NATIONAL CANCER INSTITUTE

GRANTS PROCESS AND ADMINISTRATION

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National Institutes of Health

GRANTS ADMINISTRATION BRANCH

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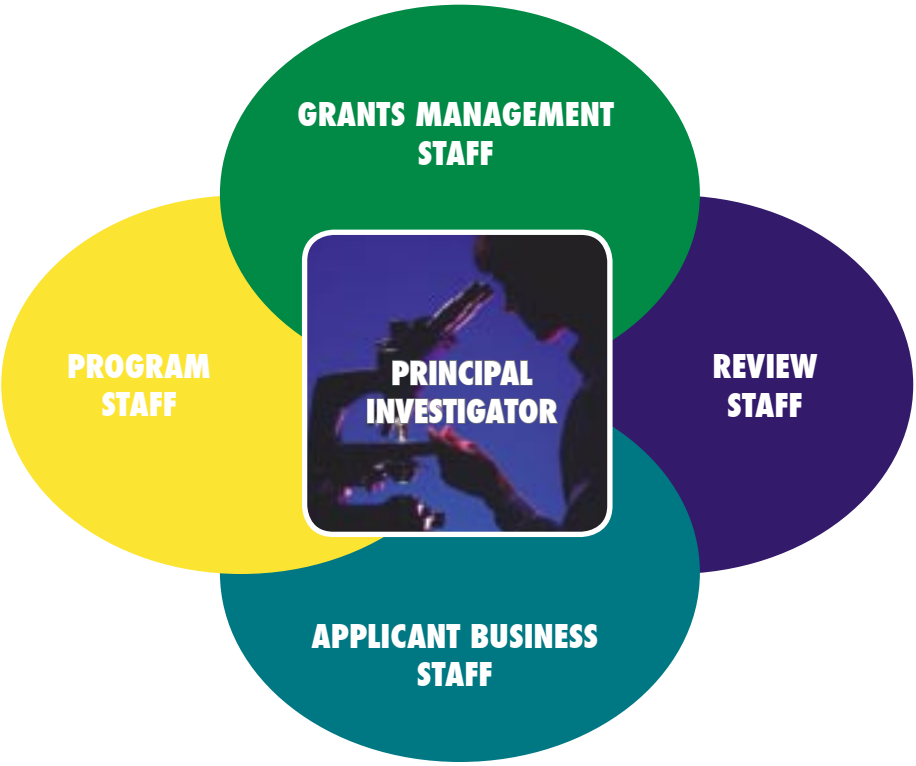
Challenge Goal to the Nation:
Eliminate the Suffering and Death
Due to Cancer by 2015

— **Andrew C. von Eschenbach, M.D.**
Director, National Cancer Institute

THE NATIONAL CANCER INSTITUTE

In Support of Biomedical Research Through Administrative Excellence



The purpose of this publication is to provide a general description of how a grant is awarded and administered. Although the discussion relates to the National Cancer Institute (NCI), the grants process is similar within the other National Institutes of Health (NIH) awarding components. We hope that this information will provide a starting point to understanding the overall grant application and award process.

Since its modest beginnings in a one-room lab in the late 1800s and its official establishment in 1930, through its current status including 27 Institutes and Centers, the NIH has continuously worked as a partner with the research community in order to improve the health and quality of life for individuals around the world. In 1937, "Conquer Cancer" was the battle cry of the Public Health Service, which resulted in the establishment of the NIH's first Institute, the NCI. Since then, advances gained through cancer initiatives have helped to prevent, diagnose, and treat cancer among millions of people. Today, the NCI Director's challenge to the nation is "to eliminate the suffering and death due to cancer by 2015."

Advances in cancer research have translated through the years into progress for other serious diseases, as well. In honor of the advances in cancer research in the last 100 years, a special section follows the table of contents in this year's publication of *Everything You Wanted to Know About the NCI Grants Process but Were Afraid to Ask*.

The organization of this publication represents a concise progression of the NCI grants process and administration.

CHAPTER 1 • Overview: the Grants Process
Provides an introduction to how we, in the Grants Administration Branch, view our role in this very important collaborative venture, including a snapshot of the NCI as an organization and a brief overview of the legal underpinnings of grants.

CHAPTER 2 • Allocation of Grant Funding
Provides a brief budget overview and a funding allocation example to help illustrate various nuances of the NCI grants process.

CHAPTER 3 • Review and Administration
Charts the path of a grant application from development, receipt, and assignment through the peer review process, NCI funding determinations, award negotiation and issuance, and finally, post-award administration.

CHAPTER 4 • Funding Mechanisms
Provides descriptions of the application types and budget mechanisms prevalent within the NCI.

CHAPTER 5 • Cross-Cutting Public Policies
Summarizes some of the requirements that apply to grants management.

CHAPTER 6 • References and Resources
Lists contacts and materials that are helpful with regard to the general approach taken in the NCI grants process.

CHAPTER 7 • Glossary
Lists definitions of terms and phrases most commonly used in the award and administration of NIH grants.

CHAPTER 8 • Exhibits
Provides samples of significant documents used in the grants process.

It is a pleasure to acknowledge the staff of the NCI and the NIH whose contributions made this publication possible.

For additional information concerning the subject matter in this publication, the staff of the NCI Grants Administration Branch are pleased to answer any inquiries. This publication, along with other general information regarding the NCI's Grants Administration Branch, can be found at:

http://www3.cancer.gov/admin/gab/index.htm.

In an effort to constantly improve the content and format of this publication, we welcome your comments via the Feedback section of this website.

Thank you,

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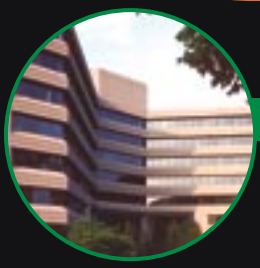
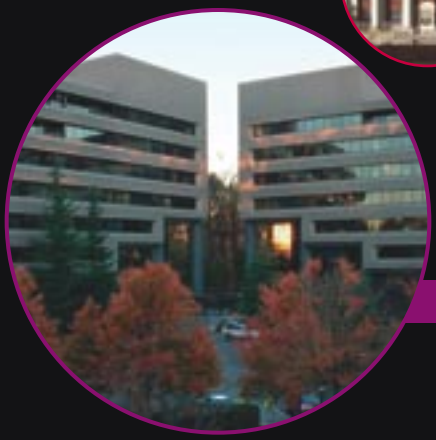
of
Health





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Acronyms

CFR	Code of Federal Regulations
CSR	Center for Scientific Review, NIH
DCB	Division of Cancer Biology, NCI
DCCPS	Division of Cancer Control and Population Sciences, NCI
DCP	Division of Cancer Prevention, NCI
DCTD	Division of Cancer Treatment and Diagnosis, NCI
DEA	Division of Extramural Activities, NCI
EAB	Extramural Advisory Board, NCI
F&A	Facilities and Administrative Costs
FSR	Financial Status Report
FY	Fiscal Year
GAB	Grants Administration Branch, NCI
GMO	Grants Management Officer
GMS	Grants Management Specialist
HHS	Department of Health and Human Services
IC	Institute and/or Center Within NIH
IRG	Integrated Review Group
MIS	Minority Investigator Supplement
NCAB	National Cancer Advisory Board
NCI	National Cancer Institute
NIH	National Institutes of Health
PA	Program Announcement
PAR	Program Announcements Reviewed in an Institute
PD	Program Director
PHS	Public Health Service
PMS	Payment Management System
R&D	Research and Development
RFA	Request for Applications
RPG	Research Project Grant
SBIR	Small Business Innovation Research
SNAP	Streamlined Noncompeting Award Process
SRA	Scientific Review Administrator
SRG	Scientific Review Group
STTR	Small Business Technology Transfer
USC	United States Code

100+ YEARS OF ADVANCES IN THE FIGHT AGAINST CANCER

'Conquer Cancer' Adopted as Battle Cry of the Public Health Service

Fatalities From Disease Are Increasing Rapidly

Congress General Parran Believes 25,000 Lives Can Be Saved Yearly by Application of Information Already Available.

U.S. Creates New Division For Research

With Backed by Congress Are Signed by President.

Victim of Dreaded Malady Donated Land for Laboratories.

Washington Post, August 6, 1937–Article printed shortly after President Roosevelt authorized the building of the National Cancer Institute.

100+ YEARS OF ADVANCES IN THE FIGHT AGAINST CANCER

1898 The first cancer research laboratory was established, Gratwick Laboratories (Roswell Park Memorial Institute).

1903 Radium found effective in treatment of tumors.

1911 P. Rous discovered a virus that causes cancer in chickens.

1912 Cancer cells were grown in the laboratory and considered the first long-term "tissue culture."

1913 The *Ladies' Home Journal* published the first known article on cancer's warning signs.

1915 Coal tar gave rabbits cancer in experimental proof of carcinogenesis.

1930 The National Institutes of Health was established by the Ransdell Act.

1937 The National Cancer Institute Act was established on July 23, 1937, providing funding for the NIH's first Institute, the NCI.

- ♦ On November 27, the first NCI grant was awarded for $27,550 to Louis F. Fieser to investigate chemical structure and carcinogenic activity.

1938 NCI BUDGET: $400,000

Left: June 6, 1938–Members of the first National Advisory Cancer Council at the groundbreaking ceremonies for the NCI building.

Right: 1939–The National Cancer Institute's first home, "Building 6."

1940–1949 NCI APPROPRIATIONS: $42 MILLION

1940 First issue of the *Journal of the National Cancer Institute* was published.

Left: October 31, 1940–President Franklin Roosevelt dedicated the first six buildings of the NIH.

Right: *Life* magazine, June 17, 1940–NCI's first Scientific Staff review.

1943 The Pap smear was introduced into medical practice.

1944 DNA found by O. Avery, C. MacLeod, and M. McCarty determined to be basic cell material.

1947 S. Farber found that a folic acid derivative inhibits acute leukemia.

1948 G. Hitchings synthesized 6-Mercaptopurine (6-MP) to combat childhood leukemia.

1949 The FDA approved Nitrogen Mustard (Methclorethanine), a drug that interacts with DNA chemically to kill cancer cells.

1950–1959 NCI APPROPRIATIONS: $330 MILLION

1950 E. Wynder, E. Graham, and Sir R. Doll confirmed cigarette smoking-cancer link.

1952 DNA found to be genetic material in some viruses.

1953 FDA approved Methotrexate as an anticancer drug.

♦ J. Watson and F. Crick discovered the structure of DNA.

1955 The National Chemotherapy Program began.

1960–1969 NCI APPROPRIATIONS: $1.8 BILLION

1960 Chromosome abnormality was first associated with leukemias.

1961 M. Nirenberg and others proved triplet code governs DNA action.

1962 The Royal College of Physicians issued a report on smoking and health.

1964 The U.S. Surgeon General issued the *Report on Smoking and Health.*

- ♦ A virus (Epstein-Barr Virus) was linked to human cancer for the first time.
- ♦ The American Society of Clinical Oncology was established.
- ♦ FDA approved:
  - 5-FU.
  - Vinblastine, a drug that binds to tubulin and is derived from the ornamental shrub *Vinca rosea.*
  - Vincristine, a sister drug to Vinblastine.
  - Melphalan (L-PAM).

1966 The NCI standardized testing of cancer-causing chemicals.

1969 R. Heubner and G. Todano proposed the oncogene hypothesis.

1970–1979 (NCI APPROPRIATIONS: $6.1 BILLION

1970 H. Temin and D. Baltimore discovered reverse transcriptase enzymes, a key to gene engineering.

1971 President Richard M. Nixon converted the Army's former biological warfare facilities at Ft. Detrick, Maryland, to house research activities on the causes, treatment, and prevention of cancer.

December 23, 1971 – President Nixon signed the National Cancer Act of 1971

1973 Computed tomography (CT) was introduced in the United States.

- ♦ Recombinant DNA techniques were developed for cloning genes.
- ♦ The Surveillance, Epidemiology, and End Results (SEER) program was established.

1974 CANCERLINE, a national database of published cancer research, was established.

1974 FDA approved doxorubicin, an antitumor antibiotic from the *streptomyces* bacterium.

1975 Methods were developed to identify and sequence DNA fragments.

1976 The Cancer Information Service (1-800-4-CANCER) opened.

- ♦ Interleukin-2 was discovered.
- ♦ The first human proto-oncogenes were discovered.

1977 The first national cancer patient education program was founded (I Can Cope).

1978 First human testing of a biological therapy (alpha-interferon).

- ♦ Tamoxifen was approved by the FDA for marketing as a treatment drug.
- ♦ FDA approved Cisplatin, a powerful anticancer drug.
- ♦ Metastatic cells were shown to arise from preexisting sub-populations of primary tumors.

1979 *p53* was discovered, the most frequently mutated gene in human cancer.

- ♦ The modified radical mastectomy replaced radical mastectomy for breast cancer treatment.
- ♦ 1970s additional advances:
  - Studies in human populations linked cancer risk to infectious agents, such as human papillomavirus (cervical cancer) and hepatitis B (liver cancer).
  - Statistical methods developed to simultaneously control several factors in the analysis of studies and to quantify cancer risks.
  - Studies clarified the patterns of cancer risk following exposure to ionizing radiation.
  - Studies linked cancer risks to hormonal drugs, such as diethylstilbestrol (DES) taken during pregnancy and hormone replacement therapy.

1980–1989 NCI APPROPRIATIONS: $12 BILLION

1981 Introduction of the first human viral vaccine that can prevent cancer (hepatitis B virus vaccine for liver cancer).

1985 Lumpectomy plus radiation was found equivalent to mastectomy for breast cancer.

1986 The first tumor-suppressor gene was cloned (Rb).

1988 Adjuvant chemotherapy was proven to increase disease-free survival in early-stage breast cancer patients.

1989 Adjuvant chemotherapy was proven to increase survival in colon cancer patients.

1980s additional advances:

- The flexible sigmoidoscopy and colonoscopy were developed to help find and remove precancerous growths.
- Continuous pain medication infusion pumps were developed.
- The first highly effective antinausea drugs were developed to alleviate side effects of chemotherapy.
- Biochemical and genetic assays were integrated into epidemiologic studies (molecular epidemiology).

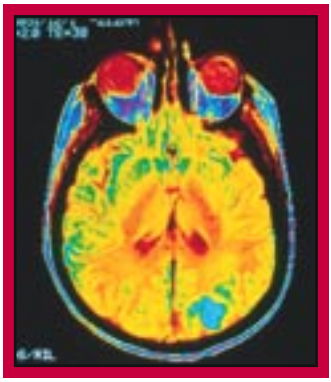
1990–1999 NCI APPROPRIATIONS: $21.8 BILLION

1990 First chemoprevention trial to show efficacy—Vitamin A analogue against mouth and throat tumors.

1991 Adjuvant radiation and chemotherapy found to improve survival in rectal cancer.

Left: Radiation Treatment

Right: MRI (Magnetic Resonance Imaging) introduced.



1993 First of the hereditary non-polyposis colon cancer genes was cloned.

1994 BRCA1, the first inherited breast cancer gene, was cloned.

FDA approvals:

- Tretonoin, the first successful differentiating agent.
- Porfimer sodium, a drug that sensitizes tumors to light, permitting photodynamic therapy in the U.S.
- Topecan, first of a class of drugs that interferes with the enzyme topoisomerase.
- Rituximab, first biotechnology product approved by FDA to treat patients with cancer.
- Trastuzumab (Herceptin), targets cancer cells that produce a protein found in high numbers of women with metastatic breast cancer.

1990s studies and trials:

- Breast Cancer Prevention Trial began, testing tamoxifen as a preventive agent in women at increased risk for the disease. In 1998, results found that tamoxifen reduced the chances of women at risk of developing breast cancer by half.
- NCI-sponsored studies in China showed the importance of nutrition in preventing cancer.
- Prostate Cancer Prevention Trial began in 1993, testing finasteride, a drug used to reduce symptoms of prostate enlargement.
- The Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial began recruiting 148,000 volunteers (the largest early-detection study).
- The Cancer Genome Anatomy Project was launched—a multiyear project to assemble the first index of genes involved in cancer.

1990s additional advances:

- Breast cancer death rates began to decline!
- The multistep nature of carcinogenesis was proven.
- The transition from film-based radiography to digital computer-assisted medical imaging began.
- Several common genetic variants were linked to the risk of lung and other cancers.
- Flourescence *in situ* hybridization (FISH) technique developed.

A New Century...

2000–2005 NCI APPROPRIATIONS: $25.5 BILLION

- The NIH announced the funding of four new Breast Cancer and the Environment Research Centers to study the prenatal-to-adult environmental exposures that may predispose women to breast cancer.
- The NCI and the National Institute on Aging (NIA) launched an initiative to accelerate research into the relationship between aging and cancer.
- International clinical trials concluded that women should consider taking letrozole after 5 years of tamoxifen treatment to continue to reduce risk of recurrence.
- Death rates from the four most common cancers—lung, breast, prostate, and colorectal—continued to decline in the late 1990s according to new data from the *Annual Report to the Nation on the Status of Cancer, 1975–2000*.

1938–2005 NCI APPROPRIATIONS: $67 BILLION!

In 2001, there were 9,600,000 cancer survivors in the U.S.

Together, we—the NIH, the NCI, clinicians, scientists, researchers, administrators, volunteers, patients, and the American public—are making a difference!

MAKING A DIFFERENCE ...
Clinicians
Scientists
Researchers
Administrators
Volunteers
Patients
American Public
TOGETHER, WE ARE CHANGING THE WORLD

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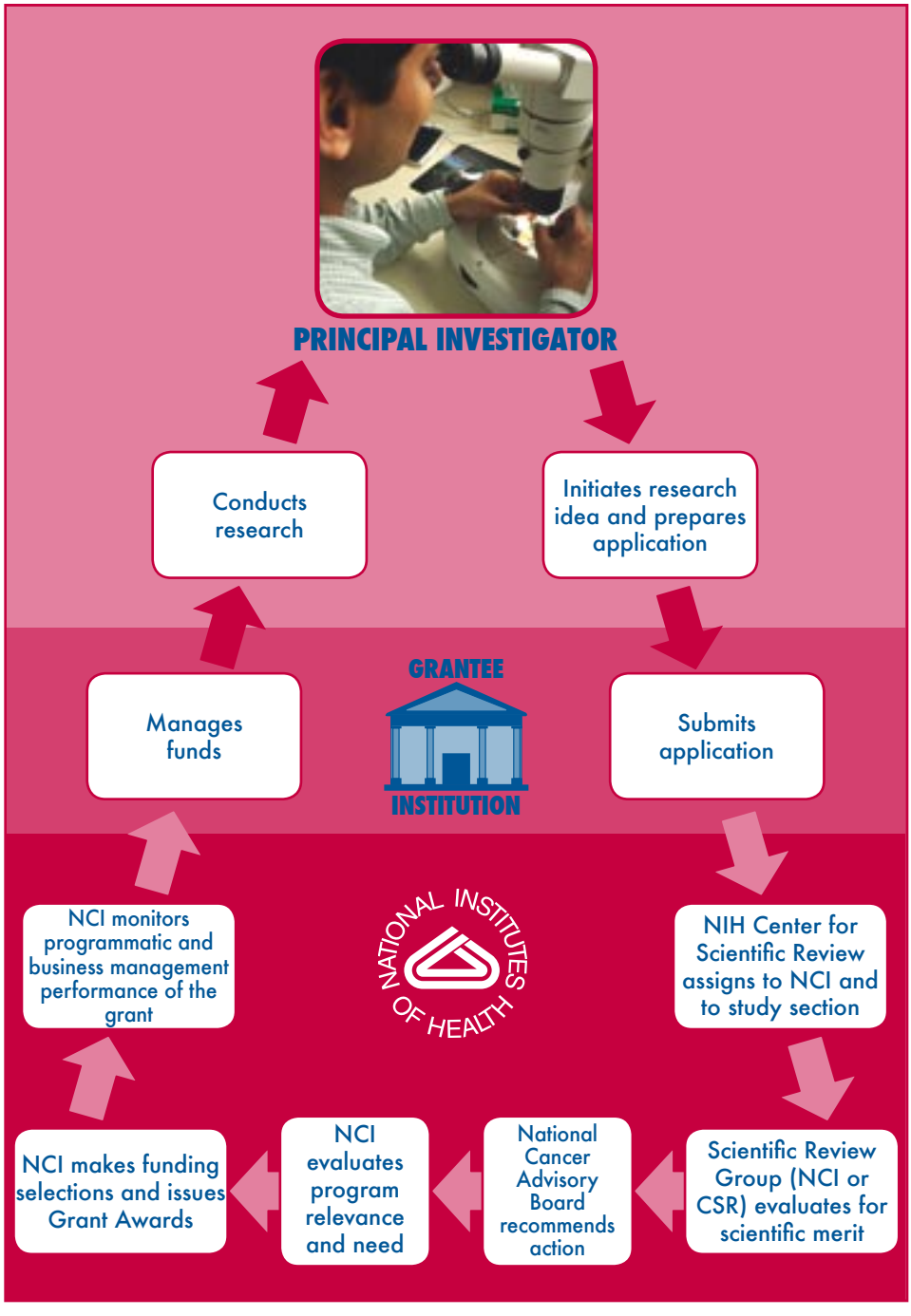
CHAPTER 1

OVERVIEW: THE GRANTS PROCESS

Aerial view of the NIH Campus

FIGURE 1 Overview of the NIH/NCI Grants Process



INTRODUCTION

Statement of Purpose

The Department of Health and Human Services (HHS) touches the lives of every American. The American public expects grants awarded by HHS's operating divisions to help the HHS achieve its health and human services goals. The general goal of grants management is to provide quality stewardship of grants. As an operating division of HHS, the National Institutes of Health (NIH) and its Institutes and Centers provide open, fair, and objective selection of projects with the highest potential for success; this is one key component of quality stewardship.

Within the National Cancer Institute (NCI), the Grants Administration Branch (GAB) is responsible for monitoring the grants process to ensure that grantees and the Federal Government perform all required business management actions in a timely manner, both prior to and after award. In carrying out this responsibility, the GAB evaluates and monitors: (1) the business management capability and performance of applicant organizations and grantees; and (2) the internal operating procedures associated with the business management aspects of the grants process. Due to the interrelationships between grants management and program matters, close coordination between GAB and program staff is most important.

The GAB directs the following statement of purpose to the grantee community and our colleagues within the NIH as a pledge to:

- Negotiate and issue quality NCI grant awards within the appropriate timeframe, thus facilitating cancer research through administrative excellence.
- Serve as the NCI's resource point for providing accurate and timely business-related grant information.
- Act as the NCI's authorized Federal office with which the grantee, program staff, or other NIH organizational elements can interact to obtain guidance, direction, and assistance regarding the review and interpretation of policies and administrative requirements as they apply to research grants and grantee institutions.
- Monitor the financial and management aspects of grants to ensure the effective utilization of Federal funds.
- Focus on building and maintaining a partnership with the grantee and with the NCI program and review staff to ensure the issuance of award documents that clearly communicate grant requirements and protect the NIH from waste, mismanagement, fraud, and costly disputes.
- Provide quality service promptly, both within the NIH and to the grantee community, reflecting a continuing commitment to improve grants management, thereby enabling the grantee to perform its research in an open Federal research environment free of unnecessary record collection and reporting requirements.

The Department of Health and Human Services (HHS)

The HHS's mission is to enhance the health and well-being of Americans by providing effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. The HHS consists of the Office of the Secretary, which provides leadership; the Program Support Center, which provides centralized administrative support; and 11 operating divisions, which manage over 300 health-related programs. These operating divisions are:

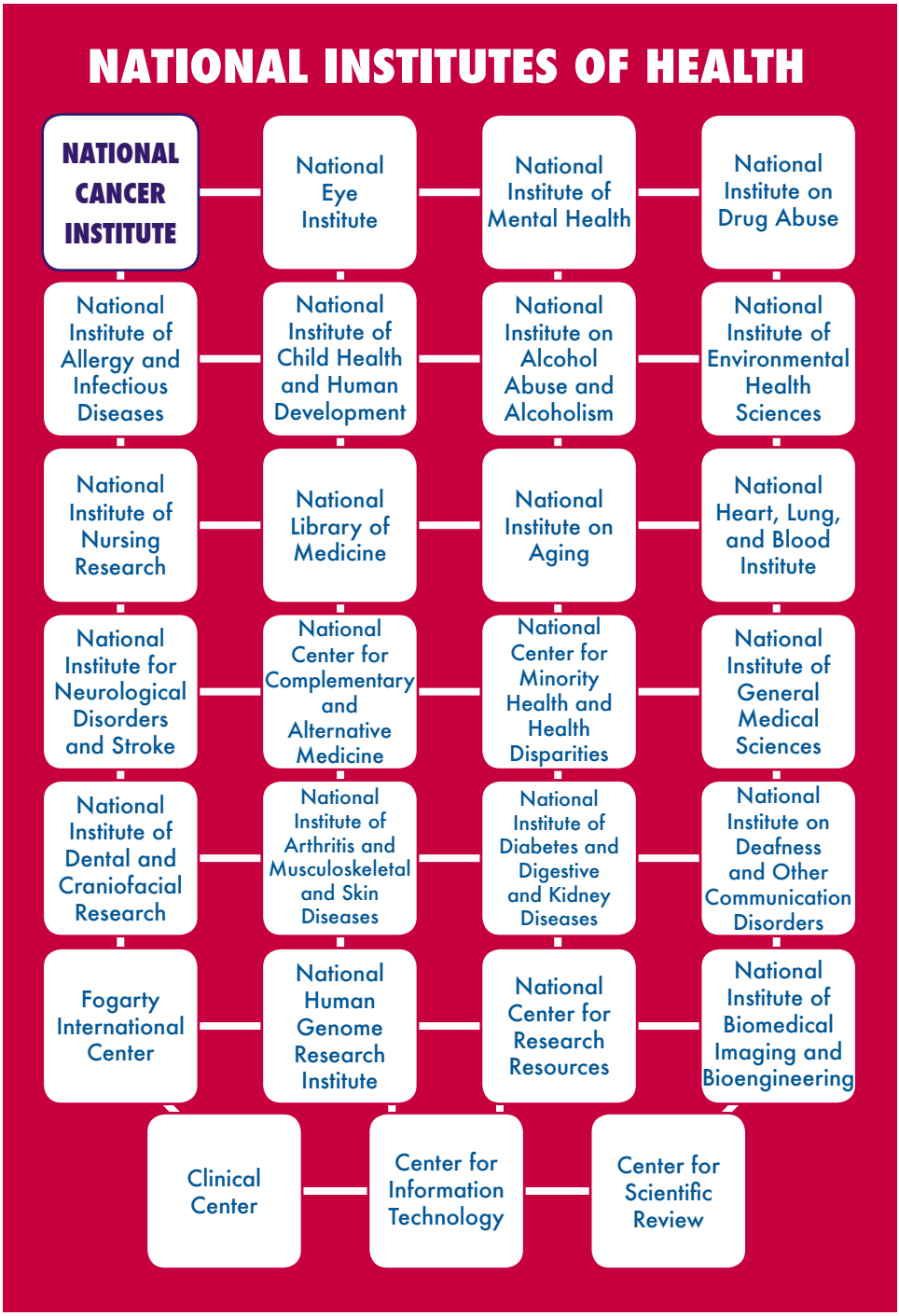
- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS) (formerly 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)**
- 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. The NIH, AHRQ, ATSDR, CDC, FDA, HRSA, IHS, and SAMHSA are all devoted to public health and comprise the Public Health Service (PHS).

The National Institutes of Health (NIH)

The 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 researchers; and fostering communication of medical information. The NIH's budget has grown from $300 in 1887, when the NIH was a one-room Laboratory of Hygiene, to more than $28.8 billion in 2004. The NIH is composed of the Office of the Director, 19 Institutes, 7 Centers, and the National Library of Medicine. Located on more than 300 acres in Bethesda, Maryland, the NIH is composed of more than 75 buildings.

FIGURE 2 NIH Organizational Chart



The National Cancer Institute (NCI)

Mission

Simply stated, the mission of the NCI is to eliminate cancer and prevent the devastation that cancer imposes on individuals, families, and society as a whole. The NCI's goal is to stimulate and support scientific discovery and its application to achieve a future where all cancers are uncommon and easily treated. The NCI works toward this goal in two major ways:

- The NCI provides vision to the nation and leadership for NCI-funded researchers across the United States and around the world.
- The NCI works to ensure that the results of research are used in clinical practice and public health programs to reduce the burden of cancer for all people.

Background

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 a professional judgment budget reflecting the full funding needs of the National Cancer Program directly to the President. This budget is referred to as the Bypass Budget. An overview of the budget process is presented in Chapter 2 of this publication.

Original road sign that reflects NCI as the only Institute of the NIH

Function

Over the years, legislative amendments have maintained the NCI's authority and responsibilities and have added new information dissemination mandates, as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice. The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer; rehabilitation from cancer; and the continuing care of cancer patients and the families of cancer patients. Specifically, the NCI:

- Supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad through research grants and cooperative agreements.
- Conducts research in its laboratories and clinics.
- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and

treatment programs relating to cancer through career awards, training grants, and fellowships.

- Supports research projects in cancer control.
- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.
- Encourages and coordinates cancer research by industrial concerns where such concerns evidence a particular capability for programmatic research.
- Collects and disseminates information on cancer.

Organization

The NCI's Office of the Director serves as the focal point for the National Cancer Program, with advice from the President's Cancer Panel, the National Cancer Advisory Board (NCAB), the Board of Scientific Counselors (BSC), and the Board of Scientific Advisors (BSA).

The Division of Extramural Activities (DEA) coordinates the review of grants and contracts and manages the functions of the NCAB and the BSA. One intramural research Center, one intramural research Division, and four extramural research Divisions monitor and administer the NCI's cancer research activities through extramural and intramural research programs.

The Office of the Director coordinates initiatives across the NCI's four extramural research divisions:

- Division of Cancer Biology (DCB)
- Division of Cancer Control and Population Sciences (DCCPS)
- Division of Cancer Prevention (DCP)
- Division of Cancer Treatment and Diagnosis (DCTD)

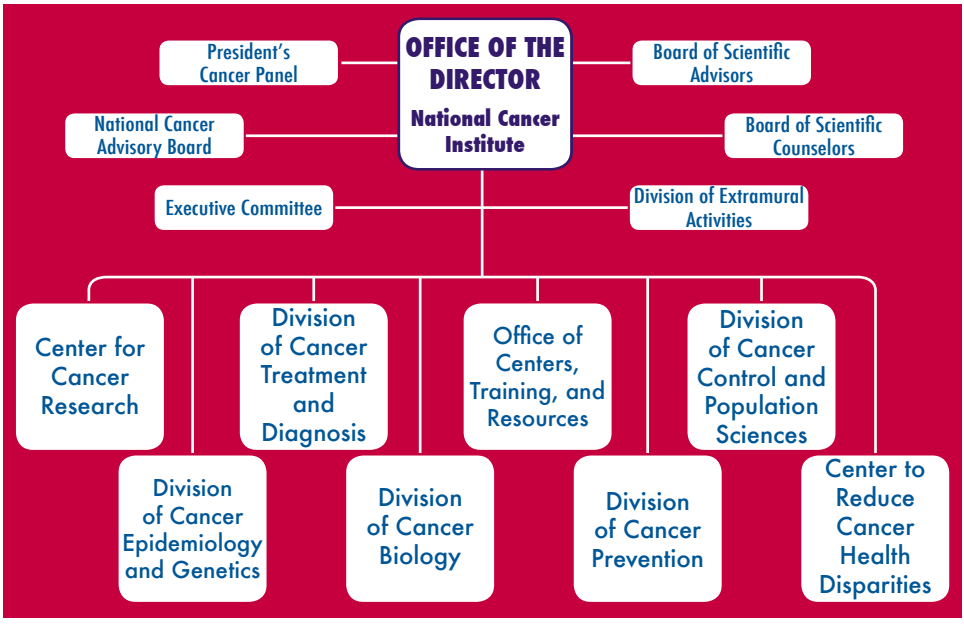
Executive Committee

The NCI Executive Committee (EC), which consists of high-level Institute managers, makes all major organizational and operating decisions affecting the NCI, including:

- Formulating scientific and management policy decisions.
- Establishing grant paylines and funding plans for those grant programs not administered solely by one Division.
- Approving certain exceptions to grant funding plans.
- Reviewing contract, cooperative agreement, and grant concepts.
- Formulating the long-range strategic plan for the Institute.
- Addressing trans-NCI policy issues affecting personnel and resources.

In addition to weekly meetings, the EC meets with other NCI staff twice a year, in the summer and winter, for 1 or 2 days, to establish budget priorities and policies for the forthcoming year.

FIGURE 3 NCI Organization and Advisory Structure



Budget

The NCI's budget is composed of four major activities:

- Research
- Resource Development
- Cancer Prevention and Control
- Program Management and Support

For additional information on the NCI budget activities and funding allocation, see Chapter 2, page 27.

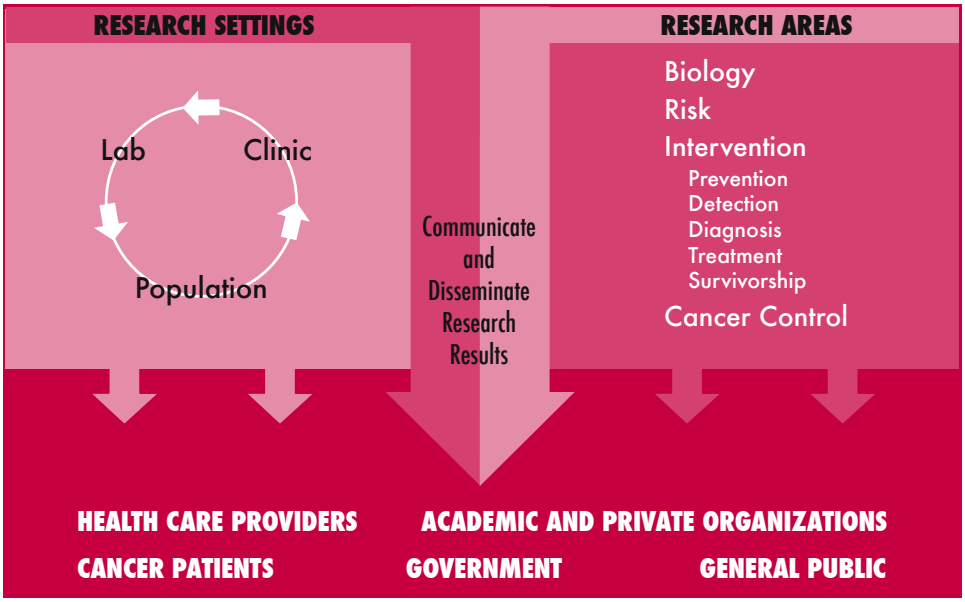
Research Settings

NCI-sponsored research takes place in the following three settings:

- Laboratory: In the laboratory, research is pursued on the biology of cancer, the fundamental properties of cancer-causing agents and processes, and the body's defense against and response to cancer.
- Clinic: In the clinic, patient-oriented research is carried out in prevention, detection, diagnosis, treatment, and rehabilitation.
- Community: In the community, research is carried out on the causes, risks, predispositions, incidence, and behavioral aspects of cancer within the population.

As the diagram in Figure 4 indicates, the interaction of these three components reflects the progression from the results of research through dissemination to application. Research results must be communicated to those who ultimately apply these results in health care and disease prevention settings.

FIGURE 4 Progression From Cancer Research to Application



Types of Funding Instruments

Using a variety of funding instruments, including contracts, grants, and cooperative agreements, the HHS accomplishes much of its mission through services provided by non-Federal entities. Each instrument has a specific purpose and application, thus creating different relationships between the parties.

The Federal Grant and Cooperative Agreement Act of 1977 requires Federal agencies to distinguish procurement relationships from assistance relationships. Although the Act does not dictate any specific terms and conditions that should be placed on contracts, grants, and cooperative agreements, it does require that the choice and use of these legal instruments reflect the type of relationship expected between the Federal and non-Federal parties.

Contracts

The NCI uses the contract instrument to procure cancer research services and other resources needed by the Federal Government. Contracts are used when the principal purpose of the transaction is to acquire a specific service or end-product for the direct benefit of, or use by, the NCI. The remainder of this publication deals only with grants and cooperative agreements.

Grants and Cooperative Agreements

In contrast to contracts, grants and cooperative agreements are Federal financial assistance mechanisms used to support and stimulate research. Assistance relationships are established when the principal purpose of the transaction is to transfer money, property, services, or anything of value

to a recipient to accomplish a public purpose or to stimulate a particular area of research authorized by law. HHS's assistance mechanisms range from providing individuals with Federal cash assistance to reimbursing states for assistance provided to refugees or other beneficiaries for whom the Federal Government has accepted responsibility. These assistance mechanisms also include loan guarantees provided through financial institutions and various types of price supports and subsidies. The two types of assistance mechanisms used by the NCI are the grant and the cooperative agreement:

- Grants are used when: (1) no substantial programmatic involvement is anticipated between the NCI and the recipient during performance of the financially assisted activities, thus allowing the recipient significant freedom of action in carrying out the research project; and (2) there is no expectation on the part of the NCI of a specified service or end-product for use by the NCI.
- Cooperative agreements are used when substantial programmatic involvement is anticipated between the NCI and the recipient during the performance of the activities. (Note: The NIH does not accept unsolicited cooperative agreement applications.)

In the following pages of this publication, the word *grant* is used to indicate an assistance mechanism and should be construed to include cooperative agreements as well.

Legal instruments reflect the type of relationship expected between the Federal and non-Federal parties.

NCI Grants Administration Branch

NCI Grants: Historical Perspective

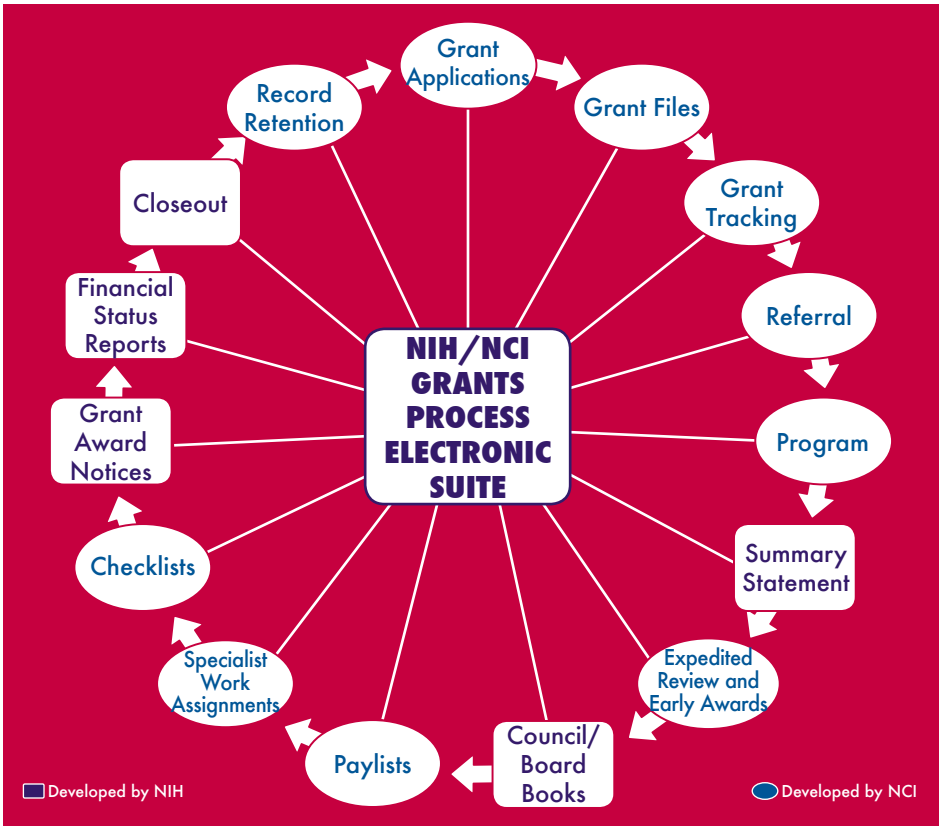
The first cancer research grant funded by the NCI was awarded to Louis F. Fieser, of Harvard University, on November 27, 1937. It was funded for $27,550 to investigate chemical structure and carcinogenic activity. The grant identification number was IC3. Since the funding of grant IC3, the NCI has funded approximately 188,000 grants, accounting for $41 billion in expenditures.

Since passage of the National Cancer Act and the creation of the National Cancer Program in 1971, the NCI's annual appropriation has increased nearly 26-fold, from $180 million in fiscal year (FY) 1971 to $4.72 billion in FY2004. Nearly $3.1 billion (over 67 percent) of the NCI's FY2004 appropriation was awarded in grants and cooperative agreements.

NIH/NCI Grants Process Electronic Suite

The NIH/NCI Grants Process Electronic Suite (GPES) is defined as the electronic process, from application receipt to record retention and disposal, that encompasses the 15 elements of the grant award process as displayed in Figure 5. The GPES is made up of an interconnected set of modules that provides for a single entry of grant data. The NCI Enterprise is composed of an Oracle database and NCI-developed applications that support the business needs of the NCI Extramural Staff.

FIGURE 5 NCI Grants Administration Branch Electronic Grants Process



Working in unison with the NIH Enterprise, the NCI Enterprise supports the grants process from pre-referral to award and crosses the business areas of NCI Referral, Program, Grants Administration, and Financial Management. The goals of the GPES are eliminating paper grant files and facilitating the ability to work the entire grants process electronically. Currently, NCI grants management staff are working 100 percent of their grant portfolio electronically.

Grants Administration Branch

The NCI's Grants Administration Branch (GAB) is the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NCI. The GAB's website can be found at http://www3.cancer.gov/admin/gab/.

In the GAB, we approach our work with grantee business officials, Principal Investigators (PIs), NIH and NCI review staff, and NCI program staff with a common goal: the accomplishment of the project for which the grant is awarded.

In our grants management role, we continually seek new and better ways to promote an environment in which PIs can pursue their research in the

most productive and cost-effective manner possible. We place emphasis on problem prevention. We accomplish this by working with grantee officials to ensure that they have adequate business management systems and internal controls to properly safeguard Federal resources. We work with review and program staff to ensure the effective stewardship of Federal funds and uniform administration of various grant programs in accordance with Federal grant requirements. Our goal is to support biomedical research through administrative excellence.

Grants Authorities

The Constitution

The requirements to which research grants are subject have their roots in a number of specific sources or authorities, the broadest of which is the U.S. Constitution. Congress has the authority to impose conditions on the receipt of Federal assistance funds. The cornerstone of Congress' authority in the grants area is Article I, Section 8, of the United States Constitution, referred to as the Spending Power Clause, which provides that "... Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and to provide for the … general welfare of the United States …." Thus, Congress can enact statutes authorizing Federal agencies to award grants and impose reasonable conditions on the receipt of Federal assistance funds.

Laws that authorize the formulation of regulations for grant programs are ultimately based on constitutional provisions. For example, the HHS and the NIH grant appeals procedures can be traced to the due process principles outlined in the Constitution under the Fifth Amendment. Another example is the Public Health Service (PHS) grant application form, which contains provisions relating to civil rights, handicapped individuals, and age and sex discrimination. These are all extensions of constitutional requirements for equal protection under the law covered in the 14th Amendment to the U.S. Constitution.

Statutes

The next broad level of Federal grant lawmaking is the enactment of specific laws by Congress. Two of the most important are authorizing legislation and appropriation legislation.

The authority to award grants is contained in the basic substantive legislation establishing a Federal program. Such legislation may authorize program expenditures for a specific or indefinite number of years. In the NCI's case, the Public Health Service Act, Section 301 (42 United States Code [USC] 241), contains the general authority, as indicated by Congress, under which research grants are awarded.

Subsequent to the enactment of authorizing legislation, Congress generally enacts appropriation laws permitting funds to be obligated for a specific program. Appropriation bills begin in the House of Representatives and then are acted upon by the Senate. Through the appropriation process,

Congress greatly influences both program and grants administration decisions by controlling the amount of funds authorized annually and by setting conditions on the use of funds.

Regulations

Because the language of many laws is vague, Federal agencies often need to publish regulations to clarify the details. A "rule" or "regulation" is a formal document issued by a Federal agency that has general or particular applicability and legal effect. Compliance with Federal regulations and statutes must be taken seriously. When finalized, regulations have the full force and effect of law.

The *Code of Federal Regulations* (CFR) (http://www.gpoaccess.gov/cfr/index.html), a codification of permanent rules published in the *Federal Register* (http://www.gpoaccess.gov/fr/index.html), contains the regulations for reviewing and administering NCI grants. These requirements provide additional guidance regarding program requirements and management. (Some programs have guidelines instead of or in addition to regulations.)

Three of the most important sections pertaining to NCI grants are:

- 42 CFR Part 52 (Grants for Research Projects) for broad grant program regulations.
- 45 CFR Part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations; and Certain Grants and Agreements With States, Local Governments and Indian Tribal Governments).
- 45 CFR Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments) for administrative regulations.

OMB Circulars

In addition to the provisions of authorizing legislation and implementing regulations, the Office of Management and Budget (OMB) issues government-wide circulars for managing grants that apply to all Federal Executive agencies. When these agencies are required to apply the directives, the effect on grantees is often the same as regulation. Among the circulars relevant to grants administration are those that have to do with administrative requirements, cost principles, and audits.

Administrative Requirements

- ♦ A-102 (rev.) Grants and Cooperative Agreements With State and Local Governments establishes consistency and uniformity among Federal agencies in the management of grants and cooperative agreements with state, local, and federally recognized Indian tribal governments.
- ♦ A-110 (rev.) Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations sets forth standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and nonprofit organizations. 45 CFR Part 74 extends the provisions of A-110 to commercial (for-profit) organizations.

Cost Principles

- A-21 (rev.) Cost Principles for Educational Institutions establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions.
- A-87 (rev.) Cost Principles for State, Local, and Indian Tribal Governments establishes standards for determining costs for Federal awards carried out through grants, cost reimbursement contracts, and other agreements with state and local governments and federally recognized Indian tribal governments.
- A-122 (rev.) Cost Principles for Nonprofit Organizations establishes principles for determining costs applicable to nonprofit organizations.
- 45 CFR Part 74 Appendix E establishes principles for determining costs applicable to hospitals.
- 48 CFR Part 31.2 (Federal Acquisition Regulations) establishes cost principles for commercial (for-profit) organizations.

Audits

- A-133 (rev.) Audits of States, Local Governments, and Other Nonprofit Organization establishes consistent and uniform audit requirements and defines Federal responsibilities for implementing and monitoring such requirements for states, local governments, and other nonprofit organizations receiving Federal awards. Audit requirements for commercial (for-profit) organizations are contained in 45 CFR Part 74. See page 73 for more information.

Agency Implementations

In addition to issuing regulations to specify details of the enabling statutes, agencies often find it helpful to publish handbooks, guidelines, or manuals. The NCI implements Federal regulations by following the policies contained in the *NIH Grants Policy Statement* and the *NIH Guide to Grants and Contracts*.

The *NIH Grants Policy Statement* is a condensation of the NIH and HHS grants administration policies, laws, and regulations. It provides both up-to-date policy guidance that serves as NIH standard terms and conditions of awards for grants and cooperative agreements and extensive guidance to individuals who are interested in NIH grants.

The *NIH Guide to Grants and Contracts* is the official publication for NIH medical and behavioral research grant policies, guidelines, and funding opportunities. It is also used by the NIH Contracting offices and other HHS agencies to announce their funding opportunities. The *NIH Guide* serves in lieu of the *Federal Register* in compliance with the Administrative Procedures Act.

The NCI has developed individual guidelines for certain types of grants. There are now guidelines available for Cancer Center Support Grants (Core P30), Program Project Grants (P01), Specialized Programs of Research Excellence (P50, SPOREs), Construction Grants (C06), Clinical Trials Cooperative Group Program Grants (U10), and Cancer Education Grants (R25).

Cross-Cutting Public Policies

A variety of statutory or administrative requirements cut across Federal programs and impact the administration of grants. These "cross-cutting" public policies, which apply to almost every grant program, are intended to ensure fairness and equity, as well as physical and other protections in activities receiving Federal financial assistance. A summary of some of these cross-cutting public policy requirements that apply to grants management is provided in Chapter 5 of this publication. NIH grantees are also subject to requirements contained in the NIH's Annual Appropriations Act that apply to the use of NIH grant funds. Some of these requirements are included in Chapter 5 of this publication because they have been included in the NIH's Annual Appropriations Act for several years without change. However, these requirements may be changed, or other requirements may be added in the future.

Notice of Grant Award

The Notice of Grant Award (NGA) is the official notification to the applicant that a project has been funded. Each grant award is authorized by statute. For example, in the sample Notice of Grant Award letter (Exhibit D, p. 121), the authorizing legislation is 42 USC 241. Each award also cites particular regulations that authorize its issuance.

The final sources of requirements imposed on projects supported by Federal grants are the specific terms and conditions that are attached to an individual grant and incorporated into the formal NGA. These terms and conditions may include the basic purpose of the award, policy statements, and OMB Circulars. These latter materials may be incorporated by reference. By accepting the award (i.e., by drawing funds from the grant payment system), every grant recipient agrees to comply with everything incorporated by reference into the NGA.

Order of Precedence

As a general rule, requirements imposed by statute (42 USC 241 et seq.) and requirements imposed by program or general regulations (42 CFR Part 52 and 45 CFR Parts 74 and 92) are supplemented by program policies and terms and conditions of individual grants. When grant requirements are inconsistent, the following order of precedence usually applies: Constitutional mandates govern statutory provisions, and statutory mandates govern regulatory provisions. Regulations published in the *Federal Register* generally govern unpublished requirements, including grant terms and conditions. Questions concerning any apparent conflict in requirements or precedence of requirements governing grants should be addressed to the Grants Management Officer, who may consult with the Office of the General Counsel.

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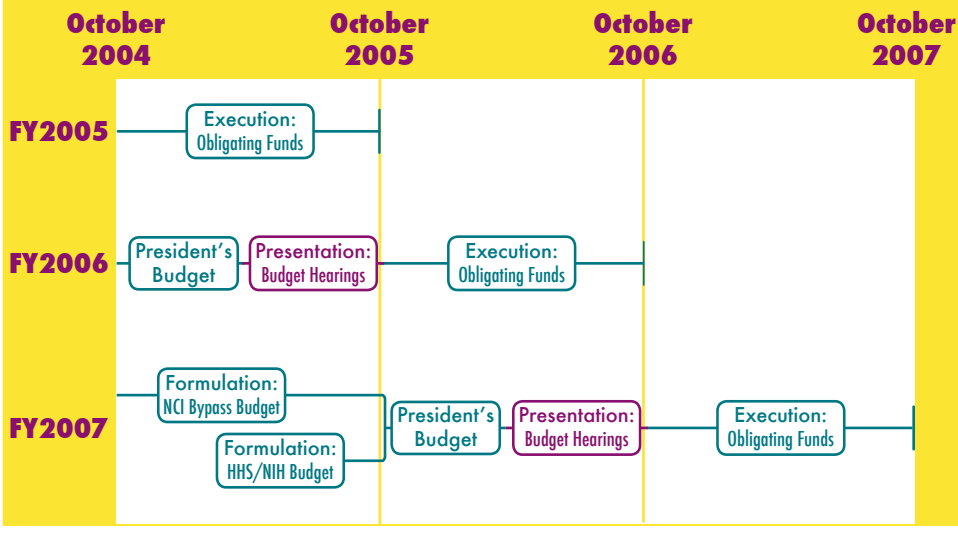
CHAPTER 2

ALLOCATION OF GRANT FUNDING

The budget development cycle for a fiscal year is about 30 months, with three phases of this process—formulation, presentation, and execution—overlapping. In the example below (Figure 6), FY2005 is being executed while FY2006 is being presented and FY2007 is being formulated.

In the spring of each year, preliminary budgets are submitted. The NIH budget is paralleled by a professional needs budget, referred to as the Bypass Budget, prepared by the NCI. In September, revised versions of these budgets are submitted to the Office of Management and Budget. In January, the President's budget is submitted, and congressional justification hearings are held in February, March, or April.

FIGURE 6 NCI Budget Development Cycle



Funding Allocation Process: 1–2–3

The following is a summarized general description of the three-step funding allocation process for Research Project Grants (RPGs):

Step 1: From the amount appropriated by Congress, deduct:

- The amount of noncompeting commitments, including the program evaluation budget.
- The amount for mandated set-asides (e.g., SBIR).
- The amount for program initiatives (RFAs).

This leaves the amount for competing grants.

Step 2: From the amount remaining for competing grants:

- Distribute to the main mechanisms (R01 and P01) and the smaller mechanisms (R03, R21, R33, and R55).
- Hold approximately 5 to 10 percent in reserve for RPG exceptions (including accelerated executive review exceptions).
- Distribute the exception reserve to Program Division Director for supplements, RPGs, exceptions, and Shannon Awards.
- Allocate across each of the three review rounds.

Step 3: Based on historical data and current review results, set paylines for RPGs.

Funding Allocation: A Practical Example

The following example provides a sample appropriation and distribution for Research Project Grants (RPGs), using the following assumptions:

- Appropriation level of $2.161 billion
- Mandate to fund 1,492 competing RPGs
- Mandate that the average cost of the competing RPGs be no more than $332,000

	Amount	No. of Awards
Step 1		
Appropriation	$2,161,000,000	
Small Business Set-Aside	100,000,000	
Noncompeting Commitments	1,567,000,000	
Competing Availability	494,000,000	
Step 1a		
Competing Availability	494,000,000	1,492
Set-Aside for RFAs	42,000,000	67
Remaining for R01, P01, R21, etc.	452,000,000	1,425
Step 2		
Remaining for R01, P01, R21, etc.	452,000,000	1,425
The breakdown would be:		
Allocation for R01, R37	302,000,000	906
Allocation for P01	52,000,000	33
Allocation for R21, R33	39,000,000	216
Allocation for R03, etc.	14,000,000	152
Reserve for exceptions	45,000,000	118

At this point, these amounts would be distributed to each of the three rounds.

Step 3 would consist of setting paylines for RPGs based on historical data and current review results.

In fiscal year 2004, the National Cancer Institute's budget totaled **$4,723,893,000**. Expenditures in the four major budget activities are outlined in the following paragraphs.

Research

Cancer Causation Research

- **FY2004 Obligations: $1,112,937,000**
- **23.6% of the NCI Budget**

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
- Nutrition research

Studies in this area focus on the following external agents that contribute to the initiation and promotion of cancer:

- Chemicals
- Radiation
- Fibers and other particles
- Viruses
- Parasitic infections
- Host factors such as hormone levels and nutritional and immunologic status
- Genetic endowment of the individual

Detection and Diagnosis Research

- **FY2004 Obligations: $335,701,000**
- **7.1% of the NCI Budget**

Detection and diagnosis research includes studies designed to:

- Improve diagnostic accuracy.
- Provide better prognostic information to guide therapeutic decisions.
- Monitor response to therapy more effectively.
- Detect cancer at its earliest presentation.
- 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 cancers.
- Transfer of molecular technologies from the laboratory to clinical practice.

- Identification of better prognostic markers.
- Increased availability of human tumor samples with associated clinical information.
- Research to identify genetic alterations involved in tumor pathogenesis and behavior.

Treatment Research

- **FY2004 Obligations: $1,092,437,000**
- **23.1% of the NCI Budget**

Treatment research is composed of preclinical and clinical research. Preclinical research focuses on the discovery of new antitumor agents and their development in preparation for testing in clinical trials. These agents include both synthetic compounds and natural products. Clinical research involves demonstrating the effectiveness of new anticancer treatments through their systematic testing in clinical trials:

- Phase I trial–The first step in testing a new treatment in humans. These studies test the best way to give a new treatment (for example, by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Since little is known about the possible risks and benefits of the treatments being tested, Phase I trials usually include only a small number of patients who have not been helped by other treatments.
- Phase II trial–A study to test whether a new treatment has an anticancer effect (for example, whether it shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.
- Phase III trial–A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into Phase III only after a treatment seems to work in Phases I and II. Phase III trials may include hundreds of people.

Cancer Biology

- **FY2004 Obligations: $758,762,000**
- **16.1% of the NCI Budget**

Cancer biology supports a broad spectrum of research, including the body's response to cancer. Since 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. Studies include:

- Investigations of cellular and molecular characteristics of tumor cells.
- Interactions between cells within a tumor.
- Components of host immune defense mechanisms.

Resource Development

Cancer Centers Support

- **FY2004 Obligations: $410,176,000**
- **8.7% of the NCI Budget**

The Cancer Centers Program consists of a group of individual, nationally recognized, geographically dispersed institutions with outstanding scientific reputations. Each institution reflects particular research talents and special technological capabilities. Cancer Center support mechanisms include P20s, P30s, P50 Specialized Programs of Research Excellence (SPOREs), and U54s.

The NCI awards planning and development grants (P20s) to encourage the development of cancer research centers in regions not currently served by existing NCI-designated Clinical or Comprehensive Centers. These awards assist eligible institutions to develop the organizational capability that could lead to the formation and/or development of cancer research centers or SPOREs. This program is currently under review. Refer to http://www3.cancer.gov/cancercenters/ccb_guidelines.html for more information.

The NCI uses the Cancer Center Support Grant (CCSG) mechanism (P30) to support Cancer Centers that conduct research and outreach activities on several different cancers. There are two types of designations: Cancer Centers have a scientific agenda that is primarily focused on basic, population sciences, or clinical research or any two of the three components; Comprehensive Cancer Centers integrate research activities across three major areas: laboratory, clinical, and population-based research.

Of the $409 million allocated to Cancer Centers in fiscal year 2004, approximately $245 million was awarded to the 63 active Centers. This accounted for 5.2 percent of the NCI budget.

Cancer Centers have developed in a number of different organizational settings. Some are independent institutional entities dedicated entirely to cancer research (freestanding 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 individual grants and contracts from the NIH and a variety of other grant-funding agencies and organizations.

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 prevention, detection, diagnosis, and treatment research for a single cancer

site. They are awarded to institutions that demonstrate the ability to perform significant translational research.

The NCI's Comprehensive Minority Institution/Cancer Center Partnership (U54) awards are cooperative agreements designed to establish comprehensive partnerships between Minority-Serving Institutions (MSIs) and NCI-designated Cancer Centers. The partnerships focus on cancer research and one or more target areas in cancer research training and career development, education, or outreach programs to minority communities. These awards improve the effectiveness of Cancer Center research through education and outreach activities specifically designed to benefit racial and/or ethnic minority populations in the region the Cancer Center serves. They also create a stable, long-term collaborative relationship between the MSI and NCI-designated Cancer Center in areas of cancer research, research training and career development, education, and/or outreach that increases the emphasis on problems and issues relevant to the disproportionate cancer incidence and mortality in minority populations.

Research Manpower Development

- **FY2004 Obligations: $173,691,000**
- **3.7% of the NCI Budget**

The NCI Research Manpower Development Program supports and maintains a pool of trained scientists qualified to perform cancer research. Grants under this program primarily provide support for basic and clinical scientists. The National Research Service Award Program is the major mechanism for providing long-term, stable support for a wide range of promising scientists and clinicians. Individual awards are made directly to both pre- and postdoctoral fellows, while institutional awards are made to scientists who, together with a group of faculty preceptors, administer a comprehensive research training program for pre- and postdoctoral trainees. The Research Career Program 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.

Cancer Prevention and Control

- **FY2004 Obligations: $511,111,000**
- **10.8% of the NCI Budget**

The NCI Cancer Prevention and Control Program conducts basic and applied research through both intramural and extramural mechanisms. 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:

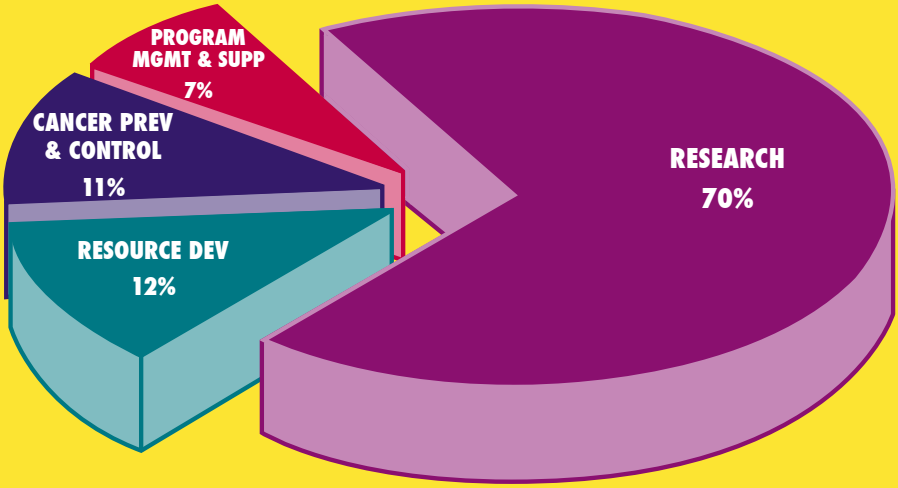
- Cancer Prevention Research.
- Cancer Control Science.
- Early Detection and Community Oncology.
- Cancer Surveillance.

Program Management and Support

- **FY2004 Obligations: $329,078,000**
- **7.0% of the NCI Budget**

Program Management and Support budgets are used for the critical technical and administrative services required for NCI to carry out its extramural, intramural, and cancer prevention and control programs. They include central administrative functions, overall program direction, grant and contract review and administration, personnel, program coordination, and financial management.

FIGURE 7 NCI FY2004 Budget Activities



BUDGET ACTIVITY	AMOUNT	% OF TOTAL
Research:		
Cancer Causation	$1,112,937	23.6%
Detection and Diagnosis Research	335,701	7.1%
Treatment Research	1,092,437	23.1%
Cancer Biology	758,762	16.1%
Subtotal, Research	3,299,837	69.9%
Resource Development:		
Cancer Centers Support	$410,176	8.7%
Research Manpower Development	173,691	3.7%
Subtotal, Resource Development	583,867	12.4%
Cancer Prevention and Control	511,111	10.8%
Program Management and Support	329,078	7.0%
*TOTAL NCI	$4,723,893	100%

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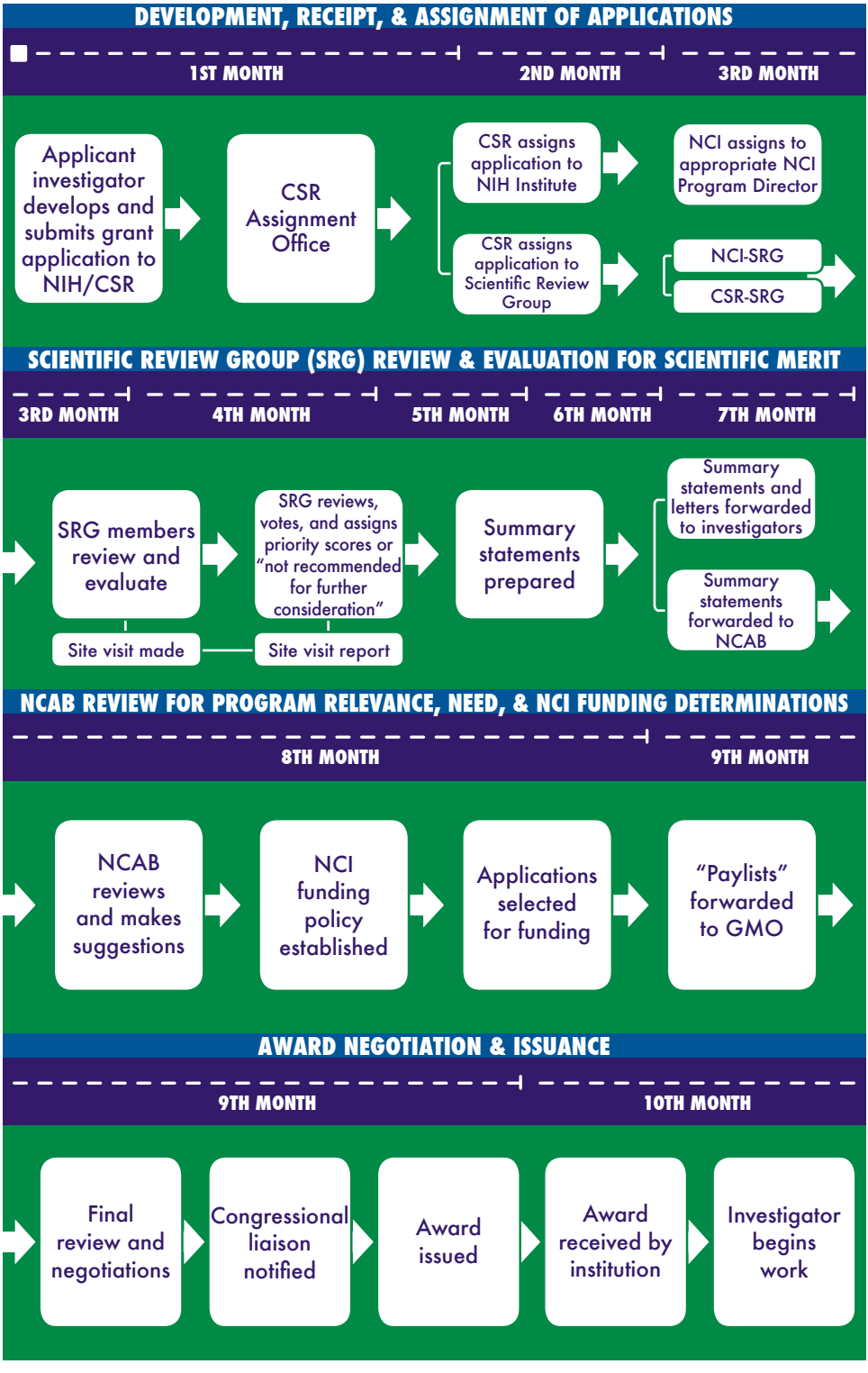
CHAPTER 3

REVIEW AND ADMINISTRATION

Building 1–James A. Shannon Building

FIGURE 8 NCI Grants Process



DEVELOPMENT, RECEIPT, & ASSIGNMENT OF APPLICATIONS

This section charts the path of a grant application from development, receipt, and assignment through the peer review process, NCI funding determinations, award negotiation and issuance, and—finally—post-award administration (see Figure 8, p. 38). Ongoing efforts to streamline the grants process at the NIH will continue to impact the manner in which grant awards are processed at the NCI. However, the core concepts discussed in this section are expected to remain essentially the same.

Grantee Eligibility

Grants may be awarded to:

- Nonprofit organizations
- For-profit organizations
- Institutions of higher education
- Hospitals
- Research foundations
- State and local governments
- Federal institutions
- Individuals (fellowships only)
- Foreign institutions and international organizations (research grants only)
- Faith-based organizations

Principal Investigator Responsibility

The Principal Investigator (PI) is the individual designated by and accountable to the grantee institution for the proper conduct of the project. By signing the grant application, the PI accepts responsibility for the scientific conduct of the project and for submission of the progress and other required reports.

Grantee Institution Responsibility

By applying for grant support, the grantee institution agrees to administer awarded grant(s) in accordance with the regulations and current policies that govern the research grant programs of the NIH. Acceptance of an award and its associated special terms and conditions imposes upon the grantee institution and the PI the responsibility for conducting the research while using grant funds prudently and in accordance with cost principles for the purposes set forth in the approved application. The grantee organization is legally responsible and accountable to the NIH for the performance and financial aspects of the grant-supported activity.

As noted in the "Notice of Grant Award" section, (p. 25) the grantee indicates acceptance of the general and special provisions of an award by drawing funds from the grant payment system. The grantee institution is not required to guarantee the success of the project, nor are penalties generally

imposed for lack of success in attaining scientific goals. However, in certain situations, the NCI may take action to resolve problems or weaknesses that arise during the course of the project. (See "Monitoring Projects," p. 70, for further information.)

Standards of Conduct

The NIH depends on the funded research community to utilize a system of self-regulation coupled with appropriate NIH oversight. Ethical concerns, such as human subjects protection (45 CFR Part 46), promotion of animal welfare (P.L. 99-158 Section 495), removal of financial conflict of interest (42 CFR Part 50, Subpart F), and prevention of scientific misconduct (42 CFR Part 50, Subpart A) are all a part of this self-regulation.

The principle of self-regulation requires a high level of trust in the fundamental integrity of the research community and sufficient oversight to enable the NIH to assure the public that self-regulation is providing adequate safeguards for the ethical integrity of science.

Development of Grant Application

The process of developing a grant application usually begins with the Principal Investigator (PI). The PI should work together with the authorized business official from his/her institution to ensure that all of the application requirements are met. Applicants should anticipate 2 or 3 weeks to prepare a small project application. Complex proposals may require as much as a year. Both the PI and the authorized business official must sign and date Form Page 1 (also known as the "face page") to certify that the application is complete and accurate. (See Exhibit A, p. 116, for an example of a grant application face page.)

Numerous resources are available from the NIH with important considerations and suggestions to assist the PI and the applicant institution in preparing a research grant application. Among these, the NCI offers the following two websites:

- *Preparing Grant Applications* (http://deainfo.nci.nih.gov/extra/extdocs/apprep.htm)
- *Grant Application and Review Process* (http://www.cancer.gov/research_funding/grants/)

Although many investigator-initiated (unsolicited) applications are received by the NIH for new, expanded, and/or high-priority programs, the NCI may encourage the submission of grant applications through the following types of solicitations:

- Program Announcements (PAs) notify the grantee community of continuing, new, or expanded program interests for which grant applications are invited. Applications in response to PAs are reviewed in the same manner as unsolicited grant applications by Scientific Review Groups (i.e., committees) of the Center for Scientific Review or NCI.
- Program Announcements Reviewed in an Institute (PARs) are announcements that contain special referral guidelines and are

reviewed by a Scientific Review Group (SRG) in the IC (Institute and/or Center) within NIH.

- Requests for Applications (RFAs) are issued to invite grant applications in a well-defined scientific area to stimulate activity in an IC's priority programs. The RFA identifies a single receipt date, the amount of funds earmarked for the initiative, the number of awards likely to be funded, and any specific criteria for scientific peer review. Applications received in response to a particular RFA are reviewed by an Institute's SRG.

All PAs, PARs, 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.

Applicants anticipating submission of an application exceeding $500,000 in direct costs in any year of the project must seek approval from the awarding IC's Program Director at least 6 weeks prior to submission. If the requested amount is significantly greater than $500,000, approval should be sought even further in advance. (See *NIH Guide* Notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.) Applications submitted in response to RFAs or other announcements that include specific budgetary limits are exempt from this requirement.

Allowable Costs

Research grant funds are awarded to supplement or complement the support of research at an institution. Grant funds may be used for:

- Allowable direct costs specifically incurred in the conduct of the research project.
- Facilities and administrative (F&A) costs (formerly known as indirect costs [overhead]) resulting from an institution providing support services.

These funds are not intended to replace support already being furnished by the institution or for expenses previously incurred.

Direct Costs

Allowable direct costs may include:

- Salaries and fringe benefits of the Principal Investigator, other key personnel, and supporting staff.
- Expenditures for project-related equipment and supplies.
- Fees and supporting costs for consultant services.
- Expenses for travel beneficial to the research.
- Research patient care costs.
- Alterations and renovations.
- Publications and other miscellaneous expenses.
- Contract services.
- Costs for consortium participants.

Facilities and Administrative Costs

In addition to direct costs, the HHS supports a policy of full reimbursement of facilities and administrative (F&A) costs for most grant programs, with a few exceptions (e.g., training, fellowships, career programs, cancer education grants, and foreign grants). F&A costs are not readily identifiable with a particular project or activity but are necessary to the general operation of the institution and the conduct of its research activities.

Allowable F&A costs may include:

- Depreciation use allowance.
- Facilities operations and maintenance.
- General administration and general expense.
- Departmental administration.
- Sponsored project administration.
- Libraries.

The grantee institution assigns the costs to an F&A cost pool from which they are appropriately distributed to all organizational activities on the basis of a rate. The rate is a ratio of the F&A costs to a direct cost base. The amount awarded for F&A costs is determined by multiplying the rate by the allowable costs in the direct cost base for the project.

Rate Agreement

In order to receive reimbursement for F&A costs, the grantee institution must prepare an annual F&A cost rate proposal, which is submitted to the cognizant Federal agency. The cognizant agency is that which provides the largest amount of funds to a grantee over a specific period and acts as a representative for all Federal agencies dealing with a grantee's common costs (e.g., F&A costs and fringe benefits). After review and negotiation of the F&A cost rate proposal, the cognizant agency establishes an accepted rate, formalized as the F&A cost rate agreement for that institution. This agreement is then made available to all other interested Federal grantor agencies. The negotiated F&A cost rate is used to calculate the applicable amount of F&A costs for each award to the grantee institution.

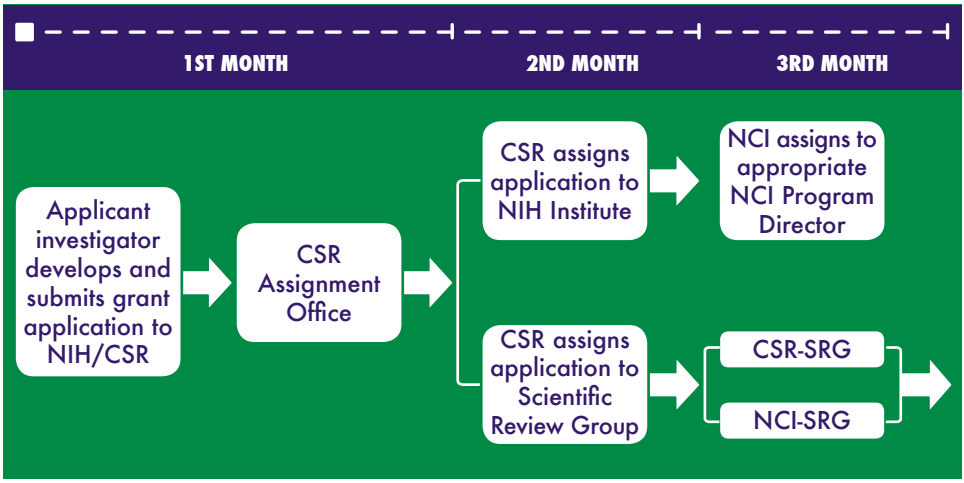
The NIH Notice of Grant Award includes both direct costs and applicable F&A costs, which are calculated by the Grants Management Specialist. Typically, this award reflects the maximum total costs provided during the budget period even if a higher F&A rate is subsequently negotiated. If the amount required for F&A costs decreases because of either a new, lower negotiated rate or post-award budgetary changes in the direct costs of the grant, the excess F&A funds awarded generally may be rebudgeted to support allowable direct costs for the project, subject to specific requirements set forth in the applicable cost principles.

Receipt and Assignment of Applications

The Referral section of the Center for Scientific Review (CSR) serves as the central receiving point for all competing applications, whether solicited or unsolicited. Within the CSR, all competing applications undergo a brief evaluation to determine what area of research each represents. CSR referral officers then assign each application to a specific NIH Institute for possible funding.

The evaluation of scientific and technical merit will be carried out by a Scientific Review Group in either CSR or an appropriate Institute or Center (IC). Applicants are notified by mail of these assignments, usually within 6 to 8 weeks of submission. Figure 9 below provides a typical timeframe from the date of receipt of an application through assignment.

FIGURE 9 Development, Receipt, and Assignment of Applications



Return of Incomplete and Late Grant Applications

A grant application is considered incomplete and will be returned to the submitting institution if:

- It is illegible.
- It fails to follow the instructions provided on the appropriate application form.
- It fails to follow specific instructions provided in an RFA or PA.
- The material presented is insufficient to permit an adequate review.

Information regarding the submission of competing Grant Applications (PHS 398), Noncompeting Grant Progress Reports (PHS 2590), and SBIR/STTR Grant Applications can be accessed at the following website: http://grants.nih.gov/grants/oer.htm.

Grant Application Identification Number

Each new application received is assigned an identification number and checked for completeness, and duplicates are forwarded to the appropriate Institute and Integrated Review Group (IRG).

The following is an example of a grant application identification number:

Application Type	Activity Code	Administering Organization	Serial No.	Suffix Grant Year	Suffix Other
1	R01	CA	100228	01	A1 or S1

The above number identifies a new (Type 1) application for a traditional research project (R01) assigned to the NCI (CA). The serial number, which is assigned sequentially by the CSR, indicates that it is the 100,228th application assigned to the NCI. The suffix (01) shows that this is the first year of requested support for this project. The next part of the suffix is used to identify an amended application (A1) or a supplement (S1).

Grant Application Referral

Once the NCI has been assigned an application by the CSR, NCI referral officers examine and direct each application to the appropriate NCI Program Director. It is the responsibility of the Program Director to then follow the progress of his/her assigned application(s) through the peer review process. The NCI establishes an official electronic file for each application and enters fiscal and scientific information into the NIH/NCI data systems.

APPLICATION TYPES

There are nine grant application types that may be used to identify the stages in the life cycle of a grant. The grant type defines the procedures and specifies the documents required to process the grant award.

Type 1–New

Request for support of a project that has not yet been funded.

Type 2–Competing Continuation

Request for an additional period of support based on a previously funded project. Competing continuation applications compete with other competing continuation, competing supplemental, and new applications for funds.

Type 3–Supplement

Request for additional funds, either for the current operating year or for any future year previously recommended, to cover increased costs (noncompeting) or to expand the scope of work (competing).

Type 4–Extension

Request for additional time and/or funds beyond those previously awarded. Typically limited to certain mechanisms, including Merit (R37), Developmental/Exploratory (R21/R33), and Fast-Track Small Business Grants SBIR/STTR (R42/R44). These grants do not compete for available funds.

Type 5–Noncompeting Grant Progress Report

Request to pay next budget increment of a current award; does not compete for available funds.

Type 6–Change of Institute or Division (Successor-in-Interest and Name-Change Agreements)

Request for NIH's acceptance of a change in business structure, such as successor-in-interest, name change, or merger.

Type 7–Change of Grantee or Training Institution

Request for support of a funded project to be transferred from one grantee or training institution to another.

Type 8–Change of Institute or Center

Noncompeting continuation (Type 5) to be transferred from one IC to another.

Type 9–Change of Institute or Center

Competing continuation (Type 2) that has been transferred from one IC to another.

Integrated Review Group (IRG)

Review activities of the Center for Scientific Review (CSR) are organized into Integrated Review Groups (IRGs). Each IRG represents a cluster of study sections around a general scientific area. Applications generally are first assigned to an IRG and then to a specific study section within that IRG for evaluation of scientific merit. These study sections, also known as Scientific Review Groups (SRGs), are the first level of the dual peer-review system of the NCI.

Scientific Review Group (SRGs)

Scientific Review Groups (SRGs) review research grant applications as formally mandated in 1974 by Section 475 of the Public Health Service Act. They function specifically in the following manner:

- Within the CSR, SRGs review and evaluate the scientific merit of research grant applications on specific topics (e.g., cell biology, clinical oncology, pathology, biochemistry, virology) regardless of the awarding NIH Institute. There are approximately 220 SRGs in the CSR, each composed of 12 to 18 individuals who advise the NIH on the scientific and technical merit of the applications they evaluate.
- Within the ICs, the SRGs review and evaluate the scientific merit of research grant applications that are closely related to the IC's mission, as well as applications submitted in response to RFAs and other specialized programs.

All NIH SRG rosters may be found at the following website: http://era.nih.gov/roster/index.cfm.

The second level of the dual peer-review system of the NCI is the National Cancer Advisory Board (NCAB), as mandated by the National Cancer Act of 1937 and incorporated into the Public Health Service Act in 1944. The NCAB reviews NCI grants through its members' knowledge in each of the relevant programmatic areas, familiarity with NCI priorities and procedures, and awareness of the missions of the diverse Institutes in biomedical research and of the health needs of the American people. The NCAB is discussed in greater detail on p. 52.

The NCI Division of Extramural Activities (DEA) organizes and manages the peer review of grant and cooperative agreement applications that are highly mission-specific to the NCI. These include applications for program projects, Cancer Center Support Grants (CCSGs), multisite clinical trials, the NCI's Clinical Trials Cooperative Groups, Ruth L. Kirschstein National Research Service Award (NRSA) grants, and cancer education grants.

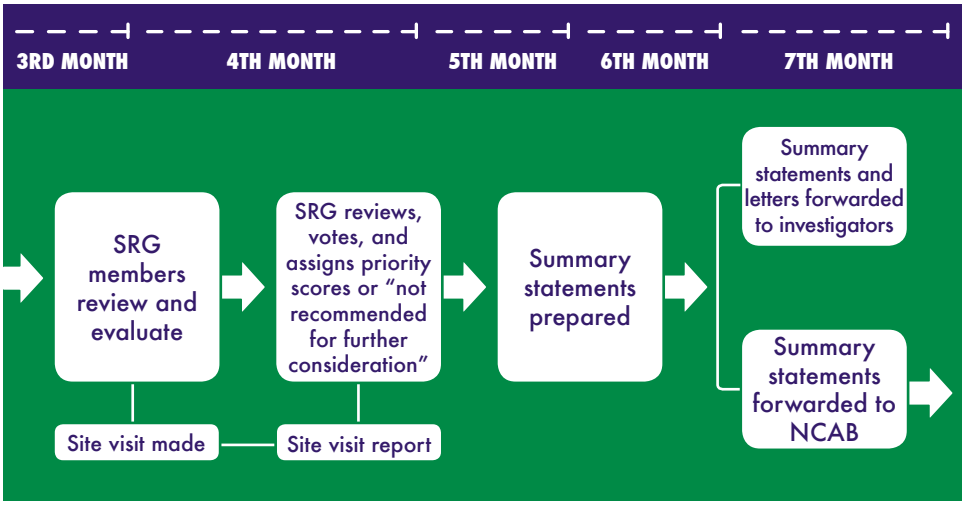
For Program Project Grants (P01), Cancer Center Support Grants (P30), and Clinical Trials Cooperative Group (U10) applications, the NCI DEA uses a two-tiered peer-evaluation process. For these applications, the first

tier of evaluation usually includes a site visit or other means of interaction between the review panel members and the applicants. The site visit provides an in-depth evaluation of each component of the application. A site visit report is prepared, which includes the recommendations of the site visitors. The second-tier evaluation is carried out by a chartered "parent" Scientific Review Group, which assigns a priority score to the application after evaluating the application and the site visit report.

For applications that cannot be reviewed by an SRG or chartered NCI review committee due to conflict of interest or lack of expertise, a Special Emphasis Panel (SEP) (formerly Special Review Committee) is assembled to conduct the review. NCI Requests for Applications (RFAs) and Program Announcements Reviewed in an Institute (PARs) are usually evaluated by NCI SEPs. The composition of the panel is determined by the expertise needed to evaluate the submitted grant applications.

Figure 10 below illustrates a representative timeline for SRG review of applications. There are three review cycles, or "rounds," annually. In each review cycle, a CSR Scientific Review Group may review between 50 and 100 grant applications. The review cycle has been shortened for applications involving Acquired Immune Deficiency Syndrome (AIDS) research and for applications in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs.

FIGURE 10 SRG Review and Evaluation for Scientific Merit



Scientific Review Administrators (SRAs)

Each Scientific Review Group (SRG) is organized and managed by a Scientific Review Administrator (SRA), the NIH staff scientist who serves as the Designated Federal Official (DFO) responsible for ensuring that grant applications are evaluated in an impartial environment.

The SRA's major responsibilities include:

- Identifying what scientific and technical information is contained in the application and assigning individual reviewers to evaluate the contents.
- Managing SRG meetings.
- Nominating study section members.
- Selecting reviewers and site visitors to serve on the committee.
- Providing orientation for members of review groups.
- Explaining and interpreting NIH review policies and procedures.
- Managing projects site visits and subsequent SRG meetings.
- Preparing summary statements documenting the review outcome and SRG recommendations.
- Attending advisory board or council meetings to provide requested information in support of the SRG's recommendations.
- Communicating with program staff on review issues.
- 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.

Project Site Visits

The purpose of a project site visit is to allow the reviewers an opportunity to gather information not available in the written application in order to evaluate its merit. The Scientific Review Administrator (SRA) assembles a project site visit team of reviewers whose number varies with the complexity of the program being evaluated. Site visits enable reviewers to meet with the Principal Investigator and other researchers, view the facilities, and raise questions or discuss objectives. The NCI Program Director generally participates in these visits to provide program information, if needed, and to gain a better understanding of the project and the reviewers' recommendations. In some cases, the SRA, Program Director, or Grants Management Officer may request that a Grants Management Specialist take part in the site visit to provide business and administrative expertise. Following the site visit, reports based on the site visit team's observations and findings are prepared for presentation at the parent Scientific Review Group meeting.

Approximately 1 percent of the research grant applications reviewed by CSR require a project site visit before the study section can complete its assessment. This action may require deferral of the review to the next review cycle. Large, complex applications evaluated by NCI, such as those for Cancer Center Support, Program Projects, and Clinical Trials Cooperative Groups, routinely require a project site visit by a team of 10 to 30 expert consultants, as well as several members from the appropriate NCI "parent" committee. The composition of the team depends on the number of individual program components and disciplines involved.

Scientific Review Group Meetings (SRGs)

Scientific Review Groups (SRGs) meet 1 to 3 months before each meeting of the National Cancer Advisory Board (NCAB). NCI Program Directors and Grants Management Specialists may be present as observers at the meetings but do not participate in the discussion or vote. Before every meeting, each reviewer is assigned several applications that fall into his/her field of special competence to examine, evaluate, and summarize. The reviewer makes an initial recommendation to the review group about the merit of each application. For applications that require a site visit, two or more members of the site visit team, usually IRG members, will summarize their findings and recommendations for the full parent committee (e.g., proposed budget and project period).

Applications are evaluated for:

- Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Innovation: Is the project original and innovative? For example: does the project challenge existing paradigms or clinical practice or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
- Investigators: Are the investigators 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? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, and in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- The adequacy of plans to include women, children, minorities, and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects are also evaluated.
- The reasonableness and duration of the proposed budget in relation to the proposed research.

- The adequacy of the proposed protection for humans, animals, and/or the environment to the extent that they may be adversely affected by the project proposed in the application.
- Responsiveness to any specific criteria set forth in announcements or requests (e.g., Requests for Applications [RFAs]).

At present, the review committee may make one of the following recommendations regarding scoring an application:

- Scoring: Applications that are judged to have significant and substantial merit are assigned a priority score. The NIH uses a scale of 1.0 (highest merit) to 5.0 (lowest merit) to score applications during the initial or first level of the scientific review process. Those applications that score in the upper half (1.0 to 3.0) with respect to scientific merit are recommended for the second level of peer review (Advisory Council/Board) by the SRG.
- Not Scoring: Applications that are considered to be in the lower half are designated as unscored and are not given a numerical score. These applications are not discussed in the review meeting. Not scoring an application requires unanimous consent.
- Not Recommended for Further Consideration (NRFC): Applications that lack significant and substantial merit or have serious ethical problems in the protection of human subjects from research risks or in the use of vertebrate animals are designated Not Recommended for Further Consideration (NRFC). Applications designated as NRFC do not proceed to the second level of peer review (Advisory Councils/Boards) because they cannot be funded.
- Deferral (DF): Applications may be deferred if additional information is needed to make a definitive recommendation.

All SRG members who participate in person or by teleconference, videoconference, or virtual meeting (as members of an Internet-assisted meeting) in the evaluation of an application may vote and score the applications. (SRG members with a conflict of interest may not participate in the discussion of an application and may not vote on or score the application for which the conflict exists).

Priority Scores

To determine the priority score, each SRG member assigns a numerical rating that reflects the reviewer's assessment of the overall impact the project could have on the field. This assessment is based on consideration of the five review criteria (significance, approach, innovation, investigators, and environment), with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. The numerical ratings range from 1.0 (best) to 5.0 (worst), with increments of 0.1. A score of 3.0 is the midpoint score; the range of scores from 1.0 to 3.0 represents the upper half of the applications, while applications with scores greater than 3.0 represent the lower half.

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. Generally, 4 to 5 months will have elapsed since the Principal Investigator submitted the application (see Figure 10, p. 47).

Percentile Rank

In addition to a priority score, most applications reviewed by the CSR receive a percentile rank. The conversion of priority scores to percentile rankings (along a 100.0 percentile band) is based on scores assigned to applications reviewed during the current plus the past two review rounds. Applications reviewed by a standing study section are ranked against all applications reviewed by that same study section over the three consecutive 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 SRGs and to minimize the impact of round-to-round quality variation. The percentile/priority score is the primary indicator of relative scientific merit when applications are being considered for funding within an Institute.

Summary Statements

During the 6 to 8 weeks after each SRG meeting, the Scientific Review Administrator (SRA) prepares summary statements reflecting the judgment of the reviewers (see Exhibit B, p. 117). The summary statement includes a concise statement of the proposed research and an evaluation of its merit. Summary statements of scored applications contain a priority score and, where applicable, a percentile. They also include Committee Budget Recommendations, which may indicate budget items recomended by the reviewers for reduction or elimination, as well as a recommendation for duration of support. Projects may be recommended for support for up to 5 years.

Early Notification to Applicant

Once the priority scores and percentiles are calculated by the SRA, a transmittal (and final) notification letter is sent to the Principal Investigator (PI) by the Program Director. The PI may obtain an electronic copy of his/her summary statement through the NIH eRA Commons (https://commons.era.nih.gov/commons/).

However, due to the presence of confidential information pertaining to the PI, the grantee's business official does not have direct access to the summary statement. The grantee business official is, however, sent a copy of the notification letter.

National Cancer Advisory Board

The second level of the dual peer-review system is the NCI's principal advisory body, the National Cancer Advisory Board (NCAB). The NCAB members are appointed by the President. Scientific experts and advocates on the NCAB advise the NCI Director on issues related to all aspects of the National Cancer Program (see the National Cancer Act of 1971) and provide a second level of review for NCI grant applications.

The NCAB is responsible for the final external review of all grant applications referred to the NCI except for the following:

- Those domestic applications requesting $50,000 (or less) in direct costs per year (without human subject, animal welfare, minority/gender/children, or biohazard concerns).
- Individual fellowship applications.
- Applications with percentiles in the bottom half of those reviewed by CSR.
- Applications not recommended for further consideration.

The NCAB's responsibility is to evaluate all grant applications in relation to the needs of the NCI and the priorities of the National Cancer Program. It also recommends support of meritorious projects to the NCI Director. In addition, the NCAB advises the Director with regard to the National Cancer Program as a whole.

Legislative Authority

On January 4, 1973, in accordance with the Federal Advisory Committee Act (P.L. 92-463), the Secretary of the Department of Health, Education, and Welfare chartered the NCAB. The NCAB's mandate is continuous, and the Board is rechartered every 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 NCAB members be appointed from among the leading representatives of the health and scientific disciplines relevant to cancer. The remaining one-third of the members shall be appointed from the public and include leaders in the fields of public policy, law, health policy, economics, and management.

Composition

The NCAB is composed of 18 members, who—by virtue of their training, experience, and background—are especially qualified to evaluate the programs of the NCI. These members serve overlapping terms of 6 years. The President also designates one of the appointed members to serve as Chair for a term of 2 years.

Ex officio members of the Board include the:

- Secretary of HHS.
- Director of the Office of Science and Technology Policy.
- Director of the NIH.

- Chief Medical Director of the Department of Veterans Affairs.
- 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.
- Chair of the Consumer Product Safety Commission.
- Assistant Secretary of Defense for Health Affairs.
- Director of the National Institute for Occupational Safety and Health.
- Director of the Office of Science, Department of Energy.

Pre-NCAB Meetings

Approximately 2 weeks before a meeting of the NCAB, the Executive Secretary calls a meeting with NCI staff members to discuss and review the materials that are to be presented to the NCAB in closed session. The closed-session materials are compiled in the *Special Actions Booklet* prepared by the Division of Extramural Activities (DEA) staff from the material provided by NCI program staff. The *Special Actions Booklet* identifies applications with:

- Concerns with respect to human subjects, animal welfare, gender/minority/children, or biohazards.
- Foreign applications.
- All appeals.
- Recommendations for MERIT (Method to Extend Research in Time) award nominations and extensions.
- Other staff recommendations.
- Any special information that needs to be brought to the attention of the NCAB.

In addition, special issues related to the pending NCAB meeting are brought to the attention of the program staff.

NCAB Meetings

The NCAB meets at the call of the NCI Director or the Board Chair no fewer than four times a year, and the meetings usually last 2 days. Meetings of the NCAB that are scheduled for January/February, May/June, and September/October include application review. The November/December NCAB meeting is reserved for review of NCI programs.

NCAB meetings are open to the public when general program activities and plans are discussed. By HHS regulation, scheduled NCAB meeting dates are published well ahead of time in the *Federal Register* (http://www.gpoaccess.gov/fr/index.html). Attendance at the closed grant application review sessions is limited to NCAB members, SRAs, the NCI Director, appropriate NCI staff, and designated representatives of the Secretary, HHS. SRAs and appropriate NCI staff members attend NCAB meetings to provide, when necessary, specific details or additional information on projects under discussion by the NCAB.

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*. NCAB members are not given access to summary statements from their own institutions. By the time the NCAB meets, approximately 1,500 summary statements, as well as other relevant materials about the applications, will have been made available to the NCAB.

Furthermore, the NCI's Division of Extramural Activities prepares and distributes special reports for review by the NCAB that detail grant applications involving human subjects, animal welfare, biohazard risks, foreign grants, and inadequate representation/justification of gender/minorities/children. In addition to these special reports, NCAB members also receive MERIT (Method to Extend Research in Time) award nominations and extensions, as well as appeal letters from PIs who disagree with the SRG's recommendation(s).

If an NCAB member has a question about an application or thinks that additional information would be helpful, he/she is encouraged to contact the assigned NCI Program Director. Most of the NCAB members' concerns are resolved through correspondence with the Program Director. If not, they are discussed during the closed session of the NCAB meeting.

During the closed session, the NCAB acts on all applications brought before it. Some applications are reviewed and discussed on an individual basis. For example, applications may be brought to the NCAB's attention by NCI program staff concerned with some aspect of the SRG review, such as the recommended funding level, period of support, or the percentile/priority score assigned. NCAB members themselves may bring up other applications for discussion. The NCAB's options are discussed in the following paragraphs.

Expedited NCAB Review

An expedited NCAB approval process is used for percentiled R01s reviewed by CSR and for all R21s, except:

- Those applications submitted in response to an RFA or PA with a set-aside.
- Applications with foreign institution involvement.
- Applications whose summary statement expresses concerns with regard to human subjects, animal welfare, biohazards, or inadequate representation/justification of gender/minorities/children.

The NCAB members approve grant applications using the *NIH Electronic Council Book*. A notification letter is then sent by the Grants Administration Branch notifying the PI of the NCAB approval and plans for expedited funding.

Recommendations

In most cases, the NCAB concurs with the SRG's recommendations. However, the NCAB may vote to change the SRG recommendations in the following ways:

- If the NCAB disagrees with an initial review based on scientific or technical merit, action is deferred. The application is returned for a re-review by 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 IRG for an additional review.
- The NCAB may recommend that an application receiving a favorable recommendation in initial review not be considered for support for reasons other than lack of scientific or technical merit.
- In the case of a split vote from the SRG, the NCAB may accept the minority opinion without returning the application for further review.

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

Once it has acted on those applications given special attention, the NCAB considers a motion for *en bloc* concurrence with the SRGs' recommendations as presented in the summary statements. NCAB members do not attend discussions or vote on applications from their own institutions or affiliated institutions and are required to sign conflict-of-interest statements. This allows them to participate in the *en bloc* concurrence without risking a conflict of interest.

In special circumstances, the second level of review is completed using the mail ballot process, whereby summary statements are forwarded to the NCAB members and they communicate concurrence or nonconcurrence. Conflict-of-interest guidelines are maintained during this process.

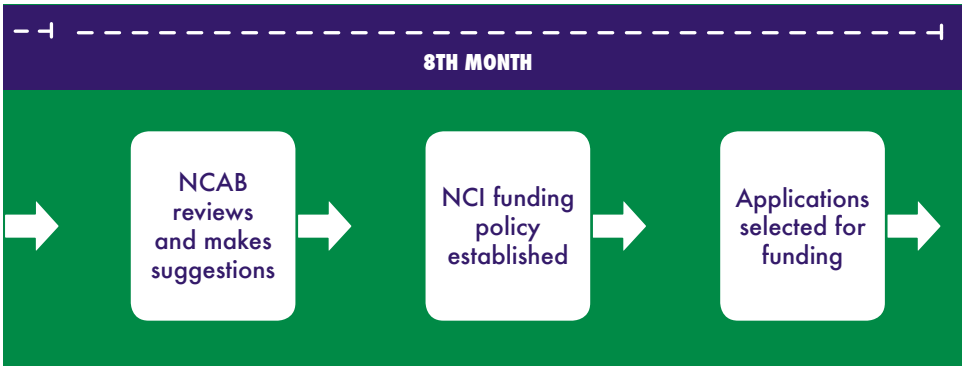
Post-NCAB Meetings

After each NCAB meeting, NCI staff members meet to discuss and review the NCAB's recommendations. Applicants who will be funded are subsequently notified at the time of the award negotiation. Ideally, approximately 8 to 9 months will have elapsed since the Principal Investigator submitted the application (see Figure 11 on the following page).

Appeals to Referral and Review of Applications

Effective with the applications submitted beginning with the June 1997 NCAB, the NIH abolished appeal of review actions beyond the Institute level. Once an appeal has been sent to the NCAB, there is no further administrative mechanism of redress offered to applicants who are unhappy with the outcome of their review other than to submit an amended application.

FIGURE 11 NCAB Review and NCI Funding Determinations



NCI FUNDING DETERMINATIONS

Funding Decisions

Around October 1, the beginning of a new Federal fiscal year, the NCI Executive Committee discusses program priorities and preliminary funding allocations for the coming fiscal year. In order to determine the program allocations, the following considerations are taken into account:

- Congressional mandates
- New scientific opportunities
- New initiatives
- Program priorities
- Previous commitments, such as noncompeting continuations
- Other projected needs
- Anticipated availability of funds

Final allocations and funding decisions cannot be made until the actual amount of the appropriation is known.

Generally, the NCI Executive Committee meets in October/November to establish funding policy for grant applications submitted for the year's first funding cycle, which begins with the September/October meeting of the NCAB. If Congress has passed an appropriations bill by this time, the funding policy for the entire year may be established.

When establishing paylines for the year, the NCI allocates funds available for competing grants among the three funding cycles. Thus, applicants with the same priority score or percentile ranking are normally paid regardless of the cycle in which they competed. The funding policy is reconsidered at least two more times during the year to coincide with the NCAB's schedule of grant review cycles.

Grant applications are grouped by mechanism for funding through one of two processes: (1) a mechanism that is used solely by one Division (training grants, for example) will have a separate budget within the Division. The

Division Director is responsible for establishing an annual funding plan for Division-controlled programs; and (2) mechanisms that are common to more than one Division (traditional research grants [R01], program project grants [P01], etc.), which compete for funds from a common budget "pool." The selection of applications to be funded from pool funds is discussed in the next section. An example of the distribution of NCI fiscal resources is found in Figures 12 and 12a (pp. 58 and 59), which display budget spending by funding mechanism for FY2004.

Funding Selections

Immediately following a meeting of the NCAB, NCI Program Directors are provided with an electronic "ranking list" of competing applications in their program areas to review for payment and to verify the program assignment. The approved grant applications are ranked in percentile or priority score order from most to least meritorious. Those percentiles or priority scores that fall within the payline move forward towards being funded. The payline is a virtual line that separates the applications that will be paid in rank order and those which may be selected based on programmatic relevance.

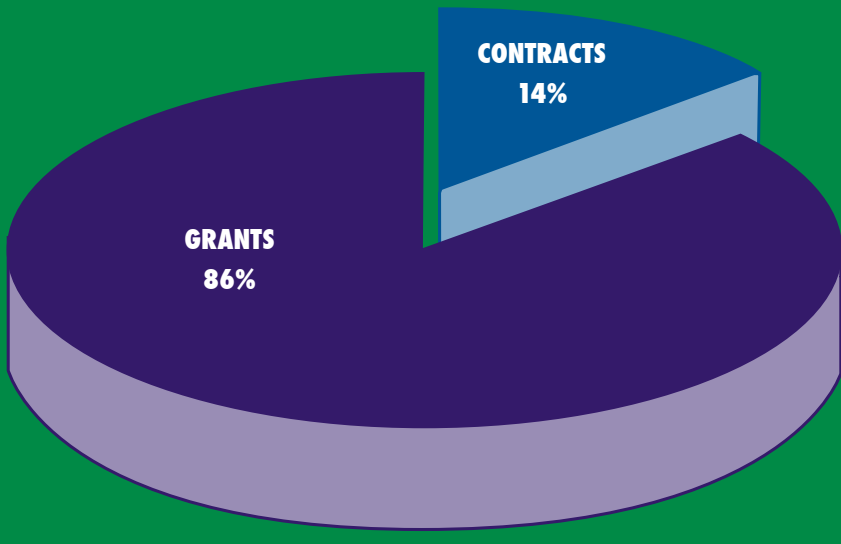
NCI Program Directors are also advised of the dollars available for each particular group of applications. Generally, Program Directors select grants for payment in straight priority or percentile score order. However, they may skip one or more applications that already receive support from other sources or for programmatic reasons and use the "saved" monies to fund applications that may be important to the program's objectives but fall outside the payline. However, NCI Executive Committee approval is required to skip an application.

Additionally, approximately 8 to 10 percent of the competing budget is set aside for each round to fund exceptions. Four times a year (once for each round and a final time at the end of the year), the NCI Executive Committee meets to consider recommendations from NCI program staff to pay Research Project Grant (RPG) applications that are outside the paylines. Also, each Division Director has discretionary authority to select RPGs for payment as exceptions within a budget and parameters established by the NCI Executive Committee.

After review and discussion with the NCI Division Director, the NCI Program Director indicates on the ranking list the applications selected for funding. After the ranking list is signed by the Program Director, the Division Director, the Chief of the Extramural Financial Data Branch or designee, and the Grants Management Officer, it becomes an authorization (paylist) (see Exhibit C, p. 120). The Grants Management Officer and grants management staff use this paylist as the authority to complete the administrative review, negotiation, and award process.

A summarized general description of the three-step funding allocation process for research project grants, as well as a practical example of a funding allocation, is provided in Chapter 2 (p. 27) of this publication.

FIGURE 12 NCI FY2004 Extramural Funds (dollars in thousands)



MECHANISM	AMOUNT	% OF TOTAL
Contracts:		
R&D Contracts	$298,828	8.1%
Interagency Agreements	79,103	2.1%
Cancer Control Contracts	136,671	3.7%
Construction Contracts	0	0%
Subtotal, Contracts	514,602	14%
Grants:		
Research Project Grants	$2,161,359	58.6%
Cancer Centers/SPOREs	409,288	11.1%
Training Activities	66,264	1.8%
Other Research Grants	314,916	8.5%
Cancer Control Grants	219,965	6.0%
Construction Grants	0	0%
Subtotal, Grants	3,171,792	86%
Total Extramural Funds	3,686,394	
Total Intramural/RMS/Control In-House	1,037,499	
*TOTAL NCI	$4,723,893	

FIGURE 12a NCI Obligations by Mechanism FY2004 (dollars in thousands)

RESEARCH GRANTS	AMOUNT	% OF TOTAL
Research Project Grants:		
Traditional Research Grants (R01)	$ 1,277,187	27.0%
Program Projects (P01)	344,491	7.3%
FIRST Awards (R29)	53	0.0%
MERIT Awards	37,888	0.8%
RFAs (R01,R03,R21,U01,U19)	168,538	3.6%
Cooperative Agreements (U01/U19)	31,376	0.7%
Exploratory Grants - Phase I (R21)	77,968	1.7%
Exploratory Grants - Phase II (R33)	42,931	0.9%
Small Grants (R03)	18,067	0.4%
AREA Grants (R15)	4,560	0.1%
Shannon Awards (R55)		0.0%
Program Evaluation	58,721	1.2%
Subtotal, RPG Pool	2,061,780	43.6%
SBIR/STTR Grants (R41,R42,R43,R44)	99,579	2.1%
Subtotal, Research Project Grants (RPGs)	2,161,359	45.8%
Centers and SPOREs:		
Cancer Centers Grants (P30,P20)	245,761	5.2%
SPOREs (P50,P20)	149,366	3.2%
Center Cooperative Agreements (U54)	14,161	0.3%
Subtotal, Centers	409,288	8.7%
Other Research:		
Career Program:		
Temin & Minority Mentored Career Dev. (K01)	15,770	0.3%
Estab. Invest. Award in CA Prevent. & Control (K05)	2,396	0.1%
Preventive Oncology Awards (K07)	11,393	0.2%
Mentored Clinical Scientist Development (K08)	17,243	0.4%
Mentored Clinical Oncology Awards (K12)	8,791	0.2%
Transitional Career Development (K22)	5,333	0.1%
Mentored POR Career Development (K24)	7,911	0.2%
Mid-Career Invest. & Patient Oriented Research (K24)	3,061	0.1%
Mentored Quantitative Research Career Dev. (R25)	712	0.0%
Institutional Curriculum Awards (K13)	1,597	0.0%
Subtotal, Career Program	74,207	1.6%
Cancer Education Program (R25)	32,214	0.7%
Clinical Cooperative Groups (U10)	154,357	3.3%
Minority Biomedical Support (S06)	3,853	0.1%
Scientific Evaluation (U09)	10,240	0.2%
Continuing Education (T15)	344	0.0%
Research Resource Grants (R24,U24)	26,572	0.6%
Exploratory Cooperative Agreements (U56)	11,331	0.2%
Conference Grants (R13)	1,798	0.0%
Subtotal, Other Research Grants	314,916	6.7%
Subtotal, Research Grants	2,885,563	61.1%
Ruth Kirschstein–NRSA Training (F31,F32,F33,T32, & T36)	66,264	1.4%
Cancer Control Grants	219,965	4.7%
Construction Grants (C06)	0	0.0%
Subtotal, All Grants	3,171,792	67.1%
R&D Contracts:	358,248	7.6%
SBIR Contracts	3,321	0.1%
Subtotal, Contracts	361,569	7.7%
Intramural Research Program:	589,597	12.5%
NIH Management Fund	119,342	2.5%
Subtotal, Intramural Research	708,939	15.0%
RMS:	151,545	3.2%
NIH Management Fund	20,033	0.4%
Subtotal, RMS	171,578	3.6%
Cancer Prevention & Cancer Control Contracts:	153,033	3.2%
In-House	145,316	3.1%
NIH Management Fund	11,666	0.2%
Subtotal, Prevention and Control	310,015	6.6%
*Total NCI	4,723,893	100.0%

*EXCLUDES projects awarded with Stamp Out Breast Cancer funds.

Role and Responsibilities of NCI Program Directors

The NCI currently has more than 200 extramural Program Directors, each of whom is assigned responsibility for a certain programmatic and scientific approach to cancer research (see Figure 13 on the following page). For example, there are Program Directors for chemical carcinogenesis, tumor biology, biochemistry and pharmacology, immunology, radiation, clinical oncology, cancer prevention, and other areas.

The Program Director is responsible for the programmatic and scientific aspects of his/her portfolio, including:

- Providing leadership and coordination in the medical and scientific communities for research groups carrying out investigations in a particular program area.
- Visiting grantee institutions to promote and explain the objectives of the program and to exchange information.
- Reviewing and evaluating the state of the art of research in a specific program area and stimulating scientific investigations in that field through the issuance of RFAs and PAs and recommending exception funding.
- Making recommendations to the NCI, NIH, and HHS policymakers on subjects related to his/her individual expertise.
- Serving as a liaison member on reviewing panels and as a participant in national and international symposia and other meetings called to discuss research in a specific program field.

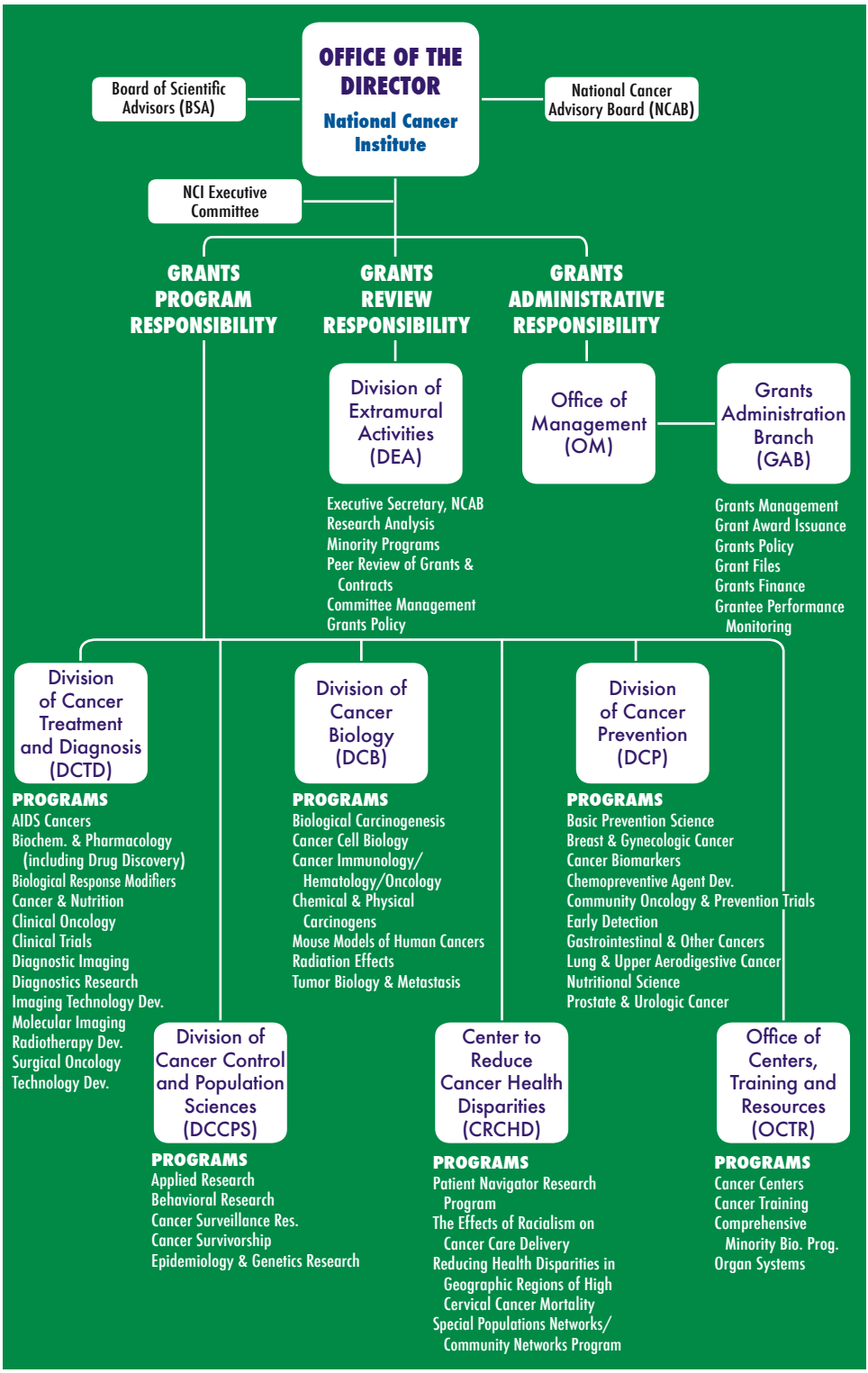
In addition to these general scientific activities, Program Directors collaborate with Grants Management Specialists in providing oversight of the NCI grants program.

Role and Responsibilities of the NCI Grants Management Officer

The Chief Grants Management Officer (GMO) and his/her staff are responsible for all business management aspects associated with the negotiation, award, and administration of grants and cooperative agreements. The GMO is responsible for:

- Advising and assisting management and program officials in developing, implementing, and evaluating program plans, strategies, regulations, announcements, guidelines, and procedures.
- Serving as the focal point for receiving and responding to all correspondence from grantees related to business management activities, such as requests for prior approval required by terms of award or by policy, or requests that could result in a change in the awarded amount.
- Reviewing grant applications from a management point of view for conformity to laws, regulations, and policies.
- Negotiating grant budgets and issuing awards.

FIGURE 13 NCI Extramural Grants Program



- Providing business management consultation and technical assistance on grant matters to internal staff, applicants, and grantees.
- Resolving audit findings involving the NCI grants program and/or commenting on findings before the agency's official position is made known to the grantee.
- Providing continuing surveillance of the financial and management aspects of grants through reviews of reports, correspondence, site visits, or other appropriate means.

The Grants Management Specialist is a member of the GMO's staff and is the individual most likely to be the point of contact for the business aspects of the grant application. A specialist maintains an annual portfolio assignment that includes an average of 200 grants. For these grants, the specialist will perform many of the duties listed above for the GMO.

Most business and management decisions have an impact on programmatic and scientific matters, and vice versa. Therefore, a close working relationship between the Program Director and Grants Management Specialist is essential to the effective administration of the grants program. The common goal of program and grants management staff is to free investigators from unnecessary administrative burden and to respond to their needs in a timely and prudent manner while exercising their responsibility as stewards of public funds.

Pre-Award Activities

After funding decisions are made and paylists are developed, NCI Program Directors complete their review of each application selected for funding. As a result of this review, Program Directors may contact applicants to request additional or updated information regarding various issues, such as:

- Other support.
- Overlap with other projects.
- Resolution of scientific concerns expressed by the initial reviewers regarding the involvement of human subjects.
- Use of live vertebrate animals.
- Minority and gender representation.
- Potential biohazard problems.

Grants management staff may contact applicants to request additional information regarding assurances and certifications or missing application documentation.

The Grants Management Specialist and Program Director continually work together throughout this pre-award phase of the award process. For example, Program Directors document their review and resolution of problems by completing and submitting to the Grants Management Specialist an NCI documentation control form for each application to be funded.

For applications reviewed by the Center for Scientific Review (CSR) and scored within a certain range, the NIH requests the following Just-in-Time (JIT) information:

- Updated other support
- Certification of Institutional Review Board (IRB) approval
- Required Education in the Protection of Human Subjects (http://grants.nih.gov/grants/policy/hs_educ_faq.htm)
- Certification of Institutional Animal Care and Use Committee (IACUC) approval

These requests are not a guarantee of funding.

Grants Management Review

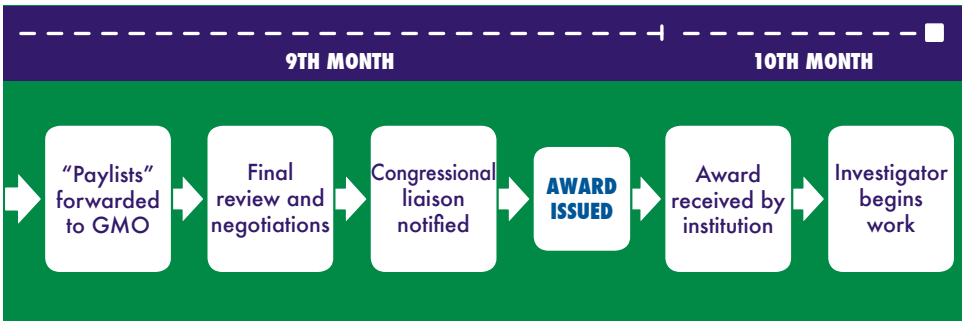
Upon receiving a documentation control form from the Program Director and verifying selection for funding, the Grants Management Specialist begins the process of developing an award (see Figure 14 below). This involves a cost analysis of the proposed categorical budget, if applicable, a review for administrative compliance with HHS and NIH policies, and negotiations with the grantee's business official and/or the Principal Investigator. Examples of these activities are outlined below.

Cost Analysis

The Grants Management Specialist reviews applications that include categorical budgets for:

- Reasonableness of costs.
- Adherence to cost principles.
- Relationship of costs to the proposed project.
- Financial management capabilities of new applicant institutions.
- Similarity to or duplication of existing programs or projects being supported by other sources (to the extent that this can be ascertained).
- Specific requirements established by a particular program (e.g., the NCI Construction Program; conference or training grants).

FIGURE 14 Award Negotiation and Issuance



The extent of this analysis is a matter of judgment, based on factors such as:

- The applicant's previous experience in managing grant funds.
- The NCI's experience with the grantee.
- The dollar amount of the grant.
- The complexity of the grant.
- The financial history of the project.
- NCI program concerns.

Administrative Review

In addition to analyzing the budget, the Grants Management Specialist determines that all necessary assurances and reporting requirements have been met and that the applicant is in compliance with all appropriate rules and policies as well as NIH and HHS requirements. The following is a brief itemization of some of the issues that must be addressed, when appropriate, before an award can be issued:

- Compliance with 45 CFR Part 46, "Protection of Human Subjects"
- Certification of required education in the Protection of Human Research Participants
- Compliance with PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions
- Civil rights, handicapped individuals, and sex and age discrimination assurances
- Compliance with Data and Safety Monitoring requirements
- Debarment, suspension, and voluntary exclusion certification
- Drug-free workplace certification
- HHS-approved entity identification number (EIN) for the applicant institution
- Facilities and administrative costs
- Financial Status Reports (FSRs)
- Invention statements
- Lobbying certification and disclosure
- Assessment of applicant institution's management capability
- Appropriate choice of mechanism (grant/contract/cooperative agreement)
- Misconduct in science assurance
- No delinquency on Federal debt certification
- Peer review recommendations
- Administrative notes from peer reviewers on the summary statement
- Program income
- Availability of proposed project staff
- Recombinant DNA compliance

- Scientific and budgetary overlap with other support
- Time and effort overcommitment

Negotiation

The primary purpose of negotiating an award is to establish the appropriate funding level, resolve identified problems, and agree on specialized terms and conditions of award, if needed. The degree and form of the negotiation depend on a variety of factors, such as the dollar amount and complexity of the project, nature of the problems identified, and fulfillment of new-grantee requirements. The Grants Management Specialist can usually complete negotiations and obtain needed information through correspondence with the grantee institution. However, it may become necessary for NCI staff to visit the grantee institution to address certain issues or problems in person.

Preparation of Awards and Obligation of Funds

The Notice of Grant Award (NGA) is the official letter notifying the applicant that the project has been funded (see Exhibit D, p. 121). Once the NGA is signed by the Grants Management Officer (GMO), it is either transmitted via e-mail or mailed, dependent upon whether the grantee institution is registered with the NIH eRA Commons (https://commons.era.nih.gov/commons/).

The Notice of Grant Award includes:

- The name and address of the grantee institution.
- The title of the project.
- The name of the Principal Investigator.
- The period of support.
- The amount recommended for future years of support.
- Any special terms and conditions of award.

In addition, all competing/noncompeting award notices, except those in the Streamlined Noncompeting Award Process (SNAP) and modular populations, show the authorized direct costs by budget category (e.g., personnel, supplies). The NGA provides approval for the expenditure of funds in the grant application and/or agreed upon during negotiations. Associated facilities and administrative (F&A) costs are also included on the NGA.

If the awarding office has determined that a prospective grantee is financially unstable, has a history of poor performance, or has a management system that does not meet the agency's standards, the awarding office may impose restrictive terms and conditions. The awarding office may also delay issuing the award until all the agency's standards have been satisfied.

In signing the grant award, the Grants Management Officer certifies that:

- The choice of the award mechanism is appropriate under applicable policy.
- The application was properly peer reviewed.

- The award amount is accurate and appropriate for the grant-supported activity.
- The applicant institution is judged to have (or is expected to acquire) adequate business management capability to administer the grant and account for Federal funds.
- The award is being made consistent with the terms and conditions specified for the particular program and the appropriate review recommendations.
- The award is consistent with governing legislation, regulations, and policies.
- All review and award actions are clearly documented in the official grant files.

The award amount is forwarded to the Office of Financial Management, NIH, where it is recorded as an obligation in the NIH official accounting records. Once the NGA letter is sent to the grantee business office, it is their responsibility to distribute the NGA to the PI. In addition, copies of the NGA are distributed to appropriate NIH and NCI offices.

Congressional Notification

For all new and competing continuation awards, Congress must be alerted at least 72 hours before the issuance of the award so the appropriate representatives have the opportunity to notify their constituents. If the award exceeds $1 million, the White House may also be informed. This requirement is fulfilled by forwarding a copy of the NGA to the Office of Congressional Liaison, HHS.

Acceptance of Award

The grantee indicates acceptance of the general and special provisions of an award by drawing down or otherwise obtaining funds from the grant payment system (see "Post-Award Administration: Award Payment," p. 68).

Continuation Support

A project may request support for up to 5 years, with the exception of a few unique programs. Awards are generally made on an annual basis, subject to the appropriation of funds by Congress. The initial award provides funds for the first 12-month period and indicates the support recommended for each budget period within the remainder of the project period.

Prior to the start date of each budget period, a Noncompeting Grant Progress Report, formerly referred to as a *noncompeting continuation application* (Form PHS 2590), must be submitted for evaluation of the project's progress and to request continued funding. This progress report can be submitted in one of the following ways:

- eSNAP application: The electronic version of the Noncompeting Grant Progress Report is due 45 days prior to the budget start date and can be submitted via the NIH eRA Commons: https://commons.era.nih.gov/commons/

- Paper copy: This is due 60 days prior to the budget start date and mailed to the following address:

  Division of Extramural Activities Support, OER
  National Institutes of Health
  6705 Rockledge Drive, Room 2207, MSC 7987
  Bethesda, MD 20892-7987 (for U.S. Postal Service regular or Express Mail)
  Bethesda, MD 20817 (for other courier/express mail delivery only)

Please refer to the following website for further information:
http://grants.nih.gov/grants/funding/2590/2590.htm

Program Directors review the Noncompeting Grant Summary Progress Report to determine whether scientific progress is adequate to justify continued support (see Exhibit E, p. 124). When all requirements are satisfied, an award for the next budget period is issued. This process is repeated each year of the project period.

Grants Management Specialists review all noncompeting progress reports, including those in the Streamlined Noncompeting Award Process (SNAP) population. The basic principle of the SNAP award is that total costs for the entire competitive segment are negotiated at the time of the initial competing award, thus eliminating the need to engage in annual total cost negotiations. As part of that negotiation, NCI staff ensure that proposed costs are allowable, allocable, reasonable, and necessary for the project. SNAP applications must include answers to the following three questions:

- Has there been a change in the "other support" of key personnel since the last reporting period?
- Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?
- Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?

If responses to these questions are not readily apparent or are incomplete, the NCI sends a letter to the grantee business official requesting that the required information be provided in writing.

It is important to note that submitting Noncompeting Grant Progress Reports on time, but without required information, results in extra work for both NCI staff and the grantee. In addition, the submission of incomplete applications frequently delays issuance of an award.

Although a specific dollar amount is indicated on the Notice of Grant Award for each future year of recommended support, the amount awarded is subject to the availability of funds appropriated for the fiscal year, as well as other considerations related to scientific progress. Grants may be negotiated and awarded for less than the recommended level. Conversely, when the grantee can justify the need for additional funds, the NCI has the authority to grant the increase as long as the approved scope of the project is not being expanded.

If the grantee wants to request additional funds to expand the scope of the project, a competing supplemental application must be submitted according to established deadlines. These applications undergo dual review and compete for funds with all other investigator-initiated competing applications.

POST-AWARD ADMINISTRATION

Award Payment

To minimize the impact of cash withdrawals on the public debt level and to reduce related financing costs, the U.S. Department of the Treasury has issued regulations governing the flow of cash to recipient organizations. Specifically, grantees should not request funds until actually needed for disbursement purposes. Grant payments are administered by the HHS Payment Management System. The grantee can access HHS grant funds by accessing SMARTLINK II via the Internet. Funds are deposited directly into the recipient's bank account on the next business day. Figure 15 illustrates this process in detail.

Information on the Payment Management System is available from:

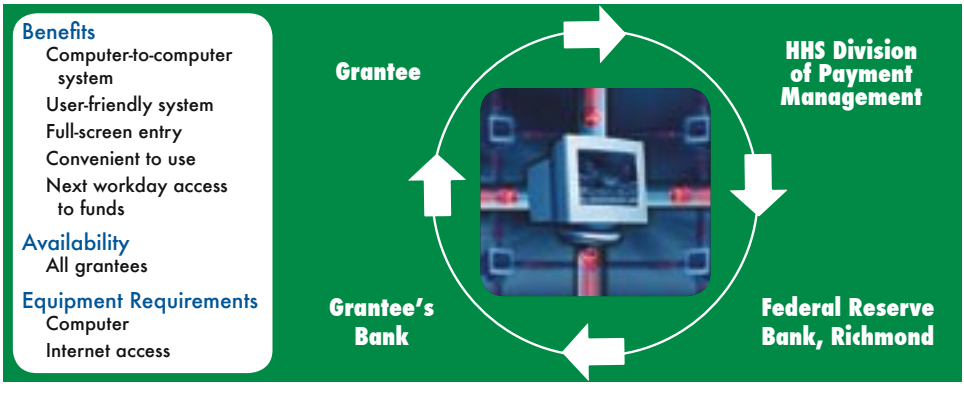
Division of Payment Management
P.O. Box 6021
Rockville, Maryland 20852
1-877-614-5533
http://www.dpm.psc.gov/default.aspx

Reporting Requirements

Reports by grantees are required at specific times, depending on the purpose of the reports and the needs of the programs. They are:

- Immediate reporting
  - ♦ Financial Conflict of Interest.
  - ♦ Inventions.

FIGURE 15 Grant Payment Management System: SMARTLINK II



- ♦ Lobbying Disclosure.
- ♦ Misconduct in Science.
- ♦ Serious Adverse Events that occur in human gene-transfer clinical studies.
- ♦ Developments that have a significant impact on the award-supported activities.
- ♦ Problems, delays, or adverse conditions that materially impair the ability to meet the objectives of the award.
- ♦ Payback Agreement: A Ruth L. Kirschstein–National Research Service Award (Kirschstein–NRSA) Payback Agreement must be signed by each postdoctoral individual for whom the appointment covers the initial 12 months of postdoctoral NRSA support. A Payback Agreement is not required for any individual who has already received 12 months of postdoctoral support under an NRSA grant or award or for predoctoral or prebaccalaureate trainees.
- ♦ Certain types of correspondence with the Food and Drug Administration (FDA) when the NIH funds all or part of a clinical study involving an investigational new drug (IND) or investigational device exception (IDE).

- Annual reports
  - ♦ Financial Status Report (FSR): HHS regulations under 45 CFR Part 74.73(d) and Part 92.41(b) dictate that Financial Status Reports (FSRs) must be submitted to the NIH within 90 calendar days after the last day of each budget period. FSRs are required annually for all projects not included in the streamlined noncompeting award process (SNAP) population. However, annual FSRs are required for all awards to Federal institutions and foreign organizations, including awards in the SNAP population. For the SNAP population, an FSR is required no later than 90 days after the expiration date of the competitive segment or after the grant transfers to a new institution (see Exhibit F, p. 125). http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-01-021.html.
  - ♦ Non-Competing Grant Progress Report (see Exhibit E, p. 124).
  - ♦ Statement of Appointment: This form must be submitted to the NIH awarding component prior to or at the start of each trainee's appointment or reappointment. A stipend (or other allowance) may not be paid until the appointment form has been submitted.
  - ♦ Kirschstein-NRSA Annual Payback Activities Certification (APAC): Individuals with an outstanding payback obligation must complete an APAC annually until their payback obligation is fulfilled.
- Final reports (due 90 calendar days after the final budget period)
  - ♦ Final Progress Report.
  - ♦ Financial Status Report.
  - ♦ Invention Statement and Certification.
  - ♦ Student Participation Report, for Academic Research Enhancement Award (AREA) grants (R15), which is an addendum to the progress report.
  - ♦ Termination Notice for Kirschstein-NRSA grants, which is the basis for validating the total period of NRSA support and the amount of payback obligation (if any) for each NRSA trainee. A Termination Notice must be submitted for each trainee immediately upon the termination of support.

Electronic Transmittal of Financial Status Reports (FSRs)

To facilitate the submission of FSRs, the NIH has developed an interactive, computer-based communications system to enable grantee organizations to electronically transmit FSRs to the NIH. The electronic process eliminates the submission and processing of the hard-copy FSR.

The current electronic system has several advantages:

- FSRs transmitted via this system are processed within 72 hours.
- The system gives users immediate feedback because it can detect errors.
- Electronically submitted FSRs cannot be lost in the mail or sent to the wrong address.
- Users of the system can access current listings of grants for which FSRs are past due or for which FSRs will become due as of a specified time (terminating grants).

Grantees are encouraged to submit FSRs electronically. Information about the electronic transmittal of FSRs can be obtained by calling the NIH Office of Financial Management (OFM), Government Accounting Branch (GAB)—the receipt point for FSRs for NIH grants and cooperative agreements.

Information about the electronic transmittal of FSRs is available from the following sources:

- http://www4.od.nih.gov/ofm/fsrfaq.pdf: A website established by the Office of Financial Management, with Frequently Asked Questions Concerning Financial Status Reports (FSRs)
- https://commons.era.nih.gov/commons/

The submission of timely and accurate FSRs is central to ensuring prudent and efficient stewardship of public resources.

Monitoring Projects

The Grants Management Specialist and Program Director are responsible for the continuous monitoring of the grants in their portfolio. Monitoring is accomplished through the review and assessment of information gathered from audit reports, progress reports, financial reports, site visits, correspondence, and peer review.

Under Federal regulation 45 CFR 74.53, the NCI and other HHS awarding agencies, the HHS Inspector General, the U.S. Comptroller General, and any duly authorized representative have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the grant awards in order to make audits, examinations, excerpts, transcripts, and copies. The grantee is also required to allow timely and reasonable access to personnel for the purpose of interviewing and discussing these documents. The rights of access are not limited to the required retention period, but last as long as records are retained.

When problems or weaknesses are found, NCI staff work with the applicant or the grantee institution to resolve the issues. It is usually possible for a mutually agreeable course of action to be worked out so that the award process can proceed. However, it may be necessary for the Grants Management Officer, designated Specialist, and/or Program Director to visit the applicant or grantee institution(s) in order to evaluate scientific progress, management systems, and adequacy of policies, procedures, and controls if:

- Problems or weaknesses are found to be severe enough to threaten the ability of the Principal Investigator or the grantee institution to administer and/or complete the research project for which the grant was awarded.
- The applicant organization refuses to adopt required assurances and certifications that reflect national social and economic policy.
- The applicant fails to comply with the terms of award.

NCI staff may then take any of the following actions:

- Not issue the new or competing continuation award
- Withhold the next noncompeting continuation award
- Adjust the level of support awarded
- Place restrictions and/or special conditions on the award
- Pay grantees on a reimbursement rather than an advance basis
- Suspend or terminate the active grant

The names, titles, and telephone numbers of the responsible Grants Management Specialist and Program Director are printed on each NGA letter.

Rebudgeting

The grantee institution is permitted to rebudget between budget categories within the total costs awarded to meet unanticipated requirements, provided the expenditures: (1) are within the scope of the approved project; (2) enhance and do not impede the successful continuation or completion of the project; and (3) are allowable under governing regulations and policies. Some rebudgeting actions may require specific prior approval from the NCI. The NIH Grants Policy Statement and the terms of the award should be consulted regarding current policies on rebudgeting and prior approval authority. The Grants Management Specialist assigned to the project may also be contacted for advice.

Audits

In general, grantees who expend $500,000 or more in Federal awards are required by OMB Circular A-133 (http://www.whitehouse.gov/omb/circulars/a133/a133.html) to have an annual audit performed by a public accountant or a Federal, state, or local government audit organization that meets generally accepted Government auditing standards. This level has been increased from the previous level of $300,000 for fiscal years ending after December 31, 2003. (See *NIH Guide* Notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.) This audit should include review of the internal controls that are maintained to provide reasonable assurance that:

- Financial operations are properly conducted.
- Financial reports are presented fairly and accurately.

- Applicable laws, regulations, and other grant terms have been complied with.
- Resources are managed and used in an economical and efficient manner.
- Desired results and objectives are being achieved in an effective manner.

The Federal Government may, at its discretion, review the internal accounting and other control systems during or after NIH support of the grant activity.

Grant Appeals

HHS regulations provide grantee institutions with the opportunity to appeal certain post-award administrative decisions made with regard to direct, discretionary project grants or cooperative agreements by HHS agencies, including the NIH (45 CFR Part 16). There are two levels of appeal: (1) an informal NIH procedure; and (2) a formal departmental procedure.

An appeal may be submitted to the NIH Appeals Office only after the grantee has received a final written decision from the Institute or Center (IC). The appeal must be submitted to the NIH Appeals Office within 30 days of receipt of that decision. A Grant Appeals Board composed of knowledgeable NIH staff from ICs other than the involved IC will be convened and chaired by the NIH Appeals Officer. The Board will review the case and make the final NIH decision. Should that determination uphold the original NIH decision, the grantee may formally appeal that determination within 30 days to the Departmental Appeal Board.

The specific adverse determinations that may be appealed are:

- Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a noncompeting continuation award for failure to comply with the terms of a previous award.
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

Grant Closeout

The grant closeout process is initiated upon conclusion of grant support. Official procedures are begun by the Grants Administration Branch after NCI staff determine that all applicable administrative actions and required work of the grantee have been completed. The grantee is required to submit:

- A final financial status report (FSR).

- A final progress report.
- A final invention statement.

These final reports must to be submitted no later than 90 days after the expiration of the project period or after the grant transfers to a new institution.

Additional Post-Award Activities

A few of the more common post-award actions include, but are not limited to:

- Approving a change of research scope, aims, or objectives.
- Approving a change in the Principal Investigator or grantee institution.
- Providing administrative supplements, phaseout support, or interim support.
- Extending grant periods with or without additional funds.
- Reviewing audit and financial reports.

Please refer to the "References and Resources" section for further information.

Record Retention

By the Grantee

Financial and programmatic records, supporting documents, and all other records that are required by the terms of a grant must be retained by the grantee as follows:

- For awards not under SNAP: 3 years from the date the final annual FSR is submitted to the NIH.
- For awards under SNAP (except those to foreign organizations and Federal institutions): 3 years from the date the FSR for the entire competitive segment is submitted to the NIH. This rule applies to all records for the entire competitive segment.
- For foreign organizations and Federal institutions: must submit annual expenditure reports for all awards, including those under SNAP, and must retain records for these awards, including those under SNAP, for 3 years from the date of submission of the annual FSR to the NIH.

If an audit or other action is in process at the expiration of the 3-year retention period, the records are to be retained until all issues arising from the audit have been resolved by the NCI.

By the NCI

In general, official grant records are retained for a period of 6 years. Construction grant records are retained for 20 years. If a grant is involved in an appeal or litigation, the retention period begins when the case is closed. There is a 3-year retention period for unfunded applications that begins upon notification to the applicant that an award will not be made or upon withdrawal of the grant application.

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CHAPTER 4

FUNDING MECHANISMS

The NCI's budget is organized according to the following nine major funding areas:

- Research Project Grants (including SBIR/STTRs)
- Cancer Centers and Specialized Programs of Research Excellence
- Other Research Grants
- Training
- R&D Contracts
- Intramural Research
- Research Management and Support
- Cancer Prevention and Control
- Construction

The following section, organized in the order outlined above, details each of the funding mechanisms used by the NCI.

RESEARCH PROJECT GRANTS

- **FY2004 Obligations: $2,161,359**
- **45.8% of the NCI Budget**

Research Project Grants (RPGs) are awards for investigator-initiated research proposals. Several types of awards are made in this category, which vary in the type of mechanism, type of applicant, total amount of support, and length of time allotted.

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 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 discrete, specified research projects 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 specifically limited in time and amount for studies in categorical program areas. Small research grants provide flexibility for initiating studies that are generally for preliminary short-term projects. These grants are nonrenewable.

R21 – Exploratory/Developmental Grant

Exploratory/Development Grants (R21s) support the development of pilot projects or feasibility studies to support creative, novel, high-risk/high-payoff research that may produce innovative advances in science. The levels of support and time are generally restricted.

R33 – Exploratory/Developmental Grant—Phase II

Phase II of the Exploratory/Development Grants (R33s) provides a second phase for the support of innovative, exploratory, and developmental research activities that may or may not have been 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 National Cancer Advisory Board review competing R01 applications to select MERIT awardees. An initial 5-year MERIT Award is followed by an opportunity for an extension of 1 to 5 years, based on an expedited review of the accomplishments during the initial period.

R41 – Small Business Technology Transfer (STTR) Grant—Phase I

Phase I Small Business Technology Transfer (STTR) awards (R41s) foster the transfer of new technology from a research institution setting to the commercial sector. 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. According to STTR statutory guidelines, support for Phase I STTR awards may not exceed $100,000 for total costs for a period of 1 year. The NIH is aware that not all STTR medical and behavioral research can be completed within the statutory guidelines; therefore, applicants are encouraged to propose a reasonable, appropriate, and justified budget and project period necessary to complete the Phase I research project. Deviations from the guidelines MUST be well justified.

R42 – Small Business Technology Transfer (STTR) Grant—Phase II

Phase II Small Business Technology Transfer (STTR) awards (R42s) continue the cooperative efforts initiated in Phase I, with the ultimate goal of achieving commercialization of the results. R42s support in-depth development of cooperative research and development projects between small, domestic, for-profit organizations and research institutions. Support for Phase II awards depends on feasibility and the potential for commercialization that has been established in Phase I (R41). Only Phase I awardees are eligible for Phase II awards.

According to the STTR statutory guidelines, Phase II awards may not exceed $750,000 in total costs and are not to exceed 2 years' duration. The NIH is aware that not all STTR medical and behavioral research can be completed within the statutory guidelines; therefore, applicants are encouraged to

propose a reasonable, appropriate, and justified budget and project period necessary to complete the Phase II research project. Deviations from the guidelines MUST be well justified.

R43 – Small Business Innovation Research (SBIR) Grant—Phase I

Phase I Small Business Innovation Research (SBIR) awards (R43s) support research efforts by for-profit, domestic, small businesses. R42s are limited in time and amount and are used to establish the technical merit and feasibility of ideas that have a potential for commercialization. These grants may also determine the quality of performance of the small business prior to providing further Federal support in Phase II (R44).

According to SBIR statutory guidelines, support for Phase I awards may not exceed $100,000 in total costs for a period of 6 months. The NIH is aware that not all SBIR medical and behavioral research can be completed within the statutory guidelines; therefore, applicants are encouraged to propose a reasonable, appropriate, and justified budget and project period necessary to complete the Phase I research project. Deviations from the guidelines MUST be well justified.

R44 – Small Business Innovation Research (SBIR) Grant—Phase II

Phase II Small Business Innovation Research (SBIR) awards (R44s) continue the cooperative efforts initiated in Phase I, with the ultimate goal of achieving commercialization of the results. R44s support in-depth development of research and development projects started in Phase I (R43). Awards are based on the results of Phase I, scientific/technical merit, and the commercial potential of the Phase II application. Only Phase I awardees are eligible for Phase II awards.

According to SBIR statutory guidelines, support for Phase II may not exceed $750,000 in total costs for 2 years. The NIH is aware that not all SBIR medical and behavioral research can be completed within the statutory guidelines; therefore, applicants are encouraged to propose a reasonable, appropriate, and justified budget and project period necessary to complete the Phase I research project. Deviations from the guidelines MUST be well justified.

R55 – James A. Shannon Director's Award

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 their research capabilities and lend additional weight to their already meritorious applications.

R56 – High-Priority, Short-Term Project Award

High-Priority Awards (R56) 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. Applicants do not submit requests for an R56.

NCI program staff nominate previously reviewed R01 applications that are beyond the current NCI payline but, because of their merit, are eligible for funding. High-priority nominees are administratively reviewed by the NCI according to standard review criteria.

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 their specific interests and competencies. This mechanism is utilized when substantial programmatic involvement is anticipated between the NCI and the recipient during performance of the contemplated activity.

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 broad-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 award. This mechanism can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort.

U43 – Small Business Innovation Research (SBIR) Cooperative Agreement—Phase I (see R43)

Phase I SBIR Cooperative Agreements (U43s) support projects, limited in time and amount, to establish the technical merit and feasibility of research and development (R&D) ideas that may ultimately lead to commercial products or services. This mechanism is utilized when an assistance relationship and substantial programmatic involvement are anticipated between the NCI and the recipient during performance of the contemplated activity. Cooperative Agreement applications will be considered only for the topics specifically listed in the current SBIR Omnibus Solicitation.

Note: Phase I award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project that is appropriate for completion within the guidelines. 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. Therefore, applicants are encouraged to propose a budget that is appropriate for completion within the guidelines. Deviations from the guidelines MUST be well justified.

CANCER CENTERS AND SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE

- **FY2004 Obligations: $409,288,000**
- **8.7% of the NCI Budget**

The Cancer Research Centers Program contains diverse approaches to cancer research, incorporating all applicable disciplines.

P20 – Planning Grant

Planning Grants (P20s) support planning for new programs, expansion or modification of existing resources, and feasibility studies of new approaches. Such awards have been particularly useful in the development of cancer centers and Specialized Programs of Research Excellence (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.
- Increasing the rate at which research discoveries are translated into medical benefits.

P50 – Specialized Center Grant

Specialized Center Grants (P50s) support any part of the full range of research and development, from very basic to clinical. Activities may involve ancillary support such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on cancer. Centers may also serve as regional or national resources for special research purposes. These grants differ from Program Project Grants (P01s) in that they are usually developed in response to an announcement of the programmatic needs of the NCI and later receive continuous attention from its staff.

Specialized Programs of Research Excellence (SPOREs) utilize the P50 mechanism to support interdisciplinary teams of investigators who are dedicated to translational research focused on an organ-specific human cancer or a highly related group of human cancer types.

U54 – Specialized Center—Cooperative Agreement

Specialized Center Cooperative Agreements (U54s) support any part of the full range of research and development from very basic to clinical; they may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These differ from Program Project Grants (P01s)

in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes, with funding-component staff helping to identify appropriate priority needs.

At the NCI, U54s support comprehensive partnerships between Minority-Serving Institutions (MSIs) and NCI-designated Cancer Centers for the benefit of both. These partnerships focus on cancer research and one or more target areas in cancer research training or career development at the MSI. They may also focus on cancer research in minority communities, with an emphasis on cancer education or cancer outreach.

OTHER RESEARCH GRANTS

- **FY2004 Obligations: $314,916,000**
- **6.7% of the NCI Budget**

Other Research Grants include the Research Career Program (all "K" awards) and any research grants not funded as a Research Project Grant, Research Center, or Cancer Prevention and Control Grant, excluding Ruth L. Kirschstein National Research Service Awards.

K01 – Mentored Research Scientist Development Award

Mentored Research Scientist Development Awards (K01s) provide research scientists with a sponsored research experience that will help the applicant gain expertise in a new research area or 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 cancer prevention, control, and population sciences research. These awards provide protected time for awardees to devote to research and act as mentors for young investigators.

K07 – Academic Career Award

Academic Career Awards (K07s) support:

- Junior candidates who are interested in developing academic and research expertise in a specific area.
- Senior individuals with acknowledged scientific expertise and leadership skills who are interested in improving the curricula and enhancing 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 provides support for the K08 through 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) support newly trained clinicians appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

K22 – Career Transition Award

Career Transition Awards (K22s) support newly trained investigators (basic or clinical) to develop their independent research skills through a two-phase program. The initial period involves an intramural appointment at the NIH, while the final period of support is conducted at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career. The NCI supports two K22 awards:

- The NCI Scholars Program provides an opportunity for outstanding new investigators to begin independent research careers. They begin intramurally, within the special environment of the NCI, and then continue their careers extramurally at an institution of their choice.
- The NCI Transition Career Development Award is a fully portable mechanism that facilitates the transition of talented clinician cancer scientists, clinicians in patient-oriented cancer research, and researchers in cancer prevention, control, and population sciences from the mentored stage of their careers to junior faculty positions or the equivalent.

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. This mechanism provides support for a period of supervised study and research for 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 for 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 the curriculum designed to improve the quality of training available to aspiring clinical investigators.

R13 – Conference Grant

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

R15 – Academic Research Enhancement Award (AREA)

AREA Grants (R15s) support small-scale research projects conducted by faculty in domestic institutions that primarily award baccalaureate degrees. Awards are for up to $150,000 in direct costs (plus applicable F&A costs) for periods not to exceed 36 months.

R24 – Resource-Related Research Project

Resource-Related Research Projects (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 the following two distinct Cancer Education programs:

- The NCI Cancer Education Grant Program (R25E) is a flexible, curriculum-driven program aimed at developing and sustaining innovative educational approaches that will ultimately reduce cancer incidence, mortality, and morbidity, as well as improve the quality of life of cancer patients. These awards address a need that is not fulfilled adequately by any other grant mechanism available at the NIH and are dedicated to areas of particular concern for the NCI.
- 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.

S06 – Minority Biomedical Research Support (MBRS)

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

T09 – Scientific Evaluation

Scientific Evaluation awards (T09s) provide funds to the Chair of a training committee for operation of a review group.

U09 – Scientific Review and Evaluation—Cooperative Agreement

Scientific Review and Evaluation Cooperative Agreements (U09s) provide funds to the Chair of an Integrated Review Group (IRG) for operation of the IRG.

U10 – Clinical Research—Cooperative Agreement

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 are usually conducted under established protocols.

U13 – Conference—Cooperative Agreement

Conference Cooperative Agreements (U13s) support international, national, or regional meetings, conferences, and workshops with substantial NCI programmatic involvement.

U24 – Resource-Related Research Project—Cooperative Agreement

Resource-Related Research Project Cooperative Agreements (U24s) support projects that contribute to improving the capability of resources that serve biomedical research.

U56 – Exploratory Grant—Cooperative Agreement

Exploratory Grant Cooperative Agreements (U56s) support planning for new programs, expansion or modification of existing resources, and feasibility studies that explore various approaches to the development of interdisciplinary programs which 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 performance of the research activities, as defined in the terms and conditions of award.

TRAINING

- **FY2004 Obligations: $66,264,000**
- **1.4% of the NCI Budget**

The Ruth L. Kirschstein National Research Service Award (Kirschstein–NRSA) is the primary mechanism for providing long-term, stable support for a wide range of promising scientists and research clinicians.

F31 – Ruth L. Kirschstein National Research Service Award Predoctoral Fellowship

The Ruth L. Kirschstein National Research Service Award Predoctoral Fellowship provides support for research training leading to a Ph.D. (or the equivalent research degree) or a combined M.D./Ph.D. (or other combined professional research doctoral degrees) in the biomedical or behavioral sciences.

F32 – Ruth L. Kirschstein National Research Service Award Postdoctoral Fellowship

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 – Ruth L. Kirschstein National Research Service Award for Senior Fellows

The National Research Service Awards for Senior Fellows (F33s) provide opportunities for experienced scientists 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 take time from regular professional responsibilities to increase capabilities to engage in health-related research.

T32 – National Research Service Award Institutional Training Grants

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

T36 - MARC Ancillary Training Activities Grant

Minority Access to Research Careers (MARC) Ancillary Training Activities Grants (T36s) increase the number of well-trained minority scientists in biomedical disciplines and strengthen the research and teaching capabilities of minority institutions. The NCI co-funds these grants with the National Institute of General Medical Sciences.

R&D CONTRACTS

- **FY2004 Obligations: $358,248,000**
- **7.6% of the NCI Budget**

The contract mechanism is appropriate when a specific end-product is desired or a project needs to be conducted with the NCI's direct involvement.

INTRAMURAL RESEARCH

- **FY2004 Obligations: $708,939,000**
- **15.0% of the NCI Budget**

The NCI Intramural Research Program, which complements the Extramural Research Program, is housed on the NIH Campus in Bethesda, Md., and at NCI–Frederick in Frederick, Md.

RESEARCH MANAGEMENT AND SUPPORT

- **FY2004 Obligations: $171,578,000**
- **3.6% of the NCI Budget**

There are many activities that provide general management and support to the NCI's cancer research efforts. Funding for research management and support (RMS) has remained relatively constant over the last several years.

CANCER PREVENTION AND CONTROL

- **FY2004 Obligations: $529,980,000**
- **11.2% of the NCI Budget**

The NCI Cancer Prevention and Control Program supports research on methods of cancer prevention and control conducted through grants, contracts, and in-house research.

CONSTRUCTION

- **FY2004 Obligations: $0**

Although the NCI has the authority to fund Construction grants, there are currently no funds appropriated to this program. This program is still active within some other NIH Institutes.

C06 – Research Facilities Construction Grant

Research Facilities Construction Grants (C06s) provide matching Federal funds for up to 50% of allowable costs for construction or major remodeling to create new facilities for cancer research. In addition to basic research laboratories, construction grants may support the construction or renovation of animal facilities, limited clinical facilities, and core facilities that are an integral part of an overall cancer research effort. The request for NCI funding must be in excess of $150,000 and not over $4 million per application.

COMPREHENSIVE MINORITY BIOMEDICAL PROGRAM

Although not a funding mechanism, the Comprehensive Minority Biomedical Branch (CMBB) coordinates the NCI's efforts to broaden participation in cancer-related research and training activities by promoting diversity in the research workforce that includes individuals with disabilities, underserved segments of the general population, and individuals seeking

reentry. Located within the NCI's Office of Centers, Training, and Resources, the ultimate goal of the CMBB is to significantly increase diversity among competitive NCI/NIH-funded cancer researchers. This goal is being implemented through the following CMBB initiatives:

- Research Supplements to Promote Diversity in Health-Related Research—support provided to improve the diversity of the research workforce for the Investigator Supplement, Individuals in Postdoctoral Training, Graduate Research Assistants, Post-Baccalaureate and Post-Master's Degree Students, Undergraduate Students, High School Students, and individuals with disabilities.
- Supplements to Promote Reentry Into Biomedical and Behavioral Research Careers—support of full- or part-time research by individuals with high potential to reenter an active research career after taking time off to attend to other responsibilities.
- Travel Award for Young Investigators—support of minority student and faculty researchers and young minority physicians to attend national American Association for Cancer Research (AACR) meetings.
- Historically Black Colleges and Universities Faculty in the Field of Cancer—support of meritorious faculty members from eligible institutions to attend annual meetings or special conferences on more focused scientific topics of the AACR.
- Ruth L. Kirschstein National Research Service Award Individual Predoctoral Fellowship Awards for Minority Students—support of minority students pursuing a Ph.D. or equivalent degree (F31).
- NCI Career Development Award for Underrepresented Minorities—support of the career development of minority health professionals utilizing the K01, K08, K22, or K23 mechanisms.
- Continuing Umbrella of Research Experiences (CURE)—supplemental support of introductory science experiences at the high school, undergraduate, and pre- and postdoctoral levels, with the aim of developing well-trained underrepresented-minority scientists capable of conducting independent cancer research for the R25T, K12, and T32 mechanisms.
- Minority-Serving Institution/Cancer Center Partnership Program (MSI/CCP)—support of programs focused on collaborations between scientists and faculty at a minority-serving institution and an NCI-designated Cancer Center.

For questions concerning the above programs, as well as new initiatives, contact the CMBB at 301-496-7344 or visit the website at: http://minorityopportunities.nci.nih.gov.

CHAPTER 5

CROSS-CUTTING PUBLIC POLICIES

There are numerous cross-cutting public policy requirements applicable to Federal grants, including those awarded by the NIH and the NCI. The term *public policy* indicates that the requirement is based on social, economic, and/or other objectives or considerations that may be attached or related to the expenditure of Federal funds by grantees, consortium participants, and contractors while conducting research or other specified activities.

In addition, NIH grantees are subject to requirements contained in NIH's annual appropriations acts that apply to the use of NIH grant funds. Some of those have been part of appropriations acts for several years without change. However, current requirements are subject to change, while others may be added in the future.

The NIH upholds high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its grantees. The public policy requirements specified in this section set many of those standards. The signature of the authorized organizational official on the application certifies that the organization is in compliance with or intends to comply with all required certifications and assurances applicable to the associated application package. These are outlined below.

Acknowledgment of Federal Funding

All HHS grantees must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Grantees are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal money; and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources (NIH Grants Policy Statement, Part II, Subpart A: Terms and Conditions of NIH Grant Awards).

Age Discrimination—45 CFR Part 91

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 91.

Animal Welfare—9 CFR Parts 1–4

Animal Welfare refers to special requirements that apply to grants involving the use of live vertebrate animals in research, training, experimentation, testing, and related purposes. All grantees must comply with the PHS Policy on Humane Care and Use of Laboratory Animals. This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply with the Animal Welfare Act as amended (7 USC 2131 et seq.) and other Federal statutes and regulations pertaining to animals, if applicable.

Architectural Barriers to the Handicapped (Elimination of)

The following policies set forth requirements to make facilities accessible to and usable by the physically handicapped and include minimum design standards:

- Architectural Barriers Act of 1968, as amended
- Federal Property Management Regulations 101-19.6 (41 CFR 101-19.6)
- Uniform Federal Accessibility Standards, issued by the General Services Administration (41 CFR 101-19.6, Appendix A)

The following requirements apply:

- All facilities constructed or renovated with NCI grant support must comply with these requirements.
- These minimum standards must be included in the specifications for any NCI-funded renovation or new construction.
- The grantee is responsible for conducting inspections to ensure compliance with these standards by any contractor performing construction services under the grant.

Civil Rights—45 CFR Part 80

The Civil Rights Act of 1964, Title VI, requires that no person in the United States shall, on the basis of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 80.

Data and Safety Monitoring

The NCI requires oversight and monitoring of all human intervention studies to ensure the safety of participants and the validity and integrity of the data. This policy is in addition to any monitoring requirements imposed by 45 CFR Part 46, the FDA, and the NIH *Guidelines for Research Involving Recombinant DNA Activities*. The level of monitoring should be commensurate with the risks, size, and complexity of the clinical trial.

Oversight and monitoring under Phase III clinical trials must be in the form of Data Safety Monitoring Boards (DSMBs). A DSMB also may be appropriate for Phase I and II clinical trials if the studies have multiple clinical sites, are blinded (masked), or employ particularly high-risk or vulnerable populations. The DSMB monitoring function is above and beyond that traditionally provided by Institutional Review Boards (IRBs). However, the IRB must be cognizant of the procedures used by DSMBs, which must provide periodic reports to investigators for transmittal to the local IRB.

Debarment—45 CFR Part 76 and 45 CFR Part 92.43

This action is taken by a debarring official in accordance with Federal agency regulations implementing Executive Order 12549 to exclude a person or organization from participating in transactions. Grantees may be debarred or suspended if they are found to have seriously and willfully not complied with grant conditions or are found to have engaged in scientific misconduct. If debarred, a grantee may not receive Federal assistance funds and may not participate in covered transactions for the period covered by the debarment.

Drug-Free Workplace—45 CFR Part 76, Subpart F

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. Under this law, employees of grantees are prohibited from engaging in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance at work. By signing the application, the authorized business official agrees that the grantee will provide a drug-free workplace and will comply with requirements to notify the NCI in the event that an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. HHS implementing regulations are set forth in 45 CFR Part 76, "Government-wide Debarment and Suspension (Non-procurement) and Government-wide Requirements for Drug-Free Workplace (Grants)."

DUNS Numbers

The Data Universal Numbering System (DUNS) Number, provided by Dun & Bradstreet, is a unique nine-digit code that helps identify and link companies worldwide. Since the DUNS number is site-specific, each physical location of an entity, such as branches, divisions and headquarters, may be assigned a DUNS number. As of October 1, 2003, a DUNS Number is a Federal requirement for any institution planning to submit a Federal grant or cooperative agreement application. Organizations can secure a DUNS number at no cost by telephone at 1-866-705-5711 or electronically at URL https://eupdate.dnb.com/requestoptions.html?cmid=EOE100537. Answers to frequently asked questions may also be found at http://grants.nih.gov/grants/duns_qa.doc.

Final Reports

Grantees are required to submit a final Financial Status Report, Final Invention Statement and Certification, and final progress report within 90 days following the end of grant support. Failure to submit timely and accurate final reports may affect future funding to the organization or awards to the PI.

Freedom of Information Act

Records and other information can be obtained by the general public from the Government under the Freedom of Information Act (FOIA) of 1966. However, there are certain rules and regulations the NCI must follow in handling requests for records under FOIA.

For further information, see http://www.nih.gov/icd/od/foia.

For more details, please contact:

NCI FOI Coordinator
9000 Rockville Pike
Building 31, Room 10A34
Bethesda, Maryland 20892
Telephone: (301) 496-2999
Fax: (301) 435-2931

Handicapped Discrimination—45 CFR Parts 84 and 85

Before a grant may be awarded, a domestic applicant organization must certify compliance with Section 504 of the Rehabilitation Act of 1973, as amended (29 USC 794). This Act provides that no handicapped individual in the United States shall, solely by reason of the handicap, be excluded from participation in, denied the benefits of, or subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Parts 84 and 85.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

New concepts introduced by the Privacy Rule:

- An individual's written authorization is required for the use or disclosure of protected health information (PHI) unless waived or excepted.
- The request must be for a specific research study—blanket authorization is not permitted.
- Authorization waivers can be granted by IRBs or Privacy Boards.
- A decedent's information is protected, but authorization is not required.
- Accounting and reporting of disclosures are required when requested.

Additional information on HIPAA can be found at:

- The Office of Civil Rights website—http://www.hhs.gov/ocr/hipaa/.
- HIPAA Information for Researchers—http://privacyruleandresearch.nih.gov.
- NIH Guide Notice published on February 5, 2003: "Impact of the HIPAA Privacy Rule on NIH Processes Involving the Review, Funding, and Progress Monitoring of Grants, Cooperative Agreements and Research Contracts"—http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

Human Embryo Research, Continued Ban on Funding

NCI-appropriated funds may not be used to support human embryo research under any extramural award instrument. NIH funds may not be used for the creation of human embryos for research purposes or for research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.208(a)(2) and subsection 498 (a) and (b) of the PHS Act. The term "human embryo(s)" includes any organism not protected as a human subject under 45 CFR 46—as of the date of enactment of the governing appropriations act—that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. In addition to the statutory restrictions on human fetal research under subsections 498 (a) and (b) of the PHS Act, by presidential memorandum of March 4, 1997, the NCI is prohibited from using Federal funds for cloning of human beings.

Human Embryonic Stem Cell Research

For the latest on human embryonic stem cell research, please refer to the following website: http://stemcells.nih.gov/research/nihresearch.

Lobbying (Anti-Lobbying)—45 CFR Part 93

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 USC 1352, "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions," from using Federal (appropriated) funds to pay any person to influence or attempt to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR Part 93, which also describes types of activities that are not subject to this prohibition, such as legislative liaison activities and professional and technical services.

Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that:

- They have not made, and will not make, such a prohibited payment.
- They will be responsible for reporting the use of nonappropriated funds for such purposes.
- They will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

The signature of the authorized business official on the application serves as the required certification of compliance for the applicant organization. NIH-appropriated funds may not be used to pay the salary or expenses of an employee of a grantee, consortium participant, or contractor or those of an agent related to any activity designed to influence legislation or appropriations pending before Congress or any state legislature.

Misconduct in Science—42 CFR Part 50

Activities that constitute misconduct in science include fabrication, falsification, plagiarism, and other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. This does not include honest error or honest differences in interpretations or judgments of data. Each institution that receives or applies for a research, research training, or research-related grant under the Public Health Service Act must submit an annual assurance certifying that it is in compliance with the provisions set forth in 42 CFR Part 50.

Overdue Federal Debt—45 CFR Part 30, Subpart B, and 4 CFR Parts 101-105

The Federal Debt Collection Act (31 USC 3711) and the Federal Claims Collection Standards (4 CFR Parts 101-105) require the NIH to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to the NIH by grantees (see also HHS claims collection regulations at 45 CFR Part 30). Debts may result from disallowances, recovery of funds, unobligated balances, or other circumstances. A major goal of OMB Circular A-129 is the collection of overdue Federal debt. Before a grant award can be made, the applicant organization must certify that it is not delinquent on the repayment of any Federal debt.

Patents and Inventions—37 CFR Part 401

Pursuant to the Bayh-Dole Act and Executive Order 12591 (April 10, 1987), all recipients of NIH research funding (i.e., all NIH grantees, contractors, consortium participants, and other organizations receiving funds under NIH grants and contracts, whether small businesses, large businesses, or nonprofit organizations) are subject to the same invention reporting requirements and regulations. These are included in the regulations issued by the Department of Commerce, found at 37 CFR Part 401.

Grantees have rights to inventions conceived or first reduced to actual practice in the performance of work under an NIH award. Grantee organizations must fulfill the requirements listed under the "Inventions and Patents" section under Part II, Subpart A, of the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_TOC54600135). Acknowledgment of Federal support in the development of a subject invention must be included in any patent application stemming from a subject invention. The Federal Government must be granted a nontransferable, nonexclusive, royalty-free, paid-up license to practice the subject invention.

For final closeout of a research grant application, the grantee must provide the awarding Institute a Final Invention Statement (Form HHS 568) within 90 days following the expiration or termination of the project period. Any issues involving extramural subject invention reporting requirements should be directed to:

Division of Extramural Reports and Technology Resources
Office of Policy for Extramural Research Administration
Office of Extramural Research
Building 31, Room 5B62
Bethesda, Maryland 20892
Telephone: (301) 435-1986

Privacy Act—45 CFR Part 5b

The Privacy Act of 1974, 5 USC 552a, provides certain safeguards for information about individuals maintained in a system of records, as identified by the Act (i.e., information may be retrieved by the individual's name or other personal identifiers). These safeguards include the rights of individuals to determine what information is maintained about them in Federal agencies' files (hard-copy or electronic) and how it is used, to have access to such records, and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated. Records maintained by the NCI with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Requests should be directed to:

NCI Privacy Act Coordinator
Building 31, Room 10A34
Bethesda, Maryland 20892

Program Fraud Civil Remedies Act—45 CFR Part 79

The Program Fraud Civil Remedies Act of 1986, Public Law 99-509, imposes civil penalties against persons who make false, fictitious, or fraudulent claims to the Federal Government for money (including money representing grants, loans, or other benefits).

Protection of Children

The Pro-Children Act of 1994, Public Law 103227, Title X, Part C, imposes restrictions on smoking in facilities where federally funded children's services are provided. For services funded by Federal funds, either directly or through state or local governments, the Act specifies that smoking is prohibited in those indoor facilities used routinely for the provision of health care, daycare, early childhood development, education, or library services to persons under 18. Applicable Federal funds include grants, both discretionary and nondiscretionary; cooperative agreements; loans; loan guarantees; contracts; and funds for construction, maintenance, and operations awarded by the Department of Health and Human Services, Education, or Agriculture.

Protection of Human Subjects—45 CFR Part 46

The protection of human subjects is required of all research activities in which human subjects are involved. A human subject is defined in 45 CFR Part 46 as:

> A living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual; or (b) identifiable private information.

The regulation also extends to the use of human organs, tissues, and body fluids that can be linked to specific individuals by the investigator(s), even if these materials were collected by others. There is additional protection for certain classes of human research involving fetuses, pregnant women, human *in vitro* fertilization, and prisoners. The regulation exempts certain categories of research involving human subjects (listed in 45 CFR Part 46.101[b]) that normally involve little or no risk.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Public Health and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, is designed to provide protection against misuse of select agents and toxins, whether inadvertent or the result of terrorist acts, against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by the Centers for Disease Control and Prevention (CDC) at 42 CFR 73. Those regulations supersede the requirements at 42 CFR 76.2 (Interstate Shipment of Etiological Agents), which established certain shipping and handling requirements for laboratory facilities that send or receive select agents. Copies of these regulations are available from the Import Permit Program and Select Agent Program, respectively, at:

Centers for Disease Control and Prevention
1600 Clifton Road, MS E-79
Atlanta, Georgia 30333
Telephone: (404) 498-2255
http://www.cdc.gov/od/sap/docs/cdc-05a.pdf

Purchase of American-Made Equipment and Products

In accordance with the requirements of NIH appropriations acts, all equipment and products purchased with grant, cooperative agreement, or contract funds should be American-made to the greatest extent possible.

Salary Limitation

The Department of Health and Human Services (HHS) Appropriation Act for FY2004, Public Law 107-116, restricts the amount of direct salary of an individual under an NCI grant, cooperative agreement, or applicable contract to Executive Level I of the Federal Executive Pay Scale. For the latest information concerning salary limitations, see the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/index.html).

Select Agent Rule

The Select Agent Rule was signed by the President on June 12, 2002, and establishes requirements regarding the possession, use, and transfer of select agents and toxins. The HHS lists these select agents and toxins in 42 CFR 73. This Rule includes the requirements concerning registration, security-risk assessments, safety plans, security plans, record keeping, inspections, etc. The CDC is the lead agency and provides the following website for more information on the Select Agent Program: http://www.cdc.gov/od/sap/index.htm.

Sex Discrimination—45 CFR Part 86

Section 901 of Title IX of the Education Amendments of 1972 (20 USC 1681), as amended, provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 86.

Smoke-Free Workplace

The NIH strongly encourages all grant recipients to provide smoke-free workplaces and promote the nonuse of tobacco products. The NIH defines the term *workplace* to mean office space (including private offices and other work space), conference or meeting rooms, corridors, stairways, lobbies, restrooms, cafeterias, and other public spaces.

Suspension—45 CFR Part 76 and 45 CFR Part 92.43

A suspension is a temporary withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by the NCI, or a decision by the NCI to terminate the award. The NIH will generally suspend (rather than immediately terminate) a grant and allow the grantee an opportunity to take appropriate corrective action prior to making a termination decision. The NIH may decide to terminate the grant if the grantee does not take appropriate corrective action during the period of suspension. However, the NIH may terminate without first suspending the grant if the deficiency is so serious as to warrant immediate termination or if concerns for public health or welfare require immediate action.

Termination—45 CFR Part 76 and 45 CFR Part 92.43

A termination is the permanent withdrawal of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including voluntary relinquishment of that authority by the grantee. The grant may be terminated without first being suspended if the deficiency is so serious as to warrant immediate termination or if concerns for public health or welfare require immediate action. A grant also may be terminated, partially or totally, by the grantee or by the NIH with the consent of the grantee.

USA PATRIOT Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act), Public Law 107-56, amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also restricts access to specified materials. *Restricted persons*, as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent. (For further information, see the definition of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002," p. 97.)

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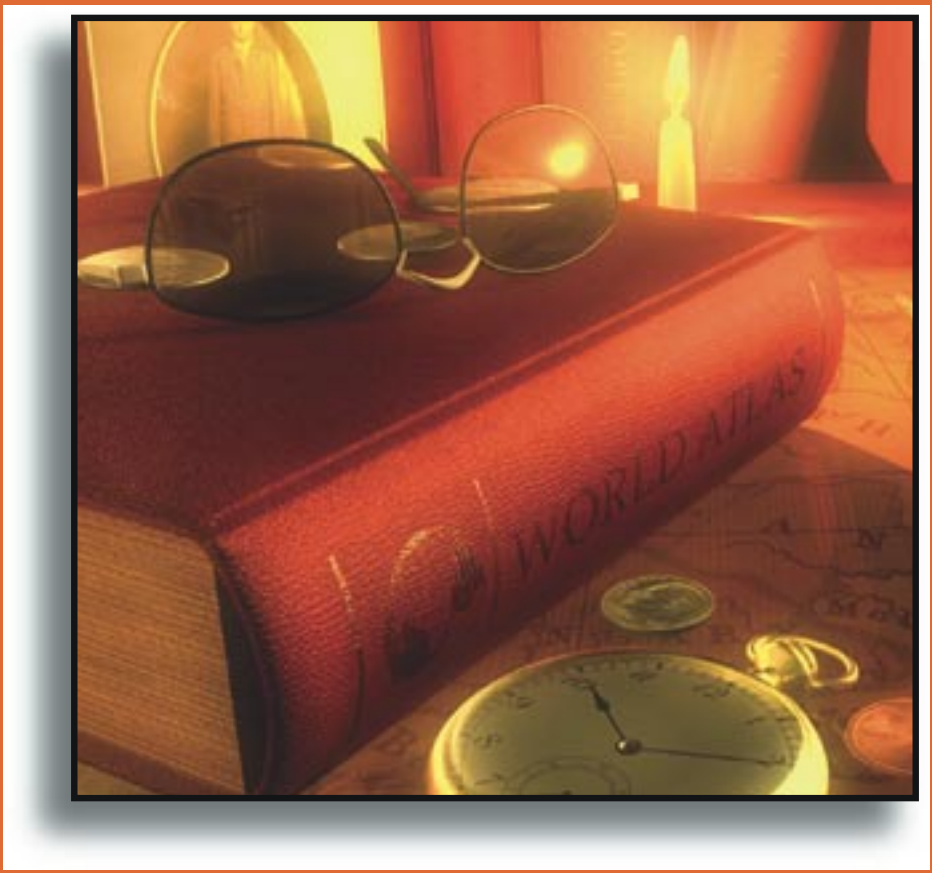
CHAPTER 6

REFERENCES AND RESOURCES



PUBLICATIONS

Most NCI publications are online at: https://cissecure.nci.nih.gov/ncipubs/

Hard copies of most NCI publications can be obtained from:

Office of Communications
National Cancer Institute
National Institutes of Health
Building 31, Room 10A16
Bethesda, MD 20892
Toll-free telephone: 1-800-4-CANCER
TTY (for persons with hearing impairments): 1-800-332-8615

- *Catalog of Federal Domestic Assistance* (CFDA): http://www.cfda.gov/default.htm
- *NCI Fact Book*: http://www.nci.nih.gov/admin/fmb/
- *NIH Grants Policy Statement* (revised 12/1/03): http://www.grants.nih.gov/grants/policy/nihgps_2003/index.html
- NIH "Welcome Wagon" Letter: http://grants.nih.gov/grants/funding/welcomewagon.htm
  Information for new grantees (also helpful to established grantees)

The following NIH publications are also available at:

Division of Extramural Outreach and Information Resources
National Institutes of Health
6701 Rockledge Drive, Suite 6095
Bethesda, MD 20892-7910
Telephone: 301-435-0714
E-mail: GrantsInfo@nih.gov

- *NIH Extramural Programs* (funding for research and research training)
- *Helpful Hints on Preparing a Research Grant Application for the NIH*
- *NIH Peer Review of Research Grant Applications*
- *The Project–Grant Application to the National Institutes of Health*
- *Ingredients of a Successful Grant Application to the National Institutes of Health: Case History*
- *Site Visits for the Review of Grant Applications to the NIH: Views of an Applicant and a Scientist Administrator*
- *Preparing a Research Grant Application to the National Institutes of Health: Selected Articles*

WEBSITES

General

- *All About Grants*: http://www.niaid.nih.gov/ncn/grants/default.htm. Includes Grant Application Basics, How to Plan a Grant Application, and How to Write a Grant Application.

- NCI GAB Home Page: http://www3.cancer.gov/admin/gab. Includes links to the *100+ Years of Advances in the Fight Against Cancer* PowerPoint presentation and an electronic version of *Everything You Always Wanted to Know About the NCI Grants Process but Were Afraid to Ask*, as well as GAB organizational and contact information.
- NCI Home Page: http://www.cancer.gov.
- NIH Home Page: http://www.nih.gov/. Links to offices within the Office of the Director, as well as to Institute and Center websites; each provides valuable tools and insights into Institute-specific areas of research emphasis.

Policy Guidance/Extramural Grant Program Information

- Applications and Forms: http://grants1.nih.gov/grants/forms.htm.
- *Code of Federal Regulations* (CFR): http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.
- Funding Opportunities: http://grants1.nih.gov/grants/oer.htm.
- Grants Policy and Guidance: http://grants1.nih.gov/grants/policy/policy.htm. Includes links to the *NIH Grants Policy Statement* (current and prior versions), as well as policy resources, guidance documents, and other related links.
- *NIH Grants Policy Statement*: http://grants.nih.gov/grants/policy/nihgps_2003/index.htm. An online version of up-to-date policy guidance with terms and conditions of NIH awards. Also provides information about NIH: its organization, staff, and grants process.
- *NIH Guide for Grants and Contracts*: http://grants.nih.gov/grants/guide. The official, weekly, online publication of NIH policies, procedures, and availability of funds.
- Office of the Federal Register, National Archives and Records Administration: http://www.gpoaccess.gov/nara/index.html.
- *SBIR/STTR Omnibus*: http://grants.nih.gov/grants/funding/sbir.htm.
- Types of Grant Programs (select programs only): http://grants.nih.gov/grants/funding/funding_program.htm. Includes RPGs, Ruth L. Kirschstein National Research Service Awards, Research Training Grant Program, NIH Career Development Awards, Small Business Awards, and other programs.
- Just-In-Time: http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm.
- Other Support: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-029.html.
- Prior Approval: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm.

Electronic Research Administration

- CRISP: http://crisp.cit.nih.gov/. A searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions.
- Edison Invention Reporting: http://www.iedison.gov/. Online invention reporting.
- Grants.gov: http://grants.gov/.
- NIH Electronic Research Administration (eRA): http://era.nih.gov/. Provides information on NIH's eRA initiative, which strives for paperless electronic transfer of applications and administrative information. The NIH Commons may be accessed through this site.

Other

- *A Straightforward Description of What Happens to Your Research Project Grant Application After It Is Received for Peer Review*: http://www.csr.nih.gov/review/peerrev.htm. A snapshot of the process for applications reviewed in the Center for Scientific Review.
- Award Data and Award Trends: http://grants1.nih.gov/grants/award/award.htm.
- Bioethics: http://www.nih.gov/sigs/bioethics/. A broad collage of annotated web links on education, research involving human participants and animals, medical and health care ethics, and the implications of applied genetics and biotechnology. May be useful for those looking to satisfy the educational requirements for training on the protection of human research participants.
- DUNS Number (Data Universal Numbering System): http://www.dnb.com/us/. Grantee organizations are required to have a DUNS Number.
- Grant Writing Tips: http://grants.nih.gov/grants/grant_tips.htm.
- NIH Roadmap: http://nihroadmap.nih.gov.

Contacts

- Center for Scientific Review (Application Receipt, Referral and Review): http://www.csr.nih.gov/. Includes application receipt dates as well as review and award schedules.
- HHS Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp. This new office at the Department of Health and Human Services leads efforts for protecting human subjects in biomedical and behavioral research.
- NIH Institutes, Centers, and Offices (links): www.nih.gov/icd/.
- NIH Office of Financial Management (FSRs): http://ofm.od.nih.gov.
- NIH Office of Laboratory Animal Welfare (OLAW): http://grants.nih.gov/grants/olaw/olaw.htm. Responsible for animal-related functions,

including the Public Health Service Policy on Humane Care and Use of Laboratory Animals, administering an educational program for PHS-supported institutions and investigators, negotiating Animal Welfare Assurances, and evaluating compliance with PHS Policy.

- Office of Extramural Research: http://grants.nih.gov/grants/oer.htm. Host to information of interest to the extramural community.
- Payment Management System (PMS): http://www.dpm.psc.gov/.

Additional Assistance

http://grants1.nih.gov/grants/funding/haveques.htm

Can the answer to my question be found in a reference document?

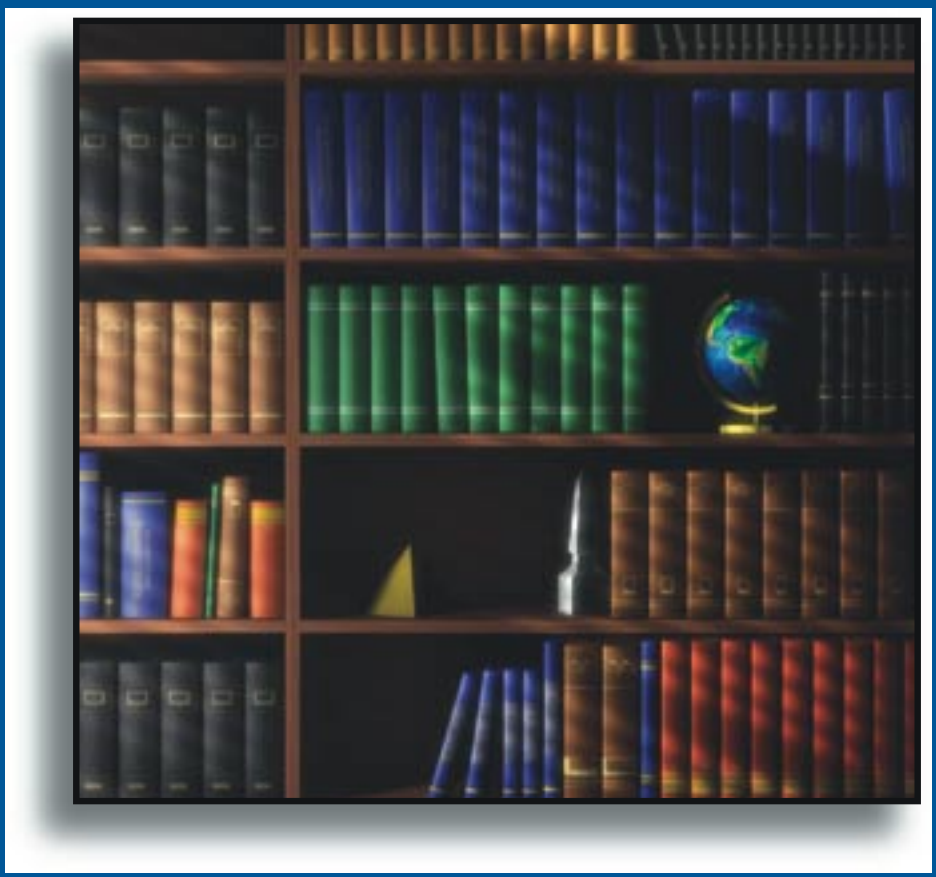
- *NIH Guide for Grants and Contracts*, grants.nih.gov/grants/guide/index.html.
- PHS 398 grant application or PHS 416-1 Individual NRSA application instructions, grants.nih.gov/grants/forms.htm.
- Answers to Frequently Asked Questions About NIH Grants, grants.nih.gov/grants/funding/giofaq.htm.
- *NIH Grants Policy Statement*, grants.nih.gov/grants/policy/nihgps_2003/.
- 45 CFR Part 74, HHS Regulations, Administration of Grants.
- 45 CFR Part 92, HHS Regulations, Administration of Grants (state/local govt).
- 45 CFR Part 74 Appendix E, Cost Principles for Hospitals.
- 48 CFR Part 31.2, Cost Principles for Profit Organizations, www.access.gpo.gov/nara/cfr/cfr-table-search.html (for all Code of Federal Regulations).
- OMB circular A-21, Cost Principles for Education Institutions, www.whitehouse.gov/OMB/circulars/a021/a021.html.
- OMB circular A-87, Cost Principles for State, Local, and Tribal Governments, www.whitehouse.gov/OMB/circulars/a087/a087.html.
- OMB circular A-122, Cost Principles for Nonprofit Organizations, www.whitehouse.gov/OMB/circulars/a122/a122.html.
- Information for New NIH Grantees, grants.nih.gov/grants/funding/welcomewagon.htm.

Can my question be answered by an NIH awarding component official?

- If your question is related to administrative and/or fiscal issues, contact the grants management staff member named on the program announcement (PA), request for application (RFA), or notice of grant award (NGA).
- If your question is a scientific one, contact the NIH scientific program official identified on the PA, RFA, or NGA.

CHAPTER 7

GLOSSARY



Application: A formal request for financial assistance for a project/activity submitted to the NIH on the appropriate application form:

- Form PHS 398 is used for all new competing applications (Type 1) or competing continuation applications (Type 2), except as shown in the table below. This form is also used for a competing supplemental application (Type 3) when requesting additional funds for a change of scope or expansion to meet the needs of a project.
- Most competing application forms have corresponding forms to be used when applying for noncompeting continuation support during an approved competitive segment. The form corresponding to PHS 398 is Form PHS 2590. These forms may be accessed at: http://grants1.nih.gov/grants/forms.htm.

Application Forms	Use Form Number
Ruth L. Kirschstein National Research Service Award or Senior International Fellowship Award	PHS 416-1
Health Services Project	PHS 5161-1
Construction Grant	PHS 424

Assistance: The award of money, property, services, or anything of value to a recipient in order to support or stimulate a public purpose authorized by Federal statute. Assistance relationships are expressed in less detail than acquisition relationships, and responsibilities for ensuring performance rest largely with the recipient or are shared with the NCI.

Award: The provision of funds by the NCI to an organization or an individual to carry out an activity or project based on an approved application and budget.

Budget: A categorical or modular request for funds required to support the proposed activity.

Budget Period: The interval of time (usually 12 months) into which the grant project period is divided for funding and reporting purposes.

***Catalog of Federal Domestic Assistance* (CFDA):** The CFDA is a government-wide compendium of Federal programs and activities that provides assistance or benefits to state and local governments; public, quasi-public, profit, and nonprofit institutions; and specialized groups and individuals. The catalog is compiled and published annually by the General Services Administration. (http://www.cfda.gov/default.htm).

Competitive Segment: The initial project period recommended for support (usually 1 to 5 years) or each extension of the prior project resulting from the award of a competing continuation grant.

Consortium Agreement: A collaborative arrangement in support of a research project in which some portion of the programmatic activity is carried out through a formalized agreement between the grantee and one or more other organizations that are separate legal entities administratively independent of the grantee.

Contract (Research & Development [R&D]): An instrument used by the NCI to procure cancer research services and other resources needed by the Federal Government. Contracts are legally binding documents and used when the principal purpose of the transaction is to acquire a specific service or end-product for the direct benefit of or use by the NCI.

Contract (under a grant): A written agreement between a grantee and a third party to acquire routine goods or services.

Cooperative Agreement: An award instrument, reflecting an assistance relationship between the NCI and a recipient, in which substantial NCI programmatic involvement is anticipated during performance of the activity.

Direct Costs: Costs that can be specifically identified with a particular activity or project.

Expedited Board Concurrence and Early Award Initiative: This NCI initiative focuses on the part of the grant review-and-award cycle in which the NCI has the most influence: award negotiation and issuance. This accounts for 2 months of the 10- to 12-month grant review-and-award process.

Facilities and Administrative (F&A) Costs: Costs (previously known as *indirect costs*) that are incurred by a grantee for common or joint objectives and therefore cannot be identified with a particular project or program.

***Federal Register*:** An official daily publication that provides a uniform system for communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance programs. The *Code of Federal Regulations* is an annually revised codification of the general and permanent rules published in the *Federal Register* (www.gpoaccess.gov/fr/index.html).

Financial Status Report (FSR): The FSR shows the status of awarded funds for the competitive segment as maintained in the official accounting records of the grantee institution.

- SNAP: The FSR is due no later than 90 days after the completion of the project period, excluding awards to Federal institutions or foreign organizations.
- Non-SNAP: The FSR is due no later than 90 days after the end of each budget period.

Grantees are required to submit FSRs for continued funding of their grant(s).

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. Performance responsibility rests primarily with the recipient, and there is little or no Federal involvement or participation in the performance of activities.

Grantee: The organization or individual awarded a grant or cooperative agreement by the NCI that assumes legal, financial, and scientific responsibility and accountability for both the awarded funds and the performance of the grant-supported activity. A grantee organization can be public or private, nonprofit or for-profit, or an educational institution, hospital, corporation, domestic or foreign agency, or other legally accountable entity.

Grants Management Officer (GMO): The individual designated by an awarding component to be responsible for ensuring that both the granting agency and grantees meet all requirements of laws, regulations, and formally established policies.

Grants Management Specialist (GMS): An individual selected by the Grants Management Officer to serve as the focal point of the awarding component for all business/management activities associated with the negotiation, award, and administration of a grant or cooperative agreement. He/she also interprets grant administration policy and provisions.

Indirect Costs: See Facilities and Administrative (F&A) Costs.

Institute/Center (IC): The NIH organizational component responsible for a particular grant program or set of activities. The NCI is an IC.

Institutional Animal Care and Use Committee (IACUC): A committee set up by an institution to review, at least once every 6 months, the institution's program for humane care and use of animals. The IACUC reviews research protocols involving the care and use of animals at the institution and makes recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.

Institutional Review Board (IRB): A board or committee set up by a research institution to ensure the protection of the rights and welfare of human research subjects participating in research conducted under its auspices. The IRB makes an independent determination to approve, require modifications to, or disapprove research protocols based on whether human subjects are adequately protected, as required by Federal regulations and local institutional policy.

Integrated Review Group (IRG): A group of study sections or peer review committees that are arrayed by scientific discipline. Study sections or peer review committees of scientists advise on the scientific and technical merit of research applications submitted for support.

Modular Grants: An initiative that expands the existing reinvention initiatives that are designed to concentrate the focus of investigators, their respective institutions, peer reviewers, and NIH staff on the science the NIH supports rather than on budget details. Under modular budget proposals, applicants are instructed to prepare the budget request in direct-cost modules of $25,000 (not including third-party F&A costs) up to a maximum direct-cost level of $250,000. (Budget requests beyond this level follow traditional application instructions.) This process eliminates the need for much budget detail, thereby relieving administrative burdens on both NIH staff and grantee organizations and simplifying cost management for NIH program staff.

Monitoring: A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Notice of Grant Award: The legally binding document that notifies the grantee and others that an award has been made. This document contains or references all terms and conditions for the award and documents the obligation of Federal funds. The award notice may be in letter format and/or may be issued electronically.

Payline: A term used to describe the funding selection process for most competing grant applications at the NIH. If one visualizes a list of grant applications sorted in rank order by percentile or priority score (often called a "paylist"), one can imagine a line drawn under the last application on that list, which will be funded based entirely on the result of peer review. That virtual line is the "payline." The payline separates the applications that will be paid in rank order from those that may be selected based on programmatic relevance, as exceptions, or not paid at all.

Peer Review (42 CFR Part 52h): A system of review of research applications that utilizes reviewers who are the professional peers of the Principal Investigator of the proposed project.

Percentile Score: A score that represents the relative position or rank of each priority score among the scores assigned by that particular study section at its last three meetings. The lower the numerical value of the percentile score, the better. The score range is from .1 to 99.9.

Pre-application: A statement in summary form of the intent of the applicant to request funds. Pre-applications are requested for all construction projects for which the need for Federal funding exists. It is used to determine the applicant's eligibility; determine how well the proposed project can compete with other, similar applications; and eliminate any proposals for which there is little or no chance for funding before applicants incur significant expenditures in preparing an application.

Principal Investigator (PI): An individual designated by the recipient organization to direct the project or activity being supported by the grant. He/she is responsible and accountable to recipient organization officials for the proper conduct of the project or program. The organization is, in turn, legally responsible and accountable to the NCI for the performance and financial aspects of the grant-supported activity.

Prior Approval: Written approval from NCI's Grants Management Officer required for specified post-award changes to the approved project or budget. Such approval must be obtained prior to undertaking the proposed activity or spending NCI funds.

Priority Score: The score determined by averaging the individual ratings given by each voting member of the IRG. Each IRG member assigns to the application a numerical rating that ranges from 1.0 (outstanding) to 5.0 (acceptable) that reflects his/her opinion of the scientific merit of the application. A composite score is then expressed on a scale of 100 to 499.

Procurement: The acquisition by purchase, lease, or barter of property or services for the direct benefit or use of the NCI or other Government agency. The procurement instrument most often used is a contract. A contract details the rights, duties, and obligations of each of the parties involved.

Program Announcement (PA): A formal statement that describes and gives notice to the grantee community of the existence of an NIH-wide or individual Institute/Center extramural research activity/interest or announces the initiation of a new or modified activity/interest or mechanism of support and invites applications for grant or cooperative agreement support. PAs are

published in the *NIH Guide to Grants and Contracts* (http://www.nih.gov/grants/guide/index.html). Funds may or may not be set aside for PAs.

Program Official: The NCI official responsible for the programmatic, scientific, and/or technical oversight and monitoring of a grant. The program official works closely with grants management staff.

Project Period: The total time for which support of a discretionary project has been programmatically approved. A project period may consist of one or more budget periods. The total project period comprises the initial competitive segment and any extensions.

Recipient: The organizational entity or individual receiving a grant or cooperative agreement. (See definition of "Grantee.")

Recommended Levels of Future Support: The funding level recommended for each of the future years approved by the IRG and the NCAB. These amounts are subject to availability of funds each year and evaluation of the scientific progress of the project. In addition, the recommended funding level may be subject to correction of arithmetic errors and adjustments made in accordance with applicable grant policies (salary cap, funding plan reductions, etc.), as appropriate.

Request for Application (RFA): A formal announcement that invites grant or cooperative agreement applications in a well-defined scientific area to support specific program initiatives, indicating the amount of funds set aside for the competition and the estimated number of awards to be made. RFAs are published in the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/index.html).

Research Project Grant (RPG): The award for an investigator-initiated research proposal.

Scientific Review Administrator (SRA): A Federal scientist who presides over a Scientific Review Group and is responsible for coordinating and reporting the review of each application assigned to his/her committee, thereby serving as an intermediary between the applicant institution and the reviewers of the application. The SRA prepares a summary statement for each application reviewed by his/her SRG.

Small Business: A business, including its affiliates, that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has no more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 CFR Part 121.

Stipend: A payment made to an individual under a fellowship or training grant in accordance with preestablished levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

Streamlined Noncompeting Award Process (SNAP): A streamlined process that eliminates two of the financial documents that are part of the noncompeting progress report: a categorical budget for the next budget period and an estimated report of expenditures for the current budget period. Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and negotiations, if applicable, and reduces the information the NIH requires to review, approve, and monitor noncompeting awards. As a result, grantees are required to submit only limited portions of the PHS-2590, including an annual progress report. For awards under SNAP (other than awards to foreign organizations or Federal institutions), a Financial Status Report (FSR) is required only at the end of a competitive segment, rather than annually. If no further award is made, this report will serve as the final FSR.

Study Section: The component part of an Integrated Review Group that advises on the scientific and technical merit of research applications.

Substantial Foreign Component: Under a grant to a domestic institution, the performance of any significant element or segment of the project outside of the United States, either by the grantee or by a researcher employed by a foreign institution, with or without grant funds.

Success Rate: The number of funded applications divided by the number of applications reviewed by Scientific Review Groups.

Technical Assistance Review: An evaluation by NCI grants management staff to assess an institution's business and financial management systems to ensure that applicable regulations and policies are being followed.

Terms and Conditions of Award: All legal requirements imposed on a grant, whether based on statute, regulation, policy, other referenced document, or the grant award document itself. The Notice of Grant Award may include both standard and special provisions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the interests of the Federal Government.

Total Project Costs: The total allowable costs (both direct and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NCI grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

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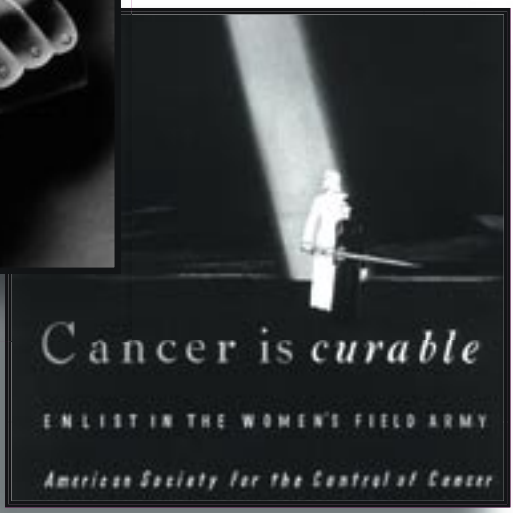
EXHIBITS



In 1936, a legion of volunteers known as The Women's Field Army was formed to wage war on cancer. These historic posters advertised their efforts. In 1935, there were 15,000 people active in cancer control throughout the United States. At the close of 1938, there were approximately 150,000!

EXHIBIT A Grant Application Face Page

Form Approved Through 09/30/2007 — OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed character length restrictions indicated.

LEAVE BLANK—FOR PHS USE ONLY

Type 1	Activity R01	Number CA-100226-01
Review Group BEM		Formerly
Council/Board (Month, Year) sept 2004		Date Received 01/26/2004

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*
Community Intervention to Reduce Adolescent Tobacco Use

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☒ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR — New Investigator ☒ No ☐ Yes

3a. NAME (Last, first, middle): Martin, Andrew
3b. DEGREE(S): Ph.D.
3h. eRA Commons User Name:
3c. POSITION TITLE: Research Scientist
3d. MAILING ADDRESS *(Street, city, state, zip code)*: Massachusetts Research Institute, 500 Aspen Lane, Concord, MA 02134
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT: N/A
3f. MAJOR SUBDIVISION: N/A
3g. TELEPHONE AND FAX *(Area code, number and extension)*: TEL: (617) 444-0002 FAX: (617) 444-0003
E-MAIL ADDRESS: AMARTIN@MRI.EDU

4. HUMAN SUBJECTS RESEARCH: No ☐ Yes ☒
4b. Human Subjects Assurance No.: FWA0000
4c. Clinical Trial: ☒ No ☐ Yes
4d. NIH-defined Phase III Clinical Trial: ☒ No ☐ Yes
4a. Research Exempt: No ☒ Yes ☐
If "Yes," Exemption No.

5. VERTEBRATE ANIMALS: ☒ No ☐ Yes
5a. If "Yes," IACUC approval Date
5b. Animal welfare assurance no.

6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
02/01/05	01/31/09	$225,000	$337,500	$900,000	$1,350,000

9. APPLICANT ORGANIZATION
Name: Massachusetts Research Institute
Address: 500 Aspen Lane, Concord, MA 02134

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☒ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
1566001393A1
DUNS NO. Cong. District 24

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name: Evan Thomas
Title: Administrative Coordinator
Address: Massachusetts Research Institute, 500 Aspen Lane, Concord, MA 02134
Tel: (617) 444-0001 FAX: (617) 444-0000
E-Mail: THOMASE@MRI.EDU

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name: Evan Thomas
Title: Administrative Coordinator
Address: Massachusetts Research Institute, 500 Aspen Lane, Concord, MA 02134
Tel: (617) 444-0001 FAX: (617) 444-0000
E-Mail: THOMASE@MRI.EDU

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.
SIGNATURE OF PI/PD NAMED IN 3a. *(In ink. "Per" signature not acceptable.)* /s/ — DATE 01/20/04

15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)* /s/ — DATE 01/20/04

PHS 398 (Rev. 09/04) Face Page Form Page

EXHIBIT B Summary Statement

SUMMARY STATEMENT
(Privileged Communication)

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

Release Date: 06/24/2004

Application Number: 1 R01 CA100228-01

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

Review Group: Behavioral Medicine Study Section - BEM

Meeting Date: 06/09/2004
Council: SEPT/OCT 2004
Requested Start: 02/01/2005

PCC: 8MPC

Project Title: Community Intervention to Reduce Adolescent Tobacco Use

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

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

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

EXHIBIT B Summary Statement (continued)

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

This application is rated with a priority score of 135.

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

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

CRITIQUES

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

CRITIQUE 1

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

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

Innovation:
This project has several innovative aspects.

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

EXHIBIT B Summary Statement (continued)

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

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

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN: ACCEPTABLE

INCLUSION OF CHILDREN: ACCEPTABLE

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

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

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

EXHIBIT C Ranking List

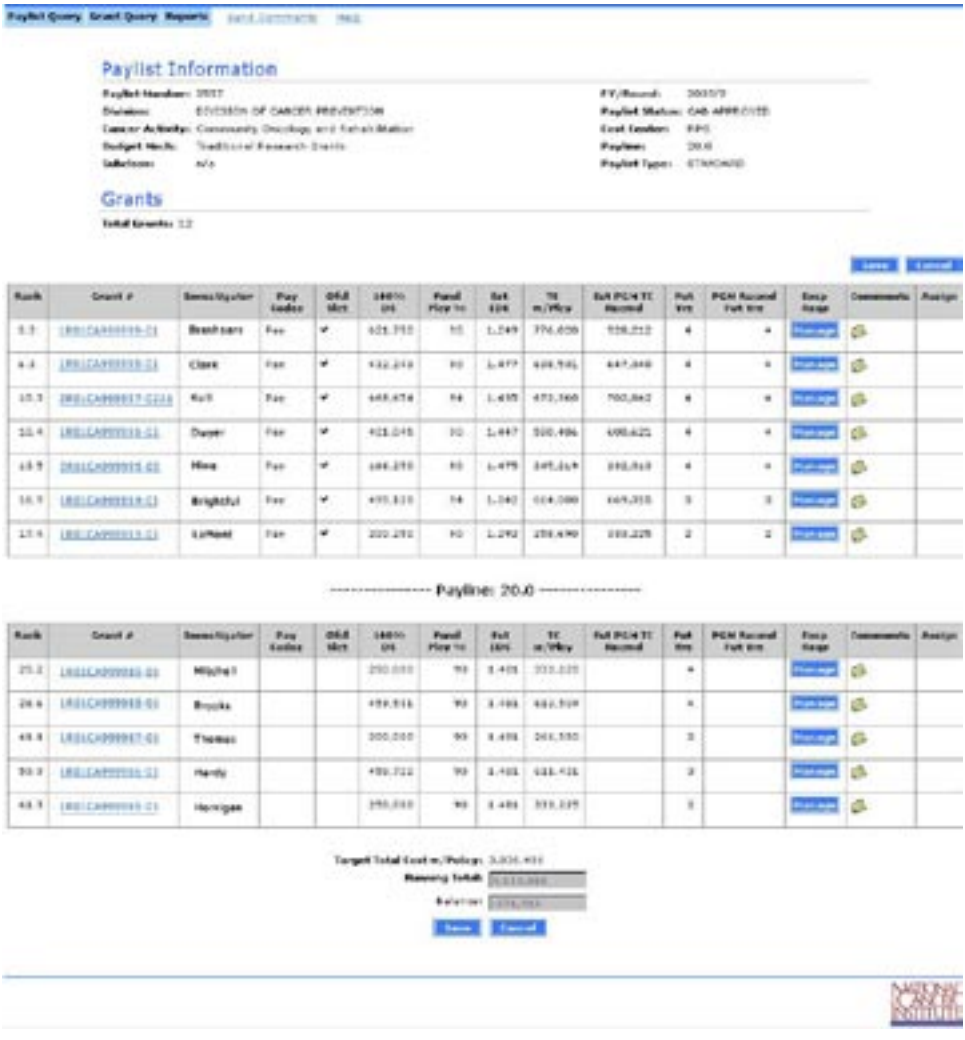


EXHIBIT D Notice of Grant Award

********** NOTICE OF GRANT AWARD **********

RESEARCH Issue Date:01/24/2005
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

****

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

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

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

Dear Business Official:

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

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

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

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

Sincerely yours,

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

EXHIBIT D Notice of Grant Award (continued)

See additional information below

SECTION I - AWARD DATA - 1 R01 CA100228-01

AWARD CALCULATION (U.S. Dollars):

Federal Direct Costs	$200,000
Federal F&A Costs	$100,000
APPROVED BUDGET	$300,000
TOTAL FEDERAL AWARD AMOUNT	$300,000

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project, is as follows.

03 $300,000
04 $300,000
05 $300,000

FISCAL INFORMATION:
CFDA Number: 93.396
EIN: 1566001393A1
Document Number: R1CA100228A

IC/	CAN	/ FY2005	/ FY2006	/ FY2007	/ FY2008
CA/	8422842/	300,000 /	300,000 /	300,000 /	300,000

NIH ADMINISTRATIVE DATA:
PCC: 5CCJ2842 / OC: A1.4A /Processed: JONESB 020117 0957

SECTION II - PAYMENT/HOTLINE INFORMATION - 1 R01 CA100228-01

For Payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at
http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 1 R01 CA100228-01

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Grant Award.
b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at
http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

This grant is awarded under the terms and conditions of the Federal Demonstration Partnership Phase III.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

EXHIBIT D Notice of Grant Award (continued)

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

Treatment of Program Income:
Additional Costs

INFORMATION This is a Modular Grant Award without direct cost categorical breakdown in accordance with guidelines published in the 12/15/98 NIH Guide for Grants and Contracts, web address: http://grants.nih.gov/grants/guide/notice-files/not98-178.html. Recipients are required to allocate and account for all costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

INFORMATION Future year total cost commitments appearing on the award notice under "Recommended Future Year Total Cost Support" have been calculated by applying the negotiated facilities and administrative cost rate(s) in effect at the time of this FY 2005 award to the committed total direct cost level for each future year.

INFORMATION For administrative and management concerns, contact the Grants Management Specialist, Beverly Jones, at (301) 496-7800. For programmatic and scientific concerns, contact the Program Director, Dr. Rebecca Sanders, at (301) 496-2331.

INFORMATION In a continuing effort to provide exceptional customer service, the NCI Grants Administration Branch has set up a Feedback address on its web site (http://www.nci.nih.gov/admin/gab/index.htm). General concerns and issues related to NCI grants policies, procedures, and practices can be sent to the Customer Liaison using this feature. Specific questions or concerns related to this grant should be addressed to the Grants Management Specialist listed in the Terms of Award.

Rebecca Sanders, Program Official
Phone: 301-496-2331 Email: progofficial@nih.gov

Beverly Jones, Grants Specialist
Phone: 301-496-7800 Email: gms@nih.gov

SPREADSHEET
GRANT NUMBER: 1 R01 CA100228-01

P.I.: Martin, Andrew Ph.D.
INSTITUTION: MASSACHUSETTS RESEARCH INSTITUTE

	YEAR 01	YEAR 02	YEAR 03	YEAR 04
TOTAL FEDERAL DC	200,000	200,000	200,000	200,000
TOTAL FEDERAL F&A	100,000	100,000	100,000	100,000
TOTAL COST	300,000	300,000	300,000	300,000

	YEAR 01	YEAR 02	YEAR 03	YEAR 04
F&A Cost Rate 1	50.00%	50.00%	50.00%	50.00%
F&A Cost Base 1	200,000	200,000	200,000	200,000
F&A Costs 1	100,000	100,000	100,000	100,000

EXHIBIT E Progress Report Summary

Principal Investigator/Program Director (Last, First, Middle): Martin, Andrew

PROGRESS REPORT SUMMARY	GRANT NUMBER CA100228-02	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Martin, Andrew	FROM 02/01/2005	THROUGH 01/31/2006

APPLICANT ORGANIZATION
MASSACHUSETTS RESEARCH INSTITUTE

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Community Intervention to Reduce Adolescent Tobacco Use

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects [X] No Change Since Previous Submission [ ] Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals [X] No Change Since Previous Submission [ ] Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

1. Has there been a change in the other support of key personnel since the last reporting period? No
2. Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project? No
3. It is anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget? No

a. Specific Aims
The aims have not beoen modified and they are the same as those listed in the original grant proposal.

b. Studies and Results
Our progess is described under each aim as follows:

1. This project's aim is to assess whether a community intervention to reduce tobacco use has a greater impact on adolescent smoking prevalence than does a school-based program alone. Six pairs of communities have been randomly assigned to a community intervention plus a school-based intervention program or to a school-based program alone.

2. The work conducted in this year has gone about as planned. Two communities were identified and recruited to participate in the project. A noteworthy feature of our work has been the development of an instrument and set of procedures for assessing the degree to which community organizations are doing things that would affect adolescent tobacco use and other representatives of those organizations have been asked to participate in a 20-minute phone interview. Thus far, 130 representatives of organizations in the two communities have been interviewed. An additional 50 interviews will be conducted in the next month. Procedures for the creation of a community board and a seto of task forces to work on issues of adolescent tobacco use have been identified.

EXHIBIT F Financial Status Report

1. Federal Agency and Organizational Element to Which Report is Submitted NATIONAL CANCER INSTITUTE	2. Federal Grant or Other Identifying Number 5R01CA100226-04		
3.Recipient Organization (Name and complete address, including ZIP code) MASSACHUSETTS RESEARCH INSTITUTE 500 ASPEN LANE CONCORD, MA 02134	4. Employer Identification Number 1566001393A1 5. Recipient Account Number AB1234 6. Final Report ☒ Yes ☐ No	7. Basis ☒ Cash ☐ Accural	
8. Funding/Grant Period	9. Period Covered by this Report		
From 02/01/2005 To 01/31/2006	From 02/01/2005 To 01/31/2009		
10. Transactions:	Previously Reported	This Period	Cumulative
a. Total outlays	0.00	1,200,000.00	1,200,000.00
b. Refunds, rebates, etc	0.00	0.00	0.00
c. Program income used in accordance with the deduction alternative	0.00	0.00	0.00
d. Net outlays (Line a, less the sum of the lines b and c)	0.00	1,200,000.00	1,200,000.00
Recipient's share of net outlay, consisting of:			
e. Third Party (in-kind) contributions.	0.00	0.00	0.00
f. Other Federal awards authorized to be used to match this award.	0.00	0.00	0.00
g. Program income used in accordance with the matching or cost sharing alternative	0.00	0.00	0.00
h. All other recipient outlays not shown on lines e, f or g	0.00	0.00	0.00
i. Total recipient share of net outlays (Sum of lines e, f, g and h)	0.00	0.00	0.00
j. Federal share of net outlays (line d less line i)	0.00	1,200,000.00	1,200,000.00
k. Total unliquidated obligations			0.00
l. Recipient's share of unliquidated obligations			0.00
m. Federal share of unliquidated obligations			0.00
n. Total Federal share (sum of lines j and m)			1,200,000.00
o. Total Federal funds authorized for this funding period			1,200,000.00
p. Unobligated balance of Federal funds (lines o minus line n)			0.00
Program Income, consisting of:			
q. Disbursed program income shown on lines c and/or g above			0.00
r. Disbursed program income using addition alternative			0.00
s. Undisbursed program income			0.00
t. Total program income realized (Sum of lines q, r and s)			0.00
11. Indirect Expense	a. Type of Rate	Provisional ☐ Predetermined ☒ Final ☐ Fixed ☐	
	b. Rate	c. Base	d. Total Amount / e. Total Amount Federal Share 100,000.00
	50.00	200,000.00	100,000.00
Total	50.00	200,000.00	100,000.00
12. Remarks			Carryover Request 0.00
13. Authorized Official	Name Evan Thomas Title Admin Coordinator	Telephone (Area code, number, and extension) 617-444-0001	Date Report Submitted 03/11/2009
14. Approved by	Name Joan Givens		Date Report Accepted 03/11/2009