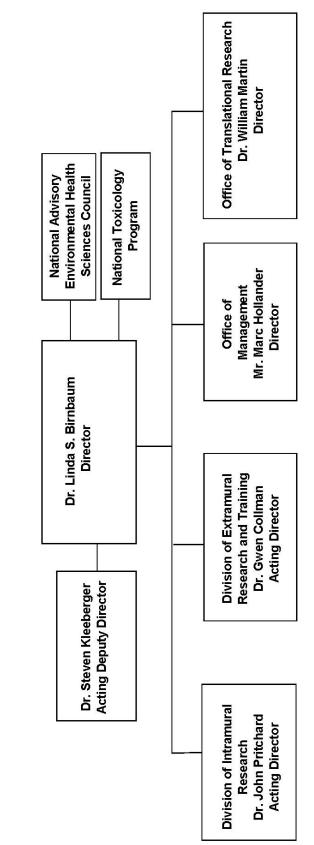
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# NATIONAL INSTITUTES OF HEALTH

# National Institute of Environmental Health Sciences (NIEHS)

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NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

**Organization Structure** 

# NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

For carrying out section 301 and 311 and title IV of the Public Health Services Act with respect to environmental health sciences [\$689,781,000] *\$707,339,000* (Public Law 111-117, Consolidated Appropriations Act, 2010).

### National Institutes of Health National Institute of Environmental Health Sciences

### Amounts Available for Obligation 1/

Source of Funding	FY 2009 Actual	FY2010 Estimate	FY 2011 PB
Appropriation	\$662,820,000	\$689,781,000	\$707,339,000
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	662,820,000	689,781,000	707,339,000
Real transfer under Director's one-percent transfer authority (GEI)	5,270,000	0	0
Comparative transfer for Public Access	-48,000	-52,000	0
Comparative transfer to/from NCBI	-105,000	-164,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	-5,270,000	0	0
Subtotal, adjusted budget authority	662,667,000	689,565,000	707,339,000
Unobligated balance lapsing	-53,000	0	0
Total obligations	662,614,000	689,565,000	707,339,000

1/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2009 - \$1,373,000 FY 2010 - \$1,373,000 FY 2011 - \$1,373,000 Excludes \$146,140 in FY 2009 and \$148,456 in FY 2010 for royalties.

### NATIONAL INSTITUTES OF HEALTH National Institute of Environmental Health Sciences (Dollars in Thousands) Budget Mechanism - Total

				udget Mechar		2						
		2009				Recovery Act		2010		2011		
MECHANISM	A	ctual	A	ctual	Est	imated	Est	imate		PB	Ch	ange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No. ,	Amount
Research Projects:												
Noncompeting	427	\$186,654	0	\$0	\$117	\$48,273	441	\$191,978	443	\$193,786	2	\$1,808
Administrative supplements	(18)	1,300	(112)	22,156	(20)	7,990	(20)	1,650	(18)	1,500	(2)	(150)
Competing:	620403250		10,000,000,000	10110000000000000000000000000000000000	100000000		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	11.2.20m (12.7.200)	1000		C. OSCILLA	
Renewal	32	15,871	8	3,309	0	0	33	14,038	30	13,586	(3)	-452
New	90	29,639	110	45,665	12	4,680	129	46,876	141	52,245	12	5,369
Supplements	0	0	18	9,981	0	0	5	2,500	5	2,500	0	C
Subtotal, competing	122	45,510	136	58,955	12	4,680	167	63,414	176	68,331	9	4,917
Subtotal, RPGs	549	233,464	136	81,111	129	60,943	608	257,042	619	263,617	11	6,575
SBIR/STTR	24	11,800	2	745	0	0	25	12,195	25	12,479	0	284
Subtotal, RPGs	573	245,264	138	81,856	129	60,943	633	269,237	644	276,096	11	6,859
Research Centers:												
Specialized/comprehensive	25	39,075	5	3,848	0	0	27	37,475	27	37,475	0	C
Clinical research	0	0	0	0	0	0	0	0	0	0	0	C
Biotechnology	0	0	0	0	0	0	0	0	0	0	0	C
Comparative medicine	0	0	0	0	0	0	0	0	0	0	0	C
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0	0	0	0	C
Subtotal, Centers	25	39,075	5	3,848	0	0	27	37,475	27	37,475	0	C
Other Research:										~		
Research careers	40	5,997	0	472	0	0	39	5,830	39	5,830	0	C
Cancer education	0	0	0	0	0	0	0	0	0	0	0	C
Cooperative clinical research	0	0	0	0	0	0	0	0	0	0	0	C
Biomedical research support	0	0	0	0	0	0	0	0	0	0	0	C
Minority biomedical research support	3	2,143	0	0	0	0	2	1,231	2	1,231	0	C
Other	31	2,323	0	427	0	0	34	2,564	36	2,853	2	289
Subtotal, Other Research	74	10,463	0	899	0	0	75	9,625	77	9,914	2	289
Total Research Grants	672	294,802	143	86,603	129	60,943	735	316,337	748	323,485	13	7,148
			-						-			
Research Training:	FTTPs		FTTPs		FTTPs		FTTPs		FTTPs			
Individual awards	46	1,788	0	0	0	0	54	2,119	54	2,219	0	100
Institutional awards	438	17,074	0	0	0	0	430	16,871	430	17,882	0	1,011
Total, Training	484	18,862	0	0	0	0	484	18,990	484	20,101	0	1,111
Research & development contracts	97	152,794	0	0	5	16,310	96	151,549	98	154,206	2	2,657
(SBIR/STTR)	(5)	(1,366)	(0)	(0)	(0)	(0)	(5)	(1,366)	(5)	(1,366)	(0)	2,007
(obinio) miy	(0)	(1,000)	107	(~)	107	(~)	(~)	(1,000)	(*)	(1,000)		(~.
	FTEs		FTEs		FTEs		FTEs		FTEs		FTEs	
Intramural research	523	176,387	0	79	0	761	531	182,030	556	187,855	25	5,825
Research management and support	112	19,822	0	421	0	2,940	120	20,659	124	21,692	4	1,033
Construction		0	1420407	0	10000	0	100.000N	0		0		0
Buildings and Facilities		0		0		0		0		0		0
Total, NIEHS	635	662,667	0	87,103	0	80,954	651	689,565	680	707,339	29	17,774

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

NATIONAL INSTITUTES OF HEALTH National Institute of Environmental Health Sciences BA by Program (Dollars in thousands)

	ΕΥ	FY 2007	FΥ	FY 2008	FΥ	FY 2009	ΕY	FY 2009	ΕΥ ;	FY 2010	ΕΥ ζ	FY 2011		Γ
<u>Extramural Research</u> <u>Detail:</u>	FTES FTES	Actual <u>Amount</u>	<u>FTEs</u> Ac	Actual <u>Amount</u>	<u>ettes</u>	Actual <u>Amount</u>	Com FTEs	Comparable <u>Es</u> <u>Amount</u>	Estir FTEs	Estimate <u>s Amount</u>	FTES	PB <u>Amount</u>	Change <u>FTEs Amo</u> u	ange <u>Amount</u>
Clinical and Translational Research: Bench to Bedside to Public Health		\$150,733		\$158,396		\$177,251		\$174,644		\$181,950		\$186,772		4,822
Toxicity Testing and Evaluation		90,353		86,923		84,127		84,127		81,228		83,228		2,000
Basic Mechanisms in Human Biology		156,195		157,932		150,077		146,883		147,948		149,074		1,126
Exposure Biology/Exposure Measurement		29,096		16,176		18,011		18,725		29,785		30,341		556
Pathways for Future Environmental Health Scientists		36,474		40,540		42,079		42,079		45,965		48,377		2,412
Subtotal Extramural		462 851		459 967		471 545		466 458		486 876		C97 794		10 916
Intramural research	558	167,002	545	173,749	523	176,435	523	176,387	531	182,030	556	187,855	25	5,825
Res. management & support	98	17,389	66	17,894	112	20,110	112	19,822	120	20,659	124	21,692	4	1,033
TOTAL	656	647,242	644	651,610	635	668,090	635	662,667	651	689,565	680	707,339	29	17,774
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research	admap for Me	dical Researc	Ŀ											

# Major Changes in the Fiscal Year 2011 Budget Request

Major changes by budget mechanism and/or budget program 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 2011 budget request for NIEHS, which is \$17.774 million more than the FY 2010 Estimate, for a total of \$707.339 million.

Research Project Grants (RPGs) (+\$6.859 million; total \$276.096 million): NIEHS expects to support a total of 644 RPG awards in FY 2011. Noncompeting RPGs will increase by 2 awards and \$1.808 million. Competing RPGs will increase by 9 awards and \$4.917 million. The NIH Budget policy for RPGs in FY 2011 is to provide an inflationary increase of 2% for noncompeting awards and allow a 2% increase in the average cost of competing RPGs. NIEHS will continue to support new investigators in FY 2011.

<u>Clinical and Translational Research: Bench to Bedside to Public Health (+\$4.822</u> <u>million; total \$186.772 million)</u>: Additional funds in this area will be used to enhance clinical and translational research activities associated with the overall NIEHS portfolio on cancer. Additional funds will also support clinical and translational research within the Virtual Centers for Transdisciplinary Environmental Research (ViCTER) program.

<u>Toxicity Testing and Evaluation (+\$2.000 million; total \$83.228 million):</u> The additional funds will be used to support cooperative agreements to assist in the creation of refined toxicology methods to evaluate long-term outcomes from exposures during development.

Pathways for Future Environmental Health Scientists (+2.412 million; total \$48.377 million): Funds will support additional awards under NIEHS' signature career development program, Outstanding New Environmental Scientists (ONES), as well as an increase in NRSA stipends.

Intramural Research (+\$5.825 million; total \$187.855 million): The additional funds will be used for scientific recruitments to broaden the intramural research scientific base with expertise consistent with the NIEHS strategic plan, including operation of the Clinical Research Unit. Funds will also be used for expenses associated with the pay increase and for laboratory supplies, materials and other expenses.

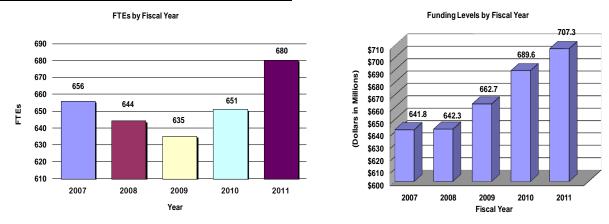
# NATIONAL INSTITUTES OF HEALTH National Institute of Environmental Health Sciences Summary of Changes

FY2010 estimate				\$689,565,000
FY 2011 estimated budget authority				707,339,000
Net change				17,774,000
	20	10 Current		
	Esti	imate Base	Change	e from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January		•		•
2010 pay increase		\$75,804,000		\$459,000
b. January FY 2011 pay increase		75,804,000		796,000
c. Zero less days of pay (n/a for 2011)		75,804,000		0
d. Payment for centrally furnished services		22,863,000		457,000
<ul> <li>e. Increased cost of laboratory supplies, materials, and other expenses</li> </ul>		83,363,000		1,433,000
materiais, and other expenses		03,303,000		1,433,000
Subtotal				3,145,000
2. Research management and support:				
a. Annualization of January				
2010 pay increase		\$13,692,000		\$83,000
b. January FY 2011 pay increase		13,692,000		144,000
c. Zero less days of pay (n/a for 2011)		13,692,000		0
d. Payment for centrally furnished services		2,827,000		57,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		4,140,000		70,000
Subtotal				354,000
Subtotal, Built-in				3,499,000

# Summary of Changes--continued

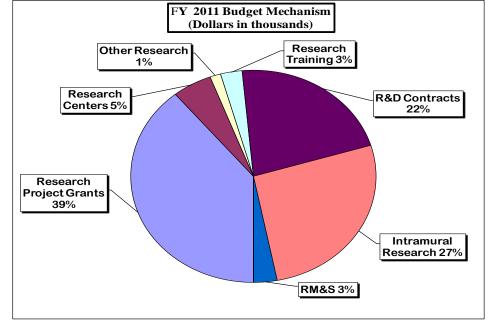
	20	010 Current		
	Es	timate Base	Chang	e from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	441	\$193,628,000	2	\$1,658,000
b. Competing	167	63,414,000	9	4,917,000
c. SBIR/STTR	25	12,195,000	0	284,000
Total	633	269,237,000	11	6,859,000
2. Research centers	27	37,475,000	0	0
3. Other research	75	9,625,000	2	289,000
4. Research training	484	18,990,000	0	1,111,000
5. Research and development contracts	96	151,549,000	2	2,657,000
Subtotal, extramural				10,916,000
	FTEs		FTEs	- , ,
6. Intramural research	531	182,030,000	25	2,732,000
7. Research management and support	120	20,659,000	4	679,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		689,565,000		14,327,000
Total changes	651		29	17,774,000

# FY 2011 Budget Graphs

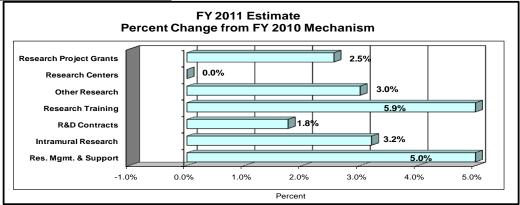


## History of Budget Authority and FTEs:

### **Distribution by Mechanism:**



# Change by Selected Mechanism:



# **Justification of Budget Request**

# National Institute of Environmental Health Sciences

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

Budget Authority:

	·····		FY 2011	
	FY 2009	FY 2010	President's	FY 2011+/-
	Appropriation	Appropriation	<u>Budget</u>	<u>FY 2010</u>
BA	\$662,667,000	\$689,565,000	\$707,339,000	\$17,774,000
FTE	635	651	680	29

This document provides justification for the Fiscal Year (FY) 2011 activities of the National Institute of Environmental Health Sciences (NIEHS), including HIV/AIDS activities. Details of the FY 2011 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.

# NIEHS DIRECTOR'S OVERVIEW

Prevention of human disease through the understanding of environmental impacts on human health is the primary goal of the NIEHS. NIEHS intramural investigators, as well as contractors and grantees across the United States, are working to understand how exposures to environmental agents trigger disease, how these diseases can be diagnosed and treated, and how these exposures and diseases can be prevented. NIEHS research addresses a wide range of disease and dysfunction including breast cancer, autism, Parkinson's Disease, asthma, reproductive malformations and dysfunction, liver disease, and birth defects, among others. Prevention of these diseases and conditions is an important aspect of establishing better health for Americans; efforts to reform health care in a sustainable fashion that delivers the most value for our health care dollar will benefit from the ability to understand environmental contributions to preventable disease and designing appropriate interventions to prevent exposure and disease.

Environmental exposures early in development affect the risk of diseases and dysfunctions occurring many years later in adulthood. There is increasing evidence that epigenetic mechanisms – cellular regulatory processes that influence the expression of genes without affecting DNA sequence – play an important role in the pathogenesis of disease. Epigenetic regulation of genes is critically important in normal developmental biology and disease development/progression, and epigenetic modifications can be

influenced by environmental exposures, which may be an important mechanism for gene/environment interactions. NIEHS has initiated several groundbreaking research programs with its own funding and as part of the NIH Roadmap, to study environmental influences on epigenetic regulation.

Endocrine disruptors are chemicals in the environment that, when absorbed, can mimic and disrupt the function of the body's internal hormones. Endocrine disruption may play a role in health issues such as early puberty in young girls, developmental male reproductive malformations, obesity, diabetes, and other similar diseases. NIEHS has a major investment in research focusing on endocrine disruptors. The National Toxicology Program (NTP), headquartered at NIEHS, conducted the major health review of bisphenol A (BPA) which prompted both widespread reconsideration of its use by industry and the introduction of alternative products such as the BPA-free water bottle, among others. Endocrine disruption continues to be a focal point in studies of commercial products that are in wide use, such as flame retardants and pesticides.

High throughput approaches to many research and testing problems have been made possible by current technology and are an increasing priority for many program objectives at NIH. NTP's Program Vision for the 21<sup>st</sup> Century is to move toxicology from a predominantly observational science to a predominantly predictive science, focusing on broad inclusion of target-specific, mechanism-based biological observations. Increasing emphasis is being placed on the use of alternative assays for targeting key pathways, molecular events, or processes linked to disease or injury. In partnership with the National Human Genome Research Institute/National Chemical Genomics Center and the Environmental Protection Agency's (EPA) National Center for Computational Toxicology, NTP is performing high throughput assays of chemicals and making the results available online.

Translational research is a priority for NIH and NIEHS. Last summer, NIEHS opened the NIEHS Clinical Research Unit (CRU), an on-campus facility that allows NIEHS clinicians to see patients and conduct studies in close proximity to their colleagues in the laboratories. One CRU research initiative focuses on the role of environmental agents in initiating new cases of asthma and in triggering asthmatic episodes. Asthma is a critically important environmental health issue; 22 million Americans have asthma, and six million of them are children. NIEHS will utilize the CRU to study other respiratory diseases and other types of environment-related diseases in the future.

The Early Autism Risk Longitudinal Investigation (EARLI) is another effort designed to identify disease etiology. NIEHS is among eight organizations contributing to EARLI, which is following a cohort of up to 1,200 pregnant women who already have children with autism. With its special cohort, multidisciplinary focus, and extensive sampling and data collection, EARLI is uniquely positioned to discover biological markers and environmental risk factors for autism and their interplay with genetic susceptibility during prenatal, neonatal, and early postnatal periods.

The use of nanoscale materials is growing exponentially; by 2015, the global nanotechnology market is expected to exceed \$3.1 trillion. However, the knowledge base for safety assessment of engineered nanomaterials and nano-enabled products is

insufficient, especially considering the diversity of materials used combined with our growing awareness of the unique physical and chemical properties that emerge at the nanoscale. NIEHS is making a critical investment in research in this area, beginning with identifying appropriate reliable and reproducible assays for characterization of nanoscale materials. NIEHS-funded multi-disciplinary research teams are exploring the impact of these materials on biological response at the systemic, cellular, and molecular levels. Understanding these effects will be critically important for informed risk assessment and prevention of potential adverse effects.

Climate change will lead to new or changing environmental exposures, including air pollutant levels, different agricultural chemicals resulting from modified agricultural practices, limited or unsafe water supplies, fires, and extreme weather events. NIEHS is a leader in supporting critical research focusing on understanding, predicting, and preventing adverse health impacts resulting from changes in the Earth's climate. NIEHS supports hundreds of projects targeted at evaluating actual climate parameters and their effects on health. NIEHS leads an Interagency Working Group on Climate Change and Health, which includes representatives from NIH, the Center for Disease Control and Prevention, EPA, the National Oceanic and Atmospheric Administration, the National Aeronautics and Space Administration, the U. S. Department of Agriculture, and others. The group is compiling a report containing recommendations for basic and applied research needs on the human health effects of climate change for use by all Federal agencies with a human/environmental health mission.

This brief overview offers only selected highlights of the many critical research programs conducted and supported by NIEHS as it moves forward in its efforts to protect human health and prevent disease.

# **Budget Policy**

NIEHS is providing a 2 percent inflationary increase for non-competing grants and a 2 percent increase in the average cost for competing grants. NIEHS has targeted a portion of the funds available for competing research project grants to support high priority projects outside of the payline, including awards to new investigators and early stage investigators. In FY 2011, NIEHS will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. The Institute also seeks to maintain a balance between solicitations issued to the extramural community and funding made available to support investigator-initiated projects.

Funds are included in R&D contracts to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program (TRND), the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory, as well as increased support for other HHS agencies through the program evaluation set-aside. Intramural Research and Research Management and Support receive additional funds to help offset the cost of pay and other increases.

# FY 2011 JUSTIFICATION BY PROGRAM

### **Program Descriptions and Accomplishments**

**Clinical and Translational Research: Bench to Bedside to Public Health:** This program encourages integration of clinical, population, and community-linked research to effectively translate findings into improved public health practice and disease prevention. For example, nitrogen dioxide gas, most prevalent in industrial settings, is also found at high levels in many poor, inner-city homes that have unvented gas stoves. NIEHS-supported researchers at Johns Hopkins University found that high levels of nitrogen dioxide gas from cooking and heating stoves in indoor environments aggravate asthma symptoms in inner-city children, especially pre-school aged children. As a result, the researchers recommended that physicians caring for children with asthma should inquire about home heating and cooking appliances and recommend using alternatives to unvented gas stoves or encourage that the stoves be properly vented.

<u>Budget Policy:</u> The FY 2011 budget estimate for this program is \$186.772 million, an increase of \$4.822 million, or 2.7 percent over the FY 2010 estimate. Resources will be used to support a variety of clinical and translational research activities. These include research on windows of susceptibility to environmental agents in increasing risk of developing breast cancer, including studies on relationships between early exposures and puberty, and funding of a coordinating center for the overall initiative on breast cancer and environment. Funding will also support clinical and translational research within the ViCTER program. Resources will also be used to support NIEHS's program on Partnerships in Environmental Public Health (PEPH), which covers research translation efforts, with a focus on capacity building (community research partnerships) and dissemination science (research on how to disseminate and translate environmental health data for the public).

### Portrait of a Program: Breast Cancer and the Environment

 FY 2010 Level:
 \$4.025 million

 FY 2011 Level:
 \$4.025 million

 Change:
 \$0.000 million

The Breast Cancer Environmental Research Program (BCERP), established in 2003 as a consortium of universities, is jointly funded by NIEHS and the National Cancer Institute. Studies investigating mammary gland development in young girls and in animals are designed to help define specific periods of susceptibility of the breast when environmental stressors in relation to genetic factors confer increased risk of future cancer. The epidemiology project within the consortium is examining the determinants of puberty in girls, integrating how environmental, genetic, lifestyle, and socioeconomic factors work together and independently, in recognition of the link between timing of pubertal maturation and future breast cancer risk. BCERP's epidemiology consortium has recruited a geographically and ethnically diverse group of 1,270 girls between the ages of 6-8 from the Bay Area of San Francisco, California, East Harlem, New York, and the Cincinnati, Ohio/Northern Kentucky Region. This group reports for the first time, that children have extraordinarily high levels of a number of hormonally active environmental chemicals. To ensure that significant conclusions can be made

regarding the role of exposure to environmental estrogens in affecting the timing of pubertal transition, these girls will be monitored over the next five years. Concurrent animal and human-based studies will be conducted to include studies of exposures during puberty and other critical developmental periods, and the relation to breast cancer risk in adulthood. These efforts are expected to lead to strategies and lifestyle choices to reduce breast cancer risk.

On June 23, 2009, the delegation of authority to establish and administer the Interagency Breast Cancer and Environmental Research Coordinating Committee was assigned to the NIEHS Director. The Committee's primary objective is to review and summarize all efforts within the Department of Health and Human Services (DHHS) concerning research being conducting on the environmental and genetic factors related to the etiology of breast cancer and to make recommendations to the Secretary, DHHS regarding research gaps and needs. NIEHS has authority to appoint the members to the Committee and to review the necessity of the Committee in the year 2011, and at least once every two years thereafter. A Call for Nominations for voting public members was advertised in the <u>Federal Register</u> in October 2009. The slate of proposed voting members has been submitted to the Office of Committee Management, and an initial meeting of members is anticipated in early spring 2010.

**Toxicity Testing and Evaluation:** This program comprises the NIEHS extramural research investment of the NTP, whose mission is to evaluate agents of public health concern, and generate information to be used by health regulatory agencies to make informed decisions affecting public health. NTP also works to develop new and improved test methods, including alternatives to animal testing and methods to test substances faster in order to more rapidly disseminate information useful from a public health perspective. For example, NTP, in partnership with the EPA and the NIH Chemical Genomics Center, is evaluating a new toxicity testing process that uses highspeed, automated assays to evaluate tens of thousands of substances for biological activity in key toxicity pathways using human cells and molecular targets instead of animals. If successful, this testing approach will generate data more relevant for humans, help prioritize substances for further testing, expand the number of environmental substances that can be tested, reduce animal use, and have widespread applicability, including use in regulatory safety testing. In April 2009, NTP signed an international memorandum of cooperation with Canada, Japan, and the European Union that provides a framework for globally harmonized evaluation of alternative toxicity test methods used in regulatory testing, and promotes international coordination on the validation and scientific review of alternative methods and the development of recommendations on their utility.

<u>Budget Policy:</u> The FY 2011 budget estimate for this program is \$83.228 million, an increase of \$2.0 million, or 2.5 percent over the FY 2010 estimate. New resources will be directed towards cooperative agreements to assist in the creation of refined toxicology methods to evaluate long-term outcomes from exposures during development.

### Portrait of a Program: Health Effect Studies of Cell Phone Radiation

FY 2010 Level:	\$ 5.000 million
FY 2011 Level:	<u>\$ 4.000 million</u>
Change:	-\$1.000 million

Although current scientific evidence has not conclusively linked cell phone use with any health problems, many people are concerned about whether cell phone use causes cancer or other serious illnesses. The Food and Drug Administration (FDA) nominated cell phone radiofrequency radiation to the NTP for study because human exposure is widespread, current exposure guidelines are based largely on protecting against acute injury from thermal effects, and there is a lack of information on whether long-term exposure to non-ionizing radiation in the radiofrequency range poses health risks. NTP is in the initial stages of conducting toxicology and carcinogenicity studies in laboratory rodents to help clarify any potential health hazards, including cancer, from exposure to cell phone radiation. These studies are the most technically challenging and complex NTP has ever designed and conducted. Because of the technical complexity, NTP worked closely with experts from the National Institute of Standards and Technology and the Foundation for Research on Information Technology in Society (ITIS), Zurich, Switzerland, to develop an exposure system that would provide uniform exposures to radiofrequency radiation in rodents in the frequency bands of mobile communications used in the United States. The studies are being conducted in three phases (pilot studies and studies of short- and long-term exposures). These studies are being carried out with both genders of rats and mice and will examine potential health effects resulting from exposures, beginning in gestation and continuing through adulthood. NTP anticipates that all phases of these studies will be completed by 2014. Collectively, these studies will provide critical information regarding the safety of exposure to cell phone radiation and strengthen the science base for determining any potential health effects in humans. This data will be used by federal agencies, including the FDA, in making decisions regarding radiofrequency radiation health issues, consistent with protection of public health and safety.

### **Basic Mechanisms in Human Biology**

This program employs environmental toxicants as laboratory probes to study the complex molecular pathways that lead to chronic disease. Environmental toxicants can interrupt normal biological processes and initiate events leading to disease. This program helps to identify methods to diagnose these diseases before they are clinically evident and develop early interventions to prevent progression to end-stage disease. New NIEHS-funded research findings suggest that preventing a specific chemical modification, S-nitrosylation, of the mitochondrial protein Drp1, by the free radical nitric oxide may reduce or even prevent neurodegeneration in Alzheimer's patients. The research team found that S-nitrosylated Drp1 facilitates mitochondrial fragmentation, which leads to synaptic injury and eventual nerve cell death. Experiments to decrease Drp1 activity, either using RNA interference or a mutation that prevented Drp1 activity, inhibited excess mitochondrial damage and protected the neurons. These findings suggest that drugs or interventions to prevent damage to Drp1 could prove to be effective prevention or treatment strategies for Alzheimer's disease.

<u>Budget Policy:</u> The FY 2011 budget estimate for this program is \$149.074 million, an increase of \$1.126 million, or .8 percent from the FY 2010 estimate. Resources will be used to enhance research investments in basic mechanisms of human biology, including studies aimed at improving the understanding of potential human health and safety impacts of low-dose exposures to endocrine-disrupting chemicals. In addition, a

new initiative is planned to support the development of new tools to measure cells' capacity for DNA repair.

## **Exposure Biology/Exposure Measurement**

This program seeks to develop improved methods to detect and measure environmental exposures sustained by humans or other organisms. A project from the Exposure Biology Program, an NIEHS-led component of NIH's Genes, Environment and Health Initiative, has made an exciting breakthrough in real-time detection of toxic gases. Researchers developed a colorimetric sensor array model that was capable of identifying 19 different toxic industrial chemicals. Researchers are now working to convert the array model into a handheld portable device for rapid, inexpensive, and highly sensitive monitoring of toxic gases.

<u>Budget Policy:</u> The FY 2011 budget estimate for this program is \$30.341 million, an increase of \$556 thousand, or 1.9 percent over the FY 2010 estimate. Resources will be directed towards expanded nanotechnology-related research efforts aimed at improving the understanding of potential human health and safety impacts of engineered nanoparticles and nano-enabled products.

### Portrait of a Program: Human Health Impact of Nanotechnology

 FY 2010 Level:
 \$24.512 million

 FY 2011 Level:
 \$25.999 million

 Change:
 \$1.487 million

In order to promote innovation while minimizing risk of adverse health impact, novel materials and products should be assessed for potential health effects prior to extensive use. Responsible development of engineered nanoscale materials (ENM) requires that material synthesis, product creation, and safety assessment occur in parallel tracks. The immediacy of safety assessment is underscored by projections that by 2015, the global nanotechnology market is expected to exceed \$3.1 trillion. The diversity of materials used to synthesize nano-enabled products, as well as the diversity of the physical and chemical properties that emerge at the nanoscale, suggest that safety assessment will be challenging. Through a combination of grants and contracts, NIEHS supports multi-disciplinary research teams who are exploring the impact of size and size-dependent properties of nanomaterials on biological response at the systemic, cellular, and molecular levels and on individuals with pre-existing disease. Because the physical and chemical properties of ENM may change across experimental timelines, or through the life cycle of a product, the studies include evaluation of potential human exposures, physical and chemical characteristics of ENM at multiple points in an exposure model, and linkage of these measurements to biological effects. This research is contributing to a body of knowledge that has begun to demonstrate trends in the relationship of physical and chemical properties to biological response. NIEHS will continue to support research to improve the understanding of potential health impacts of these novel nanoscale materials, as well as help to guide development of nano-enabled products so as to reduce adverse impact to an increasingly exposed population.

# Pathways for Future Environmental Health Scientists

This program's goal is to attract the brightest young students and scientists into the environmental health sciences field to have the right cadre to conduct the interdisciplinary research demanded. This program includes efforts at the high school and undergraduate levels (opportunities for laboratory-based training), the graduate level (institutional and individual training grants including a new training initiative designed to prepare individuals to study environment and genetic factors in disease etiology), and the faculty level (grants for young investigators and short term sabbatical awards). NIEHS' signature career development program, Outstanding New Environmental Scientists (ONES), is funding a cadre of excellent young investigators who are doing exciting work in environmental health science. Recently, a ONES awardee at Yale University was the lead author on a report showing that low-dose exposure to the acutely poisonous gas carbon monoxide, even at levels far below national exposure limits, is associated with increased risk of adverse cardiovascular outcomes in elderly persons requiring hospitalization. These findings suggest that the currently accepted regulatory level of carbon monoxide may still pose a health risk for this vulnerable population.

<u>Budget Policy</u>: The FY 2011 budget estimate for this program is \$48.377 million, an increase of \$2.412 million, or 5.2 percent over the FY 2010 estimate. Resources will be used to continue high priority projects such as 1) the ONES program, an R01 program for new independent investigators, 2) the NIEHS training grant program to increase participation of physician-scientists in environmental sciences research, 3) the NIEHS MD/PhD program, 4) the joint training program in environmental genetics and genomics, co-sponsored with NHGRI, 5) the NIH Pathway to Independence program and 6) the Short Term Educational Experiences for Research in Environmental Health (STEER) program designed to attract talented high school students and undergraduates to summer research opportunities in the environmental health sciences. In addition, National Research Service Award (NRSA) training stipends increase by 6% in FY 2011.

# **Intramural Research**

This program's mission is to investigate the role of environmental agents in human disease and dysfunction and define the important biological and chemical processes that these agents act upon. NIEHS' intramural research studies are often longitudinal and high-risk in nature with unique components, such as NIEHS' contribution to the NTP, epidemiological studies of environmentally associated diseases, and intervention and prevention studies in humans to reduce the effects of exposures to hazardous environments. Some components, previously performed under contract, now use intramural staff, allowing better oversight and control. The recent opening of NIEHS' CRU provides new opportunities for intramural clinical and basic science investigators to work together to learn how environmental exposures influence human health and disease. More than 50 years after Watson and Crick's description of the structure of the DNA double helix, the identity of the DNA polymerases that replicate the leading and lagging strands in higher organisms has remained uncertain. That situation changed recently, when NIEHS intramural investigators showed that two distinct DNA polymerases share the task of replicating the cell's nuclear genome prior to cell division. Their findings indicate that DNA polymerase epsilon is primarily responsible for replicating the leading strand; whereas, DNA polymerase delta is primarily responsible for replicating the lagging strand. Since deleterious mutations may be introduced into cells at the time of DNA replication, this advance in our understanding of replication enzymes is a critical step in establishing how environmental substances can reduce genome stability, and thereby impact diseases whose causes are tied to mutation, including cancers and defects in fetal or childhood development.

<u>Budget Policy</u>: The FY 2011 budget estimate for this program is \$187.855 million, an increase of \$5.825 million, or 3.2 percent over the FY 2010 estimate. Resources will be directed to high priority research programs designed to understand human disease and improve human health, such as bioinformatics, reproductive epidemiology and structural biology.

**Research Management and Support (RMS):** The RMS program provides administrative, budgetary, logistical and scientific support in the review, award, and monitoring of research grants and training awards. NIEHS currently oversees approximately 735 research grants and centers. In addition, RMS provides administrative support for the Intramural Research program. Other RMS functions include strategic planning, coordination, and evaluation of NIEHS programs, regulatory compliance, ethics, international coordination, and liaison with other Federal agencies, Congress, and the public.

<u>Budget Policy:</u> The FY 2011 budget estimate for RMS is \$21.692 million, an increase of \$1.033 million, or 5.0 percent over the FY 2010 estimate. This increase reflects NIH policy for FY 2011 and will be used to cover increases for pay costs, centrally furnished services and supplies and materials. Resources will be used to support increased liaison functions with other components of NIH, HHS, EPA, and other agencies and non-government organizations, to improve interagency collaboration, efficiency, and optimum prioritization of research investment.

# **NIH Common Fund**

NIEHS is a co-lead institute for the Roadmap Epigenomics Program supported through the NIH Common Fund, which will continue in FY 2011.

### **Recovery Act Implementation**

Recovery Act Funding: \$168.057 million

In FY 2009, NIEHS received \$168.1 million under the Recovery Act. Of this amount, \$87.1 million was obligated in FY 2009 and \$81.0 million will be obligated in FY 2010. These funds support grants, competitive and administrative supplements, and summer laboratory jobs for students, covering targeted areas of high public health concern. For its signature grant projects, NIEHS is supporting research into the safety of engineered nanomaterials, including methods for measuring exposure and preventing adverse public health impacts. NIEHS is also supporting research into the health effects of BPA, a widely used chemical with potential links to cancer and reproductive effects. The BPA grants program is complemented by projects in the NTP to examine BPA effects on many outcomes including behavior, obesity, diabetes, reproductive disorders, and cardiovascular diseases. NIEHS also targeted ARRA funding for several studies of gene-environment interactions and effects of prenatal exposures on risk of autism. Other important investments were made in outreach and capacity building in underserved populations and creation of environmental health sciences educational materials for the use of K-12 teachers.

Budget Authority by Object

	Budget Authority		1	
		FY 2010	FY 2011	Increase or
		Estimate	PB	Decrease
Total	ompensable workyears:	LSumate	гb	Declease
Total C	Full-time employment	651	680	29
	Full-time equivalent of overtime and holiday hours	1	1	29
	T di-time equivalent of overtime and holiday hours	1	I	0
	Average ES salary	\$178,663	\$181,772	\$3,109
	Average GM/GS grade	11.3	11.4	0.1
		11.0		0.1
	Average GM/GS salary	\$82,562	\$87,516	\$4,954
	Average salary, grade established by act of			
	July 1, 1944 (42 U.S.C. 207)	\$90,656	\$92,469	\$1,813
	Average salary of ungraded positions	129,090	131,672	2,582
		FY 2010	FY 2011	Increase or
	OBJECT CLASSES	Estimate	Estimate	Decrease
	Personnel Compensation:	<b>*</b> 40 <b>=</b> 4 4 000	<b>*</b> ( <b>* * * * * *</b>	<b>AA</b> 4 4 <b>A A A A</b>
11.1	Full-time permanent	\$40,514,000	\$42,960,000	\$2,446,000
11.3	Other than full-time permanent	19,247,000	20,457,000	1,210,000
11.5	Other personnel compensation	1,291,000	1,369,000	78,000
11.7	Military personnel	762,000	810,000	48,000
11.8	Special personnel services payments	10,249,000	10,901,000	652,000
-	Total, Personnel Compensation	72,063,000	76,497,000	4,434,000
12.0	Personnel benefits	16,984,000	18,028,000	1,044,000
12.2	Military personnel benefits	449,000	478,000	29,000
13.0	Benefits for former personnel	0	0	0
	Subtotal, Pay Costs	89,496,000	95,003,000	5,507,000
21.0	Travel and transportation of persons	2,048,000	2,098,000	50,000
22.0	Transportation of things	450,000	452,000	2,000
23.1	Rental payments to GSA	3,000	3,000	0
23.2	Rental payments to others	82,000	85,000	3,000
23.3	Communications, utilities and			
	miscellaneous charges	1,095,000	1,099,000	4,000
24.0	Printing and reproduction	77,000	81,000	4,000
25.1	Consulting services	472,000	486,000	14,000
25.2		32,822,000	33,347,000	525,000
25.3	Purchase of goods and services from			
l	government accounts	100,505,000	103,827,000	3,322,000
	Operation and maintenance of facilities	2,868,000	2,878,000	10,000
25.5	Research and development contracts	97,557,000	97,521,000	(36,000)
25.6	Medical care	41,000	41,000	0
25.7	Operation and maintenance of equipment	2,564,000	2,573,000	9,000
25.8	Subsistence and support of persons	0	0	0
25.0	Subtotal, Other Contractual Services	236,829,000	240,673,000	3,844,000
26.0	Supplies and materials	12,788,000	12,840,000	52,000
31.0	Equipment	11,363,000	11,412,000	49,000
32.0	Land and structures	0	0	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	335,327,000	343,586,000	8,259,000
42.0	Insurance claims and indemnities	4,000	4,000	0
43.0	Interest and dividends	3,000	3,000	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	600,069,000	612,336,000	12,267,000
	Total Budget Authority by Object	689,565,000	707,339,000	17,774,000

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

Salaries and	Expenses		
	FY 2010	FY 2011	Increase or
OBJECT CLASSES	Estimate	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$40,514,000	\$42,960,000	\$2,446,000
Other than full-time permanent (11.3)	19,247,000	20,457,000	1,210,000
Other personnel compensation (11.5)	1,291,000	1,369,000	78,000
Military personnel (11.7)	762,000	810,000	48,000
Special personnel services payments (11.8)	10,249,000	10,901,000	652,000
Total Personnel Compensation (11.9)	72,063,000	76,497,000	4,434,000
Civilian personnel benefits (12.1)	16,984,000	18,028,000	1,044,000
Military personnel benefits (12.2)	449,000	478,000	29,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	89,496,000	95,003,000	5,507,000
Travel (21.0)	2,048,000	2,098,000	50,000
Transportation of things (22.0)	450,000	452,000	2,000
Rental payments to others (23.2)	82,000	85,000	3,000
Communications, utilities and			
miscellaneous charges (23.3)	1,095,000	1,099,000	4,000
Printing and reproduction (24.0)	77,000	81,000	4,000
Other Contractual Services:			
Advisory and assistance services (25.1)	472,000	486,000	14,000
Other services (25.2)	32,874,000	33,347,000	473,000
Purchases from government accounts (25.3)	65,030,000	65,983,000	953,000
Operation and maintenance of facilities (25.4)	2,868,000	2,878,000	10,000
Operation and maintenance of equipment (25.7)	2,564,000	2,573,000	9,000
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	103,808,000	105,267,000	1,459,000
Supplies and materials (26.0)	12,784,000	12,836,000	52,000
Subtotal, Non-Pay Costs	120,344,000	121,918,000	1,574,000
Total, Administrative Costs	209,840,000	216,921,000	7,081,000

# Salaries and Expenses

		Authorizii	Authorizing Legislation			
	PHS Act/	U.S. Code	2010 Amount	FY 2010	2011 Amount	FY 2011
	Other Citation	Citation	Authorized	Estimate	Authorized	PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
	Section 402(a)	42§281	Indefinite	\$689,565,000	Indefinite	\$707,339,000
National Institute of Environmental Health Sciences			N		١	
Total, Budget Authority				689,565,000		707,339,000

Fiscal	Budget Estimate	House	Senate	
Year	to Congress	Allowance	Allowance	Appropriation
2002	561,570,000	557,435,000	585,946,000	566,639,000
Rescission				(1,942,000)
2003	609,705,000	609,705,000	617,258,000	618,258,000
Rescission				(4,019,000)
2004	630,774,000	630,774,000	637,074,000	636,974,000
Rescission				(4,582,000)
2005	650,027,000	650,027,000	655,100,000	650,027,000
Rescission				(5,522,000)
2006	647,608,000	647,608,000	667,372,000	647,608,000
Rescission				(6,476,000)
2007	637,323,000	637,323,000	641,292,000	642,002,000
2008	637,406,000	652,303,000	656,176,000	653,673,000
Rescission				(11,420,000)
Supplemental				3,416,000
2009	642,875,000	664,980,000	660,767,000	662,820,000
2010	684,257,000	695,497,000	683,149,000	689,781,000
2011	707,339,000			

### Appropriations History

1/ Reflects enacted supplementals, rescissions, and reappropriations.

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

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OFFICE/DIVISION	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB		
Office of the Director	38	42	46		
Division of Intramural Research	424	432	455		
Division of Extramural Research and Training	52	56	57		
Office of Management	106	106	107		
Office of Translational Research	15	15	15		
Total	635	651	680		
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research					
FTEs supported by funds from Cooperative Research and					
	(0)	(0)	(0)		
Development Agreements	(0)	(0)	(0)		
FISCAL YEAR	Average GM/GS Grade				
		5			
2007	11.2				
2008	11.2				
2009	11.3				
2010	11.3				
2011	11.4				

# Details of Full-Time Equivalent Employment (FTEs)

	Detail of Posi		
GRADE	FY 2009 Actual	FY 2010 Estimate	FY 2011 PB
	Actual	Estimate	FD (
Total, ES Positions	1	1	1
Total, ES Salary	176,023	178,663	181,772
GM/GS-15	37	39	40
GM/GS-14	58	62	64
GM/GS-13	76	80	81
GS-12	83	85	87
GS-11	111	115	121
GS-10	2	2	2
GS-9	61	65	66
GS-8	19	19	19
GS-7	25	25	26
GS-6	3	3	3
GS-5	0	0	0
GS-4	10	10	10
GS-3	2	2	2
GS-2	3	3	3
GS-1	0	0	0
Subtotal	490	510	524
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	4	4	4
Senior Grade	0	0	0
Full Grade	1	1	1
Senior Assistant Grade	2	2	2
Assistant Grade	0	0	0
Subtotal	8	8	8
Ungraded	174	179	195
Total permanent positions	482	494	508
Total positions, end of year	673	699	729
Total full-time equivalent (FTE)			
employment, end of year	635	651	680
Average ES salary	176,023	178,663	181,772
Average GM/GS grade	11.3	11.3	11.4
Average GM/GS salary	80,943	82,562	87,516

### **Detail of Positions**

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

# **New Positions Requested**

		FY2011	
	Grade	Number	Annual Salary
Senior Investigator	Title 42	2	\$158,000
Toxicology Pathologist	Title 42	1	133,000
Tenure Track Investigator	Title 42	5	115,000
Staff Scientist	Title 42	2	91,000
Clinical Pathologist	GS-15	1	121,000
Health Science Administrator	GS-14	1	103,000
Health Science Administrator	GS-13	1	87,000
Toxicologist	GS-13	2	87,000
Biologist	GS-13	5	87,000
Budget Analyst	GS-12	1	73,000
Program Analyst	GS-12	1	73,000
Administrative Coordination Specialist	GS-12	1	73,000
Medical Technologist	GS-12	1	73,000
Biologist	GS-12	1	73,000
Biologist	GS-11	2	61,000
Biologist	GS-9	2	51,000
Total Requested		29	