# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## NATIONAL INSTITUTES OF HEALTH

# National Cancer Institute

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					Division of Extramural Activities Director Dr. Paulette Gray
			rships	Division of Cancer Treatment and Diagnosis Director Dr. James Doroshow	
HEALTH te			Strategic Partne		Division of Cancer Biology Director Dr. Dinah Singer
NATIONAL INSTITUTES OF HEALTH National Cancer Institute Organization Chart	<b>Office of the Director</b> Director Dr. John E. Niederhuber	Deputy Director Dr. Alan Rabson	nced Technologies & Dr. Anna Barker	Division of Cancer Epidemiology and Genetics Director Dr. Joseph Fraumeni	Drv
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					Division of Cancer Control and Population Sciences Director Dr. Robert Croyle

## FY 2008 Proposed Appropriation Language

### 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, \$4,782,114,000 of which up to \$8,000,000 may be used for repairs and improvements at the NCI-Frederick Federally Funded Research and Development Center in Frederick, MD (Department of Health and Human Services Appropriation Act, 2006)

### Comparison of Proposed FY 2008 Appropriation Language to Most Recently Enacted Full-Year Appropriations

## 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,

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improvements at the NCI-Frederick Federally Funded Research and Development Center in

Frederick, MD (Department of Health and Human Services Appropriation Act, 2006)

# National Institutes of Health National Cancer Institute

		FY 2007	
	FY 2006	Continuing	FY 2008
Source of Funding	Actual	Resolution	Estimate
Appropriation	\$4,841,774,000	\$4,793,356,000	\$4,782,114,000
Enacted Rescissions	-48,418,000	0	0
Subtotal, Adjusted Appropriation	4,793,356,000	4,793,356,000	4,782,114,000
Real Transfer under Roadmap Authority	-42,834,000		
Real Transfer under Secretary's One-percent transfer authority	-3,293,000		
Comparative transfer from OD for NIH Roadmap	42,834,000		
Comparative Transfer to NIBIB	-332,000	-340,000	
Comparative transfer to OD	-146,000	-154,000	
Comparative Transfer to NCRR	-1,394,000	-1,640,000	
Comparative Transfers to the Office of the Assistant Secretary for Admin. And Mgmt. and to the Office of the			
Assistant Secretary for Public Affairs	-14,000	-14,000	
Subtotal, adjusted budget authority	4,788,177,000	4,791,208,000	4,782,114,000
Unobligated Balance, start of year	11,703,000		0
Revenue from Breast Cancer Stamp	4,467,000		
Unobligated Balance, end of year	-9,274,000	0	0
Subtotal, adjusted budget authority	4,795,073,000	4,791,208,000	4,782,114,000
Unobligated balance lapsing	-4,000	0	0
Total obligations	4,795,069,000	4,791,208,000	4,782,114,000

#### Amounts Available for Obligation <u>1</u>/

<u>1</u>/ Excludes the following amounts for reimbursable activities carried out by this account:
 FY 2006 - \$13,373 FY 2007 - \$13,429 FY 2008 - \$13,487
 Excludes \$32,000 in FY 2007 and \$32,000 in FY 2008 for royalties.

#### NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

(Dollars in Thousands)

		Budget Me		,				
		6		Y 2007				
	F	Y 2006	Co	ntinuing	]	FY 2008		
MECHANISM		Actual	Re	solution	]	Estimate	Ch	ange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No. A	Amount
Research Projects:								
Noncompeting	3,896	\$1,598,350	3,878	\$1,547,748	3,691	\$1,458,633	-187	-\$89,115
Administrative supplements	(291)	49,339	(290)	49,870	(290)	50,870	(0)	1,000
Competing:								
Renewal	291	139,615	280	143,148	314	158,002	34	14,854
New	987	274,771	958	257,057	1,068	289,086	110	32,02
Supplements	2	681	6	3,075	6	3,075	0	
Subtotal, competing	1,280	415,067	1,244	403,280	1,388	450,163	144	46,88
Subtotal, RPGs	5,176	2,062,756	5,122	2,000,898	5,079	1,959,666	-43	-41,232
SBIR/STTR	263	96,055	248	90,735	251	91,685	3	95(
Subtotal, RPGs	5,439	2,158,811	5,370	2,091,633	5,330	2,051,351	-40	-40,282
Research Centers:								
Specialized/comprehensive	163	463,860	165	487,505	167	495,505	2	8,00
Clinical research	0	0	0	0	0	0	0	(
Biotechnology	0	0	0	0	0	0	0	(
Comparative medicine	0	0	0	0	0	0	0	
Research Centers in Minority Institutions	0	0	0	0	0	0	0	
Subtotal, Centers	163	463,860	165	487,505	167	495,505	2	8,000
Other Research:								
Research careers	548	79,442	559	81,017	581	82,817	22	1,800
Cancer education	99	34,561	102	35,406	103	35,806	1	400
Cooperative clinical research	63	145,919	63	149,302	63	151,602	0	2,30
Biomedical research support	0	0	0	0	0	0	0	
Minority biomedical research support	0	2,914	0	2,914	0	2,914	0	
Other	171	62,863	171	63,257	171	63,257	0	(
Subtotal, Other Research	881	325,699	895	331,896	918	336,396	23	4,50
Total Research Grants	6,483	2,948,370	6,430	2,911,034	6,415	2,883,252	-15	-27,78
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	220	9,493	219	9,467	219	9,467	0	
Institutional awards	1,213	57,125	1,206	56,812	1,206	56,812	0	
Total, Training	1,433	66,618	1,425	66,279	1,425	66,279	0	
Research & development contracts	326	347,770	336	364,742	341	374,498	5	9,75
(SBIR/STTR)	(31)	(8,161)		(13,600)		(13,600)	(0)	(0
	<b>FTEs</b>		<u>FTEs</u>		FTEs		<u>FTEs</u>	
Intramural research	1,766	691,721	1,803	686,555	1,828	682,884	25	-3,67
Research management and support	622	184,135	632	186,896	641	188,796	9	1,90
Cancer prevention & control	387	505,705	395	510,400	401	515,400	6	5,00
Construction		0		0		0		
Buildings and Facilities	_	7,920	_	7,920	_	7,840	_	-8
NIH Roadmap for Medical Research	2	42,834	5	57,382	5	63,165	0	5,783
Total, NCI	2,777	4,795,073	2,835	4,791,208	2,875	4,782,114	40	-9,09

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

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

								-	H	FY 2007				
	FY	FY 2004	FY	FY 2005	FY	FY 2006	FY	FY 2006	Con	Continuing	FY	FY 2008		
	Ą	Actual	Ac	Actual	Ac	Actual	Com	Comparable	Res	Resolution	Es	Estimate	Chi	Change
<b>Extramural Research</b>	FTES	FTEs Amount	FTES	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTES	Amount	FTEs	Amount
Detail:					2		i I		2		2			
Understand the Mechanisms of Cancer		\$766,869		\$773,118		\$795,035		\$795,032		\$779,048		\$772,112		-\$6,936
Understand the Causes of Cancer		1,149,347		1,152,158		1,085,449		1,085,365		1,066,665		1,057,063		-9,602
Improve Early Detection and Diagnosis		341,080		357,485		406,767		406,362		401,359		397,282		-4,077
Develop Effective and Efficient Treatments		1,165,738		1,160,302		1,123,239		1,123,239		1,111,331		1,100,049		-11,282
Cancer Centers, Specialized Centers and SPOREs	REs	409,288		454,252		463,860		463,860		487,505		495,505		8,000
Research Workforce Development		172,685		178,532		182,015		180,621		182,702		184,902		2,200
Buildings and Facilities		8,000		7,936		7,920		7,920		7,920		7,840		-80
														000
Subtotal, Extramural *		4,013,007		4,083,783		4,064,285		4,062,399		4,036,530		4,014,753		-21,777
Intramural research (non-add)	1,971	708,314	1,832	711,009	1,766	691,721	1,766	691,721	1,803	686,555	1,828	682,884	25	-3,671
Res. management & support	592	180,182	612	182,323	622	184,135	622	184,135	632	186,896	641	188,796	6	1,900
Cancer Prevention and Control	418	529,980	410	531,634	387	505,705	387	505,705	395	510,400	401	515,400	9	5,000
NIH Roadmap for Medical Research	0	16,276	0	30,505	2	42,834	2	42,834	5	57,382	5	63,165	0	5,783
TOTAL	2,981	4,739,445	2,854	4,828,245	2,777	4,796,959	2,777	4,795,073	2,835	4,791,208	2,875	4,782,114	40	-9,094

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research \* The detail programs listed above include both extramural and intramural funding.

## NATIONAL INSTITUTES OF HEALTH

## **National Cancer Institute**

## Major Changes in the Fiscal Year 2008 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 2008 budget request for NCI, which is -\$9.094 million less than the FY 2007 Estimate, for a total of \$4,782.114 million.

<u>Research Project Grants (-\$41.232 million, total \$1,959.666 million).</u> NCI will support a total of 5079 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPGs will decrease by 187 awards and decrease by \$89.115 million. Competing RPGs will increase by 144 awards and increase by \$46.883 million.

<u>Research Careers (+\$1.8 million; total \$82.817 million):</u> NCI will support the Pathway to Independence program, by funding an additional 20 awards in FY 2008. Total support for the Pathway program in FY 2008 is 40 awards and \$3.600 million dollars.

<u>NIH Roadmap for Biomedical Research (+\$5.8 million; total \$63.165 million):</u> NCI will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

<u>Research Centers (+\$8.0 million; total \$495.505 million):</u> NCI will expand support to the NCIdesignated Cancer Centers program, add up to two Specialized Programs of Research Excellence (SPOREs), and expand support to the Comprehensive Minority Institution/Cancer Center Partnership program in FY 2008. NCI will also supplement existing Cancer Centers and SPOREs for correlative science studies for clinical trials.

<u>Research and Development Contracts (+\$9.756 million; total \$374.498 million):</u> NCI will expand support to the Community Cancer Centers Program, a three year pilot program. NCI will also expand support for infrastructure and correlative science studies for clinical trials. Additional funds are also requested for the increase in the program evaluation assessment.

Intramural Research (-\$3.671 million; total \$682.884 million): NCI will identify areas of potential savings within the Intramural Research Program which allow achievement of program goals and accomplishments as outlined in the Justification Narrative.

#### NATIONAL INSTITUTES OF HEALTH National Cancer Institute Summary of Changes

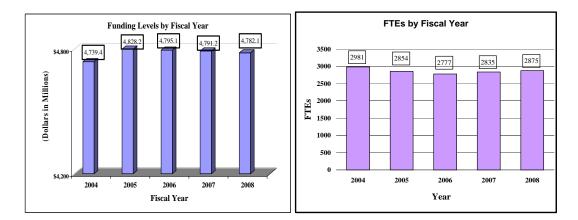
FY 2007 Continuing Resolution		\$4,791,208,000
FY 2008 Estimated Budget Authority		4,782,114,000
Net change	FY 2007	-9,094,00
	Continuing	
	Resolution	Change from Base
	Budget	Budget
CHANGES	FTEs Authority	FTEs Authority
A. Built-in:		
1. Intramural research:		
a. Annualization of January		
2007 pay increase	\$220,970,000	\$1,481,000
b. January 2008 pay increase	220,970,000	5,050,000
c. Two extra days of pay	220,970,000	856,000
d. Payment for centrally furnished services	113,002,000	1,130,000
e. Increased cost of laboratory supplies,		
materials, and other expenses	352,583,000	8,349,000
Subtotal		16,866,000
2. Research Management and Support:		
a. Annualization of January		
2007 pay increase	\$78,539,000	\$527,000
b. January 2008 pay increase	78,539,000	1,796,000
c. Two extra days of pay	78,539,000	304,000
d. Payment for centrally furnished services	20,000,000	200,000
e. Increased cost of laboratory supplies,	, ,	,
materials, and other expenses	88,357,000	2,093,000
Subtotal		4,920,000
3. Cancer Control:		
a. Annualization of January		
2007 pay increase	\$53,128,000	\$356,000
b. January 2008 pay increase	53,128,000	1,215,000
c. Two extra days of pay	53,128,000	206,000
d. Payment for centrally furnished services	15,000,000	150,000
e. Increased cost of laboratory supplies,		
materials, and other expenses	87,660,000	2,075,00
Subtotal		4,002,000
Subtotal, Built-in		25,788,000

# Summary of Changes--continued

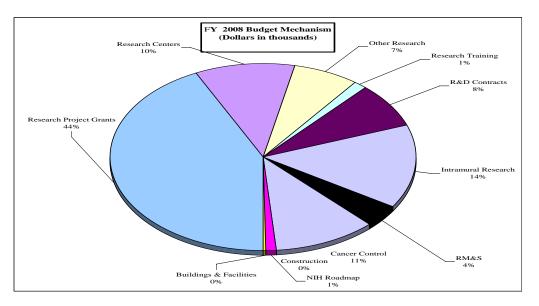
		FY 2007 Continuing Resolution	Chan	ge from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	· ·	\$1,597,618,000	-187	-\$88,115,000
b. Competing	1,244	, ,	144	46,883,000
c. SBIR/STTR	248	90,735,000	3	950,000
Total	5,370	2,091,633,000	-40	-40,282,000
2. Research centers	165	487,505,000	2	8,000,000
3. Other research	895	331,896,000	23	4,500,000
4. Research training	1,425	66,279,000	0	0
5. Research and development contracts	336	364,742,000	5	9,756,000
Subtotal, extramural				-18,026,000
	<u>FTEs</u>		<b>FTEs</b>	
6. Intramural research	1,803	686,555,000	25	-20,537,000
7. Research management and support	632	186,896,000	9	-3,020,000
8. Cancer control and prevention	395	510,400,000	6	998,000
9. Construction		0		0
10. Buildings and Facilities		7,920,000		-80,000
11. NIH Roadmap for Medical Research	5	57,382,000	0	5,783,000
Subtotal, program		4,791,208,000		-34,882,000
Total changes	2,835		40	-9,094,000

## Fiscal Year 2008 Budget Graphs

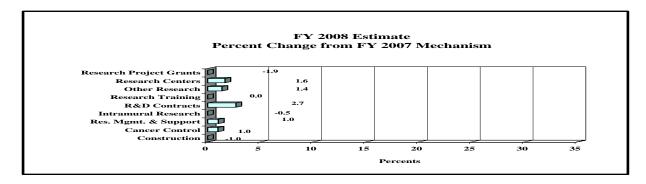




## Distribution by Mechanism:



## Changes to Selected Mechanisms:



## Justification

### National Cancer Institute

Authorizing Legislation	: Section 301 a amended.	nd title IV of the Public Heal	th Service Act, as
Budget Authority:			
FY 2006	FY 2007	FY 2008	Increase or
Actual	Estimate	Estimate	Decrease
FTE BA	<u>FTE</u> <u>BA</u>	<u>FTE</u> <u>BA</u>	<u>FTE</u> <u>BA</u>
2,777 \$4,795,073,000	2.835 \$4.791.208.	000 2.875 \$4.782.114.000	40 -\$9.094.000

This document provides justification for the Fiscal Year 2008 activities of the National Cancer Institute (NCI), including HIV/AIDS activities. Details of the FY 2008 HIV/AIDS activities are in the Office of AIDS Research (OAR) section of the Overview, Volume One. Details on the Roadmap/Common Fund are located in the Overview, Volume One.

## **DIRECTOR'S OVERVIEW**

The past year in cancer research shows a record of substantial scientific achievements that builds on existing NCI programs. The Food and Drug Administration (FDA) approval of the human papillomavirus (HPV) vaccine to protect against cervical cancer, the identification of characteristic patterns of protein expression<sup>1</sup> in cancer cells, the creation of the Nanotechnology Alliance for Cancer, and advances in lymphoma diagnosis are just a few gains that have enabled researchers to better understand and pre-empt cancer. NCI has translated knowledge into real benefits for people. NCI expanded infrastructure to include technical tools that have enabled rapid advances across the full continuum of cancer research from understanding the mechanisms of cancer to individualizing treatment for patients. NCI has increased the opportunities to prevent cancer at its earliest stage or manage this disease so that it does not become lethal.

Marking what many cancer researchers are calling an important trend, the actual number of cancer deaths in the United States fell by more than 3,000 from 2003 to 2004, the most recent year for which mortality data are available. The steady decline in the rate of cancer deaths also continued. The downturn from 556,902 deaths in 2003 to 553,888 in 2004 marks the biggest single-year decrease ever and the second consecutive year in which actual deaths - not just the death rate - have dipped. This decrease in actual number of cancer deaths, coupled with our SEER data showing a decline in the rate of cancer deaths since 1991, is extremely encouraging and highlights real progress. The new mortality numbers were released as part of an annual report released by the American Cancer Society (ACS), *Cancer Statistics 2007*, which reports on

<sup>&</sup>lt;sup>1</sup> Protein expression is a measure of the production of protein by the cells' genetic machinery.

the most recent mortality data, as well as providing cancer incidence and mortality estimates for the current year.

In FY 2006, NCI published a Strategic Plan that outlined what NCI can do to lessen the burden of cancer. This Plan will be used as a reference and guide to integrate activities around competing priorities. NCI will continue to partner with others to leverage resources and build synergy around strategic objectives. At the same time, NCI is supporting the training and mentored research of new investigators. They will propel our country's scientific capacity for years to come.

The Institute's investment encompasses two fronts:

- To preempt cancer at every opportunity by understanding the causes and mechanisms of cancer, accelerating progress in cancer prevention, improving early detection and diagnosis, and developing effective and efficient treatments.
- To ensure the best outcomes for all by understanding the factors that influence cancer outcomes; improving the quality of cancer care; improving the quality of life for cancer patients, survivors, and their families; and overcoming cancer health disparities.

NCI's many accomplishments in FY 2006 and those expected in FY 2007 are yielding new opportunities for FY 2008. But to ensure successful research outcomes NCI will seek to enable the best and brightest investigators and clinicians. By coupling the unparalleled peer review process with strategic planning, NCI can ensure that the highest quality science is directed at cancer.

## Program Highlights in FY 2006 and 2007:

- Using the Genome Map to Advance Understanding of Cancer NCI is capitalizing on the momentum generated by advances in human genetic research to accelerate understanding of the molecular basis of cancer. In collaboration with the National Human Genome Research Institute, The Cancer Genome Atlas (TCGA) Pilot Project developed and tested the science and technology needed to systematically identify the genetic changes associated with cancer, starting with brain, lung, and ovarian cancers.
- Identifying Genetic Risk for Cancer The Cancer Genetic Markers of Susceptibility (CGEMS) "scanned" the genome to identify genetic changes associated with either increased or decreased risk for breast and prostate cancer. Data from CGEMS and similar studies provides the basis for predicting cancer risk and taking appropriate steps to prevent it.
- Enhancing Access to State-of-the-Science Treatment In FY 2007, NCI launched a pilot phase of the NCI Community Cancer Centers Program (NCCCP) to research, for 3 years, how best to deliver state-of-the-art oncology care to the community setting, and how to bring science to people where they live. This initiative has clear-cut goals to improve cancer prevention, screening, and treatment; increase participation

in early phase clinical trials; and reduce healthcare disparities. Additional focus includes increased participation in biospecimen and electronic medical record initiatives. These centers facilitate a multi-specialty approach to cancer through organ-based clinical programs, a knowledge exchange network, and specialized training of cancer practitioners. NCI's Patient Navigator Research Program complements the NCCCP by addressing widespread disparities in cancer screening, treatment, and care for disadvantaged, mostly minority populations.

## Plans for FY 2008:

- Support Funding for Research Projects Funding for extramural research, primarily through investigator-initiated Research Project Grants, comprises the largest part of NCI's budget and helps to define and advance strategic opportunities. NCI funds RPGs in approximately 650 institutions across the U.S.
- Enhance the Impact of Cancer Centers NCI-designated Cancer Centers integrate multidisciplinary research across single or multiple institutions and partner with government agencies and the local community for education and other services. NCI will enhance their impact even further by facilitating increased interaction and outreach to the community. NCI will broaden their geographic reach and integrate them with community and regional healthcare delivery systems.
- Link Science and Technology

Cancer is a complex disease that involves the tumor and its biological support system. The newly established Integrative Cancer Biology Program (ICBP) will focus on the development and implementation of computational models of cancer processes. NCI will fund nine multidisciplinary and integrative cancer biology centers for research across the continuum to understand the fundamental properties of the cellular progression from normal to cancer.

Nanotechnology has emerged from the ongoing technology revolution as a key strategy for cancer diagnosis and treatment and will likely be instrumental in an era of personalized medicine. NCI will increase support of research and development in collaboration with scientific and research communities and the public and private sectors through NCI's Alliance for Nanotechnology in Cancer. These efforts capitalize on the multidisciplinary nature of nanotechnology development and will hasten its application to cancer research.

The Cancer Genome Atlas (TCGA) is a comprehensive and coordinated effort to accelerate our understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing. The NCI and the National Human Genome Research Institute have launched the TCGA Pilot Project to assess the feasibility of a full-scale effort to systematically explore the entire spectrum of genomic changes involved in human cancer. The overarching goal of TCGA is to improve our ability to diagnose, treat, and prevent cancer. Tumors to be studied in this pilot are lung, brain (glioblastoma) and ovarian.

• Integrate Science through Interdisciplinary Teams

Increasingly, scientists must be able to work in interdisciplinary teams to fully access key technologies and share expertise. NCI will expand integrative science to connect the physical and biological sciences through the application of computational biology, mathematics, and physics.

 Support Cancer Clinical Trials to Realize the Promise of Molecular Medicine NCI will advance clinical studies to lead the development of new therapies, diagnostic procedures, and biomarkers toward personalized cancer interventions. The Institute has begun to implement recommendations from the Clinical Trials Working Group (CTWG), established by the National Cancer Advisory Board. The CTWG's 22 recommendations consist of proposals for fundamental changes in how NCI's clinical trials system operates; initiatives to expand or enhance activities already underway; and two NCI-wide initiatives to establish the infrastructure to make the redesign continuous, efficient, and effective. These initiatives encompass disease-specific priorities, with the first to include gastrointestinal, gynecologic, and head and neck cancers. The CTWG incorporates five themes: prioritization/scientific quality, standardization, coordination, operational efficiency, and integrated management.

## FY 2008 Justification by Activity Detail

<u>Overall Budget Policy</u>: NCI's highest priorities for FY 2008 are to increase the number of new and competing Research Project Grants, enhance the impact of Cancer Center research, link science and technology, integrate science through interdisciplinary teams, and support cancer clinical trials to realize the promise of molecular medicine. At the same time, NCI will support the training and mentored research of new investigators, who will enhance our country's scientific capacity for years to come. These initiatives are critical to how NCI works at an operational level and key to bioscience infrastructure that facilitates the cancer research continuum. They overarch the activities described in the Program Funding Table.

NCI's Program Funding Table comprises the primary building blocks used to manage NCI's portfolio and parallels closely the objectives identified in NCI's Strategic Plan. This Plan was developed with input from advisory boards and scientific, medical, advocacy, and consumer groups. The Plan identifies opportunities in broad research areas and recommends optimal use of existing and new knowledge to develop evidence-based interventions for preventing and controlling cancer.

The largest portion of NCI's budget supports the research of scientists at universities, teaching hospitals, and Cancer Centers across the country. These extramural investigators submit proposals that are selected for funding by peer review, a process by which cancer experts identify the best science (most needed areas of discovery and emerging strategic opportunities). About 15 percent of NCI research dollars stay at NIH to support the work of intramural scientists. They focus on laboratory investigation, epidemiologic and genetics studies, translational research, and clinical research. Because of the excellence of NCI scientists and the intramural infrastructure, NCI has the ability to conduct high-risk and distinctive research, broadly distribute technology, and forge partnerships for the benefit of cancer patients and the scientific community. Patients benefit from access to research protocols and treatments available at the NIH Clinical Center.

Together, NCI-supported extramural and intramural research advance the scientific findings needed to lessen the burden of cancer on the lives of Americans and the impact of cancer on our economy. The following narrative includes representative NCI activities that highlight program plans and expected accomplishments.

## **Understand the Mechanisms of Cancer**

Cancer is a set of diseases that develop through genetic alterations in the normal cell over time. Research that improves understanding of the molecular mechanisms of cancer – from identifying genetic mutations that increase cancer risk to elucidating the process of metastasis – is essential to NCI's ability to develop and apply interventions to preempt cancer initiation and progression. Emerging technologies that enable comprehensive molecular analysis of tumors will help researchers understand the development and the vulnerabilities of specific types of cancer. Knowing how the tumor microenvironment impacts cancer initiation and progression and the effectiveness of treatment will help guide the development of rationally designed interventions. This research to unravel the molecular complexities of cancer will underpin the discovery and development of personalized interventions to prevent, detect, diagnose, and treat cancer. The challenging task of elucidating the complexity of cancer demands a multidisciplinary approach that draws on the strengths of both the intramural and extramural research communities.

Budget Policy: The FY2008 budget estimate for the Understanding the Mechanisms of Cancer program is \$772.112 million, a decrease of \$6.936 million or .9 percent from the FY 2007 estimate. Much of this decrease is a result of decreasing noncompeting Research Project Grant commitments. To support the program goals, high priority will be given to continue NCI activities including the Tumor Microenvironment Network (TMEN). This initiative will create inter-connected, multidisciplinary teams of investigators and collaborative groups that work together on projects focused on the tumor microenvironment. The main emphasis of TMEN will be a comprehensive understanding of the stroma (the supporting connective tissue of an organ), in normal tissues as well as its role in tumor initiation, progression, and metastasis. This is expected to provide novel diagnostic, therapeutic, and prevention targets. In addition, the Immunology and Carcinogenesis initiative will integrate highly productive basic, clinical, and core technology infrastructure with cross-cutting intramural and extramural research activities. The initiative will explore one of the major causes of cancer – chronic inflammation caused by infections. Investigators will elucidate the mechanisms of cancer susceptibility and chronic inflammatory diseases, the role of immunity in inflammation, and the role of cancer stem cells in carcinogenesis. The initiative will also focus on the discovery and development of inflammationrelated molecular targets for cancer prevention and therapy. Other activities include the following: (1) Applying high-throughput technologies to accelerate understanding of the genomic basis of cancer through The Cancer Genome Atlas; (2) Developing high resolution electronic microscopic imaging at the nanoscale in biology and medicine through the Imaging at the Nanoscale initiative; (3) Coordinating complex genetic and genomic analyses on biospecimens from cancer patients to advance understanding of the mechanisms of cancer through the Clinical Molecular Profiling Core; (4) Developing and deploying animal models that accurately simulate human diseases through the Mouse Models of Human Cancer Consortium; and (5) Creating the Integrative Cancer Biology Program, NCI's primary effort in the area of systems and computational biology.

### **Understand the Causes of Cancer**

NCI's etiology research focuses on identifying and understanding the origins and causes of cancer. Genetic, environmental, and lifestyle factors can all contribute to cancer development. Genetic factors may include inherited genes known to be involved in familial cancer syndromes and spontaneous mutations to genes involved in the regulation of cells. Examples of environmental factors that may affect cancer development include exposures to radiation, organic solvents, asbestos, other pollutants, and infectious agents such as viruses or bacteria. Lifestyle factors that can be associated with risk include smoking, alcohol consumption, the number of times a woman has given birth (parity), sun exposure, diet, and level of exercise. NCI's research portfolio includes population studies that link cancer to genetic, environmental or lifestyle factors in national and international cohorts.

Budget Policy: The FY2008 budget estimate for the Understanding the Causes of Cancer program is \$1,057.063 million, a decrease of \$9.602 million or .9 percent from the FY 2007 estimate. Much of this decrease is a result of decreasing noncompeting Research Project Grant commitments. To support the program goals, high priority will be given to continue NCI activities including whole genome scanning, a technique that looks for differences between the genes of patients who have cancer compared with the genes of people who have never had this disease. Researchers will further examine these differences to identify mutations that may cause cancer susceptibility. Collaboration among intramural and extramural researchers across the country and internationally is needed to recruit the large numbers of study participants needed for this research. NCI has found that its Cohort Consortium research model provides an optimal forum for successful whole genome scanning studies. In addition, NCI is forming PanScan, a Pancreatic Cancer Cohort Consortium, within the framework of the NCI-sponsored Cohort Consortium. PanScan will conduct a whole genome scan to identify genetic markers of susceptibility to pancreatic cancer, a rare, high-mortality cancer. The Cancer Genetic Markers of Susceptibility initiative will use whole genome scanning to identify susceptibility genes associated with risk for breast and prostate cancer, the second-leading cancer killers in women and men, respectively. NCI will make the results of these two studies available to the research community to accelerate the pace of discovery and characterization of genetic markers for cancer risk. NCI also expects these data to spur research on the effects of gene, environment, and lifestyle interactions on the risk for developing cancer. In summary, these studies offer a unique and powerful opportunity for meaningful advancement in understanding the etiology of these cancers in ways that will fuel the development of prevention interventions and strategies. Other activities include the following: (1) Evaluating the role of genetic susceptibility, environmental exposures, and gene-environment interactions in cancer risk through international consortia, including the Cohort Consortium, InterLymph, and the Childhood Cancer Survivor Study; (2) Supporting innovative epidemiologic research through the Epigenetic Approaches in Cancer Epidemiology initiative (epigenetics refers to heritable factors which influence the behavior of a cell without directly affecting its DNA or other genetic machinery); and (3) Conducting innovative research in genetics, imaging, and cancer molecular signatures to better understand the relationships between aging and the development and progression of cancer, in order to improve outcomes, survivorship, and symptom control in the aging population.

#### **Improve Early Detection and Diagnosis**

Detecting and diagnosing tumors early in the disease process, before the tumor becomes invasive and metastasizes, can dramatically improve the patient's odds for successful treatment and survival and reduce cancer deaths. To care for their patients, clinicians need validated biomarkers that provide accurate, validated information for cancer detection and diagnosis. They need better diagnostic and screening tools for characterizing cancers at the time of diagnosis. Accurate risk factor profiles are needed to identify patients who are likely to benefit the most from screening. Also necessary are interventions that eliminate barriers to follow-up care and ensure that patients fully comprehend the importance of recommended follow-up. Besides supporting research to discover and develop interventions to meet these needs, NCI works to move emerging research advances into the clinic by bridging gaps across the translational spectrum.

Budget Policy: The FY2008 budget estimate for the Improve Early Detection and Diagnosis program is \$397.282 million, a decrease of \$4.077 million or 1.0 percent from the FY 2007 estimate. Much of this decrease is a result of decreasing noncompeting Research Project Grant commitments. To support the program goals, high priority will be given to continue NCI activities including the Clinical Proteomic Technologies Initiative for Cancer. The study of the structure and function of proteins and their interactions represents a major effort in cancer research. Investigators have recognized potential applications for proteomic technologies, such as tests to detect early-stage cancers and technologies to identify therapeutic targets and biological markers of treatment response. However, the development of accurate, reliable proteomic technologies requires a large-scale, coordinated effort among multiple laboratories that are linked with powerful informatics capabilities. This initiative will build integrative networks of multiple research laboratories to focus on collaborative proteomic research and to generate standardized, reliable, and reproducible proteomic technologies. In addition, NCI will continue to develop imaging to detect, diagnose, and monitor cancer. Molecular imaging is a sophisticated technology that NCI expects will profoundly impact the everyday lives of many cancer patients. This technology reveals functional and molecular information about how a cell transforms from normal to cancerous. Molecular Imaging Probes allow detection of cancer in its earliest stages and can provide information to inform diagnosis and response to therapy. Molecular imaging probes are substances that are administered to the body and that can be detected by these imaging techniques. Some probes reveal developing cancer by attaching to early stage cancer cells or by responding to physiologic conditions typical of developing tumors. In addition to a grants portfolio that includes many imaging probe programs, the Cancer Imaging Program has several special initiatives that promote multidisciplinary research on molecular imaging, expedite and facilitate development of promising imaging probes from laboratory to application as an investigational new drug (IND). Investigators are also provided assistance with the regulatory IND process. Other activities include the following: (1) Researching and developing biomarkers and technologies for the clinical application of early cancer detection strategies through the Early Detection Research Network; (2) Defining the profiles, or

characteristic patterns, of gene expression<sup>2</sup> associated with all types of human lymphoid malignancies through the Lymphoma/Leukemia Molecular Profiling Clinical Trial; (3) Understanding the biological changes that lead to breast cancer through the Trans-NCI Breast Premalignancy Program; (4) Supporting basic and clinical research to develop early detection tests and effective treatments that are likely to provide more immediate benefits for lung cancer patients, through the Trans-NCI Lung Cancer Program; (5) Building a repository of blood samples through the Ovarian Cancer Recurrence Trial to develop proteomic technologies, which will identify unique patterns of protein expression associated with ovarian cancer, for detecting this disease soon after it returns; (6) Leveraging data warehousing technology to host and integrate clinical and functional genomics data from clinical trials involving patients with types of brain cancers known as gliomas through the Repository for Molecular Brain Neoplasia Data (REMBRANDT); and (7) Determining whether certain cancer screening tests reduce deaths through the Prostate, Lung, Colorectal, Ovarian Screening Study.

#### Portrait of a Program: Enabling Technology

FY 2007 Level:\$56 millionFY 2008 Level:\$66 millionChange:\$10 million

Research over the past three decades has led to significant progress in understanding of cancer at the genetic, molecular, and cellular levels. NCI undertakes a range of supporting studies in biomedical technology and bioinformatics to provide the level of understanding needed to realize a new era of molecular-based personalized cancer medicine. Examples of NCI's activities that will be ongoing in 2008 include: Informatics and Cancer. NCI is leading the development of a bioinformatics platform, caBIG<sup>TM</sup>, which will enable researchers and clinicians to access and integrate cancer research results across scientific disciplines, populations, and geography. Managing and sharing data in real time has emerged as a major challenge and has been made more daunting by the lack of consistent data standards and tools for bioinformatics applications.

This year, the pilot phase of caBIG<sup>TM</sup> which included 40 major Cancer Centers, FDA, and the private sector, was successfully completed. caBIG<sup>TM</sup> will continue to expand partnerships and provide the connectivity needed to support the advent of personalized medicine. Genetics and Cancer. A three-year pilot project will assess the feasibility of a full-scale effort to systematically identify all genetic changes involved in human cancer. The Cancer Genome Atlas (TCGA) consists of four integrated components: the Cancer Genome Characterization Centers (CGCCs), a Data Coordinating Center (DCC), a Biospecimen Core Resource (BCR), and the Genome Sequencing Centers. Tumors to be studied in this pilot are lung, brain (glioblastoma), and ovarian; all data will be publicly available to researchers worldwide through caBIG<sup>TM</sup>. Proteomics and Cancer. A new Clinical Proteomics Program is developing standards for the types and applications of technologies used to detect characteristic patterns of protein expression in human blood samples that can be used for early detection of cancer.

The goal is to develop standardized technologies that measure abnormal proteins with enough accuracy to be used as cancer diagnostic blood tests. Nanotechnology and Cancer. NCI's Nanotechnology Alliance for Cancer has begun harnessing nanotechnologies for cancer diagnostics, targeted imaging, and drug delivery. Multifunctional, targeted devices capable of bypassing biological barriers will enhance NCI's ability to effectively and efficiently treat cancer by delivering therapeutic agents directly to cancer cells.

 $<sup>^{2}</sup>$  Gene expression refers to the translation of the genetic code into the structures and function of a cell, e.g. protein production.

## **Develop Effective and Efficient Treatments**

Developing more efficient and effective cancer treatments that leave healthy tissues unharmed is a primary mission of NCI's research agenda. Research to understand the fundamental process of metastasis will provide knowledge needed to identify novel therapies to pre-empt or control metastatic tumors. Recent advances in biomedical technologies such as genomics, proteomics, metabolomics<sup>3</sup>, nanotechnology, and imaging have the potential to accelerate target identification and validation and the development of individualized treatment modalities. These advanced technologies and target identification are also invaluable in monitoring cancer progression, metastasis, and treatment response to inform cancer management strategies. The seamless continuum of discovery to delivery is key to ensuring timely translation of research findings into safe and effective therapeutics.

Budget Policy: The FY2008 budget estimate for the Develop Effective and Efficient Treatments program is \$1,100.049 million, a decrease of \$11.282 million or 1.0 percent from the FY 2007 estimate. Much of this decrease is a result of decreasing noncompeting Research Project Grant commitments. To support the program goals, high priority will be given to continue NCI activities including the Trial Assigning IndividuaLized Options for Treatment (Rx), named TAILORx. Although most women with early stage breast cancer are advised to undergo adjuvant chemotherapy, or chemotherapy given after surgery, research shows that it decreases recurrence risk in relatively few of these patients. TAILORx is addressing this predicament 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. The trial will use a new test that measures the expression of 21 genes in tumor samples to assign women to a treatment regimen. The test result is expressed as a "Recurrence Score." Women with a high recurrence score will receive a combination of adjuvant hormonal therapy and chemotherapy. Women with a score indicating a low risk of recurrence receive adjuvant hormonal therapy alone. Identification of those women who are most likely to benefit from chemotherapy holds the promise of improving outcomes for women with early stage breast cancer. Other activities include the following: (1) Quickly assessing whether experimental agents are reaching their target to produce the desired effects in humans before committing to large-scale development through the NCI Experimental Therapeutics Program (NEXT), an intramural/extramural collaboration; and (2) Evaluating key, well-characterized markers of patient response to therapies that target the epidermal growth factor receptor, a protein associated with several cancers, through the Epidermal Growth Factor Receptor Lung Trial.

#### Portrait of a Program: Clinical Trials Re-engineering

 FY 2007 Level:
 \$20.6 million

 FY 2008 Level:
 \$28.0 million

 Change:
 \$7.4 million

Cancer clinical trials are research studies in humans that answer scientific questions and attempt to find improved ways to prevent, screen for, diagnose, or treat cancer. Participants in clinical trials have an opportunity to contribute to knowledge of, and progress against, cancer while receiving new interventions and expert care. NCI currently supports over 1,300 clinical trials a year that focus on cancer prevention,

<sup>&</sup>lt;sup>3</sup> Metabolomics is the analysis of the molecules and processes associated with a biological system or cellular event.

screening, diagnostics, treatment, supportive care, and genetics.

To identify ways to enhance NCI's national clinical trials enterprise, NCI established the Clinical Trials Working Group (CTWG) in early 2004. Through a series of discussions, the CTWG identified the most critical issues that affect the conduct of clinical studies and developed possible models for making major improvements in the system. The CTWG's 22 recommendations consisted of proposals for fundamental changes in how NCI's clinical trials system operates; initiatives to expand or enhance activities already underway; and two NCI-wide initiatives to establish the infrastructure to make the redesign continuous, efficient, and effective.

In response to the CTWG's recommendations, NCI has adopted a new organizational plan to oversee the Institute's clinical trials expertise. Initiatives were developed to create a more integrated and efficient system that rapidly tests and delivers new therapies and preventions to patients. The restructuring plan contains five themes and takes into account NCI's disease-specific priorities in the form of three steering committees that provide advice, recommendations, and project management. The first disease-specific areas to be addressed are in gastrointestinal, gynecologic, and head and neck cancers. The CTWG five restructuring themes include: prioritization/scientific quality, standardization, coordination, operational efficiency, and integrated management.

Goals for NCI's clinical trials enterprise in FY2007 and FY2008 include identifying optimal early phase clinical trial design, developing standards for biomarkers, and defining prioritization criteria for quality of life studies and studies that deepen the understanding of the relationship between tumor characteristics and clinical outcomes (correlative science). Ultimately, these activities should markedly advance clinical practice for cancer in the 21st century by increasing clinical trials efficiency, decreasing redundancy and administrative burdens, and better coordinating activities to enhance the development and delivery of the best therapies to people with cancer.

#### **Cancer Prevention and Control**

Prevention is our first line of defense against cancer. Preventing cancer focuses on understanding and modifying behaviors that increase risk, mitigating the influence of genetic and environmental risk factors, and interrupting carcinogenesis through early intervention. NCI accelerates the discovery, development, and delivery of cancer prevention interventions by investing in research focused on risk assessment, systems biology<sup>4</sup>, behavior modifications, environmental and policy influences, medical and nutritional approaches, and training and education for research and health professionals. NCI works to systematically identify the most promising advances, harness their application for new prevention approaches, and encourage and monitor the adoption of prevention interventions in public health and clinical settings.

Cancer control research aims to reduce risk, incidence, and deaths from cancer as well as enhance the quality of life for cancer survivors. NCI supports and conducts research to better understand factors that influence cancer outcomes by improving outcome measurement, expanding access to data, investigating behavioral and sociocultural influences on cancer outcomes and access to care, and better understanding how to disseminate the results of research and promote their use in public health, medical practice, and policy making. This understanding will inform continued efforts to improve the quality of care across the cancer continuum, improve the quality of life for cancer survivors and their families, and overcome cancer health disparities.

<sup>&</sup>lt;sup>4</sup> Systems biology focuses on integrating information about the components of biological systems, such as genes and proteins, and their environments.

Budget Policy: The FY2008 budget estimate for the Cancer Prevention and Control program is \$515.400 million, an increase of \$5 million or 1.0 percent from the FY 2007 estimate. To support the program goals, high priority will be given to continue the development of Vaccines for Cancer Prevention. Nearly two decades ago, researchers at NCI and other institutions began searching for the underlying causes of cervical cancer. Early population studies helped establish the link between the human papillomavirus (HPV) infection and cervical cancer, a cancer that claimed more than 200,000 lives worldwide last year. Researchers then examined ways to boost the body's immune response to prevent the cancer-causing infection. This year, a vaccine that is 100 percent protective against the development of cervical cancer and genital warts caused by four subtypes of HPV was approved by the FDA and a second vaccine is being reviewed. Ongoing NCI studies are examining the vaccine's long-term safety and the extent and duration of protection. NCI and collaborators are also working on therapeutic HPV vaccines that would prevent the development of cancer among women previously exposed to HPV. NCI is also engaged in communication research to ensure that the public receives accurate, easily-understood information about HPV and to facilitate access to appropriate tests for those who need them. In addition, NCI will continue to study Energy Balance<sup>5</sup> as a Way to Control Cancer Incidence. In 2001, the Secretary of DHHS identified overweight and obesity as a public health priority. Scientists at NCI have been studying various aspects of energy balance, a high-priority topic of research. NCI created a working group in 2002 as a forum for sharing information among nutrition experts from across NCI and for fostering transdisciplinary research related to energy balance and cancer. This led to the creation of the Centers for Transdisciplinary Research on Energetics and Cancer (TREC). TREC fosters collaboration among transdisciplinary teams of scientists to accelerate progress toward reducing cancer incidence, morbidity, and mortality associated with obesity, low levels of physical activity, and poor diet. These activities are components of NCI's larger energy balance research focus, which complements the trans-NIH Obesity Task Force. Other activities include the following: (1) Conducting research on cancer prevention, early detection, treatment, long-term care, and surveillance through the Cancer Research Network, which consists of the research programs, enrolled populations, and data systems of 12 HMOs nationwide; (2) Researching safety and efficacy of breast cancer chemoprevention agents through the Breast Cancer Prevention Program; and (3) Researching the benefit of prophylactic oophorectomy, the removal of the ovaries to reduce the risk of ovarian cancer, through the Study of Prophylactic Oophorectomy to Prevent Breast/Ovarian Cancer in High Risk Women.

## **Cancer Centers, Specialized Centers and SPORE Programs**

New research paradigms hinge on interdisciplinary science, strategic partnerships, rapid application of new technologies, optimal information sharing, and close links to health care delivery systems. NCI Cancer Centers, specialized centers, and Specialized Programs of Research Excellence (SPOREs) comprise a model framework that supports team science. The 61 NCI-designated Cancer Centers integrate multidisciplinary research within and across institutions nationwide, and also provide clinical and educational services to their local communities. The Cancer Centers bring together the best of basic, translational, and population research to achieve improved cancer prevention, diagnosis, and treatment, while also stimulating

<sup>&</sup>lt;sup>5</sup> Energy balance refers to the integrated effects of diet, physical activity, and genetics on growth and body weight over an individual's lifetime.

innovative pilot projects in new investigational areas. Specialized Centers, such as the Integrative Cancer Biology Program Centers, Tumor Microenviroment Centers, Translational Research on Energetics and Cancer Centers, and Nanotechnology Centers focus on key research areas to reduce cancer morbidity and mortality, whereas SPOREs focus entirely on discovery-to-delivery research dedicated to specific cancers.

<u>Budget Policy:</u> The FY2008 budget estimate for the Cancer Centers, Specialized Centers and SPORE program is \$495.505 million, an increase of \$8 million or 1.6 percent from the FY 2007 estimate. To support the program goals, NCI activities include the following: (1) Developing an integrated biological view of cancer through the Integrated Biology Consortium and the Integrated Cancer Biology Program, which supports nine centers that use multi-discipline approaches to link biology, bioinformatics, and mathematical modeling in the understanding of cancer; and (2) Determining the reasons behind significant cancer disparities and their impact on minority populations through the Comprehensive Minority Institution/Cancer Center Partnership (U54).

#### Portrait of a Program: Improving Patient Access to Community Cancer Care

 FY 2007 Level:
 \$3.3 million

 FY 2008 Level:
 <u>\$6.6 million</u>

 Change:
 \$3.3 million

NCI recognizes that the rapidly growing population of older people in the U. S., as well as underserved or disadvantaged populations, needs support in order to access quality care. Recently, the President of the American Cancer Society aptly noted that access by cancer patients to state-of-the art care will be a bigger determinant to mortality than any risk factors identified today. However, if we are to bring the latest scientific advances to the majority of cancer patients, we must reach them in the communities where they live and receive care.

The unique clinical trial infrastructure provided by NCI-designated Cancer Centers has been foundational to the continual improvements made in all aspects of cancer care. However, the fact still remains that 85 percent of cancer patients receive their care at the local community level. To bring the latest scientific advances to the patient, NCI is continuing to develop programs to reach them in their communities. The pilot of the NCI Community Cancer Centers Program (NCCCP) will study the best ways to bring scientific advances to patients in their communities. This initiative will complement the existing network of Cancer Centers, Community Clinical Oncology Program sites, and other academic medical centers.

The NCCCP will create a multi-site cohort of cancer patients linked through electronic records and common bioinformatic databases, a research paradigm likely to speed clinical research and drug approval. The pilot will investigate ways to increase accrual to clinical trials, assess programs intended to bridge the disparities gap, develop standardized tissue banks that will enable future research, and bring community-based oncology into the era of electronic medical records and information technology networks. The NCCCP pilot will be an important step in transferring the rigors of clinical cancer care to local hospitals and clinics, raising the quality of care and acquainting community physicians with state-of-the-art cancer care management. The program will pay close attention to one of the most serious cancer-related issues, disparities in care.

#### **Research Workforce Development**

Rapid developments on the frontiers of science and technology, including molecular biology and translational medicine, have broadened the scope of cancer research and present new challenges

for training future cancer researchers. Furthermore, the success of research designed to reduce the disproportionate burden of cancer incidence and mortality in underserved populations depends on increasing the number of culturally competent, well-trained investigators. NCI helps prepare the next generation of cancer researchers to meet the challenges of multidisciplinary research that span basic, clinical, behavioral, and applied studies. NCI provides cancer research training and career development opportunities to high school, undergraduate, and graduate students, postdoctoral fellows, and physicians across the U. S.

Budget Policy: The FY2008 budget estimate for the Research Workforce Development program is \$184.902 million, an increase of \$2.2 million or 1.2 percent from the FY 2007 estimate. To support the program goals, high priority will be given to continue the Interagency Oncology Taskforce (IOTF), a partnership with the FDA. Training opportunities have arisen from this relationship, including the Fellowship Program in Research and Regulatory Review. This program provides training for a cadre of researchers to bridge the varied research and regulatory processes between scientific discovery through clinical development and regulatory review of new oncology products. Fellows also will learn how to bring state-of-the art knowledge and technology to bear on the design, conduct, and review of clinical trials. In addition, the Principal Investigator 101 training for the Rapid Access to Intervention Development program, organized through the IOTF, is being planned in 2006 and will be implemented in 2007. Other activities include the following: (1) Supporting medical school training for individuals through the Uniformed Services University/NCI Training Program; (2) Increasing the number of doctors and Oncology Registered Nurses in clinical and translational research through career awards for clinical oncology; (3) Training and mentoring physician scientists to promote the development of their expertise in laboratory or clinical-translational research through the Physician Scientist Training Program; and (4) Embracing diversity among the pool of trainee applicants to include more students from underrepresented groups and with disadvantaged backgrounds through Cancer Research Interns in Residence.

## **Buildings and Facilities**

The renovation and improvement funds for the facilities at the NCI-Frederick campus, located in Frederick, MD, were budgeted as facilities funds beginning in FY 2005. The funds are critical to maintain the operation of these facilities for the scientific missions of NCI, NIH, other government agencies, and the extramural community.

<u>Budget Policy:</u> The FY2008 budget estimate for the Building and Facilities program is \$7.840 million, a decrease of \$80 thousand or 1 percent from the FY 2007 estimate. To support the program goals, NCI activities include the following: (1) NCI plans to use the 2008 funds to initiate renovation of the 8,000 square foot small-animal imaging facility. The planned renovations will create a state-of-the-art facility that includes multiple imaging modalities (such as MRI, CT/SPECT, ultra-sound) for use in basic and preclinical research that uses animal models. Whole animal imaging allows a unique opportunity to elucidate the mechanisms of tumor growth and of responses to experimental treatments in living animals. (2) NCI also plans to use 2008 funds to renovate 2,000 square feet of chemistry laboratory space and 2,500 square feet of outdated BL-2 laboratory space for NCI's intramural research program.

## **Research Management and Support**

NCI RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of technical and administrative services including central administration, overall program direction, grant and contract administration, human resources, program coordination, and financial management. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute's programs, regulatory compliance, and liaison with other Federal agencies, Congress, and the public. The NCI regularly engages in business planning activities to streamline administrative functions. For example, NCI evaluated a new approach for reviewing program project grant applications. Under the new approach, applications were reviewed in clusters, instead of individually. Results from the evaluation demonstrated that the new process produced significant reductions in costs and overall time for reviewers and NCI staff. The NCI also commonly utilizes information technology solutions to improve efficiency and produce cost savings. The newly developed web-based application of document control forms, which improves efficiency of grants administration, is one example.

<u>Budget Policy</u>: The FY2008 budget estimate for Research Management and Support is \$188.796 million, an increase of \$1.9 million or 1 percent from the FY 2007 estimate.

<b>Budget Authority</b>	by Object
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r	Duuget Humonity	j object		
		FY 2007		
		Continuing	FY 2008	Increase or
		Resolution	Estimate	Decrease
Total c	compensable workyears:			
	Full-time employment	2,835	2,875	40
	Full-time equivalent of overtime & holiday hours		2,075	40
	Fun-time equivalent of overtime & nonday nours	/	/	0
	Average ES salary	\$163,289	\$168,188	4,899
	Average GM/GS grade	12.0	12.0	0
	Trende on ob grade	12.0	12.0	Ŭ
	Average GM/GS salary	\$86,157	\$88,742	2,585
	Average salary, grade established by act of			
	July 1, 1944 (42 U.S.C. 207)	\$82,763	\$85,246	2,483
	Average salary of ungraded positions	\$119,299	\$122,878	3,579
	Trende salary of angladed positions	¢11>,2>>	\$122,070	5,575
		FY 2007	FY 2008	Increase or
	OBJECT CLASSES			
		Estimate	Estimate	Decrease
11.1	Personnel Compensation:	\$215 625 000	\$226 272 000	10 (29 000
11.1	Full-Time Permanent	\$215,635,000	\$226,273,000	10,638,000
11.3	Other than Full-Time Permanent	49,654,000	52,104,000	2,450,000
11.5	Other Personnel Compensation	7,453,000	7,821,000	368,000
11.7	Military Personnel	6,894,000	7,235,000	341,000
11.8	Special Personnel Services Payments	53,305,000	53,305,000	0
	<b>Total, Personnel Compensation</b>	332,941,000	346,738,000	13,797,000
12.0	Personnel Benefits	75,719,000	79,435,000	3,716,000
12.2	Military Personnel Benefits	4,735,000	4,969,000	234,000
13.0	Benefits for Former Personnel	0	0	0
	Subtotal, Pay Costs	413,395,000	431,142,000	17,747,000
21.0	Travel & Transportation of Persons	14,868,000	14,348,000	-520,000
22.0	Transportation of Things	1,030,000	993,000	-37,000
23.1	Rental Payments to GSA	5,000	5,000	0
23.2	Rental Payments to Others	222,000	215,000	-7,000
23.3	Communications, Utilities &	,	- ,	.,
	Miscellaneous Charges	8,474,000	8,177,000	-297,000
24.0	Printing & Reproduction	3,542,000	3,419,000	-123,000
25.1	Consulting Services	23,963,000	23,322,000	-641,000
25.2	Other Services	137,811,000	133,104,000	-4,707,000
25.3	Purchase of Goods & Services from	137,811,000	155,104,000	-4,707,000
25.5	Government Accounts	461,178,000	466,186,000	5,008,000
25 1	Operation & Maintenance of Facilities	73,350,000	73,252,000	-98,000
25.4	*	371,668,000	369,834,000	-98,000 -1,834,000
	Research & Development Contracts			, ,
25.6	Medical Care	4,913,000	4,691,000	-222,000
25.7	Operation & Maintenance of Equipment	16,000,000	15,540,000	-460,000
	Subsistence & Support of Persons	0	0	0
25.0	Subtotal, Other Contractual Services	1,088,883,000	1,085,929,000	-2,954,000
26.0	Supplies & Materials	45,298,000	43,710,000	-1,588,000
31.0	Equipment	21,607,000	20,851,000	-756,000
32.0	Land and Structures	0	0	0
	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	3,136,471,000	3,110,134,000	-26,337,000
42.0	Insurance Claims & Indemnities	10,000	10,000	0
43.0	Interest & Dividends	21,000	16,000	-5,000
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	4,320,431,000	4,287,807,000	-32,624,000
	NIH Roadmap for Medical Research	57,382,000	63,165,000	5,783,000
	Total Budget Authority by Object	4,791,208,000	4,782,114,000	-9,094,000
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Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

## Salaries and Expenses

	1		
OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Personnel Compensation:			
Full-Time Permanent (11.1)	\$215,635,000	\$226,273,000	10,638,000
Other Than Full-Time Permanent (11.3)	49,654,000	52,104,000	2,450,000
Other Personnel Compensation (11.5)	7,453,000	7,821,000	368,000
Military Personnel (11.7)	6,894,000	7,235,000	341,000
Special Personnel Services Payments (11.8)	53,305,000	53,305,000	0
Total Personnel Compensation (11.9)	332,941,000	346,738,000	13,797,000
Civilian Personnel Benefits (12.1)	75,719,000	79,435,000	3,716,000
Military Personnel Benefits (12.2)	4,735,000	4,969,000	234,000
Benefits to Former Personnel (13.0)	0	0	201,000
Subtotal, Pay Costs	413,395,000	431,142,000	17,747,000
Travel (21.0)	14,868,000	14,348,000	-520,000
Transportation of Things (22.0)	1,030,000	993,000	-37,000
Rental Payments to Others (23.2)	222,000	215,000	-7,000
Communications, Utilities and			, ,
Miscellaneous Charges (23.3)	8,474,000	8,177,000	-297,000
Printing and Reproduction (24.0)	3,542,000	3,419,000	-123,000
Other Contractual Services:			
Advisory and Assistance Services (25.1)	22,198,000	21,622,000	-576,000
Other Services (25.2)	137,811,000	133,104,000	-4,707,000
Purchases from Govt. Accounts (25.3)	180,098,000	181,937,000	1,839,000
Operation & Maintenance of Facilities (25.4)	8,642,000	8,289,000	-353,000
Operation & Maintenance of Equipment (25.7)	16,000,000	15,540,000	-460,000
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	364,749,000	360,492,000	-4,257,000
Supplies and Materials (26.0)	44,487,000	42,930,000	-1,557,000
Subtotal, Non-Pay Costs	437,372,000	430,574,000	-6,798,000
Total, Administrative Costs	850,767,000	861,716,000	10,949,000

		Authorizi	Authorizing Legislation			
	PHS Act/ Other Citation	P.L109-482	2007 Amount Authorized	FY 2007 Continuing Resolution	2008 Amount Authorized	FY 2008 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Cancer Institute	Section 402(a)	42§2XXX	Indefinite	\$4,791,208,000	Indefinite	\$4,782,114,000
Total, Budget Authority				4,791,208,000		4,782,114,000

	Appropriations History								
Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>					
1999	2,528,760,000 <u>2/ 3/</u>	2,787,830,000	2,927,187,000	2,927,187,000					
Rescission	0	0	0	-1,940,000					
2000	2,732,795,000 <u>2/</u>	3,163,417,000	3,286,859,000	3,332,317,000					
Rescission				-17,763,000					
2001	3,249,730,000 <u>2/</u>	3,505,072,000	3,804,084,000	3,754,456,000					
Rescission				-2,005,000					
2002	4,177,203,000	4,146,291,000	4,258,516,000	4,190,405,000					
Rescission				-9,172,000					
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	4,793,356,000 4/					
2008	4,782,114,000								

 $\underline{1}$ / Reflects enacted supplementals, rescissions, and reappropriations.

2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research

 $\underline{3/}$  Reflects a decrease of \$7,301,000 for the budget amendment for Bioterrorism

4/ Annualized current rate

Details of Full-Time Equivalen	pj	~)			
OFFICE/DIVISION	FY 2006 Actual	FY 2007 Continuting Resolution	FY 2008 Estimate		
Office of the Director	692	706	716		
Center for Cancer Research	1,444	1,474	1,495		
Division of Cancer Biology	42	43	44		
Division of Extramural Activities	78	80	81		
Division of Cancer Treatment and Diagnosis	174	178	180		
Division of Cancer Prevention	82	84	85		
Division of Cancer Control and Population Sciences	116	118	120		
Division of Cancer Epidemiology and Genetics	149	152	154		
Total	2,777	2,835	2,875		
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research					
FTEs supported by funds from Cooperative Research and Development Agreements	-3	-3	-3		
FISCAL YEAR	Average GM/GS Grade				
2004 2005 2006	11.7 11.9 12.0				
2008 2007 2008	12.0 12.0 12.0				

## **Details of Full-Time Equivalent Employment (FTEs)**

	FY 2006	FY 2007 Continuting	FY 2008
GRADE	Actual	Resolution	Estimate
Total, ES Positions	4	5	5
Total, ES Salary	\$636,358	\$816,447	\$840,940
GM/GS-15	221	221	221
GM/GS-14	366	370	372
GM/GS-13	325	335	342
GS-12	446	457	467
GS-11	210	214	218
GS-10	15	15	16
GS-9	155	162	166
GS-8	80	82	83
GS-7	74	76	77
GS-6	19	19	20
GS-5	13	13	13
GS-4	5	5	5
GS-3	1	1	1
GS-2	3	3	3
GS-1	0	0	0
Subtotal	1,933	1,974	2,003
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	41	41	41
Senior Grade	14	14	14
Full Grade	10	10	10
Senior Assistant Grade	6	6	6
Assistant Grade	2	2	2
Subtotal	74	74	74
Ungraded	857	875	887
Total permanent positions	2,628	2,683	2,721
Total positions, end of year	2,868	2,928	2,969
Total full-time equivalent (FTE)			
employment, end of year	2,777	2,835	2,875
Average ES salary	\$159,089	\$163,289	\$168,188
Average GM/GS grade	12.0	12.0	12.0
Average GM/GS salary	\$83,941	\$86,157	\$88,742

#### **Detail of Positions**

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Resea

# **New Positions Requested**

		FY 2008		
	Grade	Number	Annual Salary	
Investigator	AD/401/0	4	\$111,000	
Senior Investigator	AD/602/0	2	\$207,000	
Senior Clinician	AD/602/0	2	\$200,000	
Biologist	GS 12	8	\$80,000	
Staff Scientist	AD/401/0	5	\$99,000	
Staff Clinician	AD/602/0	5	\$166,000	
Health Scientist Administrator	<b>GS</b> 14	5	\$113,000	
Research Fellow	AD/401/0	6	\$73,000	
Clinical Fellow	AD/602/0	3	\$79,000	
Total Requested		40		