

This live-attenuated RSV vaccine is designed to be administered intranasally by drops or spray to infants and young children. Based on experience with other live-attenuated RSV vaccine candidates, the present candidates are anticipated to be well tolerated in humans and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in evaluating live-attenuated RSV vaccine candidates in pediatric clinical studies, and opportunity for collaboration exists.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage:

- In vivo data assessment (animal)

Inventors: Cyril Le Nouen (NIAID), Ursula Buchholz (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-104-2020-0—U.S. Provisional Application No. 63/023,949, filed May 13, 2020.

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: February 18, 2021.

Surekha Vathyam,

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

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Generic Clearance To Support the Safe to Sleep® Campaign at the Eunice Kennedy Shriver National Institute for Child Health and Human Development

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. 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: Lorena Kaplan, M.P.H., CHES, Office of Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A32, Bethesda, Maryland 20892, or call non-toll free number (301) 496-6670 or Email your request, including your address to lorena.kaplan@nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on December 11, 2020, page 80123-80124 (85 FR 80123-80124) 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 Eunice Kennedy Shriver National Institute for Child Health and Human Development, National Institutes of Health, 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: Generic Clearance to Support the Safe to Sleep® Campaign at the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD), 0925-0701, exp., date 02/28/2021, REVISION, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a revision to a generic clearance used for submissions specific to the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Safe to Sleep® (STS) public education campaign. Submissions for the STS campaign will be used to assess the understanding and reach of STS campaign materials and messages, and to monitor and improve campaign activities such as training workshops and overall implementation. The purpose of this information collection is to monitor and modify campaign activities, to plan future campaign activities, to develop messages and materials, and to develop distribution and outreach strategies that are effective at communicating their message to bring about the intended response, awareness, and/or behavioral change for the target audiences. This generic clearance will enable the NICHD to: (1) More efficiently assess the implementation of campaign activities; (2) better understand the target audiences' knowledge, attitudes, and beliefs toward STS messages and materials; (3) better understand how the campaign activities have influenced the target audiences' behaviors and practices; and (4) monitor and improve activities such as trainings, materials, and messages. Having a way to gather feedback on the STS campaign activities is critical to assessing the reach and effect of campaign efforts. Data collected for the campaign can inform where future STS campaign resources can produce the most meaningful results. Data collected for the STS campaign generic clearance will be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign collaborators,

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
Total	26,285	49,305	13,305

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]

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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