compounds with both similar structure and similar mechanism of action, and in silico) may be more appropriate to estimate a starting dose in the FIH trial. In addition, QSP modeling may derive potential efficacy- and safety-related information and balance them in a quantitative manner to inform FIH dose selection. This guidance specifically addresses those needs by outlining how QSP models can be developed and used to estimate a MABEL for drugs and biological products entering FIH trials.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance document contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312, including the submission of rationale and dose determination, as set forth in part 312.23; the submission of detailed technical information, as set forth in part 312.31; and the submission of meeting requests and supporting documentation, as set forth in part 312.47, have been approved under OMB control number 0910–0014.

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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12619 Filed 6–22–26; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

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: Council of Councils.

Date: July 13, 2026.

Time: 03:00 p.m. to 04:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual.

Contact Person: Robin I. Kawazoe, Deputy Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892, 301–402–9852, *kawazoer@mail.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.

Information is also available on the Council of Council's home page: *http://dpcpsi.nih.gov/council/* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: June 18, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–12617 Filed 6–23–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2026 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for one eligible grant recipient funded in FY 2024 under the Prevention Technology Transfer Centers Cooperative Agreements, Notice of Funding Opportunity (NOFO) SP–24–002. The recipient may receive up to $1,198,000. The recipient has a project end date of September 29, 2029. The supplemental funding supports the implementation of a substance use prevention fellowship program. The program will be developed in collaboration with national-level state and community organizations and aims to develop and sustain a highly trained and knowledgeable workforce of prevention professionals drawn from communities that have faced challenges in maintaining sufficient prevention staffing to meet the full scope of community needs. Fellows will be equipped to understand, apply, and exemplify the core principles and evidence-based best practices of substance use prevention. This program will support a state level fellowship program and a community level program. This program will also prepare fellows to achieve certification from the International Certification and Reciprocity Consortium (IC&RC). The supplemental funding will support fellows in the following areas: hands-on experience working in state agencies and community organizations while