Dated: September 28, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–24983 Filed 10–1–15; 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; Peer review of Support of Competitive Research (SCORE) Applications.

Date: October 27, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, 3An.18, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12M, Bethesda, MD 20892, 301–594–2704, *Shinako.takada@nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of INBRE Research Grant Applications.

Date: October 27, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, 3An.12A, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12E, Bethesda, MD 20892, 301–435–0807, *slicelw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: September 28, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–24984 Filed 10–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive License: Differential Expression of Molecules Associated With Acute Stroke

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive license to VuEssence, which is located in Florida, to practice the inventions embodied in the following patents:

1. AU Patent 2005248410, issued August 5, 2010 (E–306–2003/0–AU–03)
2. US Patent 7,749,700, issued July 6, 2010 (E–306–2003/1–US–01)

The patent rights in these inventions have been assigned to the United States of America. The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to in vitro class III diagnostic device for the detection and assessment of ischemic stroke in humans.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 19, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive evaluation option license should be directed to: Susan Ano, Ph.D., NINDS Technology Transfer and Development Branch, 31 Center Drive, Suite 8A52, MS2540, Bethesda, MD 20892; Telephone: (301) 435–5515; Email: *anos@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The present technology claims methods of determining whether a subject had an ischemic stroke by detecting expression of twenty biomarkers in the blood, comparing expression levels to an individual who has not had a stroke, and determining whether there was at least a four-fold increase in the biomarker expression levels. Each of the biomarkers is detectable by a specified set of sequences.

The patent also claims a method of administering an appropriate treatment regimen for a subject who had an ischemic stroke.

The prospective start-up exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 28, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–24988 Filed 10–1–15; 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, 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Novel Radio-Labeled Agents for Imaging Alzheimer's Disease-Associated Amyloid

Description of Technology: This technology introduces novel radio-labeled agents for imaging amyloid deposits in the brains of Alzheimer's disease patients. These are small molecule, radio-ligand compounds that are analogs of benzo[d]thiazole. They are highly specific to amyloid, have low background noise, do not undergo rapid defluoridation and do not produce residual radioactivity in the brain. In addition, the compounds are stable and may be readily synthesized from commercially available starting materials. These compounds may be used in many noninvasive imaging techniques including: Magnetic resonance spectroscopy (MRS) or imaging (MRI) or positron emission tomography (PET) or single-photon emission computed tomography (SPECT) to measure amyloid. Non-invasive detection of Alzheimer's disease-associated amyloid plaques in the brain would be valuable for early diagnosis, monitoring, and for clinical development of therapeutic drugs.

Potential Commercial Applications: Imaging agents for use in magnetic resonance spectroscopy (MRS), or imaging (MRI), positron emission tomography (PET) or single -photon emission computed tomography (SPECT).

Competitive Advantages: Highly specificity to amyloid, low background, do not undergo rapid defluoridation and do not produce residual radioactivity in the brain.

Development Stage: Early-stage.

Inventors: Lisheng Cai and Victor W. Pike (NIMH).

Publications:

1. Cai L, et al. Synthesis and structure-affinity relationships of new 4-(6-iodo-H-imidazo[1,2-a]pyridin-2-yl)-N-dimethylbenzeneamine derivatives as ligands for human beta-amyloid plaques. J Med Chem. 2007 Sep 20;50(19):4746–58. [PMID 17722900]

2. Cai L, et al. Synthesis and evaluation of N-methyl and S-methyl 11C-labeled 6-methylthio-2-(4′-N,N-dimethylamino)phenylimidazo[1,2-a]pyridines as radioligands for imaging beta-amyloid plaques in Alzheimer's disease. J Med Chem. 2008 Jan 10;51(1):148–58. [PMID 18078311]

Intellectual Property:

- HHS Reference No. E–225–2011/0—US Provisional Application No. 61/535,569 filed 16 Sep 2011
- HHS Reference No. E–225–2011/1—PCT Application No. PCT/US2012/055124 filed 13 Sep 2012, which published as WO 2013/0401830 on 21 Mar 2013; US Patent Application No. 14/345,004 filed 23 Apr 2014

Related Technology: HHS Reference No. E–156–2006/0—US Patent No. 8,703,096 issued 22 Apr 2014; US Patent Application No. 14/223,782 filed 24 Mar 2014; Various international patents/applications issued/pending.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Mental Health (NIMH) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Beta-amyloid Imaging Agents. For collaboration opportunities, please contact Suzanne L. Winfield, Ph.D. at *winfiels@intra.nimh.nih.gov* or 301–402–4324.

Human Research Information System (HuRIS)

Summary: Researchers at the National Institute on Drug Abuse (NIDA) seek licensing or co-development of a Human Research Information System (HuRIS) software that automates all major functions of a clinical-research entity. The system is designed for commercial healthcare providers, community treatment centers, and clinical research facilities.

Description of Technology: The available system is the Human Research Information System (HuRIS), an integrated advanced clinical/research informatics series of systems—that is, an intelligent electronic environment for the collection, organization and retrieval of information in clinical/scientific decision support—which enables data and resource sharing in real time among authorized users at our clinics. (Individual systems or subsystems may be licensable.) Users on both the clinical side (*e.g.* doctors writing medication orders or nurses recording participants' vital signs) and on the research side (*e.g.* researchers conducting data analysis or completing reporting requirements) have access to the information on demand. At the core of this informatics infrastructure reside the clinical charts and research records of participants compiled over the entire history of their study participation, and sometimes across multiple studies. The computerized recording of participants' information starts from the time of their initial consent for screening. Data collected by our intake personnel under a screening protocol become part of the participants' clinical research records. This recording continues as participants are admitted to a clinical trial and persists throughout their progress within the prescribed activities until they are discharged. The electronic recording of participants' activities enables the use of this information as a research resource to different groups at different locations, in current and future protocols, as permitted by human subjects' protection regulations. The HuRIS has a number of intelligent decision systems built-in for real-time or on-demand query as well as HL–7 communications with external laboratories for data exchange, and it seamlessly communicates with our Human Biospecimen Tracking System. User permissions to access various components of the system are centrally controlled and all access is logged.

Potential Commercial Applications:

- Hospital Information Management
- Clinical Research Information Management
- Pharmacy Management System
- Biospecimens Tracking System
- Laboratory Information Management
- Behavioral Modification/Addiction Treatment

Competitive Advantages:

- Mature solution developed with contributions by numerous physicians, scientists, and treatment professionals at all levels
- Low-cost mechanism
- Proven advantage in prior clinical studies

Development Stage:

- Ready for commercialization
- Prototype
- Clinical

Inventors: Massoud R. Vahabzadeh, Mustapha Mezghanni, Jia-Ling Lin, Michelle K. Leff (all of NIDA)

Publications:

1. Massoud Vahabzadeh, Jia-Ling Lin, Mustapha Mezghanni, Carlo Contoreggi, and Michelle Leff, ''An EHR-Based Multi-Site Recruiting System for Clinical Trials,'' Proc. 20th IEEE International Symposium on Computer-Based Medical Systems, June 2007, pages 331–6.

2. Massoud Vahabzadeh, Jia-Ling Lin, Mustapha Mezghanni, David Epstein, and Kenzie Preston, ''Automation in an Addiction Treatment Research Clinic:

Computerized Contingency Management, Ecological Momentary Assessment, and a Protocol Workflow System,'' Drug and Alcohol Review, 28(1):3–11, January 2009.

Intellectual Property: HHS Reference No. E–266–2014/0—Software. No patent protection is being sought.

Contact Information: Vio Conley, M.S.; NCI Technology Transfer Center; Phone: 240–276–5531; Email: *conleyv@mail.nih.gov.*

Keywords: Software, Clinical Information System, Research Information System, Medical Decision Support System (DSS), Electronic Hospital Records (EHR), Physicians Order Entry (POE), Pharmacy Information System, Laboratory Information Management (LIM), Biospecimen Tracking System, Substance abuse, Drug addiction, Mental health, mPAL, HuRIS.

Optimized Gene Therapy Vector for the Treatment of Glycogen Storage Disease Type Ia

Description of Technology: NIH researchers have developed an adeno-associated viral (AAV) vector for the treatment of glycogen storage disease type Ia (GSD-Ia). GSD-Ia is an inherited disorder of metabolism associated with life-threatening hypoglycemia, hepatic malignancy, and renal failure caused by the deficiency of glucose-6-phosphatase-alpha (G6Pase-alpha or G6PC). This new AAV vector that expresses human G6Pase-alpha directed by the tissue-specific human G6PC promoter/enhancer incorporates two improvements: (1) It expresses a variant of G6Pase-alpha with enhanced enzymatic activity; (2) it is codon optimized to achieve higher enzyme expression levels and enhanced enzymatic activity.

Current therapy, which primarily consists of dietary modification, fails to prevent long-term complications in many patients, including growth failure, gout, pulmonary hypertension, renal dysfunction, osteoporosis, and hepatocellular adenomas (HCA). Gene therapy-based techniques, which directly address the underlying genetic deficiency driving the disorder, offer the prospect of long-term remission in patients with GSD-Ia.

Potential Commercial Applications: Gene therapy vector for the treatment of GSD-Ia.

Competitive Advantages:

- Protein coding sequence modified for enhanced enzymatic activity.
- Codon optimized for increased enzyme expression in target organs.

Inventor: Janice J. Chou (NICHD)

Development Stage: In vivo data available (animal).

Publications:

1. Lee YM et al. Prevention of hepatocellular adenoma and correction of metabolic abnormalities in murine glycogen storage disease type Ia by gene therapy. Hepatology 2012 Nov;56(5):1719–29. [PMID 22422504].

2. Lee YM, et al. The upstream enhancer elements of the G6PC promoter are critical for optimal G6PC expression in murine glycogen storage disease type Ia. Mol Genet Metab. 2013 Nov;110(3):275–80. [PMID 23856420].

Intellectual Property: HHS Reference No. E–039–2015/0–US–01—US Provisional Patent Application 62/096,400 filed December 23, 2014.

Related Technologies: HHS Reference No. E–552–2013/0—US Provisional Patent Application No. 61/908,861 filed November 26, 2013; PCT Application No. PCT/US2014/067415 filed November 25, 2014.

Licensing Contact: Surekha Vathyam, Ph.D.; 301–435–4076; *vathyams@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Child Health and Human Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize gene therapy vectors for the treatment of glycogen storage disease type Ia. For collaboration opportunities, please contact Joseph M. Conrad, III, Ph.D., J.D. at *jmconrad@mail.nih.gov.*

Dated: September 25, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–24987 Filed 10–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Miniature Serial Sectioning Microtome for Block-Face Imaging

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to Carl Zeiss Microscopy GmbH, which is located in Germany, to practice the inventions embodied in the following patent applications:

1. US Provisional Application 61/991,929, filed May 12, 2014 (E–121–2014/0–US–01)
2. PCT Application PCT/US2015/030359, filed May 12, 2015 (E–121–2014/0–PCT–02)

The patent rights in these inventions have been assigned to the United States of America.

The prospective start-up exclusive license territory may be worldwide and the field of use may be limited to microtomes for scanning electron microscopes (SEMs) or light microscopes for life science applications.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before November 2, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Susan Ano, Ph.D., NINDS Technology Transfer and Development Branch, 31 Center Drive, Suite 8A52, MS2540, Bethesda, MD 20892; Telephone: (301) 435–5515; Email: *anos@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: A microtome device is used in a variety of microcopy techniques to remove very thin (*e.g.,* in the tens of nanometers range) portions from the top of a sample between successive images. This technology discloses a design for a microtome device that offers several unique features and advantages over commercially available microtomes. A prototype of the microtome has been built and demonstrated to work with a serial block-face scanning electron microscopy in order to serially collect ultrathin sections from plastic embedded biological tissues. This microtome design allows for a sample to be cut at a location removed from the electron beam axis, reducing interference from debris and allowing imaging at a greater range of working distances. This microtome device is lightweight and easy to install utilizing the built-in stage of existing microscopes such that a sample's position and orientation can be controlled along three-axes of rectilinear translation and two axes of rotation. This microtome design utilizes a diamond blade coupled to both the base plate and an actuator to control the movement of the blade in a direction perpendicular to the exposed surface of the pedestal, while producing an output