''Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.'' FDA is issuing this guidance as mandated under section 3602 of FDORA, which requires that FDA update or issue guidance relating to the format and content of diversity action plans required by sections 505(z) and 520(g) of the FD&C Act (21 U.S.C. 355(z) and 360j(g) as amended by section 3601 of FDORA. This draft guidance describes the form, content, and manner of diversity action plans, the applicable medical products, and clinical studies for which a diversity action plan is required, the timing and process for submitting diversity action plans, and the criteria and process by which FDA will evaluate sponsors' requests for waivers from the requirement to submit a Diversity Action Plan. This draft guidance replaces the draft guidance for industry entitled ''Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials,'' published April 14, 2022 (87 FR 22211). The 2022 draft guidance, which issued prior to FDORA becoming law on December 29, 2022, provided recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll representative numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

Clinical studies characterize the safety and effectiveness of medical products intended for the prevention, treatment, or diagnosis of many conditions or diseases. Some populations in the United States are frequently underrepresented in biomedical research including in clinical studies, even when they have a disproportionate burden for certain conditions or diseases relative to their proportional representation in the general population. There are myriad reasons for this, including but not limited to assumptions regarding the feasibility of enrolling a population in a clinical study that is representative of the intended use population and the impact on study timelines, and the lack of the prospective development and implementation of a strategy that helps ensure enrollment and retention of a clinical study population representative of the intended use population.

Consistent with section 3602(a) of FDORA, this draft guidance primarily focuses on Diversity Action Plans for the enrollment and retention of a clinically relevant study population, to help ensure adequate representativeness of study participants that reflect different age groups, sexes, and racial and ethnic demographic characteristics. However, FDA recognizes the broader issues regarding health disparities and differential access to health care and clinical studies that may occur based on other factors, including but not limited to, geographic location, gender identity, sexual orientation, socioeconomic status, physical and mental disabilities, pregnancy status, lactation status, and comorbidity, and encourages sponsors to consider such additional factors when developing Diversity Action Plans. We welcome comments on how sponsors could effectively consider such additional factors, as appropriate, to broaden their Diversity Action Plans to include all clinically relevant populations. This draft guidance is one of many efforts by FDA to help address the participation of underrepresented populations to help ensure that clinical trials relating to FDA regulated products appropriately test the product against a representative sample of the product's intended use population.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. See 21 CFR 10.115(d). Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

An exception to that framework derives from the requirement in section 3601 of FDORA for FDA to specify in guidance the form and manner for the submission of Diversity Action Plans. Accordingly, insofar as Section VII of this document specifies the form and manner for submission of a Diversity Action Plan, it will have binding effect, once this guidance is finalized, as indicated by the use of the words, *must, shall,* or *required.*

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a separate issue of the **Federal Register**.

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.*

Dated: June 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14284 Filed 6–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): National Institute for Mental Health Strategic Plan Evaluation.

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Mental Health (NIMH), National Institutes of Health (NIH) is soliciting feedback on its current Strategic Plan for Research to inform the development of future strategic plans.

DATES: Comments must be received on or before (11:59:59 p.m. ET) on July 24, 2024 to ensure consideration.

ADDRESSES: Responses to this RFI must be submitted electronically using the web-based form at: *https://rfi.grants.nih.gov/?s=662fcf74748dc0f159063c02.*

FOR FURTHER INFORMATION CONTACT: Eliza Jacobs-Brichford, Ph.D., Science Policy and Evaluation Branch, Office of Science Policy, Planning, and Communications (OSPPC), National Institute of Mental Health, 6001 Executive Boulevard, MSC 9663, Telephone: 1–866–615–6464 (toll-free), 1–301–443–8431 (TTY), 1–866–415–8051 (TTY toll-free), Fax: 1–301–443–4279, Email: *NIMHStratPlan@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

NIMH is the lead Federal agency for research on mental illnesses. NIMH's mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. NIMH is guided by its Strategic Plan for Research, which outlines the institute's priorities, spanning fundamental science to public health impact. This notice is in accordance with the 21st Century Cures Act; NIH Institutes are required to regularly update their strategic plans.

Information Requested

NIMH is seeking feedback on its current Strategic Plan for Research (*https://www.nimh.nih.gov/about/strategic-planning-reports*) to improve the potential usability, effectiveness, and impact of future strategic plans. In particular, NIMH is interested in learning:

- Who is using the Strategic Plan
- How people are using the Strategic Plan
- What elements (*e.g.,* content, format, organization) in the Strategic Plan are useful, and which are not
- What is missing from the Strategic Plan

Submitting a Response

Responses are welcome from all interested parties, including but not limited to academic and research institutions; professional associations, organizations, and societies; advocacy organizations; and members of the public. We appreciate your input and invite you to share this RFI opportunity with your colleagues and others in your community. This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the Federal Government in general, the NIH, or NIMH specifically. Responses to this RFI are voluntary. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information shared or provide feedback to respondents with respect to any information submitted.

Submitted information will not be considered confidential. No proprietary, classified, confidential, or sensitive information should be included in your response.

Shelli Avenevoli,

Acting Director, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2024–14251 Filed 6–27–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 1009 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 General Medical Sciences Special Emphasis Panel; Review of R25, UE5 and R13 applications.

Date: July 9, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, Maryland 20892, 301–435–0807, *slicelw@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: June 11, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–14205 Filed 6–27–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Final Draft National Institute of Environmental Health Sciences FY2025–FY2029 Strategic Plan

AGENCY: National Institutes of Health, HHS.

ACTION: Request for comments.

SUMMARY: The goal of the National Institute of Environmental Health Sciences (NIEHS) strategic planning process is to set scientific areas of emphasis and priority approaches to anticipate and meet areas of opportunity for furthering environmental health sciences research, training, and translation. NIEHS makes available the final draft of the FY2025–FY2029 NIEHS Strategic Plan.

DATES: Comments must be received by 11:59:59 p.m. (ET) on July 21, 2024, to ensure consideration.

ADDRESSES: Comments should be submitted by email to *ehs-strategic-plan@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Nicole J. Garbarini, Office of Scientific Coordination, Planning, and Evaluation, email: *ehs-strategic-plan@niehs.nih.gov* or call non-toll-free number 301–435–4642.

SUPPLEMENTARY INFORMATION: This **Federal Register** notice is in accordance with the 21st Century Cures Act, requiring NIH and its Institutes and Centers to regularly update their strategic plans. NIEHS is one of the 27 institutes and centers that makes up the National Institute of Health, and conducts and supports research on factors in the environment that affect human health.

The mission of the NIEHS is to discover how the environment affects people, in order to promote healthier lives. The vision of the NIEHS is to provide global leadership for innovative research that improves public health by preventing disease and disability. NIEHS research covers all organ systems, diseases, and conditions that could be caused or affected by environmental impacts, which are defined broadly. The NIEHS achieves its mission and vision through multidisciplinary biomedical research programs, as well as prevention and intervention efforts. NIEHS research is disseminated to inform evidence-based environmental health policies to prevent disease and protect health. The NIEHS also focuses on communication and research translation strategies that encompass training, education, technology transfer, and community engagement.

During January 31–April 20, 2023, NIEHS solicited input to its strategic planning process through public comments on its 2018–2023 Strategic Plan and its associated goals, as well as any other aspect of environmental health sciences. Approximately 169 unique responses, both individual and group, were received in response to this RFI. In April 2023, NIEHS hosted a virtual community workshop including more than 100 invited participants from across diverse sectors to provide input