**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

National Institutes of Health

**National Human Genome Research Institute; 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 Human Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First Sequencing Center.

**Date:** June 14, 2016.

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

**Agenda:** To review and evaluate grant applications.

**Place:** NHGRI, 5635FL, Tabinbrook 4th Floor Conf. Rm., Twinbrook, Rockville, MD 20852 (Telephone Conference Call).

**Contact Person:** Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, pozzatt@mail.nih.gov.

**Name of Committee:** National Human Genome Research Institute Special Emphasis Panel; ENCODE MAPPING.

**Date:** June 8, 2016.

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

**Agenda:** To review and evaluate grant applications.

**Place:** Washington Dulles Airport Marriott, 45020, Dulles View, Aviation Drive, Dulles, VA 20166.

**Contact Person:** Ken D. Nakamura, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, 301–402–0838, nakamura@mail.nih.gov.

**Name of Committee:** National Human Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First Sequencing Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First Sequencing

**Date:** May 17, 2016.

**Sylvia L. Neal,**

Program Analyst, Office of Federal Advisory Committee Policy.

**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

National Institutes of Health

**Prospective Grant of Exclusive Patent License: Development of Adeno-Associated Virus Vectors for the Treatment of Glycogen Storage Disease Type Ia**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services (HHS), is contemplating the granting of an exclusive license to practice the inventions embodied in the following Patent Applications to Dimension Therapeutics, Inc. (“Dimension”) located in Cambridge, Massachusetts, USA:

**Intellectual Property**


With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide and the field of use may be limited to: “Development and commercialization of gene therapy using adeno-associated viral vectors for the treatment of Glycogen Storage Disease Type Ia.”

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 8, 2016 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: Surekha Vathyah, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E–530, MSC9702, Rockville, MD 20850–9702, Email: vathyahs@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:** The subject technologies disclose novel adeno-associated virus (AAV) vectors expressing human glucose-6-phosphatase-alpha (G6Pase-alpha or G6PC) for the treatment of glycogen storage disease, particularly 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 G6Pase-alpha, a key enzyme in maintaining blood glucose homeostasis between meals. The two novel gene therapy vectors of the invention, rAAV-GPE-G6PC and rAAV-GPE-co-G6PC are recombinant AAV vectors expressing

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**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

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* The same individuals complete both of the forms for a total of 300 respondents and responses.
wild-type G6Pase-alpha and codon-optimized (co) G6Pase-alpha, respectively. G6Pase-alpha in both vectors is directed by nucleotides -2864 to -1 of the G6Pc gene 5' flanking promoter/enhancer region (GPE). The vectors also contain an intron and stuffer sequences. The rAAV-GPE-G6PC vector not only corrects metabolic abnormalities in murine GSD-Ia (G6pc/- mice) but also prevents long-term risk of hepatocellular adenoma. The results also showed that the enhancer elements upstream the human G6PC minimal promoter at nucleotides -382 to -1 contained within the rAAV-GPE-G6PC vector are responsible for the increased efficacy in treating GSD-Ia mice.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective 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 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. 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: May 17, 2016.

Richard U. Rodriguez,  
Associate Director, NCI, National Institutes of Health.

[FR Doc. 2016–12169 Filed 5–23–16; 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: Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiac Contractility, Hypertrophy, and Failure Study Section.

Date: June 13–14, 2016.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel O’Hare—Rosemont, 5500 North River Road, Rosemont, IL 60018.

Contact Person: Olga A. Tjurmina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4030B, MSC 7814, Bethesda, MD 20892, (301) 451–1375, ot3d@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences Overview.

Date: June 14–15, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Martha L. Hare, Ph.D., RN, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8594, harem@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Auditory Neuroscience.

Date: June 14–15, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, bishop@csr.nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Clinical and Integrative Cardiovascular Sciences Study Section.

Date: June 16–17, 2016.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW, Washington, DC 20036.

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435–1195, chengy@csr.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Genetics Study Section.

Date: June 22–23, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, bloomm2@mail.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Acute Neural Injury and Epilepsy Study Section.

Date: June 22–23, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7846, Bethesda, MD 20892, (301) 237–9838, bhagavas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR14–022: Juvenile Protective Factors and Aging.

Date: June 22, 2016.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Wallace Ip, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1195, ipws@mail.nih.gov.


Dated: May 17, 2016.

Sylvia L. Neal,  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12137 Filed 5–23–16; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of Adeno-Associated Virus Vectors for the Treatment of Glycogen Storage Disease Type Ia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.