

FY 2009 Congressional Justification

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Amounts Available for Obligation

FY 2009 Budget

| 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 | | 5 |
| 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 |
| Unobligated balance lapsing | -222,000 | | |
| Total obligations | 641,551,000 | 642,253,000 | 642,875,000 |

1/ 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.



Appropriation Language

FY 2009 Budget

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).

Appropriations History

FY 2009 Budget

| Fiscal Year | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation 1/ |
|-------------|-----------------------------|-----------------|------------------|------------------|
| 2000 | \$390,718,000 24 | \$421,109,000 | \$436,113,000 | \$444,817,000 |
| Rescission | | | | -2,368,000 |
| 2001 | 460,971,000 24 | 506,730,000 | 508,263,000 | 502,549,000 |
| Rescission | | | | -495,000 |
| 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 | | | |

^{1/} Reflects enacted supplementals, rescissions, and reappropriations.

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



Authorizing Legislation

| | PHS Act/ Other Citation | U.S. Code Citation | 2007 Amount Authorized | | FY2008 Enacted | 2008 Amo Authoriz | FY 2009 Budget Estimate |
|--|-------------------------------|-----------------------|---------------------------|---|-------------------|----------------------|-------------------------------|
| Research and Investi- gation | Section 301 | 42§241 | Indefinite | | ¢642.252.000 | Indefinite | \$642,875,000 |
| Environ- mental Health Sciences | Section 402(a) | 42§281 | Indefinite | 5 | \$642,253,000 | Indefinite | \$042,875,UUU |
| ľ | | | K | | 642,253,000 | | 642,875,000 |

Budget Authority by Activity

FY 2009 Budget - Dollars in thousands

| | FY 2005 Actual | FY 2006 Actual | FY 2007 Actual | FY 2007 Comparable | FY 2008 Enacted | FY 2009 Estimate | Change |
|---|------------------------|------------------------|------------------------|-----------------------|------------------------|---------------------|-----------------|
| | Amount | Amount | Amount | Amount | Amount | Amount | Amount |
| Extramural Research (Detail:) | | | | | | | |
| Linkage of Exposures to Clinical Expression of Disease | \$52,151 | \$43,106 | \$60,281 | \$60,281 | \$58,049 | \$57,796 | -\$253 |
| Basic Mechanisms in Human Biology | 245,471 | 249,888 | 253,446 | 253,446 | 248,927 | 246,056 | -2,871 |
| Interdisciplinary, Integrated Research | 75,661 | 60,490 | 58,728 | 58,728 | 62,622 | 61,675 | -947 |
| Community-linked & Global Environmental Health Research | 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 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 FTEs 164,720 | 571 FTEs 167,084 | 558 FTEs 167,002 | 558 FTEs 166,874 | 559 FTEs 170,212 | 564 FTEs 172,850 | 5 FTEs 2,638 |
| Res. management & support | 93 FTEs 15,139 | 93 FTEs 16,739 | 98 FTEs 17,389 | 98 FTEs 17,177 | 99 FTEs 17,435 | 99 FTEs 17,705 | 0 FTEs 270 |
| Total | 651 FTEs 640,430 | 664 FTEs 630,482 | 656 FTEs 647,242 | 656 FTEs 641,773 | 658 FTEs 642,253 | 663 FTEs 642,875 | 5 FTEs 622 |

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



Budget Authority by Object

| | FY 2008 Enacted | FY 2009 Estimate | Increase or 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 |
| 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 |
| OBJECT CLASSES | FY 2008 Enacted | FY 2009 Estimate | Increase or Decrease |
| Personnel Compensation: | | | |
| 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 | 950,000 |
| 11.5 Other personnel compensation | 850,000 | 896,000 | 46,000 |
| 11.7 Military personnel | 904,000 | 946,000 | 42,000 |
| 11.8 Special personnel services payments | 10,854,000 | 11,440,000 | 586,000 |
| Total, Personnel Compensation | 70,464,000 | 74,250,000 | 3,786,000 |
| 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 | -2,312,000 |
| 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 | 109,804,000 | 0 |
| 25.6 Medical care | 43,000 | 43,000 | 0 |
| 25.7 Operation and maintenance of equipment | 2,565,000 | 2,550,000 | -15,000 |
| 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 | 12,860,000 | -323,000 |
| 31.0 Equipment | 5,590,000 | 5,450,000 | -140,000 |
| 32.0 Land and structures | 0 | 0 | 0 |
| 33.0 Investments and loans | 0 | 0 | 0 |
| 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 | 0 | 0 |
| 44.0 Refunds | 0 | 0 | 0 |
| 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 |

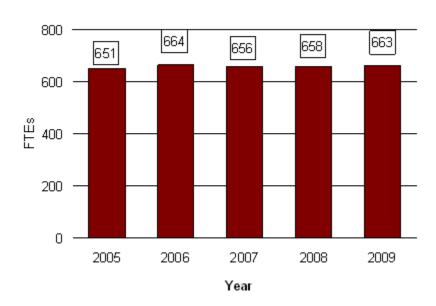
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

Budget Graphs

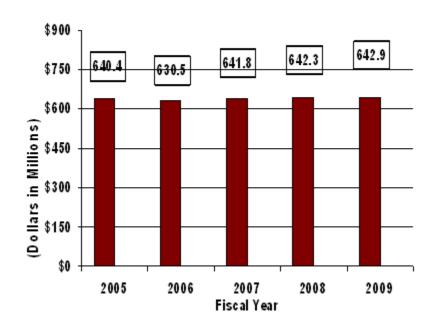
FY 2009 Budget

History of Budget Authority and FTEs

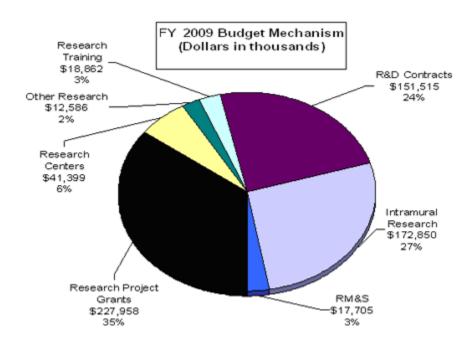
FTEs by Fiscal Year



Funding Levels by Fiscal Year

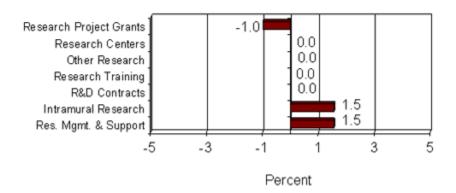


Distribution by Mechanism



Change by Selected Mechanism

FY 2009 Estimate Percent Change from FY 2008 Mechanism



Budget Mechanism Table

FY 2009 Budget

(Dollars in Thousands)

| Mechanism | | 7 2007 ctual | | 7 2008 nacted | FY 2009 Estimate | | Change | |
|---|------|----------------------|------|----------------------|---------------------|----------------------|--------|----------------------|
| | No. | Amount in Dollars | No. | Amount in Dollars | No. | Amount in Dollars | No. | Amount in Dollars |
| Research Grants: | | | | | | | | |
| 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: | | | | ŀ | | | | |
| 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 | Amount in Dollars | FTTPs | Amount in Dollars | FTTPs | Amount in Dollars | | Amount in Dollars |
| 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) | (8) | (1,366) | (8) | (1,366) | (0) | (0) |
| | FTEs | Amount in Dollars | FTEs | Amount in Dollars | FTEs | Amount in Dollars | FTEs | Amount in Dollars |
| Intramural research | 558 | 166,874 | 559 | 170,212 | 564 | 172,850 | 5 | 2,638 |
| | 98 | 17,177 | 99 | 17,435 | 99 | 17,705 | 0 | 270 |
| Research management and support | 70 | | | , | | | | |



| Buildings and Facilities | 0 | 0 | 0 | 0 | 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

- FTE = Full-time equivalent
- FTTP = Full-time temporary equivalent

Detail of Full-Time Equivalent Employment (FTE)

FY 2009 Budget

| 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 Roadmap for Medical Research | ch | | | |
| FTEs supported by funds from Cooperative Research and Development Agreements | (0) | (0) | (0) | |
| FISCAL YEAR | Avera | age GM/GS | Grade | |
| 2005 | | 11.2 | | |
| 2006 | | 11.2 | | |
| 2007 | 11.2 | | | |
| 2008 | 11.2 | | | |
| 2009 | | 11.2 | | |

The new positions requested for the Division of Intramural Research are shown in the <u>New Positions Requested</u>.

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 | 75 |
| 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

Justification Narrative

FY 2009 Budget

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

| FY 2007 Actual | | | FY 2008 Enacted | FY 2009 Estimate | | Increase or Decrease | |
|-------------------|---------------|------|--------------------|---------------------|---------------|-------------------------|-----------|
| FTEs | ВА | FTEs | ВА | FTEs | ВА | FTEs | BA |
| 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.

Budget Policy: 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.

Budget Policy: 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.

Budget Policy: 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.

Budget Policy: 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.

Budget Policy: 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 M.D./Ph.D. 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, co-sponsored 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. Budget Policy: 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.

Budget Policy: 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.



Major Changes in Budget Request

FY 2009 Budget

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.

Basic Mechanisms in Human Biology (-\$2.871 million; total \$246.056 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 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.

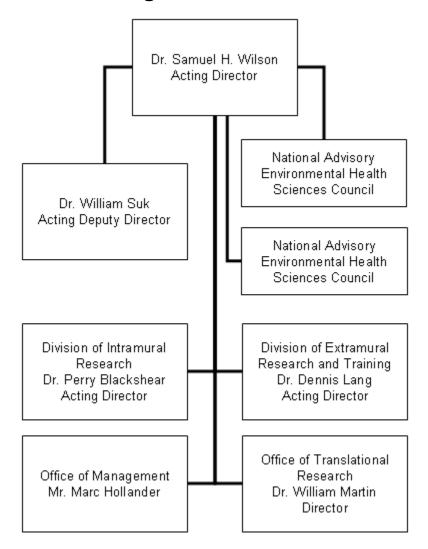
Intramural research (+\$2.638 million; total \$172.850 million): The additional funds will be used for scientific recruitments to broaden the intramural research scientific base with expertise consistent with the NIEHS strategic plan. The increase will also offset the expenses associated with the pay increase and be used for laboratory supplies, materials, and other expenses.



New Positions Requested

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

Organization Chart



Salaries & Expenses

| Object Classes | FY 2008 Enacted | FY 2009 Estimate | Increase or Decrease |
|--|--------------------|---------------------|-------------------------|
| Personnel Compensation: | | | |
| Full-Time Permanent (11.1) | \$40,270,000 | \$42,432000 | \$2,162,000 |
| Other Than Full-Time Permanent (11.3) | 17,586,000 | 18,536,000 | 950,000 |
| 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 Govt. Accounts (25.3) | 60,507,000 | 61,518,000 | 1,012,000 |
| Operation & Maintenance of Facilities (25.4) | 2,299,000 | 2,290,000 | -9,000 |
| Operation & Maintenance of Equipment (25.7) | 2,565,000 | 2,550,000 | -15,000 |
| Subsistence & 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 |

Summary of Changes

| FY 2008 Enacted | | | | |
|---|------------------------------|--------------|------------------|---------------------|
| FY 2008 Estimated Budget Authority | | | | |
| Net change | | | | |
| Changes | 2008 Current Enacted Base | | Change from Base | |
| | FTEs Budget Authority | | FTEs | Budget Authority |
| A. Built-in: | | | | |
| 1. Intramural research: | | | | |
| a. Annualization of January 2008 pay increase | | \$75,865,000 | | \$662,000 |
| b. January 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 |
| 2. 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 |
| Subtotal, Built-in | | | | 4,046,000 |

| Changes | | 2008 Current Enacted Base | | Change from Base | |
|---------------------------------------|------|------------------------------|------|------------------|--|
| | No. | Amount | No. | Amount | |
| B. Program: | | | | | |
| 1. 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 | |
| 4. Research training | 486 | 18,862,000 | -8 | 0 | |
| 5. Research and development contracts | 95 | 151,515,000 | 0 | 0 | |
| Subtotal, extramural | 3 | | | -2,286,000 | |
| | FTEs | | FTEs | 9 | |
| 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 | |