

2024 Current Fiscal Year Report: Frederick National Laboratory Advisory Committee to the National Cancer Institute

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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.
Frederick National Laboratory Advisory Committee to the National Cancer Institute	76836

4. Is this New Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/30/2023	03/30/2025	

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 U.S.C. 285a-2(b)(7)	11/20/1985	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

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

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 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?

The Committee is composed of distinguished scientists from outside the NCI. The Committee provides scientific advice on existing and new projects (extramural and intramural) to be performed at the Frederick National Laboratory for Cancer Research (FNLCR). The Committee advises the Director, NCI and Associate Director, FNLCR about the intrinsic merit of the projects, and provides insight on proposed directions for ongoing and future work to be done at the FNLCR. This Committee will periodically review the existing portfolio of projects (extramural and

intramural) at the FNLCR, evaluate their productivity, help determine which of these projects should be transitioned to more conventional mechanisms of support, i.e., (grants, contracts, cooperative agreements) and which should be considered for termination. The Committee represents viewpoints from the broader, extramural research community, and helps to assure that the operations at FNLCR are open, transparent, and in the best interest of the entire cancer research community. The Committee will submit a written description of the research and its recommendations to the Director, NCI, Deputy Directors, NCI, and the Associate Director, FNLCR. During FY2023, the Frederick National Laboratory Advisory Committee (FNLAC) was presented reports on various topics related to the organization of the FNLCR and the types of research that are being conducted. Committee discussions and reports included an overview of the Cryo-Electron Microscopy Training Program; the Patient-Derived Models Repository (PDMR); an overview of the Frederick Technology Showcase; the FNLAC RAS Ad Hoc Working Group Report; the Establishment of the NCI RAS Initiative Evaluation Team Ad Hoc Working Group; the FNLAC NCI RAS Initiative Evaluation Team (RIET) Ad Hoc Working Group Report; the Molecular Characterization Laboratory (MoCha); Molecular Pharmacodynamics of an Anti-Body Drug Conjugate (ADC): DS-8201a; the Partnership between the Cancer Genomics Research Laboratory and Division of Cancer Epidemiology and Genetics (DCEG); and an update on the RAS Initiative.

20b. How does the Committee balance its membership?

The Committee will consist of up to 16 members

selected from the public, including the Chair, appointed by the Director, NCI (appointed members). Appointed members will be authorities knowledgeable in cancer research, drug and vaccine development, clinical trials support, AIDS research, bioinformatics, genomics, nanotechnology, biological repositories, and basic research in immunology and infectious diseases. All appointed members must be eligible to serve as and will serve as Special Government Employees. Additionally, the Committee will include, as non-voting ex officio members, a representative from the National Cancer Advisory Board, the NCI Board of Scientific Advisors, and the NCI Board of Scientific Counselors, whose terms of service on this Committee will be limited to the duration of their terms on their respective Boards. No member who is affiliated with the Contractor organization will serve on this Committee.

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

Meetings are held approximately three times each fiscal year. In FY2023, the Committee met three times. FNLAC virtual meetings were held on October 12, 2022, February 27, 2023, and July 10, 2023. The FNLAC provides ongoing review of the relevance and effectiveness of the existing scientific programs (extramural and intramural) at the Frederick National Laboratory for Cancer Research (FNLCR). The FNLAC Ad Hoc National Cryo-Electron Microscopy Program Oversight Working group met virtually on March 27, 2023. The FNLAC Ad Hoc RAS Working Group met virtually on January 10, 2023 and May 26, 2023. The FNLAC Ad Hoc NCI RAS Initiative Evaluation Team Working group met virtually on December 15, 2022, January 17, 2023, and in a hybrid

meeting on January 24 - 25, 2023.

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

This Committee is composed of recognized biomedical research authorities from outside the NIH in order to secure unbiased and objective evaluation of research performed at FNLCR. Their recommendations are invaluable because the complex nature of the research requires a unique balance and breadth of expertise not available at NIH or from other established sources.

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

N/A

21. Remarks

Reports: The working group reports were deliberated on by the Frederick National Laboratory Advisory Committee to the National Cancer Institute. Members Rotating Off/On-Boarding/Vacancies: The committee has two vacancies, one member left the committee (Dr. Andrea Bild), two members rotated off (Drs. Catherine Bollard and Lincoln Stein), and five members were on-boarded (Drs. Carol Bult, Mary Hendrix, Rodney Ho, Angela Gronenborn, and Anant Madabhushi). This is why the Charter states up to 16 members, but this ACR lists 17. Members: The terms for Drs. Timothy Chan and Candace Johnson have changed due to administration extensions. As such, their term of service end dates are different than what was reported on the FY22 ACR. The term for Dr. Nilsa Ramirez Milan has changed due to reappointment. As such, her term of service end date is different than what was reported on the FY22 ACR. Dr. Andrea Bild left the committee on 8/28/2023. As

such, her term of service end date is different than what was reported on the FY22 ACR. The terms for Drs. Lisa Coussens, Serge P. Nana-Sinkam, and Nilsa Ramirez Milan are longer than the charter allows due to their reappointment to the FNLAC given their specific scientific expertise and the need to assure continuity in the functions of the FNLAC and the deliberation of issues brought before the Board. 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

Wlodek Lopaczynski Assistant Director, Division of Extramural Activities, NCI

Committee Members	Start	End	Occupation	Member Designation
BULT, CAROL	02/12/2023	06/30/2026	PROFESSOR AND KNOWLTON FAMILY CHAIR, THE JACKSON LABORATORY	Special Government Employee (SGE) Member
BUSHWELLER, JOHN	01/30/2022	06/30/2025	PROFESSOR, DEPARTMENT OF MOLECULAR PHYSIOLOGY AND BIOLOGICAL PHYSICS, DEPARTMENT OF CHEMISTRY, SCHOOL OF MEDICINE, UNIVERSITY OF VIRGINIA	Special Government Employee (SGE) Member
CHAN, TIMOTHY	07/05/2020	12/31/2023	CHAIR AND FOUNDING DIRECTOR, CENTER FOR IMMUNOTHERAPY AND PRECISION IMMUNO-ONCOLOGY, CLEVELAND CLINIC	Special Government Employee (SGE) Member

COUSSENS, LISA	10/29/2017	06/30/2024	HILDEGARD LAMFROM CHAIR IN BASIC SCIENCE, KNIGHT CANCER INSTITUTE, OREGON HEALTH AND SCIENCE UNIVERSITY UPMC ROSALIND FRANKLIN PROFESSOR AND CHAIR, DEPARTMENT OF STRUCTURAL BIOLOGY, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE	Special Government Employee (SGE) Member
GRONENBORN, ANGELA	02/12/2023	06/30/2026		Special Government Employee (SGE) Member
HENDRIX, MARY	02/12/2023	06/30/2026	PRESIDENT, SHEPHERD UNIVERSITY	Special Government Employee (SGE) Member
HO, RODNEY	02/12/2023	06/30/2026	PROFESSOR, DEPARTMENT OF PHARMACEUTICS, SCHOOL OF PHARMACY, UNIVERSITY OF WASHINGTON	Special Government Employee (SGE) Member
HUBEL, ALLISON	10/12/2021	06/30/2025	PROFESSOR, DEPARTMENT OF MECHANICAL ENGINEERING, UNIVERSITY OF MINNESOTA	Special Government Employee (SGE) Member
JOHNSON, CANDACE	05/26/2020	12/31/2023	PRESIDENT AND CEO, DIRECTOR, WALLACE FAMILY CHAIR IN TRANSLATIONAL RESEARCH, CHAIR, DEPARTMENT OF PHARMACOLOGY AND THERAPEUTICS, ROSWELL PARK CANCER INSTITUTE PROFESSOR AND CHAIR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, SCHOOL OF MEDICINE, WASHINGTON UNIVERSITY IN ST. LOUIS	Special Government Employee (SGE) Member
KHABELE, DINEO	01/30/2022	06/30/2025		Special Government Employee (SGE) Member

MADABHUSHI, ANANT	01/17/2023	06/30/2026	PROFESSOR; WALLACE H COULTER DEPARTMENT OF BIOMEDICAL, ENGINEERING, BIOMEDICAL INFORMATICS, AND PATHOLOGY; GEORGIA INSTITUTE OF TECHNOLOGY AND EMORY UNIVERSITY PROFESSOR OF MEDICINE, CHAIR, DIVISION OF PULMONARY DISEASE AND CRITICAL CARE MEDICINE, VIRGINIA COMMONWEALTH UNIVERSITY PROFESSOR OF CLINICAL PATHOLOGY, THE OHIO STATE UNIVERSITY COLLEGE OF MEDICINE, NATIONWIDE CHILDREN'S HOSPITAL PROFESSOR AND VICE CHAIR, DEPARTMENT OF IMMUNOLOGY AND MICROBIOLOGY, UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS	Special Government Employee (SGE) Member
NANA-SINKAM, SERGE	04/28/2019	06/30/2025		Special Government Employee (SGE) Member
RAMIREZ MILAN, NILSA	10/15/2017	06/30/2024		Special Government Employee (SGE) Member
VAN DYK, LINDA	10/12/2021	06/30/2025		Special Government Employee (SGE) Member

Number of Committee Members Listed: 14

Narrative Description

The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by the Frederick National Laboratory Advisory Committee (FNLAC) to the National Cancer Institute. The Committee will review major new projects proposed

to be performed at Frederick National Laboratory for Cancer Research (FNLCR) and advise the Director, NCI and Associate Director, FNLCR about the intrinsic merit of the projects (extramural and intramural) and about whether they should be done at the FNLCR. In addition, this Committee will periodically review the existing portfolio of projects (extramural and intramural) at FNLCR, evaluate their productivity, help determine which of these projects should be transitioned to more conventional mechanisms of support, i.e., (grants, contracts, cooperative agreements) and which should be considered for termination. The Committee will help to assure that the operations at FNLCR are open, transparent, and in the best interest of the entire cancer research community. The Committee will submit a written description of the research and its recommendations to the Director, NCI, Deputy Directors, NCI, and the Associate Director, FNLCR.

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 type="checkbox"/>
Major policy changes	<input 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

Based on the recommendations of this committee, effective direction of the activities at the FNLCR has the potential to provide significant advances in cancer research and public health. The projects and programs at FNLCR, for which this Committee provides advice, could lead to new approaches and tools for cancer investigation, prevention, diagnosis and therapeutic interventions. The results and technologies may be applicable

to other human health concerns.

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 new 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?

58

Number of Recommendations Comments

In addition to four general recommendations during FY23, specific recommendations by the committee include: 1) A motion to accept the report of the FNLAC RAS Ad Hoc Working was approved unanimously. 2) A motion to concur on the establishment of the FNLAC NCI RAS Initiative Evaluation Team Ad Hoc Working Group was approved unanimously. 3) A motion to approve the updated mission statements of the FNLAC Ad Hoc National Cryo-Electron Microscopy Program Oversight Working Group and the FNLAC Ad Hoc National Cryo-Electron Microscopy Program Oversight Subcommittee was approved unanimously. 4) A motion to accept the report of the FNLAC Ad Hoc NCI RAS Initiative Evaluation Team Working Group was approved unanimously.

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,

NCI 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 issues and the role of this committee, NCI 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

At each meeting, the NCI Director, the NCI Deputy Directors, and other NCI leaders provide a report to the Committee members and the public. 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 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 committee continues to review the state of research (extramural and intramural) at the Frederick National Laboratory for Cancer Research (FNLCR) and make recommendations for the best use of its capabilities and infrastructure. They reviewed major new projects proposed to be performed at FNLCR and periodically review the existing portfolio of projects at FNLCR. The Committee helped to assure that the operations at FNLCR are open, transparent, and in the best interests of the entire cancer research community. The Committee also considered proposed research and provided

advice as to whether the FNLCR is the best mechanism for carrying out these projects which it deems to be of merit and to be consistent with the mission of the National Cancer Institute (NCI) and FNLAC. There were specific discussions regarding the Cryo-Electron Microscopy Training Program; the Patient-Derived Models Repository (PDMR); the Frederick Technology Showcase; the FNLAC RAS Ad Hoc Working Group Report; the Establishment of the NCI RAS Initiative Evaluation Team Ad Hoc Working Group; the FNLAC NCI RAS Initiative Evaluation Team (RIET) Working Group Report; the Molecular Characterization Laboratory (MoCha); Molecular Pharmacodynamics of an Anti-Body Drug Conjugate (ADC): DS-8201a; the Partnership between the Cancer Genomics Research Laboratory and Division of Cancer Epidemiology and Genetics (DCEG); and an update on the RAS Initiative. FNLAC unanimously approved the motion to accept the report of the FNLAC RAS ad hoc Working Group at their October 12, 2022 meeting. The RAS ad hoc Working Group recommended the following for consideration during the next stage of the RAS Initiative: continuing efforts to translate in-house NCI RAS Initiative compounds to the clinic; continuing the pursuit of secondary targets, such as the PI3Ka-RAS “complex breaker” compound, for use as salvage or combination therapy; continuing to catalyze the renaissance in RAS targeting approaches on a global scale; and expanding community engagement to further the impact of the NCI RAS Initiative. FNLAC unanimously approved the motion to accept the report of the FNLAC NCI RIET Ad Hoc Working Group at their February 27, 2023 meeting. The RIET Working Group offered several points for consideration in planning the future of the RAS Initiative which included some of the following: the RAS Initiative has not led the field in developing RAS drugs, which so far have originated with seminal discoveries conducted by research groups in academia and industry; the RAS Initiative should improve transparency with the wider scientific community regarding how projects are transitioned to commercial entities; a process to ensure wider distribution of RAS Initiative compounds and knowledge (especially the recently developed cysteine tethering library) to the external community would be beneficial; RAS Initiative teams appear to have diffuse objectives, and a better delineation of critical goals would be needed for future success; and RAS Initiative projects should emphasize the unique capabilities of the FNLAC and have well-defined decision points before being ushered into new phases. Based on these points, two views of the future of the RAS Initiative held by the Working Group members were described. Some members held the view that the RAS Initiative’s goals largely have been met and that a phased sunseting of the program will make the extraordinary capabilities of the team available for other efforts. Whereas, other members’ position was that the program should remain because important contributions likely will continue being made. However, even the second group considers that the RAS Initiative should operate differently going forward, with the following recommendations being made: 1) Focus on research that only the RAS Initiative can tackle effectively. Research projects should meet this uniqueness

criterion, include clear decision points, and be guided by an advisory board that is constituted to make objective assessments. 2) Make reagents developed by the RAS Initiative available to the research community. 3) Provide the scientific community with greater transparency on the process whereby the RAS Initiative engages with pharmaceutical companies via the CRADA mechanism. 4) Share the RAS Initiative's outstanding biochemistry and structural biology findings with the extramural community to help guide relevant functional studies of RAS. At their July 10, 2023, meeting, a presentation was made regarding recent work involving mechanism-of-action studies of DS-8201a, an antibody drug conjugate (ADC) that is constructed by chemically linking a small-molecule drug and payload. Trastuzumab deruxtecan (DS-8201A) is the active pharmaceutical ingredient in ENHERTU®, an approved drug product for both HER2-positive breast cancer and HER2-low breast cancer. It was remarked that profound biological differences are present between the two tumor types. An overview of the valuable partnership between the Cancer Genomics Research Laboratory (CGR) and the Division of Cancer Epidemiology and Genetics (DCEG) was also provided. The key aspects of this partnership include leveraging sequencing technologies, managing high throughput samples, leveraging aliquoting capabilities for new efforts, and expanding molecular and digital pathology to enable somatic studies. It was emphasized that the partnership drives discovery in various areas, including supporting functional validation or characterization of findings, understanding how genetic variations affect cancer susceptibility and outcome, evaluating the functional consequence of genomic and epigenomic alterations, determining the pathogenesis of cancer, and supporting the training of students and fellows.

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

No

Grant Review Comments

N/A

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 checked="" type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Access Comments

Information on the FNLAC can be found at the NCI Division of Extramural Activities: Advisory Boards and Groups website at <http://deainfo.nci.nih.gov/advisory/fac/fac.htm>. Each NCI committee's charter, minutes, agenda, roster, future meeting dates, meeting PowerPoint presentations and reports is located here. Additionally, the public may view the FNLAC meetings via the NIH Videocast at the following website: <http://videocast.nih.gov/>.