THE NATIONAL CANCER INSTITUTE PRESENTS

Everything you wanted to know about the NCI Grants Process...

...but were afraid to ask

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

NATIONAL CANCER INSTITUTE

Grants Process and Administration

LEO F. BUSCHER JR.

CHIEF GRANTS MANAGEMENT OFFICER

NATIONAL CANCER INSTITUTE

GRANTS ADMINISTRATION BRANCH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

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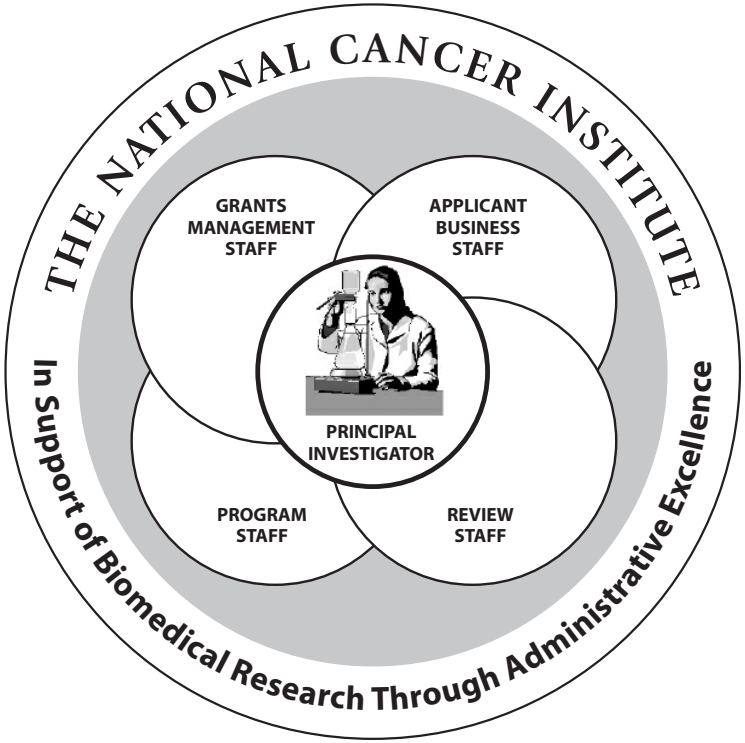

Preface

The purpose of this publication is to describe, in a general way, how a grant is awarded and administered. Although the discussion relates to the National Cancer Institute (NCI), the grants process is similar in 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. This publication can also be found on the NCI's Grants Administration Branch World Wide Web site (http://www3.cancer.gov/admin/gab/index.htm).

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

- Part I, *An Overview,* provides an introduction to how we in the Grants Administration Branch view our role in this very important collaborative venture, a snapshot of the NCI as an organization, and a brief perspective of the legal underpinnings for grants.
- Part II, *Process 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, postaward administration.
- Part III, *Funding Allocation,* provides a brief budget overview and a funding allocation example to help illustrate various nuances of the NCI grants process.
- Part IV, *Application Types and Budget Mechanisms,* provides descriptions of the application types and budget mechanisms prevalent within the NCI.
- Part V, *References and Resources,* lists contacts and materials that are helpful with regard to the general approach taken in the NCI grants process.
- Part VI, *Cross-Cutting Public Policies,* summarizes some of the requirements that apply to grants management.
- Part VII, *Glossary,* lists definitions of terms and phrases most commonly used in the award and administration of NIH grants.

It is a pleasure to acknowledge the staff of the NCI and the NIH whose contributions made this publication possible. Specifically, I would like to thank the staff of NCI's Office of Communications for their excellent logistical support.

For additional information concerning the subject matter in this publication, the staff of the NCI Grants Administration Branch is pleased to answer any inquiries. Please let us know what you think of this publication by contacting us via the Feedback section of our web site. We welcome your suggestions on improving this publication.

Leo F. Buscher Jr.

Leo F. Buscher Jr.
Chief Grants Management Officer
National Cancer Institute
(301) 496-7753

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Aerial view of the NIH Campus in Bethesda, Maryland

PART I

An Overview

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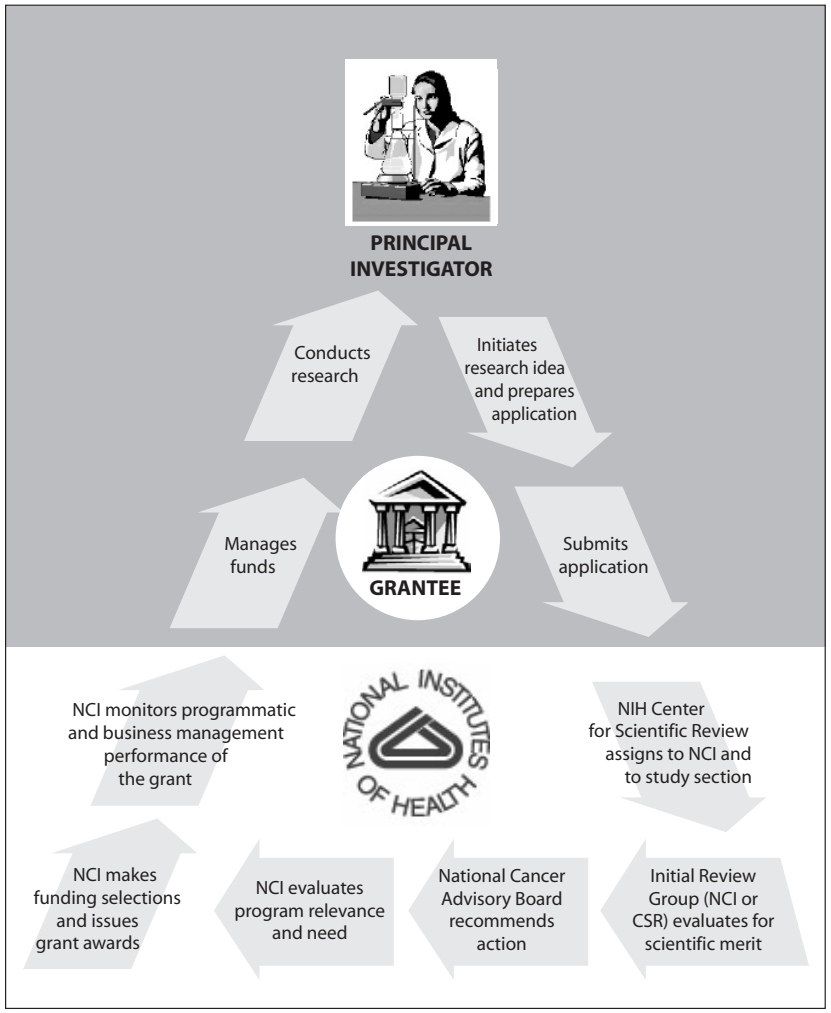


Introduction

NIH Reinvention Activities

Reinvention initiatives and other streamlining efforts under way at the National Institutes of Health (NIH) have impacted the manner in which grant awards are processed at the National Cancer Institute (NCI). NIH has achieved a number of milestones in the reinvention of its extramural research administration practices. Examples of such achievements include:

- the implementation of a streamlined non-competing award process (SNAP);
- the implementation of a streamlined process for the review of grant applications;
- the simplification of summary statements;
- the implementation of modular grant applications;
- the implementation of the Edison system (http://www.iedison.gov/), which streamlines the invention reporting process;
- the implementation of web-based CRISP (http://crisp.cit.nih.gov/), the Computer Retrieval of Information on Scientific Projects;
- the development of eSNAP (electronic SNAP); and
- the progress toward a fully electronic grant life cycle.

Despite these and future reinvention initiatives, the core concepts represented in this publication are expected to remain essentially the same.

NIH Electronic Research Administration

In response to a Congressional mandate requiring Federal agencies to migrate from paper-based to electronic systems, the NIH has undertaken the Electronic Research Administration (eRA) initiative to lower costs and administrative effort, expedite extramural grants processing, and provide better quality information to the NIH and the external grantee community. ERA integrates two parallel systems: the NIH Commons (https://www-commons.cit.nih.gov/) and IMPAC II (http://era.nih.gov/impacii/). NIH staff communicate via the IMPAC II system. NIH is working toward integrating the NIH Commons with the Federal Commons (http://www.fedcommons.gov/). The primary objectives of the eRA project are (1) to convert over two million pieces of paper in the NIH application, initial peer review and secondary National Advisory

Board/Council review, and award and post-award administrative process to an electronic medium for full electronic grants administration, and (2) to integrate with NIH business, grants, and other systems within the Federal Commons.

NCI GAB eGrants System

In keeping with the overall objectives of NIH's eRA project, NCI's Grants Administration Branch (GAB) is in the process of implementing a system of electronic modules to receive, manage, and monitor grants information without the need for paper documents. This system, known as NCI's eGrants system (Figure 2), will allow NCI grants staff to work with and manage grants information currently contained in word processing files, spreadsheet files, electronic mail messages, websites, and written documents. To prevent redundancy and a corresponding waste of resources, NCI is using some of the electronic modules already developed by NIH, such as the Grant Award Notice module, which has been in place for several years. For other electronic

Figure 2. NCI Grants Administration Branch Electronic Grants Process

modules, NCI continues to develop and refine its current versions while partnering with NIH to improve others. By the end of 2002, all of the modules will be developed and interconnected with one another, allowing for a single entry point for grant data. Once it is fully implemented, NCI's eGrants system will fulfill the goal of a paperless grants process.

Grants Administration Branch Philosophy

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 (see Figure 1, page 2). GAB's web site can be found at http://www3.cancer.gov/admin/gab/index.htm.

In 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.

Statement of Purpose

The Department of Health and Human Services (DHHS) touches the lives of every American. The American public expects grants awarded by DHHS's operating divisions to help the DHHS achieve its health and human service goals. Additionally, the public expects DHHS's grants to be well managed. The general goal of grants management is to provide quality stewardship of grants. Open, fair, and objective selection of projects with the highest potential for success is one key component of quality stewardship.

The GAB is responsible for monitoring NCI's 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 timely and accurate grant business-related information.
- Act as NCI's authorized Federal office with whom 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 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 unfettered, in an open Federal research environment free of unnecessary record collection and reporting requirements.

Leo F. Buscher Jr.

Leo F. Buscher Jr.
Chief Grants Management Officer
National Cancer Institute
(301) 496-7753

General Information

Abbreviations and Acronyms

CFR	=	Code of Federal Regulations
CSR	=	NIH's Center for Scientific Review (formerly Division of Research Grants)
DCB	=	NCI's Division of Cancer Biology
DCCPS	=	NCI's Division of Cancer Control and Population Science
DCP	=	NCI's Division of Cancer Prevention
DCTD	=	NCI's Division of Cancer Treatment and Diagnosis
DEA	=	NCI's Division of Extramural Activities
DHHS	=	Department of Health and Human Services
EAB	=	NCI's Extramural Advisory Board
F&A	=	Facilities and Administrative Costs
FSR	=	Financial Status Report
FY	=	Fiscal Year
GAB	=	NCI's Grants Administration Branch
GMO	=	Grants Management Officer
GMS	=	Grants Management Specialist
IC	=	Institute and/or Center within NIH
IRG	=	Initial Review Group
MIS	=	Minority Investigator Supplement
NCAB	=	National Cancer Advisory Board
NCI	=	National Cancer Institute
NIH	=	National Institutes of Health
ODDES	=	NCI's Office of the Deputy Director for Extramural Science
PA	=	Program Announcement
PHS	=	Public Health Service
R&D	=	Research and Development
RFA	=	Request for Applications
RPG	=	Research Project Grant
SBIR	=	Small Business Innovative Research
SNAP	=	Streamlined Non-Competing Award Process
SRA	=	Scientific Review Administrator
STTR	=	Small Business Technology Transfer
USC	=	United States Code

DHHS Mission and Organization

The DHHS's mission is to enhance the health and well being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. The DHHS consists of the Office of the Secretary, which provides leadership; the Program Support Center, which provides centralized administrative support; and 11 operating divisions, which manage 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 compose the Public Health Service (PHS).

NIH Mission and Organization

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 in the training of research investigators; and fostering communication of medical information. NIH's budget has grown from $300 in 1887, when NIH was a one-room Laboratory of Hygiene, to more than $20.3 billion in 2001. The NIH is composed of the Office of the Director, 19 Institutes, seven Centers, and the National Library of Medicine and has 75 buildings located on more than 300 acres in Bethesda, Maryland. The NCI is one of the 19 Institutes within the NIH. An organizational chart for the NIH is provided in Part V of this publication (see Figure 17, page 96).

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. 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. NCI works toward this goal in two major ways: 1) NCI provides vision to the Nation and leadership for NCI-funded researchers across the United States and around the world and 2) 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.

NCI 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 Part III of this publication.

NCI Function

Over the years, legislative amendments have maintained the NCI's authorities 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, 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.
- Supports construction of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.

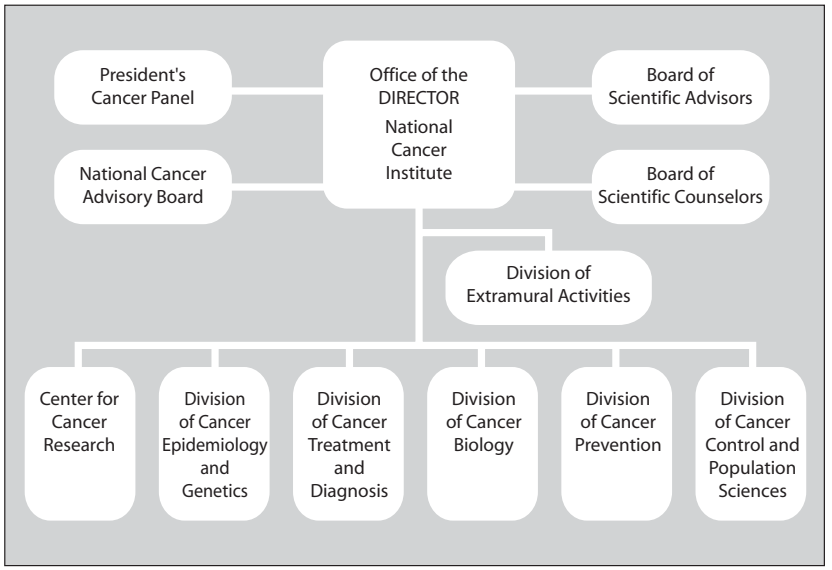
NCI Organization

The NCI's current organizational structure can be seen in Figure 3 (page 11). 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 BSA gives final concept approval for extramural Requests for Applications (RFAs) while the BSC gives final concept approval for intramural RFAs. Four extramural research divisions, one intramural research division, and one intramural research center monitor and administer NCI's cancer research activities through extramural and intramural research programs. The Office of the Deputy Director for Extramural Science (ODDES), which is part of the Office of the Director, coordinates initiatives across NCI's four extramural research divisions: the Division of Cancer Biology (DCB); the Division of Cancer Control and Population Science (DCCPS); the Division of Cancer Prevention (DCP); and the Division of Cancer Treatment and Diagnosis (DCTD). The ODDES also monitors and administers the Centers, Training, and Resources Program, as well as the grant program supporting minority initiatives. The Division of Extramural Activities (DEA) coordinates the review of grants and contracts, and manages the functions of the NCAB and the BSA.

NCI Budget

NCI's budget, as displayed in Figure 4 (page 12), is composed of three major activities: research, resource development, and cancer prevention and control. Descriptions of these three major budget activity areas may be found in the "Budget Activities" section of Part IV of this publication.

Figure 3. NCI Organization and Advisory Structure



NCI Research Settings

NCI-sponsored research takes place in three settings: the laboratory, the clinic, and the community. 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. In the clinic, patient-oriented research is carried out in prevention, detection, diagnosis, treatment, and rehabilitation. In the community, research is carried out on the causes, risks, predispositions, incidence, and behavioral aspects of cancer. As the diagram in Figure 5 (page 13) indicates, the components of this research triad interface.

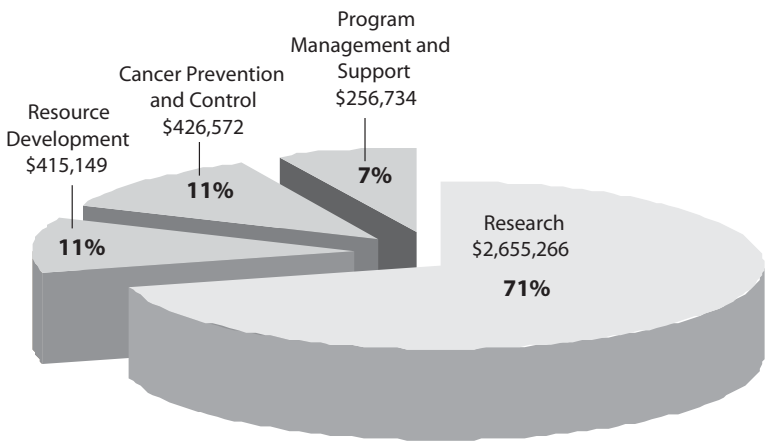
Figure 5 shows a progression from the results of research through dissemination to application. Research results must be communicated to those who ultimately apply these results in health care and disease prevention settings.

NCI 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 pay lines and funding plans for those grant programs not administered solely by one division.

Figure 4. NCI FY 2001 Budget Activities *(dollars in thousands)*



Mechanism	Amount	Percent of Total (%)
Research		
Cancer Causation	$880,612	23.5
Detection and Diagnosis Research	260,542	6.9
Treatment and Research	916,312	24.4
Cancer Biology	597,800	15.9
Subtotal, Research	2,655,266	70.7
Resource Development		
Cancer Centers Support	280,860	7.5
Research Manpower Development	131,469	3.5
Construction	3,000	0.1
Subtotal, Resource Development	415,149	11.1
Cancer Prevention and Control	426,572	11.4
Program Management and Support	256,734	6.8
TOTAL NCI	**3,753,721**	**100.0**

- Approving certain exceptions to grant funding plans.
- Reviewing contract, cooperative agreement, and grant concepts.
- Formulating the long-range strategic plan for the Institute.

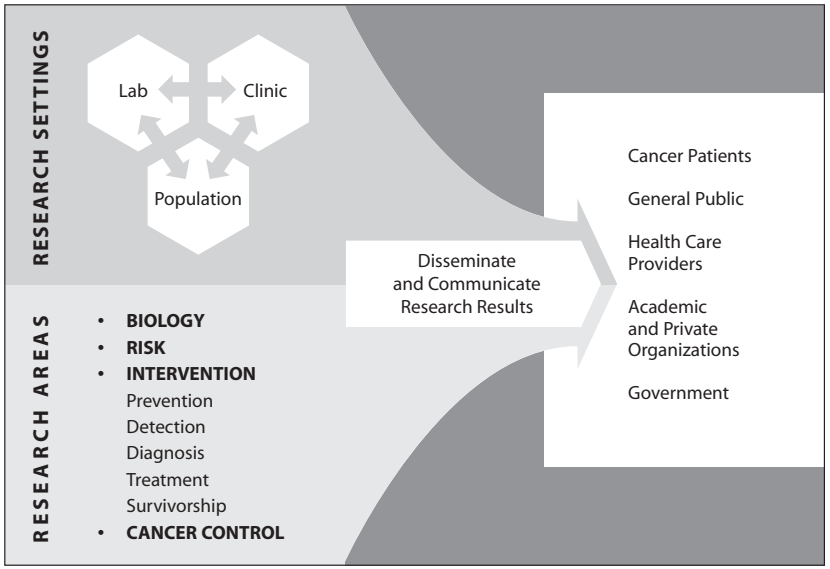
In addition to weekly meetings, the EC meets with other NCI staff twice a year in the summer and winter, for one or two days, to establish budget priorities and policies for the forthcoming year.

Types of Funding Instruments

Using a variety of funding instruments, including contracts, grants, and cooperative agreements, the DHHS 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.

Figure 5. Progression From Cancer Research to Applications



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. DHHS's assistance mechanisms range from direct Federal cash assistance to individuals to reimbursements to 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: (1) when the applicant is responding to a specific NCI announcement for cooperative agreements and must tailor the proposal to the announcement's requirements; and (2) when substantial programmatic involvement is anticipated between the NCI and the recipient during the performance of the activities.

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.

NCI Grants: Historical Perspective

The first cancer research grant funded by 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 166,000 grants accounting for $33 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 21-fold from $180 million in fiscal year (FY) 1971 to $3.75 billion in FY 2001. Nearly $2.49 billion (over 66 percent) of the NCI's FY 2001 appropriation was awarded in grants and cooperative agreements.

Grant 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 upon 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 DHHS 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 general, but nonetheless 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.gpo.gov/nara/cfr/index.html), a codification of permanent rules published in the Federal Register (http://www.access.gpo.gov/su_docs/aces/aces140.html), contains the regulations for reviewing and administering NCI grants. Program regulations expand on program legislation to provide additional guidance regarding program requirements and how the program will be managed. (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 Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments); and
- 45 CFR Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local 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.) Uniform Administrative Requirements for Grants to State and Local Governments (also known as the Common Rule). 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 With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations. Establishes consistent and uniform grants administration requirements placed by Federal agencies on non-profit organizations other than State and local governments. 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 Non-Profit Organizations. Establishes principles for determining costs applicable to non-profit 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 Audits of States, Local Governments, and Other Non-Profit Organizations (rev.). Establishes consistent and uniform audit requirements and defines Federal responsibilities for implementing and monitoring such requirements for States, local governments, and other non-profit organizations receiving Federal awards. Audit requirements for commercial (for-profit) organizations are contained in 45 CFR Part 74.

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, which is a condensation of the NIH and DHHS grants administration policies and the laws and regulations pertaining to grants administration.

The NCI has developed individual guidelines for certain kinds of grants. There are now guidelines available for Cancer Center Support Grants (Core P30), Program Project Grants (P01), Construction Grants (C06), Clinical Trials Cooperative Group Program Cooperative Agreements (U10), Cancer Education Grants (R25), Career Awards (K), and National Research Service Awards (T32, F32, and F31).

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, equity, and 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 Part VI of this publication. NIH grantees also are subject to requirements contained in NIH's annual appropriations act that apply to the use of NIH grant funds. Some of these requirements are included in Part VI of this publication because they have been included in 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 letter Notice of Grant Award (Exhibit D, page 122), 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 on 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.

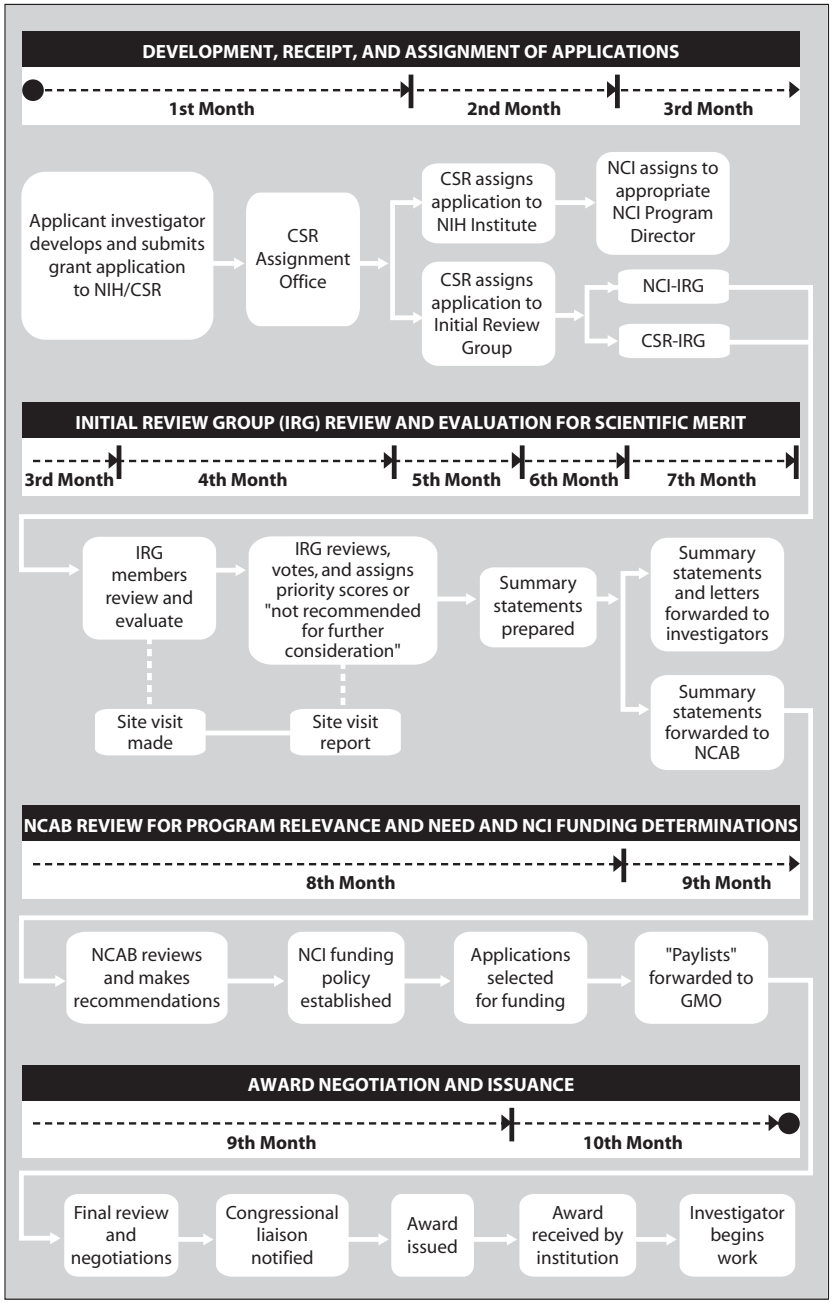
Building 1, National Institutes of Health

(Building 1 houses the Office of the NIH Director and key NIH staff)

PART II

Process and Administration

Figure 6. The National Cancer Institute Grants Process
(for new applications and renewals)



Development, Receipt, and 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 – postaward administration (see Figure 6, page 22). As mentioned previously in this publication, elements of several major reinvention initiatives, along with other streamlining efforts under way at NIH, will impact the manner in which grant awards are processed at NCI. However, the core concepts discussed in this section are expected to remain essentially the same.

Grantee Eligibility

Grants are awarded to nonprofit and for-profit organizations, institutions of higher education, hospitals, research foundations, state and local governments, Federal institutions, and, occasionally, individuals. Foreign institutions and international organizations are eligible to receive research grants only. Some programs, such as the Small Business Innovation Research (SBIR) grants, Small Business Technology Transfer (STTR) grants, and minority program grants, are established for certain categories of applicants.

Development of Grant Application

The principal investigator (PI) usually initiates an application for a grant. Both the PI and an authorized official of the applicant institution must sign the application prior to submission to the NIH (See Exhibit A for an example of a grant application "face page"). As grant applications are received (see Illustration 1, page 24) by the Center for Scientific Review (CSR), NIH, they are channeled through the peer review process described in the following pages. The NCI web sites on "Preparing Grant Applications" (http://deainfo.nci.nih.gov/extra/extdocs/apprep.htm) and "Grant Application and Review Process" (http://www.cancer.gov/research_funding/grants/) provide access to several resources available from NCI and the NIH that contain important considerations and suggestions to assist the PI and the applicant institution in preparing a research grant application. Two or three weeks may be needed for preparation of a small project application, whereas complex proposals may require as much as a year. CSR's referral division processes approximately 45,000 grant applications per fiscal year.

For new, expanded, and/or high-priority programs, the NCI may encourage the submission of grant applications through the use of the following types of solicitations:

Illustration 1. Applications Received by CSR for One Round

- **Program Announcements (PAs)** describe continuing, new, or expanded program interests for which grant or cooperative agreement applications are invited. Applications in response to PAs are reviewed in the same manner as unsolicited grant applications (i.e., by chartered peer review committees of the CSR or by NCI Initial Review Groups [IRGs]). Funds for PAs may or may not be set-aside.
- **Program Announcements Reviewed in an Institute(PARs)** are program announcements that contain special referral guidelines and are reviewed by a specific Institute's IRG.
- **Requests for Applications (RFAs)** are issued to invite grant applications in a well-defined scientific area to stimulate activity in NCI programmatic priority areas. A single application receipt date is specified, and the announcement identifies the amount of funds earmarked for the initiative and the number of awards likely to be funded. Applications are evaluated for responsiveness to the RFA before review. Applications received in response to a particular RFA are reviewed by an appropriate NCI IRG or by a special review group.

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

With the exception of applications submitted in response to RFAs or other announcements that include specific budgetary limits, applicants anticipating submission of an application exceeding $500,000 direct costs in any year of the project must seek approval from the NCI program director prior to submission. Applicants should contact NCI staff at least six weeks prior to submission of the application. If an amount significantly greater than $500,000 is requested, approval should be sought even earlier.

Receipt and Assignment of Applications

The referral section of the CSR serves as the central receipt point for all competing applications. Figure 7 (page 27) provides a typical timeframe from the date of receipt of applications through assignment of applications. Within the CSR, all new and competing continuation applications are given a brief evaluation to determine what area of research each represents. CSR referral officers then assign each application to (1) a specific NIH Institute and (2) an IRG for scientific merit review. Applicants are notified by mail of these assignments, usually within six to eight weeks of submission.

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, if it fails to follow the instructions provided on the appropriate application form, if it fails to follow specific instructions provided in an RFA or PA, or if the material presented is insufficient to permit an adequate review. A grant application also will be returned if the grant application is late.

Grant Application Identification Number

Each new application received is assigned an identification number, checked for completeness, and duplicated. There are nine application types that may be used to identify a specific grant application. A description of these nine application types is provided in the "Application Types" section of Part IV of this publication. Copies of the application are forwarded to the appropriate Institute and IRG.

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

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

The above number identifies a new (Type 1) application for a traditional research project (R01) assigned to 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

The NCI also has its own referral officers. These individuals examine and direct each NCI application to the appropriate NCI program director. The program director then follows the progress of his/her assigned application(s) through the scientific peer review process. The NCI establishes an official file for each application and enters fiscal and scientific information into the NIH/NCI data systems.

Principal Investigator

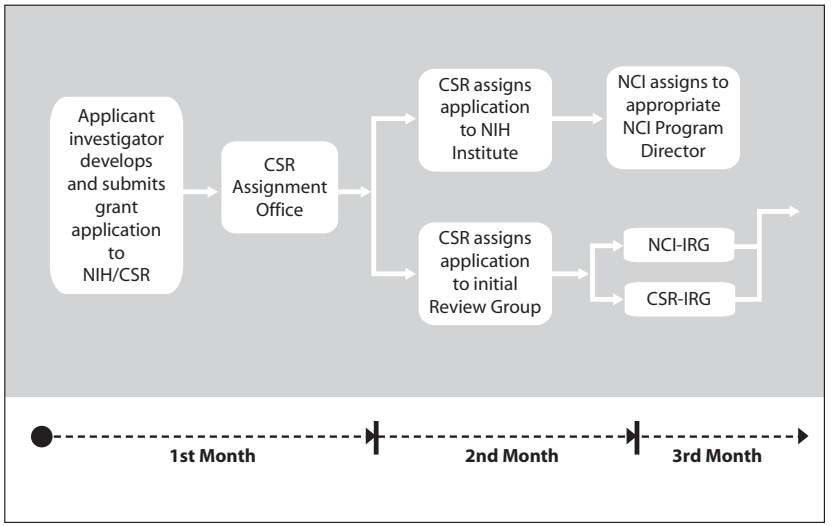
The principal investigator (PI) is the individual designated by the grantee institution to direct the grant project. The PI is responsible and accountable to grantee organizational officials for the proper conduct of the project. By signing the grant application, the PI accepts responsibility for the scientific conduct of the project and for submission of progress and any other required reports. The grantee organization is legally responsible and accountable to the NIH for the performance and financial aspects of the grant-supported activity.

Grantee Institution Responsibility

In applying for grant support, the grantee institution agrees to administer any awarded grant in accordance with the regulations and current policies that govern the research grant programs of the NIH. Acceptance of an award imposes upon the grantee institution and the PI responsibility for conducting the research and using grant funds prudently and in accordance with cost principles, for the purposes set forth in the approved application. The grantee assumes responsibility for the fiscal and administrative management of the project and fulfillment of any special terms or conditions of award that may be prescribed for conducting the research.

As noted under the previous section on "Notice of Grant Award," 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, NCI may take action to resolve problems or weaknesses that arise during the course of the project (see "Monitoring Projects" section for further information).

Figure 7. Development, Receipt, and Assignment of Applications



Standards of Conduct

The NIH utilizes and depends upon a system of self-regulation on the part of the funded research community coupled with appropriate oversight by the NIH. 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), all follow the self-regulatory pattern.

The principle of self-regulation requires (1) a high level of trust in the fundamental integrity of the research community, a community that is both aware of its responsibilities and motivated to meet those responsibilities, and (2) sufficient oversight to enable the NIH to assure the public that self-regulation is providing adequate safeguards for the ethical integrity of science.

Allowable Costs

Research grant funds are awarded to supplement 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 and for "facilities and administrative" (F&A) costs (formerly known as indirect costs [overhead]) incurred by an institution in 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;
- Inpatient and outpatient costs for research subjects;
- Alterations and renovations;
- Publications and other miscellaneous expenses;
- Contract services; and
- Costs for consortium participants.

Facilities and Administrative Costs

In addition to direct costs, the DHHS supports a policy of full reimbursement of facilities and administrative (F&A) costs (formerly known as indirect costs [overhead]) for most grant programs, with a few exceptions (e.g., reimbursement of F&A costs in the training, fellowships, and career programs; cancer education grants; and foreign grants is limited to eight percent of direct costs). F&A costs are those costs of an institution that 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; and
- Libraries.

These costs are documented and assigned to an F&A cost pool from which they are distributed to all activities of an organization 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 times the total amount of the allowable costs in the direct cost base for the project.

Rate Agreement

To be reimbursed for F&A costs, the grantee institution must prepare an F&A cost rate proposal annually and submit it to the cognizant Federal agency. The cognizant agency is generally the agency that provides the largest amount of funds to a grantee over a representative period. The cognizant agency 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, and makes it 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 calculated by the grants management specialist. These funds are the maximum amount awarded during the budget period even if a higher F&A rate is subsequently negotiated. If the amount of funds required for F&A costs decreases because of a new negotiated rate or because of postaward budgetary changes in the direct costs of the grant, the excess F&A cost funds generally may be rebudgeted to support allowable direct costs for the project, subject to specific requirements set forth in the applicable cost principles.

Peer Review

Initial Review Group and National Cancer Advisory Board Review

The dual peer review system of NIH consists of two sequential levels of review mandated by statute.

The first — or initial — level of peer review of research grant applications was formally mandated in 1974 by Section 475 of the Public Health Service Act, although the system had already been in effect for several years. This level of review is performed by Scientific Review Groups (SRGs), whose primary function is to review and evaluate the scientific merit of research grant applications.

The National Cancer Advisory Board (NCAB) performs the second level of review for NCI grants as mandated by the National Cancer Act of 1937 and incorporated into the Public Health Service Act in 1944. NCAB members bring to the grant review process knowledge in each of the relevant programmatic areas, familiarity with NCI priorities and procedures, and an awareness of the missions of the diverse Institutes in biomedical research and of the health needs of the American people.

Figure 8 (page 35) illustrates a representative timeline for the IRG review of applications. There are three review cycles or "rounds" annually. The review cycle has been shortened for applications involving Acquired Immune Deficiency Syndrome (AIDS) research and for applications in the Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer Program (STTR).

Initial Review Groups and Scientific Review Administrators

There are approximately 20 chartered Initial Review Groups (IRGs) distributed among the three review divisions within the CSR. Each IRG has 5 to 10 Scientific Review Groups (SRGs), or "study sections," that review applications on specific topics (e.g., cell biology, clinical oncology, pathology, biochemistry, virology) regardless of the awarding NIH Institute assignment. Altogether there are approximately 120 study sections in the 20 IRGs. A listing of IRGs and their study sections may be found at the following web site: (http://www.drg.nih.gov/review/irgdesc.htm).

Generally, a study section is composed of 12 to 18 mostly non-Federal scientists who are selected on the basis of their recognized competence in their respective research fields. In each of the three review cycles per year, a CSR study section may review between 50 and 100 grant applications (see Illustration 2, page 31).

Illustration 2. IRG Study Section Reviewing Grant Applications

Each study section is organized and managed by a scientific review administrator (SRA), an NIH staff scientist who is the designated Federal official responsible for ensuring that the grant applications are reviewed in an impartial environment. SRAs are responsible for overseeing the scientific peer review of applications. Their major responsibilities include managing study section meetings, nominating study section members, selecting ad hoc reviewers and site visitors, providing orientation for members of review groups, explaining and interpreting NIH review policies and procedures, managing project site visits and study section meetings, and preparing summary statements. They are also responsible for attending advisory board or council meetings to provide requested information in support of the peer review committee recommendations, communicating with program staff on review issues, and discussing review issues and policies with applicants. SRAs do not have continuing programmatic, scientific, or fiscal responsibilities for the applications after the scientific peer review is completed.

The NCI Division of Extramural Activities also has SRAs who organize and manage 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, multi-site clinical trials, NCI's clinical trials cooperative groups, National Research Service Award (NRSA) grants, and cancer education grants.

For program project grant (P01), cancer center support grant (P30), and clinical trial cooperative group cooperative agreement (U10) applications, NCI uses a two-tiered peer review process. For these applications, the first tier of

review 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 review of each component of the application. The SRA prepares a site visit report, which includes the recommendations of the site visitors. A chartered "parent" review committee then considers site visit reports for several applications. There are three "parent" committees for P01s, one for P30s, and one for clinical trials cooperative group applications. The parent review committee for each type of application reviews the application and the site visit report, and assigns a priority score to each application. The SRA prepares a final summary statement after the meeting of the parent review committee.

For applications that cannot be reviewed by a study section or chartered NCI review committee due to conflict of interest or lack of expertise, the SRA assembles a Special Emphasis Panel (SEP) (formerly Special Review Committee) to conduct the review. NCI RFAs and PARs are usually reviewed by NCI SEPs. The composition of the committee is determined by the expertise needed to review the submitted grant applications.

SRAs receive a copy of each application assigned to their committees from the NCI Referral Office. The SRA determines if the application contains sufficient scientific and technical information necessary for the review committee to review the project.

Project Site Visits

The purpose of a project site visit is to allow the reviewers to gather information not available in the written application in order to make a final evaluation of the merit of the application. The CSR SRA usually assembles a project site visit team of three to five reviewers. Site visits enable the reviewers to meet with the principal investigator and other researchers, view the facilities, and raise questions or discuss objectives. The NCI program director generally attends these visits to provide program information, if needed, and to gain a better understanding of the project and the reviewers' recommendations. In some cases, either at the request of the SRA, program director, or Grants Management Officer, a grants management specialist will attend 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 IRG meeting.

Approximately one percent of the research grant applications reviewed by CSR require a project site visit before the study section can complete its assessment. Sometimes this requires deferral of the review to the next review cycle in order to conduct the site visit.

By contrast, as described in the previous section, many of the applications reviewed by NCI review committees must be site visited because of the specialized and complex nature of the applications. Large, complex applications 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, depending on the number of individual program components and disciplines involved. Several members from the appropriate NCI chartered "parent" committee, as well as ad hoc consultants, form the site visit team.

Scientific Review Group (SRG) Meetings

Scientific Review Groups (SRGs) (CSR study sections and NCI review committees) and Special Emphasis Panels (SEPs) meet from one to three 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 have been site visited, two or more members of the site visit team, usually IRG members, will summarize their findings and recommendations, including a budget and project period, for the full parent committee.

Applications are evaluated for:

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

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

3. **Innovation:** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

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

5. **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experi-

ments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

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

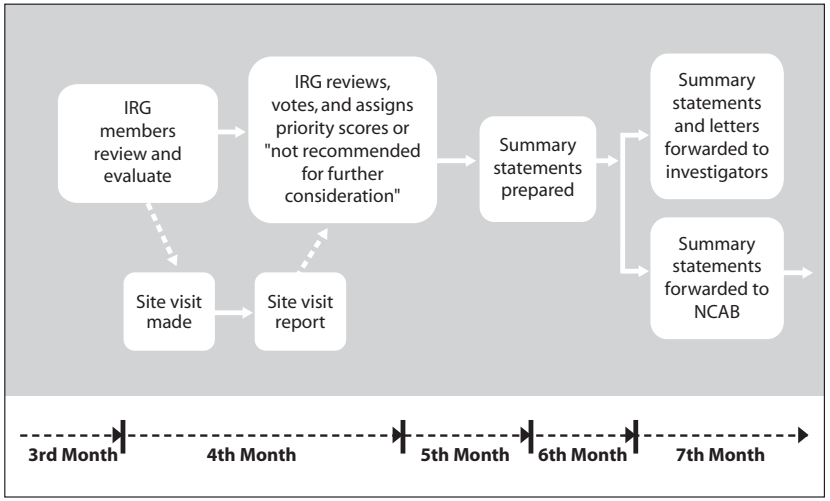
- The adequacy of plans to include gender, children, minorities, and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects are also evaluated.
- The reasonableness and duration of the proposed budget in relation to the proposed research.
- The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

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

At present, the possible recommendations by the review committee are: scoring, not scoring, not recommended for further consideration (NR), or deferral (DF). The latter two actions require a majority vote; in the event of a split vote (i.e., when two or more IRG members disagree with the majority), the recommendation is based on the majority vote, but the minority opinion is recorded in the summary statement. An application may be deferred if additional information is needed to make a definitive recommendation.

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

Figure 8. IRG Review and Evaluation for Scientific Merit



Priority Scores

To determine the priority score, each IRG member assigns a numerical rating that reflects the reviewer's assessment of the scientific merit of the application relative to the state of the art in the particular field. The numerical ratings range from 1.0 (best) to 5.0 (worst) with increments of 0.1.

After the review meeting, the SRA averages the individual reviewers' ratings for each scored application and multiplies by 100 to provide a three-digit number that is the priority score. At this point in the grant application review process, four to five months have elapsed since the principal investigator submitted the application (see Figure 8 above).

Percentile Rank

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

The overall intent of percentile ranking (or "percentiling") is to improve the comparability of scored applications across study sections and IRGs, and to minimize the impact of round-to-round quality variation. 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 six to eight weeks after each IRG meeting, the SRA prepares the summary statements (still often referred to as "pink sheets" because they used to be printed on pink paper) reflecting the judgment of the reviewers (see Exhibit B). The summary statement consists of 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. Summary statements for scored applications include Committee Budget Recommendations, which may indicate budget items that the reviewers recommend for reduction or elimination and a recommendation for the duration of support. Projects may be recommended for support for up to five years. However, in accordance with NIH cost containment principles, the average length of an award is four years. Summary statements are sent directly to the PI by CSR when they are available. NCI staff also provide the summary statements to NCAB members for their review before the NCAB meeting (see Figure 8, page 32) via the NIH Electronic Council Book (a restricted access web site).

Early Notification of Applicant

Once the priority scores and percentiles are calculated by the IRG SRA, a transmittal (and final) notification letter accompanied by the summary statement communicating the results of the IRG review is sent to the principal investigator (PI) by the program director. The grantee business official is sent a copy of the transmittal (and final) notification letter. However, the grantee business official is not sent a copy of the summary statement because it contains confidential information pertaining to the PI. Currently, CSR sends out summary statements for the following applications that are unscored or not recommended for further consideration: R01s that are non-RFAs, R15s, R41s, R42s, R43s, R44s, U41s, U42s, U43s, U44s. For fellowships, CSR sends out summary statements for unscored RFAs and non-RFAs. CSR also sends out Just-In-Time (JIT) letters to CSR-reviewed R01 applications that are within or close to the payline. NCI program directors send out all other summary statements accompanied by a letter stating that no assumptions should be made about the probability of funding.

National Cancer Advisory Board

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

Responsibilities

The NCAB is responsible for the final external review of all grant applications referred to the NCI, except 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 one-half of those reviewed by CSR, and 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 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

In accordance with P.L. 92-463, the Federal Advisory Committee Act, the Secretary of the Department of Health, Education, and Welfare chartered the NCAB on January 4, 1973. The NCAB's mandate is continuous, and the Board is rechartered every two 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 members shall be appointed from among the leading representatives of the health and scientific disciplines relevant to cancer and that 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 are appointed by the President from among persons who by virtue of their training, experience, and background are especially qualified to evaluate the programs of the NCI. Members serve overlapping terms of six years. The President designates one of the appointed members to serve as Chair for a term of two years.

Ex officio members of the Board include the Secretary of DHHS, the Director of the Office of Science and Technology Policy, the Director of the NIH, the Chief Medical Director of the Department of Veterans Affairs, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, the Director of the National Institute for Occupational Safety and Health, and the Associate Director for Health and Environmental Research of the Office of Energy Research. Members of the President's Cancer Panel also attend as non-voting members.

Pre-NCAB Meeting

Approximately two weeks before the meeting of the NCAB, the Executive Secretary of the NCAB (currently the Director, DEA, NCI) 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 DEA staff from the material provided by NCI program staff. The Special Action Booklet identifies applications which have 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; and any special information which 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 Chair, no fewer than four times a year. Meetings usually last two 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 NCI program review.

NCAB meetings are open to the public when general program activities and plans are discussed. By DHHS regulation, scheduled NCAB meeting dates are published well ahead of time in the Federal Register (http://www.access.gpo.gov/su_docs/aces/aces140.html). Attendance at the closed grant application review sessions is limited to NCAB members, IRG SRAs, the NCI Director, appropriate NCI staff, and designated representatives of the Secretary, DHHS. 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 six to eight 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. The NIH Electronic Council Book is a restricted access web site that allows NCAB members to view all the summary statements as well as the grant applications assigned to them for review based on their areas of scientific interest. NCAB members are not given access to summary statements from their own institutions, however. By the time the NCAB meets, approximately 1,500 summary statements, as well as other materials about the applications to be reviewed, will have been made available to the NCAB. NCI's Division of Extramural Activities prepares and distributes special reports which detail grant applications involving human subjects, animal welfare, biohazard risks, foreign grants, and inadequate representation/justification of gender and/or minorities and/or children for review by the NCAB. In addition to these special reports, NCAB members also receive MERIT (Method To Extend Research in Time) award nominations and extensions and appeal letters from PIs who disagree with the IRG recommendation.

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 NCI program director responsible for that application. Most of the NCAB members' concerns are resolved during telephone conversations 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 IRG review, such as the recommended 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

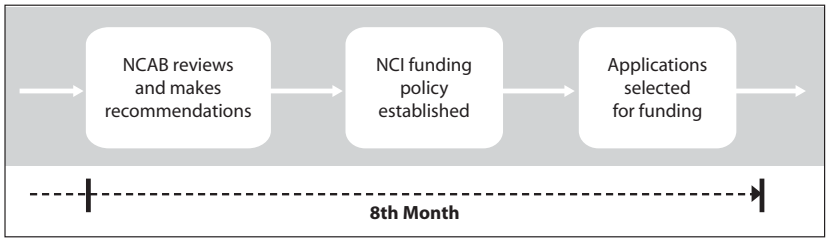
An expedited NCAB approval process is used for pencentiled R01s reviewed by CSR and for all R21s, except for those applications submitted in response to a set-aside (RFA or PA with a set-aside). In addition, applications do not undergo expedited review if they involve foreign institutions or if the summary statement expresses concerns with regards to human subjects, animal welfare, biohazards, or inadequate representation/justification of gender and/or minorities and/or children. The NCAB members approve grant applications using the NIH Electronic Council Book and a notification letter is sent to the PI 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 IRG's recommendations. However, the NCAB may vote to change the IRG 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 IRG. If, after deferral and a second review, the NCAB still wishes to change the recommendation, it may do so.
- The NCAB may recommend that an application be considered for exception funding, in which case the application need not be returned to the IRG for an additional review.

Figure 9. NCAB Review and NCI Funding Determinations



- The NCAB may recommend that an application receiving a favorable recommendation in initial review not be considered for support for reasons other than lack of scientific or technical merit.
- In the case of a split vote from the IRG, the NCAB may accept the minority opinion without returning the application for further review.

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

Once the NCAB has acted on those applications given special attention, the NCAB considers a motion for en bloc concurrence with the IRGs' recommendations as presented in the summary statements. NCAB members are required to sign conflict of interest statements. They do not attend discussions or vote on applications from their own institutions or affiliated institutions. Therefore, they can 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 their concurrence or nonconcurrence. Conflict of interest guidelines are maintained during this process.

Post-NCAB Meeting

After each National Cancer Advisory Board (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. At this point, approximately eight to nine months have elapsed since the principal investigator submitted the application (see Figure 9).

Appeals to Referral and Review of Applications

Effective with the applications going to the June 1997 NCAB, 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.

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. Considerations used in determining program allocations include Congressional mandates, new scientific opportunities, new initiatives, program priorities, previous commitments such as noncompeting continuations, other projected needs, and the anticipated availability of funds. Final allocations and funding decisions cannot be made until the actual amount of the appropriation is known.

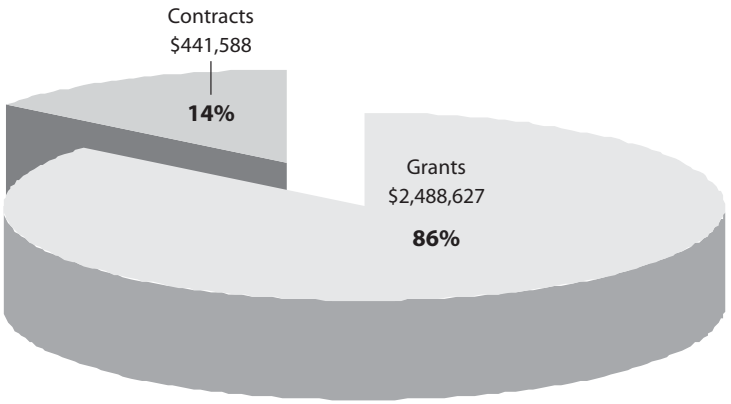
Generally, the NCI Executive Committee meets in October/November to establish funding policy for grant applications submitted for the year's first funding cycle, which begins with the September/October meeting of the NCAB. If Congress has passed an appropriation bill by this time, the funding policy for the entire year may be established. When establishing pay lines 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. 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. Those grant mechanisms that are common to more than one Division (traditional research grants [R01], program project grants [P01], etc.) 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 10 and 10a (pages 42 and 43), which display budget spending by funding mechanism for FY 2001.

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.

Figure 10. NCI FY 2001 Extramural Funds *(dollars in thousands)*



Mechanism	Amount	Percent of Total (%)
Grants		
Research Project Grants	$1,696,603	58.5
Cancer Centers/SPORES	279,731	9.6
Other Research Grants	269,201	9.3
Cancer Control Grants	183,665	6.3
Training Activities	57,927	2.0
Construction Grants	1,500	0.1
Subtotal, Grants	2,488,627	85.8
Contracts	411,588	14.2
TOTAL EXTRAMURAL FUNDS	**2,900,215**	**100.0**

Figure 10a. NCI FY 2001 Budget by Mechanism *(dollars in thousands)*

	AMOUNT	PERCENT OF TOTAL (%)
RESEARCH GRANTS:		
Research Project Grants		
Traditional Research Project Grants (R01)	$1,008,033	26.9
Program Projects (P01)	301,115	8.0
FIRST Awards (R29)	23,738	0.6
Outstanding Investigator Awards (R35)	2,186	0.1
MERIT Awards (R37)	26,682	0.7
RFAs	149,448	4.0
Cooperative Agreements (U01/U13/U19)	15,985	0.4
Exploratory Grants - Phase I (R21)	42,605	1.1
Exploratory Grants - Phase II (R33)	23,604	0.6
Small Grants (R03)	9,024	0.2
AREA Grants (R15)	358	0.0
Shannon Awards (R55)	300	0.0
Program Evaluation	17,692	0.5
Subtotal, RPGs	**1,620,770**	**43.2**
SBIR/STTR Grants (R43/R44 & R41/R42)	75,833	2.0
Subtotal, Research Project Grants (RPGs)	**1,696,603**	**45.2**
Centers		
Cancer Center Grants (P30/P20)	192,116	5.1
SPORES (P50)	76,844	2.0
Center Cooperative Agreements (U54)	10,771	0.3
Subtotal, Centers	**279,731**	**7.5**
Other Research Grants:		
Career Program:		
Temin & Minority Mentored Career Development Awards (K01)	10,398	0.3
Senior Research Scientist Awards (K05)	550	0.0
Academic Career (Preventive Oncology) Awards (K07)	6,309	0.2
Mentored Clinical Scientist Development Awards (K08)	14,500	0.4
Mentored Clinical Oncology Awards (K12)	8,409	0.2
Career Transition Awards (K22)	1,191	0.0
Mentored POR Career Development Awards (K23)	4,291	0.1
Mid-Career Investigator in POR Awards (K24)	3,796	0.1
Mentored Quantitative Research Career Dev. Awards (R25)	133	0.0
Institutional Curriculum Awards (K30)	1,600	0.0
Subtotal, Career Program	**51,177**	**1.4**
Cancer Education Program (R25)	21,740	0.6
Clinical Cooperative Groups (U10)	154,261	4.1
Minority Biomedical Support (S06)	3,479	0.1
Scientific Evaluation (U09)	5,850	0.2
Continuing Education (T15)	202	0.0
Research Resource Grants (R24/U24)	29,339	0.8
Exploratory Cooperative Agreements (U56)	1,042	0.0
Conference Grants (R13)	2,111	0.1
Subtotal, Other Research Grants	**269,201**	**7.2**
Subtotal, Research Grants	**2,245,535**	**59.8**
NRSA Training (F31, F32, F33, T32 & T36)	57,927	1.5
Cancer Control Grants	183,665	4.9
Construction Grants (C06)	1,500	0.0
Subtotal, Grants	**2,488,627**	**66.3**
Contracts (includes R&D, Interagency Agreements, Cancer Control, Construction contracts)	411,588	11.0
Intramural Research	567,297	15.1
Research Management & Support	136,509	3.6
Cancer Prevention and Control (excluding Cancer Control Grants and Contracts)	149,700	4.0
TOTAL NCI	**3,753,721**	**100.0**

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 with poorer priority or percentile scores that may be important to the program's objectives.

Additionally, a percentage of grant funds, 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 which are outside the pay lines. In addition, 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 those 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 his designee, and the Grants Management Officer, it becomes an authorization (paylist) (see Exhibit C). 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 Part III of this publication.

Award Negotiation and Issuance

Role and Responsibilities of NCI Program Directors

The NCI currently has more than 120 extramural program directors, each of whom is assigned responsibility for a certain programmatic and scientific approach to the cancer problem (see Figure 11, page 46). For example, there are program directors for chemical carcinogenesis, tumor biology, biochemistry and pharmacology, immunology, radiation, clinical oncology, cancer prevention, and others.

The program director is responsible for the programmatic and scientific aspects of his/her portfolio. In addition to the activities cited previously, the program director is responsible for:

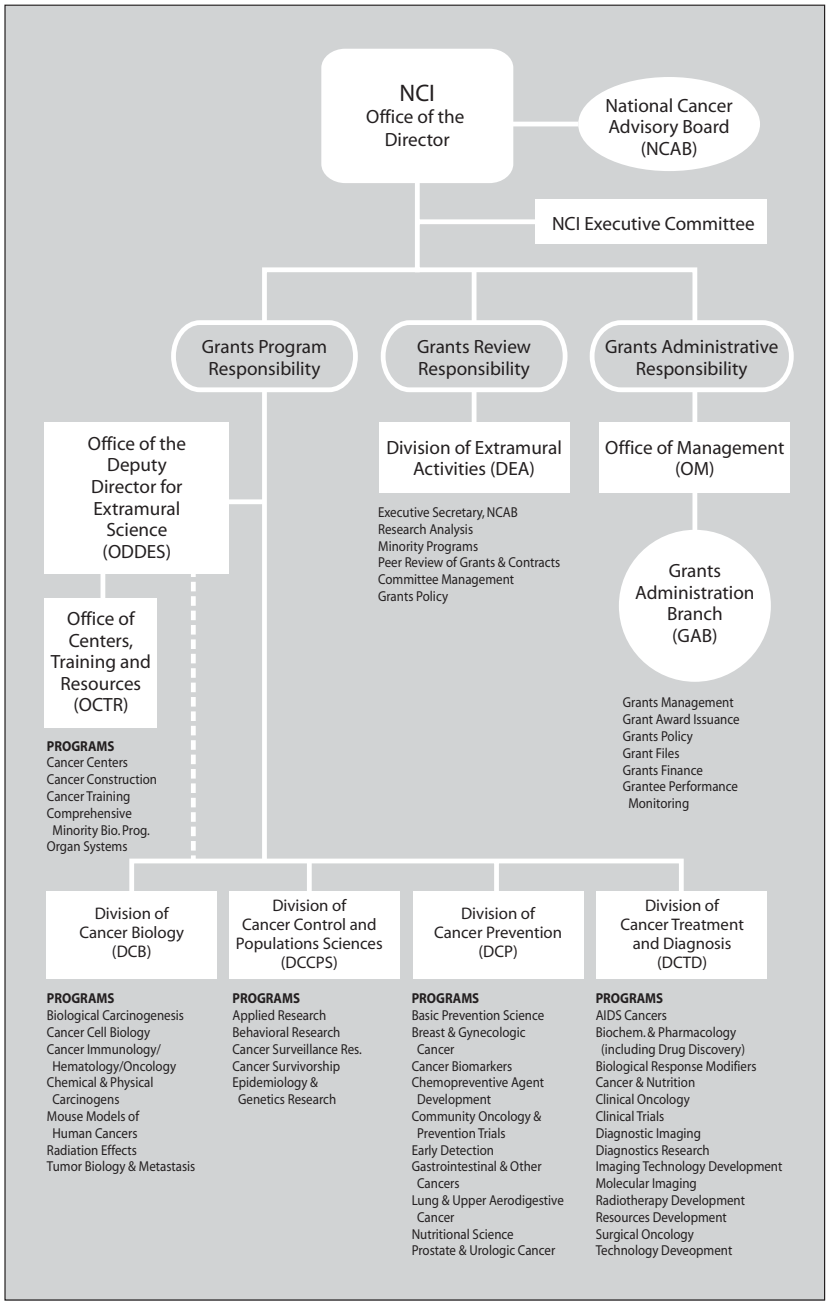
- Providing leadership and coordination in the medical and scientific communities for research groups carrying out investigations in a particular program area.
- Visiting grantee institutions to promote and explain the objectives of the program and to exchange information.
- Reviewing and evaluating 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 NCI, NIH, and DHHS 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, as noted in more detail below, 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. In addition to the preaward responsibilities cited previously and discussed in greater detail below, the GMO is responsible for:

Figure 11. National Cancer Institute Grants Program



- 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.
- 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.

Because most business and management decisions have an impact on programmatic and scientific matters and vice versa, a close working relationship between the program directors and the GMO, or his/her staff, 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. The program director reviews a grantee's request with regard to its impact on the science of the research project and informs the assigned grants management specialist of any scientific problems. NCI grants management specialists maintain an annual portfolio assignment that includes an average of over 200 grants.

Preaward 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 the applicant's other sources of support or overlap with other projects or to resolve scientific concerns expressed by the initial reviewers regarding the involvement of human

subjects, the use of live vertebrate animals, minority and gender representation, or potential biohazard problems. Grants management staff may contact applicants to request additional information regarding assurances and certifications or missing application documentation.

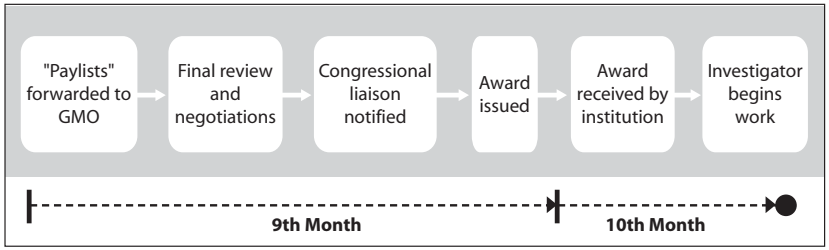
Program directors document their review and resolution of problems by completing, signing, and forwarding to the grants management specialist an NCI documentation control form for each application to be funded. The grants management specialist and program director work together during this preaward phase of the award process.

For applications reviewed by the Center for Scientific Review (CSR) and scored within a certain range, NIH requests updated other support, certification of IRB (Institutional Review Board) approval, and human subjects education certification. 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 12). This involves a cost analysis of the proposed budget; a review for administrative compliance with DHHS and NIH policies; and, finally, negotiations with the grantee business official and/or the principal investigator. Examples of these activities are outlined below.

Figure 12. Award Negotiation and Issuance



Cost Analysis

The grants management specialist reviews the application for:

- Reasonableness of costs.
- Adherence to cost principles.
- Relationship of costs to the proposed project.
- The applicant institution's financial management capabilities.
- 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).

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

- The applicant's previous experience in managing grant funds.
- 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 NIH and DHHS requirements and with other appropriate rules and policies. 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.
- DHHS-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.
- Nondelinquency 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 and the nature of the problems identified. The grants management specialist can usually complete negotiations and obtain needed information by telephone or through correspondence. However, it may become necessary to visit the grantee facility to address certain issues or problems in person. The program director may participate in the on-site visit.

Preparation of Awards and Obligation of Funds

The Notice of Grant Award (NGA) is the official notification to the applicant that the project has been funded. The NGA document is in a letter format (see Exhibit D) and is executed by the Grants Management Officer. NGAs are either transmitted electronically via e-mail or mailed, if the grantee is not e-mail enabled.

The Notice of Grant Award contains:

- The name and address of the grantee institution.
- The title of the project.
- The name of the principal investigator under whose direction the research is to be carried out.
- The period of grant support.
- The amount recommended for future years of support.
- Any special grant terms and conditions of award.

In addition, all competing award notices and all non-competing award notices, except those in the Streamlined Non-Competing Award Process (SNAP) population, show the authorized direct costs by budget category (e.g., personnel, supplies), thereby constituting prior approval for the expenditure of funds for specific purposes and items described in the grant application and/or agreed upon during negotiations. F&A costs are also included on the NGA. For additional information on F&A costs, refer to the section entitled "Facilities and Administrative Costs."

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 special conditions more restrictive than those prescribed by standard grant policy, or may delay issuing the award until it is satisfied that the agency's standards have been met.

The Grants Management Officer certifies in signing the grant award that:

- The choice of the award mechanism is proper under applicable policy.
- The application on which the award is based 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 under the terms and conditions specified for the particular program and is consistent with 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. The NGA letter is electronically transmitted to the grantee business office or is mailed if the recipient is not e-mailed enabled. It is the grantee's 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, DHHS.

Acceptance of Award

The grantee indicates acceptance of the general and special provisions of an award by drawing down or otherwise obtaining funds (see "Grant Payment" section) from the grant payment system.

Continuation Support

With the exception of a few unique programs, approval of a project may include recommended support for up to five years. Awards, however, 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.

Funds for each additional budget period within the project period must be requested by the principal investigator in a progress report summary contained in the Non-Competing Grant Progress Report, Form PHS 2590, two months before the beginning date of the next budget period. A fillable progress report summary form can be found on the PHS 2590 webpage at http://grants1.nih.gov/grants/funding/2590/2590.htm#forms under "Form Page 5: Progress Report Summary." In the following pages of this publication, the Non-Competing Grant Progress Report form is referred to as the non-competing application.

It is important to note that submitting non-competing applications (Type 5s) 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.

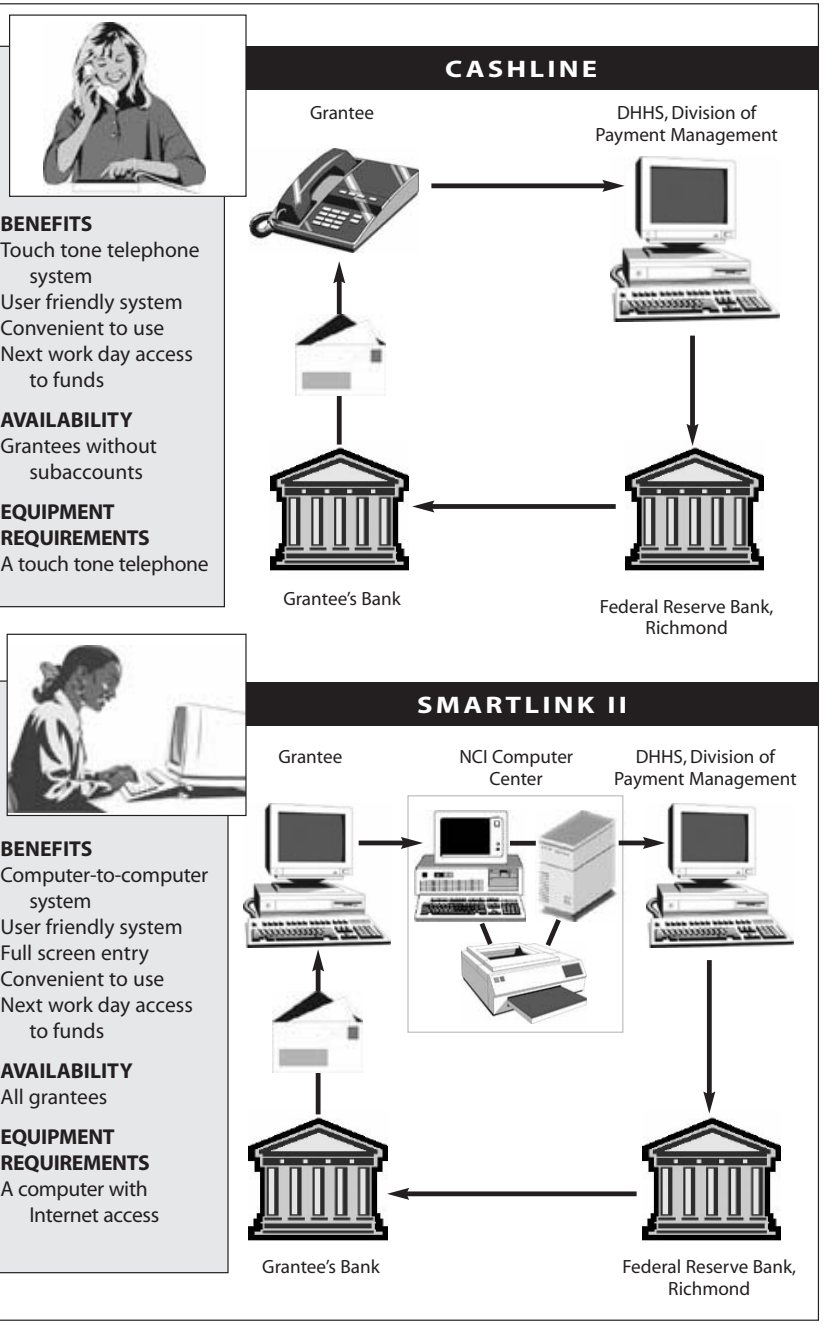
Non-competing continuation applications are reviewed by NCI grants management specialists, as outlined earlier in the section entitled "Preaward Activities." In addition, program directors carefully review the noncompeting continuation application and the applicant's annual progress report submitted with the non-competing continuation application to determine if scientific progress is adequate to justify continued support. Exhibit E is an abbreviated example of a progress report. When all requirements are satisfied, an award for the next budget period is issued. This process is repeated each year of the project period.

NCI grants management specialists also review non-competing continuation applications that fall into the 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 assures that proposed costs are allowable, allocable, reasonable, and necessary for the project. Requirements for financial documentation are streamlined in that only an annual programmatic progress report from the grantee and a quarterly Federal Cash Transaction Report are required to be submitted by the grantee. These reports enable NCI staff to monitor the scientific and financial aspects of the project. In addition, a Financial Status Report (FSR) is required within 90 days after the end of the competitive segment. SNAP applications are screened by the NCI Grants Administration Branch staff to determine if the three streamlining questions have been answered. 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.

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, in unusual situations where the grantee can justify the need for additional funds, the NCI has the authority to grant the increase as long as the peer-reviewed and 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.

Figure 13. Grant Payment Management System: Electronic Funds Transfer — CASHLINE and SMARTLINK II



Postaward Administration

Grant 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 DHHS Payment Management System. Payment is primarily made by Electronic Funds Transfer. The grantee can request DHHS grant funds by calling the Division of Payment Management and requesting to use the CASHLINE process or by accessing SMARTLINK II through the Internet. Funds are deposited directly into the recipient's bank account on the next business day. Figure 13 (page 54) illustrates these processes in detail.

Information on the Payment Management System is available from:

Division of Payment Management
P.O. Box 6021
Rockville, Maryland 20852
(301) 443-1660
http://www.dpm.psc.gov/

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.
  - 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, which materially impair the ability to meet the objectives of the award.

- Payback Agreement. A National Research Service Award (NRSA) Payback Agreement must be signed by each postdoctoral individual for whom the appointment covers his/her 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) (see Exhibit F). 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.

  - Progress Report (see Exhibit E).

  - 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.

  - 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 National Research Service Award (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 his/her support.

Electronic Transmittal of Financial Status Reports

DHHS regulations under 45 CFR Part 74.73(d) and Part 92.41(b) dictate that Financial Status Report (FSRs), must be submitted to NIH within 90 calendar days after the last day of each budget period. For awards under SNAP, excluding those awards to Federal institutions and foreign organizations, FSRs are no longer required annually but, rather, are required 90 days after the end of the competitive segment. The submission of timely and accurate FSRs is central to ensuring prudent and efficient stewardship of public resources.

To facilitate the submission of FSRs, the NIH developed an interactive computer-based communications system to enable grantee organizations to electronically transmit FSRs to the NIH mainframe computer. The electronic process eliminates the manual preparation, mailing, and handling of the hard-copy FSR, as well as the manual processing once the FSR arrives at NIH.

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; and 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 period of time (terminating grants).

In an effort to further assist the grantee community, the NIH is developing a new electronic FSR process to replace the current system. Once NIH implements this new electronic process, grantees will be able to fill out, submit, and revise FSRs electronically, using a friendly, web-based system. The FSRs will be stored and accessed electronically by NIH staff. The NIH intends to deploy the electronic FSR module in late 2002.

Additional information about the electronic transmittal of FSRs is available from:

NIH Office of Financial Management
Government Accounting Branch
Building 31, Room B1B05A
31 Center Drive MSC 2050
Bethesda, Maryland 20892-2050
(301) 402-9123

Monitoring Projects

The names, titles, and telephone numbers of the responsible grants management specialist and program director are printed on each NGA letter. These individuals are responsible for the continuous monitoring of the business management and programmatic performance of the particular project. Monitoring is accomplished through the review and assessment of information gathered from audit reports, progress reports, financial reports, site visits, correspondence, and peer review. Also, before and/or after award, the Grants Management Officer, designated specialist, and/or program director may visit a new or established institution or an institution with identified problems or weaknesses to evaluate scientific progress, management systems, and adequacy of policies, procedures, and controls.

Under Federal regulation 45 CFR 74.53, the NCI and other DHHS awarding agencies, the DHHS Inspector General, the U.S. Comptroller General, or 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 of such documents. This right also includes timely and reasonable access to a recipient's personnel for the purpose of interview and discussion related to such documents. The rights of access are not limited to the required retention period, but shall 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 or begin the resolution of the troublesome issues. It is usually possible for a mutually agreeable course of action to be worked out so that the award process can proceed.

However, 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, or if the applicant organization refuses to adopt required assurances and certifications that reflect national social and economic policy, and/or if the applicant fails to comply with terms of award, NCI staff may take any of the following actions:

- Not issue the new or competing continuation award.
- Withhold the next non-competing 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.

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 $300,000 or more in Federal awards are required by OMB Circular A-133 to have an annual audit performed by a public accountant or a Federal, state, or local government audit organization that meets the standards specified in generally accepted government auditing standards. This audit should include a 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; and 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

The regulations of the DHHS provide grantee institutions with the opportunity to appeal certain postaward administrative decisions made with regard to direct, discretionary project grants or cooperative agreements by DHHS agencies, which include the Institutes and Centers of the NIH (45 CFR Part 16). While there are two levels of appeal—an informal NIH procedure and a formal Departmental procedure—the grantee must first exhaust the informal procedure (and through it, have received a decision that upholds the agency's adverse determination) before the Departmental Appeals Board will accept an appeal. The specific adverse determinations that may be appealed are:

- A disallowance or other determination denying payment of an amount claimed under an award.

- A termination for failure to comply with the terms of an award.
- A denial of a non-competing continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.
- A voiding (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

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.

Grant Closeout

The grant closeout process is initiated upon conclusion of grant support. Official procedures are begun by GAB staff after NCI staff determine that all applicable administrative actions and all 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 are required to be submitted no later than 90 days after the expiration of the project period or after the grant transfers to a new institution. The procedures followed ensure that all necessary scientific and administrative final reports have been received, reviewed, and accepted.

Additional Postaward Activities

There are additional potaward activities, but to describe all of them would be beyond the scope of this publication. A few of the other more common postaward 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; and reviewing audit and financial reports.

Record Retention

By the Grantee

Generally, 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 for three years from the date the final annual expenditure report is submitted to the NIH. For awards under SNAP (except those to foreign organizations and Federal institutions), the retention period begins on the date the expenditure report for the entire competitive segment is submitted to the NIH and applies to all records for the entire competitive segment. 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 three years from the date of submission of the annual FSR to NIH. If an audit or other action is in process at the expiration of the three-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 three-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.

PART III

Funding Allocation

Overview of the Federal Budget Process

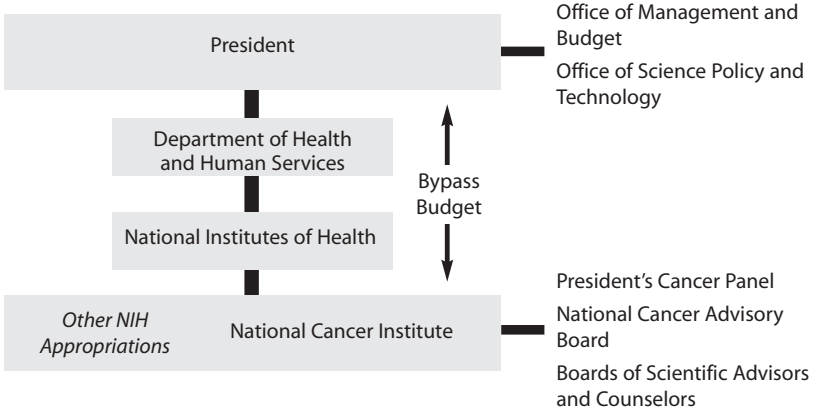
The major "players" in the NCI budget process are components of the executive and legislative branches of the U.S. Government. In the legislative branch, several committees and subcommittees control funding for NCI programs, as shown in Figure 14.

Figure 14. Legislative Branch Components of the NCI Budget Process

HOUSE OF REPRESENTATIVES		SENATE	
APPROPRIATIONS	**AUTHORIZATIONS**	**APPROPRIATIONS**	**AUTHORIZATIONS**
Appropriations Committee	Committee on Energy and Commerce	Appropriations Committee	Health, Education, Labor, and Pension Committee
Subcommittee on Labor, HHS, and Education	Subcommittee on Health	Subcommittee on Labor, HHS, Education and Related Agencies	Subcommittee on Public Health

The executive branch agencies and offices that are involved in the development of NCI's budget are shown in Figure 15.

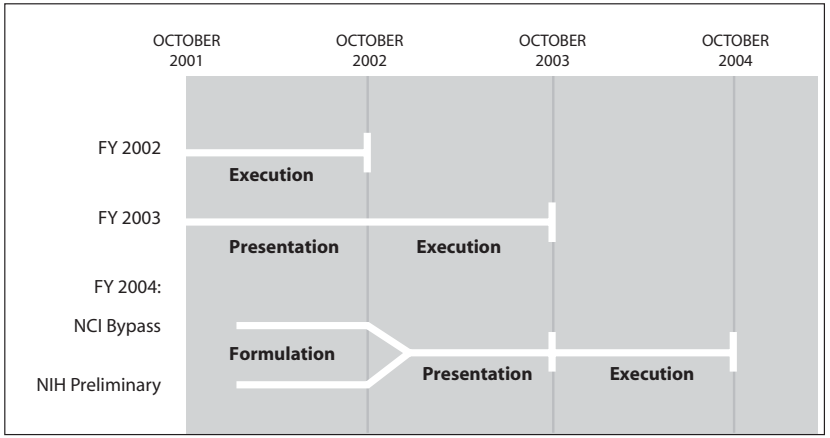
Figure 15. Executive Branch Components of the NCI Budget Process



NCI Budget Development Cycle

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 16), FY 2002 is being executed while FY 2003 is being presented and FY 2004 is being formulated during the 2002 fiscal year.

Figure 16. NCI Budget Development Cycle



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 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.

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, take out:

- The amount of non-competing commitments, including the program evaluation budget tap
- 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 pay lines for RPGs.

Funding Allocation: A Practical Example

The following is an entirely imaginary distribution of a completely fictional appropriation for Research Project Grants (RPGs) using the following theoretical assumptions:

- Appropriation level of $1.696 billion.
- Mandate to fund 1,180 competing RPGs.
- Mandate that the average cost of the competing RPGs be no more than $352,000 (an increase over the prior year equal to the biomedical inflation index).

	AMOUNT	NO. OF AWARDS
Step 1		
Appropriation	$1,696,000,000	
Small Business Set-aside	-76,000,000	
Non-competing commitments	-1,205,000,000	
Competing availability	415,000,000	
Step 1a		
Competing availability	415,000,000	1,180
Set-aside for RFAs	-29,000,000	-50
Remaining for R01, P01, R21, etc.	386,000,000	1,130
Step 2		
Remaining for R01, P01, R21, etc.	386,000,000	1,130
The breakdown would be:		
Allocation for R01, R37	255,000,000	760
Allocation for P01	46,000,000	27
Allocation for R21, R33	30,000,000	145
Allocation for R03, etc.	7,000,000	93
Reserve for exceptions	*48,000,000*	*105*

At this point, these amounts would be distributed to each of the three rounds. ***Step 3*** would consist of setting pay lines for RPGs based on historical data and current review results.

PART IV

Application Types and Budget Mechanisms

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** *(Type 1)* — Request for support of a project that has not yet been funded.

2 **Competing Continuation** *(Type 2)* — 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.

3 **Supplement** *(Type 3)* — Request for additional funds, either for the current operating year or for any future year previously recommended, to cover increased costs (non-competing) or to expand the scope of work (competing).

4 **Extension** *(Type 4)* — Request for additional time and/or funds beyond that previously awarded; limited to certain mechanisms, including MERIT (R37) and certain Fellowship (F) and Career (K) awards. These F and K applications do not compete for funds. R37s compete for funds, and require National Advisory Council review.

5 **Non-competing Continuation** *(Type 5)* — Request to pay next budget increment of a current award; does not compete for available funds.

6 **Change of Institute or Center** *(Type 6)* — Request for support of a fellowship or training project that has been transferred from one Institute or Center (IC) to another.

7 **Change of Grantee or Training Institution** *(Type 7)* — Request for support of a funded project that has been transferred from one grantee or training institution to another.

8 **Change of Institute or Center** *(Type 8)* — Non-competing continuation (Type 5) that has been transferred from one IC to another.

9 **Change of Institute or Center** *(Type 9)* — Competing continuation (Type 2) that has been transferred from one IC to another.

Budget Activities

In fiscal year 2001, the National Cancer Institute's budget totaled $3,753,721,000. Expenditures in the three major budget activities are outlined in the following paragraphs.

Research

Cancer Causation Research

Cancer causation research concentrates on the events involved in the initiation and promotion of cancer. It encompasses chemical and physical carcinogenesis, biological carcinogenesis, epidemiology, chemoprevention, and nutrition research. Studies in this area focus on external agents such as chemicals, radiation, fibers and other particles, viruses, parasitic infections, and host factors such as hormone levels, nutritional and immunologic status, and the genetic endowment of the individual, all of which contribute to the initiation and promotion of cancer. Fiscal year 2001 cancer causation research expenditures totaled $880,612,000, accounting for 23.5 percent of the NCI budget.

Detection and Diagnosis Research

Detection and diagnosis research includes studies designed to improve diagnostic accuracy, provide better prognostic information to guide therapeutic decisions, monitor the response to therapy more effectively, detect cancer at its earliest presentation, and identify populations and individuals at increased risk for the development of cancer. Areas of emphasis include improvements in the detection and diagnosis of breast, cervical, and uterine cancers and prostate cancer; the transfer of molecular technologies from the laboratory to clinical practice; the identification of better prognostic markers; increased availability of human tumor samples with associated clinical information; and research to identify genetic alterations involved in tumor pathogenesis and behavior. Fiscal year 2001 detection and diagnosis research expenditures totaled $260,542,000, accounting for 6.9 percent of the NCI budget.

Treatment Research

Treatment research is composed of preclinical and clinical research. Preclinical research focuses on the discovery of new antitumor agents and their development in preparation for testing in clinical trials. These agents include both synthetic compounds and natural products. Clinical research involves demonstrating the effectiveness of new anticancer treatments through their systematic testing in clinical trials. Phase I trials establish the maximum tolerated dose of a new agent; Phase II trials examine its efficacy against a variety of cancers; and Phase III trials compare the new treatment

with the best standard therapy in terms of improved survival and decreased toxicity. Fiscal year 2001 treatment research expenditures totaled $916,312,000, accounting for 24.4 percent of the NCI budget.

Cancer Biology

Cancer biology supports a broad spectrum of basic research on cancer and the body's response to cancer. Studies include investigations of cellular and molecular characteristics of tumor cells, interactions between cells within a tumor, and the components of the host immune defense mechanisms. Cancer is the result of genetic damage that accumulates in stages. It is the goal of cancer biology to identify and explain the stepwise progression between the initiating event in the cell and final tumor development. Fiscal year 2001 cancer biology expenditures totaled $597,800,000, accounting for 15.9 percent of the NCI budget.

Resource Development

Cancer Centers Support

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. In fiscal year 2001, there were 60 centers that received a total of $192,116,000 in support and accounted for 5.1 percent of the NCI budget.

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. Cancer centers are designated as one of three types: basic, clinical, or comprehensive.

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

The CCSG is intended to provide support to the peer-reviewed research base of the cancer center within the larger institution. The CCSG supports the operational framework (infrastructure) of the center and partially pays for shared laboratory resources and facilities. Research projects themselves are supported through the individual grants and contracts from the NIH and from a variety of other grant funding agencies and organizations.

The Specialized Programs of Research Excellence (SPOREs) are designed to stimulate translational research from the laboratory to clinical practice.

SPOREs, which are funded under the P50 grant mechanism, focus on 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.

In order to encourage the development of cancer research centers in regions not currently served by existing NCI-designated clinical or comprehensive centers, the NCI awards planning and development grants, using the P20 mechanism, to assist eligible institutions to develop the organizational capability that could lead to the formation and/or development of cancer research centers or SPOREs.

NCI's Comprehensive Minority Institution/Cancer Center Partnership (U54) awards are cooperative agreements designed to establish comprehensive partnerships between the Minority Serving Institution (MSI) and the NCI-designated Cancer Centers. The partnership focuses on cancer research and one or more target areas in cancer research training and career development, education or outreach 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 increase the emphasis on problems and issued relevant to the disproportionate cancer incidence and mortality in minority populations.

Fiscal year 2001 expenditures totaled $280,680,000 for Cancer Centers Program support (including SPOREs and Comprehensive Minority Institution/Cancer Center Partnership awards), accounting for 7.5 percent of the NCI budget.

Research Manpower Development

The NCI Research Manpower Development Program supports and maintains a pool of adequately trained scientists qualified to perform cancer research. Grants under this program primarily provide stipend and salary support for basic and clinical scientists to perform cancer research. 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 three to five years between receipt of a Ph.D., M.D., or other professional degree and

receipt of an individual investigator-initiated award. Fiscal year 2001 Research Manpower Development Program expenditures totaled $131,469,000, accounting for 3.5 percent of the NCI budget.

Construction

The NCI Construction Program supports cancer facility modernization and new construction through the award of grant funds to nonprofit cancer research institutions located at universities and medical centers throughout the Nation. This support enables institutions to construct, expand, and upgrade their cancer research laboratories and clinical trial facilities. Funds are awarded based on NCI requirements and standards as judged by a peer review panel of non-Federal scientists. At a minimum, the NCI construction investment is matched on a 1:1 basis by non-Federal funds from the recipient institution. Construction funds are also used to maintain the Federal facilities at the Institute's Frederick Cancer Research and Development Center located in Frederick, Maryland. This nearly 70-acre Government-owned, contractor-operated facility requires periodic routine maintenance and repair for over 70 buildings in use as well as modernization or creation of research space. Fiscal year 2001 Construction Program expenditures totaled $3,000,000, accounting for less than 0.1 percent of the NCI budget. Of this total, $1,500,000 was awarded for Cancer Research Facilities (extramural) grants.

Cancer Prevention and Control

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

The Cancer Prevention and Control Program includes four components and several subprograms, many of which relate to other program activities of the NCI, including information dissemination, epidemiology, and cancer treatment. The four components are Cancer Prevention Research, Cancer Control Science, Early Detection and Community Oncology, and Cancer Surveillance. Fiscal year 2001 Cancer Prevention and Control Program expenditures totaled $426,572,000, accounting for 11.4 percent of the NCI budget.

Budget Mechanisms

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

- Research Project Grants.
- 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

Research Project Grants 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. Fiscal year 2001 research project grant expenditures totaled $1,696,603,000 accounting for 45.2 percent of the NCI budget.

P01 Research Program Project Grant

Research Program Project Grants (P01s) support an integrated, multiproject research approach involving a number of independent investigators who share knowledge and common resources. A P01 has a defined central research focus involving several disciplines or several aspects of one discipline. Each individual project should contribute or be directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal.

R01 Research Project Grant

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

R03 Small Research Grant

Small Research Grants (R03s) provide research support 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 non-renewable.

R21 Exploratory/Developmental Grant

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

R29 First Independent Research Support and Transition (FIRST) Award

FIRST Awards (R29s) provide a sufficient initial period of research support for newly independent biomedical investigators to develop their research capabilities and demonstrate the merit of their research ideas. This award mechanism is in the process of being phased out.

R33 Exploratory/Developmental Grant—Phase II

Phase II of the Exploratory/Development Grants (R33s) provide a second phase for the support for innovative, exploratory, and developmental research activities initiated under the R21 mechanism.

R35 Outstanding Investigator Grant (OIG)

OIGs (R35s) provide long-term support to encourage experienced investigators with an outstanding record of research productivity to embark on long-term projects of unusual potential in a categorical program area. This award mechanism is in the process of being phased out.

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 five-year MERIT Award is followed by an opportunity for an extension of one to five more years, based on an expedited review of the accomplishments during the initial period.

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

Phase I STTR Grants (R41s) support cooperative research and development projects between small domestic for-profit organizations and research institutions. R41s are limited in time and amount and are used to establish the technical merit and feasibility of ideas that have a potential for commercialization. Generally, support for Phase I STTR awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed one year. 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 of the research project. Deviations from the guidelines must be well justified.

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

Phase II STTR Grants (R42s) support in-depth development of cooperative research and development projects between small domestic for-profit organizations and research institutions, limited in time and amount, for which feasibility has been established in Phase I (R41) and which have potential for commercialization. Generally, support for Phase II awards may not exceed $500,000 for direct and indirect costs and a fixed fee for a period normally not to exceed two years. Note: Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget and project that is appropriate for completion of the research project. Deviations from the guidelines must be well justified.

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

Phase I SBIR Grants (R43s) support research efforts by for-profit domestic small businesses. The objective of this phase is to establish the technical merit and feasibility of proposed research or research and development (R&D) efforts and determine the quality of performance of the small business awardee organization prior to providing further Federal support in Phase II (R44). Generally, support for Phase I awards may not exceed $100,000 for direct and indirect costs and a fixed fee for a period normally not to exceed six months. 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 of the research project. Deviations from the guidelines must be well justified.

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

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

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 interest 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 broadly based multidisciplinary and often long-term approach. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of research activities, as defined in the terms and conditions of 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 will exist between the NCI and a recipient and in which substantial programmatic involvement is 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 of the research project. Deviations from the guidelines must be well justified.

U44 Small Business Innovation Research (SBIR) Cooperative Agreement—Phase II (see U43 and R44)

Phase II SBIR Cooperative Agreements (U44s) support in-depth development of R&D ideas for which feasibility has been established in Phase I (U43) and that are likely to result in commercial products or services. Note: Phase II award levels and project periods are statutory guidelines. Therefore, applicants are encouraged to propose a budget that is appropriate for completion of the research project. Deviations from the guidelines must be well justified.

Cancer Centers and Specialized Programs of Research Excellence

The Cancer Research Centers Program as a whole contains a great diversity of research approaches to the problem of cancer, incorporating all applicable disciplines. Fiscal year 2001 Cancer Research Centers Program expenditures totaled $279,731,000, accounting for 7.5 percent of the NCI budget.

P20 Planning Grant

Planning Grants (P20s) support planning for new programs, expansion or modification of existing resources, and feasibility studies for new approaches. Such awards have been particularly useful in the development of cancer centers and SPORES.

P30 Cancer Center Support Grant

Cancer Center Support Grants (P30s) provide support primarily for the research infrastructure of an active and unified cancer center for the purpose of consolidating and focusing cancer-related activities, increasing research productivity, promoting shared use of research resources and improved quality control, stimulating and promoting interdisciplinary and collaborative research, and increasing the rate at which research discoveries are translated into medical 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 and 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 cancer. These grants differ from Program Project Grants 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. Centers may also serve as regional or national resources for special research purposes.

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; 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 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 the 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 cancer research career development at the MSI. These partnerships may also focus on cancer research and target areas in cancer education for or cancer outreach to minority communities.

Other Research Grants

Other research includes the Research Career Program and all other research grants not included in Research Project Grants, Research Centers, and/or Cancer Prevention and Control except for National Research Service Awards. The NCI Research Career Program includes all "K" awards. Fiscal year 2001 other research expenditures totaled $269,201,000, accounting for 7.2 percent of the NCI budget.

K01 Mentored Research Scientist Development Award

Mentored Research Scientist Development Awards (K01s) provide research scientists with an additional period of sponsored research experience as a way to gain expertise in a research area new to the applicant or in an area that would demonstrably enhance the applicant's scientific career. 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 to devote to research and to act as mentors for young investigators.

K07 Academic Career Award

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

K08 Mentored Clinical Scientist Development Award

Mentored Clinical Scientist Development Awards (K08s) support the development of outstanding clinical research scientists. These awards provide specialized study for clinically trained professionals who are committed to a career in research and have the potential to develop into independent investigators. 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 basic or clinical investigators to develop their independent research skills through a two-phase program—an initial period involving an intramural appointment at NIH and a final period of support 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 Scholars Program and the Transition Career Development Award. The NCI Scholars Program provides an opportunity for outstanding new investigators to begin independent research careers first intramurally within the special environment of the NCI and then to 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 the population sciences from the mentored stage of their careers to junior faculty positions or 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. The 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 the training available to aspiring clinical investigators.

R13 Conference Grant

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

R15 Academic Research Enhancement Award (AREA)

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

R24 Resource-Related Research Project

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

R25 Cancer Education Grant

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

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 milieu for increasing the involvement of minority faculty and students in biomedical research.

T09 Scientific Evaluation

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

U09 Scientific Review and Evaluation (Cooperative Agreement)

Scientific Review and Evaluation Cooperative Agreements (U09s) provide the chairman of an Initial Review Group (IRG) funds 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 where substantial programmatic NCI staff involvement is planned to assist the recipients.

U24 Resource-Related Research Project Cooperative Agreement

Resource-Related Research Project Cooperative Agreements (U24s) support projects contributing to the improvement of the capability of resources to 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 to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

Training

The National Research Service Award (NRSA) is the major mechanism for providing long-term, stable support for a wide range of promising scientists and research clinicians. Fiscal year 2001 NRSA expenditures totaled $57,927,000, accounting for 1.5 percent of the NCI budget.

F31 Predoctoral Individual National Research Service Award

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

F32 Postdoctoral Individual National Research Service Award

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

F33 National Research Service Award for Senior Fellows

National Research Service Awards for Senior Fellows (F33s) 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 for increasing capabilities to engage in health-related research.

T32 Institutional National Research Service Award

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

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 to strengthen the research and teaching capabilities of minority institutions. The NCI cofunds these grants with the National Institute of General Medical Sciences.

R&D Contracts

When a specific end product is desired or a project needs to be conducted with the NCI's direct involvement, the contract mechanism is appropriate. Fiscal year 2001 R&D contract expenditures totaled $283,971,000, accounting for 7.6 percent of the NCI budget.

Intramural Research

The NCI intramural research program complements the extramural research program and is housed on the NIH campus in Bethesda and at the Frederick Cancer Research and Development Center in Frederick, Maryland. Fiscal year 2001 intramural research program expenditures totaled $567,297,000, accounting for 15.1 percent of the NCI budget.

Research Management and Support

There are many activities that provide general management and support to the NCI's cancer research effort. Funding for research management and support (RMS) has remained relatively constant over the last several years. Fiscal year 2001 RMS expenditures totaled $136,509,000, accounting for 3.6 percent of the NCI budget.

Cancer Prevention and Control

The NCI cancer prevention and control program supports research on methods of cancer prevention and control conducted through grants, contracts, and in-house research. Fiscal year 2001 cancer prevention and control program expenditures totaled $459,482,000, accounting for 12.2 percent of the NCI budget.

U10 Clinical Research Cooperative Agreement (See earlier discussion under "Other Research Grants" section.)

Construction

The NCI's construction program supports the creation of additional state-of-the-art cancer research laboratories and clinics for both basic and applied cancer research. Fiscal year 2001 construction program expenditures totaled $3,000,000, accounting for less than 0.1 percent of the NCI budget.

C06 Research Facilities Construction Grant

Research Facilities Construction Grants (C06s) provide matching Federal funds for up to 75 percent 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 more than $4 million per application.

Comprehensive Minority Biomedical Program

The Comprehensive Minority Biomedical Branch (CMBB) coordinates NCI's efforts to broaden participation in cancer-related research and training activities by minorities, individuals with disabilities, underserved segments of the general population, and individuals seeking reentry. Located within NCI's Office of Centers, Training, and Resources, the CMBB oversees the following NCI initiatives: Continuing Umbrella of Research Experiences (CURE), career development program that includes patient oriented research, clinical oncology research, institutional clinical oncology research, transition career development awards, predoctoral fellowship awards and the Cancer Center Partnership and Planning Grants.

The following are ongoing initiatives within the CMBB. For questions concerning these programs as well as new initiatives, contact the Comprehensive Minority Biomedical Branch at (301) 496-7344.

Research Supplements for Underrepresented Minorities in Biomedical Research

Through the Comprehensive Minority Biomedical Branch (CMBB), the NCI provides funds to underrepresented minority individuals who are pursuing careers in the biomedical sciences that address the mission of the National Cancer Program.

- Minority Investigator Supplement (MIS)—provides short-term and long-term opportunities for minority investigators to participate in ongoing research projects while further developing their own independent research potential.
- Minority Individuals in Postdoctoral Training (MIPT)—provides support for minority individuals who wish to participate as postdoctoral researchers on ongoing research projects in preparation for independent careers in the biomedical or behavioral sciences.
- Minority Graduate Research Assistants (MGRA)—provides support to assist minority individuals who wish to develop research capabilities in the biomedical and behavioral sciences.
- Post-Baccalaureate and Post Masters Degree Students (MPBM)—provides support to minority post-baccalaureate and post masters degree graduates who intend to engage in health-related research while applying for graduate or medical school.
- Minority Undergraduate Student (MUS)—provides support to minority undergraduate students who have demonstrated an interest in biomedical or behavioral sciences and wish to pursue graduate-level training in these areas.
- Minority High School Student (MHS)—provides support to minority high school students who have an interest in the biomedical or behavioral sciences.

Supplements to Promote Reentry into Biomedical and Behavioral Research Careers

The NCI provides administrative supplements through a cofunding agreement with the NIH Office of Research on Women's Health to existing research grants for support of full- or part-time research by individuals with high potential to re-enter an active research career after taking time off to attend to family responsibilities. These supplements provide a maximum of three years of support. The program is not intended to support graduate or post-graduate training and is not intended to support career changes from non-research to research careers for individuals without prior research training.

Research Supplements to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers

The NCI provides administrative supplements to active research grants for the support of full-time research by individuals with qualifying disabilities who are capable of entering or resuming research careers.

Travel Award for Young Investigators

The NCI provides support through a travel fellowship for minority student and faculty researchers and young minority clinicians. The intent of the program is to increase the attendance of minority scientists at national meetings and, in particular, to stimulate the participation of predoctoral and postdoctoral minority individuals as well as young minority clinicians in cancer research. The Minority Scholar in Cancer Research Award covers the costs of registration, transportation, meals, and lodging at the national American Association for Cancer Research (AACR) and American Society for Clinical Oncology (ASCO) meetings.

Historically Black Colleges and Universities Faculty in the Field of Cancer Award

The NCI provides support for travel and subsistence to support the attendance of meritorious faculty members from eligible institutions at annual meetings or special conferences on more focused scientific topics of the AACR.

Predoctoral Fellowship Awards for Minority Students

The NCI awards predoctoral fellowships to minority students who are pursuing a Ph.D. or a equivalent research degree. Included in this initiative are Predoctoral Fellowship Awards for Students with Disabilities who are seeking graduate degrees.

The Minority Health Professional Training Initiative

Through this initiative, the NCI addresses the problem of low numbers of minority clinicians, clinical researchers, and other health professionals engaged in oncology research or with training in cancer-related subspecialties. Various awards under this initiative are intended for the career development of minority health professionals utilizing the K01, K07, or K08 mechanism. The following are ongoing programs:

- Research Scientist Development Award (K01).
- Minority Oncology Leadership Award (K07).
- Minorities in Medical Oncology (K08).
- Transition Career Development Award (K22).
- Mentored Patient-Oriented Research (K23).
- Regional Conferences on Recruitment and Retention of Minority Participants in Clinical Cancer Research (R13).

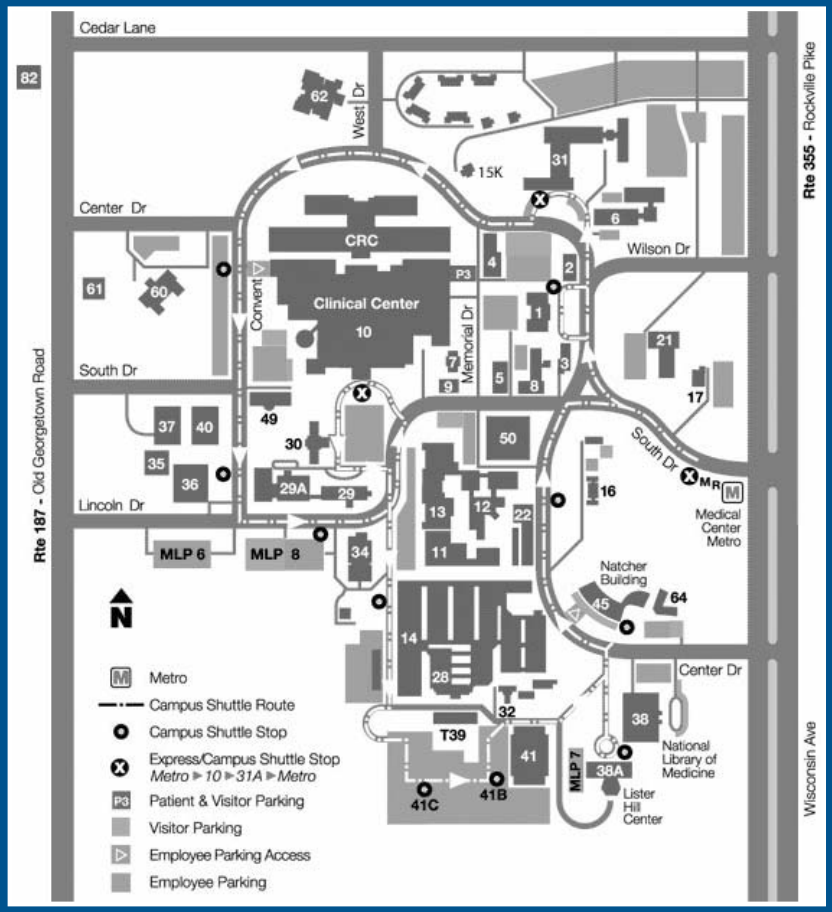
Continuing Umbrella of Research Experiences (CURE)

The NCI offers administrative supplements to the R25T, K12, T32, and P30 programs for introductory science experiences at the high school level with the aim of developing well-trained minority scientists who are capable of conducting independent cancer research.

Minority Institution/Cancer Center Program

The NCI supports the planning and implementation of pilot projects/programs for focused collaborations between scientists and faculty at a minority serving institution and at a cancer center. NCI also supports the creation of comprehensive partnerships between minority serving institutions and NCI-designated Cancer Centers or groups of centers. The long range goal of these programs is to increase the cancer research capabilities of a minority serving institution by increasing the number of minority scientists engaged in cancer research and to improve the effectiveness of NCI-designated Cancer Centers in developing and sustaining activities focused on the disproportionate incidence, mortality, and morbidity in minority populations in the region the cancer center serves.

- Planning Grant for Minority Institution/Cancer Center Collaboration (P20).
- Comprehensive Minority Institution/Cancer Center Partnership (U54).
- Cooperative Planning Grant for Comprehensive Minority Institution/Cancer Center Partnership (U56).



Map of NIH Main Campus, Bethesda, Maryland

http://des.od.nih.gov/eWeb/parking/html/parking.htm

PART V

References and Resources

Additional Sources of Information

Grant Process and Administration Information

The preceding sections of this publication provide a general description of a complex process. We hope that they have served as an introduction to the grants process and that they provide an overview of the various aspects of grant review and administration.

Grant Application Receipt Dates and Review and Award Schedule Information

Specific questions regarding grant application receipt dates and review and award schedules should be directed to the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH, at (301) 435-0715. CSR's homepage is located at http://www.csr.nih.gov/.

Pre-submission Advice

NIH policy requires applicants requesting $500,000 or more in direct costs for any year of the project to seek agreement to accept assignment from Institute/Center staff at least six weeks prior to the anticipated submission of the application. NCI staff are available to provide pre-submission advice on this or any other topic. They can provide helpful comments and advice regarding the general approach taken in preparing an application. Applicants are encouraged to contact the Office of Referral, Review, and Program Coordination, Division of Extramural Activities (DEA), NCI, at (301) 496-3428.

Program Announcements and Requests for Applications

Program announcements, which describe continuing, new, or expanded program interests for which grant applications are invited and Requests for Applications, which are issued to invite grant applications in a well-defined scientific area to accomplish a specific NCI programmatic purpose, are published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html). The *NIH Guide for Grants and Contracts* is the official publication of NIH program and policy notices. It is available via the NIH Office of Extramural Research (OER) web site (http://grants.nih.gov/grants/oer.htm).

Additional information about the *NIH Guide for Grants and Contracts* can be obtained from GrantsInfo, which is a service of the Division of Extramural Outreach and Information Resources, OER, Office of the Director, NIH. GrantsInfo is the point of contact for obtaining general information about NIH extramural research and research training programs, requesting publications, and learning more about obtaining the *NIH Guide for Grants and Contracts* and other information on the NIH system of web sites. Organizations may request application kits and forms from GrantsInfo if these materials cannot be accessed from one of the following web sites (http://grants.nih.gov/grants/forms.htm) or (http://grants.nih.gov/grants/oer.htm).

GrantsInfo
Division of Extramural Outreach and Information Resources
Office of Extramural Research
National Institutes of Health
6701 Rockledge Drive, Suite 3210
Bethesda, MD 20892-7910
Telephone: (301) 435-0714
E-mail: GrantsInfo@nih.gov

Additional Information Resources

Additional grants information may be obtained by referring to the publications listed below.

The following publications may be obtained from the Internet:

- *NIH Grants Policy Statement* (Revised 3/1/01):
  http://grants.nih.gov/grants/policy/nihgps_2001/
- *NIH "Welcome Wagon" Letter -- Information for New Grantees*
  (also helpful to established grantees)
  http://grants.nih.gov/grants/funding/welcomewagon.htm
- *Catalog of Federal Domestic Assistance (CFDA):*
  http://aspe.os.dhhs.gov/cfda/index.htm or
  http://www.cfda.gov/default.htm
- *NCI Fact Book: National Cancer Institute:*
  http://www.nci.nih.gov/admin/fmb/

Most NCI publications may be found on the web 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, Maryland 20892
Toll-free number for the public: 1-800-4-CANCER
TTY number for the deaf: 1-800-332-8615

The following publications are available from:

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.*

Useful Web Sites

The NCI and NIH web sites listed below may contain helpful information.

- *GAB Home Page:*
  http://www3.cancer.gov/admin/gab/index.htm

  (Note: The electronic version of this publication, Everything You Wanted to Know About the NCI Grants Process, can be accessed through this web site. Please let us know what you think of this publication by contacting us via the Feedback section on our web site.)
- *NCI Home Page:*
  http://www.nci.nih.gov/
- *NIH Home Page:*
  http://www.nih.gov/
- *NIH Email and Telephone Directory, Maps, Almanac, Director's Page:*
  http://www.nih.gov/about/
- *NIH Search Engine:*
  http://search.nih.gov/

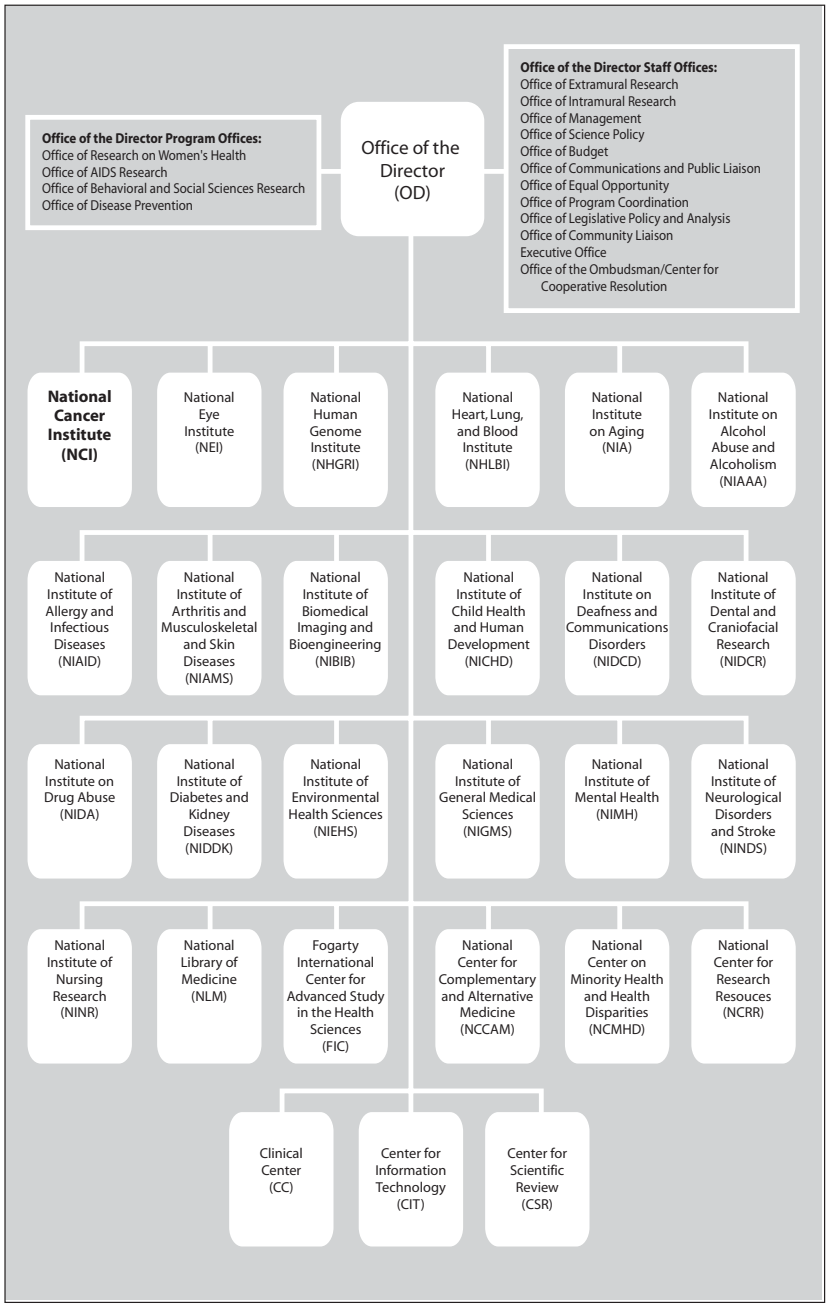
- *NIH Grants and Contracts Page:*
  http://grants.nih.gov/grants/index.cfm
- *NIH Office of Extramural Research (OER) Home Page:*
  http://grants.nih.gov/grants/oer.htm

  (Note: Electronic Research Administration (ERA), Edison, Peer Review Policy and Issues, NIH Guide for Grants and Contracts, and CRISP can all be accessed through this web site.)
- *NIH Funding Opportunities: Grants:*
  http://grants.nih.gov/grants/funding/funding.htm
- *NIH Forms and Applications:*
  http://grants.nih.gov/grants/forms.htm
- *NIH Grants Policy and Guidance:*
  http://grants.nih.gov/grants/policy/policy.htm
- *NIH Guide for Grants and Contracts:*
  http://grants.nih.gov/grants/guide/index.html

The additional web sites listed below may also contain helpful information.

- *U.S. Federal Government Agency index:*
  http://www.lib.lsu.edu/gov/fedgov.html
- *Code of Federal Regulations:*
  http://www.access.gpo.gov/nara/cfr/cfr-table-search.html
- *Office of the Federal Register, National Archives and Records Administration:*
  http://www.access.gpo.gov/nara/index.html
- *Office of Management and Budget (OMB) Circulars:*
  http://www.whitehouse.gov/omb/circulars/

Figure 17. NIH Organizational Chart



PART VI

Cross-Cutting Public Policies

Cross-Cutting Public Policies

There are 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, ecomonic, or other objectives or considerations that may be attached to the expenditure of Federal funds by grantees, consortium participants, and contractors, in general, or may relate to the expenditure of Federal funds or research or other specified activities. In addition to cross-cutting requirements that apply to Federal agencies and their grant programs, 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 requirements are included here because they have been part of appropriations acts for several years without change, but those requirements may be changed or other requirements may be added in the future. The NIH intends to uphold 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 applicable certifications and assurances referenced (and, in some cases, included) in the application package. These include the following as discussed in this section:

- **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 DHHS 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, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et seq.) and other Federal statutes and regulations pertaining to animals.

- **Architectural Barriers to the Handicapped (Elimination of)**—Architectural Barriers Act of 1968, as amended, the Federal Property Management Regulations 101-19.6 (41 CFR 101-19.6), and the Uniform Federal Accessibility Standards issued by the General Services Administration (41 CFR 101-19.6, Appendix A) set forth requirements to make facilities accessible to, and usable by, the physically handicapped, and include minimum design standards. 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 DHHS implementing regulations are codified at 45 CFR Part 80.

- **Data and Safety Monitoring**—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, FDA, and the NIH Guidelines for Research Involving Recombinant DNA Activities. The level of monitoring should be commensurate with the risks and the 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, and the DSMBs 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 organi-

zation 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 organizational official agrees that the grantee will provide a drug-free workplace and will comply with requirements to notify 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)."

- **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 unless an extension is granted by the GMO. Failure to submit timely and accurate final reports may affect future funding to the organization or awards to the same 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. Please contact:

  NCI FOI Coordinator
  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 award can be made, a domestic applicant organization must certify that it is in 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 DHHS implementing regulations are codified at 45 CFR Parts 84 and 85.

- **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 a human embryo(s) for research purposes or for research in which a human embryo(s) is 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, 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://www.nih.gov/news/stemcell/index.htm.

- **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 for influencing or attempting 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, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition. Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that (1) they have not made, and will not make, such a prohibited payment, (2) they will be responsible for reporting the use of non-appropriated funds for such purposes, and (3) 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 organizational 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) Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting or reporting research all constitute misconduct in science. 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 NIH to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by grantees (also see DHHS 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 and contractors and consortium participants and other organizations receiving funds under NIH grants and contracts, whether small businesses, large businesses, or non-profit 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 (and, in some cases, employee inventors) have rights to inventions conceived or first actually reduced to 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://grants2.nih.gov/grants/policy/nihgps_2001/part_iia_6.htm#InventionsandPatents). 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 and Certification (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 the Division of Extramural Invention Reports and Technology Resources, Office of Extramural Activities, NIH. Requests 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 identifying information). These safeguards include the rights of individuals to determine what information about them is maintained 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 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, MD 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 103-227, Title X, Part C, imposes restrictions on smoking in facilities where federally funded children's services are provided. The Act specifies that smoking is prohibited in indoor facilities (or in some cases portions of

facilities) used routinely or regularly for the provision of health care, day care, early childhood development, education, or library services to persons under 18, if the services are funded by applicable Federal funds, either directly or through State or local governments. Applicable Federal funds include grants, cooperative agreements, loans, loan guarantees, contracts, and funds for construction, maintenance, and operations awarded by the Departments of Health and Human Services, Education, or Agriculture. All grants, including both discretionary and nondiscretionary grants, are covered under this Act.

- **Protection of Human Subjects**—(45 CFR Part 46) Protection of human subjects, in accordance with 45 CFR Part 46, 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 from individually identifiable human beings. 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)) which normally involve little or no risk.

- **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.

- **Required Education in the Protection of Human Subjects**—Beginning on October 1, 2000, NIH implemented a policy requiring education on the protection of human research participants for all key personnel submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for projects involving human research participants. Before funds are awarded for applications or contract proposals involving human subjects, documentation must be submitted that all key personnel have received training in the protection of human subjects. Additional information on this requirement may be found on NIH Office of Extramural Research (OER) web site, specifically at http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

- **Salary Limitation**—The Department of Health and Human Services (DHHS) Appropriation Act for FY 2002, 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 concerning salary limitations, see the NIH Guide for Grants and Contracts (http://www.nih.gov/grants/guide/index.html) and use the search feature.

- **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 DHHS implementing regulations are codified at 45 CFR Part 86.

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

- **Suspension**—(45 CFR Part 76 and 45 CFR Part 92.43) Temporary withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by NCI, or a decision by NCI to terminate the award. NIH will generally suspend (rather than immediately terminate) a grant and allow the grantee an opportunity to take appropriate corrective action prior to NIH's making a termination decision. NIH may decide to terminate the grant if the grantee does not take appropriate corrective action during the period of suspension. However, NIH may terminate without first suspending the grant if the deficiency is so serious as to warrant immediate termination or public health or welfare concerns require immediate action.

- **Termination**—(45 CFR Part 76 and 45 CFR Part 92.43) Permanent withdrawal by NCI of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee. NIH may terminate without first suspending the grant if the deficiency is so serious as to warrant immediate termination or public health or welfare concerns require immediate action. A grant also may be terminated, partially or totally, by the grantee or by NIH with the consent of the grantee.

- **Withholding of Support**—A decision not to make a non-competing continuation award within the current competitive segment. Withholding may occur for one or more of the following reasons: 1) A grantee is delinquent in submitting required reports; 2) Adequate Federal funds are not available to support the project; 3) A grantee fails to show

satisfactory progress in achieving the objectives of the project; 4) A grantee failed to meet the terms of a previous award; 5) A grantee's management practices fail to provide adequate stewardship of Federal funds; and 6) Any reason that would indicate that continued funding would not be in the best interests of the Federal Government.

PART VII

Glossary

Glossary

This glossary defines terms and phrases most commonly used in the award and administration of NIH grants.

- **Application**—A formal request for financial assistance for a project/activity submitted to NIH on the appropriate application form:
  - Form PHS 398, except as shown in the table below, is used for all new competing applications (Type 1) or competing continuation applications (Type 2). This same form is 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 of the competing application forms have corresponding forms to be used when applying for non-competing continuation support during an approved competitive segment. The form corresponding to PHS 398 is Form PHS 2590. Some of these forms may be accessed from one of the following web sites (http://www.nih.gov/grants/forms.htm) and (http://www.nih.gov/grants/oer.htm).

APPLICATION FORMS	USE FORM NUMBER
Small Business Innovation Research Program—Phase I	PHS 6246-1
Small Business Innovation Research Program—Phase II	PHS 6246-2
Small Business Technology Transfer Program—Phase I	PHS 6246-3
Small Business Technology Transfer Program—Phase II	PHS 6246-4
Individual 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 to support or stimulate a public purpose authorized by Federal statute. Assistance relationships are expressed in less detail than are acquisition relationships, and responsibilities for ensuring performance rest largely with the recipient or are shared with the NCI.
- **Award**—The provision of funds by NCI, based on an approved application and budget, to an organization or an individual to carry out an activity or project.
- **Budget**—A categorical or non-categorical 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)***—(http://aspe.os.dhhs.gov/cfda/index.htm) or (http://www.cfda.gov/default.htm) 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.
- **Competitive Segment**—The initial project period recommended for support (usually one to five 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 (R&D)**—An instrument used by 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 that part of the grant review and award cycle in which NCI has the most influence, the award negotiation and issuance, which accounts for two months of the 10-12 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 which, therefore, cannot be identified specifically with a particular project or program.
- ***Federal Register***—(http://www.access.gpo.gov/su_docs/aces/aces140.html) 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.
- **Financial Status Report (FSR)**—A financial report due no later than 90 days after the end of each budget period or, for grants in the SNAP population, excluding those awards to Federal institutions or foreign organizations, no later than 90 days after the end of each competitive segment. The FSR shows the status of awarded funds for the competitive segment as maintained in the official accounting records of the grantee institution. 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 NCI that assumes legal, financial, and scientific responsibility and accountability both for the awarded funds and for the performance of the grant-supported activity. A grantee organization can be public or private, nonprofit or for-profit, 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**—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(s) or set of activities. NCI is an IC.
- **Initial 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.
- **Institutional Animal Care and Use Committee (IACUC)**—A committee set up by an institution to review at least once every six 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 rights and welfare of human research subjects participating in research conducted under its auspices. The IRB makes an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.
- **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 NIH supports rather than on the details of budgets. Under modular budget proposals, applicants are instructed to prepare the budget request in direct cost modules of $25,000 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 of the 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 or the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.

- **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 responsible for directing or conducting 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 range is from .1 to 99.9.
- **Preapplication**—A statement in summary form of the intent of the applicant to request funds. Preapplications 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 for 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 or 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 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 postaward changes in 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 service 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. NCI uses RFAs to announce cooperative agreements. PAs are published in the NIH Guide for 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 is comprised of the initial competitive segment and extensions.
- **Recipient**—The organizational entity or individual receiving a grant or cooperative agreement. See 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 to adjustments made in accordance with applicable grant policies, 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)**—Award for an investigator-initiated research proposal.
- **Scientific Review Administrator (SRA)**—A Federal scientist who presides over an Initial 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 IRG.

- **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 pre-established 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 Non-Competing Award Process (SNAP)**—A streamlined process that eliminated two of the financial documents that were part of the non-competing application: 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 NIH requires to review and approve non-competing continuation applications and to monitor these awards. As a result, for awards under SNAP, grantees are required to submit only limited portions of the PHS-2590, including an annual progress report. As part of the progress report, grantees must answer questions pertaining to other support, unobligated balances, and change in the level of effort of key personnel. If there is a change in performance site and/or if there is anticipated program income, grantees also must submit the PHS-2590 checklist and, if program income is anticipated, must include the estimated amount and source of the income. Grantees (other than foreign grantees and Federal institutions) also are required to submit a quarterly Federal Cash Transactions Report (FCTR) (SF-272) to the Payment Management System (PMS). 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. This FSR must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FSR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FSR

- **Study Section**—The component part of an Initial Review Group that advises on the scientific and technical merit of research applications.

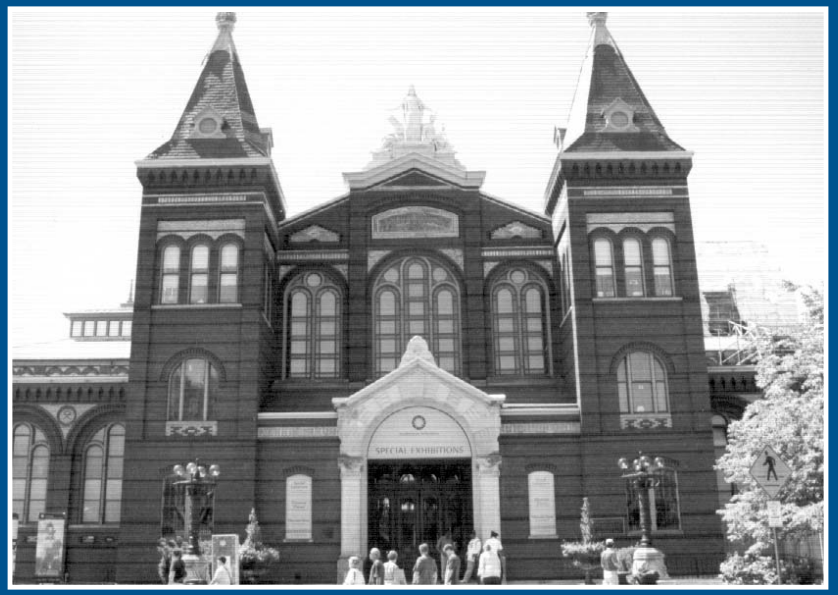
- **Substantial Foreign Component**—Under a grant to a domestic institution, the performance of any significant element or segment of the project outside of the United States, either by the grantee or by a researcher employed by a foreign institution, with or without grant funds.

- **Success Rate**—The number of funded applications divided by the number of applications reviewed by Initial 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 postaward 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 costs 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.



Exhibits

Exhibit A. Grant Application Face Page

AA

Form Approved Through 05/2004
OMB No. 0925-0001

Department of Health and Human Services
Public Health Service

Grant Application

Follow instructions carefully.
Do not exceed 56-character length restrictions, including spaces

LEAVE BLANK — FOR PHS USE ONLY.

Type	Activity	Number
1	R01	CA-100228-01

Review Group: BEM — Formerly:
Council/Board *(Month, Year)*: Sept 2001 — Date Received: 01/28/2001

1. TITLE OF PROJECT
Community Intervention to Reduce Adolescent Tobacco Use

2. RESPONSE TO SPECIFIC REQUEST FOR APPUCATIONS 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.
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, LAB, 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
4a. Research Exempt ☒ No ☐ Yes — If "Yes," Exemption No.
4b. Human Subjects Assurance No.: FWA0000
4c. NIH-defined Phase III Clinical Trial ☒ No ☐ Yes
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 REQUIRED FOR INITIAL BUDGET PERIOD		8. COSTS OF REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
02/01/2002	01/31/2006	225,000	337,500	900,000	1,350,000

9. APPLICANT ORGANIZATION
Name: MASSACHUSETTS RESEARCH INSTITUTE
Address: 500 Aspen Lane
Concord, MA 02134
Institutional Profile File Number (if known)

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
1093465660A1
DUNS No. *(if available)*
Congressional 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
Telephone: 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
Telephone: 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 nay 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.: /S/ — DATE: 01/20/2001

15 APPUCANT 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.: /S/ — DATE: 01/21/2001

PHS 398 Face Page Form Page 1

Exhibit B. Summary Statement

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

SUMMARY STATEMENT
(Privileged Communication)

Application Number: 1 R01 CA100228-01

Review Group: BEHAVIORAL MEDICINE STUDY SECTION - BEM

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

Requested Start Date: 02/01/2002

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

Project Title. Community Intervention to Reduce Adolescent Tobacco Use

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

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

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

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

Continued

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

Exhibit B. Summary Statement *(continued)*

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-year intervals will be used to achieve this aim.

SIGNIFICANCE: Evaluating the effects of community intervention aimed at reducing the prevalence 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.

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

CRITIOUE: This proposal should provide data on the outcome of a combined community-based anti-smoking program and the process by which community activities enhance more focused school-based efforts. The multiple components involved in the community programs are impressive. Parental involvement represents a step forward, but more intriguing still is the effort to expose children to anti-smoking information at the work site. Given the focus on "no smoking" rules to reduce availability at schools, it is surprising that no smoking rules at work sites are not explored. Involvement of health care providers is also useful.

Randomizing small communities to either a school program only or a program with community effort will allow a rare, experimental test of the effects of the combination relative to school alone. While it is true that a community-only condition would enhance the internal validity of the design, it appears that it may be impossible to run a community program without a school program.

The analytic plan is carefully explicated with respect to traditional norms; e.g., the power analyses seem on target, as do the statements on the analysis of treatment effects. The use of a sum score for the community activity in smoking prevention permits an additional strong test of program efficacy. It is noted that the plan for the data analysis, particularly the ANOVA strategy, is a strength of this study. Clearly, ANOVA is better than a change-score (post minus pre) approach. And with several cases, it will be possible to use modern plotting and diagnostic methods to fully understand how each community fits into the total picture.

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

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

Exhibit C. Ranking List

Paylist Report

December 2001

Cancer Activity: Prevention
Cost Center: Research Project Grants
Budget Mechanism: Traditional Research Grants

Payline: 21.00

Paylist Number: 1309

Grant Number	Principal Investigator	Board Meeting Date	Start Date	Program Director	Pri[1] Scr	Pctl[2] Rank	Total[3] Cost	Estimated Program T.C. Recommended	Pay Sel	AIDS %
100194-01	JAMES	2001/06	1/1/2002	ANTHONY	120	2.2	350,766	299,112	X[4]	N
100228-01	**MARTIN**	**2001/09**	**2/1/2002**	**SANDERS**	**135**	**5.3**	**337,500**	**300,000**	**X**	**N**
100220-01	LIU	2001/09	2/1/2002	SANDERS	140	6.1	305,710	290,344	X	N
100210-01	JOHNSON	2001/09	1/1/2002	ANTHONY	176	20.5	412,212	380,451	X	N
100224-01	STONE	2001/06	1/1/2002	SING	180	21.0	390,003	375,510	X	N
100214-01	DANIELLE	2001/09	2/1/2002	SING	199	26.0	280,990			N
100243-01	LUZAR	2001/09	2/1/2002	SANDERS	211	28.7	240,765			N
100234-01	BAILEY	2001/09	2/1/2002	ANTHONY	220	29.1	190,945			N

Notes:
1 Priority Score
2 Percentile Rank
3 Total Cost under current funding policy
4 Funding Selection

Recommending Official (Signature/Date) /s/
(Branch Chief)

Approving Official (Signature/Date) /s/
(Division Director)

Certifying Availability of Funds (Signature/Date) /s/
(Chief-NCI OM EFDB)

Grants Management Officer (Signature/Date) /s/

Exhibit D. Notice of Grant Award

********** NOTICE OF GRANT AWARD **********
RESEARCH Issue Date: 01/24/2002
Department of Health and Human Services
National Institutes of Health
NATIONAL CANCER INSTITUTE
****

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

ASSOC DIR, SPONSORED PROGRAMS
MASSACHUSETTS RESEARCH INSTITUTE
500 ASPEN LANE
CONCORD, MA 02134

Budget Period: 02/01/2002 - 01/31/2003
Project Period: 02/01/2002 - 01/31/2006

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $258,990(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.

Leo F. Buscher Jr.

Chief Grants Management Officer, NATIONAL CANCER INSTITUTE

Exhibit D. Notice of Grant Award *(continued)*

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.

02 $300,000
03 $300,000
04 $300,000

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

IC / CAN / FY2002 / FY2003 / FY2004 / FY2005
CA / 8422842 / 300,000 / 300,000 / 300,000 / 300,000

NIH ADMINISTRATIVE DATA:
PCC: 5CCJ2842 / OC: A1.4A / Processed: EDWARDSJ 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.

Exhibit D. Notice of Grant Award *(continued)*

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

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

Treatment of Program Income:
Additional Costs

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 2002 award to the committed total direct cost level for each future year.

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. The significant rebudgeting provision does not apply to Modular Grant Awards. Therefore, future noncompeting SNAP applications should indicate "N/A" for question number (2) regarding significant rebudgeting.

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://www3.cancer.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
Jennifer Edwards, Grants Specialist
Phone: 301 496-7800 Email: gms@nih.gov

SPREADSHEET

GRANT NUMBER: 1 R01 CA100228-01
P.I.: Martin, Andrew
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

Exhibit E. Summary Progress Report

Principal Investigator/Program Director (Last, first, middle): Martin, Andrew

PROGRESS REPORT SUMMARY

Grant Number
CA100228-02

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	PERIOD COVERED BY THIS REPORT FROM	THROUGH
Andrew Martin	02/01/2002	01/31/2003

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 ☒ No Change Since Previous Submission ☐ Change.

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ 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 key personnel from what was approved for this project? NO.
3. Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current yearês total budget? NO.

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

b. Studies and Results
Our progress 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 problems of youth. Organizations in each sector of the community have been sampled, and 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 set of task forces to work on issues of adolescent tobacco use have been identified.

3. Although results are not yet available about the efficacy of this intervention, we have developed numerous modules for a community intervention and have identified ways to mobilize community members to reduce tobacco use. We have also identified ways to recruit communities to participate in such a study. If we find that the intervention programs have significant effects on the attitudes of young people or their parents, we will have defined low-cost, effective methods of modifying two major influences on tobacco use - other young people and parents.

4. During the coming year, we will recruit three pairs of matched communities to participate in the project. Adolescents and a sample of their parents will be assessed in those communities plus the two communities we are already working in. Teachers will be trained to implement tobacco prevention programs in grades 6-12 in both treatment and control communities.

PHS 2590 (Rev. 05/01) Page 2 Form Page 5
(Use continuation pages if necessary)

Exhibit F. Financial Status Report

[Note: FSRs for SNAP awards are due only at the end of each competitive segment or after the grant transfers to a new institution]

ELECTRONICALLY TRANSMITTED FINANCIAL STATUS REPORT

1. NIH
2. GRANT ID 5R01CA100228-04
   Recipient Organization: MASSACHUSETTS RESEARCH INSTITUTE
4. ID 12302
5. Recipient ID 1093465660A1
8. Project Period 02/01/2002 / 01/31/2006
9. Report Period 02/01/2002 / 01/31/2006

10.

a. Net Outlays previously reported	0.00	(10A)
b. Total Outlays this report period	1,200,000.00	(10B)
c. Less: Program Income Credits-deduction alternative	0.00	(10C)
d. Net outlays this report period	1,200,000.00	(10D)
e. Net outlays to date	1,200,000.00	(10E)
f. Less: Non-Federal share of outlays	0.00	(10F)
g. Total Federal share of outlays	1,200,000.00	(10G)
h. Total unliquidated obligations	0.00	(10H)
i. Less: Non-Federal share of unliquidated obligations	0.00	(10I)
j. Total Federal share of unliquidated obligations	0.00	(10J)
k. Total Federal share-outlays & unliquidated obligations	1,200,000.00	(10K)
l. Total cumulative amount of Federal funds authorized	1,200,000.00	(10L)
m. Unobligated balance of Federal funds	0.00	(10M)
x. Grantee carryover request	0.00	(10X)
z. Previous budget period carryover request	0.00	(10Z)
v. Disbursed Program Income-Addition Alternative	0.00	(10V)
w. Undisbursed Program Income	0.00	(10W)
y. Total Program Income Realized	0.00	(10Y)

11. Indirect Expense

Rate	Base	Subtotal	Total	Fed Share
50.00 (b)	200,000.00 (c)	100,000.00 (f)	100,000.00 (d)	100,000.00 (e)

Remarks:

13a. Authorized Official	EVAN THOMAS
b. Title	ADMINISTRATIVE COORDINATOR
c. Date	06/10/2006
d. Phone	617-444-0001

RCVD: 06/11/2006
ACCEPTED: 06/11/2006

NIH Publication No. 02-1222
Revised April 2002
Printed September 2002

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