

DEPARTMENT OF HEALTH AND HUMAN SERVICES

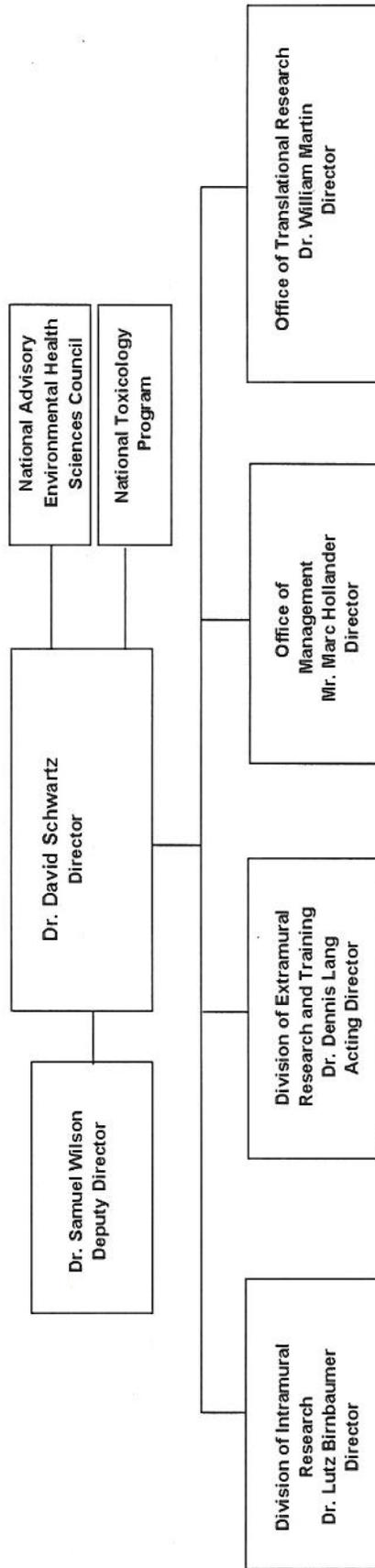
NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

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NATIONAL INSTITUTES OF HEALTH
National Institute of Environmental Health Sciences

Organization Structure



FY 2008 Proposed Appropriation Language

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, \$637,406,000.

Supplementary Exhibit

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

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 [~~\$647,608,000~~]**\$637,406,000** (Department of Health and Human Services Appropriation Act, 2006)

**National Institutes of Health
National Institute of Environmental Health Sciences**

Amounts Available for Obligation 1/

Source of Funding	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Appropriation	\$647,608,000	\$641,132,000	\$637,406,000
Enacted Rescissions	-6,476,000	---	---
Subtotal, Adjusted Appropriation	641,132,000	641,132,000	637,406,000
Real Transfer under Roadmap Authority	-5,729,000		
Real Transfer under Secretary's One-percent transfer authority	-440,000		
Real Transfer under Secretary's One-percent transfer authority	-4,480,000		
Comparative transfer from OD for NIH Roadmap	5,729,000		
Comparative Transfer to NIBIB	-92,000	-94,000	
Comparative transfer to OD	-41,000	-43,000	
Comparative Transfer to NCRR	-80,000	-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	-4,000	
Subtotal, adjusted budget authority	635,995,000	640,903,000	637,406,000
Unobligated balance lapsing	-28,000	---	---
Total obligations	635,967,000	640,903,000	637,406,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2006 - \$1,953,000; FY 2007 - \$1,953,000; FY 2008 - \$2,260,000

Excludes \$161,000 in FY 2007 and \$197,000 in FY 2008 for royalties.

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

MECHANISM	FY 2006 Actual		FY 2007 Continuing Resolution		FY 2008 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
<u>Research Projects:</u>								
Noncompeting	363	\$141,752	397	\$156,673	400	\$166,455	3	\$9,782
Administrative supplements	(39)	8,427	(32)	2,000	(32)	2,000	(0)	0
Competing:								
Renewal	37	19,051	40	14,226	34	12,050	-6	-2,176
New	132	41,302	129	45,878	104	36,875	-25	-9,003
Supplements	2	462	2	711	1	354	-1	-357
Subtotal, competing	171	60,815	171	60,815	139	49,279	-32	-11,536
Subtotal, RPGs	534	210,994	568	219,488	539	217,734	-29	-1,754
SBIR/STTR	34	10,800	34	10,980	34	10,740	0	-240
Subtotal, RPGs	568	221,794	602	230,468	573	228,474	-29	-1,994
<u>Research Centers:</u>								
Specialized/comprehensive	36	41,892	33	41,700	31	40,200	-2	-1,500
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	36	41,892	33	41,700	31	40,200	-2	-1,500
<u>Other Research:</u>								
Research careers	33	4,352	44	5,722	54	6,622	10	900
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	2,886	3	2,582	3	2,582	0	0
Other	51	9,042	23	4,070	23	3,620	0	-450
Subtotal, Other Research	87	16,280	70	12,374	80	12,824	10	450
Total Research Grants	691	279,966	705	284,542	684	281,498	-21	-3,044
<u>Research Training:</u>								
Individual awards	47	1,930	48	2,105	48	2,105	0	0
Institutional awards	460	17,258	440	16,987	433	16,757	-7	-230
Total, Training	507	19,188	488	19,092	481	18,862	-1	-230
Research & development contracts (SBIR/STTR)	99 (5)	147,425 (1,482)	98 (5)	146,395 (1,366)	98 (5)	146,395 (1,366)	0 (0)	0 (0)
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural research	571	166,961	574	166,204	583	165,076	9	-1,128
Research management and support	93	16,726	94	16,977	94	17,147	0	170
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
NIH Roadmap for Medical Research	0	5,729	0	7,693	0	8,428		735
Total, NIEHS	664	635,995	668	640,903	677	637,406	9	-3,497

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

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

	FY 2004 Actual		FY 2005 Actual		FY 2006 Actual		FY 2006 Comparable		FY 2007 Continuing Resolution		FY 2008 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research														
<u>Detail:</u>														
Clinical Research		\$46,477		\$52,151		\$43,106		\$43,106		\$43,567		\$45,874		\$2,307
Basic Mechanisms in Human Biology		247,731		245,471		249,888		249,888		257,016		253,762		-3,254
Interdisciplinary, Integrated Research		82,822		75,661		60,490		60,490		59,078		56,989		-2,089
Community-linked & Global														
Environmental Health Research		37,643		40,184		45,105		45,105		40,568		39,594		-974
Exposure Biology/Exposure														
Measurement		17,150		17,827		20,356		20,356		22,498		22,565		67
Pathways for Future Environmental														
Health Scientists		28,199		29,277		27,714		27,634		27,302		27,971		669
Subtotal, Extramural		460,022		460,571		446,659		446,579		450,029		446,755		-3,274
Intramural research	611	155,447	558	164,720	571	167,084	571	166,961	574	166,204	583	165,076	9	-1,128
Res. management & support	94	14,841	93	15,139	93	16,739	93	16,726	94	16,977	94	17,147	0	170
NIH Roadmap for Medical Research		2,082		4,075		5,729		5,729		7,693		8,428	0	735
TOTAL	705	632,392	651	644,505	664	636,211	664	635,995	668	640,903	677	637,406	9	-3,497

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

Major Changes in the Fiscal Year 2008 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 program detail and these highlights will not sum to the total change for the FY 2008 budget request for NIEHS, which is -\$3.497 million less than the FY 2007 Estimate, for a total of \$637.406 million.

Research Project Grants (-\$1.994 million; total \$228.474 million): NIEHS will support a total of 573 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPGs will increase by 3 awards and increase by \$9.782 million. Competing RPGs will decrease by 32 awards and decrease by \$11.536 million.

Research Careers (+\$.900 million; total \$6.622 million): NIEHS will support the Pathway to Independence program, by funding an additional 10 awards in FY 2008. Total support for the Pathway program in FY 2008 is 20 awards and \$1.8 million dollars.

NIH Roadmap for Biomedical Research (+\$.735 million; total \$8.428 million): NIEHS will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

Clinical Research (+\$2.307 million; total \$45.874 million): NIEHS will expand clinical protocols in FY 2008 following the opening of a new clinical research unit in late FY 2007.

Basic Mechanisms in Human Biology (-\$3.254 million; total \$253.762 million): NIEHS has redirected funds from this area to expand clinical research in FY 2008.

Interdisciplinary, Integrated Research (-\$2.089 million; total \$56.989 million): Funds in this area are being redirected from core centers to other high-priority center and non-center programs in FY 2008.

Community-linked & Global Environmental Health Research (-\$.974 million; total \$39.594 million): NIEHS plans to award new grants consistent with environmental justice goals, rather than to award specifically-targeted environmental justice grants. It is anticipated that many of the new awards will fall into other program areas.

Pathways for Future Environmental Health Scientists (+\$.669 million; total \$27.971 million): NIEHS will support the Outstanding New Environmental Scientist (ONES) Program and other activities to attract exceptional researchers to the environmental health sciences field.

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

FY 2007 Continuing Resolution		\$640,903,000	
FY 2008 Estimated Budget Authority		637,406,000	
Net change		-3,497,000	
CHANGES	FY 2007		
	Continuing Resolution	Change from Base	
	Budget	Budget	
	FTEs	FTEs	Authority
	Authority		Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January 2007 pay increase	\$72,226,000		\$607,000
b. January 2008 pay increase	72,226,000		2,463,000
c. Two extra days of pay	72,226,000		556,000
d. Payment for centrally furnished services	23,390,000		234,000
e. Increased cost of laboratory supplies, materials, and other expenses	70,716,000		1,340,000
Subtotal			5,200,000
2. Research Management and Support:			
a. Annualization of January 2007 pay increase	10,792,000		97,000
b. January 2008 pay increase	10,792,000		395,000
c. Two extra days of pay	10,792,000		83,000
d. Payment for centrally furnished services	2,074,000		21,000
e. Increased cost of laboratory supplies, materials, and other expenses	4,124,000		65,000
Subtotal			661,000
Subtotal, Built-in			5,861,000

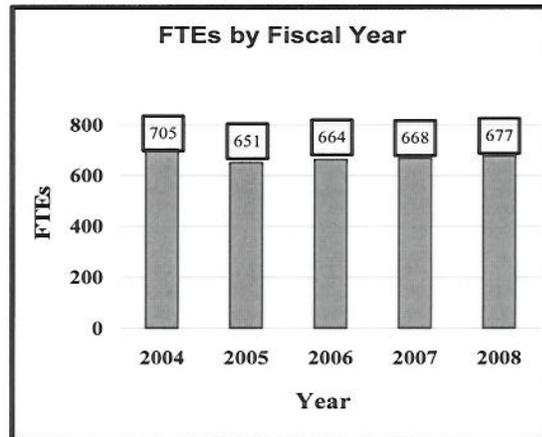
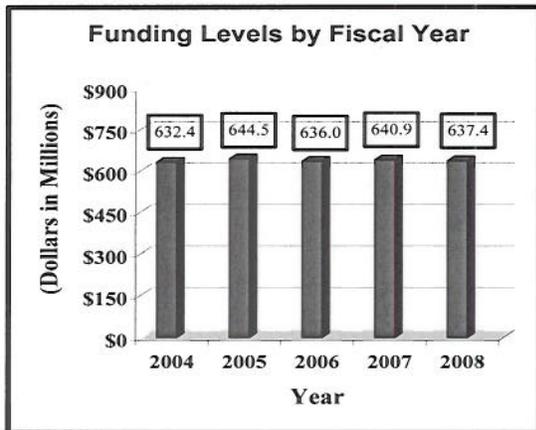
NATIONAL INSTITUTES OF HEALTH
National Institute of Environmental Health Sciences

Summary of Changes--continued

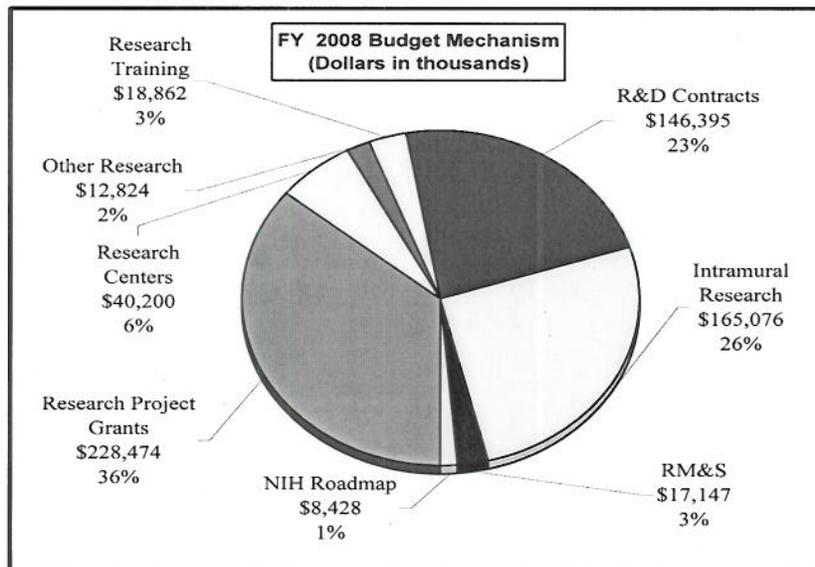
CHANGES	FY 2007 Continuing Resolution		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	397	\$158,673,000	3	\$9,782,000
b. Competing	171	60,815,000	-32	-11,536,000
c. SBIR/STTR	34	10,980,000	0	-240,000
Total	602	230,468,000	-29	-1,994,000
2. Research centers	33	41,700,000	-2	-1,500,000
3. Other research	70	12,374,000	10	450,000
4. Research training	488	19,092,000	-7	-230,000
5. Research and development contracts	98	146,395,000	0	0
Subtotal, extramural				-3,274,000
6. Intramural research	<u>FTEs</u> 574	166,204,000	<u>FTEs</u> 9	-6,328,000
7. Research management and support	94	16,977,000	0	-491,000
8. NIH Roadmap for Medical Research	0	7,693,000	0	735,000
Subtotal, program		640,903,000		-9,358,000
Total changes				-3,497,000

FY 2008 Budget Graphs

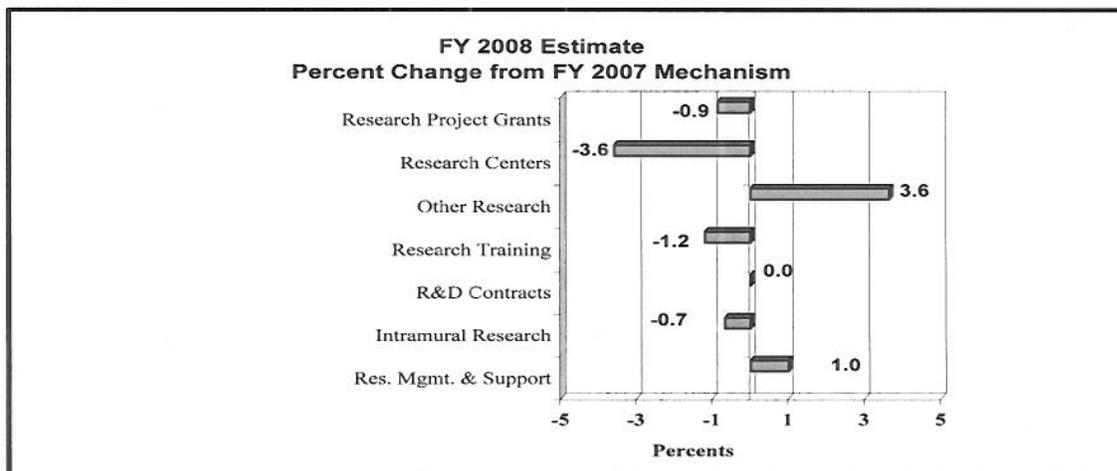
History of Budget Authority and FTEs:



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 2006		FY 2007			FY 2008		Increase or	
Actual		Continuing Resolution			Estimate		Decrease	
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	
664	\$635,995,000	668	\$640,903,000	677	\$637,406,000	9		-\$3,497,000

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

DIRECTOR’S OVERVIEW

The NIEHS supports research that focuses on preventing disease and improving human health by using environmental health sciences to understand human biology and human disease. The field of environmental health sciences examines the total body in its fullest complexity to understand how environmental exposures interact with underlying susceptibilities related to genetics, age, and other factors to set in motion molecular events that initiate disease processes. Defining the interplay of these multiple factors and how they affect human biology generates the knowledge that provides the ultimate payoff for environmental health science research – better health and longer lives for all citizens.

Due to recent advances in technology, NIEHS can pursue a more targeted research effort that employs integrated science teams to conduct disease-focused research with clinical and public health applications. The NIEHS has implemented a new strategic plan, “*New Frontiers in Environmental Sciences and Human Health*” (available online at <http://www.niehs.nih.gov/external/plan2006/>), to address this multifaceted, multidisciplinary approach to environmental health that will allow the institute to capitalize on new approaches to environmental health research. The plan highlights our future challenges and goals, including ways to attract more physician-scientists to the field, encourage integrated research that spans multiple disciplines, and move the research enterprise to a greater emphasis on disease outcomes.

Many of the goals of the new strategic plan are coming to fruition. The NIEHS launched the Disease Investigation through Specialized Clinically-Oriented Ventures in Environmental Research (DISCOVER) Program for the extramural community and the Director’s Challenge for

the intramural community. These two programs focus on the interface between basic mechanistic and clinical research to unravel the complexity of environmentally-influenced diseases that pose a health burden to society. In FY 2007, NIEHS will invest \$6 million in these programs.

The NIEHS is a lead on the new trans-NIH Genes, Environment and Health Initiative (GEI), to accelerate research discoveries on the role of genes and the environment in human disease. Through this initiative, NIEHS has established the Exposure Biology Program, to promote the development and application of new technologies that will precisely measure human exposure to environmental toxins. For more information see the program portrait on this initiative.

As a commitment to improving the health of American citizens, many NIEHS staff responded personally, and as a community, to the devastation caused by Hurricane Katrina. The NIEHS has continued to show support to this hard-hit region by creating a partnership to support the Head-off Environmental Asthma in Louisiana (HEAL) program, designed after the Inner-City Asthma Study, to address the problem of childhood asthma resulting from excessive amounts of mold, microbial toxins and airway pollutants. These efforts have also provided the foundation for a new Global Health Initiative to address pressing environmental health problems worldwide.

The environmental science field is uniquely poised to benefit from the incredible pace of biomedical discovery that has resulted from new advances in genetics, molecular biology, computational sciences, and the physical sciences. The NIEHS is working hard to meet this challenge through targeted investments in training the next generation of environmental health scientists. Recently, NIEHS launched the new Outstanding New Environmental Scientists (ONES), an R01 program for new independent investigators, and the Short Term Educational Experiences for Research (STEER) programs to attract and support the “best and brightest” new researchers to the field of environmental health sciences. The first eight recipients of the ONES awards have already been selected.

The NIEHS intramural and extramural scientists continue to unravel important biomedical problems. In the past year, there have been several significant breakthroughs, including:

- The identification of predisposing genetic mutations for breast cancer. This discovery has the potential to improve the detection and treatment of the disease in women that are at high risk, as well as providing new ways to study gene-environment interactions in this disease;
- The discovery of the role of endogenous airway relaxants that may be targeted in the treatment of chronic airway hyper-responsiveness and chronic airway inflammation caused by environmental agents as well as other sources;
- The discovery of anti-inflammatory effects of natural glucocorticoids that could one day be used in therapeutic regimens for environmental diseases such as asthma, autoimmune disease and sepsis;
- The discovery of mechanistic linkages between exposure to inhaled particulate matter in urban areas and susceptibility to cardiovascular disease;
- The elucidation of regulatory mechanisms for synaptic plasticity in the brain that impact learning and memory and that could provide objects of study for environmental effects on these pathways; and

- The identification of the structural basis for errors in DNA synthesis, due to strand misalignment, that may result from environmental stress and have profound impacts on human disease.

There has been tremendous growth in the power and sophistication of many of the technologies used in biomedical research, bioimaging, and bioinformatics. The NIEHS will continue to implement its strategic plan and pursue ways to apply these novel tools to the understanding of how environmental exposures affect human biology and alter disease risk, especially for complex diseases such as asthma, cancer, and autism that are caused by multiple environmental and genetic factors. By capturing this larger understanding of disease initiation and progression, the ultimate goals – to alleviate suffering and to improve human health, can be achieved.

JUSTIFICATION BY ACTIVITY

Overall Budget Policy: Investigator-initiated research projects and new investigator research and career development are high priorities. The NIEHS carefully evaluates investigator-initiated projects over \$500,000, which require NIEHS approval prior to submission. The level of support provided for peer-reviewed solicited projects (e.g., Request for Applications) is also evaluated. The NIEHS maintains a balance between solicitations issued to the extramural community in areas that need stimulation and funding made available to support investigator-initiated projects. Funding plans are discussed with the NIEHS Advisory Council prior to making awards.

Clinical Research: One of NIEHS' primary goals is expanding the role of clinical research that illuminates the relationship between environmental exposures and human disease. Diseases for which environmental health sciences can provide important clinical insight include degenerative diseases, cardiovascular diseases, reproductive disorders, breast cancer, and lung diseases, especially asthma. The goals of the clinical research program are: 1) to encourage clinical research that emphasizes understanding the environmental causes of common, complex diseases; 2) to develop improved research models for human disease using our knowledge of environmental sciences and human biology; and 3) to enhance the role of the clinical investigator in environmental health sciences.

Budget Policy: The FY 2008 budget estimate for the Clinical Research program is \$45.874 million, which represents a funding level of +\$2.307 million and +5.3% over the FY 2007 estimate. Resources will be used to continue activities critical to the long-term success of the Clinical Research program. These include programs to identify windows of susceptibility to breast cancer development from the prenatal period to adulthood, as well as to continue the Sister Study, which has recruited about half its goal of 50,000 sisters of women diagnosed with breast cancer, to target environmental causes of breast cancer. Another example of NIEHS' support of clinical research focusing on environment and human disease is a program grant for an ongoing 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: Scientists can employ environmental toxicants as laboratory probes to help study the complex molecular pathways that lead to chronic disease. These toxicants are able to interrupt normal processes in ways that can set in motion the events

that ultimately lead to conditions such as cancer, birth defects, and neurological disorders, thus providing a controlled method for studying mechanistic events leading to clinical disease. Because environmental agents often operate early in the disease process, they also provide a useful technique for identifying very early events in disease pathogenesis that can potentially be used both to identify methods to diagnose diseases before they are clinically evident and to develop early interventions that prevent progression to end-stage disease.

NIEHS' goal is to gain an improved understanding of the influence of gene-environment interactions and their effect on biological networks and pathways, which could ultimately lead both to ways of identifying very early, pre-clinical disease endpoints and to development of therapeutic interventions early in the disease process.

Budget Policy: The FY 2008 budget estimate for the Basic Mechanisms in Human Biology program is \$253.762 million, which represents a funding level of -\$3.254 million and -1.3% below the FY 2007 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. These include the FY 2006 NIEHS-initiated Request for Applications (RFA) entitled *Comparative Biology Elucidation of Environmental Pathways and Susceptibility*, which utilizes recently developed research tools that can be recruited to identify genetic and environmental factors in complex human diseases, particularly as they affect cellular pathways. Environmental response genes and pathways are highly conserved across species. Thus, genetic information being generated in multiple laboratory species can be used to understand the molecular underpinnings of human disease. This project examines entire biological pathways comprised of multiple genes and influenced by multiple environmental factors. Outgrowths of this research allow toxicological response studies in laboratory animals to be done in parallel with human studies in ways that could identify and predict human subgroups that are particularly susceptible to an adverse effect from an environmental agent. Partners for this RFA include the National Institute on Alcohol Abuse and Alcoholism and the National Heart, Lung, and Blood Institute.

Portrait of a Program: Manufactured Nanomaterials

FY 2007 Level	\$2,000,000
FY 2008 Level	<u>2,000,000</u>
Change	0

Nanoscale science and technology involve imaging, measuring, modeling, and manipulating matter on the scale of 1 to 100 nanometers - a scale at which novel physical, chemical, and biological properties enable novel applications. Nanoscale materials and devices frequently provide increased sensitivity and selectivity, and improved electrical and optical properties, that make nanoscale products useful for drug delivery systems, tissue engineering, biological and environmental sensor technology, and environmental remediation. Consumer products containing nanoscale materials, such as sunscreens and stain resistant fabrics, are commercially available, and by 2010, the nanoscale materials, tools, and devices industry is projected to exceed \$10 billion. Emerging technologies should create innovation while minimizing risk of adverse health effects and health effects of exposure should be assessed prior to extensive use. The

diversity of materials in constructing nanoparticles suggests that the universal safety of such systems cannot be taken for granted, and there will not be a single answer. NIEHS has released an RFA, *Manufactured Nanomaterials: Physico-chemical Principles of Biocompatibility and Toxicity* to support research that explores the systemic, cellular and molecular responses to manufactured nanoscale materials. Because the physico-chemical properties of nanoscale materials may change across experimental timelines, the studies will include evaluation of the physical and chemical characteristics of nanoscale materials at multiple points in the exposure model and link these measurements to biological effects. This research will improve the understanding of potential health impacts of these novel compounds, as well as help guide development of these products so as to reduce adverse impact to an increasingly exposed population.

Interdisciplinary, Integrative Research: Interactive, team-based scientific research approaches help NIEHS optimize its ability to integrate research from all levels of investigation to contribute to overall health and to reduce the burden of complex, multifaceted diseases. Scientific contributions from epidemiology, toxicology, molecular and cellular biology, bioinformatics, clinical medicine, and many other fields need to be coordinated and integrated. By fostering such broad-based, collaborative research, NIEHS will increase the relevance of basic scientific discoveries in environmental health sciences to human disease, and rapidly and more effectively move this knowledge into clinical and public health applications, ultimately improving human health.

Budget Policy: The FY 2008 budget estimate for the Interdisciplinary, Integrative Research program is \$56.989 million, which represents a funding level of -\$2.089 million and -3.5% below the FY 2007 estimate. NIEHS will fund fewer Core Centers in FY08, which is part of a long-range strategy to redirect resources to other projects. 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. These projects bring together basic, clinical, and population-based scientists to conduct integrative research programs on (1) understanding the cause and development of human diseases influenced by environmental factors, (2) using exposure to understand the interplay between genetic and environmental factors, and (3) applying available state-of-the-art technologies and methods to improve human health.

Support is also provided for the Centers for Children's Environmental Health and Disease Prevention Research and the Coordinating Centers for Parkinson's Disease Environmental Research. 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.

Community-linked and Global Environmental Health Research: Differences in the environment contribute substantially to the excess burden of disease in minority and disadvantaged communities, both in the U.S. and around the world. Examples of health indicators for which these disparities exist include shorter life expectancies, higher cancer rates, more birth defects, greater infant mortality, and higher incidences of asthma, diabetes, and cardiovascular disease. The ways in which poverty and other factors create these health disparities are still poorly understood. However, there is increasing evidence that poor and

minority groups are burdened with a disproportionate share of residential and occupational exposure to hazardous substances such as metals, pesticides, wood dusts, and air pollutants. In order to better define how poverty and environmental factors create health disparities, NIEHS held a Global Environmental Health workshop in January 2007 to determine those research opportunities where high-exposure conditions could yield insight into diseases common to the U.S., as well as abroad.

Budget Policy: The FY 2008 budget estimate for the Community-linked and Global Environmental Health (GEH) Research program is \$39.594 million, which represents a funding level of -\$0.974 million and -2.4% from the FY 2007 estimate. Resources will be used to continue high priority projects to optimize the Community-linked and GEH program. These include cultivating partnerships in Southeast Asia to better leverage resources in pursuit of new and emerging opportunities in global environmental research. The NIEHS will also fund research on dietary aflatoxin (from mold in food), hepatitis B, and liver cancer. Current research is focused on examining genetic alterations combined with aflatoxin-DNA adducts to predict liver cancer outcome and disease risk in populations in rural China and West Africa.

Exposure Biology/Exposure Measurement: The methodologies for detection and measurement of the actual exposure sustained by a human or other organism are often weak and imprecise. This is in striking contrast to the robust tools we employ in the fields of genetics and genomics. In order to advance the field of environmental health sciences, personalized measures of environmental exposure must be developed that are equivalent to the ability to measure genetic variability between individuals. The increasing sophistication of our understanding of the biological pathways involved in host response to a given exposure points the way toward the use of that knowledge in the development of improved methods for detecting and measuring environmental exposures.

Budget Policy: The FY 2008 budget estimate for the Exposure Biology/Exposure Measurement program is \$22.565 million, which represents a funding level of +\$67 thousand and .3% above the FY 2007 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.

Portrait of a Program: Exposure Biology Project

FY 2007 Level	\$6,684,000
FY 2008 Level	<u>6,584,000</u>
Change	-100,000

The Genes, Environment and Health Initiative (GEI), a new trans-NIH four-year program, aims to accelerate the understanding of genetic and environmental contributions to health and disease. There are two components of the initiative – the Genetics Program, led by the National Human Genome Research Institute (NHGRI), which focuses on identifying major genetic susceptibility factors for diseases of substantial public health impact, and the Exposure Biology Program

(EBP), led by NIEHS, which focuses on the development of innovative techniques to measure environmental exposures, diet, physical activity, psychosocial stress, and addictive substances that contribute to the development of disease. New exposure assessment technologies and biomarkers/biosensors developed through the EBP will be applied, to the extent feasible, to the genome-wide association studies supported through the GEI. The attempt will be to generate both exposure data and relevant biological response data at the level of the individual over multiple time points. In addition to taking advantage of new molecular biology techniques that allow for the global analysis of gene expression and gene products, this program will encourage research that can capitalize on new capabilities in molecular imaging, nanotechnology, and remote sensing and data capture. Optimally, personal monitors will be developed that can be used on individuals in large-scale studies and can provide information on multiple environmental exposures and stressors in a format that can be wirelessly transmitted for remote data capture. Results from experiments such as these would provide information of very early events in environmentally caused diseases and would suggest successful early intervention strategies to prevent disease progression. The Environmental Airway Disease Project was launched in FY 2006 as the initial research project under this program. Additionally, five Requests for Applications (RFAs) were released in FY 2007 to recruit the extramural community into this effort. By FY 2008 these efforts should be making progress in applying new technologies to assess an individual's real-world exposure and the internal or biological dose of this exposure, as well as incorporating information on factors that modify response to environmental agents. The cost for the RFAs remains flat from 2007 to 2008. The FY 2007 amount includes the cost of a workshop.

Pathways for Future Environmental Health Scientists: The NIEHS must develop innovative ways to attract some of the brightest young students and scientists into the environmental health sciences in order to have the right cadre for conducting the interdisciplinary research demanded by its strategic vision. The NIEHS implemented the Outstanding New Environmental Scientist (ONES) Program, an exceptionally competitive program which is designed to identify and attract the most promising new investigators to environmental health sciences research. Funds to encourage career development and start-up activities for these young investigators promote a long-term commitment to the field.

Budget Policy: The FY 2008 budget estimate for the Pathways for the Future Environmental Health Scientists program is \$27.971 million, which represents a funding level of +\$.669 million and +2% over the FY 2007 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) establishing a new 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, co-sponsored with NHGRI; and 6) supporting the NIH Pathway to Independence program.

Intramural Research: Scientists in the NIEHS Division of Intramural Research (DIR) investigate the role of environmental agents in human disease and dysfunction and define the important biological and chemical processes that these agents act upon. Intramural research studies are often long-term and high-risk in nature and involve unique components, such as the

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. DIR scientists interact with other laboratories regularly and are often engaged in interdisciplinary research. This encourages efficient testing of novel ideas, innovative hypotheses, and new paradigms. DIR scientists are also actively involved in translational research; new advances in cell and molecular biology are being extended not only into molecular medicine (from bench to bedside), but also into disease prevention (from bench to longer, healthier lives).

Budget Policy: The FY 2008 budget estimate for the Intramural Research program is \$165.076 million, which represents a funding level of -\$1.128 million and -.7% below the FY 2007 estimate. Reductions to the Intramural Research program will result from routine staff attrition and retirements. Available 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 under the Director’s Challenge program. The goal of this program is to create new research teams that integrate patient-oriented or public health research with basic biological and mechanistic studies to understand how environmental exposures modulate or regulate physiological processes that may lead to human disease.

Portrait of a Program: Intramural Clinical Research Unit

FY 2007 Level	\$2,580,000
FY 2008 Level	<u>3,550,000</u>
Change	+970,000

The NIEHS campus is located in Research Triangle Park, North Carolina and does not have on-site clinical capacity, a fact that limits the ability of intramural investigators to translate their laboratory findings into more real-world applicability. To correct this deficit, DIR has initiated construction of an on-site *Clinical Research Unit* (CRU) where physician-scientists can see patients. By housing this unit on campus, NIEHS can improve opportunities to “put to practice” basic environmental health research discoveries of the NIEHS intramural program. NIEHS plans to open the CRU, an 8,000-square foot structure, by the summer of 2007, with patients being seen by FY 2008. The initial focus will be on important environmental components of pulmonary disorders, such as asthma. In addition, we have instituted a new Office of Translational Research to accelerate global application of basic research discoveries to patient treatment and disease prevention.

Research Management and Support (RMS): NIEHS RMS provides administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants and training awards. NIEHS plans to oversee over 600 research project grants and centers in FY 2008. RMS functions encompass strategic planning, coordination, and evaluation of NIEHS programs, regulatory compliance, international coordination, and liaison with other federal agencies, Congress, and the public. A major project in FY 2006 was the creation and implementation of the new NIEHS Strategic Plan (available online at <http://www.niehs.nih.gov/external/plan2006/>), which took form through discussions with more than 400 scientific and public leaders from academia, government, medical professions, community advocacy groups, and the general public.

Budget Policy: The FY 2008 budget estimate for RMS is \$17.147 million, which represents a funding level of +\$170 thousand and +1% above the FY 2007 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.

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Budget Authority by Object

	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	668	677	9
Full-time equivalent of overtime & holiday hours	1	1	0
Average ES salary	\$161,695	\$166,545	\$4,850
Average GM/GS grade	11.0	11.0	0.0
Average GM/GS salary	\$75,539	\$77,805	\$2,266
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$95,281	\$98,139	\$2,858
Average salary of ungraded positions	112,103	115,466	3,363
OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	\$37,342,000	\$39,435,000	\$2,093,000
11.3 Other than Full-Time Permanent	18,084,000	19,097,000	1,013,000
11.5 Other Personnel Compensation	593,000	626,000	33,000
11.7 Military Personnel	842,000	889,000	47,000
11.8 Special Personnel Services Payments	9,956,000	10,138,000	182,000
Total, Personnel Compensation	66,817,000	70,185,000	3,368,000
12.0 Personnel Benefits	15,711,000	16,591,000	880,000
12.2 Military Personnel Benefits	490,000	518,000	28,000
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	83,018,000	87,294,000	4,276,000
21.0 Travel & Transportation of Persons	2,080,000	2,122,000	42,000
22.0 Transportation of Things	474,000	474,000	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	47,000	47,000	0
23.3 Communications, Utilities & Miscellaneous Charges	1,040,000	1,052,000	12,000
24.0 Printing & Reproduction	192,000	190,000	-2,000
25.1 Consulting Services	538,000	532,000	-6,000
25.2 Other Services	19,733,000	18,302,000	-1,431,000
25.3 Purchase of Goods & Services from Government Accounts	84,359,000	82,884,000	-1,475,000
25.4 Operation & Maintenance of Facilities	2,687,000	2,680,000	-7,000
25.5 Research & Development Contracts	113,903,000	112,413,000	-1,490,000
25.6 Medical Care	84,000	85,000	1,000
25.7 Operation & Maintenance of Equipment	2,635,000	2,621,000	-14,000
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	223,939,000	219,517,000	-4,422,000
26.0 Supplies & Materials	17,572,000	16,935,000	-637,000
31.0 Equipment	6,216,000	6,083,000	-133,000
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	298,632,000	295,264,000	-3,368,000
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	550,192,000	541,684,000	-8,508,000
NIH Roadmap for Medical Research	7,693,000	8,428,000	735,000
Total Budget Authority by Object	640,903,000	637,406,000	-3,497,000

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

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Salaries and Expenses

OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Personnel Compensation:			
Full-Time Permanent (11.1)	\$37,342,000	\$39,435,000	\$2,093,000
Other Than Full-Time Permanent (11.3)	18,084,000	19,097,000	1,013,000
Other Personnel Compensation (11.5)	593,000	626,000	33,000
Military Personnel (11.7)	842,000	889,000	47,000
Special Personnel Services Payments (11.8)	9,956,000	10,138,000	182,000
Total Personnel Compensation (11.9)	66,817,000	70,185,000	3,368,000
Civilian Personnel Benefits (12.1)	15,711,000	16,591,000	880,000
Military Personnel Benefits (12.2)	490,000	518,000	28,000
Benefits to Former Personnel (13.0)	0	0	0
Subtotal, Pay Costs	83,018,000	87,294,000	4,276,000
Travel (21.0)	2,080,000	2,122,000	42,000
Transportation of Things (22.0)	474,000	474,000	0
Rental Payments to Others (23.2)	47,000	47,000	0
Communications, Utilities and Miscellaneous Charges (23.3)	1,040,000	1,052,000	12,000
Printing and Reproduction (24.0)	192,000	190,000	-2,000
Other Contractual Services:			
Advisory and Assistance Services (25.1)	288,000	282,000	-6,000
Other Services (25.2)	19,733,000	18,302,000	-1,431,000
Purchases from Govt. Accounts (25.3)	49,238,000	47,190,000	-2,048,000
Operation & Maintenance of Facilities (25.4)	2,687,000	2,680,000	-7,000
Operation & Maintenance of Equipment (25.7)	2,635,000	2,621,000	-14,000
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	74,581,000	71,075,000	-3,506,000
Supplies and Materials (26.0)	17,572,000	16,935,000	-637,000
Subtotal, Non-Pay Costs	95,986,000	91,895,000	-4,091,000
Total, Administrative Costs	179,004,000	179,189,000	185,000

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2007 Continuing Resolution	2008 Amount Authorized	FY 2008 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Environmental Environmental Health Sciences	Section 402(a)	P.L.-109-482	Indefinite	\$640,903,000	Indefinite	\$637,406,000
Total, Budget Authority				640,903,000		637,406,000

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Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
1999	\$349,021,000 <u>2/ 3/</u>	\$356,047,000	\$375,743,000	\$375,743,000
Rescission				-249,000
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	641,132,000 <u>4/</u>
2008	637,406,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

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

3/ Reflects a decrease of \$931,000 for the budget amendment for Bioterrorism.

4/ Annualized current rate

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Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Office of the Director	26	26	26
Office of Translational Research	27	27	27
Division of Intramural Research	468	472	481
Division of Extramural Research and Training	54	54	54
Office of Management	89	89	89
Total	664	668	677
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2004	11.1		
2005	11.2		
2006	11.2		
2007	11.2		
2008	11.2		

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Detail of Positions

GRADE	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Total, ES Positions	1	1	1
Total, ES Salary	\$158,152	\$161,695	\$166,545
GM/GS-15	37	37	37
GM/GS-14	63	63	63
GM/GS-13	67	67	67
GS-12	82	82	82
GS-11	112	112	112
GS-10	1	1	1
GS-9	74	74	76
GS-8	18	18	18
GS-7	26	26	27
GS-6	8	8	8
GS-5	1	1	1
GS-4	12	12	12
GS-3	4	4	4
GS-2	0	0	0
GS-1	1	1	1
Subtotal	506	506	509
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	8	8	8
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	183	188	196
Total permanent positions	523	525	536
Total positions, end of year	709	714	725
Total full-time equivalent (FTE) employment, end of year	664	668	677
Average ES salary	\$158,152	\$161,695	\$166,545
Average GM/GS grade	11	11	11
Average GM/GS salary	\$73,884	\$75,539	\$77,805

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

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New Positions Requested

	FY 2008		
	Grade	Number	Annual Salary
Tenure Track Investigator (Clinical)	Title 42	1	\$120,000
Senior Investigator	Title 42	1	150,000
Senior Investigator	Title 42	1	130,000
Tenure Track Investigator	Title 42	1	90,000
Tenure Track Investigator	Title 42	2	80,000
Biologist	GS-7/9	3	45,106
Total Requested		9	