantages:**
- Reference materials for comparing results of assays performed by different platforms, operators, times, and sites
- Ability to uniquely distinguish plasmid control mutations spiked directly into unknown samples by alien barcode
- No limit in the number and types of mutation plasmids introduced into the test human specimen, unlike engineered cell line genome based mutation controls
- Easy design and manufacture process

**Development Stage:** In vitro data available

**Inventors:** Chih-Jian Lih, Paul Williams, David Sims, Michele Mehaffey (all of NCI)

**Licensing Contact:** Sabarni Chatterjee, Ph.D., MBA; 301–435–5587; chatterjesa@mail.nih.gov

**Collaborative Research Opportunity:** The National Cancer Institute, Cancer Diagnosis Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Mutation Based Control Plasmids for Standardizing Cancer Genomic Diagnostic Assays. For collaboration opportunities, please contact John Hewes, Ph.D. at john.hewes@mail.nih.gov.

**Use of Soluble CD27 as Potential Immunotherapy and a Diagnostic and Prognostic Serum Biomarker for Solid Tumors**

**Description of Technology:** The present invention discloses methods for diagnosing a patient with a solid tumor or a predisposition to developing a solid tumor, a patient’s suitability for immunotherapy and monitor disease progression in a patient undergoing treatment for a solid tumor, such as a prostate or colorectal tumor, by measuring the amount of soluble CD27 (sCD27) present in a serum sample obtained from a patient and detecting the amount of sCD27 present in the serum sample. Additionally, sCD27 can also be developed and an immunotherapeutic product. Such product will constitute the administration of a therapeutically effective amount of sCD27 or a functional 15 fragment thereof that is capable of stimulating a patient’s immune system.

CD27 is a tumor necrosis factor receptor. A soluble form of CD27 (sCD27), is a 32-KD protein identical to the extracellular domain of membrane-bound CD27. CD27’s role in T cell activation has been previously demonstrated.

**Potential Commercial Applications:**
- Serum biomarker for diagnosis, prognosis and therapeutic response.
- Can potentially be developed into an immunotherapeutic product.

**Competitive Advantages:**
- Potentially can be used with clinically proven platforms.
- Can be developed into a minimally invasive diagnostic test using patient’s blood sample.

**Development Stage:**
- Early-stage
- In vitro data available

**Inventors:** Jeffrey Schلوم and Jianping Huang (NCI)


**License Contact:** Sabarni Chatterjee, Ph.D., MBA; 301–435–5587; chatterjesa@mail.nih.gov.

**Collaborative Research Opportunity:** The National Cancer Institute, Laboratory of Metabolism, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize a novel non-invasive assay for the detection of colorectal cancer. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

**The Use of alpha-4 beta-7 integrin Inhibitors To Inhibit HIV Transmission and Infection**

**Description of Technology:** This invention involves the use of inhibitors of alpha-4 beta-7 (α4β7) integrin to inhibit HIV transmission/ infection, as a prophylactic to inhibit onset of the acute stage of HIV infection or to treat HIV infection. The α4β7 integrin inhibitors were previously developed for use in other diseases, such as multiple sclerosis or inflammatory bowel disease.

α4β7 integrin is a multifaceted target for HIV infection and recent studies indicate that it is important for establishing HIV infection through multiple pathways. Studies indicate that:
1. CD4 T-cells present in vaginal and anal mucosa have high levels of α4β7 integrin, making CD4 T-cells permissive to HIV infection;
2. α4β7 integrin is important for cell to cell transmission of HIV;
3. α4β7 integrin is used to dysregulate the host humoral response to HIV; and
4. HIV acts on α4β7 integrin through an epitope in V2 loop of GP120, identified as important for HIV vaccine protection. Additionally, primate studies indicate that α4β7 integrin inhibition of HIV infection preserves gut-associated lymphoid tissue (GALT) generally destroyed during the acute phase of HIV infection.

**Potential Commercial Applications:**
- Prevention and treatment of HIV infection
- Competitive Advantages:
  - α4β7 integrin is a multifaceted target for HIV infection
  - Previously developed α4β7 integrin inhibitors can be used for a new purpose

**Development Stage:**
- Pre-clinical
- In vitro data available
- In vivo data available

**Inventors:** James Arthos, Claudia Cicala, Anthony S. Fauci, Diana Goode (all of NIAID)

**Publications:**

**Intellectual Property:**
Beta-Amyloid and Tau Fibril Positron Emissions Tomography (PET) Imaging Agents


• US Patent Application 12/293,940 filed September 17, 2008 (allowed)

• European Patent Application 07797254.5 filed April 19, 2007 (pending)

Related Technologies:

• HHS Reference No. E–136–2006/0—“Beta Amyloid PET Imaging Agents Based On 2-(4-phenyl)benzo[d]thiazole Derivatives”

• HHS Reference Nos. E–225–2011/0 and/ or 1—“Beta-amyloid PET Imaging Agents Based On Benzothiazoles (BTA) Derivatives”

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

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize alpha-4 beta-7 integrin inhibitors. For collaboration opportunities, please contact Bill Ronningen, JSEP/MP, MS at 301–451–3522 or wr78k@nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

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 meetings. The meetings 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; Neural/ Vestibular Prosthesis Review

Date: March 21, 2014.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health Rockville, MD 20850, 301–402–3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; VSL Translational Applications Review

Date: March 27, 2014.

Time: 3:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6001 Executive Blvd.—Room 8343, Bethesda, MD 20892, (301) 496–8683, livingsc@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: February 27, 2014.

Melanie J. Gray, Contact Person:

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–04771 Filed 3–4–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

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 meetings. The meetings 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 General Medical Sciences Special Emphasis Panel; Review of K99 Grant Applications

Date: March 25, 2014.

Time: 8:00 a.m. to 5:00 p.m.