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

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WELCOME

My warmest congratulations on your recent appointment by President Bush to the National Cancer Advisory Board (NCAB). The NCAB, along with the President's Cancer Panel (PCP), are the only two presidentially appointed advisory bodies at the National Institutes of Health and the Department of Health and Human Services. The Board performs a wide range of activities and functions. Its primary task is advising the Department of Health and Human Services (DHHS) Secretary and the National Cancer Institute (NCI) Director on issues affecting the National Cancer Program, NCI operations, and second-level peer review of grant applications referred to the NCI for funding. I personally rely greatly on this Board for guidance and direction.

The NCI is committed to exploiting the discovery-development-delivery strategy to achieve our 2015 challenge goal of eliminating suffering and death due to cancer. In large measure, this will be accomplished through the efforts of NCI intramural and extramural scientists working in concert with its programmatic advisory Boards.

We are pleased to provide you with this NCAB Orientation Guideline. I am hopeful that it provides a comprehensive overview of the NCI and your responsibilities as members of the National Cancer Advisory Board.

I welcome you to your new position as a Board member and look forward to a mutually beneficial and productive relationship.

Andrew C. von Eschenbach, 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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EXHIBITS

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

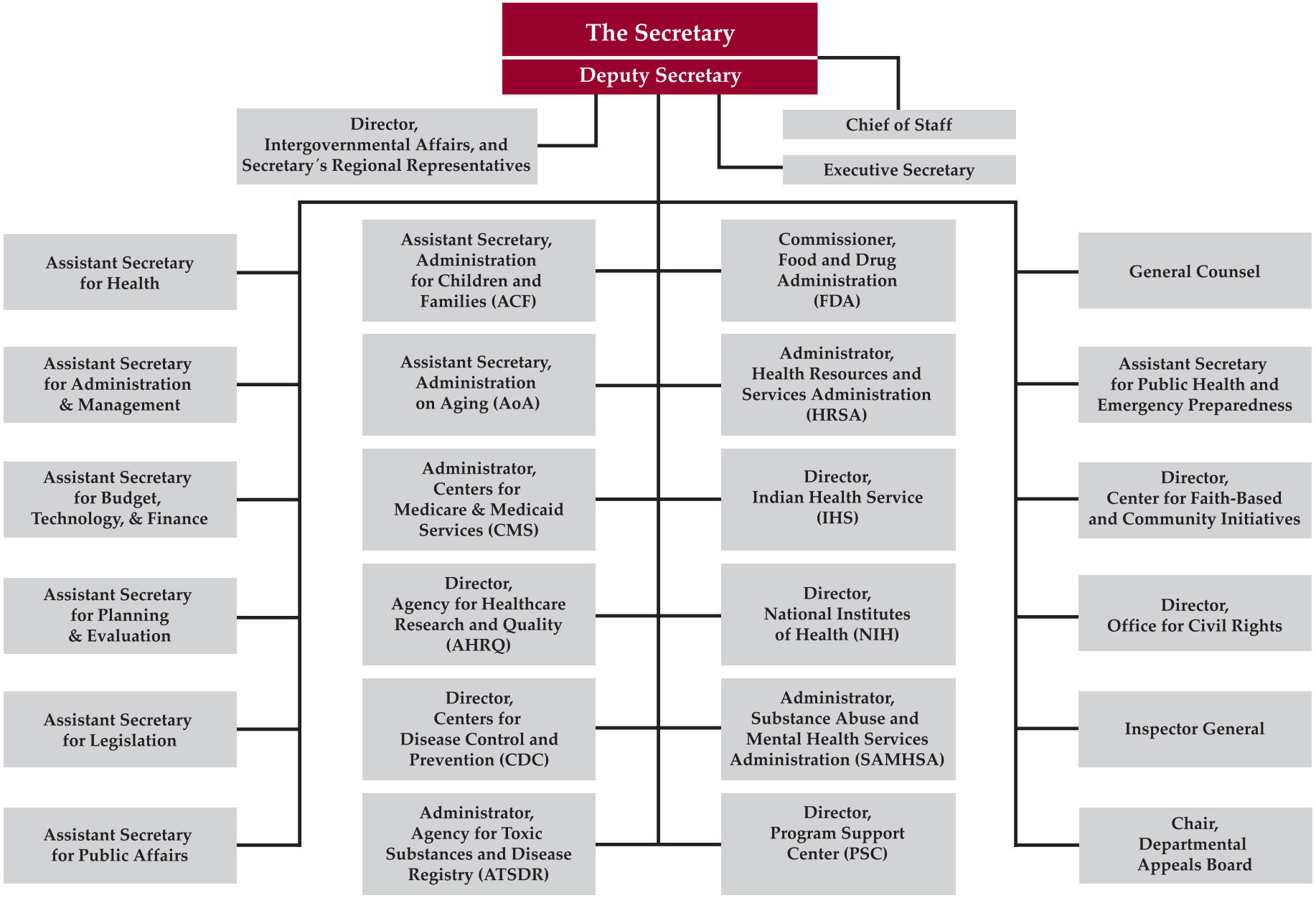
NIH's mission is to uncover new knowledge that will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout 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 $27.1 billion in 2003 (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 FY2003 Funding[1]

INSTITUTE/ CENTER	FUNDING (in millions)
NCI	4,592,348
NIMH	1,341,014
NHLBI	2,793,733
NIDCR	371,636
NIDDK	1,722,730
NIAID	3,606,789
NINDS	1,456,476
NICHD	1,205,927
NIGMS	1,847,000
NIA	993,598
NIEHS	697,767
NIAMS	486,143
NIDCD	370,382
FIC	63,465
NLM	300,135
NEI	633,148
OD	266,232
NCRR	1,138,821
NCCAM	113,407
NINR	130,584
NHGRI	464,995
NIDA	961,721
NIAAA	416,051
NCHMD	185,714
NIBIB	278,279

[1] Source: *NIH Almanac*

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

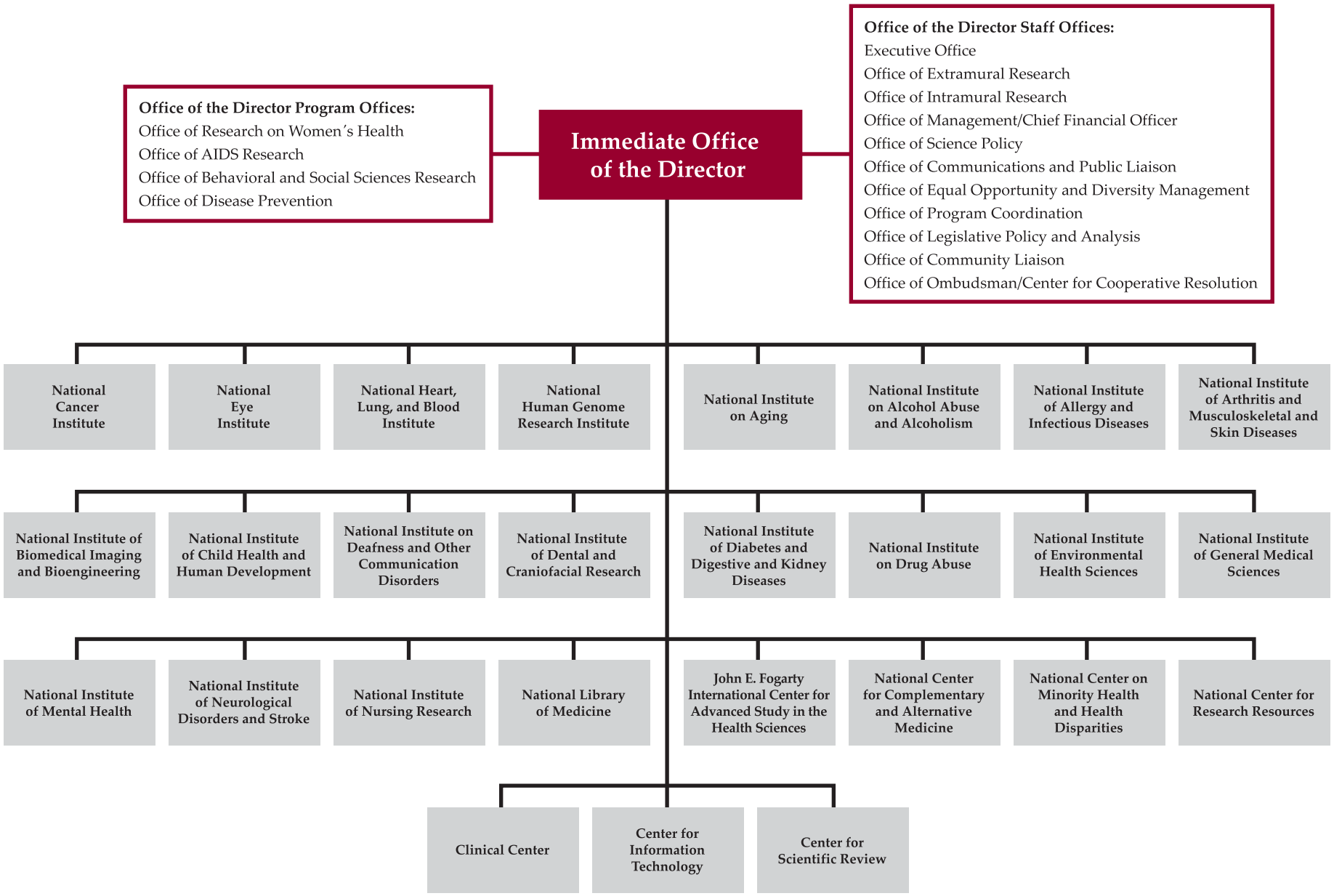
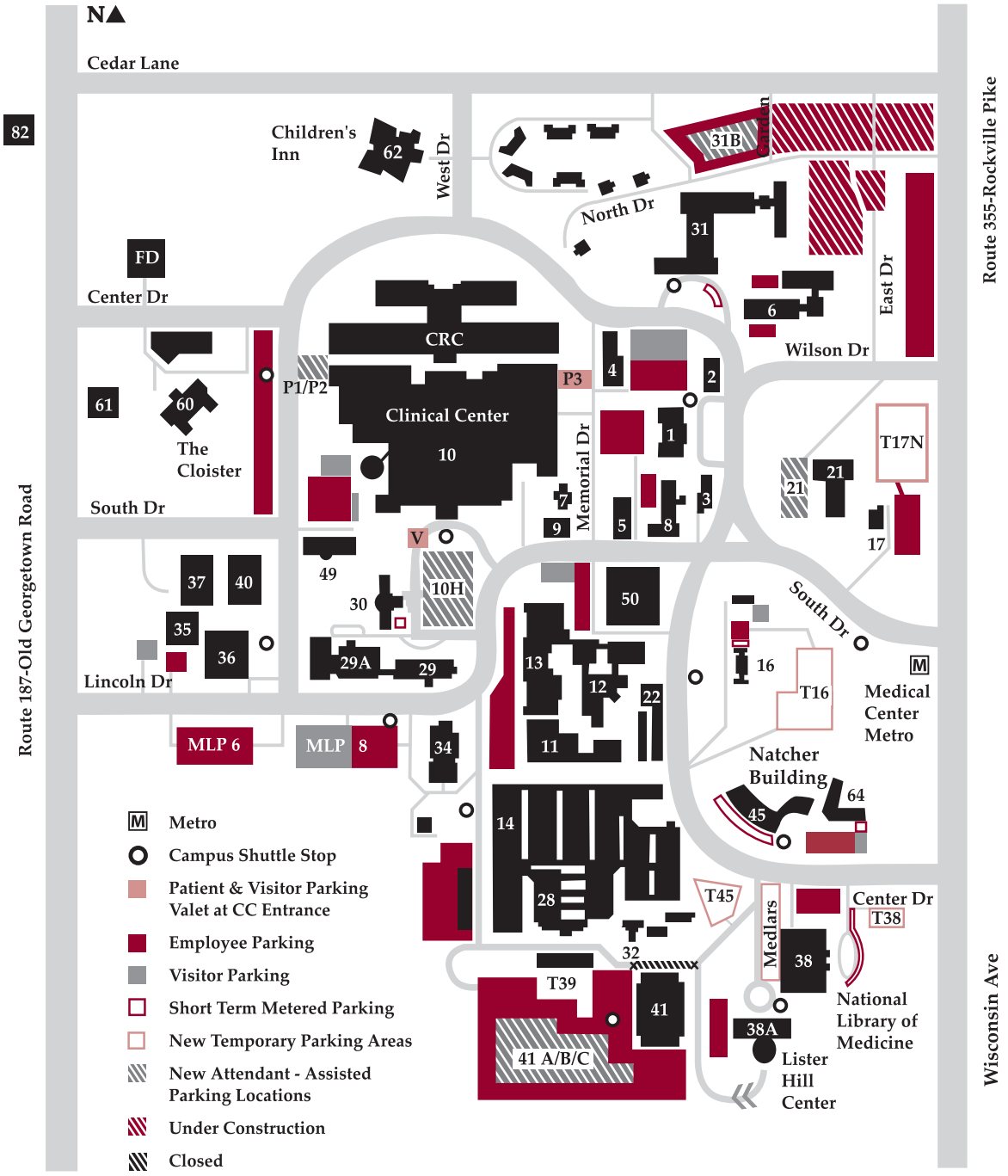


Exhibit IV. NIH Facilities Map



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 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

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 eight agencies 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 mission of the National Cancer Institute is to eliminate the suffering and death due to cancer. Under the leadership of Director Andrew C. von Eschenbach, M.D., the NCI is committed to achieve this goal by the year 2015 through a process of *discovery, development, and delivery*.

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, 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 further developed to help treat it. For example, recent advances in bioinformatics and the related explosion of technology for genomics and proteomics research are dramatically accelerating the rate for processing large amounts of information for cancer screening and diagnosis. The largest collaborative research activity is the Clinical Trials Program for testing interventions for preventing cancer, diagnostic tools, and cancer treatments as well as providing access as early as possible to all who can benefit. The NCI supports 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 (NCP), along with an indication of the associated costs.

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

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

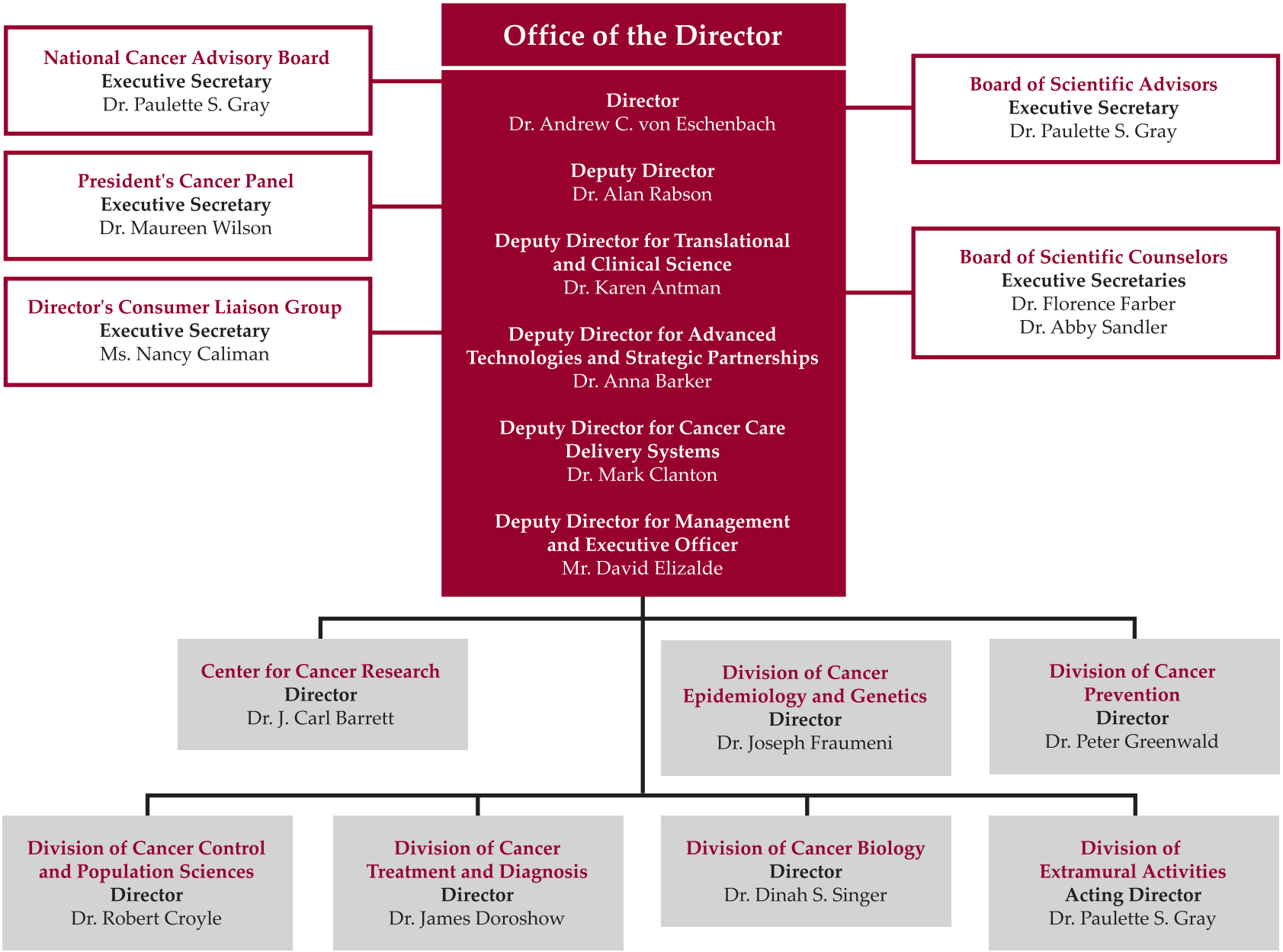
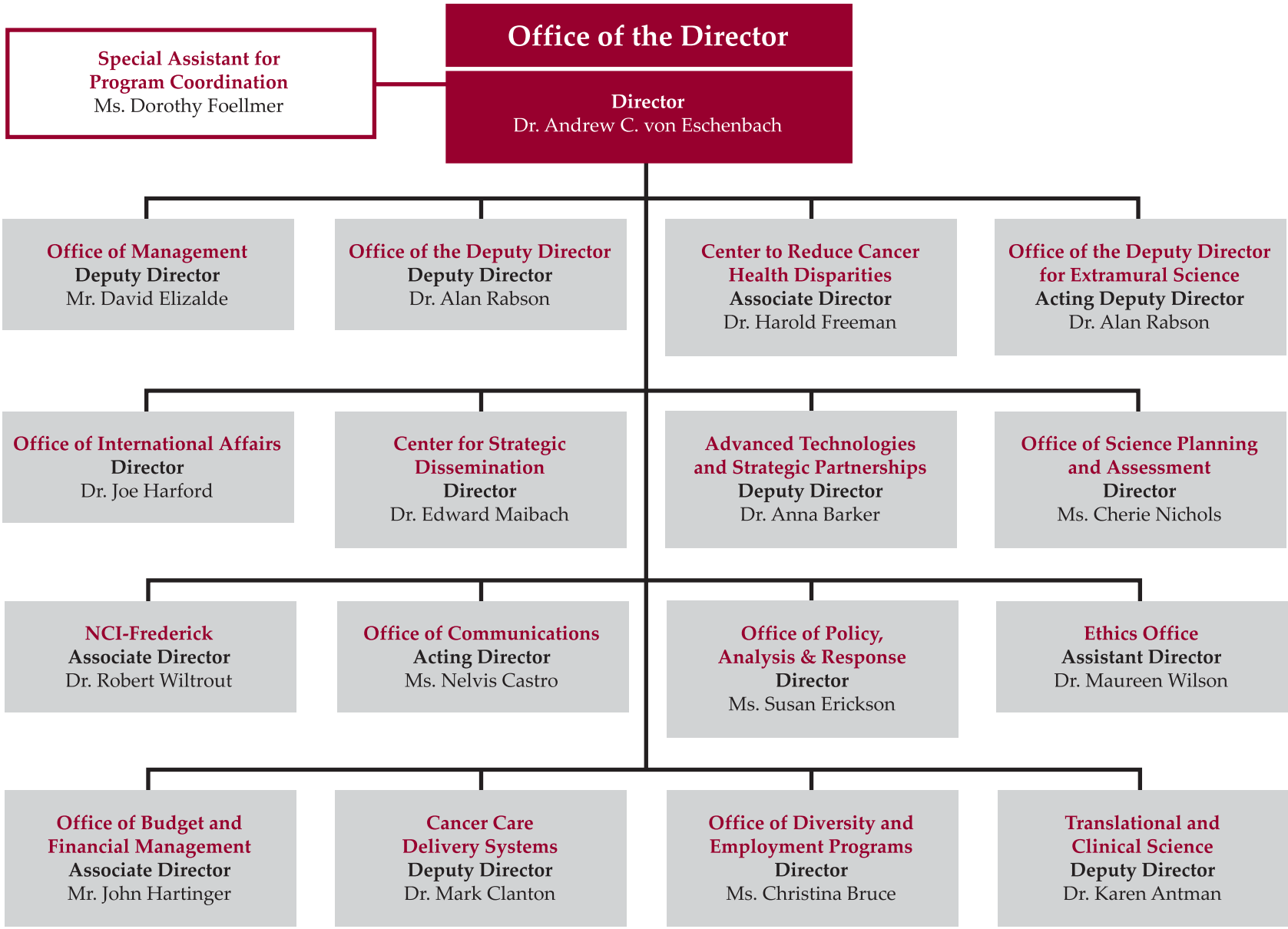


Exhibit V. The National Cancer Institute (Continued)



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 and Acting Deputy Director of the Office for Extramural Science; Dr. Anna Barker, Deputy Director, Advanced Technologies and Strategic Partnerships; Dr. Karen Antman, Deputy Director, Translational and Clinical Science; Dr. Mark Clanton, Deputy Director, Cancer Care Delivery Systems; and Mr. David Elizalde, 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, 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:

NCI Center for Bioinformatics (NCICB)
The NCICB provides biomedical informatics support and integration capabilities to the cancer research community. The Center works with both intramural and extramural groups to develop Initiative-Specific Modules. These modules are connected through intelligent interfaces, coordinated through an NCI Core Module, and deployed through open source tools and systems. The NCICB also serves as a focal point for cancer research informatics planning worldwide. The Center works with research organizations, biomedical informatics groups, and groups that develop standards to help identify and adopt information exchange standards, thus connecting research information sources wherever they may reside.

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 Liaison Activities (OLA)
The OLA supports NCI's research and related programs by fostering strong communications and relationships with the cancer advocacy community, professional societies, scientific organizations, and Federal agencies. The Office believes that the inclusion of diverse perspectives ultimately will improve the lives of those affected by cancer.

Office of Cancer Complementary and Alternative Medicine (OCCAM)
The OCCAM was established in October 1998 to coordinate and enhance the activities of the NCI in the arena of complementary and alternative medicine (CAM). The goal of OCCAM is to increase the amount of high-quality cancer research and information about the use of CAM modalities by:

- Promoting and supporting research within CAM disciplines and modalities as they relate to the prevention, diagnosis, and treatment of cancer, cancer-related symptoms, and side effects of conventional treatment.
- Coordinating NCI's CAM research and information activities.
- Coordinating NCI's collaboration with other governmental and nongovernmental organizations on CAM cancer issues.
- Providing an interface with health practitioners and researchers regarding CAM cancer issues.

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 Education and Special Initiatives (OESI)
The OESI supports NCI's priorities through activities that span NCI programs and include the participation of health care providers, professional societies, patient groups, Federal agencies, and the public. The OESI develops, implements, and evaluates educational programs over the entire cancer continuum, including prevention, screening, diagnosis, treatment, survivorship, and palliative care. The Office serves as a focus for NCI-wide clinical trial (Appendix I) issues, including the management of the NCI Web site's clinical trials portal and oversight of the clinical trials coverage agreements. The OESI also coordinates trans-NCI initiatives in the areas of palliative care, health policy, and medical ethics.

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 works to accelerate the pace of cancer research and the translation of research results into new therapies, diagnostics, and preventive agents. It encourages the development of new technology and promotes collaborations between the NCI and the private sector.

Office of the Deputy Director for Extramural Science (ODDES)
The Office of the Deputy Director for Extramural Science (ODDES) was established to coordinate initiatives across NCI's four extramural research divisions: Division of Cancer Biology (DCB); Division of Cancer Control and Population Sciences (DCCPS); Division of Cancer Prevention (DCP); and Division of Cancer Treatment and Diagnosis (DCTD). The ODDES also was established to monitor and administer the Centers, Training, and Resources Program, as well as the grant program supporting minority training initiatives.

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 will 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 goal of the NCI is to achieve a future when all cancers are controlled or eliminated, by stimulating and supporting research and its application. The NCI provides vision and leadership to the cancer community as it strives to more fully integrate **discovery** activities through interdisciplinary collaborations, to accelerate the **development** of interventions and new technology through translational research, and to ensure the **delivery** of these interventions through clinical and public health programs. 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. FY2003 cancer causation research expenditures totaled about $1.12 billion, accounting for 24.4 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. FY2003 detection and diagnosis research expenditures totaled about $318 million, accounting for 6.9 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. FY2003 treatment research expenditures totaled about $1.1 billion, accounting for 23.0 percent of the total NCI budget.

Cancer Biology
Cancer biology supports a broad spectrum of basic research on cancer and the body's response to cancer. Studies include investigations of cellular and molecular characteristics of tumor cells, interactions among cells within a tumor, and the components of the host immune defense mechanisms. Cancer is the result of genetic damage that accumulates in stages. It is the goal of cancer biology to identify and explain the stepwise progression between the initiating event in the cell and final tumor development. FY2003 cancer biology expenditures totaled approximately $724 million, accounting for 15.8 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 FY2003, there were 61 centers, which received a total of $235.8 million in support, accounting for 5.1 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 totaled approximately $169 million, accounting for 3.7 percent of the total NCI budget.

Construction

The NCI Construction Program supports cancer facility modernization and new construction through the award of grant funds to nonprofit cancer research institutions located at universities and medical centers throughout the Nation. This support enables institutions to construct, expand, and upgrade their cancer research laboratories and

clinical trial facilities. Funds are awarded based on NCI requirements and standards, as judged by a peer review panel of non-Federal scientists. At a minimum, the NCI construction investment is matched on a 1:1 basis by non-Federal funds from the recipient institution. Construction funds also are used to maintain the Federal facilities at the National Cancer Institute in Frederick, Maryland. This nearly 70-acre government-owned, contractor-operated facility requires periodic routine maintenance and repair for more than 70 buildings as well as the modernization or creation of research space. FY2003 Construction Program expenditures totaled approximately $5.2 million, accounting for less than 0.1 percent of the 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. FY2003 Cancer Prevention and Control Program expenditures totaled approximately $518 million, accounting for 11.3 percent of the total NCI budget.

NCI Funding Mechanisms

The NCI supports cancer research, cancer control, and cancer support activities through an extramural program of grants, cooperative agreements, and contracts, and through an intramural program of in-house research. In accordance with NIH tradition, 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 2003 budget for various research areas. Exhibit VIII summarizes the FY2003 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 1994–2003.

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. FY2003 research project grant expenditures totaled approximately $2.16 billion, accounting for 57.5 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 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.

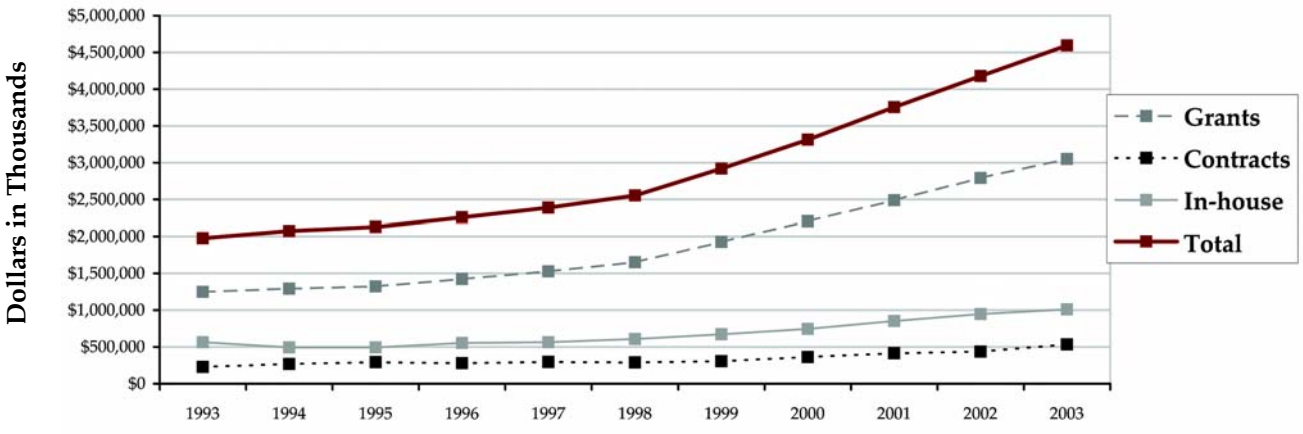
R37 Method to Extend Research in Time (MERIT) Award
MERIT Awards (R37s) provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT 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.

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 appli-

Exhibit VI. NCI Funding History*

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Grants	$1,247,981	$1,292,183	$1,322,677	$1,424,355	$1,527,962	$1,652,966	$1,926,093	$2,204,716	$2,488,627	$2,790,485	$3,047,650
Contracts	229,973	268,448	291,004	277,986	296,290	290,100	306,706	361,355	411,588	437,610	532,760
In-house	564,493	494,452	493,860	552,599	564,789	608,215	672,608	745,010	853,506	948,606	1,011,936
Total	1,978,340	2,076,218	2,129,369	2,254,940	2,389,041	2,551,281	2,918,050	3,311,081	3,753,721	4,176,701	4,592,346



* Source: Office of Financial Management, 2003

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

Disease Area	1999 Actual	2000 Actual	2001 Actual	2002 Actual	2003 Actual
Total NCI Budget	**$2,891.0**	**$3,311.1**	**$3,753.7**	**$4,176.7**	**$4,592.3**
AIDS	239.2	244.1	237.8	254.4	263.4
Brain & CNS	63.5	71.9	80.7	95.2	111.5
Breast Cancer	387.2	438.7	475.2	522.6	548.7
Cervical Cancer	66.3	67.0	72.6	67.6	79.0
Colorectal Cancer	152.9	175.8	207.4	245.0	261.6
Head and Neck Cancers	45.9	47.0	50.0	58.9	77.7
Hodgkin's Disease	8.2	9.4	10.2	11.8	16.5
Leukemia	122.2	141.7	154.0	177.2	200.9
Liver Cancer	39.8	46.2	54.5	62.5	63.7
Lung Cancer	151.0	175.0	206.5	237.5	273.5
Melanoma	60.1	67.9	71.8	82.3	90.7
Multiple Myeloma	15.3	18.0	19.7	20.8	26.3
Non Hodgkin's Lymphoma	66.2	70.4	79.5	85.6	95.2
Ovarian Cancer	56.5	65.5	76.9	93.5	99.4
Pancreatic Cancer	17.3	20.0	21.8	33.1	42.3
Prostate Cancer	135.7	203.2	258.0	278.4	305.2
Stomach Cancer	7.6	8.2	9.0	11.4	13.4
Uterine Cancer	13.8	16.0	18.8	23.1	25.5

* Source: *NCI Fact Book*, 2003

cants 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 object of this phase is 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.

Exhibit VIII. Summary of NCI Obligations by Mechanism, FY2003 (Dollars in Thousands)[*1]

		Number	Amount	% of Total
Research Project Grants	Non-Competing	3,358	$1,416,022	30.8
	Administrative Supplements	285	60,132	1.3
	Competing	1,421	491,722	10.7
	Subtotal, without SBIR/STTR Grants	4,779	1,967,876	43.2
	SBIR/STTR Grants - R41-44	356	90,857	2.0
	Subtotal, Research Project Grants	**5,135**	**2,058,733**	**45.2**
Centers & SPOREs	Cancer Centers Grants - P30	61	235,806	5.1
	SPOREs - P20/P50	47	123,107	2.7
	U54s	14	19,166	0.4
	Subtotal, Centers	**122**	**378,079**	**8.2**
Other Research	**Career Program**			
	Temin & Minority Mentored Awards - K01	105	14,210	0.3
	RCDA - K04	0	0	0
	Estab. Inv. Award - K05	12	1,462	0
	Preventive Oncology - K07	88	11,243	0.2
	Clinical Investigator - K08	141	18,512	0.4
	Physician Investigator - K11	0	0	0
	Clinical Oncology - K12	15	8,391	0.2
	Transitional Career Development - K22	32	4,876	0.1
	Mentored Patient Oriented RCDA - K23	53	6,873	0.2
	Mid-Career Invest. & Patient Orient. Res. - K24	38	4,406	0.1
	Mentored Quant. Res. Career - K25	2	273	0
	Inst. Curr. Award - K30	0	1,599	0
	Subtotal, Career Program	**486**	**71,845**	**1.6**
	Cancer Education Program - R25	102	30,041	0.7
	Clinical Cooperative Groups - U10	78	158,714	3.5
	Biomedical Research Support - S07/S10	0	3,842	0.1
	Minority Biomedical Support - S06	0	3,853	0.1
	Scientific Evaluation - U09/T09	1	8,085	0.2
	Continuing Education	4	340	0
	Resource Grants - R24/U24	54	29,976	0.7
	Explor. Coop. Agreement - U56	26	11,560	0.3
	Conference Grants - R13	104	2,112	0.1
	Subtotal, Other Research Grants	**855**	**320,368**	**7.0**
	Subtotal, Research Grants	**6,112**	**2,757,180**	**60.0**
NRSA Fellowships	*Trainees:*	1,520	65,850	1.4
R&D Contracts	R&D Contracts	267	364,965	8.0
	SBIR Contracts	24	2,582	0.1
	NIH Management Fund		3,211	0.1
	Subtotal, Contracts	**291**	**370,758**	**7.2**
Intramural Research	Program	1,983	568,255	12.4
	NIH Management Fund		124,828	2.7
	Subtotal, Intramural Research *FTEs:*	**1,983**	**693,083**	**15.2**
RMS	Research Mgmt. and Support	713	152,196	3.3
	NIH Management Fund		15,106	0.3
	Subtotal, RMS *FTEs:*	**713**	**167,302**	**3.6**
Cancer Prevention and Conrol	Cancer Control Grants	191	221,620	4.8
	Cancer Control Contracts	174	160,002	3.5
	Inhouse	470	147,601	3.6
	NIH Management Fund		3,950	0.1
	Subtotal, Prevention and Control *FTEs:*	**470**	**533,173**	**11.6**
Construction			5,000	0.1
***Total NCI** *FTEs:*		**3,166**	**4,592,346**	**99.2**

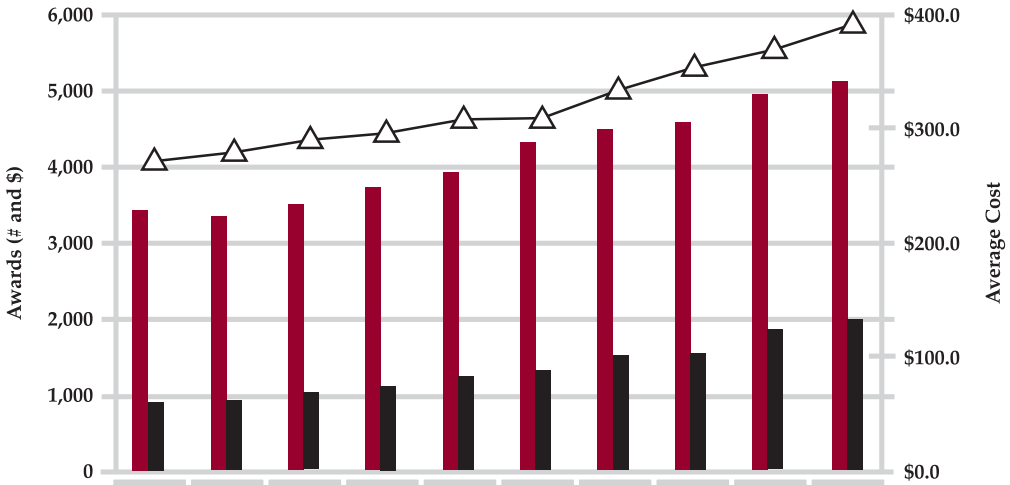
* Excludes projects awarded with Stamp Out Breast Cancer funds. In FY2003, there were 11 R21 awards for $3,130.

[1] Source: *NCI Fact Book, 2003*

Exhibit IX. RPG Awards by Activity Code, FY1994-2003*[1] (Dollars in Thousands)

		R01	P01	R35	R37	R29	RFA	U01	R03	R21	R33	R15	R55	SBIR/ STTR	Total
1994	#	1,914	163	72	154	312	319	232	46	5			9	179	3,405
	$	434,612	184,852	61,369	48,699	32,610	70,879	75,444	2,393	353			540	22,773	934,524
1995	#	1,808	149	67	142	342	314	253	44	34			19	191	3,363
	$	439,122	171,524	63,032	45,125	36,014	72,409	81,771	2,488	7,640			1,126	32,485	952,736
1996	#	1,964	144	65	110	388	268	226	85	46			14	180	3,490
	$	504,398	182,609	62,550	37,070	41,170	66,102	88,962	5,443	9,599			984	35,643	1,034,530
1997	#	2,194	149	63	90	446	195	169	101	63			21	253	3,744
	$	583,116	202,317	62,892	30,950	47,413	48,148	81,193	6,411	12,269			1,450	47,156	1,123,315
1998	#	2,454	160	57	75	485	132	157	97	76		2	14	249	3,958
	$	672,873	228,854	57,712	27,212	52,136	42,750	79,370	6,069	11,782		127	684	51,207	1,230,776
1999	#	2,796	169	38	71	413	261	31	108	159	6	2	6	291	4,351
	$	775,961	249,583	38,585	27,377	45,361	112,868	21,319	7,355	22,548	2,079	200	620	57,917	1,361,773
2000	#	3,011	179	21	60	314	269	18	100	223	20	0	5	306	4,526
	$	898,764	286,234	19,413	24,688	34,769	132,872	13,617	7,034	32,897	10,074	99	450	67,090	1,528,001
2001	#	3,231	178	1	61	210	260	18	122	231	49	3	3	328	4,695
	$	1,008,199	301,115	2,186	26,682	23,738	150,224	14,873	9,024	42,326	23,883	358	300	75,833	1,678,741
2002	#	3,376	173	0	65	112	267	17	186	308	79	10	9	374	4,976
	$	1,093,908	317,632	0	29,445	12,471	177,195	17,531	14,115	57,633	39,317	1,477	850	86,367	1,847,941
2003	#	3,573	178	0	70	14	252	27	203	360	81	21	0	356	5,135
	$	1,207,387	336,607	0	35,360	1,584	173,342	31,126	15,207	67,742	37,714	3,086	0	90,857	2,000,012

Research Project Grants and Dollars Awarded 1994-2003[1]



	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
# Awarded	3,405	3,363	3,490	3,744	3,958	4,351	4,526	4,695	4,976	5,135
$ in Millions	$935	$953	$1,035	$1,123	$1,231	$1,362	$1,528	$1,679	$1,848	$2,000
Avg Cost	$274.5	$283.3	$296.4	$300.0	$311.0	$313.0	$337.6	$357.6	$371.4	$389.5

* Excludes projects awarded with Stamp Out Breast Cancer funds. In FY2003, there were 11 R21 awards for $3,130.

[1] Source: *NCI Fact Book, 2003*

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 FY2003, expenditures totaled about $378.1 million, accounting for 10.6 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.

SPORE 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 FY2003, other research expenditures totaled approximately $320.4 million, accounting for 7.0 percent of the total NCI budget.

IV. Career Awards and Cancer Education

K01 Mentored Research Scientist Development Award and Howard Temin 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. The NCI supports two K01 awards: the Howard Temin Award and the Mentored Career Development Award.

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.

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.

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.

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. FY2003 NRSA expenditures totaled approximately $66 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 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
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 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 IRGs).

Program Announcements with Special Receipt (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 Scientific Review Group (SRG).

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 SRG.

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 Director for Extramural Science, 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 and the Director and Deputy Director of the NCI, on a wide variety of matters concerning scientific program policy and the progress and future direction of each division's 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 each division's programs.

Advisory Committee of 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.

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, 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 Scientific Review Groups (SRGs), 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. 40-41.

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 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 Serial Organization Number	Suffix Grant Year	Suffix Other
1	R01	CA 100228	01	A1 or S1

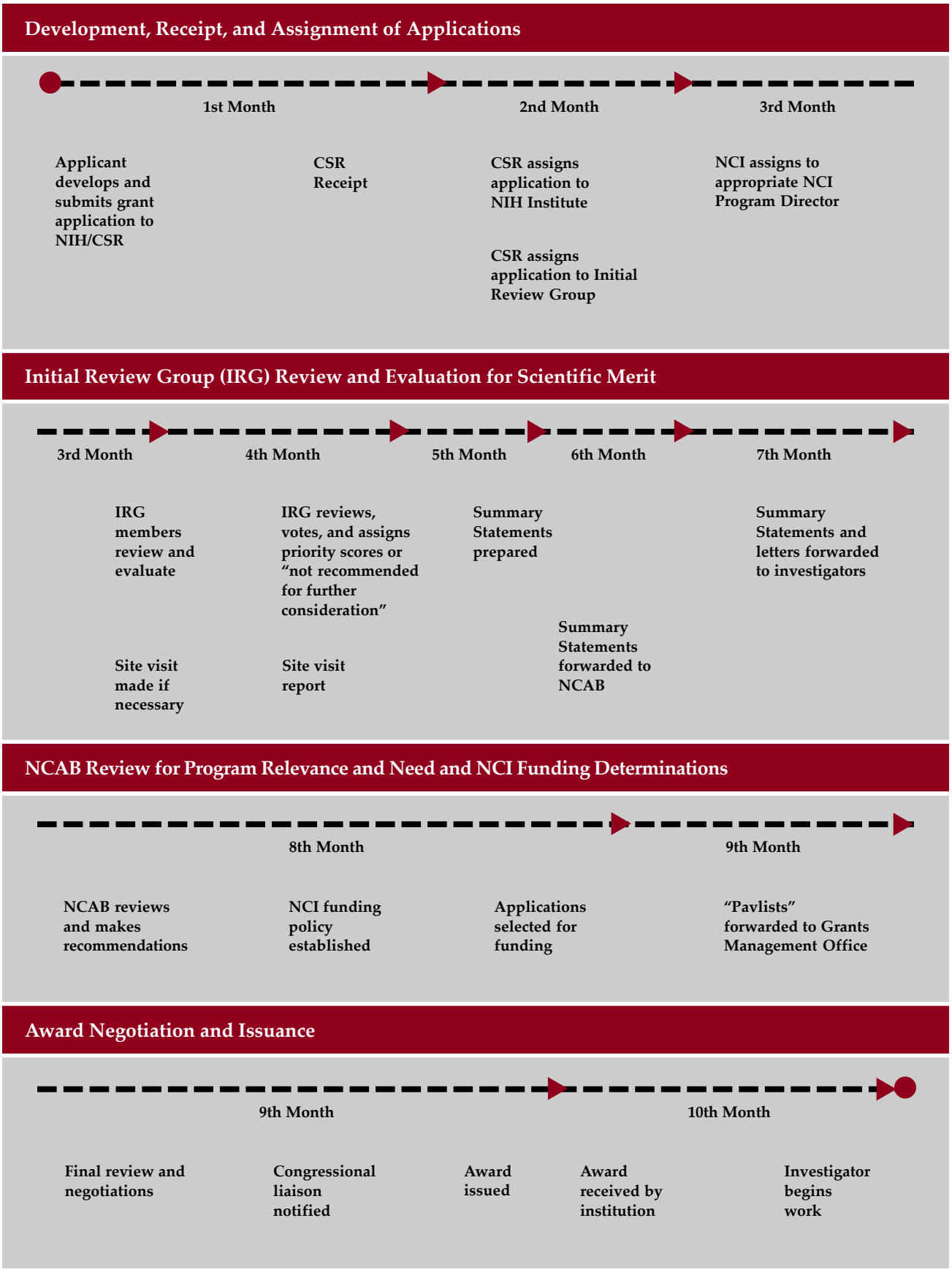
The identification number shows a new (Type 1) application for a traditional research project (R01) assigned to the NCI (CA). The serial number indicates that it is the 100,228th application assigned to the NCI. The suffix (01) shows that this is the first year of support for this project. When the grant 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 seen below. Copies of the application then are forwarded to the appropriate Institute and IRG.

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 Continuation
6	Change of Institute or Center
7	Change of Grantee or Training Institution
8	Change of Institute or Center (non-competing continuation)
9	Change of Institute or Center (competing continuation)

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



Initial Review Groups

There are approximately 26 chartered IRGs distributed among the four review divisions within the CSR. Each IRG is administered by a Scientific Review Administrator (SRA) and has 5 to 10 Scientific Review Groups (SRGs), 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 26 IRGs (see Exhibit XI). A listing of IRGs and their study sections may be found at the following Web site: http://www.drg.nih.gov/review/irgdesc.htm.

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 SRA—an NIH staff scientist who is the designated Federal official responsible for ensuring that the grant applications are reviewed in an impartial environment. SRAs 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 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. SRAs do not have continuing programmatic, scientific, or fiscal responsibilities for the applications after the scientific peer review is completed.

The SRGs 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 applications (e.g., Institute review for an RFA). These *ad hoc* committees are referred to as Special Emphasis Panels or SEPs.

Exhibit XI. IRGs Within CSR

AARR	AIDS and Related Research
BBBP	Behavioral and Biobehavioral Processes
BCS	Biochemical Sciences
BDA	Biology of Development and Aging
BPC	Biophysical and Chemical Sciences
BST	Bioengineering Sciences and Technologies
BDCN	Brain Disorders and Clinical Neuroscience
CVS	Cardiovascular Sciences
CDF	Cell Development and Function
DIG	Digestive Sciences
ENR	Endocrinology and Reproductive Sciences
GNS	Genetic Sciences
HEME	Hematology
HOP	Health of the Population (Formerly SNEM)
IMM	Immunological Sciences
IDM	Infectious Diseases and Microbiology
IFCN	Integrative, Functional, and Cognitive Neuroscience
MDCN	Molecular, Cellular, and Developmental Neuroscience
MOSS	Musculoskeletal, Oral and Skin Sciences
NMS	Nutritional and Metabolic Sciences
ONC	Oncological Sciences
PPS	Pathophysiological Sciences
RES	Respiratory Sciences
RPHB	Risk, Prevention and Health Behavior
RUS	Renal and Urological Sciences
SRB	Surgery, Radiology and Bioengineering

Selection of SRG Members

The primary requirement for serving on an SRG 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 women 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.

SRG 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 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 (IC) 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.

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. Branches of state university systems are considered in such a case to be separate institutions. No member may serve on two chartered PHS review committees simultaneously, although he or she may serve on an SEP *ad hoc* committee.

The Review Session

SRGs (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 SRA of the SRG 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 SRA assigns each application to two or more members of the SRG, 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 SRG reviews approximately 85 applications.

The SRA is responsible for providing any information or materials necessary for the review, communicating with applicants, and providing the appropriate IC advisory board/council with an accurate record of the proceedings in the form of a detailed Summary Statement (see p. 37). 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 SRG, nominated by the SRA and appointed by the Director of the NIH. The NCI Director has the authority to appoint SRG members and chairpersons within the NCI.

Criteria for Evaluation

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

2. **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. I**nnovation:** Does the project employ novel concepts, approaches, or methods? Are the

aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. **Investigator:** Is the investigator appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

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 SRG 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.

SRG 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 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 SRA 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 SRG during the current round of the study section plus the previ-

Exhibit XII. Receipt, Review, and Award Cycles

Application Receipt Dates			
Types of Applications	**Cycle I**	**Cycle II**	**Cycle III**
Institutional Ruth L. Kirschstein National Research Service (Kirschstein-NRSA Awards*) (All new, competing continuation, supplemental, and amended applications)	**January 10**	**May 10**	**September 10**
Academic Research Enhancement Award (AREA) (All new, competing continuation, supplemental, and amended applications, except those involving AIDS-related research)	**January 25**	**May 25**	**September 25**
New Research Grants and Research Career Awards	**February 1**	**June 1**	**October 1**
Program Project Grants and Center Grants (All new, competing continuation, supplemental, and amended applications)	**February 1**	**June 1**	**October 1**
Competing Continuation, Supplemental, and Amended: Research Grants and Research Career Awards	**March 1**	**July 1**	**November 1**
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants (All new, supplemental, and amended applications, except AIDS and AIDS-related applications)	**April 1**	**August 1**	**December 1**
Individual Kirschstein-NRSA Awards (Standard)†	**April 5**	**August 5**	**December 5**
Conference Grants and Conference Cooperative Agreements (All new, competing continuation, supplemental, and amended applications)	**April 15**	**August 15**	**December 15**
AIDS and AIDS-Related Grants (All new, competing continuation, supplemental, and amended applications)	**May 1**	**September 1**	**January 2**
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**

* Several NIH Institutes and Centers use only one or two of the receipt dates for Institutional NRSA Awards. Please check the program announcement for "Institutional Research Training Grants (T32)" at http://grants.nih.gov/training/nrsa.htm.

† The National Research Service Award Individual Predoctoral Fellowships for Minority Students and Students with Disabilities have special receipt dates.

‡ Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.

ous 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 SRG meeting, the SRA prepares individual reports summarizing the recommendation for each application, called Summary Statements. The Summary Statement consists of:

- the SRA's description of the discussion;
- the applicant's description of the proposed research;
- the concatenated 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, either by postal mail or e-mail (by accessing the document using the new Electronic Research Administration module). 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 face page.

Appeal of an SRG 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 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 SRG (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 SRG assignment, CSR retains the authority to determine whether or not an amended (or revised) application should be reviewed by a different SRG.

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 SRA 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

Exhibit XIII. Example of a Summary Statement Face Page

DR. REBECCA SANDERS
301 496-2331
PROGOFFICIAL@NIH.GOV

SUMMARY STATEMENT
(Privileged Communication)

Application Number: 1 R01 CA100228-01

Review Group: BEHAVIORAL MEDICINE STUDY SECTION - BEM

Meeting Dates: SRG: JUNE 2001
COUNCIL: SEPT/OCT 2001

Requested Start Date: 02/01/2002

Investigator: Martin, Andrew
Organization: MASSACHUSETTS RESEARCH INSTITUTE
City, State: CONCORD, MA

Project Title. Community Intervention to Reduce Adolescent Tobacco Use

SRG Action: Priority Score: 135 Percentile 5.3
Human Subjects: 30-HS INV-N0 SRG CONCERNS
Animal Subjects: 10-ANMLS INV-NO SRG CONCERNS
Gender: G2A-MEN and WOMEN, SCIENTIFICALLY ACCEPTABLE
Minority: M4A-MINORITY MAKE-UP SCIENTIFICALLY ACCEPTABLE
Children: C3A-CHILDREN INCLUDED, SCIENTIFICALLY ACCEPTABLE

PROJECT YEAR	DIRECT COSTS REQUESTED	ESTIMATED TOTAL COST
01	225,000	337,500
02	225,000	337,500
03	225,000	337,500
04	225,000	337,500
TOTAL	900,000	1,350,000

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

DESCRIPTION: 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 program 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 more 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.

Continued

Date Released: 07/09/2001 Date Printed: 07/09/2001

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 SRA, 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 SRG 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, program projects (P01s), and clinical trials cooperative groups) routinely require a project site visit by a team of 10 to 30 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.

In 2003, due to the continuing increase in the number of program project grants received by the NCI for review, an NCI extramural staff committee decided to try a non-site visit, i.e., cluster review model for P01s. In this scenario, applications with related science are grouped together (two to four applications) and reviewed by a single committee. Each applicant responds to questions via a conference call. After the cluster review, draft reports are sent to the parent committee, where each application receives a priority score.

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 FY2003, 11,144 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.

NCI SRAs 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, SRAs 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.

Three 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), and the Resources and Training Review Branch (RTRB).

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 five standing subcommittees of the NCI IRG*:

Subcommittee A	Cancer Centers
Subcommittee F	Manpower and Training
Subcommittee G	Education
Subcommittee H	Clinical Groups
Subcommittee I	Career Development

* Subcommittee B (Comprehensiveness) terminated in June 1996.

The RPRB has primary responsibility for reviewing unsolicited P01s, applications for SPOREs in various organ sites, and conference grant applications. It also manages the three subcommittees of the NCI IRG that are responsible for review of program project grant applications, as well as the internal NCI conference grant review committee. 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, U19, U54, U56, SBIRs (R43 and R44s), and STTRs (R41s and R42s).

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 SRG, 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 SRA 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 SRAs have worked with the NCI Office of Liaison Activities 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 patience 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 SRA of the SRG to which the application is assigned.

After the assignments are made and the SRGs and the NCI have received copies of the applications, SRAs and NCI staff examine the appropriateness of the assignments to the SRGs. In cases of questionable assignments, the referral officers and SRAs 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 SRAs, 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 Research Contracts Branch (RCB), 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 RCB 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 SRA for each contract review committee. The SRAs 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 SRA, who makes the committee findings available to the Contracting Officer. At least two 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 RCB 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 RCB 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. 49 and 51.

Following the review session, the SRA forwards the minutes containing the scores, ranking, and individual rating sheets to the Contracting Officer of the RCB, 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 RCB. The RCB 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, with the exception of those requesting $50,000 or less in direct costs per year. 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 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.

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.

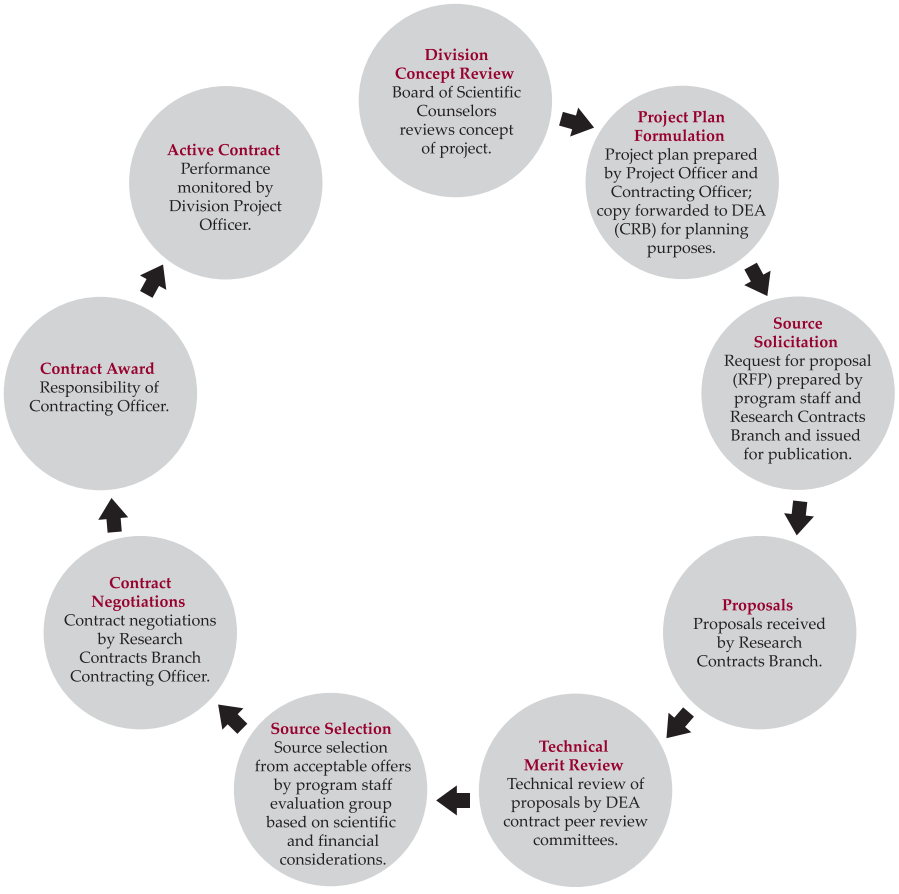
The National Cancer Act of 1971 (P.L. 92-218) and the Health Research Extension Act of 1985 (P.L. 99-158) specify that two-thirds of the appointed members should be leading representatives of the health and scientific disciplines relevant to cancer, and one-third of the members should be from the general 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;

Exhibit XIV. NCI Contract Review Process



- 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.

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 SRG 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 SRG recommendations. • Review and approve guidelines delineating the NCI staff administrative responsibility.

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, SRG Scientific Review Administrators, the NCI Director, appropriate NCI staff, and designated 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 Bioinformatics and Vocabulary
- *Ad Hoc* Subcommittee on Biomedical Technology.
- *Ad Hoc* Subcommittee on Communications
- *Ad Hoc* Subcommittee on Confidentiality of Patient Data

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 not 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 SRG 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 SRG;
- some aspect of the recommendation from the SRG 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).

SRG 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 SRG has recommended them for scoring. The Board is routinely informed of applications for which an SRG 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: The NCAB does not review applications with budgets recommended at less than $50,000 per year and without other concerns. 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 poorer 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 SRG 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 SRGs 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 SRG 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 SRG. 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 SRG 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 SRG, the NCAB may accept the minority opinion without returning the application for further review.

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

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

To avoid conflicts of interest, a Board member is required to absent himself/herself from the review of an application submitted by his/her own institution. In the case of multicampus systems, this means the entire system in which a Board member is an employee, consultant, officer, director, or trustee, or in which he has a financial interest. The NIH legal advisor has determined that certain organizations within a state are considered separate within the conflict of interest statute.

The following institutions are separate organizations under U.S.C. 208(a) and multi-campus institutions where conflict of interest prohibitions do *not* apply (Standards of Conduct Regulations, 45 CFR, Part 43, Amended):

- **Alabama**—The University of Alabama System and other Alabama state-owned institutions of higher education: **Multi-Campus Institutions**—The University of Alabama system, consisting of: the University of Alabama, the University of Alabama in Birmingham, and the University of Alabama in Huntsville.

- **California**—The California Community Colleges, the California State Universities and Colleges, and the University of California: **Multi-Campus Institutions**—The campuses of the University of California.

- **Colorado**—The Colorado State University, University of Colorado, and other Colorado state-owned institutions of higher education: **Multi-Campus Institutions**—The system consisting of Colorado State University, the University of Southern Colorado, and Fort Lewis College.

- **Connecticut**—The Connecticut Community Colleges, Connecticut State University, the Connecticut Technical Colleges, and the University of Connecticut.

- **Illinois**—The Illinois Community Colleges, Illinois State University, Southern Illinois University, the University of Illinois, and Western Illinois University.

- **Indiana**—The Indiana University and the other Indiana state-owned institutions of higher education: **Multi-Campus Institutions**—The Indiana University system, consisting of eight universities on nine campuses, with the exception of the system-wide schools: the School of Business; the School of Dentistry; the School of Medicine; the School of Nursing; and the School of Public and Environmental Affairs.

- **Iowa**—The Iowa State University and the University of Iowa.

- **Kansas**—Fort Hays State University, Kansas State University, the Kansas Technological Institute, Pittsburgh State University, the University of Kansas, and Wichita State University.

- **Louisiana**—Louisiana State University and other Louisiana state-owned institutions of higher education.

- **Massachusetts**—The University of Massachusetts and other Massachusetts state-owned institutions of higher education.

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 25, 2003

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 2003 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, 2003. 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

- **Michigan**—Michigan State University, the University of Michigan, and Wayne State University.

- **Minnesota**—The Minnesota Community College system, the Minnesota State University system, and the University of Minnesota.

- **Missouri**—The University of Missouri and other Missouri state-owned institutions of higher education.

- **Nebraska**—The University of Nebraska and other Nebraska state-owned institutions of higher education: **Multi-Campus Institutions**—The University of Nebraska system consisting of the University of Nebraska - Lincoln, the University of Nebraska - Omaha, and the University of Nebraska Medical Center.

- **New York**—The City University of New York system and the State University of New York system: **Multi-Campus Institutions**—The campuses of the State University of New York.

- **North Carolina**—North Carolina State, the University of North Carolina, and other North Carolina state-owned institutions of higher education.

- **Oregon—Multi-Campus Institutions**—The Oregon system of higher education, consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, and Oregon Institute of Technology.

- **Pennsylvania**—Lincoln University, Pennsylvania State University, Temple University, University of Pittsburgh, and other Pennsylvania state-owned colleges and universities of higher education.

- **Tennessee—Multi-Campus Institutions**—The campuses of the University of Tennessee.

- **Texas**—East Texas State University, Lamar University System, Midwestern Texas State University, Pan American University, Stephen F. Austin State University, Texas A&M System, Texas Southern University, Texas State University System, Texas Tech University, Texas Woman's University, University of Houston System, University of Texas System, University System of South Texas, and West Texas State University. **Multi-Campus Institutions**—The separate universities comprising the University of Texas systems.

- **Utah**—Utah State University and the University of Utah.

- **Wisconsin—Multi-Campus Institutions**—The separate universities comprising the University of Wisconsin system.

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 SRG action on any application from a member institution. Instead, all such applications in which Board opinion differs from that of an SRG are referred to an appropriate SRG 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 SRG 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 grants for less than $50,000 in direct costs per year. Such grants require IRG review but not NCAB approval. According to these guidelines, applications eligible for early award include:

- applications from grantee institutions within the United States and its territories only;
- 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; and
- applications in which the amount recommended for each budget period does not exceed $50,000 in direct costs.

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.

If, during a noncompeting budget period, the $50,000 direct cost ceiling is exceeded due to staff negotiations that require an administrative supplement, the action must be reported as an interim action at the next regularly scheduled meeting of the NCAB.

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 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. 30-48). 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

Exhibit XVII. Sample Notice of Grant Award

********** NOTICE OF GRANT AWARD **********
RESEARCH Issue Date:08/19/2004
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE
****

Grant Number: 1 R01 CA107106-01
Principal Investigator: FREITAS, MICHAEL A PHD
Project Title: Assays for Screening Histone Modification in Cancer

ASSOCIATE DIRECTOR
OHIO STATE UNIVERSITY RES FDN
1960 KENNY RD
COLUMBUS, OH 43210-1063
COLUMBUS, OH 432101063
UNITED STATES
Award e-mailed to: NIHaward@osu.edu

Budget Period: 09/01/2004 - 08/31/2005
Project Period: 09/01/2004 - 08/31/2008

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $235,463(see ''Award Calculation'' in Section I) to Ohio State University Foundation 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

Leo F. Buscher, Jr.
Grants Management Office
National Cancer Institute

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 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,

Exhibit XVIII. Sample Conflict of Interest Certification Statement

CONFLICT OF INTEREST CERTIFICATION

NATIONAL CANCER ADVISORY BOARD

February 18, 2004

This will certify that, during the review of applications by the National Cancer Advisory Board on February 18, 2004, 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

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 upon 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 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 I) 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,

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.

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, non-human 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, OPRR, 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 SRG 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

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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. 02-1222, September 2002.

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

RECOMMENDED WEB SITES

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

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

http://www.csr.nih.gov/REVIEW/clin_research_appls.htm

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

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

OTHER USEFUL WEB SITES

http://www.grants.gov

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

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

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
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
CCR	Center for Cancer Research
CCSG	Cancer Center Support Grant (P30)
CDC	Centers for Disease Control and Prevention
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
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
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 CSR)
K01	Mentored Research Scientist Development Award
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
MSI	Minority Serving Institution
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute
NCICB	NCI Center for Bioinformatics
NCP	National Cancer Program
NIH	National Institutes of Health
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NR	Not Recommended for Further Consideration
NRSA	National Research Service Award
ODDES	Office of the Deputy Director for Extramural Sciences
OCCAM	Office of Cancer Complementary and Alternative Medicine
OCG	Office of Cancer Genomics
OESI	Office of Education and Special Initiatives
OIA	Office of International Affairs
OLA	Office of Liaison Activities
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)
SRA	Scientific Review Administrator
SRG	Scientific Review Group
SRLB	Special Review and Logistics Branch
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

APPENDIX A

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Mr. David Elizalde
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APPENDIX B

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M.D. Anderson Cancer Center
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National Institutes of Health
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National Institutes of Health
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APPENDIX D

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Professor of Medicine and Pharmacology
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* Pending appointment

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* Pending appointment

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National Coalition for Cancer Survivorship
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Alice P. Pentland, M.D. **2005**
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Arthur T. Porter, M.D. **2005**
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Eric K. Rowinsky, M.D. **2008**
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Charles Sawyers, M.D. **2009**
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David T. Scadden, M.D. **2007**
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Steven G. Self, Ph.D. **2006**
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Paul Sondel, M.D., Ph.D. **2009**
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Michael Thun, M.D. **2005**
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Richard D. Kolodner, Ph.D. **2005**
Head
University of California
Ludwig Cancer Research
La Jolla, CA

John Kuriyan, Ph.D. **2005**
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Professor
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Northwestern University
Chicago, IL

Dan R. Littman, M.D., Ph.D. **2007**
Professor
Department of Pathology and Microbiology
New York University Medical Center
Howard Hughes Medical Institute
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Guillermina Lozano, Ph.D. **2007**
Professor and Chief
Department of Molecular Genetics
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M.D. Anderson Cancer Center
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Brooke T. Mossman, Ph.D. **2005**
Professor
Department of Pathology
College of Medicine
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Dinshaw J. Patel, Ph.D. **2005**
Member and Mauze Chair
Cellular Biochemistry and Biophysics Program
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St. Jude Children's Research Hospital
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Robert F. Siliciano, M.D., Ph.D. **2009**
Professor
Department of Medicine
Johns Hopkins University School of Medicine
Baltimore, MD

Harinder Singh, Ph.D. **2007**
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University of Chicago
Chicago, IL

Ronald I. Swanstrom, Ph.D. **2006**
Director
UNC Center for AIDS Research
UNC Lineberger Comprehensive Cancer Center
University of North Carolina - Chapel Hill
Chapel Hill, NC

Thea D. Tlsty, Ph.D. **2006**
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Department of Pathology
School of Medicine
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Jeffrey Trent, Ph.D. **2009**
President and Scientific Director
Translational Genomics Research
Phoenix, AZ

Cheryl L. Walker, Ph.D. **2006**
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The University of Texas
M.D. Anderson Cancer Center
Smithville, TX

Eileen White, Ph.D. **2005**
Professor
Department of Molecular Biology and Biochemistry
Rutgers University
Howard Hughes Medical Institute
Center for Advanced Biotechnology and Medicine
Piscataway, NJ

Executive Secretary

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

APPENDIX G

NCI DIRECTOR'S CONSUMER LIAISON GROUP

Chair

Mr. Doug Ulman **2008**
Director of Survivorship
Lance Armstrong Foundation
Austin, TX

Members

Margaret L. Anthony **2006**
Registered Nurse/Nurse Manager
Hollings Cancer Center
Medical University of South Carolina
SC Chapter, Yul Brynner Head and Neck Foundation
Charleston, SC

Vernal H. Branch **2007**
Health Educator Consultant
Y-Me National Breast Cancer Organization
Richmond, VA

William P. Bro **2008**
Chief Executive Officer
Kidney Cancer Association
Evanston, IL

Lourie Campos **2008**
Assistant Director of Policy
Community Health Partnership
San Jose, CA

Nancy Davenport-Ennis **2008**
Chief Executive Officer and President
Patient Advocate Foundation
Newport News, VA

Bobbi de Córdova-Hanks **2006**
Community Health Educator/Director
Bosom Buddies/Women's Center of Jacksonville
Jacksonville, FL

Beverly Laird, Ph.D. **2007**
Member/Owner
3D Medical Concepts L.L.C.
Member, American Cancer Society/ Susan B. Komen Foundation
Pelham, AL

Sylvia M. Ramos, M.D. **2006**
Clinical Professor of Surgery
University of New Mexico School of Medicine
Board Member
People Living Through Cancer
Albuquerque, NM

Eric Rosenthal **2006**
Medical Journalist and Cancer Communications Consultant
Wynnewood, PA

Mary Jackson Scroggins **2007**
Freelance Writer/Editor
Ovarian Cancer National Alliance
Washington, DC

Susan Sumpter **2007**
Patient Services Manager
Leukemia & Lymphoma Society/ Candlelighters Childhood Cancer Foundation
Portland, OR

Marisa Weiss, M.D. **2007**
Director of Radiology
Lankenau Hospital
President and Founder
Breastcancer.org
Wynnewood, PA

Celeste Whitewolf **2006**
Volunteer Director
Native People's Circle of Hope
Tigard, OR

Col. (Ret.) James Williams, Jr. **2008**
Member
Pennsylvania Prostate Cancer Coalition
Camp Hill, PA

Executive Secretary

Ms. Nancy Caliman
National Cancer Institute
National Institutes of Health
Bethesda, MD

APPENDIX H

ADVISORY COMMITTEE TO THE DIRECTOR

Chairperson

Andrew C. von Eschenbach, M.D.
Director
National Cancer Institute
National Institutes of Health
Bethesda, MD

Members

Frederick W. Alt, Ph.D. — **2005**
Professor of Pediatrics
Investigator
Howard Hughes Medical Institute
The Children's Hospital
Boston, MA

LaSalle D. Leffall Jr., M.D. — **2005**
Charles R. Drew Professor of Surgery
Howard University College of Medicine
Washington, DC

John E. Niederhuber, M.D., Ph.D. — **2006**
Professor
Departments of Oncology and Surgery
University of Wisconsin - Madison
Madison, WI

Margaret A. Tempero, M.D. — **2006**
Deputy Director
UCSF Cancer Center
San Francisco, CA

Robert C. Young, M.D. — **2007**
President
Fox Chase Cancer Center
Philadelphia, PA

Ex Officio Members

Paulette S. Gray, Ph.D.
Acting 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

Cherie Nichols
National Cancer Institute
National Institutes of Health
Bethesda, MD

APPENDIX I

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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