

Federal SUID/SIDS Workgroup members, SUID/SIDS stakeholders, clinical and maternal and child health professionals. These audiences may use the information collections to: (1) Develop new campaign messages, materials, and/or training curricula; (2) monitor and improve campaign activities; (3) make decisions about campaign activities; (4) inform current campaign activities; and (5) inform and/or change practices and behaviors of program participants.

Examples of the types of information collections that could be included under this generic clearance include: *Focus groups and key informant interviews*

with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages; and *Surveys* with parents/caregivers and/or health professionals to: (1) Assess the usefulness of the new STS campaign materials, including print and on-line multi-media materials, (2) track outreach experiences of program participants, (3) assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of learned outreach and education methods, and (4) assess program participants' resource needs.

The sub-studies for this generic clearance will be small in scale, designed to obtain results frequently and quickly to guide campaign development and implementation, inform campaign direction, and be used internally for campaign management purposes. NICHD's current scope and capacity for STS generic sub-studies is non-existent and this request would fill this gap.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 13,305.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response, in hours	Total annual burden hours
Focus Groups .....	General Public .....	215	1	1	215
Interviews .....	General Public .....	50	1	1	50
Pre-/Post-Tests .....	General Public .....	3,000	2	15/60	1,500
Pre-/Post-Tests .....	Health Professionals .....	20,000	2	15/60	10,000
Surveys .....	Health Professionals .....	3,000	1	30/60	1,500
Tracking/Feedback Form .....	Health Educators .....	20	2	1	40
<b>Total .....</b>		<b>26,285</b>	<b>49,305</b>		<b>13,305</b>

Dated: February 12, 2021.

Jennifer M. Guimond,

Project Clearance Liaison, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2021-03870 Filed 2-24-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Engineered Tumor Infiltrating Lymphocytes for Cancer 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 Iovance Biotherapeutics, Inc. ("Iovance"), headquartered in San Carlos, 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 March 12, 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; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-068-2018: Tethered Interleukin-15 and Interleukin-21

1. US Provisional Patent Application 62/628,454, filed February 9, 2018 (E-068-2018-0-US-01);

2. International Patent Application PCT/US2019/016975, filed February 7, 2019 (E-068-2018-0-PCT-02);

3. Australian Patent Application 2019218785, filed August 7, 2020 (E-068-2018-0-AU-03);

4. Chinese Patent Application 201980012443.3, filed August 7, 2020 (E-068-2018-0-CN-04);

5. European Patent Application 19709154.9, filed August 18, 2020 (E-068-2018-0-EP-05);

6. United States Patent Application 16/964,796, filed July 24, 2020 (E-068-2018-0-US-06); and

7. Canadian Patent Application 3,090,512, filed August 5, 2020 (E-068-2018-0-CA-07).

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 field of use may be limited to the following:

"The use of the Licensed Patent Rights to develop, manufacture, distribute, sell, and use unselected whole autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of metastatic melanoma, lung, breast, bladder, and HPV-positive cancers. Specifically excluded from this Agreement are methods of generating or using selected subpopulations of TIL and the use of T cell receptors isolated from TIL."

E-068-2018 is primarily directed to recombinant constructs for the co-expression of Interleukins-15 and 21 (IL-15 and 21). IL-15 and IL-21 have been reported to support the function of anti-tumor T cells; however, their

clinical utility has been constrained, in part, by dose-limiting toxicity following systemic administration and the need for repeated dosing. The subject invention addresses these limitations through synthetic IL-15/21 sequences which incorporate flexible linker regions and cell membrane anchors. T cells engineered to express these constructs experience autocrine IL-15/21 signaling leading to enhanced anti-tumor function in vivo.

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 establishing 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: February 12, 2021.

**Richard U. Rodriguez,**  
Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-03873 Filed 2-24-21; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request; CareerTrac**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Kristi Pettibone, Health Scientist Administrator, Program Analysis Branch, Division of Extramural Research and Training, NIEHS, NIH, 560 Davis Dr., Morrisville, NC 27560, or call non-toll-free number (984) 287-3303 or Email your request, including your address to: [pettibonekg@niehs.nih.gov](mailto:pettibonekg@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on December 12, 2020, page 79493-79494 (64 FR 15367) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Fogarty International Center (FIC), National Cancer Institute (NCI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and National Institute of Environmental Health Sciences (NIEHS), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or

after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

*Proposed Collection:* CareerTrac-0925-0568—expiration date April 30, 2021, REVISION, Fogarty International Center (FIC), National Institute of Environmental Health Sciences (NIEHS), National Cancer Institute (NCI), National Institute of Diabetes and Digestive Kidney Diseases, (NIDDK), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The purpose of this data collection system is to track, evaluate and report short and long-term outputs, outcomes and impacts of trainees involved in health research training programs—specifically tracking this for at least ten years following training by having Principal Investigators enter data after trainees have completed the program. The data collection system provides a streamlined, web-based application permitting principal investigators to record career achievement progress by trainee on a voluntary basis. FIC, NCI, NIDDK, and NIEHS management will use this data to monitor, evaluate and adjust grants to ensure desired outcomes are achieved, comply with OMB Part requirements, respond to congressional inquiries, and as a guide to inform future strategic and management decisions regarding the grant program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 12,705.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
FIC Grantee .....	90	20	40/60	1,200
NIEHS Grantee .....	60	45	40/60	1,800
NCI CRCHD Grantee .....	244	22	40/60	3,579
NCI D43 Grantee .....	20	22	40/60	293
Superfund Grantee .....	30	105	40/60	2,100