

### Blood-Based Assay for the Diagnosis and Monitoring of Hyposialylation Disorders

*Description of Technology:* Sialic acid, a monosaccharide widely distributed in glycoproteins and glycolipids, plays an important role in biological processes such as cellular adhesion, cellular communication and signal transduction. Reduced levels of sialic acid in tissues (also known as hyposialylation) affect the function of muscle, kidney, and other organ systems, and are found in a number of disorders, such as hereditary inclusion body myopathy (HIBM, also known as GNE myopathy), renal hyposialylation disorders, and congenital disorders of glycosylation.

The inventors have developed a sensitive, reliable assay for the diagnosis of hyposialylation disorders that detects a novel glycoprotein biomarker in a patient blood sample. This assay has been validated using samples from patients with GNE myopathy and other hyposialylation disorders. A distinct advantage of this assay is that it is minimally invasive, unlike many currently-available methods for diagnosing hyposialylation disorders, which typically require a tissue biopsy. In particular, this biomarker represents the first non-invasive method for diagnosis of renal hyposialylation.

#### *Potential Commercial Applications:*

- Diagnostic assay to detect hyposialylation
- Monitoring tool to track patient response to sialylation-increasing therapy

*Competitive Advantages:* A blood-based assay based on this technology would be less invasive, time-consuming, and costly than a tissue biopsy, which is the current diagnostic standard for hyposialylation disorders, particularly kidney disorders.

#### *Development Stage:*

- Early-stage
- In vitro data available

*Inventors:* Marjan Huizing (NHGRI), William Gahl (NHGRI), Nuria Carrillo-Carrasco (NCATS)

*Intellectual Property:* HHS Reference No. E-056-2013/0—U.S. Application No. 61/785,094 filed 14 Mar 2013

#### *Related Technologies:*

- HHS Reference No. E-217-2007/0—N-Acetyl Mannosamine as a Therapeutic Agent
- HHS Reference No. E-270-2011/0—Encapsulated N-Acetylmannosamine or N-Acetylneuraminic Acid to Increase Sialylation

*Licensing Contact:* Tara Kirby, Ph.D.; 301-435-4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

### Vaccine Adjuvant for Inducing Th17 Focused Response

*Description of Technology:* Adjuvant selection can be critical to a vaccine's effectiveness. Ideally, an adjuvant will target and activate specific immune pathways to increase the magnitude of a response to the vaccine. A limited range of adjuvants are presently available for human clinical use; these primarily affect T helper cells 1 and 2 (Th1 and Th2). Currently, no adjuvants are approved for human use which primarily affect IL-17-producing T helper cells (Th17) cells. Th17 focused adjuvants may prove critical for developing operative vaccines against pathogens where Th17 activity is essential for protection. This technology relates to novel adjuvants activating either caspase-associated recruitment domain protein 9 (CARD9) or caspase 1 pathways, or a combination of the two; and methods for using these adjuvants for stimulating an immune response. These adjuvants induce Th17 focused stimulation, which may prove essential to development of effective vaccines against a range of pathogens including bacteria and fungi.

*Potential Commercial Applications:* Vaccine

*Competitive Advantages:* Th17 skewing adjuvant

*Development Stage:* Early-stage

*Inventors:* Alan Sher (NIAID), Kevin Shenderov (NIAID), Vincenzo Cerundolo (University of Oxford, U.K.), Gerudyal Besra (University of Birmingham, U.K.)

*Publication:* Shenderov K, et al. Cord factor and peptidoglycan recapitulate the Th17-promoting adjuvant activity of mycobacteria through mincle/CARD9 signaling and the inflammasome. *J Immunol.* 2013 Jun 1;190(11):5722-30. [PMID 23630357]

*Intellectual Property:* HHS Reference No. E-089-2012/0—U.S. Provisional Patent Application No. 61/709,713 filed October 4, 2012

*Licensing Contact:* Edward (Tedd) Fenn, J.D.; 424-500-2005; [Tedd.fenn@nih.gov](mailto:Tedd.fenn@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 this technology. For collaboration opportunities, please contact Richard Kitei at 301-496-2644.

Dated: August 22, 2013.

**Richard U. Rodriguez,**

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

[FR Doc. 2013-20888 Filed 8-26-13; 8:45 am]

**BILLING CODE 4140-01-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 (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:* Center for Scientific Review Special Emphasis Panel; AREA: Oncological Sciences Grant Application.

*Date:* September 20, 2013.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301-435-0198, [shawdeni@csr.nih.gov](mailto:shawdeni@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 13-008: Shared Instrumentation: Confocal Microscopy and Imaging.

*Date:* September 26, 2013.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-435-1236, [smirnov@csr.nih.gov](mailto:smirnov@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: August 21, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-20884 Filed 8-26-13; 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 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; Wireless Physiologic Telemetry for Interventional MRI.

*Date:* September 16, 2013.

*Time:* 10:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate contract proposals.

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

*Contact Person:* Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, [sunnarborgsw@nhlbi.nih.gov](mailto:sunnarborgsw@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: August 21, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; 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 a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Institute of Mental Health.

*Date:* September 30–October 2, 2013.

*Time:* 4:00 p.m. to 1:30 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Rebecca C Steiner, Ph.D., Executive Secretary, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892-9606, 301-443-4525, [steinerr@mail.nih.gov](mailto:steinerr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 21, 2013.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-20881 Filed 8-26-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Research.

*Date:* September 16, 2013.

*Time:* 11:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Applications.

*Date:* October 10, 2013.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, [pateldg@niddk.nih.gov](mailto:pateldg@niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Artificial Pancreas.

*Date:* October 11, 2013.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, [pateldg@niddk.nih.gov](mailto:pateldg@niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-12-265: NIDDK Ancillary Studies in Liver Diseases-NAFLD.

*Date:* October 21, 2013.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy