

Dated: September 9, 2022.

**Paul Reed,**

*Deputy Assistant Secretary for Health,  
(Disease Prevention and Health Promotion).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Assistant Secretary for Administration for Strategic Preparedness and Response; Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Preparedness and Response (ASPR), or their successor, the priorities authority under Section 101 of the Defense Production Act (DPA) of 1950, as amended (50 U.S.C. 4501, *et seq.*), as delegated to the Secretary of the U.S. Department of Health and Human Services (HHS) by section 201 of Executive Order 13603, dated March 16, 2012 (77 FR 16651; 3 CFR, 2012, Comp., p. 225), subject to the limitation stated herein. The delegation authorizes the ASPR, on behalf of the Secretary, to approve DO-HR<sup>1</sup> priority rating requests for health resources that promote the national defense. The delegation excludes the authority to approve all priorities provisions for health resources that require DX-HR priority ratings. This delegation does not confer authority to issue regulations.

**FOR FURTHER INFORMATION CONTACT:** Paige Ezernack; Defense Production Act Office; Administration for Strategic Preparedness and Response; U.S. Department of Health and Human Services; phone: (202) 260-0365; email: [Paige.Ezernack@hhs.gov](mailto:Paige.Ezernack@hhs.gov).

**Xavier Becerra,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report: 2020-2021; Availability of Report

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Toxicology Program (NTP) Interagency Center for

the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2020-2021. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000, describes activities and accomplishments from January 2020 through December 2021.

**ADDRESSES:** The report is available at <https://ntp.niehs.nih.gov/go/2021iccvamreport>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Nicole Kleinstreuer, Acting Director, NICEATM, Division of Translational Toxicology, NIEHS, P.O. Box 12233, K2-17, Research Triangle Park, NC 27709. Phone: 984-287-3150, Email: [nicole.kleinstreuer@nih.gov](mailto:nicole.kleinstreuer@nih.gov). Hand Deliver/Courier address: 530 Davis Drive, Room K2032, Morrisville, NC 27560.

#### SUPPLEMENTARY INFORMATION:

##### Background

The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare "reports to be made available to the public on its progress under this Act." The eleventh progress report describing ICCVAM activities and accomplishments from January 2020 through December 2021 is now available.

*Summary of Report Contents:* Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- Publication by the Organisation for Economic Co-operation and Development of Guideline 497, Defined Approaches on Skin Sensitisation, the first internationally harmonized guideline to describe a non-animal approach that can be used to replace an animal test to identify skin sensitizers. Guideline 497 was drafted and sponsored by ICCVAM agency scientists and international partners.

- Recommendations in March 2021 by the ICCVAM Metrics Workgroup on

federal agency progress in promoting alternative toxicological methods. The workgroup recommended each agency develop its own metrics relevant and practical to their own situation.

- Establishment of the Workgroup on Microphysiological Systems for COVID Research, an international collaborative workgroup to coordinate use of microphysiological systems to reduce animal use in COVID-19 studies and future emerging infectious diseases. A key accomplishment of the workgroup was the establishment of a COVID-19 disease portal in an existing microphysiological systems database.

- Further development of the Collaborative Acute Toxicity Modeling Suite (CATMoS), an online resource for in silico screening of organic chemicals for acute oral toxicity. During 2020 and 2021, the utility of CATMoS for predicting acute oral toxicity in research and regulatory contexts was explored in projects conducted by ICCVAM agencies, including the U.S. Department of Defense and the U.S. Environmental Protection Agency.

- Updates of the Integrated Chemical Environment Search tool during 2020 and 2021 to enable search results to be sent to query other data resources. Updates also allowed users to explore similarities among chemicals, find information on chemical use categories, search for structurally similar chemicals, and view and interact with concentration-response curves from curated high-throughput screening data.

*Availability of Report:* The report is available at <https://ntp.niehs.nih.gov/go/2021iccvamreport>. Links to this report and all past ICCVAM annual and biennial reports are available at <http://ntp.niehs.nih.gov/go/iccvam-bien>.

*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. 285l-3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of

<sup>1</sup> Or another equivalent rating designation.

alternative test methods. Additional information about ICCVAM can be found at <http://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 testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at <http://ntp.niehs.nih.gov/go/niceatm>.

Dated: September 21, 2022.

**Brian R. Berridge**,  
Associate Director, National Toxicology Program.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 60-Day Comment Request; Regular Clearance for Autism Spectrum Disorder (ASD) Research Portfolio Analysis, National Institute of Mental Health**

**AGENCY:** National Institutes of Health, Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork

Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Andrew Hooper, National Institute of Mental Health (NIMH) Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480-8433, or email your request, including your mailing address, to [nimhprapubliccomments@mail.nih.gov](mailto:nimhprapubliccomments@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Proposed Collection Title:* Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH, 0925-0682, expiration date 1/31/2023, EXTENSION, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The purpose of the ASD research portfolio analysis is to collect research funding data from U.S. and international ASD research funders, to assist the Interagency Autism Coordinating Committee (IACC) in fulfilling the requirements of the Combating Autism Act, and to inform the committee and interested stakeholders of the funding landscape and current directions for ASD research. Specifically, these analyses will continue to examine the extent to which current funding and research topics align with the *IACC Strategic Plan for ASD Research*. The findings will help guide future funding priorities by outlining current gaps and opportunities in ASD research as well as serving to highlight annual activities and research progress.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 408.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of projects per respondent	Average time per response (in hours)	Total burden hours
U.S. Federal .....	31	28	15/60	217
U.S. Private .....	15	45	15/60	169
International Government .....	1	61	15/60	15
International Private .....	2	13	15/60	7
Total .....	49	1,630	.....	408