

11, 2015, [HHS Ref. No. E-050-2015-0-US-01];

II. International Patent Application No. PCT/US2016/022072 filed Mar. 11, 2015, [HHS Reference No. E-050-2015-0-PCT-03]; expired

III. Australian National Stage Patent Application No. 2016228751, filed Mar. 11, 2016, [HHS Ref. No. E-050-2015-0-AU-04]; pending

IV. Canadian National Stage Patent Application No. 2979229 filed Mar. 11, 2016, [HHS Ref. No. E-050-2015-0-CA-05]; pending

V. European national Stage Patent Application No. 1662623.3 filed Oct. 11, 2016, [HHS Ref. No. E-050-2015-0-EP-06]; issued (validated in DE, FR and GB)

VI. U.S. national Stage Patent Application No. 15/556,746 filed Sep. 8, 2017 [HHS Ref. No. E-050-2015-0-US-08]; issued

VII. Japanese National Stage Patent Application No. 2017-547425 filed Sep. 8, 2017 [HHS Ref. No. E-050-2015-0-JP-07]; pending

VIII. Divisional European Patent Application No. 20176667.2 filed May 26, 2020 [HHS Ref. No. E-050-2015-0-EP-13]; pending

IX. Divisional Japanese Patent Application No. 2020-167984 filed Oct. 2, 2020 [HHS Ref. No. E-050-2015-0-JP-14]; pending

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: "Development and commercialization of RP2 AAV-based gene human therapy for any ocular disease, disorder or condition, including human X-linked retinitis pigmentosa (XLRP)".

This technology discloses Adeno-Associated Viral (AAV) vectors comprising nucleotide sequences encoding RP2 or RPGR- ORF 15 transgenes and their use in treating or preventing X-linked forms of retinitis pigmentosa (XLRP).

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 in 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: July 2, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021-14682 Filed 7-9-21; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Motor function in healthy and clinical populations.

Date: August 3, 2021.

Time: 1:00 p.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 (Virtual Meeting).

Contact Person: Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, 301-594-3163, champoux@csr.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 6, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-14697 Filed 7-9-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

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.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The Open Session will be open to the public via NIH Videocast. The URL link to access this meeting is <https://videocast.nih.gov>.

Name of Committee: National Advisory Council for Complementary and Integrative Health.

Date: September 10, 2021.

Closed: 10:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy 2, 6707 Democracy Boulevard, Bethesda, MD 20817 (Virtual Meeting).

Open: 11:40 a.m. to 5:00 p.m.

Agenda: A report from the Director of the Center and Other Staff.

Place: National Institutes of Health, Democracy 2, 6707 Democracy Boulevard, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Partap Singh Khalsa, Ph.D., DC, Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892-5475, 301-594-3462, khalsap@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than 15 days after the meeting.

Information is also available on the Institute's/Center's home page: <https://www.nccih.nih.gov/news/events/advisory-council-78th-meeting>, where an agenda and any additional information for the meeting will be posted when available.

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

Dated: July 7, 2021.

Tyeshia M. Roberson-Curtis,
Program Analyst, Office of Federal Advisory
Committee Policy.

[FR Doc. 2021-14739 Filed 7-9-21; 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: High ASS1 Expressing Tumors Embody a Purine Rich Genomic Signature and Sensitivity to Purine Depletion

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Yeda Research & Development Co, Ltd ("YEDA"), the technology transfer company of the Weizmann Institute of Science, a non-profit research institution located in Rehovot, Israel for NCI's rights to the patent applications listed in the Supplementary Information section of this notice.

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 27, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager at Telephone: (240)-276-6910 or at Email: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to YEDA: PCT Patent Application PCT/IL2020/050708, filed June 24, 2020 and entitled "High ASS1 Expressing Tumors Embody A Purine Rich Genomic Signature And Sensitivity To Purine Depletion" [HHS Reference No. E-210-2020-0-PCT-01].

The patent rights in these inventions have been assigned to the Government of the United States of America and YEDA. The prospective license will be for the purpose of consolidating the patent rights to YEDA, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by YEDA will be subject to the provisions of 37 CFR parts 401 and 404.

This technology discloses methods of treating a high argininosuccinate synthase (ASS1) expressing solid tumor with a combination of a purine synthase inhibitor or an agent that increases the pyrimidine to purine ratio in a cell, and an immune-modulating drug, such as a checkpoint inhibitor.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights. 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.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. 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 in 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: July 6, 2021.

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

[FR Doc. 2021-14681 Filed 7-9-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice To Announce Request for Information (RFI) Inviting Input on the ICCFASD 2022-2026 Strategic Plan Outline

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorders (ICCFASD) is developing an updated strategic plan to guide its efforts over the next five years. As sponsor and chair of the ICCFASD, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) will be issuing a Request for Information to seek comments on the draft outline of the ICCFASD's 2022-2026 Strategic Plan from diverse stakeholders, including scientific experts, health care providers, patients and family members, advocacy groups, other federal agencies, and non-governmental scientific, professional, and healthcare organizations.

DATES: Comments must be received by August 31, 2021, to ensure consideration. Responses will be reviewed by ICCFASD members and considered during the development of the 2022-2026 Strategic Plan.

ADDRESSES: To view and comment on the strategic plan outline, please visit our online response form: RFI online response form.

FOR FURTHER INFORMATION CONTACT:
Tatiana Balachova, ICCFASD Executive
Secretary, National Institute on Alcohol
Abuse and Alcoholism, NIH, 6700B
Rockledge Drive, Bethesda, MD 20817.
Phone: 301-443-5726, Email: NIAAA-ICCFASD@mail.nih.gov.

SUPPLEMENTARY INFORMATION: In accordance with the 21st Century Cures Act, NIH institutes are required to