2025 Current Fiscal Year Report: Scientific Advisory Committee on Alternative Toxicological Methods

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Scientific Advisory Committee on Alternative Toxicological Methods	12153

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	12/18/2023	12/18/2025	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42USC 285l-3(d), as amended	12/19/2000	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start		End
SACATM Full Meeting	09/11/2025	-	09/12/2025

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The scope and objectives of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) are to advise the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for

the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, and national and international harmonization of new, revised, and alternative toxicological test methods. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties. Meeting information can be found at http://ntp.niehs.nih.gov/go/32822.

20b. How does the Committee balance its membership?

The Committee will consist of up to 15 members, including the Chair, selected by the Director, NIEHS and NTP, plus non-voting ex officio members, as described below. Members are selected from recognized authorities knowledgeable in academia, industry, state government, public health, environmental communities or organizations using new or alternative test methods, as appropriate, in accordance with the statutorily mandated requirements for representation on the SACATM. In accordance with 42 U.S.C. 285l-3(c) and 285l-3(d)(2)(B), the membership of SACATM will also include, as nonvoting ex officio members, the agency heads or their designees from the Federal agencies represented on ICCVAM, as follows: (1) Agency for Toxic Substances and Disease Registry; (2) Consumer Product Safety Commission; (3) Department of Agriculture; (4)

Department of Defense; (5) Department of Energy; (6) Department of the Interior; (7) Department of Transportation; (8) Environmental Protection Agency; (9) Food and Drug Administration; (10) National Institute for Occupational Safety and Health; (11) National Institutes of Health; (12) National Cancer Institute; (13) NIEHS; (14) National Library of Medicine; (15) Occupational Safety and Health Administration; and (16) National Institute of Standards and Technology; (17) Department of Veterans Affairs Research and Development Office, and (18) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

20c. How frequent and relevant are the Committee Meetings?

Meetings are held at least once each fiscal year. The NIEHS Director appoints voting members to the SACATM, and membership is defined in the ICCVAM Authorization Act of 2000 to include representatives from academia, state government, industry, and animal protection organizations. There was one FY2024 meeting.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The quality, scope and balance of advice provided cannot be obtained from NIH staff or from other established sources. Membership is constituted to meet the specific requirements of the mandated mission of the committee and the Institute.

20e. Why is it necessary to close and/or partially closed committee meetings?

NA

21. Remarks

The DFO and Committee Decision Maker positions are held by the same individual due to the assignment of responsibilities within this Institute. This committee did not produce any reports this fiscal year. Ex Officio Members: According to the charter language NIH has determined there are 17 Ex Officio positions associated with this committee and the max number of positions includes these members. Currently, no Ex Officio members have been identified and there are no Ex Officio members in the list of current members in this report. It has been the practice of ICCVAM members to send ad hoc attendees according to the topics being discussed rather than having ex officio members formally identified.

Designated Federal Officer

Milene Brownlow Health Scientist

Committee Members	Start	End	Occupation	Member Designation
Baines, Antonio	12/19/2021	11/30/2025	Associate Professor, North Carolina Central University	Special Government Employee (SGE) Member
Baran, Szczepan	08/29/2021	11/30/2024	Head of Emerging Technologies, Novartis Institute for Biomedical Research	Special Government Employee (SGE) Member
Berg, Ellen	01/30/2022	11/30/2025	Vice President, DISCOVERX CORPORATION	Special Government Employee (SGE) Member
Leary, Sue	08/29/2021	11/30/2024	President, Alternatives Research & Development Foundation	Special Government Employee (SGE) Member
Marty, Mary	02/11/2024	11/30/2026	Associate Director/Toxicology Science Leader, Dow Chemcial Company	Special Government Employee (SGE) Member

Miles, Kristini	02/11/2024	11/30/2026	Product Regulatory Toxicologist, Nouryon Chemicals LLC	Special Government Employee (SGE) Member
Nanez, Adrian	01/30/2022	11/30/2025	Senior Medical Science Liaison, University of Louiseville	Special Government Employee (SGE) Member
Page, Kathryn	09/12/2021	11/30/2024	Product Safety Toxicologist, The Clorox Company	Special Government Employee (SGE) Member
Price, Nathan	12/11/2023	11/30/2026	Chief Scientific Officer, Thorne HealthTech	Special Government Employee (SGE) Member
Silveyra, Patricia	12/01/2023	11/30/2026	Associate Professor, Indiana University Bloomington	Special Government Employee (SGE) Member
Sura, Priyanka	08/29/2021	11/30/2024	Director, Product Stewardship and Regulatory Compliance, Angus Chemical Company	Special Government Employee (SGE) Member
Thompsom-Iritani, Sally	12/01/2023	11/30/2026	Assistant Vice Provost and Clinical Associate Professor, University of Washington	Special Government Employee (SGE) Member
Ushio, Misti	08/29/2021	11/30/2024	Chief Executive Officer, Tara Biosystems	Special Government Employee (SGE) Member

Number of Committee Members Listed: 13

Narrative Description

This committee advises the NIEHS, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicology Methods (Center) regarding ICCVAM activities. They also advise the NIEHS and the NTP Center on the NTP Center's activities. “NIH’s mission is to seek

fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH works toward that mission by supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad. Section 492 of the PHS Act states that The Secretary ...shall by regulation require appropriate technical and scientific peer review of (A) applications...; and (B) biomedical and behavioral research and development contracts..."

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	

Cost Savings Other

Cost Savings Comments

Many of the alternative test methods promoted by SACATM may in theory reduce the cost of individual toxicity tests, but it is unclear whether reduced cost per agent tested will be offset by increasing number of agents tested.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

0

Number of Recommendations Comments

SACATM met on September 17-18, 2024, in person at the National Institute of Health campus, Bethesda, Maryland. Agenda topics included: (1) Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Report; (2) Validation Working Group Report Updates and NAMs Pipeline – Future Directions; (3) Developmental Neurotoxicity; and (4) Computational Resources Updates. For the topic of ICCVAM Biennial Report, there were suggestions for increased focus on dynamic updates to the biennial report, incorporating key performance indicators, and reorganizing the report for better clarity on implementation, and three recommendations made by the committee including launching a webinar series featuring the biennial report, reorganizing the report to focus on evolution and implementation of work and better reflecting highlights on the website and, integrating human outcome data (and mechanistic mapping) more robustly into processes. For the topic of Validation Working Group Report Updates and NAMs Pipeline – Future Directions, there were six recommendations from the committee including the need to incorporate follow-up activities from the Methods Developers Forum into discussions with agencies and other stakeholder groups, exploring opportunities for cardiotoxicology research collaboration with the Health and Environmental Sciences Institute (HESI), considerations for additional agency needs (e.g., chronic/subchronic endpoints), fostering more collaborative efforts through NIH's Complement Animal Research in Experimentation (Complement-ARIE) and NAM validation programs such as the Validation and Qualification Network (VQN) and ICCVAM, establishing resources and infrastructure to promote use and dissemination of NAMs [e.g., the Collection of Alternative Methods for Regulatory Application CAMERA)], and emphasizing alignment with the Advanced Research Projects Agency for Health (ARPA-H) and other innovation hubs for funding. Additionally, numerous suggestions were made such as focusing on technical characterization before validation, especially efforts involving identifying and sourcing reference materials and considerations around validating batteries/defined approaches (DAs) and individual components, greater focus on the integration of NAMs

into biomedical research and ensuring public-private partnerships drive the development and implementation. For the topic of Developmental Neurotoxicity (DNT), there were five recommendations from the committee including expanding reference chemical databases for validation studies, standardizing data management practices, performing battery gap analysis (e.g., developmental biomarkers, key characteristics), exploring Quantitative in Vitro to in Vivo Extrapolation (QIVIVE) models for complex in vitro systems (e.g., blood-brain barrier, placenta, etc.), providing greater clarity on how data will be used and/or interpreted [e.g., defined approaches (DAs) and integrated approaches to testing and assessment (IATA)] in addition to urging for more work on the validation of the DNT in vitro battery and greater emphasis on human relevance. Finally, for the topic of Computational Resources, there were nine recommendations from the committee including enhancing the user interface of Integrated Chemical Environment (ICE) by integrating artificial intelligence (AI) functionalities, expanding datasets for better regulatory application support, improving predictivity for chemical formulations, saturable metabolism, expanded property sets, supervised chemical quest, collaborating with academic institutions for both training opportunities and deeper integration of mechanistic understanding into models, having access to data as a prioritization strategy, linking out to protocols rather than static versions and having a system for version control, considering assays that are used to make decisions by end-users in industry (e.g., secondary pharm screens, fully validated vs. technically characterized), holding workshop to bring stakeholder input. In addition, updates to ICE were well-received and adding features to upload user-defined pharmacokinetic properties, considering the need for more data on formulations and mixtures and reporting available user access statistics, and several suggestions such as ensuring that tools are easily re-trainable and simple to maximize update and considering additional needs or data gaps.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% of Recommendations Fully Implemented Comments
Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
0%

% of Recommendations Partially Implemented Comments

Due to the complexity of the recommendations made by this committee, staff is unable to determine which recommendations have been fully or partially implemented solely in response to this committee's activities.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

Information is provided to the public at each meeting. The public can view information related to the Committee through the committee's official website. Staff identifies key outcomes of the meeting and reports back to SACATM at the next meeting on developments on the recommendations or advice (either by formal presentation or during discussion).

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The Committee makes recommendations to federal staff regarding the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Alternative methods are those that reduce, refine (lessen or avoid pain and/or distress), or replace the use of animals in testing. SACATM also provides input on ways to foster partnerships and communication with interested parties.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	
Other	

Access Comments

N/A