

programs become permanent, HRSA will seek OMB clearance for these programs using a mechanism outside of this generic umbrella clearance. OMB guidance allows for the use of generic packages in cases where there may be a need for a data collection, but the agency “cannot determine the details of the specific individual collections until a later time.”<sup>1</sup> HRSA will only use this collection for HRSA-funded programs that provide one-time funding, including pilot programs. HRSA would only request OMB approval for collections under this generic umbrella collection if the collection is low-burden, uncontroversial, and is a one-time application.

Furthermore, if Congress appropriates additional funding for such a program or HRSA uses the information from the applications for policy decisions not related to funding awards, HRSA will prepare a standard information collection request for that program, which will include the required 60- and 30-day **Federal Register** notices.

*Need and Proposed Use of the Information:* HRSA seeks to use an umbrella generic clearance for HRSA-funded programs that provide one-time funding, including pilot programs, so that funding can be awarded expeditiously. Expedient awarding of funding is helpful not only for administrative ease, but also for cases where a pilot program or a program receiving one-time funding has a statutory deadline for completion. Approval of this proposed generic

umbrella collection would enable HRSA to collect information from individual and site applicants and enable HRSA to make selection determinations for one-time awards in a timely manner.

Information collections under this umbrella generic collection would be applications for funding (solely providing applicants with an opportunity to demonstrate their capabilities in accordance with HRSA’s statement of work or selection criteria and other related information) and forms required for monitoring funding recipients. Following the award, the awardee may also be required to provide progress reports or additional documents.

*Likely Respondents:* Each fast-track ICR under this generic umbrella ICR will specify the specific manner that respondents will be enlisted. Respondents will vary by the specific program and are determined by each program’s eligibility, to include but are not limited to the following: health providers and other paraprofessionals, health facilities, accredited health professions schools or programs, State and local governments, and other eligible entities.

Respondents will be recruited by means of information listed on HRSA’s website, or advertisements in public venues. The privacy of any potential or actual respondents will be preserved to the extent requested by participants and as permitted by law.

Once applicants are selected and awards are made, these awardees will be

respondents for monitoring collections such as progress reports.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

HRSA intends to use this generic umbrella ICR for applications with a low burden and monitoring awardees. To estimate the burden for this collection, HRSA estimated how much time it would take for a respondent to complete a 2-page application with typical fields used in current collections that may fall under this generic umbrella ICR. HRSA then calculated the average burden estimate from these ICRs for the purpose of the estimate for this ICR. To estimate the burden for monitoring funding recipients, HRSA estimated how much time it would take for funding recipients to complete the average 2-page form used for program monitoring. The total burden hours over a 3-year period estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED BURDEN HOURS OVER 3 YEARS

Instrument name	Estimated number of respondents	Average number of responses per respondent	Estimated total responses	Average burden per response (in hours)	Total burden hours
Program Applications .....	5,000	1.5	7,500	1.75	13,125
Program Monitoring .....	2,500	1.0	2,500	2.00	5,000
Total .....	7,500	.....	10,000	.....	18,125

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2024–06141 Filed 3–21–24; 8:45 am]

**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, March

<sup>1</sup> Memorandum for the Heads of Executive Departments and Agencies and Independent

Regulatory Agencies (July 2016), “Flexibilities under the Paperwork Reduction Act for Compliance

with Information Collection Requirements.” Pages 4–5.

27, 2024, 10:30 a.m. to March 27, 2024, 12:30 p.m., National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on March 14, 2024, 89 FR 18652.

This meeting was amended to change the start date and end date from 03–27–2024 to 04–02–2024. The meeting is closed to the public.

Dated: March 18, 2024.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2024–06127 Filed 3–21–24; 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: Adoptive T Cell Therapy Products Produced Using a Pharmacological p38 Mitogen-Activated Protein Kinase (MAPK) Inhibitor

**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 Poolbeg Pharma (UK) Limited, incorporated in the United Kingdom.

**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 April 8, 2024 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](mailto:andy.burke@nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Intellectual Property**

1. United States Provisional Patent Application No. 62/570,708 filed October 11, 2017, entitled “Methods of Producing T Cell Populations Using P38

MAPK Inhibitors” [HHS Reference No. E–002–2018–0–US–01];

2. International Patent Application No. PCT/US2018/055206 filed October 10, 2018, entitled “Methods of Producing T Cell Populations Using P38 MAPK Inhibitors” [HHS Reference No. E–002–2018–0–PCT–02]; and

3. United States Patent Application No. 16/754,926 filed April 9, 2020, entitled “Methods of Producing T Cell Populations Using P38 MAPK Inhibitors” [HHS Reference No. E–002–2018–0–US–03].

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 the United States of America, and the field of use may be limited to the following:

“The treatment of cancer in humans using adoptive T cell therapy products produced through the use of a pharmacological p38 MAPK inhibitor.”

The E–002–2018 patent family is primarily directed to a method of producing populations of T cells for the treatment of cancer wherein the cells are cultured (*e.g.*, expanded) in the presence of a p38 mitogen-activated protein kinase (MAPK) inhibitor. In oncology, many investigational adoptive cell therapies rely on antigen-specific T cells isolated from the patient in need of treatment. However, these cells often exist in a terminally differentiated and exhausted state, or enter such a state following manipulation *ex vivo*, and are unable to mount a robust immune response following reinfusion. Recent evidence suggests that inhibition of P38 MAPK signaling in T cells during *ex vivo* expansion can ameliorate this performance defect. It is hoped that this modified cell manufacturing approach will enhance treatment efficacy. The exclusive field of use which may be granted to Poolbeg applies to only certain T cell manufacturing methods which rely on pharmacologic P38 MAPK inhibitors. Accordingly, the proposed scope of rights which may be conveyed under the license covers a portion of the possible applications of E–002–2018.

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 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 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: March 19, 2024.

**Richard U. Rodriguez,**

*Associate Director, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2024–06128 Filed 3–21–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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; Member Conflict: Respiratory Sciences.

*Date:* April 16, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, [diramig@csr.nih.gov](mailto:diramig@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular and Hematology Member Application Review.

*Date:* April 17, 2024.

*Time:* 11:00 a.m. to 3:00 p.m.