

funded by HHS by conducting criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and employees. The office serves as OIG's liaison to DOJ on all matters relating to investigations of HHS programs and personnel and reports to the Attorney General when there are reasonable grounds to believe Federal criminal law has been violated. OI serves as a liaison to CMS, State licensing boards, and other outside organizations and entities with regard to exclusion, compliance, and enforcement activities.

Section QJ.10, Office of Investigations—Organization

OI is directed by the Deputy Inspector General for Investigations, aided by Assistant Inspectors General, and performs the functions designated in the law (section 3(d)(1)(B) of the Inspector General Act) for the position of Assistant Inspector General for Investigations. The office is comprised of headquarters and regional functions.

Section QJ.20, Office of Investigations—Functions

OI conducts criminal, civil, and administrative investigations of allegations of fraud, waste, abuse, mismanagement, and violations of standards of conduct within the jurisdiction of OIG. OI establishes investigative priorities, evaluates the progress of investigations, and reports findings to the Inspector General. The office develops and implements investigative techniques, programs, guidelines, and policies; manages OI's quality assurance/peer-review program, and conducts peer reviews of other OIGs. OI also carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively and are functioning as intended. The office effectuates mandatory and permissive exclusions from participation in Federal health care programs under the Social Security Act; decides on all requests for reinstatement from, or waiver of, exclusions; and participates in developing standards governing the imposition of these exclusion authorities. The office also oversees OIG's suspension and debarment referral program. OI implements policies and procedures and plans, develops, implements, and evaluates all levels of training for OI employees. The staff provides for the personal protection of the Secretary and other Department officials, as needed, and all emergency operations

preparedness and response. OI coordinates the adoption of advanced digital forensic acquisition and examination and information security technologies to assist in the investigation, prevention, and detection of fraud and abuse; maintains an automated data and management information system used by all OI employees; provides technical expertise on computer applications for investigations; and coordinates and approves investigative computer matches with other agencies. In addition, the office operates a toll-free hotline to permit individuals to report suspected fraud, waste, and abuse within HHS programs.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2018–23935 Filed 11–5–18; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; PAR 17–158: Secondary Data Analyses For NIMH Research Domain Criteria (R03).

Date: November 28, 2018.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, cinquej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member conflict: AIDS and Related Research.

Date: November 29, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Shalanda A Bynum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, bynumsa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bone and Cartilage.

Date: November 29, 2018.

Time: 12:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, ingrahamrh@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Role of Blood Brain Barrier in Pain and Brain Tumors, Peripheral Nerve and Brain Injury.

Date: November 30, 2018.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, bhagavas@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 31, 2018.

David D. Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–24224 Filed 11–5–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Therapeutics for Insulin Resistance and Non-Alcoholic Fatty Liver Disease/Non-Alcoholic Steatohepatitis (NASH/NAFLD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to Ovensa, Inc. headquartered in Ontario, Canada, to practice the inventions embodied in the patent application(s) listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development November 21, 2018 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Ovensa: HHS Ref. No. E-103-2013-0, U.S. Provisional Patent Application 61/839,239, "Glucan-Encapsulated siRNA For Treating Type 2 Diabetes Mellitus," filed June 25, 2013, International Patent Application PCT/2014/043924 filed June 24, 2014, European Patent Application 14818342.9 filed June 24, 2018, and US Patent 10,077,446 filed June 24, 2014 and issued September 18, 2018. The patent rights in this invention have been assigned to the Government of the United States of America. The prospective license would be granted worldwide and in a field of use not broader than therapeutics for preventing or treating insulin resistance and non-alcoholic fatty liver disease/non-alcoholic steatohepatitis. The scope of any proposed licensed may also be limited to products sold that include therapeutic siRNAs encapsulated in nanoparticles made from either glucan based biopolymers and/or Ovensa's TRIOZAN™ (N,N,N-Trimethyl Chitosan) proprietary biopolymer.

The invention pertains to the use of glucan encapsulated non-immunostimulatory small interfering RNAs (siRNAs) to treat type-2 diabetes. Endocannabinoids (EC) are lipid signaling molecules that act on the same cannabinoid receptors that recognize and mediate the effects of endo- and phytocannabinoids. EC receptor CB1R activation is implicated in the

development of obesity and its metabolic consequences, including insulin resistance and type 2 diabetes. Beta-cell loss has been demonstrated in a Zucker diabetic fatty (ZDF) rat model of type-2 diabetes through CB1R-mediated activation of a macrophage-mediated inflammatory response. Conversely, rats treated with a peripheral CB1R antagonist restores normoglycemia and preserves beta-cell function. Similar results are seen following selective in vivo knockdown of macrophage CB1R by daily treatment of ZDF rats with the instant D-glucan-encapsulated CB1R small interfering RNA (siRNA). Knock-down of CB1R using glucan encapsulated siRNA represent new methods of treating type-2 diabetes or preventing the progression of insulin resistance to overt diabetes.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI 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 prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent 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: October 24, 2018.

Michael A. Shmilovich,

*Senior Licensing and Patenting Manager,
National Heart, Lung, and Blood Institute,
Office of Technology Transfer and
Development.*

[FR Doc. 2018-24225 Filed 11-5-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Heart, Lung, and Blood Institute Special Emphasis Panel Review of NHLBI Cardiac Surgery Network Coordinating Center.

Date: November 26, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924, 301-435-0303, ssehnert@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel NHLBI SBIR Phase IIB Bridge Awards.

Date: November 27, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza, Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-827-7938, johnsonwj@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel NHLBI SBIR Phase IIB Small Market Awards.

Date: November 27, 2018.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza, Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-827-7938, johnsonwj@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 31, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-24222 Filed 11-5-18; 8:45 am]

BILLING CODE 4140-01-P