2024 Current Fiscal Year Report: Office of AIDS Research Advisory

Council

Report Run Date: 04/24/2024 04:23:30 AM

1. Department or Agency			2. Fis	2. Fiscal Year	
Department of Health and Human			2024	2024	
Services			2024		
3. Committee or Subcommittee		3b. G No.	3b. GSA Committee No.		
Office of AIDS Research Advisory Council		1918	1918		
4. Is this New D	ouring 5. (Current 6. I	Expected	7. Expected	
Fiscal Year?	Ch	arter Re	newal Date	Term Date	
No	06/	27/2022 06/	27/2024		
8a. Was Termin	ated Dur	8b. Spe	cific	8c. Actual	
FiscalYear?		Termina	ation	Term Date	
		Authori	ty		
No					
9. Agency		10a leo	gislation	10b.	
Recommendati	on for Ne	ext	Ferminate?	Legislation	
FiscalYear				Pending?	
Continue		Not App	licable	Not Applicable	
11. Establishme	ent Autho	ority Statuto	ry (Congress	s Created)	
12. Specific		13.	14.	14c.	
Establishment		Effective	Commitee	Presidential?	
Authority		Date	Туре		
42 USC 300cc-4	0a	06/10/1993	Continuing	No	
15. Description	of Comm	nittee Scien	tific Technica	al Program	
Advisory Board					
16a. Total					
	No Repo	orts for			
Number of	No Repo				
Number of Reports	No Repo this Fisca				
Reports	this Fisca	alYear	Closed 0. Of	her Activities () 17d Total ()	
Reports	this Fisca	alYear	Closed 0 Ot	her Activities 0 17d. Total 0	
Reports 17a. 0 17b. Clo	this Fisca	alYear	Closed 0 Ot	her Activities 0 17d. Total 0	
Reports 17a. 0 17b. Clo Open	this Fisca	alYear	Closed 0 Ot	her Activities 0 17d. Total 0	

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20a. How does the Committee accomplish its purpose?

The Office of AIDS Research Advisory Council (OARAC) is composed of highly qualified individuals who possess scientific expertise in HIV/AIDS research and a public commitment to advance the HIV/AIDS scientific agenda. The Council provides a breadth and balance of specialized knowledge necessary to advise the Director of the Office of AIDS Research (OAR) and the Director of the National Institutes of Health. The NIH Revitalization Act of 1993 called for the establishment of OARAC to provide advice on planning, coordination, and evaluating AIDS research supported by the NIH. The OAR depends heavily on the Council's advice in the extensive process of reviewing all NIH HIV/AIDS research and developing long-term research plans. To accomplish its purpose, meetings were held on emerging and relevant topics during FY2023 to seek members' input and advise the scientific strategic direction of the OAR. Highlighted topical updates included strategic directions for PEPFAR, updates from the US Military HIV Research Program and the US Department of Veterans Affairs HIV Program; and significant changes to the clinical guidelines regarding Infant Feeding for Individuals with HIV in the United States. HIV-relevant presentations with NIH Institutes, Centers, and Offices were shared, including discussions with the National Institute on Aging and the NIH Office of Research on Women's Health regarding two OAR signature programs on HIV and Aging and Women and HIV. In addition, each of the three FY 2023 meetings included information from the five HIV clinical guidelines working groups under OARAC: Adult/Adolescent ARV, Adult/Adolescent Opportunistic Infection; Perinatal; Pediatric ARV and Pediatric Opportunistic infection, as well as the four NIH advisory councils that report to OARAC: the AIDS Research Advisory Committee (ARAC), the National Advisory Mental Health Council, the National Advisory Council on Drug Abuse, and the National Cancer Advisory Board.

20b. How does the Committee balance its membership?

The Committee will consist of not more than 18 members appointed by the Secretary (appointed members) and at least 11 nonvoting ex officio members. The nonvoting ex officio members will include the Secretary of Health and Human Services (Secretary); the Director, NIH; the Director, OAR; the Under Secretary for Health of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs; the Director, Centers for Disease Control and Prevention; and the Director, Division of AIDS, NIAID; (or their designees). The ex officio members will also include one representative from the National Advisory Allergy and Infectious Diseases Council; one representative from the National Cancer Advisory Board; and a representative from each of the advisory councils of the two national research institutes (excluding NIAID and the National Cancer Institute) that receive the greatest funding for AIDS activities; and such additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Two-thirds of the appointed members (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 OAR) will be appointed from the leading representatives of the health and scientific disciplines in the fields of molecular biology, immunology, virology, neurology, pediatrics, vaccine development, antiviral development, clinical care, animal model research, retrovirology, structural biology, infectious disease, epidemiology, mental health, and substance abuse/addictions sciences. One-third of the public members have expertise in public policy, health policy, economics, and management. Persons with HIV and their advocates will be represented on the Council, either from the general public or from the scientific community.

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

The OARAC meets three times a year to provide advice on the direction of the NIH HIV and AIDS research program; the development and annual review of a comprehensive plan for the conduct and support of all AIDS activities of the agencies of NIH; including direct involvement in budget projections for carrying out the plan which includes an estimate of the number and type of personnel needed for OAR. The Committee conducted three meetings on the following dates: 10/27/2022, 03/02/2023, and 06/22/2023.

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

The committee and membership requirements are specifically addressed in the statute. HIV/AIDS research is conducted throughout the NIH, which includes 22/27 Institutes and Centers, along with co-funding HIV/AIDS research with the OD programs. The OARAC is the only council with advisory responsibilities applicable to the entire agency-wide NIH HIV and AIDS research program. Therefore, it is essential to the coordination of the NIH HIV and AIDS scientific effort and research direction of the agency's HIV and AIDS programs.

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

21. Remarks

Reports: There was no formal, substantive committee reports made to the Agency, the President, or the Congress in FY2023. General: Per the Charter, the OARAC will consist of not more than 18 voting members and at least 11 nonvoting ex officio members. Term End: Dr. Tabia Henry Akintobi rotated off of the committee due to her term end on 09/30/2023. Administrative Extensions: The following member terms have been administratively extended until 3/29/2024 pending the appointment of their replacements: Drs. Kathleen L. Collins, Veronica Miller, Ricardo A. Rivero and John W. Sleasman. New Members: The following new members were appointed in May 2023: Drs. Omar Galarraga, Mojgan Naghavi, Anne Neilan, Luis Montaner. Ex Officios: Effective March 25, 2023, Dr. Maureen Goodenow transitioned from her role as NIH Associate Director for AIDS Research and Director of the NIH Office of AIDS Research (OAR) to a new role as Senior Advisor in the NIH Office of the Director (OD), leaving her post and OARAC Ex Officio position. On March 26, 2023, Dr. Bill G. Kapogiannis became the NIH Acting Associate Director of AIDS Research and Acting Director of OAR and Ex Officio immediately after Dr. Goodenow's departure. Dr. Laura Cheever joined as a non-chartered representative from the Health Resources and Services Administration. The four Ex Officio members who serve as Council Representative from their respective appointed Councils are paid by their appointed committee as Special Government Employees. These members serve on OARAC as required by the Charter as representatives of these other specific Councils. Individuals who have been appointed as Ex Officios during FY 23 include: Drs. Marguerita Lightfoot, Melanie Ott and Chris Friese. Dr. Francis Ali-Osman retired on 08/13/2023 and Dr. Chris Friese is his replacement. Dr. Francis Ali-Osman's term end date was extended from 3/9/2022 to 8/13/2023. This committee currently has 12 Ex Officio members.

Designated Federal Officer

Tim H Holtz Deputy Director, Office of AIDS

Tim TT Tollz Deputy Director, Onice of AIDS				
Research				
Committee Members	Start	End	Occupation	Member Designation
AKE, JULIE	02/03/2021	01/31/2026	DIRECTOR, US MILITARY HIV RESEARCH PROGRAM, WALTER REED ARMY INSTITUTE OF RESEARCH	Ex Officio Member
BECERRA, XAVIER	03/19/2021	01/20/2025	SECRETARY, HEALTH & HUMAN SERVICES	Ex Officio Member
CHEEVER, LAURA	03/01/2023	09/30/2026	ASSISTANT PROFESSOR	Ex Officio Member
COLLINS, KATHLEEN	10/25/2020	03/29/2024	STAFF PHYSICIAN, UNIVERSITY OF MICHIGAN HOSPITAL	Special Government Employee (SGE) Member
DAVEY, VICTORIA	10/01/2019	09/30/2024	CHIEF OFFICER, U.S. DEPARTMENT OF VETERANS AFFAIRS	Ex Officio Member
DIEFFENBACH, CARL	08/17/2015	09/30/2024	DIRECTOR, DIVISION OF AIDS, NIAID, NIH	Ex Officio Member
EISINGER, ROBERT	06/20/2022	11/08/2023	Acting Deputy Director for Program Coordination, Planning, and Strategic Initiatives	Ex Officio Member
FRIESE, CHRISTOPHER	08/14/2023	03/09/2026	PROFESSOR	Ex Officio Member
GALARRAGA, OMAR	05/21/2023	09/30/2024	ASSOCIATE PROFESSOR, BROWN UNIVERSITY SCHOOL OF PUBLIC HEALTH	Special Government Employee (SGE) Member
GANDHI, MONICA	04/30/2021	10/31/2023	PROFESSOR OF CLINICAL MEDICINE, UNIVERSITY OF CALIFIRONIA, SAN FRANCISCO	Ex Officio Member
HAZRA, ROHAN	02/03/2021	01/31/2026	CHIEF, MPIDB, DER, CHILD HEALTH & HUMAN DEVELOPMENT, NIH	Ex Officio Member

KAPOGIANNIS, BILL	03/26/2023	09/30/2027	ACTING DIRECTOR, OFFICE OF AIDS RESEARCH PROFESSOR,	Ex Officio Member
LIGHTFOOT, MARGUERITA	03/01/2023	09/30/2024	OREGON HEALTH AND SCIENCE UNIVERSITY- PORTLAND STAT UNIVERSITY SCHOOL OF PUBLIC HEALTH	Ex Officio Member
MEHTA, SHRUTI	02/13/2022	09/30/2024	PROFESSOR AND VICE CHAIR, JOHNS HOPKINS UNIVERSITY	Special Government Employee (SGE) Member
MERMIN, JONATHAN	08/17/2015	09/30/2024	DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION	Ex Officio Member
MILLER, VERONICA	10/25/2020	03/29/2024	EXECUTIVE DIRECTOR, FORUM OF COLLABORATIVE RESEARCH, UNIVERSITY OF CALIFORNIA BERKELEY SCHOOL OF PUBLIC HEALTH	Special Government Employee (SGE) Member
MONTANER, LUIS	05/21/2023	09/30/2025	VICE PRESIDENT FOR SCIENTIFIC OPERATIONS, THE WISTAR INSTITUTE	Special Government Employee (SGE) Member
NAGHAVI, MOJGAN	05/21/2023	09/30/2024	PROFESSOR, NORTHWESTERN UNIVERSITY	Special Government Employee (SGE) Member
NEILAN, ANNE	05/07/2023	09/30/2025	ASSISTANT PROFESSOR, MASSACHUSETTS GENERAL HOSPITAL	Special Government Employee (SGE) Member
OTT, MELANIE	03/01/2023	11/30/2024	PROFESSOR, GLADSTONE INSTITUTE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	Ex Officio Member

RIVERO, RICARDO	10/25/2020	03/29/2024	EXECUTIVE DIRECTOR, MEDWEST AIDS TRAINING & EDUCATION CENTER, UNIVERSITY OF ILLINOIS AT CHICAGO COLLEGE OF MEDICINE	Special Government Employee (SGE) Member
SLEASMAN, JOHN	10/25/2020	03/29/2024	PROFESSOR OF PEDIATRICS AND CHIEF, ALLERGY, IMMUNOLOGY & PULMONARY MEDICINE, DUKE UNIVERSITY MEDICAL CENTER	Special Government Employee (SGE) Member
TABAK, LAWRENCE	12/20/2021	01/20/2025	PERFORMING THE DUTIES OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH	Ex Officio Member
TURNBULL, IVY	04/24/2022	09/30/2024	Deputy Executive Director, The AIDS Institute	Special Government Employee (SGE) Member

Number of Committee Members Listed: 24

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. All of the NIH Institutes and Centers sponsor AIDS research. The OARAC is the only council with advisory responsibilities applicable to the entire NIH AIDS research program. Therefore, it is essential to the coordination of the NIH AIDS scientific effort and research direction of the agency's AIDS programs. At each meeting, the OARAC receives an update on the activities of the five Working Groups. These Working Groups are sponsored under the auspices of the OARAC and are responsible for the development of state-of-the-science federal guidelines for the medical management of HIV disease and its associated coinfections and opportunistic infections in adults, adolescents, and children.

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	\checkmark
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 which 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?

192

Number of Recommendations Comments

Briefing session on specific topics that are timely and of relevance were presented during FY 2023 to update the OARAC with several recommendations. October 2022: Recommendation for (1) prioritizing research to understand the impact inflammation has on aging especially in special conditions such as mpox, COVID, and other infections; (2) OAR to leverage the growing opportunities for early career scientists, particularly within the field of HIV and aging; (3) continuation of focus on special populations and collaborations with fields not traditionally engaged in HIV research; (4) OAR to expand cost-sharing initiatives with divisions and branches of Institutes and Centers; (5) NIH to evaluate how to improve inclusion and representation within HIV research; (6) prioritizing strategies to retain trainees from diverse backgrounds in HIV research. March 2023: Recommendation for (1) OAR to continue to be involved with community groups in the future; (2) OAR to discuss collaboration with the Martin Delaney Collaboratory for HIV Cure Research regarding long-term ART; (3) promotion of the new infant feeding recommendations broadly beyond traditional channel, such as engaging other groups for endorsement, and providing granular information to enhance understanding; (4) the Guidelines to include information about clinical trials and future treatment options. June 2023: Recommendation for (1) improvements to reduce the recurring gap between the execution of research and recruitment of resources to include women in the fields, such as specifically requesting information on recruiting women and diverse populations in research applications; (2) NIH to partner with the Federally Qualified Health Centers to incentivize access to PrEP and encourage investigators to develop collaborative research; (3) strong emphasis on Critical Event Supplemental Funding for career development awardees; (4) listing the Centers for AIDS Research (CFARs) core resources in a central location on OAR's Early Career Investigator Resources website; (5) further development of novel analytics of the HIV research portfolio at the NIH, and ensuring public access to these data.

What is the approximate <u>Percentage</u> of these recommendations that have been or will be <u>Fully</u> 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.

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	\checkmark

Action Comments

The Committee makes recommendations to the federal staff on the planning, coordination, and evaluation of research and other activities in respect to AIDS conducted or supported by the NIH. OARAC also advises the Secretary of Health and Human Services, the Assistant Secretary for Health, the Director of NIH, and the Director of OAR, on AIDS research programs, the development and annual review of the comprehensive plan for the conduct and support of all AIDS activities of the agencies of NIH, including research policies and priorities, and the coordination of domestic and international NIH AIDS efforts.

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	\checkmark
Online Agency Web Site	\checkmark
Online Committee Web Site	\checkmark
Online GSA FACA Web Site	\checkmark
Publications	
Other	

Access Comments

N/A