

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—CENTER FOR BIOLOGICS EVALUATION AND RESEARCH<sup>1</sup>

21 CFR part 312, subpart I; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926 .....	118	1.305	154	8	1,232
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926 .....	1,591	4.2137	6,704	16	107,264
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population <sup>2</sup> .....	28	1	28	120	3,360
§ 312.320(b); number of submissions related to a treatment IND or treatment protocol <sup>2</sup> .....	15	1	15	300	4,500
Total .....			6,901		116,356

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

<sup>2</sup> Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

The information collection reflects an increase in 254,750 burden hours and 11,568 responses annually since the last OMB review and approval of the information collection. We attribute this to an increase in the number of submission.

Dated: December 8, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

MD 20892, (301) 402-4411, [tianbi@csr.nih.gov](mailto:tianbi@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: December 9, 2021.

**Melanie J. Pantoja,**

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

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*Contact Person:* Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301-443-4032, [anna.ghambaryan@nih.gov](mailto:anna.ghambaryan@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: December 9, 2021.

**Melanie J. Pantoja,**

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

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## 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; Visual Cortex Perception.

*Date:* January 5, 2022.

*Time:* 1:00 p.m. to 4:00 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:* Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda,

## 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 Initial Review Group; Epidemiology, Prevention and Behavior Research Study Section.

*Date:* February 28–March 1, 2022.

*Time:* 9:30 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, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of 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 Council of Councils.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

A portion of 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