NIH NATIONAL CANCER INSTITUTE

Orientation for the Frederick National Laboratory Advisory Committee

National Institutes of Health
Bethesda, Maryland

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

FNLAC

APRIL 2022

Orientation

for the

Frederick National Laboratory Advisory Committee

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FOREWORD

Congratulations on your recent appointment to the Frederick National Laboratory Advisory Committee (FNLAC). As you join this distinguished committee, we could not be more honored to have you working with the National Cancer Institute (NCI).

The primary task of the FNLAC is to advise the Director of the NCI and the Associate Director, Frederick National Laboratory of Cancer Research (FNLCR), on the state of research (extramural and intramural) being conducted at the FNLCR and to make recommendations for the best use of the FNLCR capabilities and infrastructure. Specifically, you will review new projects proposed to be performed at the FNLCR with respect to the intrinsic merit of the projects and whether they should be conducted at the FNLCR. In addition, you will periodically review the existing portfolio of projects at the FNLCR, evaluate their productivity and scientific impact, 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. As a FNLAC member, you will help to ensure that the operations at the FNLCR are open, transparent, and in the best interests of the entire cancer research community.

This briefing document has been prepared to provide new members of the FNLAC with an overview of the mission, history, and activities of the FNLCR and the NCI.

The first section of the book presents the NCI in the context of the total U.S. Department of Health and Human Services (HHS) and National Institutes of Health (NIH) organization. It includes budgetary information, cites current legislative statutes, and describes organizational structure, program disciplines, and mechanisms of funding used by the NCI.

The second section provides a description of the FNLCR, including a timeline that chronicles the establishment and evolution of the FNLCR and the establishment of the FNLAC. It also delineates the roles of external committees that advise the NCI in the conduct of its activities.

We are pleased to provide you with this FNLAC Orientation Book and hope you will refer to it in fulfilling your responsibilities as a member of the FNLAC.

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Mission and Organization

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. The HHS consists of the Office of the Secretary, which provides leadership; the Program Support Center, which provides centralized administrative support; and 11 operating divisions, including eight agencies in the U.S. Public Health Service (PHS), and three human services. The Office of the Secretary (OS), the chief policy officer and general manager of HHS, administers and oversees the organization, its programs, and its activities. The deputy secretary and several assistant secretaries and offices support the OS. The operating Divisions of HHS include:

- **Administration for Children and Families (ACF)**
- **Administration of Community Living (ACL)**
- **Agency for Healthcare Research and Quality (AHRQ)**
- **Agency for Toxic Substances and Disease Registry (ATSDR)**
- **Centers for Disease Control and Prevention (CDC)**
- **Centers for Medicare and Medicaid Services (CMS)**
- **Food and Drug Administration (FDA)**
- **Health Resources and Services Administration (HRSA)**
- **Indian Health Service (IHS)**
- **National Institutes of Health (NIH)**
- **Program Support Center (PSC)**
- **Substance Abuse and Mental Health Services Administration (SAMHSA)**

The ACF supports a variety of initiatives that promote the economic and social well-being of families, children, individuals, and communities. The ACL works to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. The CMS manages health insurance programs. NIH, AHRQ, ATSDR, CDC, FDA, HRSA, IHS, and SAMHSA are all devoted to public health and compose PHS. (See **Exhibit I** for HHS Organization).

THE NATIONAL INSTITUTES OF HEALTH

Mission, Organization, and History

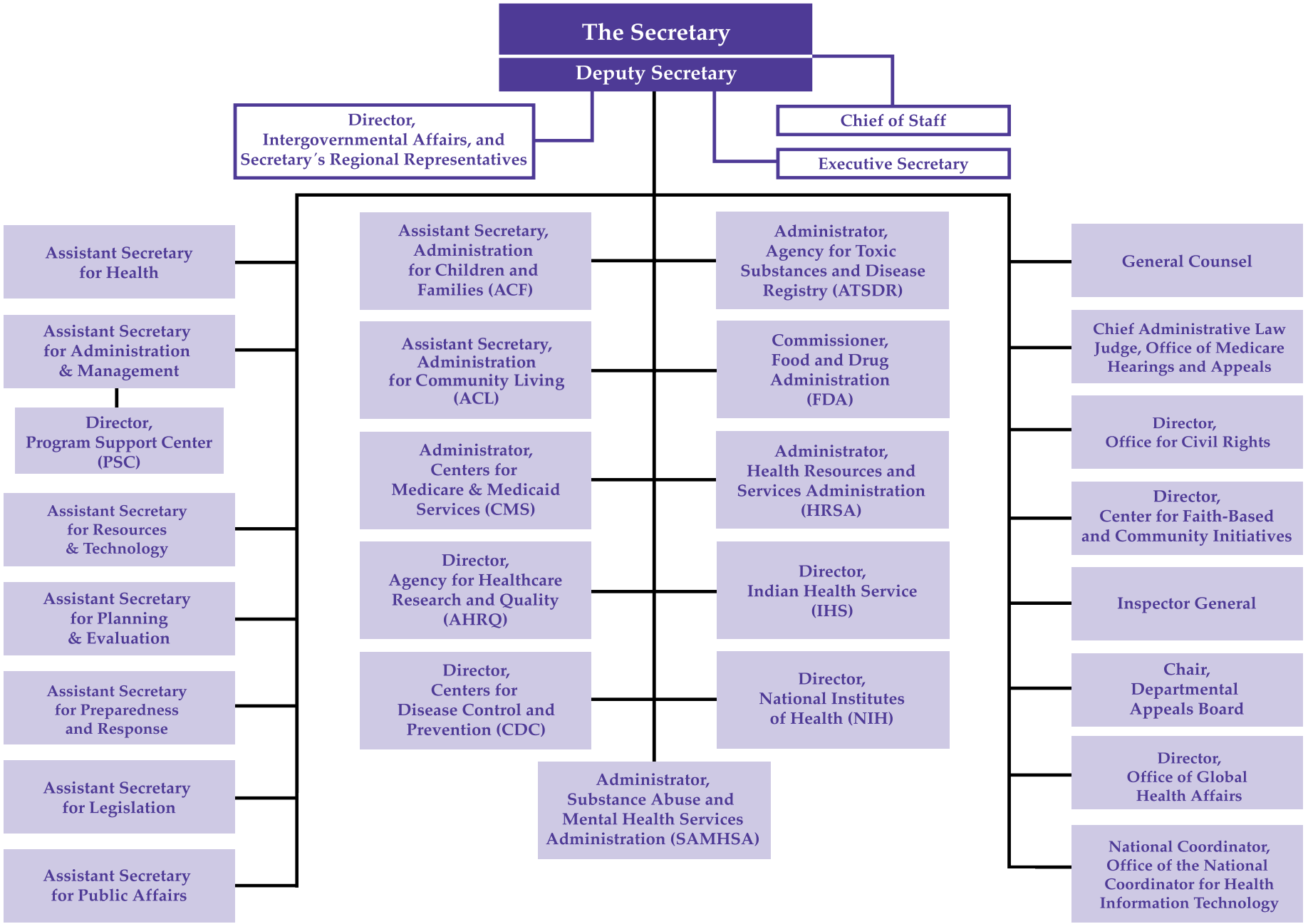
NIH's mission is to uncover new knowledge that will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping to train research investigators; and fostering communication of medical information. The NIH is composed of the Office of the Director, 20 Institutes, six Centers (four of which have funding authority), and the National Library of Medicine with 75 buildings in a campus-like environment located on more than 300 acres in Bethesda, Maryland. An organizational chart for the NIH is presented in **Exhibit II**. The NIH budget has grown from $300 in 1887, when the NIH was a one-room Laboratory of Hygiene, to $42.9 billion in 2021 (**Exhibit III**). A guide to the Bethesda campus is provided in **Exhibit IV**.

Overview of NIH History

The NIH is a component of the Public Health Service (PHS) of HHS. The PHS traces its origin to "An Act for the Relief of Sick and Disabled Seamen" of 1798 (Stat. L. 604), which authorized the establishment of marine hospitals for the care of American merchant seamen. In 1912, the Public Health and Marine Hospital Service became the Public Health Service.

The actual forerunner of the NIH was established in 1887 as the Laboratory of Hygiene, located at the Marine Hospital of Staten Island, New York. In 1930, this laboratory was renamed the National Institute of Health. The first of the present

Exhibit I. U.S. Department of Health and Human Services



Institutes, the National Cancer Institute (NCI), was established in 1937 by an act of Congress. In 1938, the National Advisory Cancer Council approved the first awards for research training fellowships in cancer research. In 1948, the National Heart Institute was established, and the National Institute of Health became the National Institutes of Health (NIH). During the years 1949–2001, the NIH expanded to include 27 Institutes and Centers.

The following timeline chronicles the establishment and evolution of the current NIH Institutes and Centers:

1798 President John Adams signed "an act for the relief of sick and disabled Seamen," which led to the establishment of the Marine Hospital Service.

1803 The first permanent Marine Hospital was authorized to be built in Boston, Massachusetts.

1836 The Library of the Office of the Surgeon General of the Army was established.

1870 President Grant signed a law establishing a "Bureau of the U.S. Marine Hospital Service" within the Treasury Department. This Bureau, headed by a Supervising Surgeon (later Surgeon General), was given central control over the hospitals.

1887 The Laboratory of Hygiene at the Marine Hospital in Staten Island, New York, was established for research on cholera and other infectious diseases.

1891 The Laboratory of Hygiene was re-designated the Hygienic Laboratory and moved from Staten Island to the Marine Hospital Service headquarters in Washington, DC.

1902 The Advisory Board for the Hygienic Laboratory was established; later became the National Advisory Health Council. Act of Congress changed the name of the Marine Hospital Service to the Public Health and Marine Hospital Service. Hygienic Laboratory was authorized by Congress to regulate laboratories that produced "biologicals." The Hygienic Laboratory was expanded to four divisions: Bacteriology and Pathology, Chemistry, Pharmacology, and Zoology.

1912 The Public Health and Marine Hospital Service was renamed Public Health Service (PHS).

1922 The Library of the Office of the Surgeon General was renamed Army Medical Library.

1930 The Hygienic Laboratory was renamed the National Institute of Health (NIH). Congress authorized construction of two buildings for the NIH and a system of fellowships.

1937 Congress authorized the establishment of the National Cancer Institute (NCI) and the awarding of research grants. Rocky Mountain Laboratory became part of the NIH. The National Advisory Cancer Council held its first meeting.

1938 The NIH was moved to land donated by Mr. and Mrs. Luke I. Wilson, located in Bethesda, Maryland. Cornerstone for the Shannon Building was laid.

1939 The Public Health Service (PHS) became part of a newly created Federal Security Agency; until that time, it was part of the Treasury Department.

1946 The Division of Research Grants (DRG) was established to process NIH grants and fellowships to non-Federal institutions and scientists. (Originally established as the Research Grants Office, it was renamed the Research Grants Division and, finally, the Division of Research Grants.)

1948 The National Heart Institute (NHI) was authorized. Several laboratories (including Rocky Mountain Laboratory) were regrouped to form the National Microbiological Institute. The Experimental Biology and Medicine Institute and the National Institute of Dental Research were established. The National Institute of Health became the National Institutes of Health.

1949 The Mental Hygiene Program of the PHS was transferred to the NIH and expanded to become the National Institute of Mental Health.

1950 The "Omnibus Medical Research Act" authorized the establishment of the National Institute of Neurological Diseases and Blindness (NINDB), as well as the National Institute of Arthritis and Metabolic Diseases (NIAMD). The latter absorbed the Experimental Biology and Medicine Institute.

1953 The PHS became part of the newly created Department of Health, Education, and Welfare. The Clinical Center opened.

1955 The National Microbiological Institute was renamed National Institute of Allergy and Infectious Diseases (NIAID). The Laboratory of Biologics Control was renamed the Division of Biologics Standards. The Division of Research Services (DRS) was created.

1956 The Armed Forces Medical Library was renamed the National Library of Medicine (NLM) and placed in the PHS.

1957 The Center for Aging Research was established.

1958 The Division of General Medical Sciences was created. The Center for Aging Research was transferred from the National Heart Institute to the Division of General Medical Sciences.

1961 The Center for Research in Child Health was established within the Division of General Medical Sciences.

1962 The NLM was moved to the NIH campus.

1963 The Division of General Medical Sciences was renamed the National Institute of General Medical Sciences (NIGMS). The National Institute of Child Health and Human Development (NICHD) was created.

1966 The Division of Environmental Health Sciences was created.

1967 The National Institute of Mental Health was separated from the NIH and became a separate bureau of the PHS.

1968 The John E. Fogarty International Center (FIC) for Advanced Study in the Health Sciences was created. The Bureau of Health Manpower and the NLM became part of the NIH. The National Eye Institute (NEI) was created. The National Institute of Neurological Diseases and Blindness was renamed the National Institute of Neurological Diseases and Stroke.

1969 The Division of Environmental Health Sciences was renamed the National Institute of Environmental Health Sciences (NIEHS). The National Heart Institute was renamed the National Heart and Lung Institute.

1972 The National Institute of Arthritis and Metabolic Diseases was renamed the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD).

1974 The National Institute on Aging (NIA) was created.

1975 The National Institute of Neurological Diseases and Stroke was renamed the National Institute of Neurological and Communicative Disorders and Stroke (NINDS).

1976 The National Heart and Lung Institute was renamed the National Heart, Lung, and Blood Institute (NHLBI).

1981 The National Institute of Arthritis, Metabolism, and Digestive Diseases was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

1986 The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases was renamed the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) was created. The Center for Nursing Research was transferred from the Health Resources and Services Administration (HRSA) and renamed the National Center for Nursing Research.

1989 The National Institute on Deafness and Other Communication Disorders (NIDCD) was established. The National Institute of Neurological and Communicative Disorders and Stroke was renamed the National Institute of Neurological Disorders and Stroke (NINDS). The National Center for Human Genome Research was established. The National Center for Biotechnology Information was established within the NLM.

1990 The National Center for Research Resources (NCRR) was created by consolidating the Division of Research Services and the Division of Research Resources.

1992 The National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), and National Institute of Mental Health (NIMH) were transferred to the NIH from the Alcohol, Drug Abuse, and Mental Health Administration.

1993 The National Center for Nursing Research was renamed the National Institute of Nursing Research (NINR).

1995 The NIH was established as an HHS Operating Division, thereby elevating it to report directly to the Secretary of HHS.

1997 The National Center for Human Genome Research was renamed the National Human Genome Research Institute (NHGRI).

1998 The Division of Research Grants was renamed the Center for Scientific Review. The National Center for Complementary and Alternative Medicine (NCCAM) was established. The National Institute of Dental Research was renamed the National Institute of Dental and Craniofacial Research (NIDCR).

2001 The National Center on Minority Health and Health Disparities was established. The National Institute of Biomedical Imaging and Bioengineering (NIBIB) was established.

2010 The National Center on Minority Health and Health Disparities was redesignated as the National Institute on Minority Health and Health Disparities (NIMHD)

2011 The National Center for Advancing Translational Sciences (NCATS) was established.

2012 NCI-Frederick Cancer Research and Development Center was renamed the Frederick National Laboratory for Cancer Research (FNLCR).

2014 The National Center for Complementary and Alternative Medicine became the National Center for Complementary and Integrative Health.

Exhibit II. National Institutes of Health

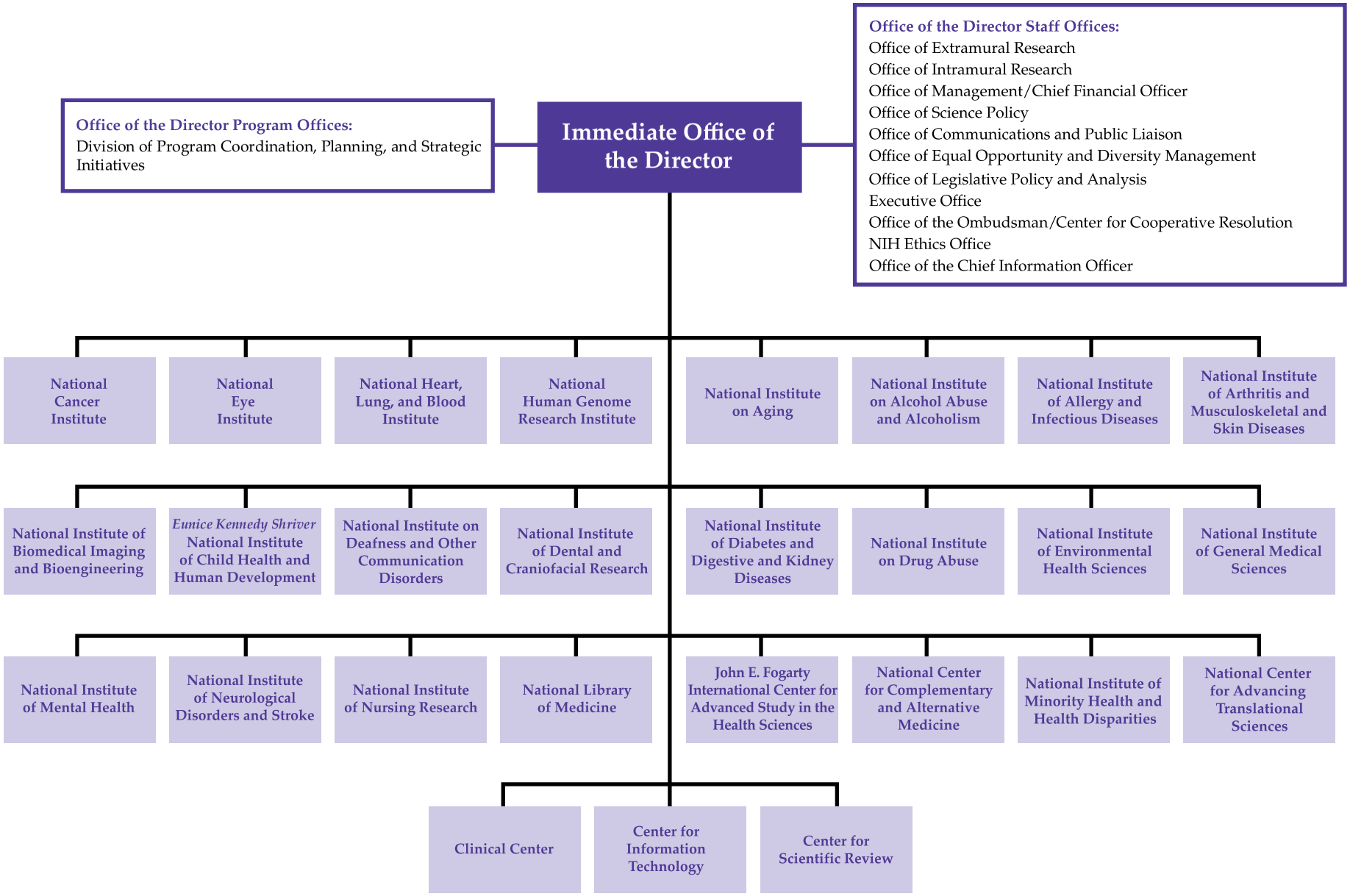
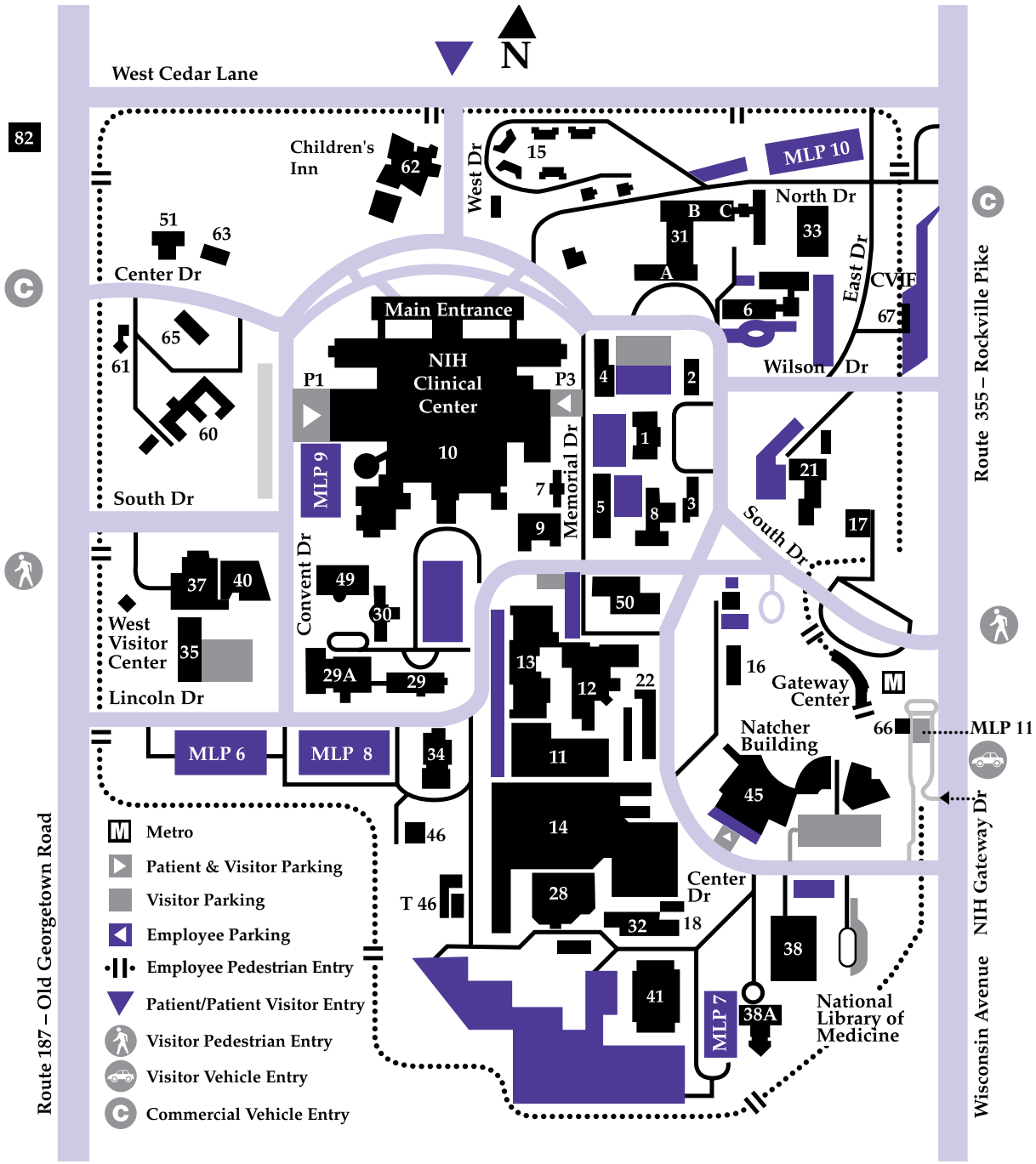


Exhibit III. NIH FY2019–2021 Funding*

INSTITUTE/CENTER	FUNDING (Dollars in Millions)		
	2019	2020	2021
NCI	6,144	6,440	6,560
NHLBI	3,488	3,624	3,665
NIDCR	462	477	485
NIDDK	2,180	2,211	2,281
NINDS	2,274	2,445	2,513
NIAID	5,523	5,885	6,070
NIGMS	2,872	2,937	2,991
NICHD	1,506	1,557	1,590
NEI	797	824	836
NIEHS	857	884	896
NIA	3,083	3,544	3,899
NIAMS	605	625	634
NIDCD	474	491	498
NIMH	1,870	2,038	2,104
NIDA	1,420	1,462	1,480
NIAAA	526	545	555
NINR	163	169	175
NHGRI	575	606	616
NIBIB	389	404	411
NIMHD	315	335	391
NCCIH	146	152	154
NCATS	806	833	855
FIC	78	81	84
NLM	442	457	464
OD	2,118	2,410	2,533
B&F	200	200	200
TOTAL	**39,313**	**41,636**	**42,940**

*Source: NIH Office of Budget, 2021.

Exhibit IV. NIH Facilities Map



Building Key

Building 1	James Shannon Building (NIH Administration)
Building 10	Warren Grant Magnuson Clinical Center; Mark Hatfield Clinical Research Center
Building 11	Central Utility Plant
Building 13	Engineering Services
Building 14	Office of Research Facilities
Building 16	Stone House
Building 31	Claude D. Pepper Building (General Office Building)
Building 36	Lowell P. Weicker Building
Building 38	National Library of Medicine
Building 38A	Lister Hill
Building 40	Vaccine Research Center
Building 45	Natcher Building and Conference Center
Building 49	Sylvio Conte Building
Building 50	Stokes Laboratories
Building 60	Mary Woodard Lasker Center
Building 62	The Children's Inn at NIH

NIH Institutes

National Cancer Institute (NCI) (see https://www.cancer.gov)

National Eye Institute (NEI) (see https://nei.nih.gov)

National Heart, Lung, and Blood Institute (NHLBI) (see https://www.nhlbi.nih.gov)

National Human Genome Research Institute (NHGRI) (see https://www.genome.gov)

National Institute on Aging (NIA) (see https://www.nia.nih.gov)

National Institute on Alcohol Abuse and Alcoholism (NIAAA) (see https://www.niaaa.nih.gov)

National Institute of Allergy and Infectious Diseases (NIAID) (see https://www.niaid.nih.gov)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (see https://www.niams.nih.gov)

National Institute of Biomedical Imaging and Bioengineering (NIBIB) (see https://www.nibib.nih.gov)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) (see https://nichd.nih.gov)

National Institute on Deafness and Other Communication Disorders (NIDCD) (see https://www.nidcd.nih.gov)

National Institute of Dental and Craniofacial Research (NIDCR) (see https://www.nidcr.nih.gov)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (see https://www.niddk.nih.gov)

National Institute on Drug Abuse (NIDA) (see https://www.drugabuse.gov)

National Institute of Environmental Health Sciences (NIEHS) (see https://www.niehs.nih.gov)

National Institute of General Medical Sciences (NIGMS) (see https://www.nigms.nih.gov)

National Institute of Mental Health (NIMH) (see https://www.nimh.nih.gov)

National Institute on Minority Health and Health Disparities (NIMHD) (see https://www.nimhd.nih.gov)

National Institute of Neurological Disorders and Stroke (NINDS) (see https://www.ninds.nih.gov)

National Institute of Nursing Research (NINR) (see https://www.ninr.nih.gov)

National Library of Medicine (NLM) (see https://www.nlm.nih.gov)

NIH Centers

Center for Information Technology (CIT) (see https://www.cit.nih.gov)

Center for Scientific Review (CSR) (see https://public.csr.nih.gov)

Fogarty International Center (FIC) (see https://www.fic.nih.gov)

National Center for Advancing Translational Sciences (NCATS) (see https://ncats.nih.gov)

National Center for Complementary and Integrative Health (NCCIH) (see https://nccih.nih.gov)

NIH Clinical Center (see https://clinicalcenter.nih.gov)

THE NATIONAL CANCER INSTITUTE

NCI Mission

The National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH), one of 11 operating divisions that compose the Public Health Service (PHS) in the U.S. Department of Health and Human Services (HHS). The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program (NCP). Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice.

The NCI is committed to dramatically lessening the impact of cancer. The NCI is the primary means of support for America's cancer research enterprise, whether in its own laboratories or in our Nation's research universities. The NCI is dedicated to the understanding, diagnosis, treatment, and prevention of cancer for all people. The NCI works toward this goal by providing vision to the Nation and leadership for both domestic and international NCI-funded researchers. The NCI also works to ensure that research results are applied in clinical practice and public health-related programs to reduce the burden of cancer for all populations.

Within this framework, NCI researchers work to more fully integrate discovery activities through interdisciplinary collaborations; accelerate development of interventions and new technology through translational research; and ensure the delivery of these interventions for application in the clinic and public health programs as state-of-the-art care for all those in need.

NCI and the National Cancer Program

As the leader of the National Cancer Program (NCP), the NCI provides vision and leadership to the global cancer community. The NCI conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and families of cancer patients. Critical to the success of its programs are collaborations and partnerships that further NCI's progress in serving cancer patients and those who care for them. **The NCI supports a broad range of research to expand scientific discovery at the molecular and cellular level, within a cell's microenvironment, and in relation to human and environmental factors that influence cancer development and progression.** Each year, more than 5,000 principal investigators lead research projects that result in better ways to combat cancer. Intramural research serves as a hub for new development through cutting-edge basic, clinical, and epidemiological research. Extramural program experts provide guidance and oversight for research conducted at universities, teaching hospitals, and other organizations. Proposals are selected for funding by peer review, a rigorous process by which scientific experts evaluate new proposals and recommend the most scientifically meritorious for funding. In addition to direct research funding, the NCI offers the Nation's cancer scientists a variety of useful research tools and services: tissue samples, statistics on cancer incidence and mortality, bioinformatic tools for analyzing data, databases of genetic information, and resources through NCI-supported Cancer Centers, Centers of Research Excellence, and the Mouse Models of Human Cancer Consortium.

The NCI also uses collaborative platforms and an interdisciplinary environment to promote translational research and intervention development. Discovery of a new tool that first helps to understand the underlying mechanism of cancer may eventually be used to help diagnose it, and then may be further developed to help treat it. For example, recent advances in bioinformatics and the related explosion of technology for genomics and proteomics research are dramatically accelerating the rate for processing large amounts of information for cancer screening and diagnosis. The largest collaborative research activity is the Clinical Trials Program for testing interventions for preventing cancer, diagnostic tools, and cancer treatments as well as providing access as early as possible to all who can benefit. The NCI supports more than 1,300 clinical trials a year, assisting more than 200,000 patients.

NCI's research impacts the delivery of improved cancer interventions to cancer patients and those who care for them. Timely communication of NCI scientific findings helps people make better health choices and advises physicians about

treatment options that are more targeted and less invasive, resulting in fewer adverse side effects. NCI researchers also are seeking the causes of disparities among underserved groups and gaps in quality cancer care, helping to translate research results into better health for groups at high risk for cancer, including cancer survivors and the aging population. In addition, the NCI is fostering partnerships with other agencies and organizations to accelerate the pace for moving targeted drugs through the pipeline of discovery, development, and delivery. Information about NCI's research and activities is available through its public website, https://www.cancer.gov.

NCI Legislative Authority

The NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the NCP. Under the National Cancer Act of 1971, the Director of the NCI is authorized to submit, directly to the President, a professional judgment budget reflecting the full funding needs of the NCP. This budget is referred to as the "Bypass Budget."

Bypass Budget

The mandate to produce a Professional Judgment Budget, more commonly known as a Bypass Budget, is a unique authority established by the National Cancer Act of 1971 and given to the NCI Director. The Bypass Budget builds on research successes and ensures that research discoveries are applied to improve human health, and allows the NCI Director to express to the President the plans and priorities of the NCI and the NCP, along with an indication of the associated costs.

Each year, the NCI produces this document to reflect the Professional Judgment of the Nation's top cancer experts about the realities of cancer research and control, and how much money could be spent wisely in the conduct of the entire program.

The authority to produce the Bypass Budget has many benefits. The extensive strategic planning process that is used to develop the Bypass Budget builds on research successes, supporting the cancer research workforce with the technologies and resources it needs. In addition to being submitted to the President, this comprehensive research plan also is provided to Congress, and is used by the greater cancer research community, professional organizations, advisory groups, advocacy organizations, and public and private policymakers. As a result, the Bypass Budget and its development serve as a planning process for the entire NCP, outlining clearly the areas of highest priority.

In addition to informing the President, the Bypass Budget document also serves as the Institute's strategic plan and has become a powerful communication and priority setting tool used by constituents across the NCP. Updated each year, the plan provides a guide for building on research successes, supporting the cancer research workforce with the technologies and resources it needs, and ensuring that research discoveries are applied to improve human health. This strategic plan is based on the authority and the responsibilities entrusted to the Presidentially appointed NCI Director to coordinate the research activities of the NCI with the other parts/members of the NCP.

In so doing, the Director is aided by the National Cancer Advisory Board (NCAB), a group composed of scientists, medical personnel, and consumers from all sectors, public and private, of the cancer enterprise who have the needed expertise and experience to help formulate a national agenda in cancer research. The NCAB meets with the President's Cancer Panel (PCP) members to facilitate transfer of PCP observations on the barriers to progress in the NCP and the development of possible solutions. Their deliberations are directly coordinated with other Government agencies through the participation of *ex officio* Federal members representing key agencies involved in executing the NCP. For example, discussions at the NCAB meetings with *ex officio* members representing the U.S. Department of Defense and Veterans Affairs health care systems directly led to the availability of NCI clinical trials through their health care systems. Close coordination across agencies is critical in the formulation of a strategic plan that takes advantage of the capabilities of each agency and the constituencies it serves.

The ability of the NCI and its partners to address the initiatives in the Bypass Budget is a measure of the success of the NCP. In this way, the Bypass Budget enables efficient strategic coordination of the NCP. As part of the evaluation process, the Presidentially appointed PCP is charged to review the implementation of such plans and identify directly for the President and the Nation the extent of their success.

NCI Organizational Structure

The current NCI organizational structure is shown in **Exhibits V** and **VI**. The Office of the Director (OD) serves as the focal point for the National Cancer Program (NCP) with advice from several external advisory groups that include the President's Cancer Panel (PCP) (**Appendix A**), the National Cancer Advisory Board (NCAB) (**Appendix B**), the Board of Scientific Advisors (BSA) (**Appendix C**), the Board of Scientific Counselors (BSC) (**Appendix D**), the Clinical Trials and Translational Research Advisory Committee (CTAC) (**Appendix E**), the Frederick National Laboratory Advisory Committee (FNLAC) (**Appendix F**), and the Council of Research Advocates (CRA) (**Appendix G**).

The NCI Director also is assisted by a Scientific Program Leadership (SPL) Committee (**Appendix H**) that meets on a regular basis to discuss various matters of NCI policy, including the review and approval of Requests for Applications (RFAs), Program Announcements (PAs), and research and development (R&D) contract concepts prior to review by the BSA; development of funding plans; grant payment by exceptions, and so on.

The research and research-related activities and functions of the Institute are monitored and administered by various NCI Divisions, Offices, and Centers (DOCs).

NCI Extramural Divisions

NCI extramural research and research-related activities are conducted by five divisions under the supervision of the OD. The functions of the divisions and the major areas of research and research support activities for which each is responsible are described below.

Division of Cancer Biology (DCB)
The mission of the DCB is to ensure continuity and stability in basic cancer research, while encouraging and facilitating the emergence of new ideas, concepts, technologies, and possibilities. The DCB strives to achieve this goal by promoting a balance between the continued support of existing research areas and selective support of emerging research areas. The DCB provides guidance, advice, funding information, and financial support to grantees and applicants. The DCB encourages the expansion of new research areas through a range of initiatives and funding mechanisms. The scientific discoveries from this research base are critical to the goal of the NCI, because they form the intellectual and scientific foundation on which strategies for the prevention, diagnosis, and treatment of cancer are developed. (https://dcb.nci.nih.gov)

Division of Cancer Control and Population Sciences (DCCPS)
The DCCPS aims to reduce the risk, incidence, and number of deaths from cancer, as well as to enhance the quality of life for cancer survivors. This division conducts and supports an integrated program of the highest quality genetic, epidemiologic, behavioral, social, applied, and surveillance cancer research. DCCPS-funded research aims to: (1) understand the causes and distribution of cancer in various populations, (2) support the development and implementation of effective interventions, and (3) monitor and explain cancer trends in all segments of the population. Central to these activities is a process of synthesis and decision making, which aids in evaluating what has been learned, identifying new priorities and strategies, and effectively applying research discoveries to reduce the cancer burden at the population level. (https://dccps.nci.nih.gov)

Division of Cancer Treatment and Diagnosis (DCTD)
The DCTD attempts to identify and exploit the most promising areas of science and technology and to initiate, enable, and conduct research that will yield important new knowledge that is likely to lead to better diagnostic or therapeutic interventions in the various childhood and adult cancers. The division administers grants, contracts, and cooperative agreements, and offers strategically planned workshops and conferences with scientists, clinicians, and public and private partners. It also sponsors a vigorous program of in-house applied research linked to investigators and goals in the extramural community. (https://dctd.cancer.gov)

Division of Cancer Prevention (DCP)
The DCP plans and conducts programs in basic and applied research and development, technology transfer, demonstration, education, and information dissemination. DCP's programs are designed to: expedite the use of new information relevant to the prevention, detection, and diagnosis of cancer; expedite the use of new information about pretreatment evaluation, treatment, rehabilitation, and continuing care; plan, direct, and coordinate the support of research on cancer prevention at Cancer Centers and community hospitals, and through organ systems programs; support cancer research training, clinical education, continuing education, and career development in cancer prevention; coordinate program activities with other divisions, Institutes, and Federal and state agencies; and establish

Exhibit V. The National Cancer Institute

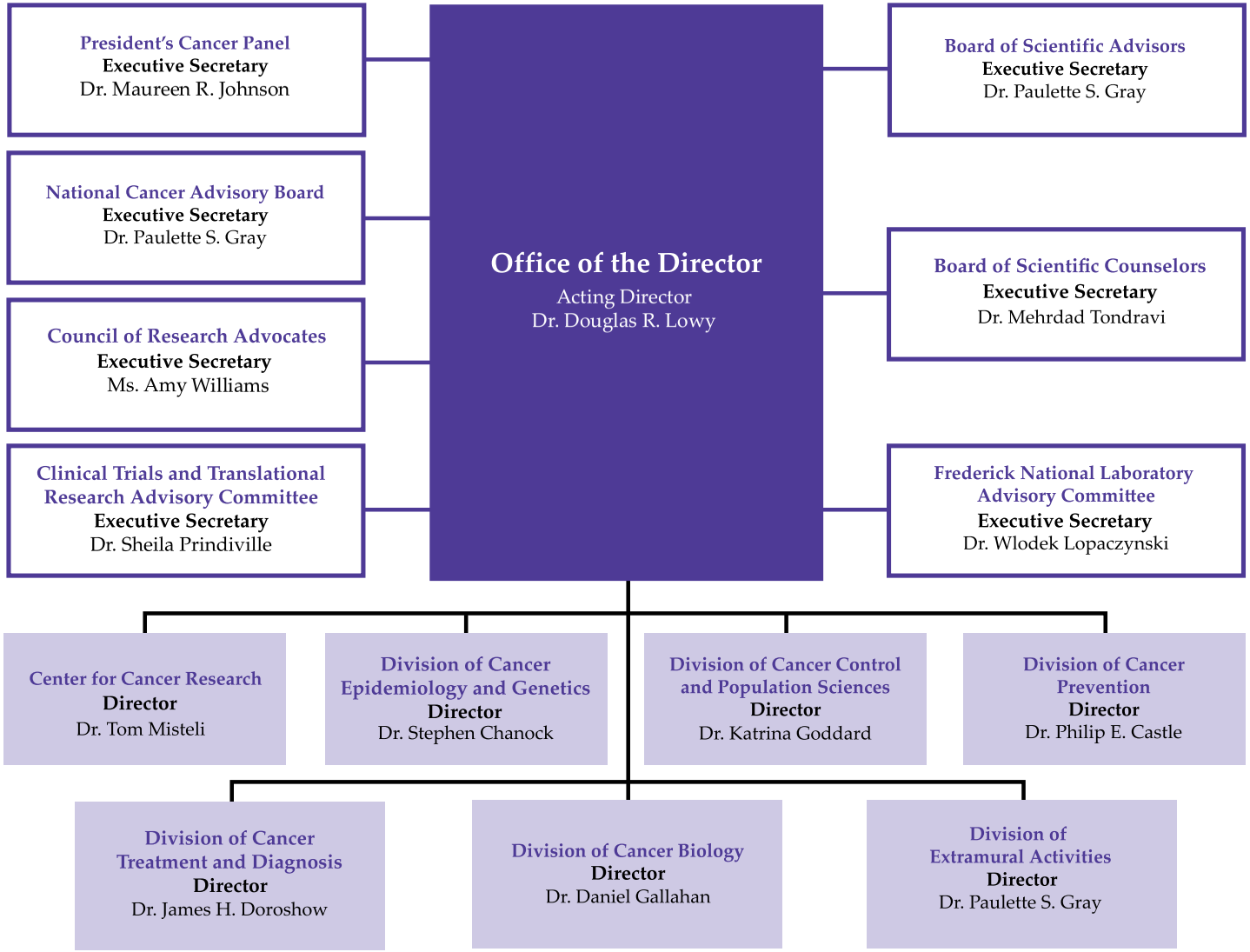
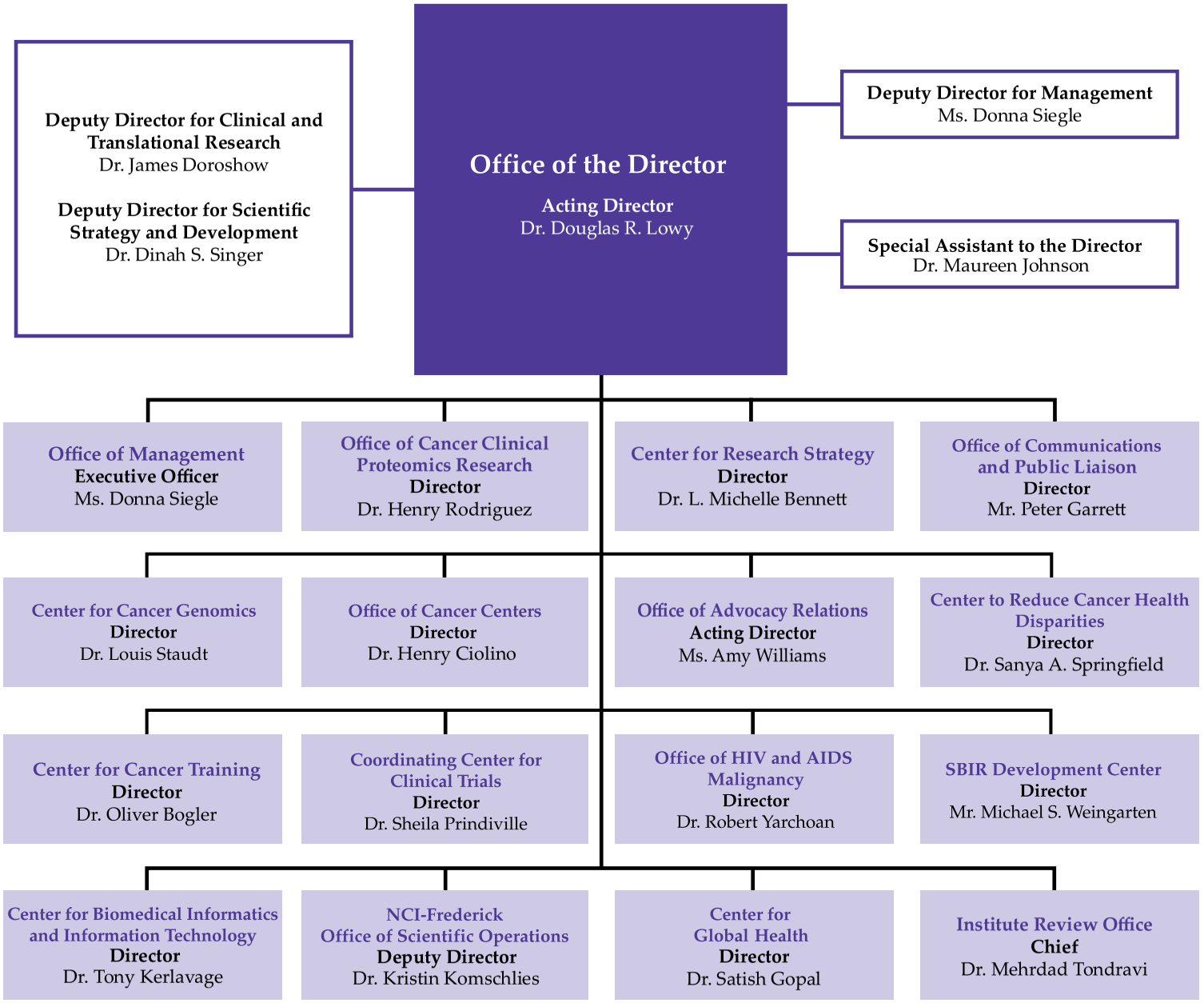


Exhibit VI. The National Cancer Institute (Continued)



liaison with professional and voluntary health agencies, Cancer Centers, labor organizations, cancer organizations, and trade associations. (https://prevention.cancer.gov)

Division of Extramural Activities (DEA)
The mission and responsibilities of the DEA in some way affect all extramural scientists receiving research or training support from the NCI. The DEA coordinates the review of special initiatives, large grants, and contracts. It is involved in all aspects of grant development and tracking, from the original conception of extramural research and training programs to follow-up after funds are dispersed. In brief, the DEA was established to: provide advice and guidance to potential applicants; receive and refer incoming grant applications to appropriate programs within the NCI; provide the highest quality and most effective scientific peer review and oversight of extramural research; coordinate and administer Federal Advisory Committee activities related to the various aspects of the NCI mission, such as the NCAB and BSA; establish and disseminate extramural policies and procedures, such as requirements for inclusion of certain populations in research, actions for ensuring research integrity, or budgetary limitations for grant applications; and track the NCI research portfolio (more than 7,500 research and training awards) using consistent, budget-linked scientific information to: (1) provide a basis for budget projections and (2) serve as a resource for the dissemination of information about cancer. (https://deainfo.nci.nih.gov)

NCI Intramural Divisions and Centers

Division of Cancer Epidemiology and Genetics (DCEG)
The DCEG is an intramural research program in which scientists conduct an international program of population-based studies to identify environmental and genetic determinants of cancer. In carrying out its mission, the DCEG is at the cutting edge of approaches to untangle complex gene–environment and gene–gene interactions in cancer etiology. To conduct these studies, investigators at all levels of their careers work collaboratively to bring together a variety of scientific disciplines. (https://dceg.cancer.gov)

Center for Cancer Research (CCR)
As the intramural component of the NCI, the CCR conducts basic clinical investigations at the Bethesda campus. The mission of the CCR is to reduce the burden of cancer through exploration, discovery, and translation. It provides a new forum for cancer research without scientific, institutional, or administrative barriers. The Center is achieving this by conducting outstanding, cutting-edge, basic and clinical research on cancer and translating these discoveries into treatment and prevention. The overall goal is to form a highly interactive, interdisciplinary group of researchers who have access to technology and are able to participate in clinical investigations. The CCR also maintains a foundation of investigator-initiated, independent research. CCR scientists conduct innovative basic and clinical research aimed at discovering the causes and mechanisms of cancer to improve the diagnosis, treatment, and prevention of cancer and other diseases. (https://ccr.cancer.gov)

NCI Offices and Centers Within the Office of the Director

NCI Center for Biomedical Informatics and Information Technology (CBIIT)
The CBIIT helps speed scientific discovery and facilitates translational research by building many types of tools and resources that enable information to be shared along the continuum from the scientific bench to the clinical bedside and back. The CBIIT (1) coordinates and deploys informatics in support of NCI research initiatives; (2) provides all manner of informatics support, including platforms, services, tools, and data to NCI-supported research initiatives; (3) participates in the evaluation and prioritization of NCI's bioinformatics research portfolio; (4) conducts or facilitates research that is required to fulfill NCI's bioinformatics requirements; (5) serves as the focus for strategic planning to address NCI's expanding research initiative's informatics needs; (6) establishes bioinformatics technology standards (both within and outside of the NCI); (7) communicates, coordinates, and establishes bioinformatics exchange standards; (8) provides direct support to four NCI research programs: the Cancer Genome Anatomy Project (CGAP), the Mouse Models of Human Cancer Consortium (MMHCC), the Director's Challenge: Toward a Molecular Classification of Cancer, and Clinical Trials and develops core infrastructure to support the integration of these efforts.

Center for Research Strategy (CRS)
The CRS is a science-based office that collaboratively develops recommendations for addressing scientific opportunities, monitors the direction and application of the NCI's scientific knowledge and resources, and identifies research funding gaps. The CRS responsibilities are to: synthesize input from NCI leadership and external stakeholders

to inform priority initiatives; identify scientific opportunities within priority initiatives; coordinate development of programs across the NCI to address opportunities; conduct portfolio analysis to support priority setting and scientific strategic planning; collect and analyze data to identify research accomplishments; and recommend strategies for allocating resources effectively.

Center to Reduce Cancer Health Disparities (CRCHD)
The CRCHD is the keystone of NCI's efforts to reduce the unequal burden of cancer in our society. As the organizational focus for these efforts, the Center directs and supports initiatives that advance the understanding of what causes health disparities. It also supports programs that develop and integrate effective interventions to reduce or eliminate these disparities. The CRCHD, through its Diversity Training Branch (DTB), leads NCI's efforts in the training of students and investigators from diverse populations who will be part of the next generation of competitive researchers in cancer and cancer health disparities research.

Center for Strategic Scientific Initiatives (CSSI)
The CSSI directs the planning, development, and implementation of a number of strategic scientific and technology initiatives and partnerships that emphasize innovation, transdisciplinary teams, and convergence of scientific disciplines to enable progress against cancer. These programs also stress the development and application of advanced technologies, the synergy of large-scale and individual initiated research, novel partnerships, and translation of discoveries into new interventions to detect, prevent, and treat cancer more effectively.

Several offices in CSSI are committed to accelerating the progress of cancer research through its technology-driven initiatives, collaboration with other government programs, and engagement with the private sector in the areas of nanotechnology, proteomics, cancer genomics, and biospecimen resources. By placing a heavy emphasis on advanced technology development, the NCI is accelerating the creation and use of tools that are already facilitating the translation of basic knowledge into clinical advances to benefit patients with a new generation of molecularly based diagnostics and therapeutics. Programs include: Information Technology for Cancer Research, Cancer Grand Challenges, Serological Sciences Network, **Center for Strategic Scientific Initiatives**, **Innovative Molecular Analysis Technologies (IMAT)**, and **Provocative Questions Initiative**.

Small Business Innovation Research (SBIR) Development Center
The SBIR Development Center serves as the NCI focal point for the management of all SBIR and Small Business Technology Transfer (STTR) Program activities, and implementation of pertinent legislation, rules, and regulations and associated matters related to the SBIR/STTR Program consisting of grant and contractor awards and providing expertise, advice, and services to applicants and NCI programs.

Center for Cancer Training (CCT)
The CCT is responsible for: (1) coordinating and providing research training and career development activities for fellows and trainees in NCI's laboratories, clinics, and other research groups; (2) developing, coordinating, and implementing opportunities in support of cancer research training, career development, and education at institutions nationwide; and (3) identifying workforce needs in cancer research and adapting NCI's training and career development programs and funding opportunities to address these needs.

Coordinating Center for Clinical Trials (CCCT)
The CCCT is central to NCI's efforts to accelerate the delivery of new tools into the clinic through its translational science and clinical trial enterprises. The CCCT facilitates collaborations that expedite translational and clinical cancer research by: supporting the implementation of the Clinical Trials Working Group and Translational Research Working Group recommendations; facilitating prioritization of NCI's most important clinical trials by Scientific Steering Committees working with NCI clinical programs; and partnering with **NCI's Center for Biomedical Informatics and Information Technology (CBIIT)** to establish the Clinical Trials Reporting Program (CTRP), a comprehensive database with up-to-date information on all NCI-funded clinical trials.

Center for Cancer Genomics (CCG)
The CCG is focused on understanding the molecular mechanisms of cancer with the ultimate goal of improving the prevention, early detection, diagnosis, and treatment of cancer. To meet this goal, the CCG provides information, technology, methods, informatics tools, and reagents to serve the needs of the cancer research community; and manages the following research programs: NCI Genomic Data Commons (GDC); Cancer Driver Discovery Program (CDDP); Cancer Genome Characterization Initiative (CGCI); Cancer Target Discovery and Development Network (CTD^2); Cancer Genome Atlas (TCGA); and

Therapeutically Applicable Research to Generate Effective Treatments (TARGET).

Center for Global Health (CGH)
The CGH coordinates NCI's worldwide activities in a number of arenas, including: liaison with foreign and international agencies; and other U.S. Government agencies involved in global health; coordination of cancer research activities under agreements between the United States and other countries; planning and implementation of international scientist exchange programs; sponsorship of international workshops; and dissemination of cancer information.

Technology Transfer Center (TTC)
The TTC builds partnerships and fosters collaboration agreements between NIH scientists, universities, nonprofits, and industry to commercialize NIH inventions, and supports research and development that benefits public health.

NCI-Frederick Office of Scientific Operations
The NCI-Frederick Office of Scientific Operations (1) oversees and manages scientific operations at FNLCR and serves as the Project Office for the three main operation and support contracts at the FNLCR; (2) directs and develops advanced technologies that are made available to customers of the FNLCR; (3) implements programmatic decisions approved by the NCI Director and the Associate Director for the FNLCR to transition new efforts to the FNLCR by developing contractual requirements and budgets, arranging for needed space, and providing technical and project management advice to the Contracting Officer; (4) works closely with customers (including other NCI and NIH components, the FDA, the DoD, the Department of Agriculture, and the Department of Homeland Security), as well as contractors to ensure that contractors understand customers' needs and that the customers receive planned outcomes; (5) assists the NCI Associate Director for Frederick with the administrative and business operations of the FNLCR; (6) assists the NCI Associate Director for Frederick with planning and prioritizing of space and the maintenance of all buildings and grounds; (7) monitors contractor performance, obtains customer satisfaction feedback, and provides this information to the Management Operations and Support Branch for the Award Fee processes; (8) tracks and reports funds received and costs associated with all work performed at NCI-Frederick; (9) develops and manages educational, employee outreach, and public outreach programs, including programs for students K–12 and internship opportunities for high school and undergraduate students; (10) coordinates the expansion of student/fellowship mentoring programs at the FNLCR; and (11) coordinates FNLCR facility "activities" such as the Spring Research Festival, Take Your Child to Work Day, the Summer Student Seminar Series, Summer Student Poster Day, the Housing Resources List, speaker requests, and visits for students, teachers, and other interested groups.

Office of Cancer Clinical Proteomics Research (OCCPR)
The mission of NCI's OCCPR is to improve prevention, early detection, diagnosis, and treatment of cancer by enhancing the understanding of the molecular mechanisms of cancer, advance proteome and proteogenome science and technology development through community resources (data and reagent), and accelerate the translation of molecular findings into the clinic. This is achieved through OCCPR-supported programs such as the Clinical Proteomic Tumor Analysis Consortium (CPTAC), partnerships with Federal agencies, and collaborations with international organizations/institutions. The OCCPR analyzes protein content in tumor cells through the application of state-of-the-art proteomic technologies and workflows, open-data policies, and community reagents to advance our understanding of proteins derived from cancer genomes in clinical research and medicine. The OCCPR also characterizes the discovery and deployment of evidence-based biomarkers for clinical use.

Office of Cancer Centers (OCC)
Currently, the OCC supports 71 NCI-designated Cancer Centers nationwide that are actively engaged in transdisciplinary research to reduce cancer incidence, morbidity, and mortality. The NCI-designated Cancer Centers are designated as either Comprehensive Cancer Centers (51), Clinical Cancer Centers (14), or Basic Laboratory Cancer Centers (7), and are a major source of discovery on the nature of cancer and of the development of more effective approaches to cancer prevention, diagnosis, and therapy. Comprehensive Cancer Centers also deliver medical advances to patients and their families, educate health care professionals and the public, and reach out to underserved populations. Cancer Centers are characterized by strong organizational capabilities, institutional commitment, and transdisciplinary, cancer-focused science; experienced scientific and administrative leadership; and state-of-the-art cancer research and patient care facilities.

Office of Advocacy Relations (OAR)
The OAR engages the advocacy and NCI communities in dialogue about cancer research opportunities and priorities to advance progress and improve outcomes. The OAR (1) serves as the Institute's expert and central resource for advocacy matters; (2) facilitates dynamic relationships and collaborations to promote mutual goals; and (3) disseminates information and fosters understanding of key cancer issues and priorities.

Office of Communications and Public Liaison (OCPL)
The OCPL advances the mission of the NCI by disseminating evidence-based cancer information to the public to improve the lives of those affected by cancer. Working closely with scientists and partners, the OCPL uses effective methods to reach diverse audiences and meet their needs for the latest, evidence-based cancer information about NCI-funded research, cancer research findings, cancer clinical trials, funding, and partnership opportunities to patients, caregivers, health professionals, researchers, advocates, the new media, and other stakeholders across the cancer community.

Office of Government and Congressional Relations (OGCR)
The OGCR advises the NCI Director, staff, and advisory boards on legislative and Congressional activities as they relate to the NCI mission. The OGCR coordinates, monitors, and analyzes Congressional activities; reviews, processes, and responds to all requests for information from the NCI that fall under the jurisdiction of the Freedom of Information (FOIA) and Privacy Act; and serves as NCI's liaison for the U.S. Government Accountability Office (GAO) and HHS Office of the Inspector General. The OGCR aims to ensure that the NCI community is kept abreast of the Congressional issues and interests that affect the Institute and, in turn, the NIH. The OGCR also works closely with other offices at both the Institute and agency level.

Office of HIV and AIDS Malignancy (OHAM)
The OHAM (1) coordinates and works with the Divisions and other Offices to manage the portfolio of HIV/AIDS and AIDS malignancy research within the NCI; (2) advises the NCI Director and other NCI managers on issues related to research in HIV/AIDS and AIDS malignancies; (3) coordinates, helps prioritize, and facilitates the NCI research effort in HIV/AIDS and AIDS malignancies and works with NCI management to redirect the HIV/AIDS and AIDS malignancy research effort, as appropriate, into the highest priority areas; (4) interfaces with the NIH Office of AIDS Research (OAR) and other ICs with regard to research in HIV/AIDS and AIDS malignancies in the NCI; and (5) directly manages certain AIDS and AIDS malignancy research programs, such as the AIDS and Cancer Specimen Resource, the AIDS-Associated Malignancies Clinical Trial Consortium (AMC), the NCI Component of the Centers for AIDS Research (CFARS), and the NCI component of the Women's Interagency HIV Study (WIHS).

Office of Acquisitions (OA)
The OA plans, negotiates, awards, and administers NCI contracts and simplified acquisitions to support a coordinated cancer research program.

Office of Budget and Finance (OBF)
The OBF advises the OD and other senior staff on financial and personnel resource management to ensure fiscally responsible and efficient operation of the NCI.

Office of Grants Administration (OGA)
The OGA manages all NCI business-related activities associated with the negotiation, award, and administration of NCI grants and cooperative agreements to help financially support cancer research activities throughout the United States and around the world.

Office of Management Policy and Compliance (OMPC)
The OMPC advises the Office of Management and other senior staff on the implementation of Institute-wide administrative policies and procedures, management controls, and evaluations while ensuring compliance with Federal requirements.

NCI Programs and Activities

The Institute conducts and leads intensive work to advance knowledge of cancer's biology and processes; to discover and develop new interventions; and to employ a bench-to-bedside approach that strives to rapidly make new treatments—the latest science—available to patients in the communities where they live. Across these complex endeavors, the NCI works to foster the collaborations of government, the private sector, and academia. In addition to the broad range of both basic and applied laboratory and clinical programs that it supports, the NCI provides various research support services, including the development and distribution of critical materials such as viruses, animals, equipment, tissues, and standardized reference bibliographies. These activities are

conducted within the DOCs of the NCI, under the supervision of the OD.

NCI Cancer Programs

Cancer Causation
Cancer causation research concentrates on the events involved in the initiation and promotion of cancer. It encompasses chemical and physical carcinogenesis, biological carcinogenesis, epidemiology, chemoprevention, and nutrition research. Studies in this area focus on external agents such as chemicals, radiation, fibers, and other particles, as well as viruses, parasitic infections, and host factors such as hormone levels, nutritional and immunologic status, and the genetic endowment of the individual. In FY2020, cancer causation research expenditures totaled about $1.30 billion, accounting for 20.5 percent of the total NCI budget.

Detection and Diagnosis
Detection and diagnosis research includes studies designed to improve diagnostic accuracy; provide better prognostic information to guide therapeutic decisions; monitor the response to therapy more effectively; detect cancer at its earliest presentation; and identify populations and individuals at increased risk for the development of cancer.

Areas of emphasis include: improvements in the detection and diagnosis of breast, cervical, uterine, and prostate cancer; the transfer of molecular technologies from the laboratory to clinical practice; the identification of better prognostic markers; increased availability of human tumor samples with associated clinical information; and research to identify genetic alterations involved in tumor pathogenesis and behavior. In FY2020, cancer detection and diagnosis research expenditures totaled about $595 million, accounting for 9.3 percent of the total NCI budget.

Treatment
Treatment research is composed of preclinical and clinical research. Preclinical research focuses on the discovery of new antitumor agents and their development in preparation for testing in clinical trials. These agents include both synthetic compounds and natural products. Clinical research involves demonstrating the effectiveness of new anticancer treatments through systematic testing in clinical trials. Phase I trials establish the maximum tolerated dose of a new agent; Phase II trials examine its efficacy against a variety of cancers; and Phase III trials compare the new treatment with the best standard therapy, in terms of improved survival and decreased toxicity. In FY2020, cancer treatment research expenditures totaled about $1.53 billion, accounting for 24.0 percent of the total NCI budget.

Cancer Biology
Cancer biology supports a broad spectrum of basic research on cancer and the body's response to cancer. Studies include investigations of cellular and molecular characteristics of tumor cells, interactions among cells within a tumor, and the components of the host immune defense mechanisms. Cancer is the result of genetic damage that accumulates in stages. It is the goal of cancer biology to identify and explain the stepwise progression between the initiating event in the cell and final tumor development. In FY2020, cancer biology expenditures totaled approximately $1.02 billion, accounting for 16.1 percent of the total NCI budget.

Cancer Prevention and Control
The NCI conducts cancer prevention and control basic and applied research through both intramural and extramural mechanisms in all phases of cancer prevention and control, as well as cancer surveillance. A key priority of this program is to develop strategies for the effective translation of knowledge gained from prevention and control research into health promotion and disease prevention activities for the benefit of the public. An integrated system of basic research, clinical trials, and applications research is in place and seeks to promote cancer prevention and control activities across the country.

The Cancer Prevention and Control Program includes four components and several subprograms, many of which relate to other program activities of the NCI, including information dissemination, epidemiology, and cancer treatment. The four components are Cancer Prevention Research, Cancer Control Science, Early Detection and Community Oncology, and Cancer Surveillance. In FY2020, the Cancer Prevention and Control Program expenditures totaled approximately $380 million, accounting for 6.0 percent of the total NCI budget.

NCI Resources

Cancer Centers
The Cancer Centers Program consists of a group of nationally recognized, geographically dispersed, individual institutions with outstanding scientific reputations. Each institution reflects particular research talents and special technological capabilities.

Cancer Centers have developed in several different organizational settings. Some are independent institutional entities entirely dedicated to cancer research (free-standing centers); some have been formed as clearly identifiable entities within academic institutions and promote interactive cancer research programs across departmental and/or college structures (matrix centers); and others involve multiple institutions (consortium centers).

The NCI uses the P30 Cancer Center Support Grant (CCSG) mechanism to provide support to the peer-reviewed research base of the Cancer Center within the larger institution. The CCSG supports the operational framework (infrastructure) of the center and partially pays for shared laboratory resources and facilities. Research projects themselves are supported through the individual grants and contracts from the NIH and from a variety of other grant funding agencies and organizations. Currently, there are 71 NCI designated Cancer Centers (51 Comprehensive, 13 Clinical, and 7 Basic), which received a total of $382 million in support, accounting for 6.0 percent of the total NCI budget.

Specialized Programs of Research Excellence (SPORE)
The SPORE Program is designed to stimulate translational research from the laboratory to clinical practice and are funded under the P50 grant mechanism. These are awarded to institutions that demonstrate the ability to perform significant translational research in the prevention, detection, diagnosis, and treatment for a single cancer site. In FY2020, the SPORE Program totaled approximately $113 million, accounting for 1.8 percent of the total NCI budget.

Comprehensive Minority Institution/Cancer Center Partnership
NCI's Comprehensive Minority Institution/Cancer Center Partnership awards are U54 Cooperative Agreements designed to establish comprehensive partnerships between the Minority Serving Institution (MSI) and the NCI-designated Cancer Centers. The partnership focuses on cancer research and one or more target areas in cancer research, training and career development, education, or outreach activities designed to benefit racial and/or ethnic minority populations in the region the Cancer Center serves. The partnership also creates a stable, long-term, collaborative relationship between the MSI and NCI-designated Cancer Centers and raises awareness about problems and issues relevant to the disproportionate rates of cancer incidence and mortality in minority populations.

Research Manpower Development
The Cancer Training Branch (CTB) in the Center for Cancer Training manages the Institute's extramural research training, career development, and education programs, and provides guidance to the extramural biomedical research community and administration of awards. This assures continued development of well-trained investigators in the basic, clinical, population, and behavioral sciences, who are prepared to address problems in cancer biology, causation, prevention and control, detection and diagnosis, treatment, and rehabilitation. Operationally, the CTB has three functions. The first is the management of NCI-funded grants in research training, career development, and cancer education. The second function is the administration of the Ruth L. Kirschstein National Research Service Award (NRSA) components (F32 and T32) of the CTB grant portfolio. The NRSA Program is the major mechanism for providing long-term, stable support to a wide range of promising scientists and clinicians. Individual awards are made directly to postdoctoral fellows (F32), and institutional awards (T32) are made to scientists who, together with a group of faculty-preceptors, administer a comprehensive training program for pre- and postdoctoral trainees. CTB administers a research career development program that supports the training of both scientists and research physicians during the first 3 to 5 years between receipt of a Ph.D., M.D., or other professional degree and receipt of an individual, investigator-initiated award. Among the career mechanisms are three additional non-NRSA institutional mechanisms (K12, R25T, and R25E) and six individual career development awards (K-series). The third function is the oversight and coordination of the NIH Loan Repayment Program. Expenditures in FY2020 totaled approximately $210 million, accounting for 3.3 percent of the total NCI budget.

NCI Funding Mechanisms

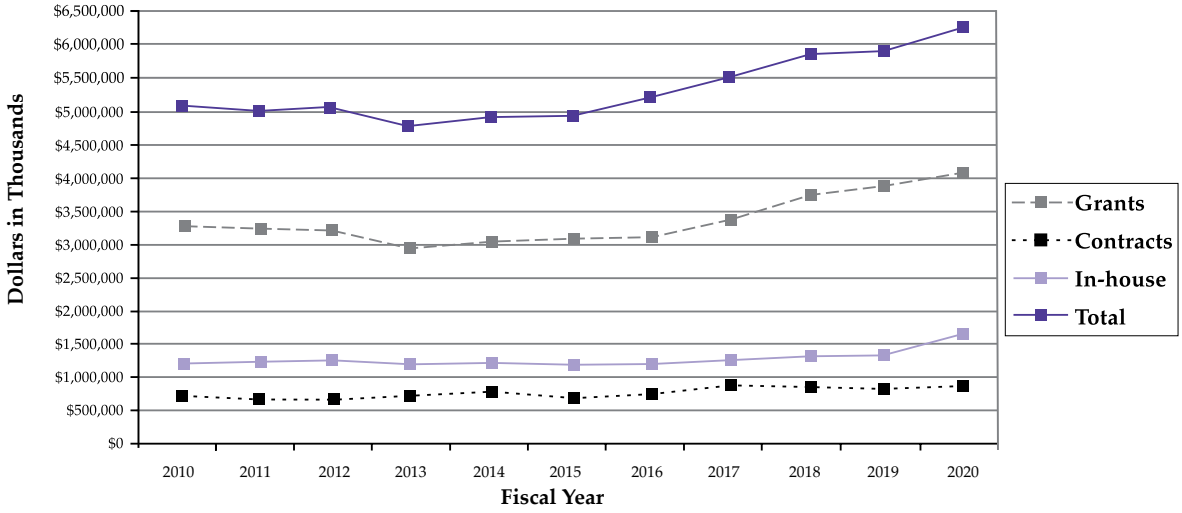
The NCI supports cancer research, cancer control, and cancer support activities through an extramural program of grants, cooperative agreements, and contracts, and through an intramural program of in-house research. In accordance with NIH tradition, NCI's extramural programs emphasize grant-supported, investigator-initiated research projects that are conducted at both nonprofit and for-profit institutions in the United States and abroad. Research contracts are awarded to both nonprofit and for-profit institutions. Intramural funds support continuing investigations by NCI

research scientists. The cooperative agreement mechanism, which is a cross between a grant and a contract, became available in 1979 as an additional

procurement mechanism. Annual appropriations from Congress provide the funds for all research supported by the NCI. Exhibits VII–IX present the NCI's funding allocations for the last several years.

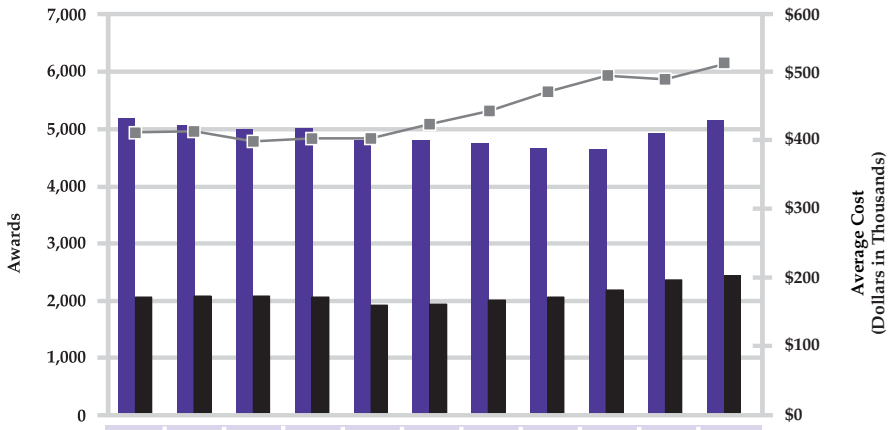
Exhibit VII. NCI Funding History, FY2010–2020*†

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Grants	$3,289,368	$3,255,003	$3,236,947	$2,987,438	$3,055,661	$3,082,008	$3,163,531	$3,399,282	$3,696,412	$3,791,407	$4,007,698
Contracts	621,682	594,955	597,635	623,950	660,283	596,951	748,344	910,377	843,406	786,095	853,012
In-house	1,187,097	1,208,147	1,232,760	1,177,626	1,216,424	1,273,633	1,294,293	1,326,732	1,387,911	1,414,788	1,522,638
Total	5,098,147	5,058,105	5,067,342	4,789,014	4,932,368	4,952,592	5,206,168	5,636,391	5,927,729	5,992,290	6,383,348



* Source: *NCI Fact Book*, FY2020.
† Includes FY2018, 2019, 2020 Cancer Cures – Moonshot Funding.

Exhibit VIII. Research Project Grants and Dollars Awarded, FY2010–2020*†



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
No. Awarded	5,079	5,019	5,021	4,816	4,814	4,767	4,666	4,663	4,780	4,984	5,070
$ in Millions	$2,093	$2,088	$2,075	$1,925	$1,940	$2,019	$2,069	$2,195	$2,367	$2,456	$2,677
Avg Cost $ in thousands	$412.0	$413.3	$399.7	$402.9	$403.0	$423.6	$443.4	$470.8	$495.1	$493.0	$514.0

* Source: *NCI Fact Book*, FY2020.
† Includes FY2018, 2019, 2020 Cancer Cures – Moonshot Funding.

Exhibit IX. Research Funding for Various Research Areas, FY2014–2019 (Dollars in Millions)*

Disease Area	2014 Actual	2015 Actual	2016 Actual	2017 Actual†	2018 Actual	2019 Actual
Total NCI Budget	$4,932.4	$4,952.6	$5,206.2	$5,636.4	$5,927.7	$6,440.4
AIDS	269.2	269.7	266.4	249.0	241.2	242.0
Brain & CNS	180.4	204.8	196.3	219.8	220.9	231.7
Breast Cancer	528.5	543.6	519.9	544.9	574.9	545.4
Cervical Cancer	71.1	57.1	65.6	68.8	71.5	86.0
Clinical Trials	749.8	748.0	801.0	806.6	895.7	794.3
Colorectal Cancer	223.0	209.3	212.2	208.4	256.0	238.8
Head and Neck Cancers	57.1	60.2	58.9	46.4	62.4	117.1
Hodgkin Disease	15.4	13.6	12.8	13.0	13.3	12.2
Leukemia	236.7	246.9	241.0	250.5	258.3	256.6
Liver Cancer	60.0	70.3	75.7	72.7	95.9	107.8
Lung Cancer	254.1	255.8	283.8	320.6	350.1	418.8
Melanoma	126.2	132.8	142.9	153.2	158.4	191.9
Multiple Myeloma	46.6	48.9	52.1	60.7	61.5	58.2
Non-Hodgkin Lymphoma	118.0	122.4	116.7	119.5	121.0	120.4
Ovarian Cancer	91.5	92.8	95.6	110.1	120.8	121.5
Pancreatic Cancer	122.4	125.3	152.6	178.3	182.1	187.0
Prostate Cancer	217.8	228.9	241.0	233.0	239.3	244.8
Stomach Cancer	11.3	13.5	13.3	13.4	14.2	14.8
Uterine Cancer	15.5	13.0	16.8	17.5	17.5	18.0

*Source: Office of Budget and Finance, NCI, FY2020.

†FY2019 data includes $400 million in Cures Act funding.

FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)—FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER (FFRDC)

Overview

The Federal Government supports a wide range of research and development (R&D), studies and analyses, and engineering endeavors conducted by various entities, including Federal laboratories, public and private colleges and universities, private companies, and other research institutions. A special class of R&D institutions, referred to as Federally funded research and development centers, or FFRDCs, where most or all of the facilities are either owed or financially supported by the U.S. Government, but operated by private contractors, provide Federal agencies with R&D capabilities that cannot be met by the Federal Government or the private sector alone. FFRDCs differ from other performers of Federal R&D—such as Federal laboratories, public or private colleges and universities, nonprofit organizations, or private firms—in that they are designed to meet a "special long-term research or development need that cannot be met as effectively by existing in-house or contractor resources" and that they have "access, beyond that which is common to the normal contractual relationship, to Government and supplier data, including sensitive and proprietary data, and to employees and installations equipment and real property." FFRDCs are Government-owned, contract-operated (commonly referred to as "GOCO") research facilities that are owned or leased by the U.S. Government, and managed by third-party contractors who operate the GOCO facilities and function in accordance with strict statutory and regulatory rules in accordance with **U.S. Code of Federal Acquisition Regulations, Section 35.017**. Although GOCO contractors operate within a Government-owned facility, they do not represent the U.S. Government.

There are currently 42 FFRDCs sponsored by 12 different Federal agencies. These FFRDCs provide a wide variety of R&D capabilities to Federal agency missions in a broad range of areas from energy (DOE), defense (DoD), health and human services (HHS), space agency modernization (NASA) to homeland security (DHS). The Frederick National Laboratory for Cancer Research (FNLCR), one of two HHS-sponsored FFRDCs, is the only FFRDC dedicated exclusively to biomedical R&D to discover, innovate, and improve human health. The other HHS-sponsored FFRDC, the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare (CAMH), established in 2012, seeks to advance the Nation's progress toward an integrated health system with improved access and quality at a sustainable cost. In FY2015, the Federal Government allocated $11.1 billion or 8.6 percent of its total $130 billion R&D expenditures to FFRDCs (https://fas.org/sgp/crs/misc/R44629.pdf).

A master list and description of activities of current FFRDCs can be accessed at https://www.nsf.gov/statistics/ffrdclist.

Frederick National Laboratory for Cancer Research (FNLCR)

The FNLCR, which is overseen by the NCI, had its origin in 1971 with the signing of the National Cancer Act by President Nixon. In 1972, the NCI-Frederick Cancer Research Center (FCRC) was established by a Presidential directive to convert the former Department of Defense (DoD) Biological Defense Research Laboratories at Frederick, Maryland, into a contractor-operated "leading center for cancer research." The directive stipulated that "operation of the NCI-Frederick should be by a private contractor, to allow the necessary flexibility, which would be difficult under direct Government operations." Litton Bionetics, Inc. was the first NCI contractor for the FCRC. In 1975, the FCRC was formerly designated as a FFRDC. In 2012, two years after Dr. Harold Varmus became the NCI director, the Center was designated as a National Laboratory, and renamed the FNLCR, elevating its broader national mission. At the same time, Dr. Varmus and the NCI, upon recommendation by the NCAB, empaneled the Frederick National Laboratory Advisory Committee (FNLAC), a committee consisting of up to 16 members, including the Chair, and appointed by the Director of NCI, to meet three times a year, to review the state of research at the FNLCR facility, align the mission and goals of NCI investigators and contract investigators, and make recommendations to the NCI Director for the best use of the FNLCR capabilities and infrastructure. Members were authorities in drug and vaccine development, clinical trials support, AIDS research, bioinformatics, genomics, nanotechnology, biological repositories, and basic research in cancer, immunology, and infectious diseases. The NFAC was subsequently renamed to the current Frederick National Laboratory Advisory Committee (FNLAC) in the fall of 2014.

As a national resource, the FNLCR provides cancer researchers a bridge between basic, translational, preclinical, and clinical practice bringing together public and private partners, including intramural investigators from the NCI and

other NIH intramural laboratories, extramural NCI-supported laboratories, biotechnical and pharmaceutical companies, and contract research groups. Because of its status as a FFRDC, FNLCR affords the NCI and other NIH Institutes with a unique national resource and capabilities (*flexibility, rapid response, and increased efficiency*) to accelerate the development and delivery of effective preventive, diagnostic, and therapeutic agents for rare and recalcitrant cancers, HIV/AIDS, and rapid response to emerging infectious disease (e.g., HIV/AIDS, Ebola, Zika, Chikungunya, Influenza, MERS, etc.) challenges.

The breadth of FNLCR activities are extensive and designed specifically to support the research goals and mission of the NIH, including investigator-initiated, hypothesis-driven research; drug discovery and development; biomarker identification and validation; translational genomics; next-generation preclinical assay development; oncology-focused computational science; production of clinical-grade biopharmaceuticals for first-in-human studies; acceleration of nanotechnology applications for treatments and diagnostics; preclinical model development, validation, and testing; Center for Cancer Research (CCR) clinical operations in support of the NCI, the National Institute of Allergy and Infectious Diseases (NIAID), and other NIH Institute-sponsored clinical trials; and management and operations of biopharmaceutical development and manufacturing programs under two current Good Manufacturing Practice (GMP) facilities.

Chronological History of the FNLCR and FNLAC

1971 President Richard Nixon signed the National Cancer Act and converted Fort Detrick, Frederick, Maryland, from a biological warfare facility to a national cancer research center. The act expanded Federal funding for cancer research and created the National Cancer Institute (NCI) in Frederick, part of the National Institutes of Health (NIH) under the U.S. Department of Health and Human Services (HHS).

1972 The Frederick Cancer Research Center (FCRC) was established on June 26. Approximately 70 acres and 67 buildings of the U.S. Army were transferred to HHS, which includes the NIH.

Litton Bionetics, Inc. was the first NCI contractor at the FCRC.

1975 The National Science Foundation (NSF) notified HHS that NCI-Frederick met the criteria for and was designated as a Federally Funded Research and Development Center (FFRDC), a Government-owned, contractor-operated (GOCO) facility designed to provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer. The FCRC at that time was one of 37 FFRDCs that were operated on behalf of nine sponsoring agencies by universities, nonprofit organizations, or industrial firms under long-term contracts or sponsoring agreements. It was, at that time, the only FFRDC in the HHS and NIH and was, and currently still is, the only FFRDC in the Nation dedicated solely to biomedical research.

1976 All buildings and acreage utilized by the FCRC were formally transferred from the Department of Defense (DoD) and the Department of the Army to HHS and the NIH.

1978 National Institute of Allergy and Infectious Diseases (NIAID) started utilizing the FCRC to do recombinant DNA experiments.

1980 FCRC was instrumental in developing a blood test to protect the Nation's blood supply from HIV infection.

1981 FCRC was renamed the Frederick Cancer Research Facility (FCRF) in December.

1982 The NCI divided the existing single FFRDC contract into five contracts: Basic Research, Operations and Technical Support, Animal Production, Computer Services, and Scientific Library Services. Required work included extensive laboratory renovations, developmental and applied cancer research, providing research resources, scientific support services, a strong safety program, computer and scientific library services, laboratory animal production, and complete facility maintenance in September.

1984 FCRF helped develop and manufacture an HIV/AIDS test on a large-scale for national use.

1985 The FCRF Advisory Committee was established on November 20 and consisted of 12 members who collectively had authorities knowledgeable in the disciplines pertinent to reviewing the activities of the Basic Research Program contract at the FCRF. The primary purpose of this Committee was to review contractor research and the overall multiple-contractor operation of the NCI FCRDC to ensure that required resources were provided.

1990 FCRF was renamed the NCI-Frederick Cancer Research and Development Center (FCRDC).

1993 NCI-Frederick Biopharmaceutical Development Program (BDP) was established. BDP supports the development of monoclonal antibodies, recombinant proteins, therapeutic peptides and DNA vaccines, oligonucleotides, virus therapeutics and vaccines, gene therapy products, and other biological agents.

1995 SAIC-Frederick (Science Applications International Corporation) competed and was selected as the operations and technical support contractor at the NCI-FCRDC.

1998 The FCRDC Advisory Committee was terminated on September 22.

2001 The name NCI-Frederick Cancer Research and Development Center was changed to National Cancer Institute at Frederick (NCI-Frederick).

2003 The Nanotechnology Characterization Laboratory (NCL) was established for accelerating nanotechnology research at Frederick. The NCI established the NCL as a collaboration with NIST and the FDA. The NCL conducts preclinical characterization and toxicity testing on nanomaterials that have been developed in academic, government, and commercial laboratories to diagnose and treat cancer.

2005 NCI-Frederick was providing scientific support for 25 of the 27 NIH Institutes and Centers. Extramural scientists also have access to its services, reagents, and facilities. Additionally, NCI-Frederick supports a significant percentage of NCI's drug discovery and development activities through its collaborative activities with the Division of Cancer Treatment and Diagnosis (DCTD). These activities include drug discovery screening, candidate selection, preclinical evaluation, and optimization of its own drug candidates. The NCI-Frederick facility and its portfolio of support functions via a contract mechanism are competitively reviewed every 5 years.

The Human Papillomavirus (HPV) Immunology Laboratory was established at Frederick to support the development of a cervical cancer vaccine that was tested in Phase III clinical trials.

2007 The NIH Director approved the renewal of the NCI-Frederick FFRDC and to extend the SAIC contract to manage and operate the FFRDC for a potential period of performance not to exceed 10 years.

2009 The Advanced Technology Partnerships (ATP) Initiative was established to accelerate the delivery of new products to cancer patients through the strategic application of advanced technologies and by facilitating translational research partnerships. A new research facility was built at Frederick by the Matan Corporation and leased by the NCI to house additional drug development laboratories.

2010 An *ad hoc* NCAB Working Group was formed to create a Strategic Scientific Vision for the National Cancer Program and to review progress at the NCI. The Working Group recommended the establishment of a chartered committee to advise and evaluate ongoing activities at the Frederick facility. The report findings and recommendations were presented at the NCAB meeting held on December 7. The Board unanimously approved the establishment of a Federal Advisory Committee at Frederick.

2011 The establishment of the NCI-Frederick Advisory Committee (NFAC) was announced on March 9. The NFAC consists of 16 members, including the Chair, appointed by the Director of NCI, to meet twice a year, review the state of research at the facility, and make recommendations for the best use of its capabilities and infrastructure. Members were authorities

in drug and vaccine development, clinical trials support, AIDS research, bioinformatics, genomics, nanotechnology, biological repositories, and basic research in immunology and infectious diseases.

An orientation was given to the NFAC members on August 31 in Bethesda, Maryland. At this orientation, the NCI Director led a discussion on the naming of the NCI-Frederick enterprise. Members discussed inclusion of different concepts in the name, including national, technology development, and translational research, as well as distinctions between intramural and extramural programs, and cancer and AIDS. Also, there were presentations on Contractor Cooperative Research and Development Agreement (c-CRADA) and the use of "Contractor-CRADAs" at other FFRDCs. Members strongly supported the establishment of a c-CRADA.

2012 **January** – The first regular NFAC meeting was held on January 25 in Frederick, Maryland. Consensus was reached to change the name from NCI-Frederick to Frederick National Laboratory for Cancer Research (FNLCR). A motion to express the NFAC's strong endorsement of the importance and usefulness of the c-CRADA was approved unanimously. NFAC members also toured the Advanced Technology Research Facility (ATRF), which was still under construction.

March – NCI-Frederick was renamed as the Frederick National Laboratory for Cancer Research (FNLCR) designating the facility as a Federal National Laboratory (FNL) and elevating its national mission.

May – The second NFAC meeting was held on May 30 in Bethesda, Maryland. Members expressed approval for the revised external website that presents the FNLCR as a national resource. The website displays products, services, and collaboration opportunities available to extramural investigators. The draft strategic plan for the FNLCR also was discussed.

June – The **Advanced Technology Research Facility (ATRF)** opened with research capabilities in Genetics and Genomics, Proteins and Proteomics, Imaging and Nanotechnology, Advanced Biomedical Computing and Cell Biology.

September – The third NFAC meeting was held on September 12 in Bethesda, Maryland. Several FNLCR updates discussed were: (1) a change of leadership within SAIC-Frederick; (2) creation of a c-CRADA policy; and (3) steps to improve how FNLCR's capabilities and resources are communicated to the extramural community. The draft strategic plan for the FNLCR also was discussed.

December – The new c-CRADA program to enhance partnering opportunities highlighting the contractor's unique capabilities at FNLCR was established. Under the c-CRADA, SAIC-Frederick initiates and manages CRADA projects that do not involve direct participation from NCI staff in research. These unique capabilities and the construction of the ATRF, whose primary function was to foster partnerships, were the driving forces behind the c-CRADA program.

2013 The fourth NFAC meeting was held on February 4 in Berkeley, California. The meeting was dedicated to the continued discussion of the draft FNLCR strategic plan.

The fifth NFAC meeting was held on September 24 in Frederick, Maryland. The RAS initiative was discussed and members expressed enthusiasm for the RAS Program and its direction and encouraged the NCI and FNLCR leadership to promote the RAS study as a model for other investigations. NFAC members also toured the ATRF.

SAIC-Frederick contractor changed its name to Leidos Biomedical Research, Inc. on September 27.

The NCI established the RAS Initiative to explore innovative approaches for attacking the proteins encoded by mutant forms of RAS genes and to ultimately create effective new therapies for RAS-related cancers. RAS initiative collaborations with both organizations and individual scientists have expanded research capabilities and maximized the impact of RAS initiative discoveries.

The NFAC approved the establishment of the: (1) *ad hoc* RAS Subcommittee; (2) Immuno-Multiple Reaction Monitoring (MRM) Working Group; and (3) *ad hoc* RAS Working Group. The *ad hoc* RAS Subcommittee was established to provide the highest quality oversight to the technical aspects of the RAS Program. The *ad hoc* RAS Working Group will provide findings and recommendations to the NFAC and the *ad hoc* RAS Subcommittee. The *ad hoc* RAS Working Group evaluated the scientific goals, direction, priorities, and progress of the hub projects at the FNLCR, as well as how the hub interfaces with industry and the extramural community.

The NFAC was instrumental in approving the concept of the RAS Initiative and suggested receiving periodic updates from the *ad hoc* RAS Working Group.

2014 The sixth NFAC meeting was held February 4–5 in Bethesda, Maryland. Members received an overview of the FNLCR and its interactions with the NCI intramural research program and an update on the RAS Project. Potential projects for the FNLCR were presented and discussed.

The seventh NFAC meeting was held on September 30 in Bethesda, Maryland. Members discussed the discrepancy between the NFAC name and the FNLCR. The Committee members voted unanimously to rename NFAC as the Frederick National Laboratory Advisory Committee (FNLAC).

2015 The eighth FNLAC meeting was held on February 3 in Bethesda, Maryland. At this meeting, it was announced that a community website, commonly referred to as RAS Central or the RAS Initiative at Cancer.gov (https://www.cancer.gov/research/key-initiatives/ras), was developed as a space for the RAS community to gather and exchange ideas, and have discussions.

The ninth FNLAC meeting held on September 30 in Bethesda, Maryland, resulted in a motion to support the launch of a National Cryo-EM User Facility at the FNLCR. The recommendation to establish a Steering Committee of experts and an evaluation in the second year was approved unanimously.

2016 The 10th FNLAC meeting was held on May 11 in Rockville, Maryland. In follow-up to the September 2015 decision to launch a National Cryo-EM Facility, the FNLAC voted via mail ballot to establish the *ad hoc* National Cryo-EM Facility Oversight Subcommittee.

The first FNLAC virtual meeting was held on October 21 in Rockville, Maryland. The RAS *ad hoc* Working Group report and recommendations were presented. A motion to accept the report was approved unanimously.

The 11th FNLAC meeting was held November 16–17 in Frederick, Maryland. A site visit review of the FNLCR included: (1) discussion of the overall operations; (2) evaluation of the research programs; and (3) discussion of unpublished RAS research findings and data. Also, a final report of the findings was written by FNLAC.

December – Final report and recommendation for the RAS Initiative Renewal Request from the FNLAC Review Team was accepted by a mail ballot and sent to the NCI Director.

2017 The establishment of the FNLAC NCI/U.S. Department of Energy (DOE) Collaborations Working Group was approved by the National Cancer Advisory Board on February 15, 2017. The FNLAC Working Group will provide scientific evaluation of programs, projects, and collaborations formed in support of or relevant to NCI–DOE collaborations. The Working Group is charged with exploring the domains and activities in which collaborations between the NCI and DOE would be mutually beneficial and advance the missions of these entities.

The 12th FNLAC meeting was held on May 8 in Bethesda, Maryland. Updates on several NCI initiatives that included the NCEF, two collaborations with DOE and the FNLCR, and the implementation of the Beau Biden Cancer Moonshot℠ Blue Ribbon Panel recommendations were presented and discussed.

The NCEF at the NCI provides cancer researchers access to the latest Cryo-EM technology for high-resolution imaging. The NCEF is a service facility under the umbrella of the FNLCR that opened for user access on May 15.

June – The FNLCR and the Weizmann Institute of Science, located in Rehovot, Israel, signed a contractor Cooperative Research and Development Agreement (c-CRADA) with the purpose of identifying small molecules that bind to or influence the activity of KRAS4b—a protein that is frequently mutated in pancreatic, colon, and lung cancers.

The second FNLAC virtual meeting was held on July 18 in Rockville, Maryland. An overview of the FNLCR research portfolio was provided and newly initiated research projects at FNLCR were presented and discussed.

August – A new solicitations page was launched on the FNLCR website on August 31. It is designed to bring increased visibility to business opportunities through a new, user-friendly platform that facilitates searching for open solicitations.

October – Ethan Dmitrovsky, M.D., was appointed as the President of Leidos Biomedical Research, Inc. and the Laboratory Director of the FNLCR. Dr. Dmitrovsky succeeded David Heimbrook, Ph.D., who retired after 6 years.

The 13th FNLAC meeting was held on October 30 in Bethesda, Maryland. Updates on several NCI initiatives, including the FNLCR operations, National Cryo-EM Facility, RAS Initiative, and the Chemical Biology Consortium were presented and discussed.

November – FNLCR entered into a new partnership with the Fred Hutchinson Cancer Research Center that, if successful, could improve current methods of donor selection and thereby make lifesaving transplant procedures more readily available for patients with leukemia, multiple myeloma, and other disorders.

2018

February – FNLCR and Georgetown University launched a Research and Education Collaboration, which aims to expand both institutions' research and training missions in the biomedical sciences.

May – The 14th FNLAC meeting was held on May 2 at the Shady Grove Campus, Rockville, Maryland. Members received an overview of the current operations and future plans for the FNLCR and updates on several NCI Initiatives, including the National Cryo-EM and the Accelerating Therapeutic for Opportunities in Medicine (ATOM). NCI staff provided overviews of the NCI Experimental Therapeutics (NExT) program, the Role of Molecular Pharmacodynamics in Drug Discovery and Development, and NCI's Early Therapeutic Trials Network.

October – The 15th FNLAC meeting was held on October 29 at the Shady Grove Campus, Rockville, Maryland. Members received an overview of the current work and future directions for the FNLCR and updates on several NCI Initiatives, including the RAS Initiative and Accelerating Therapeutics for Opportunities in Medicine (ATOM). NCI staff provided overviews of the NCI Mouse Repository and the Biopharmaceutical Development Program and the Cell Therapy Facility.

2019

June – The 16th FNLAC meeting was held on June 27 at the Shady Grove Campus, Rockville, Maryland. Members received an overview of the spectrum of science conducted at the FNLCR and updates on several NCI Initiatives, including the National Cryo-EM Facility, the NCI–DOE Collaborations, Cancer Models and Therapeutics Development, Accelerating Therapeutics for Opportunities in Medicine (ATOM), Computationally Driven Drug Discovery, and Progress in Targeting KRAS.

October – The 17th FNLAC meeting was held on October 24 at the NCI Advanced Technology Research Facility (ATRF), Frederick, Maryland. Members received updates on several NCI Initiatives, including Investigator- Initiated and Extramural Collaborative Research in the AIDS and Cancer Virus Program, Strategies for

Developing Ras-Like Projects, and the Role of FNLCR in NCI's Precision Medicine Initiative. NCI staff provided overviews of the Basic Science, Human Papillomavirus (HPV) Serology, Biopharmaceutical Development, and Laboratory Animal Sciences Programs at FNLCR.

2020 **May** – The 3rd Virtual FNLAC meeting was held on May 21. Members were updated on the FNLCR efforts in support of COVID-19 research, which included overviews of the COVID-19 serology and immunology capacity building, the work of the NCI Clinical Trials Network (NCTN) during the COVID-19 pandemics and efforts in clinical serological sciences, and NCI's plan to integrate and expand the various COVID-19 efforts into the broader NCI community.

July – The 4th Virtual FNLAC meeting was held on July 13. Members were updated on the operations at the FNLCR during the COVID-19 pandemic. NCI staff provided overviews of the COVID-19 research efforts at the FNLCR, including the extramural SeroNet, and tracking of SARS-CoV-2 seroprevalence, improved cancer prevention and screening, and immune cell engineering support for the extramural cancer community.

October – The 5th Virtual FNLAC meeting was held on October 14. Members were updated on the FNLCR resources to support extramural research, in particular, the Biopharmaceutical Development Program and the Patient-Derived Models Repository; NCI COVID-19 serological science efforts, including SeroNet, COVID-19 antibody testing, developing SARS-CoV-2 serum-based standards, and COVID-19 SeroTracker; the progress of the RAS Initiative; and a report for the NCI Task Force to evaluate the NCI–DOE collaboration.

2021 **February** – The 6th Virtual FNLAC meeting was held on February 23. Members were updated on the upcoming FNLCR contract re-competition, including the timeline; NCI staff provided a broad listing of potentially new large-scale national programs appropriate for the FNLCR; updates on NCI's SARS-CoV-2 serologic projects, including the effects of SARS-CoV-2 in cancer patients, particularly regarding the immune response to COVID-19 vaccinations; SARS-CoV-2 antibodies associated with decreased risk of new infections; and FNLCR's response to the COVID-19 pandemic and the continuity of uninterrupted operations, including recent progress in assisting NCI- and NIAID-related programs.

June – The 7th Virtual FNLAC meeting was held on June 28. Members were updated on task force recommendations made for the NCI–Department of Energy (DOE) collaborative implementation of NCI–DOE collaborations at the FNLCR; the NCI Experimental Therapeutics (NExT) Program, a government, academic, and industrial partnership that focuses on developing therapies for underrepresented malignancies and challenging cancer targets; ongoing FNLCR operations and continuity of services provided during the COVID-19 pandemic; and the COVID-19 Seroprevalence Hub.

October – The 8th Virtual FNLAC meeting was held on October 18. Members were updated on the National Cryo-EM Facility (NCEF); a presentation of structural studies of p97, an ATPase subunit, using the FNLCR NCEF; generation of various mouse models for use in cancer research; and establishment of the Mouse Models of Human Cancer Consortium (MMHCC) Mouse Repository housed at FNLCR; and the Nanotechnology Characteristic Laboratory.

FNLCR Facilities

The FNLCR campus is located 50 miles northwest of Washington, DC, and 50 miles west of Baltimore, Maryland, in Frederick, Maryland. Satellite locations include leased and Government owned facilities extending south along the I-270 Technology Corridor to Bethesda, Maryland, home of the NIH, NCI's parent organization.

Many of the original FNLCR offices and laboratories were housed in 67 buildings co-located on a 68-acre "NCI island campus" within the perimeter of the Fort Detrick U.S. Army Base in Frederick, Maryland, along with NCI-Frederick intramural laboratories and scientists from the NCI Center for Cancer Research (CCR) along with NCI staff and contractors from other NCI divisions, including the Division of Cancer Treatment (DCTD) and the Division of Cancer Epidemiology and Genetics (DCEG) (**Exhibit X**).

Exhibit X. NCI Frederick Campus Map

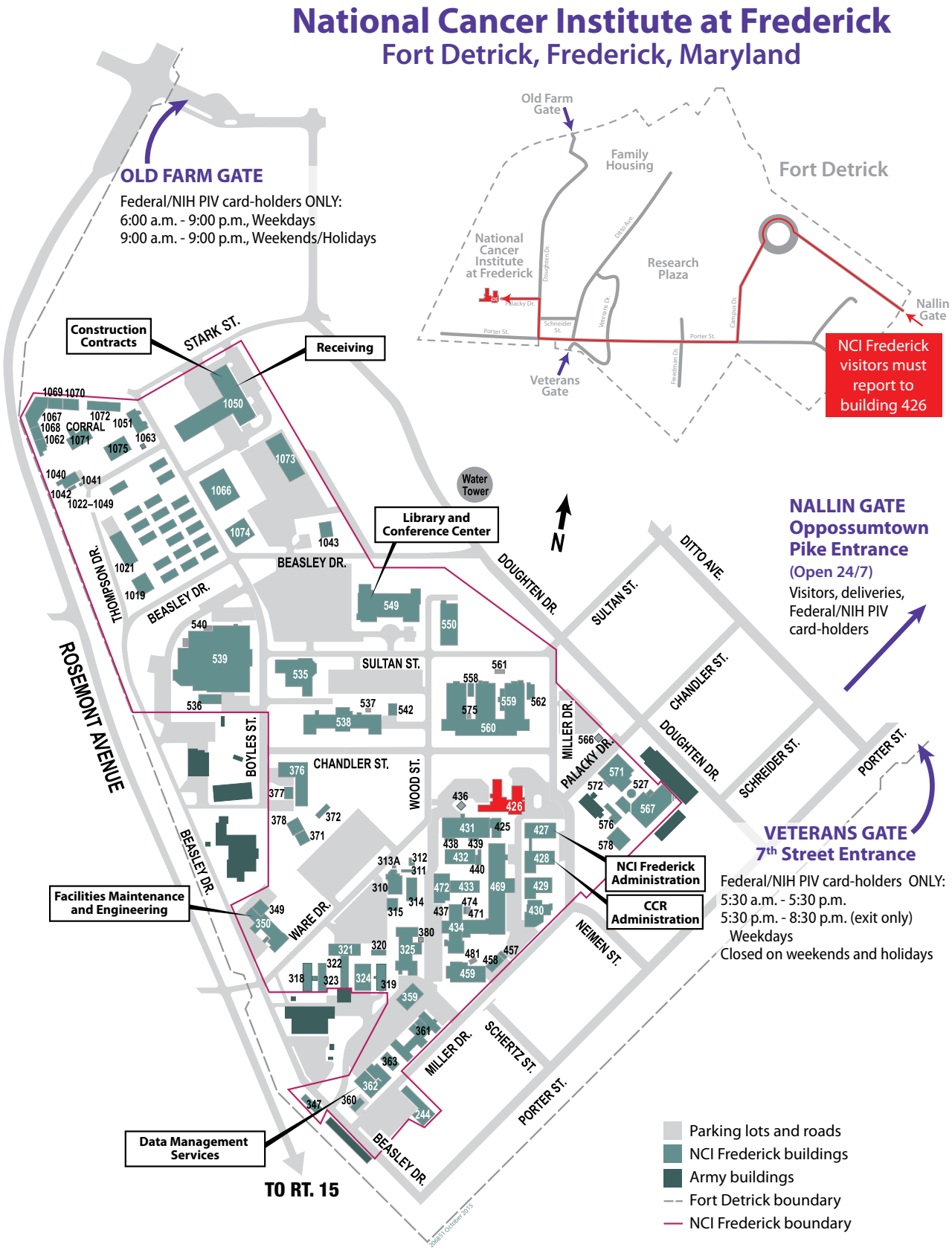


Exhibit XI. Frederick Advanced Technology Research Facility (ATRF)—Frederick, MD

In addition to the FNLCR offices and laboratories located on the main Fort Detrick NCI-Frederick campus, the FNLCR in 2012 opened the Advanced Technology Research Facility (ATRF) (Exhibit XI), a multi-building complex which consolidated many of the original FNLCR laboratories and operations that had been scattered among more than 30 buildings on the Fort Detrick NCI-Frederick campus. The ATRF is an off-site 330,000-square foot state-of-the-art R&D and production complex located at the Riverside Research Park, approximately 5 miles from the main Fort Detrick NCI-Frederick campus. The ATRF houses advanced technology laboratories, biopharmaceutical development, advanced biomedical computing, cell biology, and cGMP production facilities. The ATRF is designed to foster co-located public-private partnership projects, with dedicated laboratory and "think tank" space for collaborative work with partners across a continuum of translational R&D technologies and platforms, including genomics, proteomics, nanotechnology, molecular diagnostics, bioinformatics, and biopharmaceutical development.

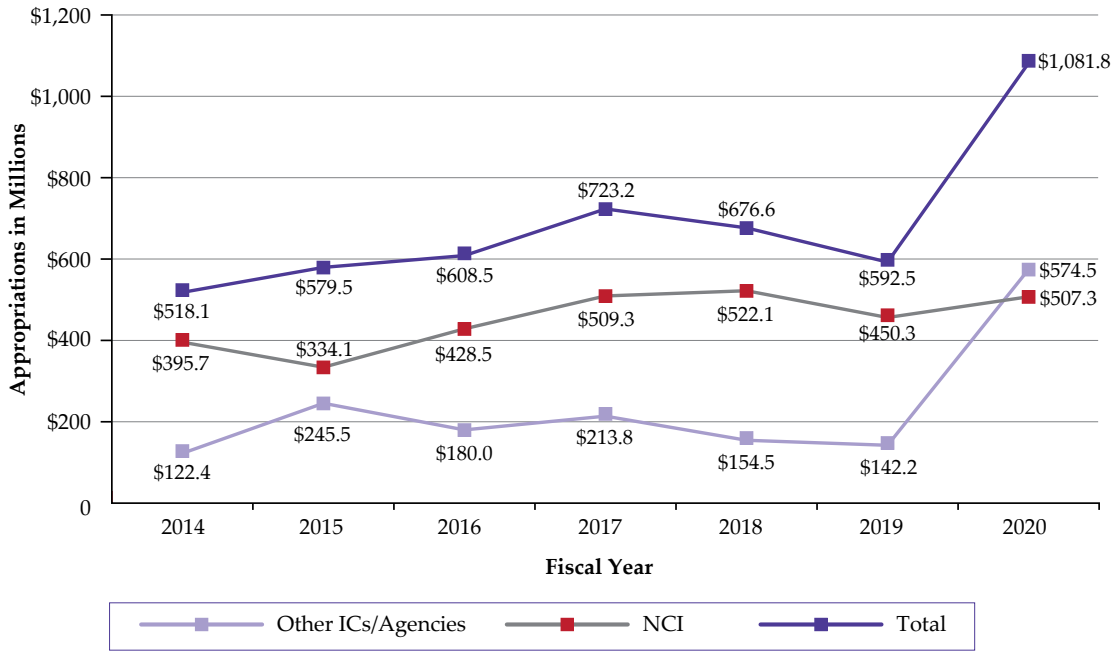
The FNLCR also manages and operates additional facilities located in Frederick, Gaithersburg, Bethesda, and Rockville, Maryland, including the NCI Advanced Technology Center (ATC), the home for the National Cryo-Electron Microscopy Facility (Frederick); the Core Genotyping Facility (Gaithersburg); the Laboratory Animal Sciences Program (LASP) (Bethesda); the Vaccine Pilot Plant for the production of clinical-stage vaccine candidates for major infectious diseases (HIV/AIDS, malaria, tuberculosis, Zika, etc.) for the National Institute of Allergy and Infectious Diseases (NIAID) (Frederick); and the Clinical Monitoring Research Program (CMRP), which provides clinical research support for human clinical trials for diseases and viruses such as cancer and AIDS, influenza, malaria, Zika, Ebola, chikungunya, parasitic diseases, and a wide range of other infectious diseases for the NCI and NIAID (Frederick and Rockville).

FNLCR Budget

Leidos Biomedical Research, Inc. (formerly known as SAIC-Frederick, Inc.) currently provides Operations and Technical Support (OTS) for the FNLCR under contract and on behalf of the National Cancer Institute (NCI). Leidos Biomedical provides operational management expertise and scientific capability to accomplish the research objectives assigned by the NCI to the FNLCR. Specific support activities include strategic Government-Contractor planning, program coordination, cooperation, and collaboration. These functions are executed through several different mechanisms, including Statement of Work (SOW) agreements and Work Order Requests formulated by, and with oversight provided by, the NCI Director and the Director, Office of Scientific Operations (NCI-Frederick).

Exhibit XII illustrates the annual appropriations of the NCI, other NIH ICs and Agencies, and the total of these to the FNLCR, excluding NCI intramural and extramural government full-time equivalent (FTE) personnel salary and benefit-

Exhibit XII. FNLCR Obligations



associated costs during the FY2014–2020 period. The budgetary obligations include support for more than 2,400 biomedical investigators, laboratory technicians, and support staff—including Leidos Biomedical employees and other contractual personnel on the NCI campus in Frederick and additional facilities in Bethesda, Rockville, and other sites in Maryland. Historically, approximately 70–75 percent of the total appropriations have been allotted to NCI DOCs for cancer research with 25–30 percent related to non-NCI support, including those associated with the NIAID Vaccine Research Center programs and other NIH ICs and agencies. In 2020, there was a significant increase in total funding to the FNLCR, with a vast majority of that increase attributed to the NIAID for the COVID-19 pandemic efforts.

FNLCR Scientific Support

During the early days of the NCI at Frederick, and even after the formal establishment of the Frederick Cancer Research Center (FCRC) as an FFRDC, the major role of the contracting agency was to provide operational and technical support to the NCI and other NIH Institutes' research missions, needs, and priorities and administrative services to maintain the FFRDC infrastructure. To fully capitalize on the unique capabilities and authorities allowed under governmental FFRDC regulations, the FNLCR, while still providing essential operational support to the NCI at Frederick and to the NCI DOCs, has developed national research programs and projects with direct benefit to the external research community. The different types of projects and support are briefly described below:

- **Government-Initiated Research Projects, Contractor-Provided Research Support:** Contractor (currently Leidos Biomed) provides technical laboratory staff to deliver tactical "hands-on" clinical or laboratory support for NCI Principal Investigator-directed intramural projects. Contractor personnel perform studies under overall guidance by Government employees. For example, Leidos technical staff are imbedded in NCI Center for Cancer Research (CCR) and Division of Cancer Epidemiology and Genetics (DCEG) Principal Investigator laboratories supporting their intramural research projects.
- **Government-Initiated Research Projects, Contractor-Provided Research Resources:** Leidos provides research resources for NCI-directed intramural and extramural research activities. Research support is generally furnished by the availability of essential core facilities, laboratory services, and specialized laboratories to facilitate the research activities of NCI and other NIH IC programs. For example, Leidos personnel provide essential Laboratory Animal Services and radiopharmacy assistance for animal husbandry, model development, imaging, immunology, and treatment evaluation.

- **Government-Initiated Research Projects, Contractor/Subcontractor-Executed Projects:** Extramural NCI-directed research projects are executed through outside subcontracts (external companies and universities). For example, investigators from the Leidos Biopharmaceutical Development Program and member institutions of the Chemical Biology Consortium in the NCI Experimental Therapeutics (NExT) Program participate in NCI extramural projects through task order agreements administered by Leidos Biomed as part of the NCI Division of Cancer Treatment and Diagnosis (DCTD) program.
- **Contractor-Initiated, Contractor-Executed Research Projects:** Leidos personnel conduct research both strategically as well as scientifically in NCI mission associated projects such as the RAS Initiative, AIDS and Cancer Virus Program, Cryo-EM Facility, Antibody Characterization Laboratory, and the Nanotechnology Characterization Laboratory (NCL). The NCI has broadly defined the objectives and missions of these initiatives while Leidos personnel conduct the day-to-day studies under the direction of the FNLCR Laboratory Director with oversight provided by the NCI Director and senior leadership.

FNLCR Support of NCI Divisions, Offices, and Centers

The FNLCR provides direct program support to numerous intramural and extramural divisions, offices, and centers (DOCs) within both the NCI and other NIH Institutes. The NCI DOCs include:

- **Center for Cancer Research (CCR)** ***(Intramural)*** — NCI intramural basic researchers, clinicians, and translational scientists who integrate basic and clinical research discovery to develop novel therapeutic interventions that better treat adults and children living with cancer or HIV/AIDS.
- **Center for Biomedical Informatics and Information Technology (CBIIT)** ***(Office of the NCI Director)*** — collaborates across the NCI to plan, provide, and coordinate technology, standards, and scientific computing in support of the NCI mission to speed discovery, facilitate open science, and progress towards precision treatment in cancer care and a learning health care system.
- **Division of Cancer Epidemiology and Genetics (DCEG)** ***(Intramural)*** — conducts population and multidisciplinary research to discover the genetic and environmental causes of cancer and ways to prevent it.
- **Division of Cancer Biology (DCB)** ***(Extramural)*** — encourages and facilitates continued support of basic research in all areas of cancer biology to provide the research foundation that enables improved understanding of the disease and may lead to new approaches for prevention, diagnosis, and treatment.
- **Division of Cancer Prevention (DCP)** ***(Extramural)*** — conducts and supports research to find ways to prevent and detect cancer, and to prevent or relieve symptoms from cancer and its treatments.
- **Division of Cancer Treatment and Diagnosis (DCTD)** ***(Extramural)*** — supports the translation of promising research into clinical applications to improve the diagnosis and treatment of cancer in areas of unmet need that are often too risky or difficult for industry or academia to develop alone.
- **Division of Cancer Control and Population Sciences (DCCPS)** ***(Extramural)*** — supports an integrated program of genetic, epidemiologic, behavioral, social, applied, and surveillance cancer research to reduce risk, incidence, and death from cancer, as well as to enhance the quality of life for cancer survivors.
- **Center for Strategic Scientific Initiatives (CSSI)** ***(Office of the NCI Director)*** — creates and implements exploratory programs focused on emerging scientific discoveries and innovative technologies to accelerate the pace of cancer research and the translation of research results into new therapies, diagnostics, and preventive agents.
- **Center for Cancer Genomics (CCG)** ***(Office of the NCI Director)*** — unifies NCI's activities in cancer genomics by aiming to synthesize research in different fields of cancer genomics — structural, functional, and computational — to improve patient outcomes.
- **Center for Global Health (CGH)** ***(Office of the NCI Director)*** — provides assistance and guidance to nations as they develop and implement cancer control plans; trains international investigators; and strengthens U.S. national, regional, multilateral, and bilateral collaboration in health research, cancer research, and cancer control to advance global cancer research, build expertise, and reduce cancer deaths worldwide.
- **Coordinating Center for Clinical Trials (CCCT)** ***(Office of the NCI Director)*** — facilitates efforts across the NCI to enhance the

effectiveness of NCI's clinical trials enterprise through collaboration and harmonization among NCI programs and extramural stakeholder communities.

In addition to providing support for NCI efforts, the FNLCR also provides significant assistance to NIAID. Support is provided to the following NIAID divisions and centers:

- **Division of Intramural Research** — conducts basic and clinical research in a wide range of disciplines related to immunology, allergies, and infectious diseases.
- **Division of Clinical Research** — provides multidisciplinary trans-NIAID services for facilitating clinical research and managing special projects as directed by NIAID leadership.
- **Division of Acquired Immunodeficiency Syndrome** — supports a global research portfolio on HIV/AIDS and its related co-infections and co-morbidities.
- **Vaccine Research Center** — conducts research that facilitates the development of effective vaccines for human disease.

Support also is provided to approximately 15 other Institutes within the NIH and other Federal agencies, including the National Heart, Lung, and Blood Institute (NHLBI); National Institute of Arthritis, Musculoskeletal, and Skin Diseases (NIAMS); National Institute of Mental Health (NIMH); National Center for Advancing Translational Sciences (NCATS); and the U.S. Army Center for Environmental Health Research.

Additional FNLCR-Supported Programs and Laboratories

The **NCI Experimental Therapeutics (NExT) Program** is led by the Division of Cancer Therapeutics and Diagnosis (DCTD) and consolidates NCI's Developmental Therapeutics Program (DTP) to create coordinated cancer therapeutics discovery and development resources in support of a balanced therapeutics pipeline, from the validation of new targets to evaluation in phase III clinical trials. The NCI partners with applicants from the external scientific community to facilitate the milestone-driven progression of new anticancer drugs (small molecules, biologics) and imaging agents towards clinical evaluation and registration. The goal is to shorten the timeline for new drug development and breakthroughs into new cancer therapies. For example, through the NExT program, promising molecules such as the angiogenesis inhibitor cediranib and olaparib, which inhibits the repair of DNA damage, are being tested as a combination treatment for ovarian cancer and mesothelioma. The NExT Program also is supporting the application of selumetinib to treat childhood brain tumors (see https://next.cancer.gov).

The **AIDS and Cancer Virus Program (ACVP)** seeks to improve the diagnosis, prevention, and treatment of HIV infection, AIDS, and AIDS-related tumors, including cancer causing viruses such as KSHV, through basic and applied research. The current program directly stems from efforts of scientists who, in 1984, helped contribute to the first generation of AIDS blood screening tests that helped prevent further spreading of the newly identified AIDS virus throughout the U.S. blood supply. The ACVP consists of highly collaborative investigator-led research sections conducting investigator-initiated research and research core support laboratories. Program scientists conduct and support AIDS studies through research, including fundamental molecular virology, *in vitro* studies, nonhuman primate models, and performing and supporting clinical and epidemiological studies in the United States and internationally. As an explicit feature of its mission and as a part of the FNLCR, the ACVP also develops and proactively shares unique and cutting-edge technologies with the broader research community to facilitate overall research progress (see https://frederick.cancer.gov/science/basic-research/aids-and-cancer-virus-program).

Clinical Monitoring Research Program (CMRP) and **Vaccine Clinical Materials Program (VCMP)** — The CMRP provides expertise in regulatory affairs, clinical trials management, pharmacovigilance, protocol development and navigation, and project/program management services to more than 400 domestic and international clinical trials, including human clinical trials, for diseases and viruses such as cancer and AIDS, influenza, malaria, Zika, Ebola, chikungunya, parasitic diseases, and a wide range of other emerging and re-emerging infectious diseases. Most recently, the CMRP supported the NIAID Vaccine Research Center's (VRC) rapid response to the global health threat posed by infectious diseases such as the Zika virus and chikungunya, thus accelerating a range of clinical research efforts to understand infection, replication, pathogenesis, and transmission, and to develop and test vaccine candidates for protection against these infections. In 2016, the program developed an accelerated schedule to produce, test, and release a Zika

vaccine candidate in just 90 days. The VCMP completed several batches of Zika vaccine vialed drug product (DP) and physical drug substance (DS) totaling roughly 10,000 vaccine doses. The CMRP also provides support for programs and initiatives such as the Brain Tumor Trials Collaborative, NCI-MATCH and other precision medicine initiatives, NCI Center for Global Health, and NIAID Vaccine Research Center and Division of Clinical Research (for CMRP see https://frederick.cancer.gov/science/clinical/clinical-monitoring-research-program and for VCMP see https://frederick.cancer.gov/science/vaccine-clinical-materials-program).

The **Laboratory Animal Sciences Program (LASP)** provides an integrated portfolio of research animal programs, including the development of genetically engineered mouse models, cryopreservation and assisted reproduction, pathology and histotechnology, a small animal imaging core, a genome modification core, gnotobiotics facility, molecular diagnostics, and animal husbandry. The LASP also provides oversight of animal research facilities by guarding against the accidental introduction of pathogens in experiments, administers accurate clinical diagnosis and preoperative care, and offers quality animal holding facilities and related services. These include the quarantine of imported animals, rederivation of pathogen-carrying strains, and the comprehensive monitoring of the health status of animal research colonies. LASP management in FY2016 included 27 rodent and nonhuman primate facilities (22 in Frederick and 5 in Bethesda) encompassing 133,000 animals, 315 LASP personnel (234 in Frederick, 81 in Bethesda), and support to 206 research investigators involved in 550 active animal study protocols (see https://frederick.cancer.gov/science/technology/laboratory-animal-sciences-program).

The **Center for Advanced Preclinical Research (CAPR)** is funded by the NCI-CCR and provides a comprehensive preclinical trial framework for evaluating the anti-tumor efficacy and selectivity, biodistribution, and metabolism of early-stage candidate drugs using genetically engineered mouse models. The CAPR serves as a national resource for the comprehensive preclinical testing of early-stage candidate drugs. Candidate compounds are assessed for anti-tumor efficacy and selectivity in genetically engineered animal models (see https://ccr.cancer.gov/capr).

The **Cancer Research Technology Program (CRTP)** leads scientific initiatives and provides technical solutions to meet the challenges of and performance of mission-driven biomedical research. A major research area for the program is NCI's RAS Initiative to explore innovative approaches for attacking proteins encoded by mutant forms of the RAS family of genes. In addition to RAS studies, the CRTP also is involved in quantification of the impact of the HIV-1 glycan shield on antibody elicitation; genetic alterations associated with prostate cancer may be identified by sequencing metastatic tumor genomes to identify molecular markers at this lethal stage of disease; and the development of nanomedicine strategies to overcome the pathophysiological barriers of pancreatic cancer (see https://ncifrederick.cancer.gov/services/accessioning/Services/LabServices.

The **Biopharmaceutical Development Program (BDP)**, established in 1993, is funded by NCI's Division of Cancer Treatment and Diagnosis (DCTD) and produces novel antibodies and proteins as therapeutics when industry is not prepared to develop them. When the Children's Oncology Group could not find a manufacturer to produce ch14.18, a monoclonal antibody being evaluated as a treatment for neuroblastoma tumors in children, BDP manufactured the antibody for the clinical trial. The trial demonstrated that ch14.18 reduced the risk of recurrence when given to children whose cancer responded to chemotherapy. The monoclonal antibody has become the standard of care for children with certain types of neuroblastoma, and the pharmaceutical company, United Therapeutics, is now manufacturing the antibody (see https://ncifrederick.cancer.gov/research/brb/biopharmaceutical.aspx).

The **Nanotechnology Characterization Laboratory (NCL)**, established in 2004, seeks to accelerate the development of nanotechnology for basic and applied cancer research. Working in collaboration with the FDA and the National Institute of Standards and Technology (NIST), the NCL standardizes the preclinical characterization of nanomaterials that academic, government, and industry researchers are developing as cancer therapeutics and diagnostics (see https://ncl.cancer.gov).

The **Basic Science Program (BSP)** pursues independent, multidisciplinary research programs in basic and applied molecular biology, immunology, retrovirology, cancer biology, and human genetics. Research efforts and support are an integral part of the intramural NCI Center for Cancer Research (CCR) at the FNLCR. The goal of the BSP is to gain new knowledge and understanding of biological processes relevant to cancer and other diseases,

and to develop cutting-edge tools to accelerate progress. Areas of focus include cancer, retrovirology, basic biology, structural biology, informatics, cellular mechanisms, and the genetic factors that influence disease susceptibility and progression (see https://frederick.cancer.gov/science/basic-research/basic-science-program).

A more extensive description of the activities and facilities provided at the FNLCR can be found at https://frederick.cancer.gov.

FNLCR National Programs and Initiatives

The FNLCR, as an FFRDC, is currently undertaking multiple scientific challenges of national importance to accelerate the development and delivery of effective preventive, diagnostic, and therapeutic products to people living with cancer and HIV/AIDS. These programs and initiatives are described below.

RAS Initiative
The **RAS Initiative** seeks to develop therapies against tumors that contain mutations in members of the RAS family of oncogenes. In contrast to outstanding progress in other areas of cancer therapeutics, researchers have not been able to successfully develop effective treatments against proteins produced by RAS oncogenes. RAS genes are mutated in more than 30 percent of all human cancers, including 95 percent of pancreatic adenocarcinomas, 45 percent of colorectal cancers, and 5 percent of lung adenocarcinomas. To address this critical challenge, Drs. Harold Varmus, the previous Director, NCI, and Doug Lowy, the previous Acting Director, NCI, with input from the FNLAC, launched the national NCI RAS Initiative in 2013 to explore innovative approaches of targeting mutant forms of RAS directly and treating RAS-driven cancers. A "Hub and Spoke" model was proposed, in which the RAS Initiative would be based at the FNLCR, which acts as the hub, and would connect with an international network of RAS investigators, including academic, contract, and biopharmaceutical partners. RAS Initiative Hub areas include Structural Biology and Biochemistry, RAS Assays, Biology of Mutant KRAS Cell Lines, Pathway Analysis, Cell Surface Analysis, and RAS Reference Reagents. Currently, the RAS Initiative is fully implemented with more than 70 FNLCR contract researchers working in collaboration with multiple external partners. By using an integrated, team-based approach centered at the FNLCR, and in collaboration with an extensive network of academic laboratories, the NCI, and industrial partners, the RAS Initiative seeks to develop drug candidates that target RAS proteins directly, or block RAS activity in cancer cells. It is expected that these candidates will advance quickly towards pre-clinical testing and that therapies for this deadly group of RAS-driven cancers will be a reality (see https://www.cancer.gov/research/key-initiatives/ras).

Human Papillomavirus (HPV) Serology Laboratory
Human Papillomavirus (HPV) is one of the major infectious agents that causes cervical and other cancers (anal, oropharyngeal, vaginal) and is responsible for approximately 5 percent of all cancers worldwide. Although an effective vaccine is available, efforts at the FNLCR are underway to increase the number of people receiving vaccinations. FNLCR's **HPV Serology Laboratory** was launched in early 2017 with the goal of establishing standardization to promote harmonization and proficiency of HPV serology testing in vaccine trials. The aim is to accelerate the development and implementation of HPV vaccines worldwide, especially in resource-limited countries where cervical cancer is a public health burden. The laboratory provides expertise and leadership on the development, validation, and standardization of HPV serology assays, which measure antibody responses following exposure to HPV or HPV vaccines to be used in vaccine trials (see https://frederick.cancer.gov/news).

Cryo-Electron Microscopy (EM) Facility
The **National Cryo-Electron Microscopy (EM) Facility (NCEF)** was launched in 2015 and provides cancer researchers access to the latest state-of-the-art cryo-EM and detector technologies for obtaining the highest resolution images of biological structures. NCEF is a user-access facility that meets the needs of cancer researchers who are engaged in structural biology cryo-EM research and who do not have access to these instruments at their own institutions. The NCEF houses a Titan Krios™ microscope, which is fitted with a Falcon II direct detector and a K2 Summit direct detector at the end of a Gatan imaging filter. Specialists in cryo-EM data collection and microscope operation staff the FNLCR NCEF facility and provide external users with data for their research. The aim of the NCEF is to produce high-resolution cryo-EM images for scientists who have high-quality specimens ready for high-resolution imaging. A FNLAC NCEF Oversight Committee and NCEF Working Group provide advice to the NCI on operational aspects of the facility. Access to the facilities was made available in 2017 to prospective users whose work is relevant to cancer research. Information on how to submit projects to the

NCEF and get access to the latest technology for high-resolution imaging can be obtained at https://www.cancer.gov/research/resources/cryoem).

Beau Biden Cancer Moonshot
Announced in 2016 by then Vice President Joe Biden, the **Beau Biden Cancer Moonshot℠** to accelerate cancer research aims to make more therapies available to more patients, while also improving the ability to prevent and detect cancer at an early stage. Congress passed the 21st Century Cures Act in December 2016 authorizing $1.8 billion in funding for the Cancer Moonshot over 7 years. An additional $300 million was appropriated in FY2017 to fund Moonshot initiatives.

The FNLCR supports four Cancer Moonshot projects:

- **High-Performance Computing/DOE Partnership:** The FNLCR plays a significant role in a national partnership to expand the use of high-performance computing in cancer research. Through work with the NCI and the Department of Energy (DOE), the FNLCR is developing a promising strategy for using exascale computing capabilities together with urgent scientific applications.
- **Precision Medicine Clinical Trial:** The FNLCR supports key components of an ambitious nationwide precision medicine clinical trial (**NCI-MATCH**) that matches cancer patients to potential therapies based on the genetic makeup of their tumors, rather than tumor location in the body (see https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match).
- **Genomic Data Commons:** The FNLCR supports Cancer Moonshot through the **Genomic Data Commons**, a data sharing platform designed to give researchers the capability to share genomic and clinical data from cancer research programs to promote precision medicine in oncology (see https://gdc.cancer.gov/about-gdc).
- **Making Cancer Research More Accessible:** The FNLCR helps make it easier for patients and oncologists to access information from clinical research trials through a partnership between the NCI and White House Presidential Innovation Fellows (see https://presidentialinnovationfellows.gov).

Accelerating Therapeutics for Opportunities in Medicine (ATOM)
The FNLCR is a founding member of the **Accelerating Therapeutics for Opportunities in Medicine (ATOM)** Consortium, a public-private c-CRADA partnership with the mission of transforming drug discovery by accelerating the development of more effective therapies for patients. The ATOM Consortium was officially established in October 2017. Founding members are GlaxoSmithKline (GSK), Lawrence Livermore National Laboratory (LLNL), FNLCR, and the University of California, San Francisco (UCSF). Scientists aim to create a new pre-competitive platform for drug discovery that integrates high-performance computing, diverse biological data sets, and emerging biotechnologies. This new platform will ultimately be offered as a shared national resource to accelerate drug discovery, transforming the process from a slow, sequential, and high-failure undertaking into a rapid, integrated, and patient-centric model. The goal is to move validated oncolytic targets to patient-ready therapeutics in less than 1 year, a process that currently takes an average of 6 years (see https://datascience.cancer.gov/collaborations/atom).

COVID-19 Research
Scientists at the FNLCR are collaborating with government, academic, and industry partners on multiple studies to learn more about SARS-CoV-2 and contribute to the rapid development of treatments and vaccines. Early in the pandemic, the FNLCR was poised to rapidly and flexibly address urgent public health priorities and leverage the expertise and advanced technology that apply to cancer research to investigate the SARS-CoV-2 virus at the cellular and molecular levels, and to develop and standardize critical assays that may contribute to diagnostic tools.

Serological Sciences Network (SeroNet)
The NCI's Serological Sciences Network (SeroNet) was launched at FNLCR in October 2020 to study the immune response to COVID-19 and increase the nation's antibody testing capacity. SeroNet is a large-scale collaboration across 25 academic research institutions to enhance the understanding of how the immune system responds to SARS-CoV-2, which causes COVID-19, and to COVID-19 vaccines. The FNLCR Human Papillomavirus (HPV) **Serology Laboratory** was expanded in a collaborative effort with the NIAID, FDA, CDC, and others to coordinate the development, validation, and standardization of serology assays for COVID-19 vaccines, neutralization assays, and possible cross-reacting sera from prior to the epidemic across the network. Serosurveillance studies for the screening of 40,000 serum samples for SARS-CoV-2 antigens were conducted as a measure of early exposure. The laboratory also is partnering with the FDA to conduct independent

evaluation of commercially available antibody test kits to ensure that the antibody tests are accurate and reliable. In early 2021, the FNLCR supported the development and production of the Human **SARS-CoV-2 Serology Standard**, a pool of plasma from four donors with antibodies to SARS-CoV-2, for calibration in COVID-19 antibody assays to enhance cross-study comparison around the United States and the world. The SeroNet Coordinating Center, headquartered and managed by the **Vaccine, Immunity, and Cancer Directorate** at FNLCR, provides program logistical support.

NIAID COVID-19 Clinical Trials

In the past, NIAID has made extensive use of the FNLCR in rapidly responding to virus epidemics, for example, SARS (2003), Ebola (2013), and Zika (2015). In concert with NIAID and as part of Operation Warp Speed, FNLCR is facilitating randomized placebo-controlled international clinical trials to combat COVID-19. These include small-molecule inhibitors as well as antibody-mediated therapeutics. FNLCR supported NIAID investigators in a multicenter, international randomized, controlled adaptive COVID-19 therapeutic trial (ACTT) of the antiviral Remdesivir in hospitalized COVID-19 patients on ventilators or oxygen dependent, in accordance with the **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)** master protocol program. There were four studies. ACTT-1 through ACTT-3 were completed, and ACTT-4 is still enrolling in the United States and international sites.

- ACTT-1: Remdesivir vs. placebo (60 sites/1,063 cases)
- ACTT-2: Remdesivir vs. +/− Baracitinib/placebo (71 sites/1,034 cases)
- ACTT-3: Remdesivir vs. +/− Interferon beta/placebo
- ACTT-4: Remdesivir + Dexamethasone/placebo vs. Baracitinib/placebo

Initial results indicated the hospitalized COVID-19 patients on Remdesivir treatment improved faster than those on placebo. FDA approval for Remdesivir for the treatment of COVID-19 was granted, and FDA Emergency Use Authorization was given for the use of Remdesivir in combination with Baracitinib.

Other Collaborations

NCI, in partnership with NIAID and NHGRI, has begun a series of genomic studies at FNLCR to identify genetic variants associated with both cancer and non-cancer patients with COVID-19. The goal is to identify genetic variants associated with an individual's outcome to infection, with the hope to identify potential targets for new treatments and provide insights that can be used for screening purposes.

NCI ADVISORY BOARDS, COMMITTEES, AND REVIEW GROUPS

The NCI relies on advisory boards, committees, and review groups to provide objective and expert advice on the coordination of the National Cancer Program (NCP), NCI scientific priorities, development of major extramural program initiatives, future directions of NCI intramural, extramural, and clinical trials programs, and the FNLCR. These advisory committees are established under the Federal Advisory Committee Act (FACA) of 1972.

The NIH Office of Federal Advisory Committee Policy (OFACP) develops policies and provides guidance and resources to the public advisory committee members, Congress, the President, and those managing Federal advisory groups at the NIH, HHS, and other Federal agencies. The NCI DEA works closely with the OFACP in establishing advisory boards and committees and in the appointment of members. The membership and activities of these advisory bodies are coordinated by the **NCI Division of Extramural Activities**.

Presidentially Appointed Panel and Board

President's Cancer Panel (PCP). The PCP consists of three members appointed by the President, who by virtue of their training, experience, and background, are exceptionally qualified to appraise the NCP. At least two members of the Panel are distinguished scientists or physicians, and the third member is a nationally recognized cancer research advocate. The Panel monitors the development and execution of the activities of the NCP and reports directly to the President. Any delays or hindrances in the rapid execution of the Program are immediately brought to the attention of the President (See **Appendix A**).

National Cancer Advisory Board (NCAB). NCI's principal advisory body is the presidentially appointed NCAB. The NCAB advises the HHS Secretary and the NCI Director on issues related to the entire NCP and provides a second level of review for grant applications referred to the NCI and for the FDA (See **Appendix B**).

Program Advisory Boards and Committees

Board of Scientific Advisors (BSA). The BSA represents the scientific community's voice in NCI-supported extramural science. The BSA, composed of distinguished scientists from outside the NCI and representatives from the advocacy community, advises the NCI leadership on the progress and future direction of the Institute's Extramural Research Program. The BSA evaluates NCI extramural programs and policies, and it reviews concepts for new research opportunities and solicitations to ensure that those concepts are meritorious and consistent with the Institute's mission (See **Appendix C**).

Boards of Scientific Counselors (BSC). The BSC, composed of scientific experts from outside, is managed through the OD, NCI, advise the NCI leadership on the progress and future direction of NCI's Intramural Research Program (IRP) residing in the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG). The BSC evaluates the performance and productivity of NCI Intramural Principal Investigators (PIs) and Staff Scientists through periodic site visits to the intramural laboratories and provide evaluation and advice on the course of research for each Laboratory and Branch (See **Appendix D**).

Clinical Trials and Translational Research Advisory Committee (CTAC). The CTAC advises and makes recommendations to the NCI Director, NCI Deputy Directors, and the NCI DOC Directors on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. In addition, CTAC makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. CTAC also will advise on the appropriate magnitude for dedicated translational research priorities and recommend allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. This responsibility encompasses oversight of all clinical trials, both extramural and intramural. The Committee provides broad scientific and programmatic advice on the investment of taxpayer dollars in clinical trials and related science (See **Appendix E**).

Frederick National Laboratory Advisory Committee (FNLAC). The FNLAC provides advice and makes recommendations to the Director, NCI, and the Associate Director, Frederick National Laboratory for Cancer Research (FNLCR), on the optimal use of the Laboratory to rapidly meet the most urgent needs of the Institute. The NCI facility in Frederick, Maryland, was established in 1972 as a Government-owned Contractor-operated facility. In 1975, the facility was designated as a Federally Funded Research and Development Center (FFRDC) to provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer and AIDS. The FFRDC has been renamed as the FNLCR. The FNLAC reviews new projects proposed to be performed at the FNLCR and advises the Director, NCI, and the Associate Director, FNLCR, about the intrinsic merit of the projects and about whether they should be done at the Frederick facility (See **Appendix F**).

NCI Council of Research Advocates (NCRA). The NCRA, previously known as the Director's Consumer Liaison Group (DCLG), advises the NCI Director with respect to promoting research outcomes that are in the best interest of cancer patients. To this end, the NCRA conducts these activities with the intent to identify new approaches, promote innovation, recognize unforeseen risks or barriers, and identify unintended consequences that could result from NCI decisions or actions. Additionally, the NCRA will provide insight into enhancing input, optimizing outreach, and promoting strong collaborations, all with respect to non-scientist stakeholders (See **Appendix G**).

NCI Review Groups and Panels

NCI Initial Review Groups (IRGs). The IRGs advise and make recommendations on the scientific and technical merit of applications for grants-in-aid for research, research training, research-related grants and cooperative agreements, and contract proposals for projects in the areas of cancer causation, diagnosis, treatment, and prevention. There are currently four NCI IRGs: Cancer Centers (Subcommittee A); Institutional Training and Education (Subcommittee F); Transition to Independence (Subcommittee I); and Career Development (Subcommittee J).

NCI Special Emphasis Panels (SEPs). The SEPs provide concept review of proposed contract or grant solicitations and review grant and cooperative agreement applications and contract proposals for research projects and for research and training activities in the broad areas of basic and clinical cancer sciences, clinical trials prioritization evaluation, and applied research and development programs of special relevance to the NCI. The preclinical and clinical discovery and development program Panels, managed by the Division of Cancer Treatment and Diagnosis (DCTD), also evaluate proposals for support to make available to the research community, on a competitive basis, contract resources for the preclinical development of drugs, biologics, clinical assays, and other developmental programs that would ultimately benefit the advancement of clinical studies. Furthermore, the Panel will provide input to the NCI on scientific prioritization of NCI Clinical Trials Network (NCTN) concepts across diseases guided by a set of criteria when there are insufficient resources to support trials for all NCTN Scientific Steering Committee approved concepts.

NCI Leadership

NCI Scientific Program Leadership (SPL). The SPL, which includes the NCI Director, Deputy Directors, Division Directors, and other senior scientific staff, meets on a regular basis to discuss various matters of NCI policy, including but not limited to review and approval of Request for Application (RFA), Program Announcements (PAs), and research and development contract concepts before review by the BSA; review of program announcements; development of funding plans; and grant payment by exceptions. NCI's cancer research activities are monitored and administrated through several extramural and intramural divisions, centers, and offices (See **Appendix H**).

FREDERICK NATIONAL LABORATORY ADVISORY COMMITTEE (FNLAC)

Background

In 1971, President Richard Nixon signed the National Cancer Act converting Fort Detrick, Frederick, Maryland from a biological warfare facility to a national cancer research center. The act expanded Federal funding for cancer research and created the National Cancer Institute (NCI) in Frederick (NCI-Frederick), part of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS). In 1972, the Frederick Cancer Research Center (FCRC) was established and administratively reorganized and renamed the Frederick Cancer Research Facility (FCRF) in 1981, which was subsequently renamed the NCI-Frederick Cancer Research and Development Center (FCRDC) in 1990. In 2010, an *ad hoc* National Cancer Advisory Board (NCAB) Working Group was convened to create a Strategic Scientific Vision for the National Cancer Program (NCP) and to review progress of the NCI. The Working Group findings were presented at the December 7, 2010 NCAB meeting and the Board unanimously approved the establishment of the chartered NCI-Frederick Advisory Committee (NFAC) to advise and evaluate ongoing activities at the NCI-Frederick facility. The first NFAC meeting was held on January 25, 2012, in Frederick, Maryland, at which time consensus was reached to change the name from NCI-FCRDC to Frederick National Laboratory for Cancer Research (FNLCR). At the September 30, 2014 NFAC meeting, committee members discussed the name discrepancy between the NFAC and the FNLCR and voted unanimously to rename NFAC as the Frederick National Laboratory Advisory Committee (FNLAC).

FNLAC Charter

FNLAC Legislative Authority

Authorized by 42 U.S.C. 285a-2(b)(7), section 413(b)(7) of the Public Health Service Act, as amended. The FNLAC (Committee) to the NCI is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Membership and Designation

The FNLAC will consist of up to 16 members, including the Chair (see **Appendix F**), appointed by the Director, NCI. 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. Additionally, a nonvoting representative from the NCAB, the NCI Board of Scientific Advisors, and the NCI Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology) will serve on the committee and are limited to the duration of their terms on their respective Boards. *Ex officio* members will include NCI Deputy Directors; select NCI Division Directors; and the Associate Director, FNLCR. All non-Federal members serve as Special Government Employees. Members and the Chair will be invited to serve overlapping 4-year terms. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members. A member may serve after the expiration of that member's term until a successor has taken office.

Description of Duties

FNLAC members will review the state of research (extramural and intramural) at FNLCR and make recommendations for the best use of the FNLCR capabilities and infrastructure. Specifically, the Committee will review major new projects proposed to be performed at FNLCR and advise the Director, NCI, and Associate Director, NCI-Frederick, with respect to the intrinsic merit of the projects and whether they should be done at the FNLCR. In addition, the Committee will periodically review the existing portfolio of projects at FNLCR, evaluate their productivity, help determine which of these projects should be conducted at FNLCR or 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 ensure that the operations at FNLCR are open, transparent, and in the best interests of the entire cancer research community.

Contractor-initiated research at the FNLCR will be monitored and evaluated periodically within the span of a contract period. The Committee will consider proposed research and provide advice

as to whether the FNLCR is the best venue for conducting these projects, which it deems to be of merit and to be consistent with the mission of the NCI and FNLCR. 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. The advisory role of the Committee is scientific and does not include deliberation of matters of public policy. No individual who is affiliated with the Contractor organization involved in management of the FNLCR will serve on this Committee.

As needed, and with the approval of the FNLAC Executive Secretary, the Committee may call upon special consultants, assemble *ad hoc* working groups, appoint subcommittees, and convene workshops and conferences to assist in the functioning of the FNLAC.

FNLAC Meetings

Meetings of the full FNLAC will be held approximately three (3) times within each fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary of Health and Human Services (Secretary) in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event that a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and within FACA regulations, a report will be prepared that will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be filed annually and will be provided to the Department Committee Management Officer (CMO)

Conflict of Interest and Ethics Rules for FNLAC Members

Regular members of the FNLAC are Special Government Employees (SGE). By definition, an SGE is an officer or employee in the Executive Branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. During the term of their appointments, SGEs must be aware of relevant statutes regarding criminal conflicts of interest, and you must follow defined Standards of Ethical Conduct for Employees of the Executive Branch.

The Office of Government Ethics (OGE) has issued the following conflict of interest guidelines for multi-campus institutions and private institutions and affiliates:

- **Policy for State Multi-Campus Institutions:** The OGE has provided a regulatory waiver under 5 CFR 2640.203(c) for SGE Federal advisory committee members employed in one university of a state multi-university system to review applications from a separate university of the same system, provided the member has no conflicting multi-institutional duties and responsibilities that affect the entire educational system.

- **Policy for Private Institutions and Affiliates:** In addition, an SGE member of an advisory committee who is employed by a private institution may participate in the review of a grant application submitted by an affiliate of the private institution if the SGE: does not hold a joint appointment with that affiliate, does not have affiliate-wide responsibilities, and has a waiver to do so.

At each FNLAC meeting, FNLAC members sign a statement certifying that they did not participate in the discussion of or vote on any application from their own institution or an institution in which they have a financial interest.

Detailed ethics rules that govern the conduct of SGEs are provided in **Appendix I.**

Additional information related to past and future FNLAC meetings, including meeting dates, agendas, minutes, and presentations, can be found at https://deainfo.nci.nih.gov/advisory/fac/fac.htm.

FNLAC Subcommittees and Working Groups

To expedite the FNLAC's work, *ad hoc* subcommittees and working groups, composed of FNLAC and non-FNLAC members, can be established to provide additional advice and oversight on specific topics or initiatives. Subcommittee meetings are open to the public and announced in the *Federal Register*. The current subcommittees are:

RAS Oversight Subcommittee

The **RAS Oversight** subcommittee provides oversight to FNLAC, the Associate Director,

FNLCR, and the Director, NCI, on the research and development of the **RAS Initiative**.

There is a high incidence of RAS mutations in cancer, but currently there are no drugs or therapies available that target mutant RAS directly or indirectly. Despite past failures, the NCI believes that new developments in structural biology, chemistry, signaling, systems biology, gene-based screening methods, immunology, and nanotechnology support the idea of a reactivated effort to make progress, especially in view of the substantial number of cancers that might be better controlled if the effects of mutant RAS could be countered. The RAS Oversight Subcommittee, which is composed of current FNLAC members and participants from academia and industry with appropriate expertise, will provide oversight of the RAS Initiative.

National Cryo-Electron Microscopy (EM) Facility Oversight Subcommittee

The **National Cryo-EM Facility (NCEF) Oversight** subcommittee provides oversight to the FNLAC, Associate Director, FNLCR, and the Director, NCI, on the operation of the NCEF, which is hosted by the FNLCR. The NCEF subcommittee will evaluate the goals, scientific priorities and scope, technical and operational aspects, and equipment and staffing needs of the NCEF in support of the cryo-EM community. The FNLCR facility houses the latest in cryo-EM technologies and is designed to support high-resolution structural analysis by cryo-EM. A major initial goal of the NCEF is to provide users who can demonstrate that they have specimens ready for high-quality data collection with rapid access to cryo-EM technology. The subcommittee will evaluate the progress of the NCEF and oversee potential expansions of staff and equipment based on demand. The findings of this subcommittee will be invaluable for assessing the effectiveness of the NCEF, and in gauging the need for cryo-EM facilities in the extramural community.

Three *ad hoc* Working Groups, a RAS, an NCEF, and an NCI–DOE Collaborations Working Group, also exist to provide in-depth analysis and recommendations to their respective subcommittees, the full FNLAC, and the Director, NCI.

***Ad Hoc* RAS Working Group**

The purpose of the *Ad Hoc* RAS Working Group is to provide the highest quality oversight to the technical aspects of the RAS Program and to provide findings and recommendations to the FNLAC and the *ad hoc* RAS Subcommittee.

The evaluations will include the scientific goals, direction, priorities, and timelines of the RAS research projects at the FNLCR hub. A major goal of the program is to mobilize the cancer research community to collaboratively undertake the mission of developing therapeutic strategies towards the KRAS oncogene. The evaluation will therefore, also include the means in which the RAS Program engages the extramural community and industry such as through collaboration, input on funding opportunities, and sharing ideas, data, and reagents. The findings of this Working Group will be invaluable for assessing the progress on this "national mission" as well as provide insight for the development of new national missions.

***Ad Hoc* National Cryo-EM Facility Oversight Working Group**

The purpose of the *Ad Hoc* National Cryo-EM Facility Oversight Working Group is to provide the highest quality oversight to the technical aspects of the NCEF and to provide findings and recommendations to the FNLAC and the *ad hoc* Cryo-EM Oversight Subcommittee.

The NCEF is designed to support high-resolution structural analysis by utilizing the latest in cryo-EM technologies. A major initial goal of the NCEF is to provide users who can demonstrate that they have specimens ready for high-quality data collection with rapid access to cryo-EM infrastructure. The Working Group will evaluate the goals, scientific priorities and scope, technical and operational aspects, and equipment and staffing needs of the NCEF in support of the cryo-EM community. The Working Group also will assess the progress of the NCEF and oversee potential expansions based on demand. The findings of this Working Group will be invaluable for assessing the effectiveness of the operations at the NCEF, and in gauging the future need for cryo-EM and related technologies and services that support the extramural community.

***Ad Hoc* NCI–DOE Collaborations Working Group**

The purpose of the *Ad Hoc* NCI/DOE Collaborations Working Group is to provide scientific evaluation of programs, projects, and collaborations formed in support of or relevant to NCI/Department of Energy (DOE) collaborations. The Working Group is charged with exploring the domains and activities in which collaborations between the NCI and DOE would be mutually beneficial and advance the missions of these entities. Activities will include technical evaluation of the Joint Design of Advanced Computing Solutions

for Cancer (JDACS4C) pilot projects, guidance on relevant partnerships with other entities, and expanding the benefits of the partnership to the broader scientific community. The Working Group will serve to optimize the functionality and output of the partnership and maximize impact on (1) the broader research community, (2) the benefits of high-performance computing (HPC) to systems biology and data science, and (3) the acceleration of predictive modeling for cancer.

The Working Group will advise the FNLAC and the Director, NCI. In accordance with the NCI–DOE memorandum of understanding (MOU), the Secretary, DOE, and DOE FACA committees may use the public products and public findings in furthering the DOE mission.

APPENDIX A

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Texas A&M University Health Science Center
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JoAnn Trejo, Ph.D. **2023**
Professor and Vice Chair of Pharmacology
Assistant Vice Chancellor for Health Sciences
Faculty Affairs
Department of Pharmacology School of Medicine
University of California, San Diego
La Jolla, CA

Marcel R. M. Van Den Brink, M.D., Ph.D. **2026**
Head and Alan N. Houghton Chair
Division of Hematologic Oncology
Memorial Sloan Kettering Cancer Center
Professor in Immunology and Medicine
Weill Cornell Medical College
New York, NY

Michelle D. Wang, Ph.D. **2024**
James Gilbert White Distinguished Professor
of Physical Sciences
Department of Physics
Cornell University
Ithaca, NY

David L. Wiest, Ph.D. **2021**
Professor
Immune Cell Development and
Host Defense Program
Blood Cell Development and Cancer Keystone
Fox Chase Cancer Center
Philadelphia, PA

John S. Witte, Ph.D. **2024**
Professor and Vice Chair of Epidemiology
and Population Health
Professor of Biomedical Data Science
and Genetics (by courtesy)
Department of Epidemiology
and Population Health
Stanford University
Stanford, CA

Designated Federal Official

Mehrdad M. Tondravi, Ph.D.
Chief
Institute Review Office
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

APPENDIX E

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC)

Chair

Neal J. Meropol, M.D. **2023**
Vice President of Research Oncology
Scientific and Clinical Lead, Clinical Research
Flatiron Health
New York, NY

Members

Smita Bhatia M.D., M.P.H. **2025**
Vice Chair of Outcomes for Pediatrics
Professor
Division of Hematology/Oncology
Department of Pediatrics
The University of Alabama at Birmingham
Birmingham, AL

Charles D. Blanke, M.D. **2024**
Chair, SWOG Cancer Research Network
Professor
Knight Cancer Institute
Oregon Health & Science University
Portland, OR

Edward Chu, M.D. **2025**
Director
Albert Einstein Cancer Center
Carol and Roger Einiger Professor of Cancer Medicine
Department of Medicine
Albert Einstein College of Medicine
Bronx, NY

Nancy E. Davidson, M.D. (BSC) **2022**
Senior Vice President, Director, and Full Member
Clinical Research Division
Fred Hutchinson Cancer Research Center
President and Executive Director
Seattle Cancer Care Alliance
Head, Department of Medicine
Division of Medical Oncology
University of Washington
Seattle, WA

Anjelica Q. Davis (NCRA) **2022**
President, Fight Colorectal Cancer
Springfield, MO

Adam P. Dicker, M.D., Ph.D. **2024**
Professor and Chair
Department of Radiation Oncology
Sidney Kimmel Cancer Center
Thomas Jefferson University
Philadelphia, PA

Gary C. Doolittle, M.D. **2026**
Capitol Federal Masonic Professor
Division of Medical Oncology
University of Kansas Medical Center
Westwood, KS

Ernest T. Hawk, M.D. **2024**
Vice President and Head
Division of Cancer Prevention and Population Sciences
T. Boone Pickens Distinguished Chair for Early Prevention of Cancer
The University of Texas MD Anderson Cancer Center
Houston, TX

Michael V. Knopp, M.D. **2023**
Professor of Radiology
Department of Radiology
Novartis Chair of Imaging Research
The Ohio State University
Columbus, OH

Seth P. Lerner, M.D., F.A.C.S. **2025**
Vice Chair for Faculty Affairs
Beth and Dave Swalm Chair in Urologic Oncology
Professor
Scott Department of Urology
Baylor College of Medicine
Houston, TX

Mia Levy, M.D., Ph.D. **2024**
Director
Rush University Cancer Center
System Vice President
Rush System for Health
Chicago, IL

Sumithra J. Mandrekar, Ph.D. **2024**
Professor of Biostatistics and Oncology
Group Statistician, Alliance for Clinical Trials in Oncology
Department of Quantitative Health Sciences
Mayo Clinic
Rochester, MN

Robert S. Mannel, M.D. **2026**
Director
Peggy and Charles Stephenson Cancer Center
College of Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, OK

Ruben A. Mesa, M.D. **2026**
Executive Director
Mays Cancer Center UT Health San Antonio
MD Anderson Cancer Center
San Antonio, TX

Carolyn Y. Muller, M.D., F.A.C.O.G. **2025**
Associate Director of Clinical Research
The Judy Putman Dirks Endowed Professor in Gynecologic Cancer Care
Department of Obstetrics and Gynecology
The University of New Mexico Health Sciences Center
Albuquerque, NM

Raphael E. Pollock, M.D., Ph.D., F.A.C.S. **2025**
Kathleen Wellenreiter Klotz Chair in Cancer Research
Director
The Ohio State University Comprehensive Cancer Center
Columbus, OH

Suresh S. Ramalingam, M.D., F.A.S.C.O. **2025**
Executive Director
Winship Cancer Institute
Roberto C. Goizueta Chair for Cancer Research
Emory University School of Medicine
Atlanta, GA

Victor M. Santana, M.D. **2023**
Associate Director for Clinical Research
Vice President, Clinical Trials Administration
St. Jude Children's Research Hospital
Memphis, TN

Patricia A. Spears **2026**
Scientific Research Manager
Patient Advocate
Lineberger Comprehensive Cancer Center
The University of North Carolina at Chapel Hill
Chapel Hill, NC

Julie M. Vose, M.D. **2023**
Neumann M. and Mildred E. Harris Professor
Chief, Division of Oncology/Hematology
Department of Internal Medicine
University of Nebraska Medical Center
Omaha, NE

George Wilding, M.D. **2026**
Retired
Professor Emeritus and Director Emeritus
University of Wisconsin–Madison
Albuquerque, NM

Ex Officio Members

William L. Dahut, M.D.
Scientific Director for Clinical Research
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, MD

James H. Doroshow, M.D.
Deputy Director
Clinical and Translational Research
Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, MD

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Michael J. Kelley, M.D., F.A.C.P.
National Program Director for Oncology
Veterans Health Administration
U.S. Department of Veterans Affairs
Durham, NC

Anthony Kerlavage, Ph.D.
Director
Center for Biomedical Informatics and Information Technology
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Richard Pazdur, M.D., F.A.C.P.
Director
Oncology Center of Excellence
U.S. Food and Drug Administration
Silver Spring, MD

Xiufen Sui, M.D, M.S.
Biostatistician
Center for Clinical Standards and Quality
Center for Medicare & Medicaid Innovation
Baltimore, MD

Designated Federal Official

Sheila A. Prindiville, M.D., M.P.H.
Director
Coordinating Center for Clinical Trials
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

APPENDIX F

FREDERICK NATIONAL LABORATORY ADVISORY COMMITTEE

Chair

Candace S. Johnson, Ph.D. **2023**
President and CEO
Director, Wallace Family Chair in Translational Research
Chair, Department of Pharmacology and Therapeutics
Roswell Park Cancer Institute
Buffalo, NY

Members

Andrea H. Bild, Ph.D. **2025**
Professor
Division of Molecular Pharmacology
Department of Medical Oncology and Therapeutics
City of Hope Comprehensive Cancer Center
Duarte, CA

Catherine M. Bollard, M.D. **2022**
Director, Center for Cancer and Immunology
Director, Program for Cell Enhancement and Technologies for Immunotherapy
Children's Research Institute
Children's National Health System
Washington, DC

John H. Bushweller, Ph.D. **2025**
Professor
Department of Molecular Physiology and Biological Physics
Department of Chemistry
School of Medicine
University of Virginia
Charlottesville, VA

Timothy A. Chan, M.D., Ph.D. **2023**
Director, Center for Immunotherapy and Precision Immuno-Oncology
Co-Director, National Center for Regenerative Medicine
Cleveland Clinic
Cleveland, OH

Lisa M. Coussens, Ph.D. **2022**
Hildegard Lamfrom Chair in Basic Science
Professor and Chair, Cell, Developmental and Cancer Biology
Associate Director for Basic Research
Knight Cancer Institute
Oregon Health & Science University
Portland, OR

Scott W. Hiebert, Ph.D. (NCAB[2]) **2022**
Hortense B. Ingram Chair in Cancer Research
Professor of Biochemistry
Department of Biochemistry
Vanderbilt University School of Medicine
Nashville, TN

Allison Hubel, Ph.D. **2025**
Professor
Department of Mechanical Engineering
University of Minnesota
Minneapolis, MN

Dineo Khabele, M.D. **2025**
Professor and Chair
Department of Obstetrics and Gynecology
Washington University School of Medicine in St. Louis
St. Louis, MO

Denise J. Montell, Ph.D. (BSC[3]) **2023**
Robert and Patricia Duggan Professor
Department of Molecular, Cellular, and Developmental Biology
University of California, Santa Barbara
Santa Barbara, CA

Patrick Nana-Sinkam, Ph.D. **2022**
Professor of Medicine
Chair, Division of Pulmonary Disease and Critical Care Medicine
Virginia Commonwealth University
Richmond, VA

Nilsa C. Ramirez Milan, M.D., F.C.A.P. **2022**
Medical Director, Biopathology Center
Director, Autopsy Pathology
Department of Pathology and Laboratory Medicine
Nationwide Children's Hospital
Professor of Clinical Pathology
The Ohio State University College of Medicine
Columbus, OH

Erle S. Robertson, Ph.D. (BSA[1]*) **2026**
Harry P. Schenk Endowed Chair Professor
Vice Chair
Department of Otorhinolaryngology
University of Pennsylvania School of Medicine
Philadelphia, PA

Lincoln D. Stein, M.D., Ph.D. **2022**
Director, Informatics and Biological Computing Platform, Ontario Institute for Cancer Research
Professor, Department of Molecular Genetics
University of Toronto
Toronto, Ontario, Canada

Linda F. van Dyk, Ph.D. **2025**
Professor and Vice Chair
Department of Immunology and Microbiology
University of Colorado Anschutz Medical Campus
Aurora, CO

Executive Secretary

Wlodek Lopaczynksi, M.D., Ph.D.
Assistant Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Representatives

[1]BSA Board of Scientific Advisors
[2]NCAB National Cancer Advisory Board
[3]BSC Board of Scientific Counselors

Ex Officio Members

Stephen J. Chanock, M.D.
Director
Division of Cancer Epidemiology and Genetics
National Cancer Institute
National Institutes of Health
Bethesda, MD

James H. Doroshow, M.D.
Deputy Director for Clinical and Translational Research
Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, MD

Paulette S. Gray, Ph.D.
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, MD

Anthony Kerlavage, Ph.D.
Director, Center for Biomedical Informatics and Information Technology
National Cancer Institute
National Institutes of Health
Bethesda, MD

Kristin L. Komschilies, Ph.D.
Deputy Director
Office of Scientific Operations
NCI at Frederick
National Cancer Institute
National Institutes of Health
Bethesda, MD

Douglas R. Lowy, M.D.
Acting Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Tom Misteli, Ph.D.
Director
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, MD

Donna Siegle
Deputy Director of Management and Executive Officer
National Cancer Institute
National Institutes of Health
Bethesda, MD

Dinah S. Singer, Ph.D.
Deputy Director for Scientific Strategy and Development
National Cancer Institute
National Institutes of Health
Bethesda, MD

* Pending.

APPENDIX G

NCI COUNCIL OF RESEARCH ADVOCATES

Chair

Angelica Q. Davis **2022**
President
Fight Colorectal Cancer
Springfield, MO

Members

Melinda Bachini **2024**
Advocacy Coordinator
Cholangiocarcinoma Foundation
Herriman, MO

Yelak S. Biru **2023**
Patient Advocate
International Myeloma Foundation
North Hollywood, CA

Victoria Buenger, Ph.D. **2025**
Clinical Professor
Department of Management
Mays School of Business
Texas A&M University
College Station, TX

Melissa F. Buffalo **2025**
Chief Executive Officer
American Indian Cancer Foundation
Minneapolis, MN

Annie Ellis **2024**
Research Advocate
Gynecologic Cancer Steering Committee
Ovarian Cancer Research Alliance
New York, NY

Jennifer W. Pegher **2022**
Executive Director
Association of American Cancer Institutes
Pittsburgh, PA

Kristen C. Santiago **2023**
Senior Director
Public Policy Initiatives
LUNGevity
Bethesda, MD

Jacqueline D. Smith **2024**
Associate Director
U.S. Oncology Advocacy and Policy
Bristol Myers Squibb Company
Lawrenceville, NJ

Kevin J. Stemberger **2024**
Research Advocate
Co-Founder and Partner
Noble Capital Partners, LLC
Farmington Hills, MI

Nicole E. Willmarth, Ph.D. **2023**
Chief Mission Officer
American Brain Tumor Association
Chicago, IL

Executive Secretary

Amy Williams
Acting Director
Office of Advocacy Relations
National Cancer Institute, NIH
Bethesda, MD

APPENDIX H

NCI SCIENTIFIC PROGRAM LEADERSHIP COMMITTEE

Members

Dr. Douglas R. Lowy
Acting Director

Dr. James Doroshow
Deputy Director for Clinical and Translational Research
Director, Division of Cancer Treatment and Diagnosis

Dr. Dinah Singer
Deputy Director for Scientific Strategy and Development

Ms. Donna Siegle
Executive Officer and
Deputy Director for Office of Management

Dr. Brigitte C. Widemann
Special Advisor to the Director for Childhood Cancer

Ms. Anne Lubenow
Chief of Staff

Dr. Oliver Bogler
Director
Center for Cancer Training

Dr. Philip E. Castle
Director
Division of Cancer Prevention

Dr. Stephen Chanock
Director
Division of Cancer Epidemiology and Genetics

Dr. Henry Ciolino
Director
Office of Cancer Centers

Dr. William Dahut
Scientific Director of Clinical Research and Clinical Director, Center for Cancer Research

Dr. Daniel Gallahan
Director
Division of Cancer Biology

Mr. Peter Garrett
Director
Office of Communications and Public Liaison

Dr. Katrina Goddard
Director
Division of Cancer Control and Population Sciences

Dr. Satish Gopal
Director
Center for Global Health

Dr. Paulette S. Gray
Director
Division of Extramural Activities

Dr. Toby Hecht
Deputy Director, Division of Cancer Treatment and Diagnosis

Dr. Tony Kerlavage
Director, Center for Biomedical Informatics and Information Technology

Mr. Patrick McCarey
Associate Director
Finance and Legislation

Dr. Glenn Merlino
Scientific Director for Basic Research
Center for Cancer Research

Dr. Tom Misteli
Director
Center for Cancer Research

Dr. Sheila Prindiville
Director
Coordinating Center for Clinical Trials

Dr. Henry Rodriguez
Director
Office of Cancer Clinical Proteomics Research

Mr. Jeffrey Shilling
Chief Information Officer

Dr. Sanya Springfield
Director
Center to Reduce Cancer Health Disparities

Dr. Thomas Stackhouse
Director
Technology Transfer Center

Dr. Louis M. Staudt
Director
Center for Cancer Genomics

Mr. Michael Weingarten
Director
Small Business Innovative Research and
Small Business Technology Transfer Programs

Dr. Robert Yarchoan
Director
Office of HIV and AIDS Malignancy

Dr. Maureen Johnson
Executive Secretary

APPENDIX I

SUMMARY OF ETHICS RULES FOR SPECIAL GOVERNMENT EMPLOYEES SERVING ON ADVISORY COMMITTEES

Introduction

As a Special Government Employee (SGE), you *are* a Federal Government employee. As such, you are covered by the Executive Branch ethics rules, although in a somewhat less restrictive manner than regular Government employees.

The Criminal Conflict of Interest Statutes 18 U.S.C. §§ 203, 205, 207, 208

Financial Conflicts: You are prohibited from participating personally and substantially in **any particular matter** that directly and predictably affects your own financial interests or the financial interests of certain other persons or organizations: your spouse, minor child, general partner, and outside organizations with which you serve as an officer, director, trustee, or employee, or with which you are negotiating for or have an arrangement for future employment. If your duties would require you to participate in any particular matter that affects your financial interests, you have a conflict of interest which you will have to resolve. Of most concern are reviews of grant proposals or contract applications, or similar funding decisions; recommendations or approvals of scientific studies, projects, clinical trials, and new drug applications; and other actions that involve deliberation, decision, or action affecting the legal rights of identified parties. You also might be prohibited from involvement in **Particular Matters of General Applicability**. For example, recommendations of regulations, policies, or standards that affect an industry, group of manufacturers, or health care providers.

Divestiture: Sell or otherwise dispose of the financial interest that is creating the conflict.

Waiver: Get written approval from a senior official to continue with your work for the committee despite the conflict. Waivers can be granted where there is a pressing need for a particular individual's services on the committee and this outweighs the potential for conflict of interest. Specific criteria must be met. This is considered a "general waiver" in that **it only allows participation in matters that affect all institutions, or types of institutions, similarly.**

Concurrent Representation: While you are serving, there are **representational restrictions** on contacting the Government on behalf of another—for example, as an agent or attorney—with intent to influence on a specific party matter that you are working on as an SGE.

Post-Employment Representation: You cannot "switch sides" in the private sector and represent back to the Government concerning the same specific party matter—the same contract or grant, for example, that you worked on as an SGE. (Remember also the restrictions resulting from employment negotiations that are covered by the financial conflict statute.)

Standards of Ethical Conduct 5 CFR Part 2635

You are prohibited from receiving compensation for **teaching, speaking, or writing** about your Government duties or about any topic if the invitation to teach, speak, or write comes from a person substantially affected by the matters on which you work as an SGE. However, you may teach courses about general topics requiring multiple presentations.

You may not accept **gifts** offered as a result of your advisory committee membership. In many circumstances, you may not participate as an **expert witness** on any matter or proceeding that you work on as an SGE.

Impartiality: You are prohibited from participating in a specific party matter where a reasonable person would question your impartiality—for example, conducting a review of a grant application submitted by your mentor or someone with whom you have a close relationship—unless authorized by an agency designee to participate.

Misuse of Position—Use of Public Office for Private Gain: This includes the misuse of nonpublic information, government property, and official time. You may not use your position to imply that

the Committee endorses your private activities or refer to your Government position for your own private gain.

Employment by, or Gifts From, Foreign Governments: Committee members may be employed by a foreign government, which includes positions with foreign universities that are government operated. There are also statutory provisions restricting acceptance of gifts, including awards, educational scholarships, and travel expenses occurring outside the Unites States, but not on travel or honoraria for a speaking engagement or employment for consulting.

Lobbying: In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. You may appear for the purpose of informing or educating the public about a particular policy and you may communicate with members of Congress at their request.

Political Activities (Hatch Act): *While on Government duty* (unlike the other rules which always apply during your time of appointment), you may not engage in partisan political activities, run for political office in a partisan election, or solicit contributions from the public. For more information on political activity restrictions, please see the Office of Special Counsel website at https://osc.gov.

Ethics for SGEs: Your Responsibilities as a Government Employee

- Complete the OGE-450 Financial Disclosure Report and submit it for review. You should not attend meetings or participate in committee business until this form is submitted and reviewed.
- Complete the HHS-697 Foreign Activities Questionnaire and submit it for review.
- If conflicts of interest are identified, work with committee managers and ethics officials to resolve them.
- Complete a financial disclosure form 30 days prior to each Board meeting.
- Complete initial ethics orientation and yearly ethics training—you should have a basic knowledge of the Standards of Ethical Conduct and the Conflict of Interest (COI) Statutes.
- Monitor changes in your circumstances that might create new conflicts.
- Be sure to contact your Designated Federal Official (DFO) or ethics officials with any questions.

Excerpted from: *Overview of the Ethics Rules for Special Government Employees Serving on an Advisory Committee,* U.S. Office of Government Ethics, NIH.

Financial Conflicts of Interest Office of Government Ethics – OGE 450 Form

Office of Government Ethics (OGE) 450 Form: https://ethics.od.nih.gov/forms450

Financial Interests to be reported on the OGE 450 Form include:

- Stocks, stock options, bonds
- Sector funds (Waiver available for biotech/health care sector funds up to aggregate value of $50,000)
- Earned income, including salaries, fees, and/or honoraria
- Limited partnerships and venture capital corporations
- Non-Federal research/training support
- Invention rights and royalties
- Real estate, trades and businesses, and partnership interests
- Speaking engagements and consultant work

SGEs report assets with a fair market value greater than $1,000 at the close of the reporting period, which produced income over $200.

Conflict of Interest and Ethics Websites

U.S. Office of Government Ethics

- Online training on Completing the OGE Form 450: https://www.oge.gov/Web/oge.nsf/Resources/How+to+file+an+OGE+Confidential+Financial+Disclosure+Form+(OGE+form+450)

A Guide on the Ethics Rules That Apply to Advisory Committee Members Serving as Special Government Employees: https://nps.edu/documents/118317542/118318098/sge_rvw_guide.pdf

Overview of the Ethics Rules for Special Government Employees Serving on Advisory Committees: https://ofacp.od.nih.gov/ethics/index.asp

Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGEs): https://ethics.od.nih. gov/sge-resources

NIH Administrative Fact Sheet for Special Government Employees: https://ofacp.od.nih.gov

Foreign Activities:

- U.S. Constitution Emoluments Clause: https://ofacp.od.nih.gov/ethics/pdfs/EmolClause.pdf
- Foreign Activities Questionnaire: https://intranet.hhs.gov/forms/hhs_forms/hhs-697.pdf

Conflict of Interest and the Special Government Employee: https://ethics.od.nih.gov/conflicts

NIH Ethics Program: https://ethics.od.nih.gov/default.htm

Bioethics Resources on the Web: https://bioethics.nih.gov/publications/index.shtml

APPENDIX J

RELATED DOCUMENTS

Cancer.gov Website
https://www.cancer.gov

NCI Budget Fact Book
https://www.cancer.gov/about-nci/budget/fact-book

Bypass Budgets
https://plan.cancer.gov

Cancer Centers
https://cancercenters.cancer.gov

Clinical Trials
https://www.cancer.gov/clinicaltrials

NCAB Orientation Book
https://deainfo.nci.nih.gov/advisory/ncab/OrientationBook.pdf

BSA Orientation Book
https://deainfo.nci.nih.gov/advisory/bsa/OrientationBook/OrientationBook.pdf

CTAC Member's Manual
https://deainfo.nci.nih.gov/advisory/ctac/OrientationBook.pdf

NCI Division of Extramural Activities
https://deainfo.nci.nih.gov

DEA Annual Report
https://deainfo.nci.nih.gov

NCI Office of Grants Administration
https://www.cancer.gov/about-nci/organization/oga

Grants and Contracts
https://www.cancer.gov/grants-training/grants-funding/funding-opportunities

Grant Mechanisms and Descriptions
https://deainfo.nci.nih.gov/flash/awards.htm

Center for Cancer Training
https://www.cancer.gov/grants-training/training/about

Center for Scientific Review (CSR) Reviewer Resources
https://public.csr.nih.gov/ReviewerResources/Pages/default.aspx

Surveillance
https://seer.cancer.gov

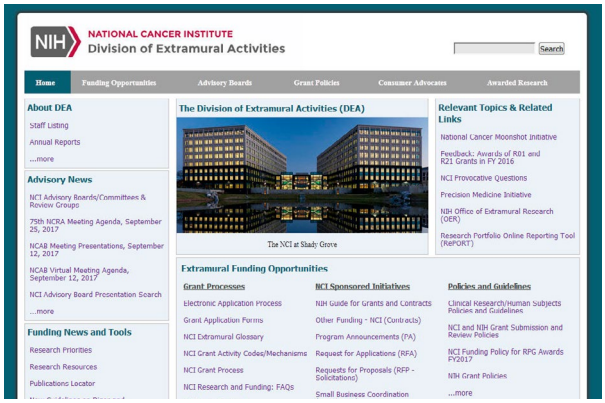
NIH Grant Review Process YouTube Videos
https://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx

APPENDIX K

WEBSITES OF INTEREST

DEA Websites

DEA home page. Includes links to individual DEA Web Pages, the mission of the Division, and contact information for DEA staff.
https://deainfo.nci.nih.gov



Links to the home pages of NCI's advisory boards.
https://deainfo.nci.nih.gov/advisory/boards.htm

President's Cancer Panel (PCP) charter; meeting agendas and meeting minutes; annual reports.
https://deainfo.nci.nih.gov/advisory/pcp/index.htm

National Cancer Advisory Board charter; rosters; meeting agendas, minutes, presentation slides.
https://deainfo.nci.nih.gov/advisory/ncab/ncab.htm

Board of Scientific Advisors (BSA) charter; subcommittee rosters; meeting agendas, minutes, presentation slides.
https://deainfo.nci.nih.gov/advisory/bsa/bsa.htm

Board of Scientific Counselors (BSC) charter, rosters, meeting dates.
https://deainfo.nci.nih.gov/advisory/bsc/index.htm

Clinical Trials and Translational Research Advisory Committee.
https://deainfo.nci.nih.gov/advisory/ctac/ctac.htm

Charter of the Initial Review Group (IRG); subcommittee rosters.
https://deainfo.nci.nih.gov/advisory/irg/irg.htm

Charter of the Special Emphasis Panel (SEP); rosters of recent meetings.
https://deainfo.nci.nih.gov/advisory/sep/sep.htm

Frederick National Laboratory Advisory Committee (FNLAC) charter, members, meeting information.
https://deainfo.nci.nih.gov/advisory/fac/fac.htm

Charter of the NCI Council of Research Advocates; meeting schedules, agendas, minutes, and meeting summaries.
https://deainfo.nci.nih.gov/advisory/ncra/ncra.htm

Links to grant-related NCI and NIH policies, such as guidelines on the inclusion of women and minorities in clinical trials and instructions for evaluating research involving human subjects.
https://deainfo.nci.nih.gov/grantspolicies/index.htm

Comprehensive information about funding for cancer research; lists of active PAs and RFAs; grant policies and guidelines; downloadable application forms.
https://deainfo.nci.nih.gov/funding.htm

Active PAs, with links to detailed descriptions.
https://deais.nci.nih.gov/foastatus/?nt=P

Active RFAs, with links to detailed descriptions.
https://deais.nci.nih.gov/foastatus/?

Grants Guidelines and Descriptions (descriptions of NCI funding mechanisms, with links to Program Announcements (PAs), RFAs, guidelines, and supplemental materials).
https://deainfo.nci.nih.gov/flash/awards.htm

NCI Glossary of Terms.
https://deais.nci.nih.gov/glossary

NCI Dictionary of Cancer Terms.
https://www.cancer.gov/publications/dictionaries/cancer-terms

NCI Websites

The NCI maintains numerous sites containing information about the Institute and its programs. All NCI websites, including those designed to provide cancer-related information to the general public and physicians, can be reached from the NCI home page.
https://www.cancer.gov

Descriptions of NCI's Divisions, Offices, and Centers.
https://www.cancer.gov/aboutnci/organization

NCI's website for the press, managed by the NCI Office of Media Relations; contains news and information on cancer research and NCI programs and resources.
https://www.cancer.gov/newscenter

A wide variety of information sources on obtaining funding for cancer research, including assistance in applying for grants; descriptions of NCI-sponsored research initiatives; review panel rosters and schedules; training opportunities; and links to other funding resources.
https://deainfo.nci.nih.gov/funding.htm

The essentials of the NCI grants process are available on this website.
https://www.cancer.gov/grants-training/grants-process

The Biorepositories and Biospecimens Research Branch is responsible for promoting a common biorepository infrastructure that promotes resource sharing and team science.
https://biospecimens.cancer.gov/researchnetwork/default.asp

Links to NCI's partnerships with the cancer research, advocacy, and support communities.
https://www.cancer.gov/researchprograms/partners

Technology Transfer Center (TTC). The NCI TTC's mission is to speed the progress of cancer research by encouraging development of new technologies and promoting scientific collaborations between the NCI and the private sector.
https://techtransfer.cancer.gov

The NCI Office of Advocacy Relations (OAR) uses a variety of methods to engage cancer research advocates in NCI activities.
https://www.cancer.gov/about-nci/organization/oar

The Cancer Moonshot Initiative aims to make more therapies available to more patients, while also improving our ability to prevent cancer and detect it at an early stage.
https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative

NCI Cancer Information Websites

Links to a wide variety of NCI's Web-based information resources for health professionals and the general public.
https://www.cancer.gov/cancerinfo

A comprehensive resource for definitions of cancer-related terms, as well as links to additional online dictionaries of medical and health-related terms.
https://cancer.gov/dictionary

The NCI Contact Center, or Cancer Information Service (CIS), is a free public service providing accurate, up-to-date, and reliable information on cancer that is easy to understand. The Cancer Information Specialists respond to calls in English and Spanish and can be reached at 1-800-4-CANCER (1-800-422-6237). Hearing-impaired callers with TTY equipment may call 1-800-332-8615.
https://www.cancer.gov/contact/contact-center

The Cancer Trials website provides information and news about cancer research studies. The site is designed to answer basic questions about clinical trials; provide resources for people considering participating in clinical trials; help people learn what clinical trials are available; and publish current, accurate information about clinical trial results and advances in cancer care.
https://www.cancer.gov/clinicaltrials

The NCI Surveillance, Epidemiology, and End Results (SEER) Program is the most authoritative source of information on cancer incidence and survival in the United States. Information on more than 2.5 million cancer cases is included in the SEER database, and approximately 160,000 new cases are added each year within the SEER catchment areas.
https://seer.cancer.gov

NIH Websites

National Institutes of Health home page.
https://www.nih.gov

National Institutes of Health Almanac.
https://www.nih.gov/about-nih/what-we-do/nih-almanac

NIH Research Portfolio Online Reporting Tool (RePORT). NIH RePORT provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research.
https://report.nih.gov

Office of Federal Advisory Committee Policy (OFACP). This site features downloadable guidelines, reference tools, and training materials. It also contains advisory committee membership lists; laws, regulations, and policies related to Federal advisory committees; and other resources.
https://ofacp.od.nih.gov

NIH Office of Extramural Research. Includes an overview of the grants process.
https://grants.nih.gov/grants/oer.htm

NIH Guide for Grants and Contracts for NIH grants and funding opportunities.
https://grants.nih.gov/grants/guide/index.html

NIH Center for Scientific Review.
https://www.csr.nih.gov

Definitions of NIH Acronyms and Glossary.
https://grants.nih.gov/grants/glossary.htm

eRA Commons is an online interface where grant applicants and Federal staff at the NIH and grantee institutions can access and share administrative information relating to research grants.
https://commons.era.nih.gov/commons

The Center for Information Technology (CIT) makes special NIH events, seminars, and lectures available to viewers on the NIH network and the Internet from the NIH VideoCasting and Podcasting website.
https://videocast.nih.gov

Information on Electronic Review of Grant Applications.
https://era.nih.gov/reviewer/index.cfm

Information on grants policy statements and notices, grant awards and NIH appropriations, policy resources, and other guidance resources.
https://grants1.nih.gov/grants/policy/policy.htm

Information on Extramural Training Mechanisms.
https://grants.nih.gov/training/extramural.htm

The NIH Event Calendar is a scheduling system for cancer-related scientific meetings and events.
https://calendar.nih.gov

The NIH Precision Medicine Initiative (PMI) Cohort Program will seek to extend precision medicine to all diseases by building a national research cohort of 1 million or more U.S. participants.
https://www.nih.gov/precision-medicine-initiative-cohort-program

PubMed comprises more than 26 million citations from Medline, life science journals, and online books.
https://pubmed.ncbi.nlm.nih.gov

General Government-Related Websites

The official U.S. Government portal to 30 million pages of Government information, services, and online transactions. FirstGov offers a powerful search engine that searches every word of every U.S. Government document. The site also features a topical index, options to contact Government agencies, links to state and local agencies, and other tools, so the user does not have to know the name of the agency to get needed information.
https://www.usa.gov

Centers for Disease Control and Prevention.
https://www.cdc.gov

U.S. Food and Drug Administration.
https://www.fda.gov

APPENDIX L

LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
B&F	Building and Facilities
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
CBIIT	Center for Biomedical Informatics and Information Technology
CCCT	Coordinating Center for Clinical Trials
CCR	Center for Cancer Research
CCSG	Cancer Center Support Grant
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CIS	Cancer Information Service
CIT	Center for Information Technology
CMO	Committee Management Office
CMS	Centers of Medicare and Medicaid Services
COG	Children's Oncology Group
COI	Conflict of Interest
CSR	Center for Scientific Review
CTAC	Clinical Trials and Translational Research Advisory Committee
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences
DCEG	Division of Cancer Epidemiology and Genetics
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DFO	Designated Federal Official
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
eRA	Electronic Research Administration
FAR	Federal Acquisition Regulations
FDA	U.S. Food and Drug Administration
FIC	Fogarty International Center
FOIA	Freedom of Information Act
GMP	Good Manufacturing Practice
HHS	U.S. Department of Health and Human Services
IAR	Internet Assisted Review
IHS	Indian Health Service
IRG	Initial Review Group
IRP	Intramural Research Program
NASA	National Aeronautics and Space Administration
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute
NCRA	NCI Council of Research Advocates
NCTN	NCI Clinical Trials Network
NExT	NCI Experimental Therapeutics
NHGRI	National Human Genome Research Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NLM	National Library of Medicine

NSF	National Science Foundation
OAR	Office of Advocacy Relations
OD	Office of the Director
OFACP	Office of Federal Advisory Committee Policy
OGA	Office of Grants Administration
OHAM	Office of HIV and AIDS Malignancy
P30	Cancer Center Support Grant
P50	Specialized Center Grant
PA	Program Announcement
PCP	President's Cancer Panel
PI	Principal Investigator
PMI	Precision Medicine Initiative
RePORT	Research Portfolio Online Reporting Tool
RFA	Request for Application
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIR	Small Business Innovative Research Program
SEER	Surveillance, Epidemiology, and End Results Program
SEP	Special Emphasis Panel
SIC	Special Interest Category
SPL	Scientific Program Leaders
SPORE	Specialized Program of Research Excellence
STTR	Small Business Technology Transfer
TARGET	Therapeutically Applicable Research to Generate Effective Treatment
TCGA	The Cancer Genome Atlas
TTC	Technology Transfer Center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