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# FACT BOOK

National  
Cancer  
Institute



1991

U.S. DEPARTMENT  
OF HEALTH AND  
HUMAN SERVICES

Public Health  
Service

National  
Institutes of  
Health

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The information set forth in this publication is compiled and amended annually by the financial management staff of the National Cancer Institute and is intended primarily for use by members of the Institute, principal advisory groups to the Institute and others involved in the administration and management of the National Cancer Program. Questions regarding any of the information contained herein may be directed to the Financial Manager, National Cancer Institute, 9000 Rockville Pike, Bethesda, Maryland 20892.

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Prologue

Organization

Cancer Statistics

1991 Budget Data

AIDS

Extramural  
Programs

Historical Trends

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## Significant Initiatives In 1991

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### Division of Cancer Biology, Diagnosis and Centers

The development of recombinant toxins as anti-cancer agents represents an exciting new therapeutic approach to cancer and other diseases.

Recombinant bacterial toxins, which lack the portion of the toxin molecule that binds to cells, can be coupled to monoclonal antibodies, growth factors, or other molecules that can target the toxin to a specific cell type. The transferrin growth factor alpha ( $TGF\alpha$ ) can effectively target and bind to cancer cells that express the epidermal growth factor receptor (EGFR).  $TGF\alpha$  has been conjugated to a portion of the *Pseudomonas* exotoxin molecule to form  $TGF\alpha$ -PE40. A clinical trial has been initiated in which  $TGF\alpha$ -PE40 will be administered into the urinary bladder as local therapy to patients with bladder cancer. Another modified toxin molecule, CD4-PE40, has been constructed in which the portion of the CD4 molecule that binds to the AIDS virus has been combined with PE40. In *in vitro* studies, CD4-PE40 has been shown to be effective in killing T cells infected with HIV; and in combination with AZT, has shown an even more powerful effect than either agent given alone. A phase I clinical trial at NIH has recently begun with CD4-PE40 being administered intravenously to patients with AIDS.

Gene therapy is yielding promising results in the treatment of an inherited immunodeficiency disease; similar approaches are being developed for the treatment of AIDS.

On September 14, 1990, the first authorized use of gene transfer to treat human disease was performed. The patient was a four year old girl with an inherited immunodeficiency disease caused by a deficiency of the gene that encodes the enzyme adenosine deaminase (ADA). Normal functional ADA genes were inserted into the girl's own peripheral blood T cells, expanded in tissue culture, and the gene corrected T cells were returned intravenously to the patient. This girl and a second patient have been treated every 5-7 weeks and both are showing signs of enhanced immunological reactivity. The first child has undergone extensive tests which indicate that her immune function approaches normal levels. Similar cellular reconstitution protocols are being developed to treat patients with AIDS in the coming year.

The oncogene *bcl-2* encodes a novel type of protein that protects cells against programmed cell death.

The phenomenon of programmed cell death is of great current interest because it has been found to be important in such diverse processes as immune killing of tumors or virus-infected cells and elimination of self-reactive cells during immune system development. One of the genes important in resistance to programmed cell death has now been shown to be the oncogene *bcl-2*. The *bcl-2* protein prolongs the life of cells in which it is expressed. *Bcl-2* was discovered as the gene on chromosome 18 that is involved in a chromosomal translocation in follicular lymphoma, the most common human lymphoma. It has now been shown to be expressed in the mitochondria of cells. Its exact function remains unknown, but overexpression leads to malignant transformation.

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## **Division of Cancer Treatment**

### ***Human Gene Therapy***

In May, 1989, in attempt to "activate" TIL cells so that they become even more effective in killing tumor cells, scientists from NCI the and National Heart, Lung and Blood Institute began the first clinical trial in which a foreign gene transfected into a human cell was given to a patient. This preliminary study involved the transduction of the neomycin resistance gene (neo) into TIL cells in order to monitor their traffic throughout the body and, thus, help scientists better understand how these cells work in cancer therapy. This landmark study, the first approved study to introduce foreign genes into humans, showed that retroviral gene insertion is feasible and safe.

The first gene therapy trial designed to infuse tumor infiltrating lymphocytes (TILS) containing the inserted human gene for tumor necrosis factor (TNF) into patients with advanced melanoma began in January, 1991. The TNF gene was selected for this trial because it has shown dramatic cancer cell-killing potential in mice. In order to maximize the cancer cell-killing potential of TNF and to minimize the anticipated toxic effects of TNF in humans, scientists intend to target these transfected TILS in a tumor specific manner, thus sparing normal cells from TNF toxicity.

This human gene therapy trial is designed to both determine the safety of administering TNF to humans and improve TIL/IL-2 therapy. The implications of this study are far-reaching; this new approach may eventually have applications to the treatment of a variety of cancers as well as provide new avenues for the treatment of a variety of disease caused by the inactivity or lack of certain genes, i.e., sickle cell anemia, cystic fibrosis, and alpha-1-antitrypsinase deficiency, among others. More recently, a second gene therapy trial has begun in cancer patients using gene modified tumor as a cancer "vaccine" to immunize patients with advanced cancers against their own tumors.

### ***Clinical Drug Resistance***

One of the major roadblocks for chemotherapeutic agents is the development of clinical resistance, i.e., the acquired ability of a neoplastic cell to become insensitive to the effects of chemotherapeutic agents through a variety of adaptive mechanisms. The antimetabolite class of antineoplastic agents represents one of the most commonly used group of agents for the treatment of a variety of human tumors including the leukemias, the lymphomas, and carcinoma of the breast, gastrointestinal, and upper aerodigestive systems. These agents produce their cytotoxic effects by inhibiting certain critical intracellular target enzymes. Recent studies have indicated that an important mechanism by which malignant cells become insensitive to these agents is by an acute amplification of these target enzymes. A critical mechanism in the regulation of this acute induction appears to be the efficiency with which the messenger RNA encoding for the enzymes is translated. The level of the target enzyme central to 5 FU therapy, thymidylate synthase, appears to be regulated by a unique autoregulatory pathway wherein the protein end product can control the efficiency of its own translation. Recent studies have suggested that the use of interferon, particularly gamma-interferon, can interdict the acute induction of thymidylate synthase and thus render malignant cells sensitive to the effects of the fluoropyrimidines. These observations have been applied to the treatment of patients with advanced gastrointestinal malignancies using the combination of 5 FU, leucovorin, and alpha-interferon. The preliminary results of these trials have been sufficiently encouraging to prompt the testing of this regimen in the adjuvant setting for patients with colon carcinoma.



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### *Tumor Suppressor Genes*

We have identified in human lung cancer a consistent pattern of somatic mutations targeted to a limited number of tumor suppressor genes. For example, we have found that the retinoblastoma gene (a paradigm for tumor suppressor genes) is inactivated in at least 95% of all small cell lung cancer samples, while in non-small cell lung tumors the retinoblastoma gene is inactivated in approximately 10% of samples tested. In small cell lung we have observed inactivation of the retinoblastoma gene resulting from large structural deletions of DNA with absent mRNA production and by subtle point mutations resulting in dysfunctional protein products. Another tumor suppressor gene, the p53 gene, is also a target for frequent somatic mutations in both small cell lung cancer and non-small cell carcinomas. Experiments in progress have shown that the re-introduction of the retinoblastoma gene into lung cancer cell lines result in suppression of tumorigenicity in nude mice assays, a finding consistent to treat previously reported in similar experiments with retinoblastoma tumor cell lines. Re-introduction of the p-53 gene has even more dramatic effects with consistent suppression of cell growth in vitro. In collaboration with the Pulmonary Branch, NHLBI, we are constructing a series of retroviral vectors containing either the retinoblastoma gene or the p53 gene to directly test tumor suppression in vivo.

### *Nitroxides as Protectors Against Oxidative Stress*

The term "oxidative stress" has emerged to encompass a broad variety of stresses, some which have obvious implications for health care. Many modalities used in cancer treatment including x-rays, and some chemotherapy drugs, exert their cytotoxicity via production of oxygen related free radicals thereby imposing added burdens to normal detoxification systems. A variety of toxic oxygen-related species including superoxide, hydrogen peroxide, and hydroxyl radical can be produced and when left unchecked these free radical species can undoubtedly damage cells and tissues. Free radicals and toxic oxygen-related species have been implicated in ischemia/reperfusion injury and have long been thought to be important in neutrophil-mediated toxicity of foreign pathogens. There is obvious interest in devising additional approaches, apart from inherent intracellular detoxification systems, to protect cells, tissues, animals, and humans against oxidative stress. We have identified a set of stable nitroxides that possess superoxide dismutase-like activity and have the advantage of being low molecular weight, cell membrane permeable, metal independent, and are capable of completely protecting mammalian cells against cytotoxicity from superoxide generated by hypoxanthine/xanthine oxidase and cytotoxicity from hydrogen peroxide exposure, although they exhibit no catalase-like activity. Further, we have recently demonstrated that nitroxides afford protection against ionizing radiation for both in vitro and in vivo systems. We have also shown that nitroxides protect against radiation-induced alopecia in mammals. Since these agents can detoxify superoxide, hydrogen peroxide, and prevent reduction of hydrogen peroxide to the highly toxic hydroxyl radical, they may ultimately have application in protection from biologic damage caused by post-ischemic reperfusion injury associated with re-opening of arteries after heart attacks or strokes, as well as lessening the life threatening toxic effects of exposure to elevated oxygen concentration as is sometimes necessary while providing life support during acute care. The Radiation Biology Section of the Radiation Oncology Branch is currently conducting studies to further understand the mechanism(s) of nitroxide protection with the aim of bringing appropriate compounds to clinical trials.

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### ***Interleukin-2 and R24.***

The Clinical Research Branch has treated 23 patients with metastatic melanoma with high doses of IL-2 alone for three weeks followed by treatment with escalating doses of the mouse monoclonal antibody R24 in combination with lower doses of IL-2. Responses have been noted in 10 of the 23 valuable patients. There appears to be no correlation between peripheral blood NK activity and tumor regression, but responding patients had significantly more IFN $\gamma$  in their sera than nonresponders. Patients continue to be treated on this study with the addition of intralesional injection of R24 to enhance local immunity.

### ***Taxol***

Taxol is one of the most important new anticancer agents developed in the last 10 to 15 years. It has demonstrated reproducible activity in women with refractory ovarian cancer, producing either partial or complete remissions in 30-35% of the patients. Although not as far advanced, studies in women with advanced breast cancer are at least equally promising, and there are preliminary indications of activity in some forms of lung cancer. A Cooperative Research and Development Agreement (CRADA) was signed with Bristol-Myers Squibb, under which that company is responsible for carrying out whatever tasks are required to obtain FDA approval for marketing and to develop as rapidly as possible alternative sources of the drug, which is currently obtained from the bark of the Pacific yew, *Taxus brevifolia*.

## **Division of Cancer Etiology**

### ***Dietary Mutagens***

A number of chemicals known as aminoimidazoazaarenes (AIAs) have been purified from cooked ground beef, a major protein source in the western diet. All but one, PhIP, characterized to date, are very potent mutagens in a bacterial assay system known as the Ames test. PhIP is a relatively weak mutagen, but it is present in ten-fold greater concentrations in cooked beef than any of the other AIAs, and is the most potent AIA in mutagenicity studies utilizing mammalian cells rather than bacteria.

Thus far only three of the AIAs, referred to as IQ, MeIQ and MeIQx, have been evaluated in long-term rodent bioassays, and all three have been found to induce a variety of tumors including tumors of the liver and gastrointestinal system. The toxic effects of this group of chemicals is thought to be based on their metabolism to reactive forms which can react with DNA to form complexes known as adducts. Synthesis of several reactive metabolites of IQ have now been accomplished. Synthesis and characterization of the major DNA-IQ adducts and examination of DNA-IQ adducts in rodents and non-human primates is underway. The role of specific cytochrome P-450s in the metabolic activation of IQ is being evaluated. One such adduct was synthesized and shown to be formed *in vitro* when either of two metabolites reacted with DNA. Recently, several cynomolgus monkeys receiving daily oral doses of IQ at 20 mg/kg were diagnosed with liver tumors. The tumors appeared approximately 30 months following exposure to a latent period similar to the latent period of diethylnitrosamine, the most effective liver carcinogen ever tested in non-human primates. Studies in non-human primates on the carcinogenic of IQ 8-meIQx and PhIP are underway. Thus far, IQ has produced tumors in 50% of monkeys given a 20 mg/kg dose, with a latency of about 3 years. The other 2 AIAs have not yet induced tumors, possible because they have not been on test for a sufficiently long period of time.

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### ***Molecular studies with p53:***

The most common cancer-related genetic change known at the molecular level is mutation in the p53 tumor suppressor gene, which is implicated in lung, breast, colon, liver and many other cancers. These p53 mutations can lead to loss of the normal tumor suppressor functions of p53 and to gain of new functions as an oncogene. Recent research findings have linked environmental exposure to a carcinogenic mold product known as aflatoxin B to specific alteration in codon 249 of the p53 gene. This observation provides strong evidence for a molecular mechanism for chemical carcinogenesis. NCI researchers detected the mutation in liver tumor cells of patients in Qidong, China who had also been exposed to aflatoxin. The same mutation in codon 249 was also detected independently by a team of researchers studying liver tumors of patients in southern Africa. Both aflatoxin exposure and viral hepatitis B infection are known risk factors for liver cancer and are suspected in the etiology of liver cancer in both these regions. While direct evidence that aflatoxin induced this specific damage to the p53 gene is still needed, in mutagenesis experiments, aflatoxin causes the same mutation (G to T transversion) observed in these studies and thus strengthens the hypothesis that aflatoxin exposure is directly involved in the etiology of these tumors. Such observations raise the exciting prospect that mutational analysis may uncover the molecular "fingerprints" left by other environmental carcinogens. Accumulating evidence indicates the the p53 mutational spectrum differs among various cancers, and analysis of these mutations is providing clues to the etiology of diverse tumors and to the function of specific regions of p53.

### ***Human Papillomaviruses and Cancer Risk***

The papillomaviruses are small DNA-containing viruses which are associated with benign warts and papillomas in a variety of higher vertebrates, including man. There are now 60 human papillomaviruses (HPVs) which have been identified. Approximately 18 of these have been associated with lesions of the human genital tract, several of which have been associated with genital warts which rarely progress to carcinoma. Others have been associated with cervical dysplasia and other pre-neoplastic lesions which may progress to malignancy. HPVs have also been linked to human cervical carcinoma and other anogenital carcinomas including cancer of the penis, vulvar carcinoma, and perianal carcinoma. Recently major advances have been made in understanding the molecular biology of the HPVs. The viral genes which are expressed in cervical cancer tissues have been identified and shown to be at least in part responsible for the malignant characteristics of the cells. Two viral genes, designated E6 and E7, are now recognized to be transforming genes of the HPVs. The E7 protein has been shown to form stable complexes with a cellular protein, the product of the retinoblastoma (RB) gene. The RB gene is missing or inactivated in a variety of human cancers, leading researchers to believe that the RB protein normally acts to regulate cell growth. By binding to the RB protein, E7 may alter the activity of RB, thereby allowing cells to grow in an uncontrolled fashion. Evidence now exists that the E6 gene product also complexes with a cellular protein that, like RB, is also involved in regulating cell growth. The identification of the viral genes which contribute directly to the deregulated growth of the cancer cell and the identification of the cellular protein with which they interact should provide insight for the screening and development of antiviral agents.

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### *Studies of Cancer in Women*

NCI epidemiologists are pursuing a wide variety of analytical studies designed to elucidate the relationship of exposures and host factors to cancer outcomes specific to women. The approaches utilized in these studies have been both retrospective and prospective in nature, with many of the studies utilizing laboratory probes to better define exposures. Cancers unique to women are the focus of these studies, and include malignancies of the breast, ovary, cervix, endometrium, and vaginal/vulva.

In a large study of breast cancer in relation to oral contraceptives and other exposures, a black-white comparison component has been added which will assess the excess rate of breast cancer among Black women at premenopausal ages. After two years of baseline data have been analyzed, biological specimens will be collected and selected biochemical measurements performed. Other NCI studies are evaluating radiotherapy for breast cancer as a possible risk factor for second primary breast cancer occurring in the contralateral breast. If such a risk exists, the dependence of risk on dose and age at exposure will be evaluated. Individual dosimetry determinations are being made; the record abstraction is underway.

### **Division of Cancer Prevention and Control**

#### *Preventing Breast Cancer with Tamoxifen*

The Tamoxifen Chemoprevention Trial was implemented in the Community Clinical Oncology Program (CCOP) network in FY 1991. The study will test the ability of tamoxifen, an anti-estrogen medication used in postsurgical treatment of early stage breast cancer, to prevent the development of breast cancer in women at increased risk of developing the disease. Based on results from treatment clinical trials, scientists estimate that tamoxifen has the potential to reduce the incidence rate of breast cancer in high-risk women by at least 30 percent. Approximately 16,000 women at increased risk for breast cancer due to age, family history, and personal history (i.e., age at first birth, age at menarche, and previous breast biopsies) will be randomized to receive tamoxifen (20 mg/day) or placebo for an initial period of five years.

While tamoxifen acts as an anti-estrogen in breast tissue by blocking effects of natural estrogens on the breast cells, it has estrogen-like actions at other sites in the body than resemble the effects of estrogen replacement therapy in postmenopausal women. Tamoxifen lowers serum cholesterol, mainly LDL cholesterol, and may slow bone loss associated with osteoporosis. Thus, while the study focuses on decreasing incidence of breast cancer as the major endpoint, cardiovascular effects, alterations in bone/mineral metabolism, occurrence of second primary cancers, and impact on quality of life will also be assessed. The total trial will last ten years.

#### *Polyp Prevention Trial*

This initiative is one of the NCI's first large trials involving dietary modification. In this trial, diets will be modified to a low-fat, high-fiber pattern in an effort to prevent the recurrence of adenomatous polyps of the colon. The multi-center randomized trial involving 2,000 men and women also will investigate the relationships between dietary intervention and intermediate endpoints and between those endpoints and subsequent neoplasia.

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### *Minorities, the Underserved, and Cancer*

NCI has established major initiatives to address the cancer needs of U.S. minorities, low-income groups, and other medically underserved populations who are identified in the report of the Secretary's Task Force on Black and Minority Health in 1983 and emphasized as part of the Healthy People Objectives for the year 2000. Supported by recent data on cancer, program for Black Americans, Native American (American Indians/Alaskan Natives and Native Hawaiians) and Hispanic populations as well as low-income, inner-city, and other medically underserved populations.

The National Black Leadership Initiative on Cancer (NBLIC) is a continuing activity that was implemented by the NCI in late 1987. The purpose of this health education initiative is to solicit the assistance of Black Americans who are leaders in business, civic, religious, and lay communities to develop coalitions that promote NCI's cancer prevention and control goals and stimulate the involvement of the Black American community in this effort. The NBLIC has created a network of concerned and active Black American leaders throughout the country to help organize, implement, and support cancer prevention programs at the national and local level.

The National Hispanic Leadership Initiative on Cancer (NHLIC), modeled after the NBLIC, will address cancer control barriers including risk factors and cancer control service utilization aspects of Hispanic communities through the establishment of six regional offices. NHLIC will directly or indirectly impact an estimated 16 million Hispanics (80 percent of the U.S. Hispanic population) during the first five years. This new initiative will mobilize community leaders to promote utilization of culturally sensitive cancer prevention and control programs.

Because poverty and geographic distance from quality cancer prevention and control services constitute a barrier to the delivery of health care for the people of Appalachia, NCI will initiate the Appalachia Leadership Initiative on Cancer specifically to address these regional concerns.

### *Science Enrichment Program*

In early 1989, the Science Enrichment Program was developed as a two-year pilot project with the goal of encouraging underrepresented minority and underserved youth—namely, African-Americans, Hispanic-Americans, Native Americans (American Indians, Alaska Natives and Native Hawaiians), as well as individuals from low-income backgrounds—to pursue professional careers in science research fields. In the second year of the project, a five-week resident program was conducted at Hood College in Frederick, Maryland, from June 30 to August 3, 1991. Approximately 145 nationally selected students participated and came from states as far away as Hawaii and Alaska including the Territory of American Samoa. Plans are underway for program expansion, and it is NCI's expectation that the Science Enrichment Program will be a successful training avenue for increasing the Nation's reserve of future research scientists.

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***The American Stop Smoking Intervention Study  
(ASSIST)***

ASSIST represents a collaborative effort between the National Cancer Institute, the American Cancer Society, State and local health departments, and other voluntary organizations to develop comprehensive tobacco control programs. The purpose of ASSIST is to demonstrate that the wide-spread, coordinated application of the best available strategies to prevent and control tobacco use through community-based coalitions will significantly accelerate the current downward trend in smoking and tobacco use, thereby reducing the number and rate of tobacco-related cancers in the United States. ASSIST is expected to help up to 4.5 million smokers. Currently, 17 sites are being funded.

***Screening Trial for Prostate, Lung, Colorectal and Ovarian Cancers  
(PLCO)***

This is a 16-year randomized trial in which 37,000 men will be screened for four years for prostate, lung, and colorectal cancers and 37,000 will be screened for the same period of time for lung, colorectal, and ovarian cancers. Equal numbers of men and women will be followed with routine medical care as controls. There will be a 10-year follow-up of study subjects and controls to determine the effects of screening for those four sites on mortality. Genetic marker studies of diagnostic biopsy specimens relating genetic aberrations to these cancers will be conducted.

***Community Clinical Oncology Program (CCOP)***

The CCOP has established a network of cancer specialists, surgeons, and primary care physicians with access to cured cancer patients and their families and other individuals at increased risk of developing cancer. The network includes physicians practicing in community settings as well as those in university hospitals and medical schools across the country. It is through this network that several large-scale chemoprevention trials are being implemented to study the effectiveness of various agents to prevent cancer. The Tamoxifen Chemoprevention Trial was implemented in the CCOP clinical trials network in FY 1991.

***Cancer Centers and Cancer Control in Minority Populations***

Through the Comprehensive Minority Biomedical Program (CMBP) Cancer Centers Minority Enhancement Awards (MEAs), the National Cancer Institute seeks to expand minority involvement in cancer control research. MEAs are awarded competitively as supplements to funded NCI Cancer Centers for the purpose of facilitating the participation of minority groups in cancer control research. By broadening the operational base of cancers, MEAs allow expansion of center-based control efforts in prevention, early detections, screening, pre-treatment evaluation, treatment, continuing care and rehabilitation, as well as stimulating the increased involvement of those primary care providers who serve minority populations.

**Division of  
Extramural Activities**

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### ***The Minority Health Professional Training Initiative (MHPTI)***

The overall intent of the first phase of the MHPTI is to provide a range of career development mechanisms for clinicians and cancer researchers, primarily at minority health professional institutions interested in increasing or enhancing their programs in oncology. The first phase of this Initiative began in 1991 with the award of four grants following from the publication of three NCI Requests for Applications (RFAs)—the Minority Oncology Leadership Award (K07), the Clinical Investigator Award for Research on Special Populations (K08) and the Minority School Faculty Development Award (K14)—each describing a specific modification of the NIH Clinical Investigator Award. The second phase of MHPTI will focus on institutional enhancement at those schools that have traditionally made the major contribution to the production of minority health professionals.

### ***Research Supplements for Underrepresented Minorities***

Through the NIH-wide supplemental program entitled “Initiatives for Underrepresent Minorities in Biomedical Research,” CMBP has considerably expanded its support to minority individuals who are pursuing careers in the biomedical research sciences. This program, which began as an extension of of the NCI Minority Investigator Supplement Program, now includes supplements for Minority High School Students, Minority Undergraduate Students, Minority Graduate research Assistants and Minority Individuals in Postdoctoral Training. While this mechanism provides support indirectly to minority scientists and students by way of investigators, the ultimate intent of these awards is to influence a greater number of minority individuals to develop their research capabilities and pursue independent careers as cancer research investigators.

### ***Co-funding***

For the purpose of encouraging undergraduate and graduate students to pursue training related to cancer research, CMBP co-funds, with the Minority Access to Research Careers (MARC) Program of NIGMS, Pre-doctoral Fellowships to minority students and Honors Undergraduate Training Grants to minority institutions. Similarly, through co-funding with the Minority Biomedical Research Support program, NCI provides support for specific cancer-related projects at participating minority institutions.

### ***Other NCI Training Opportunities***

The Summer Training Supplement is an extension of the Minority Access to Research Careers (MARC) program and provides increased training opportunities for MARC scholars by way of short-term intramural laboratory training at the NCI.

### ***Support for Meeting Attendance***

CMBP continues to encourage participation of minority students and researchers in annual professional scientific meetings by providing travel support to such organizations as the American Association for Cancer Research and the Electron Microscope Society of America.

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### ***Cancer Information Dissemination***

As the result of a joint venture initiated with the NCI Office of Cancer Communications, the Comprehensive Minority Biomedical Program currently supports contracts that enable implementation of model strategies for the dissemination of cancer information to the Black populations by utilizing minority academic institutions, in particular the Historically Black Colleges and Universities.

### **Office of the Director**

### ***Health Communication Internship/Fellowship Program***

To increase the number of persons trained in cancer communications, this program provides a variety of training experiences for graduate-level students in health communications. Fellows are located in various parts of the Office of Cancer Communications and the International Cancer Information Center, where they work with staff members on health education projects or science writing.

### ***Cancer Biology***

Cellular oncogenes have been recognized as critical factors in the development of tumors in animals and man. Oncogenes act by disturbing or interfering with normal growth controls. An example of such interaction is the recently discovered relationship between *trk* and nerve growth factor (NGF). The *trk* oncogene was isolated from a primary human colon cancer in 1985. The *trk* protein product is a cellular receptor which is expressed in a specialized subset of sensory neurons. The nerve growth factor is the ligand that attaches to this receptor. NGF has stood at the center of neurobiology research for over four decades. Recently, an entire family of *trk*-like genes has been identified, all of which encode receptors that bind to nerve growth factors like NGF. The presence of the *trk* receptor is crucial to nerve cell function. Expression of large quantities of *trk* proteins accelerates nerve cell development and stimulates nerve cell differentiation and survival by affecting the *trk* receptor.

### **International Cancer Information Center**

To increase the dissemination of critical cancer information to physicians and health professionals involved in cancer care, the International Cancer Information Center (ICIC) developed CancerFax, a service enabling NCI to send current data on cancer treatment to anyone with a Fax machine. CancerFax provides treatment guidelines directly from NCI's comprehensive and current source of cancer treatment information, the PDQ (Physician Data Query) database.

The ICIC is also involved in a CRADA (Cooperative Research and Development Agreement) with private industry to develop an Integrated Oncology Workstation. The Oncology Workstation is a personal computer workstation for the practicing physician which allows for management of medical records in patient care and provides easy access to information resources such as PDQ and CANCERLIT to support medical decision making and clinical trials management. The CRADA is the mechanism for linking the required sources to build and market the workstation among community-based practicing oncologists.



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## **Prevention Highlights: Meeting the Year 2000 Objectives**

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### **Key Dates:**

- 1970-1979—Basic research contributed new knowledge of cancer process including the finding that cancer is multi-staged and that there are at least two distinct stages—initiation and promotion.
- 1980—Establishment of a new division, forerunner of the Division of Cancer Prevention and Control.
- 1981-1982—NCI developed new strategy that focused on cancer prevention and applied research.
- 1983—Year 2000 Goal was established which is based on prevention, early detection, and widespread application of the latest treatment results.

### **Cancer Network**

In 1991, NCI's Cancer Network included the following:

- Cancer Information Service (CIS)—a national toll-free telephone service that provides immediate answers to cancer-related questions from cancer patients, families, the public, and health professionals.
- Cancer Centers—a program of cancer research centers across the country which significantly contributes to progress in basic research, clinical studies, education, and cancer prevention and control.
- Community Clinical Oncology Program (CCOP)—a program involving community physicians in clinical trials research on cancer treatment, prevention and control.
- Physicians Data Query (PDQ)—an on-line computer system that provides state-of-the-art information on cancer detection, diagnosis and treatment.
- Cooperative Group Outreach Program (CGOP)—designed to increase patient enrollment in clinical trials and to upgrade the skills of community physicians and other health professionals.
- Minority Recruitment Network Office—established to develop, implement, and evaluate systematic recruitment of minority students to participate in NCI biomedical training and postgraduate fellowship programs.
- Cancer Control Research Networks—established to attract and stimulate the research interest of investigators sensitive to the cancer prevention and control needs of special populations. Networks have been established for African Americans, American Indians and Alaska Natives, Hispanics, and Native Hawaiians.

### **Prevention Trials**

- The first generation of candidate chemopreventive agents has progressed to clinical efficacy trials. They include the retinoids (nine studies), beta-carotene (seven studies) and calcium compounds (three studies). In addition, a second generation of six promising new compounds are in Phase I trials. These are piroxicam, ibuprofen, oltipraz (a dithiolthione) difluormethylornithine, glycyrrhetic acid, and N-acetylcysteine.
- A randomized chemoprevention trial has been implemented of the antiestrogen tamoxifen in women at high risk for developing breast cancer.
- A colon polyp prevention trial has begun, with the major objective of determining whether a low-fat, high-fiber diet will decrease the recurrence rate of large bowel adenomatous polyps, believed to be precursors for neoplasia.

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### **Agency Coordination**

- A 3-year pilot study has been initiated to develop and evaluate strategies for recruiting minorities and low-income women into an intervention trial and for changing their usual dietary pattern to a low-fat pattern designed to reduce total fat intake to 20% of calories and to increase the intake of fruits, vegetables, and grain products. In addition, the pilot study will assess trial costs and effect of a low-fat eating pattern on physiological outcomes such as blood lipids, steroid hormones and potential biological markers for dietary adherence. This pilot study has been designed as a component of the National Institutes of Health Women's Health Initiative.
- The National Institute on Aging is collaborating with NCI's Surveillance Program on a pilot project to develop a research protocol that investigates the effects of old age on early diagnosis and treatment of elderly cancer patients.
- NCI, the Centers for Disease Control, and the Food and Drug Administration are cooperating in the development and implementation of a National Strategic Plan for Early Detection and Control of Breast and Cervical Cancer.
- The Director, Division of Cancer Etiology (DCE), represents NCI on the National Toxicology Program Executive Committee of the National Institute of Environmental Health Sciences and on the government-wide Committee to Coordinate Environmental Health and Related Programs (CCEHRP).
- DCE maintains interagency agreements with the U.S. Environmental Protection Agency and the National Institute for Occupational Safety and Health through which collaborative studies on environmental and occupational carcinogenesis are carried out.
- The Division of Cancer Prevention and Control (DCPC) maintains two intra-agency agreements with the Indian Health Service to assess cancer risk and develop cancer control programs for Native American populations.
- Senior DCPC officials represent the NCI on the Interagency Forum on Aging-Related Statistics, a government-wide consortium that focuses on policy issues related to the quality of national statistical data for public health use.
- DCPC is developing the survey instrument for the 1992 National Health Interview Survey, which will be conducted by the National Center for Health Statistics.

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## **Smoking**

- The Smoking, Tobacco and Cancer Program (STCP) is a primary means of accelerating the downward trend in national smoking prevalence rates. The STCP represents an Institute-wide effort involving programs of basic and applied research, clinical and community-based intervention trials, and demonstration projects. Since 1984, the STCP has supported more than 100 separate projects and studies examining more effective ways of intervening in smoking behavior.
- To aid in the national dissemination of STCP trial results, a series of monographs are now in production. The purpose of these publications is to provide, in a single volume, detailed information on effective public health strategies for reducing smoking and tobacco use behavior, synthesizing information derived from NCI's large portfolio of STCP trials.
- The Community Intervention Trial For Smoking Cessation (COMMIT) is testing whether a community-based intervention protocol can be effectively disseminated nationwide in order to meet the Year 2000 objective to reduce smoking prevalence. The COMMIT design involves 11 pairs of communities in North America that were matched in size, demographics, and location. The four-year intervention effort involves more than 1,000 physicians, 700 dentists, 1,400 worksites, 1,000 community organizations, 250 media outlets, 400 schools, and 60 cessation service providers.
- The American Stop Smoking Intervention Study (ASSIST), funded currently in 17 sites across the Nation, is a demonstration project applying the best available strategies to prevent and control tobacco use. ASSIST is expected to help up to 4.5 million smokers.

## **Nutrition**

- Research is being conducted intramurally on cellular and molecular regulation relevant to nutrition and cancer. A multidisciplinary approach using the methods and strategies of nutritional science, biochemistry, molecular biology, and cell biology is focusing on mechanisms underlying epidemiologic relationships between diet and cancer.
- The Cancer Preventive Designer Food Research Project, aimed toward the development of new experimental foods, will evaluate phytochemicals in food and is expected to develop new food substances for testing in clinical prevention trials.
- Supported by a grant from the NCI, the California Department of Health in 1991 enlisted the cooperation of food industry marketers and producers in the "Five a Day for Better Health" campaign to encourage Californians to eat five servings of fruits and vegetables per day. Similar campaigns are being adapted to Vermont and Louisiana. Based on the success of this approach, NCI will develop a national campaign.
- New research will use controlled feeding and metabolic studies to identify and/or develop noninvasive, specific, and sensitive biologic indicators for clinical monitoring of dietary modification and adherence.

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**Worksite Health Promotion**

- Research is underway to explore the potential of the worksite to improve a broad set of cancer prevention and control behaviors. “Working Well” is a large, Phase III project involving four research centers, a coordinating center, and 120 randomized worksites. The project is designed to determine effective worksite-based intervention methods to reduce tobacco use, achieve cancer preventive dietary modification, increase screening prevalence, and reduce occupational exposures. Smaller worksite-based projects will develop mechanisms to assist worksite managers to choose appropriate cancer control materials and develop interactive computer-based nutrition self-help programs.

**Screening and Early Detection**

- Prescribe for Health is designed to improve the adoption and continued use of screening tests by primary care providers. This program will work through intermediary organizations—organizations with influence over the routine practice of primary care medicine—such as Health Maintenance Organizations, professional societies, medical liability insurance companies, family practice networks, and community health centers.
- Two national surveys have been designed and are being implemented. Field work has been completed for one study that will provide information regarding the extent to which screening mammograms are being utilized by Medicare beneficiaries. The second survey is designed to collect national data on the process of the delivery of mammographic screening service, such as pricing, nature of services offered, and clinical performance of the mammography facilities.
- During the past year, several NCI breast cancer screening grants have completed supplements to design, implement, and evaluate one-year interventions to increase breast cancer screening rates in women 65 and older. In addition, a fourth grant was supplemented to sponsor two forums on breast cancer screening in older women.
- A collaborative network of institutions is being established to conduct research in bridging the gap between new findings in the molecular and cellular biology laboratories and their testing for clinical application. A tissue bank will provide the opportunity for cellular and molecular studies. A goal of this project is to identify and test specific markers to assess trials and other studies on the early detection of cancer.
- NCI has responded to widespread concern about the quality assurance in cervicovaginal cytology, particularly as it relates to the reporting system for cervical cancer screening tests. A new system of reporting, named The Bethesda System, was developed, replacing the Papanicolaou (PAP) classification.

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## **Data Systems**

- The Surveillance, Epidemiology, and End Results (SEER) Program maintains a database on all cancer cases diagnosed since 1973 among residents in nine regions of the country, covering approximately 10 percent of the U.S. population. Efforts to expand the SEER Program to increase population coverage of Hispanics and other underrepresented groups were initiated in FY 1991.
- The SEER Program serves as an effective resource for a broad range of cancer surveillance efforts. A series of short-term special projects are being initiated, some of which are aimed at improving our understanding of factors that influence or explain observed changes in cancer trends while validation studies are conducted to address issues of efficiency and quality in data collection procedures.
- The NCI has provided significant scientific and administrative leadership in developing the cancer control supplement for the 1992 National Health Interview Survey. These data, coupled with the 1987 survey will provide national data for assessing trends in cancer risk factors and health behavior pertinent to cancer control.
- Analyses are underway using a database consisting of SEER data linked with Medicare claims data to permit a better understanding of the patterns of care and sources of costs following cancer diagnosis among Medicare beneficiaries.
- A cancer mapping program is under development to assist local health officials in better targeting cancer services in their areas.
- The Data-Based Grants Program is being enhanced to provide state and local health agencies with further funding and technical assistance to extend data collection and analysis for application to public health approaches to cancer prevention and control.

## Year 2000 Goal and Objectives

The National Cancer Institute has established a goal to reduce the United States cancer mortality rate by 50 percent by the year 2000. The ability to meet this goal is based on the knowledge that: (1) smoking is directly responsible for some 30 percent of all cancer deaths; (2) diet and nutrition may be related to 35 percent or more of cancer deaths; (3) screening for breast and cervical cancer has been proven effective in reducing mortality; (4) widespread application of state-of-the-art cancer treatment could reduce the mortality rate for some sites as much as 25 percent; and (5) gains in early detection, diagnosis, and treatment methodologies will continue over the next decade, thereby contributing to an improved five-year survival rate and reduced cancer mortality.

The following is an outline of the cancer prevention and control objectives:

<b>Control Area</b>	<b>Brief Rationale</b>	<b>Year 2000 Objectives</b>
Prevention/Smoking	The causal relationship between smoking and cancer has been scientifically established.	Reduce the percentage of adults and youths who smoke to 15 percent or less.
Prevention/Diet	Research indicates that high-fat and low-fiber consumption may increase the risk for various cancers. In 1982 NAS reviewed research on diet and cancer and recommended a reduction in fat; more recent studies led NCI to recommend an increase in fiber. Research is underway to verify the causal relationship and to test the impact on cancer incidence.	Reduce average consumption of fat from 40 percent to 30 percent or less of total calories  Increase average consumption of fiber from 8 to 12 grams per day to 20 to 30 grams per day.
Early Detection and Screening/Breast	The effectiveness of breast cancer screening in reducing mortality has been scientifically established in randomized trials.	Increase the percentage of women ages 40 or more who have an annual physical breast exam from 80% to 90% and 11% for mammography to 80%.
Early Detection and Screening/Cervical	The effectiveness of cervical screening has been shown to reduce mortality in large populations.	Increase the percentage of women who have a Pap smear at least every 3 years to 86% from 75%.
Early Detection and Screening/Rectum/Colon	The effectiveness of screening for colon and rectal cancers with digital rectal exam, stool blood and proctoscope is under continued study. Case control and mathematic modeling studies indicate mortality reduction with regular sigmoidoscopy examination. Encourage routine application of guidelines.	Increase the percentage who have digital rectal exams from 53% to 76%, stool blood exams from 48% to 75% and proctoscope from 18% to 48%.
Early Detection and Screening/Melanoma	The effectiveness of screening the skin has been shown in other countries to reduce mortality by 20%. Educational effort planned.	Increase the percentage examined for early melanoma. Every person should have skin examined annually. High-risk groups can be identified.
Early Detection and Screening/Prostate	Second leading cause of cancer death in males. Early detection trials are in planning stages using digital rectal exams and Prostate Specific Antigen.	All males over 60 years should be regularly examined for early prostate cancer.

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<b>Control Area</b>	<b>Brief Rationale</b>	<b>Year 2000 Objective</b>
Early Detection and Screening/Oral Cancer	Screening for early oral cancer is economical and effective. Can be performed by dentists as well as physicians.	High-risk group is readily identified and can be targeted.
Early Detection and Screening/Testicular Cancer	Early detection is simple. Early treatment produces excellent survival.	All males over 20 years should manually examine testes for lumps or signs of cancer.
Treatment/Transfer of Research Results to Practice	NCI review of clinical trial and SEER data indicates that, for certain cancer sites, mortality in SEER is greater than mortality experienced in clinical trials.	Increase adoption of state-of-the-art treatment, including improved treatment of micrometastases.

## Public Information Dissemination

As part of its legislated mission, the National Cancer Institute actively supports cancer information dissemination activities. NCI works to ensure that the public, as well as the primary-care physician, is afforded easy access to up-to-date information regarding cancer prevention, detection and diagnosis, and treatment measures.

The NCI devoted over \$90 million in 1990 to the furtherance of its Information Dissemination activities. This included efforts in behavior modification studies, e.g., smoking and breast screening, as well as activities specifically directed towards professional and public audiences. The Physician Data Query (PDQ) system is a database containing treatment recommendations and summary information on all active clinical trials supported by NCI. A directory of physicians and organizations that provide cancer care is also included in the PDQ system.

The Cancer Information Service (CIS), known to the public as 1-800-4-CANCER, is staffed by health professionals equipped to respond to public inquiries regarding cancer; often the PDQ system will be consulted. Over one-half of the callers receive a publication or other written material as a result of this service. Heightened public interest in new cancer treatment (i.e., gene vaccine therapy, taxol), results in a flood of calls to this toll-free number.

The CIS consists of a nationwide network of 22 regional offices, 18 of which receive direct NCI funding. In addition to providing direct response to the public, the field offices support NCI's major outreach activities and conduct cancer education programs to meet specific local and regional needs.

In addition to individual mailings of pamphlets/brochures by the local network offices, the NCI widely distributes bulk volumes of pamphlets/brochures to hospitals, supermarkets, physician organizations, etc., for subsequent distribution to the public.

Pamphlets/Brochures Distributed				
	CIS Inquiries	Publication Ordering Service Calls	Total Literature Distributed	PDQ Searches
FY 1991	540,000	137,000	16,000,000	18,500

### *Scientific Information Dissemination*

The International Cancer Information Center (ICIC) continues to promote the use of PDQ to the widest audiences possible. The ICIC has increased the number of distributors and methods of access (online, CD-ROM, PDG 'C' and MUMPS) to PDQ and the NCI's literature database, CANCERLIT. CancerFax provides access to NCI's treatment guidelines from PDQ through the fax machine, as well as news and significant information from the NCI, like the Clinical Announcement on Rectal Cancer which was released in March of 1991. Staff of the ICIC provide PDQ demonstrations and presentations at national and international medical meetings to enhance the awareness of these scientific information services. The Journal of the National Cancer Institute, the NCI's semi-monthly publication, has become a recognized leader and vehicle for providing cancer news and the latest clinical and research developments to cancer professionals worldwide. In collaboration with the Office of International Affairs, complimentary subscriptions of PDQ and CANCERLIT on CD-ROM, as well as the Journal of the National Cancer Institute, are being provided to institutions in Central and Eastern Europe and Latin America and other developing nations to speed the development of national or regional cancer control programs around the world.





## Directory of Personnel

### Direct-in Dialing

<i>Director, National Cancer Institute</i>	<i>Building 31</i>
Dr. Samuel Broder* .....	11-A-48..... 496-5615
<i>Special Assistant</i>	<i>Building 31</i>
Dr. Judith E. Karp .....	11-A-27..... 496-3505
<i>Special Assistant for Minority Affairs</i>	<i>Building 31</i>
(Vacant).....	11-A-27..... 496-3506
<i>Program Manager, Employment Opportunity Office</i>	<i>Building 31</i>
Ms. Maxine I. Richardson .....	10-A-33..... 496-6266
<i>Director, Office of Legislation and Congressional Activities</i>	<i>Building 31</i>
Ms. Dorothy Tisevich.....	11-A-23..... 496-5217
<hr/>	
<i>Deputy Director</i>	<i>Building 31</i>
Dr. Daniel C. Ihde* .....	11-A-48..... 496-1927
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<i>Assistant Director</i>	<i>Building 31</i>
Dr. Elliott Stonehill.....	4-A-32..... 496-1148
<hr/>	
<i>Assistant Director for Program Operations and Planning</i>	<i>Building 31</i>
Ms. Iris Schneider* .....	11-A-48..... 496-5534
<i>Chief, Planning, Evaluation, and Analysis Branch</i>	<i>Building 31</i>
Ms. Cherie Nichols .....	11-A-19..... 496-5515
<hr/>	
<i>Associate Director for Prevention</i>	<i>Building 31</i>
Dr. Peter Greenwald* .....	10-A-52..... 496-6616
<hr/>	
<i>Associate Director for Cancer Communications</i>	<i>Building 31</i>
Mr. J. Paul Van Nevel .....	10-A-31..... 496-6631
<i>Chief, Information Resources Branch</i>	<i>Building 31</i>
Ms. Nancy Brun .....	10-A-30..... 496-4394
<i>Chief, Reports and Inquiries Branch</i>	<i>Building 31</i>
Ms. Eleanor Nealon .....	10-A-31..... 496-6631
<i>Chief, Information Projects Branch</i>	<i>Building 31</i>
Dr. Sharyn Sutton.....	10-A-11..... 402-3304
<hr/>	
<i>Associate Director for International Affairs</i>	<i>Building 31</i>
Dr. Federico Welsch.....	4-B-55..... 496-4761
<i>Associate Director for International Cancer Information Center</i>	<i>Building 82</i>
Ms. Susan P. Hubbard .....	102..... 496-9096
<i>Chief, Computer Communications Branch</i>	<i>Building 82</i>
Mr. Nicholas B. Martin .....	219..... 496-8880

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Dialing**

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<i>Chief, Scientific Publications Branch</i>	
<i>Managing Editor, Journal of the National Cancer Institute</i>	<i>Building 82</i>
Ms. Julianne Chappell .....	235..... 496-1997
<i>Chief, International Cancer Research Data Bank Branch</i>	<i>Building 82</i>
Dr. Gisele Sarosy .....	113..... 496-7403
<hr/>	
<i>Associate Director for Administrative Management</i>	<i>Building 31</i>
Mr. Philip D. Amoruso* .....	11-A-48..... 496-5737
<i>Deputy Associate Director for Administrative Management</i>	<i>Building 31</i>
Mr. Donald Christoferson .....	11-A-48..... 496-5737
<i>Chief, Administrative Services Branch</i>	<i>Building 31</i>
Ms. Susan Kiser .....	11-A-35..... 496-5801
<i>Chief, Financial Management Branch</i>	<i>Building 31</i>
Mr. John P. Hartinger .....	11-A-16..... 496-5803
<i>Budget Officer</i>	<i>Building 31</i>
Ms. Mary C. Cushing .....	11-A-16..... 496-5803
<i>Chief, Personnel Management Branch</i>	<i>Building 31</i>
Ms. Marianne Wagner .....	3-A-19..... 496-3337
<i>Chief, Research Contracts Branch</i>	<i>Executive Plaza South</i>
Mr. John P. Campbell, Jr. ....	604-B..... 496-8628
<i>Chief, Management Analysis Branch</i>	<i>Building 31</i>
Mr. Thomas L. Kearns.....	4-A-47..... 496-6985
<i>Chief, Grants Administration Branch</i>	<i>Executive Plaza South</i>
Mr. Leo F. Buscher, Jr.....	216..... 496-7753
<i>Chief, Extramural Financial Data Branch</i>	<i>Executive Plaza South</i>
Mr. Stephen M. Hazen.....	643..... 496-7660
<i>Chief, Management Information Systems Branch</i>	<i>Executive Plaza North</i>
Ms. Betty Ann Sullivan .....	804..... 496-1038
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<i>Director, Office of Laboratory Animal Science</i>	<i>Building 31</i>
Dr. John Donovan .....	4-B-59..... 496-1866

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**Direct-in  
Dialing**

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<i>Director, Office of Technology Development</i>	<i>Building 31</i>
Dr. Thomas D. Mays .....	4-A-51 ..... 496-0477
Frederick Cancer Research and Development Center	
<i>Associate Director for Frederick Cancer Research and Development Center</i>	<i>Frederick, Maryland</i>
Dr. Werner Kirsten* .....	<i>Building</i> 427 ..... FTS-8-846-5096
<i>General Manager/Project Officer</i>	<i>Frederick, Maryland</i>
Dr. Cedric W. Long .....	<i>Building</i> 427 ..... FTS-8-846-1108
<i>Deputy General Manager</i>	<i>Frederick, Maryland</i>
Mr. Richard Carter .....	<i>Building</i> 427 ..... FTS-8-846-1106
<hr/>	
<i>Director, Division of Cancer Etiology</i>	<i>Building 31</i>
Dr. Richard H. Adamson* .....	11-A-03 ..... 496-6618
<i>Administrative Officer</i>	<i>Building 31</i>
Mr. Mark F. Kochevar .....	11-A-11 ..... 496-6556
<hr/>	
<i>Director, Division of Cancer Biology, Diagnosis, and Centers</i>	<i>Building 31</i>
Dr. Alan S. Rabson* .....	3-A-03 ..... 496-4345
<i>Administrative Officer</i>	<i>Building 31</i>
Mr. Lawrence D. Willhite .....	3-A-05 ..... 496-3381
<hr/>	
<i>Director, Division of Cancer Treatment</i>	<i>Building 31</i>
Dr. Bruce A. Chabner* .....	3-A-48 ..... 496-4291
<i>Administrative Officer</i>	<i>Building 31</i>
Mr. Lawrence J. Ray .....	3-A-48 ..... 496-2775
<hr/>	
<i>Director, Division of Extramural Activities</i>	<i>Building 31</i>
Mrs. Barbara S. Bynum* .....	10-A-03 ..... 496-5147
<i>Administrative Officer</i>	<i>Building 31</i>
Ms. Elise Kreiss .....	10-A-10 ..... 496-5915
<hr/>	
<i>Director, Division of Cancer Prevention and Control</i>	<i>Building 31</i>
Dr. Peter Greenwald* .....	10-A-52 ..... 496-6616
<i>Administrative Officer</i>	<i>Building 31</i>
Mr. Nicholas Olimpio .....	10-A-50 ..... 496-9606

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\*NCI Executive Committee Members

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## National Cancer Institute Leadership

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### **Director's Biography**

*Dr. Samuel Broder*

Dr. Samuel Broder was named Director of the National Cancer Institute by President Reagan on December 22, 1988 and sworn in on January 10, 1989. Dr. Broder is a medical oncologist whose major research interest is clinical immunology, with special attention to the relationship between immune abnormalities and neoplastic diseases.

Before becoming Director, Dr. Broder had been since 1981 Associate Director for the Clinical Oncology Program in NCI's Division of Cancer Treatment. He came to NCI as a clinical associate in the Metabolism Branch of the Division of Cancer Biology and Diagnosis in 1972. In 1975, he became an investigator in the Medicine Branch, DCT, and returned to the Metabolism Branch as a Senior Investigator.

Dr. Broder's research has centered on the biology of the immune system with emphasis on abnormal immunoregulation in cancer, and on the relationship between cancer and immunodeficiency states. Dr. Broder and his co-workers identified certain types of suppressor cells which induced immune impairment in some cancer patients. He and his co-workers also identified and characterized neoplasms which arose from helper and suppressor cells. In addition to his cancer research, Dr. Broder and his co-workers have worked on drug development, taking drugs rapidly from the test tube to patients, for the treatment of AIDS and related disorders. Such drugs include AZT, ddC, ddI, and related drugs in the dideoxynucleoside family, used alone and in combination. His major focus there as Director has been the need to ensure balance among the three foundation stones of the Institute: basic research, clinical trials (in prevention and therapy), and cancer centers.

Dr. Broder obtained his undergraduate and medical degrees from the University of Michigan. His internship and residency were at Stanford University. He is board certified in Internal Medicine and in Medical Oncology.

### **President's Cancer Panel**

Harold Freeman, M.D. ('94)

Chairman  
*Department of Surgery  
Harlem Hospital Center  
New York, NY*

Mrs. Nancy Brinker ('93)

Founder and Chairman  
*Susan G. Komen Foundation  
Dallas, TX*

Geza Jako, M.D. ('92)

*Boston University School of Medicine  
Melrose, MA*

Executive Secretary:

*Elliott H. Stonehill, Ph.D.  
National Cancer Institute  
Building 31, Room 4A34  
Bethesda, MD 20892*

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## Former Directors of the National Cancer Institute

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**Dr. Vincent T. DeVita, Jr., M.D.**  
January 1980 – June 1980 (Acting)  
July 1980 – August 1988

Dr. DeVita joined NCI in 1963 as a Clinical Associate in the Laboratory of Chemical Pharmacology. He served NCI as head of the Solid Tumor Service, Chief of the Medicine Branch, Director of the Division of Cancer Treatment and Clinical Director prior to his appointment as Director of NCI. In September 1988, Dr. DeVita resigned as NCI Director to become Physician-in-Chief at Memorial Sloan-Kettering Cancer Center.

**Dr. Arthur Canfield Upton, M.D.**  
July 1977 – December 1979

Prior to his tenure as NCI Director, Dr. Upton served as Dean of the School of Basic Health Sciences at the State University of New York at Stony Brook.

**Dr. Frank Joseph Rauscher, Jr., Ph.D.**  
May 1972 – October 1976

Dr. Rauscher served as Scientific Director for Etiology, NCI, prior to his appointment as Director of NCI in 1972.

**Dr. Carl Gwin Baker, M.D.**  
November 1969 – July 1970 (Acting)  
July 1970 – April 1972

During his tenure with PHS, Dr. Baker served as Scientific Director for Etiology, NCI, and as Acting Director of NCI prior to his appointment as Director in July 1970.

**Dr. Kenneth Milo Endicott, M.D.**  
July 1960 – November 1969

Dr. Endicott served as Chief of the Cancer Chemotherapy National Service Center, PHS, and as Associate Director, NIH, prior to being appointed Director, NCI in July 1960.

**Dr. John Roderick Heller, M.D.**  
May 1948 – June 1960

Dr. Heller joined PHS in 1934 and became Chief of the Venereal Disease Division prior to his appointment as Director of NCI in 1948.

**Dr. Leonard Andrew Scheele, M.D.**  
July 1947 – April 1948

Dr. Scheele served in various capacities during his tenure with PHS prior to his appointment as Assistant Chief and, subsequently, Director of NCI in July 1947.

**Dr. Roscoe Roy Spencer, M.D.**  
August 1943 – July 1947

Dr. Spencer became NCI's first Assistant Chief and, subsequently, was appointed Director of the Institute in 1943.

**Dr. Carl Voegtlin, Ph.D.**  
January 1938 – July 1943

Dr. Voegtlin served as Professor of Pharmacology and Chief of the Division of Pharmacy at the Hygienic Laboratory prior to becoming the first Director of NCI in 1938.

## National Cancer Advisory Board

Appointees	Expiration of Appointment	Appointees	Expiration of Appointment	Appointees	Expiration of Appointment
Dr. Paul Calabresi, <i>Chairperson</i> <i>Rhode Island Hospital</i> <i>Providence, Rhode Island</i>	1996	Dr. Bernard Fisher <i>University of Pittsburgh</i> <i>Pittsburgh, Pennsylvania</i>	1992	Mrs. Irene S. Pollin <i>Linda Pollin Foundation</i> <i>Bethesda, MD</i>	1992
Dr. Frederick F. Becker <i>University of Texas</i> <i>Houston, Texas</i>	1996	Dr. Phillip Frost <i>The IVAX Corporation</i> <i>Miami, Florida</i>	1992	Dr. Sydney Salmon <i>Arizona Cancer Center</i> <i>Tucson, Arizona</i>	1996
Dr. Erwin P. Bettinghaus <i>Michigan State University</i> <i>East Lansing, Michigan</i>	1994	Mrs. Brenda L. Johnson <i>BrenMar Industries, Inc.</i> <i>New York, New York</i>	1994	Dr. Howard M. Temin <i>University of Wisconsin</i> <i>Madison, WI</i>	1994
Dr. David G. Bragg <i>University of Utah</i> <i>Salt Lake City, Utah</i>	1994	Dr. Walter Lawrence, Jr. <i>Virginia Commonwealth University</i> <i>Richmond, Virginia</i>	1994	Dr. Samuel Wells, Jr. <i>Washington University</i> <i>St. Louis, Missouri</i>	1994
Ms. Zora K. Brown <i>Broadcast Capital Fund, Inc.</i> <i>Washington, DC</i>	1992	Mrs. Marlene A. Malek <i>Vincent Lombardi Cancer Center</i> <i>McLean, Virginia</i>	1996	<b>Executive Secretary</b> Mrs. Barbara S. Bynum <i>National Cancer Institute, NIH</i> <i>Bethesda, Maryland</i>	
Dr. Kenneth Chan <i>University of Southern California</i> <i>Los Angeles, California</i>	1996	Deborah K. Mayer, R.N., M.S.N. <i>MGH Institute of Health Professions</i> <i>Boston, MA</i>	1996		
Dr. John R. Durant <i>University of Alabama</i> <i>Birmingham, Alabama</i>	1992				
<b>Ex Officio Members</b>					
The Honorable Louis W. Sullivan, M.D. <i>Secretary for Health and Human</i> <i>Services</i> <i>Washington, DC</i>		Dr. James W. Holsinger, Jr. <i>Department of Veterans' Affairs</i> <i>Washington, DC</i>		Ms. Ann Graham <i>Consumer Product Safety Commission</i> <i>Washington, DC</i>	
Dr. Bernadine Healy <i>Director, National Institutes of Health</i> <i>Bethesda, Maryland</i>		Dr. David A. Kessler <i>Food and Drug Administration</i> <i>Rockville, Maryland</i>		Dr. Kenneth Olden <i>National Institute of Environmental</i> <i>Health Services</i> <i>Research Triangle Park, North</i> <i>Carolina</i>	
The Honorable Lynn Martin <i>Secretary of Labor</i> <i>Washington, DC</i>		Dr. J. Donald Millar <i>National Institute for Occupational</i> <i>Safety and Health</i> <i>Atlanta, Georgia</i>		Dr. J. Thomas Ratchford <i>Office of Science and Technology</i> <i>Policy</i> <i>Washington, DC</i>	
Dr. David J. Galas <i>U.S. Department of Energy</i> <i>Washington, DC</i>		Mr. David Newhall, III <i>Department of Defense</i> <i>Washington, DC</i>		Mr. William K. Reilly <i>Environmental Protection Agency</i> <i>Washington, DC</i>	
<b>Alternates to Ex Officio Members</b>					
Ms. Rachael Levinson <i>Office of Science and Technology</i> <i>Policy</i> <i>Washington, DC</i>		Mr. Richard A. Lemen <i>National Institute for Occupational</i> <i>Safety and Health</i> <i>Washington, DC</i>		Dr. Ralph E. Yodaiken <i>Department of Labor</i> <i>Washington, DC</i>	
Dr. Miriam R. Davis <i>National Institute of Environmental</i> <i>Health Sciences</i> <i>Bethesda, Maryland</i>		Dr. Hugh McKinnon <i>Environmental Protection Agency</i> <i>Washington, DC</i>		Captain Bimal C. Ghosh, MC, USN <i>Department of the Navy</i> <i>Washington, DC</i>	
Dr. John R. Johnson <i>Food and Drug Administration</i> <i>Rockville, Maryland</i>		Dr. Raymond L. Sphar <i>Department of Veterans' Affairs</i> <i>Washington, DC</i>		Dr. Robert W. Wood <i>Department of Energy</i> <i>Washington, DC</i>	
		Dr. Andrew Ulsamer <i>Consumer Product Safety Commission</i> <i>Bethesda, Maryland</i>			

## Division Boards of Scientific Counselors

<b>Division of Cancer Biology, Diagnosis and Centers</b>	Albert H. Owens, Jr., M.D. <i>Chairperson</i>	1993	Albert H. LoBuglio, M.D.	1994
			Richard G. Lynch, M.D.	1991
			O. Ross McIntyre, M.D.	1994
	Barbara F. Atkinson, M.D.	1995	Azorides R. Morales, M.D.	1995
	Eugene A. Bauer, M.D.	1992	Robert L. Reddrick, M.D.	1995
	Judith L. Campbell, Ph.D.	1993	Howard K. Schachman, Ph.D.	1992
	Walter Eckhart, Ph.D.	1992	R. Babu Venkataraghavan, Ph.D.	1993
	Lois B. Epstein, M.D.	1995	Noel L. Warner, Ph.D.	1993
	Leon A. Heppel, M.D., Ph.D.	1991	Carolyn D. Whitfield, Ph.D.	1993
Margaret L. Kripke, Ph.D.	1993			
<b>Division of Cancer Treatment</b>	John E. Niederhuber, M.D. <i>Chairperson</i>	1991	Robert W. Holden, M.D.	1994
			William M. Hryniuk, M.D.	1992
			Frank M. Huennekens, Ph.D.	1991
	Robert L. Baehner, M.D.	1992	Loretta M. Itri, M.C.	1994
	Charles M. Balch, M.D.	1991	Donald W. Kufe, M.D.	1994
	Paul P. Carbone, M.D.	1993	Ronald Levy, M.D.	1993
	James D. Cox, M.D.	1991	Victor Ling, Ph.D.	1994
	Phillip Crews, Ph.D.	1993	JoAnne Stubbe, Ph.D.	1993
	Mark T. Grodine, M.D., Ph.D.	1991	Ralph R. Weichselbaum, M.D.	1993
<b>Division of Cancer Etiology</b>	G. Barry Pierce, M.D. <i>Chairperson</i>	1994	James S. Felton, Ph.D.	1992
			Peter J. Fischinger, M.D., Ph.D.	1994
			Stephen S. Hecht, Ph.D.	1992
	Marcel A. Baluda, Ph.D.	1993	Ru Chih C. Huang, Ph.D.	1994
	Webster Cavanee, Ph.D.	1992	Abraham M. Nomura, M.D.	1992
	Allan H. Conney, Ph.D.	1991	David Schottenfeld, M.D.	1992
	Pelayo Correa, M.D.	1991	Roy Shore, Ph.D.	1991
	Myron Essex, Ph.D.	1991	Mimi C. Yu, Ph.D.	1994
<b>Division of Cancer Prevention and Control</b>	M. Alfred Haynes, M.D., M.P.H., <i>Chairperson</i>	1993	Cutberto Garza, Ph.D.	1994
			Charles H. Hennekens, M.D., Dr., P.H.	1994
	David S. Alberts, M.D.	1994	Rumaldo Z. Juarez, Ph.D.	1993
	Sister Mary M. Ashton, M.H.A., M.S.W.	1994	Shirley B. Lansky, M.D.	1992
	Carol N. D'Onofrio, Dr., P.H.	1993	Michael Pertschuk, J.D.	1993
	Harmon J. Eyre, M.D.	1993	Ross L. Prentice, Ph.D.	1993
	Elaine B. Feldman, M.D.	1994	Maryann Roper, M.D.	1994



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**Frederick Cancer  
Research and  
Development Center**

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<b>FCRDC Advisory Committee</b>	Edward B. Ziff, Ph.D. <i>Chairperson</i>	1992*
	Renato Baserga, M.D.	1992
	Carmia G. Borek, Ph.D.	1992*
	James R. Broach, Ph.D.	1992*
	Donald R. Helinski, Ph.D.	1994
	Phyllis J. Kanki, D.V.M., D.Sci.	1993
	Alexandra M. Levine, M.D.	1993
	Frank Lilly, Ph.D.	1993
	Raymond W. Ruddon, Jr., M.D., Ph.D.	1993
	Steven R. Tannenbaum, Ph.D.	1993
<b>Ad Hoc BSC Representatives</b>	R. Babu Venkataraghavan, Ph.D. (DCBDC)	1993
	Marcel A. Baluda, Ph.D. (DCE)	1993
	vacant (DCPC)	
	Ralph R. Weichselbaum, M.D. (DCT)	1993
<b>Ex Officio Member of NCAB</b>	vacant	

\* Pending extension

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## **Executive Committee Members**

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Dr. Samuel Broder  
*Director*

Dr. Daniel C. Ihde  
*Deputy Director*

Mr. Philip Amoruso  
*Associate Director for Administrative Management*

Dr. Richard Adamson  
*Director, Division of Cancer Etiology*

Mrs. Barbara Bynum  
*Director, Division of Extramural Activities*

Dr. Bruce Chabner  
*Director, Division of Cancer Treatment*

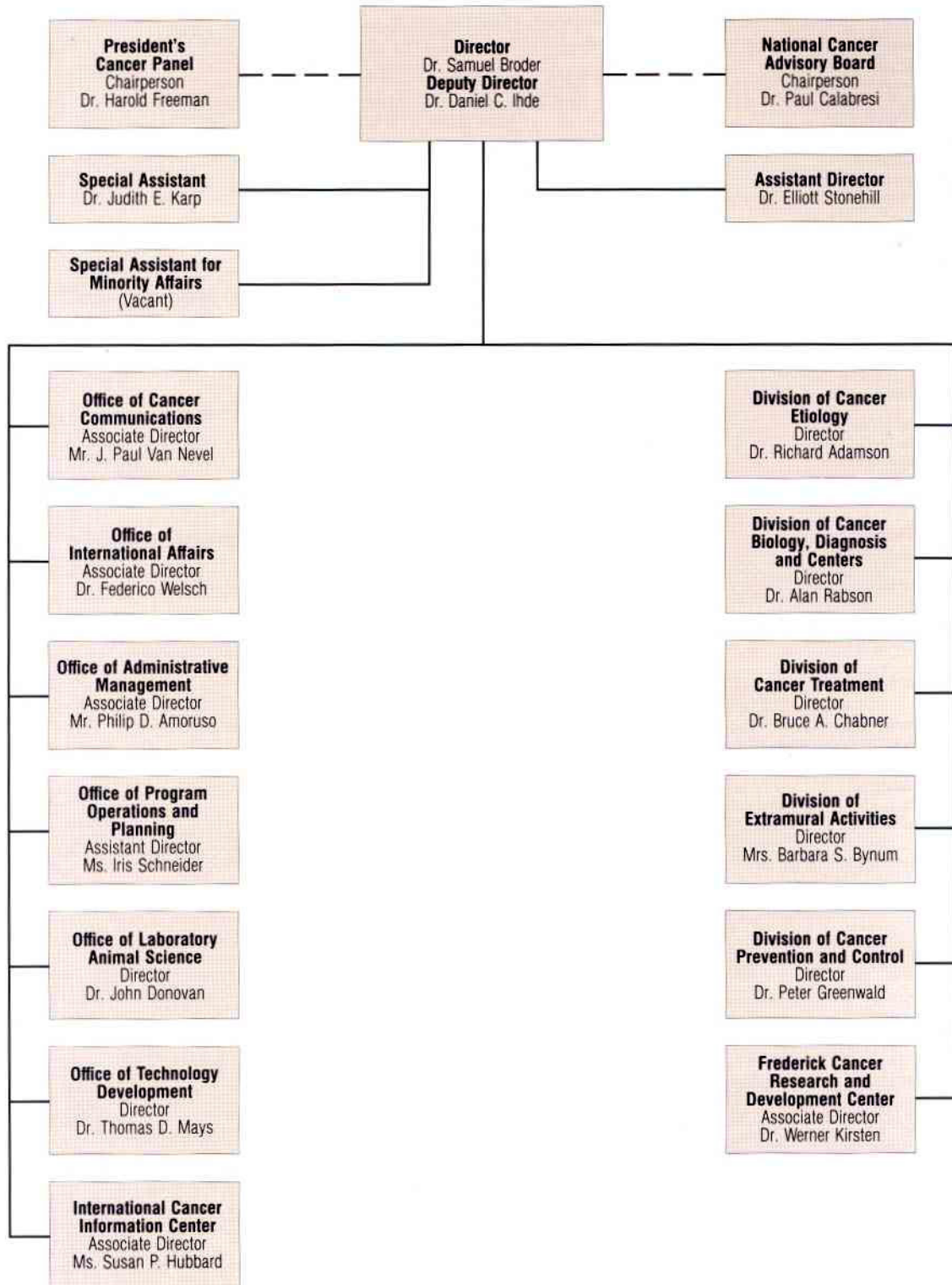
Dr. Peter Greenwald  
*Director, Division of Cancer Prevention and Control*

Dr. Werner Kirsten  
*Associate Director, Frederick Cancer Research and Development Center*

Dr. Alan Rabson  
*Director, Division of Cancer Biology, Diagnosis and Centers*

Ms. Iris Schneider  
*Executive Secretary*

# National Cancer Institute Organization

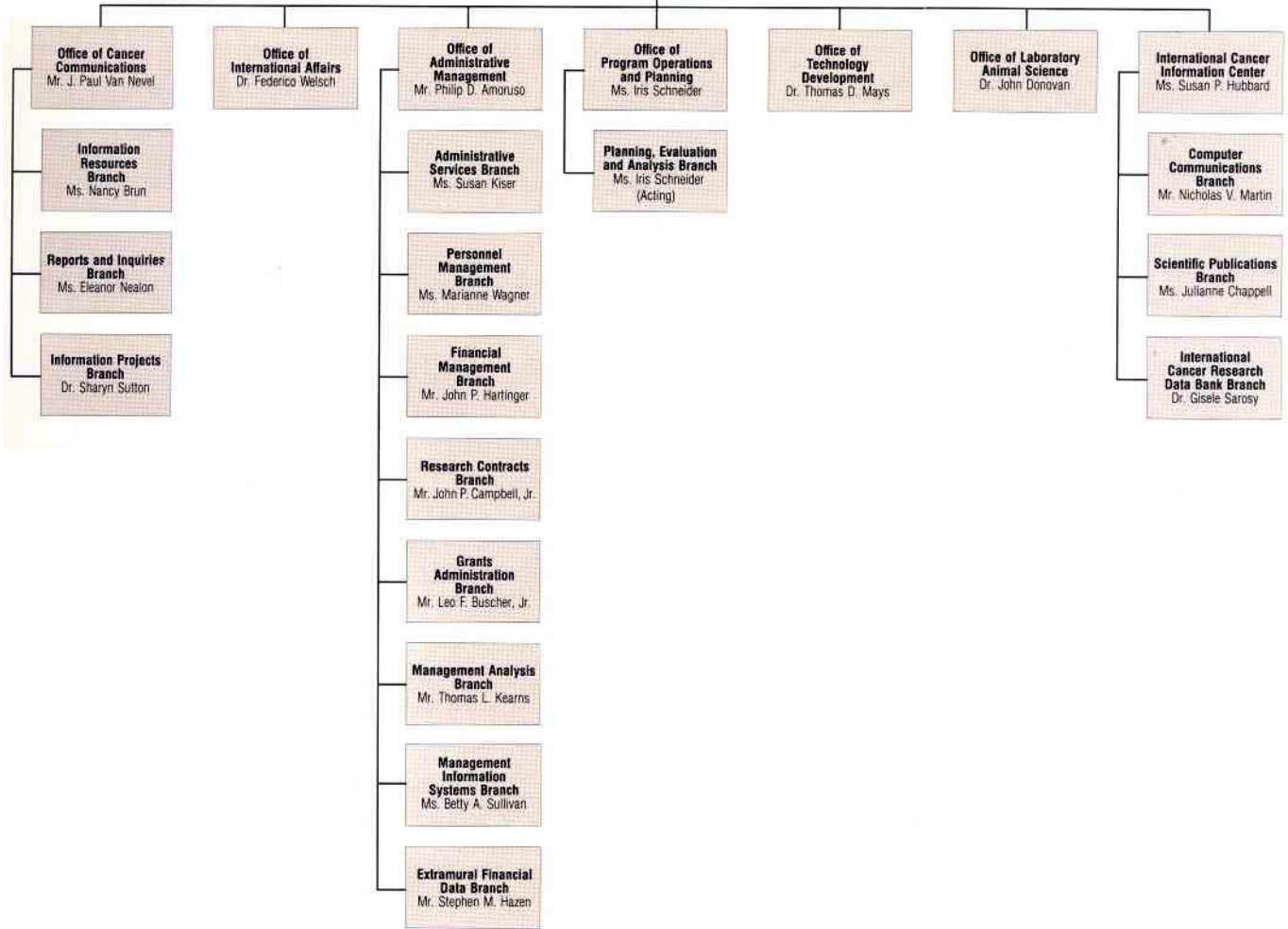


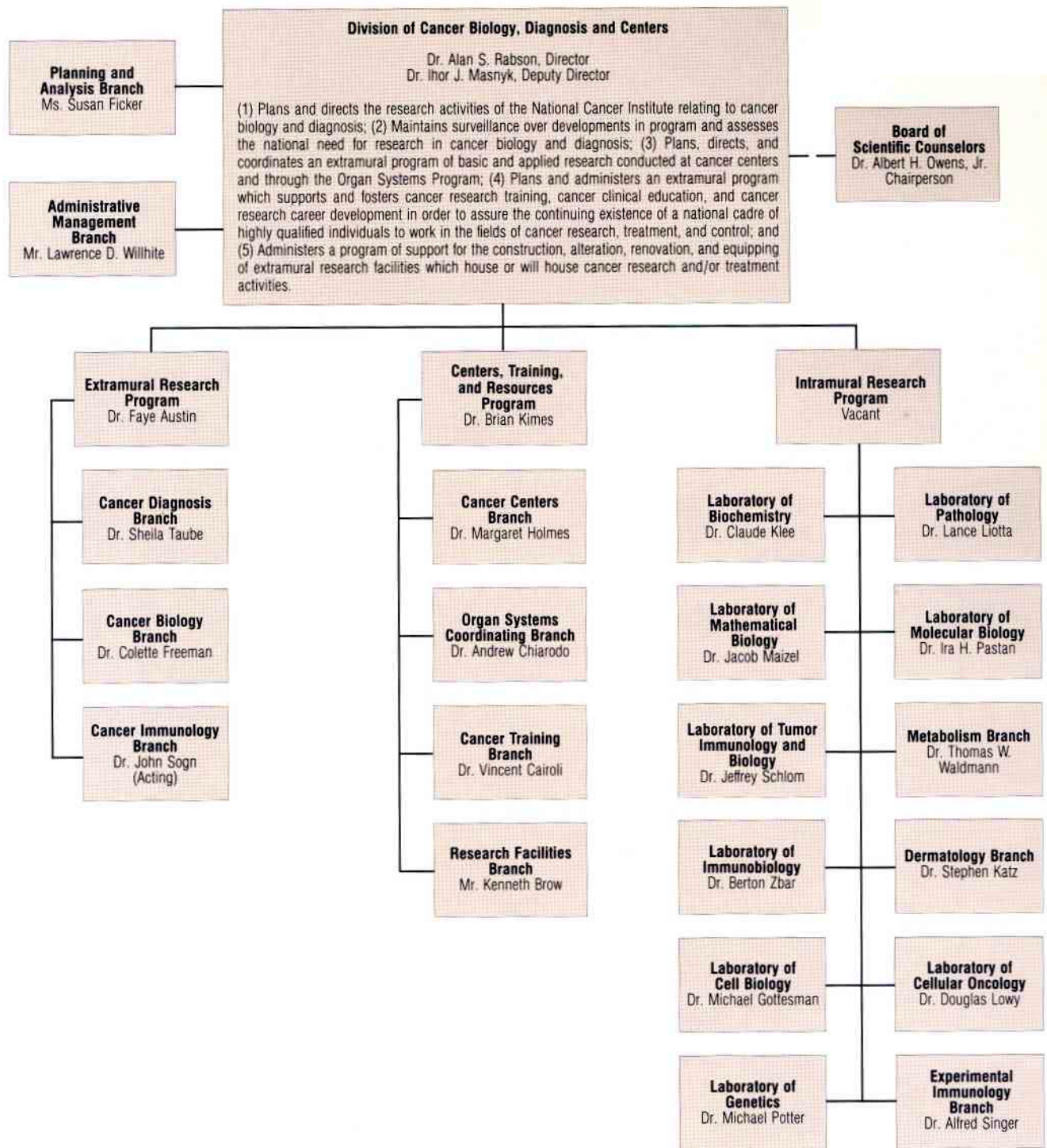
**Office of the Director**  
 Dr. Samuel Broder, Director  
 Dr. Daniel C. Ihde, Deputy Director

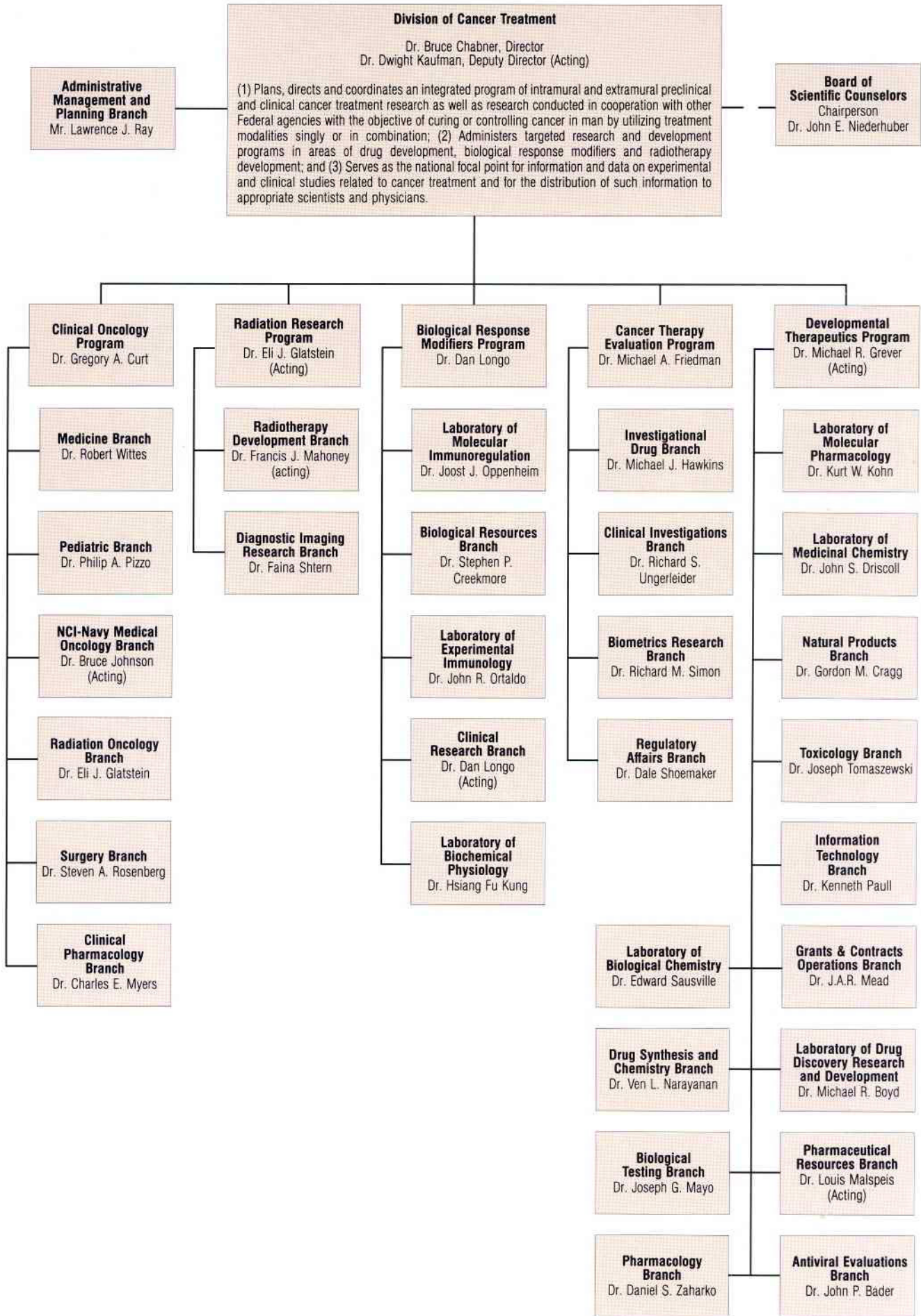
(1) Serves as the focal point for the National Cancer Program; (2) Develops a National Cancer Plan; and monitors implementation of the Plan; (3) Directs and coordinates the Institute's programs and activities, and (4) Develops and provides policy guidance and staff direction to the Institute's programs in areas such as program coordination, program planning, clinical care and administrative management.

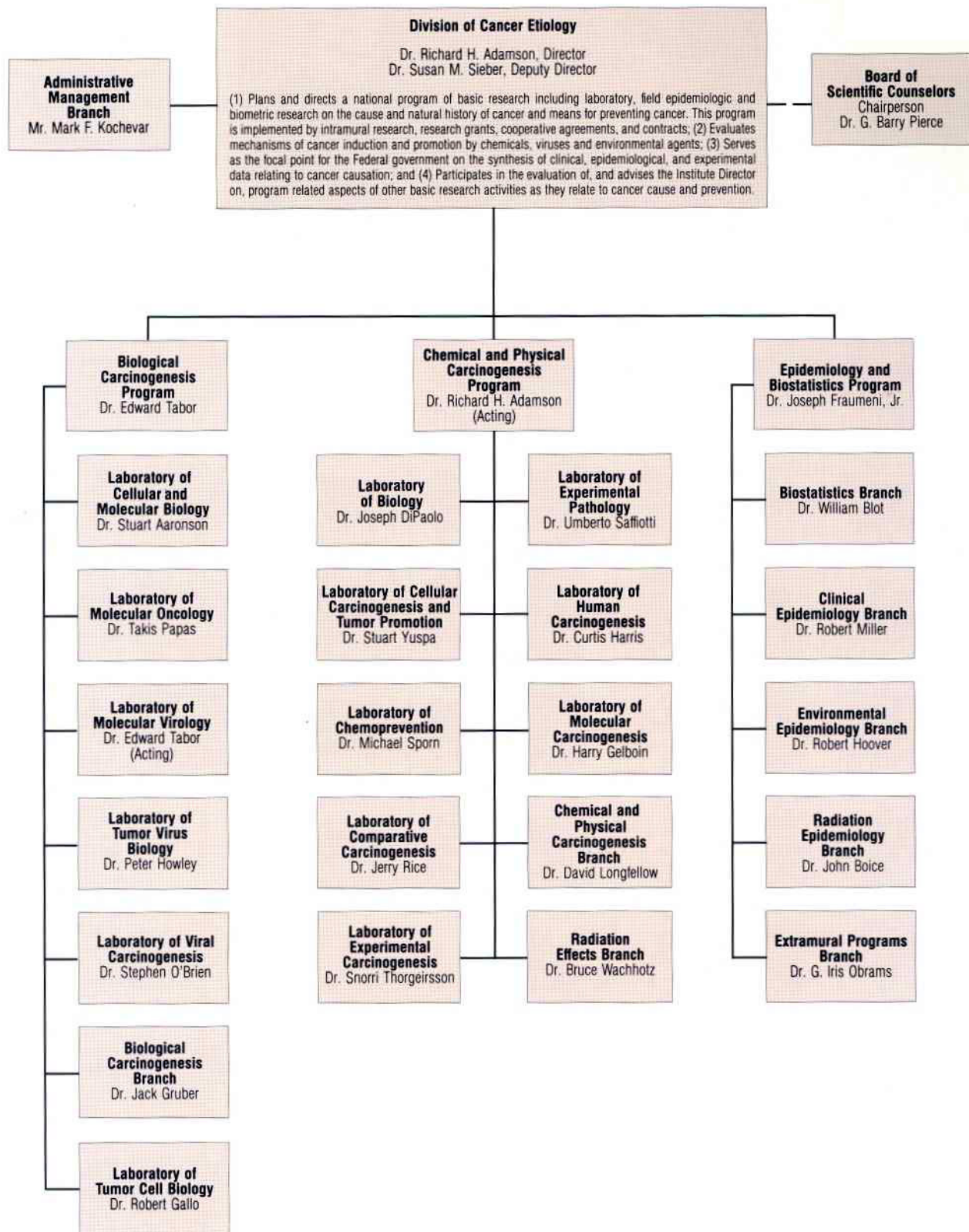
**Legislative Office**  
 Ms. Dorothy Tisevich

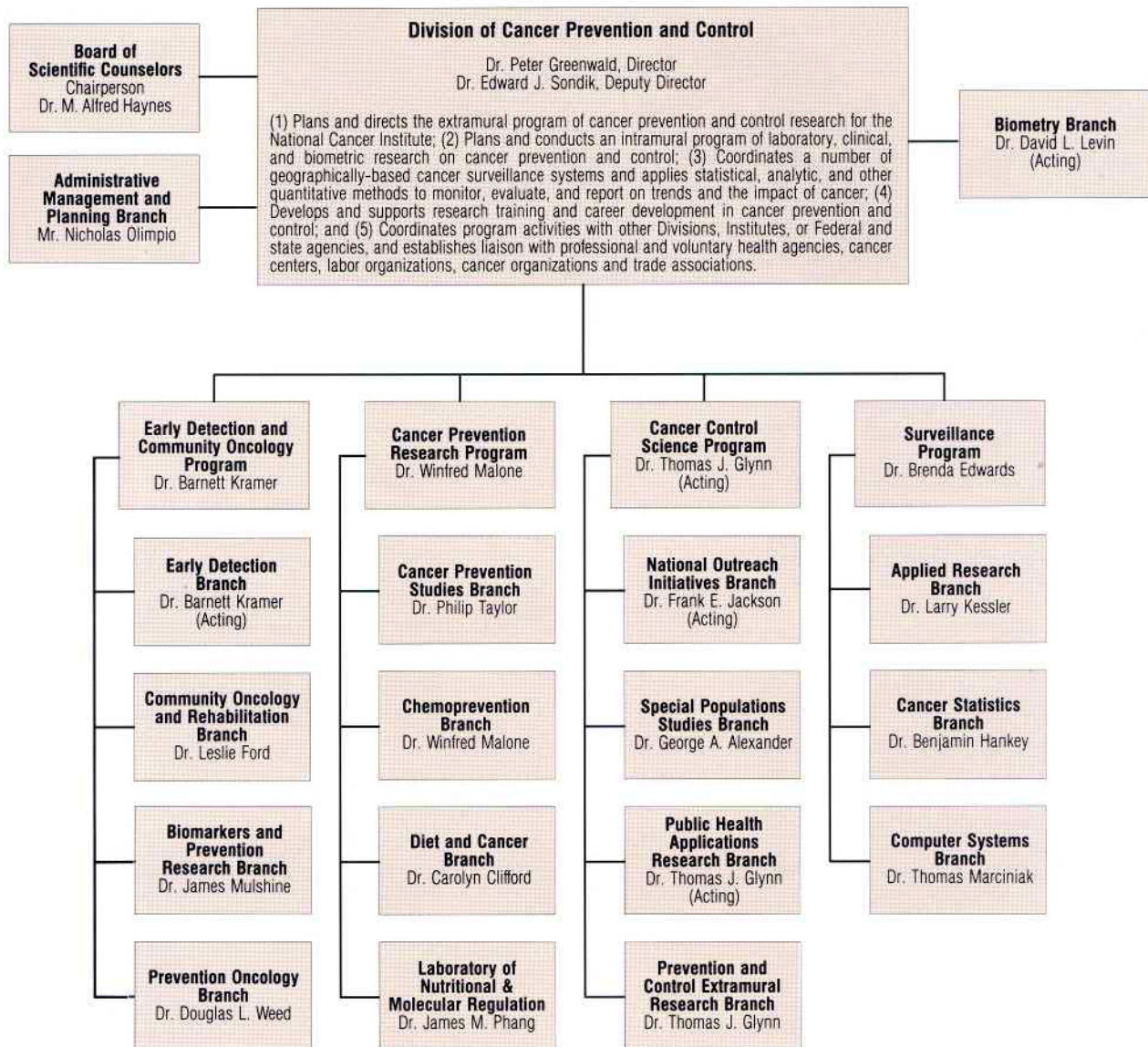
**EEO Officer**  
 Ms. Maxine I. Richardson









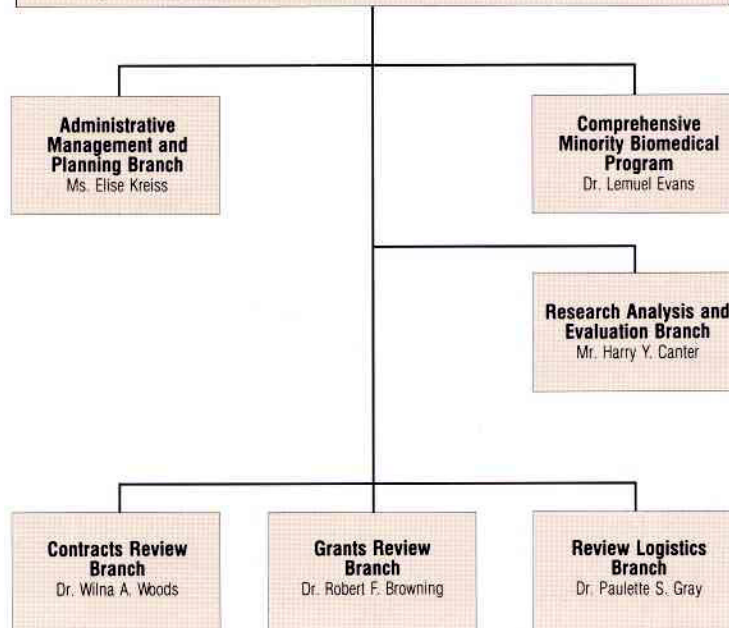




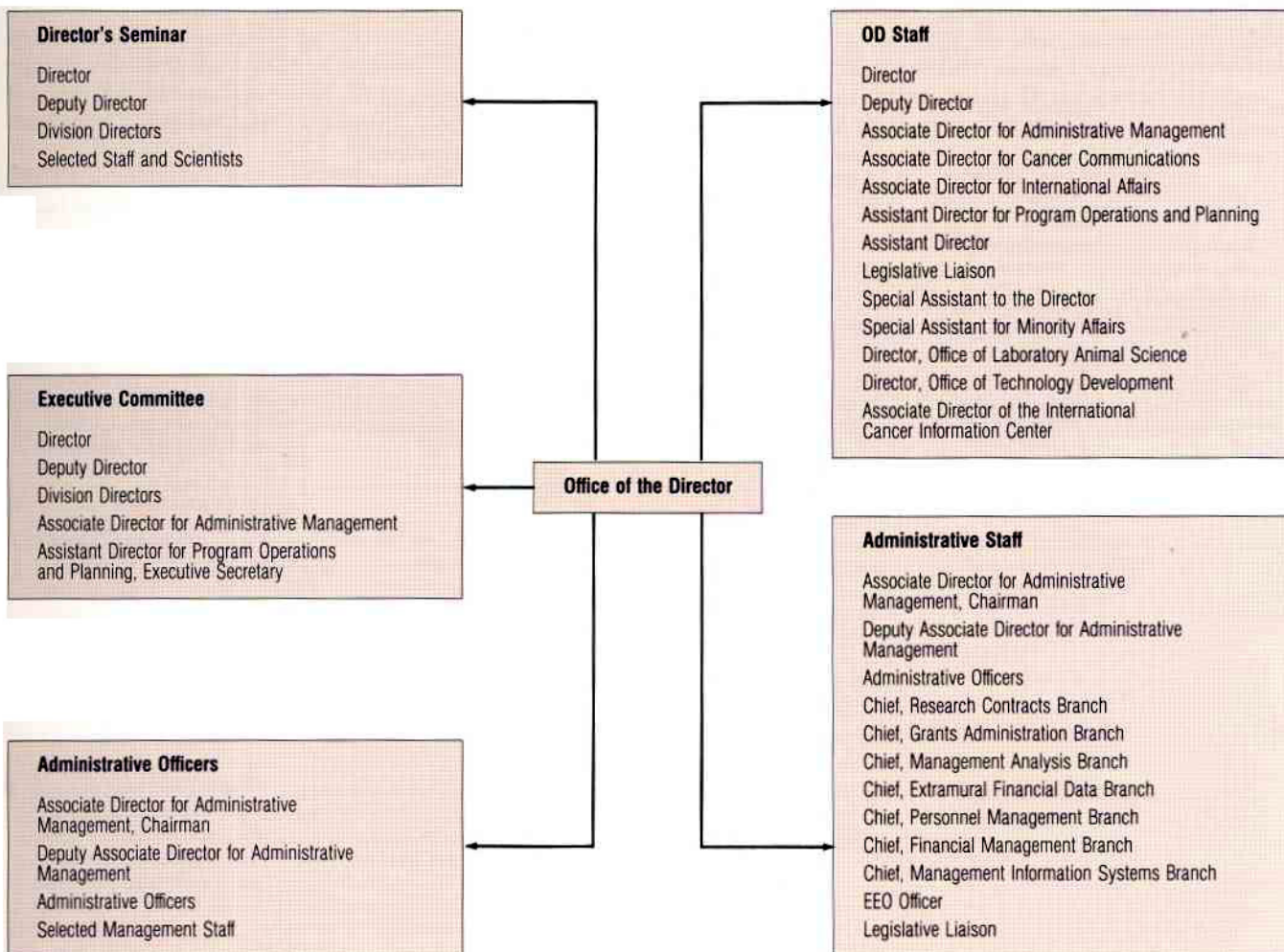
**Division of Extramural Activities**

Mrs. Barbara S. Bynum, Director  
Dr. Marvin Kait, Deputy Director  
Dr. Vincent Oliverio, Associate Director

(1) Administers and directs the Institute's grant and contract review and processing activities; (2) Provides initial technical and scientific merit review of grants and contracts for the Institute; (3) Represents the Institute on overall NIH extramural and collaborative program policy committees, coordinates such policy within NCI, and develops and recommends NCI policies and procedures as related to the review of grants and contracts; (4) Coordinates the Institute's review of research grant and training programs with the National Cancer Advisory Board; (5) Coordinates the implementation of committee management policies within the Institute and provides the Institute's staff support for the National Cancer Advisory Board; (6) Monitors and coordinates the operation of the divisional Boards of Scientific Counselors to assure uniformity and timeliness of the concept review of projects to be developed under contract or in response to RFAs; (7) coordinates program planning and evaluation in the extramural area; (8) provides scientific reports and analysis to the Institute's grant and central programs; and (9) administers programs to broaden participation by minorities in cancer-related research and training activities and to enhance the effectiveness of programs in cancer treatment and control in reaching the minority community and other historically underserved segments of the general population.



## Information Flow for Program Implementation



## Intramural Review Process

<p><b>Board of Scientific Counselors</b></p> <hr/> <p>BSC Approves Site Visit Schedule</p>	<p>Chairman, BSC Selects Site Visit Chairman</p> <p>Site Visit Chairman Selects Site Visit Team</p>	<p>BSC Site Visit Team Reviews Material Prepared by Division</p>	<p>BSC Site Visit Team Inspects and Reviews Laboratory</p>	<p>Site Visit Team Prepares Report and Presents it to BSC. After Review and Approval, BSC Transmits Final Recommendations to the Division Director.</p>		
<p><b>Step 1</b> Scheduling and Approval</p>	<p><b>Step 2</b> Team Selection Site Visit</p>	<p><b>Step 3</b> Preparation for Site Visit</p>	<p><b>Step 4</b> Site Visit</p>	<p><b>Step 5</b> Site Visit Report and Recommendations</p>	<p><b>Step 6</b> Implementation of Recommendations</p>	<p><b>Step 7</b> Follow-up Report</p>
<p><b>NCI Divisions</b></p> <hr/> <p>Division Prepares Proposed Site Visit Schedule</p>		<p>Division Prepares Background Material on Laboratory to be Site Visited and Sends to Site Visit Team</p>	<p>Site Visit Preparation by Laboratory</p>		<p>Division Implements Recommendations Contained in Site Visit Report</p>	<p>Division Prepares Report to BSC on Actions Taken</p>

## Research Positions at the National Cancer Institute<sup>1</sup>

The National Cancer Institute recognizes that one of the most valuable resources to be drawn upon in the fight against cancer is the wealth of scientific talent available in the U.S. and around the world. In an effort to attract and maintain the highest quality scientific staff, two personnel

systems are used: the U.S. Civil Service System and the PHS Commissioned Corps. In addition, the Staff Fellowship Program and the NIH Visiting Program have been designed to meet special needs. Other special programs are available for those who qualify.

Position	Eligibility	Annual Salary	Mechanism of Entry
<b>I. Civil Service</b>			
A. Civil Service (tenured)	Appropriate advanced education, experience and knowledge needed by NCI to conduct its programs.	Minimum starting Ph. D.—\$44,348 Physicians—\$54,694	Office of Personnel Management; Contact Division Director or Laboratory Chief in area of interest or the NCI Personnel Office.
<b>II. Special Appointment of Experts and Consultants</b>			
A. Special Appointment of Experts and Consultants (non-tenured appointment which can be extended up to 4 years)	Applicants shall possess outstanding experience and ability as to justify recognition as authorities in their particular fields of activity.	Salary range is equivalent to GS-13 and above w/ maximum limited to level V of the Executive Schedule \$101,300	Recommendation by Division Directors. Final approval rests with the Director, NCI.
<b>III. Clinical Associate Program</b>			
A. Clinical Associates	Appointment for 2 or 3 years with an additional 1-year extension for an initial 2-year appointment. Graduate of accredited medical or osteopathic school and completion of internship. Completion of 2 or 3 years of clinical training beyond the M.D. degree must be a U.S. Citizen or a permanent U.S. resident. <b>NOTE:</b> Foreign M.D.s in a U.S. residency training program are also eligible through a Fogarty International Center appointment.	\$38,500-\$42,500	Apply to NIH Office of Education Building 10 Room 1C-129
B. Medical Staff Fellows in Pharmacology (PRAT Fellows). For physicians committed to research careers in pharmacological sciences, or clinical pharmacology.	Appointment for 2 years. Graduate of an accredited medical, osteopathic or graduate school. Completion of an internship and 2-3 years of clinical training beyond the M.D. degree. Candidate must be committed to research careers in clinical pharmacology or the pharmacological sciences. Must be a U.S. Citizen.	\$31,000-\$42,500	Apply to PRAT Program Westwood Building Room 919
<b>IV. Visiting Program (limited tenure)<sup>2</sup></b>			
A. Visiting Fellow (maximum 3 years)	1-3 years postdoctoral experience or training.	First year salaries range from \$25,000-\$28,000	Contact Division Director or Laboratory Chief in area of interest.
B. Visiting Associate (1 year with renewals to end of project)	3+ years postdoctoral experience or training with appropriate knowledge needed by NCI.	\$25,717-\$48,481	Contact Division Director or Laboratory Chief in area of interest.
C. Visiting Scientist (duration of project)	6+ years postdoctoral experience with appropriate specific experience and knowledge needed.	\$37,294-\$80,138	Contact Division Director or Laboratory Chief in area of interest.
<b>V. Staff Fellowships</b>			
A. Staff Fellowship	Physician or other doctoral degree equivalent (awarded within last 5 years) and who has less than 7 years of relevant research experience. U.S. citizen or resident alien. Maximum 7-year appointment.	Staff Fellows Physicians \$28,000-\$41,486 Other Doctorates \$24,000-\$43,509 Senior Staff Fellows Physicians \$32,000-\$57,650 Other Doctorates \$28,000-\$48,782	Contact Director or Laboratory Chief in area of interest or the NCI Personnel Office.

<sup>1</sup>Does not necessarily indicate that positions are currently available at the National Cancer Institute.

<sup>2</sup>Under most circumstances, the various visiting programs are limited to non-citizens.

<b>Position</b>	<b>Eligibility</b>	<b>Annual Salary</b>	<b>Mechanism of Entry</b>
<b>VI. Civil Service Summer Employment Programs</b>			
A. Summer Clerical Program	Must be 18 years of age or older (16 if high school graduate). Noncitizens may compete provided they have permanent visa status and are from countries allied with the U.S.	GS-1 through GS-4. Grade is based on education and/or experience.	Apply to NIH on or before March 15.
B. Summer Undergraduate Program	Students majoring in biological and/or physical sciences or related field, or applicants with appropriate experience. Noncitizens may compete provided they have permanent visa status and are from countries allied with the U.S.	GS-1 through GS-4. Grade is based on education and/or experience.	Apply to NIH by March 15.
C. Summer Graduate Program	College graduate, graduate student planning to attend graduate school, faculty member or equivalent experience and/or education. Noncitizens may compete provided they have permanent visa status and are from countries allied with the U.S.	GS-5 through GS-12. For some occupations superior scholastic work may qualify for a higher grade level.	Apply to NIH by March 15.
D. Summer Employment for Needy Youth	Educationally and economically disadvantaged youths in their formative years (must have reached 16th birthday). Disabled students are not required to meet economic criteria. Noncitizens may compete provided they have permanent visa status and are from countries allied with the U.S.	Federal minimum wage.	Register with the local office of the State Employment service and apply to NCI.
E. Summer Employment Program for Native Americans Under the Job Training Partnership Act	Participants must be Native American or of Native American descent and unemployed, under-employed, or economically disadvantaged. Must reside within the states of Tennessee, Kentucky, or the District of Columbia.	Paid by the United South and Eastern Tribes, Inc. (USET) depending on education and experience.	Apply to USET for referral to NCI.

Position	Eligibility	Annual Salary	Mechanism of Entry
<b>VII. Special Programs</b>			
A. Guest Researcher sponsored by organization other than NIH, PHS	Usually a scientist, engineer or other scientifically trained specialist who would benefit from the use of NCI facilities in furthering his/her research. Cannot perform services for NCI.	Established by sponsoring organization.	Contact Division Director or Laboratory Chief in area of interest; also apply to sponsoring agency, e.g., American Cancer Society, Eleanor Roosevelt Cancer Foundation, Leukemia Society of America, Inc., etc.
B. Commissioned Officer Student Training and Extern Program (COSTEP) Program (operates year-round). Maximum 120 days per 12-month period.	U.S. citizen. Must have completed one year of study in a medical, dental or veterinary school, or a minimum of two years of baccalaureate program in a health-related field such as engineering, nursing, pharmacy, etc. May be enrolled in a master's or doctoral program in a health-related field (designated by the Assistant Secretary for Health). Physical requirements of PHS Commissioned Corps. Plans to return to college.	Pay and allowance of a Junior Assistant Health Service Officer. \$1,850 per month	Director, Division of Commissioned Personnel Attention: COSTEP Coordinator Room 435, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD. 20857.
C. Fogarty International Scholars in Residence Program.	International reputation, productivity, demonstrated ability in biomedical field.	\$80,000 for 1 year.	Recommendation to Fogarty Center by Institute Director, any senior tenured member of the NIH scientific staff, or former scholar.
D. Stay-in-School Program	Economically disadvantaged students who are attending accredited schools on a full-time or substantially full-time basis, and are in good academic standing. (Must have reached 16th birthday.) Disabled students are not required to meet economic criteria.	Salary is commensurate with duties assigned and student's education and/or experience.	Register with the local office of the State Employment service and apply to NCI. No deadline required for applying. However, no new appointments are made between May 1 to August 30.
E. The Federal Junior Fellowship Program	Graduating high school senior in a public or private school. Must have demonstrated satisfactory academic performance with cumulative G.P.A. equivalent to a "C+" or above. Must plan to attend or have been accepted for admission to an accredited college or university and need financial assistance to attend school. Must be a United States citizen or a resident of American Samoa or Swains Island. May be a non-citizen if lawfully admitted to the U.S. as a permanent resident and will be able to meet citizenship requirements prior to conversion and is a national of an allied country.	GS-1 through GS-4.	Nominations are submitted directly to NIH by high school principals or counselors.
<b>VIII. Other Training Programs</b>			
A. Cancer Prevention Fellowship Program (Three-year non-tenured civil service position).	1) M.D., D.D.S., Ph.D., or other doctoral degree in a related discipline (epidemiology, biostatistics, and the biomedical, nutritional, public health or behavioral sciences); 2) U.S. citizen or resident alien eligible for citizenship within four years.	First year for an M.D. or D.O. \$26,000-\$37,000 for Ph.D. \$18,000-\$31,000.	Program Director, CPFP, Executive Plaza South, Room T41, Bethesda, Maryland 20892.
B. Biotechnology Fellow	Physicians with little or no experience or training in fundamental research, but with an interest in biotechnology including its application to prevention and new treatment and diagnostic techniques, would be eligible. Ph.D. scientists with little or no experience or training in clinically related programs but with an interest in clinical applications of fundamental research methodology related to biotechnology would also be eligible. Typically, these candidates will have less than three years post-doctoral experience. The Biotechnology Training Program is established for United States citizens, or resident aliens who will be eligible for U.S. citizenship within four years.	First year Ph.D. \$25,000-\$31,000 Physicians \$37,000-\$41,000	Contact Division Director or Laboratory Chief in area of interest.

Position	Eligibility	Annual Salary	Mechanism of Entry
C. Cancer Nurse Training Program	Applications will be accepted from graduates of NLN accredited baccalaureate nursing programs. Each candidate must submit academic transcripts demonstrating a minimum of a "B" average in undergraduate work, three references regarding their academic and clinical capability, a letter describing their interest in the program, and a Personal Qualification Statement, SF-171. The program is also available to all new graduate applicants to the Cancer Nursing Service; some may not be aware of the program prior to their contact with Clinical Center.	Stipends for the program will be \$2,400 per month.	Contact the Division of Cancer Treatment.
D. Student Research Training Program	The review and selection of candidates, as well as the day-to-day administration of the fellowships, will be the responsibility of each Division's Administrative Office. Must be bona-fide high school, college, medical school, or graduate student. Must be 16 years of age, must have a cumulative GPA of 2.75 or above, must be either a U.S. citizen or resident alien. The length of the training fellowships may vary from 2 to 6 months, not to exceed 6 months during any one 12-month period.	Stipends are based on education and experience at a pay range of \$802-\$1,872 per month.	Contact Division Director or Laboratory Chief in area of interest. Application deadlines are March 1 for spring/summer months and October 1 for fall/winter months.
E. Special Volunteer Program	Volunteer service may be accepted for direct patient care, clerical assignments, technical assistance, or any other activities necessary to carry out the authorized functions of the NCI. Applicants must be at least 16 years of age.	N/A	Contact Division Director or Laboratory Chief in area of interest.
F. General Fellowship Program	M.D., Ph.D. or equivalent degrees as well as pre-doctoral candidates pursuing graduate work with the aim of achieving a doctoral degree. U.S. citizens, permanent residents, or foreign citizens are eligible.	Salary is commensurate with duties assigned and candidate's education and/or experience.	Contact Division Director or Laboratory Chief in area of interest.
G. Cancer Epidemiology and Biostatistics Training Program	M.D.s and Ph.D.s with an interest in and an aptitude for epidemiology and/or biostatistical research in cancer. Ph.D. candidates in approved doctoral programs in epidemiology or biostatistics whose research would be the source of their dissertation. Master's level scientists whose degree is in a discipline related to epidemiology or biostatistics. Must be U.S. citizen or resident alien who will be eligible for U.S. citizenship within four years.	First year for M.D. \$26,000-\$35,000 for Ph.D. \$18,000-\$31,000 for Master's level \$17,000-\$19,000	Contact the Administrative Office of the Division of Cancer Etiology
H. Intramural Research Training Award (IRTA)	Appointments for 1 or 2 years with a maximum of 3 years to candidates with physician or other doctoral degree in the biomedical, behavioral or related sciences and 3 or fewer years of relevant postdoctoral research experience.	First year salaries range from \$25,000-\$28,000 based on years of experience.	Contact Division Director or Laboratory Chief in area of interest.





## Number of Deaths for the Five Leading Cancer Sites by Age Group and Sex

All Ages		Under 15		15-34		35-54		55-74		75+	
Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Lung	Lung	Leukemia	Leukemia	Leukemia	Breast	Lung	Breast	Lung	Lung	Lung	Colon & Rectum
87,962	45,169	362	262	687	675	8,887	8,757	55,037	27,444	23,858	14,948
Prostate	Breast	Brain & CNS	Brain & CNS	Non-Hodgkin's Lymphoma	Leukemia	Colon & Rectum	Lung	Colon & Rectum	Breast	Prostate	Breast
28,980	42,169	234	200	451	413	2,340	5,209	14,379	20,333	17,303	12,403
Colon & Rectum	Colon & Rectum	Endocrine	Endocrine	Brain & CNS	Brain & CNS	Brain & CNS	Colon & Rectum	Prostate	Colon & Rectum	Colon & Rectum	Lung
27,985	28,779	115	88	438	313	1,360	1,932	11,339	11,745	11,062	12,392
Pancreas	Ovary	Non-Hodgkin's Lymphoma	Soft Tissue	Hodgkin's Disease	Cervix	Non-Hodgkin's Lymphoma	Ovary	Pancreas	Ovary	Pancreas	Pancreas
11,722	12,213	75	47	241	308	1,338	1,622	6,558	6,559	3,345	5,833
Leukemia	Pancreas	Soft Tissue	Kidney & Renal Pelvis	Melanoma	Non-Hodgkin's Lymphoma	Pancreas	Cervix	Esophagus	Pancreas	Leukemia	Ovary
9,831	12,126	39	33	217	205	1,269	1,419	4,299	5,579	3,512	3,868

Source: Mortality tape (1988) from National Center for Health Statistics.

## Relationship of Cancer to the Leading Causes of Death in the United States

Rank	Cause	Number of Deaths	Crude Death Rate per 100,000 Population	Percent of Total Deaths
	<b>ALL CAUSES</b>	2,167,999	882.0	100.0%
1	Diseases of the Heart	765,156	311.3	35.3
2	CANCER	485,048	197.3	22.4
3	Cerebrovascular	150,517	61.2	6.9
4	Accidents	97,100	39.5	4.5
5	Bronchitis, Emphysema & Asthma	82,853	33.7	3.8
6	Pneumonia & Influenza	77,662	31.6	3.6
7	Diabetes Mellitus	40,368	16.4	1.9
8	Suicide	30,407	12.4	1.4
9	Cirrhosis of the Liver	26,409	10.7	1.2
10	Nephritis & Nephrosis	22,086	9.1	1.0
11	Atherosclerosis	22,392	9.0	1.0
12	Homicide	22,032	9.0	1.0
13	Septicemia	20,925	8.5	1.0
14	Diseases of Infancy	18,220	7.4	0.8
15	Human Immunodeficiency Virus Infection	16,602	6.8	0.8
	Other & Ill-defined	290,222	118.1	13.4

Source: National Center for Health Statistics, 1988.

**Estimated New Cancer Cases and Deaths by Sex for All Sites 1991\***

	Estimated New Cases			Estimated Deaths		
	Total	Male	Female	Total	Male	Female
<b>All Sites</b>	1,100,000*	545,000*	555,000*	514,000	272,000	242,000
<b>Buccal Cavity &amp; Pharynx (ORAL)</b>	30,800	20,600	10,200	8,150	5,275	2,875
Lip	3,600	3,100	500	100	75	25
Tongue	6,200	3,900	2,300	1,850	1,200	650
Mouth	11,600	6,900	4,700	2,400	1,400	1,000
Pharynx	9,400	6,700	2,700	3,800	2,600	1,200
<b>Digestive Organs</b>	240,800	125,400	115,400	122,975	64,700	58,275
Esophagus	10,900	7,600	3,300	9,800	7,300	2,500
Stomach	23,800	14,500	9,300	13,400	8,100	5,300
Small Intestine	2,900	1,600	1,300	925	500	425
Large Intestine } (COLON-RECTUM)	112,000	54,000	58,000	53,000	26,000	27,000
Rectum	45,500	25,000	20,500	7,500	4,000	3,500
Liver & Biliary Passages	15,000	7,800	7,200	12,100	6,300	5,800
Pancreas	28,200	13,700	14,500	25,200	12,000	13,200
Other & Unspecified Digestive	2,500	1,200	1,300	1,050	500	550
<b>Respiratory System</b>	178,000	114,000	64,000	148,025	95,800	52,225
Larynx	12,500	10,000	2,500	3,650	2,900	750
<b>LUNG</b>	161,000	101,000	60,000	143,000	92,000	51,000
Other & Unspecified Respiratory	4,500	3,000	1,500	1,375	900	475
<b>Bone</b>	2,000	1,100	900	1,150	550	500
<b>Connective Tissue</b>	5,800	3,100	2,700	3,300	1,600	1,700
<b>SKIN</b>	32,000†	17,000†	15,000†	8,500‡	5,400	3,100
<b>BREAST</b>	175,900	900	175,000	44,800	300	44,500
<b>Genital Organs</b>	201,000	129,300	71,700	56,125	32,625	23,500
Cervix Uteri } (UTERUS)	13,000	—	13,000	4,500	—	4,500
Corpus, Endometrium	33,000	—	33,000	5,500	—	5,500
Ovary	20,700	—	20,700	12,500	—	12,500
Other & Unspecified Genital, Female	5,000	—	5,000	1,000	—	1,000
Prostate	122,000	122,000	—	32,000	32,000	—
Testis	6,100	6,100	—	375	375	—
Other & Unspecified Genital, Male	1,200	1,200	—	250	250	—
<b>Urinary Organs</b>	75,500	52,800	22,700	20,100	12,700	7,400
Bladder	50,200	37,000	13,200	9,500	6,400	3,100
Kidney & Other Urinary	25,300	15,800	9,500	10,600	6,300	4,300
<b>Eye</b>	1,700	900	800	300	150	150
<b>Brain &amp; Central Nervous System</b>	16,700	9,000	7,700	11,500	6,200	5,300
<b>Endocrine Glands</b>	13,900	4,100	9,800	1,675	700	975
Thyroid	12,400	3,300	9,100	1,000	350	650
Other Endocrine	1,500	800	700	675	350	325
<b>Leukemias</b>	28,000	15,800	12,200	18,100	9,800	8,300
Lymphocytic Leukemia	11,700	6,800	4,900	5,200	3,000	2,200
Granulocytic Leukemia	11,600	6,300	5,300	7,600	4,000	3,600
Other & Unspecified Leukemia	4,700	2,700	2,000	5,300	2,800	2,500
<b>Other Blood &amp; Lymph Tissues</b>	56,900	30,000	26,900	29,400	15,200	14,200
Hodgkin's Disease	7,400	4,200	3,200	1,600	1,000	600
Non-Hodgkin's Lymphomas	37,200	19,600	17,600	18,700	9,600	9,100
Multiple Myeloma	12,300	6,200	6,100	9,100	4,600	4,500
<b>All Other &amp; Unspecified Sites</b>	41,000	21,000	20,000	40,000	21,000	19,000

NOTE: The estimates of new cancer cases are offered as a rough guide and should not be regarded as definitive. Especially note that year-to-year changes may only represent improvements in the basic data. ACS six major sites appear in boldface caps.

\* Carcinoma in situ and nonmelanoma skin cancers are not included in totals. Carcinoma in situ of the uterine cervix accounts for more than 50,000 new cases annually, carcinoma in situ of the female breast accounts for about 15,000 new cases annually, and melanoma carcinoma in situ accounts for about 5,000 new cases annually. Overall, about 100,000 new cases of carcinoma in situ of all sites of cancer are diagnosed each year. Nonmelanoma skin cancer accounts for about 600,000 new cases annually.

† Melanoma only.

‡ Invasive cancer only.

§ Melanoma 6,500; other skin 2,000

INCIDENCE ESTIMATES ARE BASED ON RATES FROM NCI SEER PROGRAM 1985-87.

To Ed.

## The Cost of Cancer

The direct cost of cancer is derived from the figures for care of patients. It does not include the cost of the productivity lost while individuals are away from their work due to treatment of disability or the value of lost productivity due to premature death. Figures for the direct cost of cancer and for all health care for 1990 are as follows:

All Costs in Millions	Direct Cost
All Cancers	\$ 35,256
All Health Care	\$585,300
Percent Relationship Of Cancer to Total	6%

### Sources:

Brown, M.L. The National Economic Burden of Cancer: An Update. *Journal of the National Cancer Institute*, 1990, 82:1881-1814.

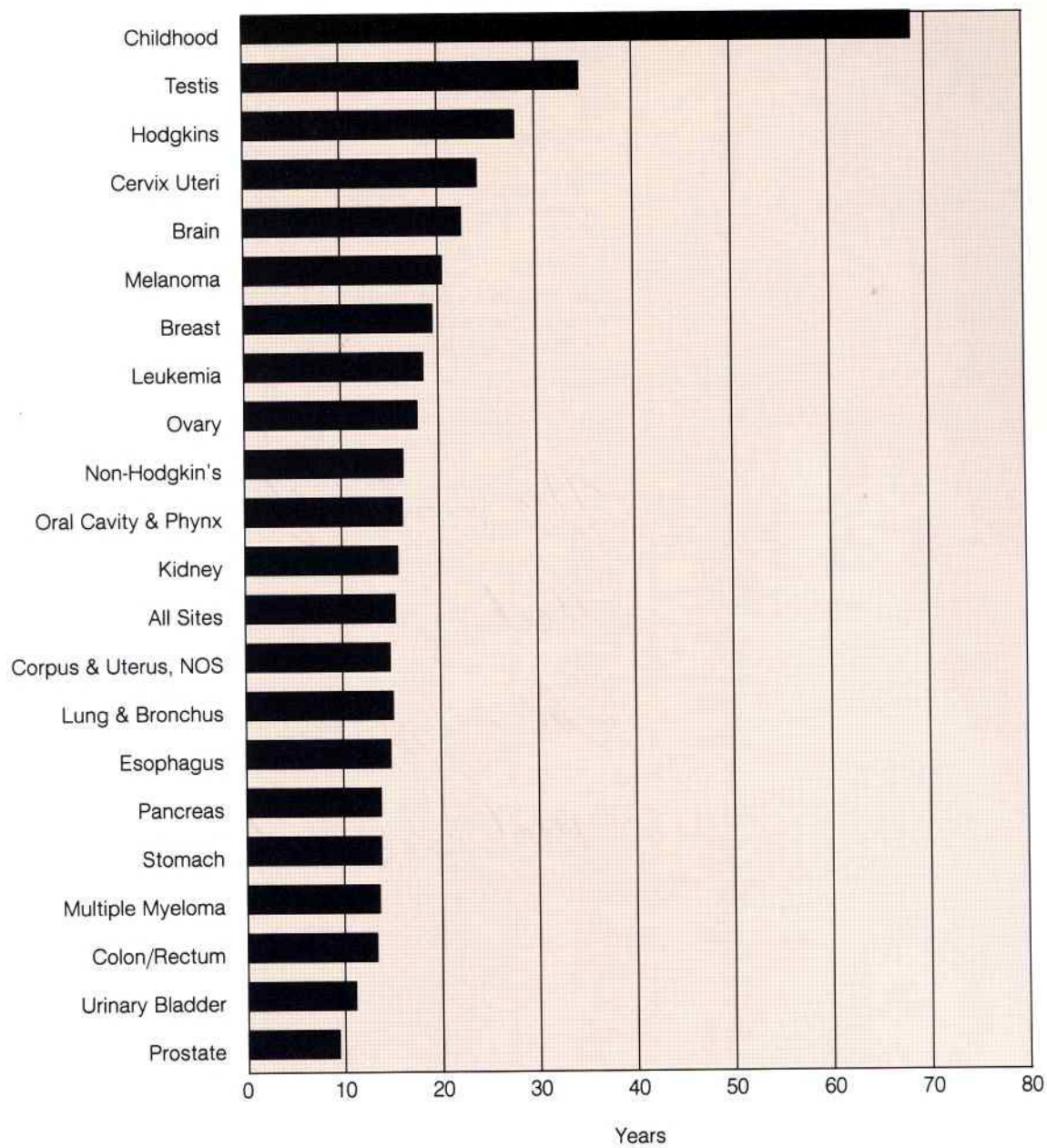
Office of the Actuary, Health Care Financing Administration.

The costs of cancer re:  
hardship, pain, suffering cannot  
be estimated and are not  
included above

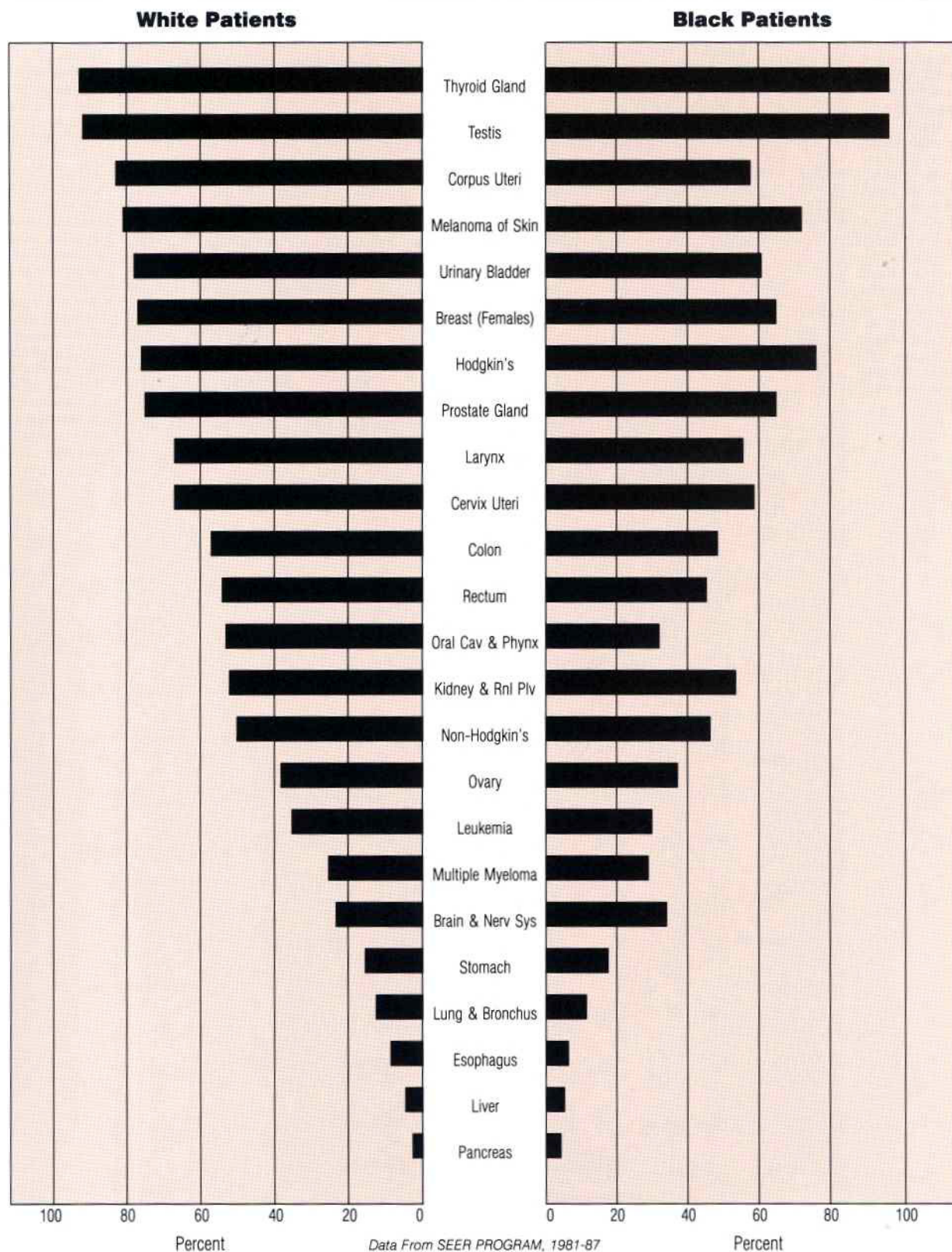
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**Average Years of Life Lost  
Per Person Dying of Cancer  
All Races, Both Sexes, 1988**

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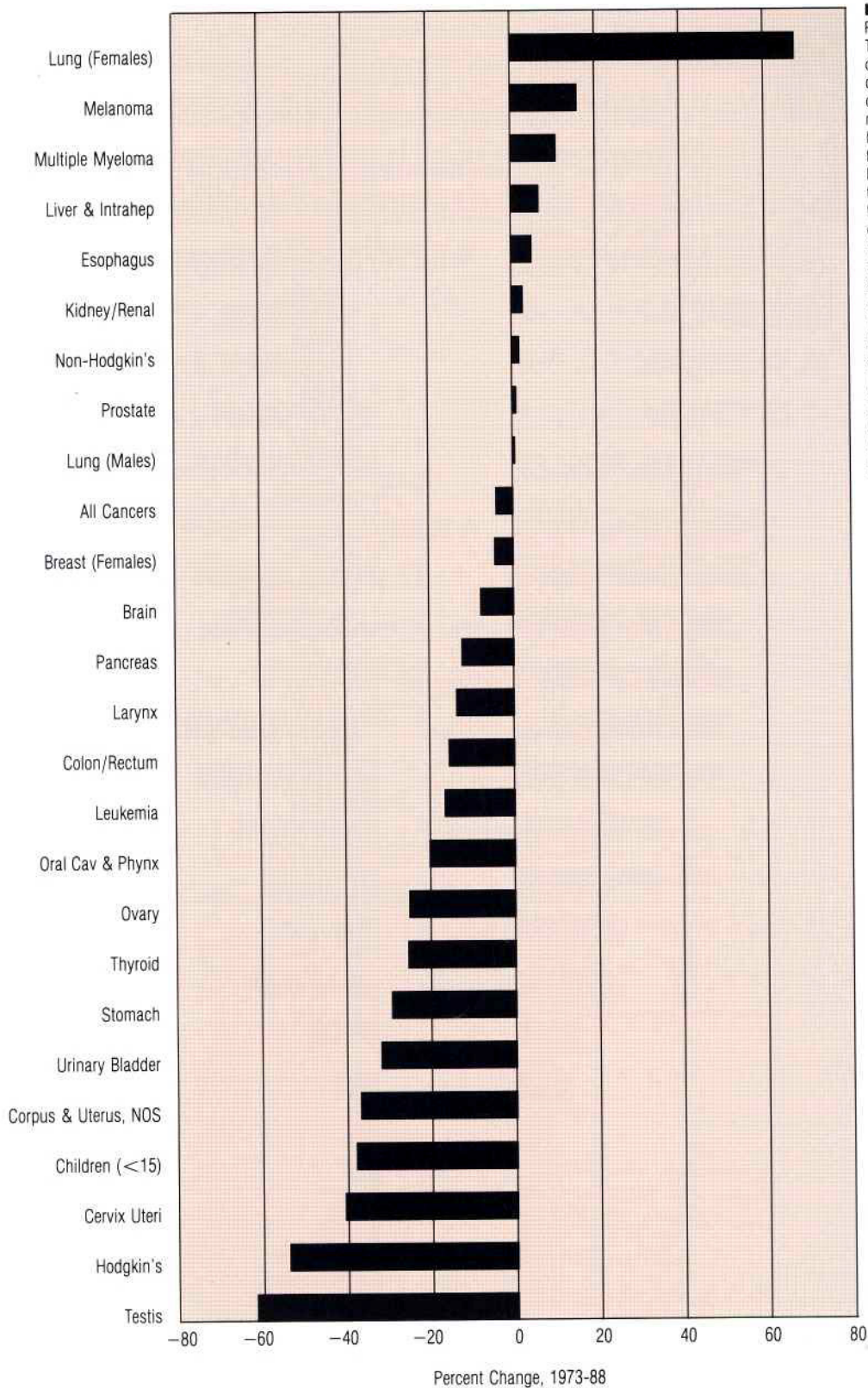


**5-Year Relative Survival Rates, by Site**  
**White versus Black Patients**  
**1981 to 1987**



# Cancer Mortality Rates Changes from 1973 to 1988

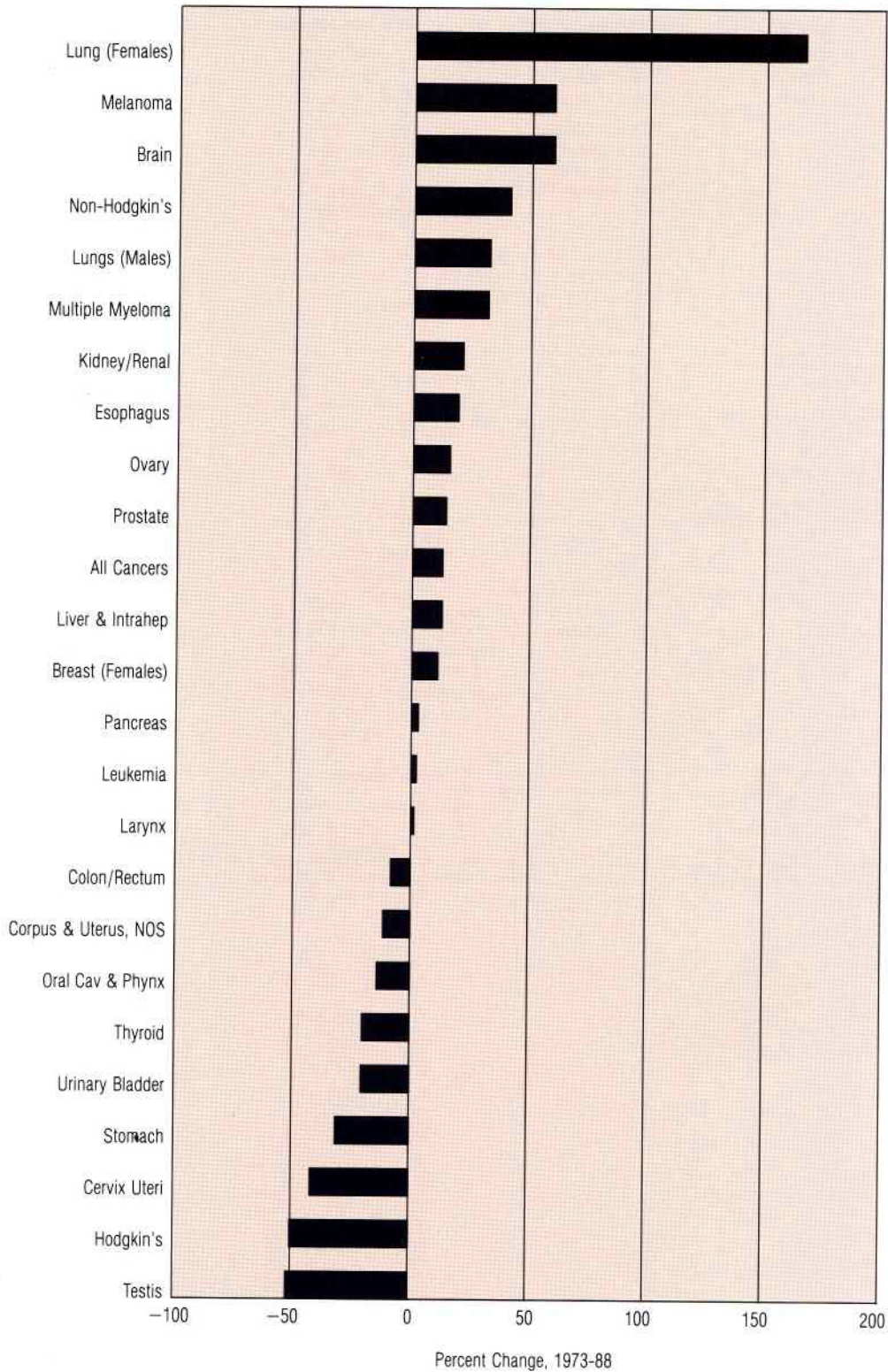
Ages < 65



**Note:**  
Progress and problems: This graph illustrates percent changes in the annual death rate for a wide range of cancers. Cancers to the right of the zero axis have had increased cancer mortality rates, those to the left have had decreased mortality rates. If the graph is turned counter-clockwise on its side, the bars pointing down show the major tumors in which a significant reduction in annual death rate has occurred. Progress is apparent: a reduction has occurred in the annual death rates since 1973 in both common and uncommon cancers. This definitely shows progress in the age group under 65, albeit more progress needs to be made.

# Cancer Mortality Rates Changes from 1973 to 1988

**Ages > 65**



**Note:** Progress and problems: Comparing this chart to that for individuals under 65, it is clear that not as much progress is being made in reducing cancer death rates in older groups. The cancer deaths to the right of the zero axis have risen, those to the left have decreased. This graph should be compared to the accompanying graph addressing changes in mortality rates for people under age 65. Issues such as low-income, patterns of medical care, and other related factors are thought to be important considerations in the older population.

## Cancer Mortality Rates United States, 1984-1988

Cancer Site	Mortality Rate per 100,000		Ratio
	Blacks	Whites	Blacks/Whites
All Sites	216.1	167.9	1.3
Males	298.1	212.7	1.4
Females	160.1	138.3	1.2
Esophagus	8.6	2.8	3.1
Cervix Uteri	7.1	2.7	2.7
Prostate	47.0	22.2	2.1
Multiple Myeloma	5.4	2.6	2.1
Larynx	2.6	1.2	2.1
Stomach	8.8	4.5	1.9
Oral Cavity and Pharynx	5.2	2.9	1.8
Corpus & Uterus NOS	5.9	3.4	1.7
Liver & Intrahep.	3.8	2.3	1.6
Pancreas	11.5	8.2	1.4
Lung & Bronchus	56.6	46.6	1.2
Males	98.5	72.5	1.4
Females	26.4	27.6	1.0
Colon and Rectum	22.8	20.0	1.1
Colon	20.0	17.3	1.2
Rectum	2.8	2.7	1.0
Breast (Females)	29.5	27.3	1.1
<50 years	9.2	6.0	1.5
≥50 years	92.1	93.2	1.0
Thyroid	0.4	0.3	1.0
Urinary Bladder	3.3	3.4	1.0
Kidney & Renal Pelvis	3.0	3.4	0.9
Leukemia	5.8	6.5	0.9
Hodgkin's Disease	0.6	0.7	0.9
Ovary	6.2	7.9	0.8
Non-Hodgkin's Lymphomas	3.8	6.0	0.6
Brain & CNS	2.4	4.3	0.6
Testis	0.1	0.3	0.5
Melanoma of Skin	0.4	2.4	0.2
All Sites Except Lung	159.5	121.3	1.3
Males	199.5	140.1	1.4
Females	133.7	110.7	1.2

NOTE: The annual number of cancer deaths per 100,000 persons derived from estimates of the National Center for Health Statistics, adjusted to the 1970 US population age distribution.



## Cancer Incidence Rates United States, 1984-1988

Cancer Site	Incidence Rate per 100,000		Ratio
	Blacks	Whites	Blacks/Whites
All Sites	405.4	373.6	1.1
Males	522.7	433.1	1.2
Females	324.9	339.8	1.0
Esophagus	10.9	3.2	3.4
Multiple Myeloma	8.2	3.9	2.1
Cervix	15.8	7.8	2.0
Stomach	12.9	7.1	1.8
Liver & Intrahep.	3.9	2.1	1.8
Pancreas	14.6	9.1	1.6
Larynx	7.2	4.6	1.6
Prostate	134.0	92.2	1.5
Lung and Bronchus	77.8	56.8	1.4
Males	127.8	82.5	1.5
Females	40.7	37.8	1.1
Oral Cavity and Pharynx	14.7	10.8	1.4
Kidney and Renal Pelvis	8.5	8.2	1.0
Colon and Rectum	51.0	50.6	1.0
Colon	39.3	35.9	1.1
Rectum	11.7	14.7	0.8
Leukemia	8.7	10.1	0.9
Breast (Females)	91.7	108.8	0.8
<50 years	34.1	32.6	1.0
≥50 years	269.3	343.7	0.8
Ovary	9.8	14.6	0.7
Non-Hodgkin's Lymphomas	8.6	13.7	0.6
Brain and Other Nervous	4.0	6.5	0.6
Corpus & Uterus NOS	14.0	22.7	0.6
Hodgkin's Disease	1.8	3.1	0.6
Thyroid	2.4	4.3	0.6
Bladder	9.8	18.0	0.5
Testis	0.7	4.7	0.1
Melanoma of skin	0.7	10.9	0.1
All Sites except Lung	327.6	316.9	1.0
Males	394.9	350.5	1.1
Females	284.2	302.0	0.9

NOTE: The annual number of new cancer cases per 100,000 persons derived from NCI's SEER Program, adjusted to the 1970 US population age distribution.

**The Prevalence of Cancer:  
Estimated Number of Persons  
Diagnosed with Cancer  
United States, 1991**

	1991 Estimated Prevalence		
	Total	Males	Females
<b>ALL SITES</b>	7,076,000	2,731,000	4,345,000
Oral & Pharynx	206,000	129,000	77,000
Stomach	70,000	40,000	30,000
Colon/Rectal	1,236,000	573,000	663,000
Colon	877,000	391,000	486,000
Rectum	359,000	182,000	177,000
Pancreas	23,000	11,000	12,000
Larynx	137,000	109,000	28,000
Lung & Bronchus	360,000	206,000	154,000
Melanoma of Skin	365,000	173,000	192,000
Breast	1,702,000	—	1,702,000
Cervix Uteri	194,000	—	194,000
Corpus & Uterus	504,000	—	504,000
Ovary	169,000	—	169,000
Prostate Gland	542,000	542,000	—
Testis	103,000	103,000	—
Urinary Bladder	539,000	384,000	155,000
Kidney & Renal Pelvis	153,000	93,000	60,000
Brain & Nervous System	72,000	37,000	35,000
Thyroid	175,000	42,000	133,000
Hodgkin's Disease	131,000	71,000	60,000
Non-Hodgkin's Lymphomas	239,000	118,000	121,000
Leukemia	100,000	52,000	48,000

NOTE: Based on estimates of number of persons diagnosed with cancer prepared by the Connecticut Cancer Registry and population estimates from the National Cancer Institute; projections based on linear extrapolation.



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**Fiscal Year  
1991 Budget***(Dollars in Thousands)*

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**A. Actual Obligations Resulting From Appropriated Funds:**

FY 1991 Appropriation	\$1,766,324
Sequester Order	22
Section 514(b)-travel reduction	8,972
Section 514(b)-S&E reduction	42,568
Transfer to other NIH Institutes for Shannon Program	2,091
	<u>1,712,671</u>

**Less:**

Lapse	(2)
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**ACTUAL NCI OBLIGATIONS** **1,712,669****B. Reimbursable Obligations:****Major Components—**

- Acquired Immune Deficiency Syndrome (AIDS):
  - Office of the Director, NIH 2,254
- Construction reimbursement from NIH 1,300
- Other Reimbursements 27,027

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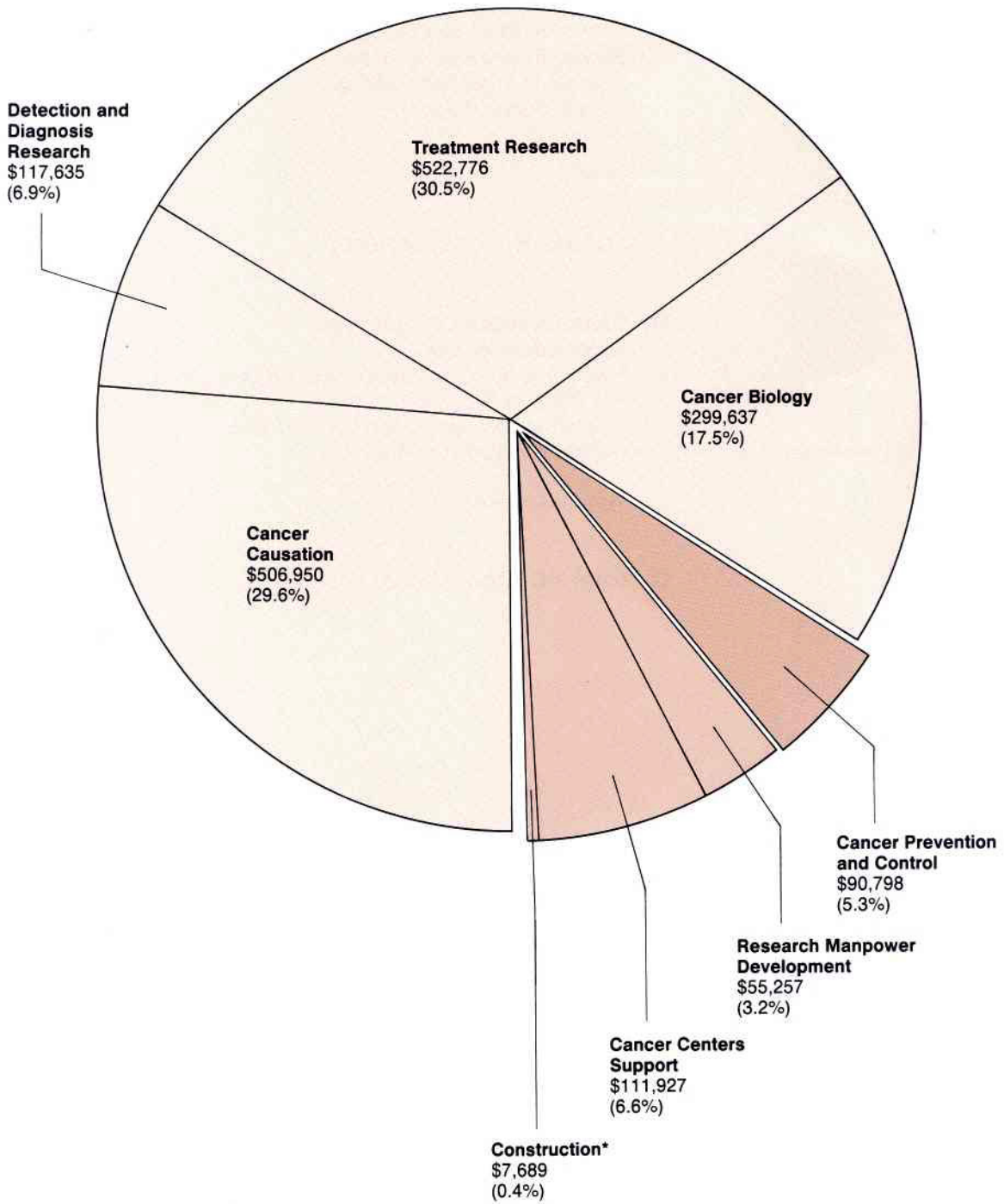
Reimbursements	30,581
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**C. Total NCI Obligations:** **\$1,743,250**

**Program Structure  
Fiscal Year 1991**

(Dollars in Thousands)

**TOTAL DOLLARS**  
\$1,712,669

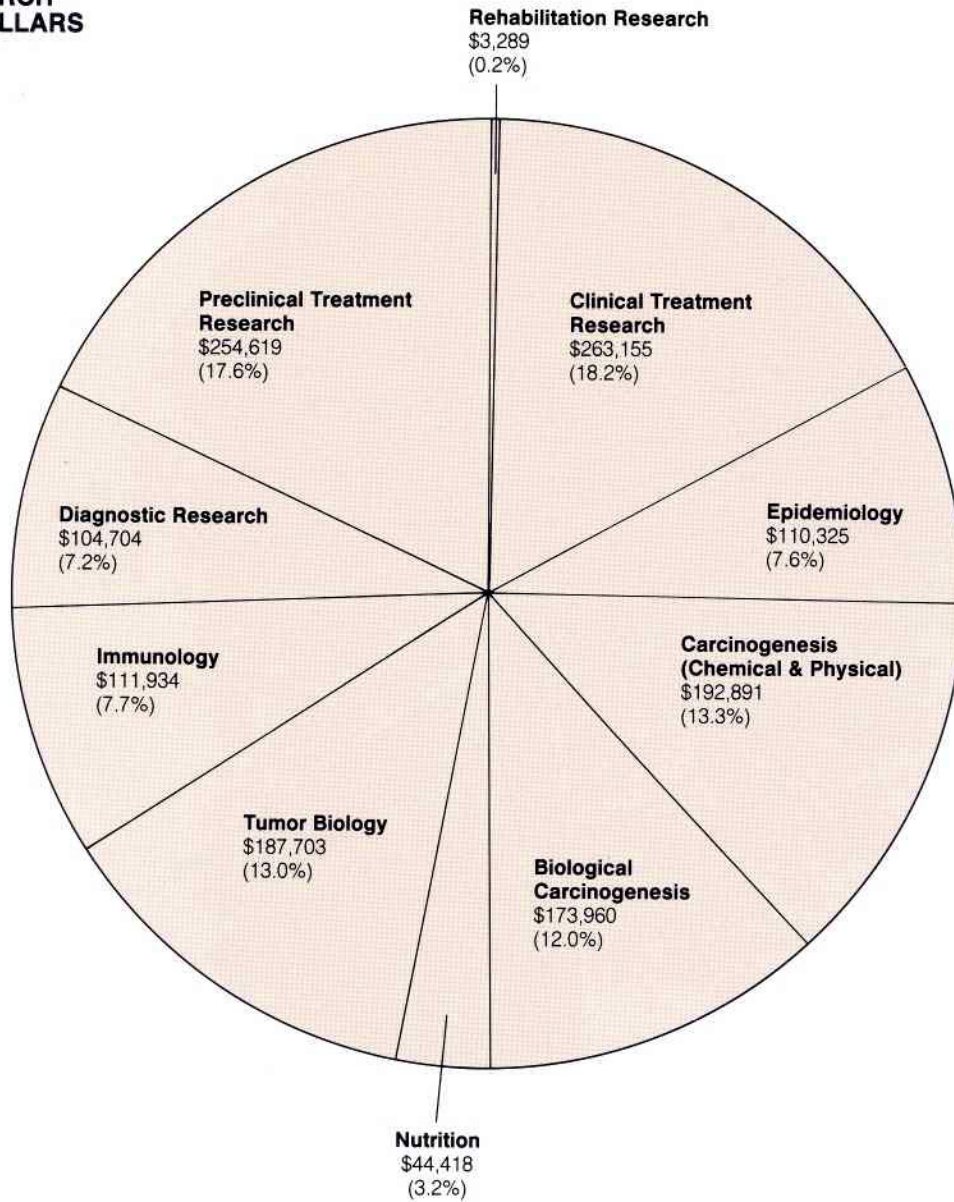


- RESEARCH \$1,446,998 (84.5%)
- RESOURCE DEVELOPMENT \$174,873 (10.2%)
- CANCER PREVENTION AND CONTROL \$90,798 (5.3%)

**NCI Research Programs  
Fiscal Year 1991**

(Dollars in Thousands)

**TOTAL RESEARCH  
PROGRAM DOLLARS**  
\$1,446,998

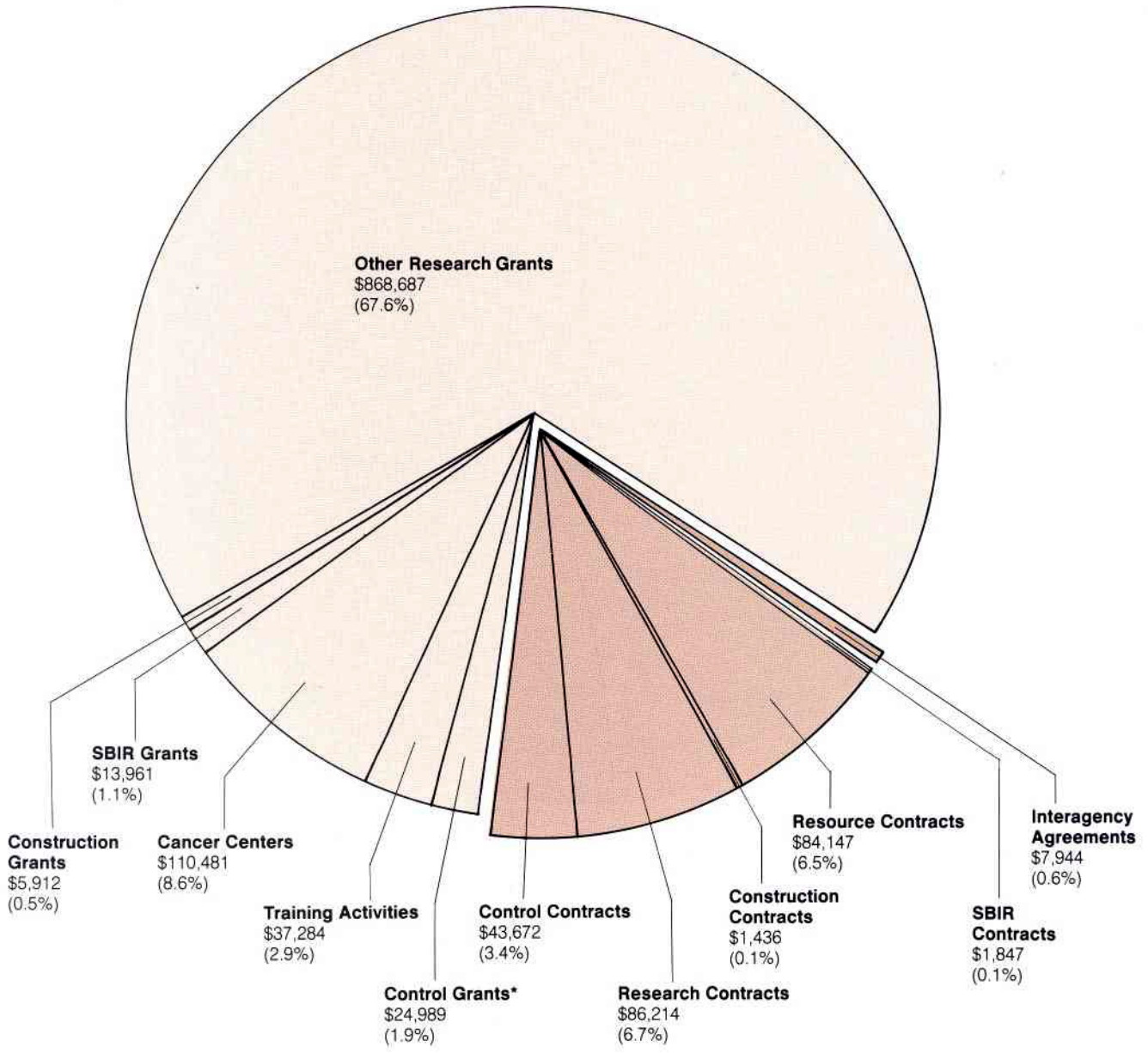


Research Programs	Dollars (Thousands)	Percent of Total
<b>Research Programs</b>	\$1,446,998	84.5%
<b>Resource Development</b>		
Cancer Centers Support	111,927	6.6%
Research Manpower Development	55,257	3.2%
Construction*	7,689	0.4%
<b>Cancer Prevention and Control</b>	90,798	5.3%
<b>Total NCI</b>	\$1,712,669	100.0%

**Extramural Funds  
Fiscal Year 1991**

(Dollars in Thousands)

**TOTAL EXTRAMURAL**  
\$1,286,005



- GRANTS** \$1,060,745
- CONTRACTS** \$217,316
- INTERAGENCY AGREEMENTS** \$7,944

**TOTAL INTRAMURAL/RMS/CONTROL** \$426,664  
**TOTAL NCI** \$1,712,669

\*Includes rehabilitation

**Total Dollars by  
Mechanism  
Fiscal Year 1991**

(Dollars in Thousands)

Amount	Mechanism	Percent of Total	Amount	Mechanism	Percent of Total
<b>Research Project Grants</b>			<b>Training Program</b>		
\$381,932	Traditional	22.3%	32,678	NRSA Institutional	1.9%
190,470	Program Projects	11.1	4,606	NRSA Individual	0.3
29,494	FIRST Awards	1.7	37,284	Total	2.2
43,687	MERIT Awards	2.6	<b>Research and Development Contracts</b>		
13,962	SBIR Grants	0.8	170,361	Research and Resource Contracts	9.9
62,137	Outstanding Investigator Grants	3.6	7,943	Interagency Agreements	0.5
37,435	RFAs	2.2	1,848	SBIR Contracts	0.1
32,431	Coop Agreements	1.9	180,152	Total	10.5
791,548	Total	46.2	<b>Cancer Prevention and Control</b>		
<b>Cancer Centers Grants</b>				Grants:	
110,481	Center Core Grants	6.5	478	Rehabilitation	—
<b>Other Research Grants</b>			24,420	Cancer Control	1.5
3,148	Instrumentation Grants	0.2	24,898	Subtotal Grants	1.5
2,726	Shannon Awards	0.2	43,672	Contracts	2.5
384	Conference Grants	—	16,820	Inhouse	1.0
60,849	Clinical Coop Group	3.6	85,390	Total	5.0
2,949	Small Grants	0.2	<b>Inhouse</b>		
2,477	Comp. Min. Bio. Supp. Prog.	0.1	326,160	Intramural Research	19.0
4,449	Scientific Evaluation	0.2	83,684	Research Management and Support	4.9
3,095	Cancer Education Program	0.2	409,844	Total	23.9
	Research Career Programs:		<b>Construction</b>		
2,573	RCDA	0.1	5,912	Grants	0.3
68	RCA	—	1,436	Contracts	0.1
3,150	Phys. Invest. Awds.	0.2	7,348	Total	0.4
1,140	Preventive Oncology	0.1	<b>Total</b>		
3,325	Clin. Invest. Awds.	0.2	\$1,712,669	NCI	100.0%
289	Minority Careers	—			
10,545	Subtotal Careers	0.6			
90,622	Total	5.3			
<b>Total</b>					
\$992,651	Research Grants	58.0%			



**Division Obligations  
by Mechanism  
Fiscal Year 1991**

(Dollars in Thousands)

	DCBDC	DCT	DCE	AIDS Task Force	DCPC	DEA	FCRDC	OD	Program Support	TOTAL NCI
<b>Research Grants:</b>										
Research Project Grants	\$226,473	\$245,512	\$230,470		\$73,177	\$1,955				\$777,587
SBIR Grants	2,851	8,510	1,909		691					13,961
Subtotal, Research Project Grants	229,324	254,022	232,379		73,868	1,955				791,548
Cancer Centers Grants	109,699					782				110,481
Other Research Grants:										
Clinical Cooperative Groups		60,849								60,849
Cancer Education Program	3,095									3,095
Career Program	10,256					289				10,545
Instrumentation Grants	3,148									3,148
Exploratory/Developmental										
Conference Grants	129	54	108		63	30				384
Small Grants	1,160	1,329	460							2,949
Shannon Awards	1,026	850	850							2,726
Minority Biomedical Support						2,477				2,477
Scientific Evaluation						4,449				4,449
Subtotal, Other Research Grants	18,814	63,082	1,418		63	7,245				90,622
Subtotal, Research Grants	357,837	317,104	233,797		73,931	9,982				992,651
<b>NRSA Fellowships</b>	36,887					397				37,284
<b>Research and Development Contracts:</b>										
R&D Contracts	4,953	62,579	35,604	498	15,270		50,053	9,348		178,305
SBIR Contracts		924			923					1,847
Subtotal, Contracts	4,953	63,503	35,604	498	16,193		50,053	9,348		180,152
<b>Cancer Prevention and Control:</b>										
Grants										
Rehabilitation Grants					478					478
Cancer Control					24,420					24,420
Subtotal, Grants					24,898					24,898
Control Contracts					43,672					43,672
Inhouse					16,820					16,820
Total, Prevention & Control					85,390					85,390
<b>Inhouse<sup>1</sup></b>	55,800	88,862	65,083	2	3,085	7,516	1,225	44,301		265,874
NIH Management Fund								124,025		124,025
Construction	5,912						1,436			7,348
All Other <sup>2</sup>									19,945	19,945
<b>Division Totals</b>	<b>\$461,389</b>	<b>\$469,469</b>	<b>\$334,484</b>	<b>\$500</b>	<b>\$178,599</b>	<b>\$17,895</b>	<b>\$52,714</b>	<b>\$177,674</b>	<b>\$19,945</b>	<b>\$1,712,669</b>

<sup>1</sup>Includes Research Management and Intramural Research

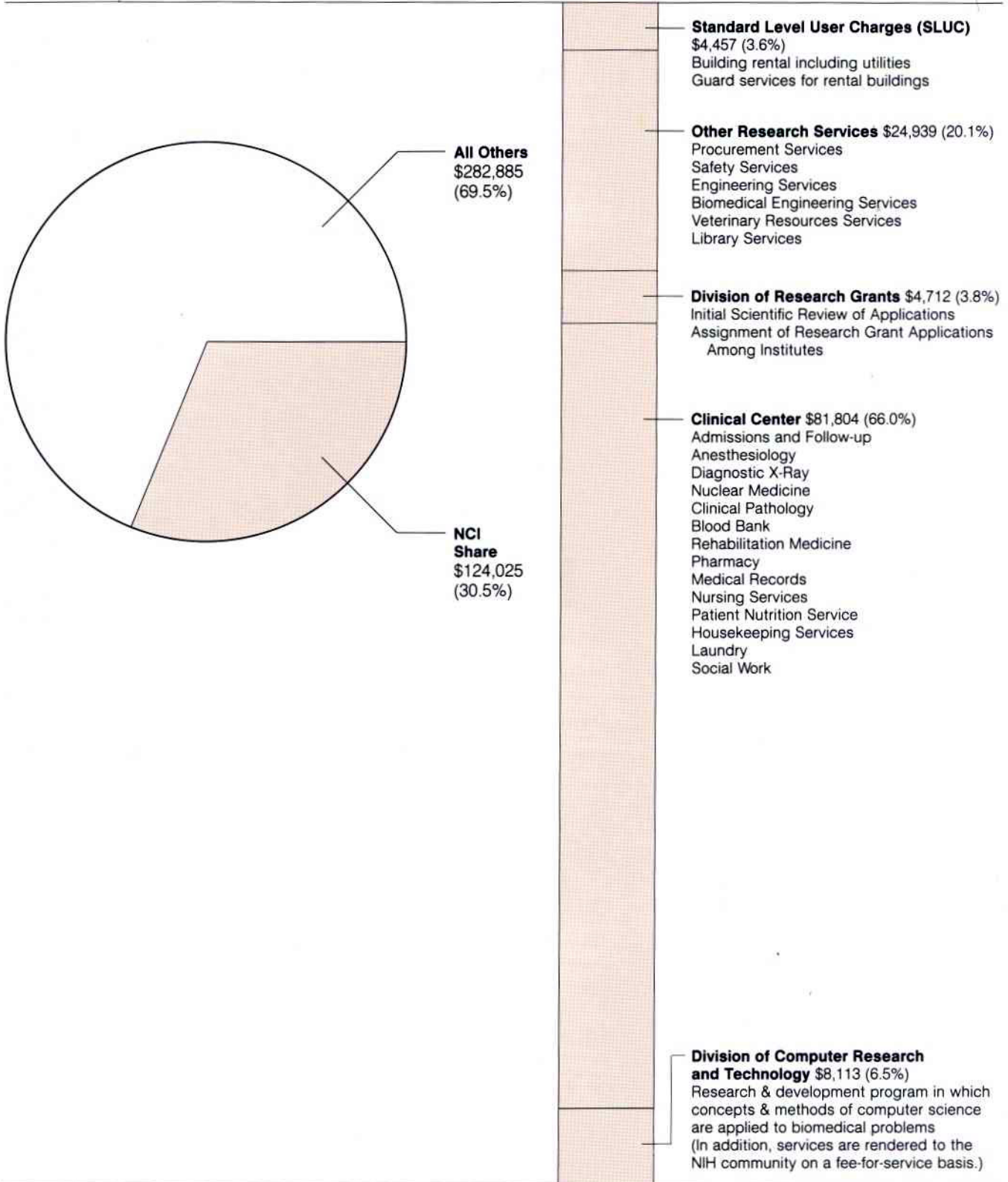
<sup>2</sup>Includes Central Assessments for General Expense, Program Evaluation and NCI General Account (covers costs associated with trans-NCI activities like telephones)

**Reimbursement to NIH  
Management Fund  
Fiscal Year 1991**

(Dollars in Thousands)

**TOTAL NIH SERVICES**  
\$406,910

**DISTRIBUTION OF  
NCI SERVICES \$124,025**



The Management Fund provides for the financing of certain common research and administrative support activities which are required in the operations of NIH.

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## Special Sources of Funds

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### *CRADAs*

As a result of the Federal Technology Transfer Act of 1986, government laboratories are now authorized to enter into Cooperative Research and Development Agreements (CRADAs) with private sector entities. Licensing agreements are usually incorporated into the CRADA document, which addresses patent rights attributable to research supported under the CRADA.

### *Royalty Income*

NCI can now retain royalty income generated by the patents related to NCI-funded research. A major portion of this royalty income is used to reward employees of the laboratory, to further scientific exchange and for education and training in accordance with the terms of the Act. A portion of the receipts is used to support the National Technical Information Service (NTIS), Department of Commerce, who handles the processing and collection phases. Support is also provided to NIH to cover their associated expenses.

#### History of Funding (dollars in thousands)

	Years Available	Obligated Funds Received*	Inventor Payments	Other Uses
Royalty Income:	1988/1989	\$ 982	\$427	\$ 555
	1989/1990	813	575	238
	1990/1991	1,442	871	571
	1991/1992	2,072	428	1,644

\*Does not include assessments by NIH and NTIS.



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## Acquired Immunodeficiency Syndrome (AIDS) Key Discoveries

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The National Cancer Institute has assumed a leading role in Acquired Immunodeficiency Syndrome (AIDS) research since the disease was first recognized in 1981. Because of the research programs and administrative mechanisms already in place, investigators were able to rapidly apply existing methods in drug screening and advances in cancer virus research technology to the study of AIDS. Key discoveries by NCI investigators include:

- Development, testing and successful clinical trials of the drug azidothymidine (AZT), confirming its effectiveness as an anti-retroviral agent against AIDS.
- Demonstration in clinical trials that another dideoxynucleoside drug, dideoxyinosine (ddI) has activity against HIV infection. ddI has been approved by the FDA for use in both adults and children with AIDS who are intolerant to or failing treatment with AZT.
- Progress in treating children with AIDS has occurred through the rapid introduction of antiretroviral agents into clinical trials. The studies performed by the Pediatric Branch contributed to the licensure of AZT for children in May of 1990 and dideoxyinosine (ddI) in October 1991. The latter, based solely on Pediatric Branch Studies, occurred simultaneously with licensure for adults, a historical event. Building on the benefits of these single agents, the Pediatric Branch is currently completing studies of combination regimens to optimize activity (e.g., AZT plus ddI) as well as to offset toxicity (e.g., AZT plus G-CSF and erythropoietin).
- Preliminary work indicates that viral plasma levels will prove to be a valuable tool in assessing the dosing schedule and effectiveness of treatment in both children and adults. Quantitative viral levels may provide a therapeutic index for drug effectiveness in future trials.
- There is evidence that HIV from patients on long-term AZT therapy which has become resistant to AZT preserves its sensitivity to ddI and ddC. Preliminary results of combination therapy with AZT, acyclovir, ddI and ddC in patients with AIDS or severe ARC suggest that patients feel better, have increases in their T4 cells, and have decreases in HIV p24 antigen on the regimen.
- Identification through the high-capacity AIDS drug screen of many new compounds which are active against the AIDS virus in tissue culture experiments. These compounds include both synthetic drugs and natural products. Several of these are in the initial phases of development.
- NCI investigators have shown that an enzyme known as topoisomerase I (topo I) is present in HIV and that a chemical known as camptothecin inhibits this enzyme, at least *in vitro*. Topo I is an important enzyme because it is thought to play a role in the virus' life cycle. Camptothecin is a cytotoxic natural product obtained from plants and which has potent antitumor activity against a wide range of experimental tumors and human colon cancer. Recently, NCI researchers have found that camptothecin at non-cytotoxic levels inhibits HIV infection of human T cells in tissue culture.
- The Laboratory of Biochemical Physiology (LBP) has been investigating new anti-HIV agents from Chinese herbs. A potent, nontoxic inhibitor of HIV infection and replication has been purified from plant-derived protein. The names of these proteins are derived from the genus of their plant source and their molecular weight in kilodaltons. For example, a 30 kilodalton protein isolated from the seeds of the Chinese bitter melon *Momordica charantia* is called MAP 30 (for *Momordica* anti-HIV protein). Another anti-HIV protein, TAP 29, has been obtained from the root of *Trichosanthes kirilowii*, a Chinese medicinal plant.
- HIV-infected cells may release biologically active Tat, the protein product of the *tat* gene, which can be taken up by cells in close proximity and induce cell proliferation, viral transactivation and perhaps other toxic effects. In particular, scientists have learned that the *tat* gene can trigger the AIDS virus to replicate at an increased rate. Thus, manipulation of the *tat* gene could lead to control of the growth of the virus.
- Demonstration that, in addition to CD4 + T-lymphocytes, HIV can bind to and infect monocytes/macrophages, which also possess CD4 receptor molecules on their surfaces. In monocytes infected with HIV-1 and HIV-2, viral expression can be regulated in several ways: 1) latency (provirus with no viral expression); 2) restricted expression (intracytoplasmic viral antigens, RNA and virions but little or no detectable virus released); and 3) continuous production.

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- Individuals infected with HIV may be asymptomatic for years before progressing to overt AIDS. Since monocytes can be a reservoir for HIV in infected individuals, their role in viral persistence and spread was studied. Latently infected monocytoid THP-1 cells and freshly isolated adherent monocytes from asymptomatic seropositive individuals did not show detectable viral expression until they are co-cultured with activated T cells from HIV-negative normal donors. Cell-cell contact is required and seems to induce factor(s) in monocytes capable of overcoming latency. Thus, monocytes in AIDS patients can harbor latent HIV, inducible by T cells, during an immune response. HIV produced by such monocytes infects T cells leading to viral-induced pathology.
  - Negative regulation of the 65+50 kD NF-kB dimer markedly decreased HIV transcription in chronically infected monocytes. In THP-1 cells with restricted HIV expression, there is an absence of DNA protein binding with the HIV-1 promoter-enhancer associated with markedly less production of viral RNA. This absence of binding is localized to the NF-kB region of the HIV enhancer with the 65+50 kD NF-kB heterodimer being preferentially lost. Addition of purified NF-kB protein to nuclear extracts from cells with restricted expression overcomes this lack of binding. In addition, treatment of these nuclear extracts with sodium deoxycholate restores their ability to form the heterodimer, suggesting the presence of an inhibitor of NF-kB activity. Both NF-kB binding complexes are needed for optimal viral transcription. The binding of the 65+50 kD heterodimer to the HIV-1 enhancer can be negatively regulated in monocytes, thus providing one mechanism leading to restricted HIV gene expression.
  - Growth Hormone (GH) exerts significant thymopoietic and hematopoietic effects when administered in vivo and promotes human T cell engraftment when human peripheral blood lymphocytes (huPBL) are transplanted into immunodeficient mice. GH-deficient dwarf mice present with greatly hypoplastic thymuses that are greatly deficient in T cell progenitor cells. Treatment of these mice with GH results in the reappearance of these progenitor cells within the thymopoietic effects in vivo and is critical for normal T cell differentiation to occur within the murine thymus. When huPBL are transplanted into immunodeficient mice, significantly greater engraftment of human T cells is noted in the recipients that also received human GH. Additionally, human T cells localize within the murine thymus after GH-treatment. Thus, human GH can be used to optimize long-term peripheral T-cell engraftment in these human mouse chimeras and may also be useful clinically in the treatment of T cell deficiencies. GH also exerts numerous hematopoietic growth-promoting effects when administered in vivo. When mice are placed on AZT and given GH, the anemia that occurs after AZT treatment is reversed. Thus, the immunological and hematopoietic effects of GH make it an attractive therapy for AIDS and after bone marrow transplantation.
  - Development of a sensitive T-helper lymphocyte assay which can detect exposure to the AIDS virus before the individual's sera becomes positive for HIV antibodies (the current standard, world-wide test used to screen blood). This assay represents the most sensitive test for HIV exposure developed to date.
  - The CD4 AIDS virus receptor on the surface of human T-cells has been found to be physically associated with a proto-oncogene known as  $p^{56}$  lck; the protein product of which is a tyrosine-specific kinase. The efficacy of daily intramuscular injections of recombinant CD4 in preventing progression of simian AIDS in rhesus monkeys has been demonstrated. This protein may be useful as a therapeutic agent for the treatment of human AIDS.
  - Construction of a recombinant toxin conjugate for the treatment of AIDS, CD4-PE40, in which the portion of the CD4 molecule that binds to the HIV virus is joined to a bacterial toxin. A Phase I trial of CD4-PE40 has been initiated in AIDS patients at the NIH Clinical Center.
  - Determination of the first crystal structure of retroviral protease and its successful use to predict the structure of the HIV protease and substrate using super-computer methodology.
  - Demonstration that prevention of a common, spontaneous retrovirus-induced immunosuppressive disease in rhesus monkeys (Simian Acquired Immunodeficiency Syndrome or SAIDS) is now possible through vaccination.

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- Eukaryotic recombinant expression vector systems, in particular the baculovirus-insect cell and metallothione promoter vector systems, HIV, simian immunodeficiency virus (SIV), and proviral molecular clones of bovine immunodeficiency virus (BIV), are being used to engineer novel noninfectious pseudovirions. These virus-like particles are designed to contain Gag proteins, Gag-Pol-Env, or Gag and a combination of T- and/or B-cell reactive virus Env epitopes (e.g., primary neutralizing and/or fusion domains) or immunomodulators (e.g., IL-2).
  - The bovine immunodeficiency-like virus (BIV) is a unique member of the lentivirus subfamily of retroviruses. Chronic infection in specific pathogen-free rabbits (*Oryctolagus cuniculus*) has been established with a natural isolate or progeny of an infectious molecular clone of BIV. The infection results in a rapid and sustained BIV-specific humoral response suggesting that infection is targeted to cells of the immune system.
  - Identification of portions of the AIDS virus envelope that are recognized by cytotoxic and helper T-cells and which elicit immune responses in healthy and symptomatic HIV-infected individuals.
  - Studies of the immune responses of HIV-positive mothers and their children recently established a correlation between maternal antibodies to the HIV envelope protein gp120 and reduced risk of HIV transmission to her offspring. Determination of the precise antigenic determinant (epitope) on the gp120 molecule which confers this protective effect is of extremely high priority to the development of methods to prevent perinatal transmission to the babies of HIV-infected women.
  - More precise identification, by means of a multi-center study of male hemophiliacs, of predictors for an increased risk of developing AIDS. In particular a decline in CD4+ lymphocytes, the appearance of HIV antigen, and increased levels of alpha-interferon. The decline in immunity is associated with an increase in the infection rate of female spouses. This represents a major risk factor in the sexual transmission of HIV.
  - NCI epidemiologists have detected an apparent decrease in the expected incidence of AIDS in the U.S. This decrease was rather an abrupt one and began in 1987. The most plausible explanation for this finding is the impact of therapy on preventing seriously immune compromised persons from progressing to AIDS, although a marked reduction in HIV incidence between 1983 and 1985 may also be contributing to this phenomenon. It is noteworthy that these effects were most prominent in persons with best access to care, but were not seen in groups such as drug abusers who have limited access to therapy.
  - Kaposi's sarcoma (KS) has gained importance because of the high incidence (20 to 30 percent) in patients with HIV infection and AIDS. Recently NCI researchers demonstrated that KS cells can be maintained in tissue culture if they are grown in conditioned media from HTLV-1 or HTLV-2 transformed or activated CD+4 T-cells. AIDS-KS cells release into the medium a number of cytokines which induce the AIDS-KS derived cells to proliferate. The factors have been shown to be biologically active growth-promoting proteins (cytokines) released by the T cells and not products of the virus itself.
  - The striking production of autostimulatory and angiogenic growth factors by KS cells suggest that these factors should be an important target for therapy. A new inhibitor of angiogenesis Fumagillin and its synthetic analog, TNP-470, are currently under pre-clinical development, with Phase I trials projected to begin in approximately one year.
  - Recent investigations on the development of tumors in patients with AIDS or AIDS-related complex (ARC) on long-term HIV therapy showed that eight out of 55 patients on long-term AZT containing regimens developed non-Hodgkin's lymphomas. When the development of the lymphomas was plotted by the methods of Kaplan and Meier, the chance of developing a non-Hodgkin's lymphoma was 46 percent in patients with AIDS or severe ARC who were maintained on AZT-based therapy for three years.

**Acquired Immunodeficiency Syndrome (AIDS) Funding by Functional Category Fiscal Year 1991** *(Dollars in Thousands)*

<b>I. Basic Science Research</b>		
A. Biomedical Research		
1. HIV and HIV genome		\$ 29,993
2. Immunology		8,774
3. Blood/Blood products		358
5. Animal models & related studies		6,362
Subtotal, Biomedical Research		<u>45,487</u>
D. Therapeutic Agents		
1. Development		42,508
2. Clinical Trials		39,177
Subtotal, Therapeutic Agents		<u>81,685</u>
E. Vaccines		
1. Development		15,148
2. Clinical Trials		0
Subtotal, Vaccines		<u>15,148</u>
	TOTAL, BASIC SCIENCE RESEARCH	142,320
<b>II. Risk Assessment and Prevention</b>		
A. Surveillance		
1. Diseases associated with HIV		2,348
2. HIV surveys (incidence, prevalence)		0
3. Knowledge, attitudes, behaviors		0
Subtotal, Surveillance		<u>2,348</u>
B. Population-Based Research		
1. Transmission		
a. Sexual		1,631
b. Intravenous drug abusers		0
c. Hemophilic populations		1,369
d. Blood recipient/donor studies		0
e. Perinatal infection		914
f. Occupationally related		0
g. Other/Miscellaneous		4,281
Subtotal, Transmission		<u>8,195</u>
2. Natural history and cofactors		8,006
Subtotal, Population-Based Research		<u>16,201</u>
	TOTAL, RISK ASSESSMENT AND PREVENTION	18,549
	<b>Total, NCI</b>	<b>\$160,869</b>

Note: The functional codes of AIDS activities were developed by PHS at the request of Dr. Mason, Deputy Secretary of HHS. These functional categories are intended to identify AIDS research in terms of "deliverables."



**Acquired Immunodeficiency  
Syndrome (AIDS)  
Funding by Activity  
Fiscal Year 1991**

(Dollars in Thousands)

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<b>By Mechanism:</b>	<u>Amount</u>
Research Project Grants	\$ 18,791
Cancer Center Grants	4,278
Conference Grants	6
R&D Contracts	56,479
Intramural Research	75,187
Research Management and Support	6,128
Total, NCI	<u>\$160,869</u>

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<b>By Research Program:</b>	<u>Amount</u>
Causation Research	\$ 78,100
Detection and Diagnosis Research	422
Treatment Research	66,387
Cancer Biology	11,682
Total Research	<u>156,591</u>
Resource Development	
Cancer Center Grants	4,278
Total, NCI	<u>\$160,869</u>

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<b>By Division:</b>	<u>Amount</u>
Division of Cancer Biology, Diagnosis and Centers	\$ 13,457
Division of Cancer Treatment	56,359
Division of Cancer Etiology	48,126
Frederick Cancer Research and Development Center	20,159
AIDS Vaccine Task Force	499
Division of Extramural Activities	1,097
Office of the Director	4,641
NIH Management Fund*	16,531
Total, NCI	<u>\$160,869</u>

\*Supports common services shared by NIH Institutes; in this case is used principally for support costs associated with NCI's activities at the NIH Clinical Center.

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**Acquired Immunodeficiency  
Syndrome (AIDS)  
Funding History  
Fiscal Years 1982-1991***(Dollars in Thousands)*

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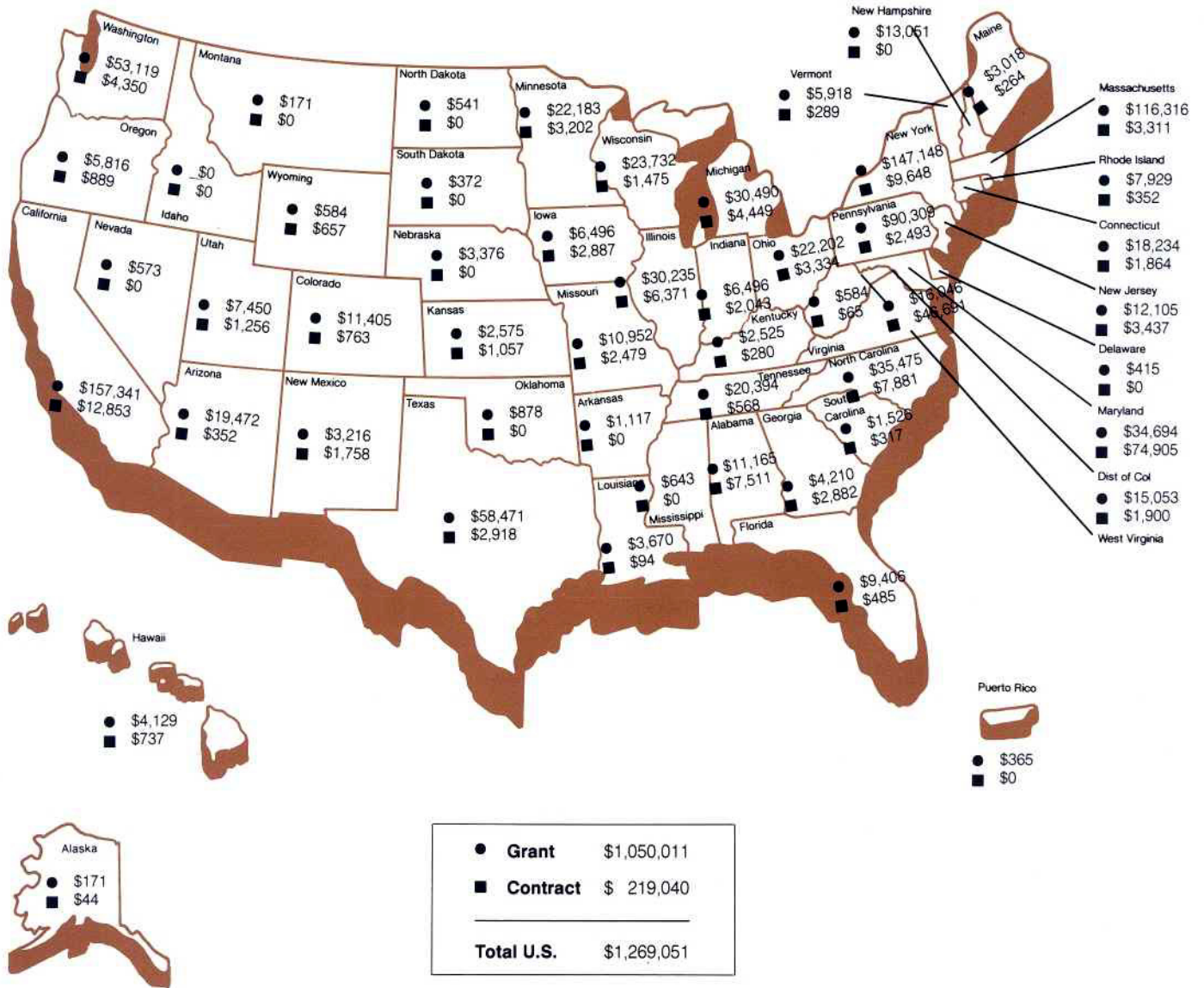
<b>Fiscal Year</b>	<b>NCI Amount</b>	<b>NIH Amount</b>	<b>% NCI To NIH</b>
1982	\$2,406	\$3,355	72%
1983	9,790	21,668	45%
1984	16,627	44,121	38%
1985	26,874	63,737	42%
1986	45,050	134,667	33%
1987	63,755	260,907	24%
1988	89,944	473,285	19%
1989	122,247	627,076	19%
1990	150,304	740,509	20%
1991	160,869	799,821	20%

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# Grant and Contract Awards by State Fiscal Year 1991

(Dollars in Thousands)



Note: Grant figures exclude foreign grants of \$6,236 and Scientific Evaluation of \$4,449; contract figures exclude foreign contracts of \$6,223; all figures include grant and contract funding for Cancer Prevention and Control activities.

**Institutions Receiving  
More than \$5,000,000  
in NCI Support  
Fiscal Year 1991**

(Dollars in Thousands)

State	Institution	Grants	Contracts	Construction	Total NCI	
Alabama	University of Alabama at Birmingham	\$8,213	\$1,851	\$0	\$10,064	
	Southern Research Institute	1,747	5,468	0	7,215	
Arizona	University of Arizona	16,948	0	0	16,948	
California	University of California San Francisco	70,768	1,677	0	72,445	
	Stanford University	18,377	271	0	18,648	
	University of Southern California	15,146	227	0	15,373	
	Scripps Research Institute	7,448	0	0	7,448	
	Salk Institute for Biological Studies	6,845	0	0	6,845	
	La Jolla Cancer Research Foundation	5,489	0	0	5,489	
Colorado	SRI International	2,441	2,795	0	5,236	
	University of Colorado Health Sciences	5,913	0	0	5,913	
Connecticut	Yale University	17,549	569	0	18,118	
DC	Georgetown University	6,141	80	0	6,221	
	U.S. Walter Reed Army Med Center	49	5,866	0	5,915	
Florida	University of Miami	5,012	485	0	5,497	
Illinois	University of Chicago	12,864	602	0	13,466	
	University of Illinois at Chicago	6,951	1,663	0	8,614	
Maryland	Johns Hopkins University	27,853	861	0	28,714	
	Advanced Bioscience Laboratories, Inc.	0	16,540	0	16,540	
	Westat, Inc.	0	10,877	0	10,877	
	U.S. Frederick Cancer Research Facility	298	6,948	0	7,246	
	Information Management Services	0	5,437	0	5,437	
Massachusetts	Dana-Farber Cancer Institute	24,541	408	0	24,949	
	Harvard University	17,882	0	0	17,882	
	Massachusetts General Hospital	16,766	0	0	16,766	
	Brigham and Women's Hospital	10,831	0	0	10,831	
Michigan	Massachusetts Institute of Technology	10,106	0	210	10,316	
	University of Michigan at Ann Arbor	12,964	0	3,238	16,202	
	Wayne State University	8,049	0	0	8,049	
Minnesota	University of Minnesota of Mnpls-St. Pa	11,964	181	0	12,145	
	Mayo Foundation	8,337	621	0	8,958	
Missouri	Washington University	6,236	288	0	6,524	
New Hampshire	Dartmouth College	12,913	0	0	12,913	
New York	Memorial Hospital for Cancer & Allied D	32,211	2,573	0	34,784	
	Columbia University	16,418	0	0	16,418	
	Roswell Park Memorial Institute	14,554	1,860	0	16,414	
	New York University	13,816	44	0	13,860	
	Yeshiva University	11,898	0	0	11,898	
	American Health Foundation	9,291	800	0	10,091	
	University of Rochester	9,176	0	0	9,176	
	Cold Spring Harbor Laboratory	9,221	0	0	9,221	
	State University of New York	7,350	471	0	7,821	
	North Carolina	Duke University	17,744	293	0	18,037
		University of North Carolina System	13,894	522	0	14,416
Ohio	Research Triangle Institute	0	5,127	0	5,127	
	Ohio State University	5,794	424	0	6,218	
Pennsylvania	Case Western Reserve University	7,560	0	0	7,560	
	Fox Chase Cancer Center	20,371	603	0	20,974	
	University of Pittsburgh	19,857	877	821	21,555	
	University of Pennsylvania	13,252	593	0	13,845	
	Wistar Institute of Anatomy and Biology	11,341	0	0	11,341	
	Pennsylvania State University Hershey M	6,162	0	0	6,162	
Tennessee	Thomas Jefferson University	5,673	66	0	5,739	
	St. Jude Children's Research Hospital	8,891	0	0	8,891	
Texas	Vanderbilt University	7,544	0	0	7,544	
	University of Texas System	42,624	1,954	0	44,578	
	Baylor College of Medicine	6,141	0	0	6,141	
Utah	Cancer Therapy and Research Center	5,978	0	0	5,978	
	University of Utah	7,284	1,256	0	8,540	
Vermont	University of Vermont & St Agric. College	5,854	39	0	5,693	
Virginia	Program Resources, Inc.	0	42,744	0	42,744	
	American College of Radiology	6,067	675	0	6,742	
	University of Virginia Charlottesville	5,307	0	0	5,307	
Washington	Fred Hutchinson Cancer Research Center	35,511	3,712	1,081	40,304	
	University of Washington	11,198	171	0	11,369	
Wisconsin	University of Wisconsin System	20,838	633	0	21,471	
	<b>Total</b>	<b>\$785,271</b>	<b>\$129,152</b>	<b>\$5,350</b>	<b>\$919,773</b>	
	Percent of Total Awarded Above	85.4%	14.0%	0.6%	100.0%	
	Total NCI Fiscal Year 1990 Obligations				\$1,712,669	
	Percent of Total NCI Obligations	45.9%	7.5%	0.3%	53.7%	

## Cancer Centers Funding History

(Dollars in Thousands)

Fiscal Year	Center Support	Percent Increase
1984	\$ 79,273	—
1985	84,957	7.2%
1986	88,426	4.0
1987	95,819	8.3
1988	100,427	4.8
1989	101,127	0.7
1990	105,268	4.1
1991	110,481	5.0

Cancer centers supported by the NCI multidisciplinary research programs at academic and other organizations are one of the key elements of the research infrastructure for cancer research. As a group, they are engaged in all aspects of cancer research, including basic, clinical and cancer control research, also serving as a stable resource for training new cancer investigators.

The cancer centers concept was initiated nearly 20 years ago in order to promote interactions between basic scientists, clinical scientists, and physicians that would stimulate more rapid translation of laboratory findings into medical practice. As major advances in research provided an increased understanding of the causes and etiology of different forms of cancer, cancer centers became engaged in a broader range of research activities as well as in community outreach activities in the areas of education and prevention.

The types of NCI-designated centers include laboratory centers engaged in basic research, clinical centers emphasizing both basic research and clinical research, and comprehensive centers engaged in all aspects of cancer research, including cancer prevention and control. A fourth type of center, the consortium cancer center, stimulates and facilitates multi-institutional collaboration and interacts with regional public health agencies and other organizations that have the ability to conduct programs of cancer prevention and control. Of the 57 cancer center support grants (CCSG) awarded in FY 1991, 15 were to basic laboratory centers, two were to consortium centers, 12 were to clinical centers, and 28 have been awarded comprehensive status.

The Cancer Centers Program provides a small but critical portion of the total research support to NCI-designated cancer centers through the CCSG. This grant specifically promotes research by stimulating interactions and collaborations between basic and clinical scientists who already have received peer-reviewed research support to take advantage of research opportunities, promotes cost-effectiveness of research resources, provides access to the newest technologies, and together with other support mechanisms such as the NCI Cancer Information Service contracts, enhances the interactions of the center with its local and regional communities. The CCSGs achieve their objectives by stabilizing the leadership of the center, which will be responsible for facilitating, catalyzing, and promoting an interactive, collaborative research environment and by requiring the commitment of the institution to the cancer center concept.

The revitalization of the Cancer Centers Program has continued in FY 1991. Significant progress has been achieved during the past year with efforts in six major areas: (1) substantial completion of the transition to new guidelines for comprehensive status with heightened emphasis on the conduct of high-priority clinical trials, cancer education, public information, cancer prevention and control research, and regional and community responsibilities; (2) enhancement of the Cancer Centers Program through improved program administration and fiscal management as well as initiation of a complete revision of the CCSG guidelines; (3) completion of two mini-workshops plus the annual National Cancer Institute (NCI) Cancer Center Directors Workshop in Baltimore in June, 1991; (4) integration of the Cancer Centers Branch with other components of the NCI; (5) the announcement of a Request for Applications (RFA) initiative to increase geographic distribution of cancer centers in under-represented areas; and (6) continuation of programs focusing on special problems of cancer in minority and other underserved populations.

Since 1978, the NCI has recognized a special class of NCI-designated cancer centers which provided a comprehensive set of cancer research and community services: the NCI designated comprehensive cancer centers. On January 1, 1990, the Institute issued new guidelines that redefined the concept of an NCI-designated comprehensive cancer center and described the application processes that centers may use to attain and renew this designation. In order to receive this designation, a clinical cancer center with an active CCSG award must provide evidence that they meet eight key criteria for comprehensiveness (see below).

### Criteria for Comprehensiveness

Together with scientific excellence and leadership, the essential characteristics of a comprehensive cancer center include:

- 1) **Basic Laboratory Research:** A critical mass of integrated personnel, facilities and peer-reviewed support for interdisciplinary basic research is essential in a comprehensive cancer center.
- 2) **Basic/Clinical Research Linkage:** A comprehensive cancer center should facilitate the transfer of exciting laboratory discoveries to innovative clinical applications, including clinical treatment and prevention.
- 3) **Clinical Research:** A significant clinical research program utilizing patient resources of the institution and its region is essential to a comprehensive center.
- 4) **High-Priority Clinical Trial Research:** Comprehensive centers should participate significantly in clinical trials that have been accorded high-priority status by the NCI, *unless* the center is participating in trials testing competing hypotheses for the same disease site.
- 5) **Cancer Prevention and Control Research:** Comprehensive cancer centers are expected to have peer-reviewed research in cancer prevention and control and to have planned or ongoing involvement in cancer control on a regional and national basis.
- 6) **Education, Training and Provision of Updates on Current Technology:** It is essential that a comprehensive center be a focal point for clinical and research training, including state-of-the-art research and technology, for health care professionals locally and within the region.
- 7) **Information Services:** A comprehensive cancer center should have an established patient education program and the ability to provide patients and their families with up-to-date information on local as well as national resources that may be needed. In addition, the center should participate in its region's Cancer Information Service.
- 8) **Community Service and Outreach:** A comprehensive cancer center should define the community it serves, take steps to identify cancer issues and problems in this community, and carry out appropriate outreach programs addressing these concerns including cancer prevention and control activities.

## Cancer Centers by State

State	Grantee Institution
Alabama	University of Alabama at Birmingham
Arizona	University of Arizona
California	Beckman Research Institute/City of Hope California Institute of Technology Charles R. Drew University of Medicine and Science La Jolla Cancer Research Foundation Salk Institute for Biological Studies University of California at Los Angeles Beckman Research Institute University of California at San Diego University of Southern California University of Colorado System
Colorado	Yale University
Connecticut	Georgetown University Medical Center
District of Columbia	University of Miami Medical School
Florida	Illinois Cancer Center
Illinois	University of Chicago
Indiana	Purdue University West Lafayette
Maine	Jackson Laboratory
Maryland	Johns Hopkins University
Massachusetts	Dana-Farber Cancer Institute Massachusetts Institute of Technology Worcester Foundation for Experimental Biology
Michigan	University of Michigan at Ann Arbor Wayne State University
Minnesota	Mayo Foundation
Nebraska	University of Nebraska Medical Center
New Hampshire	Dartmouth College
New York	Albert Einstein College of Medicine (Yeshiva University) American Health Foundation Cold Spring Harbor Laboratory Columbia University Memorial Sloan-Kettering Cancer Center New York University State University of New York (Roswell Park) University of Rochester
North Carolina	Duke University University of North Carolina Chapel Hill
Ohio	Wake Forest University Ohio State University
Pennsylvania	Case Western Reserve University Fox Chase Cancer Center Temple University University of Pennsylvania University of Pittsburgh Wistar Institute of Anatomy and Biology
Rhode Island	Roger Williams Medical Center
Tennessee	St. Jude Children's Research Hospital
Texas	University of Texas Cancer Center
Utah	University of Utah
Vermont	University of Vermont and State Ag. College
Virginia	Medical College of Virginia (Virginia Commonwealth University) University of Virginia
Washington	Fred Hutchinson Cancer Research Center
Wisconsin	University of Wisconsin Madison

**NCI Foreign Research  
Grants and Contracts  
Fiscal Year 1991**

*(Dollars in Thousands)*

<b>Country</b>	<b>Number Grants</b>	<b>Grant \$</b>	<b>Number Contracts</b>	<b>Contract \$</b>	<b>Total Dollars Awarded</b>	<b>Percent of Total Dollars Awarded</b>
Australia	7	\$733	1	\$550	\$1,283	10.3%
Belgium	1	274	0	0	274	2.2
Canada	24	2,140	2	760	2,900	23.3
China	0	0	4	319	319	2.5
Denmark	1	196	2	38	234	1.9
Finland	0	0	2	2,396	2,396	19.2
France	6	944	1	20	964	7.7
Israel	7	682	0	0	682	5.5
Italy	2	475	0	0	475	3.8
Jamaica	0	0	1	645	645	5.2
Japan	0	0	2	156	156	1.3
Sweden	4	419	3	404	823	6.6
New Zealand	0	0	3	300	300	2.4
Switzerland	2	173	0	0	173	1.4
Tanzania	0	0	1	45	45	0.4
Trinidad/TOB	0	0	1	590	590	4.7
United Kingdom	2	200	0	0	200	1.6
<b>Total Foreign</b>	<b>56</b>	<b>6,236</b>	<b>23</b>	<b>6,223</b>	<b>12,459</b>	<b>100.0%</b>



**Total Research  
Project Grants  
Fiscal Years 1985-1991**

(Dollars in Thousands)

Fiscal Year	Type Awarded	Requested		Recommended		Awarded		Percent Funded <sup>1</sup>
		Number	Amount	Number	Amount	Number	Amount	
1985	Competing							
	New	2,400	\$398,621	2,042	\$282,590	599	\$83,691	29.3%
	Renewal	782	183,483	758	140,472	416	84,708	54.9
	Board Supplement	19	1,659	13	850	2	65	15.4
	Subtotal	3,201	\$583,763	2,813	\$423,912	1,017	\$168,464	36.2%
	Noncompeting					1,964	348,011	
	<b>Total</b>					<b>2,981</b>	<b>\$516,475</b>	
1986	Competing <sup>2</sup>							
	New	2,354	\$392,028	1,997	\$277,698	564	\$84,470	28.2%
	Renewal	787	198,814	765	160,021	385	77,012	50.3
	Board Supplement	12	775	10	366	1	14	10.0
	Subtotal	3,153	\$591,617	2,772	\$438,085	950	\$161,496	34.3%
	Noncompeting					2,111	397,664	
	<b>Total</b>					<b>3,061</b>	<b>\$559,160</b>	
1987	Competing <sup>2</sup>							
	New	2,034	\$390,474	1,782	\$292,044	557	\$97,643	31.3%
	Renewal	898	241,189	882	195,014	504	120,550	57.1
	Board Supplement	7	731	7	429	0	0	0
	Subtotal	2,939	\$632,394	2,671	\$487,487	1,061	\$218,193	39.7%
	Noncompeting					2,042	424,960	
	<b>Total</b>					<b>3,103</b>	<b>\$643,153</b>	
1988	Competing <sup>2</sup>							
	New	2,167	\$419,638	1,857	\$316,789	470	\$83,083	25.3%
	Renewal	951	262,675	932	226,227	506	122,229	54.3
	Board Supplement	15	1,717	12	1,404	3	66	25.0
	Subtotal	3,133	\$684,030	2,801	\$544,420	979	\$205,378	35.0%
	Noncompeting					2,078	460,025	
	<b>Total</b>					<b>3,057</b>	<b>\$665,403</b>	
1989	Competing <sup>2</sup>							
	New	2,290	\$474,978	2,090	\$385,584	402	\$73,081	19.2%
	Renewal	823	246,172	802	202,283	324	85,645	40.4
	Board Supplement	14	2,883	9	1,485	2	49	22.2
	Subtotal	3,127	\$724,033	2,901	\$589,352	728	\$158,775	25.1%
	Noncompeting					2,374	564,234	
	<b>Total</b>					<b>3,102</b>	<b>\$723,009</b>	
1990	Competing <sup>2</sup>							
	New	2,193	\$527,256	2,078	\$429,203	421	\$82,656	20.3%
	Renewal	849	278,541	834	233,096	302	87,497 <sup>3</sup>	36.2
	Board Supplement	15	2,837	13	1,867 <sup>4</sup>	305	991	38.5
	Subtotal	3,057	\$808,634	2,925	\$664,166	728	\$171,144	24.9%
	Noncompeting					2,288	568,336	
	<b>Total</b>					<b>3,016</b>	<b>\$739,480</b>	
1991	Competing <sup>2</sup>							
	New	2,195	\$512,665	2,036	\$422,161	513	\$102,364	25.0%
	Renewal	837	286,858	836	245,420	323	94,231	39.0
	Board Supplement	8	1,161	8	897	4	421	50.0
	Subtotal	3,040	\$800,684	2,880	\$668,478	840	\$197,016	29.0%
	Noncompeting					2,207	594,532	
	<b>Total</b>					<b>3,047</b>	<b>\$791,548</b>	

Note: Includes R01 traditional grants, P01 program projects, R23 new investigator research awards, R29 FIRST Awards, R35 Outstanding Investigator Grants, R37 MERIT awards, U01 Cooperative Agreement Awards, R01 and U01 awards of RFAs and R43/R44 Small Business Innovative Research awards.

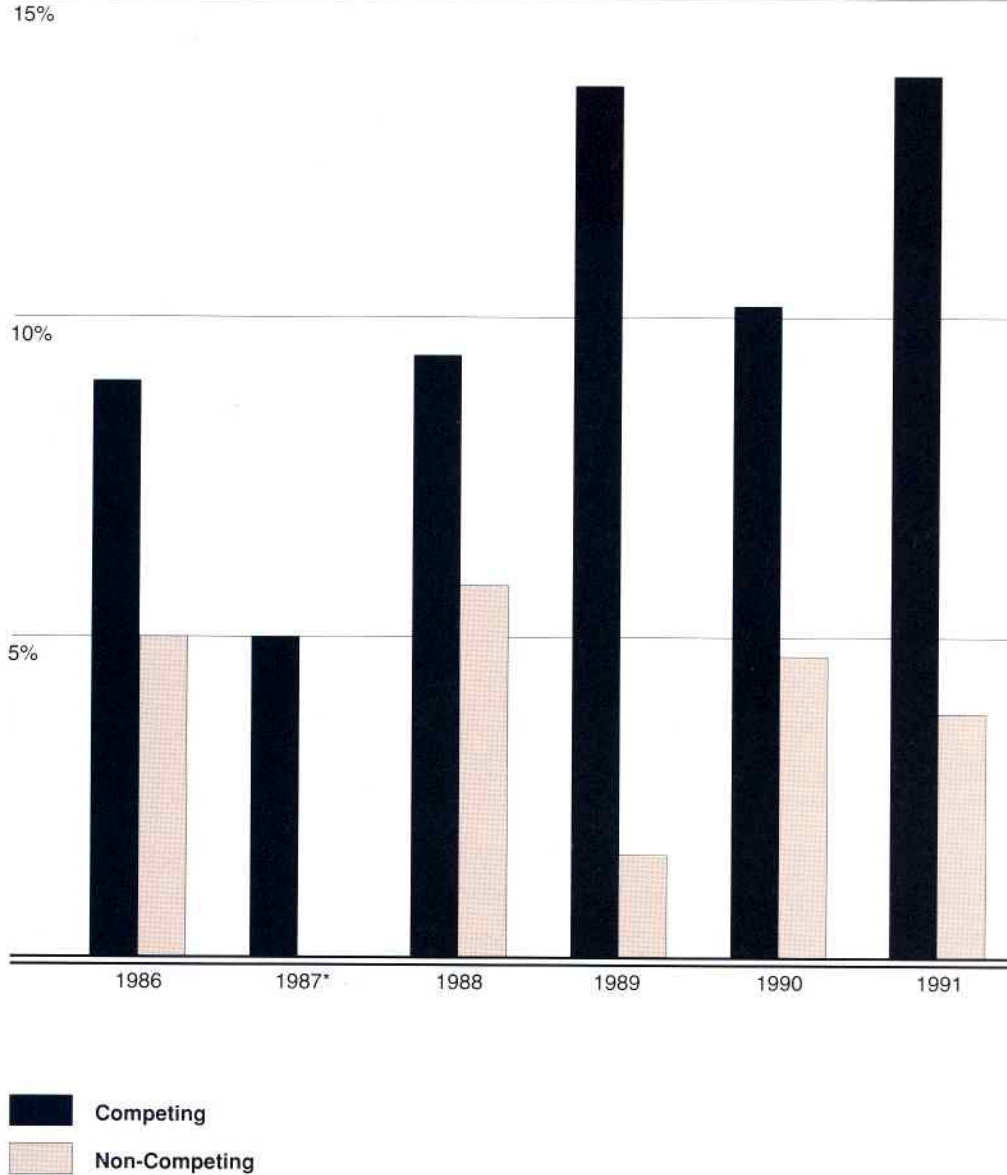
<sup>1</sup> Percent Funded; Number Awarded ÷ Number Recommended

<sup>2</sup> Because of fiscal restraints, grants were awarded below recommended levels.

<sup>3</sup> Includes two Type 4 MERITs for \$570.

<sup>4</sup> Includes seven Type 4 MERITs for \$1,699.

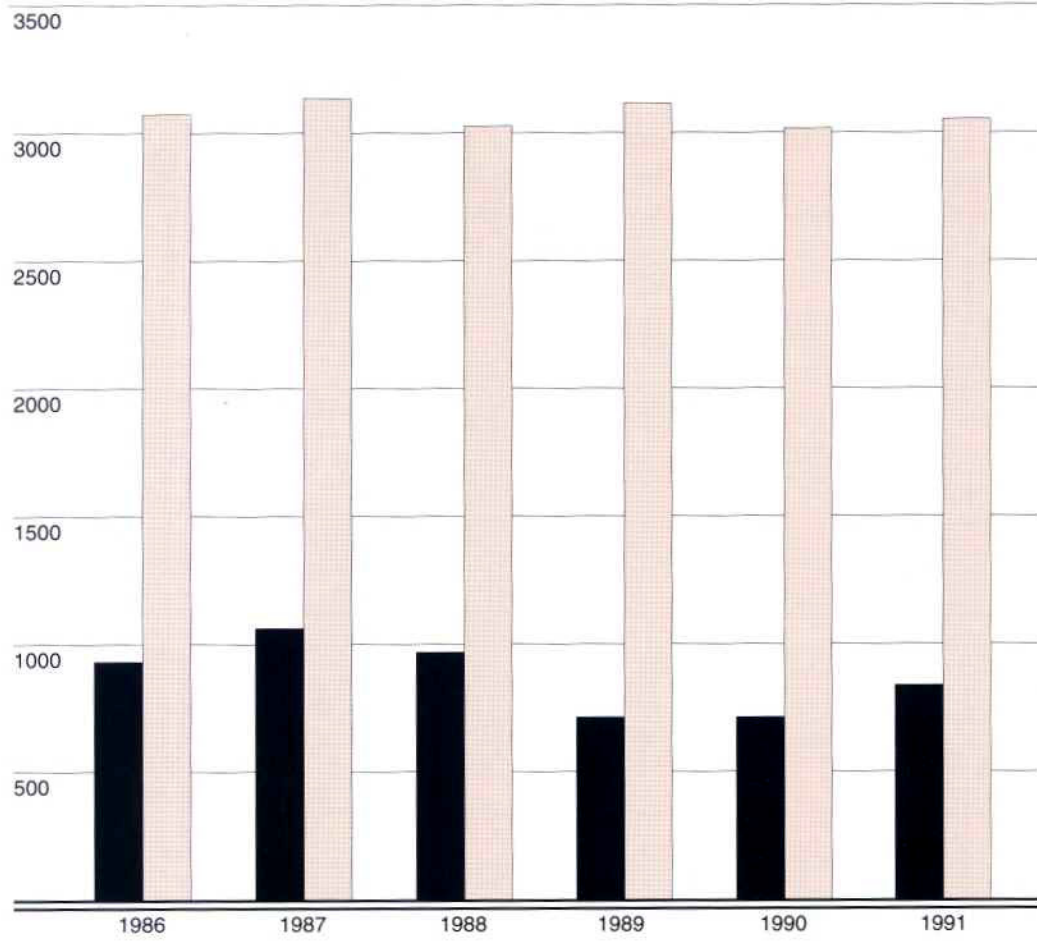
## Research Project Grants Historical Downward Negotiations Fiscal Years 1986–1991



NOTE: Future year (non-competing) approved amounts have been reduced by the percentage reductions applied during the competing grant cycle. The percent reductions shown are taken against this adjusted base.

\*FY 1987 non-competing awards were paid at the recommended level.

**Research Project Grants  
Number of Awards  
Fiscal Years 1986-1991**



■ Competing  
■ Total

**Research Project Grants  
Awarded  
History by Activity  
Fiscal Years 1987-1991**

(Dollars in Thousands)

TYPE	1987		1988		1989		1990		1991	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount	Number	Amount
R01	2,434	\$381,956	2,322	\$367,475	2,239	\$377,164	2,068	\$371,225	1,949	\$381,932
P01	155	161,009	159	170,119	165	188,015	162	185,130	165	190,470
R35	57	35,123	69	45,227	75	52,973	78	57,857	84	62,137
R37	62	15,011	105	24,114	132	32,353	153	39,264	163	43,687
U01	57	16,508	57	18,490	70	20,939	87	31,145	85	32,431
R29	85	8,042	171	15,713	232	21,244	280	25,547	316	29,494
R01-RFA	90	13,304	94	14,727	108	18,884	101	17,335	154	37,435
R43/R44	91	8,323	56	8,325	79	11,332	87	11,977	131	13,962
R23	72	3,877	24	1,213	2	105	0	0	0	0
<b>TOTAL</b>	<b>3,103</b>	<b>\$643,153</b>	<b>3,057</b>	<b>\$665,403</b>	<b>3,102</b>	<b>\$723,009</b>	<b>3,016</b>	<b>\$739,480</b>	<b>3,047</b>	<b>\$791,548</b>

**R01 Research Project (Traditional)**

To support a discrete, specified, circumscribed project to be performed by the named, investigator(s) in an area representing his specified interest and competencies.

**P01 Research Program Projects**

For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project is directed toward a range of problems having a central research focus in contrast to the usually narrower thrust of the traditional research project.

**R35 Outstanding Investigator Grants**

To provide long-term support to an experienced investigator with an outstanding record of research productivity. This support is intended to encourage investigators to embark on long-term projects of unusual potential in a categorical program area.

**R37 Method to Extend Research in Time (MERIT) Award**

To 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. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of competing research grant applications prepared and submitted in accordance with regular PHS requirements.

**U01 Research Project (Cooperative Agreement)**

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

**R29 First Independent Research Support and Transition (FIRST) Award**

To 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.

**RFA Request for Applications**

A formal statement which invites grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program purposes and indicates the amount of funds set aside for the competition and/or the estimated number of awards to be made.

**R43 Small Business Innovative Research (SBIR) Grants—Phase I**

To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

**R44 Small Business Innovative Research (SBIR) Grants—Phase II**

To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services.

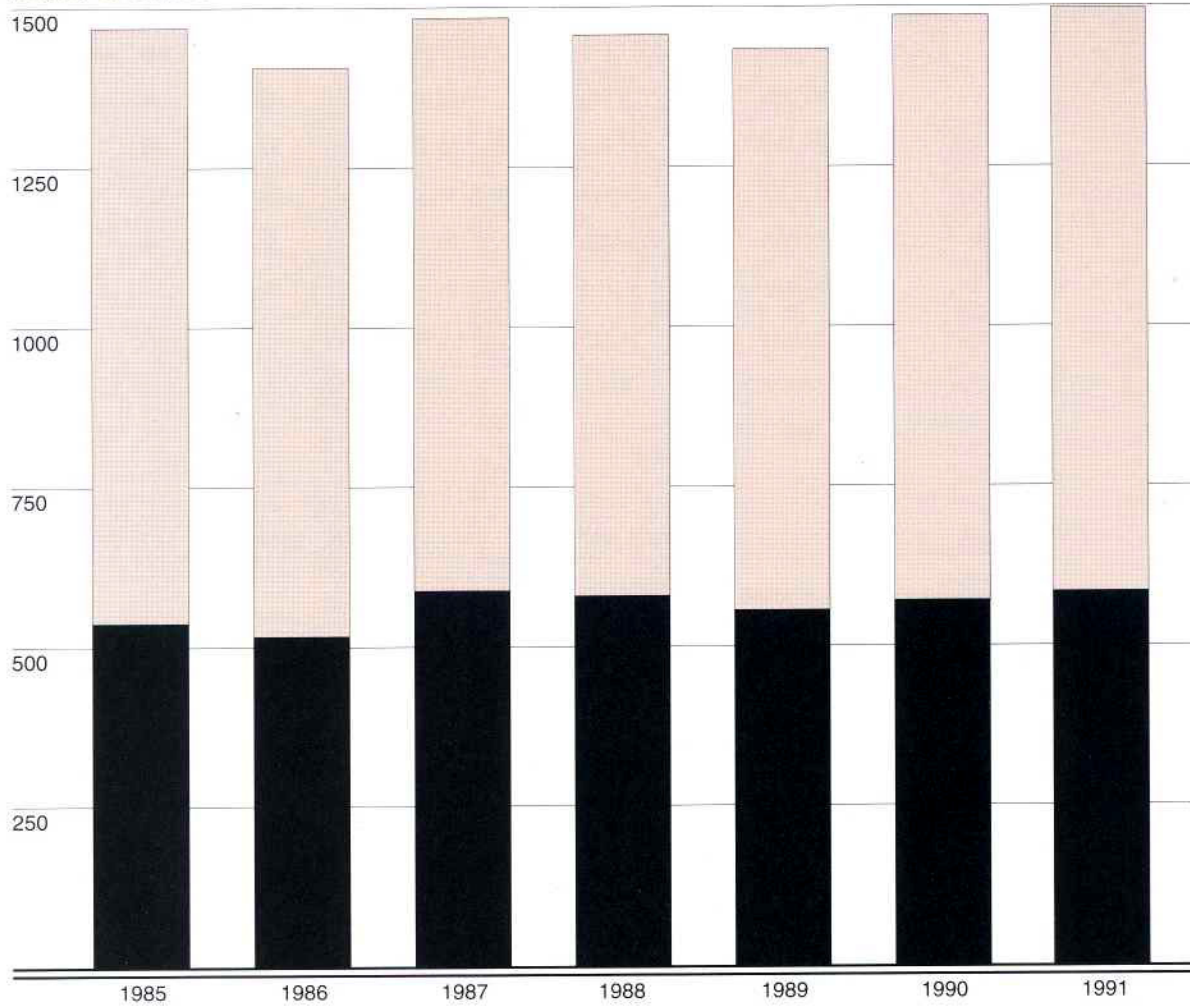
**R23 New Investigator Research Awards**

To support basic and clinical studies so that newly trained investigators remain active during the development stage of their career.

**National Research  
Service Awards  
Fiscal Years 1985-1991**

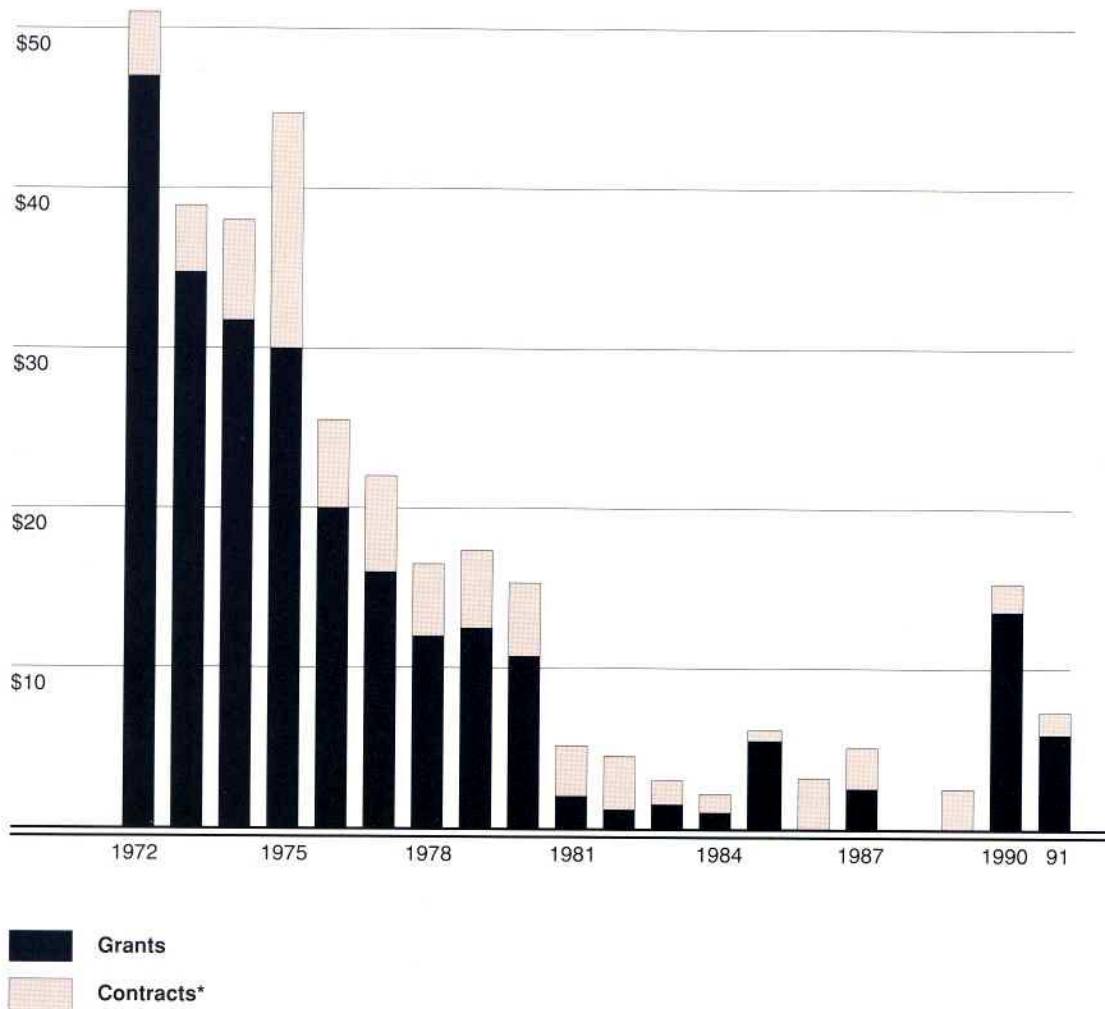
*(Number of Trainees)*

Number of Trainees



# Construction/ Renovation Funding Fiscal Years 1972–1991

(Dollars in Millions)



NOTE: Fiscal year 1990 includes \$10 million which was transferred to NCI from other NIH Institutes to partially fund several grants responding to an NIH Construction RFA.  
\*Includes repair and maintenance at the Frederick Cancer Research and Development Center.

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## **Selected Minority Focused Activities Fiscal Year 1991**

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### **Objectives:**

- Reduce cancer incidence, morbidity and mortality in minority populations by increasing their involvement in the planning and implementation of intervention programs.
- Increase the number of minority patients involved in NCI-supported clinical trials in order to improve survival and cure rates in these populations.
- Enhance the intervention capabilities of minority researchers and influence them to develop careers as cancer investigators.
- Heighten awareness about cancer risk and prevention.
- Pursue basic research intended to understand the etiology and biology of cancer in defined minority populations.

### **Strategy:**

The National Cancer Institute (NCI) has developed mechanisms to broaden participation by minority institutes and individuals in cancer-related research and training activities. It seeks to enhance the effectiveness of cancer treatment and control programs in reaching the minority community and other historically underserved segments of the general population, through the following:

### **Minority Activities**

#### ***Minority Accrual to Clinical Trials:***

A number of factors are potential barriers to minorities participating in clinical trials. Economic and geographic constraints, foreign language barriers, cultural reluctance to seek early medical attention and/or experimental therapy for cancer, and possible physiologic differences, may explain why racial and ethnic minority patients tend to survive for a shorter time after cancer diagnosis than the national average. As part of a multi-faceted NCI plan to improve the access of minority participation at all levels of cancer research, the Cancer Therapy Evaluation Program of the DCT coordinates interrelated clinical programs. The individuals intended to benefit from these programs are Americans of Black (African-American) ancestry, Hispanics of Mexican, Puerto Rican, Cuban or Central American descent, and Native Americans, including Alaskan and Hawaiian Natives. In addition, a new Minority Initiative program widens the potential base of clinical activities made available to minority groups. Six Cooperative Groups (NSABP, GOG, SWOG, RTOG, CALGB, and ECOG) have developed plans to recruit and train new institutions with predominantly minority patients, to encourage early diagnosis and clinical trials participation among potential patients, and to overcome language and logistic barriers for specific minority groups.

#### ***Special Populations Studies:***

For special populations who experience high cancer rates and are underserved in terms of cancer prevention and control programs, NCI supports initiatives which focus research on interventions designed to address such barriers as cultural and behavioral nuances unique to population groups as well as obstacles within the health care delivery systems. Special populations research also investigates primary prevention interventions designed to meet the specific needs of these groups. In addition, support for several cancer control networks is intended to facilitate the cohesion of a strong core of scientists and to attract a cohort of potential researchers for the future.

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***Minority Statistics:***

NCI's Surveillance Program continues to expand and refine the data collection and analyses of minority populations. For example, increased coverage of Hispanics and other underrepresented groups was initiated in the Surveillance, Epidemiology, and End Results Program in 1991. In addition, data from the Black/white Cancer Survival Study is being analyzed to assess the significance of social, behavioral, lifestyle, biological, treatment, and health care factors as contributors to the observed differences in survival among Black and white cancer cases. Further analyses have been initiated on survival of patients in cancer therapy trials conducted by NCI-sponsored cooperative groups.

**Minority-Based Community  
Clinical Oncology Program  
(MBCCOP):**

Supports participation of minority populations and their physicians in cancer treatment and cancer prevention and control clinical trials, providing access to advances in diagnosis, treatment, and cancer control to minority patients and opportunities for studies in selected high-risk minority populations which may lead to a better understanding of cancer etiology and control. Twelve awards are funded through FY 1993.

**Comprehensive Minority  
Biomedical Program (CMBP):**

***Minority Health Professional Training Initiative (MHPTI):***

The first phase of the MHPTI which began in 1991 is supporting training and career development opportunities for minority health professionals by engaging them in research in oncology or by providing them with training in subspecialties related to cancer. Such opportunities will increase the number of minority clinicians, clinical researchers, and other health professionals who are prepared to deal with the problem of excess mortality among minority populations due to cancer. As the result of the three Requests for Applications (RFAs) published this year, four awards to minority clinicians were made. This activity will be reannounced in FY 1992.

**Cancer Communications**

"Once a Year . . . for a Lifetime," a film carrying NCI's mammography message and targeted to Black and Hispanic women, was produced in conjunction with Revlon and distributed to more than 1,200 television stations. The half-hour special has been aired in more than 75 cities including all of the NBC owned-and-operated stations.

Easy-to-read pamphlets on breast and cervical cancers were completed and used during a number of 1991 NCI promotions including National Minority Cancer Awareness Week and Breast Cancer Awareness Month. These materials were also provided to hundreds of intermediary organizations. Two versions of a pap test booklet were developed, one for Black Americans and one for Hispanic Americans. A generic low literacy version of the booklet was completed and is available for distribution to underserved populations.

Significant collaboration between NCI and the Hispanic media informed these audiences of cancer prevention and control measures. In particular, the early detection of breast and cervical cancers was highlighted.

Critical cancer patient publications are being adapted for the Hispanic patient. These include *Eating Hints*, *Chemotherapy and You*, and *Radiation Therapy and You*.



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The creation of graphic concepts to communicate nutrition messages to seven ethnic and/or low-literate audiences (Blacks, Hispanics, American Indians, Native Hawaiians, Native Alaskans, Asians, and low-literate whites) was initiated by NCI. The project involved health and nutrition experts who work with and are members of the seven different populations. These experts identified the most important nutrition messages specific to their population. Nutrition materials for the ethnic audiences have been designed and are now being pretested. Completed materials will be tested for distribution in a variety of health-care settings.

A Black Americans Cookbook called "Down Home Healthy" was developed to promote traditional Black recipes revised to meet NCI nutritional guidelines. Produced in conjunction with Project LEAN/American Dietetic Association, the publication is slated for release in early 1992.

OCC is working closely with Cancer Information Service offices who have targeted low-literate populations. These offices are developing strategies and materials to more successfully communicate cancer risk reduction messages to poor readers.



# Appropriations of the NCI 1938-1992

**14.7%**  
**\$3,718,759,220**

1938 through 1968 \$1,690,550,220  
 1969. . . . . 185,149,500  
 1970. . . . . 190,486,000  
 1971. . . . . 230,383,000  
 1972. . . . . 378,794,000  
 1973. . . . . 492,205,000  
 1974. . . . . 551,191,500

**85.3%**  
**\$21,609,273,000**

1975. . . . . 691,666,000<sup>1</sup>  
 1976. . . . . 761,727,000  
 "TQ" . . . . . 152,901,000<sup>2</sup>  
 1977. . . . . 815,000,000  
 1978. . . . . 872,388,000<sup>3</sup>  
 1979. . . . . 937,129,000  
 1980. . . . . 1,000,000,000<sup>4</sup>  
 1981. . . . . 989,355,000<sup>5</sup>  
 1982. . . . . 986,617,000<sup>6</sup>  
 1983. . . . . 987,642,000<sup>7</sup>  
 1984. . . . . 1,081,581,000<sup>8</sup>  
 1985. . . . . 1,183,806,000  
 1986. . . . . 1,264,159,000<sup>9</sup>  
 1987. . . . . 1,402,837,000<sup>10</sup>  
 1988. . . . . 1,469,327,000<sup>11</sup>  
 1989. . . . . 1,593,536,000<sup>12</sup>  
 1990. . . . . 1,664,000,000<sup>13</sup>  
 1991. . . . . 1,766,324,000<sup>14</sup>  
 1992. . . . . 1,989,278,000<sup>15</sup>

**Total**  
**(1938-1992) . . . . \$25,328,032,220**

**Transition Quarter ("TQ")**—July 1, 1976 through September 30, 1976. The Interim Period in the changing of the Federal Fiscal Year from July 1 through June 30 to October 1 through September 30.

<sup>1</sup>Includes \$18,163,000 for training funds provided by Continuing Resolution.

<sup>2</sup>Includes \$3,201,000 for training funds provided by Continuing Resolution.

<sup>3</sup>Includes \$20,129,000 for training funds provided by Continuing Resolution.

<sup>4</sup>1980 appropriation authorized under a Continuing Resolution.

<sup>5</sup>Reflects 1981 rescission of \$11,975,000.

<sup>6</sup>Amount included in Continuing Resolution. Includes \$47,988,000 transferred to the National Institute of Environmental Health Sciences for the National Toxicology Program.

<sup>7</sup>Appropriated under Continuing Resolution and Supplemental Appropriation Bill.

<sup>8</sup>Includes \$23,861,000 for training funds provided by a Continuing Resolution and \$4,278,000 in a Supplemental Appropriation Bill.

<sup>9</sup>Includes \$6,000,000 from a Supplemental Appropriation Bill.

<sup>10</sup>Authorized under Omnibus Continuing Resolution.

<sup>11</sup>Authorized under Omnibus Continuing Resolution.

<sup>12</sup>Appropriation prior to reduction contained in G.P. 517 (-\$19,122,000) and G.P. 215 (-\$2,535,000) and P.L. 100-436, Section 213, (-\$1,013,000).

<sup>13</sup>Appropriation prior to reduction contained in P.L. 101-166 (-\$6,839,000) and P.L. 101-239 (-\$22,829,000).

<sup>14</sup>Appropriation prior to reductions in P.L. 101-517 (-\$8,972,000 for salary and expense reduction; -\$42,568,000 for across-the-board reduction).

<sup>15</sup>Appropriation prior to reductions in P.L. 102-170 (-\$21,475,000 for salary and expense reduction; -\$1,262,000 for travel reduction; \$15,000,000 transferred to other institutes for cancer research).

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**By-Pass Budget  
Requests  
Fiscal Years 1973-1993**

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<b>Fiscal Year</b>	<b>Request</b>
1973 .....	\$ 550,790,000
1974 .....	640,031,000
1975 .....	750,000,000
1976 .....	898,500,000
1977 .....	948,000,000
1978 .....	955,000,000
1979 .....	1,036,000,000
1980 .....	1,055,000,000
1981 .....	1,170,000,000
1982 .....	1,192,000,000
1983 .....	1,197,000,000
1984 .....	1,074,000,000
1985 .....	1,189,000,000
1986 .....	1,460,000,000
1987 .....	1,570,000,000
1988 .....	1,700,000,000
1989 .....	2,080,000,000
1990 .....	2,195,000,000
1991 .....	2,410,000,000
1992 .....	2,612,000,000
1993 .....	2,775,000,000

*NOTE: Following the original passage of the National Cancer Act in December 1971, a provision was included for the Director of the National Cancer Institute to submit a budget request directly to the President; hence it has come to be called the By-Pass Budget. The budget submitted for fiscal year 1973 was the initial submission.*

**Clinical Trials  
Activities  
Fiscal Years 1985-1991**

(Dollars in Millions)

	1985	1986	1987	1988	1989	1990	1991
Clinical Trials:							
Treatment/Detection/ Diagnosis	\$ 129.1	\$ 124.0	\$ 154.3	\$ 151.2	\$ 152.3	\$ 182.6	\$ 178.7
[Clinical Cooperative Groups]	[ 50.8]	[ 49.3]	[ 57.1]	[ 59.3]	[ 60.2]	[ 60.2]	[ 60.8]
Prevention & Control	27.0	29.5	29.1	35.7	36.2	37.1	46.4
Subtotal	156.1	153.5	183.4	186.9	188.5	219.6	225.1
Center Core Support	10.6	22.1	24.0	25.1	25.3	26.3	29.3
Subtotal, Trials Support	166.7	175.6	207.4	211.9	213.8	246.0	254.4
[Support for AIDS trials]	[ —]	[ —]	[ —]	[ 14.8]	[ 23.4]	[ 32.7]	[ 39.2]
Total NCI Budget	\$1,177.9	\$1,228.8	\$1,402.8	\$1,469.3	\$1,572.9	\$1,634.2	\$1,712.7
Groups as % of NCI	4.3%	4.0%	4.1%	4.0%	3.8%	3.7%	3.5%
Trials as % of NCI	14.2%	14.3%	14.8%	14.4%	13.6%	15.1%	14.9%

NOTES:

1. Beginning in 1986, Core Support for centers includes indirect costs.
2. Separate clinical trials data for AIDS not reported prior to 1988.
3. 1986 includes \$17 million transfer for AIDS from NIH.
4. 1989 includes \$2.5 million transfer from NIH.
5. 1990 excludes \$10.1 million construction transfer.

**Comparison of Dollars,  
Positions and Space  
Fiscal Years 1972-1991**

	<b>Dollars</b>		<b>Positions</b>		<b>Space</b>	
	Obligations (\$000's)	Percent of Increase Over Prior Year	Actual Full-Time Permanent Employees	Percent of Increase Over Prior Year	Allocated Space (Square Feet)	Percent of Increase Over Prior Year
1972	378,636	—	1,665	—	329,587	—
1973	431,245	13.9	1,736	4.3	357,972	8.6
1974	581,149	34.8	1,805	4.0	381,436	6.6
1975	699,320	20.3	1,849	2.4	382,485	0.3
1976	760,751	8.8	1,955	5.7	387,324	1.3
1977	814,957	7.1	1,986	1.6	428,285	10.6
1978	872,369	7.0	1,969	-0.9	491,725	14.8
1979	936,969	7.4	1,973	0.2	493,156	0.3
1980	998,047	6.5	1,837	-6.9	467,730	-5.2
1981	989,338	-0.9	1,815	-1.2	472,633	1.0
1982	986,564	-0.3	1,703	-6.2	477,782	1.1
1983	986,811	0.03	1,731	1.6	484,093	1.3
1984	1,081,460	9.6	1,698	-1.9	466,890	-3.6
1985	1,177,853	8.9	1,596	-6.0	466,890	0.0
1986	1,210,284	2.8	1,573	-1.4	465,790	-0.2
1987	1,402,790	15.9	1,642	4.4	465,790	0.0
1988	1,468,435	4.7	1,708	4.0	458,556	-1.6
1989	1,570,342	6.9	1,701	-0.4	483,778	5.5
1990	1,644,330*	4.7	1,837	8.0	489,604	1.2
1991	1,712,669	4.2	1,921	4.6	499,396	1.02

\* Includes \$10,130 which was transferred to NCI from other NIH Institutes to partially fund several grants responding to an NIH Construction RFA.

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**Personnel  
Resources**

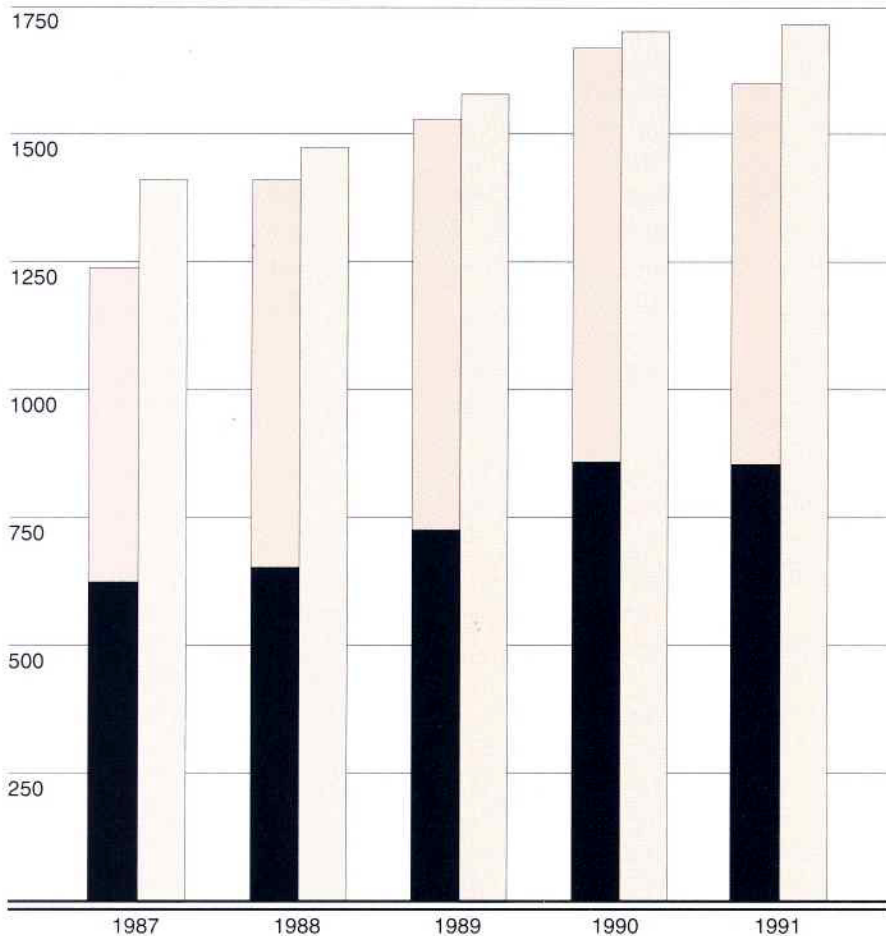
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<b>Fiscal Year</b>	<b>—Number of FTEs*—</b>			<b>Number of Employees</b>
	<b>Cancer</b>	<b>AIDS</b>	<b>Total</b>	
1984	2,344	72	2,416	2,371
1985	2,145	85	2,230	2,195
1986	2,003	98	2,101	2,096
1987	1,981	129	2,110	2,272
1988	2,137	146	2,283	2,302
1989	1,985	188	2,173	2,201
1990	1,960	232	2,192	2,322
1991	2,045	300	2,345	2,437

\*Full-Time Equivalents

**National Cancer Institute  
Obligations and Outlays  
Fiscal Years 1987-1991**

(Dollars in Millions)



- Prior Year Outlays
- Current Year Outlays
- Current Year Obligations

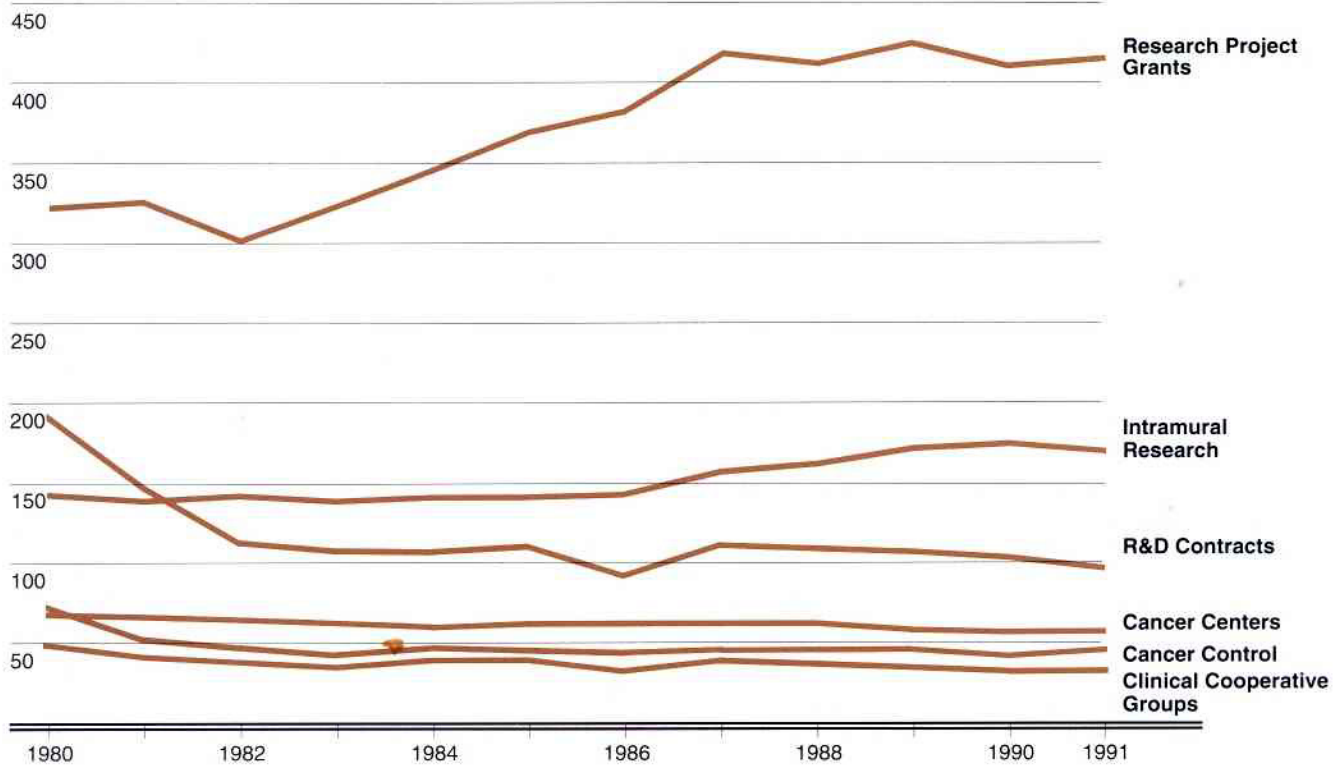
**Obligations:** Orders placed, grants and contracts awarded, salaries earned and similar financial transactions which legally utilize or reserve an appropriation for expenditure.

**Outlays:** Payments (cash or checks) made from current or prior year appropriations.



**Constant Dollar Trends  
Obligations By Mechanism  
Fiscal Years 1980-1991**

*(Dollars in Millions)*



1980 Constant Dollars in Millions

NATIONAL  
CANCER  
INSTITUTE

NIH Publication No. 92-512  
May 1992



