

2025 Current Fiscal Year Report: Novel and Exceptional Technology and Research Advisory Committee

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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.
Novel and Exceptional Technology and Research Advisory Committee	1013
4. Is this New During Fiscal Year?	5. Current Charter
No	09/24/2025
	6. Expected Renewal Date
	09/24/2027

8a. Was Terminated During Fiscal Year?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	2025 Secretary Directive	09/30/2025

9. Agency Recommendation for Next Fiscal Year	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	No	Not Applicable

11. Establishment Authority	Authorized by Law		
12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
42 USC 282(b)(16)	11/04/1988	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this Fiscal Year

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
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Program Advisory 12/03/2024 - 12/03/2024

Program Advisory 09/29/2025 - 09/29/2025

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$4,800.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$321,888.00	\$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)	\$89,542.00	\$0.00
18e. Total Costs	\$416,230.00	\$0.00
19. Federal Staff Support Years (FTE)	1.10	0.00

20a. How does the Committee accomplish its purpose?

In April 2019, the NIH renamed the Recombinant DNA Advisory Committee the Novel and Exceptional Technology and Research Advisory Committee (NxTRAC) and restored it to its vision of focusing on the scientific, safety, and ethical

issues associated with emerging biotechnologies. The NxTRAC continued in its role as a forum for public discussion on these matters to incorporate diverse perspectives and broad scientific and public participation. The Committee provided advice to the NIH Director on issues associated with emerging biotechnologies. The NxTRAC included experts from a broad range of scientific and medical fields, as well as ethicists and patient and public representatives. In FY25, the Committee convened twice—on December 3, 2024, and September 29, 2025. Both meetings included updates from the Working Group on Engaging the Public as Partners in Clinical Research.

20b. How does the Committee balance its membership?

The Committee consisted of up to 25 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting appointed members were knowledgeable in relevant emerging scientific fields (e.g., gene therapy, gene editing, synthetic biology). As needed, the Committee included persons knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human participants in research, the environment, ethics, law, public attitudes or related fields.

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

The NxTRAC met twice per year and on an as needed basis, as outlined in the Committee Charter, to provide advice to the NIH and to serve as a public forum for discussing the scientific, safety, and ethical issues associated with emerging biotechnologies. These issues are of interest to a wide range of stakeholders, including

researchers, the biotechnology industry, other Federal agencies, research participants, and the broader public. In FY25, the Committee met twice—on December 3, 2024, and September 29, 2025—to receive updates from the Working Group on Engaging the Public as Partners in Clinical Research. The Working Group convened on 10/2/24, 10/7/24, 10/17/24, 10/23/24, 11/4/24, 11/6/24, 12/4/24 (two sessions), 12/9/24, 12/19/24, 1/8/25, 1/16/25, 6/9/25, 6/18/25, 7/7/25, 7/21/25, and 8/19/25.

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

Per "2025 Secretary Directive" this FACA Committee has been terminated. The NxTRAC was composed of recognized experts in the field of biotechnology research as well as nationally known experts in fields such as law, ethics, standards of professional conduct and practice, and public engagement. To reduce the costs associated with managing and supporting advisory committees, the NxTRAC was sunset as an advisory committee in late FY25. The type of transparent discourse that was fostered by the NxTRAC will continue to be prioritized by NIH in other venues.

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

N/A

21. Remarks

Per "2025 Secretary Directive" this FACA Committee has been terminated. Reports: The NxTRAC produced one report in FY25. Recommendations: In FY25, the Committee issued four recommendations, bringing its lifetime total to 874. Membership: As a result of the

Secretary Directive, all active member terms concluded on September 30, 2025. Prior to termination, the Committee was authorized to appoint up to 25 members and had 14 active members and 11 vacancies. Membership (Retired): Dr. Pilar Ossorio's term ended on January 27, 2025, prior to the Committee's termination. Administrative Extensions: Prior to termination of the NxTRAC, the terms of the following members were administratively extended to allow the Committee to fully complete its charge: Drs. Bloss, Collins, Gronvall, Hyun, Leshner, Oye, Riley, and Saunders. The DFO and Committee Decision Maker roles were held by the same individual due to internal assignment of responsibilities within the Institute.

Designated Federal Officer

Jessica Tucker Deputy Director, Office of Science Policy

Committee Members	Start	End	Occupation	Member Designation
BAKKEN, SUZANNE	08/27/2023	09/30/2025	PROFESSOR, DEPARTMENT OF BIOMEDICAL INFORMATICS, SCHOOL OF NURSING, COLUMBIA UNIVERSITY	Special Government Employee (SGE) Member
BLOSS, CINNAMON	10/11/2020	09/30/2025	PROFESSOR AND ASSOCIATE DEAN, ACADEMIC AFFAIRS, HERBERT WERTHEIM SCHOOL OF PUBLIC HEALTH AND HUMAN LONGEVITY SCIENCE, UNIVERSITY OF CALIFORNIA, SAN DIEGO	Special Government Employee (SGE) Member

CAINDEC, KAREN	08/27/2023	09/30/2025	CHAIRPERSON, BOARD OF DIRECTORS, SOUTHCENTRAL FOUNDATION	Special Government Employee (SGE) Member
CALLIER, SHAWNEEQUE	03/26/2023	09/30/2025	ASSOCIATE PROFESSOR, CLINICAL RESEARCH AND LEADERSHIP, SCHOOL OF MEDICINE AND HEALTH SCIENCES, GEORGE WASHINGTON UNIVERSITY VIRGINIA M. ULLMAN PROFESSOR OF NATURAL HISTORY AND THE ENVIRONMENT, SCHOOL OF LIFE SCIENCES, ARIZONA STATE UNIVERSITY	Special Government Employee (SGE) Member
COLLINS, JAMES	01/17/2023	09/30/2025	SENIOR SCHOLAR, JOHNS HOPKINS CENTER FOR HEALTH SECURITY, ASSOCIATE PROFESSOR, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH	Special Government Employee (SGE) Member
GRONVALL, GIGI	09/27/2020	09/30/2025	DIRECTOR, CENTER FOR LIFE SCIENCES AND PUBLIC LEARNING, MUSEUM OF SCIENCE	Special Government Employee (SGE) Member
HYUN, INSOO	08/14/2022	09/30/2025		

KHETERPAL, SACHIN	08/27/2023	09/30/2025	KEVIN K. TREMPER, PHD, MD RESEARCH PROFESSOR IN ANESTHESIOLOGY, ASSOCIATE DEAN FOR RESEARCH INFORMATION TECHNOLOGY, DEPARTMENT OF ANESTHESIOLOGY, UNIVERSITY OF MICHIGAN MEDICAL SCHOOL EMERITUS CHIEF EXECUTIVE OFFICER	Special Government Employee (SGE) Member
LESHNER, ALAN	09/27/2020	09/30/2025	AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE	Special Government Employee (SGE) Member
OSSORIO, PILAR	11/08/2020	01/27/2025	PROFESSOR OF LAW AND BIOETHICS, UNIVERSITY OF WISCONSIN LAW SCHOOL	Special Government Employee (SGE) Member
OYE, KENNETH	10/11/2020	09/30/2025	PROFESSOR, POLITICAL SCIENCE AND DATA SYSTEMS AND SOCIETY, DIRECTOR PROGRAM ON EMERGING TECHNOLOGIES, CENTER FOR INTERNATIONAL STUDIES, MASSACHUSETTS INSTITUTE OF TECHNOLOGY	Special Government Employee (SGE) Member
RICHARDSON, SARAH	08/27/2023	09/30/2025	CHIEF EXECUTIVE OFFICER, MICROBYRE, INC.	Special Government Employee (SGE) Member
RILEY, MARGARET	11/08/2020	09/30/2025	PROFESSOR OF LAW, UNIVERSITY OF VIRGINIA SCHOOL OF LAW	Special Government Employee (SGE) Member

SAUNDERS, KEVIN	09/25/2022	09/30/2025	ASSOCIATE	Special
			PROFESSOR, DUKE UNIVERSITY	Government Employee
WYATT, LETISHA	02/26/2023	09/30/2025	SCHOOL OF MEDICINE	(SGE) Member
			DIRECTOR OF DIVERSITY IN RESEARCH, RESEARCH AND INNOVATION	Special Government Employee
			OFFICE, DEPARTMENT OF NEUROLOGY, OREGON, HEALTH AND SCIENCE UNIVERSITY	(SGE) Member

Number of Committee Members Listed: 15

Narrative Description

NIH’s mission was to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. The mission of the Novel and Exceptional Technology and Research Advisory Committee was to provide advice to the Director of the National Institutes of Health (NIH) on matters related to the conduct and oversight of research involving emerging technologies in biomedical science (also referred to as emerging biotechnologies). The Committee conducted all of its meetings in public and webcast the proceedings to inform researchers and the public.

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

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

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

874

Number of Recommendations Comments

During the life of the Committee, NxTRAC made a total of 874 recommendations. In FY25, the Committee issued four recommendations stemming from the Working Group on Engaging the Public as Partners in Clinical Research.

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 breadth and complexity of the recommendations made by this committee,

which affected the broader biomedical research enterprise (including both federally and privately funded research), NIH staff were unable to determine which recommendations had been fully or partially implemented solely in response to the 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 breadth and complexity of the recommendations made by this committee, which affected the broader biomedical research enterprise (including both federally and privately funded research), NIH staff were unable to determine which recommendations had been fully or partially implemented solely in response to the 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

The agency provided meeting minutes, written reports, and oral presentations. Information was made available to the public at each meeting. The public could view materials related to the Committee through the Committee's official website.

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

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

The Novel and Exceptional Technology and Research Advisory Committee provided advice on scientific, safety, and ethical issues associated with emerging biotechnologies.

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