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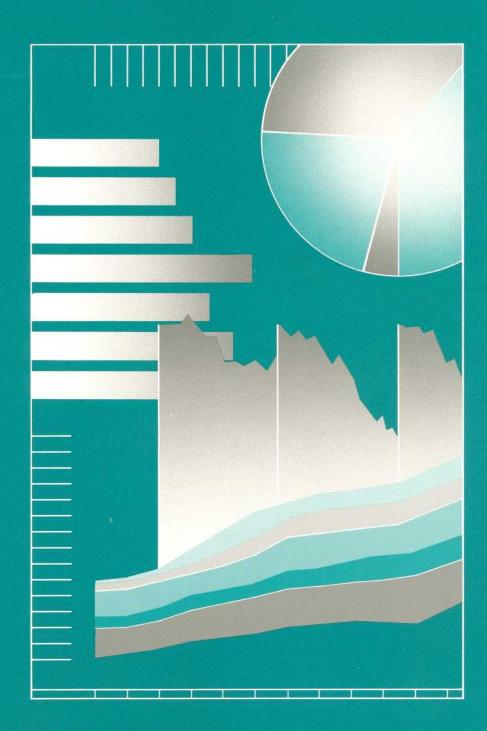
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# FACT BOOK

National Cancer Institute



1994

NATIONAL INSTITUTES OF HEALTH

# FACT BOOK

National Cancer Institute 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 Management Branch, National Cancer Institute, 9000 Rockville Pike, Bethesda, Maryland, 20892.

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# Significant Initiatives in 1994

Division of Cancer Biology, Diagnosis, and Centers

# Characterization of Genetic Alterations Associated with Familial Colorectal Cancer

Characterization of the genetic alterations underlying hereditary non-polyposis colon cancer, HNPCC, has identified an important new pathway of cancer pathology. Mutations in two genes, hMSH2 and hMLH1, are associated with a high percentage of HNPCC cases. The genes encode enzymes involved in DNA repair, and mutations in these genes result in generalized genomic instability. This instability is characterized by amplifications and deletions of small repeated sequences scattered throughout the genome, resulting in disruption of normal functions. These alterations can serve as a marker for identifying members of HNPCC families with increased risk of disease. The role of these genes in sporadic cases of colon cancer is being evaluated, and recent evidence has suggested that genomic instability may play a significant role in tumors of other organs as well. Further study is needed to confirm that genomic instability is an important mechanism in cancer pathology.

# Cloning of Familial Breast Cancer Gene: BRCA1

The BRCA1 gene, located on chromosome 17, is estimated to underlie about half of early-onset familial breast cancer. Investigators recently cloned the gene which will allow them to identify the range of alterations associated with familial breast cancer. This information can then be used to develop diagnostic tests that will identify women in these families who are at increased risk. These investigators have also identified a region on chromosome 13 that contains a second familial breast cancer gene, BRCA2, and are attempting to identify and clone the relevant gene. Although a small, preliminary study suggested that BRCA1 mutations are uncommon in sporadic breast cancers, further study will be necessary to determine whether the gene plays a role in sporadic disease.

# Enhanced Understanding of the Control of Programmed Cell Death (Apoptosis)

Understanding of the control of programmed cell death (apoptosis) by the Bcl-2 proto-oncogene product has been enhanced by the recent discovery of a family of Bcl-2-related proteins that interact with each other and play a role in both positive and negative regulation of apoptosis. The bcl-2 gene, discovered at the t(14;18) chromosomal translocation breakpoint found in most follicular B-cell lymphomas, is the first proto-oncogene that has been shown to cause tumors by blocking apoptosis. It was shown to prevent apoptotic cell death in cultured cells deprived of growth factors. However, bcl-2 is not able to block apoptosis induced by cytokine deprivation or receptor-mediated signaling in all *in vitro* cell culture systems. *In vivo*, bcl-2 prevents many, but not all, forms of apoptotic cell death that occur during lymphoid development. These results suggest the existence of either multiple independent intracellular mechanisms of apoptosis or additional

pathways which involve proteins that differentially regulate bcl-2 function. A search for additional members of the bcl-2 gene family and other apoptotic molecules will be the focus of further research effort in this field. Understanding how the various members of the Bcl-2 family interact with each other is vital in the elucidation of the basic mechanism of apoptosis.

Discovery of a Second Costimulatory Molecule for T Lymphocytes

Discovery of a second costimulatory molecule for T lymphocytes provides a new tool for enhancing the recognition of tumors by the immune system. T-cell activation is the critical step in the development of an effective immune response to a tumor. T-cell responses are normally antigen-specific because the most important activation signal comes from the interaction between the T-cell antigen receptor and an antigenic protein fragment displayed on the surface of an antigen-presenting cell (APC). However, full T-cell activation requires a second, or costimulatory, signal that is not antigen-specific. It is clear from many studies that the presence or absence of costimulatory signals can determine whether an immune response will occur and whether it will be effective. The major costimulatory signal receptor on T cells is known to be a molecule called CD28. Until recently, it was thought that the only ligand for CD28 was a molecule called B7, which is present on many APCs. Several groups have now shown that B7 (now renamed B7-1) is not the only ligand for CD28, and that a newly discovered molecule, B7-2, may be the more important co-stimulator of T cells under some conditions. Unlike B7-1, B7-2 mRNA is constitutively expressed in un-stimulated B cells. As such, it may provide the critical early costimulatory signal determining whether a T cell is stimulated or becomes paralyzed (anergic). The discovery of a second costimulatory molecule on APCs is prompting a reexamination of results obtained over the past few years on the failure of tumor cells to provide adequate co-stimulation to potential antitumor T cells.

# Helper T Cells in Resistance to AIDS and Cancer

NCI scientists have found that the balance between certain subsets of helper T cells, in particular Th1 and Th2, could play a role in determining the type and effectiveness of the specific immune response generated against an infectious agent or a tumor. Stimulation of Th1 cells leads to the production of distinct set of cytokines and the promotion of cellular immunity, whereas stimulation of Th2 cells leads to the production of a different set of cytokines and the production of antibodies. Recent studies have demonstrated that cellular immunity, but not humoral immunity (antibody production), confers protection against the establishment of HIV infection and delays progression of infection to AIDS. HIVexposed individuals who remain antibody-negative and free of clinical HIV disease generate brisk HIV-targeted Th1-type cytokine responses. Conversely, longitudinal studies of HIV-infected individuals demonstrate a shift in the Th1-Th2 balance toward a Th2-type cytokine profile. This switch correlates with a progressive loss of immune function associated with progression to AIDS. It has recently been shown that similar alterations in the Th1-Th2 balance occur in patients with certain types of cancer.

# Division of Cancer Treatment

# The Quality of Clinical Research

During the past year the quality assurance process of clinical research sponsored and supported by the National Cancer Institute have been subjected to intense scrutiny. Stimulated by the discovery of scientific fraud and misconduct a more

structured process was developed to report such events and a more comprehensive oversight process was initiated as a prevention measure to include the creation of a new branch within a Cancer Therapy Evaluation Program, the Clinical Trials Monitoring Branch

A comprehensive examination is under way on how to monitor clinical trials and track and maintain quality assurance. Committees of Extramural Consultants, the Cooperative Clinical Trials Groups and Intramural NCI staff are meeting to develop new, more effective and efficient mechanisms for assuring that the conclusions of clinical trials are accurate.

# **Drug Discovery**

For several years, initial *in vitro* screening of new agents for anticancer and anti-HIV activity has been carried out utilizing standardized procedures, at an annual input level of about 10,000 synthetic compounds and an equal number of natural product extracts. The cancer screen has utilized a panel of 60 human tumor cell lines which initially represented seven tumor categories, lung, colon, renal, melanoma, CNS, ovarian, and leukemia. Although of great clinical importance, breast and prostate lines were not included initially because of difficulty in developing suitable cell lines. During the past year, both breast and prostate cell lines have been incorporated into the cancer screening panel. In addition, testing against a separate panel of prostate cell strains and testing against AIDS-related lymphoma cell lines has been implemented. It is of interest that a substantial portion of the agents demonstrating patterns of activity against the breast cancer lines appear to be tubulin-interactive agents, an observation that will be explored further.

A considerable effort, involving intramural, extramural, and collaborative investigators, has been devoted to the characterization of the 60 human tumor cell lines with regard to specific molecular targets, such as multi-drug resistance, p53, bcl-2, ras, etc. Utilizing the COMPARE computer analysis, it has been possible to develop patterns of cell line sensitivity representative of these targets so that new compounds can be detected with patterns peculiar to a target. Mechanisms are now being developed to implement this approach and carry out confirmatory testing in the target model. Materials found to affect a specific target can then be directed toward specific groups of patients, and combination therapies developed to take advantage of this information.

#### Vaccine Development

Researchers in NCI's Surgery Branch, Clinical Oncology Program have identified the antigen recognized by T-lymphocytes which mediate tumor rejection in man. This work was done by constructing a library from the DNA of a melanoma which responded dramatically to treatment with Tumor Infiltrating Lymphocytes (TIL) and interleukin-2. The genes from this library were then inserted, one at a time, into a MHC-identical melanoma cell line resistant to TIL therapy. This technique allowed the isolation, cloning and expression of MART-1 (Melanoma Antigen Recognized by T-cells). Important, co-incubation of naive peripheral lymphocytes with MART-1 converts them into high efficiency lytic cells specific for that tumor. MART-1 is currently under study for its potential to prevent and treat malignant melanoma.

#### Vaccine Studies

Animal studies have been performed demonstrating that mice can be protected against a tumor transformed by a mutant ras oncogene by immunization with the free mutant ras protein. The immunity elicited is specific for tumor cells expressing the same mutation as the protein used for immunization. Nearly 40 percent of human cancers contain a mutated ras oncogene, with the mutations clustering around changes in codons 12, 13, and 61. Purified mutant ras oncoproteins have been generated for administration to humans and are about to begin a clinical trial evaluating whether patients with tumors expressing a mutated ras protein may develop immunity after immunization with mutant ras protein.

# Lymphoma Idiotype Antigen Vaccines

The idiotype of the surface immunoglobulin molecule expressed by a given B-cell malignancy can serve as a unique tumor-specific antigen (Id). A pilot study in humans has already demonstrated that this autologous protein can be formulated into an immunogenic therapeutic vaccine, and tumor regressions were observed. The goals for vaccine development at the NCI in larger-scale clinical trials based on preclinical studies are: 1) the development of vaccine formulations which are more effective in activating the cellular arm of the immune system, and 2) to increase vaccine potency.

The first phase II clinical trial is testing Id in combination with adjuvants designed to induce primarily T-cell responses (IL-2 and GM-CSF) in newly diagnosed patients with low-grade follicular lymphomas in first remission following ProMACE induction chemotherapy who have accessible lymph nodes as starting material for custom vaccine production. The clinical grade manufacturing process has been validated, and this trial is being conducted under an approved IND. Immunological, molecular, and clinical endpoints will be analyzed. At the close of 1994 13 patients were enrolled. Patient accural is continuing in 1995.

#### DNA Repair Biology

Within the Clinical Pharmacology Branch extensive studies have been initiated on the human biology of nucleotide excision repair, in patients with ovarian cancer and patients with brain cancer.

Such studies have focused on the rate limiting step of nucleotide excision repair. This step is DNA damage recognition and excision, and appears to be mediated by genes of the ERCC and XP groups. Current data clearly demonstrates that in human ovarian cancer, genes involved in the first steps of nucleotide excision repair show the following patterns. ERCC1 (which affects DNA damage recognition and excision), ERCC3 (which affects linkage of DNA repair and DNA transcription), XPA (which "fine tunes" DNA damage recognition and localization), and ERCC6 (which affects gene specific repair), are all concurrently up-regulated in tumor tissues from ovarian cancer patients that are clinically resistant to platinum based therapy. These four genes are concurrently down-regulated in tumor tissues of patients that are clinically sensitive to platinum based therapy. Another feature seen in ovarian cancer patients is loss of concordant expression between ERCC1 and ERCC2. ERCC2 performs an important helicase function in nucleotide excision repair. This loss of concordant expression between ERCC1 and ERCC2 appears to be a feature of malignant ovarian cancer tissues, but is not seen in any of five different normal tissue settings that have been studied.

Similar patterns for the genes within the ERCC and XP groups have been observed in brain cancer patients. Also, in tumor tissues from patients with brain cancer, we have observed gene amplification of ERCC1 in brain cancer specimens, without concurrent amplification of ERCC2. This is particularly noteworthy since these two genes are approximately 200 kilobases apart on chromosome 19q.

# Identification and Characterization of Plant-derived Proteins and Compounds with Potential Anti-HIV and Anti-Tumor Activities

Through collaborative studies several single-chain ribosome inactivating proteins (SRIP) have been identified from medicinal plants which inhibit HIV infection and replication. These plant proteins also exhibited growth-inhibitory effect on certain tumor cell lines.

# Modulation of P-glycoprotein Mediated Drug Resistance by an Anti-tumor RNase In vitro and In vivo

NCI researchers have found that Onconase (a frog RNase), currently in clinical trials as an anti-cancer agent, enhanced vincristine and adriamycin cytotoxicity in cultured parental HT29<sup>PAR</sup> and in drug resistant HT29<sup>MDR1</sup> human colon carcinoma cells as well as in MCF-7Adr' human mammary cancer cells. The *in vitro* results were confirmed in nude mice given transplants of HT29<sup>MDR1</sup> cells followed by treatment with a combination of vincristine and Onconase, thus establishing that Onconase can overcome drug resistance caused by the P-glycoprotein. This was the first study to establish Onconase as a chemosensitizer to VCR. Furthermore, Onconase was found to enhance the effectiveness of MRK-16, an antibody that reverses drug resistance. This observation was particularly interesting since combinations of MRK-16 with conventional chemosensitizers were not more effective than MRK-16 with single agents alone. Since Onconase does not cause myelosuppression, combination therapies are well tolerated in patients. Consequently, Onconase may present a viable new approach to treating the problem of drug resistance.

## TGFB Abrogation of Chemotherapy-Induced Stem Cell Toxicity

Preclinical studies have shown for the first time that a negative regulator (TGF $\beta$ ) of hematopoiesis can be used to protect critical progenitor/stem cells from the destructive effects of chemotherapy. This observation has allowed the development of new strategies for the safe delivery of increased amounts of the cell-cycle active chemotherapeutic drug 5-fluorouracil in preclinical animal models. At the same time TGF $\beta$  has been shown to also protect mice from some nonhematologic organ toxicity induced by doxorubicin. These findings suggest that TGF $\beta$  may have protective effects for multiple organ systems against chemotherapy-induced toxicities.

# Activation-induced Lymphoma Cell Growth Arrest

A number of signals that activate normal B cells result in the irreversible growth arrest (and sometimes apoptosis) of neoplastic B cells both *in vitro* and *in vivo*. For example, CD40, a receptor in the nerve growth factor/tumor necrosis factor receptor family, is universally expressed on normal and neoplastic B cells. Physiologically, it is involved in interactions of B cells with T cells. The CD40 ligand or an antibody of CD40 is capable of curing SCID mice bearing established human B cell lymphomas. We expect to bring this novel treatment strategy to clinical trials in the next year.

Allogeneic Marrow Donor Immunization Against Myeloma Idiotype Antigen Multiple myeloma remains a largely incurable disease with current therapy. The idiotype of the rearranged immunoglobulin gene product of a myeloma can serve as a unique tumor specific antigen for vaccine development. Immunization of a healthy donor, with subsequent adoptive transfer of anti-tumor immunity to the cancer patient, would represent a novel strategy. In collaborative trials with the University of Arkansas, we are testing the hypothesis that myeloma-specific immunity can be transferred from bone marrow transplant (BMT) donor to recipient at the time of BMT, thereby enhancing the specific antitumor effect of allogeneic marrow grafts.

This was accomplished in the first patient, whose HLA matched sibling donor was immunized with myeloma IgG, purified from the plasma of the BMT recipient, conjugated to a carrier protein, and emulsified in an adjuvant. Analysis of the BMT recipients peripheral blood mononuclear cells (PBMC) revealed a significant lymphoproliferative response to autologous idiotype 60 days after, but not prior to, BMT. An idiotype-specific T-cell line of donor origin has subsequently been established from recipient PBMC. Furthermore, the recipient experienced a clinical response to this therapy. We anticipate accrual of approximately 10-20 donor-recipient pairs per year who will be eligible to receive this therapy.

# Progress Report for the Monoclonal Antibody/Recombinant Protein Production Facility (MARP)

The Biological Response Modifiers Program (BRMP) is establishing a biologics pharmaceutical production facility at the Frederick Cancer Research and Development Center (FCRDC), Frederick, Maryland. This facility will make biologic drugs available on a more predictable schedule and more economically than had been possible using outside vendors. These products will be made available to both intramural and extramural investigators on a priority basis determined by an expert review committee.

# Division of Cancer Etiology

# Inter-Agency Working Group on Breast and Gynecological Cancer

The NIH Revitalization Act of 1993 included language directing the NCI to coordinate research in breast and gynecological cancer across the PHS and other Federal agencies. The Inter-Agency Working Group, chaired by the Deputy Director of the Division of Cancer Etiology, has been established to fulfill this mandate. The Group's membership is broad-based, with representation from throughout the NIH as well as the PHS and other Government agencies. The Working Group has recently been designated by the Secretary, DHHS as the programmatic focal point for the coordination of activities and the dissemination of information under the National Breast Cancer Action Plan and will work in concert with the Department of Defense on the Army's Breast Cancer Research program.

## The Long Island Breast Cancer Study Project

The Congressionally mandated Long Island Breast Cancer Study Project, conducted under the joint auspices of NCI and NIEHS, seeks to determine the relative contributions of diverse environmental factors to breast cancer risk in the New York counties of Nassau, Suffolk, and Schoharie and in Tolland county, Connecticut. This large epidemiologic study will examine a wide variety of environmental elements, including exposures to pesticides and other

organochlorine toxins, contaminated drinking water, indoor air pollution, aircraft and auto emissions, electromagnetic fields, hazardous waste and municipal waste. Dietary factors, radiation, estrogen exposures, and occupational exposures are also being assessed.

# The Northeast/Mid-Atlantic Study

Also mandated by the Congress and jointly funded by NCI and NIEHS, the Northeast/Mid-Atlantic Study encompasses an area that covers the District of Columbia and nine states from Maryland to New England. The goal of this epidemiologic study is to define and quantitate the contributions of a number of environmental factors to breast cancer risk, with a particular emphasis on pesticide exposures.

# The Agricultural Health Study

In collaboration with NIEHS and the EPA, a prospective cohort study of over 100,000 farmers and their families is underway to evaluate cancer and other disease risks associated with various agricultural exposures such as pesticides, herbicides, fertilizers, viruses, UV-light, chemical solvents and engine exhausts. An important component of the study involves the evaluation of cancer risks among women and children that may arise from indirect, nonoccupational exposures to agricultural chemicals such as ambient air drifts, handling contaminated clothing, and any residues found on rugs, children's toys, and in drinking water. Also under study is the identification and quantification of cancer risks associated with diet, various cooking practices, and chemicals resulting from the cooking process.

# Migrant and Seasonal Farm Workers Feasibility Study

As a parallel project to the Agricultural Health Study, a feasibility study has been initiated to evaluate the potential for conducting a study of cancer risks from pesticides and other agricultural exposures that may affect migrant and seasonal farm workers and their families. Special efforts are being made to reach out to Hispanic and other minority farm workers so that their cancer experiences can be included for evaluation. The study will attempt to devise ways to surmount the practical difficulties associated with tracking these underserved populations, including the frequent migration of these groups between the U.S. and other countries and the barriers that prevent their use of the U.S. health care system.

### A New Species of Helicobacter

A new species of *Helicobacter* (provisionally designated as *Helicobacter hepaticus sp. nov.*) that selectively and persistently colonizes the hepatic bile canaliculi of mice (and possibly the intrahepatic biliary system and large bowel) has recently been identified. The novel *Helicobacter* is a likely candidate for the etiology of the high incidence of a chronic, active hepatitis associated with hepatocellular tumors that was discovered in diseased mice at NCI's Frederick Cancer Research and Development Center in 1992. The *Helicobacter*-associated chronic active hepatitis represents a new model to study the mechanisms of carcinogenesis by this genus of bacteria, another species of which, *Helicobacter pylori*, is associated with gastric adenocarcinoma.

# Cytochrome P450

Cytochrome P450s are involved in both steroidogenesis and steroid metabolism as well as in the metabolism and detoxification of drugs and other chemicals. One of the enzymes currently being studied is aromatase, the enzyme that converts androgens to estrogens. Because some cancers are estrogen dependent, this enzyme may prove to be a useful target for new chemotherapeutic compounds. In addition,  $16\alpha$ -hydroxyestrone formation may be a biomarker for breast cancer. Ongoing studies are seeking to determine both estrogen synthesis and metabolism in human breast, ovary, cervical, and adipose tissues.

# **Heterocyclic Aromatic Arylamines**

Ongoing studies on the metabolism and DNA adduction of heterocyclic amines (HAAs) have shown that these procarcinogens are produced in meats during the process of cooking and are mutagenic in the Ames Salmonella assay after metabolic activation by cytochrome P450. Studies with the HAA known as PhIP show that cynomolgus monkeys are able to metabolically activate it *in vivo*, resulting in DNA adducts that can be found in all tissues examined to date, including white blood cells. These metabolism studies suggest that PhIP may prove to be carcinogenic in nonhuman primates. In studies of the metabolism of HAAs in the mammary gland of rats, PhIP metabolites in breast milk have been identified and their potential role in mammary carcinogenesis is currently being assessed. HAAs may also be associated with cardiac abnormalities. Studies have shown that cynomolgus monkeys chronically treated with IQ had elevated levels of DNA adducts in the heart and developed foci of cardiac myocyte necrosis. Research efforts will continue to explore the various aspects of the metabolic activation of HAAs and their carcinogenic potential.

# Division of Cancer Prevention, and Control

# The American Stop Smoking Intervention Study (ASSIST) National 5-A-DAY Program

The National 5-A-DAY Program, designed to encourage Americans to eat five or more servings of fruits and vegetables every day, represents a significant public/private partnership between NCI and the Produce for Better Health Foundation. NCI's role in providing credible information plays an integral part in communicating the 5-A-DAY message. Research grants awarded to state health agencies, universities, and cancer centers are evaluating the effect of 5-A-DAY activities in schools, workplaces and other community settings.

# Cancer in Minorities and the Underserved

Reducing cancer in minority and underserved populations is facilitated by the mobilization of professional and lay leaders in the community to address the specific cancer needs of that community as well as through coalition building among health-related, academic and community organizations. The NCI supports three such initiatives in an effort to address the cancer prevention and control needs of certain populations.

A major goal of the National Black Leadership Initiative on Cancer (NBLIC) is to address the barriers that limit or prevent Black Americans from gaining access to quality cancer control services. As of April 1994, the NBLIC has established 47

coalitions and is forming others in six regional areas of the U.S. The NBLIC recently established a collaborative working relationship with the American Association of Retired Persons (AARP) to plan and conduct more effective outreach programs targeting senior citizens.

The National Hispanic Leadership Initiative on Cancer (NHLIC) addresses cancer control barriers including risk factors, and cancer control service utilization in Hispanic communities. The NHLIC has established nine outreach sites involved in mobilizing community leaders to promote awareness and utilization of culturally sensitive and linguistically competent cancer prevention and control programs.

The third of these initiatives, the Appalachian Leadership Initiative on Cancer (ALIC) is a rural health initiative to establish community-based cancer prevention and control outreach programs for the medically underserved population in the Appalachian region of the United States. Among the ALIC's priorities are the promotion of smoking cessation, diet modification, and early detection screening and treatment. Measurable improvements are expected in this region in knowledge about prevention and early detection of cancer, and access and utilization of diagnostic and treatment services.

Cancer has become the leading cause of death for Alaskan Native women and the second leading cause of death among both Native American and Native Hawaiian women. The Native American Women's Cancer Initiative was developed in response to emerging cancer needs and issues of Native American women. Numerous barriers have been identified that interfere with cancer prevention and control efforts among indigenous women. In addition, the types and impact of such barriers vary among native communities in different regions of the country. Research projects focus on identifying barriers to culturally appropriate quality cancer control services and reducing cancer risk behaviors in Native American women.

## Women's Health Trial: Feasibility Study in Minority Populations

NCI also has been exploring a dietary intervention, specifically fat restriction, to reduce the risk of developing breast, colorectal, and possibly cardiovascular diseases in postmenopausal women in the Women's Feasibility Study in Minority Populations. Approximately 2,250 women, 45 to 69 years of age have been enrolled to this multi-center randomized clinical trial. This study is testing methods to enable these women to modify their eating habits to a low-fat eating pattern as well as evaluating the impact of social customs, culture, and economic status on achieving and maintaining a dietary pattern that reduces fat intake. Elements of this trial have been used in the design and implementation of dietary interventions with the projected 10-year trans-NIH, multidisciplinary Women's Health Initiative, a national study of dietary modification, vitamin and mineral supplementation and hormonal replacement therapy in post-menopausal women.

National DES Educational Program for Health Professionals and the Public NCI is sponsoring a cooperative agreement to develop, implement, and evaluate health education programs to inform DES exposed mothers, daughters, sons, and the health professionals who care for them about risks associated with DES exposure and of appropriate early detection, diagnosis and treatment strategies

for DES-related malignancies and other conditions. Diethylstilbestrol (DES) is a synthetic estrogen used to prevent miscarriages from the 1940s through 1971. DES was later found to be associated with an increased incidence of rare vaginal clear cell cancer in young women who had been DES exposed in utero. Mothers who were prescribed DES have also been found to have a 40 percent increased risk of breast cancer. A national education is now being conducted to test a regional breast cancer screening program for women exposed to DES. Members of existing cohorts of women exposed to DES as well as members of various DES action groups and callers to the CIS Hotline are being used to identify those eligible for screening.

# Screening for Prostate, Lung, Colorectal, and Ovarian Cancers

The Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) is a randomized, controlled clinical trial designed to determine whether particular screening modalities for prostate, lung, colorectum, and ovary will reduce the number of deaths through early detection of these cancers. Over the next eight years this trial will randomize 148,000 participants with equal numbers of men and women ages 60-74 years. Individuals in this age group are being asked to volunteer for the trial because the risk of these cancers is high in this age group. The 37,000 men randomized to the intervention arm of the study will have a yearly digital rectal examination and a blood test for prostate-specific antigen (PSA) for prostate cancer, an annual chest x-ray for lung cancer, and a flexible sigmoidoscopy at the initial visit and another three years later for colorectal cancer. Equal numbers of women in the intervention group will receive an annual chest x-ray, and a sigmoidoscopy at the initial visit and another three years later, for lung and colorectal cancers respectively. For ovarian cancer screening women will have an annual ovarian palpation, transvaginal ultrasound, and blood test for the tumor marker, CA-125. The pilot phase of the trial concluded in September of 1994 and a thorough evaluation of this phase will be completed in early 1995.

# Prostate Cancer Prevention Trial with Finasteride

The Prostate Cancer Prevention Trial (PCPT) is being conducted in the CCOP clinical trials network. The trial is an intergroup study involving over 225 community and university hospitals across the country and is coordinated by the Southwest Oncology Group (SWOG). The study tests the ability of finasteride (Proscar), a 5-alpha-reductase inhibitor of androgen synthesis, to reduce the incidence of prostate cancer, the most common cancer in men.

The PCPT will include approximately 18,000 men from across the United States. Participation is open to all men between ages 55 and 70. Black men and men with a family history of prostate cancer are being aggressively recruited because they may have the greatest risk of developing prostate cancer. Men entering the study are randomized to receive finasteride or placebo for 7 years. The total trial will last 10 years. Prostate cancer will be detected during follow-up by physical examinations and blood tests and, at the end of the study, by prostate biopsy. The trial will also help determine the worth of annual prostate examinations and serial prostate-specific antigens (PSA) blood tests in detecting prostate cancers. The trial will provide the first biopsy-based characterization of the prevalence of occult prostate tumors in men over age 55.

## Breast Cancer Prevention Trial with Tamoxifen

The Breast Cancer Prevention Trial (BCPT) with tamoxifen is currently underway in the CCOP clinical trials network. The trial is being conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and includes participants from over 300 centers across the U.S. and Canada with nearly 11,000 participants enrolled and randomized to either tamoxifen or placebo. The study tests the ability of tamoxifen, an anti-estrogen medication used in post-surgical treatment of early stage breast cancer, to prevent the development of breast cancer in women at increased risk for developing the disease. Approximately 16,000 women at increased risk for breast cancer due to various factors such as 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 a period of 5 years.

# Community Clinical Oncology Program (CCOP)

The Community Clinical Oncology Program (CCOP) links community cancer specialists, primary care physicians, and other health care professionals to conduct both clinical treatment research and cancer prevention and control research studies. Research areas include: early detection and screening, chemoprevention, patient management, continuing care, and rehabilitation; testing intervention strategies such as chemoprevention in large populations; and assessing the impact of targeted research on community practices.

Through the network's access to cured cancer patients, their families, and other individuals at increased risk of developing cancer, NCI implements large-scale chemoprevention trials to study the effectiveness of various agents to prevent cancer. Examples include the Breast Cancer Prevention Trial (BCPT) with tamoxifen, and the Prostate Cancer Prevention Trial (PCPT) with finasteride.

The current program involves 48 community programs in 27 States with over 315 hospitals and 2,900 physicians. Annually, the CCOP enters approximately 4,000 patients onto treatment clinical trials, representing about one third of the annual accrual to NCI-approved randomized Phase III clinical trials.

# Minority-Based Community Clinical Oncology Program (MBCCOP)

The Minority-Based Community Clinical Oncology Program (MBCCOP) is a network of community cancer specialists, primary care physicians and other health care professionals who conduct both clinical treatment research and cancer prevention and control research studies.

The MBCCOP provides a vehicle to develop and implement effective treatment and cancer control strategies in minority populations and allows for the study of minority recruitment and accrual to cancer clinical trials. This program was initiated to provide minority cancer patients with access to state-of-the-art cancer treatment and control technology. Ten programs with greater than 50 percent of new cancer patients from minority populations are currently funded.

# Division of

# Extramural Activities Cancer Centers and Cancer Control in Minority Populations

The National Cancer Institute seeks to expand minority involvement in cancer control research, through the Comprehensive Minority Biomedical Program (CMBP) and the Cancer Center Minority Enhancement Awards (MEAs). MEAs are awarded competitively as supplements to NCI Cancer Centers for the purpose of facilitating the participation of minority groups in cancer control research. By broadening the operational base of cancer centers, MEAs allow expansion of center-based cancer control efforts in prevention, early detection, 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. Three awards were made to institutions in prior years. An additional award was approved for funding in 1994.

# The Minority Health Professional Training Initiative (MHPTI)

The MHPTI, which began in 1991, supports training and career development opportunities for minority health professionals by providing opportunities in oncology research and other subspecialities 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. Awards were made to minority clinicians in 1992 and 1993. Efforts are being made to expand this program.

# Research Supplements for Underrepresented Minorities

The NIH-wide supplemental program "Initiatives for Underrepresented Minorities in Biomedical Research", began as an extension of the NCI Minority Investigator Supplement Program. This program provides supplemental funding to existing grants to fund participation of minorities in specific research projects. The targeted groups include for minority high school students, minority undergraduate students, minority graduate research assistants, minority individuals in postdoctoral training and minority staff or faculty. While this mechanism provides support indirectly to minority scientists and students by way of funded grantees, 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, NCI co-funds, with the Minority Access to Research Careers (MARC) Program of National Institute of General Medical Sciences, pre-doctoral fellowships to minority students and Honors Undergraduate Training Grants to minority institutions. Similarly, through co-funding with the Minority Biomedical Research Support (MBRS) program, NCI provides support for specific cancer-related projects at participating minority institutions.

Through the High School Apprentice Program, the NCI contributed to the broadened involvement of high school researchers. Fifty awards were issued in 1994.

# Other NCI Training Opportunities

The Summer Training Supplement is an extension of the 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.

#### Cancer Information Dissemination

The CMBP, jointly with the Office of Cancer Communications (OCC), continues its efforts to heighten awareness about cancer risk and prevention in Black Americans. A contract solicitation was undertaken, and the published Request for Proposal (RFP) was targeted to the network of Black colleges and universities in a variety of settings with close ties to the Black community. The aim of this undertaking is to develop and disseminate information through educational programs regarding steps that can be taken to control or reduce cancer in Black Americans.

# 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 Information Service

The Office of Cancer Communications supports a nationwide network of offices known as the Cancer Information Service (CIS). The CIS serves as the NCI's primary mechanism to disseminate accurate up-to-date information to the American public at the community level. As OCC field offices, the CIS provides information on cancer and local resources through its toll free phone service.

Over 500,000 calls are received each year. In addition, the CIS serves as a catalyst for the adoption and adaptation of NCI education programs. Under a new program structure implemented in 1993, regional CIS offices now serve the entire continental United States, Alaska, Hawaii, and Puerto Rico. The CIS offices are funded through a contract mechanism with NCI designated cancer centers and community hospitals.

## International Cancer Information Center

To increase the dissemination of cancer research and treatment information to physicians, researchers and other health professionals involved in cancer care, the International Cancer Information Center (ICIC) established the National Cancer Institute Information Associates Program, a membership service providing access to all of the NCI's scientific information products and services for health professionals through one point of contact and for one low yearly fee. Benefits of membership include a subscription to the Journal of the National Cancer Institute and copies of all Journal of the National Cancer Institute

Monographs; access to a toll-free dial-up Bulletin Board Service (BBS), which in turn provides access to the PDQ database, CANCERLIT Citation and Abstract Digests, Fact Sheets for Patients from the Office of Cancer Communications, and electronic mail and on-line conferences; Internet access to PDQ; and a toll-free member service line staffed with trained, bilingual representatives.

The ICIC has also been designated as a Public Health Service Reinvention Laboratory under Vice President Al Gore's National Performance Review. Designed to foster innovation in government, reinvention laboratories are areas within the federal government selected to demonstrate how re-engineering work processes, increasing delegations of authority, and empowering employees can improve efficiency and increase customer satisfaction.

The ICIC is also exploring ways to make its products and services available through Mosaic software on the World Wide Web. Mosaic enables users to access full-color photographs, video, and sound.

In conjunction with the Patient Education Section of the Office of Cancer Communications, the ICIC is co-directing the PDQ/PIF Demonstration Project, in which eight sites around the country will work to develop more effective ways to present and disseminate the patient information in PDQ. Phase I of the PDQ/PIF Project was completed last year.

#### Office Of International Affairs

OIA coordinates collaborative research between American and foreign scientists by cosponsoring international workshops and scientist exchanges. Fifteen workshops and 200 scientist exchanges were sponsored during 1994. Many more required no OIA funding. Eight European Organization for Research and Treatment of Cancer (EORTC) and ten Japanese Foundation for Cancer Research (JFCR) exchangees came to American laboratories. NCI also contributed toward the funding of over 100 short-term International Cancer Technology Transfer Fellowships (ICRETT), a program administered by the International Union Against Cancer (UICC). In addition, over 700 foreign scientists were at NCI under the NIH Visiting Program.

The Oncology Research Faculty Development Program for scientists from the developing world supported 16 trainees during 1994. A new program of Career Development Awards for Young Cancer Researchers in the newly independent states of the former USSR was begun in 1994. Awards have been made to scientists in Tallinn (Estonia), Riga (Latvia), Vilnius (Lithuania), Novosibirsk, Obninsk, and St. Petersburg (Russia), and Kiev (Ukraine).

A CD-ROM product containing the PDQ and CANCERLIT databases has been installed at over 50 cancer centers in Central and Eastern Europe, Latin America, the Caribbean, and developing Asian and African countries. Due to limitations inherent in this method of information dissemination, OIA is beginning a transition to alternative means of accessing cancer information through Internet electronic mail (e-mail).

OIA maintains liaison between the NCI and international agencies involved in cancer research and prevention, such as the EORTC, IARC, UICC, OECI, PAHO, WHO, and with national organizations which have international components, such as the American Cancer Society (ACS) and NAS in the U.S.; the United Kingdom Coordinating Committee for Cancer Research (UKCCCR), the Cancer Research Campaign (CRC), and Imperial Cancer Research Fund in the United Kingdom, the Association pour la Recherche sur le Cancer (ARC); Centre National de la Recherche Scientifique (CNRS), and Institut National de la Sante et de la Recherche Medicale (INSERM) in France; the JFCR, and the Japan Society for the Promotion of Science (JSPS); and many more.

# 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, including patient, and health professionals, are afforded easy access to up-to-date information regarding cancer prevention, detection and diagnosis, and treatment measures.

The NCI's information dissemination efforts include behavior modification interventions, such as smoking cessation and breast cancer screening, as well as education activities specifically directed towards professional, public, and patient audiences. The 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, accessible to the public by dialing 1-800-4-CANCER, is staffed by information specialists 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 therapy, taxol), results in a flood of calls to this toll-free number.

The Cancer Information Service consists of a nationwide network of 19 regional offices. 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

PDQ Searches	Total Literature Distributed	Publication Ordering Calls	CIS Inquiries		
30,000	25,000,000	200,000	600,000	1994	

### Scientific Information Dissemination

The International Cancer Information Center continues to promote the use of its products and services to the widest audiences possible, primarily through the NCI Information Associates Program, and also through its individual electronic products and services. PDQ's Treatment, Supportive Care, Screening and Prevention, and Drug Information Statements, along with Fact Sheets on various cancer-related topics, Search Citations and Abstracts from the CANCERLIT database, and news items, are available via fax through CancerFax® and via Internet electronic mail through CancerNet<sup>TM</sup>. Many of these items are also available on gopher servers around the world.

The *Journal of the National Cancer Institute*, the NCI's peer-reviewed scientific journal, continues to provide information regarding clinical and basic research advances to cancer professionals worldwide. Journal articles are currently the most frequently cited out of 78 oncology journals worldwide.

The ICIC continues to promote the Information Associates Program and the other scientific information services for health professionals at national and international medical meetings.

# Directory of Personnel

Director, National Cancer Institute		
Dr. Samuel Broder	Building 31 11-A-48	301-496-5615
Acting Deputy Director		
Dr. Edward J. Sondik	Building 31 11-A-48	301-496-1927
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Director, Office of Legislation and Congressional Activities		
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	T.	
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Acting Chief, Reports and Inquiries Branch		
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Acting Chief, Information Projects Branch	produced beautiful construction of the constru	
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Mr. Nicholas B. Martin	Building 82 219	301-496-8880
Chief, Scientific Publications Branch	<u> </u>	
Managing Editor, Journal of the National Cancer Institute		
Ms. Julianne Chappell	Building 82 235	301-496-1997
Chief, International Cancer Research Data Bank Branch	<u> </u>	
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Director, Office of Technology D		6 11 04 4 4 54	204 400 0477
	Dr. Thomas D. Mays	Building 31 4-A-51	301-496-0477
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	d Development Center, Frederick Dr. Jerry Rice	Building 427 9	8-301-846-5096
Director	Dr. Jerry Rice	Building 427 9	0001040000
General Manager/Project C	Officer		
General Managem Toject C	Dr. Cedric W. Long	Building 427 8	8-301-846-1108
Deputy General Manager	Dr. Courie VI. Long		(T)
Doputy Contra manager	Mr. Richard Carter	Building 427 3	8-301-846-1106
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Acting Director, Division of Cand			
DO THE SE SE THE NOT HE AND REPORTED	Dr. Jerry Rice	Building 31 11-A-03	301-496-6618
Acting Administrative Office		8 7 7 8 7 7 7 7	004 400 0550
	Ms. Virginia Kiesewetter	Building 31 11-A-11	301-496-6556

Director, Division of Cancer Biol	logy, Diagnosis, and Centers		
	Dr. Alan S. Rabson	Building 31 3-A-11	301-496-4345
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	Mr. Lawrence D. Willhite	Building 31 3-A-11	301-496-3381
Director, Division of Cancer Trea	atment		
	Dr. Bruce A. Chabner	Building 31 3-A-44	301-496-4291
Administrative Officer			
	Mr. Lawrence J. Ray	Building 31 3-A-44	301-496-2775
Director Division of Extramural	Activities		
DIFECTOR, DIVISION OF EXCIDING A	ACUVIUES		
Director, Division of Extramural	Dr. Marvin Kalt	Executive Plaza North 600	301-496-5147
Administrative Officer		Executive Plaza North 600	301-496-5147
		Executive Plaza North 600 Executive Plaza North 604	
	Dr. Marvin Kalt		
Administrative Officer	Dr. Marvin Kalt  Ms. Deborah Jarman		
	Dr. Marvin Kalt  Ms. Deborah Jarman  vention and Control	Executive Plaza North 604	301-496-5915
Administrative Officer  Director, Division of Cancer Pres	Dr. Marvin Kalt  Ms. Deborah Jarman		
Administrative Officer	Dr. Marvin Kalt  Ms. Deborah Jarman  vention and Control	Executive Plaza North 604	301-496-5915

# Former Directors of the National Cancer Institute

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

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

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

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

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

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

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

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

Dr. Carl Voegtlin, Ph.D. January 1938 - July 1943 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.

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. Rauscher served as Scientific Director for Etiology, NCI, prior to his appointment as Director of NCI in 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. 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. Heller joined PHS in 1934 and became Chief of the Venereal Disease Division prior to his appointment as Director of NCI in 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. Spencer became NCI's first Assistant Chief and, subsequently, was appointed Director of the Institute in 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

Expiration Appointees Appointr			ation of pointment	Appointees	Expiration of Appointment
Mrs. Barbara K. Rimer, Dr.P.H. Chairperson Duke University Durham, NC	2000	Pelayo Correa, M.D. Louisiana State University Medical Center New Orleans, Louisiana	1998	Sydney Salmon, M.D. Arizona Cancer Center Tucson, AZ	1996
Frederick F. Becker, M.D. University of Texas Houston, TX	1996	Robert W. Day, M.D., MPH, Ph.D Fred Hutchinson Cancer Research Center Seattle, Washington	1998	Philip S. Schein, M.D. U.S. Bioscience, Inc. West Conshohocken, PA	2000
J. Michael Bishop, M.D. The George Williams Hopper Research Foundation San Francisco, CA	2000	Mrs. Barbara P. Gimbel The Society of Memorial Sloan- Kettering Cancer Center New York, New York	1998	Ellen V. Sigal, Ph.D SIGAL Environmental Inc. Washington, D.C.	1998
Mrs. Zora K. Brown Cancer Awareness Program Washington, D.C.	1998	Alfred L. Goldson, M.D., F.A.C.A.R. Howard University Hospital Washington, D.C.	2000	Vainuts K. Vaitkevicius, M.D. Michigan Cancer Foundation Detroit, MI	2000
Paul Calabresi, M.D., Rhode Island Hospital Providence, RI	1996	Mrs. Marlene A. Malek Vincent Lombardi Cancer Center McLean, VA	1996	Charles B. Wilson, M.D. Brain Tumor Research Center U.C.S.F. San Francisco, Ca.	1998
Kenneth Chan, Ph.D Ohio State University Columbus, Ohio	1996	Deborah K. Mayer, R.N., M.S.N. Ontario Cancer Institute Toronto, Canada	1996	Executive Secretary Marvin R. Kalt, Ph. D. National Cancer Institute Bethesda, MD 20892	
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The Honorable Donna E. Shalala, Ph.D Secretary for Health and Human Services Washington, D.C.	S	Kenneth W. Kizer, M.D.M.P.H. Department of Veterans' Affairs Washington, D.C.		Ann Brown Consumer Product Safety Comm Bethesda, MD	nission
Harold Varmus, M.D. Director, National Institutes of Health Bethesda, MD		David A. Kessler, M.D. Food and Drug Administration Rockville, MD		Kenneth Olden,M.D. National Institute of Environment Health Sciences Research Triangle Park, NC	al
The Honorable Robert B. Reich Secretary of Labor Washington, D.C.		Linda Rosenstock, M.D., M.P.H. NIOSH Washington, D.C.		Rachel Levinson, Ph.D. Office of Science and Technology Policy Washington, D.C.	
The Honorable Edward Martin, M.D. Acting Assistant Secretary of Defense Washington, D.C.		Ari Patrinos, Ph.D. Department of Energy Washington, D.C.		Carol M. Browner Environmental Protection Agenc Washington, D.C.	у
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Marilyn A. Fingerhut, Ph.D. NIOSH Washington, D.C.		Hugh McKinnon, M.D. Environmental Protection Agency Washington, D.C.		Ralph E. Yodaiken, M.D. Department of Labor Washington, D.C.	
John R. Johnson,M.D. Food and Drug Administration Rockville, MD		Raymond L. Sphar,M.D. Department of Veterans' Affairs Washington, D.C.		Captain Bimal C. Ghosh, M.D. Department of the Navy Washington, D.C.	
		Andrew Ulsamer, Ph.D. Consumer Product Safety Commiss. Bethesda, MD	on	John C. Wooley,Ph.D. Department of Energy Washington, D.C.	

# Division Boards of Scientific Counselors

Division of Cancer	Robert L. Reddick, M.D.	1995		
Biology, Diagnosis, and	Chairperson		Stanley J. Korsmeyer, Jr., M.D.	1998
Centers			Michael E. Lamm, M.D.	1997
	Martin D. Abeloff, M.D.	1995	David M. Livingston, M.D.	1996
	Barbara F. Atkinson, M.D.	1995	Sue Ellen Martin, M.D., Ph.D.	1997
	Esther H. Chang, Ph.D.	1996	Ruth McCorkle, Ph.D.	1998
	Albert E. Dahlberg, M.D., Ph.D.	1996	Azorides R. Morales, M.D.	1995
	William F. Dove, Ph.D.	1998	Curtis L. Parker, Ph.D.	1997
	Lois B. Epstein, M.D.	1995	Alan Solomon, M.D.	1996
	Max E. Gottesman, M.D.	1996	Jouni Uitto, M.D.,Ph.D.	1996
Division of Cancer	Clara D. Bloomfield, M.D.	1995		
Treatment	Chairperson		Barbara J. McNeil, M.D., Ph.D.	1998
			Beverly S. Mitchell, M.D.	1996
	William R. Brody, M.D., Ph.D.	1998	Rodrique Mortel, M.D.	1995
	Charles A. Coltman, Jr., M.D.	1997	Allen I. Oliff, M.D.	1996
	Phillip Crews, Ph.D.	1994	Lester J. Peters, M.D.	1995
	Carlo M. Croce, M.D.	1995	Ralph A. Reisfeld, Ph.D.	1998
	Stephen H. Friend, M.D., Ph. D.	1998	Anna Marie Skalka, Ph.D.	1998
	Zvi Y. Fuks, M.D.	1997	Paul M. Sondel, M.D., Ph.D.	1997
	Philip D. Greenberg, M.D.	1996	Glenn D. Steele, Jr., M.D., Ph.D.	1995
	Sidney M. Hecht, Ph.D.	1997	Wendell Wierenga, Ph.D.	1998
Division of Cancer	G. Barry Pierce, M.D.	1994		
Etiology	Chairperson			
			Nancy E. Mueller, S.D.	1997
	Donald S. Davies, Ph.D.	1995	Nancy L. Oleinick, Ph.D.	1995
	Virginia L. Ernster, Ph.D.	1997	Alan P. Poland, M.D.	1995
	Stephen S. Hecht, Ph.D.	1993	Herman A. Schut, Ph.D.	1998
	Maurice R. Hilleman, Ph.D.	1993	James Swenberg, D.V.M., Ph.D.	1997
	Ru Chih C. Huang, Ph.D.	1994	Mimi C. Yu, Ph.D.	1994
Division of Cancer	Arnold D. Kaluzny, Ph.D.	1995		
Prevention and Control	Chairperson		Cutberto Garza, M.D., Ph.D.	1005
	John G. Boyce, M.D.	1996	E. Robert Greenberg, M.D.	1995
	Helene G. Brown	1995	Melvin R. Moore	1995
	David L. DeMets, Ph.D.	1995		1997
	Eric R. Fearon, M.D., Ph.D.	1997	G. Marie Swanson, Ph.D., M.P.H.	1996
	Suzanne W. Fletcher, M.D.	1997	Ian M. Thompson, Jr., M.D. Melvyn S. Tockman, M.D., Ph.D.	1996 1996
	5	Z-(MGC)	Some residual (CV) con a contra de contra de la contra del la contra de la contra del la	
rederick Cancer	Donald R. Helinski, Ph.D.	1994	Bottoman II Bottom	5 2723 623829
Research and	Chairperson		Raymond L. Erikson, Ph.D.	1997
Development Center		proposition of the state of the	John M. Essigmann, Ph.D.	1998
	John N. Abelson, Ph.D.	1996	Rasika M. Harshey, Ph.D.	1996
	Arnold J. Berk, M.D.	1997	John E. Johnson, Ph.D.	1997
	John M. Coffin, Ph.D.	1996	James L. Sherley, M.D., Ph.D.	1996
	Frank Costantini, Ph.D.	1997	Colin L. Stewart, D. Phil.	1998
	Elizabeth A. Craig, Ph.D.	1998	Susan S. Taylor, Ph.D.	1998

# President's Cancer Panel

Harold Freeman, M.D. 1994 Chairman

Director of Surgery Harlem Hospital Center New York, NY

Frances M. Visco, Esq. 1996

President

National Breast Cancer Coalition

Philadelphia, Pa.

Henry C. Pitot., M.D., Ph.D. 1995 Professor of Oncology and Pathology McArdle Laboratory University of Madison Madison, Wisconsin

Executive Secretary Maureen O. Wilson, Ph.D.

Assistant Director National Cancer Institute Building 31, Room 4A34 Bethesda, MD 20892

# Executive Committee Members

Dr. Samuel Broder

Director

Dr. Edward J. Sondik

Acting Deputy Director

Mr. Philip D. Amoruso

Associate Director for Administrative Management

Dr. Jerry Rice

Acting Director, Division of Cancer Etiology

Dr. Marvin A. Kalt

Director, Division of Extramural Activities

Dr. Bruce A. Chabner

Director, Division of Cancer Treatment

Dr. Peter Greenwald

Director, Division of Cancer Prevention and Control

Dr. Jerry Rice

Associate Director, Frederick Cancer Research and Development Center

Dr. Alan Rabson

Director, Division of Cancer Biology, Diagnosis and Centers

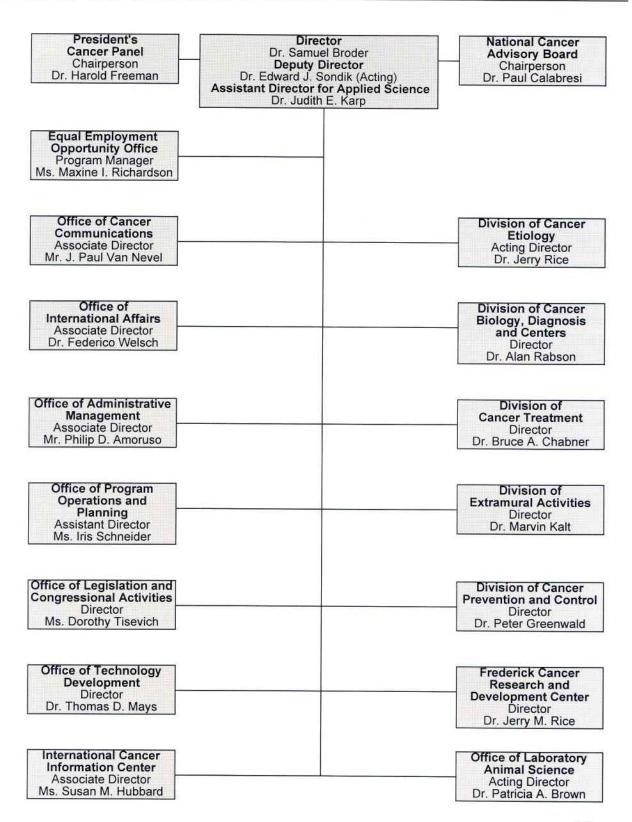
Dr. Judith E. Karp

Assistant Director for Applied Science

Ms. Iris Schneider

**Executive Secretary** 

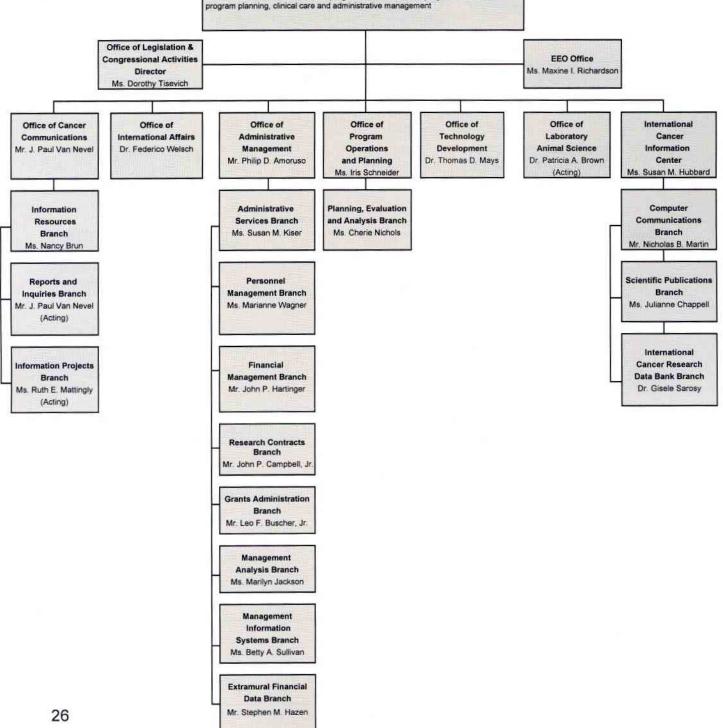
# National Cancer Institute Organization

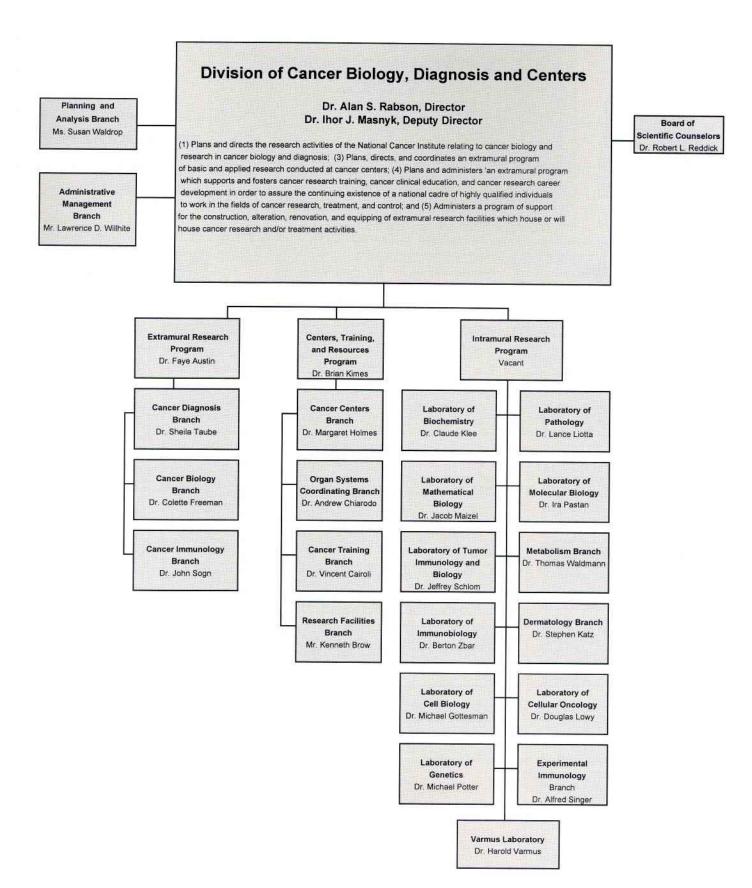


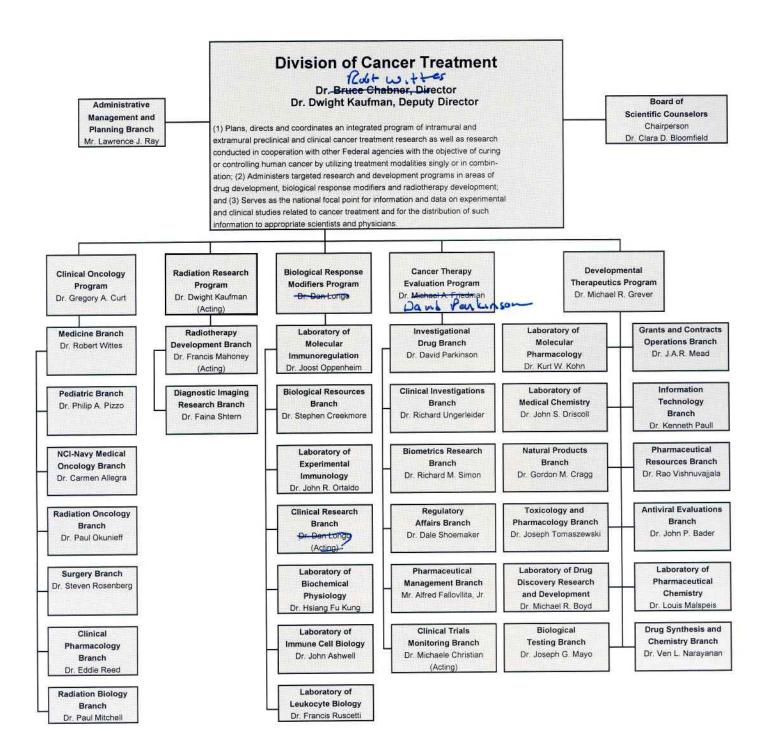
# Office of the Director

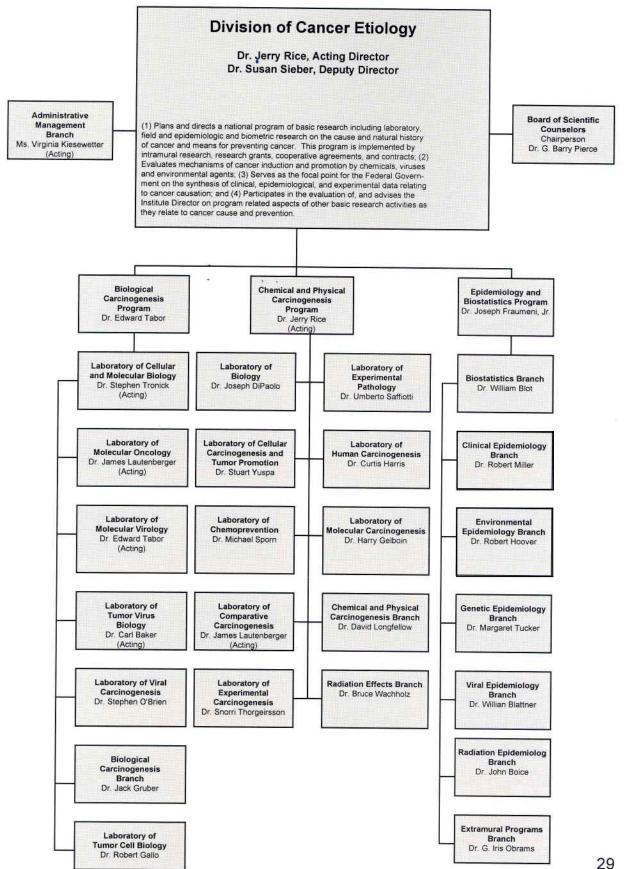
Dr. Samuel Broder, Director
Dr. Edward J. Sondik, Acting Deputy Director
Dr. Judith E. Karp, Assistant Director for Applied Science

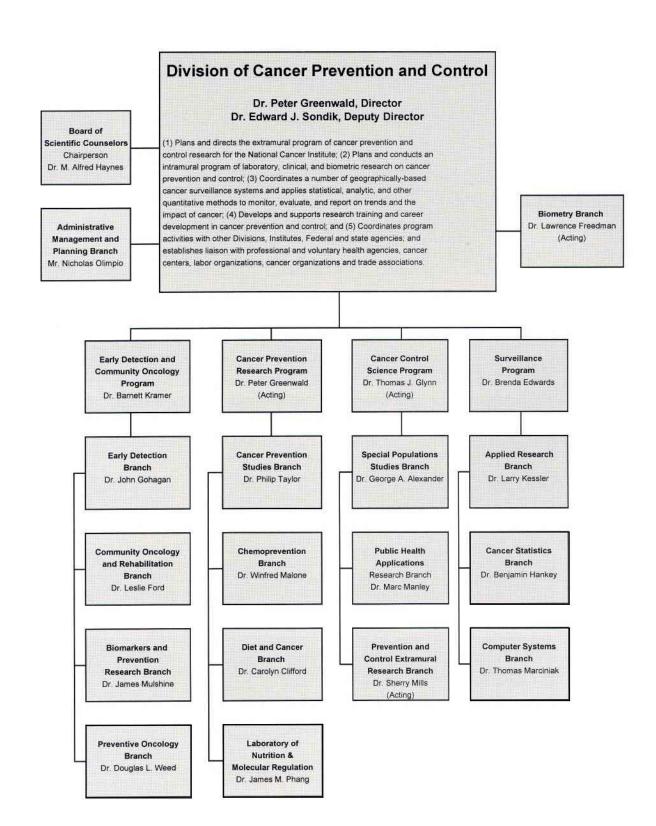
(1) Serves as the focal point for the National Cancer Program, (2) Develops a National Cancer Plan; and monitors implementation of the Plan; (3) Directs and coordinates the Institute's programs and activities, and (4) Develops and provides policy guidance and staff direction to the Institute's programs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







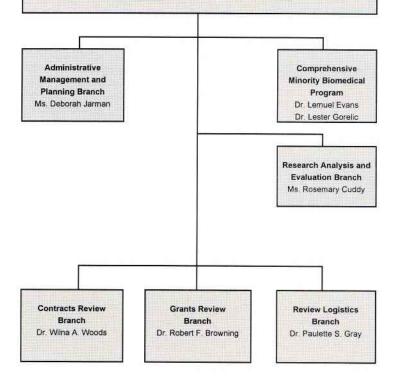




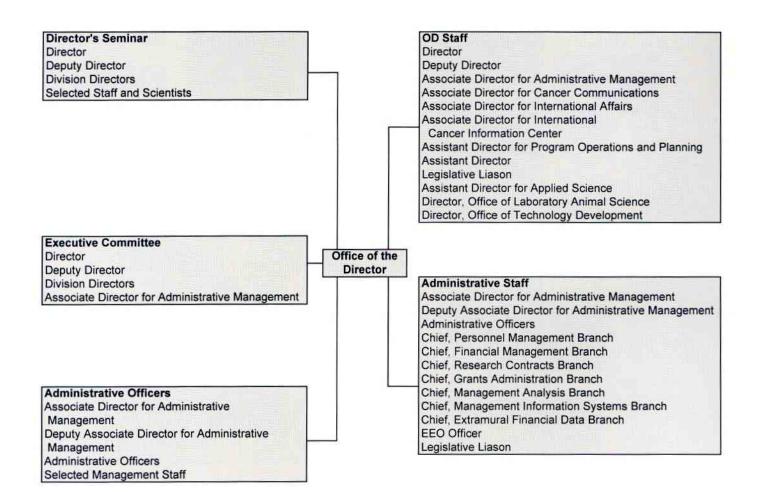
#### **Division of Extramural Activities**

Dr. Marvin Kalt, Director
Dr. Paulette S. Gray, Deputy Director (Acting)
Dr. Vincent Oliverio, Associate Director
Dr. Elliot Stonehill, Special Assistant to the Director

(1) Administers and directs the Institute's grant and contract review 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 and other historically underserved segments of the general population.



## Information Flow for Program Implementation



## Intramural Review

## **Process**

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

# 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
I. Civil Service			
Civil Service (tenured)	Appropriate advanced education, experience and knowledge needed by NCI to conduct its programs.	Minimum starting Ph.D \$47,920 (GS-13/1) Physicians - \$59,099 (GS- 13/8)	Office of Personnel Management; Contact Division Director of Laboratory Chief in area of interest or the NCI Personnel Office.
II. Special Appointment of E	xperts and Consultants		
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-13/1 and with maximum limited to level IV of the Executive Schedule \$115,700 <sup>2</sup> .	Final approval rests with the Division Director or Deputy Director, NCI depending on recommended action.

<sup>&</sup>lt;sup>1</sup>Does not necessarily indicate that positions are currently available at the National Cancer Institute. 2Medical Officer (Research), GS-602 Special Rate Scale

Position	Eligibility	Annual Salary	Mechanism of Entry
III. Clinical Associate Progra	ım		
A. Clinical Associates	Initial appointment for 2 years with the possibility of 1-year extension. 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. NOTE: Foreign M.D.'s in a U.S. residency training program are also eligible through a Fogarty International Center appointment.	\$38,500 1st yr \$40,500 2nd yr \$42,500 3rd yr	Apply to NIH Office of Education Building 10 Room 1C-129
B. Pharmacology Research Associates (PRAT). Physicians committed to research careers in phar macologic sciences, or clinical pharmacology.	Appointment for 2 years. Candidates must be U.S. citizens or permanent residents of the U.S. who have been awarded a doctoral degree or who have been certified by a university as meeting all the requirements leading to a doctorate. The degree must be in a biomedical or related science and must have been received within the 5 years preceding the date of application.	First year salaries range from \$33,500 for pH.Ds to \$37,000 for M.D.s based on years of postdoctoral experience.	Apply to PRAT Program, NIGMS Natcher Building Room 2AS-43

Position	Eligibility	Annual Salary	Mechanism of Entry
IV. Visiting Program (limite	ed tenure)¹		
A. Visiting Fellow (maximum 5 years)	5 years or less of relevant postdoctoral experience or training.	First year salaries range from \$25,000 to \$42,000 based on years of postdoctoral experience	Contact Division Director or Laboratory Chief in area of interest.
B. Visiting Associate (1 year initial appointment with renewals to end of project)	3+ years of postdoctoral experience or training with appropriate knowledge needed by NCI.	\$28,000 - (GS9/1) \$53,000 - (GS12/10)	Contact Division Director or Laboratory Chief in area of interest.
C. Visiting Scientist (duration of project)	6+ years of postdoctoral experience with appropriate specific experience and knowledge needed.	\$41,000 - (GS12/1) \$87,000 - (GS15/10)	Contact Division Director or Laboratory Chief in area of interest.

<sup>&</sup>lt;sup>1</sup>Under most circumstances, the various visiting programs are limited to non-citizens.

Position	Eligibility	Annual Salary	Mechanism of Entry
V. Staff Fellowships			
A. Staff Fellowship	Physician or other doctoral degree equivalent who has less than 3 years of relevant professional level postdoctoral research experience. U.S. citizen or resident alien. Typical appointments are made for two years. Additional one-year extensions may also be made with a maximum of 7 years.	Physicians \$28,000 - \$48,196 (Maximum GS11/8) Other Doctors \$28,000 - \$47,013 (Maximum GS12/6)	Contact Division Director or Laboratory Chief in area of interest or the NCI Personnel Office.
B. Senior Staff Fellowship	Physician or other doctoral degree equivalent who has 3 to 7 years of relevant professional level postdoctoral research experience. U.S. citizen or resident alien. Typical appointments are made for two years. Additional one-year extensions may also be made with a maximum of 7 years.	Physicians \$39,000 - \$73,472 (Maximum GS13/10) Other Doctors \$33,504 - \$62,293 (Maximum GS13/10)	Contact Division Director or Laboratory Chief in area of interest or the NCI Personnel Office.

Position	Eligibility	Annual Salary	Mechanism of Entry
VI. Civil Service Summer E	Employment Programs		
Summer Aides	Provides summer employment opportunity for students who meet economic needs criteria. Must be 16 years of age or older. Disabled students are not required to meet economic criteria. Noncitizens may compete provided they have permanent visa status and are from a country allied with the United States.	Federal minimum wage.	Register with the local office of the State Employment service and apply to NCI.
VII. Special Programs			
A. Guest Researcher- 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 or 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.

Position	Eligibility	Annual Salary	Mechanism of Entry
B. Commissioned Officer Student Training and Extern Program (COSTEP) Program	U.S. citizen. Must have completed one year of study in a medical, dental, podiatry, optometry or	Receive the basic pay quarters (if appropriate),	Apply to Director, Division of Commissioned Personnel
(operates year-round). Maximum 120 days per 12-month period.	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.	and subsistence allowance of a Junior Assistant Health Service Officer (pay grade 0-1).	Attention: COSTEP Coordinator Room 4-35, Parklawn Building, 5600 Fishers Lane, Rockville, MD. 20857.
C. Fogarty International Scholars in Residence Program.	International reputation, productivity, demonstrated ability in biomedical field.	\$90,000 for 1 year.	Nominations are submitted to Fogarty Center by Institute Director, any senior tenured member of the NIH scientific staff, or former scholar.
D. Stay-in-School Program	Provides employment opportunity for students who meet economic needs criteria, attend accredited schools on a full-time basis, and are in good academic standing. Must be 16 years of age or older. Disabled students are not required to meet economic criteria. Noncitizens may compete provided they are from a country allied with the United States.	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 Personal Office, EPS, Room 537, 6120 Executive Blvd., Rockville, MD 20892-7209. No deadline required for applying. However, no new appointments are made between May 1 to August 30.

Position	Eligibility	Annual Salary	Mechanism of Entry
E. The Federal Junior Fellowship Program	Graduating high school senior in a public or private school. Must have demonstrated satisfactory academic performance with accumulative 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. Must qualify under financial needs criteria based upon family income. Must be a U.S. 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-2 through GS-5.	Nominations are submitted directly to NIH by high school principals or counselors.
F. 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 (work permit required if under 18).	N/A	Contact Division Director or Laboratory Chief in area of interest,

Position	Eligibility	Annual Salary	Mechanism of Entry
G. Cooperative Education Program	Must be 16 years of age or older, enrolled in an accredited educational program, high school, undergraduate, graduate, or professional degree program and be in good academic standing (GPA at least 2.0). School must participate in the coop program. Must be enrolled in a field of study related to the assigned work with at least half-time academic course load. U.S. citizen or national (resident of American Samoa or Swains Island) or noncitizen lawfully admitted to the U.S. as a permanent resident who will be able to meet citizenship requirements prior to conversion, and is a national of a country allied with the U.S.	GS-1 through GS-11	Contact NCI Personal Office, EPS, Room 537, 6120 Executive Blvd., Rockville, MD 20892-7209.
VIII. Other Training Programs  A. Cancer Prevention Fellowship Program	Must be an M.D., D.D.S., D.O., O.R., Ph.D., or other doctoral degree in a related discipline (epidemiology, biostatistics, and the biomedical, nutritional, public health, or behavioral sciences). Must be a U.S. citizen or resident alien eligible for citizenship within four years.	First year for an M.D., D.D.S., or D.O. \$30,000 - \$41,000 for Ph.D. \$22,000 - \$35,000.	Apply to Program Director, CPFP, Executive Plaza South, Room T41, MSC 7105, 6120 Executive Blvd., Rockville, MD 20892-7209. Bethesda, Maryland, 20892.

Position	Eligibility	Annual Salary	Mechanism of Entry
B. Biotechnology Training Program	Physicians with little or no experience or training in fundamental research, but with an interest in biotechnology including its application to prevention	First year Ph.D. \$25,000 - \$38,000 Physicians \$37,000 - \$45,000	Contact Division Director or Laboratory Chief in area of interest.
	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 postdoctoral 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.	ψ-10,000	
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 work and clinical capability, a letter describing their interest in the program, and a Personal Qualification Statement, SF-171.	Stipends for the program will be \$2,600 per month.	Contact the Division of Cancer Treatment.

Position	Eligibility	Annual Salary	Mechanism of Entry
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. Applicants must be bona fide high school, college, graduate or medical school students be 16 years of age, have a cumulative GPA of 2.75 or above, 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 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. General Fellowship Program	M.D., Ph.D. or equivalent degrees as well as predoctoral 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 the duties assigned and candidate's education and/or experience.	Contact Division Director or Laboratory Chief in area of interest.

Position	Eligibility	Annual Salary	Mechanism of Entry
F. 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. and Ph.D. Mathematical Statisticians \$31,000 - \$42,000 for other Ph.D. \$23,000-\$36,000 for Master's level \$16,000 - \$20,000	Contact the Administrative Office of the Division of Cancer Etiology.
G. Intramural Research Training Award (IRTA)	(1) Postdoctoral: Appointments of 1 or 2 years with a maximum of 5 years to candidates with physician or other doctoral degree in the biomedical, behavioral or related sciences and 7 or fewer years of relevant postdoctoral research	First year salaries range from \$25,000 - \$38,000 based on years of experience.	Contact Division Director or Laboratory Chief in area of interest.
	experience.  (2) Predoctoral: Fellowships are granted to students enrolled in PhD, MD, DDS, DMD, DVM, or equivalent degree programs. Students will have completed their graduate course work and will engage full-time in a laboratory research program for the purpose of developing and writing a thesis in an intramural laboratory.	Based on years of post-baccalaureate education ranging from \$16,000 - \$21,000.	Contact Division Director or Laboratory Chief in area of interest.

Position	Eligibility	Annual Salary	Mechanism of Entry
H. Technology Transfer Fellowship Program	Physicians, PhDs, JDs(lawyers), individuals with a master's degree in health communications, biomedical science, behavioral science, computer science, informatics, library science, health education, marketing, journalism, English, a graduate degree in law, or a graduate degree in another discipline with legal/paralegal expertise, with little or no experience or training in technology transfer or communications research but with an interest in these areas.	Based on years of (1) postdoctoral experience starting at \$25,000 - \$38,000 or (2) post-Master's degree starting at \$22,000 - \$34,000.	Contact following program in area of interest: International Cancer Information Center, the Office of Cancer Communications, the Division of Cancer Prevention and Control, the Office of Technology Development, or the Planning, Evaluation, and Analysis Branch.

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

All	Ages	Und	er 15	15	-34	35	-54	55	5-74		75+
Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Lung	Lung	Leukemia	Leukemia	Leukemia	Breast	Lung	Breast	Lung	Lung	Lung	Lung
91,600	52,020	350	260	661	660	8,726	9,188	55,836	30,126	26,881	16,387
Prostate	Breast	Brain & CNS	Brain & CNS	Non- Hodgkin's Lymphoma	Leukemia	Colon & Rectum	Lung	Colon & Rectum	Breast	Prostate	Colon & Rectum
33,563	43,582	252	220	497	433	2,342	5,367	13,823	19,900	20,909	15,634
Colon & Rectum	Colon & Rectum	Endocrine	Endocrine	Brain & CNS	Brain & CNS	Non- Hodgkin's Lymphoma	Colon & Rectum	Prostate	Colon & Rectum	Colon & Rectum	Breast
28,025	28,751	112	70	414	328	1,716	1,959	12,306	10,988	11,657	13,834
Pancreas	Pancreas	Non- Hodgkin's Lymphoma	Soft Tissue	Melanoma	Cervix	Brain & CNS	Ovary	Pancreas	Ovary	Pancreas	Pancreas
12,373	13,161	63	33	240	307	1,577	1,750	6,730	6,605	4,299	6,637
Leukemia	Ovary	Soft Tissue	Bone	Hodgkin's	Non- Hodgkin's Lymphoma	Pancreas	Cervix	Esophagus	Pancreas	Leukemia	Ovary
10,286	13,028	48	28	233	209	1,298	1,533	4,600	5,669	3,734	4,527

Source: Mortality tape (1991) from National Center for Health Statistics.

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

		Number	Crude Death	Percent
		of	Rate per	of
Rank	Cause	Deaths	100,000	Total
			Population	Deaths
	All Causes	2,168,492	860.2	100.0%
1	Diseases of the Heart	720,755	285.9	33.2
2	CANCER	514,636	204.1	23.7
3	Cerebrovascular	143,467	56.9	6.6
4	Bronchitis, Emphysema & Asthma	90,640	35.9	4.2
5	Accidents	89,227	35.4	4.1
6	Pneumonia & Influenza	77,846	30.9	3.6
7	Diabetes Mellitus	48,949	19.4	2.3
8	Suicide	30,790	12.2	1.4
9	Human Immunodeficiency Virus Infection	29,545	11.7	1.4
10	Homicide	26,432	10.5	1.2
11	Cirrhosis of the Liver	25,411	10.1	1.2
12	Nephritis & Nephrosis	21,358	8.5	1.0
13	Septicemia	19,688	7.8	0.9
14	Atherosclerosis	17,419	6.9	0.8
15	Diseases of Infancy	16,781	6.7	0.8
	Other & III-defined	295,998	117.4	13.6

## Estimated New Cancer Cases and Deaths by Sex for All Sites 1994

	Estin	nated New Ca	ises	Es	timated Death	ns
	Total	Male	Female	Total	Male	Female
All Sites	1,208,000	632,000	576,000	538,000	283,000	255,000
Oral Cavity & Pharynx	29,600	19,800	9,800	7,925	5,150	2,775
Lip	3,300	2,800	500	75	50	25
Tongue	6,000	3,800	2,200	1,750	1,100	650
Mouth	11,100	6,600	4,500	2,100	1,200	900
Pharynx	9,200	6,600	2,600	4,000	2,800	1,200
Digestive System	233,300	123,100	110,200	121,450	64,550	56,900
Esophagus	11,000	8,000	3,000	10,400	7,800	2,600
Stomach	24,000	15,000	9,000	14,000	8,400	5,600
Small Intestine	3,600	2,000	1,600	950	500	450
Colon	107,000	52,000	55,000	49,000	24,000	25,000
Rectum	42,000	23,000	19,000	7,000	3,800	3,200
Liver & Intrahepatic Bile Duct	16,100	8,800	7,300	13,200	7,200	6,000
Pancreas	27,000	13,000	14,000	25,900	12,400	13,500
Other & Digestive	2,600	1,300	1,300	1,000	450	550
Respiratory System	189,000	112,800	76,200	158,200	97,900	60,300
Larynx	12,500	9,800	2,700	3,800	3,000	800
Lung & Bronchus	172,000	100,000	72,000	153,000	94,000	59,000
Other & Unspecified Respiratory	4,500	3,000	1,500	1,400	900	500
Bones & Joints	2,000	1,100	900	1,075	600	475
Soft Tissues	6,000	3,300	2,700	3,300	1,600	1,700
Melanomas of Skin	32,000	17,000	15,000	6,900	4,300	2,600
Breast	183,000	1,000	182,000	46,300	300	46,000
Genital Organs	283,400	208,100	75,300	63,725	38,525	25,200
Cervix Uteri	15,000		15,000	4,600	·	4,600
Corpus and Uterus, NOS	31,000		31,000	5,900		5,900
Ovary	24,000		24,000	13,600		13,600
Other Female Genital	5,300		5,300	1,100	ŀ	1,100
Prostate	200,000	200,000		38,000	38,000	
Testis	6,800	6,800		325	325	
Other Male Genital	1,300	1,300		200	200	
Urinary System	78,800	55,000	23,800	21,900	13,800	8,100
Bladder	51,200	38,000	13,200	10,600	7,000	3,600
Kidney & Other Urinary	27,600	17,000	10,600	11,300	6,800	4,500
Eye and Orbit	1,750	950	800	250	125	125
Brain & Central Nervous System	17,500	9,600	7,900	12,600	6,800	5,800
Endocrine Glands	14,450	4,150	10,300	1,725	750	975
Thyroid	13,000	3,400	9,600	1,025	400	625
Other Endocrine	1,450	750	700	700	350	350
Leukemias	28,600	16,200	12,400	19,100	10,500	8,600
Lymphomas and Myelomas	65,600	35,900	29,700	32,550	17,100	15,450
Hodgkin's Disease	7,900	4,400	3,500	1,550	900	650
Non-Hodgkin's Lymphomas	45,000	25,000	20,000	21,200	11,200	10,000
Multiple Myeloma	12,700	6,500	6,200	9,800	5,000	4,800
All Other and Unspecified Sites	43,000	24,000	19,000	41,000	21,000	20,000

Boring CC, Squires T, Tong T, Montgomery S., Cancer Statistics 1994. CA Cancer J Clin 1994; 44:7-26. Excludes basal and squamous cell skin and in situ carcinomas except urinary bladder. Incidence estimates are based on rate from the NCI SEER Program 1988-90.

SOURCE:

# 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 follow:

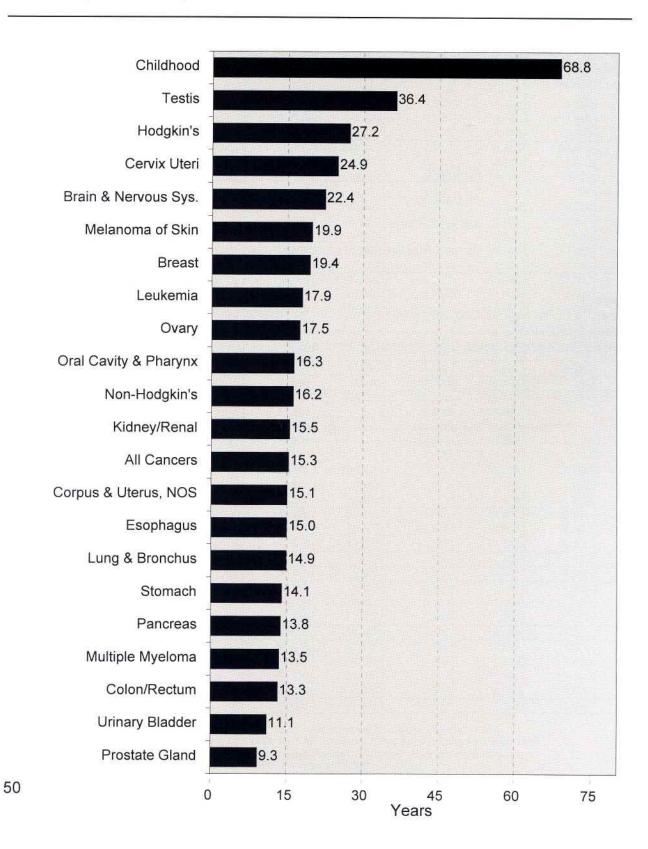
#### (in Millions)

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

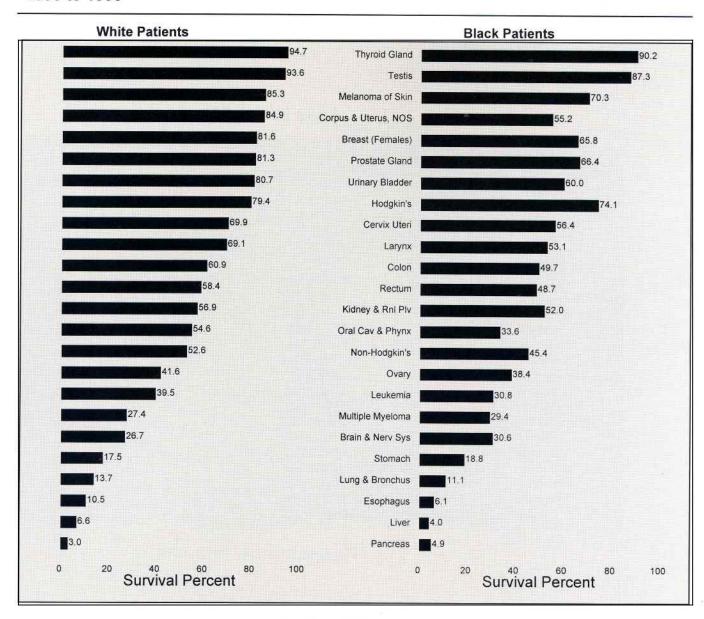
#### Sources:

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.

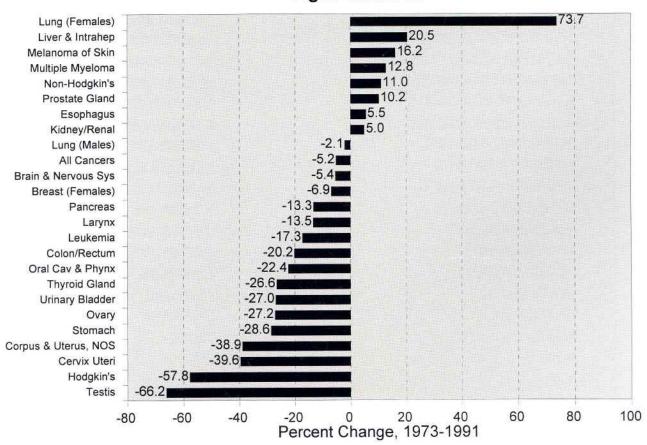


5 Year Relative Survival Rates, by Site White and Black Patients 1983 to 1990



Data From SEER Program 1984-1990 Males and Females

## Ages Under 65

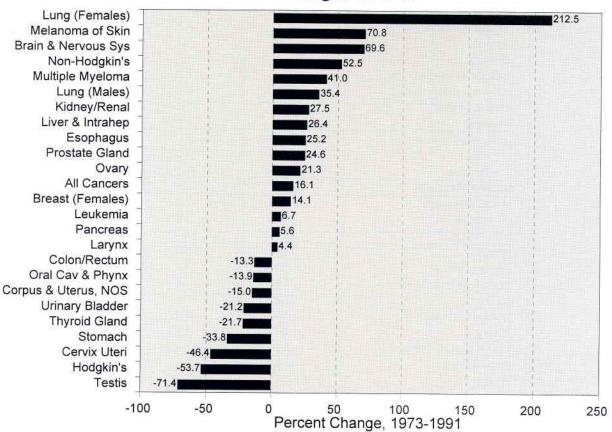


#### Note:

#### 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.

#### Ages Over 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, 1987-1991

	Mortality Rat	e per 100,000	Ratio
Cancer Site	Blacks	Whites	Blacks/Whites
All Sites	226.2	169.0	1.3
Males	316.8	213.3	1.5
Females	166.9	139.6	1.2
Esophagus	8.5	3.0	2.8
Cervix Uteri	6.7	2.6	2.6
Prostate	52.0	23.6	2.2
Multiple Myeloma	5.8	2.7	2.1
Larynx	2.8	1.2	2.3
Stomach	8.9	4.3	2.1
Oral Cavity and Pharynx	5.2	2.7	1.9
Corpus & Uterus NOS	6.0	3.2	1.9
Liver & Intrahep.	4.2	2.5	1.7
Pancreas	11.9	8.1	1.5
Lung and Bronchus	61.2	48.6	1.3
Males	105.5	73.0	1.4
Females	30.4	30.9	1.0
Colon and Rectum	23.5	18.8	1.3
Breast (Females)	31.2	27.2	1.1
<50 years	9.2	5.9	1.6
> 50 years	99.1	93.1	1.1
Thyroid	0.4	0.3	1.3
Urinary Bladder	3.3	3.3	1.0
Kidney & Renal Pelvis	3.3	3.5	0.9
Leukemia	6.0	6.4	0.9
Hodgkin's Disease	0.6	0.6	1.0
Ovary	6.5	8.0	0.8
Non-Hodgkin's Lymphomas	4.3	6.4	0.7
Brain & CNS	2.6	4.5	0.6
Testis	0.1	0.3	0.3
Melanoma of Skin	0.4	2.5	0.2
All Sites Except Lung & Bronchus	165.0	120.4	1.4
Males	211.3	140.3	1.5
Females	136.5	108.8	1.3

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

## Cancer Incidence Rates Unites States, 1987-1991

	Incidence Rat	es per 100,000	Ratio
Cancer Site	Blacks	Whites	Blacks/Whites
All Sites	422.1	392.0	1.1
Males	557.2	464.0	1.2
Females	331.8	348.0	1.0
Esophagus	10.0	3.4	2.9
Multiple Myeloma	9.1	4.1	2.2
Cervix	14.0	7.8	1.8
Stomach	12.7	6.7	1.9
Liver & Intrahep.	4.7	2.4	2.0
Pancreas	13.8	8.6	1.6
Larynx	7.1	4.4	1.6
Prostate	163.1	121.2	1.3
Lung and Bronchus	77.2	57.9	1.3
Males	122.4	80.7	1.5
Females	44.5	41.3	1.1
Oral Cavity and Pharynx	14.0	10.5	1.3
Kidney and Renal Pelvis	9.5	8.8	1.1
Colon and Rectum	52.4	47.8	1.1
Colon	40.6	34.0	1.2
Rectum	11.9	13.8	0.9
Leukemia	8.9	10.2	0.9
Breast (Females)	94.0	113.2	0.8
<50 years	33.0	33.2	1.0
>50 years	281.9	359.8	0.8
Ovary	10.3	15.6	0.7
Non-Hodgkin's Lymphomas	10.2	15.0	0.7
Brain and Other Nervous	3.9	6.7	0.6
Corpus & Uterus NOS	14.5	22.2	0.7
Hodgkin's Disease	2.1	3.1	0.7
Thyroid	2.5	4.5	0.6
Bladder	9.7	18.2	0.5
Testis	0.8	5.1	0.2
Melanoma of Skin	0.9	12.4	0.1
All Sites Except Lung & Bronchus	344.9	334.0	1.0
Males	434.8	383.3	1.1
Females	287.2	306.7	0.9

NOTE: The annual number of new cancer cases per 100,000 persons is 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, 1994

	1994 E	stimated Prev	alence
	Total	Males	Females
ALL SITES	7,184,000	2,808,500	4,375,500
Oral & Pharynx	194,100	120,300	73,800
Stomach	68,600	39,400	29,200
Colon/Rectal	1,227,800	577,300	650,500
Colon	885,600	403,300	482,300
Rectum	342,200	174,000	168,200
Pancreas	24,200	10,400	13,800
Larynx	135,600	108,600	27,000
Lung & Bronchus	380,900	211,800	169,100
Melanoma of Skin	389,800	184,700	205,100
Breast	1,721,700	-	1,721,700
Cervix Uteri	183,900	-	183,900
Corpus & Uterus	486,000	-	486,000
Ovary	170,500	-	170,500
Prostate Gland	565,600	565,600	
Testis	109,400	109,400	-
Urinary Bladder	541,200	385,000	156,200
Kidney & Renal Pelvis	158,700	97,700	61,000
Brain and Nervous System	81,600	42,100	39,500
Thyroid	181,300	43,900	137,400
Hodgkin's Disease	136,300	72,800	63,500
Non-Hodgkin's Lymphomas	260,300	129,300	131,000
Leukemia	125,000	65,200	59,800

NOTE: Previous published prevalence national estimates of cancer have been revised using age-specific cancer rates. There has been no decline in prevalence-the number of cancer survivors has increased during recent years.

## Fiscal Year 1994 Budget

(Dollars in Thousands)

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

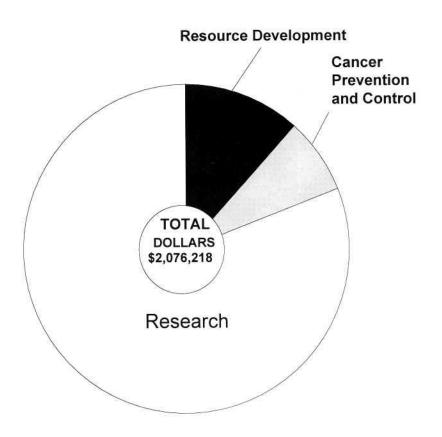
FY 1994 Appropriation	\$2,082,267
Rescission in accordance with P.L. 103-211	-5,885
Lapse	-164
Actual Subtotal	2,076,218
Comparative transfer to the	
Office of AIDS Research, NIH	
for HIV Activities	-212,868
Actual NCI Obligations	1,863,350

#### B. Reimbursable Obligations:

Reimbursements	10.856
Other Reimbursements	8,883
AIDS Reimbursement from Office of the Director, NIH	1,973

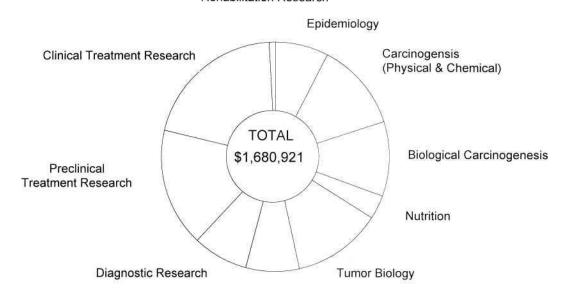
#### C. Total NCI Obligations

\$1,874,206



Budget Activity	Dollars	Percent
Research		
Cancer Causation	\$584,895	28.2%
Detection and Diagnosis Research	143,059	6.9%
Treatment Research	641,773	30.9%
Cancer Biology	311,194	15.0%
Subtotal Research	1,680,921	81.0%
Resource Development		
Cancer Centers Support	160,534	7.7%
Research Manpower Development	64,086	3.1%
Construction	16,822	0.8%
Subtotal Resource Development	241,442	11.6%
Cancer Prevention and Control	153,855	7.4%
Total NCI	\$2,076,218	100.0%

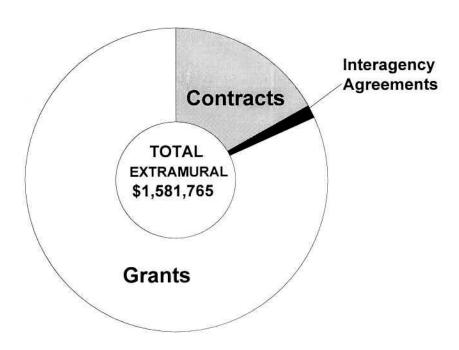
#### Rehabilitation Research



111	1111	uH	UI	ogy

Dollars	Percent of Total
\$1,680,921	81.0%
160,534	7.7%
64,086	3.1%
16,822	0.8%
153,855	7.4%
\$2,076,218	100.0%
	\$1,680,921 160,534 64,086 16,822 153,855

December Burdent Autility	D-II	Percent
Research Budget Activity	Dollars	of Total
Epidemiology	\$126,298	7.5%
Carcinogenesis (Physical & Chemical)	210,791	12.5%
Biological Carcinogenesis	176,382	10.5%
Nutrition	56,741	3.4%
Tumor Biology	211,824	12.6%
Immunology	127,247	7.6%
Diagnostic Research	131,969	7.9%
Preclinical Treatment Research	281,112	16.7%
Clinical Treatment Research	343,229	20.4%
Rehabilitation Research	15,328	0.9%
Total	\$1,680,921	100.0%



	Dollars	Percent	
Contracts:			
SBIR Contracts	\$1,154	0.1%	
Research Support Contracts	182,902	11.6%	
Cancer Control Contracts	84,392	5.3%	
Construction Contracts	0	0.0%	
Subtotal Contracts	\$268,448	17.0%	
Interagency Agreements	21,135	1.3%	
Grants:			
Research Project Grants	934,524 158,318	59.1%	
Cancer Centers/SPORES		10.0%	
Training Activities	37,463	2.4%	
Other Research Grants	107,476	6.8%	
Cancer Control Grants	37,902	2.4%	
Construction Grants	16,499	1.0%	
Subtotal Grants	1,292,182	81.7%	
Total Extramural Funds	1,581,765	100.0%	
Total Intramural/RMS/Control	494,453		
Total NCI	\$2,076,218		

			_	Percent
		Number	Amount	of Total
Research Grants:				
Research Project Grants:	A			
Traditional	Awards:	1,914	\$434,612	20.9%
Program Projects		163	184,852	8.9%
FIRST Awards		312	32,610	1.6%
MERIT Awards		154	48,699	2.3%
Outstanding Investigator Grants		72	61,369	3.0%
RFAs		319	70,879	3.4%
Cooperative Agreements		232	75,444	3.6%
Shannon Awards		9	540	0.0%
Small Grants		46	2,393	0.1%
Exploratory/Developmental Grants		5	353	0.0%
SBIR Grants		179	22,773	1.1%
Subtotal, Research Project Grants		3,405	934,524	45.0%
Cancer Centers Grants		54	126 260	6.60/
SPOREs		9	136,269	6.6%
Subtotal, Centers		63	22,049 158,318	1.1% 7.6%
Cubicital, Collinois		90]	100,010	7.070
Other Research Grants:				
Career Program				
RCDA-KO4		19	1,235	0.1%
Clinical Oncology-K12		17	2,398	0.1%
Physician Investigator-K11		50	4,110	0.2%
Preventive Oncology-K07		23	1,884	0.1%
Clinical Investigator-KO8		54	4,186	0.2%
Minority Faculty Development-K14		24	486	0.0%
Subtotal, Career Program		187	14,299	0.7%
Cancer Education Program		74	0.402	0.407
			8,183	0.4%
Clinical Cooperative Groups		154	76,398	3.7%
Minority Biomedical Support		2	3,070	0.1%
Scientific Evaluation			4,197	0.2%
Instrumentation Grants		39	742	0.0%
Continuing Education Grants			171	0.0%
Conference Grants		47	416	0.0%
Subtotal, Other Research Grants		503	107,476	5.2%
Subtotal, Research Grants		3,971	1,200,318	57.8%
IRSA Fellowships	Trainees:	1,463	37,464	1.8%
Research and Development Contracts:				
R&D Contracts	Awards:	260	204,037	9.8%
SBIR Contracts	rwai us.	7	1	0.1%
Subtotal, Contracts		267	1,154 205,191	9.9%
dational, dollination		20,	200,101	5.570
ntramural Research:				
Intramural Research	FTEs:	1,697	251,850	12.1%
Management Fund		4.007	122,874	5.9%
Subtotal, Intramural Research		1,697	374,724	18.0%
esearch Management & Support:				
Research Management & Support	FTEs:	516	84,310	4.1%
Management Fund			12,112	0.6%
Subtotal, RMS		516	96,422	4.6%
ancer Prevention and Control:				
Cancer Control Grants			37,902	1.8%
Cancer Control Contracts				4.1%
	ETE.	400	84,392	
Inhouse	FTEs:	169	21,568	1.0%
Management Fund			1,738	0.1%
Subtotal, Prevention and Control		169	145,600	7.0%
onstruction		5	16,499	0.8%

# Division Obligations

## by Mechanism

## Fiscal Year 1994

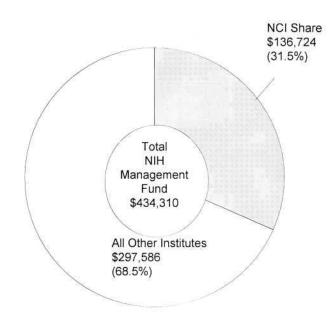
(Dollars in Thousands)

						1		Research	Program	TOTAL
	DCBDC	DCT	DCE	DCPC	DEA	FCRDC	OD	Grants	Support(1)	NCI
Research Grants:										
Research Project Grants								\$911,751	,	\$911,751
SBIR Grants								22,773		22,773
Subtotal, Research Project Grants								934,524		934,524
Cancer Centers Grants	\$136,269	Ì		.		Į į				136,269
SPOREs	21,972				\$77					22,049
Subtotal, Centers	158,241	!			77					158,318
Other Research Grants:										
Career Program	13,813				486					14,299
Cancer Education Program	8,183	ł				1 1			1	8,183
Clinical Cooperative Groups	· ·	\$76,398						1		76,398
Minority Biomedical Support					3,070					3,070
Scientific Evaluation					4,197	( )			ĺ	4,197
Instrumentation Grants			ï					742		742
Continuing Ed. Train. Grants	ļ					ļ		171	<b>,</b>	171
Conference Grants						i		416		416
Subtotal, Other Research Grants	21,996	76,398			7,753			1,329		107,476
Subtotal, Research Grants	180,237	76,398			7,830			935,853		1,200,318
NRSA Fellowships	37,336				128					37,464
Research and Development										!
•								ļ ;		
Contracts: R&D Contracts	7,430	59,306	\$38,013	\$14,724	1,403	\$55,887	\$17,128	ļ	\$10,146	204,037
SBIR Contracts	7,430	39,300	\$30,013	Ψ14,724	1,400	Ψ55,007	1,154	ļ	\$10,140	1,154
Subtotal, Contracts	7,430	59,306	38,013	14,724	1,403	55,887	18,282	<del></del>	10,146	205,191
Suptotal, Contracts	7,400	50,000	30,010	11,72-1	1,100	35,551	10,202		,,,,,	
Intramural Research:										
Intramural Research	64,954	95,307	67,372	2,998	169	11,880	6,013		3,157	251,850
Management Fund				<u></u>					122,874	122,874
Subtotal, Intramural Research	64,954	95,307	67,372	2,998	169	11,880	6,013		126,031	374,724
Research Management & Support:									•	
Research Management & Suppt.	1,969				7,909	3,000	47,094		24,338	84,310
Management Fund	· [							ĺ	12,112	12,112
Subtotal, RMS	1,969				7,909	3,000	47,094		36,450	96,422
Cancer Prevention and Control:			,				1			
Cancer Control Grants				37,902						37,902
Cancer Control Contracts				84,392	i			}		84,392
Inhouse				21,568						21,568
				21,500					1,738	1,738
Management Fund				143,862					1,738	145,600
Total Prevention & Control				140,002					.,,,,,	
Construction	15,447					928			124	16,499
Division Totals	\$307,373	\$231,011	\$105,385	\$161,584	\$17,439	\$71,695	\$71,389	\$935,853	\$174,489	\$2,076,218
										l

<sup>(1)</sup> Includes Central Assessments for DHHS-NIH General Expense, Management Fund, and Program Evaluation

## NIH Management Fund Reimbursement Fiscal Year 1994

(Dollars in Thousands)



DISTRIBUTION OF NCI PAYMENT		
	Dollars	Percent
Clinical Center	\$89,790	65.7%
Division of Research Grants	4,725	3.5%
Division of Computer Research and Technology	6,899	5.0%
GSA Rental Payments for Space	5,693	4.2%
Other Research Services	29,617	21.7%
Total, NCI Payment	\$136,724	100.0%

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

Clinical Center: Admissions and followup, anesthesiology, diagnostic x-ray, nuclear medicine, clinical pathology, blood bank, rehabilitation medicine, pharmacy, medical records, nursing services, patient nutrition service, housekeeping services, laundry, and social work

Division of Research Grants: initial scientific review of applications, assignment of research grant applications to institutes

Division of Computer Research and Technology: Research and development program in which concepts and methods of computer science are applied to biomedical problems

GSA Rental Payments for Space: building rental including utilities and guard services

Other Research Services: procurement, safety, engineering, biomedical engineering, veterinary resources, and library

# Special Sources of Funds

#### **CRADAs**

As a result of the Federal Technology Transfer Act of 1986, government laboratories are 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.

## **CRADA Receipts Deposited to the U.S. Treasury**

(dollars in thousands)

Carry	over/
from	<b>Prior</b>

	Year	Receipts	Obligations
1990	\$ 116	\$ 61	\$125
1991	52	115	66
1992	101	1,627	466
1993	1,262	2,509	1,582
1994	2,189	2,248	1,917
1995	2,520		

#### Royalty Income

NCI retains a portion of the 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. Receipts are also used to support the costs of processing and collecting royalty income. Support is also provided to cover expenses associated with technology transfer efforts in NCI and NIH.

## **Royalty Income Funding History**

(dollars in thousands)

Years Available	Collections*	Inventor Payments	Other**
1989/1990	\$ 813	\$ 575	\$ 238
1990/1991	1,452	871	581
1991/1992	2,084	431	1,653
1992/1993	2,105	451	1,654
1993/1994	5,700	983	4,717
1994/1995	11,244	1,235	10,009

<sup>\*</sup> Does not include assessments by NIH and NTIS.

<sup>\*\*</sup> To be used for the furtherance of technology transfer

## Acquired Immunodeficiency Syndrome (AIDS) Key Discoveries

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. The large scale preparation of HIV-1 in permanent cell lines led to the development of a serological test for AIDS which enabled the detection of AIDS in our nation's blood supply. Detection of the virus in latent form has been established through the *in situ* hybridization method which allowed scientists to detect the virus in brain and blood cells, T lymphocytes and macrophages. Selected recent key discoveries, by NCI investigators include:

- Development, testing and successful clinical trials of the drugs azidothymidine (AZT), dideoxyinosine (ddl) and dideoxycytidine (ddC), confirming their effectiveness as anti-retroviral agents against AIDS.
- 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 (ddl) in October 1991. The latter, based solely on Pediatric Branch Studies, occurred simultaneously with licensure for adults, a historical event. The Pediatric Branch is currently completing studies of combination regimens to optimize activity (e.g., AZT plus ddl) as well as to offset toxicity (e.g., AZT plus G-CSF and erythropoietin).
- Viral particles are detectable in plasma throughout the early stages of primary infection. The number of viral particles in plasma decrease by up to 200-fold following the initial viremia of primary infection, but increases again as the infection moves from the asymptomatic phase in AIDS-related complex (ARC) to full blown AIDS. The increase in viral particles bears an inverse relationship to CD4 count. Scientists at NCI and elsewhere have adapted Polymerase Chain Reaction (PCR) technology to detect and quantitate the amount of HIV-1 RNA present in plasma. A new adaptation of PCR technology, designated "immuno-PCR", is capable of detecting minute amounts of HIV regulatory proteins (e.g. Tat, Rev) in solution or in tissue. "Immuno-PCR" can be applied to the *in situ* analysis of certain clinical specimens, such as lymph node. Thus, PCR technologies provide the opportunity to correlate HIV protein expression with virulence and pathogenicity in both the laboratory and clinical settings, and may serve as sensitive markers by which to measure response to therapy.
- The ability to provide effective long-term anti-retroviral therapy using single agents for HIV infection is complicated by the emergence of drug-resistant HIV strains. Longitudinal studies of the phenotypic and genotypic changes of HIV strains isolated before and after prolonged therapy with either an alternating regimen of AZT and ddC or ddl alone demonstrate that HIV develops reduced susceptibility to AZT more readily than to ddC and with ddl. A new acyclic purine analog, PMEA, inhibits both HIV RT and DNA polymerase-alpha from CMV and other herpes viruses and may inhibit latent as well as replicating HIV, with perhaps a special activity against the HIV reservoir in monocytes/macrophages. NCI scientists began the Phase I clinical testing of PMEA in combination with AZT in January 1994, in conjunction with assessment of intrinsic or induced HIV resistance to PMEA.
- A recent clinical trial by NCI investigators suggests that the simultaneous administration of AZT and ddl results in higher and more sustained elevations of CD4+ cells over a one year period than alternating drug administration. This difference in clinical activity may relate to differential intracellular drug activation. AZT is preferentially phosphorylated to the active triphosphate form (AZT-TP) in proliferating cells. In contrast, the phosphorylation of ddl (to ddATP) and ddC (to ddC-TP) occurs preferentially in resting cells. Thus, the data suggest that AZT, ddC and ddl may exert their antiviral

effects depending on the activation state of the target cells; i.e., ddl and ddC likely exert antiviral activity against resting cells, while AZT protects actively growing cells against HIV infection. The combination of AZT+ddl may target both latent and actively replicating pools of virus, providing complementary and possibly synergistic anti-HIV activity.

- 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's AIDS Drug Screen has recently uncovered an active compound with an unprecedented mechanism of action, namely the disruption of the highly conserved zinc finger regions of the HIV nucleocapsid protein, p7. The nucleocapsid protein is necessary for the incorporation of the viral RNA genome into intact viral particles and the ultimate packaging of the infectious virions. The ability to block viral reproduction and dissemination by inhibiting the structural and functional integrity of p7 will serve two critical goals: a heightened molecular understanding of the late stages of the viral life cycle, and a template for rational drug design based upon the protein sequence and structure.
- The HIV-1 enzyme reverse transcriptase (RT) is the target for inhibition by many of the currently available anti-retroviral agents, in particular the nucleosides (AZT, ddl, ddC, d4T). Unfortunately, RT is able to undergo mutations that confer resistance to the inhibitory effects of these drugs. Scientists at NCI's Frederick Cancer Research and Development Center have both structural and biochemical data to suggest that the Leu74Val mutation, which causes resistance to ddl, affects the interaction between RT and its nucleic acid substrate. In addition, these scientists continue to define the structure of HIV-1 RT and the complexes formed between RT and its nucleic acid substrates.
- Integration of RT-transcribed HIV DNA into the host genome is facilitated by HIV integrase, an
  enzyme encoded by the HIV <u>pol</u> gene. NCI scientists have devised rapid fluorescent assays that
  identify both the DNA cleavage reaction and the subsequent integration process in response to
  purified HIV integrase. The ability to quantitate integrase activity by measuring cleavage-induced
  changes in fluorescence will also identify agents that block integrase action and thus present a novel
  molecular target for therapy.
- Determination of the first crystal structure of retroviral protease and its successful use to predict the structure of the HIV protease and substrate using supercomputer methodology. HIV protease is an enzyme whose action is required in the processing of HIV proteins and production of infectious virions. NCI scientists have identified several inhibitors of the HIV protease including KNI-272 which has exhibited potent anti-HIV activity and favorable pharmacokinetics in test animals. In March 1994 NCI scientists began Phase 1 clinical trials of KNI-272.
- Individuals infected with HIV may be asymptomatic for years before progressing to overt AIDS. Since monocytes possess surface CD4 molecules, they can bind and act as a reservoir for HIV in infected individuals. 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. In addition to monocytes, NIAID scientists determined that follicular dendritic cells (FDC) also serve as reservoirs for latent HIV infection, sequestering HIV for eventual transmission to CD4+ cells.
- IL-12, produced by macrophages and B cells in response to diverse infectious pathogens, is a natural killer (NK) cell stimulatory factor which activates NK cells in vitro and appears to have a significant antitumor effect in tumor-bearing animals. IL-12 drives the differentiation of naive CD4+ T cells into T<sub>H</sub>1 cells, thereby promoting cell-mediated immunity. IL-12 may have a special role as an immunostimulant in HIV infection, where both NK cell and T<sub>H</sub>1 cell functions are defective. IL-12 may also be able to restore the HIV-related imbalance between T<sub>H</sub>1 and T<sub>H</sub>2 cells which, in turn, leads to defects in cellular immunity and excessive humoral (antibody) responses.

- The magnitude of CNS disease is often more prominent and the latency period which precedes HIV-related encephalopathy shorter in children than in adults, suggesting that fetal or developing brain cells (in particular, glial cells) may release cytokines capable of activating expression of latent HIV. To address the pathogenesis of neurologic disorders in HIV-1 infected children, NCI scientists have developed an *in vitro* model using a normal fetal olfactory neuroblast cell line, to investigate the potential contributions of direct viral infection and virally-induced cytokines in glial (and perhaps other accessory) cells to neurodevelopmental impairment.
- NCI epidemiologists have played a major role in uncovering the emergence of a new peak of tuberculosis (TB)-associated death in young individuals (ages 20-49) that appears linked to AIDS.
- Recent studies of vaginally-delivered multiple birth cohorts in HIV-infected women demonstrate that HIV transmission is greatest for the first-born infant, suggesting that some component of HIV transmission occurs at the time of the delivery in the cervix or vagina.
- Indeed, about 60 percent of mother-to-infant HIV transmission occurs at the time of birth. On this basis, scientists are designing a clinical trial of inexpensive viricidal solution to cleanse the birth canal to lower the risk of HIV transmission in this setting.
- NCI has established a multi-state AIDS/cancer match registry linking AIDS and cancer registries in five areas of NCI's Surveillance, Epidemiology and End Results (SEER) program (San Francisco, Los Angeles, Atlanta, Detroit and Connecticut) and 10 other sites (New York City and state, New Jersey, Puerto Rico, San Diego, Sacramento, Florida, Illinois, Colorado and Massachusetts). The Registry encompasses about 75 percent of all reported AIDS cases and involves approximately 85,000 matches of individuals with AIDS to cancer registries. This very large data base allows for the first time quantitative estimates of rare as well as common malignancies and provides a framework for determining the role of HIV as a cofactor in the development of diverse malignancies. The registry will also serve to identify patients with concomitant AIDS and cancer from whom tumor tissue and other biologic specimens can be obtained for molecular epidemiologic studies.
- NCI scientists have developed prototype synthetic vaccines consisting of broadly-recognized
  histocompatibility determinants of T helper cells (so-called "cluster peptides") and a combined site
  constructed to elicit both cytotoxic T lymphocytes (CTL) and neutralizing antibody. Clinical trials of
  these constructs are now being launched.
- NCI scientist have constructed novel vaccines comprised of various recombinant and live vectors carrying HIV-1, HIV-2 and SIV antigenic proteins or protein units. These constructs are now being tested in rhesus macaques for their efficacy as initial immunogens, followed by "boosters" using purified native or viral antigens, in eliciting protective immune responses. Recombinant constructs coupling vaccinia virus (poxvirus) vectors to various HIV antigens induce virus-specific cellular and humoral responses in primates. Vaccine constructs coupling adenovirus with HIV-1 MN or IIIB env genes have been shown to elicit both T cell and neutralizing antibody responses, and will be examined in chimpanzees for their protective effects against viral challenge. Finally, influenza recombinants, designed such that the V3 loop is located within a region of the hemagglutinin molecule that is conformationally accessible to antibodies, are being developed as a booster immunogen.
- NCI investigators have put the poly Tat activation region (TAR) which binds to the viral regulatory protein, Tat, into the HIV promoter, thereby inhibiting viral replication. Since binding of Tat to TAR is necessary for RNA expression and viral replication, the polymeric TAR (poly TAR) provides a molecular decoy which inhibits viral replication. Cultures containing the protected cells show a gradual decline in virus production that reaches 90 percent in two months. Six months after infection the protected cell cultures express little detectable virus and are resistant to reinfection. Poly TAR

appears to be an effective antiviral gene that may have eventual clinical application as a gene therapy modality.

- NCI investigators have detected large numbers of KS-like spindle cells in cultures of circulating peripheral blood of HIV+ patients with active KS or at high risk for development of KS. These cells have spindle-shaped morphology and immunophenotypic characteristics of activated endothelial cells, and produce angiogenic factors. The numbers of peripheral blood spindle cells from HIV+ patients with active KS and from those at high risk are increased 78-fold and 18-fold, respectively, over the numbers detectable in HIV- or HIV+ low-risk individuals. The ability to detect such cells may predict susceptibility to develop KS and could serve to monitor the impact of therapeutic and prevention interventions.
- NCI scientists have developed spindle cell strains that provide models of KS for the exploration of new therapeutic approaches. Most recently, a unique KS patient-derived cell line exhibits unlimited cellular life span in vitro and aggressive, metastatic behavior in vivo in immunosuppressed mice, with formation of highly vascularized tumor nodules. This model mimics KS progression in the human setting and thus may provide an excellent model for dissection of KS pathophysiology and development of targeted antitumor modalities.
- Multiple cytokines (growth factors) with inflammatory, growth-promoting and immunostimulating activities make pivotal contributions to the molecular pathogenesis and clinical phenotype of AIDS-KS. The HIV Tat protein, in particular the biologically active form that is released extracellularly, augments both viral and host gene expression. Basic fibroblast growth factor (b-FGF), an inflammatory cytokine produced by AIDS-KS cells as well as stromal cells, promotes new blood vessel formation (angiogenesis) and wound healing. It has now been shown that b-FGF and Tat interact synergistically to induce proliferation of normal vascular cells and produce KS-like angiogenic lesions in mice *in vivo*. This cooperation is magnified in the HIV+ setting, where b-FGF, extracellular Tat and Tat receptors are present to drive the emergence and aggressive progression of KS.
- A glycoprotein growth factor known as Oncostatin M, derived from activated T-cells, is a potent growth stimulator for AIDS-KS cells. This growth factor is distinct from other important cytokines in AIDS-KS, namely IL-6 and the HIV Tat protein, but binds to the active subunit of the IL-6 receptor. Oncostatin M appears to cause AIDS-KS cell proliferation both directly and in part by enhancing the expression of IL-6 by vascular endothelial cells, and further induces morphologic changes in AIDS-KS cells, namely to the spindle configuration of smooth muscle cells.
- NCI scientists have found a non-cytotoxic bacterial product, a sulfated polysaccharide-peptidoglycan compound (SP-PG) which inhibits the growth and vascular responses, in particular the induction of angiogenesis and hyperpermeability, of AIDS-KS spindle cells in vitro and in a nude mouse model.
- The striking production of autostimulatory and angiogenic growth factors by KS cells suggest that these factors should be an important target for therapy. Phase I clinical trials of angiogenesis inhibitors are underway.
- NCI scientists are investigating the antitumor effects of the cytotoxic natural product taxol, a unique tubulin-binding agent, in AIDS-related Kaposi's sarcoma (KS). Of 17 patients treated to date, 50 percent have achieved objective partial responses with roughly 50 percent decreases in number, size and/or nodularity of KS lesions and an additional 40 percent have had stabilization of disease.
- Profound cellular immunodeficiency plays a central role in lymphomagenesis. NCI investigators have found that the most important risk factor determinant for both the AZT- and ddl-treated cohort/s is a CD4 count below the critical level of 50/mm<sup>3</sup>. In addition, elevated serum levels of IL-6 predict a high risk for NHL development.

- The remarkable occurrence of high-grade B-cell, non-Hodgkin's lymphomas (NHL) has recently emerged as a major sequela of HIV infection, especially in patients who survive other consequences of AIDS in a protracted state of profound immunosuppression. NHLs develop in approximately 10 percent of AIDS patients treated with dideoxynucleosides. NCI investigators have developed a "lymphoma subpanel" comprised of two AIDS lymphoma cell lines including an EBV+ Burkitt's lymphoma, and eight non-AIDS lymphoma cell lines for screening potential therapeutic compounds.
- The severe combined immunodeficiency (SCID) mouse provides a unique model for the study of AIDS-related lymphoma biology and anti-lymphoma drug development. To date, about 500 agents have been examined for *in vitro* antitumor activity against an EBV+ Burkitt's lymphoma derived from an HIV-infected patient. This human tumor cell line has been established as a reproducible *in vivo* model within the SCID mouse. Approximately 18 agents have been evaluated in the *in vivo* model with 3 showing antitumor activity. Further, the CNS involvement of the SCID mouse with this lymphoma provides an opportunity to predict agents that have access to this frequently involved sanctuary in patients. The lymphoma subpanel is being expanded to establish and characterize new AIDS-related lymphoma cell lines, develop "mechanism of action" assays (e.g. IL-6 inhibition, induction of programmed cell death, antiviral effects targeting EBV or other viral cofactors) and define the differential drug sensitivity testing in the *in vivo* SCID model.

## Acquired Immunodeficiency

(Dollars in Thousands)

## Syndrome (AIDS)

## **Funding by Activity**

## Fiscal Year 1994

By Mechanism:	
Research Project Grants	\$27,747
Cancer Center Grants	3,637
Cooperative Clinical Groups	323
Conference Grants	7
Small Grants	0
R&D Contracts	68,803
Intramural Research	104,929
Research Management and Support	7,422
Total, NCI	\$212,868
By Research Thrust:	
Cancer Causation	\$73,737
Detection and Diagnosis Research	8,785
Treatment Research	100,281
Cancer Biology	26,428
Total Research	209,231
Cancer Center Grants	3,637
Total, NCI	\$212,868
By Division:	
Division of Cancer Biology, Diagnosis and Centers	\$28,772
Division of Cancer Treatment	74,573
Division of Cancer Etiology	46,652
Frederick Cancer Research and Development Center	27,880
Division of Extramural Activities	1,449
Office of the Director	5,451
NIH Management Fund*	28,091
Total, NCI	\$212,868

<sup>\*</sup>Supports common services shared within the NIH; in AIDS the Management Fund is used principally for support costs associated with NCI's activities at the NIH Clinical Center.

## Acquired Immunodeficiency Syndrome (AIDS) Funding History Fiscal Years 1983-1994

(Dollars in Thousands)

Fiscal Year	NCI Amount	NIH Amount	% NCI To NIH
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%
1992 (including ADAMHA)	165,668	1,047,294	16%
1993 (including ADAMHA)	173,029	1,073,957	16%
1994 (including ADAMHA)	212,868	1,298,996	16%

#### Note:

1983-1991 excludes Alcohol Drug Abuse and Mental Health Administration (ADAMHA), 1992-1994 includes ADAMHA

## Grant and Contract Awards by State Fiscal Year 1994

State	Gra	ants	Cont	tracts	Total NCI
	Number	Amount	Number	Amount	
Alabama	51	\$16,166	17	\$12,056	\$28,222
Alaska	4	802	1	64	866
Arizona	50	22,573	1	199	22,772
Arkansas	10	2,182			2,182
California	583	181,066	29	12,523	193,589
Colorado	70	23,192	6	3,059	26,251
Connecticut	71	19,935	4	2,332	22,267
Delaware	1	259			259
District of Columbia	71	22,984	9	2,150	25,134
Florida	61	14,057	6	1,643	15,700
Georgia	30	5,300	11	3,393	8,693
Hawaii	24	9,117	3	1,691	10,808
idaho		, i		'	,
Illinois	148	36,688	14	5,331	42,019
Indiana	26	6,605	5	1,280	7,885
lowa	22	3,498	4	2,998	6,496
Kansas	21	4,184	4	1,891	6,075
Kentucky	29	3,494	5	2,501	5,995
Louisiana	18	3,387	1	129	3,516
Maine	10	3,086	1	806	3,892
	168	52,911	109		
Maryland	441	140,099	15	112,320	165,231
Massachusetts				5,675	145,774
Michigan	168	36,795	12	8,545	45,340
Minnesota	95	30,633	7	3,488	34,121
Mississippi	5	507	^	4 700	507
Missouri	64	13,573	9	4,726	18,299
Montana	2	207			207
Nebraska	24	5,542			5,542
Nevada	5	631	4	00	631
New Hampshire	34	12,732	1	60	12,792
New Jersey	54	13,150	4	3,704	16,854
New Mexico	15	5,665	4	2,410	8,075
New York	470	153,035	23	11,348	164,383
North Carolina	177	52,335	16	10,224	62,559
North Dakota	6	728			728
Ohio	126	29,056	4	4,129	33,185
Oklahoma	11	1,514			1,514
Oregon	23	5,815	3	870	6,685
Pennsylvania	341	101,951	8	4,772	106,723
Rhode Island	34	8,927	1	844	9,771
South Carolina	18	3,229	1	948	4,177
South Dakota	3	490			490
Tennessee	89	24,242	4	1,524	25,766
Texas	300	86,150	14	5,497	91,647
Utah	33	9,635	5	1,363	10,998
Vermont	16	4,310	1	274	4,584
Virginia	58	19,494	15	37,769	57,263
Washington	171	64,377	9	5,396	69,773
West Virginia	9	1,595	3	1,736	3,331
Wisconsin	95	25,914	9	4,126	30,040
Wyoming		·		.	,
Total	4,355	1,283,817	398	285,794	1,569,611
Puerto Rico	1	303		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	303
US Virgin Islands	l i	101			101
Total	4,357	\$1,284,221	398	\$285,794	\$1,570,015

Country		ant	Cont		Total NCI	Percent of Total
	Number	Amount	Number	Amount	Awards	Dollars Awarded
Australia	7	\$747		i	\$747	6.4%
Belgium	2	438			438	3.7%
Canada	22	2,101	1	\$79	2,180	18.5%
China			4	704	704	6.0%
Costa Rica			1	238	238	2.0%
Denmark	2	337	2	433	771	6.6%
Finland	1	104	2	668	772	6.6%
France	2	504			504	4.3%
Ghana			1	68	68	0.6%
Israel	4	622			622	5.3%
Italy	2	583			583	5.0%
Jamaica			2	726	726	6.2%
Japan			1	66	66	0.6%
Netherlands	1	102			102	0.9%
New Zealand			2	760	760	6.5%
Republic of						
South Africa	1	61			61	0.5%
Sweden	5	951	2	357	1,308	11.1%
Switzerland	1	24			24	0.2%
Tanzania			1	20	20	0.2%
Trinidad			2	723	723	6.2%
United Kingdom	6	338			338	2.9%
Total Foreign	56	\$6,911	21	\$4,843	\$11,754	100.0%

(Dollars in Thousands)

## Institutions Receiving More than \$10,000,000 in NCI Support Fiscal Year 1994

State	Institution	Grants	Contracts	Construction	Total NCI
Alabama	University of Alabama System	\$11,126	\$4,420		\$15,546
	Southern Research Institute	3,880	7,636		11,516
Arizona	University of Arizona	18,262	199	\$1,570	20,031
California	University of California	76,198	1,874		78,072
	Stanford University	21,053			21,053
	University of Southern California	14,284	2,485	67	16,836
	Scripps Research Institute	10,650			10,650
Colorado	University of Colorado System	9,368	977		10,345
Connecticut	Yale University	18,982	879		19,861
District of Columbia	Georgetown University	12,767	717		13,484
Illinois	University of Chicago	12,654	105		12,759
	University of Illinois System	9,094	2,704		11,798
Maryland	Johns Hopkins University	37,773	1,236	1,570	40,579
	Organon Teknika Corporation		31,910		31,910
	Westat, Inc.		15,030		15,030
Massachusetts	Dana-Farber Cancer Institute	29,865		1,970	31,835
	Harvard University	17,813	175		17,988
	Massachusetts General Hospital	13,791		7,400	21,191
	Brigham and Women's Hospital	16,839			16,839
	Massachusetts Institute of Technology	10,026			10,026
Michigan	University of Michigan at Ann Arbor	19,157			19,157
Minnesota	University of Minnesota	16,179	1,756		17,935
	Mayo Foundation	11,809	631		12,440
Missouri	Washington University	9,559	776		10,335
New Hampshire	Dartmouth College	12,711	60		12,771
New York	Memorial Sloan-Kettering	30,969	2,756		33,725
	Columbia University	15,601	1		15,601
	New York University	14,632			14,632
	Yeshiva University	13,033			13,033
	Cold Spring Harbor Laboratory	10,256	1		10,256
	American Health Foundation	9,344	781		10,125
	New York State Dept. of Health	16,010	2,709		18,719
North Carolina	University of North Carolina System	21,856	322		22,178
	Duke University	21,683	930		22,613
Ohio	Case Western Reserve University	13,098	1,080		14,178
	Ohio State University	9,260	1,140		10,400
Pennsylvania	University of Pittsburgh	23,461	1,920		25,381
	University of Pennsylvania	16,510	110		16,620
	Fox Chase Cancer Center	21,979	2,730		24,709
	Thomas Jefferson University	13,036	,		13,036
Tennessee	St. Jude Children's Research Hospital	12,665			12,665
Гехаѕ	University of Texas System	57,217	3,809		61,026
	Cancer Therapy and Research Center	15,607	, ,	900	16,507
Jtah	Utah State Higher Education System	9,454	1,363	230	10,817
/irginia	Dyncorp		30,378		30,378
	Fred Hutchinson Cancer Research Center	43,236	4,071		47,307
-	University of Washington	14,214	22		14,236
A <i>li</i> naanain	University of Wisconsin System	22,034	1,784		23,818
Visconsin	Total versity of viscolisia system	22.0041	1.70		23 KTK1

#### **Cancer Centers Funding History**

Fiscal Year	1989	1990	1991	1992	1993	1994
Center Support	\$101,127,000	\$105,268,000	\$110,481,000	\$127,351,000	\$123,930,000	\$136,269,000
Annual Growth	0.7%	4.1%	5.0%	15.3%	-2.7%	10%

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. Cancer Centers also serve as a stable resource for training new cancer investigators. Of the 54 cancer center support grants (CCSG) awarded in FY 1994, 12 were to basic laboratory centers, 1 was to a consortium center, 15 were to clinical centers, and 26 were to comprehensive centers. In addition, the 14 P20 Cancer Center Planning Grants which were funded in FY 1992 and FY 1993, received continuing support in FY 1994. Cancer Center Planning Grants were initiated in FY 1992 to increase geographic distribution of cancer centers in underrepresented areas of the country.

New funding initiatives were specifically designed to strengthen the Cancer Centers Program and promote the fulfillment of its mission. Highlights of the past year include the following: (1) P20 planning grants for the development of breast cancer programs in NCI-designated cancer centers were awarded with \$4.0 million. Additional funds from the National Institute on Aging and the National Institute for Environmental Health Sciences provided further support, allowing co-funding of a number of applications whose research emphasis was of high programmatic priority to the co-sponsoring Institutes; (2) funds were awarded to 16 cancer centers to further the development of solid and enduring research programs in the area of cancer prevention and control. Funds are intended to support the recruitment of new investigators in the prevention and control research tenure track (or equivalent positions) or for the support of pilot projects; (3) among the P20 breast cancer program awards, four grants specifically incorporated a major focus on environmental carcinogenesis and epidemiology consistent with the Long Island Breast Cancer Study, a major study initiated in response to a congressional mandate; (4) funds were awarded to 35 institutions, representing 28 established cancer centers and seven centers with planning grants, for the purchase of either a single piece of equipment or an integrated set of equipment items to be used for a single purpose; (5) a revised policy on the inclusion of women and minorities in clinical trials, issued in March, 1994, has brought heightened attention to this issue in competing CCSG applications; (6) institutions that are not current recipients of CCSGs, in addition to institutions that were awarded planning grants in 1992, submitted competing applications to become NCIdesignated cancer centers; (7) one new CCSG was awarded in FY 1994, to the University of California, Irvine; (8) under the auspices of a special chartered committee, the revised quidelines for designation as a NCI Comprehensive Cancer Center, implemented in 1993, have now been applied to the review of ten centers; (9) pilot projects in high-priority research areas of prostate, ovarian, breast, and cervical cancer; gene therapy; vaccine development; AIDS-related cancer; and Kaposi's sarcoma, initiated in FY 1992, are coming to completion while others are being initiated reflecting continuing interest of cancer centers in these research areas; (10) workshops for Cancer Center Directors and P20 Planning Grant Directors .

The P20 Planning Grant for Breast Cancer Research Programs was activated in FY 1994 and was co-sponsored by the NCI, the National Institute on Aging, and the National Institute for Environmental Health Sciences. Through this RFA, Cancer Centers were invited to develop broad, multidisciplinary research programs including basic, clinical and prevention and control approaches to breast cancer research. The RFA emphasized inclusion of research not only on breast cancer in young women and populations of women with higher rates of breast cancer, but also environmental influences on breast cancer. Eighteen grants were funded with future year commitments. Another nine grants were funded for one year.

As a way to further encourage the representation of cancer centers in underserved areas, an RFA was again issued in FY 1994 to announce the availability of planning and development grants for cancer centers for this purpose. This initiative was intended to provide current P20 recipients an opportunity to continue their planning and development activities or for new institutions to begin similar ventures. In addition to basic cancer research, these centers are expected to emphasize clinical and prevention/control research that will ultimately impact on the populations in their regions, paying particular attention to minority, rural, and other underserved populations. Approximately three to five awards are expected to be made in FY 1995 in response to this initiative.

Since 1978, the NCI has recognized a category of cancer centers designated as Comprehensive, and so termed because of the broad array of cancer research, training, information, and outreach services they provide to their communities. Comprehensive Guidelines, initially issued in 1990 and revised in 1993, refined and clarified the concept of an NCI-designated comprehensive cancer center, the application procedures and the peer review criteria that centers were to use to attain and renew this designation. The revised guidelines introduced greater rigor and consistency to the process of achieving comprehensive status, requiring meritorious achievement in the following review criteria.

#### 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.
- 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 (P30 Core Grants)

State	Grantee Institution	Туре	Awarded
Alabama	University of Alabama at Birmingham	Comprehensive	\$3,780,307
Arizona	University of Arizona	Comprehensive	1,808,420
California	Beckman Research Institute/City of Hope	Clinical	1,336,446
	La Jolla Cancer Research Foundation	Lab/Basic	1,355,570
	Salk Institute for Biological Sciences	Lab/Basic	1,641,560
	University of California at Los Angeles	Comprehensive	3,036,287
	University of California at San Diego	Clinical	1,318,854
	University of California, Irvine Clinical Cancer Center	Clinical	1,070,140
	University of Southern California	Comprehensive	3,400,597
Colorado	University of Colorado Health Sciences Center	Clinical	2,178,677
Connecticut	Yale University	Comprehensive	2,209,458
District of Columbia	Georgetown University	Comprehensive	1,846,778
Florida	University of Miami	Comprehensive	2,160,259
Illinois	Northwestern University	Clinical	1,271,473
	University of Chicago	Clinical	2,032,340
Indiana	Purdue University West Lafayette	Lab/Basic	637,777
Maine	Jackson Laboratory	Lab/Basic	1,318,447
Maryland	Johns Hopkins University	Comprehensive	4,393,104
Massachusetts	Dana-Farber Cancer Institute	Comprehensive	3,350,714
	Massachusetts Institute of Technology	Lab/Basic	1,732,849
Michigan	University of Michigan at Ann Arbor	Comprehensive	2,074,698
-	Wayne State University	Comprehensive	1,091,822
Minnesota	Mayo Foundation	Clinical	2,192,496
Nebraska	University of Nebraska Medical Center	Lab/Basic	936,406
New Hampshire	Dartmouth College	Comprehensive	1,697,631
New York	Cold Spring Harbor Laboratory	Lab/Basic	2,754,715
	Columbia University New York	Clinical	3,131,341
	Kaplan Comprehensive Cancer Center/NYU	Comprehensive	3,374,087
	Roswell Park Memorial Institute	Comprehensive	1,810,838
	Memorial Sloan-Kettering	Comprehensive	5,561,534
	University of Rochester	Clinical	2,511,802
	American Health Foundation	Lab/Basic	2,060,812
	Albert Einstein College of Medicine	Clinical	3,926,496
North Carolina	Duke University	Comprehensive	3,670,729
	University of North Carolina Chapel Hill	Comprehensive	2,336,982
	Wake Forest University/Bowman Gray Sch. of Medicine	Comprehensive	1,429,475
Ohio	Case Western Reserve University	Clinical	1,348,871
	Ohio State University	Comprehensive	2,897,712
Pennsylvania	Fox Chase Cancer Center	Comprehensive	6,671,045
·	Temple University	Lab/Basic	995,441
	University of Pennsylvania	Comprehensive	2,200,528
	University of Pittsburgh	Comprehensive	1,657,260
	Wistar Institute of Anatomy and Biology	Lab/Basic	2,832,805
Tennessee	St. Jude Children's Research Hospital	Clinical	3,615,702
	Drew-Meharry-Morehouse Consortium Cancer Center	Consortium	1,149,312
Texas	San Antonio Cancer Institute	Clinical	1,820,605
	M.D. Anderson Cancer Center/Univ. of Texas	Comprehensive	2,272,590
Utah	University of Utah	Clinical	1,254,148
Vermont	University of Vermont	Comprehensive	1,038,433
Virginia	University of Virginia	Lab/Basic	695,616
J.:	Medical College of Virginia/VCU	Clinical	850,250
Washington	Fred Hutchinson Cancer Research Center	Comprehensive	5,533,841
Wisconsin	McArdle Laboratory for Cancer Research	Lab/Basic	2,548,268
	University of Wisconsin Madison	Comprehensive	2,812,287
ł	Total P30s	54	124,636,635
	P20 Planning Grants		11,632,365
ŀ	Total Cancer Centers	L	\$136,269,000

# Specialized Programs of Research Excellence SPOREs

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In 1992, the NCI established the Specialized Programs of Research Excellence (SPOREs) to promote interdisciplinary research and to speed the bidirectional exchange between basic and clinical science in order to move basic research findings from the laboratory to applied settings involving patients and populations. The ultimate goal of the SPORE program is to bring novel ideas that have the potential to reduce cancer incidence and mortality, improve survival, and to improve the quality of life to clinical care settings.

Laboratory and clinical scientists work collaboratively in planning, designing and implementing research programs that impact on cancer prevention, detection, diagnosis, treatment and control. To facilitate this research, each SPORE develops and maintains specialized resources that benefit all scientists working on the specific cancer site, as well as SPORE scientists. An additional SPORE element is a career development program that recruits scientists both within and outside the SPORE institution to enlarge the cadre of laboratory and clinical scientists dedicated to translational research on human cancer. SPOREs meet annually to share data, assess research progress, identify new research opportunities and establish priorities for research most likely to reduce incidence and mortality and to increase survival.

In 1994, NCI funded a total of 9 SPOREs and 24 P20 Planning Grants for a total of \$22,049,000. SPOREs are funded through both the P50 and P20 mechanisms. Nine institutions received full support as P50 SPOREs. Twelve P20s were awarded to institutions to conduct feasibility studies to determine whether they would qualify to become fully funded SPORE institutions. In the upcoming years, NCI may increase the use of the SPORE mechanism to include funding for other major cancer sites.

<u>Site</u>	Type	Number of Awards	Amount of Funding
Breast	P50	4	\$7,969,000
	P20	6	773,000
	Total Breast	10	8,742,000
Gastrointestinal	P50	1	1,540,000
	Total Gastrointestinal	1	1,540,000
Lung	P50	2	4,147,000
	P20	2	439,000
	Total Lung	4	4,586,000
Prostate	P50	2	5,191,000
	P20	5	617,000
	Total Prostate	7	5,808,000
Brain Tumor	P20	11	1,373,000
	Total Brain Tumor	11	1,373,000
i	D20	24	40.047.000
	P20 P50	24 9	18,847,000 3,202,000
	Total SPORES		\$22,049,000

## **Total Research Project Grants**

(Dollars in Thousands)

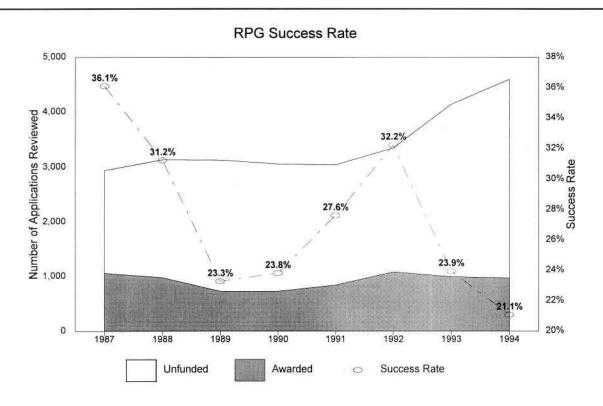
## **Fiscal Years 1988-1994**

Fiscal		Requ	ested	Awa	rded	Success	
Year	Type Awarded	No.	Amt.	No.	Amt.	Rate	
	Competing						
	New	2,167	\$419,638	470	\$83,083		
	Renewal	951	262,675	506	122,229		
1988	Board Supplement	15	1,717	3	66		
	Subtotal	3,133	684,030	979	205,378	31.2%	
	Noncompeting			2,078	460,025		
	Total			3,057	665,403		
	Competing						
	New	2,290	\$474,978	402	\$73,081		
	Renewal	823	246,172	324	85,645		
1989	Board Supplement	14	2,883	2	49		
	Subtotal	3,127	724,033	728	158,775	23.3%	
	Noncompeting	•	·	2,374	564,234		
	Total			3,102	723,009		
	Competing				,,,,,,		
	New	2,193	\$527,256	421	\$82,656		
	Renewal	849	278,541	302	87,497		
1990	Board Supplement	15	2,837	5	991		
	Subtotal	3,057	808,634	728	171,144	23.8%	
	Noncompeting		,	2,288	568,336	20.070	
	Total			3,016	739,480		
	Competing			0,010	100,100		
	New	2,195	\$512,665	513	\$102,364		
	Renewal	837	286,858	323	94,231		
1991	Board Supplement	8	1,161	4	421		
	Subtotal	3,040	800,684	840	197,016	27.6%	
	Noncompeting	0,040	000,004	2,207	594,532	21.0 %	
	Total			3,047	791,548		
	Competing			3,047	131,346		
	New	2,508	\$612,369	664	\$119,091		
	Renewal	815	332,428	398	133,413		
1992	Board Supplement	23	3,704	17	1,347		
1002	Subtotal	3,346	948,501	1,079	253,851	32.2%	
	Noncompeting	3,340	940,501	2,231	620,006	32.2%	
	Total			3,310	873,857		
	Competing	<u>-</u>		3,310	6/3,65/		
	New	3,173	\$746,912	644	\$114,227		
	Renewal	891	328,657	340			
1993	Board Supplement	75			107,949		
1993	· · · · · · · · · · · · · · · · · · ·		8,554	7	1,698	00.00	
	Subtotal	4,139	1,084,123	991	223,874	23.9%	
	Noncompeting			2,346	692,436		
	Total			3,337	916,310		
	Competing	222	A707.00 /		0445 :55		
	New	3,643	\$787,824	657	\$118,403		
4004	Renewal	935	342,068	308	110,723		
1994	Board Supplement	20	3,311	4	733		
	Subtotal	4,598	1,133,203	969	229,859	21.1%	
	Noncompeting		ļ	2,436	704,665		
	Total			3,405	934,524		

Note: RPGs include 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 Request for Applications, R03 small grants, R21 Exploratory/Developmental Grants and R43/R44 Small Business Innovative Research awards.

Success rate is the number of awarded grants divided by the number of awards requested. Requested data from 1986 through 1990 includes all submitted applications. Beginning in 1991, the requested data excludes applications not recommended for further review by DRG. 1993 requested data was updated since printing the 1993 Factbook.

## Success Rate: Fiscal Years 1987-1994

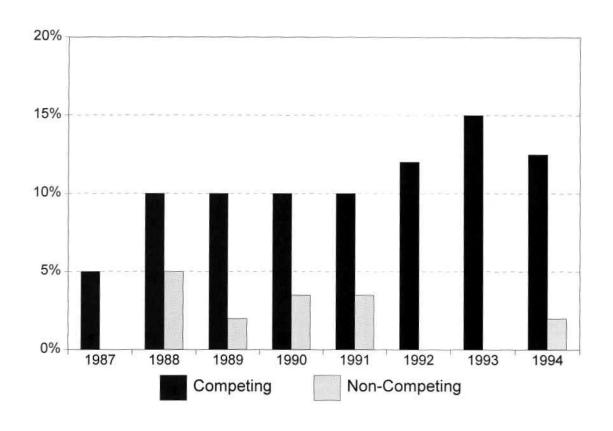


RPG Applications	1987	1988	1989	1990	1991	1992	1993	1994
Annual % Change:								
in Awarded		-8%	-26%	0%	15%	28%	-8%	-2%
in Success Rate Base		7%	0%	-2%	-1%	10%	24%	11%
in Success Rate		-13%	-25%	2%	16%	17%	-26%	-12%
Numbers of RPGs:								
Awarded	1061	979	728	728	840	1079	991	969
Success Rate Base	2939	3133	3127	3057	3040	3346	4139	4598
Success Rate	36.1%	31.2%	23.3%	23.8%	27.6%	32.2%	23.9%	21.1%

The success rate base is the number of applications reviewed.

The success rate is the number awarded as a percent of the success rate base (the number of applications reviewed)

## Research Project Grants Adjustments from Recommended Levels Fiscal Years 1987-1994

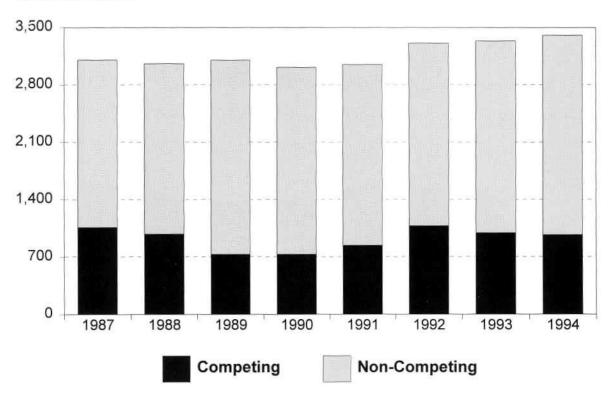


TYPE	1987	1988	1989	1990	1991	1992	1993	1994
Competing	5.0%	10.0%	10.0%	10.0%	10.0%	12.0%	15.0%	12.5%
Non-Competing	0.0%	5.0%	2.0%	3.5%	3.5%	0.0%	0.0%	2.0%

NOTE: Future year (non-competing) approved amounts are reduced by the average percentage reductions applied during the competing grant cycle. The percent reductions shown are taken against this adjusted base. FY 1987,1992 and 1993 non-competing awards were paid at the committed level.

## Research Project Grants Number of Awards Fiscal Years 1987-1994

## Number of Awards



TYPE	1987	1988	1989	1990	1991	1992	1993	1994
Competing	1,061	979	728	728	840	1,079	991	969
Non-Competing	2,042	2,078	2,374	2,288	2,207	2,231	2,346	2,436
Total	3,103	3,057	3,102	3,016	3,047	3,310	3,337	3,405

#### **Research Project Grants**

(Dollars in Thousands)

#### **Awarded**

## History by Activity

#### **Fiscal Years 1989-1994**

	1	989	1	990	1991		1992		1993		1994	
TYPE	Number	Amount										
RO1	2,239	\$377,164	2,068	\$371,225	1,949	\$381,932	2,050	\$424,954	1,955	\$430,203	1,914	\$434,612
PO1	165	188,015	162	185,130	165	190,470	183	205,330	176	202,852	163	184,852
R35	75	52,973	78	57,857	84	62,137	76	59,878	75	61,337	72	61,369
R37	132	32,353	153	39,264	163	43,687	162	47,414	166	51,633	154	48,699
UO1	70	20,939	87	31,145	85	32,431	123	44,171	171	56,199	232	75,444
R29	232	21,244	280	25,547	316	29,494	309	29,726	291	29,053	312	32,610
RFA	108	18,884	101	17,335	154	37,435	208	45,107	282	63,267	319	70,879
R43-R44	79	11,332	87	11,977	131	13,962	199	17,277	215	20,401	179	22,773
R03			!								46	2,393
R21						i					5	353
R23	2	105										l
R55									6	1,365	9	540
TOTAL	3,102	\$723,009	3,016	\$739,480	3,047	\$791,548	3,310	\$873,857	3,337	\$916,310	3,405	\$934,524

#### RO1 Research Project (Traditional)

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

#### PO1 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.

#### UO1 Research Project (Cooperative Agreement)

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

#### R03 Small Grants

To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies, which are generally for preliminary short-term projects and are non-renewable.

#### R21 Exploratory/Developmental Grants

To encourage the development of new research activities in categorical program areas. Support generally is restricted in level of support and in time.

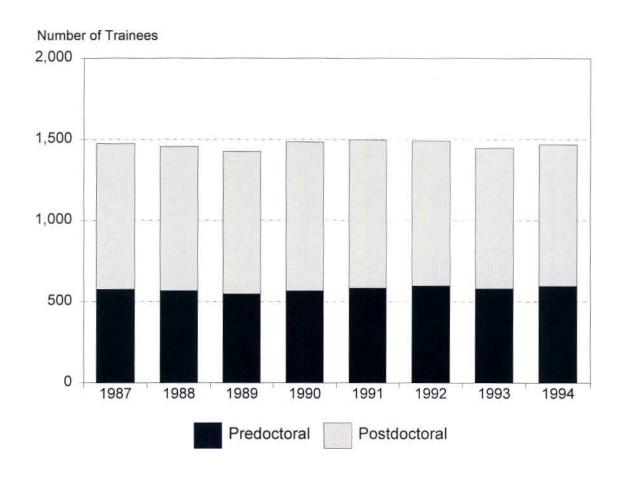
#### R23 New Investigator Research Awards

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

#### R55 Shannon Awards

To provide discrete limited support to scientists whose research applications fall short of the cutoff for funding yet are at the "margin of excellence" whereby the perceived quality of the grant is statistically indistinguishable from grants that are funded.

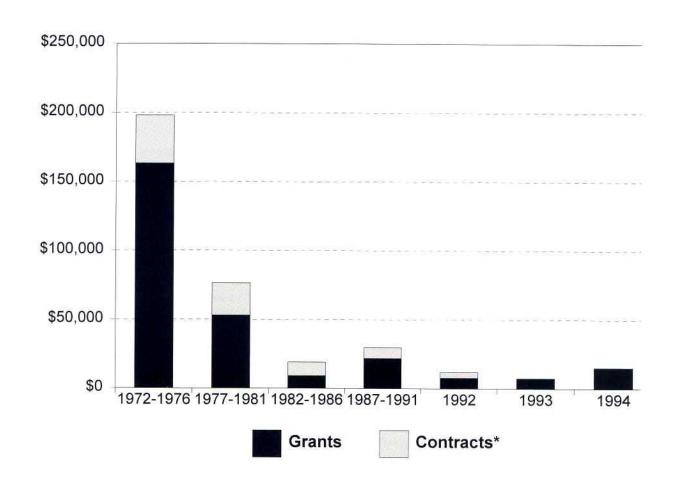
## National Research Service Awards Fiscal Years 1987-1994



TYPE	1987	1988	1989	1990	1991	1992	1993	1994
Predoctoral	577	568	548	567	584	597	578	596
Postdoctoral	898	888	880	918	913	894	868	873
Total	1,475	1,456	1,428	1,485	1,497	1,491	1,446	1,469

# Construction/ Renovation Funding Fiscal Years 1972-1994

(Dollars in Thousands)



1972-1976	1977-1981	1982-1986	1987-1991	1992	1993	1994
\$163,433 34,644	\$53,293 23,232	\$9,225 10.093	\$22,068 7,935	\$8,000		\$15,447 1.052
198,077						16.499
	\$163,433 34,644	\$163,433 \$53,293 34,644 23,232	\$163,433 \$53,293 \$9,225 34,644 23,232 10,093	\$163,433 \$53,293 \$9,225 \$22,068 34,644 23,232 10,093 7,935	\$163,433 \$53,293 \$9,225 \$22,068 \$8,000 34,644 23,232 10,093 7,935 4,000	\$163,433 \$53,293 \$9,225 \$22,068 \$8,000 \$7,182 34,644 23,232 10,093 7,935 4,000 346

## Selected Minority Focused Activities Fiscal Year 1994

#### 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. NCI 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.

## 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 access to minority participation at all levels of cancer research, the Cancer Therapy Evaluation Program coordinates interrelated clinical programs. The individuals intended to benefit from these programs are Americans of African-American ancestry, Hispanics of Mexican, Puerto Rican, Cuban, or Central American descent, Asian-Americans, and Native Americans, including Alaskans and Hawaiian natives. Eight Cooperative Groups (NSABP, GOG, CCSG, NCCTG, SWOG, RTOG, CALGB, and ECOG) have developed plans to encourage early diagnosis and clinical trials participation among potential patients and to overcome language and logistic barriers for specific minority groups. The NCI has an internal committee to address increasing minority accruals to clinical trials.

#### **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 special population groups as well as obstacles within the health care delivery systems. A study of the impact of socioeconomic status on cancer risk and survival promises to provide information on more effective delivery of cancer intervention programs. In addition, a cancer mapping program will assist local health officials to better target cancer services to such populations. Special populations research also investigates primary prevention interventions designed to meet the specific needs of these groups. Support for several cancer control networks has allowed channeling of cancer prevention and

control information to stimulate interest from culturally sensitive researchers to address the unique needs of special populations.

Etiologic studies are aimed at identifying factors that place specific minority groups at unusual risk for cancer. For example, a series of population-based case-control studies is evaluating possible reasons for African-Americans having higher rates than Caucasians for multiple myeloma and cancers of the pancreas, esophagus and prostate, and to estimate the extent to which race-specific factors may explain these differences. A major prospective study has been launched to evaluate cancer and other health outcomes among farmers and their families, and will include a study site in North Carolina with a large African-American population. Another project is being designed to develop resources for evaluating cancer risks among migrant and seasonal farm workers, with special efforts to include Hispanic and other underserved groups. Studies are also underway to clarify risk factors responsible for the high rates of lung, stomach, oral and cervical cancers among specific minority populations.

#### **Minority Statistics:**

NCI's Surveillance Program continues to expand and refine the data collection and analyses of minority populations. Efforts to increase population coverage of Hispanics continued in 1993 and similar efforts are being undertaken for other racial and ethnic groups, low-income populations and the elderly. Expansion of the Program in FY 1992 increased coverage to approximately 14 percent of the total U.S. population. The two new areas included, Los Angeles County and four counties in the San Jose-Monterey area south of San Francisco. The population of Hispanics in these two areas is nearly four million which brings SEER coverage to 22 percent of the total Hispanic population residing in the U.S. This expansion increased coverage of minority populations, notably Asian and Pacific Islanders and African Americans. In addition, 3,400 patients are being followed for survival in the Black/White Survival Study, which was designed to investigate 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. Also underway are efforts to describe the cancer incidence and mortality in Alaskan Natives and American Indians as well as the patterns of care, risk factors, and cultural entities that form barriers to early detection and treatment of cancer in these groups.

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

Supports the development and implementation of effective cancer control and treatment strategies in minority populations by including these groups in clinical trials research as well as provides minority cancer patients with access to state-of-the-art cancer treatment and technology. MBCCOPs are located in seven states and Puerto Rico and are funded through 1994 involving over 275 physicians. Nearly 1,000 patients have been enrolled onto cancer prevention, control, and treatment clinical trials through this program.

Through this effort NCI aims to meet an important need of cancer patients and individuals at risk by establishing a system of oncology programs for participation in clinical research trials through the NCI networks.

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

Initiated in 1991, the MHPTI is supporting training and career development opportunities for minority health professionals by engaging them in cancer research or by providing them with training in subspecialities 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 three Requests for Applications (RFAs) published in 1992, four awards to minority clinicians were made. The program has continued through program announcements and two additional awards which were approved for funding in 1993.

Awards are made through the K07, K08, and K14 mechanisms, with an R25 under development. An RFA was issued inviting applications from traditionally historic clack colleges and universities. Awards will be issued in FY 95.

#### **Cancer Communications:**

To promote clinical trials to minority and low literate target audiences, special training will be designed for NCI staff, educational resources for patient audiences will be developed, and training programs and resources will be designed for health professionals. Preliminary work has begun on the development of easy-to-read consent forms and this work will be expanded. Future efforts will involve continued work with the clinical trials cooperative groups in efforts to address the recruitment of minority patients.

The Cancer Information Service (CIS) awarded 19 new five year contracts which assure regional CIS services will be provided to the entire US population. The CIS Outreach Coordinators work with NCI-designated programs to tailor NCI messages and initiatives to local populations, with a special focus on minority populations. As part of CIS's outreach function, regional offices develop relationships with programs at the regional and state levels to promote knowledge of cancer control and education activities and to provide technical support and materials within the service area. Many designated programs are specifically concerned with minority health including: CCOPs (including the Minority CCOPS), NBLIC, ALIC and NHLIC, CDC Breast and Cervical Cancer Screening Grantees, and State Health Departments. In addition, it is the role of the CIS Outreach Coordinators to act as advocates for minority and low literate populations when working with Comprehensive and Clinical Cancer Centers, Patient Educators Network, and Data-Based Intervention Research Grantees on regional initiatives. The outreach efforts of the CIS also includes working with minority media and mass media with messages of interest to regional minority populations.

Existing resources for patients and health professionals are continually revised. The special needs of minority populations and low-literate groups are incorporated in the revision of all resources and the development and design of new resources.

The NCI's Comprehensive Minority Biomedical Program (CMBP) continues its efforts to heighten awareness about cancer risk and prevention in African Americans. The aim of this undertaking is to develop and disseminate information through educational programs regarding steps that can be taken to control or reduce cancer in African Americans.

The NCI's CMBP issued an RFA inviting research grant applications from interested investigators with access to large or predominantly minority populations. The Minority Enhancement Awards promote minority group participation in cancer research with a special focus on cancer control research. Support provided by this initiative broadens the operational base of each institution by: expanding cancer control and prevention efforts in early detection, prevention screening, pre-

treatment evaluation treatment, continuation care, and rehabilitation; increasing the involvement of minority population primary care providers early in the course of clinical treatment research; promoting the involvement in treatment research at the institutional level with a focus on the development of treatment protocols for cancers that have a high incidence in minorities; supporting programs involving diet and nutrition cancer control activities.

NCI continued to expand its African American Cancer Education program -- "Do the right thing...Get a new attitude about cancer." "Do the right thing" urges African Americans to adopt a "new attitude" and make some simple lifestyle changes as crucial steps toward maintaining good health.

NCI also continued distribution and promotion of the Hispanic Program Kit "Hagalo hoy...Por su salud y su familia," which focused on early detection of breast and cervical cancers. The kit, developed for community leaders and organizations serving the Hispanic population, serves as a resource for community leaders to develop cancer equation programs, particularly for breast and cervical cancer. The kit contains education materials such as brochures and factsheets that can be used for community events such as fairs, workshops, meetings and conferences. It also contains articles and camera-ready graphics to be used for local media placements. Short and simple breast and cervical cancer bilingual brochures were printed in large quantities for mass distribution.

Project Awareness is a collaborative program designed to provide underserved women with breast cancer education, mammography, clinical breast exams, and followup medical care. It was completed in 10 cities including: Washington, D.C.; Detroit, Michigan; Los Angeles, California; Baltimore, Maryland; Atlanta, Georgia; Raleigh/Durham, North Carolina; St. Louis, Missouri; and Miami, Florida. Evaluation data on the effectiveness of the education campaign is now being completed. A revised program manual has been produced and will be available to interested cities. The community-based model is now being used by the YWCA in cooperation with the CDC to institutionalize the program. The Cancer Information Service (CIS) and National Black Leadership Initiative on Cancer (NBLIC) will "cochair" local efforts providing media relations and technical support as needed.

NCI continued distribution and promotion of the half-hour television special and public service announcements on mammography "Una Vez al ano...Para toda una vida." The TV special was developed as a tool for educating Hispanic women on the need for breast cancer screening. "Una vez..." aired on the Univision Spanish-language television network for the second time during Breast Cancer Awareness Month in October 1993. Over 8,000 copies have been distributed to organizations serving the Hispanic population in the United States and Puerto Rico. The film is also being used widely by the Centers for Disease Control and Prevention Breast and Cervical Cancer Grantees, State Heath Departments, the Puerto Rico Department of Health, and by many units of the American Cancer Society.

The NCI produced a 9-minute video entitled, "Taking Control of Your Health: The Pap Test and Cervical Cancer." This video is the first culturally-appropriate, intertribal video on cervical cancer for Native American women. Clear, simple language is used to give an overview of the cervical cancer problem among Native American women (many times more prevalent than in the population at large), an explanation of the Pap test, recommendations for screening, and ways that women may be able to protect themselves from the disease. Women of all ages are addressed in the video, from sexually active teens to women past menopause. The film was premiered at a national meeting of Native American women. The film

in conjunction with its original musical score and support materials will be distributed through Native American intermediaries.

Several basic print brochures on cervical cancer were developed and tested for special audiences including low literate, African American and Hispanic women.

A tipsheet on how to quit smoking for African Americans and a bilingual piece for Hispanics were developed and widely disseminated during National Minority Cancer Awareness Month and throughout the year.

NCI collaborated in the revision and update of the "Guia para dejar de fumar," a smoking cessation guide developed by the University of San Francisco Network on Hispanic/Latino Tobacco Control Program. The Guia will be printed by the NCI and be part of the Hispanic Education Program resources.

NCI developed and tested nutrition education materials for low literacy segments of specific ethnic populations. These populations include American Indians, Alaskan Natives, Hawaiian Natives, Chinese, Filipino, Vietnamese, Hispanics, African Americans, and Caucasians. A total of 43 pieces have been developed which include tipsheets, booklets, posters, and scripts for three video and one audio tape. Some of these materials are bilingual and are currently being pretested with appropriate groups across the country. A guide for physicians, "Teaching Your Ethnic Patients," is also being developed. These materials will be available in the Fall of 1994.

The "Down Home Healthy Cookbook" was developed by NCI in conjunction with two nationally known African American chefs. They worked with the NCI by taking recipes that are popular among African Americans and making them lower in fat and sodium. This cookbook is being used by numerous African American organizations in their nutrition education programs. The regional CIS offices have been working with local intermediaries for distribution of the booklet.

## Appropriations of the NCI 1938-1994

	1938 through 1968	\$1,690,550,220	
	1969	185,149,500	
	1970	190,486,000	
14.0%	1971	230,383,000	
\$4,410,425,220	1972	378,794,000	
	1973	492,205,000	
	1974	551,191,500	1.7967
	1975	691,666,000	1
	C		
	1976	761,727,000	020
	"TQ"	152,901,000	2
	1977	815,000,000	
	1978	872,388,000	3
	1979	937,129,000	
	1980	1,000,000,000	4
	1981	989,355,000	5
	1982	986,617,000	6
86.0%	1983	987,642,000	7
\$27,142,476,000	1984	1,081,581,000	8
	1985	1,183,806,000	
	1986	1,264,159,000	9
	1987	1,402,837,000	10
	1988	1,469,327,000	11
	1989	1,593,536,000	12
	1990	1,664,000,000	13
	1991	1,766,324,000	14
	1992	1,989,278,000	15
	1993	2,007,483,000	16
	1994	2,082,267,000	
	1995	2,135,119,000	17
	Total		
	(1938-1995)	31,552,901,220	

#### Transition Quarter ("TQ") --

July 1, 1976 through September 30, 1976. The interim period in changing of the Federal Fiscal Year from July 1 through June 30 to October 1 through September 30.

- Includes \$18,163,000 for training funds provided by Continuing Resolution.
- Includes \$3,201,000 for training funds provided by Continuing Resolution.
- 3 Includes \$20,129,000 for training funds provided by Continuing Resolution.
- 4 1990 appropriation authorized under a Continuing Resolution.
- 5 Reflects 1981 rescission of \$11,975,000.
- 6 Amount included in continuing resolution. Includes \$47,988,000 transferred to the National Institute of Environmental Health Sciences for the National Toxicology Program.
- 7 Appropriated under Continuing Resolution and Supplemental Appropriation Bill.
- B Includes \$23,861,000 for training funds provided by a Continuing Resolution and \$4,278,000 in a Supplemental Appropriation Bill.
- 9 Includes \$6,000,000 from a Supplemental Appropriation Bill.
- 10 Authorized under Omnibus Continuing Resolution.
- 11 Authorized under Omnibus Continuing Resolution.
- 12 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).
- 13 Appropriation prior to reduction contained in P.L. 101-166 (-\$6,839,000) and P.L. 101-239 (-\$22,829,000).
- 14 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)
- 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).
- Appropriation prior to reductions in P.L. 102-294 (-\$16,060,000 for .8% reduction to all line items, -\$9,933,000 for S&E reduction, -\$139,000 for consultant services reduction.)
- 17 Appropriation prior to reductions in PL 103-211 (-\$1,883,000 for Procurement Reduction;-\$116,000 for SLUC Reduction;-\$1,052,000 for Bonus Pay Reduction).

  Includes \$218,199,000 of AIDS funding.

## By-Pass Budget Requests Fiscal Years 1973-1996

Fiscal	
Year	Request
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
1994	3,200,000,000
1995	3,600,000,000
1996	3,640,000,000

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 Bypass Budget. The Budget submitted for 1973 was the initial submission.

## Comparison of Dollars, Positions and Space Fiscal Years 1972-1994

	Dollars					
	Obligations (\$000's)	Percent of Increase Over Prior Year				
1974	581,149					
1975	699,320	20.3%				
1976	760,751	8.8%				
1977	814,957	7.1%				
1978	872,369	7.0%				
1979	936,969	7.4%				
1980	998,047	6.5%				
1981	989,338	-0.9%				
1982	986,564	-0.3%				
1983	986,811	0.0%				
1984	1,081,460	9.6%				
1985	1,177,853	8.9%				
1986	1,210,284	2.8%				
1987	1,402,790	15.9%				
1988	1,468,435	4.7%				
1989	1,570,342	6.9%				
1990	1,644,330 *	4.7%				
1991	1,712,669	4.2%				
1992	1,947,571	13.7%				
1993	1,978,340	15.5%				
1994	2,076,218	6.6%				

Positions							
Actual Full-Time Permanent Employees	Percent of Increase Over Prior Year						
1,805							
1,849	2.4%						
1,955	5.7%						
1,986	1.6%						
1,969	-0.9%						
1,973	0.2%						
1,837	-6.9%						
1,815	-1.2%						
1,703	-6.2%						
1,731	1.6%						
1,698	-1.9%						
1,596	-6.0%						
1,573	-1.4%						
1,642	4.4%						
1,708	4.0%						
1,701	-0.4%						
1,837	8.0%						
1,921	4.6%						
2,042 ***	6.3%						
1,951 ***	-4.5%						
1,840 ***	-5.7%						

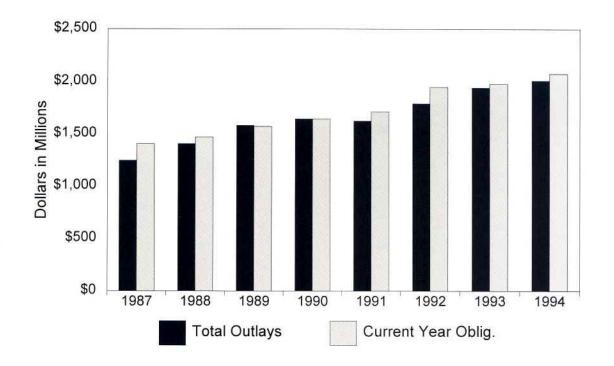
Spa	ıce**
Allocated Space (Square Feet)	Percent of Increase Over Prior Year
381,436	
382,485	0.3%
387,324	1.3%
428,285	10.6%
491,725	14.8%
493,156	0.3%
467,730	-5.2%
472,633	1.0%
477,782	1.1%
484,093	1.3%
466,890	-3.6%
466,890	0.0%
465,790	-0.2%
465,790	0.0%
458,556	-1.6%
483,778	5.5%
489,604	1.2%
499,396	2.0%
477,067	-4.5%
493,186	3.4%
472,545	-4.2%

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

<sup>\*\*</sup> Does not include space at the Frederick Cancer Research and Development Center.

<sup>\*\*\*</sup> Source NIH TDCS 866

Fiscal	Number	Number of		
Year	Cancer	AIDS	Total	Employees
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
1992	2,219	306	2,525	2,604
1993	2,184	300	2,484	2,425
1994	2,081	301	2,382	2,307



\$ in Millions	1987	1988	1989	1990	1991	1992	1993	1994
Prior Year Outlays	\$680	\$723	\$815	\$885	\$885	\$831	\$1,099	\$1,108
Current Year Outlays	565	680	765	759	739	961	843	901
Total Outlays	1,245	1,403	1,580	1,644	1,624	1,792	1,942	2,009
Current Year Obligations	\$1,403	\$1,468	\$1,570	\$1,644	\$1,713	\$1,948	\$1,978	\$2,076

Obligations: Orders placed, grants awarded, contract increments funded, salaries earned and similar financial

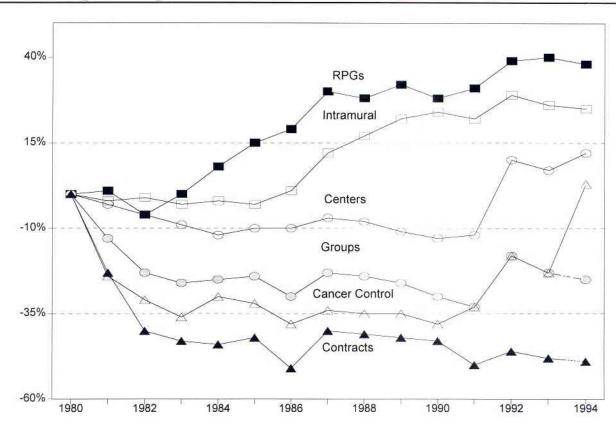
transactions which legally utilize or reserve an appropriation for expenditure.

Outlays: Payments (cash or checks) made from appropriations.

## Constant Dollar Trends Fiscal Years 1980-1994

#### (Dollars in Millions)

## Percent Change in Obligations as 1980 Constant Dollars



Constant Dollars:	1980	1982	1984	1986	1988	1990	1992	1994
Research Project Grants	\$321	\$300	\$346	\$382	\$412	\$412	\$445	\$443
Cancer Prevention & Control	67	46	47	42	43	42	55	69
Centers & SPOREs	67	63	59	60	62	59	74	75
Intramural Research	142	141	139	143	166	177	183	178
Clinical Cooperative Groups	48	37	36	34	37	33	39	36
R&D Contracts	189	114	106	92	111	107	102	97
Subtotal	834	701	734	753	831	829	898	897
All other mechanisms	124	90	77	75	77	81	93	86
Total NCI	\$958	\$791	\$811	\$827	\$908	\$910	\$991	\$983
NCI Change over 1980	base	-17%	-15%	-14%	-5%	-5%	3%	3%
Current Dollars:								
Research Project Grants	\$321	\$358	\$461	\$559	\$666	\$740	\$874	\$935
Cancer Prevention & Control	67	55	63	61	70	75	108	145
Centers & SPOREs	67	75	79	88	100	105	145	158
Intramural Research	142	168	186	209	269	317	360	375
Clinical Cooperative Groups	48	44	48	49	59	60	77	76
R&D Contracts	189	136	142	135	180	192	201	205
Subtotal	834	836	979	1,101	1,344	1,489	1,765	1,894
All other mechanisms	124	107	103	109	125	145	183	182
Total NCI	\$958	\$943	\$1,082	\$1,210	\$1,469	\$1,634	\$1,948	2,076
Deflators	1.0	1.2	1.3	1.5	1.6	1.8	2.0	2.1

