

psychopharmacology, psychiatry, epidemiology, statistics, and related specialties, as well as needed consumer and industry representation. FDA also follows the requirements in section 505(n)(3) regarding membership of drug product advisory committees. (21 U.S.C. 355(n)(3)).

Ensuring Fair Balance: Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area.

Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

4. List of all other Federal advisory committees of the agency:

FDA maintains the following Federal advisory committees:

- Anesthetic and Analgesic Drug Products Advisory Committee
- Antimicrobial Drugs Advisory Committee
- Blood Products Advisory Committee
- Cardiovascular and Renal Drugs Advisory Committee
- Cellular Tissue and Gene Therapies Advisory Committee
- Dermatologic and Ophthalmic Drugs Advisory Committee
- Device Good Manufacturing Practice Advisory Committee
- Digital Health Advisory Committee
- Drug Safety and Risk Management Advisory Committee
- Endocrinologic and Metabolic Drugs Advisory Committee
- Gastrointestinal Drugs Advisory Committee
- Genetic and Metabolic Disease Advisory Committee
- Medical Devices Advisory Committee
- National Mammography Quality Assurance Advisory Committee (Administratively Inactive)
- Nonprescription Drugs Advisory Committee
- Obstetrics Reproductive and Urologic Drugs Advisory Committee
- Oncologic Drugs Advisory Committee
- Patient Engagement Advisory Committee
- Pediatrics Advisory Committee
- Peripheral and Central Nervous System Advisory Committee
- Pharmacy Compounding Advisory Committee
- Pulmonary-Allergy Drugs Advisory Committee
- Risk Communication Advisory Committee (Administratively Inactive)

- Science Board to the Food and Drug Administration
- Technical Electronic Product Radiation Safety Standards Committee
- Tobacco Products Scientific Advisory Committee

5. Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source:

The Committee advises and informs the Commissioner or designee(s) about the existing and relevant evidence of benefits and risks of marketed and investigational human drug products for use in the practice of psychiatry and related specialties.

The topics considered by the Psychopharmacologic Drugs Advisory Committee require specialized expertise in the practice of psychiatry and related specialties that is not within the primary scope of other FDA advisory committees. As such, these issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue:

Summary of Previous Accomplishments: The Psychopharmacologic Drugs Advisory Committee serves the public interest by ensuring that patients with psychiatric conditions have access to safe and effective treatments through informed regulatory decision-making.

In 2024, the committee met jointly with the Drug Safety and Risk Management Advisory Committee and discussed the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. The issues the Committees discussed included whether clozapine healthcare providers have sufficient knowledge and access to resources about the risk of neutropenia and need for absolute neutrophil count (ANC) monitoring, and whether ANC monitoring would be performed without the requirements of the REMS.

Impact: The committee's recommendations informed the FDA's decision to no longer expect prescribers, pharmacies, and patients to participate in the REMS program for clozapine or

to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business:

The Committee plays a critical role in enabling FDA to meet the requirements of section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. The Psychopharmacologic Drugs Advisory Committee is the only FDA advisory committee that provides specialized expertise in the practice of psychiatry and related fields. Without the Psychopharmacologic Drugs Advisory Committee, FDA's ability to obtain external input on issues related to the approval and regulation of drug products for psychiatric indications would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health 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 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: June 22, 2026.

Closed: 9:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: 11:00 a.m. to 1:45 p.m.

Agenda: Presentation of the NIMH Director's report, discussion of NIMH programs, and concept clearances.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Elizabeth S Church, Ph.D., Acting Director, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, Bethesda, MD 20892. (301) 496-4000 elizabeth.church@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 Institute's/Center's home page: www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 26, 2026,

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Extension to the Currently Approved 0930-0395 0930-0395 Generic Clearance for Grant Program Monitoring Activities

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting approval from the Office of Management and Budget (OMB) for an extension of the generic information collection request (ICR) entitled Generic Clearance for Grant Program Monitoring Activities currently approved under the OMB number 0930-0395. This generic ICR allows SAMHSA to collect standardized information from its grant recipients necessary to perform agency program oversight activities such as monitoring progress on recipient activities and determining and responding to recipient's training and technical assistance (T/TA) needs. SAMHSA currently manages grant programs that provide prevention, treatment, recovery support services, and T/TA for substance use treatment and mental health providers along the continuum of care including prevention, harm reduction, treatment, and

recovery. To carry out OMB Circular A-102¹ and 2 CFR part 215.51,² SAMHSA must collect grant program information necessary to ensure compliance with federal and programmatic requirements.

SAMHSA's grant recipients are currently required to submit various types of performance reports in accordance with their individual program requirements. For example, recipients often submit bi-annual progress reports as one form of information collection.

When required, performance reports shall generally contain, for each award, brief information on each of the following:

- Update on the status of key personnel required by the grant and staffing levels proposed by the recipient.
- Annual number of clients served, or individuals trained compared to the proposed/planned and the actual clients served/individuals trained.
- Comparison of actual progress and accomplishments with the goals and objectives established for the period.
- Obstacles and next steps for achieving established goals that were not met, if appropriate.
- Success stories of positive outcomes of clients served or impact of the program on the community.
- Other pertinent information including, when appropriate, program specific questions that reflect statutory requirements, the agency's strategic priorities, and/or program's policy goals.
- Information previously requested in a grant Notice of Funding Opportunities (NOFO).

SAMHSA program offices have ever-evolving monitoring needs, dependent on both internal and external factors, such as, but not limited to current grant recipient activities and needs; uses of federal funds; changes to aspects of programs based on statutory authority, federal regulations or policy, and/or Congressional appropriations; availability of program office funds for site visits (desk monitoring); matters of importance related to national health and safety needs of the public, or other events that lead to program changes. There are times when standardized collections of quantitative and qualitative information allows for program offices the ability to monitor recipient activities and needs.

A generic clearance would provide SAMHSA's program offices the

¹ Circular A-102: Grants and Cooperative Agreements with State and Local Governments.

² 2 CFR part 215.51: <https://www.govinfo.gov/content/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-subtitleA.pdf>.