



The Nation's

# Investment

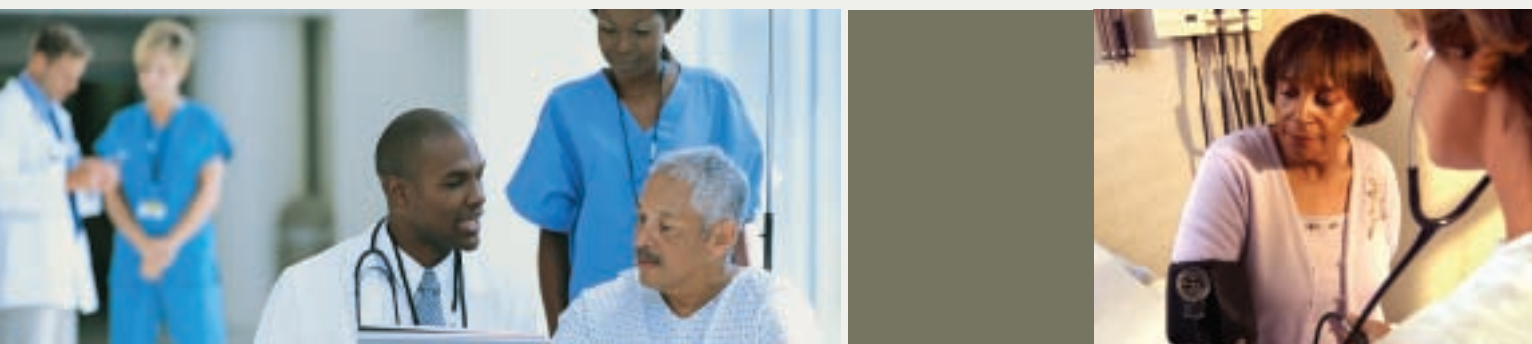
in Cancer Research

**A Plan and Budget Proposal for Fiscal Year 2008**

Prepared by the Director, National Cancer Institute  
as mandated by The National Cancer Act (P.L. 92-218)

## Moving Forward ...

Progress in our understanding of cancer, coupled with increased detection and treatment abilities, has resulted in a real and continuing decline in cancer mortality rates. Cancer deaths in the United States have declined—for the first time since 1930, the year our country began compiling statistics on its toll. This comes despite a rapidly aging population. In 1971, at the time of the National Cancer Act, there were three million cancer survivors. Today, there are more than 10 million.



*...as patient survival tells a compelling story of the promise for continued advances in reducing the burden of cancer.*

One of the many places where research success is translated to real hope for cancer patients is the NIH Clinical Center, the world's largest clinical research complex. These quotations were excerpted from the many testimonials the Clinical Center receives each year from patients, clinicians, and families.

*“Do you know what you were doing five years ago? I do—you were saving my life. It will be five years soon that I will be in remission. I’m a mother of two little children, have a full career, and I feel very good.”*

*“I don’t know how widely it is known that you save lives at the National Cancer Institute—offering hope and treatment to people, like my son, who have run out of options. Patrick was deteriorating... having correctly diagnosed PCNS Lymphoma, you offered to develop a state-of-the-art chemotherapy regimen, using new medications. Were it not for the quick action in diagnosing and then treating his Lymphoma, Patrick would not now be rebuilding his life with a healthy future ahead of him.”*

## Director's Message

**E**ach of us, in some way, has been touched by this terrible disease we call cancer. At the National Cancer Institute, we begin each day with an acute awareness of our responsibility to lead this country's researchers and cancer physicians in the difficult work of conducting quality research that continues to drive down cancer mortality.

This document takes an in-depth look at our nation's investment in cancer research, current and future. It tells the story of our work on numerous fronts to provide a scientific basis for more-successful outcomes tailored to the individual, along with our efforts to reduce the impact of cancer on the lives of all Americans and on our country's economy.

We live in a period of unparalleled scientific opportunity. The pace at which we accumulate new knowledge has never been so great, and it is making possible unprecedented opportunities to accelerate progress against cancer. At NCI, we support the strongest, most-promising research, and we continuously seek to leverage new knowledge, so that effective interventions can get to patients as quickly as possible.

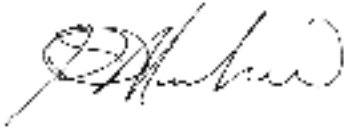
Scientists now understand that cancer is a disease of genetic changes that accumulate over a lifetime—or that add to genetic alterations we inherit. We are gaining new insight into the biological processes that render a cell malignant and into the complex interactions of the cancer cell with its microenvironment and host. By understanding the workings of a tumor and its biological support system, we are starting to develop highly targeted treatments that minimize harm to healthy tissue. We are now beginning to individualize cancer treatment for patients. We are also employing the skills, talents, and unique perspectives of experts in related scientific and technology fields, to share knowledge more extensively and diagnose cancers earlier.

The pages ahead highlight many accomplishments and opportunities, from broad analyses of cancer research trends to specific examples of targeted projects. We are confronting the rapidly approaching time when "access" to optimal state-of-the-art therapies and preventions may be the greatest determinant of mortality from cancer. To address this issue of access for all, we have developed a research pilot project with community-based cancer centers, to study the best ways to bring science to patients—wealthy or poor, young or old—in the communities where they live. This program also has the potential to harness electronic medical records and interconnected informatics systems, to create a national cohort of cancer patients.

Leadership that effectively advances cancer research requires disciplined fiscal management. In this era of essentially flat budgets, NCI's leadership team is carefully planning and optimally investing our research dollars. That means we must aggressively address NCI's strategic objectives, honor our commitment to a base of ongoing research, and fund critical new initiatives. At the same time, we must support the training and mentored research of new investigators, who will enhance our country's scientific capacity for years to come. With the input of researchers, advisory boards, and the larger cancer community, our leadership team is making difficult decisions among competing priorities. We will also work to foster responsible, productive partnerships with other government agencies, academia, and the private sector. And we seek ways to share the story of scientific opportunity and its immense potential economic impact, with a stronger, more unified voice throughout the cancer community.

The Institute's investment proposal for Fiscal Year 2008 is outlined at the end of this document. In our judgment, the proposed budget will enable NCI to ensure outcomes from currently-funded research, fund key strategic new initiatives, and provide training support to draw the best minds to a field vital to our nation's health and economy.

Ultimately, we recognize our responsibility to the American people is to deliver return on investment. We hope this document will serve as an important guide to the President and Congress, as we strive to reduce the burden of cancer.

A handwritten signature in black ink, appearing to read "John E. Niederhuber". The signature is fluid and cursive, with a large initial "J" and "N".

John E. Niederhuber, M.D.

October 2006

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# Science Leads the NCI

## Current Patterns Shaping the Future of Research

Remarkable advances have been made in the fight against cancer since the National Cancer Act became law in 1971, as each success fuels new scientific ideas, discoveries, and the creation of new technologies. We are driven to acquire new knowledge, build upon the findings gained and lessons learned from our past progress, and continue creating the foundations for future advancements.

### **The Promise of the Future**

Imagine a time when doctors no longer determine cancer treatments based upon estimates for the entire population and interventions are tailored specifically to meet individual needs—in many cases preventing the disease process before it starts. Current science is ripe with potential for exponential progress against cancer. Our combination of rich scientific ideas and talent, infrastructure, interconnected knowledge, partnerships, and expertise is coupled with an extraordinary array of advanced technologies. NCI leadership has brought to life five key forces that will drive the promise and hope for a better world where cancer is preempted and the best outcomes are assured for all.



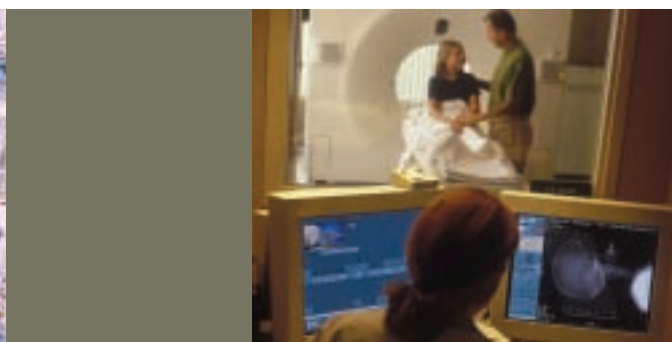
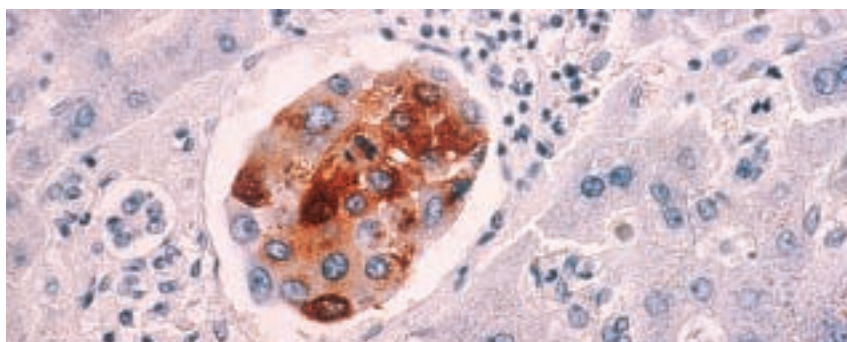
**Convergence** — *where advanced technology and science meet*

It is now understood that cancer is caused by molecular disruptions that can be treated with molecular interventions, yet it is difficult to understand why individual responses to interventions are different

systematic identification and characterization of human proteins and their biological functions.

Computational biology will provide computerized models to process and understand the amazing amount of information that will be available, which physicians

to treat cancer as a complex biological system can be modeled to provide predictions of disease behavior, prognosis, and a patient's response to therapy. In the past, as different fields of science were explored in depth, they became highly specialized and isolated. Over the past five years, we have



even when the pathology is the same. Furthermore, with the ever increasing amount of information available, the human mind can't possibly sort all the possibilities.

The convergence of proteomics, computational biology, and nanotechnology will allow researchers to use this growing knowledge to develop and refine interventions against cancer. Cutting-edge technologies directly enhance proteomics research to speed the

can then use to inform and improve the care of individual patients. Nanotechnology has enabled us to create instrumentation on a very small scale that will make it possible for us to perform molecular classification of tumors, deliver treatments with precision, and predict therapeutic effectiveness.

**Integrative Approaches** — *where the understanding of biology and a systems approach meet*

As we learn more about the molecular events that lead to the development of cancer, new approaches

discovered that areas of research that once were thought to be compartmentalized now are beginning to intersect. With the understanding that tumors are collections of interactive parts, it has become apparent that the focus in studying cancer needs to broaden.

This objective can only be accomplished by bringing together individuals with diverse perspectives that address complex information issues, including scale, modeling, simulations, and interpretation of

the information. In addition, we must maintain a keen awareness of how the information is interrelated and connected. NCI is supporting efforts designed to bring together collaborative groups with unique specialties spanning the clinical and basic research spheres. The hope is that their research findings can be linked together to inform new ways of preventing, detecting, and treating cancer.

these partnerships begin to connect to a broader scientific picture—the individual knowledge of each investigator is amplified and leveraged. Multidisciplinary teams composed of physicians, mathematicians, engineers, chemists, computational biologists, epidemiologists, geneticists, sociologists, nanotechnologists, and others hold the collective keys to our future advancements in cancer research.

extensive knowledge base that will enable scientists from all fields of biomedical research to establish new standards of cancer care.

### **Leveraging Resources and Knowledge** — *where collaborative efforts and entities meet*

The partnerships multiplying between the public and private sectors, nonprofit organizations, our national laboratories, and academia are changing the way we work together to address the burden of cancer. Efforts to involve individual state government agencies in these types of partnerships are increasing to better harness the advances made in local universities and regional biotechnology sectors. In addition, such collaborations not only span the United States but also extend globally. Collaborations with national and international universities and commercial firms yield expanded capabilities and resources. Success in cancer research will be predicated by mechanisms and models that encourage such collaborations and consortia to form and grow.

Cooperative relationships also make other scientific resources and tools available. NCI's research



### **Connectivity** — *where different disciplines and common goals meet*

The talents and solutions needed to address scientific problems no longer rest in the hands of any one investigator or discipline. When researchers join together—and as

NCI is forging partnerships with others to build upon the information gained from NIH's human genome project to understand the genetic and molecular basis of cancer. The goal is to create an



facilities in Frederick, Maryland comprise a unique resource by offering world-class biomedical research and technology support through collaborations within NCI and with other NIH Institutes, Government agencies, and extramural investigators. NCI-Frederick

### **Community** — *where scientific advances and community-based cancer care meet*

The dawning of the era of personalized medicine will require new programs that deliver state-of-the-art oncology care to community settings as efficiently as possible. The

advances in cancer care and prevention are the direct result of participation in clinical trials. Ensuring widespread participation in these studies by more people can be achieved by fostering strong relationships between Comprehensive Cancer Centers, community-based



is also home to a fully-integrated, high-performance, scientific super-computing facility.

The need to find new ways to exploit insights, derived from research data, highlights the need to foster innovation and entrepreneurship, and emphasizes the importance of novel partnerships with the private and philanthropic sectors. Among the challenges that must be addressed for successful public-private partnerships are intellectual property strategies that will not only ensure public availability of discoveries but also preserve incentives for commercialization.

major problem we will face is one of patient access to science advances and new technologies that are increasingly capable of preventing cancer and providing early diagnosis, novel therapies, and highly-specific treatments when cancer occurs. Innovative programs are in development that will play a major role in communities with the goal of bringing together the many facets needed to improve cancer prevention, screening, and treatment, and reduce health disparities. Furthermore, continued

clinical oncology programs, and organizations that reside in and serve local neighborhoods.

*Looking to the future, as we leverage all five scientific forces through collaboration with key partners, we imagine achieving the goal of a world free from cancer. We envision care that is evidence based, that focuses on prevention and wellness with patient education and navigation, and that includes programs to address health disparities, so that the results of our research reach all segments of our population.*

# Advances in 2006

## A Year of Unprecedented Progress

The nation's investments in cancer research returned unprecedented gains in 2006. For example, knowing the sequence of the human genome catapulted our understanding of cancer at the genomic and proteomic level to a new height. Together, this knowledge and recent advances in biomedical technologies and bioinformatics are ushering in a new era of personalized medicine. The paragraphs below highlight examples of the exciting advances made in 2006 in cancer prevention, diagnosis, treatment research, and infrastructure development that will enable us to understand, pre-empt, and manage cancer based on patient-specific disease characteristics.

## A New Era of Cancer Prevention, Diagnosis, and Treatment

These featured advances demonstrate the potential to drastically reduce the burden of cancer through a comprehensive understanding of critical steps in cancer development.

**Vaccines for Cervical Cancer Prevention.** Cervical cancer, claiming more than 200,000 lives worldwide last year, is caused almost exclusively by human papillomavirus (HPV) infection.

translated through public and private research efforts to solve significant public health problems, and in this case, perhaps the elimination of cervical cancer as a threat to women's health.

**Advances in Lymphoma Diagnosis.** NCI researchers used gene expression arrays, which measure the levels of activity of thousands of genes in cells, to identify three distinct subclasses of diffuse large B-cell lymphoma (DLBCL), each requiring a different approach to therapy.

## Infrastructure to Advance Personalized Medicine

NCI and some of its partners undertook several bold projects to provide new knowledge and integrate diverse components of infrastructure across the cancer research enterprise. This infrastructure will help overcome major barriers to generating, integrating, sharing, and deploying critical cancer information to hasten and support a new era of personalized medicine. Examples include:



This year, the Food and Drug Administration (FDA) approved Gardasil®, a vaccine that is 100 percent protective against the development of cervical cancer and genital warts caused by four subtypes of HPV. A second vaccine is being reviewed by the FDA. These vaccines show how basic discoveries arising from population studies, molecular biology, and immunology can be rapidly

Importantly, the researchers were able to distinguish between DLBCL and Burkitt's lymphoma, which are similar in appearance microscopically but require very different treatments that dramatically affect survival rates. This research also shows clearly that an individual's response to therapy is based both on the tumor's molecular characteristics and inherited genes that control the patient's response to drugs.

**The cancer Biomedical Informatics Grid (caBIG™).** As investigators increasingly rely on computerized data analysis and bioinformatics, managing and sharing data in real time has emerged as a major challenge. This movement toward "digital biology" is made more daunting by the serious lack of consistent data formats, vocabularies, standards, and tools for bioinformatics



applications. This year, the pilot phase of caBIG™, an open source “plug and play,” grid-based computing program, was successfully completed. The 80 participants in this achievement included 40 major Cancer Centers, FDA, and the

private sector. caBIG™ will expand partnerships to increasingly provide the connectivity needed to support the advent of personalized medicine.

**Cancer Genetic Markers of Susceptibility (CGEMS).** Genetic changes called single nucleotide polymorphisms (SNPs) may be

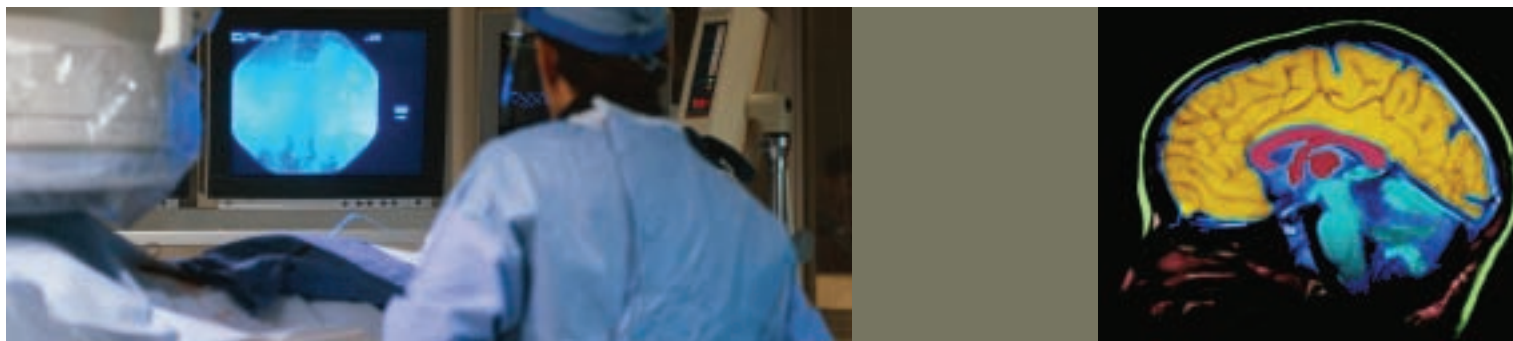
associated with increased risk of some cancers. In 2006, NCI initiated CGEMS to scan the entire human genome and identify SNPs associated with either increased or decreased risk for breast and prostate cancer. Data from CGEMS and similar studies will provide the basis for predicting cancer risk and taking appropriate steps to prevent it.

**The Cancer Genome Atlas (TCGA).** NCI and the National Human Genome Research Institute launched TCGA as a three-year pilot program to take the first step in identifying all important genetic changes in every cancer. TCGA leverages data from thousands of researchers working over several decades. The project also capitalizes on data from the completed human genome project and advances in genome analysis technologies and bioinformatics. The pilot will develop and test the complex science and technology framework needed to systematically identify and characterize the

genomic changes associated with cancer. All data will be publicly available to researchers worldwide through caBIG™.

**The Repository for Molecular BRAIn Neoplasia DaTa (REMBRANDT).** NCI and the National Institute of Neurological Disorders and Stroke created REMBRANDT, a publicly available bioinformatics knowledge base of primary brain

**Essential Infrastructure.** A new Clinical Proteomics Program is developing the standards needed to characterize patterns of protein markers in human serum for very early detection of cancer. NCI's Integrative Cancer Biology Program in computational and mathematical models began the difficult task of analyzing the accelerating volume of data generated by so many advanced technologies. Finally,



tumor data. REMBRANDT integrates extensive clinical and genomic data from brain tumor patients participating in clinical trials. This single resource enables data sharing among many institutions and investigators, helping researchers and clinicians identify and evaluate personalized, molecularly-targeted therapies for patients with brain cancer.

the NCI's Nanotechnology Alliance for Cancer began harnessing nanotechnologies for cancer diagnostics, targeted imaging, and drug delivery. These and other efforts will fill critical knowledge gaps and provide the level of understanding needed to realize a new era of molecular-based personalized cancer medicine in the next decade.



## Looking to the Future

### *NCI Community Cancer Centers Program*

#### **A Case Study: Implementing NCI Strategic Objectives Through Integration of Research Across the Cancer Continuum**

To deliver state-of-the-art oncology care to the community setting, including the earliest phase translational science, NCI is launching a community cancer care project—the NCI Community Cancer Centers Program (NCCCCP). This initiative, in partnership with NCI-designated Cancer Centers, will have clear-cut goals of improving cancer prevention, screening, and treatment; increasing participation in clinical trials; and reducing healthcare disparities. Additional focus

will include increased participation in biospecimen and electronic medical record initiatives. The centers will facilitate a multi-specialty approach to cancer with organ-based clinical programs and specialized training of cancer practitioners.

The NCCCCP cross-cuts the NCI strategic objectives, described on the following pages, and demonstrates how specific initiatives are moving from “silo” research arenas into integrative approaches that span the research continuum. Success will depend on the ability to fully integrate activities and partner with others to develop specific initia-

tives, such as the NCCCCP. In all of our planning we aim to remain responsive to the power of new scientific and technologic opportunities as we leverage community resources in the accomplishment of a world free of cancer.





In January 2006, the National Cancer Institute issued a pivotal planning document to advance cancer research and outcomes: *The NCI Strategic Plan for Leading the Nation*. Expert and wide-ranging teams from NCI staff and the cancer research community contributed to the plan, and also agreed that it would be a living document for the coming years. This *Plan and Budget Proposal for Fiscal Year 2008* marks NCI's first opportunity to describe the proposed implementation of the Strategic Plan's stated goals and objectives.

To lessen the burden of cancer, NCI conducts and leads intensive work to advance cancer research progress in knowledge discovery, patient-centered translation of discovery, and bench-to-bedside delivery. Our partners are critical to this complex set of endeavors.

NCI's Strategic Objectives are central to the focus of these efforts:

*To Preempt Cancer at Every Opportunity*

- > Understand the causes and mechanisms of cancer
- > Accelerate progress in cancer prevention
- > Improve early detection and diagnosis
- > Develop effective and efficient treatments

*To Ensure the Best Outcomes for All*

- > Understand the factors that influence cancer outcomes
- > Improve the quality of cancer care
- > Improve the quality of life for cancer patients, survivors, and their families
- > Overcome cancer health disparities

The following pages provide background for each of these strategic objectives. The section titled *Today's Research* lists components of NCI's current portfolio of funded research. The section titled *Tomorrow's Strategies* outlines next steps for achieving the objectives. The *Moving Research Forward* section provides a glimpse of the many emerging research results for each objective.

# NCI Strategic Objectives and Progress

## Understanding the Causes and Mechanisms of Cancer

We will conduct and support basic, clinical, and population research to better understand how genetic, epigenetic, environmental, behavioral, and sociocultural factors relate to cancer. Our work will focus on the biologic processes that affect our resistance to or likelihood of developing cancer; allow cancer to start (initiation), grow (progression), and spread (metastasis); and cause it to regress or recur.

### Today's Research

Research to discover the causes and mechanisms of cancer is essential to enable us to develop and apply treatments or interventions to keep cancers from starting or progressing. NCI's diverse portfolio of research projects and programs addresses this need, spanning research on cancer risk to studies on the process of metastasis. Examples of ongoing NCI research include:

- > Identifying cancer risks associated with interactions between genes and both environmental and lifestyle factors
- > Investigating cellular and molecular mechanisms of cancer initiation, progression, and metastasis
  - Epigenetic pathways, genes, and proteins
  - Factors related to cancer development, including certain viruses, angiogenesis (new blood vessel growth), and the movement of cells within the body
  - Normal cell and molecular biology
  - Cell metabolism and growth
  - Structure and function of genes and proteins
  - Developmental biology and cell-to-cell interactions
- > Understanding how cancer risk factors disrupt normal cells

### Tomorrow's Strategies

Cancer is a complex set of diseases that must be understood from many perspectives. NCI will use the following strategies to pinpoint the causes and mechanisms of cancer:

- > Increase our understanding of behavioral, environmental, genetic, and epigenetic causes of cancer and how they interact.
- > Gain a full understanding of how changes in genes can cause cancer to develop.
- > Improve cancer diagnosis through an integrative approach to improving our understanding of:
  - Normal cellular and molecular biology
  - Macroenvironmental influences (i.e., outside the body)
  - Microenvironmental influences (i.e., within the body)
- > Apply new technologies to expand our knowledge of cancer risk factors and biologic mechanisms.
- > Investigate links between cancer and other human diseases.

## **Moving Research Forward** ***...through Identifying and Understanding Cancer Risk Progression***

**NCI supports large-scale studies to identify exposures, lifestyles, and genes that affect cancer risk. For example, scientists linked recent, rapidly rising rates of esophageal cancers to two factors: increasing rates of obesity and gastrointestinal acid reflux, which increases the risk of a pre-malignant condition called Barrett's esophagus.**

**NCI also supports research to understand the many factors involved in a normal cell becoming cancerous and spreading to other parts of the body. Basic laboratory and animal research provides clues about the inner workings of cells that would otherwise be beyond our reach.**

### ***...and Progress in Pursuit of our Goal***

- > Understanding the Role of Bone Marrow Cells in Metastasis.** A recent study in mice shows that normal bone marrow cells may play an important role in metastasis, the spread of cancer. The researchers replaced the bone marrow cells of the mice with bone marrow cells tagged green with a biochemical marker, so they could be tracked. Then the researchers injected the mice with red-tagged cancer cells that were expected to travel to the lungs. However, the bone marrow cells reached the lungs first, appearing to prepare a niche for the cancer cells to use when they arrived in the lungs. When the researchers inhibited the migration of the bone marrow cells, they prevented metastases from forming in the mice. Further research will explore how cancer cells recruit bone marrow cells and use them to establish new tumors. This may help researchers learn how to stop the movement of bone marrow cells as a way to prevent metastasis.
- > Understanding the Normal Biology of Aging.** NCI researchers reported that a gene known for its link to a premature aging syndrome, Hutchinson-Gilford Progeria Syndrome (HGPS), also appears to play a role in the normal aging process. Mutations in a gene called LMNA produce a faulty form of the protein lamin A that has been linked to HGPS. Investigators found that, compared with cells in young individuals, cells from HGPS patients and those of healthy older individuals shared many of the same cellular defects. Laboratory experiments showed that the lamin A protein probably has a role in causing the age-related defects. A better understanding of the mechanisms of normal and premature aging will help scientists understand the molecular mechanisms involved in creating the microenvironment required for a cell to become cancerous.

## Accelerating Progress in Cancer Prevention

**We will accelerate the discovery, development, and delivery of cancer prevention interventions by focusing on risk assessment, systems biology, behavior modifications, environmental and policy influences, medical and nutritional approaches, and training and education for research and health professionals.**

### Today's Research

Prevention is our first line of defense against cancer. NCI's portfolio supports research to identify medical and behavioral approaches to cancer prevention that can be applied in public health settings. Examples of ongoing NCI research include:

- > Understanding the role of nutrients and micronutrients in human health and cancer occurrence
- > Developing prevention vaccines to stimulate the immune system to attack cancer cells or cancer-causing agents
- > Identifying effective vaccine delivery strategies
- > Developing drugs to prevent primary and secondary cancers
- > Investigating behavioral factors that affect cancer risk and developing strategies to change these behaviors
- > Exploring complementary and alternative methods for cancer prevention

### Tomorrow's Strategies

Research must identify the most promising advances and translate them into new prevention approaches. NCI will broaden and strengthen its prevention portfolio with a rigorous agenda:

- > Support a systematic review of epidemiologic evidence on possible carcinogens and risk factors for cancer.
- > Develop and promote the adoption of medical interventions, including nutritional approaches, chemoprevention drugs, and prevention vaccines that suppress cancer initiation and progression.
- > Develop and test behavioral approaches for reducing cancer risk.
- > Study the impact of environmental and policy interventions on cancer risk.
- > Explore the biology behind successful cancer prevention interventions through a transdisciplinary systems approach.
- > Evaluate the impact of knowledge and intervention dissemination and diffusion programs for cancer prevention using an outcome monitoring system.
- > Train scientists, clinicians, and other health professionals for cancer prevention research.

## **Moving Research Forward** **...with Cancer Chemoprevention Studies**

Chemoprevention is the use of natural or synthetic substances to reduce the risk of developing cancer, or to reduce the chance that cancer will recur. Chemoprevention trials look at possible ways to prevent cancer with interventions that include drugs, vitamins, diet, hormone therapy, or other agents. NCI's chemoprevention research effort, started in the early 1980s, is yielding exciting results. For example, based on findings of the NCI Breast Cancer Prevention Trial, the U.S. Food and Drug Administration approved tamoxifen for reducing the incidence of breast cancer in women at high risk for the disease. This success confirms the usefulness of large-scale chemoprevention clinical trials for identifying ways to stop many of the people at risk for cancer from becoming cancer patients.

### **...and Progress in Pursuit of our Goal**

- > **Results of the Study of Tamoxifen and Raloxifene (STAR) Trial.** STAR, the largest breast cancer chemoprevention trial ever conducted, compared two selective estrogen receptor modulators (SERMs). These drugs work by blocking the tumor-promoting effects of estrogen that are seen in about two-thirds of breast cancer patients. STAR findings show that the anti-osteoporosis (anti-bone thinning) drug raloxifene (Evista®) reduces breast cancer risk in postmenopausal women as well as tamoxifen. Moreover, raloxifene appears less likely to cause some of the rare but serious side effects seen with tamoxifen, such as uterine cancer. These findings are promising because this combination of effective treatment and reduced chance of serious side effects may be what is needed to make breast cancer prevention more of a reality for many women.
- > **SELECT (the Selenium and Vitamin E Cancer Prevention Trial).** Previous studies suggest that the mineral selenium and vitamin E (alone or in combination) may reduce the risk of prostate cancer. Only a large clinical trial, such as the NCI SELECT, can confirm those initial findings. SELECT finished enrolling patients in June 2004, with 35,534 participants. The trial is expected to end by 2011.
- > **Finasteride Follow-up Studies.** In June 2003, the Prostate Cancer Prevention Trial (PCPT) was stopped early because of a clear finding that finasteride reduced the incidence of prostate cancer. However, men who did develop prostate cancer while taking finasteride experienced a slightly higher incidence of high-grade tumors. Follow-up studies are investigating whether finasteride actually caused high-grade tumors.

NCI also is supporting chemoprevention research to benefit patients at high risk for other cancers, including colorectal, lung, esophageal, bladder, cervical, and oral cavity cancer.

## Improving Early Detection and Diagnosis

**We will support the development and dissemination of interventions to detect and diagnose early-stage malignancy.**

### Today's Research

Detecting and diagnosing tumors early in the disease process, before the tumor invades surrounding tissue, can dramatically improve the patient's odds for successful treatment and eliminate a large portion of cancer deaths. Examples in this area include:

- > Identifying genes, proteins, or other molecules that signal the presence of cancer based on their patterns or levels of expression (the extent to which they are activated)
  - Identifying protein biomarkers for hard to detect cancers, such as ovarian and pancreatic cancers, and finding new biomarkers for prostate cancer
  - Using genomic and proteomic profiling to improve prognosis and guide treatment
  - Developing anatomical and molecular imaging techniques to detect tumors, improve diagnostic accuracy, and find metastases
  - Supporting preclinical evaluation and clinical testing of biomarker and imaging technologies
- > Understanding how and why patients accept and comply with cancer screening methods

### Tomorrow's Strategies

NCI will help bridge the gaps across the translational spectrum to speed the movement of effective early detection and diagnostic approaches to the clinic. To achieve this, we will:

- > Promote collaborative, multidisciplinary research to validate biomarkers of early detection and screening.
- > Develop better diagnostic and screening tools for early detection, risk assessment, and disease recurrence.
  - Apply evidence-based research findings to intervention development.
  - Encourage and provide investigator training to facilitate the development and application of new tests.
- > Develop risk factor profiles for identifying patients who are likely to benefit most from cancer screening.
- > Determine why abnormal findings from screening examinations have less than acceptable rates of follow-up and develop strategies to improve this part of the health care system.
- > Make experimental data accessible across the cancer research community.
- > Translate evidence-based research into public health and medical practice.



## **Moving Research Forward** ***...with Molecular Profiling of Cancer***

Our nation's investment in identifying molecular profiles, or signatures, of cancer has been producing impressive results. As early as 2000, NCI researchers were using gene expression profiling to distinguish between different subtypes of lymphoma. Two years later, investigators were reporting preliminary success using proteomic technologies to detect and diagnose some cancers at early stages. Since then, researchers have been discovering and validating molecular profiling techniques that many experts believe are setting the stage for improved cancer detection and diagnosis.

### ***...and Progress in Pursuit of our Goal***

- > **Defining Ovarian Cancer Subtypes.** A new study helped clarify the relationship between low malignant potential (LMP), low-grade, and high-grade serous ovarian tumors. The study suggests that LMP tumors are not early precursors of aggressive ovarian cancer, as had been suspected, but may be part of an entirely different class of tumors. Moreover, the study showed that low-grade serous tumors are more similar to LMP tumors than to high-grade tumors. These findings suggest the need to reexamine treatment options for women with low-grade disease, who currently receive the same therapy as patients with high-grade disease.
- > **Improved Diagnosis of Burkitt's Lymphoma.** A worldwide team of researchers, including some from NCI, showed that gene expression profiling can accurately distinguish between Burkitt's lymphoma and diffuse large B-cell lymphoma (DLBCL). Burkitt's lymphoma and DLBCL cells appear similar when viewed under a microscope, but correct diagnosis is critical because they require very different treatments. If Burkitt's lymphoma patients are treated with intensive therapy, the survival rate is roughly 80 percent. However, if they are misdiagnosed and treated with the lower intensity chemotherapy recommended for DLBCL patients, the survival rate drops to 20 percent or less.
- > **Sputum Testing for Early Lung Cancer Detection.** A prospective clinical trial has found that testing the sputum (coughed up mucus and other matter) of individuals at high risk for lung cancer, by analyzing certain genes and chemicals, may help identify early signs of the disease. The experimental test screens 14 genes associated with lung cancer for the presence of chemicals called methyl groups that can modify genes and silence them (turn them off). The test identified 65 percent of individuals who later developed symptoms of lung cancer, but it also identified 35 percent of cancer-free control participants. Therefore, at this point a patient who tests positive would also need to receive a diagnostic bronchoscopy or x-ray to see if tumors exist.

## Developing Effective and Efficient Treatments

**We will support the development and dissemination of interventions to treat malignancy either by destroying all cancer cells or restraining and controlling metastasis, both with little or no harm to healthy tissue.**

### Today's Research

A large part of NCI's research portfolio focuses on discovering, developing, and evaluating more efficient and effective treatment strategies. Developing cancer treatments that leave surrounding healthy tissue unharmed is at the heart of NCI's research agenda. Examples of NCI research include:

- > Developing and improving localized therapies such as surgery or radiation therapy to directly target the tumor and if necessary, surrounding tissue
- > Investigating systemic (whole body) therapies including cytotoxic (cell-killing) or hormonal agents, vaccines, antibodies (immune system proteins), gene therapy, angiogenesis inhibitors, and differentiating agents
- > Researching molecularly targeted therapies that act primarily on the tumor and associated tissue
- > Developing combination therapies that use two or more drugs and/or treatment types to increase treatment effectiveness
- > Investigating complementary/alternative treatment approaches

### Tomorrow's Strategies

NCI's portfolio will include a special focus on facilitating the research and development of individualized therapies tailored to the specific characteristics of a patient's cancer. Treatment strategies may include localized, systemic, molecularly targeted, complementary and alternative, or combination treatment approaches. NCI will:

- > Identify the molecular and cellular factors that cause metastatic behavior.
- > Validate biomarkers for cancer prognosis, metastasis, treatment response, and progression.
- > More quickly identify, develop, and validate potential targets and strategies for cancer treatment by integrating preclinical (laboratory and animal) and clinical research.
- > Integrate clinical trial networks and programs to ensure that the most promising treatment opportunities are identified, the necessary clinical trials are conducted rapidly, and clinicians have effective use of information and resources.
- > Work to manage the toxic effects of cancer therapy.

## **Moving Research Forward** ***...with Improved Treatment Delivery***

FDA approval of a new drug to fight cancer and its availability to patients are only the beginning of the story of cancer treatment research. Even before a new drug is used in the first patient, researchers are planning how to improve ways of giving the drug to patients to make it more effective. For example, part of the remarkable improvement in childhood leukemia survival over the past 20 years has been achieved by modifying the delivery methods and dosing schedules of successful treatment drugs. NCI continues to test both established and new ways to improve the delivery of cancer drugs.

### ***...and Progress in Pursuit of our Goal***

- > **A New Approach to Immunotherapy.** An NCI research team confirmed the effectiveness of using a new cell-based immunotherapy approach combined with chemotherapy for treating advanced stage metastatic melanoma. The goal is to fight cancer tumors by stimulating and reintroducing a patient's own T cells (rare disease-fighting immune cells). The promise of this therapy is that a patient's own immune system may be used to effectively treat existing tumors.

In a recent clinical trial using this immunotherapy approach, 51 percent of the patients (18 of 35) experienced a significant reduction in the size or the disappearance of their tumors—patients who previously had not responded to treatment. A Phase II trial is under way that will enable researchers to evaluate the effectiveness of this immunotherapy approach among a larger group of participants.

- > **Abdominal Chemotherapy for Ovarian Cancer.** A recent NCI study shows that intraperitoneal (IP) chemotherapy, which delivers drugs directly to the abdominal cavity through a catheter (tube), can significantly increase survival for some women with ovarian cancer. About 400 women in the study were given chemotherapy after successful removal of their tumors. Half received intravenous (IV) cisplatin and paclitaxel, and the others received IV paclitaxel, plus IP cisplatin and paclitaxel. The women who received IP chemotherapy lived on average 16 months longer than women who had IV chemotherapy alone, an unusually large survival benefit for a clinical trial. One year after treatment, both groups of patients reported a similar quality of life. As the results of the study were made public, NCI issued a rare clinical announcement to inform physicians and patients about the potential benefit of IP chemotherapy for ovarian cancer.

## Understanding the Factors that Influence Cancer Outcomes

**We will support and conduct studies to increase our understanding of and ability to measure the environmental, behavioral, sociocultural, and economic influences that affect the quality of cancer care, survivorship, and health disparities.**

### Today's Research

Building on more than two decades of population-based surveillance research (tracking and studying cancer trends), NCI is intensifying its efforts to define, foster, and support studies to improve our understanding of the factors that affect the outcomes of cancer and the impact of cancer care. Examples of NCI research include:

- > Improving measurement of cancer outcomes
  - Alternative approaches to measuring health-related quality of life, economic burden, and satisfaction in cancer care
  - Psychometric (psychological measurement) approaches to increase the accuracy and reduce the cost of outcomes assessment conducted at the patient level
- > Supporting large, prospective cohort (defined population) studies to investigate cancer outcomes
  - The impact of high-profile interventions on patient-centered outcomes
  - Dissemination of new therapies in the community
  - The influence of modifiable risk factors
  - Racial/ethnic- and gender-related disparities in care
  - Use the results of outcomes research from community settings to improve methodology

### Tomorrow's Strategies

NCI will improve outcomes research methods, increase use of evidence-based cancer interventions, and expand use of research knowledge to guide cancer policies. NCI will:

- > Develop standardized measures of cancer care outcomes across the cancer continuum (prevention, early detection, diagnosis, treatment, survivorship, and end of life).
- > Identify research databases to study influences on cancer care and outcomes.
- > Use improved outcome measurement techniques and database resources to increase the understanding of behavioral and sociocultural factors that influence cancer outcomes.
- > Study the factors that affect access to cancer care.
- > Build sustainable community-based structures to support research on cancer outcomes.
- > Understand how to disseminate research results and promote the adoption of evidence-based cancer interventions by a diverse population of patients, health care providers, and the public.

## **Moving Research Forward** ***...by Transforming Cancer Care Outcomes Research***

In 1999, NCI launched its Quality of Cancer Care Initiative to improve the state of the science for defining, monitoring, and improving the quality of cancer care. Since then, research on several fronts is shaping a new model for moving research results from the laboratory bench to the bedside, particularly the effects of cancer care interventions on patients' lives.

NCI's wide-ranging outcomes research agenda focuses on the many aspects of cancer care to improve the experience of individuals after a cancer diagnosis. This research is intended to generate tools and information to enhance the quality of cancer care decision making and ultimately the quality of cancer care.

### ***...and Progress in Pursuit of our Goal***

- > **The Patient-Reported Outcomes Measurement Information System (PROMIS).** NCI is taking an important role in PROMIS, a National Institutes of Health Roadmap Initiative. PROMIS aims to develop ways to measure patient-reported symptoms, such as pain and fatigue, and aspects of health-related quality of life across a wide variety of chronic diseases and conditions, including cancer. Two years into development, researchers are designing and building an innovative technology that promises to revolutionize how patients report clinically important symptoms and outcomes. This technology will provide clinical research communities with a consistent and validated approach to measure these clinically relevant, but subjective and difficult-to-measure outcomes.
- > **The Cancer Care Outcomes Research and Surveillance Consortium (CanCORS).** Through CanCORS, NCI is supporting the largest ever observational study of cancer care delivered in diverse, population-based health care settings. This prospective cohort study has enrolled 10,000 patients with newly diagnosed lung or colorectal cancer. Vital information will be collected on how clinical practices affect outcomes, and what influence certain characteristics — of patients, providers, and community health care delivery systems — have on the services that patients eventually receive. CanCORS is providing a unique opportunity to examine community practices regarding palliative (non-curative symptom control) and end-of-life care. This study takes into account the perspective of the patient, caregiver, and providers among a diverse group of patients followed over time. NCI is supporting developmental research to test the feasibility of collecting such measures routinely within clinical practice.

## Improving the Quality of Cancer Care

**We will support the development and dissemination of quality improvement interventions and measure their success in improving health-related outcomes across the cancer continuum.**

### Today's Research

For cancer, high quality care means delivering the full range of evidence-based interventions that are safe, patient-centered, effective, timely, efficient, and equitable. Such care must be provided with technical competence and cultural sensitivity and must foster patient choice based on informed decision making. Examples of NCI research include:

- > Refining process and outcome measures
- > Researching patterns of care
- > Improving and disseminating quality of care research resources
- > Understanding behavioral and sociocultural factors that influence the quality of cancer care
- > Developing interventions that target patients and their families
- > Improving symptom management and palliative care
- > Improving the training of specialized care providers
- > Evaluating patient psychological and social distress, the quality of supportive care for advanced cancer patients, and the impact of aging on quality of care

### Tomorrow's Strategies

NCI will foster the development and dissemination of research resources for quality of care studies and will help make quality of care interventions available to the people who need them. We will support research to:

- > Foster the use of research evidence about patterns of care and care outcomes, to develop quality improvement interventions.
- > Begin using advanced information systems and interoperable electronic health records to inform future research and guide clinical practice.
- > Turn symptom management and palliative care research findings into interventions to improve care for patients and survivors throughout their cancer experience, and particularly at the end of life.
- > Ensure that the best scientific evidence about quality measures and assessment informs Federal, state, and private sector decision making about cancer care.
- > Ensure that new information about cancer prevention, treatment, and follow-up reaches the people who need it.
- > Strengthen the methods used to evaluate quality improvement efforts.



## **Moving Research Forward** ***...with Improved Access to Quality Cancer Care***

NCI supports research to provide the scientific evidence needed for public and private decision making related to care delivery, insurance coverage, purchasing, regulation, and standard setting. This research gives cancer patients, survivors, and caregivers the information they need to enhance the efficiency and quality of cancer care services. For example, some NCI research findings provide guidance to the cancer community on how to improve cancer patients' and survivors' access to the full range of evidence-based interventions that may benefit them.

### ***...and Progress in Pursuit of our Goal***

- > **Health Insurance and Quality of Cancer Treatment.** Researchers recently studied the association between treatment received and insurance status (private insurance, Medicaid or Medicare only, or no insurance) for 10 common cancers with established evidence-based treatment guidelines. The study was based on a sample of more than 7,000 patients identified through NCI's Surveillance, Epidemiology, and End Results (SEER) program. Patients who depended on Medicare or Medicaid alone for insurance, especially non-Hispanic Black patients with Medicaid only, were least likely to receive guidelines-based treatment. In a follow-up study, the investigators will examine how insurance status affects survival after cancer diagnosis.
- > **Factors Affecting Completion of Colon Cancer Treatment.** A recent study showed that colon cancer patients who were female, widowed, elderly, or hospitalized during treatment were less likely to complete adjuvant (post-surgical) chemotherapy, even though stopping meant increasing their risk of dying from the disease. The strongest predictor of an incomplete treatment course was a hospital stay after surgery and after beginning chemotherapy, perhaps because of complications from treatment. The investigators suggest that improving social and physical support during treatment may be needed to increase the number of patients who complete treatment.

## Improving the Quality of Life for Cancer Patients, Survivors, and Their Families

**We will support the development and dissemination of interventions to reduce the adverse effects of cancer diagnosis and treatment and improve health-related outcomes for cancer patients, survivors, and their families/caregivers.**

### Today's Research

Advances in our ability to detect, treat, and support cancer patients are turning this disease into one that is chronic or readily managed for many and curable for increasing numbers.

NCI quality-of-life research includes:

- > Investigating the effects of cancer and its diagnosis and treatment on survivors and their families/caregivers
  - Long-term and late effects of breast and other cancers
  - Impact of physical, psychosocial, economic, and behavioral factors
- > Supporting both descriptive and intervention survivorship research
- > Researching pediatric cancer survivorship
  - Acute lymphoblastic leukemia
  - Other pediatric cancers

### Tomorrow's Strategies

NCI will support survivorship research to improve the health and quality of life of all cancer patients following their diagnosis and initial treatment. These studies will include both the prevention and control aspects of chronic disease epidemiology. NCI will:

- > Increase research to understand biologic, physical, psychological, and social factors and their interactions that affect a cancer patient's response to disease, treatment, and recovery.
- > Expand the development and use of tools to assess the health-related quality of life of cancer survivors and their family members and caregivers.
- > Increase the pace of intervention research designed to reduce cancer-related acute, chronic, or late morbidity (adverse effects caused by treatment) and mortality.
- > Ensure that new information, interventions, and best practices for addressing the health needs of survivors and their families reach the people who need them.

## **Moving Research Forward**

### ***...with Motivation for Healthy Behavior Change after Cancer***

The challenges imposed by a cancer diagnosis can be life-altering, particularly in terms of changing the health behaviors of patients and survivors. Indeed, some feel that cancer represents an important “teachable moment” for many cancer survivors that can lead to positive choices and healthier lifestyles. These changes may improve the emotional outlook and overall health of cancer survivors, and even alter the course of their disease.

NCI supports research on the motivation potential of a cancer diagnosis. This research is of special importance because cancer survivors are at increased risk for progressive or recurring disease, second cancers, osteoporosis, obesity, cardiovascular disease, diabetes, and functional decline. Although more research is needed, opportunities exist for medical teams to promote lifestyle changes that may improve the length and quality of survivors’ lives.

### ***...and Progress in Pursuit of our Goal***

- > **Physical Activity to Extend Survival and Improve Quality of Life.** Physical inactivity following cancer is a known risk with an adverse effect on weight and health. A number of researchers have shown that exercise interventions can improve survivors’ physical and emotional health, functional well-being, and quality of life. Moreover, evidence now shows that physical activity interventions can alter the course of disease recurrence or death. Two recent NCI studies found that patients with early- to later-stage colorectal cancer (but not distant metastases) who engaged in regular activity after diagnosis decreased the chance of cancer recurrence and mortality by 40 to 50 percent or more, compared with patients who engaged in little to no activity.
- > **Lowering Dietary Fat to Reduce Breast Cancer Recurrence.** Similarly, the first evidence of a positive effect of dietary change on cancer has been reported. The NCI-sponsored Women’s Intervention Nutrition Study (WINS) was the first large-scale intervention trial to study the influence of dietary fat on breast cancer outcomes in postmenopausal women treated for early-stage breast cancer. WINS investigators reported that lowering dietary fat may lower the risk of breast cancer recurrence in this population.

These behavioral change studies hold the promise of reducing cancer-related morbidity and promoting general health. At the same time, these interventions also appear to have great appeal to cancer survivors eager to reduce the stress in their lives and to regain control of their lives and bodies after cancer diagnosis and treatment.

## Overcoming Cancer Health Disparities

**We will study and identify factors contributing to disparities, develop culturally appropriate approaches, and disseminate interventions to overcome those disparities across the cancer control continuum from disease prevention to end-of-life care.**

### Today's Research

It is well known that many population groups across the United States and around the world suffer more severely from cancer and its sequelae (after-effects). Overcoming cancer health disparities is one of the best opportunities we have for lessening the burden of cancer. NCI's investments are speeding the development and use of interventions to combat disparities across the cancer control continuum and among all underserved populations. Examples of NCI research include:

- > Supporting health disparities research through NCI's biology, etiology, prevention, detection, and treatment research portfolios
- > Addressing economic, social, cultural, psychological, behavioral, and biologic factors that contribute to cancer health disparities
- > Developing and supporting resources and infrastructure for health disparities research
  - Informatics
  - Specimens, drug, and reagent resources
  - Clinical trials groups
  - Statistical methodology
  - Centers and consortia
- > Supporting education and training for careers in cancer health disparities research

### Tomorrow's Strategies

Addressing the needs of the medically underserved by applying emerging evidence-based findings and research resources is a critical component of NCI's strategies to reduce cancer health disparities. Specifically, we will:

- > Build on our understanding of the factors that cause cancer health disparities.
- > Work with communities to develop interventions targeted to the specific needs of underserved populations.
- > Provide the knowledge base for and develop interventions to better coordinate and integrate cancer services for underserved populations.
- > Develop innovative, educationally- and culturally-appropriate approaches for disseminating information on research results to underserved populations. Work with others to put these approaches into practice.
- > Examine the role of health policy in reducing and eliminating cancer health disparities.
- > Work with others to develop a workforce of researchers and clinicians who will address cancer health disparities.

## **Moving Research Forward** ***...by Addressing the Causes of Cancer Health Disparities***

With support from NCI, scientists are learning more about why some population groups have higher cancer incidence and mortality rates than others. For example, we know that many evidenced-based interventions, including cancer screening, are not adequately reaching all populations. Other research shows that, in addition to uneven access to cancer care interventions, there may be a genetic component to some cancer health disparities.

### ***...and Progress in Pursuit of our Goal***

- > **Interventions to Improve Cancer Screening.** An NCI study found that centralized telephone care management increases screening rates for breast, cervical, and colorectal cancer in women. The study included more than 1,400 women who obtained care at community and migrant health centers in New York City. Women who were overdue for cancer screening were randomly assigned to one of two groups. Women in the usual care group received one telephone call to answer questions and review their status. Women in the intervention group received a series of telephone calls that provided information about screening, scheduled appointments, and motivational support. Screening rates in the intervention group increased by 10 percent for Pap testing for cervical cancer, 17 percent for mammography, and 60 percent for colorectal cancer screening. The findings show how a modest intervention can increase screening rates in largely minority populations.
- > **Differences in Smoking-related Lung Cancer Risk.** In one of the largest prospective studies of its kind, NCI researchers found significant racial and ethnic differences in smoking-related lung cancer risk, after ruling out differences in diet, occupation, and education level. Analyzing data from almost 200,000 study participants, researchers found that among individuals who smoked 10 cigarettes or less a day, Whites had a 55 percent lower risk of lung cancer than Blacks, and among those who smoked 11 to 20 cigarettes daily, the risk was 43 percent lower. Among Hispanics and Japanese Americans, the percentages were lower still. However, the risk difference was minimal among people who smoked 30 cigarettes or more a day. While research into the environmental factors that influence lung cancer risk across populations is still vital, the investigators suggest that genomic research may eventually pinpoint genes that increase susceptibility to smoking-related lung cancer and may help explain these racial and ethnic differences.



## **National Cancer Institute Director John E. Niederhuber, M.D.**

Dr. John Niederhuber was appointed the 13th Director of the National Cancer Institute in August 2006. Throughout his distinguished career, he has had ties to both NCI and the National Institutes of Health. In addition to his work as a surgeon, professor, researcher, department chair, senior associate dean, and cancer center director, Dr. Niederhuber has also been the chair of the National Cancer Advisory Board, an external NCI advisor and grant reviewer, and a laboratory investigator supported by NCI and the NIH. He joined NCI in September 2005 as deputy director for translational and clinical sciences, and became NCI's acting director in June 2006.

In addition to his leadership of the NCI, Dr. Niederhuber heads the Laboratory of Tumor and Stem Cell Biology in NCI's Center for Cancer Research, and also holds a clinical appointment on the NIH Clinical Center Medical staff. His lab is studying tissue stem cells as the cell-of-origin for cancer, as well as the complex relationship between tumor cells and their microenvironment.

As a surgeon, Dr. Niederhuber's clinical emphasis is on gastrointestinal cancer, hepatobiliary (liver, bile duct, and gallbladder) cancer, and breast cancer. Recognized for his pioneering work in hepatic artery infusion chemotherapy, he was also the first to demonstrate the feasibility of totally implantable vascular access devices.

Prior to his coming to NCI, Dr. Niederhuber spent his years as Director of the University of Wisconsin School of Medicine Comprehensive Cancer Center, and a professor of surgery and oncology at that same university. Earlier in his career he chaired the Department of Surgery at Stanford University, and held professorships at the Johns Hopkins University School of Medicine and at the University of Michigan.

A native of Steubenville, Ohio, Dr. Niederhuber is a graduate of Bethany College in West Virginia and the Ohio State University School of Medicine.



As NCI supports the full continuum of cancer research, it is crucial that we observe, analyze, understand, and integrate the emerging trends that will determine how *Science Leads the NCI*. *Tracking Advances in 2006* is key to recognizing both the impact of research results and the emergence of new findings and opportunities. Our *Strategic Objectives* allow the Institute to chart a course focused on targeted, collaborative efforts to realize a future free of cancer.

An organization as multi-faceted as the National Cancer Institute requires effective management at a tactical and operational level to implement its research priorities. The following section, *How We Work*, describes NCI's key bioscience infrastructure that enables progress in the National Cancer Program.

NCI is organized into an Office of the Director, two intramural divisions (in-house research) and five extramural divisions (support for research throughout the United States and internationally). This structure serves as the foundation for furthering discovery, development, and delivery, through mechanisms for: investigator initiated research; clinical trials; centers, networks, and consortia; technology development; surveillance and outreach; and career training and development.

The following pages describe how NCI uses its bioscience infrastructure to coordinate and collaborate with the cancer research community, in order to expedite progress against cancer. The proposed NCI budget request reflects this vital, integrated approach.

# How We Work

## **Intramural Research**

A portion of NCI's research dollars supports the work of scientists in the two intramural divisions, the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG), which together comprise the Intramural Research Program (IRP). The IRP is a recognized leader in identifying genetic and environmental determinants of cancer and AIDS. Improved understanding of virology, the study of viruses and the diseases caused by them, will help advance progress against cancer. IRP researchers are able to rapidly translate their discoveries into clinical applications by utilizing the infrastructure provided by the NIH Clinical Center, the largest clinical research hospital in the world. Over the years, NCI's intramural program has produced new drugs and technologies to treat patients with cancer and AIDS as well as improve their quality of life.

### ***A Closer Look— Collaborative Science at NCI***

Nearly two decades ago, researchers at NCI and other institutions began searching for the underlying causes of cervical cancer. That scientific quest led to Food and Drug Administration (FDA) approval of the vaccine Gardasil® this year. Gardasil® protects against infection from the two types of human papillomavirus (HPV) that cause the majority of cervical cancers worldwide.

Population studies conducted in part by NCI helped to establish the link between HPV infections and the disease. The research revealed that while most HPV infections clear on their own and do not lead to cancer, virtually all cases of cervical cancer are caused by HPV infection. NCI scientists then examined ways to boost the body's immune response to prevent the cancer-causing infection. This work led to development of the technology on which the HPV vaccine is based. The vaccine opens a new era in cancer prevention and has the potential to save women's lives, as well as to reduce health disparities in the United States and around the world.

*“NCI's immunology and vaccine research regarding HPV infection is far from finished. We continue to work on improved vaccines and immunization technology, to make these prevention strategies even more effective and accessible to women worldwide.” Dr. John Niederhuber, Director, National Cancer Institute*

## **Extramural Research**

Funding and conducting innovative research are the highest priorities at NCI. The largest allocation of NCI's budget is dedicated to building the capacity of the cancer research enterprise by providing infrastructure, resources, and other support. An essential component of this infrastructure is the NCI Extramural Research Program that supports basic and clinical cancer research in institutions outside of the NIH. The program reaches nearly 650 universities, hospitals, Cancer Centers, and other sites throughout the United States and in more than 20 other countries. Approximately 85 percent of NCI's budget funds extramural research activities.

## **A Closer Look—Support for Extramural Research**

The majority of NCI's extramural funding supports investigator-initiated Research Project Grants (RPGs); in Fiscal Year (FY) 2007, NCI anticipates investing more than \$2.1 billion in support of about 5,000 RPGs. NCI also invests in a significant portfolio of extramural projects solicited through various initiatives. For instance, in FY07 NCI expects to invest more than \$440 million in Specialized Programs of Research Excellence (SPOREs), Cancer Centers, and specialized centers. NCI's extramural budget also supports cancer control, investigator training, health disparities, research collaborations with the private sector, and other types of research and development activities.

Program experts in NCI's Divisions of Extramural Activities (DEA), Cancer Biology (DCB), Cancer Treatment and Diagnosis (DCTD), Cancer Prevention (DCP), and Cancer Control and Population Sciences (DCCPS) guide and administer the NCI investment in extramural biomedical research. Central responsibilities of the DEA involve establishing and disseminating extramural policy, coordinating scientific and merit review, and all aspects of grant development and tracking. DCB and DCTD manage a portfolio of grants, cooperative agreements, and contracts in areas relevant to cancer biology (DCB) and diagnostic/therapeutic cancer interventions (DCTD). DCP supports extramural research focused on cancer prevention, early intervention, symptom management, and supportive care, while DCCPS conducts an integrated program of genetic, epidemiologic, behavioral, social, and surveillance cancer research.



## **Clinical Trials**

**NCI supports over 1,300 clinical trials a year, assisting more than 200,000 patients. NCI convened the Clinical Trials Working Group (CTWG) to identify ways that NCI's national clinical trial enterprise could be restructured in order to realize the promise of molecular medicine. The goal is to markedly advance clinical practice for cancer in the 21st century. Ultimately, the true value of the CTWG's restructuring plan will be demonstrated by measures of whether clinical trial initiatives better promote the development of new therapies, diagnostic procedures, and biomarkers that enhance the specificity with which cancer treatments are delivered.**

### **A Closer Look—*Personalized Treatment Trial for Breast Cancer***

A new NCI clinical trial, the Trial Assigning Individualized Options for Treatment (Rx), dubbed TAILORx, is being hailed by leading breast cancer researchers as an important step toward more individualized treatment of cancer based on factors such as the expression (activity) of specific genes within a patient’s tumor cells. TAILORx is designed to determine whether adjuvant hormonal therapy alone is as effective as adjuvant hormonal therapy in combination with chemotherapy for certain women with early-stage breast cancer. Trial results will help individualize treatment for each breast cancer patient in order to achieve improved clinical outcomes.

The trial will use the results of a new test that measures the expression of 21 genes in tumor samples from women with early-stage invasive breast cancer to assign participants to their treatment regimen. The genomic test used in this trial can more precisely estimate a woman’s risk of cancer recurrence than standard characteristics that doctors normally use to assess



recurrence risk (such as tumor size and grade). The test result is expressed as a “Recurrence Score.” The higher the score, the greater the chance of breast cancer recurrence if a woman is treated with hormone therapy alone. The treatment that patients receive in this trial will depend upon the results of the Recurrence Score.

Although about 90 percent of women with early-stage breast cancer are advised to undergo adjuvant chemotherapy, studies have shown that it decreases recurrence risk in only a small percentage of them. TAILORx could change the way breast cancer is treated, helping to more accurately identify women who are likely to benefit from chemotherapy and those who are not.

### **Centers, Networks, and Consortia**

**The new research paradigm hinges on interdisciplinary science, strategic partnerships, immediate application of new technologies, optimal information sharing, and close links to health care delivery systems. The centers, networks, and consortia created and supported by NCI over the last 12 years**

comprise a model framework to support team science. They also provide a means of fostering coalitions with other cancer research funding organizations, professional societies, business and industry, and local and state governments. Examples of NCI centers, networks, and consortia include:

- > NCI-designated Cancer Centers integrate multidisciplinary research across single or multiple institutions and reach out to the local community with education and other services.
- > Specialized Programs of Research Excellence (SPOREs) focus entirely on discovery-to-delivery research dedicated to specific cancers.
- > Clinical Trial Cooperative Groups and the Community Clinical Oncology Program extend the opportunity for participation in clinical trials to patients treated in the community rather than at Cancer Centers.
- > The SEER (Surveillance, Epidemiology and End Results) network tracks incidence, mortality, and survival.
- > The NCI Community Cancer Centers Program (NCCCP) is a concept designed to work through partnerships with NCI-designated Cancer Centers to improve quality of care.
- > NCI Centers of Excellence connect specialized groups of scientists.

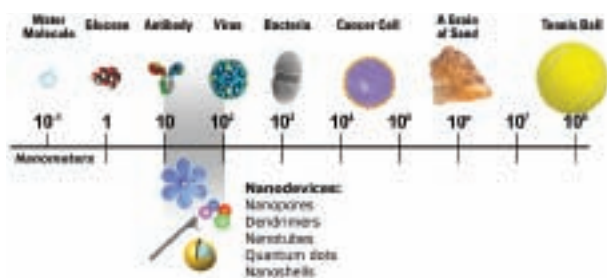
### ***A Closer Look—The Cohort Consortium***

Networks and consortia are geographically dispersed groups that focus on developing or validating new interventions or research in specialty areas. The NCI Cohort Consortium demonstrates the power of pooling biologic samples and resources in a collaborative effort to enhance our understanding of genetic susceptibility to cancer. The consortium combines the long-term investment in biobanks from large cohorts of individuals followed for many years. It applies the power of genome-wide scans on samples from roughly 800,000 individuals to assess 500,000 genetic markers in order to uncover those that determine cancer risk. Groups of toxicologists, developmental biologists, and epidemiologists studied the effects of specific environmental agents and the subsequent risk of hormone-related cancers. These and similar studies have begun to identify genes previously unrecognized as important to cancer susceptibility. Laboratory, clinical, and population researchers are rapidly following-up on these discoveries to elucidate the underlying responsible mechanisms.

## **Technology Development**

**Research over the past three decades has led to significant progress in our understanding of cancer at the genetic, molecular, and cellular levels. As we work to apply these discoveries to cancer prevention, early detection, and management, it is increasingly important to integrate research, science, and technology as effectively as possible. NCI supports a range of studies and projects to pursue the benefits of these combined approaches. Some of these activities are described below.**

**Bioinformatics:** Using powerful information technology, NCI is leading the development of a bioinformatics platform that will enable researchers and clinicians to access and integrate cancer research results across scientific disciplines, populations, and geography. Under the cancer



As an additional example, the width of a human hair is approximately 80,000 nanometers.

Biomedical Informatics Grid™ (caBIG™) umbrella, NCI and a large group of private and public collaborators are building a voluntary network or grid, including common terminology and tools, to connect scientists and institutions into a virtual World Wide Web of cancer research. The overall goal is to speed the delivery of innovative approaches for preventing and treating cancer, including increased mutually beneficial flow of bench-to-bedside interactions.

**Cancer Imaging:** Imaging methods are being combined with emerging technologies such as nanotechnology, proteomics, and high throughput screening to identify cancers earlier and help assess the effectiveness of therapy. Imaging informatics brings cancer imaging data to research and clinical environments more efficiently and effectively. Image-guided cancer intervention is a rapidly evolving area that may be used to cure some cancers and precancerous lesions, and also to provide minimally invasive, well-tolerated palliative treatments. As our knowledge of the molecular basis of cancer increases, molecular imaging methods are providing researchers with powerful discovery tools and clinicians with telling biomarkers for cancer risk and treatment efficacy.

**Proteomics:** Evidence suggests that measurements of proteins and peptides circulating in the blood may represent reliable indicators of early-stage cancer. Proteins serve complex and diverse functions in the body, from giving structure to our cells to regulating processes such as digestion, breathing, and the growth rate of cells. When proteins fail to function properly, normal body processes can go awry. For example, errors in proteins that regulate when and how fast cells reproduce, as well as the timing of cell death, can result in cancer. One of the goals in cancer research is to develop technologies that measure and evaluate these abnormal proteins with enough accuracy to be used as cancer diagnostic blood tests.

**Nanotechnology:** Nanotechnology offers researchers a paradigm-changing opportunity to study and interact with both normal and cancer cells at molecular and cellular scales. For reference, 8 to 10 atoms span one nanometer; the human hair is approximately 70,000 to 80,000 nanometers thick. Increasing abilities to perform research at this nano level will enhance cancer diagnosis and treatment. For example, imaging agents and diagnostics designed with nanoscale precision will optimize their usefulness and function and allow clinicians to detect cancer in its earliest, most treatable stage. Multifunctional, targeted devices capable of bypassing biological barriers will



enhance our ability to effectively and efficiently treat cancer by delivering multiple therapeutic agents at high concentrations—and with physiologically appropriate timing—directly to cancer cells. In preclinical studies, nanotech-based cancer treatments are demonstrating increased efficacy and significant decreases in life-threatening side effects.

### **A Closer Look—*Nanotechnology Characterization Laboratory***

NCI is engaged in efforts to harness the power of nanotechnology to radically change the way we detect, diagnose, treat, and prevent cancer. NCI has established the Nanotechnology Characterization Laboratory (NCL) at its NCI-Frederick facility to provide critical infrastructure support to this rapidly developing field.

The NCL is an effective scientific collaboration between three Federal agencies: NCI, Food and Drug Administration (FDA), and the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce. Scientists from each agency bring critical knowledge, experience, and skills to the new laboratory setting. NCI brings expertise in the biomedical research arenas necessary for the biological and chemical characterization of the nanoparticles and devices. FDA brings a strong and standardized model for evaluating diagnostics, a new integrated program for regulating diagnostic devices, and initial exploratory methods for evaluating multiple complex technologies for their possible use in drug development. NIST provides expertise in determining the best measurement tools, protocols, and analysis algorithms for physically characterizing nanoparticles.

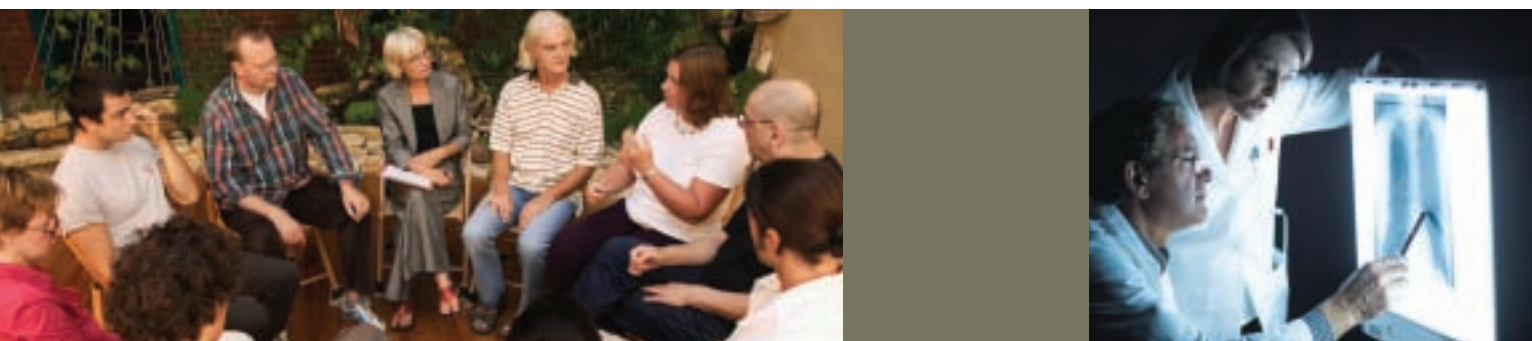
The NCL enables researchers to develop their nanotechnology concepts into clinical applications by characterizing the material's properties as they relate to biological systems. Tests developed by the NCL and its partners will be codified and then distributed as a “gold standard” for academic, industry, and government laboratories. The NCL will serve as a national resource and knowledge base for cancer researchers to aid the regulatory review of nanotechnologies intended for cancer therapies and diagnostics. By providing the critical infrastructure and characterization services to nanomaterial providers, the NCL can accelerate the translation of basic nanoscale particles and devices into clinical applications.

### **Surveillance and Outreach**

**Cancer surveillance provides quantitative measures of the burden of cancer and the impact of cancer control in the general population. Moreover, the national cancer registry system in the United States provides a powerful tool for cancer research. The system is comprised of interdependent Federal, state, and private sector programs and provides surveillance data on all cancers. NCI and other Federal agencies help support cancer registries in all 50 states, the District of Columbia, and several United States territories. NCI is working with multiple partners to better integrate surveillance data into cancer control planning. This use of cancer surveillance to help guide resource allocation is essential to reducing the cancer burden in all populations.**



**Outreach through cancer communication empowers people: it can raise their awareness of health problems and help them make informed cancer-related decisions. Effective cancer communications are targeted to users' needs across the cancer continuum — prevention, detection and diagnosis, treatment, survivorship, and end-of-life issues. Changes in the role and accessibility of this information are continually altering health care practices, patient-physician relationships, and the way patients acquire and use information. Besides consulting their physicians, many consumers now seek health information from Internet and other media sources, which can vary in quality and reliability. NCI is working to ensure that everyone has ready access to timely, reliable, understandable information that is also culturally appropriate.**



### **A Closer Look — *NCI Outreach***

NCI launched the Centers of Excellence in Cancer Communications Research (CECCR) initiative in 2003. CECCR provides the infrastructure for interdisciplinary teams at four centers to promote advances in cancer communications, develop interventions, translate theory into practice, and train health communicators. Their recent work includes:

- > The University of Michigan's "Guide to Decide" project is exploring ways of communicating risk about using tamoxifen for breast cancer prevention to women at high risk for the disease across all sociodemographic groups.
- > The University of Pennsylvania is studying cancer-related information searching and scanning behavior in the general population, assessing associations with post-diagnosis treatment choices or cancer screening and prevention behavior.
- > The Saint Louis University Ozioma News Service project is developing and testing a computer-based news service that will contribute community-specific stories and cancer data to local Black newspapers.
- > The University of Wisconsin-Madison is examining whether Comprehensive Health Enhancement Support Systems that create "healing relationships" for patients over time improve cancer outcomes and survivorship experiences. This project supports the Institute of Medicine goal to improve health outcomes for patients with chronic conditions.

## Training and Career Development

Rapid developments on the frontiers of science and technology, including molecular biology and translational medicine, have broadened the scope of cancer research and have presented new challenges for training future cancer researchers in diverse disciplines. NCI devotes approximately four percent of its annual budget and multiple strategies to preparing the next generation of cancer researchers for challenges that increasingly are multidisciplinary and span basic, clinical, behavioral, and applied research. Each year, we provide cancer research training and career development opportunities to more than 2,000 graduate students, postdoctoral fellows, and oncologists. Some of this training takes place on the NIH campus, but most occurs in universities and teaching hospitals across the United States.

All sponsored traineeships are intended to increase the number of scientists who specialize in the basic or clinical biomedical research fields. We invest in training to support the use of advanced technologies and provide career opportunities to equip scientists to address cancer in underserved populations. We foster development of interdisciplinary teams of scientists to carry out critical translational research. These investments will ensure a steady flow of well-trained investigators to focus on the challenges of fighting cancer.

### *A Closer Look—A Researcher's Story*

NCI training and career development experiences provided a young investigator with the background and resources that facilitated a notable cancer scientific advance. The Principal Investigator and his team were able to generate mice that develop pancreatic cancer that mimics the human disease. They then isolated a molecular signature in the blood serum of these mice that reliably predicts the presence of early pancreatic cancer. This new mouse model has helped to advance the work of other researchers studying the development, detection, and treatment of pancreatic cancer.

NCI mechanisms of support for the investigator included funding through the Medical Scientist Training Program for his sub-specialization in medical oncology. He was able to advance his mouse model research through an NCI fellowship training grant, and as a result of his success he has received additional funding to continue his investigation in this promising area.

*“I have always been attracted to illnesses that had few efficacious treatments, and pancreatic cancer is at the top of my short list. Finding the right environment to start your career is the most important thing. Sufficient funding is required from the beginning.”* NCI-funded investigator

## **Cancer in America — *What the Statistics Tell Us***

Although the nation's investment in cancer research is making a difference in the lives of Americans every day, cancer remains one of our most urgent health concerns and the disease many fear most. The lifetime risk for developing cancer is one in two for men, and one in three for women. Nearly 1.4 million new cancer cases will be diagnosed this year and more than a half million people will die of the disease. In 2005, the economic burden of cancer to the nation was estimated to be over \$200 billion.



Progress has been made toward our goal of reducing the many types of cancer burden in the United States. Overall cancer mortality continues the gradual decline that began in the early 1990s. The number of deaths from some of the most common cancers — colorectal, breast, and prostate continues to decrease. These trends reflect effective prevention and risk reduction interventions, better screening and early detection methods, and improved treatment and medical management.

Today, approximately 10 million people are alive with a history of cancer, and with a better quality of life than was possible years ago. More than two-thirds of people diagnosed with cancer can expect to live for five

years or longer. For children diagnosed with cancer, five-year overall survival exceeds 75 percent. Increasingly, with new imaging techniques and the identification of novel biomarkers, we are finding cancers at earlier, more curable stages, and are able to predict clinical outcomes. Improved diagnostic tools are advancing individualized, tailored therapy, while newly discovered molecular targets are transforming the way we develop interventions.

## **NCI Tracks Cancer Trends and Progress:**

### **Annual Report to the Nation on the Status of Cancer**

First issued in 1998, this publication is a collaborative effort of the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), NCI, and the North American Association of Central Cancer Registries (NAACCR). The publication provides updated information on cancer rates and trends in the United States. NCI's SEER databases are a major source of information.

### **Cancer Trends Progress Report**

This is a biannual NCI electronic publication about our nation's progress against cancer, including prevention, early detection, diagnosis, treatment, life after cancer, and end of life. The information is gathered through a collaborative effort with other key agencies and groups, such as CDC and the ACS. The report was first issued in 2001 and will be updated again in 2007.

### **Surveillance, Epidemiology, and End Results (SEER) Program**

The NCI SEER program currently collects and publishes cancer incidence and survival data from 14 population-based cancer registries and three supplemental registries covering approximately 26 percent of the U.S. population.

### **NCI Cancer Bulletin**

The NCI Cancer Bulletin is a weekly online publication that provides updates on NCI activities, the research and clinical trials funded by the Institute, and other activities of both the U.S. and international cancer communities.

This budget request consists of two components: (1) the increase required to maintain our present level of operations or “Current Services” and (2) the increases required to expand existing initiatives. The Current Services increase is the amount that will be required to sustain NCI programs and provide for some minimal growth. Noncompeting Research Project Grants (RPGs) would be funded at committed levels, the success rate for competing RPGs would be maintained at its current rate, there would be a small growth in the number of Cancer Centers, and most other mechanisms would receive sufficient increases to cover cost of living adjustments based on the Biomedical Research and Development Price Index (BRDPI). This budget level also includes funds to make critically needed capital repairs and improvements at the NCI-Frederick Federally Funded Research and Development Center. The funds needed to expand existing initiatives are add-ons to the Current Services level. These funds are distributed by budget mechanism in the column labeled “Additional Resources” on the following page.

**At a Glance\***

(dollars in thousands)

<b>Fiscal Year 2007 Estimate</b>	<b>\$4,696,227</b>
<b>Current Services Increase</b>	<b>282,998</b>
<b>Subtotal</b>	<b>4,979,225</b>
<b>Fiscal Year 2008 Additional Resources</b>	
Increase Success Rate for Research Project Grants	277,000
Expanding Cancer Center Research	77,000
Linking Science and Technology	170,000
Integrating Science through Interdisciplinary Teams	196,000
Cancer Clinical Trials	100,000
<b>Subtotal</b>	<b>820,000</b>
<b>Total NCI</b>	<b>5,799,225</b>

\* Does not include the NCI contribution to the NIH Roadmap.

# NCI Budget Request for Fiscal Year 2008

# Fiscal Year 2008 National Cancer Institute Professional Judgement Budget Request

(dollars in thousands)	FY 2006 Estimate	FY 2007 Estimate
<b>Research Grants</b>		
<b>Research Project Grants</b>		
Noncompeting	\$ 1,621,004	\$ 1,594,683
Administrative Supplements	50,461	48,655
Competing	412,596	416,945
Subtotal	2,084,061	2,060,283
SBIR/STTR	94,611	93,735
<b>Subtotal, RPG</b>	<b>2,178,672</b>	<b>2,154,018</b>
<b>Research Centers and SPOREs</b>	<b>463,510</b>	<b>446,818</b>
<b>Other Research</b>		
Research Careers	78,044	76,657
Cancer Education	36,134	33,806
Cooperative Clinical Research	146,326	139,302
Biomedical Research Support	—	—
Minority Biomedical Research Support	3,316	3,116
Other	61,446	41,261
<b>Subtotal, Other Research</b>	<b>325,266</b>	<b>294,142</b>
<b>Total Research Grants</b>	<b>2,967,448</b>	<b>2,894,978</b>
<b>National Research Service Awards</b>	<b>69,492</b>	<b>66,279</b>
<b>Research &amp; Development Contracts</b>	<b>324,420</b>	<b>330,441</b>
<b>Intramural Research</b>	<b>677,724</b>	<b>696,263</b>
<b>Research Management &amp; Support</b>	<b>193,421</b>	<b>183,246</b>
<b>Cancer Prevention &amp; Control</b>	<b>506,805</b>	<b>517,100</b>
<b>Construction</b> (Capital Improvements)	—	—
<b>Buildings &amp; Facilities</b>	<b>7,920</b>	<b>7,920</b>
<b>Subtotal, NCI</b>	<b>4,747,230</b>	<b>4,696,227</b>
<b>NCI's Roadmap Contribution†</b>	<b>42,834</b>	<b>57,382</b>
<b>Total, NCI</b>	<b>4,790,064</b>	<b>4,753,609</b>

† Roadmap estimate for FY 2008

## Research Project Grants

RPGs are the primary funding mechanisms for extramural research and comprise the largest part of the NCI budget. We provide about 5,000 RPGs each year to nearly 600 institutions across the United States at an average cost of \$400,000 per grant.

## SBIR/STTR

Small Business Innovation Research (SBIR) awards support projects that may ultimately have commercial viability. The government-wide Small Business Technology Transfer (STTR) program promotes technology transfer by helping investigators form public/private partnerships.

## Research Centers and SPOREs

NCI-designated Cancer Centers serve as hubs for cutting-edge research, quality cancer care, and community outreach. Centers of Excellence like the SPOREs use flexible funding to investigate specific focus areas and move research quickly from the laboratory to the patient.

## Other Research

Other funding mechanisms support the education and training of cancer investigators, Clinical Cooperative Research grants for large-scale, multi-institutional clinical trials, and Resource-Related Research Project grants to increase the availability of research resources.

Current Services Increase	Fiscal Year 2008			% Inc Over FY 2007 Estimate
	Current Services	Additional Resources	Total Bypass	
\$ (36,851)	\$ 1,557,832	\$ 0	\$ 1,557,832	(2.3%)
1,849	50,504	—	50,504	3.8%
152,055	569,000	354,000	923,000	121.4%
117,053	2,177,336	354,000	2,531,336	22.9%
3,562	97,297	21,000	118,297	26.2%
<b>120,615</b>	<b>2,274,633</b>	<b>375,000</b>	<b>2,649,633</b>	<b>23.0%</b>
<b>22,979</b>	<b>469,797</b>	<b>199,000</b>	<b>668,797</b>	<b>49.7%</b>
4,913	81,570	37,000	118,570	54.7%
1,285	35,091	—	35,091	3.8%
5,293	144,595	46,000	190,595	36.8%
—	—	—	—	0.0%
118	3,234	—	3,234	3.8%
1,568	42,829	7,000	49,829	20.8%
<b>13,177</b>	<b>307,319</b>	<b>90,000</b>	<b>397,319</b>	<b>35.1%</b>
<b>156,771</b>	<b>3,051,749</b>	<b>664,000</b>	<b>3,715,749</b>	<b>28.4%</b>
<b>3,519</b>	<b>69,798</b>	<b>6,000</b>	<b>75,798</b>	<b>14.4%</b>
<b>12,557</b>	<b>342,998</b>	<b>78,000</b>	<b>420,998</b>	<b>27.4%</b>
<b>26,458</b>	<b>722,721</b>	<b>25,000</b>	<b>747,721</b>	<b>7.4%</b>
<b>6,963</b>	<b>190,209</b>	<b>11,000</b>	<b>201,209</b>	<b>9.8%</b>
<b>19,650</b>	<b>536,750</b>	<b>36,000</b>	<b>572,750</b>	<b>10.8%</b>
<b>30,000</b>	<b>30,000</b>	—	<b>30,000</b>	<b>100.0%</b>
<b>27,080</b>	<b>35,000</b>	—	<b>35,000</b>	<b>341.9%</b>
<b>282,998</b>	<b>4,979,225</b>	<b>820,000</b>	<b>5,799,225</b>	<b>23.5%</b>
—	<b>66,563</b>	—	<b>66,563</b>	<b>16.0%</b>
<b>282,998</b>	<b>5,045,788</b>	<b>820,000</b>	<b>5,865,788</b>	<b>23.4%</b>

#### National Research Service Awards

Individual NRSA's enable experienced scientists to enhance and expand their research knowledge and skills. Institutional NRSA's support predoctoral and postdoctoral training at qualified institutions.

#### Research & Development Contracts

Research and development contracts are used for various NCI research programs including drug development, technology advancement, and epidemiology.

#### Intramural Research

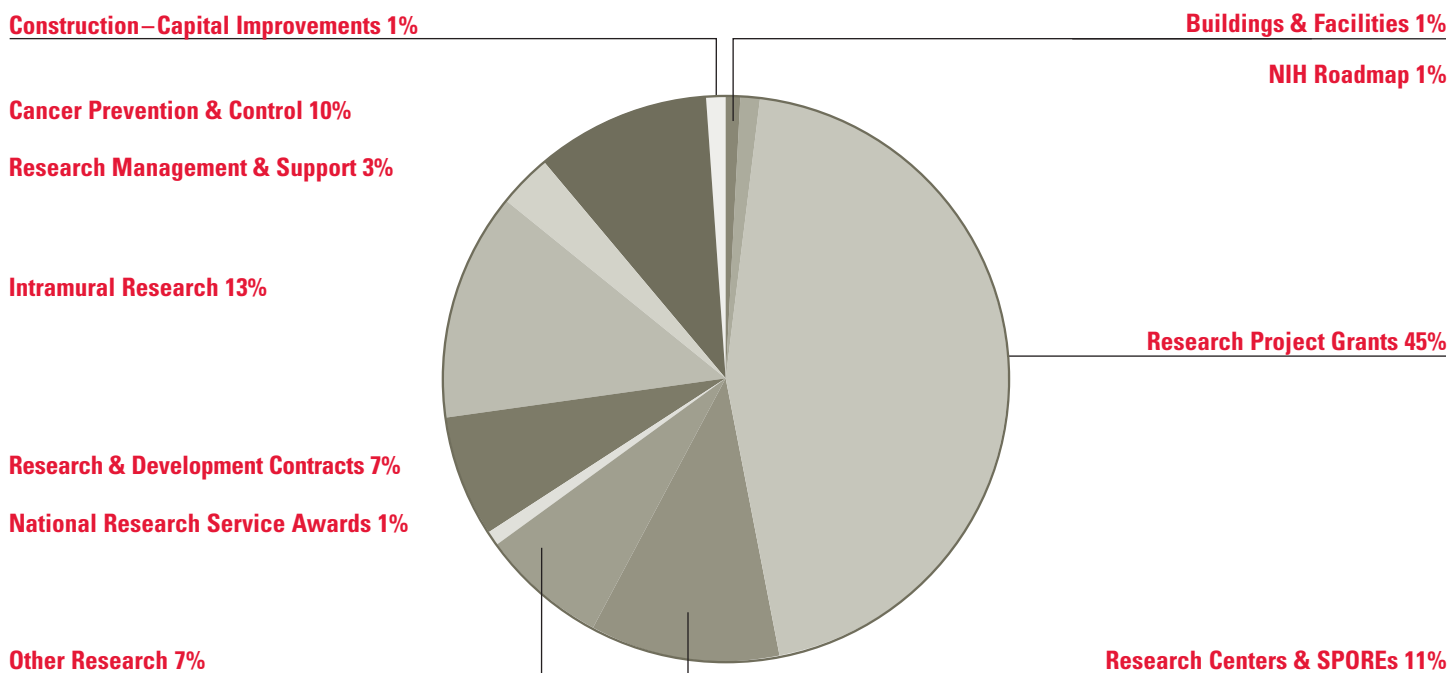
The NCI intramural research program provides a uniquely interactive, interdisciplinary environment for basic laboratory and long-term epidemiologic and genetics studies and their rapid translation to intervention development and clinical testing.

#### Research Management & Support

Research management and support funds are used for technical and administrative services including central administration, overall program direction, grant and contract administration, human resources, program coordination, and financial management.



## Distribution of Fiscal Year 2008 Budget Request (\$5,865,788,000)



### Cancer Prevention & Control

Cancer prevention and control funds are used to support research, communication, and other activities to reduce cancer risk, incidence, morbidity, and mortality and improve the quality of life for cancer patients.

### Construction (Capital Improvements)

The NCI capital improvements program supports the creation of additional state-of-the-art laboratories and clinics for basic and applied research including biorepositories, imaging, and bioinformatics facilities.

### Buildings & Facilities

NCI's building and facilities program supports repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

## Links to Additional Information

### Cancer Information

National Cancer Institute  
<http://www.cancer.gov>

*Searchable for programs or terms from this document*

NCI Cancer Information Service  
<http://cis.nci.nih.gov/>

*Specialists provide cancer information to patients, families, caretakers, and the public, at no charge*

Also by phone: 1-800-4-CANCER  
(1-800-422-6237)

And TDD: 1-800-332-8615

Cancer News  
<http://www.cancer.gov/newscenter>

NCI Cancer Bulletin  
<http://www.cancer.gov/ncicancerbulletin>

Cancer Topics  
<http://www.cancer.gov/cancertopics/>

NCI Fact Sheets  
<http://www.cancer.gov/cancertopics/factsheet>

Cancer Mortality Maps and Graphs  
<http://www.cancer.gov/atlasplus>

Surveillance, Epidemiology, and End Results  
<http://seer.cancer.gov>

### NCI Planning and Priority Setting

This document online  
<http://plan.cancer.gov>

Office of Science Planning and Assessment  
<http://planning.cancer.gov/>

The NCI Strategic Plan for Leading the Nation  
<http://strategicplan.nci.nih.gov/>

### Cancer Research Portfolio and Funding

NCI Cancer Research Portfolio  
<http://researchportfolio.cancer.gov>

International Research Portfolio  
<http://www.cancerportfolio.org>

NCI Research and Funding  
<http://www.cancer.gov/researchandfunding>

Centers, Networks, and Consortia  
NCI Cancer Centers Program  
<http://www.cancer.gov/cancercenters>

Specialized Programs of Research Excellence  
<http://spores.nci.nih.gov>

Early Detection Research Network  
<http://edrn.nci.nih.gov>

Mouse Models of Human Cancer Consortium  
<http://emice.nci.nih.gov/>

Cancer Care Outcomes Research and Surveillance (CanCORS) Consortium  
<http://healthservices.cancer.gov/cancors>

### Clinical Trials

Community Clinical Oncology Program  
<http://www.cancer.gov/prevention/ccop/>

Cancer Therapy Evaluation Program  
<http://ctep.cancer.gov/>

Cancer Trials Support Unit  
<http://www.ctsu.org>

Clinical Trials Working Group  
<http://integratedtrials.nci.nih.gov/ict/>

NIH Clinical Center  
<http://clinicalcenter.nih.gov>

Clinical Studies Support Center (CSSC)  
<http://ccr.cancer.gov/trials/cssc/staff/services.asp>

NCI Clinical Trials  
<http://www.cancer.gov/clinicaltrials>

Technology Development & Cancer  
Cancer Genome Atlas  
<http://www.genome.gov/17516564>

NCI Alliance for Nanotechnology in Cancer  
<http://nano.cancer.gov>

cancer Biomedical Informatics Grid™  
<https://cabig.nci.nih.gov>

Office of Technology and Industrial Relations  
<http://otir.cancer.gov>

Cancer Imaging Programs  
<http://imaging.cancer.gov/>

Education, Input, and Outreach  
Office of Education and Special Initiatives  
<http://cancer.gov/aboutnci/oesi>

Office of Liaison Activities  
<http://ola.cancer.gov>

NCI Advisory Boards  
<http://deainfo.nci.nih.gov/advisory/boards.htm>

### Ordering Copies of this Document

*By email:* [cisocc@pop.nci.nih.gov](mailto:cisocc@pop.nci.nih.gov)

*By phone:* 1-800-4-CANCER

*By fax:* 301-330-7968

*By internet:*

<http://www.cancer.gov/publications>

The National Cancer Institute is one of the 27 Institutes, Centers, and Offices of the National Institutes of Health (<http://www.nih.gov>). NIH is a Federal Government agency in the U.S. Department of Health and Human Services (<http://www.hhs.gov>)

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*Note: A number of contributors provided support in several areas but are listed only once due to space constraints.*

Each year, as mandated by the National Cancer Act of 1971 (Public Law 92-218), the National Cancer Institute (NCI) prepares a plan and budget proposal outlining the nation's investment in research accomplishments and opportunities to decrease the burden of cancer. Although a document this size can convey only a cross-section of the National Cancer Program, it covers broad trends, concrete strategies, and examples of specific projects to provide vital support for the most promising research progress and its translation to people's health.

Congress mandated that NCI "prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the National Cancer Program". Because its content is relevant to all whose lives are affected by cancer, as well as to others whose health or illness is impacted by NCI's biomedical discoveries and groundbreaking tools, this document is also valuable to many other groups. Its audiences include: the research community; healthcare professionals and their organizations; advisory groups; information, education, and advocacy organizations; policy makers in both public agencies and private industry; and concerned citizens across the country.



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