

information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910-0119. The collections of information for general records and postmarket adverse experience reporting pertaining to biological products have been approved under OMB control number 0910-0308. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910-0230. The collections of information resulting from special protocol assessments have been approved under OMB control number 0910-0470. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910-0139. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910-0338. The collections of information in FDA's guidance entitled "Emergency Use Authorization of Medical Products and Related Authorities" have been approved under OMB control number 0910-0595. The collections of information pertaining to expedited review programs for serious conditions and under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as amended by the Food and Drug Administration Safety and Innovation Act) have been approved under OMB control number 0910-0765. The collections of information for the content and format of prescription drug labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, [https://www.fda.gov/regulatory-information/search-fda-](https://www.fda.gov/regulatory-information/search-fda)

[guidance-documents](https://www.regulations.gov/guidance-documents), or <https://www.regulations.gov>.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-08331 Filed 4-19-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS-0990-0419]

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.

DATES: Comments on the ICR must be received on or before June 20, 2023.

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 0990-New-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.

Type of Collection: Extension.

OMB No.: 0990-0419.

Abstract: The Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources, Office of Acquisitions, Acquisition Policy Division is requesting an approval by OMB for an extension of a previously approved information collection request, Acquisition Regulation Clause Patent Rights and Rights in Data. HHS found that systematically, over a period of several years, when Determination of Exceptional Circumstances (DEC) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR 27.306 were necessary. A DEC is executed consistent with the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.*, to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health.

Likely Respondents: administrative, technical, legal and management personnel.

ANNUALIZED BURDEN HOUR TABLE

Type of respondent and hours for each	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Technical (4), Legal (2), Management (2)	63	1	8	504
Technical (8), Legal (2), Management (2)	63	1	12	756
Technical (8), Legal (3), Management (1)	63	3	12	2,268
Technical (8), Legal (4), Management (2)	63	3	14	2,646
Technical (6), Legal (2), Management (2)	63	1	10	630
Technical (4), Legal (2), Management (2)	63	1	8	504
Administrative (8)	63	3	8	1,512
Administrative (2), Management (1)	63	3	3	567
Technical (4), Legal (2), Management (2)	63	3	8	1,512

ANNUALIZED BURDEN HOUR TABLE—Continued

Type of respondent and hours for each	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Total	10,899

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2023-08339 Filed 4-19-23; 8:45 am]
BILLING CODE 4150-04-P

Dated: April 14, 2023.
Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.
 [FR Doc. 2023-08289 Filed 4-19-23; 8:45 am]
BILLING CODE 4140-01-P

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

Name of Committee: National Institute on Aging Initial Review Group; Career Development for Clinicians/Health Professionals Study Section Career development for clinicians and health professional awards.

Date: June 12-13, 2023.
Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maurizio Grimaldi, M.D., Ph.D., Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-496-9374, grimaldim2@mail.nih.gov.

Name of Committee: National Institute on Aging Initial Review Group; Career Development for Early Career Investigators Study Section.

Date: June 26-27, 2023.
Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carmen Moten, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-8589, cmoten@mail.nih.gov.

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

Dated: April 14, 2023.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.
 [FR Doc. 2023-08295 Filed 4-19-23; 8:45 am]

BILLING CODE 4140-01-P

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; Topics in Immunology and Infectious Disease.

Date: May 8, 2023.
Time: 11:00 a.m. to 5:00 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: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867-5309, jiragedb@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

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 Initial Review Group; Career Development Facilitating the Transition to Independence Study Section.

Date: May 31-June 1, 2023.
Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (301) 496-6208, joshua.park4@nih.gov.

Name of Committee: National Institute on Aging, Initial Review Group; Career Development for Established Investigators and Conference Grants Study Section.

Date: June 12-13, 2023.
Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Even Hotel Rockville, Previously Holiday Inn, 1775 Rockville Pike, Rockville, MD 20852.