2025 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	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Frederick National Laboratory Advisory Committee to the National Cancer Institute	76836

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

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	2025 Secretary Directive	02/19/2025

9. Agency Recommendation for Next FiscalYear	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. Commitee 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 FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	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 FY2024, 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 included the FNLCR and the NCI's new Precision Medicine Initiatives: MDNet, iMATCH, ComboMATCH, and the MyeloMATCH; the Cryo-EM Study of the SARS-CoV-2 Polyprotein Cleavage by the Main Protease Mpro and the National Cryo-EM Program (NCEP); the Division of Cancer Treatment and Diagonsis Biopharmaceutical Development and Production at the FNLCR; the National Cancer Institute (NCI) and Department of Energy (DOE) Collaborations: AI-Driven Multi-Scale Investigation of the RAS/RAF Activation Lifecycle (ADMIRRAL) Project, Innovative Methodologies and New Data for Predictive Oncology Model Evaluation (IMPROVE); and MOSSAIC: Achieving Near Real-Time Cancer Surveillance with Automatic Record Abstraction; Frederick National Laboratory/NCI Support of Friends of Cancer Research's Tumor Mutational Burden (TMB) and

Homologous Recombination Deficiency (HRD) Harmonization Projects; RAS Initiative Update: Testing Our Drugs in the Clinic; and the Serological Sciences Network (Seronet): NCI's Response to COVID-19.

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?

FNLAC meetings are held approximately three times each fiscal year. During FY2024, the Committee met three times with virtual meetings convened on October 19, 2023, March 11, 2024, and July 10, 2024. The FNLAC provides ongoing review of the relevance and effectiveness of the existing scientific programs (extramural and

intramural) at the FNLAC. The FNLAC also establishes working groups to provide the highest quality oversight to the technical aspects of high-visibility/ high-impact FNLCR programs such as the NCI RAS Initiative and the National Cryo-EM Program and to provide findings, recommendations, and reports to the Frederick National Laboratory Advisory Committee (FNLAC) on an as needed basis. The FNLAC RAS Ad Hoc Working Group typically meet 3-4 times/year. This group met virtually on December 7, 2023, April 6, 2024, and on August 5, 2024 during FY2024. The FNLAC Ad Hoc National Cryo-Electron Microscopy Program Oversight Working Group meetings are typically held twice/year. A virtual meeting was convened on April 26, 2024.

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
Per Executive Order (E.O.) 14217, "COMMENCING THE REDUCTION OF THE FEDERAL BUREAUCRACY" this FACA Committee has been terminated. Reports: The Frederick National Laboratory Advisory Committee to the National Cancer Institute did not produce a

report this fiscal year. Members: The terms for Drs. Timothy Chan and Candace Johnson have changed due to reappointment. As such their terms of service end date differ with what was reported on the FY23 ACR. The terms for Drs. Lisa Coussens and Nilsa Ramirez-Milan have changed due to administration extensions. As such, their terms of service end date differ with what was reported on the FY23 ACR. The terms for Drs. Coussens, Johnson, and 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

Christopher Dennis Kane Supervisory Health Scientist Administrator and Program Officer

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	06/30/2025	CHAIR AND DIRECTOR, CENTER FOR IMMUNOTHERAPY AND PRECISION IMMUNO-ONCOLOGY, CLEVELAND CLINIC	Special Government Employee (SGE) Member
COUSSENS, LISA	10/29/2017	12/27/2024	HILDEGARD LAMFROM CHAIR IN BASIC SCIENCE, PROFESSOR AND CHAIR, CELL DEVELOPMENTAL AND CANCER BIOLOGY , ASSOCIATE DIRECTOR FOR BASIC RESEARCH, KNIGHT CANCER INSTITUTE, OREGON HEALTH AND SCIENCE UNIVERSITY	Special Government Employee (SGE) Member
GRONENBORN, ANGELA	02/12/2023	06/30/2026	UPMC ROSALIND FRANKLIN PROFESSOR AND CHAIR, DEPARTMENT OF STRUCTURAL BIOLOGY, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE	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	06/30/2025	PRESIDENT & CEO, ROSWELL PARK COMPREHENSIVE CANCER CENTER M&T BANK PRESIDENTIAL CHAIR IN LEADERSHIP, ROSWELL PARK COMPREHENSIVE CANCER CENTER	Special Government Employee (SGE) Member
KHABELE, DINEO	01/30/2022	06/30/2025	PROFESSOR AND CHAIR, DEPARTMENT OF OBSTETRICS AND GYNOCOLOGY, SCHOOL OF MEDICINE, WASHINGTON UNIVERSITY IN ST. LOUIS	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	Special Government Employee (SGE) Member
NANA-SINKAM, SERGE	04/28/2019	06/30/2025	PROFESSOR OF MEDICINE, CHAIR, DIVISION OF PULMONARY DISEASE AND CRITICAL CARE MEDICINE, VIRGINIA COMMONWEALTH UNIVERSITY	Special Government Employee (SGE) Member
RAMIREZ MILAN, NILSA	10/15/2017	12/27/2024	PROFESSOR OF CLINICAL PATHOLOGY, THE OHIO STATE UNIVERSITY COLLEGE OF MEDICINE, NATIONWIDE CHILDREN'S HOSPITAL	Special Government Employee (SGE) Member

VAN DYK, LINDA	10/12/2021	06/30/2025	PROFESSOR AND VICE CHAIR, DEPARTMENT OF IMMUNOLOGY AND MICROBIOLOGY, UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS	Special Government Employee (SGE) Member
VANDER HEIDEN, MATTHEW	06/30/2024	06/30/2027	DIRECTOR, KOCH INSTITUTE FOR INTERGRATIVE CANCER RESEARCH, MASSACHUSETTS INSTITUTE OF TECHNOLOGY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

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	✓
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

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	
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 ways to treat and prevent diseases.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
62

Number of Recommendations Comments
The committee made four general recommendations during FY24.

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	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

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 FNLCR. There were specific discussions regarding FNLCR New Precision Medicine Initiatives: MDNet, iMATCH, ComboMATCH, and MyeloMATCH; the National Cryo-EM Program (NCEP) and a Cryo-EM study of the SARS-CoV-2 Polyprotein Cleavage by the Main Protease Mpro; the Division of Cancer Treatment and Diagnosis Biopharmaceutical Development and Production at the FNLCR; the NCI and Department of Energy (DOE) Collaborations: i) AI-Driven Multi-Scale Investigation of the RAS/RAF Activation Lifecycle (ADMIRRAL) Project, ii) Innovative Methodologies and New Data for Predictive Oncology Model Evaluation (IMPROVE), iii) MOSSAIC: Achieving Near Real-time Cancer Surveillance with Automatic Record Abstraction; Frederick National Lab/NCI support of Friends of Cancer Research Tumor Mutational Burden (TMB) and Homologous Recombination Deficiency (HRD) Harmonization Process; and NCI National Missions status updates including i) NCI RAS Initiative: Testing our Drugs in the Clinic, and ii) the Serological Sciences Network (Seronet): NCI’s Response to COVID-19. The October 19, 2023, discussion focused on FNLCR impact to translational research and collaborations with the extramural cancer research community. This included presentations regarding the NCI’s Precision Medicine Initiatives and National Cryo-EM Program (NCEP). The new Precision Medicine Initiatives emphasized a coordinated effort across the NCI, FNLCR, and extramural research community and highlighted the FNLCR for its role in producing data, developing assays, and providing oversight across the national network of laboratories. Points of emphasis included: i) the iMATCH treatment regimen was determined in discussion with extramural investigators. The decision was made based on activity in other tumor types and in combination with immunotherapy, ii)

the NCI-MATCH pathology slides have been digitized and are being used in relevant studies. ComboMATCH is pursuing similar digitization efforts of samples that are submitted for further analysis, and iii) lists of genes for screening will be updated as needed, based on the current data. The lists are based on guidance from international consensus groups, but harmonization remains an ongoing challenge. The study is focused on predictive, not prognostic, findings. The National Cryo-EM Facility (NCEF) was established in 2017 to support the extramural community, and the facility was intended to expand as technologies continue to develop. The NCEP was created in 2019 to explore new platforms and to support methods and technology development for the cryo-EM field. The NCEP supports three user groups: (1) research groups with experience in cryo-EM technology, (2) structural biologists from adjacent disciplines (e.g., X-ray, nuclear magnetic resonance), and (3) biologists focused on important biomedical problems who are interested in adding cryo-EM methods to their toolkit. Key aspects of National Cryo-EM Program (NCEP) include: i) Increased capacities for high-resolution measurements provide opportunities for small-molecule drug discovery. The NCEP is interested in exploring this area further in the future, but potential applications depend on the molecule of interest, ii) NCEP has considered conducting training for support staff and facility managers, which could help with the operation of other facilities. Training of young investigators also is critical, iii) advances in tomography would expand capabilities for users. The NCEP is interested in establishing the platform, and the effort will constitute a multiyear process. The March 11, 2024, FNLAC meeting featured strategically important collaborations with either the extramural research community or between United States Government agencies. The FNLCR Biopharmaceutical Development and Production (BDP) aims to provide resources to the community, fill gaps, foster development of new biotechnologies, disseminate the knowledge gained, and share unique resources with NIH partners. The division is focused on developing biological isolates and extracts, recombinant proteins, antibodies, antibody–drug conjugates and associated imaging agents, virus products and virus-like particles, and bacterial-based therapies. Newer areas of focus include engineered cells and synthetic biology. Key points included: i) GMP development and production is extremely expensive, and the science is generally well established for these clinical studies. Other partners, such as the members of the Can-ACT network, are well equipped to study scientific questions that can transition to a clinical trial, ii) the Can-ACT network is focused on centralized manufacturing; logistics establishment; and well-controlled, repeatable, robust manufacturing and analytical processes. The team has established a cryopreservation-based logistics process with the appropriate chain of custody documentation, iii) a workshop or symposium highlighting FNLCR’s activities in this space could provide valuable information to the research community, iv) Access to BDP’s services is controlled through associated networks and programs. Availability is strained by recent increases in demand. The long-term,

interagency collaboration between the NCI and DOE the NCI–U.S. Department of Energy (DOE) started in 2016 and is in its second 5-year Memorandum of Understanding period among various national laboratories, including the FNLCR, Argonne National Laboratory (ANL), Oak Ridge National Laboratory (ORNL), and Los Alamos National Laboratory (LLNL). This collaboration has supported several projects, including ADMIRRAL, IMPROVE, and MOSSAIC. ADMIRRAL was started in collaboration with NCI and is a part of the RAS Initiative. The LLNL provides capabilities for high-performance computing at scale. The team is performing molecular dynamic (MD) simulations verified by experimental results. IMPROVE which is focused on analyzing and improving predictive models for tumor drug response. They explained that AI offers potential for predicting the outcome of cancer therapies, particularly chemotherapy, but this technology is still in early development. IMPROVE is focused on trustworthiness and reproducibility of the AI being used in this application. MOSSAIC in achieving near real–time cancer surveillance with automatic record abstraction. They explained that NCI's Surveillance Epidemiology, and End Results (SEER) Program provides the framework for MOSSAIC's work. SEER was authorized by the National Cancer Act with the mission to support research, and the SEER registries submit deidentified data to NCI, which are made available to researchers through appropriate authentication and authorization processes. Collectively, the collaborations between NCI and DOE enables cancer researchers analyze basic science, translational, and clinical data with DOE's state-of-the-art artificial intelligence, machine learning, and other advanced analytics to accelerate cancer research through predictive modeling and advanced computing. The July 10, 2024, FNLAC meeting focused on a translational extramural collaboration and status updates from two NCI National Mission Programs; The NCI RAS Initiative and the Serological Sciences' Seronet. The translational collaboration took place with the "Friends of Cancer Research" consortium and was focused on harmonization of Tumor Mutational Burden (TMB); an assay used as a predictive biomarker that correlates with clinical benefit from cancer immunotherapies. However, methods of TMB estimation and reporting vary widely across clinical studies and the FNLCR played a major role in the initiative to facilitate standardization and best practices for estimating and reporting TMB. The approach was to convene multi-stakeholder working group to conduct studies that generate evidence to drive alignment & consensus solutions. TMB estimates varied substantially between participating labs and particular calibration methods may be a viable approach to align across panel TMB scores. Recent progress and outcomes of NCI National Mission Programs was also provided. The NCI RAS Initiative shared clinical development progress for BBO-8520, the team's first clinical candidate covalent KRAS G12C inhibitor that binds the GTP (ON) active state. They also disclosed preclinical evaluation of a first-in-class KRAS/PI3Kalpha complex breaking inhibitor name BBO-10203. Importantly, the team is evaluating BBO-8520 and BBO-10203 combinations and other combination

therapy options with a view towards the treatment of KRAS drug resistant tumors. Seronet was established through supplemental funding from Congress of $306M enacted on April 24th, 2020, for NCI to develop, validate, improve, and implement serological testing and associated technologies COVID-19-focused and distinct from annual appropriation. The program established a nationwide network supporting a broad range of serological sciences research to advance understanding of all aspects of the immune response to SARS-CoV-2 infection & vaccination. Seronet functions as a coordinated research network that i) provided U54 and U01 research grant funding; supported capacity building for FNLCR contracts, the FNLCR Serology Lab, and the FNLCR Network Coordinating Center. Importantly, its efforts focused on special populations including subject with cancer and immune-mediated disease, and other at-risk populations with respect to COVID-19 infections. Seronet undertook frequent assessments for adjustments to meet current research needs. As the COVID-19 pandemic diminished over time, the Capacity Building Centers (CBC) now maintain a single CBC through 2024 for breadth of longitudinal study cohorts and ongoing research and will discontinue efforts at other 3 CBCs. A recent assessment of the impact of Seronet funded research programs demonstrated that SeroNet articles have a higher percent of highly-cited articles compared to other COVID articles coauthored by U.S. researchers or funded by NIH.

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	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	✓

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/.