

2024 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		2024	
3. Committee or Subcommittee		3b. GSA Committee No.	
Novel and Exceptional Technology and Research Advisory Committee		1013	
4. Is this New Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/30/2023	06/30/2025	
8a. Was Terminated During Fiscal Year?	8b. Specific Termination Authority		8c. Actual Term Date
No			
9. Agency Recommendation for Next Fiscal Year	10a. Legislation Req to Terminate?	10b. Legislation Pending?	
Continue	Not Applicable	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	17b. Closed	17c. Partially Closed	Other Activities
0	0	0	0
17d. Total			
0			
Meetings and Dates			
No Meetings			

	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. 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?

In April 2019 the NIH renamed the Recombinant DNA Advisory Committee the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) and restored it closer to its original vision of focusing on the scientific, safety, and ethical issues associated with emerging biotechnologies. The NExTRAC will continue in its role as a forum for public discussion on these matters to incorporate diverse perspectives and broad scientific and public participation. It provides advice to the NIH Director on issues associated with emerging biotechnologies. The NExTRAC is

composed of experts from a wide range of scientific and medical disciplines and also includes ethicists and patient and public representatives. In FY23, the Committee met one time. The meeting on August 29, 2023 included a presentation, discussion, and vote to finalize the Draft Report of the Working Group on Data Science and Emerging Technology with minor edits. Additionally, the Acting NIH Director delivered a new charge to the Committee on Engaging the Public as Partners in Clinical Research during the August 29, 2023 meeting.

20b. How does the Committee balance its membership?

Under its current charter, the Committee will consist of up to 25 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting appointed members must be knowledgeable in relevant emerging scientific fields (e.g., gene therapy, gene editing, synthetic biology). As needed, the Committee may include 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 NExTRAC will meet as needed, approximately two times per year, to provide advice to NIH and to serve as a public forum for scientific, safety, and ethical issues associated with emerging biotechnologies. The issues are of interest to a broad range of individuals and organizations, including researchers, the biotechnology industry, other Federal agencies, research participants, and other members of the

public. In FY23, the Committee met once on August 29, 2023 to deliberate on the Draft Report of a working group formed to consider issues related to data science and emerging technology. The Working Group on Data Science and Emerging Technology met on the following dates: 10/31/22, 12/12/22, 1/31/23, 3/6/23, 3/20/23, 4/3/23, 4/17/23, 5/4/23, 5/18/23, 6/8/23, 6/15/23, 6/22/23, 6/29/23, 7/6/23, and 7/13/23.

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

This Committee is composed of recognized experts in the field of biotechnology research as well as non-scientists who are nationally known experts in fields such as law, ethics, standards of professional conduct and practice, and public engagement. The composition of the NExTRAC provides a unique balance of expertise and opinions that cannot be obtained from federal staff or on an ad hoc basis because of the diversity in scientific and non-scientific viewpoints needed, the importance of non-federal perspectives, and the need for continuity as the Committee considers issues over time.

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

N/A

21. Remarks

Reports: The committee produced one public report in FY23: "Data Science and Emerging Technology in Biomedical Research Report.

<https://osp.od.nih.gov/wp-content/uploads/2023/09/NExTRAC-Report-on-Data-Science-and-Eme>

Memberships: The NExTRAC is authorized to appoint up to 25 members. Currently, there are 16 active members and 10 vacancies. The following members committee terms have ended in FY23:

Zach Adelman (07/30/2023), Lorraine Albritton (03/14/2023), Kathleen Boris-Lawrie (07/30/2023), Benhur Lee (on 02/25/2023), and Matthew Porteus (07/30/2023). Dr. Angela Birnbaum's term ended early on 06/26/2023, due to passing. The following 4 new members were appointed in FY23: Drs. Bakken, Caindec, Kheterpal, and Richardson.

Administrative Extensions: The following member's terms have been administratively extended until 01/27/2024: Drs. Bloss, Gronvall, Leshner, Ossorio, Oye, Riley, Turner. The terms are longer than the charter allows due to their administrative extensions given their specific scientific expertise and the need to continue to assure continuity on the committee.

Recommendations: The FY23 meeting focused on an update from the Working Group on Data Science and Emerging Technology and discussion of next steps regarding the current charge to the committee. Thus, the Committee put forth 8 recommendations in FY23. The DFO and Committee Decision Maker positions are held by the same individual because of the assignment of responsibilities within the Institute.

Designated Federal Officer

Jessica Tucker Acting Deputy Director, Office of Science Policy, Office of the Director, NIH

Committee Members	Start	End	Occupation	Member Designation
BAKKEN, SUZANNE	08/27/2023	07/31/2026	PROFESSOR, DEPARTMENT OF BIOMEDICAL INFORMATICS, SCHOOL OF NURSING, COLUMBIA UNIVERSITY	Special Government Employee (SGE) Member
BLOSS, CINNAMON	10/11/2020	01/27/2024	PROFESSOR, DEPARTMENT OF PSYCHIATRY AND HEALTH, UNIVERSITY OF CALIFORNIA, SAN DIEGO	Special Government Employee (SGE) Member

CAINDEC, KAREN	08/27/2023	07/31/2026	CHAIRPERSON, BOARD OF DIRECTORS, SOUTHCENTRAL FOUNDATION	Special Government Employee (SGE) Member
CALLIER, SHAWNEEQUE	03/26/2023	07/31/2026	ASSOCIATE PROFESSOR, CLINICAL RESEARCH AND LEADERSHIP, SCHOOL OF MEDICINE AND HEALTH SCIENCES, GEORGE WASHINGTON UNIVERSITY VIRGINIA M. ULLMAN PROFESSOR OF NATURAL HISTORY	Special Government Employee (SGE) Member
COLLINS, JAMES	01/17/2023	07/31/2025	AND THE ENVIRONMENT, SCHOOL OF LIFE SCIENCES, ARIZONA STATE UNIVERSITY ASSOCIATE PROFESSOR, DEPARTMENT OF ENVIRONMENTAL HEALTH AND ENGINEERING, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH	Special Government Employee (SGE) Member
GRONVALL, GIGI	09/27/2020	01/27/2024	DIRECTOR, CENTER FOR LIFE SCIENCES AND PUBLIC LEARNING, MUSEUM OF SCIENCE	Special Government Employee (SGE) Member
HYUN, INSOO	08/14/2022	07/31/2025	KEVIN K. TREMPEL, PHD, MD RESEARCH PROFESSOR IN ANESTHESIOLOGY, ASSOCIATE DEAN FOR RESEARCH INFORMATION TECHNOLOGY, DEPARTMENT OF ANESTHESIOLOGY, UNIVERSITY OF MICHIGAN MEDICAL SCHOOL	Special Government Employee (SGE) Member
KHETERPAL, SACHIN	08/27/2023	07/31/2026		Special Government Employee (SGE) Member

LESHNER, ALAN	09/27/2020	01/27/2024	CHIEF EXECUTIVE OFFICER, EMERITUS, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE	Special Government Employee (SGE) Member
OSSORIO, PILAR	11/08/2020	01/27/2024	PROFESSOR OF LAW AND BIOETHICS, UNIVERSITY OF WISCONSIN LAW SHCOOL	Special Government Employee (SGE) Member
OYE, KENNETH	10/11/2020	01/27/2024	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	07/31/2026	CHIEF EXECUTIVE OFFICER, MICROBYRE, INC.	Special Government Employee (SGE) Member
RILEY, MARGARET	11/08/2020	01/27/2024	PROFESSOR OF LAW, UNIVERSITY OF VIRGINIA SCHOOL OF LAW	Special Government Employee (SGE) Member
SAUNDERS, KEVIN	09/25/2022	07/31/2025	ASSOCIATE PROFESSOR, DUKE UNIVERSITY SCHOOL OF MEDICINE	Special Government Employee (SGE) Member
TURNER, LEIGH	09/27/2020	01/27/2024	PROFESSOR, HEALTH, SOCIETY & BEHAVIOR, PROGRAM IN PUBLIC HEALTH, UNIVERSITY OF CALIFORNIA, IRVINE	Special Government Employee (SGE) Member

		DIRECTOR OF DIVERSITY IN RESEARCH, RESEARCH AND INNOVATION OFFICE, DEPARTMENT OF NEUROLOGY, OREGON, HEALTH AND SCIENCE UNIVERSITY	Special Government Employee (SGE) Member
WYATT, LETISHA	02/26/2023 07/31/2026		

Number of Committee Members Listed: 16

Narrative Description

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. The mission of the Novel and Exceptional Technology and Research Advisory Committee is to provide advice to the Director, 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 Novel and Exceptional Technology and Research Advisory Committee conducts all of its meetings in public and webcasts the proceedings in order 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	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

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?

871

Number of Recommendations Comments

The NExTRAC is an advisory committee focusing on the scientific, safety, and ethical issues associated with emerging biotechnologies. NExTRAC is a forum for public discussion on these matters to incorporate diverse perspectives and broad scientific and public participation. In FY23 the Committee made 8 recommendations arising from the efforts of the Working Group on Data Science and Emerging Technology. These recommendations centered on how NIH can strengthen safeguards of personal health data captured and analyzed through current and emerging technologies and used in research. In addition, the committee produced one public report in FY23: "Data Science and Emerging Technology in Biomedical Research Report"

<https://osp.od.nih.gov/wp-content/uploads/2023/09/NExTRAC-Report-on-Data-Science-and-Emerging-Technology-in-Biomedical-Research-Report.pdf>

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 large breadth and complexity of the recommendations made by this committee that affect the broader biomedical research enterprise (both federally and privately funded research), NIH 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 large breadth and complexity of the recommendations made by this committee that affect the broader biomedical research enterprise (both federally and privately funded research), NIH 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

The agency provides meeting minutes, written reports, and oral presentations. Information is provided to the public at each meeting. The public can view information 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 will provide

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	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A