DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences (NIEHS)

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NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

Organization Structure

NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, **[**\$667,502,000**]**\$681,782,000.

Amounts Available for Obligation¹

(Dollars in Thousands)

			FY 2016
Source of Funding	FY 2014 Actual	FY 2015 Enacted	President's
			Budget
Appropriation	\$665,439	\$667,502	\$681,782
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-1,670	0	0
FY 2014 Second Secretary's Transfer	-131	0	0
Subtotal, adjusted appropriation	\$663,638	\$667,502	\$681,782
OAR HIV/AIDS Transfers	0	-169	0
National Children's Study Transfers	2,187	0	0
Subtotal, adjusted budget authority	\$665,825	\$667,333	\$681,782
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$665,825	\$667,333	\$681,782
Unobligated balance lapsing	-168	0	0
Total obligations	\$665,657	\$667,333	\$681,782

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

FY 2014 - \$5,316 FY 2015 - \$5,570 FY 2016 - \$5,576

Budget Mechanism - Total¹

No.AmountNo.AmountNo.AmountNo.AmResearch Projects: Noncompeting444\$175,307414\$171,841411\$165,236-3	-\$6,605 -1,100 -829 12,832 0
Research Projects: 444 \$175,307 414 \$171,841 411 \$165,236 -3	-\$6,605 -1,100 -829 12,832 0
Noncompeting 444 \$175,307 414 \$171,841 411 \$165,236 -3	-\$6,605 -1,100 -829 12,832 0
	-1,100 -829 12,832 0
Administrative Supplements (28) $2,675$ (27) $2,600$ (15) $1,500$ (-12)	-829 12,832 0
Competing:	-829 12,832 0
Renewal 18 7,463 17 7,049 15 6,220 -2	12,832 0
New 148 50,422 141 48,111 177 60,943 36	0
Supplements 5 2,016 5 2,000 5 2,000 0	
Subtotal, Competing 171 \$59,902 163 \$57,160 197 \$69,163 34	\$12,003
Subtotal, RPGs 615 \$237,884 577 \$231,601 608 \$235,899 31	\$4,298
SBIR/STTR 48 14,774 47 14,547 52 15,984 5	1,437
Research Project Grants 663 \$252,658 624 \$246,148 660 \$251,883 36	\$5,735
Research Centers:	
Specialized/Comprehensive 21 \$31,119 30 \$37,161 33 \$40,407 3	\$3,246
Clinical Research 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	0
Institutions	
Research Centers 21 \$31,119 30 \$37,161 33 \$40,407 3	\$3,246
Other Research:	
Research Careers 52 \$6,691 50 \$6,391 50 \$6,391 0	\$0
Cancer Education 0	0
Cooperative Clinical Research 0 0 0 0 0 0	0
Biomedical Research Support 0 0 0 0 0 0 0	0
$\begin{array}{c c} \text{Support} \\ 0 \\ \end{array} \begin{array}{c c} 200 \\ 0 \\ \end{array} \begin{array}{c c} 0 \\ 200 \\ 0 \\ \end{array} \begin{array}{c c} 0 \\ 0 \\ 0 \\ 0 \\ \end{array} \begin{array}{c c} 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ \end{array} \begin{array}{c c} 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 \\ 0 $	-200
Other 30 2,290 31 2,488 31 2,488 0	0
Other Research 82 \$9,182 81 \$9,079 81 \$8,879 0	-\$200
Total Research Grants 766 \$292,959 735 \$292,388 774 \$301,169 39	\$8,781
Ruth L Kirchstein Training Awards: FTTPs FTTPs	
Individual Awards 32 \$1,590 32 \$1,590 32 \$1,590 0	\$0
Institutional Awards 391 17,922 385 17,922 379 17,922 -6	0
Total Research Training 423 \$19,512 417 \$19,512 411 \$19,512 -6	\$0
Research & Develop. Contracts 142 \$146,406 142 \$146,406 142 \$149,974 0	\$3,568
(SBIR/STTR) (non-add) (0) (84) (0) (181) (0) (32) (0)	(-149)
Intramural Research 519 181,870 523 183,697 523 185,543 0	1,846
Res. Management & Support 138 25,078 138 25,330 138 25,584 0	254
Res. Management & Support (SBIR (0) (91) (0) (191) (0) (0)	(-191)
Hamin (non-aaa) Control NIEHS 657 \$665,825 661 \$667,232 \$661 \$661,722 0	\$14 440

(Dollars in Thousands)

¹ All items in italics and brackets are non-add entries.

 $^2~$ Does not include \$10 million Ebola-related transfer from CDC.

Major Changes in the Fiscal Year 2016 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that these highlights will not sum to the total change for the FY 2016 President's Budget for NIEHS, which is \$14.449 million above the FY 2015 Enacted level, for a total of \$681.782 million.

<u>Research Project Grants (RPGs) (+\$5.735 million; total \$251.883 million):</u> NIEHS plans to support a total of 660 RPG awards in FY 2016. Noncompeting RPGs will decrease by three awards and \$6.605 million from the FY 2015 level. Competing RPGs will increase by 34 awards or \$12.003 million. \$4.917 million of the increase in competing awards will support the new NIH Precision Medicine Initiative. NIEHS will continue to support new investigators in FY 2016.

Precision Medicine (\$7.339 million) NIH proposes to launch a national research cohort of one million or more Americans – to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing. Participants who voluntarily choose to join this effort will be able to share their genomic data, biological specimens, and behavioral data, and, if they choose, link it to their electronic health records (EHRs), taking advantage of the latest in social media and mobile applications, and with appropriate privacy protections in place. Bona fide researchers from across the country will have access to data voluntarily provided, thereby crowdsourcing rich data to the brightest minds in biomedical research. The cohort will be built largely by linking existing cohorts together taking advantage of infrastructure, data security and expertise already in place. NIH will help to connect these existing cohorts, but the current sponsors of the cohorts will maintain their ownership and management. Research on this scale promises to lead to new prevention strategies, novel therapeutics and medical devices, and improvements in how we prescribe drugs – on an individual and personalized basis.

Summary of Changes

(Dollars in Thousands)

FY 2015 Enacted FY 2016 President's Budget		\$667,333 \$681,782
Net change		\$14,449
	FY 2016 President's Budget	Change from FY 2015
CHANGES	FTEs Budget Authority	FTEs Budget Authority
A. Built-in:		
1. Intramural Research:		
a. Annualization of January 2015 pay increase & benefits	\$78,507	\$220
b. January FY 2016 pay increase & benefits	78,507	661
c. One more day of pay (n/a for 2016)	78,507	296
d. Differences attributable to change in FTE	78,507	0
e. Payment for centrally furnished services	23,625	576
f. Increased cost of laboratory supplies, materials, other	83 412	92
expenses, and non-recurring costs	03,112	
Subtotal		\$1,846
2. Research Management and Support:		
a. Annualization of January 2015 pay increase & benefits	\$16,688	\$47
b. January FY 2016 pay increase & benefits	16,688	141
c. One more day of pay (n/a for 2016)	16,688	65
d. Differences attributable to change in FTE	16,688	0
e. Payment for centrally furnished services	2,083	51
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs	6,813	-49
Subtotal		\$254
Subtotal, Built-in		\$2,100

Summary of Changes - Continued

(Dollars in Thousands)

	FY 2016 Pres	ident's Budget	Change fro	om FY 2015
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	411	\$166,736	-3	-\$7,705
b. Competing	197	69,163	34	12,003
c. SBIR/STTR	52	15,984	5	1,437
Subtotal, RPGs	660	\$251,883	36	\$5,735
2. Research Centers	33	\$40,407	3	\$3,246
3. Other Research	81	8,879	0	-200
4. Research Training	411	19,512	-6	0
5. Research and development contracts	142	149,974	0	3,568
Subtotal, Extramural		\$470,655		\$12,349
	<u>FTEs</u>		FTEs	
6. Intramural Research	523	\$185,543	0	\$0
7. Research Management and Support	138	25,584	0	0
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	661	\$681,782	0	\$12,349
Total changes				\$14,449

Fiscal Year 2016 Budget Graphs

History of Budget Authority by FTEs:



Distribution by Mechanism (dollars in thousands):



Change by Selected Mechanism:



Budget Authority by Activity¹

	FY 20	14 Actual	FY 201	5 Enacted	FY Preside	7 2016 nt's Budget	FY FY	2016 +/- 2015
<u>Extramural Research</u>	<u>FTE</u>	Amount	FTE	Amount	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	Amount
<u>Detail</u>								
Fundamental Research		\$180,220		\$175,106		\$182,061		\$6,955
Exposure Research		54,326		55,613		55,754		141
Translational Research and Special Populations		99,525		101,909		106,053		4,144
Predictive Toxicology		87,008		87,008		87,008		0
Training and Education		37,801		38,670		39,779		1,109
Subtotal, Extramural		\$458,879		\$458,306		\$470,655		\$12,349
Intramural Research	519	\$181,870	523	\$183,697	523	\$185,543	0	\$1,846
Research Management & Support	138	\$25,078	138	\$25,330	138	\$25,584	0	\$254
TOTAL	657	\$665,827	661	\$667,333	661	\$681,782	0	\$14,449

(Dollars in Thousands)

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

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	PHS Act/	U.S. Code	2015 Amount	FY 2015	2016 Amount	FY 2016
	Other Citation	Citation	Authorized	Enacted	Authorized	President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Environmental Health				\$667,333,000		\$681,782,000
Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$667,333,000		\$681,782,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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
Rescission				\$0
2008	\$637,406,000	\$652,303,000	\$656,176,000	\$653,673,000
Rescission				(\$11,420,000)
2009	\$642,875,000	\$664,980,000	\$660,767,000	\$662,820,000
Rescission				\$0
Supplemental				\$3,416,000
2010	\$684,257,000	\$695,497,000	\$683,149,000	\$689,781,000
Rescission				\$0
2011	\$707,339,000		\$706,227,000	\$689,781,000
Rescission				(\$6,057,112)
2012	\$700,537,000	\$700,537,000	\$676,033,000	\$686,869,000
Rescission				(\$1,298,182)
2013	\$684,030,000		\$686,103,000	\$685,570,818
Rescission				(\$1,371,142)
Sequestration				(\$34,410,941)
2014	\$691,348,000		\$686,753,000	\$665,439,000
Rescission				\$0
2015	\$665,080,000			\$667,502,000
Rescission				\$0
2016	\$681,782,000			

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 (BA):

			FY 2016	
	FY 2014	FY 2015	President's	FY 2016 +/-
	Actual	Enacted	Budget	FY 2015
BA	\$665,825,010	\$667,333,000	\$681,782,000	+\$14,449,000
FTE	657	661	661	0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

Of all the things that influence our health – our age, genetic makeup, and the ways in which we interact with the environment around us – our environment is the one thing we can change. In that respect, our environment, including the air we breathe, the water we drink, the choices we make about what we consume and what we have in our homes – all of these things contribute to our health status and quality of life. Understanding these complex interactions is the work of the National Institute of Environmental Health Sciences (NIEHS).

The research priorities of NIEHS, in its mission to learn about environmental effects on human health, reflect the priorities of NIH: from generating knowledge in basic, foundational science, to innovating tools for turning discoveries into prevention and interventions, to developing technologies to organize and apply what is known, to recruiting and training the best minds to engage in these critical efforts. As the world around us and the global environmental health problems we face become more complicated and urgent, NIEHS will never stop searching for solutions and never lose sight of NIEHS's mission: to discover how the environment affects people in order to promote healthier lives.

Unraveling Life's Mysteries through Basic Research: In science, solutions don't typically arise *de novo*, but rather are the result of often years of patient and focused study that adds to the body of knowledge through both small, incremental observations and great bursts of understanding. NIEHS seeks to foster both. Over 20 years of support for the Agricultural Health Study, a longitudinal prospective study of cancer and other health outcomes in a cohort of licensed pesticide applicators and their spouses from Iowa and North Carolina, has yielded a plethora of insights such as links between exposure to pesticides and risk of prostate cancer and

associations between mixing of organochlorine pesticides and diabetes in women.^{1,2} Approaching a known problem from a new perspective led NIEHS-funded investigators to a recent observation that maternal exposure during pregnancy to certain less-studied polybrominated diphenyl ether (PBDE) congeners in house dust may be a risk factor for acute lymphoblastic leukemia, the most common childhood leukemia, which usually strikes between the ages of two and five.³

Translating Discovery into Health: The same innovative thinking that prompts researchers to come at a problem in a different way is being brought to bear on devising new, more powerful means of screening the agents in our environment that may pose a risk to health. Scientists in the NIEHS/National Toxicology Program (NTP), in collaboration with the National Center for Advancing Translational Science (NCATS), have screened a library of 10,000 environmental chemicals and drugs against cell-based assays. Now they are taking this a step further to develop predictive modeling tools to analyze and understand which of these compounds may pose a risk to health. A new study looking at estrogen receptor activity has demonstrated that such quantitative high-throughput screening, which includes the so-called "tissue on a chip" technology, is both feasible and accurate at identifying environmental chemicals.⁴ On the other side of the equation, the 1,000 genomes toxicity screening project of the NIEHS-NCATS-University of North Carolina Toxicogenetics Challenge generated cytotoxicity data on 1,086 human lymphoblast cell lines representing nine populations from five continents, and demonstrated that population-based in vitro toxicity screening is more powerful than traditional in vitro testing for understanding the genetic determinants of inter-individual variability and for assessing hazard in chemical toxicity, as well as allowing for identification of susceptible subpopulations.

Harnessing Data and Technology to Improve Health: Although these projects demonstrate the massive amounts of data that can now be generated more quickly and efficiently than ever before, NIEHS is keenly aware that the data is only as good as the insights you can glean from it and the application you can make to real-life human health problems. Developing systems for harnessing the power of such data by organizing it into useable frameworks is the work of two exciting and ongoing projects at NIEHS. NIEHS/NTP has developed a systematic review framework that extends approaches developed for clinical medicine to the greater range of data

¹ Koutros S, Beane Freeman LE, Lubin JH, Heltshe SL, Andreotti G, Barry KH, DellaValle CT, Hoppin JA, Sandler DP, Lynch CF, Blair A, Alavanja MC. Risk of total and aggressive prostate cancer and pesticide use in the Agricultural Health Study. Am J Epidemiol. 2013 Jan 1;177(1):59-74. ² Starling AP, Umbach DM, Kamel F, Long S, Sandler DP, Hoppin JA. Pesticide use and incident diabetes among

wives of farmers in the Agricultural Health Study. Occup Environ Med. 2014 Sep;71(9):629-35.

³ Ward MH, Colt JS, Deziel NC, Whitehead TP, Reynolds P, Gunier RB, Nishioka M, Dahl GV, Rappaport SM, Buffler PA, Metayer C. 2014. Residential levels of polybrominated diphenyl ethers and risk of childhood acute lymphoblastic leukemia in California. Environ Health Perspect. 122:1110-1116; http://dx.doi.org/10.1289/ehp.1307602

⁴ Huang R, Sakamuru S, Martin MT, Reif DM, Judson RS, Houck KA, Casey W, Hsieh JH, Shockley KR, Ceger P, Fostel J, Witt KL, Tong W, Rotroff DM, Zhao T, Shinn P, Simeonov A, Dix DJ, Austin CP, Kavlock RJ, Tice RR, Xia M. Profiling of the Tox21 10K compound library for agonists and antagonists of the estrogen receptor alpha signaling pathway. Sci Rep. 2014 Jul 11;4:5664.

relevant to environmental health sciences. The approach, published in FY 2014, includes a seven-step framework for evaluating the scientific literature and reaching conclusions in literature-based, non-cancer health assessments.⁵ Such a framework will enhance the transparency and quality of how NTP reaches conclusions from its evaluations and communicates them to audiences. Groups outside NIEHS are now looking to the lessons learned from the development of this framework to guide similar systematic review procedures in other fields. A complementary effort led by NIEHS is bringing together researchers, informationists, publishers, data scientists, risk communicators, and other relevant expertise around the issue of standardization of language for environmental health research and communications. Standardized language can help to ensure that the content of datasets can be equally understood by the broader research community, thus enhancing reproducibility, reuse, and integration. Common and consistent terms will allow researchers to ask common questions across disparate databases and reconcile the results of their queries for analysis, which will lead to new ways to prevent, diagnose, and treat environmentally-related disease.

Preparing a Diverse and Talented Biomedical Research Workforce: To move all these exciting technologies into the future, and to reap the rewards of NIH's research investments, NIEHS will need to continue to bring promising students and scientists into the field and provide the multidisciplinary training needed to explore the wide-ranging aspects of the environmental health sciences. NIEHS continues a long tradition of recruiting and training future environmental health leaders through programs such as ScholarsConnect, which recognizes the value that diverse perspectives bring to science and seeks to ensure that those who study environmental health are representative of all of our communities. The program is designed to provide an opportunity for highly motivated science, technology, engineering, and math (STEM)-focused undergraduate students from the surrounding Historically Black Colleges & Universities (HBCUs), and other nearby academic institutions with students from underrepresented groups, to engage in the process of mentored research. The hope is that these efforts will help excite and inspire students to continue in a science-related training path through baccalaureate, graduate, and post-graduate study.

Overall Budget Policy:

The FY 2016 President's Budget request is \$681.782 million, an increase of \$14.449 million, or 2.2 percent above the comparable FY 2015 level. NIEHS will continue to support new investigators and will increase the number of competing RPGs in FY 2016. NIEHS will maintain the average cost of competing grants at the FY 2014 actual level. Support for the NRSA training mechanism will remain the same as in FY 2015.

Program Descriptions and Accomplishments

Fundamental Research: NIEHS's program in Fundamental Research investigates the basic biological processes of how our bodies function and of the pathways and systems that are susceptible to the effects of environmental stressors. This research addresses all levels of biological organization–molecular, biochemical pathway, cellular, tissue, organ, model organism, human, and population–and builds on the knowledge from new tools and techniques

⁵ Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. Environ Health Perspect. 2014 Jul;122(7):711-8.

that allow us to ask more in-depth questions about the effects of our environment on biological systems.

Lupus is a chronic autoimmune disease that can affect any part of the body and is estimated to strike more than 1.5 million Americans, 90 percent of whom are women of childbearing age. There is no cure for lupus and the leading cause of death is from cardiovascular disease due to lupus-accelerated atherosclerosis. Because symptoms vary widely between affected individuals and the disease comes and goes throughout its course, diagnosis can take years before it is definitively made. The lack of animal models for lupus has hindered research progress. Recently, while following up on a genome-wide association study that identified a common genetic variant associated with lupus in two large human populations, NIEHS-funded scientists constructed a mouse model that develops lupus-like disease.⁶ Further investigation provided insight into the mechanisms involved in lupus, including the role of an important DNA enzyme for maintenance of genome integrity and alterations in normal immunological processes. This important work contributes to understanding the role of a common variant associated with lupus and provides mechanistic insight that may lead to improved diagnosis or therapies for lupus.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$182.061 million, an increase of \$6.955 million, or 4.0 percent over the FY 2015 level. The additional funds will fund an additional 34 competing RPGs. Many of the new awards will support NIH's new Precision Medicine Initiative.

⁶ Senejani AG, Liu Y, Kidane D, Maher SE, Zeiss CJ, Park HJ, Kashgarian M, McNiff JM, Zelterman D, Bothwell AL, Sweasy JB. 2014. Mutation of POLB causes lupus in mice. Cell Rep. 6(1):1-8.

Program Portrait: Understanding Mitochondria-Cell Signaling in Response to Environmental Stress

FY 2015 Level:	\$7.7 million
FY 2016 Level:	\$3.4 million
Change:	-\$4.3 million

Cells respond to environmental stressors through several key pathways, including response to reactive oxygen species (ROS), detection of nutrients and energy molecules, DNA damage response, and epigenetic regulation of gene expression. Mitochondria, the cell's "power plants," play a central role in these pathways through cell signaling (cross-talk between mitochondria and the cell) related to mitochondrial morphology, biogenesis, fission/fusion, cell death, and epigenetic regulation. Recent studies suggest that stressors such as toxic metals, pesticides, and air pollution can alter epigenetic activity, possibly through changes in the way mitochondria respond to differences in cell signaling. Mitochondria are also tightly integrated with cellular responses to DNA damage to both mitochondrial DNA and nuclear DNA, and are clearly involved in sensing and responding to ROS and oxygen levels in the cell. These are important areas of study because impacts on mitochondrial processes are of interest as potential contributors to a variety of diseases and conditions including autism, heart disease, cancer, diabetes, and obesity.

Current approaches to studying these mechanisms are often limited by the lack of precise measures of mitochondria-cell signaling. NIEHS has initiated a program to spur the development of innovative new technologies and experimental models that will enable a more comprehensive understanding of mitochondrial-cell signaling in response to environmental stressors. The initial activity is a two-year exploratory research project focused on developing and demonstrating the performance of the technology or experimental model at the pilot scale using at least one environmental toxicant. Examples of environmental toxicants of interest due to their possible effects on mitochondria include pesticides, air pollution components, industrial chemicals, toxic metals, endocrine-disrupting compounds, ultraviolet light and ionizing radiation, and toxins produced by pathogenic organisms. A deeper understanding of signaling between the mitochondria and the nucleus or other cell pathways will lead to better understanding of how cells sense and respond to environmental stress, forming a more solid basis for developing early biomarkers for environmentally-related diseases. The FY 2016 for this program is \$3.3 million, a decrease of \$4.3 million. Less funding is needed in FY 2016 because earlier projects are ending.

Exposure Research: This program is focused on the study of environmental exposures, both internal and external; not only chemical environmental pollutants, but also exposures arising from other sources such as the microbiome and nutritional sources. The program goals are to develop improved methods to detect and measure environmental exposures in humans, including biological markers, sensor and detector tools, remote exposures detection, better analytical methods, and informatics technologies.

Indoor air represents a significant source of exposure since people in the United States spend 90 percent of their time indoors. Indoor air quality can be compromised in water-damaged buildings where fungal growth is present. Adverse health outcomes in human populations, including neuropsychological impairments and movement disorders, have been linked to poor indoor air quality and fungal presence. Studies have indicated that man-made environmental agents may pose significant risk factors for developing Parkinson's Disease (PD). To investigate whether environmental chemicals produced by common fungus found in moldy homes contribute to the onset of PD, NIEHS funded researchers from Rutgers Robert Wood Johnson

Medical School and the Health and Exposome Research Center: Understanding Lifetime Exposures (HERCULES) at Emory University screened a variety of naturally occurring fungal toxicants using fruit flies. Genetic, biochemical, and immunological studies identified a compound from mold that exerts toxicity at low levels by disrupting dopamine handling.⁷ Dopamine is a chemical normally produced in the brain to help control muscle movement. In patients with PD, the brain cells that produce dopamine waste away, resulting in malfunction between the brain and the muscle. Increased incidence of PD has been shown in rural populations and the presence of mold in these environments may contribute to the incidence of PD. Future work will require epidemiological studies to provide a link between human populations exposed to the compound from mold and PD.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$55.754 million, an increase of \$0.141 million, or 0.3 percent above the FY 2015 level.

Translational Research and Special Populations: This program includes a wide set of research activities encouraging integration of clinical, population, and community-based research to translate findings into improved public health practice and disease prevention. These activities include research investments targeted towards understanding environmental risks to special populations (elderly people, children, and underserved populations) with an eye to developing interventions and solutions to real-world problems.

Research that is part of the NIEHS Breast Cancer and the Environment Research Program, a prospective cohort of more than 1,200 girls, found that breast development is occurring at earlier ages than previously documented, and that earlier development was strongly associated with greater body mass index (BMI).⁸ Earlier-than-average maturation is a risk factor for obesity and hypertension, as well as breast, ovarian, and endometrial cancer. From 2004 to 2011, researchers followed girls in the San Francisco Bay Area, Greater Cincinnati, and New York City who were six to eight years old when enrolled in the study. At regular intervals, staff assessed the girls' sexual maturity using standardized measures. They found that the age at onset of breast development (stage 2) varied by race/ethnicity, BMI at baseline, and geographical site. BMI was the strongest predictor of earlier age of breast maturity. For African American, Hispanic, white non-Hispanic, and Asian participants, the median age at onset of breast stage 2 was 8.8, 9.3, 9.7, and 9.7 years, respectively. Girls with BMIs greater than the 85th percentile reached breast stage 2 at younger ages regardless of race or ethnicity. Compared to data from studies conducted in the 1990s, white non-Hispanic girls are now maturing at younger ages while the maturation age for African American girls is similar to that found in the earlier studies. This cohort continues to be followed, creating possibilities for future analyses to provide clues to the causes of these developmental observations.

⁷ Inamdar AA, Hossain MM, Bernstein AI, Miller GW, Richardson JR, Wennstrom Bennett J. 2013. Fungal-derived semiochemical 1-octen-3-ol disrupts dopamine packaging and causes neurodegeneration. Proc Natl Acad Sci USA. 110(48):19561-6.

⁸ Biro FM, Greenspan LC, Galvez MP, Pinney SM, Teitelbaum S, Windham GC, Deardorff J, Herrick RL, Succop PA, Hiatt RA, Kushi LH, Wolff MS. 2013. Onset of breast development in a longitudinal cohort. Pediatrics 132:1019-1027.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$106.053 million, an increase of \$4.144 million, or 4.1 percent higher than the FY 2015 level.

Program Portrait: Household Air Pollution and Cookstoves

FY 2015 Level:\$4.1 millionFY 2016 Level:\$3.0 millionChange:-\$1.1 million

Chronic exposure to smoke from traditional cooking practices causes a range of health effects, including heart disease, stroke, and acute respiratory infections. Most deaths occur in low- and middle-income countries, with women and children disproportionately exposed, but many rural households in the U.S. are also exposed to indoor smoke. The NIEHS Household Air Pollution program takes a multi-pronged approach to understanding the global health impact of cookstoves, including research to assess exposures and determine health outcomes, support of improved cookstove design and intervention trials, as well as training and capacity building to support these efforts.

NIEHS currently supports 32 individual grants in 17 different countries. A newly funded study will evaluate the impact of a clean cookstove and fuel intervention on exposure to airborne pollutants, health, and poverty in Western Rwanda. This public-private partnership will include distribution of free cookstoves to 50 households and the implementation of a fuel pellet business, in tandem with a randomized control trial to assess the impact of this intervention on exposure of the primary household cook to carbon monoxide, particulate matter, and polycyclic aromatic hydrocarbons, and modeling of the dose-response relationship between exposure and cardiovascular disease risk. Another new study will test the efficacy of two intervention strategies for reducing indoor wood smoke PM2.5 exposures and children's risk of lower respiratory tract infections (LRTIs) in western Montana, Navajo Nation communities, and Alaska Native communities.

The key to improving the success of cookstove programs is being able to answer the question, "How clean is clean enough?" Another effort will inform this answer through development of a comprehensive profile of gaseous and particulate pollutants emitted from traditional and improved cookstoves combined with a controlled human exposure study to investigate acute, subclinical effects of exposure to emissions from prevalent cookstove technologies. This is the first study to examine the relationship between markers of cardiorespiratory health and exposure to a broad range of stove technologies.

Limited past research has shown that despite the enormity of the public health problem that household air pollution presents, demand for clean cookstoves is low and households continue to use traditional hearths even when they have clean stoves—behaviors that threaten to undermine intervention programs such as those promoted by the Global Alliance for Clean Cookstoves. A new study will harness past investment in an existing cohort in Ghana to study factors that increase the adoption of clean cookstoves and to test strategies to promote adoption and continued use so that health gains may be realized.

Predictive Toxicology: The mission of the NIEHS extramural research investment in the National Toxicology Program (NTP) is to evaluate environmental agents of public health concern, and generate information to be used by health regulatory agencies to make informed decisions affecting public health. NTP also works to develop new and improved test methods, including alternatives to animal testing and high-throughput methods to test substances faster, in order to disseminate useful public health information more rapidly. NTP research also helps to develop new and improved models of toxicity that can help to predict cancer and other adverse health outcomes that may result from fetal or early life exposures.

In FY 2014, the NIEHS Division of the National Toxicology Program (DNTP) made significant advancements in developing public health tools with the release of the NTP Nonneoplastic Lesion Atlas. The NTP Nonneoplastic Lesion Atlas is a web-based resource that contains over a thousand high-quality images and guidelines for diagnosing nonneoplastic lesions in experimental rodent models.⁹ Nonneoplastic diseases, such as cardiovascular and pulmonary diseases, are a major cause of illness and death, and many are thought to have environmental causes. Diagnosing nonneoplastic lesions can be challenging, because terminology and diagnostic strategies vary among pathologists. The purpose of the Nonneoplastic Lesion Atlas is to standardize the terminology, diagnostic strategy, and recording of nonneoplastic rodent lesions. Thus, the Nonneoplastic Lesion Atlas will improve the consistency of the NTP nonneoplastic lesion database and facilitate database searches, comparisons between studies, and generation of historical control data.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$87.008 million, the same as the FY 2015 level.

Training and Education: This program's goal is to attract the brightest students and scientists into the environmental health sciences field, to continue mentored training along the career trajectory, and to build research capacity, both here and abroad, to ensure a cadre of professionals to conduct the interdisciplinary research necessary to solve critical environmental health problems. The program includes efforts at the high school and undergraduate levels (opportunities for laboratory-based training), the graduate level (institutional training grants and individual fellowships), and the faculty level (grants for young investigators).

The NIEHS co-funds, with the Fogarty International Center, the Hubs of Interdisciplinary Research and Training in Global Environmental and Occupational Health (GEOHealth) – Research Training (U2R) program. The GEOHealth program is designed to support the development of institutions in low- or middle-income countries (LMICs) to serve as regional hubs for collaborative research, data management, training, curricula and outreach material development, and policy support. GEOHealth hubs are expected to bring together multiple disciplines to advance the pace of scientific discovery around high priority local, national, and regional environmental and occupational health threats such as household air pollution, climate change, agricultural health, electronic waste, worker safety, and others. Each GEOHealth hub is supported by two coordinated and linked awards: one to an LMIC institution for research and one to a U.S. institution to coordinate research training. NIEHS currently supports GEOHealth hubs in Nicaragua, Uganda, Peru, Romania, Ghana, Ukraine, Thailand, Ethiopia, Gambia, China, and Colombia.

The goal of the training component of GEOHealth is to develop research training and career development programs for LMIC scientists and health research professionals in a variety of disciplines directly in support of and informed by the research activities supported by the grant. Mentored training is targeted toward individuals who will pursue responsible positions in

⁹ Cesta MF, Malarkey DE, Herbert RA, Brix A, Hamlin MH 2nd, Singletary E, Sills RC, Bucher JR, Birnbaum LS. The National Toxicology Program Web-based nonneoplastic lesion atlas: a global toxicology and pathology resource. Toxicol Pathol. 2014; 42(2): 458-60.

research and environmental and occupational health-oriented public health in their home countries, and aimed at facilitating the transition of trainees to positions of responsibility, authority, and influence in their home countries, regionally, and internationally. The program also supports the development of curricula for research training in environmental and occupational health that will help build in-depth scientific expertise in fields such as exposure science and epidemiology; provide training in inter- or multidisciplinary research; and enhance complementary skills such as data management, scientific communication, and ethical treatment of human subjects.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$39.779 million, an increase of \$1.109 million, or 2.9 percent over the FY 2015 level. The increase will support the Outstanding New Environmental Scientist (ONES) program described in the following portrait.

Program Portrait: Outstanding New Environmental Scientist (ONES)

 FY 2015 Level:
 \$5.4 million

 FY 2016 Level:
 \$6.0 million

 Change:
 +\$0.6 million

NIEHS continues to build momentum in preparing a talented biomedical research workforce through its ONES program. Launched in 2006, this thriving program has awarded ONES funding to 42 promising new scientists, in the first decade of their careers. The program is uniquely tailored to early investigators to support career advancement of the next generation of outstanding new environmental scientists across multiple, diverse fields within environmental research. Not only do ONES awardees receive research funding, but also they are provided money designated for lab resources and equipment, travel to conferences, and travel to visit other labs. These special benefits provide an infrastructure that could be the difference between surviving and thriving in the biomedical research workforce.

The ONES awardees' accomplishments demonstrate the resounding success of our program with more than half receiving tenure or promotion to associate professor, one who received full professorship and became the director of a Section within the Department of Medicine at the University of Chicago, and another awardee who won the prestigious Presidential Early Career Award for Scientists and Engineers (PECASE) for outstanding research. In addition, ONES awardees have been successful at winning 38 additional NIEHS grants outside of the ONES grant and have published hundreds of papers that contribute to the advancement of environmental health sciences. The triumph of the NIEHS's innovative ONES program has garnered attention outside of the institute resulting in our sister institute, the National Institute of Mental Health, modeling their thriving Behavioral Research Awards for Innovative New Scientists (BRAINS) program after our ONES program. In FY 2015, NIEHS welcomed five new awardees into the program and will continue to invest in the future of environmental scientists.

Intramural Research: NIEHS intramural research programs investigate the role of environmental agents in human disease and dysfunction and define the important biological and chemical processes that these agents affect. NIEHS intramural research studies are often longterm and comprise unique components, such as NIEHS's contribution to the NTP through its Division of the National Toxicology Program; epidemiological studies of environmentally associated diseases and exposures (including the study of individuals exposed by the Gulf Oil Spill); and intervention and prevention studies to reduce the effects of exposures to hazardous environments. The NIEHS Clinical Research Unit provides opportunities for clinical and basic scientists in the intramural programs to collaborate and learn how environmental exposures influence human health and disease.

The NIEHS intramural programs foster an environment conducive to high caliber science with high impact breakthroughs. During the past year, in support of the NIEHS Strategic Plan to examine susceptibility across the life span to environmental exposures, NIEHS intramural scientists have coupled high throughput screening tools and bioinformatic approaches to identify key regulatory components that act at different stages of development and are responsible for maintaining embryonic stem cells or allowing differentiation of cells into various organ systems. One example of a key regulatory component NIEHS intramural scientists have identified is a complex of proteins called INO80.¹⁰ The INO80 complex was shown to be required for maintaining embryonic stem cells, allowing differentiated cells to undergo reprogramming to another cell type, and forming a key structure in early embryonic development necessary for life. By focusing on basic research, NIEHS scientists have begun to unravel the mystery surrounding the mechanisms that allow embryonic stem cells to remain undifferentiated. For the first time, our scientists have shown that the INO80 complex does its job by regulating key genes and epigenetic processes. Ongoing efforts are being made to tease apart the details of these regulatory mechanisms, identify periods of susceptibility to environmental exposures, and expand these findings to the development of different organ systems using genetically engineered animal models. This work will provide important clues for identifying critical periods and mechanisms of susceptibility during human development.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$185.543 million, an increase of \$1.846 million, or 1.0 percent over the FY 2015 level. Additional funds will cover pay related costs, including the 1.3% pay raise, the increase in retirement contributions, and the increase in federal employee health benefit premiums.

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 oversees approximately 840 research grants and centers. RMS also provides administrative support for the Intramural Research program. Other RMS functions include strategic planning, coordination, and evaluation of NIEHS programs; regulatory compliance; ethics training and compliance; and liaison with other Federal agencies, Congress, stakeholders, and the public.

NIEHS and the Fogarty International Center (FIC) have developed a new tool, CareerTrac, a novel database to track the post-training career decisions of our trainees. Its primary purpose is to follow and report short and long-term trainee outcomes, thereby enabling informed management decisions about biomedical research training programs. CareerTrac currently includes outcome data for nearly 10,000 trainees, including long-term and qualitative data that

¹⁰ Wang L, Du Y, Ward JM, Shimbo T, Lackford B, Zheng X, Miao Y, Zhou B, Han L, Fargo DC, Jothi R, Williams CJ, Wade PA, Hu G. 2014. INO80 facilitates pluripotency gene activation in embryonic stem cell self-renewal, reprogramming, and blastocyst development. Cell Stem Cell. 14(5):575-91.

will help NIEHS to improve training programs and continue to be able to meet the environmental health challenges faced by our country and our world.

Budget Policy:

The FY 2016 President's Budget estimate for this program is \$25.584 million, an increase of \$0.254 million, or 1.0 percent over the FY 2015 level. Additional funds will cover pay related costs, including the 1.3% pay raise, the increase in retirement contributions, and the increase in federal employee health benefit premiums.

Budget Authority by Object Class¹ (Dollars in Thousands)

		FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Total co	mpensable workyears:			
	Full-time employment	661	661	0
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	\$175	\$175	\$0
	Average GM/GS grade	11.6	11.6	0.0
	Average GM/GS salary	\$88	\$89	\$1
	Average salary, grade established by act of July 1,	¢07	909	¢ 1
	1944 (42 U.S.C. 207)	\$97	\$98	\$1
	Average salary of ungraded positions	\$132	\$133	\$1
			FY 2016 President's	FY 2016
	OBJECT CLASSES	FY 2015 Enacted	Budget	+/-
	Description of the second seco			FY 2015
111	Personnel Compensation	¢ 40.017	¢ 40,001	\$504
11.1	Full-Time Permanent	\$42,217	\$42,801	\$584
11.3	Other Than Full-Time Permanent	21,300	21,594	295
11.5	Other Personnel Compensation	854	866	12
11./	Military Personnel	903	916	12
11.8	Special Personnel Services Payments	7,468	7,571	103
11.9	Subtotal Personnel Compensation	\$72,742	\$73,748	\$1,006
12.1	Civilian Personnel Benefits	\$20,405	\$20,817	\$412
12.2	Military Personnel Benefits	617	629	12
13.0	Benefits to Former Personnel	0	0	0
21.0	Subtotal Pay Costs	\$93,764	\$95,194	\$1,431
21.0	Travel & Transportation of Persons	\$1,664	\$1,691	\$27
22.0	Provide Deservation of Things	582	591	9
23.1	Rental Payments to GSA	0	0	0
23.2	Communications Utilities & Miss. Charges	1 205	1 216	0
25.5	Drinting & Depreduction	1,293	1,510	21
24.0	Consulting Services	/ دعرون	/ ۲۵۱۵	\$2
25.1	Other Services	¢209 41 655	\$213 40.860	چې 705
23.2	Purchase of goods and services from government	41,035	40,000	-195
25.3	accounts	94,522	99,137	4,614
25.4	Operation & Maintenance of Facilities	\$4,231	\$4,231	\$0
25.5	R&D Contracts	101,970	102,174	203
25.6	Medical Care	227	233	6
25.7	Operation & Maintenance of Equipment	4,190	4,257	67
25.8	Subsistence & Support of Persons	0	0	0
25.0	Subtotal Other Contractual Services	\$247,005	\$251,104	\$4,099
26.0	Supplies & Materials	\$9,333	\$9,405	\$71
31.0	Equipment	6,833	6,843	10
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	306,822	315,603	8,781
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	2	2	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	\$573,569	\$586,588	\$13,018
	Total Budget Authority by Object Class	\$667,333	\$681,782	\$14,449

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015	
Personnel Compensation				
Full-Time Permanent (11.1)	\$42,217	\$42,801	\$584	
Other Than Full-Time Permanent (11.3)	21,300	21,594	295	
Other Personnel Compensation (11.5)	854	866	12	
Military Personnel (11.7)	903	916	12	
Special Personnel Services Payments (11.8)	7,468	7,571	103	
Subtotal Personnel Compensation (11.9)	\$72,742	\$73,748	\$1,006	
Civilian Personnel Benefits (12.1)	\$20,405	\$20,817	\$412	
Military Personnel Benefits (12.2)	617	629	12	
Benefits to Former Personnel (13.0)	0	0	0	
Subtotal Pay Costs	\$93,764	\$95,194	\$1,431	
Travel & Transportation of Persons (21.0)	\$1,664	\$1,691	\$27	
Transportation of Things (22.0)	582	591	9	
Rental Payments to Others (23.2)	27	27	0	
Communications, Utilities & Misc. Charges (23.3)	1,295	1,316	21	
Printing & Reproduction (24.0)	7	7	0	
Other Contractual Services:				
Consultant Services (25.1)	209	213	3	
Other Services (25.2)	41,655	40,860	-795	
Purchases from government accounts (25.3)	62,162	63,251	1,089	
Operation & Maintenance of Facilities (25.4)	4,231	4,231	0	
Operation & Maintenance of Equipment (25.7)	4,190	4,257	67	
Subsistence & Support of Persons (25.8)	0	0	0	
Subtotal Other Contractual Services	\$112,448	\$112,812	\$364	
Supplies & Materials (26.0)	\$9,333	\$9,405	\$71	
Subtotal Non-Pay Costs	\$125,355	\$125,848	\$493	
Total Administrative Costs	\$219,119	\$221,043	\$1,924	

Detail of Full-Time Equivalent Employment (FTE)

	FY 2014 Actual		FY 2015 Est.		FY 2016 Est.				
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Research	(0)		(0)	(0		(0	(0		(0
Direct:	69	-	69	69	-	69	69	-	69 1
Total:	1 70	-	1	1 70	-	1 70	1 70	-	1
Total:	70	-	70	70	-	70	70	-	70
Division of Intramural Research									
Direct:	320	3	323	324	3	327	324	3	327
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	321	3	324	325	3	328	325	3	328
Division of National Toxicology Program									
Direct:	107	1	108	107	1	108	107	1	108
Reimbursable:	107	-	100	107	1	100	107	_	100
Total:	107	1	108	107	1	108	107	1	108
Total.	107	1	100	107	1	100	107	1	100
Office of Management									
Direct:	101	2	103	101	2	103	101	2	103
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	101	2	103	101	2	103	101	2	103
Office of the Director									
Direct	50	2	52	50	2	52	50	2	52
Beimburgable:	50	2	52	50	2	52	50	2	52
Total:	50	2	52	50	2	52	50	2	52
Total.	50	2	52	50	2	52	50	2	52
Total	649	8	657	653	8	661	653	8	661
Includes FTEs whose payroll obligations at	Includes FTEs whose payroll obligations are supported by the NIH Common Fund.								
FTEs supported by funds from									
Cooperative Research and Development	0	0	0	0	0	0	0	0	0
Agreements.									
FISCAL YEAR	Average GS Grade								
2012	11.5								
2013	11.5								
2014	11.6								
2015					11.6				
2016	11.6								

GRADE	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	175,017	176,767	178,535
GM/GS-15	40	40	40
GM/GS-14	48	48	48
GM/GS-13	106	106	106
GS-12	103	104	104
GS-11	94	95	95
GS-10	1	1	1
GS-9	48	48	48
GS-8	15	15	15
GS-7	28	28	28
GS-6	4	4	4
GS-5	1	1	1
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	1	1	1
Subtotal	489	491	491
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	4	4	4
Senior Grade	1	1	1
Full Grade	3	3	3
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	8	8	8
Ungraded	183	185	185
Total permanent positions	494	498	498
Total positions, end of year	681	685	685
Total full-time equivalent (FTE) employment, end of year	657	661	661
Average ES salary	175.017	176.767	178.535
Average GM/GS grade	11.6	11.6	11.6
Average GM/GS salary	87,563	88,439	89,323

Detail of Positions¹

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.