

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Appointment of Representative; *Use:* This form would be completed by beneficiaries, providers and suppliers (typically their billing clerk, or billing company), and any party who wish to appoint a representative to assist them with their initial Medicare claims determinations, and filing appeals on Medicare claims. The authority for collecting this information is under 42 CFR 405.910(a) of the Medicare claims appeal procedures.

The information supplied on the form is reviewed by Medicare claims and appeals adjudicators. The adjudicators make determinations whether the form was completed accurately, and if the form is correct and accepted, the form is appended to the claim or appeal that it pertains to. *Form Number:* CMS-1696 (OMB control number: 0938-0950); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 270,544; *Total Annual Responses:* 270,544; *Total Annual Hours:* 67,637. (For policy questions regarding this collection contact Katherine E. Hosna at 410-786-4993.)

Dated: May 19, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021-10911 Filed 5-21-21; 8:45 am]

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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, 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; RFA-RM-

20-016: Harnessing Data Science for Health Discovery and Innovation in Africa Research Training Program.

Date: June 22, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Karen Nieves Lugo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 3148, MSC 7770, Bethesda, MD 20892, (301) 594-9088, karen.nieveslugo@nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group Genomics, Computational Biology and Technology Study Section.

Date: June 23-24, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301-827-7088, methode.bacanamwo@nih.gov.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Integrative Myocardial Physiology/Pathophysiology A Study Section.

Date: June 23-24, 2021.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301-435-2365, aitouchea@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-RM-20-015: Harnessing Data Science for Health Discovery and Innovation in Africa—Research Hubs.

Date: June 23-25, 2021.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: June 23-24, 2021.

Time: 11:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Joanne T. Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435-1178, fujij@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: May 19, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-10893 Filed 5-21-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, 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 Patents and Patent Applications listed in the Supplementary Information section of this Notice to Lyell Immunopharma, Inc. (“Lyell”), located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before June 8, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276-5484; Facsimile: (240) 276-5504; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property*E-109-2020: High-Throughput Generation of iPSC Carrying Antigen Specific TCRs From Tumor Infiltrating Lymphocytes*

1. US Provisional Patent Application 63/068,458 filed August 21, 2020 (E-109-2020-0-US-01).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

“Manufacture and commercialization of adoptive T cell therapy products generated from autologously-derived, induced pluripotent stem cells for the treatment of cancer in humans.”

E-109-2020 generally discloses methods of producing induced pluripotent stem cells from isolated tumor infiltrating lymphocytes which express antigen-specific T cell receptors.

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 Cancer Institute receives written evidence and argument which 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 from 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: April 29, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-10819 Filed 5-21-21; 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: Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application 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 patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Antibodies With Potent and Broad Neutralizing Activity Against Antigenically Diverse and Highly Transmissible SARS-CoV-2 Variants

Emergence of highly transmissible SARS-CoV-2 variants of concern that are resistant to current therapeutic antibodies highlights the need for continuing discovery of broadly reactive antibodies.

Scientists at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases discovered and characterized a group of human monoclonal antibodies that target unique epitopes on the receptor binding domain of SARS-CoV-2 spike protein. These antibodies ultra-potently neutralize >12 variants of SARS-CoV-2, including P1, B.1.429, B.1.1.7 and B.1.351, as shown in a pseudovirus neutralization assay. These antibodies target 3 distinct epitopes in the receptor binding domain of the spike protein and function by blocking ACE2 binding. These antibodies are not impacted by spike mutations that knockout binding to other therapeutic antibodies,

including E484K, N439K, Y453F, L452R and K417N. Several antibodies are able to simultaneously bind to the spike protein and are compatible for use in combination therapies. In *in vitro* assays, these combinations were shown to decrease the appearance of escape mutants suggesting the potential to mitigate resistance development when used as combination therapy.

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

- Treatment of SARS-CoV-2 infection

Competitive Advantages

- Ultra-potent neutralization of currently identified SARS-CoV-2 variants
- Combinations show the potential to mitigate resistance
- Mechanism of Action—These antibodies bind to block ACE2 receptor binding to the SARS-CoV-2 spike protein

Development Stage: Preclinical Research.

Inventors: John Misasi (VRC, NIAID), Lingshu Wang (VRC, NIAID), John Mascola (VRC, NIAID), Daniel Douek (VRC, NIAID), Nancy Sullivan (VRC, NIAID), Amy Renseir Henry (VRC, NIAID), Tongqing Zhou (VRC, NIAID), Peter Kwong (VRC, NIAID), Wei Shi (VRC, NIAID), Yi Zhang (VRC, NIAID), Eu Sung Yang (VRC, NIAID), Mario Roederer (VRC, NIAID), Rosemarie Mason (VRC, NIAID), Amarendra Pegu (VRC, NIAD).

Publications: Wang, L. *et al.*, (2021). Antibodies with potent and broad neutralizing activity against antigenically diverse and highly transmissible SARS-CoV-2 variants. *BioRxiv*.

Intellectual Property: HHS Reference Number E-037-2021 includes U.S. Provisional Patent Application Number 63/147,419 filed February 9, 2021.

Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov.

Dated: April 27, 2021.

Surekha Vathiyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-10821 Filed 5-21-21; 8:45 am]

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