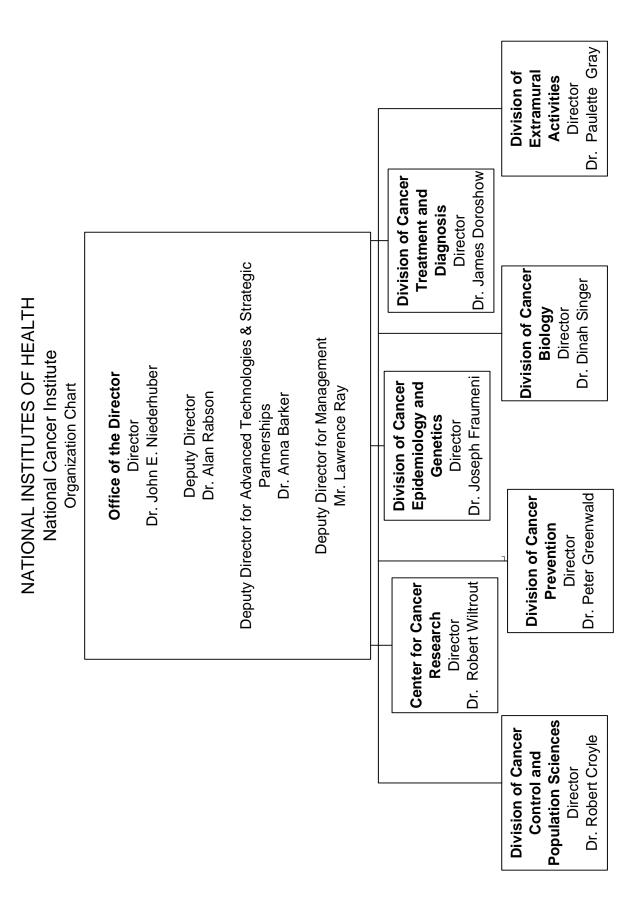
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# NATIONAL INSTITUTES OF HEALTH

# National Cancer Institute

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# 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, \$4,890,525,000 **\$4,809,819,000** 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, 2008)

#### National Institutes of Health National Cancer Institute

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$4,793,356,000	\$4,890,525,000	\$4,809,819,000
Pay cost add-on	4,283,000	0	0
Rescission	0	-85,437,000	0
Subtotal, adjusted appropriation	4,797,639,000	4,805,088,000	4,809,819,000
Real transfer under Director's one-percent transfer authority (GEI)	-5,015,000	0	0
Comparative transfer to NIBIB	-340,000	0	0
Comparative transfer to OD	-154,000	0	0
Comparative transfer to NCRR	-1,640,000	0	0
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	0	0
Comparative transfer under Director's one- percent transfer authority (GEI)	5,015,000	0	0
Subtotal, adjusted budget authority	4,795,491,000	4,805,088,000	4,809,819,000
Unobligated balance lapsing	-9,000	0	0
Total obligations	4,795,482,000	4,805,088,000	4,809,819,000

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

 1/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2007 - \$15,081,000 FY 2008 - \$15,339,000 FY 2009 - \$15,407,000 Excludes \$30,000,000 in FY 2008 and \$30,000,0000 in FY 2009 for royalties. Excludes \$3,006,106 of revenue collected in FY 2007 from the Breast Cancer Stamp.

#### NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

(Dollars in Thousands) Budget Mechanism - Total

		Budget Mech	anism - T	otal				
	F١	2007	FY	2008	F١	Y 2009		
MECHANISM	A	ctual	Ei	nacted	Es	stimate	Ch	ange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No. A	mount
Research Projects:								
Noncompeting	3,966	\$1,597,609	3,857	\$1,560,675	3,714	\$1,521,414	(143)	-\$39,261
Administrative supplements	(277)	39,864	(385)	46,000	(400)	51,000	(15)	5,000
Competing:	. ,		. ,		. ,		. ,	
Renewal	269	152,954	302	155,099	317	162,777	15	7,678
New	1,042	283,253	980	273,853	1,015	283,417	35	9,564
Supplements	19	1,886	21	4,490	37	9,145	16	4,655
Subtotal, competing	1,330	438,093	1,303	433,442	1,369	455,339	66	21,897
Subtotal, RPGs	5,296	2,075,566	5,160	2,040,117	5,083	2,027,753	(77)	-12,364
SBIR/STTR	278	93,677	251	89,121	251	89,121	0	0
Subtotal, RPGs	5,574	2,169,243	5,411	2,129,238	5,334	2,116,874	(77)	-12,364
Research Centers:								
Specialized/comprehensive	196	519,820	198	528,374	198	528,374	0	0
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
Subtotal, Centers	196	519,820	198	528,374	198	528,374	0	0
Other Research:								
Research careers	523	77,955	543	80,605	543	80,605	0	0
Cancer education	89	31,337	89	31,537	89	31,537	0	0
Cooperative clinical research	138	238,403	135	244,853	135	244,853	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	2,435	0	2,435	0	2,435	0	0
Other	150	63,559	153	64,160	153	64,160	0	0
Subtotal, Other Research	900	413,689	920	423,590	920	423,590	0	0
Total Research Grants	6,670	3,102,752	6,529	3,081,202	6,452	3,068,838	(77)	-12,364
Research Training:	<u>FTTPs</u>		FTTPs		FTTPs			
Individual awards	232	9,766	234	9,866	234	9,941	0	75
Institutional awards	1,223	58,457	1,233	58,957	1,233	59,457	0	500
Total, Training	1,455	68,223	1,467	68,823	1,467	69,398	0	575
Research & development contracts	470	558,410	466	569,342	466	569,342	0	0
(SBIR/STTR)	(45)	(12,387)		(15,000)		(15,000)	(0)	(0)
	FTES	· · · /	FTEs	· · /	FTEs	· · /	<u>FTEs</u>	( )
Intramural research	1,811	705,671	1,814	719,879	1,828	730,979	14	11,100
Research management and support	1,017	352,515	1,019	357,922	1,026	363,422	7	5,500
Construction		0		0		0		0
Buildings and Facilities		7,920		7,920		7,840		(80)
Total, NCI	2,828	4,795,491	2,833	4,805,088	2,854	4,809,819	21	4,731

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

	FY 2005	FY 2006	900	ΕΥ	FY 2007	FΥ	FY 2007	ΕY	FY 2008	ΕY	FY 2009		
	Actual	Actual	ual	Ac	Actual	Com	Comparable	Ш	Enacted	Est	Estimate	Change	nge
<b>Extramural Research</b>	<u>FTEs</u> Amount	FTEs A	Amount	FTES	Amount	FTES	Amount	<u>FTEs</u>	Amount	<u>FTEs</u>	Amount	FTEs Amount	mount
<u>Detail:</u>													
Understand the Mechanisms of Cancer	\$773,118	è.	\$795,035	~	\$796,449		\$797,987		\$785,981		\$781,683	3	(\$4,298)
Understand the Causes of Cancer	1,152,158	1'1	1,085,449	~	1,094,106		1,094,120		1,091,861		1,092,524		663
Improve Early Detection and Diagnosis	357,485	7	406,767		410,618		411,411		407,048		405,018		(2,030)
Develop Effective and Efficient Treatments	1,160,302	÷.	1,123,239	Ļ	1,146,272		1,148,486		1,149,803		1,156,725		6,922
Cancer Prevention and Control	377,616	• *	350,619		333,224		333,868		344,023		341,502		(2,521)
Cancer Centers, Specialized Centers and SPOREs 454,252	SPOREs 454,252	7	463,860		471,669		471,669		479,565		479,565		0
Research Workforce Development	178,532		182,015		179,155		177,515		180,965		181,540		575
Buildings and Facilities	7,936		7,920		7,920		7,920		7,920		7,840		(80)
Subtotal, Extramural*	4,461,399	4,	4,414,904	4	4,439,413		4,442,976		4,447,166		4,446,397		(769)
Intraminal research (non-add)	1 832 711 009	1 766	691 721	1811	706 179 1 811	1 811	705.671	71814	719 879	1 828	730 979	71	11 100
				25-	5				) ) ) -	2425	) -) -) -) -)		000
Res. management & support	1,022 336,340	1,011	339,221	1,017	353,211	1,017	352,515	1,019	357,922	1,026	363,422	7	5,500
TOTAL	2,854 4,797,739 2,777 4,754,125 2,828 4,792,624 2,828 4,795,491	2,777 4,7	754,125	2,828 4	,792,624	2,828		2,833	4,805,088	2,854	2,854 4,809,819	21	15,831
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research * The detail programs listed above include both extramural and intramural funding	l from the NIH Road Iclude both extramu	Roadmap for Medical Research ramural and intramural funding.	1edical R∈ ramural fu	ssearch Inding.									

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

# Major Changes in the Fiscal Year 2009 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 2009 budget request for NCI, which is \$4.731 million more than the FY 2008 Enacted, for a total of \$4,809.819 million.

<u>Research Project Grants (-\$12.364 million, total \$2,027.753 million).</u> NCI will support a total of 5,083 Research Project Grant (RPG) awards (not including SBIR/STTR) in FY 2009. Noncompeting RPGs will decrease by 143 awards and decrease by \$39.261 million. Competing RPGs will increase by 140 awards and increase by \$21.897 million. The NIH budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs.

National Research Service Awards (+\$575 thousand, total \$69.398 million). The NCI will provide a 1 percent stipend increase for all pre- and post-doc NRSA trainees.

Intramural Research (+\$11.100 million, total \$730.979 million). The NIH policy for Intramural Research is a 1.5% increase to partially pay for mandatory increases.

<u>Research Management and Support (+\$5.500 million, total \$363.422 million).</u> The NIH policy for Research Management and Support is a 1.5% increase to partially pay for increased operating expenses.

<u>Cancer Prevention and Control (-\$15 thousand, total \$511.004 million).</u> Beginning in FY 2009 Cancer Prevention and Control Activities, formerly shown as a separate line on the mechanism table, are spread back across the grant, R&D Contract and Research Management and Support mechanism lines. FY 2007 and 2008 have also been made comparable. The amount showing here for Cancer Prevention and Control is different from the figures showing on pages 6 and 21 because it includes control inhouse. The lower figures reflect the shift of control inhouse to the research management and support line.

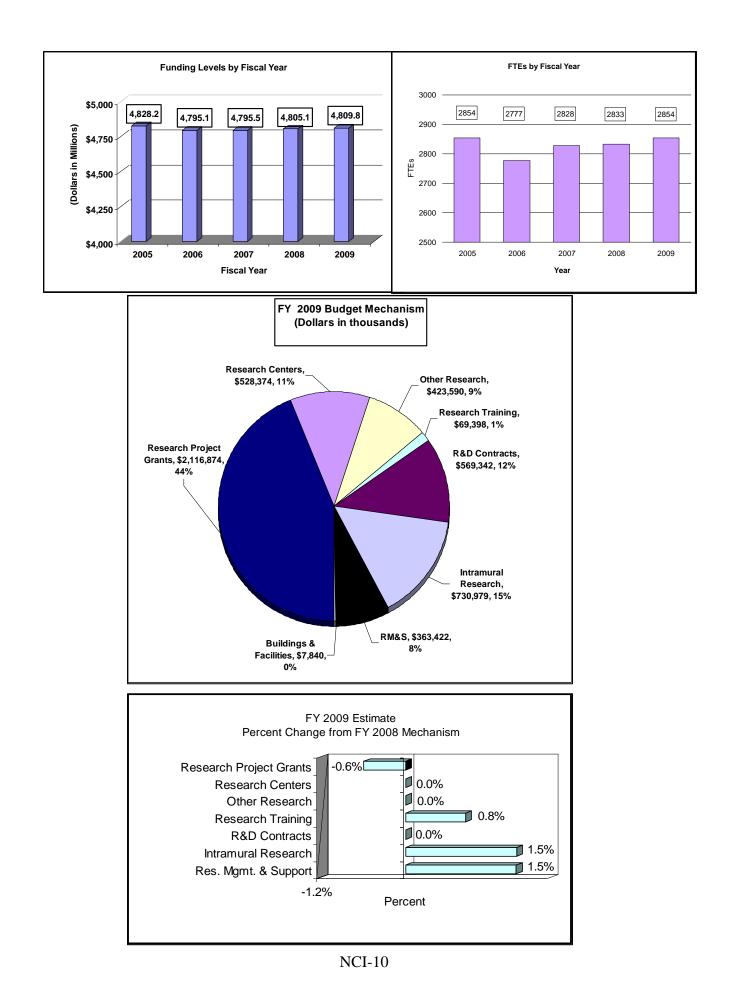
<u>Translational Research and Drug Discovery (+\$5 million, total \$60.000 million).</u> NCI will increase efforts in this program to continue the development of the Chemical Biology Consortium (CBC). This initiative is envisioned as a comprehensive drug development platform that will move basic academic research discoveries into preclinical development. This program is described further on page NCI-20.

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

Net change4,731,02008 Current Enacted BaseChange from Base BudgetBudgetBudgetBudgetFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityAuthorityAuthorityAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthorityFTESAuthority2008 pay increaseSubtotal15,867,07,389,0Subtotal15,867,00Subtotal15,867,00Subtotal15,867,00Subtotal15,140,000Sis,140,000Sis,140,000 <td< th=""><th>FY 2008 enacted</th><th></th><th></th><th>ç</th><th>\$4,805,088,000</th></td<>	FY 2008 enacted			ç	\$4,805,088,000
2008 Current Enacted BaseCHANGESFTEsAuthorityFTEsAuthorityA. Built-in:1.Intramural research: a. Annualization of January 2008 pay increase\$232,162,000\$2,596,0b. January FY 2009 pay increase232,162,000\$0,030,0c. One less day of pay232,162,000(889,0)d. Payment for centrally furnished services116,042,0001,741,0e. Increased cost of laboratory supplies, materials, and other expenses371,675,0007,389,0Subtotal15,867,02. Research management and support: a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase135,140,000\$1,511,0c. One less day of pay135,140,000\$1,511,0d. Payment for centrally furnished services135,140,000\$1,511,0e. Increased cost of January 2008 pay increase135,140,000\$1,511,0b. January FY 2009 pay increase135,140,000\$1,511,0c. One less day of pay135,140,000\$1,511,0d. Payment for centrally furnished services36,240,000\$44,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0	FY 2009 estimated budget authority				4,809,819,000
Enacted BaseChange from BaseCHANGESBudgetBudgetA. Built-in:1. Intramural research: a. Annualization of January 2008 pay increase\$232,162,000\$2,596,0b. January FY 2009 pay increase232,162,000\$0,00,0c. One less day of pay232,162,000(889,0)d. Payment for centrally furnished services116,042,0001,741,0e. Increased cost of laboratory supplies, materials, and other expenses371,675,0007,389,0Subtotal15,867,02. Research management and support: a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase135,140,000\$2,928,0c. One less day of pay135,140,000\$1,511,0b. January FY 2009 pay increase\$135,140,000\$1,511,0c. One less day of pay135,140,000\$1,511,0d. Payment for centrally furnished services36,240,000\$44,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0	Net change				4,731,000
CHANGESBudgetBudgetA. Built-in:1. Intramural research: a. Annualization of January 2008 pay increase\$232,162,000\$2,596,0b. January FY 2009 pay increase232,162,000\$0,00c. One less day of pay232,162,000(889,0)d. Payment for centrally furnished services116,042,0001,741,0e. Increased cost of laboratory supplies, materials, and other expenses371,675,0007,389,0Subtotal15,867,02. Research management and support: a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase c. One less day of pay135,140,000\$1,511,0d. Payment for centrally furnished services36,240,000\$44,0e. Increased cost of laboratory supplies, materials, and other expenses135,140,000\$1,511,0b. January FY 2009 pay increase c. One less day of pay d. Payment for centrally furnished services e. Increased cost of laboratory supplies, materials, and other expenses36,240,000\$44,0					
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2008 pay increase \$232,162,000 \$2,596,0   b. January FY 2009 pay increase 232,162,000 5,030,0   c. One less day of pay 232,162,000 (889,0)   d. Payment for centrally furnished services 116,042,000 1,741,0   e. Increased cost of laboratory supplies, materials, and other expenses 371,675,000 7,389,0   Subtotal 15,867,0 15,867,0   2. Research management and support: a. Annualization of January 2008 pay increase \$135,140,000 \$1,511,0   b. January FY 2009 pay increase 135,140,000 \$1,511,0   c. One less day of pay 135,140,000 \$14,000   d. Payment for centrally furnished services 36,240,000 \$44,0   e. Increased cost of laboratory supplies, materials, and other expenses 186,542,000 \$44,0					
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materials, and other expenses371,675,0007,389,0Subtotal15,867,02. Research management and support: a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase135,140,000\$1,511,0c. One less day of pay135,140,000\$1,80,000d. Payment for centrally furnished services e. Increased cost of laboratory supplies, materials, and other expenses186,542,000\$44,00			116,042,000		1,741,000
Subtotal15,867,02. Research management and support: a. Annualization of January 2008 pay increase\$135,140,000b. January FY 2009 pay increase\$135,140,000c. One less day of pay135,140,000d. Payment for centrally furnished services e. Increased cost of laboratory supplies, materials, and other expenses186,542,000			274 075 000		7 200 000
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a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase135,140,0002,928,0c. One less day of pay135,140,000(518,0)d. Payment for centrally furnished services36,240,000544,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0	Subtotal				15,867,000
a. Annualization of January 2008 pay increase\$135,140,000\$1,511,0b. January FY 2009 pay increase135,140,0002,928,0c. One less day of pay135,140,000(518,0)d. Payment for centrally furnished services36,240,000544,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0	2. Research management and support:				
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b. January FY 2009 pay increase135,140,0002,928,0c. One less day of pay135,140,000(518,0)d. Payment for centrally furnished services36,240,000544,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0	-		\$135,140,000		\$1,511,000
c. One less day of pay135,140,000(518,0)d. Payment for centrally furnished services36,240,000544,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0			135,140,000		2,928,000
d. Payment for centrally furnished services36,240,000544,0e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0			135,140,000		(518,000)
e. Increased cost of laboratory supplies, materials, and other expenses186,542,0003,708,0					544,000
Subtotal 8,173,0	materials, and other expenses		186,542,000		3,708,000
	Subtotal				8,173,000
Subtotal, Built-in 24,040,0	Subtotal Built-in				24,040,000

## Summary of Changes--continued

	2	008 Current		
	E	nacted Base	Chai	nge from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	3,857	. , , ,	257	(\$34,261,000)
b. Competing	1,303	433,442,000	66	21,897,000
c. SBIR/STTR	251	89,121,000	0	0
Total	5,411	2,129,238,000	323	(12,364,000)
2. Research centers	198	528,374,000	0	0
3. Other research	920	423,590,000	0	0
4. Research training	1,467	68,823,000	0	575,000
5. Research and development contracts	466	569,342,000	0	0
Subtotal, extramural				(11,789,000)
	<b>FTEs</b>		<u>FTEs</u>	( · · · ,
6. Intramural research	1,814	719,879,000	14	(4,767,000)
7. Research management and support	1,019	357,922,000	7	(2,673,000)
8. Construction		0		0
9. Buildings and Facilities		7,920,000		(80,000)
Subtotal, program		4,805,088,000		(19,309,000)
Total changes	2,833		21	4,731,000



# Justification

# National Cancer Institute

Authorizing Legislation:

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

Budget Authority:

FY 2007	FY 2008	FY 2009	Incr	ease or
Actual	Enacted	Estimate	Dec	rease
FTE BA	<u>FTE</u> BA	<u>FTE BA</u>	FTE	BA
2,828 \$4,795,491,000	2,833 \$4,805,088,000	2,854 \$4,809,819,000	21	\$4,731,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Cancer Institute (NCI), including NIH/AIDS activities. Details of the FY 2009 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

# DIRECTOR'S OVERVIEW

Cancer is an extraordinarily complex set of diseases. For most of those whom it strikes, cancer is a disease of aging, the result of a lifetime of genetic alterations, additions, and subtractions that accumulate in our genes and impact their function. Yet cancer also may strike in the prime of life or, tragically, in the earliest years of childhood. With intricate cellular and molecular pathways that influence its development and its course, a cancer may manifest itself in our bloodstream or in one of many tissues and organs of our body.

The National Cancer Institute (NCI) is charged with leading the battle against cancer. It is a research mission that encompasses knowledge of cancer's cellular and molecular initiation; its development into a mass that causes symptoms; and its metastasis – the lethal spread to distant organs in the body. In addition, NCI is moving rapidly to decode the genetics of cancer, so that we might develop personalized and preemptive interventions and treatments.

NCI's demonstrated, sustained history of progress against cancer is yielding new scientific opportunities today and for the years ahead. To ensure successful research outcomes in FY 2009 and beyond, NCI will strive to enable the best and brightest

investigators and clinicians. By coupling strategic planning with the unparalleled peer review process, NCI can ensure that the highest quality science is directed at cancer.

# Program Choices in 2008:

# • Support Funding for Research Projects

Funding for extramural research, primarily through investigator-initiated Research Project Grants (RPGs), 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 United States.

# • 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 extend the impact of cancer centers further, by enhancing translational and clinical research and outreach to the community.

# • Link Science and Technology

Genetic science has progressed from a so-called candidate gene approach that probed the human genome for a single target at a time, to a technology-driven field that scans across the genomes of thousands of patients per study. These Genome Wide Association Studies (GWAS), as well as information from the Cancer Genome Atlas, are generating huge volumes of data on genetic alterations, but much research must be done to turn this knowledge into treatments. Likewise, nanotechnology has emerged as a key future strategy for cancer diagnosis and treatment. NCI will continue to support research and development in this field through the Alliance for Nanotechnology in Cancer. In addition, NCI is planning to enhance research into the function of proteins through its Clinical Proteomic Technologies for Cancer Initiative.

# Integrate Science Through Interdisciplinary Teams

Increasingly, scientists must be able to work in interdisciplinary teams to fully utilize key technologies and share expertise. NCI will support integrative science projects 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 trials to lead to 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, incorporating five themes: prioritization/scientific quality, standardization, coordination, operational efficiency, and integrated management.

# Plans for FY 2009:

• Empowering Cancer Research. Advances in our understanding of the molecular causes of cancer and the enhanced ability to translate that knowledge into clinical

practice have opened up a future of personalized cancer medicine when doctors will determine prognosis and treatment options by understanding each patient's unique genetic makeup and how it has led to his or her cancer. This future is evident in the accelerating discovery of biomarkers for detecting and measuring changes in protein and cellular function associated with specific cancers. Increasing use of these profiles to assess a patient's disease and select the most promising therapy is an application of this knowledge.

- Reaching All Communities Touched by Cancer. NCI will work to make significant progress in disseminating new knowledge, best practices, and clinical opportunities to physicians and patients, regardless of location or socioeconomic status. Furthermore, we know that progress will continue to be made only if we make a concerted effort to identify, nurture, and train the next generation of talented researchers and clinicians.
- Realizing the Promise of Prevention and Early Diagnosis. For most cancers, there exists a mix of genetic changes and numerous potential environmental influences that challenge the development of simple prevention strategies. Part of the prevention solution involves identifying biomarkers of risk through genome-wide association studies, such as those led by the Cancer Genetic Markers of Susceptibility (CGEMS) Initiative, which identify new genetic variants associated with risk. Other successful prevention initiatives that NCI will continue include anti-obesity programs, the development of new chemopreventive agents, and programs to reduce smoking rates. Detecting and diagnosing cancer early in the disease process can dramatically improve the patient's odds for successful treatment. NCI's Early Detection Research Network (EDRN) brings together dozens of institutions to evaluate new ways of diagnosing cancer in its earliest stages, such as an early detection test for pancreatic cancer.

# FY 2009 Justification by Activity Detail

# **Program Descriptions and Accomplishments**

**Overall Budget Policy:** NCI's highest priorities for FY 2009 are to empower cancer research, reach all communities touched by cancer, and realize the promise of prevention and early diagnosis. 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. Intramural Research and Research Management and Support receive modest increases to help offset the cost of pay and other increases. NCI will continue to support new investigators and to maintain an adequate number of competing RPGs.

NCI's Program Funding Table comprises the principal 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). The NCI Intramural Research Program includes laboratory investigation, epidemiologic and genetics studies, translational research, and clinical research. The excellence of NCI scientists and the intramural infrastructure enable the Institute 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 knowledge needed to reduce the burden of cancer on the lives of Americans and the impact of cancer on our economy. The following narrative describes representative NCI activities that highlight program plans and expected accomplishments.

# **Understand the Mechanisms of Cancer**

Expanding our knowledge of the molecular mechanisms of cancer is a keystone of NCI's research mission. Emerging technologies that enable comprehensive molecular analysis of tumors and their surrounding systems will help researchers understand the development and the vulnerabilities of specific types of cancer. This knowledge will guide the development of rationally designed interventions. Research to unravel the molecular complexities of cancer demands a multidisciplinary approach that draws on the strengths of both the intramural and extramural research communities.

One example of progress in understanding the mechanisms of cancer is researchers' recent discovery of new biomarkers for liver cancer that can accurately predict whether the cancer will metastasize (spread). Using samples obtained from liver cancer patients, they identified a unique gene expression signature – pattern of gene activity – that predicted the development of metastatic or recurrent disease in 92 percent of patients. Since some of these markers are found in the blood of patients with liver cancer, where they can be easily detected, they may be useful biomarkers for early diagnosis of this deadly disease.

**Budget Policy:** The FY 2009 budget estimate for the Understanding the Mechanisms of Cancer program is \$781.683 million, a decrease of \$4.298 million or -0.5% percent from the FY 2008 enacted. To support the program goals, NCI will continue high priority activities including the Tumor Microenvironment Network (TMEN). This initiative consists of inter-connected, multidisciplinary teams of investigators and collaborative groups that work together on projects focused on the tumor microenvironment<sup>1</sup>. The

<sup>&</sup>lt;sup>1</sup> The local and systemic architecture surrounding a cancer cell. It includes other cells, growth factors, enzymes, and parts of the blood and lymphatic systems.

main emphasis of TMEN is to develop 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 research is expected to uncover novel diagnostic, therapeutic, and prevention targets. In addition, the cancer and inflammation program integrates highly productive basic, clinical, and novel technologies with cross-cutting intramural and extramural research activities. The initiative explores one of the major cancer influences – chronic inflammation caused by infections and other factors. Investigators are elucidating 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 also will focus on the discovery and development of inflammation-related molecular targets for cancer prevention and therapy.

Other activities include: (1) Developing high-resolution electronic microscopic imaging at the nanoscale in biology and medicine through the Imaging at the Nanoscale Initiative; (2) 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; and (3) Integrating mouse models as discovery and translational tools for many aspects of human cancer research through the Mouse Models of Human Cancer Consortium. The significant advances to date in animal modeling are due in large measure to the Consortium's emphasis of trans-disciplinary, high-risk research, which will continue into the next phase of this program.

# **Understand the Causes of Cancer**

NCI's etiology research focuses on genetic, environmental, and lifestyle factors, which can all contribute to cancer development. The study of genetic and environmental risk factors for cancer has advanced considerably in the past year. An important opportunity has been created through NCI's sustained investment in collaborative population studies that help researchers exploit the potential of genetics and identify gene variants that affect cancer risk, diagnosis, and prognosis.

Recent NCI research has focused on validating new models of breast cancer risk that focus on breast density. Investigators found that breast density was a highly clinically significant predictor of breast cancer risk, almost as powerful a predictor as age. If validated in further research, these prediction models could help identify women who may benefit from preventive interventions or more intensive surveillance.

**Budget Policy:** The FY 2009 budget estimate for the Understanding the Causes of Cancer program is \$1,092.524 million, an increase of \$663 thousand or 0.1 percent above the FY 2008 enacted. To support the program goals, high priority will be given to continuing NCI activities such as whole genome scans in which DNA from patients with specific cancers is compared to DNA from people who have never had the disease. Researchers will further examine the DNA samples to identify common variations in genes that may raise or lower the risk for different types of cancer. Under the auspices of the NIH Genes and Environment Initiative (GEI), a genome-wide association study

(GWAS) will be conducted to investigate the genetic determinants of lung cancer risk and identify genes that contribute to smoking persistence and different lung cancer outcomes. The Early Detection Research Network (EDRN) will launch a validation study of biomarkers for early detection of bladder cancer and bladder cancer recurrence based on a non-invasive test to detect abnormal epigenetic patterns in urine sediment of bladder cancer patients. Preliminary data suggest that such markers can predict cancer as well as or better than the current standard of care (cytology and cystoscopy) for early detection and recurrence of superficial bladder cancer.

Other activities include: (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 novel molecular research through the Epigenetic Approaches in Cancer Epidemiology Initiative, with the key objective of using population studies to evaluate cancer risk associated with DNA methylation<sup>2</sup>; 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.

<sup>&</sup>lt;sup>2</sup> The genome contains two kinds of information, genetic (DNA) and epigenetic (chemical modifications to the DNA). Genetic information provides the blueprint for the manufacture of all the proteins necessary to create a living organism, whereas the epigenetic information provides additional instructions on how, where, and when the genetic information will be used. A common epigenetic modification is DNA methylation. One of the current challenges is to understand the regulation of gene function, an activity that is dependent to a large extent on epigenetic control.

#### Identifying Genetic Cancer Risk

FY 2008 Level: \$71 million FY 2009 Level: <u>\$71 million</u> Change: \$0

**Genetic Risk.** Deciphering the entire human genome sequence was a watershed event early in this decade. For cancer researchers, this major advance paved the way for new approaches to determine genetic variations, among individuals, that either predispose them to cancer or help to prevent it. New techniques, known collectively as **Genome Wide Association Studies (GWAS)**, have resulted in a flood of data about the underlying genetic contributions to different forms of cancer and other diseases. GWAS involves scanning the complete genomes of many people to identify genetic variations associated with a particular disease. Researchers can rapidly hone in on areas that are altered in people with a particular form of cancer and identify specific genetic changes that trigger or promote that malignancy. These discoveries can lead to the development of better strategies to detect, treat, and prevent the disease.

**Program Efforts.** NCI is leading the application of exciting new technology in several initiatives: The **Cancer Genetic Markers of Susceptibility (CGEMS)**, funded at \$5 million, and the **Pancreatic Cancer Cohort Consortium (PanScan)**, funded at \$1.36 million, are strategic initiatives that aim to identify common genetic variations associated with cancer risk. By scanning DNA samples from individuals who developed cancer and those who did not, CGEMS investigators recently pinpointed variations associated with elevated risk of breast and prostate cancers. FY09 funding will focus on initiatives that target other cancers, including non-Hodgkin lymphoma, colorectal adenocarcinoma, and estrogen receptor negative (ER-) breast cancer, along with cancers of the brain and ovary. Future initiatives will target other cancers, including cancers of the bladder, kidney, lung, and other sites that can be evaluated through large-scale epidemiologic studies. Similarly, PanScan investigators are scanning the genome to identify markers of susceptibility for high-mortality pancreatic cancer.

A separate effort, known as the **Breast and Prostate Cancer Cohort Consortium (BPC3), funded at \$5.154 million,** is conducting collaborative studies of hormone-related gene variants and environmental factors that are suspected of involvement in breast and prostate cancer development. The BPC3 is proposing to genotype 2/3rds of the approximately 16,000 prostate cancer cases/controls. Since this is a genome-wide association study, the investigators will not be limiting the genotyping to select candidate genes, but scanning the entire genome for genes that are most likely to be associated with cancer risk. BPC3 is a complement to CGEMs. Several of the cohorts in BPC3 are also involved in CGEMs. BPC3 investigators will serve as a test set for the Single Nucleotide Polymorphisms (SNPs) identified in the CGEMs genome-wide scans while also performing additional analysis to identify genes that increase risk in subsets of breast and prostate cancer.

NCI has played a leading role in HIV research since AIDS became a national epidemic in the 1980s, with groundbreaking contributions such as identifying the human immunodeficiency virus as the causative agent leading to development of blood tests for HIV and the ability to screen donated blood for this virus, and developing effective anti-HIV therapies. To detect genes that impact HIV infection and AIDS progression, using a candidate gene approach, several genetic polymorphisms have been shown to associate with risk of **HIV infection and/or AIDS progression**. The genes tested in this approach are known to encode products that either contribute to the immune response against HIV or to the HIV replication cycle. While yielding substantial success, this approach is deficient in that many genes with yet-to-be-characterized roles in HIV disease pathogenesis, some of which may have therapeutic/vaccine potential, are ignored. Genome wide association (GWA) analysis of existing AIDS cohorts are now being performed to detect undiscovered genetic polymorphisms that affect different stages of HIV/AIDS pathogenesis. Chip technology to perform the work has been established and appropriate analyses are being developed to handle the incoming data.

**Underpinning Success.** Underpinning the success of these studies is the long-term investment in the **NCI Cohort Consortium**, comprised of 34 cohorts – separate study groups – that together include 3.5 million people. This international cooperative endeavor covers diverse populations; biospecimens, including DNA, and extensive risk factor data that is essential for genomic studies are available for each individual. **The Cancer Genome Atlas Pilot Project**, a joint three-year initiative with NHGRI that was launched in December 2005 and ends in December 2008, is developing a comprehensive catalog of the many genetic changes that occur in brain, lung and ovarian cancers, from chromosome rearrangements to DNA mutations to epigenetic changes (chemical modifications of DNA). **The Childhood Cancer Therapeutically Applicable Research to Generate Effective Treatments (TARGET)** Initiative has the immediate goal of identifying and validating therapeutic targets for childhood cancers beginning with acute lymphoblastic leukemia and neuroblastoma.

## **Improve Early Detection and Diagnosis**

Accurate tools for detecting and diagnosing tumors can markedly improve the likelihood of a cancer patient's successful treatment and survival. These tools are of greatest benefit early in the disease process, before the tumor becomes invasive. To improve care for their patients, clinicians need validated biomarkers for cancer detection and diagnosis, prognosis, and treatment monitoring.

Progress is being made in early detection and diagnosis of patients at high risk for melanoma. In one study, researchers identified a link between an inherited and an acquired<sup>3</sup> genetic factor that dramatically increased the chance of developing a very common type of melanoma. Applying discoveries such as these may help identify individuals at higher risk for melanoma and lead to improved diagnostic and treatment interventions.

**Budget Policy:** The FY 2009 budget estimate for the Improving Early Detection and Diagnosis program is \$405.018 million, a decrease of \$2.030 million or -0.5 percent from the FY 2008 enacted. To support the program goals, high priority will be given to continuing NCI activities including the Clinical Proteomic Technologies for Cancer Initiative. Studying the structure and function of proteins and their interactions is a major focus 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 program builds such integrative research laboratory networks for collaborative proteomic research, which can generate standardized, reliable, and reproducible proteomic technologies.

Molecular imaging is another sophisticated technology that NCI expects will profoundly affect the everyday lives of many cancer patients. This technology reveals functional and molecular information about how a cell transforms from normal to cancerous.

<sup>&</sup>lt;sup>3</sup> Acquired genetic mutations develop in individual cells during one's lifetime and are not inherited.

Molecular imaging probes make it possible to detect cancer at its earliest stages and can provide information to inform diagnosis and response to therapy. Molecular imaging probes are substances that when administered to the body can be detected by imaging techniques. Some probes reveal developing cancer by attaching to early stage cancer cells or by responding to physiologic conditions typical of developing tumors.

Other activities include: (1) Defining the profiles, or characteristic patterns, of gene expression<sup>4</sup> associated with all types of human lymphoid malignancies, through the Lymphoma/Leukemia Molecular Profiling Clinical Project, (2) Understanding and detecting the early biological events that lead to breast cancer, through the Trans-NCI Breast Premalignancy Program. A recent initiative will support research studies on the biology of breast premalignancy through multidisciplinary efforts to characterize the genetic, molecular, and/or cellular changes of pre-malignancy states of human breast cancer. (3) 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; (4) Building a repository of high quality biospecimens through clinical trials to develop proteomic technologies in target cancer types. The goal is to detect cancer at its earliest stage or soon after it returns. A multi-institutional trial is ongoing accruing women in first ovarian cancer clinical remission. Serially obtained blood samples are being stored for subsequent use for development of proteomic tools for detection of minimal residual disease. These tools will be applied towards early detection of ovarian cancer. (5) 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 of Molecular Brain Neoplasia Data (REMBRANDT) Initiative; and (6) Determining whether certain cancer screening tests reduce deaths through the Prostate, Lung, Colorectal, Ovarian Screening Study (PLCO). Pre-diagnostic samples from PLCO and the NIH Women's Health Initiative may yield information on the leadtime before clinical diagnosis of ovarian cancer, narrowing the list of candidate biomarkers and potentially leading to an ovarian cancer diagnostic test within the next few years.

# **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. Knowledge of the unique molecular make-up of patients' tumors is used to classify cancer patients into defined populations – those who will respond best to one type of therapy versus another. The outcome is tailored cancer treatment for patients.

NCI is developing a Chemical Biology Consortium to bridge the gap between basic scientific investigation and clinical research. This initiative will focus on identifying novel targets and developing new molecules that will be used to study those targets and serve as lead compounds around which potential drugs can be designed. The goal is to enhance the entry of early stage drug candidates into the therapeutics pipeline.

<sup>&</sup>lt;sup>4</sup> Gene expression refers to the translation of the genetic code into the structures and function of a cell, e.g. protein production.

**Budget Policy:** The FY 2009 budget estimate for the Developing Effective and Efficient Treatments program is \$1,156.725 million, an increase of \$6.922 million or 0.6 percent above the FY 2008 enacted. To support the program goals, high priority will be given to continuing 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 – chemotherapy given after surgery – research shows that it decreases recurrence risk in relatively few of these patients. TAILORx is addressing this issue by determining 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 is using a new test that measures the expression of 21 genes in tumor samples to assign women to a treatment regimen. Identifying women most likely to benefit from chemotherapy holds the promise of improving outcomes for women with early stage breast cancer.

Other activities include: (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, an intramural/extramural collaboration. (2) Evaluating key, well-characterized markers of patient response to therapies, through the Epidermal Growth Factor Receptor Inhibitor Biomarker Lung Trial. These therapies target the epidermal growth factor receptor, a protein associated with several cancers.

#### **Translational Research and Drug Discovery**

FY 2008 Level: \$55 million FY 2009 Level: <u>\$60</u> million Change: \$5 million

**Moving Scientific Discoveries into Clinical Application.** The **Translational Research Working Group** developed a set of recommendations to help NCI prioritize the most compelling translational research initiatives in order to strengthen existing components of disease-oriented studies and promote industry collaboration and operational effectiveness. The path of moving discovery into clinical use may include animal studies, safety profiling, use of sophisticated production and assay technologies, clinical and population studies, and the negotiation of complex research regulations, both with local institutions and the Food and Drug Administration. NCI is in the process of implementing the recommendations of the TRWG. Translation of discoveries to the cancer patient will be enhanced by a Chemical Biology Consortium that will help with the next steps in agent development.

A Proposed Program. The Chemical Biology Consortium (CBC) is envisioned as a comprehensive drug development platform comprised of resources and identified experts in synthetic chemistry and cancer biology that will optimize lead compounds to feed into the NCI's drug development pipeline. At the heart of NCIs' internal efforts to find and develop new cancer drugs is its NCI's Developmental Therapeutics Program (DTP), which serves as a vital resource in acquiring preclinical information and providing research materials for investigational new drug-directed studies. DTP has been involved in the discovery or development of more than 70 percent of the anticancer therapeutics on the market today. Within DTP, NCI's Rapid Access to Intervention Development (RAID) program provides preclinical drug and biologic development resources to academic investigators who want to conduct their own clinical trials. Once an optimal compound is selected, RAID facilitates further preclinical development

through its contract program. Within the **NCI Experimental Therapeutics Program**, certain investigational drugs will go through an evaluation process with the goal of shortening the drug development timeline. **Phase 0 Trials** represent an important new element in this early development process and will determine, through the use of pharmacodynamics measurements or imaging, a rational dosage (low dose) regimen for testing the agent in subsequent clinical trials based on how the drug acts in the patient's body. This will enable testing fewer patients, with minimal risk to them at the earliest stage.

Integrating Activities. The enormous potential for more "personalized" cancer treatment, coupled with the complexity of evaluating therapeutic agents and diagnostic tests, demands a national clinical trials enterprise that integrates a new kind of cross-disciplinary research endeavor. To address this goal, the Clinical Trials Working Group (CTWG) developed a detailed blueprint for "Restructuring the National Cancer Clinical Trials Enterprise." The strategy leverages successful elements of the existing NCI-supported clinical trials system: the Cancer Centers Program, NCI's Specialized Programs of Research Excellence (SPOREs), the Clinical Trials Cooperative Group Program, the Cancer Trials Support Unit, the Community Clinical Oncology Program, the Minority-Based Community Clinical Oncology Program, and the Center for Cancer Research; to create a more integrated approach to clinical research. Finally, the NIH Clinical Research Center, the world's largest hospital dedicated solely to clinical research, is an ideal venue for drug discovery and the earliest phases of drug testing. Integrating these activities, promises to shorten drug development time, improve drug safety, and drive down development cost.

# **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. National studies have shown that cancer healthcare delivery is inadequate or lacking for large numbers of patients and disadvantaged groups. NCI supports and conducts cancer control research to better understand factors that influence cancer outcomes, improve the quality of care, improve the quality of life for cancer survivors and their families, and overcome cancer health disparities.

NCI has taken a transdisciplinary approach to health disparities in estrogen receptor (ER-negative) breast cancer. Researchers suspect that a higher proportion of ERnegative tumors in the African American population may contribute to their higher breast cancer mortality rates. NCI is supporting research on the basic biologic attributes of ERnegative breast cancer, including molecular mechanisms that can be targeted with prevention, early detection, and treatment interventions.

Progress in overcoming cancer health disparities is being demonstrated by the formation of the Regional Health Disparities Research Networks. A steady expansion of NCI's cancer health disparities research and diversity training programs has spurred the development of regional "hubs" of research to improve cancer outcomes in populations with an excess burden of cancer. These hubs will investigate critical basic, clinical, population, and community-based research questions targeted to the specific needs of underserved populations. This network emerged from a focus on health disparities research and training partnerships with Minority Serving Institutions (MSIs) and NCI-

designated Cancer Centers, Community Networks Program (CNP) regional partnerships, the NCI Community Cancer Centers Program (NCCCP) pilot, and through Patient Navigation Research Program partnerships.

**Budget Policy:** The FY 2009 budget estimate for the Cancer Prevention and Control program is \$341.502 million, a decrease of \$2.521 million or -0.7 percent from the FY 2008 enacted. The Food and Drug Administration (FDA) approved the human papillomavirus (HPV) vaccine for prevention of cervical cancer in 2006. 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. In addition, NCI is also engaged in the development of novel vaccines for cancer immunotherapy and HIV/AIDS.

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. 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). TRECs foster 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 Health Maintenance Organization (HMO) Cancer Research Network (CRN). This network consists of the research programs, enrolled populations, and data systems of 13 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.

#### **Community-Based Research**

FY 2008 Level: \$6.6 million FY 2009 Level: \$6.6 million Change: \$0

Access to Care...The Need for Research. Rapidly advancing knowledge and new treatments are intensifying the need for more effective and immediate ways of translating these benefits to cancer patient

<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.

care. As national studies have demonstrated, cancer care delivery is inadequate or lacking entirely for many patients. For most Americans, especially senior citizens and minorities – who bear a heavy burden of cancer – an NCI-designated Cancer Center may be too far away, too removed from family and other support systems, or simply out of reach for economic, personal, or other reasons. Only 3 percent of adults with cancer participate in clinical trials, yet clinical trials provide access to cutting-edge advances and help develop new preventatives, diagnostics, and treatments. Limited access poses a serious health risk to patients. The hope is that programs to widen access to state-of-the-art care will overcome this risk.

An Innovative Pilot. NCI has launched the pilot phase of the NCI Community Cancer Centers Program (NCCCP). Identified in the 2008 Congressional Justification and now officially launched, the work plan for the pilot of 16 participating sites lays out clear-cut goals. 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, develop standardized tissue banks, and provide close links to NCI research and to the network of NCI-designated Cancer Centers. The NCCCP pilot will be an important step in learning how to transfer the latest scientific advances to community hospitals, 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. Pilot sites will share best practices and refine the overall concept as a prelude to launching a new national network of research-driven cancer care at the community level.

**Complementary Community Initiatives.** The NCCCP initiative will complement the existing network of cancer centers, **Community Clinical Oncology Program (CCOP)** sites, and other academic medical centers. For example, the CCOPs have facilitated the participation of community physicians in national studies, bringing them and their real-life experiences to the research table. Participating in these trials ultimately enhances their ability to put successful regimens into practice quickly. The **Community Networks Program (CNP)** aims to reduce cancer health disparities through community-based participatory education, training, and research among racial/ethnic minorities and underserved populations. The **Patient Navigation Research Program (PNRP)** is developing innovative patient navigation interventions designed to decrease the time between identification of an abnormal finding, definitive diagnosis, and delivery of quality standard cancer care services.

# Cancer Centers, Specialized Centers and Specialized Programs of Research Excellence (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 SPOREs comprise a model framework that supports team science.

In addition, NCI has launched the NCI Community Cancer Centers Program as a pilot program to study how community hospitals nationwide could most effectively bring the latest scientific advances and multi-specialty care to a much larger population of cancer patients.

**Budget Policy:** The FY 2009 budget estimate for the Cancer Centers, Specialized Centers and SPORE programs is \$479.565 million, level with the FY 2008 enacted. The 63 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 innovative pilot projects in new investigational areas. Specialized centers, such as the Integrative Cancer Biology Program Centers (ICBP), Tumor Microenvironment Centers, TREC 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.

Other activities include: (1) NCI is developing an integrated biological view of cancer through the development and application of systems biology programs and predictive computational modeling to understand the complexity of cancer. The primary effort in this area is the Integrated Cancer Biology Program that supports nine centers that use multidisciplinary approaches to link biology, bioinformatics, and mathematical modeling across the spectrum of cancer biology and translational research. (2) The Comprehensive Minority Institution/Cancer Center Partnerships are designed to build and stabilize independent competitive cancer research capacity at minority-serving institutions (MSIs); improve the effectiveness of the NCI-designated Cancer Center activities specifically designed to address the cancer disparities experienced by underserved racial and ethnic minorities and the socio-economically disadvantaged, and improve minority accrual to cancer clinical trials. In addition, they aim to create stable, long-term collaborative relationships between the MSI and the cancer center in all areas of cancer research, training, education and outreach.

# **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. NCI career development opportunities prepare the next generation of cancer researchers to meet the challenges of multidisciplinary research. NCI provides cancer research training and career entree to high school, undergraduate and graduate students, postdoctoral fellows, and physicians across the United States.

**Budget Policy:** The FY 2009 budget estimate for the Research Workforce Development program is \$181.540 million, an increase of \$575 thousand or 0.3 percent above the FY 2008 enacted. 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 that range from 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 was implemented in 2007. Other activities include: (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; and (3) Training and mentoring physician scientists to expand their expertise in laboratory or clinical translational research through the Physician Scientist Training Program.

# **Buildings and Facilities**

The renovation and improvement funds for the facilities at the NCI-Frederick campus, located in Frederick, Maryland, 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

**Budget Policy**: The FY 2009 budget estimate for the Building and Facilities program is \$7.840 million, a decrease of \$80 thousand or -1.0 percent from the FY 2008 enacted. NCI is evaluating and prioritizing the specific projects to be funded in FY 2009.

# **Research Management and Support (RMS)**

NCI RMS 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.

NCI successfully implemented a new, efficient, single-stage review process for program project grant applications. Under the new single tier approach, review quality has been maintained, applicants receive results sooner, and there has been a significant reduction in the number of reviewers and review panels. This new review paradigm has improved scoring consistency and achieved significant reductions in costs.

**Budget Policy:** The FY 2009 budget estimate for RMS is \$363.422 million, an increase of \$5.5 million or 1.5 percent from the FY 2008 enacted.

# **Common Fund Activities**

The NCI is the lead institute for the Imaging Probe Database Roadmap Initiative, supported through the NIH Common Fund.

#### Budget Authority by Object

	Budget Authori			
		FY 2008	FY 2009	Increase or
		Enacted	Estimate	Decrease
Total of	compensable workyears:			
	Full-time employment	2,833	2,854	21
	Full-time equivalent of overtime and holiday hour	6	6	0
		<b>#</b> 407.000	<b>#470.057</b>	<b>*</b> 4.040
	Average ES salary	\$167,208	\$172,057	\$4,849
	Average GM/GS grade	12.0	12.0	0.0
	Average GM/GS salary	\$90,886	\$93,522	\$2,635
	Average salary, grade established by act of	<i><i><i>qcc,ccc</i></i></i>	<i> </i>	<i><b>4</b></i> <u></u> ,000
	July 1, 1944 (42 U.S.C. 207)	\$85,403	\$87,880	\$2,477
	Average salary of ungraded positions	123,561	127,144	3,583
	Werage salary of dirigitated positions	120,001	121,177	0,000
		FY 2008	FY 2009	Increase or
	OBJECT CLASSES	Estimate	Estimate	Decrease
	Personnel Compensation:	Lotinate	LStinate	Declease
11.1		\$231,226,000	\$243,560,000	\$12,334,000
	Other than full-time permanent	45,135,000	47,543,000	2,408,000
	Other personnel compensation	10,102,000	10,641,000	539,000
	Military personnel	7,017,000	7,391,000	374,000
	Special personnel services payments	52,938,000	53,732,000	794,000
11.0	Total, Personnel Compensation	346,418,000	362,867,000	16,449,000
12.0	Personnel benefits	79,095,000	83,314,000	4,219,000
	Military personnel benefits	4,829,000	5,087,000	258,000
13.0		4,029,000	0,007,000	230,000
13.0	Subtotal, Pay Costs	430,342,000	451,268,000	20,926,000
21.0	Travel and transportation of persons	14,700,000	14,700,000	0
	Transportation of things	1,065,000	1,065,000	0
	Rental payments to GSA	8,000	8,000	0
	Rental payments to others	89,000	89,000	0
	Communications, utilities and	00,000	00,000	Ű
20.0	miscellaneous charges	8,660,000	8,660,000	0
24.0	Printing and reproduction	2,550,000	2,550,000	0
25.1		23,703,000	23,703,000	0
	Other services	151,057,000	151,057,000	0
	Purchase of goods and services from	- , ,	- , ,	_
	government accounts	542,525,000	545,963,000	3,438,000
25.4	Operation and maintenance of facilities	89,028,000	89,028,000	0
	Research and development contracts	379,854,000	372,010,000	(7,844,000)
	Medical care	4,950,000	4,950,000	0
25.7	Operation and maintenance of equipment	14,785,000	14,785,000	0
25.8	Subsistence and support of persons	0	0	0
25.0	Subtotal, Other Contractual Services	1,205,902,000	1,201,496,000	(4,406,000)
26.0	Supplies and materials	41,114,000	41,114,000	0
	Equipment	21,108,000	21,108,000	0
32.0	Land and structures	0	0	0
	Investments and loans	0	0	0
	Grants, subsidies and contributions	3,079,521,000	3,067,732,000	(11,789,000)
	Insurance claims and indemnities	0	0	0
	Interest and dividends	29,000	29,000	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	4,374,746,000	4,358,551,000	(16,195,000)
	Total Budget Authority by Object	4,805,088,000	4,809,819.000	4,731,000
		,,	,,.,.,.,.,.,.,.,.,.,.,.,.,.,.,.,,.,,	,,

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

# Salaries and Expenses

	-		
	FY 2008	FY 2009	Increase or
OBJECT CLASSES	Enacted	Estimate	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$231,226,000	\$243,560,000	\$12,334,000
Other than full-time permanent (11.3)	45,135,000	47,543,000	2,408,000
Other personnel compensation (11.5)	10,102,000	10,641,000	539,000
Military personnel (11.7)	7,017,000	7,391,000	374,000
Special personnel services payments (11.8)	52,938,000	53,732,000	794,000
Total Personnel Compensation (11.9)	346,418,000	362,867,000	16,449,000
Civilian personnel benefits (12.1)	79,095,000	83,314,000	4,219,000
Military personnel benefits (12.2)	4,829,000	5,087,000	258,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	430,342,000	451,268,000	20,926,000
Travel (21.0)	14,700,000	14,700,000	0
Transportation of things (22.0)	1,065,000	1,065,000	0
Rental payments to others (23.2)	89,000	89,000	0
Communications, utilities and			
miscellaneous charges (23.3)	8,660,000	8,660,000	0
Printing and reproduction (24.0)	2,550,000	2,550,000	0
Other Contractual Services:			
Advisory and assistance services (25.1)	15,400,000	15,400,000	0
Other services (25.2)	151,057,000	151,057,000	0
Purchases from government accounts (25.3)	275,278,000	278,716,000	3,438,000
Operation and maintenance of facilities (25.4)	4,700,000	4,700,000	0
Operation and maintenance of equipment (25.	14,785,000	14,785,000	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	461,220,000	464,658,000	3,438,000
Supplies and materials (26.0)	40,897,000	40,897,000	0
Subtotal, Non-Pay Costs	529,181,000	532,619,000	3,438,000
Total, Administrative Costs	959,523,000	983,887,000	24,364,000

		Authorizir	Authorizing Legislation			
	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2008 Enacted	2008 Amount Authorized	FY 2009 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Cancer Institute	Section 402(a)	42§281	Indefinite	\$4,805,088,000	Indefinite	\$4,809,819,000
Total, Budget Authority				4,805,088,000		4,809,819,000

		Appropriations His	tory		
Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1</u>	/
2000	\$2,732,795,000 <u>2/</u>	\$3,163,417,000	\$3,286,859,000	\$3,332,317,000	
Rescission	0	0	0	(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 <u>2/</u>	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	4,797,639,000	
2008	4,782,114,000	4,870,382,000	4,910,160,000	4,890,525,000	
Rescission				(85,437,000)	
2009	4,809,819,000				

Appropriations Histo

 $\underline{1}$ / Reflects enacted supplementals, rescissions, and reappropriations.  $\underline{2}$ / Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

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OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	715	716	719
Center for Cancer Research	1,459	1,462	1,472
Division of Cancer Biology	38	39	40
Division of Extramural Activities	82	82	83
Division of Cancer Treatment and Diagnosis	179	179	181
Division of Cancer Prevention	83	83	84
Division of Cancer Control and Population Sciences	123	123	124
Division of Cancer Epidemiology and Genetics	149	150	152
Total	2,828	2,833	2,854
Includes FTEs which are reimbursed from the			
FTEs supported by funds from Cooperative			
Research and Development Agreements	(9)	(9)	(9)
FISCAL YEAR	Avera	ige GM/GS (	Grade
2005		44.0	
2005 2006		11.9 12.0	
2007 2008		12.0 12.0	
2008		12.0	
		•	

# Details of Full-Time Equivalent Employment (FTEs)

	Detail of Pos	bitions	
	FY 2007	FY 2008	FY 2009
GRADE	Actual	Enacted	Estimate
Total, ES Positions	5	8	8
Total, ES Salary	\$800,115	\$1,287,369	\$1,324,703
GM/GS-15	212	212	212
GM/GS-14	377	377	377
GM/GS-13	349	350	351
GS-12	473	474	475
GS-11	198	198	198
GS-10	13	13	13
GS-9	140	141	143
GS-8	90	90	90
GS-7	74	74	74
GS-6	20	20	20
GS-5	10	10	10
GS-4	7	7	7
GS-3	7	7	7
GS-2	2	2	2
GS-1	0	0	0
Subtotal	1,972	1,975	1,979
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	36	36	36
Senior Grade	16	16	16
Full Grade	11	11	11
Senior Assistant Grade	5	5	5
Assistant Grade	4	4	4
Subtotal	73	73	73
Ungraded	851	853	854
Total permanent positions	2,475	2,479	2,484
Total positions, end of year	2,919	2,924	2,945
Total full-time equivalent (FTE) employment, end of year	2,828	2,833	2,854
Average ES salary	\$160,023	\$167,208	\$172,057
Average GM/GS grade	12.0°	12.0°, 12.0	۹ <i>۲۲2</i> ,037 12.0
Average GM/GS salary	\$86,981	\$90,886	\$93,522
	<b>\$00,00</b>	<i>\\</i> 00,000	<i>\$30,022</i>

#### **Detail of Positions**

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

# **New Positions Requested**

	FY 2009		
	Grade	Number	Annual Salary
Investigator	AD/401/0	3	\$119,000
Senior Investigator	AD/602/0	1	\$217,000
Senior Clinician	AD/602/0	1	\$209,000
Biologist	GS 11	2	\$71,000
Staff Scientist	AD/401/0	2	\$104,000
Staff Clinician	AD/602/0	2	\$172,000
Health Scientist Administrator	GS 14	5	\$117,000
Research Fellow	AD/401/0	2	\$77,000
Clinical Fellow	AD/602/0	1	\$81,000
Adminstrative Officer	GS 12	2	\$82,000
Total Requested		21	