National Cancer Institute

Orientation for the National Cancer Advisory Board

NCAB

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

Orientation

for the National Cancer Advisory Board

NCAB

U.S. Department of Health and Human Services
Public Health Service
National Institutes of Health
National Cancer Institute
Division of Extramural Activities

WELCOME

Please accept my warmest congratulations on your recent appointment by President Bush to the National Cancer Advisory Board (NCAB). Notably, the NCAB and the President's Cancer Panel are the only advisory bodies at either the National Institutes of Health or the Department of Health and Human Services whose members are appointed by the President. As you join this distinguished and historic panel, we could not be more honored to have you working with the National Cancer Institute (NCI).

The primary task of the NCAB is to advise the Secretary of Health and Human Services, the Director of the NCI, and ultimately the President of the United States on a range of issues affecting the Nation's cancer program and, specifically, NCI operations. As a result of the National Cancer Act of 1971, the NCAB is required to conduct second-level peer review of grant applications and cooperative agreements referred to the NCI for funding. The details of your responsibilities in providing second-level review will be explained during briefings before your inaugural meeting.

On a personal level, I rely greatly on the NCAB for the expansive knowledge and wise counsel of its members. As we move to a more personalized era of oncology, which will require multiple agents to target multiple pathways in the same patient, the NCI will lead a vital effort to facilitate essential collaborations of the public sector, private industry, and academic centers, to bring these approaches from the bench to the bedside. The NCAB will be front and center in this vital work, from basic research to drug development, to the challenge of making sure our latest scientific accomplishments are available to all patients in the communities where they live. In all that we do, the NCI is committed, first and foremost, to cancer patients and those who care for them. Thank you for agreeing to join us in such an important mission.

We are pleased to provide you with this NCAB Orientation Guidelines. I hope you will find it a comprehensive overview of the NCI and your responsibilities as a member of the NCAB. I welcome you to your new position as a Board member and look forward to a mutually beneficial and productive relationship.

John E. Niederhuber, M.D.
Director
National Cancer Institute

FOREWORD

This briefing document has been prepared to provide new members of the National Cancer Advisory Board (NCAB) with an overview of the mission, history, and activities of the National Institutes of Health (NIH) and the National Cancer Institute (NCI).

The first section attempts to present the NCI in the context of the total NIH organization. It includes budgetary information, cites current legislative statutes, and describes organizational structure, program disciplines, and mechanisms of funding used by the NCI. It also delineates the roles of those committees that advise the NCI in the conduct of its activities.

The second section describes the process used in the review of grant and cooperative agreement applications and contract proposals. It outlines the initial review procedures followed by the Center for Scientific Review (CSR) and the initial review groups of the NCI. Attention also is given to the initiation of special actions by NCI staff and the part played by the NCAB.

We propose to revise this document biennially as each new group of members takes its place on the Board. The Institute would appreciate your suggestions regarding the inclusion of additional material or changes in subsequent revisions that would enhance the value or usefulness of this document.

Paulette S. Gray, Ph.D.
Executive Secretary
National Cancer Advisory Board
National Cancer Institute

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DHHS MISSION AND ORGANIZATION

The mission of the Department of Health and Human Services (DHHS) 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 DHHS consists of the Office of the Secretary, which provides leadership; the Program Support Center, which provides centralized administrative support; and 11 operating divisions, which manage more than 300 health-related programs. These operating divisions are:

Administration for Children and Families (ACF)

Administration on Aging (AoA)

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) [formerly the Health Care Financing Administration (HCFA)]

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 is responsible for temporary assistance to needy families; children's welfare, care and support; disabilities programs; and other services. The AoA serves the elderly. The CMS manages health insurance programs, while the PSC provides products and services to the DHHS and other Federal agencies. The NIH, AHRQ, ATSDR, CDC, FDA, HRSA, IHS, and SAMHSA are all devoted to public health and compose the Public Health Service (PHS) (see Exhibit I).

THE NATIONAL INSTITUTES OF HEALTH

Mission, Organization, and History

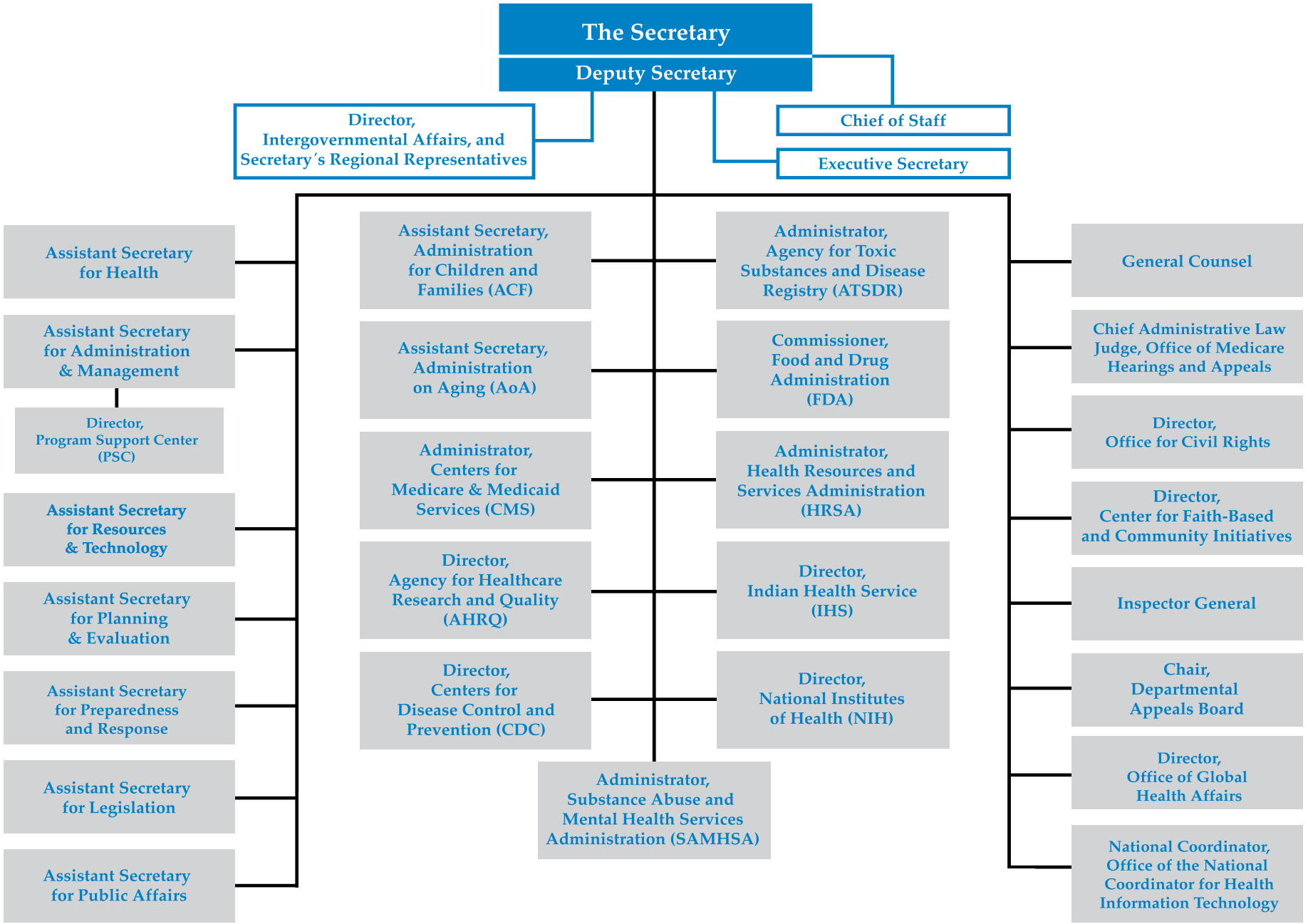
NIH's mission is to uncover new knowledge that will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping to train research investigators; and fostering communication of medical information. NIH's budget has grown from $300 in 1887, when the NIH was a one-room Laboratory of Hygiene, to more than $29.4 billion in 2008 (see Exhibit II). The NIH is composed of the Office of the Director, 19 Institutes, 7 Centers (four of which have funding authority), and the National Library of Medicine; it has 75 buildings located on more than 300 acres in Bethesda, Maryland. An organizational chart for the NIH is presented in Exhibit III. Exhibit IV is a guide to the Bethesda campus.

Overview of NIH History

NIH is a component of the Public Health Service (PHS) of DHHS. 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 National Institutes of Health 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 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

Exhibit I. Department of Health and Human Services



established, and the National Institute of Health became the National Institutes of Health (NIH). During the years 1949-2001, NIH expanded to include 27 Institutes and Centers. The current NIH Institutes, in order of their establishment, are:

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 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 in cholera and other infectious diseases.

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

1902 The Advisory Board for Hygienic Laboratory was established; later became the National Advisory Health Council. Act of Congress changed name of 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 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 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 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 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

Exhibit II. NIH FY2006-2008 Funding*

INSTITUTE/ CENTER	FUNDING (Dollars in Thousands)		
	2006	2007	2008
NCI	4,793,356	4,797,639	4,805,088
NHLBI	2,921,757	2,922,929	2,922,908
NIDCR	389,336	389,703	389,703
NIDDK	1,854,925	1,855,868	1,855,868
NINDS	1,534,757	1,535,545	1,543,901
NIAID	4,315,801	4,268,708	4,560,655
NIGMS	1,935,618	1,935,808	1,935,808
NICHD	1,264,769	1,254,707	1,254,708
NEI	666,756	667,116	667,116
NIEHS	720,240	721,119	719,799
NIA	1,046,631	1,047,260	1,047,260
NIAMS	507,932	508,240	508,586
NIDCD	393,458	393,668	394,138
NIMH	1,403,515	1,404,494	1,404,493
NIDA	1,000,029	1,000,621	1,000,700
NIAAA	435,930	436,259	436,259
NINR	137,342	137,404	137,476
NHGRI	486,049	486,491	486,779
NIBIB	296,810	296,887	298,645
NCRR	1,099,101	1,133,240	1,149,446
NCCAM	121,465	121,576	121,577
NCMHD	195,405	199,444	199,569
FIC	66,378	66,446	66,558
NLM	314,910	320,850	320,962
OD	478,066	1,046,901	1,109,099
B&F	81,081	81,081	118,966
TOTAL	28,461,417	29,030,004	29,456,087

*Source: *NIH Almanac*, 2008.

National Institute of Neurological Diseases and Blindness, as well as the National Institute of Arthritis and Metabolic Diseases. 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. The Laboratory of Biologics Control was renamed the Division of Biologics Standards. The Division of Research Services 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

Exhibit III. National Institutes of Health

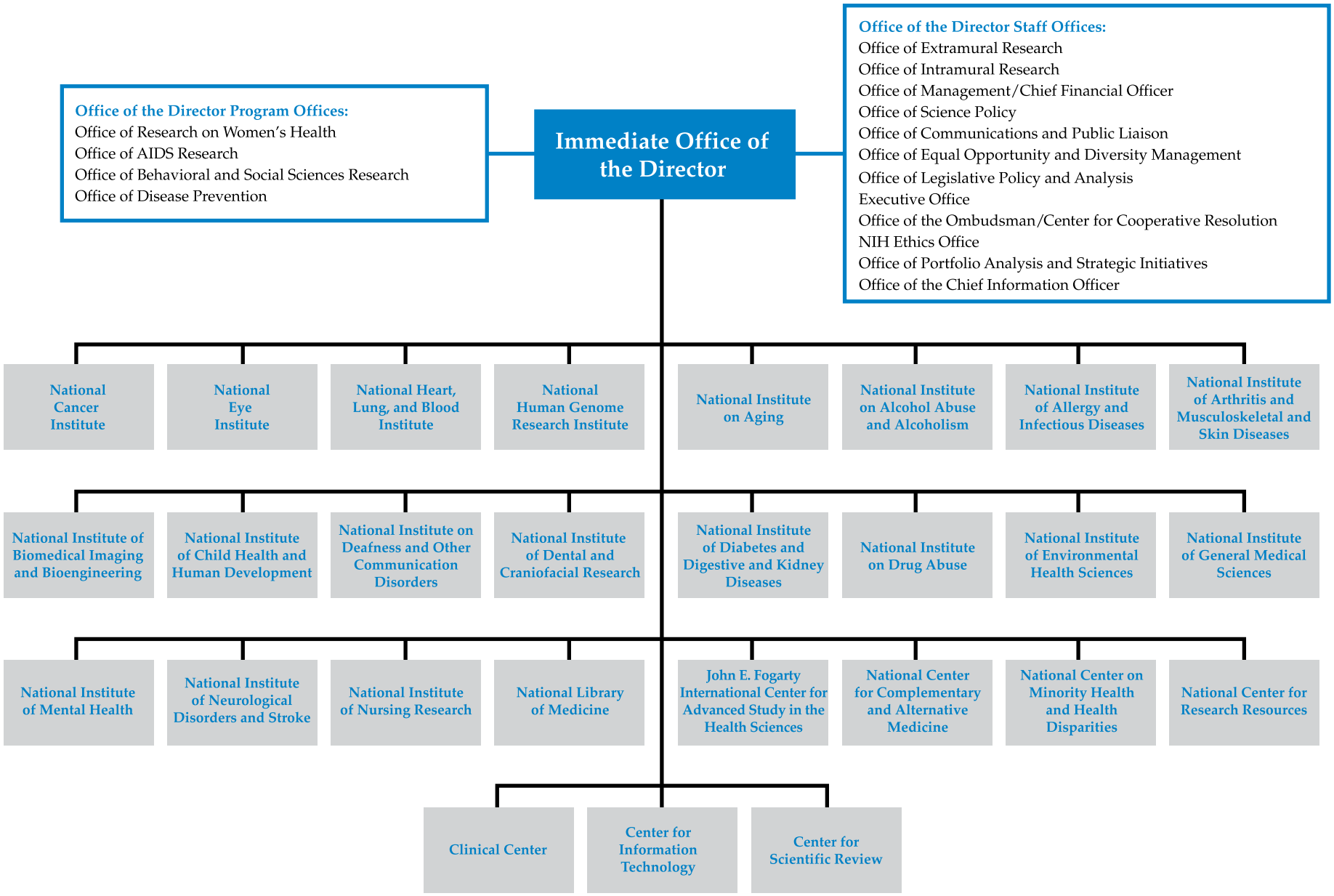
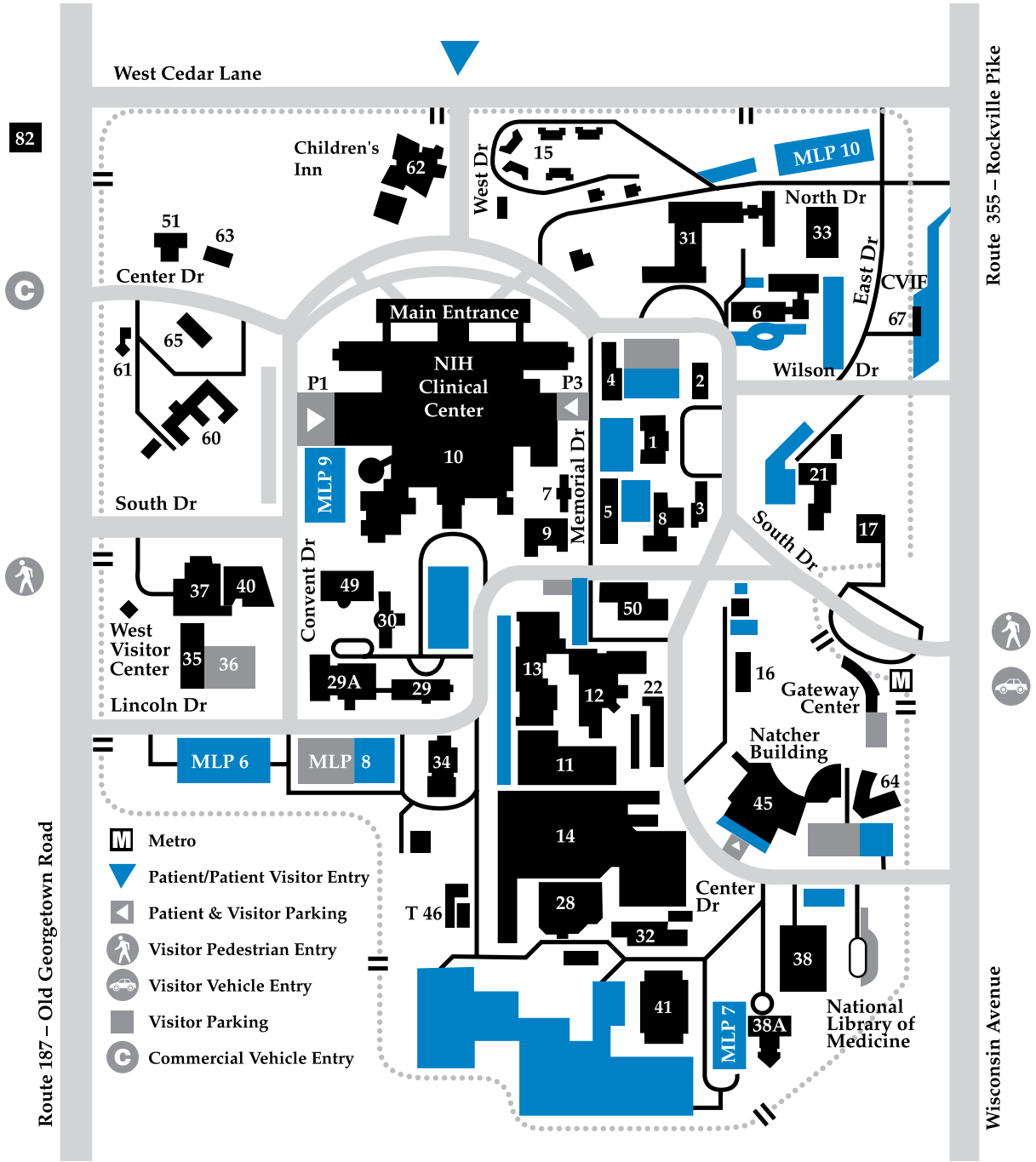


Exhibit IV. NIH Facilities Map



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
Blue, Parking Area	

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.

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.

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 Department of Health and Human Services (DHHS). 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. 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 National Cancer Institute 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 heath 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, and the continuing care 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, almost 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 fur-ther 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 can-cer 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 over 1,300 clinical trials a year, assisting more than 200,000 patients.

The NCI research impacts the *delivery of improved cancer interventions to cancer patients and those who care for them*. Timely communication of NCI scientific findings help people make better health choices and advise physicians about treatment options that are more targeted and less invasive, resulting in fewer adverse side effects. The 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 new public Web site, http://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 National Cancer Program. 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 National Cancer Program. This budget is referred to as the Bypass Budget.

Bypass Budget

The mandate to produce a "Bypass Budget" is a special authority 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 National Cancer Program, 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 National Cancer Program, 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 National Cancer Program. 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 National Cancer Program.

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 formulate a national agenda in cancer research. The NCAB meets with the President's Cancer Panel (PCP) members, who have *ex officio* seats on the Board, 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 National Cancer Program. For example, discussions at the NCAB meetings with *ex officio* members representing Department of Defense and Veterans Affairs health care systems directly lead 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.

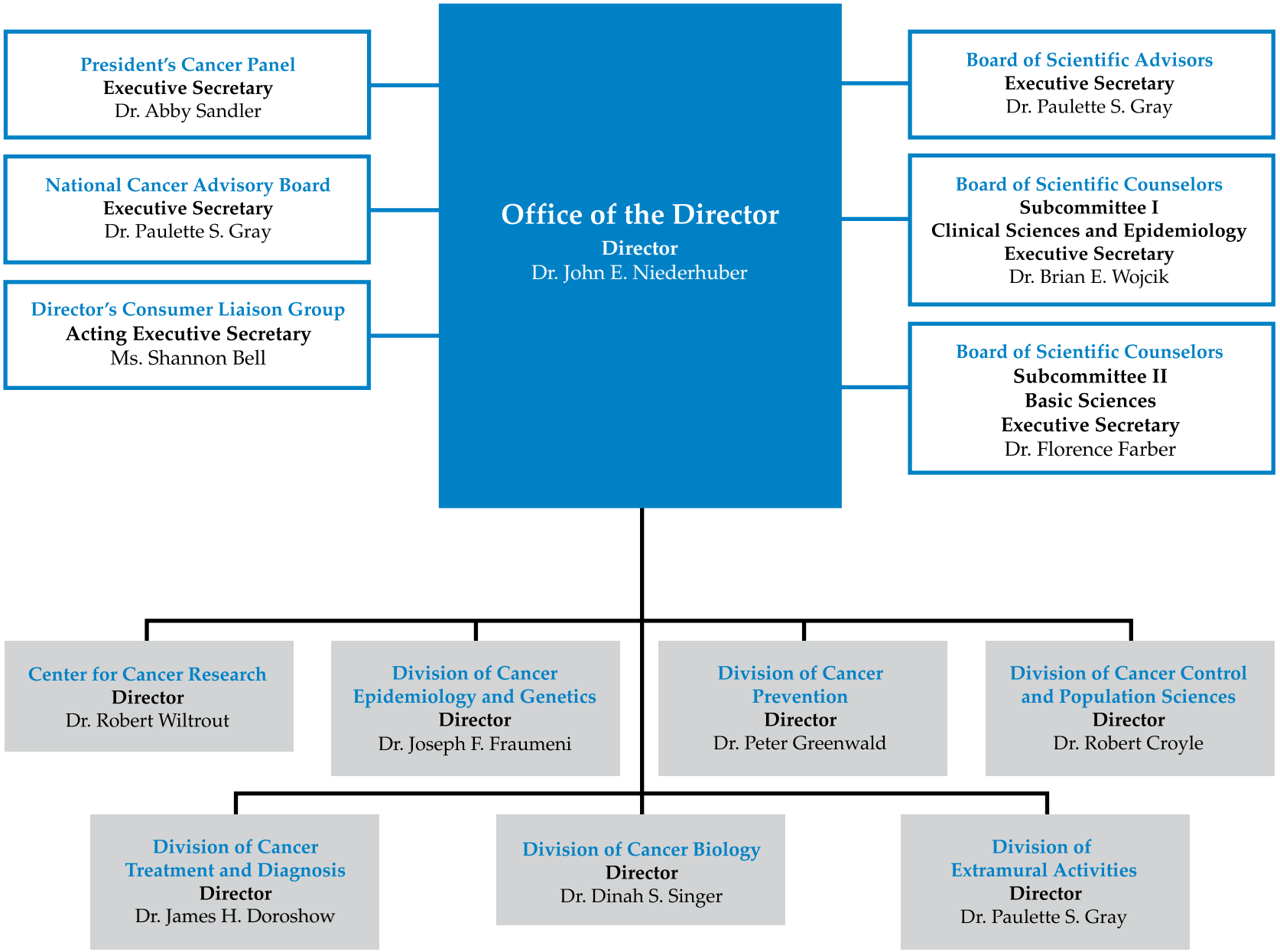
The ability of the NCI and its partners to address the initiatives in the Bypass Budget is a measure of the success of the NCP. In this way, the Bypass Budget enables efficient strategic coordination of the NCP.

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

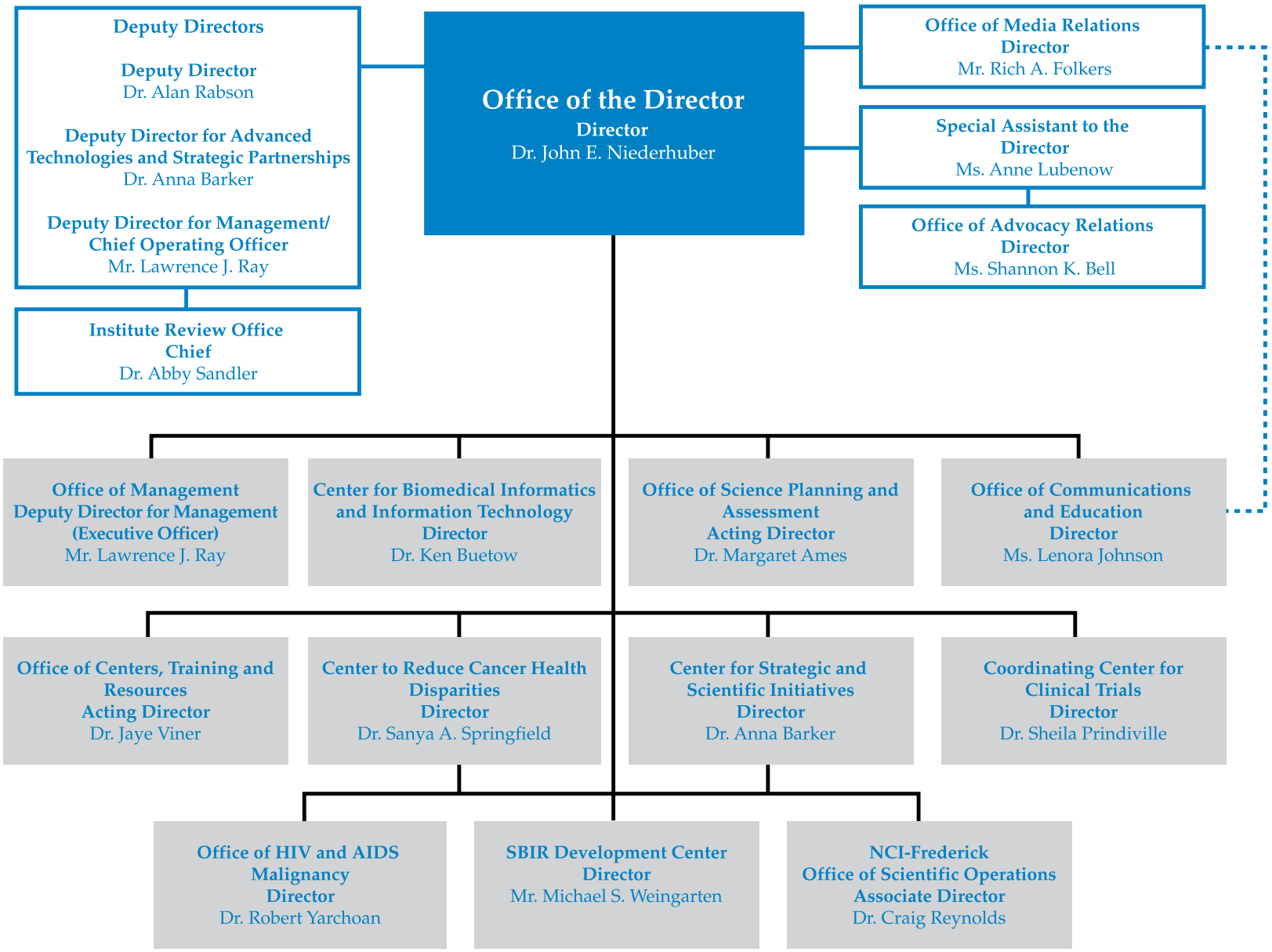
The NCI's current organizational structure can be seen in Exhibit V. NCI's Office of the Director serves as the focal point for the NCP, with advice from the President's Cancer Panel, the NCAB, the Board of Scientific Counselors (BSC), and the

Exhibit V. The National Cancer Institute*



*Source: *NCI Fact Book,* FY2007.

Exhibit V. The National Cancer Institute (Continued)*



*Source: *NCI Fact Book*, FY2007.

Board of Scientific Advisors (BSA). The BSA gives final concept approval for extramural Requests for Applications (RFAs) and Requests for Proposals (RFPs), while the BSC conducts intramural laboratory and branch reviews. The Director of the Institute is assisted by several Deputy Directors: Dr. Alan Rabson, Deputy Director of the NCI; Dr. Anna Barker, Deputy Director, Advanced Technologies and Strategic Partnerships; and Larry Ray, Deputy Director, Office of Management. The Executive Committee (EC) of the Institute (see Appendix A) includes the Director, Deputy Directors, Division Directors, and other senior administrative staff. The EC meets on a regular basis to discuss various matters of NCI policy, including but not limited to, RFA and research and development contract concept review and approval before review by the BSA; review of program announcements; development of funding plans; grant payment by exceptions, etc. Four extramural research divisions, two extramural centers and one office, one intramural research division, and one intramural research center monitor and administer NCI's cancer research activities through extramural and intramural research programs.

Office of the Director

Examples of offices and centers within the Office of the Director include:

Center for Biomedical Informatics and Information Technology (CBIIT)
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: Towards a Molecular Classification of Cancer, and Clinical Trials and develops core infrastructure to support the integration of these efforts.

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.

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 Centers, Training and Resources (OCTR)
The OCTR (1) plans, directs, coordinates, evaluates, and supports extramural grant programs that require broad scientific objectives of each extramural division and that are designed to develop and enhance cancer research in academic and research institutions; (2) through the extramural funding of specialized and/or broad multidisciplinary centers devoted to the basic, clinical, and populations sciences, advances the knowledge and understanding of the causes, mechanisms, diagnosis, and treatment of cancer and promotes transitional research or the movement of discoveries in the laboratory into patient and population research settings; (3) assists extramural research efforts through support of the improvement, renovation, and construction of research facilities; (4) provides training opportunities for health professionals to create a national cadre of highly skilled individuals capable of transferring research discoveries to applications in cancer diagnosis, treatment, and prevention; and (5) establishes program priorities, allocates resources, integrates the projects of various branches, evaluates program effectiveness relative to the goals and objectives of the Institute, and represents the program area in management and scientific decision-making meetings within the Institute.

Coordinating Center for Clinical Trials (CCCT)
The mission of the CCCT is to enhance the best of all the components of the NCI-supported clinical trials system to develop a cooperative enterprise built on a strong scientific infrastructure and a broadly engaged coalition of critical stakeholders.

This will involve: (1) enhancing coordination and cooperation by ensuring that comprehensive information on cancer clinical trials is readily available for all stakeholders, that collaborative team science, as well as individual achievement, is rewarded, and that NCI clinical trials are effectively coordinated with federal regulatory systems; (2) enhancing scientific quality and prioritization so that NCI supports the best-designed trials that address the most important questions, thereby leveraging the most significant scientific advances; (3) enhancing standardization of tools and procedures for trial design, data capture, data sharing, and administrative functions to decrease effort and minimize duplication; and (4) enhancing operational efficiency by increasing the rate of patient accrual and reducing operational barriers so that trials can be conducted in a timely, cost-effective manner.

Office of Cancer Genomics (OCG)
The OCG's efforts are directed towards 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 OCG:

- Provides information, technology, methods, informatics tools, and reagents to serve the needs of the cancer research community.
- Manages the following research programs: the Cancer Genome Anatomy Project (CGAP), the NIH Mammalian Gene Collection (MGC), and the Initiative for Chemical Genetics (ICG).
- Establishes and maintains relationships with advisory groups for each of the above programs.
- Develops educational resources for the general public.

Office of Cancer Content Management (OCCM)
The OCCM oversees the development, publication, maintenance, and updating of the majority of cancer information products disseminated by NCI's Office of Communications (OC). The OCCM also manages the clearance process for all OC cancer information products.

Office of International Affairs (OIA)
The OIA coordinates NCI's worldwide activities in a number of arenas, including: liaison with foreign and international agencies; 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.

Office of Science Planning and Assessment (OSPA)
OSPA's primary responsibilities are to develop and coordinate NCI's scientific planning and evaluation activities. OSPA staff accomplish this through consultation, guidance, analysis, and document preparation in support of various Institute-wide and division-level programs. These critical activities enable the NCI to identify needs and opportunities for cancer research, establish research goals, and develop sound plans for reaching those goals.

Office of Technology and Industrial Relations (OTIR)
The OTIR is 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: Alliance for Nanotechnology in Cancer, Clinical Proteomic Technologies Initiative, Innovative Molecular Analysis Technologies, and Nanotechnology Characterization Laboratory.

Office of HIV and AIDS Malignancy
The Office of HIV and AIDS Malignancy (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).

Small Business Innovation Research (SBIR) Development Center
The SBIR Development Center serves as the NCI focal point for the management of all Small Business Innovation Research (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.

NCI-Frederick Office of Scientific Operations
The NCI-Frederick Office of Scientific Operations (1) oversees and manages scientific operations at NCI-Frederick and serves as the Project Office for the three main operation and support contracts at NCI-Frederick; (2) directs and develops advanced technologies that are made available to customers of NCI-Frederick; (3) implements programmatic decisions approved by the NCI Director and the Associate Director for NCI-Frederick to transition new efforts to NCI-Frederick 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 Food and Drug Administration, the Department of Defense, the Department of Agriculture, and the Department of Homeland Security) and 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 NCI-Frederick; (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 NCI-Frederick; and (11) coordinates NCI-Frederick 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.

Extramural Divisions

The research and research-related activities of the NCI are conducted by five divisions under the supervision of the Office of the Director. The functions of the divisions and the major areas of research and research support activities for which each is responsible are:

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 upon which strategies for the prevention, diagnosis, and treatment of cancer are developed. (http://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 decisionmaking, 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. (http://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. (http://cancer.gov/dctd/)

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 liaison with professional and voluntary health agencies, Cancer Centers, labor organizations, cancer organizations, and trade associations. (http://www3.cancer.gov/prevention)

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 followup 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 7,000 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. (http://deainfo.nci.nih. gov/funding.htm)

Intramural Center and Division

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. (http://ccr.nci.nih.gov/)

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. (http://dceg.cancer.gov/)

NCI Programs and Activities

Research Programs

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—our 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 divisions and center of the NCI, under the supervision of the Office of the Director.

Cancer Causation Research
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. FY2007 cancer causation research expenditures totaled about $1.05 billion, accounting for 22.0 percent of the total NCI budget.

Detection and Diagnosis Research
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. FY2007 detection and diagnosis research expenditures totaled about $391 million, accounting for 8.2 percent of the total NCI budget.

Treatment Research
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 (see Appendix I) 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. FY2007 treatment research expenditures totaled about $1.12 billion, accounting for 23.3 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. FY2007 cancer biology expenditures totaled approximately $753 million, accounting for 15.7 percent of the total NCI budget.

Resource Development

Cancer Centers Program
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. In FY2007, there were 63 centers, which received a total of $273 million in support, accounting for 5.6 percent of the total NCI budget.

The NCI uses the ***Cancer Center Support Grant*** (CCSG) mechanism (P30) to support centers that conduct research and outreach activities on several different cancers. Cancer Centers are designated as one of three types: basic, clinical, or comprehensive.

Cancer Centers have developed in a number of 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 CCSG is intended 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.

The ***Specialized Programs of Research Excellence*** (SPOREs) are designed to stimulate translational research from the laboratory to clinical practice. SPOREs, which are funded under the P50 grant mechanism, focus on research in prevention, detection, diagnosis, and treatment for a single cancer site. These are awarded to institutions that demonstrate the ability to perform significant translational research.

To encourage the development of cancer research centers in regions not currently served by existing NCI-designated clinical or comprehensive centers, the NCI awards ***Planning and Development Grants***, using the P20 mechanism, to help eligible institutions develop the organizational capability to form and/or develop cancer research centers or SPOREs.

NCI's ***Comprehensive Minority Institution/Cancer Center Partnership*** (U54) awards are 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 rate of cancer incidence and mortality in minority populations.

Research Manpower Development

The Cancer Training Branch (CTB) manages the Institute's 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. Kirstein 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. Program expenditures in FY2007 totaled approximately $168 million, accounting for 3.5 percent of the total NCI budget.

Cancer Prevention and Control

The NCI Cancer Prevention and Control Program conducts 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. FY2007 Cancer

Prevention and Control Program expenditures totaled approximately $498 million, accounting for 10.4 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, the Institute's extramural programs emphasize grant-supported, investigator-initiated research projects, which 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.

Exhibit VI illustrates the relationship between total NCI obligations and the grant, contract, and intramural/other components of the NCI budget. Exhibit VII shows the 2007 budget for various research areas. Exhibit VIII summarizes the FY2007 budget obligations by mechanisms. Exhibit IX shows the RPG awards by activity code and presents the number of grants awarded, the total dollars awarded, and the average cost of a grant for the period 1998–2007.

Grants

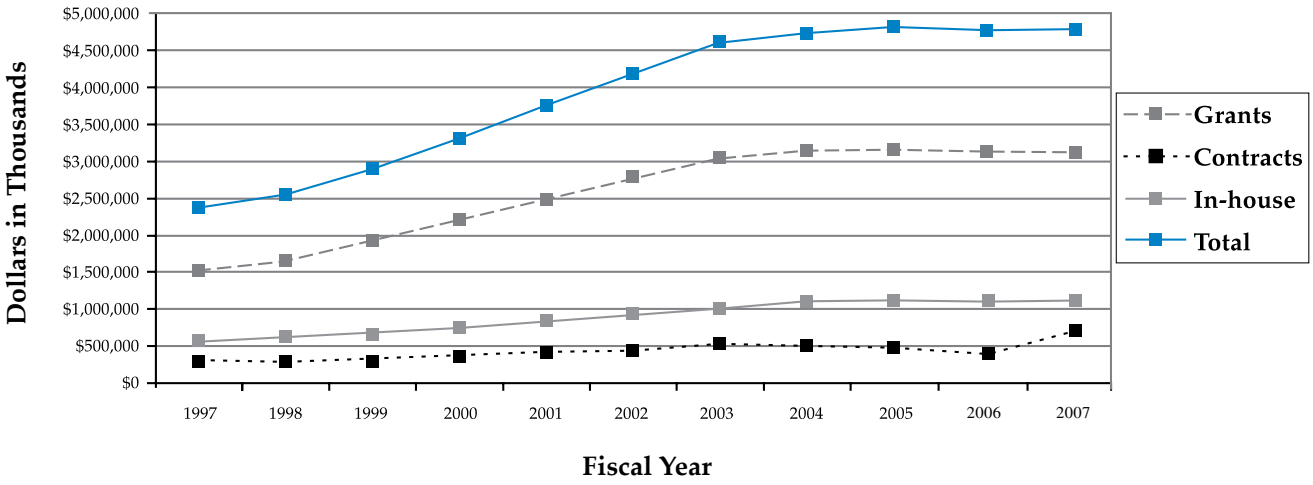
I. Research Project Grants

Research Project Grants are awards for investigator-initiated research applications. Several types of awards are made in this category; they vary in type of mechanism, type of applicant, total amount of support, and length of time. FY2007 research project grant expenditures totaled approximately $2.11 billion, accounting for 44.1 percent of the total NCI budget.

P01 Research Program Project Grant
Research Program Project Grants (P01s) support an integrated, multiproject research approach involving a number of independent investigators who share knowledge and common resources. A P01 has a defined, central research focus involving several disciplines or several aspects of one discipline. Each individual project should contribute or be directly related to the common theme of

Exhibit VI. NCI Funding History*

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Grants	$1,527,962	$1,652,966	$1,926,093	$2,204,716	$2,488,627	$2,790,485	$3,047,650	$3,171,792	$3,251,216	$3,227,919	$3,174,713
Contracts	296,290	290,100	306,706	361,355	411,588	437,610	532,760	514,602	504,798	492,822	558,510
In-house	564,789	608,215	672,608	745,010	853,50	948,606	1,011,936	1,037,499	1,038,730	1,026,484	1,059,392
Total	2,389,041	2,551,281	2,918,050	3,311,081	3,753,721	4,176,701	4,592,346	4,723,893	4,794,744	4,747,225	4,792,615



*Source: Office of Financial Management, 2008.

Exhibit VII. Research Funding for Various Research Areas (Dollars in Millions)*

Disease Area	2003 Actual	2004 Actual	2005 Actual	2006 Actual	2007 Actual
Total NCI Budget	**$4,592.3**	**$4,723.9**	**$4,794.7**	**$4,747.2**	**$4,792.6**
AIDS	263.4	267.0	265.9	253.7	253.7
Brain & CNS	111.5	132.3	107.2	130.3	148.2
Breast Cancer	548.7	566.2	560.1	584.7	572.4
Cervical Cancer	79.0	79.0	81.7	83.3	82.4
Clinical Trials	799.5	800.0	781.8	822.3	843.7
Colorectal Cancer	261.6	262.0	253.1	244.1	258.4
Head and Neck Cancers	77.7	88.2	89.5	71.3	66.2
Hodgkin's Disease	16.5	17.4	17.2	20.9	16.5
Leukemia	200.9	214.7	220.6	223.5	205.5
Liver Cancer	63.7	63.0	60.5	62.7	67.7
Lung Cancer	273.5	276.5	266.1	242.9	226.9
Melanoma	90.7	94.9	102.9	108.0	97.7
Multiple Myeloma	26.3	23.9	28.2	30.3	32.3
Non Hodgkin's Lymphoma	95.2	99.6	107.0	114.1	113.0
Ovarian Cancer	99.4	99.5	97.7	95.1	96.9
Pancreatic Cancer	42.3	52.7	66.7	74.2	73.3
Prostate Cancer	305.2	308.5	309.0	293.2	296.1
Stomach Cancer	13.4	11.6	11.0	11.5	12.0
Uterine Cancer	25.5	27.0	31.1	19.4	16.6

*Source: *NCI Fact Book*, FY2007.

the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal.

R01 Research Project Grant
Research Project Grants (R01s) support a discrete, specified research project to be performed by the named investigator(s) in an area representing his/her specific interest and competencies. This is generally referred to as a "traditional research project grant."

R03 Small Research Grant
Small Research Grants (R03s) provide research support that is limited in time and amount, for studies in categorical program areas. Small research grants provide flexibility and are generally used to initiate studies for preliminary, short-term projects. These grants are nonrenewable.

R21 Exploratory/Developmental Grant
Exploratory/Development Grants (R21s) support the development of new research activities in categorical program areas. Support generally is restricted, in terms of the level of support and time.

R33 Exploratory/Developmental Grant—Phase II
Phase II Exploratory/Developmental Grants (R33s) provide additional support to innovative, exploratory, and developmental research activities that were initiated under the R21 mechanism.

R37 Method to Extend Research in Time (MERIT) Award
MERIT Awards (R37s) provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT Award. After initial review, NCI staff and the NCAB review competing R01 applications to select MERIT awardees. An initial, 5-year MERIT Award is followed by possible extensions of 1 to 5 more years of support. Extensions are based upon an expedited review of the investigator's accomplishments during the initial period.

Exhibit VIII. Summary of NCI Obligations by Mechanism, FY2007 (Dollars in Thousands)*†

		Number	Amount	% of Total
Research Project Grants	Non-Competing	3,882	1,546,958	32.3
	Administrative Supplements	(259)	36,466	0.8
	Competing	1,312	434,713	9.1
	Subtotal, without SBIR/STTR Grants	5,194	2,018,137	42.1
	SBIR/STTR Grants	278	93,677	2.0
	Subtotal, Research Project Grants	**5,472**	**2,111,814**	**44.1**
Centers & SPOREs	Cancer Centers Grants - P20/P30	63	273,184	5.7
	SPOREs - P50	62	123,808	2.6
	Other Specialized Centers	42	74,677	1.6
	Subtotal, Centers	**167**	**471,669**	**9.8**
Other Research	**Career Program**			
	Temin & Minority Mentored Awards - K01	126	17,831	0.4
	Estab. Inv. Award - K05	17	2,266	0.1
	Preventive Oncology - K07	99	13,269	0.3
	Clinical Investigator - K08	112	14,119	0.3
	Clinical Oncology - K12	16	9,472	0.2
	Transitional Career Development - K22	46	7,114	0.2
	Mentored Patient Oriented RCDA - K23	51	6,845	0.1
	Mid-Career Invest. & Patient Orient. Res. - K24	16	2,491	0.1
	Mentored Quant. Res Career - K25	17	2,343	0.1
	Inst. Curr. Award - K30	5	1,462	0.0
	Pathway to Independence Awards - K99	20	2,383	0.1
	Subtotal, Career Program	**525**	**79,595**	**1.7**
	Cancer Education Program - R25	89	31,337	0.7
	Clinical Cooperative Groups - U10	66	148,193	3.1
	Minority Biomedical Support - S06	0	2,435	0.1
	Sci. Eval. (U09/T09)-Res. Enhancement (SC1)	1	366	0.0
	Continuing Education	7	748	0.0
	Resource Grants - R24/U24	41	46,321	1.0
	Explor. Coop. Agreement - U56	15	10,409	0.2
	Conference Grants - R13	82	3,477	0.1
	Subtotal, Other Research Grants	**826**	**322,881**	**6.7**
Subtotal, Research Grants		**6,465**	**2,906,364**	**60.6**
NRSA Fellowships	*Trainees:*	1,455	68,223	1.4
R&D Contracts	R&D Contracts	293	404,463	8.4
	SBIR Contracts	45	12,387	0.3
	Subtotal, Contracts	**338**	**416,850**	**8.7**
Intramural Research	Program		582,037	12.1
	NIH Management Fund/SSF Assessment		124,142	2.6
	Subtotal, Intramural Research *FTEs:*	**1,811**	**706,179**	**14.7**
RMS	Research Mgmt. and Support		166,996	3.5
	NIH Management Fund/SSF Assessment		21,687	0.5
	Subtotal, RMS *FTEs:*	**619**	**188,683**	**3.9**
Cancer Prevention and Control	Cancer Control Grants	207	200,126	4.2
	Cancer Control Contracts	132	133,740	2.8
	In-house	398	148,745	3.1
	NIH Management Fund/SSF Assessment		15,785	0.3
	Subtotal, Prevention and Control *FTEs:*	**398**	**498,396**	**10.4**
Building and Facilities			**7,920**	**0.2**
Construction			0	0
***Total NCI**	*FTEs:*	**2,828**	**4,792,615**	**100.0**

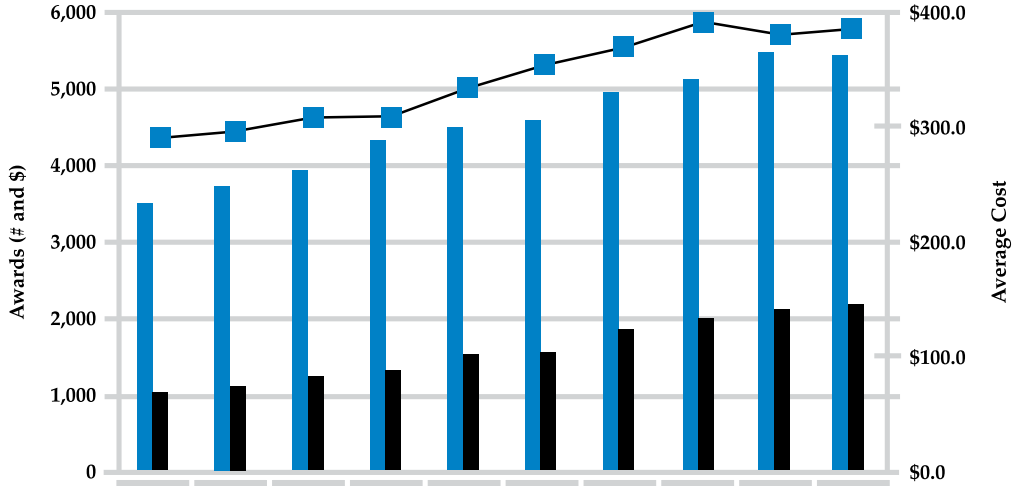
*Excludes projects awarded with Stamp Out Breast Cancer funds.

†Source: *NCI Fact Book,* FY2007.

Exhibit IX. RPG Awards by Activity Code, FY1998-2007*† (Dollars in Thousands)

		R01	P01	R35	R37	R29	RFA	U01	U19	R03	R21	R33	R15	R55	R56	SBIR/ STTR	Total
1998	#	2,454	160	57	75	485	132	157	0	97	76	0	2	14	0	249	3,958
	$	672,873	228,854	57,712	27,212	52,136	42,750	79,370	0	6,069	11,782	0	127	684	0	51,207	1,230,776
1999	#	2,796	169	38	71	413	261	31	0	108	159	6	2	6	0	291	4,351
	$	775,961	249,583	38,585	27,377	45,361	112,868	21,319	0	7,355	22,548	2,079	200	620	0	57,917	1,361,773
2000	#	3,011	179	21	60	314	269	18	0	100	223	20	0	5	0	306	4,526
	$	898,764	286,234	19,413	24,688	34,769	132,872	13,617	0	7,034	32,897	10,074	99	450	0	67,090	1,528,001
2001	#	3,231	178	1	61	210	260	18	0	122	231	49	3	3	0	328	4,695
	$	1,008,199	301,115	2,186	26,682	23,738	150,224	14,873	0	9,024	42,326	23,883	358	300	0	75,833	1,678,741
2002	#	3,376	173	0	65	112	267	17	0	186	308	79	10	9	0	374	4,976
	$	1,093,908	317,632	0	29,445	12,471	177,195	17,531	0	14,115	57,633	39,317	1,477	850	0	86,367	1,847,941
2003	#	3,573	178	0	70	14	252	27	0	203	360	81	21	0	0	356	5,135
	$	1,207,387	336,607	0	35,360	1,584	173,342	31,126	0	15,207	67,742	37,714	3,086	0	0	90,857	2,000,012
2004	#	3,780	177	0	73	0	233	26	0	240	425	96	20	0	0	397	5,467
	$	1,277,185	344,489	0	37,888	53	168,539	31,377	0	18,067	77,970	42,931	4,560	0	0	99,579	2,102,638
2005	#	3,848	176	0	74	0	254	30	1	223	430	88	20	2	1	256	5,412
	$	1,312,762	338,660	0	40,007	0	171,403	34,100	1,049	16,894	76,566	36,250	4,091	200	407	97,775	2,130,164
2006	#	3,909	173		76		273	26	3	218	405	73	14		2	263	5,435
	$	1,293,880	339,616		40,067		173,304	31,292	4,365	16,558	70,650	28,726	2,983		649	96,055	2,098,145
2007	#	3,849	172		73		285	22	3	284	437	48	19		2	278	5,472
	$	1,266,622	326,968		38,232		177,423	24,295	4,212	21,640	78,748	16,739	4,042		495	93,677	2,053,093

Research Project Grants and Dollars Awarded FY1998-2007[1]



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
# Awarded	3,958	4,351	4,526	4,695	4,976	5,135	5,467	5,412	5,435	5,472
$ in Millions	$1,231	$1,362	$1,528	$1,679	$1,848	$2,000	$2,103	$2,130	$2,098	$2,053
Avg Cost	$311.0	$313.0	$337.6	$357.6	$371.4	$389.5	$384.6	$393.6	$386.0	$375.2

*Excludes projects awarded with Stamp Out Breast Cancer funds and Extramural Assessments.

†Source: *NCI Fact Book,* FY2007.

R41 Small Business Technology Transfer (STTR) Grant—Phase I
Phase I STTR Grants (R41s) support cooperative research and development projects between research institutions and small, domestic, for-profit organizations. R41s are limited in time and amount and are used to establish the technical merit and feasibility of ideas that have a potential for commercialization. Generally, support for Phase I STTR awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 1 year. *Note:* Phase I award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of their research project. Deviations from the guidelines must be well justified.

R42 Small Business Technology Transfer (STTR) Grant—Phase II
Phase II STTR Grants (R42s) support in-depth development of cooperative research and development projects between research institutions and small, domestic, for-profit organizations. They are limited in time and amount, and applicants must have established during phase I their project's feasibility and potential for commercialization. Generally, support for Phase II awards may not exceed $500,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 2 years. *Note:* Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R43 Small Business Innovation Research (SBIR) Grant—Phase I
Phase I SBIR Grants (R43s) support research efforts by for-profit, domestic, small businesses. The objectives of this phase are to: (1) establish the technical merit and feasibility of proposed research or research and development (R&D) efforts, and (2) evaluate the performance of the small business awardee organization prior to providing further Federal support in Phase II (R44). Generally, support for Phase I awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 6 months. Note: Phase I award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R44 Small Business Innovation Research (SBIR) Grant—Phase II
Phase II SBIR Grants (R44s) continue those R&D efforts that were started in Phase I (R43). Awards are based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. Only Phase I awardees are eligible for Phase II. Generally, support for Phase II may not exceed $750,000 for direct and indirect costs and a fixed fee for a period normally not to exceed 2 years. Note: Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

R55 James A. Shannon Director's Award
Applicants do not submit requests for Shannon Awards (R55). Instead, NCI program staff nominate previously reviewed R01 and R03 applications that are beyond the current NCI payline but, because of their merit, are eligible for funding. After each of the three review cycles per year, Shannon Award nominees are administratively reviewed by the NCI according to standard review criteria, then submitted to the Office of Extramural Research, NIH, for expedited review and concurrence prior to funding.

Shannon Awards (R55s) provide a limited award to investigators to further develop, test, and refine research techniques; perform secondary analysis of available data sets; test the feasibility of innovative and creative approaches; and conduct other discrete projects that can demonstrate the investigator's research capabilities and lend additional weight to his or her already meritorious applications.

R56 High Priority, Short-Term Project Award
Applicants do not submit requests for a High Priority Award (R56). Instead, NCI program staff nominate previously reviewed R01 applications that are beyond the current NCI payline but, because of their merit, are eligible for funding. After each of the three review cycles per year, High Priority nominees are administratively reviewed by the NCI according to standard review criteria. The NCI then determines whether any awards are made from NCI funds.

High Priority Awards (R56s) provide limited, interim support to enable an applicant to gather additional data for revision of a new or competing renewal application. The R56 will assist early career stage scientists trying to establish research

careers as well as more experienced scientists who just missed receiving funds.

II. Cancer Centers and Specialized Programs of Research Excellence

The Cancer Centers and SPORE Program contain a great diversity of research approaches. In FY2007, expenditures totaled about $471.7 million, accounting for 9.8 percent of the total NCI budget.

P20 Planning Grant
Planning Grants (P20s) support planning for new programs, expansion or modification of existing resources, and feasibility studies for new approaches. Such awards have been particularly useful in the development of Cancer Centers and SPOREs.

P30 Cancer Center Support Grant
Cancer Center Support Grants (P30s) provide support primarily for the research infrastructure of an active and unified Cancer Center, for the purpose of: consolidating and focusing cancer-related activities; increasing research productivity; promoting shared use of research resources and improved quality control; stimulating and promoting interdisciplinary and collaborative research; and increasing the rate at which research discoveries are translated into medical developments.

P50 Specialized Center Grant
Specialized Center Grants (P50s) support any part of the full range of R&D, from very basic to clinical activities. They also may support ancillary activities, such as the protracted patient care that may be necessary while conducting primary research or R&D. The spectrum of activities comprises a multidisciplinary attack on cancer. These grants differ from Program Project Grants in that they usually are developed in response to an announcement of the programmatic needs of the NCI and receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes.

The Specialized Programs of Research Excellence (SPORE) grant is one type of Specialized Center. The NCI SPORE is an organ site application, which includes basic and clinical investigation, thus having a significant translational component.

U54 Specialized Center – Cooperative Agreement (see Cooperative Agreement Section)

U56 Exploratory Grant – Cooperative Agreement (see Cooperative Agreement Section)

III. Other Research Grants

Other research includes the Research Career Program and all other research grants not included in Research Project Grants, Research Centers, and/or Cancer Prevention and Control, except for National Research Service Awards. The NCI Research Career Program includes all "K" awards. In FY2007, other research expenditures totaled approximately $322.8 million, accounting for 6.7 percent of the total NCI budget.

IV. Career Awards and Cancer Education

K01 Mentored Research Scientist Development Award
Mentored Research Scientist Development Awards (K01s) provide research scientists with an additional period of sponsored research experience as a way to gain expertise in a research area that (1) is new to the applicant, or (2) would demonstrably enhance the applicant's scientific career.

K05 Senior Scientist Award
Senior Scientist Awards (K05s) support outstanding established scientists who have demonstrated a sustained, high level of productivity, research accomplishments, and contributions to research in the fields of cancer prevention, control, and population sciences. These awards provide protected time to devote to research and to act as mentors for young investigators.

K07 Academic Career Award
Academic Career Awards (K07s) support more junior candidates who are interested in developing academic and research expertise in a specific area. They also support more senior individuals with acknowledged scientific expertise and leadership skills who are interested in improving the curricula and enhancing the research capability within an academic institution.

K08 Mentored Clinical Scientist Development Award
Mentored Clinical Scientist Development Awards (K08s) support the development of outstanding clinical research scientists. These awards provide specialized study for clinically trained professionals who are committed to a career in research and have the potential to develop into independent investigators. The NCI supports two K08 awards: the Clinical Investigator Award and the Minorities in Clinical Oncology Award.

K12 Mentored Clinical Scientist Development Program Award
Mentored Clinical Scientist Development Program Awards (K12s) help newly trained, appointed clinicians gain independent research skills and experience in a fundamental science within the framework of an interdisciplinary R&D program.

K22 Career Transition Award
Career Transition Awards (K22s) help newly trained, basic or clinical investigators to develop their independent research skills through a two-phase program: an initial period involving an intramural appointment at the NIH, and a final period of support at an extramural institution. The award is intended to enable the investigator to establish a record of independent research to sustain or promote a successful research career. The NCI supports two K22 awards: the Scholars Program and the Transition Career Development Award. The NCI Scholars Program provides an opportunity for outstanding new investigators to begin independent research careers, intramurally, within the special environment of the NCI. It then enables awardees to continue their careers extramurally at an institution of their choice, where they are appointed to junior faculty positions or the equivalent. The NCI Transition Career Development Award is a fully portable mechanism that facilitates the professional advancement of talented clinician cancer scientists, clinicians in patient-oriented cancer research, and researchers in cancer prevention, control, and the population sciences.

K23 Mentored Patient-Oriented Research Career Development Award
Mentored Patient-Oriented Research Career Development Awards (K23s) provide support for the career development of investigators who focus their research endeavors on patient-oriented research. The mechanism provides support for a period of supervised study and research to clinically trained professionals who have the potential to develop into productive clinical investigators in patient-oriented research.

K24 Mid-Career Investigator in Patient-Oriented Research Award
Mid-Career Investigator in Patient-Oriented Research Awards (K24s) provide clinicians the opportunity to dedicate time to patient-oriented research and to mentor other clinical investigators in patient-oriented research.

K25 Mentored Quantitative Research Career Development Award
Mentored Quantitative Research Career Development Awards (K25s) support the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine, who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical).

K30 Institutional Curriculum Award
Institutional Curriculum Awards (K30s) support the development, conduct, and evaluation of curricula that are designed to improve the quality of training for aspiring clinical investigators.

K99/R00 Howard Temin Pathway to Independence Awards in Cancer Research
Howard Temin Pathway to Independence Awards in Cancer Research (K99/R00) support highly promising, postdoctoral research scientists. The initial phase is followed by independent support contingent on securing an independent research position. The goal of this award is to facilitate an investigator receiving an R01 award earlier in his/her research career.

V. Training (NRSA)

The National Research Service Award (NRSA) is the major mechanism providing long-term, stable support to a wide range of promising scientists and research clinicians. FY2007 NRSA expenditures totaled approximately $68.2 million, accounting for 1.4 percent of the NCI budget.

F31 Predoctoral Individual National Research Service Award
Predoctoral Individual National Research Service Awards (F31s) provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward a research degree (e.g., Ph.D.).

F32 Postdoctoral Individual National Research Service Award
Postdoctoral Individual National Research Service Awards (F32s) provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified, health-related areas.

F33 National Research Service Award for Senior Fellows
National Research Service Awards for Senior Fellows (F33s) enable experienced scientists to take time away from their regular professional responsibilities to: make major changes in the direction of research careers; broaden scientific background; acquire new research capabilities; enlarge command of an allied research field; or increase capabilities to engage in health-related research.

T32 Institutional National Research Service Award
Institutional National Research Service Awards (T32s) support training opportunities at the predoctoral or postdoctoral level at qualified institutions. Applicants must have the staff and facilities for the proposed program. After the award is made, the institution's training Program Director is responsible for selecting the trainees and for administering the program. This program does not support residencies.

Other Grant Mechanisms

R13 Conference Grant
Conference Grants (R13s) support national or international meetings, conferences, and workshops that are of value in promoting the goals of the National Cancer Program.

R15 Academic Research Enhancement Award (AREA)
Academic Research Enhancement Award (AREA) Grants (R15s) support small-scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $75,000 in direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R24 Resource-Related Research Project
Resource-Related Research Project Grants (R24s) support research projects that will enhance the capability of resources to serve biomedical research.

R25 Cancer Education Grant
Cancer Education Grants (R25s) support the development and implementation of programs related to education, information provision, training, technical assistance, coordination, or evaluation. The NCI supports two distinct Cancer Education programs: the Cancer Education and Career Development Program, and the Cancer Education Grant Program (CEGP). The NCI Cancer Education and Career Development Program (R25T) is an institutional grant program that supports the development and implementation of curriculum-dependent programs to train predoctoral and postdoctoral candidates in cancer research settings that are highly interdisciplinary and collaborative. The NCI CEGP is a flexible, curriculum-driven program aimed at developing and sustaining innovative educational approaches that ultimately will reduce cancer incidence, mortality, and morbidity. The program also focuses on improving the quality of life for cancer patients. The CEGP awards (R25Es) address a need that is not fulfilled adequately by any other grant mechanism available at the NIH. These awards are dedicated to areas of particular concern by the NCI.

S06 Minority Biomedical Research Support (MBRS)
Minority Biomedical Research Support Grants (S06s) provide funds to strengthen the biomedical research and research training capability of ethnic minority institutions, thus creating a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

Cooperative Agreements

The cooperative agreement is a mechanism to provide funding assistance for a variety of activities. The Federal Grant and Cooperative Agreement Act of 1977 authorized use of the cooperative agreement and formally defined the circumstances under which this mechanism is to be employed by Federal agencies. These instruments are used for situations in which an assistance relationship will exist between the NCI and a recipient and substantial programmatic involvement is anticipated.

U01 Research Project Cooperative Agreement
Research Project Cooperative Agreements (U01s) support discrete, specified, circumscribed projects to be performed by the named investigator(s) in an area representing his/her specific interest and competencies. This mechanism is utilized when substantial programmatic involvement is anticipated between the NCI and the recipient.

U10 Clinical Research Cooperative Agreement (Clinical Cooperative Groups)
Clinical Research Cooperative Agreements (U10s) support clinical evaluations of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and usually are conducted under established protocols.

U13 Conference Cooperative Agreement
Conference Cooperative Agreements (U13s) support international, national, or regional meetings, conferences, and workshops for which substantial programmatic NCI staff involvement is planned to assist the recipients.

U19 Research Program Cooperative Agreement
Research Program Cooperative Agreements (U19s) support research programs that have multiple projects directed toward a specific major objective, basic theme, or program goal, requiring a broadly based, multidisciplinary, and often long-term approach. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of research activities, as defined in the terms and conditions of the award. This mechanism can

provide support for certain basic, shared resources, which facilitate the total research effort, including clinical components.

U24 Resource-Related Research Project Cooperative Agreement
Resource-Related Research Project Cooperative Agreements (U24s) support projects that help improve the capability of resources to serve biomedical research.

U43 Small Business Innovation Research (SBIR) Cooperative Agreement—Phase I (see R43)
Phase I SBIR Cooperative Agreements (U43s) support finite projects to establish the technical merit and feasibility of R&D ideas that ultimately may lead to the development of commercial products or services. This mechanism is utilized when an assistance relationship will exist between the NCI and a recipient and in which substantial programmatic involvement is anticipated. Cooperative agreement applications are considered only for the topics specifically listed in the current SBIR Omnibus Solicitation. *Note:* Phase I award levels and project periods are statutory guidelines. Applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

U44 Small Business Innovation Research (SBIR) Cooperative Agreement—Phase II (see U43 and R44)
Phase II SBIR Cooperative Agreements (U44s) support in-depth development of R&D ideas for which feasibility has been established in Phase I (U43) and that are likely to result in commercial products or services. *Note:* Phase II award levels and project periods are statutory guidelines. Applicants are encouraged to propose a budget and project period that are appropriate for completion of the research project. Deviations from the guidelines must be well justified.

U54 Specialized Center—Cooperative Agreement
Specialized Center Cooperative Agreements (U54s) support any part of the full range of R&D, from basic concepts to clinical applications. The U54 may involve ancillary supportive activities, such as the provision of protracted patient care during the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. The U54s differ from program projects in that they usually are developed in response to an announcement of the programmatic needs of an Institute or division and subsequently receive continuous attention from its staff. Centers also may serve as regional or national resources for special research purposes, with funding staff helping to identify appropriate priority needs. At the NCI, U54s support comprehensive partnerships between Minority Serving Institutions (MSIs) and the NCI-designated Cancer Centers, for the benefit of both. These partnerships focus on cancer research career development at the MSI or cancer research plus one or more target areas in cancer research training. These partnerships also may focus on cancer research and target areas in cancer education for, or cancer outreach to, minority communities.

U56 Exploratory Grant—Cooperative Agreement
Exploratory Grant Cooperative Agreements (U56s) support planning for new programs, expansion or modification of existing resources, and development of feasibility studies to explore the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers. Substantial Federal programmatic staff involvement is intended to assist investigators during the performance of the research activities, as defined in the terms and conditions of award.

Solicitation of Grant Applications

Program Announcements (PAs)
PAs describe continuing, new, or expanded program interests for which grant or cooperative agreement applications are invited. Applications in response to PAs are reviewed in the same manner as unsolicited grant applications (i.e., by chartered peer review committees of the Center for Scientific Review [CSR] or by the NCI). Review groups in CSR are referred to as an Integrated Review Group (IRG), while those in the NCI are referred to as Initial Review Group (IRG) subcommittees or Special Emphasis Panels (SEP).

Program Announcements with Special Receipt/ Review (PARs)
PARs are program announcements that contain special referral guidelines and receipt dates and are reviewed either by CSR or by a specific Institute's IRG.

Requests for Applications (RFAs)
RFAs are issued to invite grant or cooperative agreement applications in a well-defined scientific area, to stimulate activity in NCI programmatic priority areas. Usually a single application receipt date is specified, and the announcement identifies the amount of funds earmarked for the initiative and the number of awards likely to be funded. Applications are evaluated before review for responsiveness to the RFA. Applications received

in response to a particular RFA are reviewed by an appropriate NCI IRG.

All PAs and RFAs are published in the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/index.html) and, when appropriate, in scientific journals and periodicals.

Contracts

Research and Development Contracts

To stimulate scientific inquiry, direct it toward promising areas of current research, and solve specific research problems, the NCI awards research, development, demonstration, and support contracts to both nonprofit and commercial organizations. The idea for a contract may be generated by the NCI program staff (usually the Project Officer), or it may originate from members of the scientific community. The negotiated contract used by the NCI is awarded through a competitive process, in which bidders are judged on the basis of technical (scientific merit), business, and cost factors. The responsibility for reviewing the technical merit of proposals for R&D contracts is lodged in the Special Review and Logistics Branch (SRLB), DEA, NCI. Review responsibility is separated from those responsibilities of the Project and Contracting Officers. After award, the NCI is substantially involved in monitoring the project; this may range from tight control to general surveillance and support. Contracts may be used in support of either research or resource projects. In a research contract, the NCI defines the specific area of research and may identify general approaches. Such a contract usually is used to stimulate work in an area that has been neglected by the private sector.

Loan Repayment Program (LRP)

The LRP was started in 1989 to recruit and retain highly qualified professionals as AIDS researchers. Using the contract mechanism, this program provides for repayment of up to $35,000 (principal and interest) of eligible, educational loans for qualified clinical and pediatric investigators, for each year of their research service. To be eligible, the awardee must agree to engage in clinical or pediatric research for a minimum of 2 years. Originally confined to intramural researchers, the LRP was expanded in 2002 to include extramural investigators.

L30 Clinical Research Loan Repayment Program
The Clinical Research Loan Repayment Program is for eligible investigators, in exchange for a 2-year commitment to clinical research. To participate in the program, individuals must hold an appropriate terminal degree from an accredited institution, must conduct research for 20 hours per week (based on a 40-hour week), and must conduct research that is supported by a domestic, nonprofit institution or by a U.S. Government entity.

L40 Pediatric Research Loan Repayment Program
The Pediatric Research Loan Repayment Program is for eligible investigators, in exchange for a 2-year commitment to pediatric research. To participate in the program, individuals must hold an appropriate terminal degree from an accredited institution, must conduct research for 20 hours per week (based on a 40-hour week), and must conduct research that is supported by a domestic, nonprofit institution or by a U.S. Government entity.

NCI Advisory Committees

President's Cancer Panel (PCP)
The President's Cancer Panel (see Appendix B) is an NCI Federal advisory committee that reports directly to the U.S. President on the activities of the National Cancer Program. The panel was established by the Public Health Service Act, as amended by the National Cancer Act (P.L. 92-218), and was chartered in accordance with the Federal Advisory Committee Act (P.L. 92-463). The Panel consists of three members who are appointed by the President for terms of 3 years. One of the members is appointed by the President as Chairperson of the Panel for a 1-year term. At least two members must be distinguished scientists or physicians, and the third may be a lay person. The panel, which meets at least four times a year, is responsible for monitoring the development and execution of the National Cancer Program, evaluating its efficacy, making suggestions for its improvement, and submitting periodic progress reports to the President.

National Cancer Advisory Board (NCAB)
The NCAB (see Appendix C) advises, assists, consults with, and makes recommendations to the Secretary of the DHHS, and the Director of NCI, regarding the activities carried out by and through the Institute as well as policies respecting these activities. The NCAB may make recommendations regarding support grants and cooperative agreements, technical and scientific peer review, and functions pertaining to the NCI as described under sections 405, 406, 413, and 414 of the PHS Act, as amended.

The NCAB may implement procedures for expediting *en bloc* concurrence of Scientific Review Group recommendations. Several members may be selected by the Chair and/or Executive Secretary to provide *en bloc* concurrence on behalf of the Board.

Only those applications that do not require individual consideration are included in this expedited process. A report of the *en bloc* recommendations is presented at each Board meeting.

Board of Scientific Advisors (BSA)
The BSA (see Appendix D) advises NCI's Director and Deputy Directors, and the Director of each NCI division on a wide variety of matters. Topics include scientific program policy and the progress and future direction of each division's extramural research programs. The BSA's responsibilities include the evaluation of NCI awarded grants, cooperative agreements, and contracts, as well as concept review of those activities that it considers to be meritorious and consistent with the Institute's programs. The advisory role of the Board is scientific and does not include deliberation on matters of public policy. As necessary, the Board and its subcommittees may call upon special consultants, assemble *ad hoc* working groups, and convene conferences, workshops, or other activities.

Board of Scientific Counselors (BSC)
The BSC (see Appendixes E and F) advises the Directors of NCI's Intramural Division of Cancer Epidemiology and Genetics (DCEG) and Center for Cancer Research (CCR) and the Director and Deputy Directors of the NCI, on a wide variety of matters concerning scientific program policy and the progress and future direction of each of the intramural research programs. The BSC evaluates performance and productivity of each division, including the staff scientists, through periodic site visits to intramural laboratories. It also offers advice on the course of programs comprising DCEG and CCR.

Advisory Committee to the Director (ACD)
The ACD (see Appendix H) advises and makes recommendations to the Director of the NCI regarding the oversight and integration of various planning and advisory groups serving the broad programmatic and institutional objectives of the Institute. The Committee serves as the official channel through which the findings and recommendations emerging from these groups are submitted to the NCI. The Committee may consider the reports of the various review groups as sources of information, advice, or recommendations, and will help the NCI to identify opportunities to be pursued in cancer research that cut across the intramural and extramural programs. As necessary, at the call of the Chair, the Committee may call upon special consultants, assemble *ad hoc* working groups, and convene conferences and workshops. These consultants are not members of the Committee and do not participate in any votes or other actions of the Committee.

Director's Consumer Liaison Group (DCLG)
The DCLG (see Appendix G) provides advice and makes recommendations to the Director of the NCI, from the perspective and viewpoint of cancer consumer advocates. The DCLG addresses a wide variety of issues, programs, and research priorities, and serves as a channel through which consumer advocates may voice their views and concerns.

Clinical Trials Advisory Committee (CTAC)
The Committee advises, assists, consults with, and makes recommendations to the Director, NCI, NCI Deputy Directors, and the Director of each NCI Division 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. This encompasses oversight of all trials both extramural and intramural. The Committee will provide broad scientific and programmatic advice on the investment of tax payer dollars in clinical trials and supportive science. This will lead to enormous potential for more specific cancer treatment, coupled with the complexity of evaluating new, highly specific agents integrating knowledge, insights, and skills of multiple fields into a new kind of cross-disciplinary, scientifically driven, cooperative research endeavor. The goal is to foster an open, collaborative system involving all the critical stakeholders in the prioritization process bringing diverse institutions and individuals together into an integrated and efficient, but innovative and responsive effort, thus moving therapies to patients.

Initial Review Group (IRG)
The IRG advises the Director of the NCI, and the Director, Division of Extramural Activities, NCI, on the scientific and technical merit of applications for grants for research, research training, research-related grants and cooperative agreements, or contract proposals relating to scientific areas relevant to carcinogenesis, cancer biology and diagnosis, Cancer Center administration, medicine, radiological and surgical oncology, cancer chemotherapy, cancer epidemiology, cancer prevention and control, cancer education, cancer information services, community outreach, cancer detection and diagnosis, cancer treatment and restorative care, dentistry, nursing, public health, nutrition, education of health professionals, medical oncology, surgery, radiotherapy, gynecologic oncology, pediatric oncology, pathology, and biostatistics. The IRG is composed of several chartered subcommittees that primarily review the following applications: Cancer Centers, clinical trials, program projects, organ site SPOREs, institutional training grants, and career development awards.

PEER REVIEW

INTRODUCTION

Because of the magnitude, diversity, and complexity of its research mission, as well as its pursuit of excellence, the National Institutes of Health (NIH) draws on a national pool of scientists actively engaged in research. These scientists advise the NIH about how to select research projects based on scientific merit.

As discussed in the previous section, the National Cancer Institute (NCI) supports research through three major mechanisms: grants for investigator-initiated projects, cooperative agreements for projects in which programmatic involvement between the NCI and a recipient is anticipated, and research and development contracts for projects that are undertaken in response to NCI Requests for Proposals. All undergo peer review before funding decisions are made.

The dual peer review system of the NIH consists of two sequential levels of review, mandated by statute. Although the system already had been in effect for many years, the first or initial level of peer review of research grant applications was formally mandated in 1974 by Section 475 of the Public Health Service Act. The review of grant applications by national boards/councils was mandated by the National Cancer Act in 1937, and incorporated into the Public Health Service Act in 1944. In 1978, P.L. 95-224 authorized and directed the use of cooperative agreements, which also are subject to peer review.

The NCAB performs the second level of review for NCI grants, as mandated by the National Cancer Act of 1937 and incorporated into the Public Health Service Act in 1944. NCAB members bring to the grant review process their knowledge in each of the relevant programmatic areas. They also are familiar with the NCI priorities and procedures and are aware of the missions of the diverse Institutes in biomedical research as well as the health needs of the American people.

A board or council is composed of both scientific and lay public representatives who are selected for their expertise, interest, or activity in matters related to the mission of the specific Institute for which the board or council serves. Board recommendations are based not only on consideration of scientific merit as judged by the CSR Integrated Review Groups (IRGs) or the NCI Initial Review Group (IRG) or Special Emphasis Panel (SEP), but also on the relevance of the proposed study to an Institute's programs and priorities. By statute, Congress established the National Advisory Cancer Council as the National Cancer Advisory Board.

The dual review system—which separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated—permits a more objective evaluation than would a single level of peer review. It guarantees that the NCI program staff will assess only the programmatic aspects of an application, while the members of the scientific research community evaluate the project's technical merit. This dual system provides the responsible NIH official with the best advice available regarding both scientific and societal values and needs.

LEGAL BASIS FOR PEER REVIEW

The Federal Advisory Committee Act of 1972 (P.L. 92-463), as well as various sections of the Public Health Service Act and its amendments, set forth the legal basis for rules and regulations that govern the creation, operation, and duration of Advisory committees in the Executive Branch of the Federal Government. The PHS Peer Review Regulations (42 CFR 52.12 and 52h) provide for implementation of peer review procedures for grant applications and contract proposals as required by the 1974 amendments to the National Cancer Act (P.L. 93-352). The PHS Grants Policy Statement sets forth PHS guidelines based upon these regulations for the nomination, appointment, and participation of peer review group members and the operation of review committees. The NIH peer review policy is presented in a series of memoranda issued by the NIH Office of the Director.

The following describes the review of grant applications in detail. Review of contract proposals is described on pp. 42-44.

ELECTRONIC SUBMISSION OF GRANT APPLICATIONS

NIH Transitions from Paper PHS398 Grant Application Submissions to Electronic Submission Using the SF424 (R&R) Application

The National Institutes of Health is transitioning from paper submission of grant applications to electronic submission via the Web portal of http://www.Grants.gov, while simultaneously phasing out the PHS398 grant application form and replacing it with the SF424 [Research and Research-related (R&R)] application. This staged transition began in December 2005.

Applications for the research program transitioning receipt date and beyond must be submitted electronically through http://www.Grants.gov. Applications for receipt dates before the transition must be submitted on a paper PHS398 application form. For additional information, please go to http://era.nih.gov/ElectronicReceipt/faq_submission.htm.

CSR INITIAL PROCESSING OF GRANT APPLICATIONS

Receipt and Assignment of Grant Applications

The referral section of the Center for Scientific Review (CSR) serves as the central receipt point for all competing applications, including applications submitted in response to specifically targeted, pre-announced RFAs or program announcements in areas of Institute interest. Exhibit X provides a typical timeframe, from the date of receipt of applications through assignment of applications. Within CSR's Division of Receipt and Referral, referral officers, who are Health Scientist Administrators, determine the relevance of the applications to NIH's overall mission and assign each acceptable application to an appropriate CSR IRG and to an Institute. The choice of an IRG is based upon the relevance of a proposed research project to the review responsibilities of the IRG members, but assignment to an Institute is based upon that Institute's legislatively mandated program responsibility. If the subject matter of an application is pertinent to the mission of two Institutes, a dual assignment may be made. When an application clearly is not appropriate to any of the established IRGs, it usually is assigned to a Special Emphasis Panel (SEP) consisting of experts in that particular field. Applicants are notified by mail of these assignments, usually within 6 to 8 weeks of submission.

To avoid a conflict of interest, an application from a currently active IRG member is not reviewed by the committee on which that member serves. It is assigned to another appropriate IRG or to an SEP, usually consisting of at least five members.

Most NIH Institutes, including the NCI, have established their own review units to review specialized grant applications of high programmatic interest, such as those related to Cancer Control, Cancer Centers, Clinical Cooperative Groups, National Research Service Awards, Clinical Cancer Education Programs, Program Projects, and RFAs and special Program Announcements. The NCI peer review processes are discussed in the "Initial Review Groups" section on p. 32.

Coding of Applications

Grant Application Identification Number

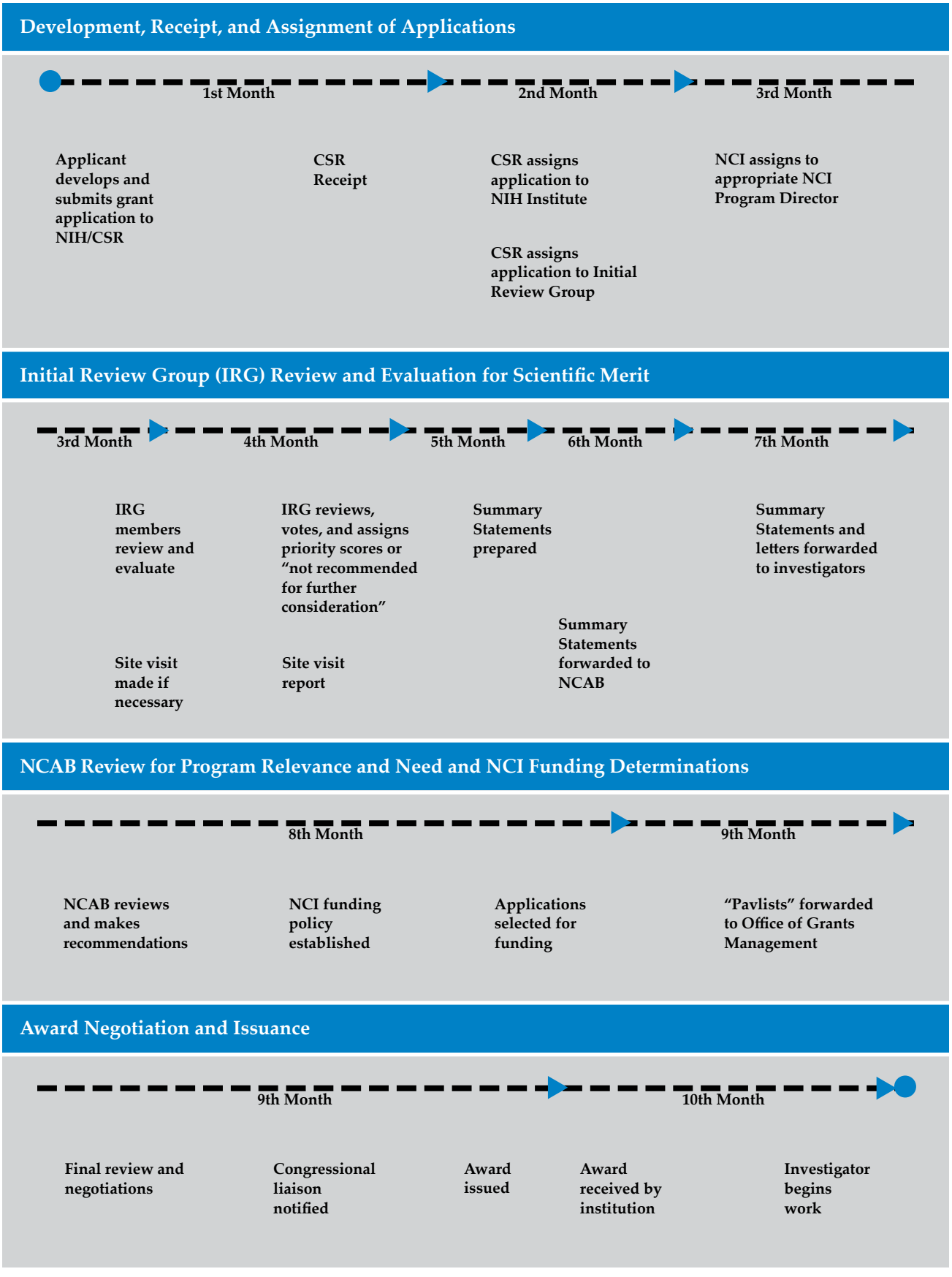
As each new application is received, it is assigned an identification number, checked for completeness, and duplicated. The following is an example of a grant application identification number:

Application Type	Activity Code	Administering Organization Serial Number	Suffix Grant Year	Suffix Other
1	R01	CA 100228	01	A1 or S1

The identification number shows a new (Type 1) application for a traditional research project (R01) assigned to the NCI (CA). The serial number indicates that it is the 100,228th application assigned to the NCI. The suffix (01) shows that this is the first year of support for this project. When the grant year is followed by an A1, it is the first revised or amended application; if followed by an S1, it is for the first supplement. Applicants are allowed to submit two amended applications, for which the serial number of the application remains the same. If an application is submitted for a fourth time, it is given a new grant number.

There are nine application types that may be used to identify a specific grant application. A description of these nine application types is shown on p. 32. Copies of the application then are forwarded to the appropriate Institute and IRG.

Exhibit X. The Grants Process From Receipt to Award: Timeline



The following types of grant applications are designated by the CSR:

Code	Application Type
1	New
2	Competing Continuation
3	Supplement
4	Extension
5	Non-competing Grant Progress Report
6	Change of Institute or Center
7	Change of Grantee or Training Institution
8	Change of Institute or Center (non-competing continuation Type 5)
9	Change of Institute or Center (competing continuation Type 2)

Integrated Review Groups

There are approximately 24 chartered IRGs distributed among the four review divisions within the CSR. Each IRG is administered by a Scientific Review Officer (SRO) and has 5 to 10 Scientific Review Groups, or "study sections," that review applications on specific topics (e.g., cell biology, clinical oncology, pathology, biochemistry, virology), regardless of the awarding NIH Institute assignment. There are approximately 120 study sections in the 24 IRGs (see Exhibit XI). A listing of IRGs and their study sections may be found at the following Web site: http://cms.csr.nih.gov/PeerReviewMeetings/csrirgdescription.

Generally, a study section is composed of 12 to 18 mostly non-Federal scientists who are selected on the basis of recognized competence in their respective research fields. In each of the three review cycles per year, a CSR study section may review between 50 and 100 grant applications.

Each study section is organized and managed by an SRO—an NIH staff scientist who is the designated Federal official responsible for ensuring that the grant applications are reviewed in an impartial environment. SROs are responsible for overseeing the scientific peer review of applications. Their major responsibilities include managing study section meetings, nominating study section members, selecting *ad hoc* reviewers and site visitors, providing orientation for members of review groups, explaining and interpreting the NIH review policies and procedures, managing project site visits and study section meetings (and sometimes site visits), and preparing Summary

Exhibit XI. IRGs Within CSR

AARR	AIDS and Related Research
BBBP	Biobehavioral and Behavioral Processes
BCMB	Biological Chemistry and Macromolecular Biophysics
BDA	Biology of Development and Aging
BST	Bioengineering Sciences and Technologies
BDCN	Brain Disorders and Clinical Neuroscience
CB	Cell Biology
CVS	Cardiovascular Sciences
DIG	Digestive Sciences
EMNR	Endocrinology, Metabolism, Nutrition and Reproductive Sciences
ETTN	Emerging Technologies and Training in Neurosciences
GGG	Genes, Genomes and Genetics
HOP	Health of the Population
HEME	Hematology
IMM	Immunology
IDM	Infectious Diseases and Microbiology
IFCN	Integrative, Functional, and Cognitive Neuroscience
MDCN	Molecular, Cellular, and Developmental Neuroscience
MOSS	Musculoskeletal, Oral and Skin Sciences
ONC	Oncological Sciences
RES	Respiratory Sciences
RPHB	Risk, Prevention and Health Behavior
RUS	Renal and Urological Sciences
SBIB	Surgical Sciences, Biomedical Imaging, and Bioengineering

Statements. They also are responsible for attending advisory board or council meetings to provide requested information in support of the peer review committee recommendations; communicating with program staff on review issues; and discussing review issues and policies with applicants. SROs do not have continuing programmatic, scientific, or fiscal responsibilities for the applications after the scientific peer review is completed.

The IRGs described above are chartered committees the members of which usually serve terms of 4 years. It often is required to recruit *ad hoc* committees to review single or groups of related applications (e.g., Institute review for an RFA). These *ad hoc* committees are referred to as Special Emphasis Panels or SEPs.

Selection of IRG Members

The primary requirement for serving on an IRG or SEP is competence as an independent investigator in a scientific or clinical discipline or research specialty. Assessment of a candidate's competence is based upon the quality of his or her research; publications in refereed scientific journals; and other significant scientific activities, achievements, and honors. Usually, an individual with a doctoral degree or its equivalent is sought. Service on IRGs requires mature judgment, balanced perspective and objectivity, the ability to work effectively in a group context, and commitment to completing work assignments. Personal integrity also is important to assure confidentiality of applications and discussions and to avoid actual or potential conflicts of interest. Other factors also must be considered, such as geographic distribution and adequate representation of ethnic minority and female scientists. Also, in clinical reviews where it is appropriate, patient advocates are recruited and asked to provide personal insights that are relevant to patients' issues.

IRG members are appointed by the Director of the NIH for 4-year terms, which usually begin in July, end on June 30 of the fourth year (regardless of the date of appointment), and normally are not extended. There must be a break in service before a retired reviewer may be appointed to the same NIH committee. However, an individual may serve on another Institute or Center (I/C) IRG, or any other type of advisory committee immediately after his or her term on an advisory committee. In some cases, a person may serve on two committees at the same time if they are in separate I/Cs.

IRG appointments are staggered, so that approximately one-fourth of the membership of a group is replaced each year. Two members from a single institution may be appointed to the same IRG at the same time in the same city if they are in different departments and there is no supervisory relationship. Separate branches of state university systems are considered to be separate institutions. A member may serve on two chartered PHS review committees simultaneously if they are in different I/Cs, and he or she may serve on an SEP *ad hoc* committee.

The Review Session

IRGs (CSR study sections and NCI review committees) and SEPs meet from 1 to 3 months before each meeting of the National Cancer Advisory Board (NCAB). Before the meeting, the SRO of the IRG studies all of the applications assigned to his or her committee and obtains any additional information necessary for the review from the principal investigators or applicant institutions. Six to eight weeks before the meeting date, the SRO assigns each application to two or more members of the IRG, who prepare detailed critiques and lead the discussion of the application at the review meeting. Each member reviews approximately 10 or more applications in detail. In addition, every member is expected to read and comment on as many applications as possible to be reviewed at the meeting. During the three annual meetings, each of which lasts 2 to 3 days, each IRG reviews approximately 85 applications.

The SRO is responsible for providing any information or materials necessary for the review, communicating with applicants, and providing the appropriate I/C advisory board/council with an accurate record of the proceedings in the form of a detailed Summary Statement (see pp. 37-39). At the review meeting, each assigned reviewer makes an initial recommendation to the review group about the merit of each application. (For applicants that have been site visited, two or more members of the site visit team, usually IRG members, will summarize their findings and recommendations, including a budget and project period, for the full parent committee.) A discussion ensues, following which each member of the committee votes on the application's technical merit. Scores are summed and averaged for each application. The meeting is presided over by the chairperson, who is a member of the IRG, nominated by the SRO and appointed by the Director of the NIH. The NCI Director has the authority to appoint IRG members and chairpersons within the NCI.

Criteria for Evaluation

1. **Significance:** Does the study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple Program Directors/Principal Investigators (PD/PI)s, is the leadership approach, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PD/PIs?

3. I**nnovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. **Investigator:** Are the PD/PI(s) and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. **Environment:** Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

6. **Multiple PD/PI Leadership Plan:** For applications designating multiple PD/PIs, a new section of the research plan entitled "Multiple PD/PI Leadership Plan" (Section 14 of the Research Plan Component in the SF424 R&R or Section I of the Research Plan in the PHS 398), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs must be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the Notice of Grant Award (NOGA).

In addition to the above criteria, in accordance with NIH policy, all applications are reviewed with respect to the following:

- The adequacy of plans to include women as well as men, children, minorities, and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects also are evaluated.

- The reasonableness and duration of the proposed budget in relation to the proposed research.

- The adequacy of proposed protection for humans, animals, or the environment (to the extent that they may be adversely affected by the project proposed in the application).

RFAs, which are published in *The NIH Guide to Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html), list the specific criteria for scientific peer review of applications submitted in response to a particular RFA.

The IRG meetings also are attended by staff members of ICs to which applications have been assigned, liaison members for certain other Federal agencies, and appropriate NIH staff. The review of applications is conducted in closed sessions, which are attended only by review committee members and appropriate Institute staff. Exhibit XII shows the yearly NIH grants review schedule.

IRG Recommendations

At present, the possible recommendations by the review committee are: scoring, not scoring, not recommended for further consideration (NR), or deferral (DF). All actions require a majority vote. In the event of a split vote (i.e., when two or more

Exhibit XII. Receipt, Review, and Award Cycles

Application Receipt Dates‡			
Types of Applications	**Receipt Cycle I**	**Receipt Cycle II**	**Receipt Cycle III**
Program Project Grants and Center Grants – All P Series (New, renewal, resubmission, revision*)	**January 25** (old date Feb. 1)	**May 25** (old date June 1)	**September 25** (old date Oct. 1)
Research Grants – R10, R18, R24, R25 (New, renewal, resubmission, revision*)	**January 25** (old date Feb. 1, March 1)	**May 25** (old date June 1, July 1)	**September 25** (old date Oct. 1, Nov. 1)
Research-Related and Other Programs – All S and G Series, C06, M01 (New, renewal, resubmission, revision*)	**January 25** (old date Feb. 1)	**May 25** (old date June 1)	**September 25** (old date Oct. 1)
Institutional Ruth L. Kirschstein National Research Service Awards – T Series (Training)† (New, renewal, resubmission, revision*)	**January 25** (old date Jan. 10)	**May 25** (old date May 10)	**September 25** (old date Sept. 10)
Research Grants – R01 (New)	**February 5** (old date Feb. 1)	**June 5** (old date June 1)	**October 5** (old date Oct. 1)
Research Career Development – All K Series (New)	**February 12** (old date Feb. 1)	**June 12** (old date June 1)	**October 12** (old date Oct. 1)
Research Grants – R03, R21, R33, R21/R33, R34, R36 (New)	**February 16** (old date Feb. 1)	**June 16** (old date June 1)	**October 16** (old date Oct. 1)
Academic Research Enhancement Award (AREA) – R15 (New, renewal, resubmission, revision*)	**February 25** (no change)	**June 25** (no change)	**October 25** (no change)
Research Grants – R01 (Renewal, resubmission, revision*)	**March 5** (old date March 1)	**July 5** (old date July 1)	**November 5** (old date Nov. 1)
Research Career Development – All K Series (Renewal, resubmission, revision*)	**March 12** (old date March 1)	**July 12** (old date July 1)	**November 12** (old date Nov. 1)
Research Grants – R03, R21, R33, R21/R33, R34, R36 (Renewal, resubmission, revision*)	**March 16** (old date March 1)	**July 16** (old date July 1)	**November 16** (old date Nov. 1)
New Investigator – R01 (Resubmission* for those applications involved in pilot ONLY (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html)	**March 20** (no change)	**July 20** (no change)	**November 20** (no change)
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants – R41, R42, R43, R44 (New, renewal, resubmission, revision*)	**April 5** (old date April 1)	**August 5** (old date Aug. 1)	**December 5** (old date Dec. 1)
Individual Ruth L. Kirschstein National Research Service Awards (Standard) – All F Series Fellowships (New, renewal, resubmission*)	**April 8** (old date April 5)	**August 8** (old date Aug. 5)	**December 8** (old date Dec. 5)
Conference Grants and Conference Cooperative Agreements – R13, U13 (New, renewal, resubmission, revision*)	**April 12** (old date April 15)	**August 12** (old date Aug. 15)	**December 12** (old date Dec. 15)
AIDS and AIDS-Related Grants – ALL of the mechanisms cited above (New, renewal, resubmission, revision*)	**May 1** (no change)	**September 1** (no change)	**January 2** (no change)
Review and Award Schedule			
Scientific Merit Review	**June - July**	**October - November**	**February - March**
Advisory Council Review	**September - October**	**January - February**	**May - June**
Earliest Project Start Date‡	**December**	**April**	**July**

* The move to electronic applications also has brought a change in terminology. The new Grants.gov terminology (included in the table above) corresponds to traditional NIH terms as follows: New = new; Resubmission = a revised or amended application; Renewal = Competing Continuation; Continuation = Noncompeting Progress Report; Revision = Competing Supplement.

† **Institutional Research Training Grants (T32)** are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates.

‡ Applicants should contact the relevant IC for specific dates.
http://grants.nih.gov/grants/guide/notice-files/not-od-07-001.html

IRG members disagree with the majority), the recommendation is based on the majority vote, but the minority opinion is recorded in the Summary Statement. An application may be deferred if additional information is needed to make a definitive recommendation.

If an application has significant and substantial scientific merit, it is given a priority score and, in the case of CSR-reviewed applications, a percentile ranking is calculated for the application. An action for scoring is equivalent to a recommendation that a grant be awarded, provided that sufficient funds are available. If it does not meet these standards, it is "not recommended for further consideration" or, in the case of streamlined review, simply not scored. In the streamlined review process that is implemented at the NIH (particularly for single-project applications), the reviewers identify but do not discuss or score applications that are not in the top half of the applications being reviewed by that committee for that round. For reviews of applications received in response to an RFA, reviewers may be asked to identify the applications that are not in the top half of the group of applications under review. Reviewers' critiques of unscored applications are provided as feedback to grant applicants.

Priority Scores

To determine the priority score, each IRG member assigns a numerical rating that reflects the reviewer's assessment of the scientific merit of the application, relative to the state-of-the-art in the particular field. The numerical ratings range from 1.0 (best) to 5.0 (worst) with increments of 0.1. After the review meeting, the SRO averages the individual reviewers' ratings for each scored application and multiplies by 100, to provide a three-digit number that is the priority score. At this point in the grant application review process, 4 to 5 months have elapsed since the principal investigator submitted the application (see Exhibit XII).

Percentile Rank

In addition to a priority score, most applications reviewed by the CSR receive a percentile rank. The percentile rank represents the relative position of each priority score (along a 100.0 percentile band) among the scores assigned by the IRG during the current round of the study section plus the previous two rounds. Applications reviewed by NCI review groups receive priority scores only, and percentile ranks are not calculated for these applications.

The overall intent of percentile ranking (or "percentiling") is to improve the comparability of scored applications across study sections and IRGs, and to minimize the impact of round-to-round quality variation. When applications are being considered for funding within an Institute, the percentile/priority score is the primary indicator of relative scientific merit.

Summary Statements

Immediately after the IRG meeting, the SRO prepares individual reports summarizing the recommendation for each application, called Summary Statements. The Summary Statement consists of:

- the Resume and Summary of Discussion prepared by the SRO;
- the applicant's description of the proposed research;
- the essentially unedited comments prepared by the application's reviewers;
- the priority score; and
- the budget and project term recommended.

Special notations also may be included, such as a split vote, a potentially hazardous experimental procedure, or a concern about the welfare of laboratory animals or human subjects.

Before the three annual grant review meetings, copies of Summary Statements are posted on the Web as part of the Electronic Council Book. Before the NCAB meets, applicants routinely are provided with copies of their own Summary Statements by accessing the document using the NIH Electronic Research Administration Commons. Upon completion of advisory board action, the principal investigator and applicant institution are notified of the Board's concurrence or nonconcurrence with the study section recommendation. Exhibit XIII is an example of a Summary Statement.

Appeal of an IRG Recommendation

If the principal investigator believes that the review was affected by bias, conflict of interest, insufficient or inappropriate expertise, or factual errors, he/she may appeal the recommendations of the committee. Applicants who disagree with the assessment of the review group may contact the Program Director to discuss the Summary Statement

Exhibit XIII. Example of a Summary Statement

SUMMARY STATEMENT
(Privileged Communication)

Rebecca Sanders
301-496-2331
progofficial@nih.gov

Release Date: 06/24/2004

Application Number: 1 R01 CA100228-01

MARTIN, ANDREW, PHD
MASSACHUSETTS RESEARCH INSTITUTE
500 ASPEN LANE
CONCORD, MA 02134

Review Group: Behavioral Medicine Study Section - BEM

Meeting Date: 06/09/2004
Council: SEPT/OCT 2004 *PCC:* 8MPC
Requested Start: 02/01/2005

Project Title: Community Intervention to Reduce Adolescent Tobacco Use

SRG Action: Priority Score: 135 Percentile: 5.3
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 3A-No children included, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	225,000	337,500
2	225,000	337,500
3	225,000	337,500
4	225,000	337,500
TOTAL	900,000	1,350,000

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

Exhibit XIII. Example of a Summary Statement (Continued)

RESUME AND SUMMARY OF DISCUSSION: This is an application to compare the impact of school-based with community-based intervention on adolescent tobacco use. This is an excellent proposal that should provide insights into a most difficult problem.

This application is rated with a priority score of 135.

DESCRIPTION (provided by applicant):
The project is designed to evaluate the effects of a community intervention aimed at reducing the prevalence of adolescent tobacco use. Fourteen small communities will be randomly assigned to receive a community intervention plus a school-based prevention program or to receive a school-based progam alone. The community intervention is designed to mobilize community leaders and organizations to modify environmental influences on adolescent tobacco use so that experimentation is reduced, experimenters are prevented from becoming regular users, and regular users are encouraged to quit. Task forces will be created to (a) conduct media campaigns that promote nonuse of tobacco by adolescents, (b) increase parental skill and efforts to promote adolescent nonuse of tobacco, (c) increase screening and counseling of adolescents to encourage quitting or remaining tobacco free, (d) reduce access to tobacco products and situations in which to consume them, and (e) increase incentives for adolescent nonuse of tobacco. The study will also examine the effects of the community intervention on efforts of community organizations and leaders to affect adolescent tobacco use.

Finally, the study will examine the relationship between adolescents' exposure to social influences not to use tobacco and their attitudes, intentions, and actual use. Data from panels of seventh and ninth grade students who are followed over 2- and 3- intervals will be used to achieve this aim.

CRITIQUES

The written critiques of individual reviewers are provided in essentially unedited form in the "Critique" section below. Please note that these critiques were prepared prior to the meeting and may not have been revised subsequent to any discussions at the review meeting. The "Resume and Summary of Discussion" section above summarizes the final opinions of the committee.

CRITIQUE 1

Significance:
Evaluating the effects of community intervention aimed at reducing the prevalance of adolescent tobacco use is extremely important in developing and refining these health-related efforts.

Approach:
The project is well designed and is expected to provide important information about the effects of community intervention aimed at reducing the prevalence of adolescent tobacco use.

Innovation:
This project has several innovative aspects.

Investigator:
Dr. Martin, Principal Investigator, is a 1973 Ph.D. from the Ohio State University in Social Psychology. He is currently a Research Scientist at the Massachusetts Research Institute, Concord, Massachusetts, and lists 7 published book chapters, 5 manuscripts in submission, and 38 publications in refereed journals in areas relevant to the grant application.

Exhibit XIII. Example of a Summary Statement (Continued)

Environment:
The environment at Massachusetts Research Institute is highly supportive of the proposed project.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMININSTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN: ACCEPTABLE

INCLUSION OF CHILDREN: ACCEPTABLE

INCLUSION OF MINORITIES: ACCEPTABLE

INCLUSION OF VERTEBRATE ANIMALS: NONE

COMMITTEE BUDGET RECOMMENDATIONS The budget is high for the tasks planned. Therefore, the budget is reduced by one module.

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address: http://grants.nih.gov/grants/policy/amendedapps.htm
NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in $25,000 modules, without budget detail for individual categories. Further information can be obtained from the Modular Grants Web site at http://grants.nih.gov/grants/funding/modular/modular.htm

[A list of reviewers (not included here) is a part of the summary statement.]

and the situation relative to the application. Most often, the applicant revises and resubmits the application.

If the applicant feels that there were significant problems with the review of the application, he or she must submit to the assigned Program Director a letter or e-mail describing the concerns with the review. That correspondence also must be copied to the institutional official who signed the face page of the application. (Note that differences of scientific opinion are not appealable.) The Program Director then will prepare documentation regarding the appeal and a recommendation to the NCAB indicating what action the Program Director recommends. The appeal letter, along with the Program Director's recommendation and a copy of the Summary Statement, are sent to those NCAB members to whom the application has been assigned. After reviewing the appeal information and discussing the appeal with the Program Director, the NCAB member decides whether the appeal is brought to the full attention of the NCAB for discussion in the closed session.

Resubmission

When an application is revised and resubmitted, it should have been structured in the following way. The introductory section of the amended application should contain: (1) a documented response to the criticisms raised by the IRG (new information, corrections, or other changes to remedy the deficiencies pointed out in the Summary Statement); (2) an indication of the modifications to the application that reflect the areas of criticism with which the principal investigator agrees. Although the principal investigator may request a change in IRG assignment, CSR retains the authority to determine whether or not an amended (or revised) application should be reviewed by a different IRG.

Project Site Visits

The purpose of a project site visit is to give the reviewers an opportunity to gather information not available in the written application, in order to make a final evaluation regarding the merit of the application. The CSR SRO usually assembles a project site visit team of three to five reviewers. Site visits enable the reviewers to meet with the principal investigator and other researchers, view the facilities, and raise questions or discuss research objectives. The NCI Program Director generally attends the site visits to provide program information, if needed, and to gain a better understanding of the project and the reviewers' recommendations. In some cases, either at the request of the SRO, Program Director, or Grants Management Officer, a grants management specialist or an administrative consultant will attend the site visit to provide business and administrative expertise. Following the site visit, reports based upon the site visit team's observations and findings are prepared for presentation at the IRG meeting.

Approximately 1 percent of the research grant applications reviewed by the CSR require a project site visit before the study section can complete its assessment. Sometimes this requires deferral of the review to the next review cycle, to allow time for conducting the site visit.

By contrast, as described in the previous section, several types of applications reviewed by the NCI review committees were site visited because of the specialized and complex nature of their applications. Large, complex applications (such as those for Cancer Center support and clinical trials cooperative groups) routinely require a project site visit by a team of 5 to 15 expert consultants, depending upon the number of individual program components and disciplines involved. Several members from the appropriate NCI chartered "parent" committee, as well as *ad hoc* consultants, form the site visit team.

Due to the continuing increase in the number of program project grant applications received by the NCI for review, a committee composed of NCI extramural staff from all of the program divisions and the DEA recommended a pilot of a two-tier, non-site visit cluster review process for P01 applications reviewed for funding in FY05 and FY06. After evaluation of the cluster review pilot in late 2005, the committee recommended a pilot of review of P01 applications by a single-tier, "paper only" review process for applications reviewed for funding in FY07 and FY08.

In the single-tier review pilot, all P01 review panels are constituted as SEPs. The applications are grouped by science, and each SEP may include up to 10 applications, although they usually include between 5 and 8 applications. There are usually five SEPs: Molecular Biology; Cellular and Tissue Biology; Discovery and Development; Clinical Studies; and Prevention, Control, and Population Sciences. The SEPs include members of NCI IRG subcommittees C, D, and E as well as additional scientists with appropriate expertise for the applications being reviewed. The SEP reviewers evaluate

and score projects, cores and integration, and then assign the overall priority score for each application.

A formal evaluation of the single-tier P01 review process was undertaken in early 2008. The results showed that the single-tier review process promotes more consistent scoring of the applications and is fair to all applicants. The single-tier review process makes very efficient use of reviewers and their time and effort without compromising the quality of the review. The single-tier review process also is more efficient for NCI review and program staff and saves a significant amount of money. Structured reviewer feedback collected during each review meeting indicates that reviewers also like the new process, and that they feel that all necessary expertise is present on the SEPs and that the process is fair, thorough, and objective. Based on this evaluation, the NCI Executive Committee recommended continuation of this review format for P01 applications.

NCI INITIAL REVIEW

NCI Referral of Grant Applications: Program Assignment

As the central receipt and distribution (referral) point, the CSR assigns applications to the NCI based on negotiated criteria (referral guidelines). Then, the NCI Referral Office refers all applications assigned to the NCI by CSR to one of the 45 NCI extramural research program areas. The NCI Referral Office staff assigns all incoming applications, tracks their review status, and distributes them to the appropriate NCI Program Director. In FY2007, 12,147 grant applications were received for referral.

NCI Review of Grant Applications

The NCI conducts its own initial review of certain specialized or complex cancer-oriented applications, including Research Program Projects, Cancer Center Support Grants, Cooperative Clinical Research Grants, Conference Activities, Research Demonstration and Dissemination Projects, SPOREs, SBIRs, and others. These reviews are conducted by either NCI chartered or *ad hoc* SEP peer review committees. In FY2007, the DEA reviewed 2,100 grant and cooperative agreement applications.

NCI SROs take advantage of several electronic approaches to assist in the peer review process. First, they use CDs to collate the electronic grant application files for their meetings and distribute those CDs to their peer reviewers. The CD approach reduces printing, processing, and mailing costs. Second, SROs take advantage of a system known as Internet Assisted Review (IAR). IAR is a Web-based system that allows peer reviewers to post their preliminary priority scores and critiques to a central NIH site. This utility facilitates and expedites the premeeting review process and the postmeeting production of Summary Statements.

Four branches are responsible for organizing, managing, and reporting the scientific peer review of applications for a wide variety of grant mechanisms: the Research Programs Review Branch (RPRB), the Special Review and Logistics Branch (SRLB), the Resources and Training Review Branch (RTRB), and the Program Coordination and Referral Branch (PCRB).

The RTRB has primary responsibility for reviewing applications for Cancer Centers, cancer training and career development, and cancer clinical trials, as well as for managing the corresponding six standing subcommittees of the NCI IRG*:

Subcommittee A	Cancer Centers
Subcommittee F	Manpower and Training
Subcommittee G	Education
Subcommittee H	Clinical Trials
Subcommittee I	Career Development
Subcommittee J	Population and Patient-Oriented Training

The RPRB has primary responsibility for reviewing unsolicited P01s and applications for SPOREs in various organ sites. It also manages the three subcommittees of the NCI IRG that are responsible for review of program project grant applications, although the subcommittees have not been convened during FY07 or FY08 during the pilot of the single-tier P01 review process. The RPRB standing subcommittees are:

Subcommittee C	Basic and Preclinical Research
Subcommittee D	Clinical Studies
Subcommittee E	Cancer Epidemiology, Prevention, and Control

The SRLB is responsible for the review of most applications submitted in response to the initiatives published by the Institute, including RFAs, PAs, and RFPs. All of these reviews are conducted by SEPs and include the following types of mechanisms: P50, R03, U19, U54, U56, SBIRs (R43 and R44s), and STTRs (R41s and R42s). The PCRB provides review support for several grant applications, including conference grants (R13).

*Subcommittee B (Comprehensiveness) was terminated in June 1996.

The various committees are responsible for advising the NCI Director and the NCAB concerning the scientific and technical merit of grant applications assigned to the NCI for the initial review, which addresses each application's scientific merit in terms of its discipline and the clinical implications of its research protocol. This review is conducted according to the established NIH procedures described in the CSR Initial Review section (p. 30). With the exception of the parent committees used to review P01 and Cancer Centers, Summary Statements are prepared in the same general format that is used by the CSR.

Once a grant application receives an NCI program assignment, an NCI Program Director follows its progress through the review process and, if an award is made, through the post-award period. For the duration of that project period, the Program Director is the contact point, negotiator, advisor, and advocate for the principal investigator. This individual evaluates the relevance of the research, considers the appropriateness of the appraisal by the study section, and makes recommendations to the NCAB regarding any need for special action in a particular case.

Selection of NCI Review Committee Members

The NCI policy for selecting review committee members specifies that, within a given IRG, representation of scientific disciplines, clinical specialties, or technical areas must reflect a proper balance of subspecialties to cover the range of applications being reviewed. The SRO of each NCI review committee, who determines which specialties are needed within that group, is assisted by NCI program and administrative officials. In the case of the standing subcommittees identified above, the final decision on nominations for NCI review subcommittee members is made by the Director of the DEA. Appointments to the committees are made by the Director of the NCI. Members of the NCI review subcommittees serve overlapping terms of up to 4 years.

Since 1996, DEA SROs have worked with the NCI Office of Advocacy Relations to identify non-scientist advocates who are able and willing to participate in the peer review process. These advocates, individuals who are either cancer patients or relatives of cancer patients, assist in the peer review of applications in which human subjects are involved. They assess issues related to:

- factors that may affect study design;
- feasibility of plans for recruitment/retention and follow-up of subjects;
- feasibility of protocols with specific populations (e.g., complexity, compliance);
- clarity and patient acceptability of protocols;
- feasibility of protocols in the context of total patient care;
- cultural and socioeconomic aspects of protocol implementation;
- outreach and special challenges (e.g., need for multicultural staff);
- Community Advisory Board (e.g., composition and role);
- ethical issues, human subjects protection, adequacy of consent forms; and
- inclusion of women/minorities/children in the trial.

CSR/NCI Interface

Because of the structure and mechanics of the assignment process, the relationship between the NCI and CSR is continuous, dynamic, and interactive. During the assignment process, there is interaction between referral officers and the SRO of the IRG to which the application is assigned. After the assignments are made and the IRGs and the NCI have received copies of the applications, SROs and NCI staff examine the appropriateness of the assignments to the IRGs. In cases of questionable assignments, the referral officers and SROs discuss the application. If no agreement is reached, the final decision is made by the Office of the Director in the Division of Receipt and Referral (DRR) of CSR. Questions regarding assignments usually are handled by the Office of the Deputy Director (DRR), which makes the final determination, after conferring with the NCI staff and the Referral Officer.

CSR staffers also review questions from applicants who have been notified about the assignment of their applications. Following discussions involving the Referral Officer and the appropriate SROs, a final decision is made by the Director, DRR, CSR.

Review of Contract Proposals

The NCAB has no direct involvement with the Research and Development (R&D) contract program of the NCI; R&D contract concepts are reviewed by the BSA.

The contract solicitation process begins when an NCI program staff member (usually the individual who will become the Project Officer) develops a concept for a contract project through personal initiative, discussion with advisory groups, consultation with others in the program, and/or interactions with members of the scientific community. The relevance, priority, and need for the anticipated project are assessed by NCI program staff, and the concept is subjected to a series of internal clearances, including review by the Executive Committee of the NCI. Federal regulations (the 1974 Amendments to the National Cancer Act and Section 75 of the Public Health Service Act) require presolicitation peer review of the project concept before an RFP may be issued. NCI policy requires concept review of all intra- and interagency agreements, and all renewals and recompetitions of existing contracts and extensions of $100,000 or more for a 6-month or longer period. This review is performed by the BSA.

In reviewing a project concept, the BSA evaluates a proposed concept according to the following criteria:

- congruence of the proposed project with the missions and objectives of the Institute;
- scientific merit of its purpose, scope, and objectives;
- appropriateness of the period of performance for accomplishing project objectives;
- proper classification of the proposed project as a resource or research contract and competitive or noncompetitive contract; and
- consideration of whether the proposed project should be supported using the grant mechanism or cooperative agreement instead of a contract.

Once a concept is approved and recommended to the Division Director, the Project Officer, consulting with the Contracting Specialist in the NCI Office of Acquisitions (OA), prepares a statement of work and evaluation criteria. The documents are incorporated into a Request for Contract Project Plan, which is the basis for the official RFP. This document then is presented to the division's senior scientific and management staff for review, comment, and approval. A copy of the plan also is forwarded to the DEA to help verify the evaluation criteria and establish a timetable for the procurement process. The final version of the project plan is incorporated into the RFP by the Contracting Officer, in conjunction with the Project Officer. RFPs must be published in the *Commerce Business Daily* and/or the *NIH Guide for Grants and Contracts*. Occasionally, an RFP may receive wider distribution through publication in scientific journals. Proposals are received by the OA and are checked to be sure they fulfill the RFP requirements and conform to Federal regulations.

R&D proposals that are submitted by the private sector in response to an RFP are evaluated for technical merit by *ad hoc* SEP review groups in a manner similar to that used for the peer review of grant applications. The purpose of the technical merit review is to obtain expert advice on the qualifications of the offeror's staff, the merit of the scientific/technical approaches, the sufficiency of staff and institutional experience, and the availability of equipment and facilities. A DEA SRLB staff member serves as the SRO for each contract review committee. The SROs schedule review sessions, send proposals to committee members in advance of the sessions, and supervise the preparation of the contract review summary reports—brief synopses of the review sessions that contain the numerical scores (as required) and reflect the deliberations and considerations of the reviewers.

In arriving at their recommendations, the peer review committee reviews each proposal. The results of its deliberations are documented by the NCI SRO, who makes the committee findings available to the Contracting Officer. At least three reviewers are assigned to report in depth on each contract proposal during the review meeting. Proposals are reviewed for technical merit and rated for conformance to the evaluation criteria published in the RFP. If competitive, they are scored independently by each committee member, based upon the weighted review criteria in the RFP. The individual scores are totaled and averaged to produce a technical merit score for each proposal. Concurrently but independently, the OA evaluates proposals for business considerations.

Project Officers are the NCI program staff members who are responsible for developing and supervising the contract projects. They attend review meetings to provide factual information, but are not permitted to make judgmental or evaluative comments. Representatives of the OA must attend the review sessions to provide guidance on policy and regulations. Review is conducted in accordance with Federal conflict-of-interest regulations, summarized on pp. 48 and 50.

Following the review session, the SRO forwards the minutes containing the scores, ranking, and individual rating sheets to the Contracting Officer of the OA, who then convenes a Source Evaluation Group (SEG). This group usually consists of the Project Officer and other program staff members, who advise the Contracting Officer on the establishment of a competitive range, based upon technical merit scores, cost, and other considerations. Occasionally, site visits are determined to be necessary subsequent to completion of the technical review.

The Contracting Officer informs each offeror in the competitive range of the proposal's deficiencies, ambiguities, or other considerations, as identified by the reviewers or members of the SEG. Offerors are given an opportunity to make minor adjustments in their proposals, which then are reviewed by the contracting and program staff, who serve as a Source Selection Group (SSG). The final decision regarding award of a contract rests with the Contracting Officer who arranges for negotiations with the prospective contractor with advice from the SSG. The total contracting cycle requires 9 to 10 months from receipt of proposals to issuance of an award. Exhibit XIV portrays the NCI contract review process.

Following award, the NCI Project Officer performs project surveillance, assisted by the OA. The OA is responsible for debriefing competitors.

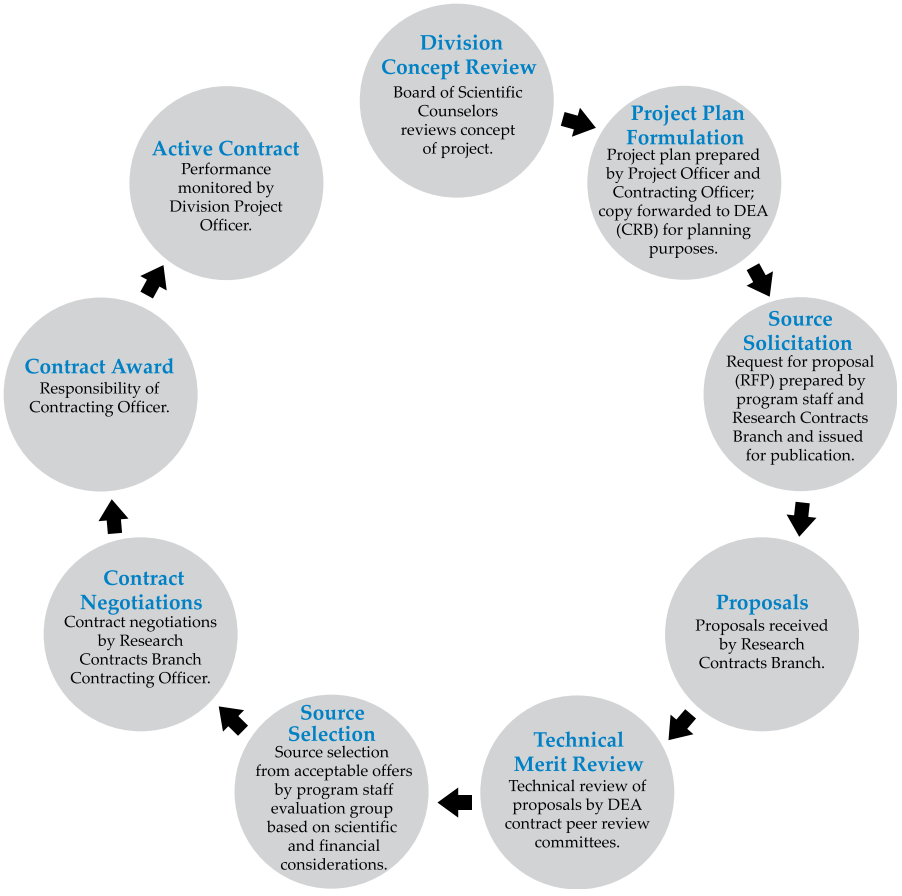
NATIONAL CANCER ADVISORY BOARD REVIEW

NCAB Responsibilities

The National Cancer Advisory Board is responsible for the final review of all grant applications referred to the NCI. The Board recommends to the Director of the NCI approval of meritorious grant applications. The NCAB appraises all grant applications with reference to the needs of the Institute and the priorities of the National Cancer Program. The review responsibilities of the NCAB are shown in Exhibit XV.

The Health Research Extension Act of 1985 changed the reporting requirements of the NCAB. Rather

Exhibit XIV. NCI Contract Review Process



than submit a separate, annual report on the progress of the National Cancer Program to the Secretary of the DHHS, the NCAB may prepare comments on the Board's activities and the NCI's progress in meeting its objectives, then make recommendations regarding future directions of the NCI. These comments then would be included in the NCI's biennial report, which in turn is included in the NIH Director's biennial report to the President and to Congress. In addition, the Federal Advisory Committee Act requires that the President report annually to the Congress on advisory committees. This report is prepared by each IC Committee Management Officer; the General Services Administration compiles the information from each agency and submits the report to the President. The President forwards the report to Congress.

Exhibit XV. Grant Review Responsibilities of the NCAB

Receive and Review Materials (Prior to a Board Meeting)

- Summary Statements
- List of all applications identified by IRG as having ethical problems, such as biohazard risk, gender, etc.
- List of applications determined to have biohazard risks or animal welfare problems (no action required).
- List of merit award nominations and extensions.
- List of foreign grants meeting criteria for funding.
- Staff recommendations for special actions.

Actions To Be Taken

- Present subcommittee recommendations to the full Board.
- Review staff recommendations for special actions.
- Act on IRG recommendations.
- Review and approve guidelines delineating the NCI staff administrative responsibility.

NCAB Legislative Authority

In 1937, P.L. 75-244 established the National Advisory Cancer Council to advise the newly created NCI. In 1971, the National Advisory Cancer Council was renamed and restructured as the 23-member NCAB by P.L. 92-218, the National Cancer Act. In accordance with P.L. 92-453, the Federal Advisory Committee Act, the NCAB was chartered by the Secretary of the DHHS. The Board's mandate is continuous, although the NCAB is rechartered every 2 years.

The Biomedical Research and Training Amendments of 1978 (P.L. 95-6221) further expanded the membership and responsibilities of the Board, with particular emphasis on the areas of environmental and occupational carcinogenesis. The Board now consists of 30 members, 12 of whom are *ex officio*, nonvoting members and 18 of whom are voting members. The Director of the DEA serves as the Executive Secretary of the Board. The Health Research Extension Act of 1985 did not significantly change the authority or responsibility of the NCAB.

NCAB Composition

NCAB Voting Members

The NCAB is composed of 18 voting members, who are appointed by the President based upon their training, experience, background, and qualifications to evaluate the programs of the NCI. Members serve overlapping terms of 6 years, and they may serve after the expiration of their terms until successors have been appointed. The President designates one of the appointed members to serve as Chair for a term of 2 years.

The National Cancer Act of 1971 (P.L. 92-218) and the Health Research Extension Act of 1985 (P.L. 99-158) specify that two-thirds of the appointed members should be leading representatives of the health and scientific disciplines relevant to cancer, and one-third of the members should be from the general public, including leaders in the fields of public policy, law, health policy, economics, and management. P.L. 99-158 continues the requirement that five or more of the appointed members be knowledgeable in environmental carcinogenesis, including occupational and dietary factors.

NCAB *Ex Officio* Members

Ex officio members of the Board include the following officials or their designees:

- Secretary of DHHS;
- Director of the Office of Science and Technology Policy;
- Director of NIH;
- Chief Medical Director of Veterans Affairs;
- Director of the National Institute for Occupational Safety and Health;
- Director of the National Institute of Environmental Health Sciences;
- Secretary of Labor;
- Commissioner of the Food and Drug Administration;
- Administrator of the Environmental Protection Agency;
- Chairman of the Consumer Product Safety Commission;
- Assistant Secretary of Defense for Health Affairs; and
- Director of the Office of Energy Research of the Department of Energy.

NCAB Meetings

The Board meets at the call of the Director of the NCI or the Chairperson, not less than four times a year. Meetings usually last 3 days. Summary Statements are reviewed three times per year at regularly scheduled meetings. The December NCAB meeting is reserved for the NCI intramural laboratory and extramural program review.

NCAB meetings are open to the public when Summary Statements are not being discussed. Scheduled NCAB meeting dates are published in the *Federal Register* (http://www.gpoaccess.gov/fr/index.html), as required by DHHS regulations. Attendance at the closed grant review sessions is limited to Board members, Scientific Review Officers, the NCI Director, appropriate NCI staff, and desig-nated representatives of the Secretary of DHHS. A quorum for conducting business will consist of a majority of the currently appointed members.

Approximately 6 to 8 weeks before the NCAB meeting, Summary Statements within the competitive range for applications to be reviewed at the upcoming meeting are made available to all NCAB members via the NIH Electronic Council Book (ECB). This is a restricted access Web site that allows NCAB members to view all of the Summary Statements, as well as the grant applications assigned to them for review based upon their areas of scientific interest. (*Note:* NCAB members are not given access to Summary Statements from their own institutions.) By the time the NCAB meets, approximately 1,500 Summary Statements will have been made available to the Board members. As described in its Charter, a key role of the NCAB is to "...advise, assist, consult with, and make recommendations to the Secretary, and the Director, National Cancer Institute, ...relating to support of grants and cooperative agreements, following technical and scientific peer review..." This important function is accomplished in the closed session of the NCAB meeting by a committee of the whole known as the Special Actions Subcommittee.

NCAB Subcommittees

To expedite the Board's work, five standing subcommittees and four *ad hoc* committees have been established to provide individual review of applications requiring special attention or detailed discussion, and to handle other Board-related business as necessary. The subcommittees are:

- Subcommittee on Activities and Agenda
- Subcommittee on Cancer Centers
- Subcommittee on Clinical Investigations
- Subcommittee on Planning and Budget
- Subcommittee on Special Actions
- *Ad Hoc* Subcommittee on Biomedical Technology
- *Ad Hoc* Subcommittee on Communications
- *Ad Hoc* Subcommittee on Confidentiality of Patient Data
- *Ad Hoc* Subcommittee on Experimental Therapeutics

Each Board member is assigned to serve on one or more of the above subcommittees. (*Note:* The

Subcommittee on Special Actions functions as a Committee of the Whole.) Subcommittee meetings are announced in the *Federal Register*. During the NCAB meeting, each subcommittee chairperson makes a report of current activities. After discussion, the NCAB votes for the acceptance, rejection, or modification of each report.

Special Actions Subcommittee

NCI's Division of Extramural Activities prepares for review by the NCAB special reports detailing grant applications that involve human subjects, animal welfare, biohazard risks, foreign grants, and inadequate representation/justification of gender, minority and children. The latter materials are posted on the ECB 1 to 2 weeks prior to the NCAB meeting. In addition to these special reports, all NCAB members receive MERIT (Method to Extend Research in Time) Award nominations and extensions, as well as appeal letters from principal investigators who disagree with IRG recommendations. The MERIT and appeal documentation is sent by courier to NCAB members.

Because MERIT Award extensions do not go through a formal peer review process before coming to the NCAB, the Office of General Council has ruled that the NCAB must serve as the locus of review for all MERIT Award extensions. The Executive Secretary of the NCAB asks two members of the Board to serve as peer reviewers for each MERIT extension. These reviews are discussed in the closed session. MERIT Award nominations and extensions are voted upon individually by the Board.

If a Board member has a question about an application or thinks that additional information would be helpful, he/she is encouraged to contact the NCI Program Director responsible for that application. The Program Director's name and telephone number appear in the upper left-hand corner of each Summary Statement. Further discussion of applications requiring special consideration may take place during the full Board meeting in closed session.

Applications that may require special consideration or detailed review include those in which:

- a policy issue has been identified;
- there is a split vote or minority recommendation by the IRG;
- some aspect of the recommendation from the IRG is questioned; or
- the research proposed is of particular interest or concern.

Foreign Grants: Applications from foreign institutions must be brought to the attention of the Board and identified for possible funding. These applications are reviewed for concurrence with the NIH policy on foreign grants. Grant applications from domestic institutions, which contain substantial foreign components, do not require special NCAB concurrence, except when special considerations are involved (e.g., unusually large budget for the foreign component, potential controversy, or other extenuating factors).

IRG Concerns: All applications for which reviewers have concerns about or objections to the participation of human subjects must be individually called to the attention of the Board, whether or not the IRG has recommended them for scoring. The Board is routinely informed of applications for which an IRG has expressed concern about any biohazard, animal, child, gender, or minority welfare concern. Information items may be presented to the Board by NCI staff as appropriate.

Delegated Authorities: Every year at the February NCAB meeting, the members of the Board are asked to reapprove several authorities that deal with the Institute's ability to: (1) appoint special experts for limited service; (2) appoint advisory committees to advise the Director; and (3) expeditiously manage the NCAB review of grant applications. In the latter case, the authorities describe and reaffirm the NIH-wide policies used to manage Board review. These include the following: Individual National Research Service Award Applications (postdoctoral fellowships) also are exempt from this presentation requirement. In addition, applications over the 50th percentile will not have their Summary Statements presented to the NCAB unless the Institute is considering an award. Applications assigned raw scores that are not percentiled will not be presented to the NCAB if the score is lower than 250. Expedited concurrence is reaffirmed. Finally, the Board delegates to the Director of the NCI permission to allow staff to negotiate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards for those applications recommended by the Board.

Expedited Council Concurrence

The NCI has implemented a procedure to streamline the concurrence with IRG recommendations to expedite funding actions by the Institute. The expedited NCAB approval process is used for

percentiled R01s reviewed by CSR and for all R21s, except for those applications submitted in response to a set-aside (RFA or PA with a set-aside). The Executive Secretary of the NCAB selects four members of the NCAB to provide *en bloc* concurrence on behalf of the entire NCAB, and the Institute establishes a "range of consideration." For every application within the "range," the name of the principal investigator, institution, project title, and priority score/percentile are provided. As the CSR IRGs meet and their scores are added to the NIH IMPAC 2 database, the four NCAB members mentioned above receive periodic e-mail notifications regarding applications that await their review and expedited council concurrence.

Applications do not undergo expedited review if they involve foreign institutions or if the Summary Statement expresses concerns with regard to human subjects, animal welfare, biohazards, or inadequate representation/justification of gender and/or minorities and/or children. (*Note:* Any application can be identified for NCAB discussion and removed from this process by any NCAB member.) The NCAB members approve grant applications using the NIH ECB expedited process, and a notification letter is sent to the principal investigator by the Grants Administration Branch of the NCI, notifying the principal investigator of the NCAB's approval and plans for expedited funding.

Nonconcurrence

Usually the Board concurs with the initial reviewers' recommendations. On occasion, however, the Board may vote to change the IRG recommendations in the following ways:

- If the NCAB disagrees with an initial review based upon scientific or technical merit, the action is deferral. The application is returned for a second review by either the same or a different IRG. If, after deferral and a second review, the NCAB still wishes to change the recommendation, it may do so.

- The NCAB may recommend that an application be considered for exception funding, in which case the application need not be returned to the IRG for an additional review.

- The NCAB may recommend that an application receiving a favorable recommendation in initial review not be considered for support for reasons other than lack of scientific or technical merit.

- In the case of a split vote from the IRG, the NCAB may accept the minority opinion without returning the application for further review.

- The NCAB may reverse an "unscored" recommendation from an IRG and recommend that the application be considered for exception funding.

In all cases of nonconcurrence with the IRG recommendation, within 10 working days after the NCAB meeting, the NCAB must communicate to the SRO of the IRG its rationale for questioning or disagreeing with the IRG decision.

Mail Ballots

In some circumstances, a grant application does not come before the full Board for review; instead, the Summary Statement is sent to individual Board members for review by mail ballot (see Exhibit XVI). Board members may vote by fax for concurrence or nonconcurrence with the IRG recommendations. They may note any questions or concerns regarding an application on the mail ballot; if necessary, the issue is raised at the next full Board meeting. Applications requiring immediate attention are handled in this manner.

Conflict of Interest

Members of the NCAB 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 (130 days maximum), SGEs must be aware of relevant statutes regarding criminal conflicts of interest, and they must follow defined standards of ethical conduct.

The Office of Government Ethics (OGE) has issued the following new conflict of interest guidelines for State 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

Exhibit XVI. Sample of an NCAB Mail Ballot

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MAIL BALLOT

Please return by noon, September 17, 2007

NATIONAL CANCER ADVISORY BOARD

Division of Extramural Activities

The grant applications listed on the attached sheet have received initial review by the appropriate study section but were not listed with the applications which were reviewed by the September 2005 meeting of the NCAB. We are requesting your concurrence with the study section recommendations by this mail ballot in order that these applications may be considered for funding action. If you wish to register nonconcurrence with any of the recommendations, please do so, noting that we would appreciate its return no later than September 25, 2005. Please FAX your ballot to Dr. Vener at 301-402-0742.

_____ Concurrence *en bloc*

_____ Concurrence except as noted for the applications listed below

GRANT NUMBER INVESTIGATOR BOARD MEMBER'S COMMENTS

_____

_____

_____

_____ _____
(Board Member's printed name and signature) Date

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 Council meeting, council 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.

In addition, the NCAB has agreed not to reverse the IRG action on any application from a member institution. Instead, all such applications in which Board opinion differs from that of an IRG are referred to an appropriate IRG for review.

AWARD OF GRANTS

Selection for Funding

Many more grants are approved by the NCAB than can be financed from the NCI budget. Early in the fiscal year, the NCI formulates funding guidelines for its programs based upon expected allocations of funds, program requirements, and prior history. Final funding decisions are made by the Director of the NCI and NCI staff, based primarily on IRG percentile/priority score ratings of scientific merit, the Institute's program objectives, avoidance of duplicate effort, and other considerations. The funding mechanisms are reevaluated prior to each grant review cycle and adjusted to the current level of funds available and future funding.

Administrative/Business Review

Following the NCAB grant review session, the NCI conducts an administrative/business review of all applications selected for funding. Applications are reviewed for compliance with NIH policies and for necessary or desirable adjustments in the amounts and terms of the recommended awards.

Early Awards

The NCI also has established guidelines, approved by the NCAB and the Director of the NIH, for the award of R01 grants subjected to early council concurrence (*vide supra*). According to these guidelines, applications eligible for early award include:

- applications from grantee institutions within the United States and its territories only; and
- applications whose IRG priority score is at least as high as what was required for funding in the last round or what is anticipated for the next round.

Applications not eligible for early award include:

- applications from foreign institutions and organizations. NIH policy requires that applications from foreign institutions and organizations considered for funding must first be called to the attention of the Board; and
- applications with identified policy problems, such as ethical issues or hazardous experiments. Awards will not be issued until the problem has been resolved.

Notice of Award

The list of applications selected for payment is signed by the NCI Program Director and the Division Director. The signed documents are forwarded to the Extramural Financial Data Branch of the NCI, and the Grants Management Specialist negotiates the award. The funds then are obligated and recorded in the NIH official accounting records. Thereafter, the award is mailed to the grantee institution and copies are distributed to appropriate NIH and NCI offices.

For each application selected for payment, a notice of grant award is issued by the Grants Management Officer. It contains the name and address of the grantee institution and the title of the project. The notice also names the principal investigator under whose direction the work is to be carried out, the direct and indirect cost awarded, the period of the grant, future years of support, and any special conditions or restrictions under which the grant is awarded. Exhibit XVII is a (fictitious) sample of a Notice of Grant Award.

Congress must be alerted at least 45 hours before the issuance of each new and renewed grant award, so that the appropriate Congressman may notify his or her constituents. If the award exceeds $1 million, 72 hours' advance notice is required, so that the White House may be informed. This requirement is fulfilled by forwarding a copy of

Exhibit XVII. Sample Notice of Grant Award

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***************************** NOTICE OF GRANT AWARD **********************
RESEARCH                                          Issue Date:01/24/2005
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE
**************************************************************************

Grant Number: 1 R01 CA100228-01
Principal Investigator: Martin, Andrew Ph.D.
Project Title:  Community Intervention to Reduce Adolescent Tobacco Use


ADMINISTRATIVE COORDINATOR
MASSACHUSETTS RESEARCH INSTITUTE
500 ASPEN LANE
CONCORD, MA 02134
UNITED STATES
Award e-mailed to: THOMASE@MRI.EDU



Budget Period:  02/01/2005 - 01/31/2006
Project Period: 02/01/2005 - 01/31/2009


Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of
$300,000(see ''Award Calculation'' in Section I) to MASSACHUSETTS RESEARCH
INSTITUTE in support of the above referenced  project. This award is
pursuant to the authority of 42 USC 241  42 CFR 52 and is subject to
terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is
acknowledged by the grantee when funds are drawn down or otherwise
obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or
reduced to practice in the performance of work under this grant.  Rights
to inventions vest with the grantee organization provided certain
requirements are met and there is acknowledgement of NIH support.  In
addition, recipients must ensure that patent and license activities are
consistent with their responsibility to make unique research resources
developed under this award available to the scientific community, in
accordance with NIH policy.  For additional information, please visit
http://www.iedison.gov.

If you have any questions about this award, please contact the
individual(s) referenced in the information below.

Sincerely yours,



Leo F. Buscher Jr.
Chief Grants Management Officer
NATIONAL CANCER INSTITUTE
```

the award notice to the NIH Office of Congressional Liaison at the same time the approval list is signed.

SPECIAL CONCERNS

Conflict of Interest

A number of procedures have been established by the DHHS and the NIH to avoid violation of conflict of interest laws and regulations. Some of these procedures have been described in brief in the sections on CSR and NCI review (pp. 30-50). DHHS guidelines for the conduct of peer review provide that: When a member of any given peer review group or a member's spouse, parent, child, partner, or close professional associate is named on a grant application or contract proposal as the principal investigator (or as an investigator who is currently, or is expected to be, responsible for conducting a project), that peer review group may not review the particular application or proposal. Instead, the application or proposal must be evaluated by another chartered or *ad hoc* group.

When peer review group members have participated in reviewing contract projects during development of detailed project approaches or RFPs, or in post-RFP evaluations, no contracts resulting from that solicitation may be awarded to those members, their relatives, close professional associates, or organizations. Participation in presolicitation project concept review and recommendations only does not preclude peer group members (or their associates, relatives, or institutions) from receiving subsequent contract awards, provided such reviews and recommendations are limited to the broad purposes and objectives of proposed projects.

To help avoid conflicts of interest and undue influence, and to help ensure continuing objectivity in the peer review process, I/C staff may not participate as members of scientific peer review groups in reviewing projects, applications, or proposals if they have been or are expected to be involved in decisions or actions in the award and administration of the corresponding grants or contracts. Project Officers and other I/C staff may attend meetings of peer review groups that are evaluating applications, projects, or proposals within their purview, so that they may provide essential technical, administrative, and program information. However, they may not join in the scientific technical evaluations and recommendations of peer groups concerning those projects.

After scientific peer review meetings, the NCAB Executive Secretary must obtain written certification from all consultants that they have not participated in any reviews of proposals or applications in which they, their close relatives, associates, or organizations have a financial interest. Voting members of the Board must sign a conflict of interest document at NCAB meetings. Exhibit XVIII is an example of the certification statement signed by NCAB voting members.

Confidentiality

Regulations prohibit the disclosure to unauthorized persons of information obtained by the NIH in connection with a grant application. Review materials and proceedings of review meetings are privileged communications prepared for use by consultants and staff only. Members of the NCAB are requested to leave all review materials with the Executive Secretary at the conclusion of the closed session of the NCAB meeting. Privileged information in grant applications must not be used to the benefit of the reviewer or shared with anyone.

Under no circumstances should consultants advise applicants of recommendations or discuss the review proceedings with applicants. Premature advice to the applicants represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of fellow consultants serving on review committees and site visit teams. The protection of the confidentiality of review proceedings is in the best interest of the highly respected NIH peer review system and the NIH tradition of allocating public funds on the basis of research excellence.

Communication With Applicants

There should be no direct communication between members of the NCAB and the applicants. In the event such a contact occurs, the Executive Secretary of the NCAB must be notified immediately. All communications are handled by the Executive Secretary of the NCAB. Telephone inquiries and correspondence from applicants should be referred or sent directly to the Executive Secretary.

Freedom of Information and Privacy Acts

The Freedom of Information Act (P.L. 93-502) and the Privacy Act (P.L. 93-579), both enacted in 1974, have affected the NIH review process. The Freedom of Information Act (FOIA) provides for

Exhibit XVIII. Sample Conflict of Interest Certification Statement

CONFLICT OF INTEREST CERTIFICATION

NATIONAL CANCER ADVISORY BOARD

February 7, 2006

This will certify that, during the review of applications by the National Cancer Advisory Board on February 7, 2006, I absented myself so as not to participate in the discussion of, nor did I vote on, any application or project in which, to my knowledge, any of the following has a financial interest: (a) myself or my spouse, parent, child, or close professional associate; (b) any organization in which I am serving as an officer, director, trustee, partner, or employee, or am otherwise similarly associated; and any organization with which I am negotiating or have any arrangement concerning prospective employment or other similar association.

I fully understand the confidential nature of the applications and summary statements and related committee discussions, and agree to respect the privileged status of the information contained in these documents.

In Board actions in which we voted on a block of applications without discussing any individual application – the "en bloc" actions – my vote did not apply to any application from any institution fulfilling the criteria in the above statements.

_____

Signature

disclosure of all Federal records, unless they are covered by one or more of nine exemptions. The NIH seeks the advice of grantees when receiving requests for grant materials. FOIA officials ordinarily release funded grant applications but delete patentable and other commercial information and any information that would invade personal privacy. They do not release grant applications that have never been funded, nor do they release the opinion portions of site visit reports and Summary Statements. The Privacy Act safeguards the privacy of individuals in the face of this disclosure.

Under the Privacy Act, principal investigators upon request may have access to documents generated during the review of their grant applications. Such documents include site visit reports, Summary Statements, and reviewers' written comments, if available. Reviewers' written comments, however, are not retained after their substance has been incorporated into Summary Statements or site visit reports.

Exhibit XIX compares and contrasts the major points of the two Acts.

Research Involving Human Subjects

The Public Health Service Act, as amended in 1974 (P.L. 93-348) and 1985 (P.L. 99-157), requires that, in accordance with DHHS Regulations (45 CFR 46), all research grant applications and contract proposals involving human subjects must be evaluated by the NIH IRGs and I/C staff for adequacy of protection for human subjects. This evaluation must take into account the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

Applicant organizations have the primary responsibility for safeguarding the rights and welfare of individuals who participate as subjects in research activities supported by the NIH. However, the NIH also relies on its scientific review groups and National Advisory Councils or Boards to evaluate, for compliance with the DHHS human subject regulations, all applications and proposals involving human subjects.

There are several considerations for review of applications involving human subjects. These considerations can be clustered into two broad areas: protection of subjects from research risks, and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities, and children.

Assessment of scientific and technical merit of applications involving human subjects must include an evaluation of the proposed composition of the study population and its appropriateness for the scientific objectives of the study. If representation of women, minorities, or children in the study design is considered to be inadequate to answer the scientific question(s) addressed, and if there appears to be inadequate justification for the selected study population, reviewers should consider this to be a scientific weakness or deficiency in the study design and must keep this in mind when assigning a priority score.

Based on the evaluation of whether the applicant has adequately addressed human subjects protection, the study section may score the application with no concerns or with comments or concerns that may affect the score to a level commensurate with the seriousness of the concern. A "concern" occurs when a scientific review group uncovers a finding about human subjects that requires resolution by program staff prior to award; a "comment" occurs when a scientific review group makes an observation that will be communicated in the Summary Statement as a suggestion to the principal investigator. No awards are made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

More detailed instructions for reviewing grant applications involving human subjects, as well as exemptions, are available at: http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Inclusion of Women and Minorities as Subjects in Clinical Research

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research (see Appendix I), unless a clear and compelling rationale and justification establish that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion, except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

The inclusion of women and members of minority groups, as well as their subpopulations, must be

Exhibit XIX. The Freedom of Information and Privacy Acts

	Freedom of Information Act (P.L. 93-502, Nov. 1974)	Privacy Act of 1974 (P.L. 93-579, Dec. 1974)
Purpose	To make available certain information to the public and for public guidance.	To provide certain safeguards for an individual against an invasion of personal privacy.
Scope	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain information • formal and informal procedures available for obtaining information • rules of procedure required to obtain information • rules of applications authorized by law and statements of general agency policy • all modifications to the above.	Applies to any Federal agency that maintains a system of records. Pertains to: • any record(s) of identifiable personal information that contains an individual's name, identifying number or symbol, or other identifying particular assigned to the individual • any system of records from which information is retrieved by an individual's name or other personal identifier as described above.
Requirements	Requires Federal agencies to: • publish organizational descriptions and locating information in the *Federal Register* • make all agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting information • make records promptly available to any person following the established guidelines for requesting such information • make available for public inspection a record of the final votes of each member in every agency proceeding, except as exempted. *Agencies must release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletion of commercial information, information that would invade personal privacy, and internal government opinions and advice.	Requires Federal agencies to: • disclose no information contained in a system of records without a written request or prior written consent of the individual to whom the record pertains • permit any individual, upon his/her request, to gain access to his/her record or any information pertaining to him, and to review and copy same • permit the individual to request, and appeal, amendment of any record pertaining to him/her • maintain only information relevant and necessary to accomplish the agency purpose, and to collect such information, whenever possible, from the individual • publish annually a notice in the *Federal Register* indicating the existence and character of the systems of records • insure the security and confidentiality of records and to protect against embarrassment or unfairness to the individual.
Summary	Makes possible disclosure of policy, procedures, and information to the public.	Safeguards the privacy of individuals in the face of disclosure.

addressed in the research design in a way that is appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, as well as a rationale for selection of subjects. Such a plan should contain a description of the proposed programs for recruiting women and minorities as participants. The objective should be to actively recruit and retain the most diverse study population, given the purposes of the research project. When an NIH-defined Phase III clinical trial (see Appendix J) is proposed, the Research Plan must include a description of plans to conduct valid analysis by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable. Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research is available at: http://grants.nih.gov/grants/funding/women_minwomen_min.htm.

Inclusion of Children as Participants in Research

It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research that is supported by the NIH, not solely in clinical research, as is the case for women and minorities, unless there are scientific or ethical reasons not to include them. This policy applies to all research involving human subjects, including research that is otherwise "exempt." Proposals for research involving human subjects must include a plan for including children. If children are excluded from the research, the application must present an acceptable justification for the exclusion. Pertinent information on the inclusion of children in NIH-supported research may be found at: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Research Involving Animals

The Animal Welfare Act of 1966, as amended in 1970, 1975, and 1985 (P.L. 89-544, 91-579, 94-279, and 99-198) provides for the proper care of animals used for research purposes. The Public Health Service Act, as amended in 1985 (P.L. 99-158), mandates specific additional requirements for research that is conducted or supported by the Public Health Service (PHS).

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH staff, scientific review groups, and Councils and Boards also share this responsibility. Care and use of vertebrate animals in research must conform to applicable law and PHS policy, especially the "Principles for Use of Animals." These principles can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.

- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner that avoids any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

IRGs may recommend concurrence, restriction, or limitation of the research, or unscoring of the application, based upon acceptability of the proposed research and standards regarding humane care and use of laboratory animals. Although evaluation and priority ratings are based solely upon scientific merit, any comments, concerns, restrictions, or limitations regarding the use or care of laboratory animals are noted in the Summary Statements. All applications about which there are concerns or objections are called to the attention of the Board for concurrence or nonconcurrence. No award is made until NCI staff, NIH, and the applicant institution have resolved all concerns concurred upon by the Board. Follow-up reports of action taken on each grant application are presented at the next Board meeting.

Biohazardous Research

The investigator and the sponsoring institution are responsible for protecting both the environment and the research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the IRG to the identification of potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special biohazards, these hazards are identified on the Summary Statement. Any concerns about the adequacy of safety procedures are highlighted with a special note (biohazard). No award is made until all concerns

about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

REFERENCES

1. *NIH Guide for Grants and Contracts*. (NIH, published every week.)

2. DHHS *Grants Administration Manual*. (DHHS, regular issuances.)

3. 1800 4000 6000 Series. NM-i Manual Issuances. Office of the Director, NIH.

4. "Public Health Service Policy for the Humane Care and Use of Laboratory Animals." In the *NIH Guide to Grants and Contracts*, Vol. 14, No. 8, June 25, 1955.

5. *Guide for the Care and Use of Laboratory Animals*. National Academy of Sciences, Washington, DC, 140 pp., 1996.

6. *Responsibility for Care and Use of Animals*. NIH Manual Issuance 4206 and 5000-3-4.55. Office of Extramural Research and Training, NIH.

7. *Everything You Wanted To Know About the NCI Grants Process But Were Afraid To Ask*. NIH Publication No. 05-1222, September 2005.

8. *NIH Committee Management Handbook*. November 3, 2000.

RECOMMENDED WEB SITES

The following Web sites have valuable information regarding peer review policy and procedures and other useful information:

http://grants.nih.gov/grants/grant_tips.htm

http://cms.csr.nih.gov

http://csr.nih.gov/EVENTS/AssignmentProcess.htm

http://csr.nih.gov/review/policy.asp

http://www.cancer.gov

http://deainfo.nci.nih.gov/funding.htm

http://era.nih.gov/ElectronicReceipt/

OTHER USEFUL WEB SITES

http://www.grants.gov

http://deainfo.nci.nih.gov/grantspolicies/IntFundLtrFY03.htm

http://grants.nih.gov/grants/policy/policy.htm

http://grants.nih.gov/grants/guide/index.htm

http://grants.nih.gov/training/extramural.htm

http://deainfo.nci.nih.gov/flash/fum/training.htm

http://deais.nci.nih.gov/Query/

ABBREVIATIONS USED

ACD	Advisory Committee to the Director
ACF	Administration for Children and Families
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
AMC	AIDS-Associated Malignancy Clinical Trials Consortium
AoA	Administration on Aging
AREA	Academic Research Enhancement Award
ATSDR	Agency for Toxic Substances and Disease Registry
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 (P30)
CDC	Centers for Disease Control and Prevention
CFARs	Centers for AIDS Research
CFR	Code of Federal Regulations
CGAP	Cancer Genome Anatomy Project
CMS	Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration [HCFA])
CRCHD	Center to Reduce Cancer Health Disparities
CSR	Center for Scientific Review
CTAC	Clinical Trials Advisory Group
CTB	Cancer Training Branch
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences
DCEG	Division of Cancer Epidemiology and Genetics
DCLG	Director's Consumer Liaison Group
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DF	Deferred
DHHS	Department of Health and Human Services (HHS)
ECB	Electronic Council Book
F31	Predoctoral Individual National Research Service Award (NRSA)
F32	Postdoctoral National Research Service Award (NRSA)
F33	National Research Service Award (NRSA) for Senior Fellows
FDA	Food and Drug Administration
FOA	Funding Opportunity Announcement
HRSA	Health Resources and Services Administration
IAR	Internet Assisted Review
I/C	Institute/Center
ICG	Initiative for Chemical Genetics
IHS	Indian Health Service
IRG	Initial Review Group (in NCI)
IRG	Integrated Review Group (in CSR)
K01	Mentored Research Scientist

K05	Senior Scientist Award
K07	Academic Career Award
K08	Mentored Clinical Scientist Development Award
K12	Mentored Clinical Scientist Development Program Award
K22	Career Transition Award
K23	Mentored Patient-Oriented Research Career Development Award
K24	Mid-Career Investigator in Patient-Oriented Research Award
K25	Mentored Quantitative Research Career Development Award
K30	Institutional Curriculum Award
L30	Clinical Research Loan Repayment Program
L40	Pediatric Research Loan Repayment Program
LRP	Loan Repayment Program
MARC	Minority Access to Research Careers
MBRS	Minority Biomedical Research Support (S06)
MERIT	Method to Extend Research in Time (R37)
MGC	Mammalian Gene Collection
MMHCC	Mouse Models of Human Cancers Consortium
MSI	Minority Serving Institution
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute
NCICB	NCI Center for Bioinformatics
NCP	National Cancer Program
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NR	Not Recommended for Further Consideration
NRSA	National Research Service Award
OAR	Office of Advocacy Relations
OC	Office of Communications
OCCAM	Office of Cancer Complementary and Alternative Medicine
OCCM	Office of Cancer Content Management
OCG	Office of Cancer Genomics
OCTR	Office of Centers, Training and Resources
OESI	Office of Education and Special Initiatives
OIA	Office of International Affairs
OLA	Office of Advocacy Relations
OSO	Office of Scientific Opportunities
OSPA	Office of Science Planning and Assessment
OTIR	Office of Technology and Industrial Relations
PA	Program Announcement
PAR	Program Announcement with Special Receipt
PCP	President's Cancer Panel
PCRB	Program Coordination and Review Branch
PL	Public Law
P01	Research Program Project Grant
P20	Planning Grant
P30	Cancer Center Support Grant
P50	Specialized Center Grant (SPORE)

PHS	Public Health Service
PSC	Program Support Center
R&D	Research and Development
RCB	Research Contracts Branch
RFA	Request for Applications
R01	Research Project Grant
R03	Small Research Grant
R13	Conference Grant
R15	Academic Research Enhancement Award (AREA)
R21	Exploratory/Developmental Grant
R24	Resource-Related Research Project
R25	Cancer Education Grant
R33	Exploratory/Developmental Grant - Phase II
R37	MERIT Award
R41	Small Business Technology Transfer (STTR) Grant Phase I
R42	Small Business Technology Transfer (STTR) Grant Phase II
R43	Small Business Innovation Research (SBIR) Grant Phase I
R44	Small Business Innovation Research (SBIR) Grant Phase II
R55	James A. Shannon Director's Award
R56	High Priority, Short-Term Project Award
RFP	Request for Proposals
RO	Referral Officer
RPRB	Research Programs Review Branch
RTRB	Resources and Training Review Branch
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIR	Small Business Innovation Research Grant (Phase I R43; Phase II R44)
SEG	Source Evaluation Group
SEP	Special Emphasis Panel
SGE	Special Government Employee
SPORE	Specialized Programs of Research Excellence (P50)
SRG	Scientific Review Group
SRLB	Special Review and Logistics Branch
SRO	Scientific Review Officer
S06	Minority Biomedical Research Support (MBRS)
STTR	Small Business Technology Transfer Grant (Phase I R41; Phase II R42)
T32	Institutional National Research Service Award (NRSA)
U01	Research Project Cooperative Agreement
U10	Clinical Research Cooperative Agreement
U13	Conference Cooperative Agreement
U19	Research Program Cooperative Agreement
U24	Resource-Related Research Project Cooperative Agreement
U43	Small Business Innovation Research (SBIR) Cooperative Agreement Phase I
U44	Small Business Innovation Research (SBIR) Cooperative Agreement Phase II
U54	Specialized Center - Cooperative Agreement
U56	Exploratory Grant - Cooperative Agreement
WIHS	Women's Interagency HIV Study

APPENDIX A

NCI EXECUTIVE COMMITTEE

Voting Members

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Director

Dr. Alan Rabson
Deputy Director

Dr. Anna Barker
Deputy Director
Advanced Technologies and Strategic Partnerships

Dr. Ken Buetow
Director
Center for Biomedical Informatics
and Information Technology

Dr. Robert Croyle
Director
Division of Cancer Control and Population Sciences

Dr. James Doroshow
Director
Division of Cancer Treatment and Diagnosis

Dr. Joseph Fraumeni
Director
Division of Cancer Epidemiology and Genetics

Dr. Paulette Gray
Director
Division of Extramural Activities

Dr. Peter Greenwald
Director
Division of Cancer Prevention

Mr. Lawrence Ray
Deputy Director for Management
and Executive Officer

Dr. Dinah Singer
Director
Division of Cancer Biology

Dr. Sanya Springfield
Director
Center to Reduce Health Disparities

Dr. Robert Wiltrout
Director
Center for Cancer Research

Ms. Joy Wiszneauckas
Executive Secretary

Executive Committee Non-Voting Members

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Acting Director
Office of Science Planning and Assessment

Mr. Richard Folkers
Director
Office of Media Relations

Mr. John Hartinger
Consultant to the NCI Director

Dr. Lee Helman
Scientific Director for Clinical Research
Center for Cancer Research

Dr. Simone John
Special Assistant to the Director

Ms. Lenora Johnson
Director
Office of Communications and Education

Ms. Anne Lubenow
Special Assistant to the Director

Ms. Kathy McBrien
Acting Deputy Executive Officer for
Management and Human Resources

Dr. Craig Reynolds
Associate Director
NCI Frederick

Ms. Kathleen Schlom
Special Assistant to the Director

Dr. Linda Weiss
Chief
Cancer Centers Branch

APPENDIX B

PRESIDENT'S CANCER PANEL

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LaSalle D. Leffall Jr., M.D. **2009**
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Department of Surgery
Howard University College of Medicine
Howard University Hospital
Washington, DC

Members

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Executive Vice President and Chief Academic Officer
Vivian L. Smith Distinguished Chair
The University of Texas M.D. Anderson Cancer Center
Houston, TX

Joseph P. Torre* **2011**
Manager
Los Angeles Dodgers
Los Angeles, CA

Executive Secretary

Abby B. Sandler, Ph.D.
Chief
Institute Review Office
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

*Pending.

APPENDIX C

NATIONAL CANCER ADVISORY BOARD

Chairperson

Carolyn D. Runowicz, M.D. **2010**
Director, The Carole and Ray Neag
Comprehensive Cancer Center
Northeast Utilities Chair in Experimental Oncology
Professor of Obstetrics and Gynecology
Division of Gynecologic Oncology
University of Connecticut Health Center
Farmington, CT

Board Members

Anthony Atala, M.D. **2012**
Director
Wake Forest Institute for Regenerative Medicine
Professor and Chairman
Department of Urology
Wake Forest University School of Medicine
Winston-Salem, NC

Bruce Allan Chabner, M.D. **2012**
Clinical Director
Massachusetts General Hospital Cancer Center
Chief of Hematology/Oncology
Massachusetts General Hospital
Boston, MA

Victoria L. Champion, D.N.S.* **2014**
Associate Dean for Research
Mary Margaret Walther Distinguished
Professor of Nursing
Center for Research and Scholarship
Indiana University School of Nursing
Indianapolis, IN

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The Catherine Iola and J. Smith Michael
Distinguished Professor of Urology
Professor of Urology/Oncology/Pathology/
Pharmacology and Molecular Science
Johns Hopkins University School of Medicine
Baltimore, MD

Lloyd K. Everson, M.D. **2010**
Vice Chairman and Member of
the Board of Directors
US Oncology Incorporated
Houston, TX

Kathryn Giusti, M.B.A. **2010**
CEO and Founder
Multiple Myeloma Research Foundation, Inc.
Multiple Myeloma Research Consortium
Norwalk, CT

Mr. William H. Goodwin, Jr.* **2014**
Chairman and President
CCA Industries
Richmond, VA

Waun Ki Hong, M.D.* **2014**
Professor
Head, Division of Cancer Medicine
Department of Thoracic/Head & Neck
Medical Oncology
The University of Texas M.D. Anderson
Cancer Center
Houston, TX

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Vice Chairman, Pharmaceuticals
GlaxoSmithKline
Research Triangle Park, NC

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Medical Director, Native American
Programs
Mayo Comprehensive Cancer Center
Professor of Oncology
Department of Medical Oncology
Mayo Clinic
Rochester, MN

Mr. David H. Koch **2010**
Executive Vice President
Koch Industries
New York, NY

*Pending.

Ms. Mary Vaughan Lester* **2014**
University of California,
San Francisco Foundation
Los Angeles, CA

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Professor
Department of Microbiology and Immunology
University of Miami Miller School of Medicine
Miami, FL

H. Kim Lyerly, M.D.* **2014**
Director
Duke Comprehensive Cancer Center
George Barth Geller Professor of Cancer Research
Duke University Medical Center
Durham, NC

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Professor and Associate Dean for Research
University of Alabama at Birmingham
School of Nursing
Birmingham, AL

Jennifer A. Pietenpol, Ph.D.* **2014**
Director
Vanderbilt-Ingram Cancer Center
B.F. Byrd Jr. Professor of Oncology
Professor of Biochemistry
Vanderbilt University Medical Center
Nashville, TN

Daniel D. Von Hoff, M.D., F.A.C.P. **2010**
Physician in Chief, Senior Investigator
Translational Genomics Research Institute (TGen)
Clinical Professor of Medicine
University of Arizona, Arizona Cancer Center
Arizona Health Sciences Center
Phoenix, AZ

Ex Officio Members

The Honorable Elaine Chao, M.B.A.
Secretary of Labor
Washington, DC

John Howard, M.D., M.P.H., J.D., LL.M.
Director
National Institute for Occupational Safety and Health (NIOSH)
Washington, DC

Mr. Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
Washington, DC

The Honorable Dr. Michael J. Kussman
Acting Under Secretary for Health
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
Washington, DC

The Honorable John H. Marburger III, Ph.D.
Science Advisor to the President
Director
Office of Science and Technology Policy
Executive Office of the President
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Ms. Nancy A. Nord
Acting Chairperson
Consumer Product Safety Commission
Bethesda, MD

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Department of Energy
Washington, DC

David A. Schwartz, M.D.
Director
National Institute of Environmental Health Sciences
National Institutes of Health
Research Triangle Park, NC

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
Rockville, MD

*Pending.

The Honorable Dr. William Winkwerder Jr.
Assistant Secretary
Defense for Health Affairs
The Pentagon
Washington, DC

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
Bethesda, MD

Alternates to *Ex Officio* Members

Michael A. Babich, Ph.D.
Directorate for Health Sciences
Consumer Product Safety Commission
Bethesda, MD
(Nancy A. Nord, J.D. - CPSC)

Patricia Bray, M.D., M.P.H.
Acting Director, Office of Occupational Medicine
OSHA/Department of Labor
Washington, DC
(The Honorable Elaine Chao - DOL)

Allen Dearry, Ph.D.
Interim Associate Director
National Toxicology Program
National Institute of Environmental Health Sciences
National Institutes of Health
Research Triangle Park, NC
(David A. Schwartz, M.D. - NIEHS)

Diane C. DiEuliis, Ph.D.
Senior Policy Analyst
Office of Science and Technology Policy
Executive Office of the President
Washington, DC
(The Honorable John H. Marburger III, Ph.D. - OSTP)

Michael Kelley, M.D., F.A.C.P.
National Program Director for Oncology
Veterans Health Administration
Department of Veterans Affairs
Washington, DC
(The Honorable Dr. Michael J. Kussman)

Raynard Kington, M.D., Ph.D.
Deputy Director
National Institutes of Health
Bethesda, MD
(Elias A. Zerhouni, M.D. - NIH)

Peter Kirchner, M.D.
Senior Scientist
Office of Biological and Environmental Research
Medical Sciences Division
Department of Energy
Germantown, MD
(Ari Patrinos, Ph.D. - DOE)

Richard Pazdur, M.D.
Division Director
Division of Oncology Drugs
Food and Drug Administration
Rockville, MD
(Andrew C. von Eschenbach, M.D. - FDA)

John F. Potter, M.D.
Director
United States Military Cancer Institute
Walter Reed Army Medical Center
Washington, DC
(The Honorable Dr. William Winkwerder Jr. - DOD)

R. Julian Preston, Ph.D.
Acting Associate Director for Health
Environmental Protection Agency
Research Triangle Park, NC
(Mr. Stephen L. Johnson - EPA)

Dori Reissman, M.D., M.P.H.
Senior Medical Advisor
Office of the Director, NIOSH
Capt (sel), U.S. Public Health Service
Washington, DC
(John Howard, M.D., M.P.H., J.D., LL.M. - NIOSH)

Executive Secretary

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

APPENDIX D

BOARD OF SCIENTIFIC ADVISORS

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Philadelphia, PA

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Robert L. Kroc Endowed Professor of Pathology
Department of Pathology and Immunology
Washington University School of Medicine
St. Louis, MO

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Professor of Oncology
Chair, Departments of Epidemiology and Cancer Prevention and Control
Roswell Park Cancer Institute
Buffalo, NY

Kirby I. Bland, M.D. **2009**
Fay Fletcher Kerner Professor and Chairman
Department of Surgery
Deputy Director
Comprehensive Cancer Center
University of Alabama at Birmingham
Birmingham, AL

Andrea Califano, Ph.D.* **2013**
Director
Center for the Multiscale Analysis of Genetic Networks
Columbia University Medical Center
New York, NY

Michael A. Caligiuri, M.D. **2012**
Director
The Comprehensive Cancer Center
The Ohio State University (OSUCCC)
Columbus, OH

Curt I. Civin, M.D. **2012**
Herman and Walter Samuelson Professor of Oncology
Professor of Pediatrics
The Johns Hopkins University
School of Medicine
The Sidney Kimmel Comprehensive Cancer Center
Baltimore, MD

Susan J. Curry, Ph.D. **2010**
Director, Institute for Health Research and Policy
Professor, Health Policy and Administration
University of Illinois at Chicago
Chicago, IL

William S. Dalton, M.D., Ph.D. **2010**
Chief Executive Officer and Center Director
H. Lee Moffitt Cancer Center and Research Institute
University of South Florida
Tampa, FL

Robert B. Diasio, M.D.* **2013**
Director
Mayo Clinic Cancer Center
Professor of Pharmacology
Mayo Clinic College of Medicine
Rochester, MN

Kathleen M. Foley, M.D. **2009**
Director
Pain and Palliative Care Service
Department of Neurology
Memorial Sloan-Kettering Cancer Center
New York, NY

*Pending.

Sanjiv S. Gambhir, M.D., Ph.D. **2009**
Professor
Department of Radiology and Bio-X Program
Director, Molecular Imaging Program
Stanford University
Stanford, CA

Todd R. Golub, M.D. **2011**
Associate Professor of Pediatrics
Pediatric Oncology
Dana-Farber Cancer Institute
Boston, MA

Joe W. Gray, Ph.D. **2009**
Director
Division of Life Sciences
Associate Director, Biosciences
Lawrence Berkeley National Laboratory
Berkeley, CA

Leland H. Hartwell, Ph.D. **2009**
President and Director
Fred Hutchinson Cancer Research Center
Department of Genetics
University of Washington
Seattle, WA

James R. Heath, Ph.D. **2010**
Elizabeth W. Gilloon Professor
and Professor of Chemistry
Division of Chemistry
and Chemical Engineering
California Institute of Technology
Pasadena, CA

Mary J. Hendrix, Ph.D. **2009**
President and Scientific Director
Children's Memorial Research Center
Professor of Pediatrics
Feinberg School of Medicine
Northwestern University
Chicago, IL

Leroy E. Hood, M.D., Ph.D. **2009**
President and Founder
Institute for Systems Biology
Seattle, WA

Marc A. Kastner, Ph.D. **2012**
Dean
School of Science
Donner Professor of Science
Massachusetts Institute of Technology
Cambridge, MA

Timothy J. Kinsella, M.D. **2012**
Vincent K. Smith Chair in Radiation
Oncology Professor
Department of Radiation Oncology
Case Western Reserve University School of
Medicine
Cleveland, OH

Christopher J. Logothetis, M.D. **2009**
Chairman and Professor
Department of Genitourinary Medical
Oncology
The University of Texas M.D. Anderson
Cancer Center
Houston, TX

Kathleen H. Mooney, Ph.D., F.A.A.N., R.N. **2010**
Louis S. Peery, M.D., and Janet B. Peery
Presidential Endowed Chair in Nursing
Research Professor
University of Utah College of Nursing
Salt Lake City, UT

James L. Omel, M.D. **2012**
Education and Advocacy
Volunteer, International Myeloma
Foundation
Volunteer, Multiple Myeloma Research
Volunteer, Leukemia, Lymphoma, Myeloma
Society
Grand Island, NE

Edith A. Perez, M.D. **2009**
Professor of Medicine
Division of Hematology/Oncology
Mayo Medical School
Director, Breast Cancer Program
Mayo Clinic
Jacksonville, FL

Richard L. Schilsky, M.D.* **2013**
Professor of Medicine
Section of Hematology/Oncology
Biological Sciences Division
University of Chicago
Pritzker School of Medicine
Chicago, IL

Robert D. Schreiber, Ph.D. **2010**
Alumni Endowed Professor
of Pathology and Immunology
Department of Pathology and Immunology
Washington University School of Medicine
St. Louis, MO

*Pending.

Stuart L. Schreiber, Ph.D. **2012**
Morris Loeb Professor and Chair
Director, Chemical Biology
Harvard University
Cambridge, MA

Ellen V. Sigal, Ph.D. **2009**
Chairperson
Friends of Cancer Research
Arlington, VA

Bruce W. Stillman, Ph.D. **2012**
President and Chief Executive Officer
Cold Spring Harbor Laboratory
Cold Spring Harbor, NY

Victor J. Strecher, Ph.D., M.P.H. **2012**
Professor
Department of Health Behavior and Health Education
Cancer Prevention and Control
School of Public Health
University of Michigan
Ann Arbor, MI

Louise C. Strong, M.D.* **2013**
Professor
Department of Cancer Genetics
The University of Texas M.D. Anderson Cancer Center
Houston, TX

Jean Y. Wang, Ph.D. **2011**
Adjunct Professor
Professor of Medicine, School of Medicine
Department of Medicine
Moores University of California, San Diego Cancer Center
La Jolla, CA

Jane C. Weeks, M.D. **2009**
Professor of Medicine
Chief, Division of Population Sciences
Department of Medical Oncology
Dana-Farber Cancer Institute
Boston, MA

Irving L. Weissman, M.D.* **2012**
Director
Stanford University Comprehensive Cancer Center
Stanford University
Stanford, CA

James K. Willson, M.D. **2011**
Director
Simmons Comprehensive Cancer Center
University of Texas Southwestern Medical Center
Dallas, TX

Executive Secretary

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

*Pending.

APPENDIX E

BOARD OF SCIENTIFIC COUNSELORS
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Department of Radiation Oncology
The University of Michigan Health System
Ann Arbor, MI

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Wadih Arap, M.D., Ph.D. **2011**
Professor of Medicine and Cancer Biology
The University of Texas M.D. Anderson Cancer Center
Houston, TX

Martin Blaser, M.D. **2010**
Professor and Chairman
Department of Medicine
New York University School of Medicine
New York, NY

Bruce Blazar, M.D. **2012**
Professor and Anderson Chair in Transplantation Immunology
Department of Pediatrics
University of Minnesota
Minneapolis, MN

Eugenia Calle, Ph.D. **2011**
Managing Director
Analytic Epidemiology
Department of Epidemiology and Surveillance Research
American Cancer Society
Atlanta, GA

William Cance, M.D. **2011**
Professor and Chairman
University of Florida College of Medicine
Gainesville, FL

David Carbone, M.D., Ph.D. **2010**
Professor
Vanderbilt-Ingram Cancer Center
Vanderbilt University School of Medicine
Nashville, TN

Susan Chang, M.D.* **2013**
Professor
Department of Neurological Surgery
University of California San Francisco School of Medicine
San Francisco, CA

Scott Davis, Ph.D. **2010**
Professor and Chairman
Department of Epidemiology
Member, Fred Hutchinson Cancer Research Center
University of Washington
Seattle, WA

Ethan Dmitrovsky, M.D.* **2013**
Chairman
Department of Pharmacology and Toxicology
Dartmouth Medical School
Hanover, NH

William Evans, Pharm.D. **2012**
Director and CEO
St. Jude Children's Research Hospital
Memphis, TN

Jo Freudenheim, Ph.D. **2012**
Chair
Department of Social and Preventive Medicine
University of Buffalo
State University of New York
Buffalo, NY

Judy Garber, M.D. **2012**
Associate Professor of Medicine
Department of Adult Oncology
Dana Farber Cancer Institute
Boston, MA

*Pending.

Barbara Gilchrest, M.D. **2009**
Professor and Chairman
Department of Dermatology
Boston University School of Medicine
Boston, MA

Richard Hoppe, M.D. **2010**
Professor and Chairman
Department of Radiation Oncology
Stanford University School of Medicine
Stanford, CA

Elizabeth Jaffee, M.D. **2010**
Professor
Department of Oncology
The Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins University School of Medicine
Baltimore, MD

Maria Martinez, Ph.D. **2010**
Professor
Arizona Cancer Center
University of Arizona
Tucson, AZ

Susan Mayne, Ph.D. **2009**
Professor
Department of Epidemiology and Public Health
Yale University School of Medicine
New Haven, CT

Monica Morrow, M.D. **2010**
Chief
Breast Surgery Service
Memorial Sloan Kettering Cancer Center
New York, NY

Andrew Olshan, Ph.D. **2009**
Professor and Chair
Department of Epidemiology
University of North Carolina
School of Public Health
Chapel Hill, NC

Timothy Rebbeck, Ph.D. **2009**
Professor
Department of Biostatistics and Epidemiology
University of Pennsylvania
School of Medicine
Philadelphia, PA

Nancy Roach* **2013**
Consumer Advocate
C3: Colorectal Cancer Coalition
Hood River, OR

Charles Sawyers, M.D. **2009**
Chairman
Human Oncology and Pathogenesis Program
Memorial Sloan Kettering Cancer Center
New York, NY

Daniel Schaid, Ph.D. **2011**
Professor
Section of Biostatistics
Mayo Clinic
Rochester, MN

Thomas Sellers, Ph.D.* **2013**
Director
Moffitt Research Institute
H. Lee Moffitt Cancer Center & Research Institute
University of South Florida
Tampa, FL

Paul Sondel, M.D., Ph.D. **2009**
Head
Division of Pediatric Hematology/Oncology
University of Wisconsin
Madison, WI

Ann Thor, M.D. **2010**
Professor and Chair
Department of Pathology
University of Colorado at Denver and Health Sciences Center
Aurora, CO

Robert Tigelaar, M.D.* **2013**
Professor of Dermatology and Immunobiology
Department of Dermatology
Yale University School of Medicine
New Haven, CT

Walter Urba, M.D., Ph.D.* **2013**
Director, Cancer Research
Robert W. Franz Cancer Research Center
Earle A.Chiles Research Institute
Providence Portland Medical Center
Portland, OR

Executive Secretary

Brian Wojcik, Ph.D.
Institute Review Office
Office of the Director
National Cancer Institute
Bethesda, MD

*Pending.

APPENDIX F

BOARD OF SCIENTIFIC COUNSELORS
Basic Sciences

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Frank Rauscher, Ph.D. **2010**
Deputy Director
The Wistar Institute Cancer Center
Professor and Chairman
The Gene Expression and Regulation Program
The Wistar Institute
Philadelphia, PA

Board Members

Cory Abate-Shen, Ph.D. **2011**
Professor of Urology
Columbia University College of Physicians and Surgeons
Herbert Irving Comprehensive Cancer Center
New York, NY

Dafna Bar-Sagi, Ph.D. **2011**
Professor and Chair
Department of Biochemistry
New York University School of Medicine
New York, NY

Christine Biron, Ph.D. **2010**
Esther Elizabeth Brintzenhoff Professor and Chairperson
Department of Molecular Microbiology and Immunology
Division of Biology and Medicine
Brown University
Providence, RI

Selina Chen-Kiang, Ph.D. **2011**
Professor
Department of Pathology
Weill Medical College of Cornell University
New York, NY

Nelson Fausto, M.D. **2012**
Chair
Department of Pathology
University of Washington School of Medicine
Seattle, WA

Olivera Finn, Ph.D. **2010**
Professor and Chair
Department of Immunology
University of Pittsburgh School of Medicine
Pittsburgh, PA

Michael Gould, Ph.D. **2009**
Professor
Department of Oncology
McArdle Laboratory for Cancer Research
University of Wisconsin-Madison
Madison, WI

James Haber, Ph.D. **2010**
Director, Rosenstiel Basic Medical Sciences Research Center and Abraham and Etta Goodman Professor of Biology
Department of Biology
Brandeis University
Waltham, MA

Nancy Haigwood, Ph.D. **2011**
Director
Oregon National Primate Research Center
Oregon Health & Science University
Beaverton, OR

Thomas Hamilton, Ph.D. **2011**
Chairman
Department of Immunology
Cleveland Clinic Foundation
Cleveland, OH

Laurence Hurley, Ph.D. **2011**
Chair in Pharmaceutical Sciences
Associate Director, BIO5 Institute
University of Arizona
Tucson, AZ

Chris Ireland, Ph.D.* **2013**
Professor and Chair
Department of Medicinal Chemistry
University of Utah
Salt Lake City, UT

Marc Jenkins, Ph.D.* **2013**
Professor
Department of Microbiology
Center for Immunology
University of Minnesota Medical School
Minneapolis, MN

Michael Karin, Ph.D. **2010**
Professor
Department of Pharmacology
University of California San Diego
La Jolla, CA

Laimonis Laimins, Ph.D. **2009**
Professor
Department of Microbiology-Immunology
Northwestern University
Chicago, IL

Wendell Lim, Ph.D. **2011**
Professor
Department of Cellular & Molecular Pharmacology
University of California
San Francisco, CA

A. Thomas Look, M.D.* **2013**
Vice Chair for Research
Department of Pediatric Oncology
Dana-Farber Cancer Institute
Boston, MA

Nita Maihle, Ph.D. **2012**
Professor
Departments of Obstetrics, Gynecology and Reproductive Sciences; Pathology; and Pharmacology
Yale University School of Medicine
New Haven, CT

Lynn Matrisian, Ph.D. **2012**
Professor and Chair
Department of Cancer Biology
Vanderbilt University School of Medicine
Nashville, TN

Ann Marie Pendergast, Ph.D. **2012**
Professor
Department of Pharmacology and Cancer Biology
Duke University Medical Center
Durham, NC

James Prestegard, Ph.D.* **2013**
Professor
Complex Carbohydrate Research Center
University of Georgia
Athens, GA

Leona Samson, Ph.D. **2010**
Professor
Biological Engineering and Toxicology
Biological Engineering Division
Massachusetts Institute of Technology
Cambridge, MA

Robert Siliciano, M.D., Ph.D. **2009**
Investigator, HHMI
Professor
Department of Medicine
Johns Hopkins University
School of Medicine
Baltimore, MD

Paul Spearman, M.D. **2011**
Professor and Division Director
Pediatric Infectious Diseases, Epidemiology, and Immunology
Department of Pediatrics
Emory University School of Medicine
Atlanta, GA

Joseph Testa, Ph.D. **2010**
Director, Human Genetics Program
Carol and Ken Weg Chair in Human Genetics
Fox Chase Cancer Center
Philadelphia, PA

Paul Ts'o, Ph.D. **2010**
Managing Director
CCC Diagnostics LLC
Ellicott City, MD

*Pending.

Jerry Workman, Ph.D. **2009**
Investigator
Stowers Institute for Medical Research
Kansas City, MO

Ming You, Ph.D. **2011**
Professor
Department of Surgery
Washington University School of Medicine
St. Louis, MO

Executive Secretary

Florence E. Farber, Ph.D.
Institute Review Office
Office of the Director
National Cancer Institute
Bethesda, MD

APPENDIX G

NCI DIRECTOR'S CONSUMER LIAISON GROUP

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Douglas E. Ulman **2009**
President
Lance Armstrong Foundation
Austin, TX

Vice Chairperson

Beverly Laird, Ph.D. **2009**
Member/Owner
3D Medical Concepts L.L.C.
Pelham, AL

Members

William P. Bro **2009**
President/Chief Executive Officer
Kidney Cancer Association
Evanston, IL

Grace L. Butler, Ph.D. **2010**
Professor Emeritus
University of Houston
President and Founder
Hope Through Grace, Inc.
Houston, TX

Yvette Colon, Ph.D. **2010**
Director of Education and Internet Services
American Pain Foundation
Ypsilanti, MI

Kelly L. Cotter, J.D. **2010**
Initiative Fundraising Manager
United Way of Lake County
Gurnee, IL

Marie E. Dahlstrom, M.A. **2011**
Advocate and Volunteer
De La Mano Frente Al Cancer: Latino Cancer Coalition
Portland, OR

Gwen Darien* **2012**
Director, Survivorship and Patient Advocacy Programs
American Association for Cancer Research
Editor-in-Chief
Collaboration Results Magazine
Philadelphia, PA

Everett E. Dodson **2011**
Advocate and Volunteer
Prostate Health Education Network
Prostate NET
Silver Spring, MD

Joyce Wilcox Graff, M.A. **2011**
Executive Director
VHL Family Alliance
Boston, MA

Cheryl Jernigan, CPA, FACHE* **2012**
Advocate and Volunteer
Susan G. Komen for the Cure
Kansas City Area Affiliate
Kansas City, MO

*Pending.

Alan M. Kaye **2010**
Chair of the Board of Directors
National Cervical Cancer Coalition
President/CEO
PathNet Esoteric Laboratory Institute
Van Nuys, CA

Deborah Morosini, M.D.* **2012**
Advocate for Lung Cancer Awareness
Oncology Pathologist
Pharmaceutical Research and Development
AstraZeneca Pharmaceuticals, Inc.
Boston, MA

Phyllis Jehn Pettit Nassi, M.S.W.* **2012**
Manager, Special Populations
Department of Prevention and Outreach
Huntsman Cancer Institute
University of Utah
Salt Lake City, UT

Wendy Selig, M.S.* **2012**
Vice President, External Affairs
and Strategic Alliances
The American Cancer Society
Cancer Action Network
McLean, VA

Arlene Wahwasuck, M.S.N. **2011**
Board Member
Four Tribes Women's Wellness
Coalition
Horton, KS

Acting Executive Secretary

Shannon Bell
Office of Advocacy Relations
National Cancer Institute
National Institutes of Health
Bethesda, MD

*Pending.

APPENDIX H

ADVISORY COMMITTEE TO THE DIRECTOR

Chairperson

John E. Niederhuber, M.D.
Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Members

Theodore S. Lawrence, M.D., Ph.D. **2009**
Chairman
Department of Radiology/Oncology
University of Michigan
Ann Arbor, MI

Lasalle D. Leffall, Jr., M.D. **2009**
Charles R. Drew Professor of Surgery
Department of Surgery
Howard University College of Medicine
Howard University Hospital
Washington, DC

Frank Rauscher, Ph.D. **2010**
Deputy Director
The Wistar Institute Cancer Center
Professor and Chairman
The Gene Expression and Regulation Program
Philadelphia, PA

Carolyn D. Runowicz, M.D. **2010**
Director
The Carole and Ray Neag Comprehensive Cancer Center
Northeast Utilities Chair in Experimental Oncology
Professor of Obstetrics and Gynecology
Division of Gynecologic Oncology
University of Connecticut Health Center
Farmington, CT

Douglas E. Ulman **2009**
President
Lance Armstrong Foundation
Austin, TX

Robert C. Young, M.D. **2009**
Chancellor
Fox Chase Cancer Center
Philadelphia, PA

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

Alan S. Rabson, M.D.
Deputy Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Executive Secretary

Kathleen Schlom
Executive Secretary
National Cancer Institute
National Institutes of Health
Bethesda, MD

APPENDIX I

CLINICAL TRIALS ADVISORY COMMITTEE

Chairperson

John E. Niederhuber, M.D.
Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Members

James L. Abbruzzese, M.D. **2010**
Chairman
Department of Gastrointestinal Medical Oncology
The University of Texas M.D. Anderson Cancer Center
Houston, TX

Peter C. Adamson, M.D. **2010**
Professor
Pediatrics and Pharmacology
Chief
Clinical Pharmacology and Therapeutics
The Children's Hospital of Philadelphia
University of Pennsylvania
Philadelphia, PA

David S. Alberts, M.D.* **2009**
Director
Arizona Cancer Center
The University of Arizona College of Medicine
Tucson, AZ

Kirby I. Bland, M.D. (BSA) **2009**
Fay Fletcher Kerner Professor and Chairman
Department of Surgery
School of Medicine
Deputy Director
UAB Comprehensive Cancer Center
University of Alabama at Birmingham
Birmingham, AL

Deborah W. Bruner, Ph.D., R.N. **2009**
Independence Professor in Nursing Education
School of Nursing
University of Pennsylvania
Philadelphia, PA

Stephen S. Grubbs, M.D. **2010**
Chief of Oncology
Medical Oncology Hematology Consultants, PA
Newark, DE

Bruce J. Hillman, M.D.* **2009**
Theodore E. Keats Professor of Radiology
Department of Radiology
Professor
Department of Health Evaluation Sciences
University of Virginia School of Medicine
Charlottesville, VA

Sandra J. Horning, M.D. **2009**
Professor of Medicine
Stanford Comprehensive Cancer Center
Stanford University Medical Center
Stanford, CA

K. Gabriel Leung, M.S. **2010**
Executive Vice President
President, Oncology
OSI Pharmaceuticals
Melville, NY

*Pending.

Nancy P. Mendenhall, M.D. **2009**
Professor
Department of Radiation Oncology
University of Florida Health Science Center
Gainesville, FL

Heidi Nelson, M.D. **2009**
Fred C. Anderson Professor
Division of Colon and Rectal Surgery
Department of Surgery
Mayo Clinic Foundation
Rochester, MN

David R. Parkinson, M.D. **2010**
President and CEO
Nodality, Inc.
San Francisco, CA

Edith A. Perez, M.D. (BSA) **2009**
Professor of Medicine
Division of Hematology/Oncology
Mayo Medical School
Director
Breast Cancer Program
Mayo Clinic Foundation
Jacksonville, FL

Timothy R. Rebbeck, Ph.D. (BSC) **2009**
Professor
Department of Biostatistics and Epidemiology
University of Pennsylvania School of Medicine
Philadelphia, PA

Carolyn D. Runowicz, M.D. (NCAB) **2010**
Director
The Carole and Ray Neag Comprehensive Cancer Center
Northeast Utilities Chair in Experimental Oncology
University of Connecticut Health Center
Farmington, CT

Daniel J. Sargent, Ph.D. **2009**
Director
Cancer Center Statistics
Professor
Division of Biostatistics
Mayo Clinic College of Medicine
Mayo Clinic Foundation
Rochester, MN

Richard L. Schilsky, M.D.* (BSA) **2013**
Professor of Medicine
Associate Dean for Clinical Research
Biological Sciences Division
University of Chicago
Pritzker School of Medicine
Chicago, IL

Joel E. Tepper, M.D. **2010**
Professor and Chair
Department of Radiation Oncology
University of North Carolina
North Carolina Clinical Cancer Center
Chapel Hill, NC

James L. Wade, III, M.D. **2009**
Director of Medical Oncology
Department of Clinical Research
Decatur Memorial Hospital Cancer Care Institute
President
Cancer Care Specialists
Decatur, IL

Ex Officio Members

Anna Barker, Ph.D.
Deputy Director
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

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

Leslye K. Fitterman, Ph.D.
Epidemiologist
Centers for Medicare and Medicaid Services
Baltimore, MD

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

*Pending.

Lee Helman, M.D.
Chief
Pediatric Oncology Branch
Deputy Director
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, MD

Richard Pazdur, M.D., F.A.C.P.
Director
Division of Oncology Drug Products
Food and Drug Administration
Rockville, MD

John F. Potter, M.D.
Director
United States Military Cancer Institute
Walter Reed Army Medical Center
Washington, DC

Alan Rabson, M.D.
Deputy Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Executive Secretary

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 J

CLINICAL RESEARCH AND CLINICAL TRIALS

Clinical Research: NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. *Note:* Not considered clinical research by this definition is: research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Clinical Trial: For purposes of reviewing applications submitted to the NIH, a clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are sage, efficacious, and effective. Clinical trials of experimental drug, treatment, device, or behavioral intervention may proceed through four phases:

- **Phase I** clinical trials are conducted to test a new biomedical or behavioral intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., determine a safe dosage range, and identify side effects).
- **Phase II** clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- **Phase III** studies are conducted to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.
- **Phase IV** studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

NIH-Defined Phase II Clinical Trial: For the purpose of the NIH Grants Policy Guidelines, an NIH-defined Phase III "clinical trial" is a broadly based prospective Phase II clinical investigation, usually involving several hundred of more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such an investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included.

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