

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 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 |
| Yes | 2025 Secretary Directive | 04/01/2025 |

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|--|---|----------------------------------|
| 9. Agency Recommendation for Next Fiscal Year | 10a. Legislation Req to Terminate? | 10b. Legislation Pending? |
| Terminate | No | Not Applicable |

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|---|---------------------------|---------------------------|---------------------------|
| 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 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

| | | |
|---------|-------|-----|
| Purpose | Start | End |
|---------|-------|-----|

Number of Committee Meetings Listed: 1

| | Current FY | Next FY |
|--|-----------------------|--------------------|
| 18a(1). Personnel Pmts to Non-Federal Members | \$2,400.00 | \$0.00 |
| 18a(2). Personnel Pmts to Federal Members | \$0.00 | \$0.00 |
| 18a(3). Personnel Pmts to Federal Staff | \$14,276.00 | \$0.00 |
| 18a(4). Personnel Pmts to Non-Member Consultants | \$600.00 | \$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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings) | \$0.00 | \$0.00 |
| 18d. Other (all other funds not captured by any other cost category) | \$13,810.00 | \$0.00 |
| 18e. Total Costs | \$31,086.00 | \$0.00 |
| 19. Federal Staff Support Years (FTE) | 0.00 | 0.00 |

20a. How does the Committee accomplish its purpose?

The Committee was composed of distinguished scientists from outside the NCI. The Committee provided scientific advice on existing and new projects (extramural and intramural) to be performed at the Frederick National Laboratory for Cancer Research (FNLCR). The Committee

advised the Director, NCI and Associate Director, FNLCR about the intrinsic merit of the projects, and provided insight on proposed directions for ongoing and future work to be done at the FNLCR. This Committee periodically reviewed the existing portfolio of projects (extramural and intramural) at the FNLCR, evaluated their productivity, helped determine which of these projects should be transitioned into more conventional mechanisms of support, i.e., (grants, contracts, cooperative agreements) and which should be considered for termination. The Committee represented viewpoints from the broader, extramural research community, and helped to ensure that the operations at FNLCR were open, transparent, and in the best interests of the entire cancer research community. The Committee submitted a written description of the research and its recommendations to the Director, NCI, Deputy Directors, NCI, and the Associate Director, FNLCR.

20b. How does the Committee balance its membership?

The Committee consisted of up to 16 appointed members from the public, including the Chair, selected by the Director of NCI. These appointed members were authorities in areas such as cancer research, drug and vaccine development, clinical trial support, AIDS research, bioinformatics, genomics, nanotechnology, biological repositories, and basic research in immunology and infectious diseases. All appointed members were eligible to serve—and served—as Special Government Employees. In addition to the appointed members, the Committee included non-voting ex officio members representing the National Cancer Advisory Board, the NCI Board of Scientific Advisors, and the NCI Board of Scientific

Counselors. Their service on this Committee was limited to the duration of their terms on their respective Boards. No individual affiliated with the Contractor organization served on this Committee.

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

FNLAC meetings were planned for three occasions during the fiscal year. However, during FY2025 only a single virtual committee meeting was convened on October 23, 2024 while all subsequent meetings were cancelled. The FNLAC provided ongoing review of the relevance and effectiveness of the existing scientific programs (extramural and intramural) at the FNLAC. The FNLAC also established working groups to provide the highest quality oversight to the technical aspects of high-visibility/ high-impact FNLAC 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 5, 2024 and subsequent meetings were canceled. The FNLAC Ad Hoc National Cryo-Electron Microscopy Program Oversight Working Group meetings are typically held twice/year. No Cryo-Electron Microscopy Working Group meetings were held during FY25. This Committee was composed of recognized biomedical research authorities from outside the NIH to secure unbiased and objective evaluation of research performed at FNLAC. Their recommendations were invaluable because the complex nature of the research required a unique balance and breadth of expertise not available at NIH or from other established sources.

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

This Committee was composed of recognized biomedical research authorities from outside the NIH to ensure unbiased and objective evaluations of the research conducted at FNLCR. Their recommendations were invaluable, as the complex nature of this research requires a unique balance and breadth of expertise not readily available within the NIH or through other established sources.

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

N/A

21. Remarks

Termination determined through a directive by HHS Secretary Robert F. Kennedy, Jr. in response to Executive Order 14217, Commencing the Reduction of the Federal Bureaucracy.

Website: The committee does not have a website.

Reports: The committee did not produce any public reports. Max Number of Members Total:

The Charter authorized up to 16 members, including the Chair. At the time of termination, the committee had 15 SGE members. Members:

Member term end dates differ from those reported in the FY2024 ACR due to the committee's termination. DFO/Committee Decision Maker:

These roles are held by the same individual based on the Institute's assignment of responsibilities.

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 | 03/31/2025 | PROFESSOR AND KNOWLTON FAMILY CHAIR, THE JACKSON LABORATORY | Special Government Employee (SGE) Member |
| BUSHWELLER, JOHN | 01/30/2022 | 03/31/2025 | 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 | 03/31/2025 | CHAIR AND DIRECTOR, CENTER FOR IMMUNOTHERAPY AND PRECISION IMMUNO-ONCOLOGY, CLEVELAND CLINIC | Special Government Employee (SGE) Member |
| COUSSENS, LISA | 10/29/2017 | 12/31/2024 | 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 | 03/31/2025 | UPMC ROSALIND FRANKLIN PROFESSOR AND CHAIR, DEPARTMENT OF STRUCTURAL BIOLOGY, UNIVERSITY OF PITTSBURGH | Special Government Employee (SGE) Member |
| HENDRIX, MARY | 02/12/2023 | 03/31/2025 | SCHOOL OF MEDICINE PRESIDENT, SHEPHERD UNIVERSITY | Special Government Employee (SGE) Member |

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|-----------------------|------------|------------|---|--|
| HO, RODNEY | 02/12/2023 | 03/31/2025 | PROFESSOR, DEPARTMENT OF PHARMACEUTICS, SCHOOL OF PHARMACY, UNIVERSITY OF WASHINGTON | Special Government Employee (SGE) Member |
| HUBEL, ALLISON | 10/12/2021 | 03/31/2025 | PROFESSOR, DEPARTMENT OF MECHANICAL ENGINEERING, UNIVERSITY OF MINNESOTA | Special Government Employee (SGE) Member |
| JOHNSON, CANDACE | 05/26/2020 | 03/31/2025 | 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 | 03/31/2025 | PROFESSOR AND CHAIR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, SCHOOL OF MEDICINE, WASHINGTON UNIVERSITY IN ST. LOUIS | Special Government Employee (SGE) Member |
| MADABHUSHI, ANANT | 01/17/2023 | 03/31/2025 | 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 | 03/31/2025 | PROFESSOR OF MEDICINE, CHAIR, DIVISION OF PULMONARY DISEASE AND CRITICAL CARE MEDICINE, VIRGINIA COMMONWEALTH UNIVERSITY | Special Government Employee (SGE) Member |

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|------------------------|------------|------------|---|--|
| RAMIREZ MILAN, NILSA | 10/15/2017 | 12/31/2024 | 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 | 03/31/2025 | 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 | 03/31/2025 | 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 that helps prevent, detect, diagnose, and treat disease and disability—from the rarest genetic disorders to the common cold. The NIH mission is to uncover scientific insights that will lead to better health for all people. NIH advances this mission in part through the Frederick National Laboratory Advisory Committee (FNLAC) to the National Cancer Institute (NCI). The Committee is responsible for reviewing major new projects proposed for the Frederick National Laboratory for Cancer Research (FNLCR) and advising the NCI Director and the Associate Director of FNLCR regarding the intrinsic merit of these intramural and extramural projects, including whether they are appropriate to be conducted at FNLCR. In addition, the Committee periodically reviews the existing portfolio of intramural and extramural projects at FNLCR to evaluate their productivity. It helps determine which projects should transition to more conventional mechanisms of support—such as grants, contracts, or cooperative agreements—and which should be considered for

termination. Through this process, the Committee helps ensure that FNLCR operations remain open, transparent, and in the best interests of the broader cancer research community. The Committee provides its findings and recommendations in writing to the NCI Director, NCI Deputy Directors, and the Associate Director of 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 had the potential to provide significant advances in cancer research and public health. The projects and programs at FNLCR, for which this Committee provided 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

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. Robust prioritization of promising programs, therapies, and diagnostics lowered the opportunity cost of complex biomedical R&D.

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

64

Number of Recommendations Comments

The committee made two general recommendations during FY25.

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 were unable to determine which recommendations have been fully 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, NCI staff were unable to determine which recommendations have been 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 provided reports to the Committee members and the public. Information related to the Committee could also be viewed by the public 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 continued 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. The October 23, 2024 discussion focused on FNLCR impact to translational research and collaborations with the extramural cancer research community. This included presentations regarding the NCI's Natural Products Branch, the National Cryo-EM Program (NCEP), and a potential partnership to enable a Systems Biomedicine Approach to Cancer Treatment. The first discussion explained that natural products continued to make a significant impact in cancer chemotherapy and highlighted examples of two natural products that are moving forward toward clinical approval for cancer. Natural products and their derivatives have a record of success in clinical trials. FNLCR holds the largest U.S. repository of crude and natural extracts, representing collections from around the world and from various sources (e.g., marine, plants, microbes). To date, more than 680,000 fractions have been produced from NCI crude extracts. A pre-fractionated library of 500,000 natural product samples has been publicly released, and more than 9 million wells have been shipped to screening centers. Discovery and development activities for EC8042, a mithramycin analog, for treatment of

Ewing sarcoma was highlighted. The team's data suggested that for this drug to be effective in reversing the oncogenic transcriptome, it must be administered continuously, and this work presented an opportunity to evaluate the continuous infusion based on the mechanistically defined schedule. The discussion concluded by emphasizing that this work reflects efforts by DTP, DCTD, NPB, extramural researchers, and industry partners. This is currently an approved next-development project moving into broader animal toxicity studies, with a goal of being advanced to the clinic. The importance of NCI and FNLCR was underscored in these efforts. 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 program 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. The technology development team has pushed the boundaries of resolution using lower-energy electron microscopes and pairing them with next-generation or newer-generation detectors to assess whether inexpensive platforms can yield high-resolution structures. NCEF has collected data for 160 investigators from more than 60 institutions. The team completed 1,300 imaging sessions, with an average of 19 imaging sessions per month in 2024. This work resulted in 128 scientific papers throughout the past 7 years (with 21 papers in the past year), many of which are published in high-impact journals. More than 240 structures have been deposited in the Electron Microscopy Data Bank, and NCEF users are distributed across the United States. Recent NCEF user successes were highlighted including multiple nucleoside analogs, which can be applied to the development of cancer and antiviral therapeutics. The team identified differences in their binding and transport properties that will inform future drug design. The third discussion provided an introduction to the development of SysCan, a systems cancer biomedicine demonstration project. SysCan builds on the successes of previous FNLCR projects, with a focus on emerging needs across the cancer research community. The team invited leading cancer researchers from across the research continuum to discuss ideas for FNLCR projects. All the ideas were reviewed, organized by topic, and assigned to either FNLCR or NCI, as appropriate. SysCan, which synthesizes three of the themes for FNLCR (spatial systems biology, experimental therapeutics, and perturbation technology) into a single initiative. This initiative approaches cancer as a disease that affects the entire body. SysCan is an FNIH/NCI demonstration project to develop, deploy, and test a systems biomedicine-based treatment strategy for an important human cancer that simultaneously attacks cancer cells directly and purposefully manipulates multiple intercellular interactions to create strong antitumor (i.e., tumoricidal) microenvironments. The project was envisioned in two phases. First, the team plans to engage leaders from the intramural and extramural

research communities, potential pharmaceutical and biotechnology partners, relevant academic societies, patients and advocates, and regulatory agencies to refine the overall approach. The proposed next phase of the project would focus on implementation. proposed that FNLCR could act as a hub for SysCan, coordinating such activities as engagement with regulatory agencies, academic research and technology development, public and private informatics initiatives, biotechnology partnerships for diagnostics and therapeutic delivery platforms, pharmaceutical partnerships for drug development, and coordination between FNIH and NCI. This concept is still in the early stages, and it was agreed to keep the FNLAC members updated on the team's progress.

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 type="checkbox"/> |
| Online Committee Web Site | <input 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 was previously available on the NCI Division of Extramural Activities: Advisory Boards and Groups website at <http://deainfo.nci.nih.gov/advisory/fac/fac.htm>, which is no longer active. This site provided access to each NCI committee's charter, minutes, agenda, roster, future meeting dates, meeting PowerPoint presentations, and reports. In addition, the public could view FNLAC meetings through the NIH Videocast service at <http://videocast.nih.gov/>.