

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cohort 2—Youth Aged 11 to 18.	Cohort 2—Youth Base-line Questionnaire.	2,667	1	2,667	0.75 (45 minutes) ...	2,000
	Cohort 2—Youth 1st, 2nd, 3rd Followup Questionnaire.	6,270	1	6,270	0.75 (45 minutes) ..	4,703
Totals	16,525

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

To accommodate the additional data collection for media tracking, FDA requests approval to increase the number of burden hours under the existing control number. The previous number of approved screener responses for media tracking was 60,000 and the associated burden was 1,800 hours. The previous burden for the media tracking questionnaires was 6,000 and the associated burden was 3,000 hours. We are requesting an additional 20,000 screener responses and 2,000 questionnaire completions, which adds 600 burden hours and 1,000 burden hours respectively. Deducting the responses and burden for the completed evaluation components associated with Cohort 1 (general population screening (13,413 responses, 2,281 hours), parent interviews (3,342 responses, 569 hours), youth questionnaires (8,954 responses, 6,144 hours)) and for the rural smokeless evaluation (2,610 responses, 1,794 hours) results in a decrease of 6,319 annual responses and 9,187 hours.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10320 Filed 5–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Council of Research Advocates, May 20, 2019, 9:30 a.m. to 4:00 p.m., National Institutes of Health, Building 40, Room 1201/1203, 40 Convent Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 11, 2019, 84 FR 14662.

This meeting notice is amended to change the meeting start time from 9:00 a.m. to 9:30 a.m. on May 20, 2019 at the National Institutes of Health, Building

40, Room 1201/1203, 40 Convent Drive, Bethesda, MD 20892. This meeting is open to the public.

Dated: May 13, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–10217 Filed 5–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Resources for Technology Dissemination (U24) Review Meeting (2019/08).

Date: June 27, 2019.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging, and Bioengineering,

National Institutes of Health, Two Democracy Boulevard, Suite 920, 6707 Democracy Blvd., Bethesda, MD 20892, 301–451–4794, dennis.hlasta@nih.gov.

Dated: May 13, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–10235 Filed 5–16–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed 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 on Alcohol Abuse and Alcoholism.

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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: June 6, 2019.

Time: 1:30 p.m. to 2:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 1206, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Advisory Council, Director, Office of Extramural Activities, National Institute On Alcohol Abuse And Alcoholism, 6700 B

Rockledge Drive, Room 1458, MSC 6902, National Institutes Of Health, Bethesda, MD 20892, 301-443-9737, bautista@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.niaaa.nih.gov/about-niaaa/our-work/advisory-council> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: May 13, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-10219 Filed 5-16-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; RFA AA19-004 Specialized Alcohol Research Centers.

Date: August 13-14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Conference Rooms B & C, Bethesda, MD 20817.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 2116, Rockville, MD 20852, 301-443-0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: May 13, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-10218 Filed 5-16-19; 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: RP2 AAV Vectors for Treating X-Linked Retinitis Pigmentosa

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye 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 U.S. and foreign Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to IVERIC bio, Inc. located in New York, NY.

DATES: Only written comments and/or applications for a license which are received by the National Eye Institute c/o National Cancer Institute's Technology Transfer Center on or before June 3, 2019 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: Alan Hubbs, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702, Telephone: (240)-276-5530, Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

Intellectually Property

1. U.S. Provisional Patent Application No. 62/131,661, filed March 11, 2015 [HHS Reference No. E-050-2015/0-US-01];

2. PCT Patent Application No. PCT/US2016/022072 filed March 11, 2016 [HHS Reference No. E-050-2015-0-PCT-03];

3. Australian Patent Application No. AU2016228751A, filed on March 11, 2016 [HHS Reference No. E-050-2015-0-AU-04];

4. Canadian Patent Application No. CA2979229A, filed on March 11, 2016 [HHS Reference No. E-050-2015-0-CA-05];

5. European Patent Application No. EP16762623.3A, filed on March 11, 2016 [HHS Reference No. E-050-2015-0-EP-06];

6. Japanese Patent Application No. JP2017547425A, filed on March 11, 2016 [HHS Reference No. E-050-2015-0-JP-07];

7. United States Patent Application No. US15/556,746, filed on March 11, 2016 [HHS Reference No. E-050-2015-0-US-08].

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: "Human therapeutics for treating x-linked retinitis pigmentosa: The license will also be limited by licensed products covered by patent rights that pertain to AAV-mediated gene therapy delivering an RP2 transgene."

This technology discloses adeno-associated virus (AAV) vectors comprising nucleotide sequences encoding RPGR-ORF15 or RP2 and related pharmaceutical compositions. It also discloses methods of treating or preventing x-linked retinitis pigmentosa, increasing photoreceptor number in the retina of a mammal, and increasing visual acuity of a mammal using the vectors and pharmaceutical compositions.

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 Eye 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