

not promiscuous kinase inhibitors. The subject kinase inhibitors have broad potential commercial applicability's for cancer, immune suppression, preventing organ rejection, treating diabetic neuropathic pain, malaria, or protozoa infection. To date, there are no approved therapeutics targeting DNAJB1-PRKCA, an oncogenic gene fusion, which is ubiquitously and exclusively detected in the tumors of patients with ultra-rare fibrolamellar hepatocellular carcinoma FLHCC.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

*NIH Reference Number:* E-044-2022.

*Related Technologies:* E-202-2023 and E-162-2024.

*Product Type:* Therapeutic.

*Therapeutic Area(s):* Oncology, Infectious Disease, Rare/Neglected Diseases.

*Potential Commercial Applications:*

- Gastric cancer.
- Ultra-rare adolescent liver cancer.
- Solid cancers susceptible to kinase inhibitors.

- Cushing's Disease.
- Transplantation.
- Diabetic neuropathic pain.
- Malaria.
- Protozoa infection.

*Competitive Advantages:*

- Applicability to numerous clinically relevant kinases, including:
  - Oncogenic gene fusion DNAJB1-PRKACA (PKADJ).
  - Wild type protein kinase A (PKA).
  - Protein kinase G (PKG).
  - Cdc2-like kinases (CLK) 1 and 2.
  - DYRK family of kinases.
- Applicable to a range of kinases, but are not promiscuous kinase inhibitors.
- Broad potential commercial applicability for several blockbuster indications including:
  - cancer, immune suppression, transplantation, diabetic neuropathic pain, malaria, and protozoa infection.

• No approved therapeutics targeting DNAJB1-PRKCA.

*Publications:*

• O'Keefe BR, et al. Biochemical Discovery, Intracellular Evaluation, and Crystallographic Characterization of Synthetic and Natural Product Adenosine 3',5'-Cyclic Monophosphate-Dependent Protein Kinase A (PKA) Inhibitors. PMID: 37082750, <https://pubmed.ncbi.nlm.nih.gov/37082750/>.

• O'Keefe BR, et al. Discovery and Synthesis of a Naturally Derived Protein Kinase Inhibitor that Selectively Inhibits Distinct Classes of Serine/Threonine Kinases. PMID: 37843072, <https://pubmed.ncbi.nlm.nih.gov/37843072/>.

*Patent Status:*

- E-044-2022: PCT/US2023/070304.
- E-202-2023: PCT/US2024/038376.

- E-162-2024: 63/672,577.

*Development Stage:* Pre-clinical (*in vivo* validation).

Dated: November 12, 2024.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 1009 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 Center for Complementary and Integrative Health Special Emphasis Panel; NCCIH Conference Grant (R13 Clinical Trial Not Allowed).

*Date:* December 10, 2024

*Time:* 2:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Michael E. Authement, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, 6707 Democracy Boulevard, Bethesda, MD 20817, [michael.authement@nih.gov](mailto:michael.authement@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: November 8, 2024.

**David W. Freeman,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government Owned Inventions Available for Licensing or Collaboration: Improved Methods for Cryopreservation of Cells, Tissues, and Organs

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

**ACTION:** Notice.

**SUMMARY:** The National Eye Institute (NEI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of licensing and/or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing and/or collaboration to achieve expeditious commercialization of results of federally-funded research and development.

#### FOR FURTHER INFORMATION CONTACT:

Inquiries related to these licensing and/or collaboration opportunities should be directed to: Hiba Alsaffar, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: [hiba.alsaffar@nih.gov](mailto:hiba.alsaffar@nih.gov) or Phone: 240-276-7489.

#### SUPPLEMENTARY INFORMATION:

Researchers at the NEI seek licensing and/or co-development research collaborations for improved methods of cryopreservation of cells, tissues, and organs via FOXO1 activation. The cornea is a critical part of the eye that helps prevent debris from entering and refracts light for proper vision. Corneal disorders such as keratoconus, Fuchs dystrophy, and infectious keratitis require corneal transplantation to restore vision. Approximately 185,000 corneal transplants are performed annually worldwide to treat corneal disorders. Corneas for those transplants are supplied by donor eyes that are stored at eye banks in select countries. Currently, Optisol-GS™ is the corneal preservation solution that is most widely used to store donated corneas at eye banks. Per NEI guidelines, corneas preserved in Optisol-GS™ have a 12-day shelf life. With the high demand for corneal transplantations worldwide, a 12-day shelf life cannot meet the requirement for long term cryogenic storage of corneas at large eye banks. Scientists at the NEI have developed improved methods for cryopreservation of cells, tissues, and organs (with focus of corneal tissue/cells) that increases

cold storage shelf life 2.5 times longer than current market products.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E-013-2021.

Related Technologies: E-073-2018.

Product Type: Medical/Research Tool.

Therapeutic Area(s): Eye, Ear, Nose or Throat.

Potential Commercial Applications:

- Corneal biobanks.
- Transplantation to remedy a wide range of corneal disorders.
- Improved method of cryopreserving corneal cells and other cell types.

Competitive Advantages:

- Superior corneal shelf life: 16-day compared to 12-day maximum shelf-life of current market products.
- Better meets requirement for larger eye bank cryopreservation.
- 95% endothelial cell survival after 4 weeks in cold storage.

Patent Status: National Stage Filings in the US, CA, AU, CN, EP.

Development Stage: Discovery.

Dated: November 12, 2024.

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

[FR Doc. 2024-26661 Filed 11-14-24; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Regulations To Implement SAMHSA's Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930-0242)—Revision**

Section 1955 of the Public Health Service Act (42 U.S.C. 300x-65), as amended by the Children's Health Act of 2000 (Pub. L. 106-310) and sections 581-584 of the Public Health Service Act (42 U.S.C. 290kk et seq., as added by the Consolidated Appropriations Act (Pub. L. 106-554)), set forth various provisions which aim to ensure that religious organizations are able to

compete on an equal footing for federal funds to provide substance use services. These provisions allow religious organizations to offer substance use services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Use Prevention, Treatment, and Recovery Services Block Grant (SUBG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance Abuse and Mental Health Services Administration (SAMHSA) discretionary grant programs (programs that pay for substance use treatment and prevention services, not for certain infrastructure and technical assistance activities). Every effort has been made to assure that the reporting, recordkeeping and disclosure requirements of the proposed regulations allow maximum flexibility in implementation and impose minimum burden.

No changes are being made to the regulations or the information collection provisions. A minor change reflecting current state reporting has been made to the annual burden estimates in 54.8(c)(4) resulting in total burden costs reported decreasing.

Information on how states comply with the requirements of 42 CFR part 54 was approved by OMB as part of the Substance Use Prevention and Treatment Block Grant FY 2019-2021 annual application and reporting requirements approved under OMB control number 0930-0168.

42 CFR citation and purpose	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Part 54—States Receiving SUBG and/or Projects for Assistance in Transition from Homelessness					
Reporting:					
96.122(f)(5) Annual report of activities the state undertook to comply with 42 CFR part 54 .....	60	1	60	1	60
54.8(c)(4) Total number of referrals to alternative service providers reported by program participants to States (respondents).					
SUBG .....	7	7 (avg.)	47	1	47
PATH .....	10	5	50	1	50
54.8 (e) Annual report by PATH grantees on activities undertaken to comply with 42 CFR part 54 .....	56	1	56	1	56
Disclosure:					
54.8(b) Program participant notice to program beneficiaries of rights to referral to an alternative service provider.					
SUBG .....	60	1	60	.05	3
PATH .....	56	1	56	.05	3
Recordkeeping:					