DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Delivery of a Corrective Glucose-6-Phosphatase-Alpha Gene to Treat Glycogen Storage Disease Type 1a (GSD-1a) in Humans

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to Panacea Opportunity, Ltd.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Child Health and Human Development c/o National Cancer Institute’s Technology Transfer Center on or before July 9, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs, Ph.D., Senior Technology Transfer Manager at Telephone: (240)–276–5530 or Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

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 license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: "Delivery of a corrective glucose-6-phosphatase-alpha gene to treat glycogen storage disease type 1a (GSD-1a) in humans.”

This technology discloses a gene therapy to treat glycogen storage disease type 1a (GSD-1a) in humans using adeno-associated virus mediated delivery of a corrective glucose-6-phosphatase-alpha (G6Pase-α) gene nucleic acid sequence that codes for a protein having an amino acid sequence that differs from the wildtype human amino acid sequence at amino acid position 293.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Child Health and Human Development 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. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Name of Committee: National Institutes of Health

National Institute of General Medical Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory General Medical Sciences Council, September 01, 2021, 09:30 a.m. to September 02, 2021, 05:00 p.m., National Institutes of Health, Natcher Building, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the Federal Register on December 31, 2020, FR Doc 2020–28902, 85 FR 86940.

The meeting notice is amended to change the meeting date and time from September 1–2, 2021, 9:30 a.m. to 5:00 p.m. to September 9, 2021, 9:00 a.m. to 4:30 p.m. The meeting is partially closed to the public.

Dated: June 14, 2021.

David W. Freeman,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–13377 Filed 6–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Special Emphasis Panel; Newborn Screening Pilot Studies.

Date: August 6, 2021.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131D, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131D, Bethesda, MD 20817, (301) 455–6680, skandasas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: June 14, 2021.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–13348 Filed 6–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 Child Health and Human Development Special Emphasis Panel; Newborn Screening Pilot Studies.

Date: August 6, 2021.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, (301) 827–8231, luис_dettin@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: June 14, 2021.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–13339 Filed 6–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Intramural Research Administration, National Institutes of Health, Gateway Building, 7201 Wisconsin Ave., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–827–2061, ivan.navarro@nih.gov.


David W. Freeman,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–13339 Filed 6–23–21; 8:45 am]