### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

### National Institute of Environmental Health Sciences

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Office of Translational Research Dr. William Martin Director **Environmental Health** National Toxicology National Advisory Sciences Council Program Management Mr. Marc Hollander Director Office of Dr. Samuel H. Wilson **Acting Director** Research and Training Dr. Dennis Lang Division of Extramural **Acting Director** Acting Deputy Director Dr. William Suk Division of Intramural Research Dr. Perry Blackshear **Acting Director** 

National Institute of Environmental Health Sciences

Organization Structure

NATIONAL INSTITUTES OF HEALTH

### **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 [\$653,673,000] **\$642,875,000** (Department of Health and Human Services Appropriation Act, 2008).

# National Institutes of Health National Institute of Environmental Health Sciences

### Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$641,132,000	\$653,673,000	\$642,875,000
Pay cost add-on	870,000		
Rescission		-11,420,000	
Subtotal, adjusted appropriation	642,002,000	642,253,000	642,875,000
Real transfer under Director's one-percent transfer authority (GEI)	5,240,000		
Comparative transfer to NIBIB	-94,000		
Comparative transfer to OD	-43,000		
Comparative transfer to NCRR	-88,000		
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-4,000		
Comparative transfer under Director's one- percent transfer authority (GEI)	-5,240,000		
Subtotal, adjusted budget authority	641,773,000	642,253,000	642,875,000
Subtotal, adjusted budget authority	641,773,000	642,253,000	642,875,000
Unobligated balance lapsing	-222,000		
Total obligations	641,551,000	642,253,000	642,875,000

<sup>1/</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2007 - \$884,000 FY 2008 - \$1,525,000 FY 2009 - \$1,525,000 Excludes \$144,000 in FY 2008 and \$290,000 in FY 2009 for royalties.

### NATIONAL INSTITUTES OF HEALTH

### National Institute of Environmental Health Sciences

(Dollars in Thousands) Budget Mechanism - Total

		2007		/ 2008	F۱	/ 2009		
MECHANISM		ctual		nacted		timate	С	hange
Research Grants:	No.	Amount	No.	Amount	No.	Amount		mount
Research Projects:								
Noncompeting	397	\$155,843	411	\$174,972	408	\$177,236	-3	\$2,264
Administrative supplements	(47)	1,991	(47)	1,991	(47)	1,991	(0)	0
Competing:	, ,	•	, ,		, ,		. ,	
Renewal	39	19,075	20	7,626	18	6,858	-2	-768
New	128	44,728	89	34,354	79	30,639	-10	-3,715
Supplements	2	522	1	334	1	334	0	0
Subtotal, competing	169	64,325	110	42,314	98	37,831	-12	-4,483
Subtotal, RPGs	566	222,159	521	219,277	506	217,058	-15	-2,219
SBIR/STTR	38	11,217	34	10,967	34	10,900	0	-67
Subtotal, RPGs	604	233,376	555	230,244	540	227,958	-15	-2,286
Research Centers:								
Specialized/comprehensive	34	41,200	29	41,399	29	41,399	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	34	41,200	29	41,399	29	41,399	0	0
Other Research:								
Research careers	43	5,799	58	7,250	58	7,250	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	3	2,507	3	2,101	3	2,101	0	0
Other	27	3,879	22	3,235	22	3,235	0	0
Subtotal, Other Research	73	12,185	83	12,586	83	12,586	0	0
Total Research Grants	711	286,761	667	284,229	652	281,943	-15	-2,286
Research Training:	FTTPs		FTTPs		FTTPs		_	_
Individual awards	53	2,128	53	2,105	48	2,105	-5	0
Institutional awards	421	16,964	433	16,757	430	16,757	-3	0
Total, Training	474	19,092	486	18,862	478	18,862	-8	
Research & development contracts	95	151,869	95	151,515	95	151,515	0	0
(SBIR/STTR)	(8)	(1,366)		(1,366)	(8)	(1,366)	(0)	(0)
,	FTEs	( , ,	FTEs	( , ,	FTEs	( , ,	<u>FTEs</u>	( )
Intramural research	558	166,874	559	170,212	564	172,850	5	2,638
Research management and support	98	17,177	99	17,435	99	17,705	0	270
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIEHS	656	641,773	658	642,253	663	642,875	5	622

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

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

	F	FY 2005	F	FY 2006	FΥ	FY 2007	FY	FY 2007	占	FY 2008	Ŧ	FY 2009		
	Ac	Actual	ď	Actual	Ă	Actual	Com	Comparable	ᇤ	Enacted	Est	Estimate	Change	ge
Extramural Research	FTES	FTEs Amount	FTES	-TEs Amount	FTES	FTEs Amount	FTEs	Amount	FTES	Amount	FTEs ,	Amount	FTEs Amount	mount
<u>Detail:</u>														
Linkage of Exposures to												7.0		
Clinical Expression of Disease		\$52,151		\$43,106		\$60,281		\$60,281		\$58,049		\$57,796		-\$253
Basic Mechanisms in Human						. <del></del>								
Biology		245,471		249,888		253,446		253,446		248,927		246,056		-2,871
Interdisciplinary, Integrated						ō		16		9		X.		×
Research		75,661		60,490		58,728		58,728		62,622		61,675		-947
Community-linked & Global														
Environmental Health Research	<u></u>	40,184		45,105		31,808		31,808		31,834		33,134		1,300
Exposure Biology/Exposure														
Measurement		17,827		20,356		29,096		24,055		24,502		24,315		-187
Pathways for Future Environmental	al													
Health Scientists		29,277		27,714		29,492		29,404		28,672		29,344		672
Subtotal, Extramural		460,571		446,659		462,851		457,722		454,606		452,320		-2,286
Intramural research	558	164,720	571	167,084	558	167,002	558	166,874	559	170,212	564	172,850	2	2,638
Res. management & support	93	15,139	93	16,739	98	17,389	98	17,177	66	17,435	66	17,705	0	270
TOTAL	651	640,430	664	630,482	929	647,242	656	641,773	658	642,253	663	642,875	5	622

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

### Major Changes in the Fiscal Year 2009 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 2009 budget request for NIEHS, which is +\$.622 million more than the FY 2008 Enacted, for a total of \$642.875 million.

Research Project Grants (RPGs) (-\$2.286 million; total \$227.958 million): NIEHS will support a total of 540 RPG awards in FY 2009. Noncompeting RPGs will decrease by -3 awards and increase by +\$2.264 million. Competing RPGs will decrease by -12 awards and decrease by -\$4.483 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. Intramural Research and Research Management and Support receive modest increases to help offset the cost of pay and other increases. NIEHS will continue to support new investigators and to maintain an adequate number of competing RPGs.

<u>Basic Mechanisms in Human Biology (-\$2.871 million; total \$246.056 million):</u> Fewer competing awards will be made in this area. NIEHS is also redirecting some funds from this area to Community-linked & Global Environmental Health Research and Pathways for Future Environmental Health Scientists.

Interdisciplinary, Integrated Research (-\$.947 million; total \$61.675 million): Fewer competing awards will be made in this area. NIEHS is also redirecting some funds from this area to Community-linked & Global Environmental Health Research.

Community-linked & Global Environmental Health Research (+\$1.300 million; total \$33.134 million): Funds are being redirected to this area to support a variety of research, outreach and education activities to prevent, reduce, or eliminate environmental exposures that may lead to adverse health outcomes in communities.

Pathways for Future Environmental Health Scientists (+\$.672 million; total \$29.344 million): NIEHS will continue to support the Outstanding New Environmental Scientists (ONES) Program and other activities to attract exceptional researchers to the environmental health sciences field. In FY 2009 NIEHS will provide 1% stipend increases for all pre- and post-doc National Research Service Award trainees. This increase is offset by a decrease in the number of trainees.

Intramural research (+\$2.638 million; total \$172.850 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. The increase will also offset the expenses associated with the pay increase and be used for laboratory supplies, materials, and other expenses.

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

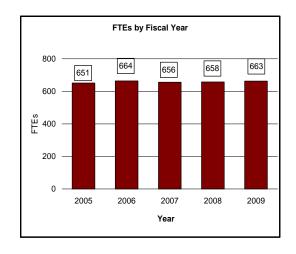
FY 2008 enacted				\$642,253,000
FY 2009 estimated budget authority				642,875,000
Net change				622,000
	200	08 Current		
	Ena	cted Base	Char	nge from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
Intramural research:				
a. Annualization of January				
2008 pay increase		\$75,865,000		\$662,000
b. January FY 2009 pay increase		75,865,000		1,650,000
c. One less day of pay		75,865,000		-290,000
d. Payment for centrally furnished services		25,217,000	)	378,000
e. Increased cost of laboratory supplies,			_	
materials, and other expenses		69,130,000	)	1,246,000
Subtotal				3,646,000
Research management and support:				
a. Annualization of January				
2008 pay increase		11,336,000	)	99,000
b. January FY 2009 pay increase		11,336,000	)	247,000
c. One less day of pay		11,336,000	)	-43,000
d. Payment for centrally furnished services		2,454,000	)	37,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		3,645,000	)	60,000
Subtotal				400,000
0.1444.0.7%				4.040.000
Subtotal, Built-in				4,046,000

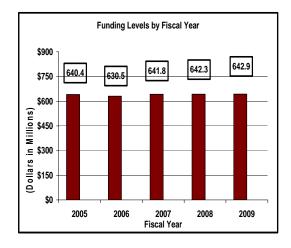
### **Summary of Changes--continued**

		08 Current acted Base	Chan	ge from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research project grants:				
a. Noncompeting	411	\$176,963,000	-3	\$2,264,000
b. Competing	110	42,314,000	-12	-4,483,000
c. SBIR/STTR	34	10,967,000	0	-67,000
Total	555	230,244,000	-15	-2,286,000
2. Research centers	29	41,399,000	0	0
3. Other research	83	12,586,000	0	0
Research training	486	18,862,000	-8	0
5. Research and development contracts	95	151,515,000	0	0
Subtotal, extramural				-2,286,000
,	<u>FTEs</u>		<u>FTEs</u>	, ,
6. Intramural research	559	170,212,000	5	-1,008,000
7. Research management and support	99	17,435,000	0	-130,000
Subtotal, program		642,253,000		-3,424,000
Total changes				622,000

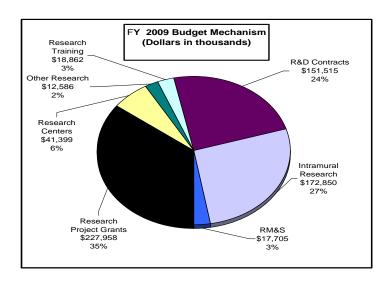
### FY 2009 Budget Graphs

### **History of Budget Authority and FTEs:**

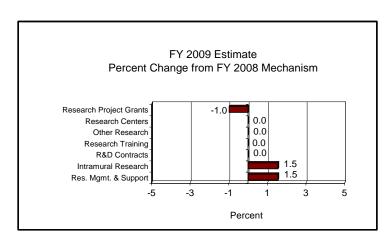




### **Distribution by Mechanism:**



### **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 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		ease or crease
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>
656	\$641,773,000	658	\$642,253,000	663	\$642,875,000	5	\$622,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Institute of Environmental Health Sciences (NIEHS), including HIV/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

The impact of environmental health science research on decisions to reduce exposure to contaminants such as ozone, air particulates, dioxin, lead and mercury, in order to predict and preempt disease before symptoms and damage occur, is familiar to most. Many of the decisions resulting in these reductions have been based on results of NIEHS-supported research and have had a tremendous health impact in reducing the risks to environmentally influenced cardiopulmonary deaths, cancers, asthma and neurobehavioral problems. Environmental health science covers a wide spectrum, including understanding exposure-disease relationships grounded in a vast body of research that examines cellular and molecular responses to toxicants and the genetic susceptibilities than can alter these responses. While less visible to the public, this body of work touches the everyday lives of many Americans. As an example, look no further than a recently prescribed bottle of Coumadin.

Coumadin, a brand name of the blood-thinner warfarin, is the first widely-used drug to include genetic testing information on its label, moving the concept of personalized medicine into the mainstream. This was possible because an NIEHS-supported scientist discovered a variant of the enzyme responsible for breaking down, or metabolizing, warfarin. This variant metabolizes warfarin poorly, so this discovery was key to identifying which patients would need a lower dose, as excess levels of warfarin increase the risk of bleeding. This work was part of a broad effort at NIEHS to

understand the important enzyme system that metabolizes environmental agents: the cytochrome P-450 system. NIEHS-supported researchers made key discoveries in this family of enzymes, identifying the genes coding, the different variants of these genes and the consequence of these variations on enzyme activity and toxicity. This information has been useful to the pharmaceutical industry because the same enzymes act to break down pharmaceuticals. Thus, NIEHS-supported research has led to greater understanding of how individuals can differ in the way they respond to identical doses of a drug. This will become increasingly important as genetic testing techniques become less expensive and doses can be tailored in ways that reduce unwarranted side effects.

The P-450 system is one of several important environmental response pathways of relevance in molecular toxicology. Understanding the consequences of genetic damage by environmental agents has been another extensive field of study. The genetic code embedded in DNA is critical to normal cell functioning and to life itself. It is vulnerable to damage and to mistakes made when DNA is duplicated during cell division; any alterations to the DNA code arising from these events can translate into serious health consequences. For this reason, the body has elaborate systems for identifying damage to DNA, for repairing this damage, and for excising areas that are damaged. NIEHS has supported extensive research examining the biological and clinical consequences of alterations in DNA arising from mutations caused by environmental agents or by mistakes in routine events such as replication. This work has helped identify the different types of "breaks" that can occur in DNA and the complex enzymatic repair mechanisms that attempt to correct this damage. Insights from this research have led to the development of signatures or fingerprints of cellular response that hold promise for identifying environmental causes of disease in human populations with a precision that has not previously been possible. Proof of the value of this concept has recently been demonstrated in studies in the Balkans.

Balkan endemic nephropathy is a disease people in the Balkans have suffered from for hundreds of years, causing kidney failure and malignant tumors of the urinary tract. Reading about the symptoms of Balkan endemic nephropathy, an NIEHS grantee was struck by how much it resembled kidney damage found in people that used the Chinese herbal medicine *Aristolochia*. He assembled a multidisciplinary research team in the Balkans and the U.S. and was able to discover the way in which Aristolochia, growing as weeds in wheat fields, entered the food supply. Using new molecular techniques, this research team identified two distinct DNA binding sites, or adducts, of Aristolochia that could be assayed in the tissues of patients to assess exposure to this herb. Additionally, they built on this research to discover the actual mutational changes that gave rise to the urinary tract cancers. The DNA adducts and mutational changes were also validated as "fingerprints" that were subsequently used to verify that chronic dietary poisoning by aristolochic acid was responsible for endemic nephropathy and its associated urothelial cancer (PNAS, 2007, 104:12129-12134). This herb, used in folk medicine throughout the world, is now being investigated by other governments who can use the molecular fingerprint techniques to investigate if a large portion of kidney failure cases in their own countries arise from exposure to this herb. More importantly, this work validates the technique of using cellular fingerprints for identifying chronic environmental exposures that can produce clinical disease years after initial exposures.

This ability should greatly accelerate our understanding of the environmental underpinnings of common diseases and help eliminate them.

There is a broader importance in defining environmental response pathways. The body is frugal and uses the same pathways for responding to environmental agents and to oxidants released during digestion of foods or during energy generation, in responding to drugs and in responding to pathogenic attack. Thus, all research in molecular toxicology reveals important insights into normal cellular pathways and responses. New advances in genomic technologies have greatly expanded our ability to understand these processes through the identification of the actual genes that control the multiple response pathways that are elicited by toxicant exposures. Combined with improved exposure assessment technologies that will emerge from the NIH-wide Genes, Environment and Health Initiative, researchers will have a greater ability to identify exposure-disease linkages important to the public health. In these ways, the field of environmental health science will move our country to a future where the prevention of disease will be the norm, obviating the need for expensive treatments to ameliorate disease once it has occurred.

### **JUSTIFICATION BY ACTIVITY**

### **Program Descriptions and Accomplishments**

Linkage of Exposures to Clinical Expression of Disease: Studying individual patients increases our understanding of environmental causes of common, complex diseases, and thus enables the development of improved research models for human disease. This program encourages partnerships between clinical investigators and other researchers in environmental health sciences. This program also provides important clinical insight into the environmental underpinnings of degenerative diseases, cardiovascular diseases, reproductive disorders, breast cancer, and lung diseases.

A recent NIEHS-sponsored report shows links between exposure to lead and the risk of heart disease in aging men. Men with the highest blood or bone lead levels had more heart attacks or angina than men with lower overall lead exposure. The lead levels correlated with an approximate 25 percent increase in risk for ischemic heart disease, suggesting that the health effects of lead exposure can persist long after the initial exposure occurs.

<u>Budget Policy:</u> The FY 2009 budget estimate for the Linkage of Exposures to Clinical Expression of Disease program is \$57.8 million, which represents a reduced funding level of -\$253 thousand and -.4% from the FY 2008 estimate. Resources will be used to continue activities critical to the long-term success of the program. These include programs to identify windows of susceptibility to breast cancer development from the prenatal period to adulthood, and continuation of the Sister Study, which studies sisters of women diagnosed with breast cancer, to target environmental and genetic causes of breast cancer. In addition, NIEHS will continue funding a cohort study of 6,000 children from 12 communities in Southern California, examining genetics, air pollution, and children's respiratory health, with a goal of identifying environmental and host factors,

and examining the genetic variation in oxidative stress pathways that modulate response to air pollution.

Basic Mechanisms in Human Biology: The Basic Mechanisms in Human Biology program employs environmental toxicants as laboratory probes to study the complex molecular pathways that lead to chronic disease. Environmental toxicants can interrupt normal processes and set in motion events leading to disease. This program helps to identify methods to diagnose those diseases before they are clinically evident and develop early interventions to prevent progression to end-stage disease.

In 2007, the National Toxicology Program (NTP), a toxicological testing program headquartered at NIEHS, began including results of its short-term studies on the NTP website, in addition to results of it's two-year cancer bioassays that were already available. Greater access to information increases the public's understanding of the toxic potential of chemicals to which they may be exposed and enhances the ability of scientists worldwide to build upon results arising from NTP studies for use in making public health decisions.

<u>Budget Policy:</u> The FY 2009 budget estimate for the Basic Mechanisms in Human Biology program is \$246 million, which represents a funding level of -\$2.9 million and -1.1% from the FY 2008 estimate. NIEHS anticipates that several initiatives in capacity building in environmental genomics will have essentially been completed, reducing resources required for this program. While modest investments in these areas will continue, resources will primarily be directed to high-priority activities critical to the long-term success of the Basic Mechanisms in Human Biology program, and to address research questions and concerns with the highest priorities.

### Portrait of a Program: Defining the Toxicity of Emerging Nanotechnologies

FY 2008 Level \$8,047,000 FY 2009 Level 8,047,000 Change 0

Nanoscale science and technology involve imaging, measuring, modeling and manipulating matter on the scale of 1 to 100 nanometers. At this scale, novel physical, chemical and biological properties of these materials enable novel applications such as drug delivery systems, tissue engineering, biological and environmental sensor technologies and environmental remediation. Consumer products containing nanocomponents, such as sunscreens, cosmetics, and stain resistant fabrics are commercially available, with recent figures showing over \$32 billion worth of products incorporating nanotechnology sold in 2005 (Lux Research, *How Industry Leaders Organize for Nanotech Innovation*, Lux Research Inc., New York, NY, 2006).

The diversity of nanomaterials, their widespread presence in the environment and in consumer products, and their persistence in the human body, make the safety of such materials a compelling research and regulatory question. NIEHS has awarded grants under two targeted Requests for Applications to support research exploring the systemic, cellular and molecular responses to nanomaterials. Grants awarded for an

RFA entitled Nanotechnology Research Grants Investigating Environmental and Human Health Effects of Manufactured Nanomaterials: a Joint Research Solicitation – EPA, NSF, NIOSH, NIEHS, began in 2006 and continue through 2009 at a cost of approximately \$1 million. Grants for the RFA entitled Manufactured Nanomaterials: Physico-chemical Principles of Biocompatibility and Toxicity, have an anticipated start date of December 2008, and will be funded for 3 years at a cost of approximately \$2 million. These studies will evaluate the physical and chemical characteristics of nanoscale materials at multiple points in the exposure model, and link these measurements to biological effects.

In addition, NIEHS is spearheading a new initiative, the NanoHealth Enterprise, which is still in the planning/developing stage. The NanoHealth Enterprise will comprise a public-private partnership of NIH institutes, federal agencies, academia, non-governmental organizations and industry partners, coordinated through the Foundation for NIH, to pursue the very best science, leverage investment for research efficiencies and minimize the time from discovery to application of engineered nanomaterials.

NIEHS efforts in nanomaterials research will improve the understanding of the potential health impacts of these novel compounds, as well as help to guide development of these products so as to reduce adverse effects on an increasingly exposed population. These efforts are consistent with, and in support of, the National Science and Technology Council's 2006 report, *Environmental Health Science Research Needs for Engineered Nanoscale Materials* 

Interdisciplinary, Integrative Research: The purpose of NIEHS' Interdisciplinary, Integrative Research program is to coordinate and integrate scientific contributions from all levels of investigators in many fields, such as epidemiology, toxicology, molecular and cellular biology, bioinformatics, clinical medicine. Fostering such broad-based, collaborative research increases the relevance of basic scientific discoveries in environmental health sciences to human disease with more rapid and effective knowledge into clinical and public health applications to ultimately improve human health.

NIEHS grantees recently reported that children living within 500 meters of freeways in California have reduced lung-function compared to children living 1,500 meters or more from freeways. The research points to diesel exhaust as an important component of the impaired lung function. This shows that some children are at a higher risk than others of adverse respiratory effects resulting from environmental pollutants.

<u>Budget Policy:</u> The FY 2009 budget estimate for the Interdisciplinary, Integrative Research program is \$61.7 million, which represents a reduced funding level of -\$.9 million and -1.6% from the FY 2008 estimate. Resources for the Interdisciplinary, Integrative Research program will be used to continue high priority projects to optimize the Interdisciplinary and Integrative Research program. These include grants awarded under the DISCOVER program, which fosters collaborations across teams of scientists with complementary skills and areas of expertise.

Support is also provided for the Centers for Children's Environmental Health and Disease Prevention Research and an RFA, *Centers for Neurodegeneration Science* that

NIEHS is funding in conjunction with the National Institute of Aging. In addition, NIEHS will continue designing and implementing several new models for research that integrate clinical, epidemiological, and toxicological research with basic mechanistic studies to address disease cause, development, susceptibility, and progression.

### Portrait of a Program: Early Environmental Exposures and Breast Cancer Risk

FY 2008 Level \$3,000,000 FY 2009 Level 3,000,000 Change 0

To uncover the links between early environmental exposures and subsequent breast cancer risks, in 2003 NIEHS partnered with the National Cancer Institute to fund 4 Breast Cancer and the Environment Research Centers. These Centers represent an innovative multidisciplinary partnership between scientists and breast cancer advocates to conduct research to address a gap in our knowledge about the impact of environmental exposures early in life on future breast cancer risk. The impact of childhood exposures on mammary gland development and the potential of these exposures to alter the risk of breast cancer in later adulthood are being investigated. Toward this goal, the Centers employ both animal studies and epidemiologic studies in human populations. An important feature of this initiative is the active role that breast cancer advocates play, including their participation in the dialogue about scientific themes to be pursued, their outreach to the general public and their development of educational material on environmental contributions to breast cancer risks. The Centers are planned to continue until 2010.

### Portrait of a Program: Environmental Factors in Neurodegenerative Diseases

FY 2008 Level \$4,000,000 FY 2009 Level 4,000,000 Change 0

Although it is increasingly clear that the neurodegenerative disorder Parkinson's Disease (PD) arises from the interaction of individual genetic susceptibilities with environmental exposures, it is less clear what the mechanisms and pathways are by which these interactions lead to actual disease causation. To accelerate the pace of progress in this important area and to enhance the translation of basic findings into valid interventions, NIEHS created the Collaborative Centers for Parkinson's Disease Environmental Research (CCPDER) in 2002. CCPDER has been instrumental in developing a Parkinson's Disease Registry in California, an achievement that will improve scientists' ability to track and monitor PD incidence and to identify geographic clusters.

In the laboratory, CCPDER investigators have shown that combined exposure to iron and the herbicide, paraquat, in mice accelerated age-related degeneration of neurons that is the hallmark of PD. In other studies, CCPDER provided evidence in mice that the pesticide, dieldrin, increased the vulnerability of these same neurons to oxidative

stress, thus suggesting a mechanism by which pesticide exposure could act as a promoter of PD. CCPDER also investigated whether smoking can protect against PD. Studies showed that primates given long-term exposure to nicotine had lower incidence of PD symptoms following exposure to a neurotoxin known to elicit these symptoms in humans. Based on the success of these programs, the NIEHS has decided to extend this initiative to include other neurogenerative diseases. As a body of evidence for molecular pathways of environmentally-induced neurodegeneration evolves, promising avenues for intervention and treatment are expected to emerge.

Community-linked and Global Environmental Health Research: The goal of the Community-linked and Global Environmental Health Research program is to better understand how differences in the environment contribute to the excess burden of disease in minority and disadvantaged communities, creating health disparities in the U.S. and around the world. This program explores evidence that poor and minority groups are disproportionately exposed to hazardous substances such as metals, pesticides, wood dusts, and air pollutants, which can lead to shorter life expectancies, higher cancer rates, more birth defects, greater infant mortality, and higher incidences of asthma, diabetes, and cardiovascular disease.

NIEHS held a workshop in 2007 to evaluate opportunities in global environmental health to identify potential partners, as well as possible barriers. This workshop's success and identification of key issues led to a forum nine months later with the inclusion of foundations and non-government organizations (NGOs). This meeting was designed to foster informal collaborative networks among U.S. and foreign public and private sector organizations. Participants focused on identifying cost-effective, sustainable partnership strategies with government agencies, foundations, NGOs, community groups and private industry to apply environmental health science in the developing world to improve human health.

<u>Budget Policy:</u> The FY 2009 budget estimate for the Community-linked and Global Environmental Health Research program is \$33.1 million, which represents a funding level of +\$1.3 million and +4.1% from the FY 2008 estimate. NIEHS is developing a unified program referred to as "Partnerships for Environmental Public Health" that will support a variety of research, outreach and education activities to prevent, reduce, or eliminate environmental exposures that may lead to adverse health outcomes in communities, with the active participation of those communities in all stages of the work.

**Exposure Biology/Exposure Measurement:** The Exposure Biology/Exposure Measurement program supports efforts to increase our understanding of the biological pathways involved in host response to a given exposure. The program seeks to develop improved methods to detect and measure environmental exposures sustained by humans or other organisms.

NIEHS awarded twenty grants in 2007 to develop new personal monitors that can be worn by people to measure environmental factors. The information revealed by these devices can be cross-referenced to underlying genetic susceptibilities in these individuals in ways that will improve our understanding of how genes and environment interact in human health and disease. This more precise understanding of individual

risks and exposures will greatly enhance people's ability to participate in partnership with their physicians to manage their health. Diseases for which greater understanding can be developed in this way include cancer, heart disease, asthma, and diabetes.

<u>Budget Policy</u>: The FY 2009 budget estimate for the Exposure Biology/Exposure Measurement program is \$24.3 million, which represents a reduced funding level of -\$187 thousand and -.8% from the FY 2008 estimate. Resources will be used to continue high priority projects to optimize the Exposure Biology/Exposure Measurement program. These include development of biomarkers that would 1) be accurate for the relevant timeframes (such as previous or historical exposures); 2) be mechanistically linked to diseases of interest; and 3) serve to link environmental exposures with biological effects. Research areas with a critical need for specific biomarkers include common biological responses (inflammation, oxidative stress, apoptosis, and DNA damage), markers of gene and protein expression, and markers of organ dysfunction.

Pathways for Future Environmental Health Scientists: The Pathways for Future Environmental Health Scientists program's goal is to continue 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. The program includes efforts at the high school and undergraduate level (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 at the faculty level (Outstanding New Environmental Scientist (ONES) grants and short term sabbatical awards).

In fiscal years 2006 and 2007, NIEHS' ONES program awarded 5-year grants totaling approximately \$7.1 million to exceptionally talented and creative new scientists to pursue careers in environmental health research. These grantees are in the early, formative stages of their careers and intend to make a long term career commitment to research in the mission areas of NIEHS. The grants will assist them in launching an innovative research program focusing on problems of environmental exposures and human biology, human pathophysiology and human disease.

Budget Policy: The FY 2009 budget estimate for the Pathways for the Future Environmental Health Scientists program is \$29.3 million, which represents a funding level of +\$.7 million and +2.3% from the FY 2008 estimate. Resources will be used to continue high priority projects to strengthen the Pathways for the Future Environmental Health Scientists program. These include 1) the ONES program, an R01 program for new independent investigators; 2) re-engineering the NIEHS training grant program to increase participation of physician-scientists in environmental sciences research; 3) promoting the NIEHS MD/PhD program; 4) continuing the Institutional Career Development Program (a program of K12 awards to support the early career development of patient-oriented researchers in the environmental health sciences); 5) continuing a joint training program in environmental genetics and genomics, cosponsored with NHGRI; and 6) supporting the NIH Pathway to Independence program.

**Intramural Research:** The Intramural Research 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 long-term 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.

NIEHS scientists recently made an important discovery about a critical new role that an enzyme called DNA polymerase epsilon plays in replicating DNA in higher organisms, such as yeast, and perhaps even humans. The researchers used an innovative strategy to demonstrate that in bakers yeast, DNA polymerase epsilon has a primary role in replicating the leading strand of DNA. DNA polymerase epsilon was found to be a key determinant of preserving the precise coding of DNA as well as of cellular responses to DNA damage resulting from exposures to environmental stress.

<u>Budget Policy</u>: The FY 2009 budget estimate for the Intramural Research program is \$172.9 million, which represents a funding level of +\$2.6 million and +1.5% from the FY 2008 estimate. Resources will be directed to high priority areas in the Intramural Research program, such as clinical studies and interdisciplinary research programs designed to understand human disease and improve human health.

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 670 research grants and centers. Other RMS functions also include strategic planning, coordination, and evaluation of NIEHS programs, regulatory compliance, international coordination, and liaison with other federal agencies, Congress, and the public.

<u>Budget Policy:</u> The FY 2009 budget estimate for RMS is \$17.7 million, which represents a funding level of +\$270 thousand and +1.5% from the FY 2008 estimate. Resources will be used to continue funding the important RMS activities mentioned above which support the infrastructure that allows NIEHS to pursue and achieve its mission.

### NIH Common Fund

NIEHS is the lead institute for the Roadmap Epigenomics Program supported through the NIH Common Fund, which will continue in FY 2009.

# NATIONAL INSTITUTES OF HEALTH National Institute of Environmental Health Sciences Budget Authority by Object

Budget Authority b			ı
	FY 2008	FY 2009	Increase or
	Enacted	Estimate	Decrease
Total compensable workyears:			_
Full-time employment	658	663	5
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary	\$162,100	\$166,200	\$4,100
Average GM/GS grade	11.2	11.2	0.0
	<b>^</b>		
Average GM/GS salary	\$77,600	\$80,000	\$2,400
Average salary, grade established by act of			
July 1, 1944 (42 U.S.C. 207)	\$103,400	\$106,400	\$3,000
Average salary of ungraded positions	119,800	123,300	3,500
	FY 2008	FY 2009	Increase or
OBJECT CLASSES	Enacted	Estimate	Decrease
Personnel Compensation:	Liladida	Lotimato	Dooroado
11.1 Full-time permanent	\$40,270,000	\$42,432,000	\$2,162,000
11.3 Other than full-time permanent	17,586,000	18,536,000	
11.5 Other personnel compensation	850,000	896,000	
11.7 Military personnel	904,000	946,000	
11.8 Special personnel services payments	10,854,000	11,440,000	
Total, Personnel Compensation			
	70,464,000	74,250,000	
12.0 Personnel benefits	16,235,000	17,112,000	877,000
12.2 Military personnel benefits	502,000	525,000	23,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	87,201,000	91,887,000	4,686,000
21.0 Travel and transportation of persons	2,053,000	2,115,000	62,000
22.0 Transportation of things	313,000	313,000	0
23.1 Rental payments to GSA	4,000	4,000	0
23.2 Rental payments to others	34,000	34,000	0
23.3 Communications, utilities and			
miscellaneous charges	1,004,000	1,015,000	11,000
24.0 Printing and reproduction	132,000	131,000	-1,000
25.1 Consulting services	2,356,000	2,300,000	-56,000
25.2 Other services	16,427,000	14,115,000	
25.3 Purchase of goods and services from	, ,	, ,	, ,
government accounts	101,396,000	102,410,000	1,014,000
25.4 Operation and maintenance of facilities	2,299,000	2,290,000	-9,000
25.5 Research and development contracts	109,804,000		
25.6 Medical care	43,000		
25.7 Operation and maintenance of equipment	2,565,000	· ·	
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	234,890,000	233,512,000	-1,378,000
26.0 Supplies and materials	13,183,000		
31.0 Equipment	5,590,000		
32.0 Land and structures	5,5 <del>5</del> 5,666	0,400,000 0	- 1 <del>-1</del> 0,000
33.0 Investments and loans	Ő	Ő	, o
41.0 Grants, subsidies and contributions	297,849,000	295,554,000	-2,295,000
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	0	l n	l o
44.0 Refunds	0	n	l o
Subtotal, Non-Pay Costs	555,052,000	550,988,000	-4,064,000
Total Budget Authority by Object	642,253,000	642,875,000	622,000

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

### Salaries and Expenses

	FY 2008	FY 2009	Increase or
OR IECT OF ASSES			
OBJECT CLASSES	Enacted	Estimate	Decrease
Personnel Compensation:	<b>*</b> * * * * * * * * * * * * * * * * * *	<b>*</b> 40 400 000	<b>A.</b> 100 000
Full-time permanent (11.1)	\$40,270,000	\$42,432,000	
Other than full-time permanent (11.3)	17,586,000	18,536,000	-
Other personnel compensation (11.5)	850,000	896,000	46,000
Military personnel (11.7)	904,000	946,000	42,000
Special personnel services payments (11.8)	10,854,000	11,440,000	586,000
Total Personnel Compensation (11.9)	70,464,000	74,250,000	3,786,000
Civilian personnel benefits (12.1)	16,235,000	17,112,000	877,000
Military personnel benefits (12.2)	502,000	525,000	23,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	87,201,000	91,887,000	4,686,000
Travel (21.0)	2,053,000	2,115,000	62,000
Transportation of things (22.0)	313,000	313,000	0
Rental payments to others (23.2)	34,000	34,000	0
Communications, utilities and			
miscellaneous charges (23.3)	1,004,000	1,015,000	11,000
Printing and reproduction (24.0)	132,000	131,000	-1,000
Other Contractual Services:			
Advisory and assistance services (25.1)	1,482,000	1,426,000	-56,000
Other services (25.2)	16,427,000	14,115,000	-2,312,000
Purchases from government accounts (25.3)	60,507,000	61,519,000	1,012,000
Operation and maintenance of facilities (25.4)	2,299,000	2,290,000	-9,000
Operation and maintenance of equipment (25.	2,565,000	2,550,000	-15,000
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	83,280,000	81,900,000	-1,380,000
Supplies and materials (26.0)	13,183,000	12,860,000	-323,000
Subtotal, Non-Pay Costs	99,999,000	98,368,000	-1,631,000
Total, Administrative Costs	187,200,000	190,255,000	3,055,000

		Authorizin	Authorizing Legislation			
	PHS Act/	U.S. Code	2007 Amount	FY 2008	2008 Amount	FY 2009
	Other Citation	Citation	Authorized	Enacted	Authorized	<b>Budget Estimate</b>
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
Environmental Health Sciences Section	Section 402(a)	42§281	Indefinite	\$642,253,000	Indefinite	\$642,875,000
			Q			
Total, Budget Authority				642,253,000		642,875,000

**Appropriations History** 

Fiscal	Budget Estimate	House	Senate	A	4.7
Year	to Congress	Allowance	Allowance	Appropriation	<u>1/</u>
2000	\$390,718,000 <u>2</u> /	\$421,109,000	\$436,113,000	\$444,817,000	
Rescission				-2,368,000	
2001	460,971,000 <u>2</u> /	506,730,000	508,263,000	502,549,000	
Rescission				-495,000	
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	
2009	642,875,000				

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

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

-		. ,	
OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	58	58	58
Division of Intramural Research	457	458	463
Division of Extramural Research and Training	53	54	54
Office of Management	88	88	88
Total	656	658	663
Includes FTEs which are reimbursed from the	NIH Roadma	ap for Medica	al Research
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Avera	age GM/GS	Grade
2005 2006 2007 2008		11.2 11.2 11.2 11.2	
2008 2009		11.2 11.2	

The new positions requested for the Division of Intramural Research are shown in the New Positions Requested chart on page 26.

### **Detail of Positions**

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	1	1	1
Total, ES Salary	158,152	162,100	166,200
GM/GS-15	38	38	38
GM/GS-14	61	61	61
GM/GS-13	71	71	71
GS-12	80	80	82
GS-11	104	105	105
GS-10	1	1	1
GS-9	75	75	76
GS-8	16	16	16
GS-7	26	26	26
GS-6	4	4	4
GS-5	1	1	1
GS-4	15	15	15
GS-3	2	2	2
GS-2	1	1	1
GS-1	1	1	1
Subtotal	496	497	500
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	1	1
Director Grade	7	7	7
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	8	8	8
Ungraded	174	174	174
Total permanent positions	506	507	510
Total positions, end of year	678	679	682
Total full-time equivalent (FTE)			
employment, end of year	656	658	663
Average ES salary	158,152	162,100	166,200
Average GM/GS grade	11.2	11.2	11.2
Average GM/GS salary	75,225	77,600	80,000

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

### **New Positions Requested**

		FY 2009		
	Grade	Number	Annual Salary	
Tenure Track Investigator Staff Scientist Biologist	Title 42 Title 42 GS-11	2 2 1	\$98,000 80,000 57,000	
Total Requested		5		