

nine participants whose submissions meet the eligibility and selection criteria in a 12-month period for the initial phase of the EDSTM.

FDA has a longstanding commitment to ensure medicines marketed in the United States are safe through continued surveillance and research following approval. In the postmarket setting, regulated industry is obligated to review all adverse drug experience information received or otherwise obtained and submit timely reports to FDA. Both industry and regulatory authorities face challenges with timely and efficient collection, processing, and evaluation of single and aggregate patient safety data compounded by ever-increasing case volumes. Advances in emerging technology have the potential to address some of these challenges by creating more efficiencies within a PV system. For example, early adopters of AI are leveraging these emerging technologies to automate fundamental tasks (e.g., adverse event intake, data entry, and processing) with the intention to drive down associated administrative burden and costs. These technologies can also make safety surveillance more efficient and effective by capturing, aggregating, and analyzing larger and more diverse data sets.

FDA recognizes industry’s interest in dialogue around AI capabilities that advance PV. Knowledge and awareness of emerging technology tools, such as AI, and how they are used to advance PV will help inform CDER’s regulatory approaches and policies. FDA expects that increased communication with industry and/or other relevant parties during EDSTMs will accelerate FDA’s understanding of how AI enabled tools are being used for PV, their associated risks and benefits, and barriers to implementation.

FDA has established an EDSTP website that includes EDSTM eligibility and selection criteria, instructions for submission of a meeting request, meeting request and package content descriptions, and submission timelines. The program’s website address is <https://www.fda.gov/drugs/science-and-research-drugs/cder-emerging-drug-safety-technology-program-edstp>.

II. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). For the initial phase of this program, FDA will request information from no more than nine sponsors. Initial requests from sponsors interested in participation in the program are not “information” in accordance with 5 CFR 1320.3(h)(1). Therefore, clearance by the Office of Management and Budget under the PRA is not required.

Dated: June 6, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–12770 Filed 6–10–24; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
[Document Identifier: 0937–0191–60D]
Agency Information Collection Request; 60-Day Public Comment Request
AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. The ICR is for extending the use of the approved information collection assigned OMB control number 0937–0191, which expires on June 30, 2024. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before August 12, 2024.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264–0041 and PRA@HHS.GOV.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937–0191–60D

and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, PRA@HHS.GOV or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Application Packets for Real Property for Public Health Purposes

Type of Collection: Reinstatement, with no change.
OMB No.: 0937–0191.
Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Real Property Assistance Program is requesting OMB approval on a previously approved information collection, 0937–0191. 40 U.S.C. 550 (the “Act”), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held exempt from taxation under section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Type of respondent: Responses are dependent on when Federal surplus real property is made available and is desired by a respondent/applicant for acquisition. Likely respondents include State, local, or Tribal units of government or instrumentalities thereof, and not-for-profit organizations.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Applications for surplus Federal real property	10	1	200	2,000
Total	10	1	200	2,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–12683 Filed 6–10–24; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Council of Research Advocates.

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 meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: National Cancer Institute Council of Research Advocates (NCRA).

Date: June 26, 2024.

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

Agenda: Welcome and Chairwoman's Remarks, NCI Director's Update, NCI Updates, and Legislative Update.

Place: National Institutes of Health, Building 31, 9000 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Amy Williams, Director, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, (301) 496–9723, william@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.

Information is also available on the Institute's/Center's home page: <https://deainfo.nci.nih.gov/advisory/ncra/ncra.htm>, where an agenda and any additional information for the meeting will be posted when available.

(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: June 6, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–12736 Filed 6–10–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; Understanding Neurobiology of Aging and Neurodegeneration.

Date: July 9, 2024.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7846, Bethesda, MD 20892–7846, 301–827–7238, zhaow@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member conflict: Topics on Biobehavioral Processes.

Date: July 9–10, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, (301) 435–6809, beheraak@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: June 6, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–12734 Filed 6–10–24; 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 Meetings

Pursuant to section 1009 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Special Emphasis Panel for Member Conflict Applications.

Date: July 1, 2024.

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

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20892, (301) 443–8599, espinozala@mail.nih.gov.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Fellowship Review Panel.

Date: July 9, 2024.

Time: 9:00 a.m. to 7:00 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).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol