

within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Tawanda Abdelmouti, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 805–C, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0978 or Email your request, including your address to ProjectClearanceBranch@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was

previously published in the **Federal Register** on April 22, 2021, page 21324 (86 FR 21234) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. Office of the Director, Office of Extramural Research (OER), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Inclusion Enrollment Form Conversion to Common Form—NEW, 0925–XXXX, Expiration Date XX/XX/XXXX, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: NIH’s Office of Extramural Research (OER) Office of Policy and Extramural Research Administration (OPERA) is converting the Inclusion Enrollment Report form to allow its use by the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 194,574.

ESTIMATED ANNUALIZED BURDEN HOURS

| Information collection forms | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|---------------------------------|-----------------------|------------------------------------|--|---------------------------|
| Inclusion enrollment form | 64,858 | 1 | 3 | 194,574 |
| Total | | 64,858 | | 194,574 |

Dated: July 30, 2021.
Lawrence A. Tabak,
Principal Deputy Director, National Institutes of Health.
 [FR Doc. 2021–17037 Filed 8–6–21; 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 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 on Aging Special Emphasis Panel; AD Risk Factors.

Date: September 8, 2021.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–496–9667, nijaguna.prasad@nih.gov.

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

Dated: August 4, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16950 Filed 8–6–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; PHS Applications and Pre-Award Related Reporting (Office of the Director)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/

PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or Email your request, including your address to *ProjectClearanceBranch@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 12, 2021, pages 18992–18993 (86 FR 18992) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director (OD), Office of Policy and Extramural Research Administration (OPERA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Public Health Service (PHS) Applications and Pre-Award Reporting Requirements, Revision, OMB 0925–0001, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection is being revised to omit the Inclusion Enrollment Report form, which is being converted to a Common form to include the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. Starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the *Grants.gov* updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more accurate assessment of the time it takes our applicants to complete the various forms and applications. This collection also continues to includes PHS applications and pre-award reporting requirements: PHS 398 [paper] Public Health Service Grant Application forms and instructions; PHS 398 [electronic] PHS Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R); PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships [electronic]; PHS 416–1 Ruth L. Kirschstein National Research Service Award Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]; Instructions for a Change of Sponsoring Institution for NRSA Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships; PHS 416–5 Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice; and PHS 6031 Payback Agreement. The PHS 398 (paper and electronic are currently approved under 0925–0001. All forms expire 2/28/2023. Post-award reporting

requirements are simultaneously consolidated under 0925–0002 and include the Research Performance Progress Report (RPPR). The PHS 398 and SF424 applications are used by applicants to request Federal assistance funds for traditional investigator-initiated research projects and to request access to databases and other PHS resources. The PHS 416–1 is used only for a change of sponsoring institution application. PHS Fellowship Supplemental Form and agency specific instructions is used in combination with the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416–5 is used by individuals to indicate the start of their NRSA awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements will facilitate NIH’s development of data systems to facilitate oversight of clinical trials as well as understand where gaps in the research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with *ClinicalTrials.gov*.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,023,454.

| Information collection forms | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|---|-----------------------|------------------------------------|--|---------------------------|
| PHS 398—Paper | | | | |
| PHS 398/424—Electronic | 4,247 | 1 | 35 | 148,645 |
| PHS Assignment Request Form | 37,120 | 1 | 30/60 | 18,560 |
| PHS 398 Cover Page Supplement | 74,239 | 1 | 1 | 74,239 |
| PHS 398 Modular Budget | 56,693 | 1 | 1 | 56,693 |
| PHS 398 Training Budget | 1,122 | 1 | 2 | 2,244 |
| PHS 398 Training Subaward Budget Attachment(s) Form | 561 | 1 | 90/60 | 842 |
| PHS 398 Research Plan | 70,866 | 1 | 10 | 708,660 |
| PHS 398 Research Training Program Plan | 1,122 | 1 | 10 | 11,220 |

| Information collection forms | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|---|-----------------------|------------------------------------|--|---------------------------|
| Data Tables | 1,515 | 1 | 4 | 6,060 |
| PHS 398 Career Development Award Supplemental Form | 2,251 | 1 | 10 | 22,510 |
| PHS Human Subjects and Clinical Trial Information | 54,838 | 1 | 13 | 712,894 |
| Biosketch (424 Electronic) | 80,946 | 1 | 2 | 161,892 |
| PHS Fellowship Supplemental Form (includes F reference letters) | 6,707 | 1 | 12.5 | 83,838 |
| Biosketch (Fellowship) | 6,707 | 1 | 2 | 13,414 |
| 416-1 | 29 | 1 | 10 | 290 |
| PHS 416-5 | 6,707 | 1 | 5/60 | 559 |
| PHS 6031 | 6,217 | 1 | 5/60 | 518 |
| VCOC Certification | 6 | 1 | 5/60 | 1 |
| SBIR/STTR Funding Agreement Certification | 1,500 | 1 | 15/60 | 375 |
| Total | | 413,393 | | 2,023,454 |

Dated: July 30, 2021.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2021-17031 Filed 8-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be held as a virtual meeting and is open to the public. 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 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: National Advisory Child Health and Human Development Council.

Date: September 9-10, 2021.

Open: September 9, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, NICHD Director's Report, and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 10, 2021, 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20894 (Virtual Meeting).

Contact Person: Ms. Lisa Neal, Committee Management Officer, Committee Management Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6701B Rockledge Drive, Room 2208, Bethesda, MD 20892, (301) 204-1830, lisa.neal@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.

Individuals will be able to view the meeting via NIH Videocast. Select the following link for Videocast access instructions: <http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx>.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: August 4, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-16914 Filed 8-6-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration's National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given of the meeting on August 30, 2021 of the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Advisory Council (SAMHSA NAC). The meeting is open to the public and can only be accessed virtually. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: <https://www.samhsa.gov/about-us/advisory-councils/meetings>. The meeting will include remarks and discussion with the new Assistant Secretary for Mental Health and Substance Use; updates on SAMHSA priorities; follow up on topics related to the previous SAMHSA NAC meeting; new grant opportunities and initiatives, and a council discussion on clinical trends and emerging national issues with SAMHSA NAC members.

DATES: August 30, 2021, 1:00 p.m. to approximately 5:00 p.m. (EDT)/Open.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Carlos Castillo, Committee Management