

of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16930 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIEHS Videocast at the following link: <https://www.niehs.nih.gov/news/webcasts/index.cfm>.

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 Environmental Health Sciences Council.

Date: September 12–13, 2023.

Open: September 12, 2023, 9:00 a.m. to 9:15 a.m.

Agenda: Call to Order and Opening Remarks, Review of Confidentiality and

Conflict of Interest, and Consideration of June 2023 Meeting Minutes.

Open: September 12, 2023, 9:15 a.m. to 10:00 a.m.

Agenda: All of Us.

Open: September 12, 2023, 10:00 a.m. to 10:45 a.m.

Agenda: AI, NAM and Toxicology.

Open: September 12, 2023, 10:45 a.m. to 11:30 a.m.

Agenda: AI and multi-omic integration.

Open: September 12, 2023, 12:30 p.m. to 1:15 p.m.

Agenda: AI and the Exposome.

Open: September 12, 2023, 1:15 p.m. to 2:00 p.m.

Agenda: Ethical AI.

Open: September 12, 2023, 2:00 p.m. to 2:45 p.m.

Agenda: DTT Speaker ToxPipe: Semi-Autonomous AI Integration of Diverse Toxicological Data Streams.

Open: September 12, 2023, 2:45 p.m. to 3:45 p.m.

Agenda: Council Discussion.

Closed: September 12, 2023, 4:00 p.m. to 4:15 p.m.

Agenda: To review and evaluate review of Confidentiality and Conflict of Interest.

Closed: September 12, 2023, 4:15 p.m. to 5:00 p.m.

Agenda: To review and evaluate consideration of Grant Applications.

Date: September 13, 2023.

Open: September 13, 2023, 9:00 a.m. to 10:00 a.m.

Agenda: Report of the NIEHS Director.

Open: September 13, 2023, 10:00 a.m. to 10:45 a.m.

Agenda: Report of the DERT Director.

Open: September 13, 2023, 10:45 a.m. to 11:15 a.m.

Agenda: Report on Multi-Omics Program with HG.

Open: September 13, 2023, 11:15 a.m. to 12:00 p.m.

Agenda: EPCOT Concept.

Open: September 13, 2023, 12:00 p.m. to 12:45 p.m.

Agenda: Worker Training Program Concept.

Place: NIEHS, Building 101, Rodbell Auditorium, Research Triangle Park, NC.

Contact Person: David M. Balshaw, BA, Ph.D., Acting Director and Chief, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–27, Research Triangle Park, NC 27709–2233, 984–287–3234, balshaw@niehs.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.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility

will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: www.niehs.nih.gov/dert/c-agenda.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16854 Filed 8–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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: Center for Inherited Disease Research Access Committee.

Date: September 8, 2023.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892, (301) 402–8837, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16855 Filed 8–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Kidney, Urologic and Hematologic Diseases D Study Section.

Date: October 17–19, 2023.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Boulevard, Room 7343, Bethesda, MD 20892–2542 (301) 594–8898 hoffertj@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16857 Filed 8–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 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 attend and need special assistance, such as sign language interpretation or other reasonable accommodations, 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 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: Council of Councils.

Date: September 7, 2023.

Open: 10:00 a.m. to 3:15 p.m.

Agenda: Call to Order and Introductions; Announcements; NIH Program Updates; Strategic Plans; and Other Business of the Committee.

Place: National Institutes of Health, Building 1, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Closed: 3:15 p.m. to 4:15 p.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, Building 1, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Council of Councils, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, GriederF@mail.nih.gov, 301–435–0744.

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.

Information is also available on the Council of Council's home page at <http://dpcpsi.nih.gov/council/> where an agenda will be posted before the meeting date.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 2, 2023.

David W Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16853 Filed 8–7–23; 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 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 Institute on Aging Special Emphasis Panel; Epigenetics of Aging and Age-Associated Diseases.

Date: November 3, 2023.

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 (Virtual Meeting).

Contact Person: Joshua Jin-Hyok Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–9666, joshua.park4@nih.gov.

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

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16856 Filed 8–7–23; 8:45 am]

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