DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods: Request for Comment on Draft Report on Validation, Qualification, and Acceptance of New Approach Methodologies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces availability of the draft document, ''Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies.'' ICCVAM will accept public comments on the document through September 5, 2023; 5:00 p.m. EDT.

DATES:

Document Availability: The draft document is available at *https://ntp.niehs.nih.gov/go/ICCVAM-submit.*

Written Public Comments Submissions: Submit comments to *amber.daniel@inotivco.com* by September 5, 2023; 5:00 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Director, National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), email: *nicole.kleinstreuer@nih.gov,* telephone: 984–287–3150.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM, a congressionally mandated committee, promotes the scientific validation and regulatory acceptance or qualification of testing methods that accurately assess the chemical safety and hazards of relevant products in an effort to replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

Shortly after its establishment as a standing committee in 1997, ICCVAM published a report, ''Validation and Regulatory Acceptance of Toxicological Test Methods,'' which outlined criteria for the validation and regulatory acceptance for new and alternative test methods (62 FR 11901). This and subsequent related documents described a validation model that, while being initially useful, has lately demonstrated limitations such as being lengthy and resource-intensive and not being compatible with many modern approaches to toxicity testing. Furthermore, for some contexts of use, methods may not need to undergo every step of the validation process described by these documents to yield valuable data for a federal agency.

In 2021, ICCVAM established its Validation Workgroup to update the 1997 document and align it with the principles articulated in the 2018 ICCVAM publication, ''A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States'' (83 FR 7487). The Strategic Roadmap provides a conceptual framework promoting better communication between agencies and test method developers and more flexibility in how confidence is established, to help ensure the adoption of new methods by federal agencies and regulated industries once validated for a specific purpose or context of use.

A draft version of the new document, ''Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies,'' is now available for public comment.

Requests for Comments: ICCVAM invites public comments from all ICCVAM stakeholders on the draft document. The document can be found on the NICEATM website at *https://ntp.niehs.nih.gov/go/ICCVAM-submit.*

Stakeholders may submit comments via email to Ms. Amber Daniel at *amber.daniel@inotivco.com.* Commenters should include their name, affiliation (if any), mailing address, telephone, email, and sponsoring organization (if any) with their comments. Guidelines for public statements submitted to NTP are available at at *http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.* All comments received will be posted on the NICEATM website and identified by the individual's name, affiliation, and sponsoring organization. Comments should be received by September 5, 2023; 5:00 p.m. EDT, to ensure consideration as the draft document is finalized.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at *https://ntp.niehs.nih.gov/go/iccvam.*

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at *https://ntp.niehs.nih.gov/go/niceatm.*

Dated: August 4, 2023.

Richard P. Woychik,

Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health.

[FR Doc. 2023–17120 Filed 8–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Neurotrauma and dementia.

Date: September 12, 2023.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, RM: 3208, Bethesda, MD 20892, 301–496–3562, *neuhuber@ninds.nih.gov*.

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

Dated: August 4, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–17123 Filed 8–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; 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 at *carlos.graham@samhsa.hhs.gov*.

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.

Project: SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment

SAMHSA is requesting approval from the Office of Management and Budget (OMB) for their Generic clearance for purposes of conducting qualitative research. SAMHSA conducts qualitative research to gain a better understanding of emerging substance use and mental health policy issues, improve the development and quality of instruments, and to ensure SAMHSA leadership, centers and offices have recent data and information to inform program and policy decision-making. SAMHSA is requesting approval for at least four types of qualitative research: (a) interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods.

SAMHSA is the agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders, and their families. It's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes. SAMHSA pursues this mission by providing grant funding opportunities and guidance to states and territories, as well as tribal and local communities; technical assistance to grantees and practitioners; publishing and sharing resources for individuals and family members seeking information on prevention, harm reduction, treatment and recovery; collecting, analyzing, and sharing behavioral health data; collaborating with other Federal agencies to evaluate programs and improve policies; and raising awareness of available resources through educational messaging campaigns and events. Integral to this role, SAMHSA conducts qualitative research and evaluation studies, develops policy analyses, and estimates the cost and benefits of policy alternatives for SAMHSA related programs.

Qualitative research and assessment are the main objectives of the activities included in this clearance. The goal of establishing the SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment is to help public health officials, policymakers, community practitioners, and the public to understand mental health and substance use trends and how they are evolving; inform the development and implementation of targeted evidence-based interventions; focus resources where they are needed most; and evaluate the success of programs and policies. A key objective is to decrease the burden on stakeholders while expanding and improving data collection, analysis, evaluation, and dissemination. To achieve this objective, SAMHSA is streamlining and modernizing data collection efforts, while also coordinating evaluation across the agency to ensure funding and policies are data driven. Additionally, the agency is utilizing rigorous evaluation and analytical processes that are in alignment with the Foundations for Evidence-Based Policymaking Act of 2018. SAMHSA, using robust methods to collect, analyze, and report valid, reliable, trustworthy, and protected data, is key to improving and impacting behavioral health treatment, prevention, and recovery for communities most in need. By using rigorous methods, and improving the quality and completeness of program data, data can be disaggregated across different population groups to assess disparities within the behavioral health care system. SAMHSA's vision will be accomplished by better leveraging optimal data to inform the agency's policies and programs.

The qualitative research participants will include grant recipients; policy experts; national, state, and local public health representatives; human service, and healthcare providers; and representatives of other health organizations. A variety of instruments and platforms will be used to collect information from respondents. The annual burden hours requested (15,000) are based on the number of collections we expect to conduct over the requested period for this clearance. The burden estimates were calculated based on the amount of IC submissions to the 0930–0393 Fast Track Generic Clearance for the Collection of Qualitative Feedback on the Substance Abuse and Mental Health Services Administration (SAMHSA) Service Delivery that are ineligible for OMB approval under it. This Generic information collection will provide a viable replacement option. Internal assessments of projected IC submission over the next three years estimate the burden hours for this information collection to be