2024 Current Fiscal Year Report: National Toxicology Program Board of Scientific Counselors

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1. Department or Agency 2. Fiscal Year

Department of Health and Human Services 2024

3b. GSA

Committee No.

National Toxicology Program Board of

Scientific Counselors

4. Is this New During 5. Current 6. Expected 7. Expected Fiscal Year? Charter Renewal Date Term Date

No 11/14/2022 11/14/2024

8a. Was Terminated During 8b. Specific Termination Authority 8c. Actual Term Date

No

9. Agency 10b.

Recommendation for Next Req to Terminate?

FiscalYear Legislation Legislation Pending?

Continue Not Applicable Not Applicable

11. Establishment Authority Authorized by Law

12. Specific 13. 14.

Establishment Effective Committee Presidential?

Authority Date Type

42 U.S.C. 217a 11/17/1962 Continuing No

15. Description of Committee Other Committee

16a. Total

No Reports for this FiscalYear

Reports

17a.

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

Meetings and Dates

No Meetings

Current Next

FY 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. Other(rents,user charges, graphics, printing, mail, etc.)	\$0.00\$0.00
18d. Total	\$0.00\$0.00
19. Federal Staff Support Years (FTE)	0.00 0.00

20a. How does the Committee accomplish its purpose?

The National Toxicology Program (NTP) Board of Scientific Counselors (BSC) is a technical advisory body established to advise the NTP Executive Committee and NTP Director on matters relating to scientific program content and to evaluate the scientific merits of the intramural and collaborative programs of the NTP. Meetings are open to the public and webcast, written comments are received, and time provided at meetings for oral public comment. Information about BSC meetings can be found at http://ntp.niehs.nih.gov/go/164.

20b. How does the Committee balance its membership?

Members of the BSC are selected from

recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, mutagenesis, immunology, carcinogenesis, industrial hygiene, reproductive toxicology, and biostatistics. The Secretary, Health and Human Services, appoints members to the BSC. The members review the NTP activities in the above areas and provide scientific oversight to the program.

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

The BSC typically meets twice annually and convenes working groups and subcommittees to address special programmatic issues as needed. Continuation of the BSC is necessary because there is no other available source that can provide a proper blend of programmatic review and advice needed by the NTP. The BSC met four times in FY2023, on December 15, 2022, May 4, May 16 and July 11, 2023. One recommendation was made at each of these meetings based on the discussions at hand, totaling 4 recommendations made by NTPBSC in FY23.

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

Due to the unique function and objectives of the NTP within the public sector, an independent advisory board is required that includes a breadth of scientific expertise within the membership and a membership that can evaluate and advise on activities ranging from basic research to large-scale chemical testing.

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

21. Remarks

Committee Function - Other, Scientific and Technical Peer Review. Based on the assignment of duties within the National Toxicology Program, the designated federal officer (DFO) and committee decision maker positions are held by the same individual. Effective summer 2023, a new DFO and Decision Maker is in place for the committee, Dr. Gayle Bernabe. Reports: This committee did not produce any reports during this fiscal year. Members: Dr. Pamela Lein was reassigned as Chair in 2022 and co-chaired during the transition with Dr. Eaton through the end of his term.

Designated Federal Officer

K Gayle Bernabe Health Science Policy Analyst

Committee Members BLOMME, ERIC	Start 07/18/2021	End 06/30/2024	Occupation VICE PRESIDENT, ABBVIE	Member Designation Special Government Employee (SGE)
GRAY, KATHLEEN	07/18/2021	06/30/2024	DIRECTOR, CENTER FOR PUBLIC ENGAGEMENT WITH SCIENCE, UNIV OF NORTH CAROLINA AT CHAPEL HILL	Member
Haynes, Erin	01/17/2023	06/30/2025	Professor, University of Kentucky	Special Government Employee (SGE) Member
Kimbro, K	01/29/2023	06/30/2025	Full Professor, North Carolina Central University	Special Government Employee (SGE) Member

LEIN, PAMELA	07/18/2021	06/30/2024	PROFESSOR, SCHOOL OF VETERINARY MEDICINE, UNIV OF CALIFORNIA, DAVIS	Special Government Employee (SGE) Member
MARTIN, MATTHEW	07/18/2021	06/30/2024	DIRECTOR, PFIZER, INC.	Special Government Employee (SGE) Member
Meeker, John	01/17/2023	06/30/2025	Professor, School of Public Health, University of Michigan ASSISTANT	Special Government Employee (SGE) Member
PAYNE-STURGES, DEVON	07/18/2021	06/30/2024	PROFESSOR, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF MARYLAND, COLLEGE PARK	Special Government Employee (SGE) Member
Russi, Mark	10/12/2021	06/30/2024	PROFESSOR, YALE UNIVERSITY	Special Government Employee (SGE) Member
SINGLA, VEENA	07/18/2021	06/30/2024	SENIOR SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL	Special Government Employee (SGE) Member
Yang, Janet	01/29/2023	06/30/2025	Professor, University of Buffalo	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

Narrative Description

The National Toxicology Program Board of Scientific Counselors (Board) is a technical advisory body established to advise the National Toxicology Program (NTP) Executive Committee and Program Director on matters relating to the scientific program content and to evaluate the scientific merits of the intramural and

collaborative programs of the NTP, and as requested by the Secretary, undertake peer review of extramural funding applications as required by section 492 of the Public Health Service Act, as amended.

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	
Outcome Comments NA	
Outcome Comments NA	
	is committee?
NA	is committee? Checked if Applies
NA	
NA What are the cost savings associated with th	Checked if Applies
NA What are the cost savings associated with the	Checked if Applies
What are the cost savings associated with the None Unable to Determine	Checked if Applies
What are the cost savings associated with the None Unable to Determine Under \$100,000	Checked if Applies
What are the cost savings associated with the None Unable to Determine Under \$100,000 \$100,000 - \$500,000	Checked if Applies
What are the cost savings associated with the None Unable to Determine Under \$100,000 \$100,000 - \$500,000 \$500,001 - \$1,000,000	Checked if Applies
What are the cost savings associated with the None Unable to Determine Under \$100,000 \$100,000 - \$500,000 \$500,001 - \$1,000,000 \$1,000,001 - \$5,000,000	Checked if Applies

Cost Savings Comments

NIH supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

What is the approximate <u>Number</u> of recommendations produced by this committee for the life of the committee?

267

Number of Recommendations Comments

The BSC held 4 public meetings in FY23: 1. The NTP BSC met on December 15, 2022. The meeting held presentations and discussion on three contract concepts in support of NIEHS activities. a. Chemistry Support Services for the NIEHS: The objective of this contract is to provide chemistry support to the NIEHS' Division of Translational Toxicology (DTT), using robust and accurate analytical methods and state-of-the-art techniques. Test articles may include chemical or physical agents. Support is typically provided by the contractor on a per-test article basis to provide key pieces of information at each step of the toxicological evaluation process. Because many of the DTT research programs study the same test articles, this approach allows chemistry support to be applied to multiple studies conducted at different times and research facilities. b. Toxicology Support Services for the NIEHS: The objective of this contract is to provide support for conducting toxicity evaluations. The overall research approach utilized by DTT is designed to identify potential environmental contributors to human health effects and disease-based outcomes. The research approach for individual projects may be tiered, with early phases informing study design of later phases, and facilitating timely dissemination of information to the public. Test agents may include chemical, physical and biological agents, as well as nonchemical stressors. The Division has a need to evaluate the utility and relevance of rapidly evolving technologies and determine the potential for routine incorporation into toxicology evaluations. There is also a need to conduct in vitro studies, as well as short-term and long-term in vivo studies. In many cases, projects will require the generation and integration of in vitro and in vivo data to inform translation to human health effects. c. Pathology Support Services for the NIEHS: The objective of this contract is to provide pathology support for the diverse research initiatives within NIEHS' DTT and the Division of Intramural Research (DIR). These groups have need for pathology support including peer review for DTT/NTP studies, pathology evaluations for NIEHS studies, histology, molecular pathology, comparative pathology/medicine, digital imaging, in vitro studies and bioinformatics expertise supporting various investigative/mechanistic studies, and also scientific publication support for technical writing, content updates for atlases, and toxicologic pathology training material. To provide this support, a wide range of organ systems expertise as well as diverse technical capabilities are needed. The scope of the required activities and the space and personnel needed to conduct these studies, exceeded the resources available at the NIEHS; therefore, there was a request for support through contract mechanisms. The BSC agreed that contract mechanisms are

appropriate to support the proposed activities and voted unanimously in favor of the motion to approve the three contract concepts. 2. The NTP BSC met on May 4, 2023. The meeting held presentations and deliberations of the BSC WG's assessments of the NTP author's responses to input from federal agencies and/or external peer reviewers received during development of the State of the Science Monograph and Meta-Analysis Manuscript on fluoride. As outcome of that meeting, the BSC voted to accept in full the NTP Board of Scientific Counselors Working Group Report on the Draft State of the Science Monograph and Draft Meta-Analysis Manuscript on Fluoride, with the exception of text related to an IQ statistic that the BSC asked the WG to verify or correct. 3. The NTP BSC met on May 16, 2023, as a continuation of the NTP BSC meeting on May 4, 2023. The BSC deliberated the Working Group's revised 8.P text and voted unanimously to accept the revised 8.P as written, acknowledging the BSC WG Chair's clerical addition of the word "total" to qualify fluoride exposure among individuals. 4. The NTP BSC met on July 11, 2023. The meeting held presentation and discussion on contract concept in Support for Predictive Toxicology and Evidence Integration for NIEHS activities, representing the following key DTT capability areas: a) Developing, evaluating, and implementing computational tools and methodologies b) Developing, validating, and implementing alternative approaches for toxicity testing c) Searching, screening, evaluating, and synthesizing information from environmental health literature d) Compiling and preparing reports for publication, editing documents, and providing technical review for completeness, accuracy, and readability e) Managing logistics for external peer reviews, including identifying and maintaining a directory of scientific experts, conducting conflict of interest screening, and preparing documents for peer review f) Managing logistics for remote and in-person events, including Federal Advisory Committee Act (FACA) meetings, interagency engagements, and public workshops g) Assessing the quality (accuracy, consistency, and completeness) of products, including toxicology study reports, literature evaluation reports, manuscripts, and data pipelines by comparing their content to original records and documentation h) Identifying knowledge gaps and formulating discrete research questions i) Tracking contract project spending, milestones, and deliverables, and managing personnel with efficient coordination of schedules to meet project needs The scope of the required activities and the space and personnel needed to conduct these studies, exceeded the resources available at the NIEHS; therefore, there was a request for support through contract mechanisms. The BSC agreed that contract mechanisms are appropriate to support the proposed activities and voted unanimously in favor of the motion to approve the contract concept.

What is the approximate <u>Percentage</u> of these recommendations that have been or will be Fully implemented by the agency?

% of Recommendations Fully Implemented Comments

Due to the large breadth and 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 will be Partially implemented by the agency?	
% of Recommendations Partially Implemented NA	ed Comments
Does the agency provide the committee with implement recommendations or advice offer Yes No Not Applicable	
Agency Feedback Comments Information is provided to the public at each merelated to the Committee through the committee	•
What other actions has the agency taken as recommendation?	a result of the committee's advice or
	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. The National Toxicology Program (NTP) Board of Scientific Counselors (BSC) advises the NTP Executive Committee and NTP Director on matters relating to scientific program content and to evaluate the scientific merits of the intramural and collaborative programs of the NTP.

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

Grant Review Comments

Although grant reviews are included in the duties of this Board, there were no grant reviews performed during this fiscal year.

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

Contact the Designated Federal Officer.