OMB No. 0990–NEW—Office of Population Affairs—OASH–OS

Abstract

The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS) is requesting 3 years of approval by OMB on a new collection. The Components Study of REAL Essential Curriculum will identify the components that matter the most for promoting positive health behaviors and outcomes among adolescents. The study will examine program components (for example, content and dosage), implementation components (for example, attendance and engagement), and contextual components (for example, participant characteristics) to determine which components influence participant outcomes the most. In addition, the study will measure youth engagement in programming from various perspectives and examine the role of engagement as a mediating factor to achieving youth outcomes. Sites participating in the study will use the REAL Essentials Advance (REA) relationship curriculum, a popular program among federal pregnancy prevention grantees. The study will enroll schools from spring to fall 2022 (and possibly spring 2023, if necessary). The study will collect youth outcomes surveys at baseline, at program exit and 6 months following the completion of the program. The study will also collect extensive implementation data, which includes youth engagement exit ticket surveys after REA sessions, focus groups with youth and program facilitator logs and attendance records. Study staff will also interview facilitators and site leadership.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Youth Outcome Survey Baseline	Youth	507	1	40/60	338
Youth Outcome Survey—Program Exit.	Youth	507	1	40/60	338
Youth Outcome Survey—Six Month Follow-up.	Youth	480	1	40/60	320
Youth Focus Group Topic Guide	Youth	133	1	90/60	200
Youth Engagement Exit ticket	Youth	533	12	2/60	213
Fidelity Log	Program Facilitators	13	24	10/60	52
Facilitator Interview Topic Guide	Facilitators	5	2	1	10
District/CBO Leadership Interview Topic Guide.	District/School/CBO leadership	11	2	45/60	17
Total			44		1488

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–07285 Filed 4–8–21; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: N-butyldeoxynojirimycin To Treat Smith-Lemli Opitz Syndrome (SLOS) and Diseases That Exhibit a Similar NPC-Like Cellular Phenotype

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 SubRed Pty Ltd located in Australia, registered in Victoria.

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 April 26, 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 at Email: *hubbsa@mail.nih.gov*.

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

Intellectually Property

1. Great Britain Patent Application No. 712494.4, filed on June 27, 2007 [HHS Reference No. E–206–2007–0–GB–01];

2. PCT Patent Application No. PCT/GB2008/002207, filed June 26, 2008 [HHS Reference No. E–206–2007–0–PCT–02];

3. Issued Australian Patent No. 2008269585, filed on June 26, 2008, Issued July 2, 2015 [HHS Reference No. E–206–2007–0–AU–03];

4. Issued Canadian Patent No. 2691937, filed on June 26, 2008, Issued January 23, 2018 [HHS Reference No. E–206–2007–0–CA–04];

5. Issued European Patent No. 2182936, filed on June 26, 2008, Issued April 1, 2020 [HHS Reference No. E–206–2007–0–EP–05];

6. Issued US Patent No. 8,557,844, filed January 19, 2010, Issued October 15, 2013 [HHS Reference No. E–206–2007/0–US–06];

7. Issued United States Patent No. 9,428,541, filed on September 13, 2013, Issued August 30, 2016 [HHS Reference No. E–206–2007–0–US–09]

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: ''The use of N-butyldeoxynojirimycin in humans to treat Smith-Lemli Opitz Syndrome (SLOS) and diseases that exhibit a similar NPC-like cellular phenotype.''

This technology discloses pharmaceutical compositions and methods of use to treat SLOS and diseases having a secondary NPC like cellular phenotype or wherein the disease is an inborn error in cholesterol synthesis.

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.

Dated: March 22, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021–07316 Filed 4–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public by videocast as indicated below.

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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering, NACBIB, May 2021.

Date: May 19, 2021.

Open: 12:00 p.m. to 2:50 p.m.

Agenda: Report from the Institute Director, Council members and other Institute Staff.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David T. George, Ph.D., Associate Director, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 920, Bethesda, MD 20892, *georged@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nibib.nih.gov/about-nibib/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

Dated: April 6, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07341 Filed 4–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pitts, Ph.D., 240–669–5299; *elizabeth.pitts@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows.

Polyvalent Influenza Virus-Like Particles (VLPs) and Use as Vaccines
Description of Technology

Influenza virus is a major public health concern, causing up to 500,000 deaths annually. The current strategy of reformulating vaccines annually against dominant circulating strains leads to variable protective efficacy and is unlikely to protect against novel influenza viruses with pandemic potential. Thus, there is a great need for a vaccine that provides ''universal'' protection against influenza viruses.

This technology relates to a broadly protective, universal influenza vaccine candidate composed of a mixture of virus-like particles (VLPs) expressing the hemagglutinin protein or the neuraminidase protein from influenza virus strains belonging to different virus subtypes. Vaccinating animals with a mixture of VLPs expressing four or more hemagglutinin subtypes provides broad and heterosubtypic protection against lethal challenge with influenza virus strains in both mice and ferrets. This vaccine technology has great potential to provide protection against both annual epidemic and pandemic-potential influenza viruses.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- Vaccines against influenza virus
- Universal influenza virus vaccine

Competitive Advantages

- Broad/universal protection against both seasonal and pandemic-potential influenza viruses
- Does not require yearly reformulation as is necessary with current commercially available influenza vaccines

Development Stage

- In vivo data assessment (animal)