

**DATES:** Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before January 18, 2017 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: Eggerton Campbell Ph.D., Licensing and Patenting Manager, Technology Transfer Office (TTO) National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 3058, MSC 9307, Bethesda, MD 20892-9307. Telephone: 301-402-1648. Fax: 301-402-9722. email: [eggerton.campbell@nih.gov](mailto:eggerton.campbell@nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Intellectual Property

1. US Provisional Patent Application No.: 61/792,081  
HHS Ref. No.: E-243-2012/0-US-01
2. PCT Patent Application No.: PCT/2014/028045  
HHS Ref. No.: E-243-2012/0-PCT-02
3. EP Patent Application 14729502.6  
HHS Ref. No.: E-243-2012/0-EP-03
4. US Patent Application No.: 14/773,885  
HHS Ref. No.: E-243-2012/0-US-04
5. US Patent Application No.: 15/070,787  
HHS Ref. No.: E-243-2012/1-US-01

and all continuing applications and foreign counterparts. 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 worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following:

Development, manufacture and commercialization of gene therapy products for human gene therapy use to treat and/or prevent Methylmalonic Acidemia (MMA) comprised of the following: all of or fragments of the synthetic methylmalonyl-CoA mutase (MUT) human polynucleotide (synMUT) and/or recombinant synMUT constructs, in combination with the following:

the Anc80 vector or vectors derived from the Anc80 vectors, wherein the derived Anc80 vectors have capsid sequences possessing 90% or greater sequence identity to the Anc80 capsid sequences.

For purposes of clarity, the above gene therapy products may be combined with Selecta's synthetic vaccine particles (SVP™) technology encapsulating an immunomodulator.

The subject technology discloses a synthetic codon-optimized human

methylmalonyl-CoA mutase (MUT) cDNA gene (co-MUT) encoding human MUT protein, co-MUT constructs and uses thereof for treatment of MMA disorders. Such uses, may include the administration of immunomodulator(s) in order to maximize the advantage of the gene therapy, with fewer side effects. MMA is an autosomal recessive disorder caused by defects in the mitochondria-localized enzyme methylmalonyl-CoA mutase (MUT). MUT deficiency, the most common cause of MMA, is characterized by the accumulation of methylmalonic acid. MMA can lead to metabolic instability, seizures, strokes, and kidney failure, and can be lethal even when patients are being properly managed. If successfully developed, this invention would be a first of its kind therapy for MMA, by administering the disclosed nucleic acid, vector, or recombinant virus to a subject, optionally with an immunomodulator.

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 National Human Genome Research Institute 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: December 27, 2016.

**Claire T. Driscoll,**

*Director, NHGRI Technology Transfer Office.*

[FR Doc. 2016-31834 Filed 12-30-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, February 16, 2017, 08:00 a.m. to February 17, 2017, 05:00 p.m., Bethesda North Marriott Conference Hotel, 5701

Marinelli Road, Bethesda, MD 20852 which was published in the **Federal Register** on December 13, 2016, 81 FR 89953.

The meeting notice is amended to change the date of the meeting to February 16, 2017 from 8:00 a.m. to 5:00 p.m. The meeting is closed to the public.

Dated: December 27, 2016.

**David Clary,**

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

[FR Doc. 2016-31759 Filed 12-30-16; 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 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, Grant Review Neonatal Anemia.

*Date:* January 25, 2017.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301-435-0297, [nagelinmh2@nhlbi.nih.gov](mailto:nagelinmh2@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: December 27, 2016.

**Michelle Trout,**

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

[FR Doc. 2016-31760 Filed 12-30-16; 8:45 am]

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