

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 July 2, 2019 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, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240)-276-5484; Facsimile: (240)-276-5504; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

Group A

HLA-A3-Restricted T Cell Receptors Against Mutated RAS

1. U.S. Provisional Patent Application 62/749,750, filed October 24, 2018 (E-166-2018-0-US-01).

HLA Class II-Restricted T Cell Receptors Against RAS With G12R Mutation

1. U.S. Provisional Patent Application 62/795,203, filed January 22, 2019 (E-029-2019-0-US-01).

Group B

Methods of Producing T Cell Populations Using Hydroxycitric Acid and/or a Salt Thereof

1. U.S. Provisional Patent Application 62/661,941, filed April 24, 2018 (E-094-2018-0-US-01); and

2. International Patent Application PCT/US2019/028513, filed April 22, 2019 (E-094-2018-0-PCT-02).

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:

Fields of Use Applying to Intellectual Property Groups A and B

“Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated KRAS, as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are retrovirally-engineered peripheral blood T cell therapy products for the treatment of human cancers.

Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

Fields of Use Applying to Intellectual Property Group B

“Development, manufacture and commercialization of autologous, peripheral blood T cell therapy products engineered by CRISPR to express T cell receptors reactive to mutated p53, as claimed in the Licensed Patent Rights, for the treatment of cancer in humans.

“Development, manufacture and commercialization of autologous, tumor infiltrating lymphocyte (TIL)-based adoptive T cell therapy products reactive to mutated p53, isolated as claimed in the Licensed Patent Rights, for the treatment of human cancers. Specifically excluded from this field of use are genetically engineered TIL cell therapy products for the treatment of human cancers.

Development, manufacture and commercialization of companion diagnostics approved or cleared by the FDA or equivalent foreign regulatory agency for Licensee-proprietary T cell therapy products.”

Intellectual Property Group A is primarily directed to isolated T cell receptors (TCRs) reactive to mutated Kirsten rat sarcoma viral oncogene homolog (KRAS), within the context of several human leukocyte antigens (HLAs). Mutated KRAS, which plays a well-defined driver role in oncogenesis, is expressed by a variety of human cancers, including: pancreatic, lung, endometrial, ovarian and prostate. Due to its restricted expression in precancerous and cancerous cells, this antigen may be targeted on mutant KRAS-expressing tumors with minimal normal tissue toxicity.

Intellectual Property Group B is primarily directed to methods of preparing isolated populations of T cells by culturing them in the presence of hydroxycitric acid and/or a salt thereof, and methods of treating cancer using populations of T cells cultured in such a manner.

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: June 3, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019-12707 Filed 6-14-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; High Priority Research Networks.

Date: June 26, 2019.

Time: 12:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Ave, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7702, firthkm@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 12, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-12712 Filed 6-14-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report. Office of the Director (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of Laboratory Animal Welfare (OLAW) in the Office of Extramural Research has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. The purpose of this notice is to allow 60 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received

within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To submit comments in writing or request more information on the proposed collection, contact: Eileen M. Morgan, Director, Division of Assurances, Office of Laboratory Animal Welfare, NIH, call (301) 594-2289 or email your request to olawdocs@mail.nih.gov. Formal requests for information collection forms must be requested via email to olawdocs@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report,

OMB#0925-NEW, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Laboratory Welfare (OLAW) is responsible for the implementation, general administration, and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as codified in 42 CFR 52.8. The PHS Policy implements the Health Research Extension Act (HREA) of 1985 (Pub. L. 99-158 as codified in 42 U.S.C. 289d). The PHS Policy requires entities that conduct research involving vertebrate animals using PHS funds to have an Institutional Animal Care and Use Committee (IACUC), provide assurance that requirements of the Policy are met, and submit an annual report. An institution's animal care and use program is described in the Animal Welfare Assurance (Assurance) document and sets forth institutional compliance with PHS Policy. The purpose of the Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the HREA, illustrate institutional adherence to PHS Policy, and enable OLAW to carry out its mission to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

OMB approval is requested for 3 years. The total estimated annualized burden hours are 8,140.

ESTIMATED ANNUALIZED BURDEN HOURS

Document	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Annual burden hours
Interinstitutional Assurance	Foreign	40	1	30/60	20
Interinstitutional Assurance	Domestic	660	1	30/60	330
Foreign Assurance	Renewal and New	60	1	1	60
Domestic Assurance	Renewal	220	1	26	5,720
Domestic Assurance	New	20	1	30	600
Annual Report	All Domestic	940	1	90/60	1,410
Total			1,940		8,140

Dated: June 11, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019-12734 Filed 6-14-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

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,