

—if relevant, related FDA guidances or existing programs addressing the challenge highlighted in the submission.

Notice of this meeting series is given pursuant to 21 CFR 10.65.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10801 Filed 6–12–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Sudden Unexpected Infant Death Prevention

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing period of performance extension with funding for the Sudden Unexpected Infant Death (SUID) Prevention Program.

SUMMARY: HRSA will provide additional award funds to the one recipient of the SUID Prevention Program with period of performance ending in fiscal year 2025 to extend the current period of performance by 12 months to continue the activities of the program related to reducing infant deaths.

FOR FURTHER INFORMATION CONTACT: Diane Pilkey, Senior Nurse Consultant, Division of Child Adolescent and Family Health, Maternal and Child Health Bureau, Health Resources and Services Administration, at dpilkey@hrsa.gov and 301–500–9637.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: American Academy of Pediatrics (AAP).

Amount of Non-Competitive Award(s): One Award of \$500,000.

Project Period: July 1, 2025, through June 30, 2026.

Assistance Listing (CFDA) Number: 93.110.

Award Instrument: Cooperative Agreement.

Authority: This non-competitive supplemental funding is authorized by 42 U.S.C. 701(a)(2) (title V, sec. 501(a)(2) of the Social Security Act).

Purpose/Justification: HRSA will provide a non-competitive supplement of \$500,000 to the SUID Prevention Program recipient, AAP, to extend the period of performance by an additional year, July 1, 2025, to June 30, 2026, to connect families with the resources that

they need and to help improve family capacity to practice safe sleep. This Program was awarded on July 1, 2022, for a 3-year period (HRSA 22–082). The purpose of the program is to reduce overall rates of SUID by supporting pediatric health care practitioners to provide evidence-based counseling and education to infant caregivers and families; to guide system improvements; and to identify and support policy changes that address state- and community-specific SUID risks. The awardee has demonstrated progress during this period and will be able to expand that progress if extended by 1 year.

Funds are available for award for this non-competitive supplement. A non-competitive supplement is necessary to ensure on time, high-quality implementation of best practices for reducing infant deaths that the current recipient is uniquely positioned to continue. The recipient is in good standing with current HRSA grant requirements and has been a leader in Sudden Infant Death Syndrome (SIDS) and SUID prevention for decades, starting with the initial Back to Sleep campaign in the 1990s that urged parents and caregivers to place infants to sleep supine following the emergence of data that supported this recommendation. More recently, the AAP Task Force on SIDS has published comprehensive recommendations for the prevention of SIDS, Accidental Suffocation and Strangulation in Bed, and other sleep-related deaths, based on a detailed and impartial analysis of all available evidence. In addition, AAP directs several initiatives aimed at improving child health outcomes.

The current recipient will use their existing infrastructure to maintain implementation without disruption and they are the only organization with a unique existing network of practicing pediatricians and related professionals who are part of a National Safe Sleep Champion Network, a network of pediatrician experts in safe sleep to promote safe sleep recommendations and education for providers to better serve families.

The recipient will be expected to ensure continued efforts around reducing infant deaths by disseminating and implementing best practices, increasing connections with state and local infant fatality review teams and AAP Chapters, supporting implementation of a community

engagement toolkit, and expanding their National Safe Sleep Champion Network.

Thomas J. Engels,
Administrator.

[FR Doc. 2025–10738 Filed 6–12–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0278]

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 July 14, 2025.

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:

Natalie Klein, Natalie.Klein@hhs.gov or (240) 453–6900. When submitting comments or requesting information, please include the document identifier 0990–0278–30D and project title, Federalwide Assurance (FWA) Form, 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: Federalwide Assurance (FWA) Form.

Type of Collection: Revision.

OMB No.: 0990–0278.

Abstract: The Office of the Assistant Secretary for Health, Office for Human

Research Protections (OHRP) is requesting a revision of the currently approved collection for the OMB No. 0990–0278, Federalwide Assurance (FWA) Form. The form is currently approved through October 31, 2026. The purpose of the FWA form is to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the assurance requirements of (1) Section 491(a) of the Public Health Service Act (the PHS Act) (42 U.S.C. 289); and (2) HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this

information collection are institutions engaged in HHS-conducted or supported research involving human subjects. With this revision, OHRP is seeking to remove information from the FWA form to adopt the changes for assurances at 45 CFR 46.103 of the 2018 Requirements and reduce burden on respondents. The proposed changes to the FWA form include: (1) removing the Pre-2018 Common Rule requirement that institutions provide a statement of ethical principles; (2) removing the Pre-2018 Common Rule requirement that an institution designate one or more IRBs to review the research to which the FWA applies; (3) removing “check the

box”, or the option for U.S. institutions to voluntarily apply the Common Rule, or the Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46, to all of an institution’s nonexempt human subjects research regardless of the source of support; and (4) eliminating the requirement for institutions outside the U.S. to provide procedural standards they apply for human subjects research when assuring compliance with the Terms of the Federalwide Assurance. Updates to the software applications OHRP uses to manage the FWA application process will be deployed to enable such changes.

ANNUALIZED BURDEN HOUR TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
Federalwide Assurance (FWA)	13,000	1.0	0.33	4,290
Total	4,290

Catherine Howard,

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

[FR Doc. 2025–10739 Filed 6–12–25; 8:45 am]

BILLING CODE 4150–36–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 1009 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 open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, 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/>.

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, 2025.

Open: September 09, 2025, 9:30 a.m. to 10:30 a.m.

Agenda: NICHD Director’s Report and other Council Business.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (In Person and Virtual Meeting).

Open: September 09, 2025, 12:45 p.m. to 5:00 p.m.

Agenda: Council Business.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (In Person and Virtual Meeting).

Closed: September 10, 2025, 9:45 a.m. to 12:45 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892, (In Person and Virtual Meeting).

Contact Person: Rebekah S. Rasooly, Ph.D., Director, Division of Extramural Activities, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2316, Bethesda, MD 20817, Phone: 301–827–2599, Email: Rebekah.rasooly@nih.gov.

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: June 10, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–10779 Filed 6–12–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Institute of General Medical Sciences Special Emphasis Panel, Review of the Centers of Biomedical Research Excellence (COBRE) Phase 1, July 09, 2025, 9:30 a.m. to July 10, 2025, 6:00 p.m., National Institute of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 which was published in the **Federal Register** on April 4, 2025, FR Doc. 2025–05832, 90 FR 14842.

This meeting has been transferred from National Institute of General Medical Sciences (NIGMS) to Center for Scientific Review CSR.