

The collection of information for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal has been approved under OMB control number 0910-0645.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/Biologics/BloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: October 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-23666 Filed 10-29-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0221]

Agency Information Collection Request; 30-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 November 29, 2019.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

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.

Title of the Collection: Family Planning Annual Report (FPAR).

Type of Collection: Renewal with change.

OMB No.: 0990-0221.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health is requesting an extension on a currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990-0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the Title X Family Planning Program ["Population Research and Voluntary Family Planning Programs" (Pub. L. 91-572)], which was enacted in 1970 as Title X of

the Public Health Service Act (Section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool will include a new module to collect substance use disorder (SUD) screening data in this request to extend an OMB approval to collect essential, annual data from Title X grantees.

Need and Proposed Use of the Information

The Title X Family Planning Program ("Title X program" or "program") is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (e.g., screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus). By law, priority is given to persons from low-income families (Section 1006(c) of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

Likely Respondents: Respondents for this annual reporting requirement are centers that receive funding directly from OPA for family planning services authorized and funded under the Title X Family

This weighted average hour burden accounts for differences in reporting burden by type of grantee agency grantee (e.g., public health department or private agency), as found in the 2009 FPAR Burden Study. For purposes of this estimate, the average hour burden ranges between 39 hours (public health department) and 32 hours (private agency).

ANNUALIZED BURDEN HOUR TABLE

Type of respondents	Form name	Number of respondents	Number of responses per respondents	Average annualized burden per response (hours)	Annualized total burden (hours)
Grantees	FPAR	93	1	36	3,348
Total	93	1	36	3,348

Terry Clark,

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

[FR Doc. 2019-23675 Filed 10-29-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; HIV Vaccines Clinical Trials Network Leadership and Operations Center (UM1 Clinical Trial Required).

Date: November 21, 2019.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Audrey O. Lau, Ph.D., MPH Acting Senior Scientific Review Officer, AIDS Review Branch, Scientific Review Program, RM 3E70, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852-9834, 240-669-2081, audrey.lau@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: November 25, 2019.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Audrey O. Lau, Ph.D., MPH Scientific Review Officer, AIDS Review Branch, Scientific Review Program, RM 3E70, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852-9834 240-669-2081 audrey.lau@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 24, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-23641 Filed 10-29-19; 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 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: Center for Scientific Review Special Emphasis Panel; PAR-19-177: High-End Instrumentation (HEI) Grant Program.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Songtao Liu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, Bethesda, MD 20817, 301-827-6828, songtao.liu@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Interdisciplinary Molecular Sciences and Technologies (S10).

Date: November 22, 2019.

Time: 9:00 a.m. to 7:00 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: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046B, MSC 7892, Bethesda, MD 20892, 301-408-9655, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Synapses, Neurodegeneration and Signaling.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4185, MSC 7850, Bethesda, MD 20892, (301) 402-3726, boycevs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Science B.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301-496-0726, prenticekj@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Science B.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Michael J. McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301-480-1276, mike.mcquestion@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Dermatology.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Interventions, Nursing & Aging.

Date: November 22, 2019.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rock Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mark Allen Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, mark.vosvick@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle Pathobiology and Regeneration.

Date: November 22, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Psychosocial Risks and Disease Prevention.

Date: November 22, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).