

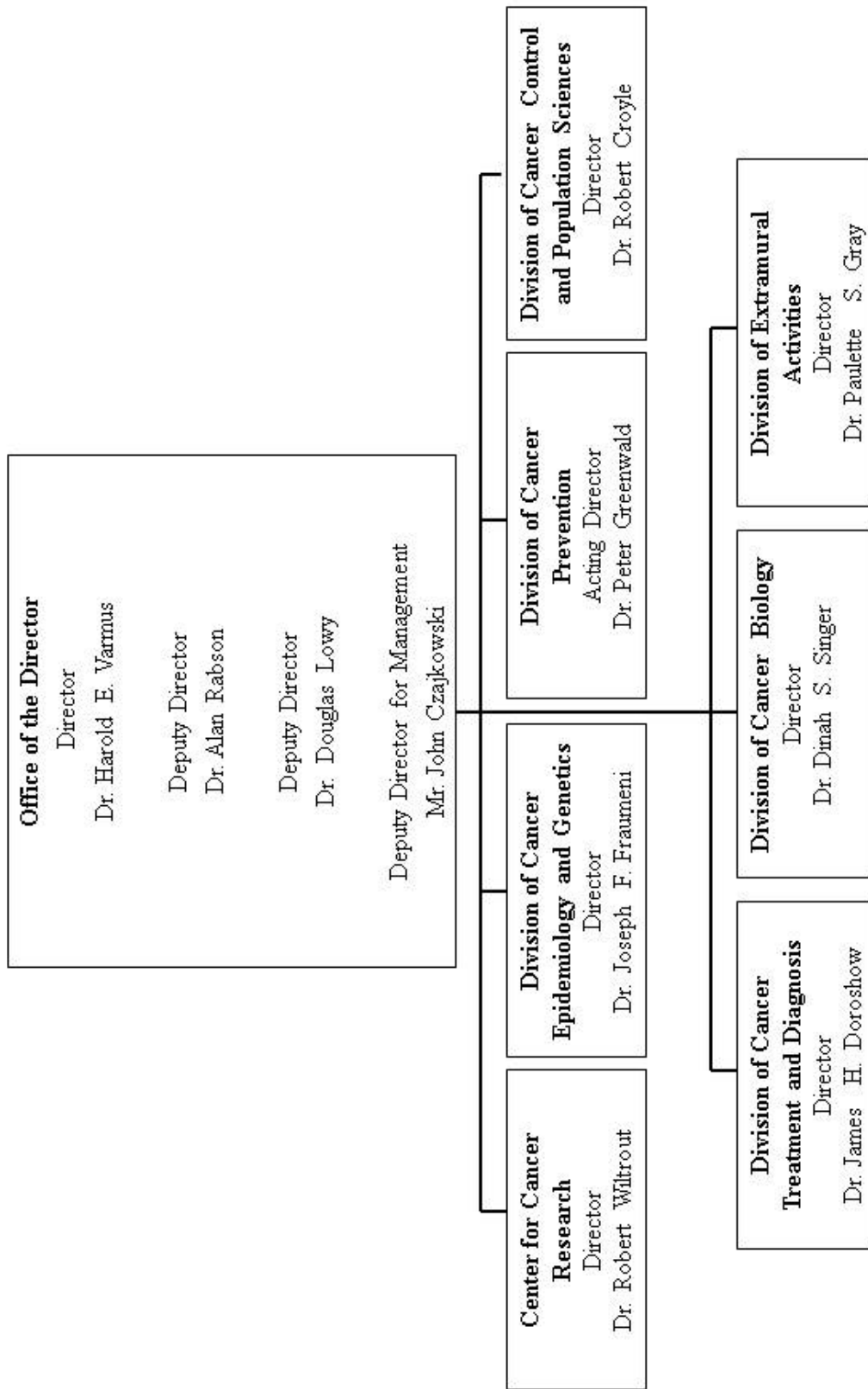
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

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NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
Organization Chart



NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

For carrying out Section 301 and title IV of the Public Health Service Act with respect to cancer, \$5,196,136,000, of which up to \$8,000,000 may be used for facilities repairs and improvements at the National Cancer Institute-Frederick Federally Funded Research and Development Center in Frederick, Maryland.

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Amounts Available for Obligation ¹
(Dollars in Thousands)

Source of Funding	FY 2010 Actual	FY 2011 CR	FY 2012 PB
Appropriation	5,103,388	5,103,388	5,196,136
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	5,103,388	5,103,388	5,196,136
Real transfer under Director's one-percent transfer authority (GEI)	(4,459)	0	0
Real transfer under Secretary's one-percent transfer authority	(760)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(1,802)	(4,341)	0
Comparative transfer under Director's one-percent transfer authority (GEI)	4,459	0	0
Comparative transfer under Secretary's one-percent transfer authority	0	0	0
Subtotal, adjusted budget authority	5,100,826	5,099,047	5,196,136
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	5,100,826	5,099,047	5,196,136
Unobligated balance lapsing	(22)	0	0
Total obligations	5,100,804	5,099,047	5,196,136

¹ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2010 - \$18,738 FY 2011 - \$20,000 FY 2012 - \$20,000

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
Budget Mechanism- Total ^{1/}
(Dollars in Thousands)

MECHANISM	FY 2010 Actual		FY 2011 CR		FY 2012 PB		Change vs. FY 2010	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	3,615	\$1,534,670	3,755	\$1,711,914	3,676	\$1,726,389	61	\$191,719
Administrative Supplements	252	27,940	297	25,940	297	25,940	45	(2,000)
Competing:								
Renewal	310	161,217	228	141,217	228	141,217	(82)	(20,000)
New	940	353,890	869	319,784	983	372,968	43	19,078
Supplements	3	1,491	3	1,491	3	1,491	0	0
Subtotal, Competing	1,253	\$516,598	1,100	\$462,492	1,214	\$515,676	(39)	(\$922)
Subtotal, RPCs	4,868	\$2,079,208	4,855	\$2,200,346	4,890	\$2,268,005	22	\$188,797
SBIR/STIR	207	\$85,669	205	\$84,660	205	\$87,160	(2)	\$1,491
Research Project Grants	5,075	\$2,164,877	5,060	\$2,285,006	5,095	\$2,355,165	20	\$190,288
<u>Research Centers</u>								
Specialized/Comprehensive	250	\$611,134	246	\$565,133	246	\$565,133	(4)	(\$46,001)
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	250	\$611,134	246	\$565,133	246	\$565,133	(4)	(\$46,001)
<u>Other Research</u>								
Research Careers	452	\$74,914	444	\$73,914	444	\$73,914	(8)	(\$1,000)
Cancer Education	91	35,444	89	34,944	89	34,944	(2)	(500)
Cooperative Clinical Research	131	254,487	131	254,487	131	254,487	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	466	0	466	0	466	0	0
Other	153	77,301	150	73,801	150	73,801	(3)	(3,500)
Other Research	827	\$442,612	814	\$437,612	814	\$437,612	(13)	(\$5,000)
Total Research Grants	6,152	\$3,218,623	6,120	\$3,287,751	6,155	\$3,357,910	3	\$139,287
<u>Research Training</u>								
Individual Awards	<u>FTIPs</u> 211	\$9,270	<u>FTIPs</u> 211	\$9,460	<u>FTIPs</u> 211	\$9,840	0	\$570
Institutional Awards	1,217	58,294	1,217	59,484	1,217	61,834	0	3,540
Total Research Training	1,428	\$67,564	1,428	\$68,944	1,428	\$71,674	0	\$4,110
Research & Development Contracts <i>(SBIR/STTR)</i>	470	\$620,381	450	\$568,672	450	\$580,972	(20)	(\$39,409)
	<i>71</i>	<i>\$25,020</i>	<i>71</i>	<i>\$25,520</i>	<i>71</i>	<i>\$25,520</i>	<i>0</i>	<i>(\$500)</i>
Intramural Research	<u>FIEs</u> 1,934	\$805,221	<u>FIEs</u> 1,937	\$790,721	<u>FIEs</u> 1,937	\$798,721	<u>FIEs</u> 3	(\$6,500)
Research Management and Support	1,122	381,117	1,124	375,039	1,124	378,939	2	(2,178)
Construction		0		0		0		0
Buildings and Facilities		7,920		7,920		7,920		0
Total, NCI	3,056	\$5,100,826	3,061	\$5,099,047	3,061	\$5,196,136	5	\$95,310

1/ All items in italics are "non-adds"; items in parenthesis are subtractions

Major Changes in the Fiscal Year 2012 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2012 budget request for the National Cancer Institute, which is \$95.310 million more than the FY 2010 level, for a total of \$5,196.136 million.

Research Project Grants (RPGs; +\$188.797 million; total \$2,268.005 million): NCI will continue to support competing RPGs – 1,214 awards in FY 2012, a decrease of 39 awards from FY 2010. A total of 3,676 noncompeting awards, totaling \$1,726.389 million also will be made in FY 2012. The noncompeting amount increases by \$191.719 million.

Research Centers (-\$46.001 million; total \$565.133 million): NCI will identify savings and reductions in Centers, Specialized Programs of Research Excellence (SPOREs) and Specialized Centers in order to award more RPGs.

R&D Contracts (-\$39.409 million; total \$580.972 million): NCI will identify savings and reductions in R&D Contracts in order to award more RPGs.

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
Summary of Changes
(Dollars in Thousands)

FY 2010 Actual				\$5,100,826
FY 2012 Estimate				5,196,136
Net change				\$95,310
CHANGES	2012 Estimate		Difference Between FY 2010 Actual & FY 2012 Estimate	
	FTEs	Amount	FTEs	Amount
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2010 and January 2011 pay increase		\$324,264		\$1,954
b. January FY 2012 pay increase		324,264		0
c. One less day of pay (n/a for 2011)		324,264		(1,252)
d. Payment for centrally furnished services		117,904		1,167
e. Increased cost of laboratory supplies, materials, and other expenses		356,553		3,485
Subtotal				\$5,354
2. Research Management and Support:				
a. Annualization of January 2010 and January 2011 pay increase		\$169,256		\$1,020
b. January FY 2012 pay increase		169,256		0
c. One less day of pay (n/a for 2011)		169,256		(654)
d. Payment for centrally furnished services		32,407		321
e. Increased cost of laboratory supplies, materials, and other expenses		177,276		1,730
Subtotal				\$2,417
Subtotal, Built-in				\$7,771

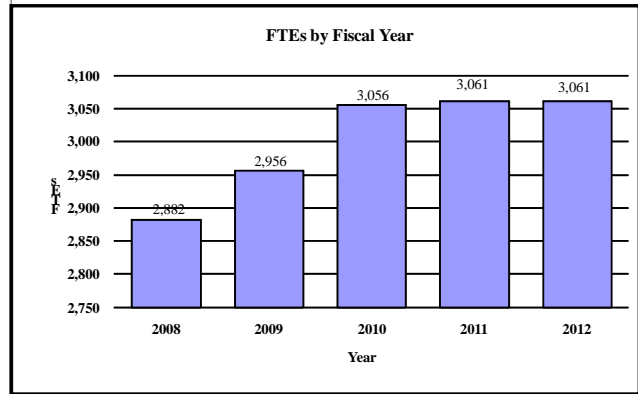
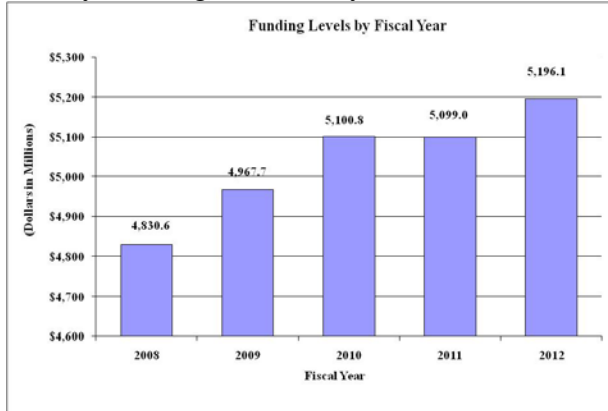
**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Summary of Changes--continued

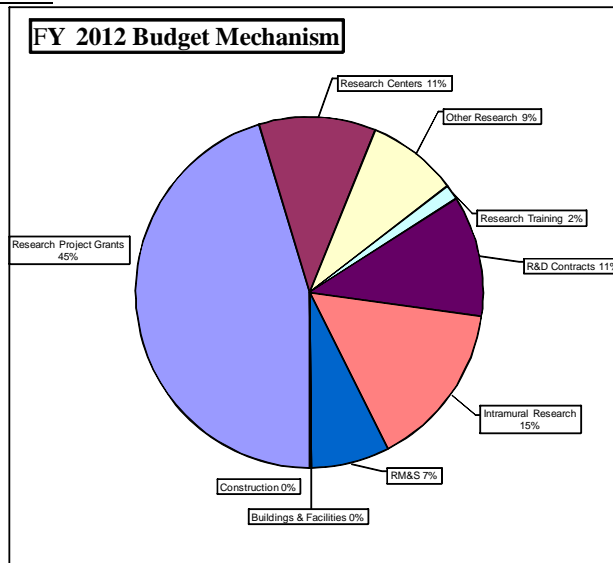
CHANGES	2012 Estimate		Difference Between FY 2010 Actual & FY 2012 Estimate	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	3,676	\$1,752,329	61	\$189,719
b. Competing	1,214	515,676	(39)	(922)
c. SBIR/STTR	205	87,160	(2)	1,491
Total	5,095	\$2,355,165	20	\$190,288
2. Research Centers	246	\$565,133	(4)	(\$46,001)
3. Other Research	814	437,612	(13)	(5,000)
4. Research Training	1,428	71,674	0	4,110
5. Research and development contracts	450	580,972	(20)	(39,409)
Subtotal, Extramural		\$4,010,556		\$103,988
6. Intramural Research	<u>FTEs</u> 1,937	\$798,721	<u>FTEs</u> 3	(\$11,854)
7. Research Management and Support	1,124	378,939	2	(4,595)
8. Construction		0		0
9. Buildings and Facilities		7,920		0
Subtotal, program	3,061	\$5,196,136	5	\$87,539
Total	3,061	\$5,196,136	5	\$95,310

Budget Graphs

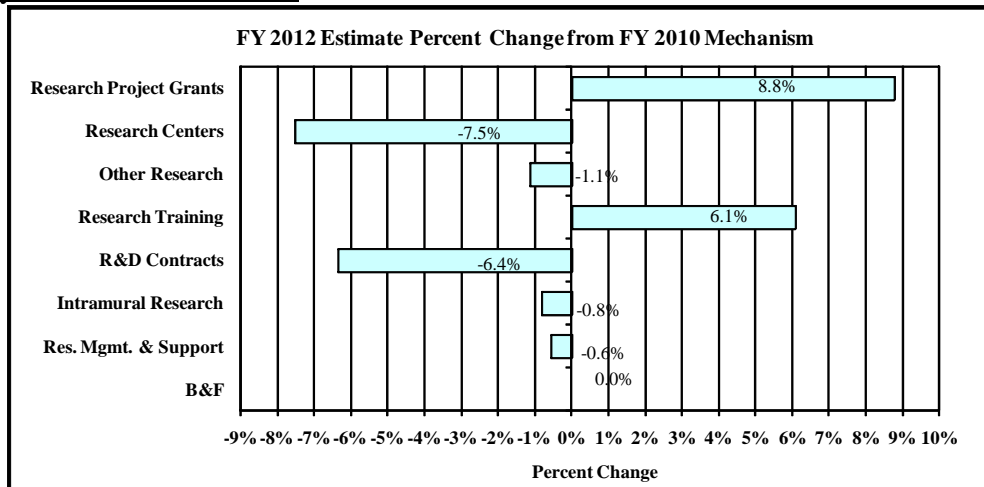
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Cancer Institute
Budget Authority by Activity
(Dollars in thousands)

	FY 2010 Actual		FY 2011 CR		FY 2012 PB		Change vs. FY 2010	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<u>Extramural Research</u>								
<u>Detail:</u>								
Understanding the Mechanisms of Cancer		\$803,599		\$827,537		\$831,086		\$27,487
Understanding the Causes of Cancer		1,232,577		1,239,121		1,284,331		51,754
Improve Early Detection and Diagnosis		436,930		436,207		454,727		17,797
Develop Effective and Efficient Treatments		1,247,541		1,263,781		1,282,432		34,891
Cancer Prevention and Control		229,033		226,951		232,045		3,012
Cancer Centers		584,187		544,689		544,124		-40,063
Research Workforce Development		177,922		177,802		180,532		2,610
Buildings and Facilities		7,920		7,920		7,920		0
Subtotal, Extramural*		\$4,719,709		\$4,724,008		\$4,817,197		\$97,488
Intramural Research	1,934	\$805,221	1,937	\$790,721	1,937	\$798,721	3	(\$6,500)
Research Management & Support	1,122	\$381,117	1,124	\$375,039	1,124	\$378,939	2	(\$2,178)
TOTAL	3,056	\$5,100,826	3,061	\$5,099,047	3,061	\$5,196,136	5	\$95,310

1. Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research.

2. Includes Real Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

*The detail programs listed above include both extramural and intramural funding.

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2011 Amount Authorized	FY 2010 Estimate	2012 Amount Authorized	FY 2012 PB
Research and Investigation	Section 301	42§241	Indefinite	\$5,100,826,000	Indefinite	\$5,196,136,000
	Section 401(a)	42§281	Indefinite		Indefinite	
National Cancer Institute						
Total, Budget Authority				\$5,100,826,000	\$5,196,136,000	

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2003	\$4,673,510,000	\$4,673,510,000	\$4,642,394,000	\$4,622,394,000
Rescission				(\$30,046,000)
2004	\$4,770,519,000	\$4,770,519,000	\$4,770,519,000	\$4,770,519,000
Rescission				(\$31,264,000)
2005	\$4,870,025,000	\$4,870,025,000	\$4,894,900,000	\$4,865,525,000
Rescission				(\$40,267,000)
2006	\$4,841,774,000	\$4,841,774,000	\$4,960,828,000	\$4,841,774,000
Rescission				(\$48,418,000)
2007	\$4,753,609,000	\$4,753,609,000	\$4,799,063,000	\$4,797,639,000
Rescission				\$0
2008	\$4,782,114,000	\$4,870,382,000	\$4,910,160,000	\$4,890,525,000
Rescission				(\$85,437,000)
Supplemental				\$25,559,000
2009	\$4,809,819,000	\$4,975,039,000	\$4,958,594,000	\$4,968,973,000
Rescission				\$0
2010	\$5,150,170,000	\$5,150,170,000	\$5,054,099,000	\$5,103,388,000
Rescission				\$0
2011	\$5,264,643,000		\$5,256,409,000	
Rescission				
2012	\$5,196,136,000			

Justification of Budget Request

National Cancer Institute

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 Budget Request	FY 2012 + / - FY 2010
BA	\$5,100,826,000	\$5,099,047,000	\$5,196,136,000	\$95,310,000
FTE	3,056	3,061	3,061	+5

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The National Cancer Institute (NCI) is dedicated to the support and conduct of research to understand the origins and behaviors of the many diseases called cancers; to prevent, detect, classify, and treat cancers more effectively; and to improve the quality of life of patients diagnosed with the disease. It is estimated that more than 1.5 million people in the United States were diagnosed with cancer in 2010 and approximately 570,000 people died from the disease. There are also more than 11 million Americans now living with a history of cancer. Accumulated scientific knowledge and new technologies make this an exciting time to lead the nation's efforts in cancer research, offering opportunities for rational strategies to prevent and treat cancers based on an increasingly profound understanding of the disease.

The research projects in NCI's portfolio are supported through numerous mechanisms and carried out in diverse settings throughout the United States and around the world. These mechanisms include: solicited and unsolicited research project grants (RPGs); an intramural program of laboratory and clinical research; support for 66 NCI-designated Cancer Centers; and a nationally coordinated set of cooperative groups for the conduct of clinical trials. The NCI has also launched and planned several initiatives to address specific topics.

NCI's research spans a variety of activities that can be summarized under five scientific themes:

- Understanding the Mechanisms of Cancer
- Understanding the Causes of Cancer
- Improving Early Detection and Diagnosis
- Developing Effective and Efficient Treatments
- Improving Cancer Prevention and Control.

In FY 2012, NCI plans to build on past investment and successes in these areas, continuing its commitment to traditional mechanisms of support and developing new initiatives that address

new opportunities, many of which coincide with the four initiatives articulated by the NIH Director as trans-NIH initiatives.

For example, NCI is using new technologies to develop a deeper understanding of the molecular and genetic mechanisms that cause cancers. The NCI is establishing the Center for Cancer Genomics to coordinate activities related to genome structure and function across the Institute. The major component of the Center for Cancer Genomics, The Cancer Genome Atlas, is a multi-institutional, collaborative study, conducted jointly with the NHGRI, that has recently cataloged the genetic alterations in two important cancers for which early diagnostic methods, broadly applicable prevention strategies, and effective therapies are not yet available: the uniformly lethal brain cancer, glioblastoma multiforme (GBM), and serous ovarian carcinoma. The new information has established at least four distinct subtypes of GBM, based on genetic profiling. The ovarian cancers have very few conventional mutations, other than the nearly universal loss of function of the tumor suppressor gene, p53, but show evidence of rampant reorganization of cancer cell genomes. These findings establish definitive molecular features of these tumor types that will inform all future efforts to develop new treatments. Another recent, but more limited genetic analysis of an aggressive form of non-Hodgkin lymphoma, demonstrated an unexpected functional aspect of the molecular changes in the cancer—the involvement of the B-cell receptor signaling pathway—implying that this well-studied pathway may offer viable therapeutic targets for this cancer, which often strikes young adults.

The NCI continues to devote resources to direct efforts to improve patient outcomes through early diagnosis. Data recently announced by the NCI-sponsored National Lung Screening Trial indicate that screening with low-dose computed tomography (CT) results in twenty percent fewer lung-cancer deaths among current and former heavy smokers. This development marks the first time that a screening test has been found to reduce mortality from lung cancer, the most common cause of cancer deaths in the United States and the world.

Advances have also been made in new and improved cancer therapies. New drugs targeted against mutant proteins in metastatic melanoma and lung adenocarcinoma—drugs whose development resulted from the recent identification of mutant oncogenes in the respective tumor—have proven to be remarkably effective at inducing remissions in advanced disease in early clinical trials. Other clinical trials found that the addition of novel antibody and immune stimulants to standard therapy increased survival of pediatric neuroblastoma patients by two years.

NCI has launched initiatives that will re-engineer the therapeutic development pipeline and move potential treatments to patients more quickly. The Special Translational Research Acceleration Projects (STRAP) program was developed to provide resources that address program, infrastructure, or developmental funding gaps and accelerate high-priority translational projects to the point of early clinical testing. In addition, NCI is implementing changes to its **Cooperative Groups Clinical Trials Program** that will improve efficiency, oversight, and collaboration of trials, as recommended in an April 2010 Institute of Medicine report. These changes include: consolidation of the adult clinical trials groups; standardization of clinical trials data management software for NCI-sponsored multi-site trials; acceleration of clinical trial activation through the implementation of a real-time, internet-based dashboard containing

clinical trial information for all parties involved in the process; collaboration with the Food and Drug Administration (FDA) by involving FDA scientists in NCI's disease-specific scientific steering committees; standardization of language for clinical trial and intellectual property agreements; improving funding of studies and increasing incentives for patient and physician participation by increasing per case reimbursement rates and developing a credentials registry for investigators and clinical trial sites.

Much of the progress against cancer in recent decades has stemmed from successes in the areas of cancer prevention and control. Research in this area includes the identification of factors that influence cancer risk as well as the development and evaluation of interventions to help people reduce their risk—for example, by smoking cessation. In an NCI-sponsored comparative effectiveness study of smoking cessation, the combination of a nicotine patch and a lozenge was the most effective of the five tested interventions.

Overall Budget Policy: The FY 2012 request for NCI is \$5,196.136 million, an increase of \$95.31 million or 1.9 percent over the FY 2010 level. Funds are included in R&D contracts to reflect NCI's share of NIH-wide funding required to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program, the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory. For example, each IC that will benefit from the new synchrotron will provide funding to total NIH's commitment to support this new technology--\$10 million.

NIH will provide an increase of four percent for stipend levels under the Ruth L. Kirschstein National Research Service Award training program to continue efforts to attain the stipend levels recommended by the National Academy of Sciences. This will build on the two percent increase in stipend levels for FY 2011. Stipend levels were largely flat for several years, and the requested increase will help to sustain the development of a highly qualified biomedical research workforce.

Program Descriptions and Accomplishments

Understanding the Mechanisms of Cancer: Expanding knowledge of the molecular and pathological processes that drive cancer development and progression is a key component of cancer research. Emerging technologies that permit comprehensive analysis of tumors and their environments enable researchers to capture snapshots of the changes that accompany cancer. Insights gained through these high-throughput studies can inform the design of experiments that probe the disease relevance of identified molecules and pathways and potentially lead toward new diagnostic and therapeutic approaches.

Budget Policy: The FY 2012 budget request for the Understanding the Mechanisms of Cancer program is \$831.086 million, an increase of \$27.487 million, or 3% over percent the FY 2010 level. Studies of the mechanisms of carcinogenesis are performed mainly through investigator-initiated projects (RPGs). NCI also has a number of large and small programs that support other research on carcinogenic mechanisms. The most important are **The Cancer Genome Atlas (TCGA)** and **Therapeutically Applicable Research to Generate Effective Treatments (TARGET)** initiatives, which use a series of high throughput technical platforms to determine the genetic abnormalities in a variety of adult and pediatric cancers (see *Portrait of a Program:*

Center for Cancer Genomics). The **Mouse Models of Human Cancers Consortium (MMHCC)** supports the use of genetically engineered mice to probe the processes that drive cancer in a physiologically appropriate setting of experimental animals rather than by studying cancer cells growing in culture.

Portrait of a Program: Center for Cancer Genomics

FY 2010 Level: \$30 million

FY 2009/2010 ARRA: \$170 million

Total : \$200 million

FY 2012 Level: \$61 million

Cancer is now well-established as a collection of disorders in which abnormal behaviors of cells are attributable to alterations in the sequence, modification, and expression of the genome. The Center for Cancer Genomics will use modern methods to define these alterations and to facilitate conversion of such knowledge into methods that improve the detection, diagnosis, treatment, monitoring, and prevention of cancers. The Center will also oversee the implementation of those methods into the practice of oncology by working with other agencies that are responsible for regulating changes in practice and establishing standards of care.

The **Center for Cancer Genomics** will support programs to characterize the properties of cancer genomes from adult and pediatric patients in the U.S. and abroad and from animal models, especially mouse models, in concert with the **MMHCC**. As part of the Center and in collaboration with NHGRI, **TCGA** is cataloguing various kinds of mutations and alterations in gene expression in more than 20 types of human cancer, with the goal of improving the ability to diagnose, treat, and prevent cancer. For example, a recent TCGA study revealed four distinct subtypes of glioblastoma multiforme (GBM)--the most common type of malignant brain cancer in adults--with responses to aggressive chemotherapy and radiation differing by subtype. Likewise, NCI's **TARGET** program is generating comprehensive characterization of five pediatric cancers to identify novel therapeutic targets.

Programs that will support the Center entail: the procurement and characterization of tumor samples; the generation of data about the genome and its functions; analysis and interpretation of the data; and application of the findings to clinical problems. The **cancer Human Biobank** (caHUB) is an initiative to obtain the highest quality tissue, blood, and tumor samples that are rigorously and ethically collected, properly stored, and extensively annotated. caHUB will provide a continuous supply of high-quality biospecimens and biobanking services to programs, including the Center. The new Center will also depend on the services of the **Center for Bioinformatics and Information Technology** (CBIIT) and the **Cancer Biomedical Informatics Grid** (caBIG) program for informatics tools and support that are critical for genome-based sciences.

Understanding the Causes of Cancer: The likelihood of developing cancer is determined by a complex interplay of environmental, behavioral, and genetic factors. NCI's past investment in population cohorts has laid the groundwork for additional studies to identify these factors and a variety of population-based and laboratory research has helped to define the nature of their interactions. For example, genome-wide association studies (GWAS) that have compared the DNA from people with and without cancer have identified inherited genetic variants associated with a higher risk of breast, prostate, and pancreatic cancer.

Budget Policy: The FY 2012 budget request for the Understanding the Causes of Cancer program is \$1,284.331 million, an increase of \$51.754 million, or 4 percent over the FY 2010 level. NCI will conduct **genome-wide association studies** on genetic determinants of lung cancer risk, survival, and smoking persistence. Studies through NCI's **Cohort Consortium**—a large-scale, international collaboration of cohorts that together include over 4 million people—will evaluate the role of genetic susceptibility, environmental exposures, including nutrition, and gene-environment interactions for a range of cancer types. Many of the awards that support

studies of interactions between cancer cells and adjacent host cells are part of the **Integrative Cancer Biology Program (ICBP)** and the **Tumor Microenvironment Network**. The **Breast Cancer and the Environment Research Program** uses a transdisciplinary approach in which basic scientists, epidemiologists, clinicians, and community partners work together to examine the effects of environmental exposures that may predispose a woman to breast cancer throughout her lifetime. The role of **viruses and other microbial agents** in cancer causation will be studied to gain a better understanding of the relationship between infection, immunity, and genetics. Current evidence indicates that as many as one in five cancers may have an infectious cause. When infectious causes are discovered, the agent can represent a molecular target for intervention, through the use of vaccines and/or antimicrobials against such agents, or as a biomarker for screening, as with HPV infection of the cervix and chronic HBV and HCV infection of the liver. The increased incidence of cancer in the setting of host immunodeficiency, including tumor- and HIV-induced immune dysfunction, will be explored, as will the contributions of **chronic inflammation** to cancer development. Research into the effects of **obesity and physical activity** (also called **energy balance**) on cancer risk will be supported, and efforts will also be made to develop improved measures and methods for assessing energy intake, fat distribution, and physical activity, in order to facilitate research in this area.

Portrait of a Program: Host Role in Cancer Predisposition and Development

FY 2010 Level: \$18 million

FY 2012 Level: \$21 million

Cancer development is influenced by both internal factors, such as obesity and inherited variations, and external factors like infectious agents and environmental exposures. Internal factors can influence how the body responds to external exposures, and which can be beneficial or detrimental to the development of cancer. Through grants to extramural institutions and through its intramural program, NCI is actively investigating therapies that utilize host immune cells and responses to combat tumor growth and metastasis. For instance, the **Center for Excellence in Immunology (CEI)**, an intramural research program, fosters the discovery, development, and delivery of novel immunologic approaches for the prevention and treatment of cancer and cancer-associated viral diseases. The development of a tumor within the body is not an isolated event; rather, a complex series of interactions in the vicinity of the developing tumor are required to sustain growth. The **Tumor Microenvironment Network (TMEN)** focuses on expanding the understanding of the role of the tumor microenvironment in cancer initiation, progression, and metastasis, as well as host responses to treatment.

The current obesity epidemic is placing a growing number of people at an increased risk for developing cancer. Supported by research in lifestyle changes for cancer prevention, NCI continues to study **Energy Balance** (the integrated effects of diet, physical activity, and genetics on growth and body weight) as a way to control cancer incidence. The **Transdisciplinary Research on Energetics and Cancer (TREC)** Program was developed to foster collaboration among scientists and accelerate progress toward reducing cancer incidence, morbidity, and mortality associated with obesity, low levels of physical activity, and poor diet. By better understanding how biological responses influenced by human behavior affect cancer risk, NCI can help inform cancer control.

Improving Early Detection and Diagnosis: Tools that can accurately detect and diagnose tumors can markedly improve outcomes for cancer patients. Ideally, these tools would detect cancer early, before it has spread throughout the body and when treatment is more likely to be curative. Researchers are working to identify clinically meaningful molecules—nucleic acids, proteins, metabolites, and other substances—that can be used to identify the presence of cancer cells and guide the development of reliable and noninvasive assays to measure tumor growth and response to therapy. Recent substantial improvements in mass spectrometry for detecting

proteins and techniques for capturing circulating cancer cells that are occasionally shed into the blood stream from solid tumors provide critical tools for developing such assays, increasing the prospect of success.

Budget Policy: The FY 2012 budget request for the Improving Early Detection and Diagnosis program is \$454.727 million, an increase of \$17.797 million, or 4 percent over the FY 2010 level. The **Early Detection Research Network (EDRN)** and the **Repository for Molecular Brain Neoplasia Data (REMBRANDT)** are funding research intended to identify and validate candidate biomarkers of early disease, with the goal of developing clinically useful diagnostic tests. The efforts of individual investigators working on early detection and improved diagnosis can be augmented by findings from genomic studies (e.g. **TCGA**) and technologies developed through recently launched initiatives on **nanotechnology, proteomics, and physical sciences.**

Developing Effective and Efficient Treatments: Developing treatment regimens that successfully eradicate cancer cells while sparing healthy tissues is an important goal of NCI research. Identification of the genes, proteins, and molecular processes that contribute to cancer is facilitating the development of treatment strategies based on the molecular traits of patients and their tumors. These molecularly targeted therapies have generally proven to be less toxic to patients than traditional chemotherapy regimens.

Budget Policy: The FY 2012 budget request for the Developing Effective and Efficient Treatments program is \$1,282.432 million, an increase of \$34.891 million, or 3 percent over the FY 2010 level. Development of targeted therapies builds on the knowledge of the molecules and pathways that contribute to cancer, gained through basic research. Once potential targets are identified and validated, researchers use high-throughput assays to screen small molecules or biological agents in order to identify entities that can interact with the desired target and interfere with its cancerous activity. Consortia of chemists and biologists optimize the agents and move them into production and preclinical testing (see *Portrait of a Program: Turning Knowledge into Cancer Control*). Several NCI programs and initiatives enable work along this drug development continuum. The **Chemical Biology Consortium** develops chemical tools for probing signaling pathways involved in cancer, with a focus on molecules that have traditionally been difficult to target. To understand how various treatments will translate to human tumors, expanded research programs have been created to study treatment effects. The mission of the **Comparative Oncology Program (COP)** is to provide an integrated mechanism through which the study of naturally occurring cancers in animals can generate new information about cancer and help translate biological concepts to clinical application. As part of this effort, and to evaluate novel therapeutic strategies for cancer, COP has established a multicenter collaborative network of extramural comparative oncology programs to design and implement preclinical trials involving domesticated animals. Other preclinical models, including the mouse models available through MMHCC, can also provide insights into new therapeutic strategies before they are tested in clinical trials. Clinical trials are a critical step in moving potential therapies into clinical practice. NCI supports clinical trials through a number of mechanisms, especially the Cooperative Group Program. The Cooperative Groups are now being reorganized to streamline the development and execution of trials, to select and prioritize trials through stringent peer review, and to fully fund the most promising and innovative studies. In an effort to maximize

molecular characterization of cancers, biological specimens will be collected for future research. Other trials are conducted within the intramural research program and under the aegis of RPGs.

In order to facilitate management and coordination of the clinical trials portfolio, NCI is creating the **Clinical Trials Reporting Program (CTRP)**, a comprehensive database that will contain regularly updated information on all interventional trials. NCI has also implemented the **Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP)**, which supports the conduct of promising correlative studies related to biomarkers, imaging, and patient quality of life, in association with Phase III and large Phase II trials. By expanding the network of NCI programs beyond major academic health institutions, more patients, including underrepresented minorities, will have access to potentially life-saving clinical trials. In addition, clinical trial enrollment will be enhanced, which should facilitate more rapid assessment of the efficacy of potential treatments. The **Community Clinical Oncology Programs (CCOPs)** enroll patients onto approved cancer prevention, control, and treatment trials, enrolling one-third of all participants on NCI trials nationwide. The 47 current CCOPs represent 340 hospitals and 2,900 physicians. The **Minority-Based Community Clinical Oncology Programs (MBCCOPs)** enroll patients onto approved trials in areas with at least 40 percent underserved or minority populations. The 16 current MBCCOPs comprise 55 hospitals and 475 physicians, including 100 minority investigators. MBCCOPs have an average of 64 percent minority participants on trials at their sites. The **NCI Community Cancer Centers Program (NCCCP)** is being expanded from the original 16 pilot sites to a total of 30 sites with the goal of improving the quality of cancer care for more than 50,000 new cancer patients from rural, inner-city, and underserved communities each year and providing them the opportunity to participate in cancer research. The **Centers for Population Health and Health Disparities (CPHHD)** program supports transdisciplinary research involving social, behavioral, biological, and genetic studies to improve knowledge of the causes of health disparities and devise effective methods of preventing, diagnosing, and treating disease and promoting health. The **Geographic Management of Cancer Health Disparities Program (GMaP)** is working to overcome the lack of technological resources available at institutions in underserved communities, in order to support biospecimen collection and the development of health disparities research projects.

Portrait of a Program: Turning Knowledge into Cancer Control

FY 2010 Level: \$61 million

FY 2012 Level: \$58 million

The goal of NCI-funded research is to better understand cancer and translate knowledge gained in the laboratory to improve prevention, diagnosis, and treatment for cancer patients. NCI is able to achieve this by supporting intramural and extramural initiatives, and in some cases, collaborations between the two. For example, the **NCI Experimental Treatment Program (NExT)** is an initiative aimed at shortening the typical 10- to 12-year drug development timeline by up to 6 years, getting promising drugs into human trials and rapidly eliminating those likely to be ineffective. Supported both intramurally and extramurally, the NExT platform will facilitate the many back-and-forth handoffs that occur between academic research laboratories and the private sector in order to achieve the ultimate goal of translation to patients. In support of NExT initiative, the **Center for Advanced Preclinical Research (CAPR)** will accelerate development of therapeutics and diagnostics for human diseases by providing state-of-the-art animal models for preclinical studies that are genetically programmed to develop diseases in the same way they arise in humans.

Innovative research in genetics, imaging, and cancer molecular signatures is laying the groundwork for customized cancer patient care. The **Advanced Technology Program** provides expertise and technologies in support of NCI investigators. This program accelerates the delivery of new treatments to patients by developing and applying advanced technologies—such as biomedical imaging. The **NCI imaging facility** for clinical cancer research will fuse imaging and pathology in the evaluation of patients throughout treatment. The **NIH Center for Interventional Oncology** offers new and expanded opportunities to investigate cancer therapies using imaging technology to diagnose and treat localized cancers in a targeted and minimally or noninvasive manner. This interdisciplinary environment combines training, patient treatment, and translational research and development in interventional oncology. Cancer is a growing burden in the developing world, where countries are frequently ill-prepared to address this disease. It is estimated that up to 60 percent of the current cancer burden in sub-Saharan Africa is highly preventable. Part of NCI's goal in translating knowledge in control of cancer will be in the worldwide application of this information. The **Center for Global Cancer Research** will utilize NCI's knowledge to prepare developing countries to undertake this growing cancer burden.

Improving Cancer Prevention and Control: Prevention is the first line of defense against cancer. Cancer is defined by the stages of initiation and premalignant change, pre-invasion, invasion, local progression, and metastasis. This evolutionary process is driven by genomic alterations, such as mutations that lead to abnormal cell growth and complex changes in gene expression. Cancer prevention research focuses on a number of areas, including understanding and modifying behaviors that affect risk, mitigating the influence of genetic and environmental risks, and interrupting cancer development through early intervention. Increased knowledge about how various factors interact to influence cancer risk will eventually allow targeting of preventive interventions based on an individual's genetic characteristics, exposures, and lifestyle. Research in the area of cancer control also seeks to better understand the factors that influence cancer outcomes, quality of care, quality of life, and cancer-related health disparities.

Budget Policy: The FY2012 budget request for the Cancer Prevention and Control program is \$232.045 million, an increase of \$3.012 million, or 1 percent over the FY 2010 level. The stages in the development and progression of cancer provide opportunities to prevent, halt, or reverse the process. These interventions can include vaccinations (e.g., against HBV and HPV), lifestyle modifications (e.g., tobacco cessation and diet modification), early detection and screening strategies (e.g., colonoscopies and Pap smears), and, in some instances, specific drugs (e.g., chemoprevention with tamoxifen and raloxifene). Developing ways to identify high-risk populations likely to benefit from such interventions is an important part of prevention research. **Genome-wide association studies** are large-scale efforts to catalog genetic determinants of cancer risk. The **Surveillance, Epidemiology and End Results (SEER)** program, which has collected data since 1973, regularly samples approximately 26 percent of the U.S. population and has obtained information on 5.7 million cancer cases—380,000 cases are added each year. The **Health Maintenance Organization (HMO) Cancer Research Network (CRN)** conducts cancer prevention, early detection, treatment, long-term care, and surveillance research, using data systems of 14 HMOs nationwide. Studies of lifestyle change include research into energy balance (integrated effects of diet, physical activity, and genetics on growth and body weight) as a way to control cancer incidence. **The Consortia for Early Phase Prevention Trials** involve six major cancer research centers that lead multiple collaborative networks to assess the cancer prevention potential of new agents, with a focus on Phase I and II clinical trials. In addition to designing and conducting trials and recruiting participants, the Consortia work to (1) characterize

the effects of potential agents on molecular targets; (2) identify biological events associated with cancer development; and (3) correlate these effects with clinical endpoints. Continued emphasis will be placed on identifying molecular drug targets, developing successful prevention strategies, and bringing these findings into clinical practice.

Cancer Centers: Many areas of research benefit from interdisciplinary partnerships, information sharing, and close links to health care delivery systems. Cancer Centers provide environments conducive to collaborations and team science. In addition to bringing scientists together, these programs are also increasingly reaching out to community oncology practices and minority and underserved patient populations.

Budget Policy: The FY 2012 budget request for the Cancer Centers program is \$544.124 million, a decrease of \$40.063 million, or 7 percent under the FY 2010 level. The 66 **NCI-designated Cancer Centers** conduct some of the best basic, translational, and population research to improve cancer prevention, diagnosis, and treatment while also stimulating innovative pilot projects in new investigational areas. In FY 2011 and 2012 NCI will seek to identify savings and reductions in the Cancer Centers program in order to award more competing Research Project Grants, many of which will go to investigators at Cancer Centers.

Research Workforce Development: Training in emerging disciplines such as genomics, computational biology, nanotechnology, and bioinformatics will be critical to build and translate the knowledge of the molecular basis of disease into the practice of medicine. New training programs are designed to prepare the next generation of cancer researchers to meet the challenges of multidisciplinary research. NCI provides cancer research training and career development opportunities for high school, undergraduate, and graduate students; postdoctoral fellows; and physicians across the United States.

Budget Policy: The FY 2012 budget request for the Research Workforce Development program is \$180.532 million, an increase of \$2.610 million, or 1 percent over the FY 2010 level. NCI supports training within the intramural research program and through training awards to institutions and individuals in the extramural community. NCI also supports the training and mentoring of M.D./Ph.D. students in laboratory and/or clinical research through the **Medical Scientist Training Program (MSTP)**. Additionally, the **Basic Behavioral and Social Science Opportunity Network (OppNet)** is one of several opportunities offering educational activities and short-term career development experience to encourage new and established investigators to engage in the field of basic behavioral and social science research. The **Cancer Clinical Investigator Team Leadership** awards provide two years of funding to exceptional mid-level clinical investigators who lead NCI-sponsored clinical trials but are not principal investigators at NCI-designated Cancer Centers. In addition, the Institute sponsors a number of specialized training and career development programs. One of these efforts is the **Interagency Oncology Taskforce (IOTF)**, a partnership with the U.S. Food and Drug Administration (FDA) that is designed to train a cadre of scientists in cancer-related scientific research and research-related regulatory review, policies, and regulations.

Buildings and Facilities: The renovation and improvement funds for the facilities at the NCI-Frederick campus, located in Frederick, Maryland, have been budgeted as facilities funds since

FY 2005. The funds are necessary to maintain the operation of these facilities for the scientific missions of NCI, the National Institutes of Health, other government agencies, and the extramural research community.

Budget Policy: The FY 2012 budget request for the Buildings and Facilities program is \$7.920 million, the same as the FY 2010 level.

Research Management and Support: NCI's research management and support activities provide support for the review, award, and monitoring of technical and administrative services. These services include central administration, overall program direction, grant and contract administration, human resources, program coordination, and financial management. NCI regularly engages in business planning activities to streamline administrative functions.

Budget Policy: The FY 2012 budget request for Research Management and Support is \$378.939 million, a decrease of \$2.178 million, or 1 percent under the FY 2010 level.

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Budget Authority by Object
(Dollars in Thousands)

	FY 2010 Actual	FY 2012 PB	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	3,056	3,061	5	0.2%
Full-time equivalent of overtime and holiday hours	5	5	0	0.0%
Average ES salary	\$165,171	\$165,171	\$0	0.0%
Average GM/GS grade	12.0	12.0	0.0	0.0%
Average GM/GS salary	\$97,431	\$97,431	\$0	0.0%
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$95,734	\$95,734	\$0	0.0%
Average salary of ungraded positions	126,984	126,984	0	0.0%
OBJECT CLASSES	FY 2010 Actual	FY 2012 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	\$202,108	\$202,886	\$778	0.4%
11.3 Other than full-time permanent	118,631	119,076	445	0.4%
11.5 Other personnel compensation	12,344	12,391	47	0.4%
11.7 Military personnel	5,278	5,458	180	3.4%
11.8 Special personnel services payments	56,778	56,989	211	37.2%
Total, Personnel Compensation	\$395,139	\$396,800	\$1,661	0.4%
12.0 Personnel benefits	\$92,918	\$93,271	\$353	38.0%
12.2 Military personnel benefits	3,518	3,532	14	39.8%
13.0 Benefits for former personnel	0	0	0	0.0%
Subtotal, Pay Costs	\$491,575	\$493,603	\$2,028	41.3%
21.0 Travel and transportation of persons	\$16,185	\$15,875	(\$310)	-1.9%
22.0 Transportation of things	1,304	1,279	(25)	-1.9%
23.1 Rental payments to GSA	7	7	0	0.0%
23.2 Rental payments to others	116	115	(1)	-0.9%
23.3 Communications, utilities and miscellaneous charges	6,846	6,762	(84)	-1.2%
24.0 Printing and reproduction	2,271	2,246	(25)	-1.1%
25.1 Consulting services	16,981	16,491	(490)	-2.9%
25.2 Other services	210,977	203,869	(7,108)	-3.4%
25.3 Purchase of goods and services from government accounts	538,488	572,999	34,511	6.4%
25.4 Operation and maintenance of facilities	39,510	34,004	(5,506)	-13.9%
25.5 Research and development contracts	475,435	429,015	(46,420)	-9.8%
25.6 Medical care	4,030	3,934	(96)	-2.4%
25.7 Operation and maintenance of equipment	15,998	15,638	(360)	-2.3%
25.8 Subsistence and support of persons	10	10	0	0.0%
25.0 Subtotal, Other Contractual Services	\$1,301,429	\$1,275,960	(\$25,469)	-2.0%
26.0 Supplies and materials	\$48,622	\$47,471	(\$1,151)	-2.4%
31.0 Equipment	21,607	21,157	(450)	-2.1%
32.0 Land and structures	0	0	0	0.0%
33.0 Investments and loans	0	0	0	0.0%
41.0 Grants, subsidies and contributions	3,210,859	3,331,656	120,797	3.8%
42.0 Insurance claims and indemnities	0	0	0	0.0%
43.0 Interest and dividends	5	5	0	0.0%
44.0 Refunds	0	0	0	0.0%
Subtotal, Non-Pay Costs	\$4,609,251	\$4,702,533	\$93,282	2.0%
Total Budget Authority by Object	\$5,100,826	\$5,196,136	\$95,310	1.9%

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

**Salaries and Expenses
(Dollars in Thousands)**

OBJECT CLASSES	FY 2010 Actual	FY 2012 PB	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-time permanent (11.1)	\$202,108	\$202,886	\$778	0.4%
Other than full-time permanent (11.3)	118,631	119,076	445	0.4%
Other personnel compensation (11.5)	12,344	12,391	47	0.4%
Military personnel (11.7)	5,278	5,458	180	3.4%
Special personnel services payments (11.8)	56,778	56,989	211	0.4%
Total Personnel Compensation (11.9)	\$395,139	\$396,800	\$1,661	0.4%
Civilian personnel benefits (12.1)	\$92,918	\$93,271	\$353	0.4%
Military personnel benefits (12.2)	3,518	3,532	14	0.4%
Benefits to former personnel (13.0)	0	0	0	0.0%
Subtotal, Pay Costs	\$491,575	\$493,603	\$2,028	0.4%
Travel (21.0)	\$16,185	\$15,875	(\$310)	-1.9%
Transportation of things (22.0)	1,304	1,279	(25)	-1.9%
Rental payments to others (23.2)	116	115	(1)	-0.9%
Communications, utilities and miscellaneous charges (23.3)	6,846	6,762	(84)	-1.2%
Printing and reproduction (24.0)	2,271	2,246	(25)	-1.1%
Other Contractual Services:				
Advisory and assistance services (25.1)	16,981	16,491	(490)	-2.9%
Other services (25.2)	210,977	203,869	(7,108)	-3.4%
Purchases from government accounts (25.3)	362,301	358,451	(3,850)	-1.1%
Operation and maintenance of facilities (25.4)	21,590	21,097	(493)	-2.3%
Operation and maintenance of equipment (25.7)	15,998	15,638	(360)	-2.3%
Subsistence and support of persons (25.8)	10	10	0	0.0%
Subtotal Other Contractual Services	\$627,857	\$615,556	(\$12,301)	-2.0%
Supplies and materials (26.0)	\$48,622	\$47,471	(\$1,151)	-2.4%
Subtotal, Non-Pay Costs	\$703,201	\$689,304	(\$13,897)	-2.0%
Total, Administrative Costs	\$1,194,776	\$1,182,907	(\$11,869)	-1.0%

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2010 Actual			FY 2011 CR			FY 2012 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director	817	4	821	818	4	822	818	4	822
Center for Cancer Research	1,515	23	1,538	1,518	23	1,541	1,518	23	1,541
Division of Cancer Biology	41	0	41	41	0	41	41	0	41
Division of Cancer Treatment and Diagnosis	188	5	193	189	5	194	189	5	194
Division of Cancer Prevention	78	2	80	78	2	80	79	1	80
Division of Cancer Control and Population Sciences	129	3	132	129	3	132	129	3	132
Division of Extramural Activities	89	0	89	89	0	89	89	0	89
Division of Cancer Epidemiology and Genetics	153	9	162	153	9	162	153	9	162
Total	3,010	46	3,056	3,015	46	3,061	3,016	45	3,061
Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research									
FTEs supported by funds from Cooperative Research and Development Agreements									
			7			7			7
FISCAL YEAR	Average GS Grade								
2008	12.0								
2009	12.0								
2010	12.0								
2011	12.0								
2012	12.0								

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**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Detail of Positions

GRADE	FY 2010 Actual	FY 2011 CR	FY 2012 PB
Total, ES Positions	4	5	5
Total, ES Salary	660,684	784,562	825,855
GM/GS-15	246	247	247
GM/GS-14	427	428	428
GM/GS-13	393	394	394
GS-12	499	500	500
GS-11	197	198	198
GS-10	12	12	12
GS-9	158	158	158
GS-8	95	95	95
GS-7	65	65	65
GS-6	11	11	11
GS-5	11	11	11
GS-4	13	13	13
GS-3	6	6	6
GS-2	2	2	2
GS-1	0	0	0
Subtotal	2,135	2,140	2,140
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	0
Director Grade	25	25	25
Senior Grade	7	7	7
Full Grade	11	11	11
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Co-Step Grade	2	2	2
Subtotal	46	46	45
Ungraded	974	974	975
Total permanent positions	2,193	2,196	2,196
Total positions, end of year	3,159	3,164	3,164
Total full-time equivalent (FTE) employment, end of year	3,056	3,061	3,061
Average ES salary	165,171	165,171	165,171
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	97,431	97,431	97,431

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

New Positions Requested

	FY 2012		
	Grade	Number	Annual Salary
Biologist	GS-11	1	\$71,835
Clinical Fellow	AD/602/0	1	83,637
Research Fellow	AD/401/0	1	80,332
Investigator	AD/401/0	1	114,932
Staff Scientist	AD/401/0	1	113,682
Total Requested		5	\$464,418