

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either 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

Dated: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0430, 0431, 0432, 0433, 0434]

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 26, 2018.

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: Crime Control Act—Requirement for Background Checks.

Type of Collection: Extension.

OMB No.: 0990–0430—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

Abstract: Crime Control Act—Requirement for Background Checks: Performance of HHS mission requires the support of contractors. In some circumstances, depending on the requirements of the specific contract, the contractor is tasked to provide personnel who will be working with children under the age of 18. After contract award, contractor personnel must undergo a criminal background check as required by HHS Acquisition Regulation (HHSAR) 337.103(d)(3) and the clause at HHSAR 352.237–72 Crime Control Act—Requirement for Background Checks before working on the contract as required by federal law (Crime Control Act of 1990). The contractor is therefore required to provide a list of the names of its relevant personnel for purposes of enabling HHS to conduct a criminal background check.

The Agency is requesting a 3 year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Business (contractor)	160	1	1	160
Total	160	1	1	160

Title of the Collection: Acquisitions Involving Human Subjects.

Type of Collection: Extension.

OMB No.: 0990–0431—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

Abstract: Acquisitions Involving Human Subjects: Performance of HHS mission requires the support of contractors involving human subjects. Before awarding a contract to any

contractor that will need to use human subjects, the Contracting Officer is required to verify that, the contractor holds a valid Federal Wide Assurance (FWA) approved by the Office for Human Research Protections (OHRP), as described in HHSAR Subpart 370.3—Acquisitions Involving Human Subjects. The provisions are implemented via contract clauses found at HHSAR 352.270–4a (Protection of Human Subjects), the clause at HHSAR 352.270–4b (Protection of Human

Subjects), the provision at HHSAR 352.270–10 (Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required), and the clause at HHSAR 352.270–11 (Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required).

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Business (contractor)	90	4	5	1,800

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Total	90	4	5	1,800

Title of the Collection: Acquisitions Involving the Use of Laboratory Animals.

Type of Collection: Extension.

OMB No.: 0990-0432—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

Abstract: Acquisitions Involving the Use of Laboratory Animals: Performance of HHS mission requires the use of live

vertebrate animals. Before awarding a contract to any contractor, which will need to use live vertebrate animals, the Contracting Officer is required to verify that the contractor holds a valid Animal Welfare Assurance (AWA) from the Office of Laboratory Animal Welfare (OLAW) within NIH. Contractors are required to show that they have an AWA or will have the appropriate Assurance as described in HHSAR Subpart 370.4—Acquisitions Involving

the Use of Laboratory Animals. The applicable clauses are found at HHSAR 352.270-5a (Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals), and the clause at HHSAR 352.270-5b (Care of Live Vertebrate Animals).

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Business (contractor)	36	1	3	108
Total	36	1	3	108

Title of the Collection: Indian Child Protection and Family Violence Act.

Type of Collection: Extension.

OMB No.: 0990-0433—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

Abstract: Indian Child Protection and Family Violence Act: Performance of IHS mission requires the support of contractors. In some circumstances,

depending on the requirements of the specific contract, the contractor is tasked to provide personnel who will be dealing with Indian children under the age of 18. After contract award contractor personnel must undergo a criminal background check as required by HHSAR 337.103(d)(4) and the clause at HHSAR 352.237-73 Indian Child Protection and Family Violence Act before working on the contract as

required by federal law (Indian Child Protection and Family Violence Act (ICPFVA)). The contractor is therefore required to provide a list of names of the relevant personnel so that a proper background check can be performed, as stated in the HHS Acquisition Regulation.

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Business (contractor)	40	4	1	160
Total	40	4	1	160

Title of the Collection: Meetings, Conferences, and Seminars.

Type of Collection: Extension.

OMB No.: 0990-0434—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

Abstract: Meetings, Conferences, and Seminars: Performance of HHS mission requires the support of contractors. In

some circumstances, depending on the requirements of the specific contract, the contractor is tasked to conduct meetings, conferences, and seminars. HHSAR 311.7101(a) (Responsibilities) and the clause at HHSAR 352.211-1 (Accessibility of meetings, conferences and seminars to persons with disabilities) require contractors to provide a plan describing the contractor's ability to meet the

accessibility standards in 28 CFR part 36. HHSAR 311.7202(b) (Responsibilities) and the clause at HHSAR 352.211-2 (Conference sponsorship request and conference materials disclaimer) require contractors to provide funding disclosure and a content disclaimer statement on conference materials. As a result of these clauses, HHS contractors providing conference, meeting, or

seminars services are required to provide specific information to HHS as

stated in the HHS Acquisition Regulation.

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Business (contractor)	1,604	1	1	1,604
Total	1,604	1	1	1,604

Terry Clark,

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

[FR Doc. 2018–23484 Filed 10–25–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; NRSA Individual Predoctoral and Postdoctoral Fellowship.

Date: November 2, 2018.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Room BC 1st Floor, Bethesda, MD 20817.

Contact Person: Richard A. Rippe, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda MD 20817, 301–443–8599, rippera@mail.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.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review Member Conflict Applications AA (03).

Date: November 28, 2018.

Time: 10:00 a.m. to 12:30 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 20817 (Telephone Conference Call).

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, Bethesda MD 20817, 301–443–4032, anna.ghambaryan@nih.gov.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review Member Conflict Applications ZAA1 AA (02).

Date: November 29, 2018.

Time: 12:30 a.m. to 3:00 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 20817 (Telephone Conference Call).

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, Bethesda MD 20817, 301–443–4032, anna.ghambaryan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: October 22, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23394 Filed 10–25–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice to Close 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 Institute of Nursing Research Special Emphasis Panel; Lasker Clinical Research Scholars Program.

Date: November 5, 2018.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Boulevard, 6701 Democracy Boulevard, Suite 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weiqun Li, MD., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 710, Bethesda, MD 20892, (301) 594–5966, wli@mail.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. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: October 19, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23429 Filed 10–25–18; 8:45 am]

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