

2023 Current Fiscal Year Report: National Center for Advancing Translational Sciences Advisory Council

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1. Department or Agency	Department of Health and Human Services	2. Fiscal Year	2023
3. Committee or Subcommittee	National Center for Advancing Translational Sciences Advisory Council	3b. GSA Committee No.	79630
4. Is this New Fiscal Year?	No	5. Current Charter	02/07/2022
		6. Expected Renewal Date	02/07/2024
8a. Was Terminated During Fiscal Year?	No	8b. Specific Termination Authority	
9. Agency Recommendation for Next Fiscal Year	Continue	10a. Legislation Req to Terminate?	Not Applicable
		10b. Legislation Pending?	Not Applicable
11. Establishment Authority	Authorized by Law		
12. Specific Establishment Authority	42 USC 217a	13. Effective Date	11/17/1962
		14. Committee Type	Continuing
15. Description of Committee	Other Committee		
16a. Total Number of Reports	No Reports for this Fiscal Year		
17a. Open	0	17b. Closed	0
		17c. Partially Closed	3
		Other Activities	0
17d. Total	3		

Meetings and Dates

Purpose	Start	End
Second Level Level Peer Review and Program Advisory.	01/26/2023	- 09/28/2023

Second Level Peer Review and Program Advisory. 05/25/2023 - 05/25/2023

Second Level Peer Review and Program Advisory. 09/28/2023 - 09/28/2023

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel		
Pmts to Non-Federal Members	\$5,200.00	\$5,200.00
18a(2). Personnel		
Pmts to Federal Members	\$2,110.00	\$2,110.00
18a(3). Personnel		
Pmts to Federal Staff	\$305,329.00	\$286,638.00
18a(4). Personnel		
Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$9,253.00	\$19,220.00
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.)	\$23,325.00	\$23,657.00
18d. Total	\$345,217.00	\$336,825.00
19. Federal Staff Support Years (FTE)	1.80	1.50

20a. How does the Committee accomplish its purpose?

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.... This committee is composed of highly qualified scientists and public representatives with expertise related to the interests of the Center. It provides a breadth and balance of specialized knowledge necessary to assess the long-range goals, program concepts, research opportunities, and direction of ongoing research and future plans. Of the applications that were reviewed by initial review groups for the National Center for Advancing Translational Sciences, the Council reviewed 1153 applications in the amount of \$3,405,622,089. In addition the Council reviewed 7 contracts in the amount of \$3,319,561.

20b. How does the Committee balance its membership?

The Council will consist of not more than 18 members appointed by the Secretary (appointed members) and the following nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NCATS; and any additional officers or employees of the Department of Health and Human Services as the Secretary determines necessary for the Council to effectively carry out its functions. Of the appointed members, two-thirds will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NCATS, particularly representatives of the health and scientific disciplines in the areas of drug development and translational sciences. One-third of the members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and

management.

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

Meetings are scheduled to be held not less than three times each fiscal year. The Council met three times during this reporting period, January 26, 2023; May 25, 2023; and September 28, 2023. The National Center for Advancing Translational Sciences Advisory Council provides advice on a continuing basis on the type of scientific research programs that should be supported and on how to carry out the designated mission and responsibilities of the Institute. It also provides ongoing review of the relevance and effectiveness of the existing programs.

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

The National Center for Advancing Translational Sciences Advisory Council is composed of both scientific and public members who provide the second level of review for research grant applications; advise on policy development, program implementation and evaluation; and identify research needs and opportunities of the Center. The quality, scope, and balance of advice from this council cannot be obtained from NIH staff or from other established sources because the membership of the council is constituted to meet the specific requirements of the mandated mission of the council and of the Center.

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

The meetings of the National Center for Advancing Translational Sciences Advisory Council were partially closed to the public for the review of grant applications. Sections 552b(c)(4)

and 552b(c)(6) of the Government in the Sunshine Act permits the closing of meetings where discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

21. Remarks

Committee Function: Other - National Scientific and Advisory. Reports: This committee did not produce any public reports during the fiscal year. The DFO and Decision Maker are the same person, the Director, Office of Grants Management and Scientific Review, based on the assignment of duties within the Center. Dr. Shireman changed institutes 04/06/2022, this was not previously changed in FY22 report. Dr. Rebecca Jackson - Deceased 10/10/2022. Dr. Joni Rutter officially became Director of NCATS 11/08/2022. Dr. Rajesh Ranganathan - Resigned 06/08/2023. Drs. Andrew Lo and Theodore Holman were administratively extended to 04/29/2023. Dr, Joni Rutter's term end date changed from 04/15/2023 to 10/31/2024. Dr. Lawrence Tabak's title was updated from Performing the Duties of the NIH Director to Acting Director, NIH this fiscal year.

Designated Federal Officer

Anna L. Ramsey-Ewing Director, Office of Grants Management and Scientific Review

Committee Members	Start	End	Occupation	Member Designation
Aguilar-Gaxiola, Sergio	01/17/2023	10/31/2025	Director and Professor of Clinical Internal Medicine, University of California, Davis	Special Government Employee (SGE) Member
Becerra, Xavier	03/19/2021	01/19/2025	Secretary, HHS	Ex Officio Member

Harris, Paul	06/05/2021	10/31/2024	Professor, Vanderbilt University	Special Government Employee (SGE) Member
Holman, Theodore	08/29/2019	04/29/2023	Professor, University of California - Santa Cruz	Special Government Employee (SGE) Member
Jackson, Rebecca	09/13/2021	10/10/2022	Professor and Associate Dean, Ohio State University	Special Government Employee (SGE) Member
Kennedy, Anne	09/13/2021	10/31/2024	Chief of Policy and Advocacy, Everylife Foundation for Rare Diseases	Special Government Employee (SGE) Member
Kretzler, Matthias	06/06/2021	10/31/2023	Warner-Lambert/Parke-Davis Professor, University of Michigan	Special Government Employee (SGE) Member
LO, ANDREW	12/19/2019	04/29/2023	CHARLES E. AND SUSAN T. HARRIS PROFESSOR SLOAN SCHOOL OF MANAGEMENT MASSACHUSETTS INSTITUTE OF TECHNOLOGY	Special Government Employee (SGE) Member
McVeary, Kelly	08/30/2021	10/31/2024	Chief Executive Officer, The Hypatia Group, Inc.	Special Government Employee (SGE) Member
Mermelstein, Robin	01/17/2023	10/31/2025	Professor, University of Illinois at Chicago	Special Government Employee (SGE) Member
Mueller, Keith	06/05/2021	10/31/2024	Gerhard Hartman Professor and Department Head, University of Iowa	Special Government Employee (SGE) Member
Ranganathan, Rajesh	09/13/2021	06/08/2023	Vice President, Sun Pharma Advanced Research Company, LTD	Special Government Employee (SGE) Member
Rutter, Joni	04/16/2021	10/31/2024	Director, National Center for Advancing Translational Sciences	Ex Officio Member

Shireman, Paula	06/05/2021	10/31/2024	Executive Associate Dean, Office of the Dean, College of Medicine, Texas A&M Health	Special Government Employee (SGE) Member
Summar, Marshall	06/05/2021	10/31/2023	Director, Children's National Medical Center	Special Government Employee (SGE) Member
Tabak, Lawrence	12/20/2021	01/20/2025	Acting Director, National Institutes of Health	Ex Officio Member
Wayman, Annica	01/17/2023	10/31/2025	Associate Dean for Shady Grove Affairs, University of Maryland, Baltimore County	Special Government Employee (SGE) Member

Number of Committee Members Listed: 17

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. NIH works toward that mission by: conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical and health sciences information. Section 492 of the Public Health Service 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..." The National Center for Advancing Translational Sciences Advisory Council provides second level peer review, makes recommendations for support of grants, contracts proposals, and cooperative agreements; advises on policy development, program implementation and evaluation; and identifies research needs of the Center.

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

N/A

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 new diagnostic tests and new way to treat and prevent diseases.

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

11,627

Number of Recommendations Comments

The number of recommendations includes the second level review of grant applications and reviewed contracts.

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

Information on the research funded by NIH is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at <http://report.nih.gov>.

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

Information on the research funded by NIH is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at <http://report.nih.gov>.

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 the open session of each Council meeting through reports and the Director's update. The public can view information related to the Council through the council'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
- Reallocated resources
- Issued new regulation

- Proposed legislation
- Approved grants or other payments
- Other

Action Comments

An action of “approved” or “recommended” for grants receiving review by this Council [or Board] does not infer that the grant will be or has been funded. Research grant applications submitted to NIH must go through a two-step review process that includes the initial peer review for scientific and technical merit and a second step of review and approval by a National Advisory Council that includes program relevance. In addition, prior to an award or funding being made, NIH staff must conduct an administrative review for a number of other considerations. These include alignment with NIH’s funding principles, review of the project budget, assessment of the applicant’s management systems, determination of applicant eligibility, and compliance with public policy requirements. After all these steps have been completed, NIH officials make funding decisions on individual grant applications.

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

Yes

What is the estimated Number of grants reviewed for approval

What is the estimated Number of grants recommended for approval 1,153
1,153

What is the estimated Dollar Value of grants recommended for approval
\$3,405,622,089

Grant Review Comments

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