

The collections of information in 21 CFR part 314 (new drug applications) have been approved under OMB control number 0910-0001; the collections of information in 21 CFR part 601 (biologics license applications) have been approved under OMB control number 0910-0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration, including assignment of an NDC) have been approved under OMB control number 0910-0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910-0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910-0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910-0139 and 0910-0834; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910-0806.

#### IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: December 23, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-28141 Filed 12-27-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Collaborative Partnerships in Cancer Research P20.

*Date:* February 25, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Timothy C. Meeker, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W606, Rockville, MD 20850, 240-276-6464, [meekert@mail.nih.gov](mailto:meekert@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; TEP-10: SBIR Contract Review Meeting.

*Date:* February 26, 2020.

*Time:* 11:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W032, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W116, National Cancer Institute, Rockville, MD 20892-9750, 240-276-5413, [klaus.piontek@nih.gov](mailto:klaus.piontek@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Validation of Cancer Markers (UH2/UH3).

*Date:* February 26, 2020.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W240, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Hasan Siddiqui, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W240, Rockville, MD 20850, 240-276-5122, [hasan.siddiqui@nih.gov](mailto:hasan.siddiqui@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Utilizing the PLCO Biospecimens Resources (U01).

*Date:* February 27, 2020.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room

7W108, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Bethesda, MD 20892-8329, 240-276-6343, [schweinfestcw@mail.nih.gov](mailto:schweinfestcw@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Predoc to Postdoc Fellow Transition Award (F99/K00).

*Date:* March 3-4, 2020.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

*Contact Person:* Scott A. Chen, Ph.D., Scientific Review Officer, National Cancer Institute, 9609 Medical Center Drive, RM 7W604, Rockville, MD 20850, 240-276-6038, [chensc@mail.nih.gov](mailto:chensc@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award (R50).

*Date:* March 5, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W242, Bethesda, MD 20892, 240-276-6372, [zouzhiq@mail.nih.gov](mailto:zouzhiq@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; SEP-1: NCI Clinical and Translational R21 and Omnibus R03.

*Date:* March 16, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Timothy C. Meeker, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W606, Rockville, MD 20850, 240-276-6464, [meekert@mail.nih.gov](mailto:meekert@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 23, 2019.

**Ronald J. Livingston, Jr.,**

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

[FR Doc. 2019-28151 Filed 12-27-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) 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:* National Institute on Aging Special Emphasis Panel; Exploratory Alzheimer's Disease Research Centers Evaluation.

*Date:* January 31, 2020.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301-496-9374, [grimaldim2@mail.nih.gov](mailto:grimaldim2@mail.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Marmoset Model U34 Review.

*Date:* February 18, 2020.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301-480-1266, [neuhuber@ninds.nih.gov](mailto:neuhuber@ninds.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Microbiome and Aging Meeting.

*Date:* February 28, 2020.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Admiral Fell Inn, Conference Room, Admiral Ballroom, 888 South Broadway, Baltimore, MD 21231.

*Contact Person:* Greg Bissonette, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301-402-1622, [bissonettegb@mail.nih.gov](mailto:bissonettegb@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 20, 2019.

**Miguelina Perez,**

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

[FR Doc. 2019-28155 Filed 12-27-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; 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 Eye Institute Special Emphasis Panel—BRAIN Initiative: New Concepts and Early-Stage Research for Large-Scale Recording and Modulation in the Nervous System (R21).

*Date:* January 23, 2020.

*Time:* 12:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Eye Institute 6700B Rockledge Drive Bethesda, MD 20818 (Virtual Meeting).

*Contact Person:* Brian Hoshaw, Ph.D., Acting Review Chief, National Eye Institute, National Institutes of Health, Division of Extramural Research, 6700 B Rockledge Dr., Ste. 3400, Rockville, MD 20892, (301) 451-2020, [hoshawb@mail.nih.gov](mailto:hoshawb@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 20, 2019.

**Miguelina Perez,**

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

[FR Doc. 2019-28152 Filed 12-27-19; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-Day Comment Request Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD/OPERA)

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Project Clearance Branch, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 803-C, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number (301) 435-0941, or email your request, including your address to: [projectclearancebranch@mail.nih.gov](mailto:projectclearancebranch@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on April 12, 2019, Volume 84, No. 71 pages 14958-14959 and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director, NIH, may not conduct or