DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences (NIEHS)

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NOTE: The FY 2016 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

Toxicology Program Division of National Dr. John Bucher Director **Environmental Health** National Advisory **Sciences Council** National Institute of Environmental Health Sciences **Acting Director** Mr. Chris Long Management Office of NATIONAL INSTITUTES OF HEALTH **Organization Structure** Dr. Linda S. Birnbaum Director Research and Training Division of Extramural Dr. Gwen Collman Director Dr. Richard Woychik **Deputy Director** Division of Intramural Dr. Darryl Zeldin Research Director

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, [\$693,702,000]\$681,613,000.

Amounts Available for Obligation¹

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	\$667,502	\$693,702	\$693,533
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(0)	(0)	(0)
Other Mandatory financing	(0)	(0)	(11,920)
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	\$667,502	\$693,702	\$693,533
OAR HIV/AIDS Transfers	-169	-169	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	\$667,333	\$693,533	\$693,533
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$667,333	\$693,533	\$693,533
Unobligated balance lapsing	-128	0	0
Total obligations	\$667,205	\$693,533	\$693,533

 $^{^1}$ Excludes the following amounts for reimbursable activities carried out by this account: FY 2015 - \$9,912 FY 2016 - \$10,011 FY 2017 - \$10,111

NATIONAL INSTITUTES OF HEALTH FY 2017 Congressional Justification **NIEHS**

Budget Mechanism - Total¹

MECHANISM	(Dollars in Tho			2016 Enacted	FY 20	17 President's	FY 2017 +/-	
MECHANISM	FY	2015 Actual	FY.	2016 Enacted		Budget ³		+/- FY 2016
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	414	\$169,423	439	\$172,171	433	\$172,393	-6	\$222
Administrative Supplements	(40)	3,276	(31)	2,500	(31)	2,500		
Competing:								
Renewal	13	5,403	14	5,796	14	5,796		
New	165	52,470	179	56,890	175	55,694	-4	-1,196
Supplements	5	1,849	5	2,000	5	2,000		
Subtotal, Competing	183	\$59,722	198	\$64,686	194	\$63,490	-4	-\$1,196
Subtotal, RPGs	597	\$232,421	637	\$239,357	627	\$238,383	-10	-\$974
SBIR/STTR	39	14,752	41	15,613	41	16,483	10	870
Research Project Grants	636	\$247,173	678	\$254,970	668	\$254,866	-10	-\$104
Research Centers:								
Specialized/Comprehensive	29	\$36,066	29	\$38,850	29	\$37,850		-\$1,000
Clinical Research								
Biotechnology								
Comparative Medicine								
Research Centers in Minority Institutions								
Research Centers	29	\$36,066	29	\$38,850	29	\$37,850		-\$1,000
Other Research:								
Research Careers	49	\$6,575	49	\$6,642	49	\$6,642		
Cancer Education								
Cooperative Clinical Research								
Biomedical Research Support								
Minority Biomedical Research Support		200		200		200		
Other	35	2,211	32	3,040	32	3,040		
Other Research	84	\$8,986	81	\$9,882	81	\$9,882		
Total Research Grants	749	\$292,225	788	\$303,702	778	\$302,598	-10	-\$1,104
Ruth L Kirchstein Training Awards:	FTTPs	61.526	FTTPs	01.556	FTTPs	¢1 577	<u>FTTPs</u>	¢21
Individual Awards	34	\$1,536		\$1,556	34	\$1,577		\$21
Institutional Awards	367 401	17,976	377	18,722	377	18,975		253
Total Research Training		\$19,512	411	\$20,278	411	\$20,552		\$274
Research & Develop. Contracts	112	\$145,365	112	\$151,051	112	\$149,581		-\$1,470
(SBIR/STTR) (non-add) ²	520	(145)	526	(208)	526	(218)		(10)
Intramural Research	530	\$185,028	536		536	\$194,240		\$1,932
Res. Management & Support	126	25,202	126	26,194	126	26,562		368
Res. Management & Support (SBIR Admin) (non-add) ²				(323)		(340)		(17)
Office of the Director - Appropriation ²								
Office of the Director - Other								
ORIP/SEPA (non-add) ²								
Common Fund (non-add) ²								
Buildings and Facilities								
Appropriation								
Type 1 Diabetes								
Program Evaluation Financing								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing	igspace					-11,920		-11,920
Subtotal, Labor/HHS Budget Authority	igspace	\$667,333		\$693,533		\$681,613		-\$11,920
Interior Appropriation for Superfund Res.	igspace			A-04 F		A-04-51-		
Total, NIH Discretionary B.A.	+	\$667,333		\$693,533		\$681,613		-\$11,920
Type 1 Diabetes	+							
Proposed Law Funding	+							
Cancer Initiative Mandatory Financing	igspace							
Other Mandatory Financing	igwdown			A-04 F		11,920		11,920
Total, NIH Budget Authority	igspace	\$667,333		\$693,533		\$693,533		
Program Evaluation Financing	igwdown			A-04 F		A-02 =		
Total, Program Level		\$667,333		\$693,533		\$693,533		

All Subtotal and Total numbers may not add due to rounding; excludes Ebola-related transfer from CDC to NIEHS.
 All numbers in italics and brackets are non-add.
 Includes mandatory financing.

Major Changes in the Fiscal Year 2017 President's Budget Request

There are no major program or budget mechanism changes. The FY 2017 President's Budget for NIEHS is the same as the FY 2016 Enacted level of \$693.533 million.

Summary of Changes

FY 2016 Enacted FY 2017 President's Budget		\$693,533 \$693,533
Net change		\$0
	FY 2017 President's Budget ¹	Change from FY 2016
CHANGES	FTEs Budget Authority	FTEs Budget Authority
A. Built-in:		
1. Intramural Research:		
a. Annualization of January 2016 pay increase & benefits	\$83,361	\$326
b. January FY 2017 pay increase & benefits	83,361	1,167
c. Two less days of pay	83,361	-639
d. Differences attributable to change in FTE	83,361	0
e. Payment for centrally furnished services	23,873	582
f. Increased cost of laboratory supplies, materials, other	87,006	495
expenses, and non-recurring costs	67,000	
Subtotal		\$1,932
2. Research Management and Support:		
a. Annualization of January 2016 pay increase & benefits	\$16,181	\$64
b. January FY 2017 pay increase & benefits	16,181	227
c. Two less days of pay	16,181	-124
d. Differences attributable to change in FTE	16,181	0
e. Payment for centrally furnished services	2,889	70
f. Increased cost of laboratory supplies, materials, other	7,491	131
expenses, and non-recurring costs	7,471	
Subtotal		\$368
Subtotal, Built-in		\$2,300

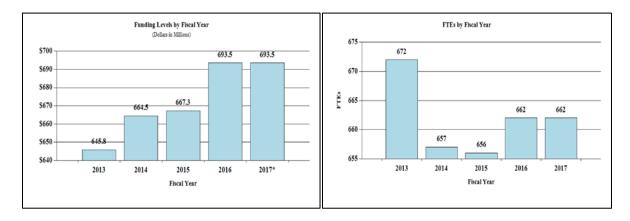
Summary of Changes - Continued

	FY 2017 Preside	ent's Budget¹	Change fro	m FY 2016
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	433	\$174,893	-6	\$222
b. Competing	194	63,490	-4	-1,196
c. SBIR/STTR	41	16,483	0	870
Subtotal, RPGs	668	\$254,866	-10	-\$104
2. Research Centers	29	\$37,850	0	-\$1,000
3. Other Research	81	9,882	0	0
4. Research Training	411	20,552	0	274
5. Research and development contracts	112	149,581	0	-1,470
Subtotal, Extramural		\$472,731		-\$2,300
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	536	\$194,240	0	\$0
7. Research Management and Support	126	26,562	0	0
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	662	\$693,533	0	-\$2,300
Total changes				\$0

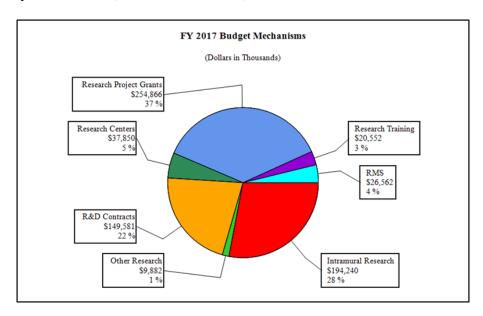
¹ Includes mandatory financing.

Fiscal Year 2016 Budget Graphs

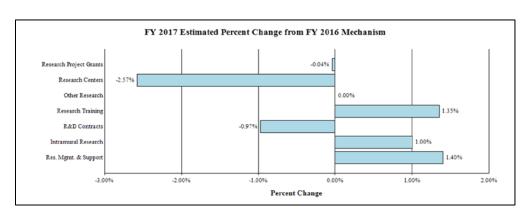
History of Budget Authority by FTEs:



Distribution by Mechanism (dollars in thousands):



Change by Selected Mechanism:



Budget Authority by Activity¹ (Dollars in Thousands)

	FY 2015 Actual		FY 2016 Enacted			President's dget ²	FY 2 + FY2	-
Extramural Research	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
<u>Detail</u>								
Fundamental Research		\$205,100		\$213,144		\$212,266		-\$878
Exposure Research		64,722		67,261		66,779		-482
Translational Research and Special Populations		76,830		79,843		79,270		-573
Predictive Toxicology		85,777		89,141		88,503		-638
Training and Education		24,674		25,642		25,913		271
Subtotal, Extramural		\$457,103		\$475,031		\$472,731		-\$2,300
Intramural Research	530	\$185,028	536	\$192,308	536	\$194,240	0	\$1,932
Research Management & Support	126	\$25,202	126	\$26,194	126	\$26,562	0	\$368
TOTAL	656	\$667,333	662	\$693,533	662	\$693,533	0	\$0

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Environmental Health Sciences

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget¹
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Environmental Health			^	\$693,533,000		\$681,613,000
Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total Budget Authority				\$693 533 000		\$681 613 000
Company of the Compan				000000000000000000000000000000000000000		000000000000000000000000000000000000000

¹Excludes mandatory financing.

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2007	\$637,323,000	\$637,323,000	\$641,292,000	\$642,002,000
Rescission				\$0
2008 Rescission	\$637,406,000	\$652,303,000	\$656,176,000	\$653,673,000 \$11,420,000
2009 Rescission	\$642,875,000	\$664,980,000	\$660,767,000	\$662,820,000 \$0
Supplemental 2010 Rescission	\$684,257,000	\$695,497,000	\$683,149,000	\$3,416,000 \$689,781,000 \$0
2011 Rescission	\$707,339,000		\$706,227,000	\$689,781,000 \$6,057,112
2012 Rescission	\$700,537,000	\$700,537,000	\$676,033,000	\$686,869,000 \$1,298,182
2013 Rescission Sequestration	\$684,030,000		\$686,103,000	\$685,570,818 \$1,371,142 (\$34,410,941)
2014 Rescission	\$691,348,000		\$686,753,000	\$665,439,000 \$0
2015 Rescission	\$665,080,000			\$667,502,000 \$0
2016 Rescission	\$681,782,000	\$675,783,000	\$695,900,000	\$693,702,000 \$0
2017¹	\$693,533,000			

¹ Includes mandatory financing.

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 2017	
	FY 2015	FY 2016	President's	FY 2017 +/-
	Actual	Enacted	Budget	FY 2016
BA	\$667,333,000	\$693,533,000	\$693,533,000	\$0
FTE	656	662	662	0

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

Director's Overview

The National Institute of Environmental Health Sciences (NIEHS) will be celebrating its 50th anniversary in FY 2017! NIEHS was established November 1, 1966. Throughout its history, NIEHS has worked to fulfill its mandate from Congress: "the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly." The NIEHS mission statement flows directly from its legislative origin: "to discover how the environment affects people in order to promote healthier lives."

NIEHS's task – understanding environmental exposures and their effects on human biology and health – is a broad one, enabling this institute to make profound contributions across almost all aspects of health and disease. As always, basic biomedical science is the key to future advances; this knowledge can pave the way for new strategies to prevent and treat diseases and developmental disorders. For example, in one of the first U.S.-wide studies of air pollution and autism, NIEHS grantees reported that when women were exposed to high levels of fine particulate matter from air pollution during pregnancy – particularly in the third trimester – those levels were associated with an elevated risk of having a child with autism compared with that observed in mothers exposed to low levels of particulate matter. ¹ The results suggest that reducing pregnant women's exposure to air pollution may reduce the incidence of this complex neurodevelopmental disorder that creates a life-long burden on children and their families.

When it comes to our environmental health, as in most other things, not all of us are the same. It is important to understand not just what environmental exposures can do, but also the differences in the effects of these exposures from one individual to another. NIEHS is leading the way in creating new methods to measure and understand differences in susceptibility to environmental

¹ Raz R, Roberts AL, Lyall K, Hart JE, Just AC, Laden F, Weisskopf MG. 2014. Autism spectrum disorder and particulate matter air pollution before, during, and after pregnancy: A nested case-control analysis within the Nurses' Health Study II Cohort. Environ Health Perspect; doi:10.1289/ehp.1408133

agents; this capacity will ultimately form a critical component of the Precision Medicine Initiative. For example, NIEHS investigators are using a recently developed population of mice, known as Diversity Outbred mice, which have been shown to possess a level of genetic variability similar to humans. In a recent study with these mice, the researchers observed differences in the toxicity response to benzene, a known human carcinogen.² In such studies, scientists can improve their ability to estimate exposure thresholds as well as better pinpoint genetic variants that determine individual responses to toxicant exposures and better model the human population.

Individual response variability can also be related to the lifestage at which exposure occurs. NIEHS continues to expand its study of known factors of environmental susceptibility into the time, or developmental, dimension. Some types of maternal exposures during gestation have been shown to affect both fetal development and even offspring's health outcomes later in life. Other developmental "windows of susceptibility" such as puberty are being studied as well, in such diseases as breast cancer; they hold the promise of understanding pathogenic mechanisms of common, complex diseases which have previously proven difficult to unravel.

Realizing the full promise of Precision Medicine, including its environmental component, will ultimately require combining information on individual variability with information on the full range of environmental exposures experienced by an individual, sometimes termed the "exposome." To be able to do this, environmental health researchers are in great need of better tools and technologies to help them measure a wide range of exposures in their studies. To meet this need, NIEHS is moving forward with a new program in the area of children's environmental health research: the Children's Health and Exposure Assessment Resource (CHEAR). The CHEAR infrastructure will have three units: a National Exposure Assessment Laboratory Network will provide access to state-of-the-art infrastructure for analysis of biological samples and responses associated with those exposures; a Data Repository, Analysis, and Science Center will provide support for data collection, statistical analysis and interpretation, and development of data standards; and a Coordinating Center will support the effort and provide an interface with the research community. As with all "omics" technologies, studying the exposome is a "big data" enterprise; obtaining the full value of this research depends on the use of high level data science to analyze and understand the huge volumes of data generated.

NIEHS's obligation to its stakeholders and to the Nation as a whole requires a commitment to good stewardship of the resources entrusted to it. NIEHS takes this responsibility very seriously. The concept of stewardship and good decision-making was the fundamental basis for the extensive work undertaken by NIEHS three years ago to establish its Strategic Plan. NIEHS continues to use its plan to guide management of its research investments; the institute also tracks plan implementation using a variety of data metrics. An excellent example of the institute's commitment to transparency and good stewardship is the establishment of a framework in the National Toxicology Program for applying systematic review methodologies to

² Diversity Outbred Mice Identify Population-Based Exposure Thresholds and Genetic Factors that Influence Benzene-Induced Genotoxicity. French, JE (NTP), Gatti, DM, Morgan, DL (NTP), Kissling, GE (DIR), Shockley, KR (DIR), Knudsen, GA (OD), Shepard, KG, Price, HC, King, D (NTP), Witt, KL (NTP), Pedersen, LC (DIR), Munger, SC, Svenson, KL and Churchill, GA. Environ. Health Perspect. (2014)[ePub]

³ https://www.niehs.nih.gov/research/supported/dert/programs/chear/index.cfm

environmental health questions. Another example is the institute's practice of conducting Town Halls and other forms of outreach, which are designed to ensure that NIEHS addresses the public's concerns in its research investment priority-setting. NIEHS will continue to be responsive to the needs of the Nation for the best possible information and innovative research that improves public health by preventing disease and disability.

Overall Budget Policy:

The FY 2017 President's Budget request is \$693.533 million, the same as the FY 2016 Enacted level. NIEHS will maintain the average cost of competing grants at the FY 2016 operating level. Support for the NRSA training mechanism will increase.

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, cellular, tissue, organ, model organism, human, and population—and builds on the knowledge from new tools and techniques that allow us to ask more in-depth questions about the effects of our environment on biological systems.

In one example of the power and promise of fundamental science, researchers supported by NIEHS and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (including a recipient of an innovative NIEHS Pioneer Award), used a creative comparative approach to investigate the epigenetics of type 2 diabetes and found a strong similarity between obesity-induced epigenetic marks in mice and humans. ⁴ These findings might provide new routes to prevent and study obesity as well as insight into how the environment might bring about epigenetic changes that can lead to obesity-related diseases such as type 2 diabetes.

Epigenetic marks are chemical modifications, such as the addition of a methyl group, that change how DNA is expressed without changing the genetic code. The researchers analyzed more than seven million sites in the DNA of fat cells in lean and obese mice and found clear differences in methylation patterns. They also looked at how DNA methylation changes in people before and after gastric bypass surgery. Of the 625 regions of DNA with methylation patterns associated with obesity in the mice, 249 regions showed significant conserved methylation changes associated with obesity in people.

The investigators used genetic association data from a large type 2 diabetes genome-wide association study (GWAS) to link their findings with disease. This revealed that some of the obesity-associated methylation patterns affected genes known to raise diabetes risk while others affected genes that had not been conclusively linked to the disease but that did have roles in metabolism. It also identified some DNA regions that might be susceptible to environmental factors that influence methylation.

NIEHS-15

⁴ Multhaup ML, Seldin MM, Jaffe AE, Lei X, Kirchner H, Mondal P, Li Y, Rodriguez V, Drong A, Hussain M, Lindgren C, McCarthy M, Näslund E, Zierath JR, Wong GW, Feinberg AP. 2015. Mouse-human experimental epigenetic analysis unmasks dietary targets and genetic liability for diabetic phenotypes. Cell Metab. 21(1):138-149.

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$212.266 million, a decrease of \$0.878 million or 0.4 percent compared to the FY 2016 Enacted level.

Program Portrait: Developmental Origins of Health and Disease (DOHaD): The Role of the Placenta

FY2016 Level: \$2.3 million FY2017 Level: \$3.6 million Change: +\$1.3 million

Prenatal exposure to environmental chemicals during development (in utero and early childhood) can modify normal cellular and tissue development and function, especially at the level of the stem cell, resulting in increased susceptibility to effects such as delays in neurological development, asthma and other respiratory symptoms, reproductive effects, obesity and metabolic disorders, and cancer over the course of a person's lifetime. NIEHS supports research on such developmental origins of health and disease (DOHaD), examining the effects of agents such as Bisphenol A (BPA), phthalates, Polychlorinated Biphenyls (PCBs), pesticides, mercury, arsenic, ozone, and other air pollutants. This work is carried out in a wide variety of programs including the Centers for Children's Environmental Health & Disease Prevention Research, the BPA Research Program, the National Toxicology Program, and individual research projects. Recent studies have shown associations between early exposure to pesticides and ADHD, particulate air pollution and autism, and phenols, including the common soap ingredient triclosan, and early puberty onset in girls. A new NIEHS program, Environmental Influences on Placental Origins of Development (ePOD), will focus on understanding the role of the placenta, a physiologically active tissue that has the potential to impact the health of the fetus and the mother. The goals of this initiative are to accelerate the development and application of innovative models and approaches for placental exposure assessment, as well as to understand better the effects of environmental chemicals on early stage placental physiology, and endocrine and metabolic functions, including subsequent effects on fetal development. The ePOD program will foster collaborations with the National Institute of Child Health and Human Development's (NICHD's) Human Placenta Project to develop biomarkers to assess placental function across gestation to increase, ultimately, the chances of successful pregnancy outcomes.

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.

The controlled, *in situ* burning of contained crude oil trapped within surface booms on the water surface of the Gulf of Mexico during the 2010 Deepwater Horizon oil spill released numerous pollutants, including particulate matter. A study, funded by NIEHS and the National Institute of Allergy and Infectious Diseases (NIAID), revealed that acute exposure to the particulate matter from this burning is associated with lung inflammation and exacerbated allergic asthma in mice. For the study, the researchers used particulate matter collected from controlled-burn plumes. In cell studies, they found that the particulate matter caused toxicity and generated harmful reactive oxygen species and superoxide radicals. Mice exposed to the particulate matter exhibited significant decreases in body weight gain, systemic oxidative stress, and airway inflammation. The researchers also exposed a mouse model of allergic asthma to the particulate matter and

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⁵ <u>Jaligama S, Chen Z, Saravia J, Yadav N, Lomnicki SM, Dugas TR, Cormier SA.</u> 2015. Exposure to Deepwater Horizon crude oil burnoff particulate matter induces pulmonary inflammation and alters adaptive immune response. Environ Sci Technol 49(14):8769-8776

found an exacerbated allergic asthma response via increased T helper 2 cells, lung inflammation, and airway mucus production.

These findings provide valuable information for understanding potential health effects in people, especially those with preexisting lung conditions.

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$66.779 million, a decrease of \$0.482 million or 0.7 percent compared to the FY 2016 Enacted 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 (e.g., elderly people, children, and underserved populations) with an eye to developing interventions and solutions to real-world problems.

Researchers from two NIEHS Environmental Health Science Core Centers found that hospitalizations for heart conditions, neurological illness, and other health problems were higher among people living near unconventional gas and oil drilling sites in Pennsylvania. The work points to a need for more research looking at whether specific toxicants or mixtures from these sites may be increasing hospitalization rates.

From 2007 to 2011, the researchers examined the link between drilling well density and health care use by zip code in three northeastern Pennsylvania counties. Bradford and Susquehanna counties experienced a significant increase in drilling activity from 2007 to 2011, while Wayne county acted as the control because of a ban on drilling in that county. Using databases that contained over 198,000 hospitalizations (including multiple hospitalizations for the same person), the researchers associated the top 25 specific medical categories for hospitalizations with patients' proximity to active wells.

The analysis showed that the number of people hospitalized for cardiology and neurologic health problems were significantly higher in areas closer to active wells. Hospitalizations for skin conditions, cancer, and urologic problems were also associated with the proximity of dwellings to active wells. The authors say that more studies are necessary to compare toxicant exposure to number of wells. A more recent study using electronic health record data on over 9,000 mothers also associated exposure to unconventional natural gas development activity with two pregnancy outcomes, preterm birth and physician-recorded high-risk pregnancy.⁷

⁷ Casey JA, Savitz DA, Rasmussen SG, Ogburn EL, Pollak J, Mercer DG, Schwartz BS. Unconventional natural gas development and birth outcomes in Pennsylvania, USA. *Epidemiology* 2015 Sep 30, epub ahead of print. <u>PMID:</u> 26426945

⁶ Jemielita T, Gerton GL, Neidell M, Chillrud S, Yan B, Stute M, Howarth M, Saberi P, Fausti N, Penning TM, Roy J, Propert KJ, Panettieri RA Jr. 2015. Unconventional gas and oil drilling Is associated with increased hospital utilization rates. PLoS One. 2015 Jul 15;10(7):e0131093.

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$79.270 million, a decrease of \$0.573 million or 0.7 percent compared to the FY 2016 Enacted level.

Program Portrait: Breast Cancer

FY2016 Level: \$30.6 million FY2017 Level: \$30.6 million Change: \$0.0 million

The NIEHS and National Cancer Institute (NCI)-funded Breast Cancer and Environmental Research Program (BCERP) is entering a third phase, during which it will build upon successes to date while drawing upon the expert recommendations of the Interagency Breast Cancer and Environmental Research Coordinating Committee to tackle emerging opportunities. Key new directions include promoting transdisciplinary research, in which scientists in the lab (conducting animal or cell-based studies), those conducting human studies, and community partners work together. By exchanging information, sharing resources, and integrating knowledge, such teams, including six to eight new groups, will be better able to stimulate new research approaches and accelerate the translation of research findings into disease prevention. BCERP investigations will also expand to other intermediate risk factors for breast cancer such as breast density and health disparities. New funding announcements will promote dissemination n research to support more effective translation of research findings into risk messages and preventive strategies. In addition to BCERP, NIEHS supports breast cancer research through more than 80 individual grants, a strong program of epidemiological research, and innovative research across multiple disciplines. Recent findings from the Two Sister Study, an offshoot of the Sister Study, showed that estrogen hormone therapy was found to offer some protection against young-onset breast cancer, while combined estrogen and progestin hormone therapy was not associated with the disease. Genomic research has identified a mutation-causing enzyme, known as A3A, as most likely the main cause of DNA mutations in certain cancers, including breast cancers. Other research is mounting evidence that exposure to environmental chemicals such as endocrine disruptors in the womb or early childhood increases the risk for development of breast cancer as an adult.

Program Portrait: Centers of Excellence on Health Disparities Research

FY 2016 Level: \$1.5 million FY 2017 Level: \$1.5 million Change: \$0.0 million

Environmental factors are fundamental determinants of public health and can lead to disease and health disparities when the environments where people live, work, learn, and play are burdened by chemicals and social inequities, such as socioeconomic status, literacy levels, and healthcare access. Environmental health disparities exist when health outcomes differ between populations based on the extent of environmental risk factors and social inequities. In the United States, people of color, low-income communities, and tribal populations have been, and continue to be, disproportionately exposed to environmental conditions that can harm their health. The economic burden of health disparities has been estimated at \$1.24 trillion in the United States between 2003-2006. Reducing environmental health disparities is a key component of NIEHS' Strategic Plan and the Centers of Excellence on Environmental Health Disparities (EHD) Research, a joint research program with the Environmental Protection Agency (EPA) and the National Institute of Minority Health and Disparities (NIMHD), are one piece of our investment in this area of need. NIEHS is funding five EHD Centers that combine basic and translational research and community involvement to improve understanding of environmental health disparities as well as identify mitigation and prevention strategies to decrease the public health burden. One of the centers, Maternal And Developmental Risks from Environmental and Social Stressors (MADRES) Center for Environmental Health Disparities, will examine the determinants of childhood and maternal obesity among Hispanic children and mothers in California, where the largest Hispanic population in the U.S. resides, and who have the greatest cumulative burden of harmful environmental exposures, as well as elevated rates of obesity. Another program at the University of New Mexico, the Center for Indigenous Environmental Health Research, will partner with several American Indian communities to evaluate environmental exposures through traditional foods, water, air, and household environments, while the

Community Engagement Core will translate and communicate research findings to mitigate and prevent health disparities in affected populations. By emphasizing Native-focused community engagement, the Center for Native American Environmental Health Equity Research will integrate risk and resilience factors across multiple tribes, improve understanding of the determinants of existing health disparities, and develop evidence-based risk reduction and prevention strategies to reduce health disparities faced by Native American populations.

Predictive Toxicology: The mission of the 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 January 2014, a liquid used to wash coal was spilled into the West Virginia Elk River, a primary municipal water source serving about 300,000 people in the Charleston area. At the request of the senior U.S. Senator from West Virginia and of the CDC, NTP was tasked with designing and carrying out a rapid research program to evaluate the adequacy of the acceptable contaminant levels in the public water supply that were recommended at the time of the spill. NTP assessed the primary spilled chemicals in a series of innovative toxicity studies to predict the potential for toxicity to pregnant women, the group thought to be most potentially sensitive to adverse health effects. The studies focused on developmental effects in rodents, zebrafish, and worms, genetic effects in bacteria, and toxic and hormonal effects in human cells exposed in vitro, coupled with chemical structure activity computer modeling. Throughout the year of conducting these toxicity tests, NTP regularly updated the public and other Federal agencies on study findings. NTP's studies found that 4-methylcyclohexanemethanol (MCHM), the main component of the spill, was a skin irritant at high concentrations, and caused decreased weight gain in fetuses of pregnant rats exposed to very high doses. No significant health effects were found for the other spilled chemicals. Collectively, the findings from the NTP studies supported the adequacy of the public health drinking water advisory levels established at the time of the chemical spill.

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$88.503 million, a decrease of \$0.638 million or 0.7 percent compared to the FY 2016 Enacted 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 NIH Pathway to Independence Award provides up to five years of support for young investigators at a critical time in their career development. NIEHS has had a long standing

commitment in this area; the current Pathway awards are based in part on an earlier NIEHS program. The current program has two phases: the initial award (K99) provides one to two years of mentored, postdoctoral support. The second phase (R00) provides up to three years of independent research support and is activated when the awardee accepts a full time tenure track (or equivalent) faculty position. NIEHS currently funds 24 K99 awardees and 33 R00's. In one example of the promising work being done by these exciting young scientists, a K99 investigator used environment-wide association studies and computational methods to create the first "exposome globe," a tool capable of depicting complex relationships between multiple different exposures, as well as adverse health outcomes.⁸

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$25.913 million, an increase of \$0.271 million or 1.1 percent compared to the FY 2016 Enacted level.

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 long-term 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 identify and understand fundamental shared mechanisms or common biological pathways, which underlie a broad range of complex diseases such as cancer, NIEHS intramural scientists have coupled studies in yeast models, high throughput DNA sequencing, and bioinformatic approaches applied to large publically available data sets in The Cancer Genome Atlas to identify key regulatory components that act to induce mutations that lead to the development of cancer in humans.

One example of a key regulatory component NIEHS intramural scientists have identified is a group of enzymes called APOBEC cytidine deaminases (Chan et al., 2015). APOBEC cytidine deaminases are single-strand DNA specific enzymes that are a major source of mutation in several cancer types. By focusing on basic research, NIEHS scientists have begun to identify which APOBEC cytidine deaminases are responsible for hypermutation found in human cancers. Ongoing efforts are being made to identify other members of this family of enzymes that can lead to cancer causing mutations, to tease apart the details of the regulatory mechanisms that

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⁸ Development of exposome correlation globes to map out environment-wide associations. <u>Patel CJ</u>, <u>Manrai AK</u>. Pac Symp Biocomput. 2015;231-42.http://www.ncbi.nlm.nih.gov/pubmed/25592584

⁹ Chan K, Roberts SA, Klimczak LJ, Sterling JF, Saini N, Malc EP, Kim J, Kwiatkowski DJ, Fargo DC, Mieczkowski PA, Getz G, Gordenin DA. An APOBEC3A hypermutation signature is distinguishable from the signature of background mutagenesis by APOBEC3B in human cancers. *Nat. Genet.*, 47(9):1067-1072, 2015.

control these enzymes, and to identify environmental exposures that alter the regulation and function of these enzymes to help point the way towards the development of applicable prevention and intervention strategies.

Other areas of the NIEHS Intramural Program focus on clinical environmental health research and environmental epidemiology. NIEHS has partnered with NCI for more than 20 years on the Agricultural Health Study, a prospective cohort of farmers and their spouses from Iowa and North Carolina. This long-term investment in an important research area has been coming to fruition over the past several years, with an abundance of landmark reports coming out in the published scientific literature. The researchers have looked at a wide variety of health outcomes, such as Parkinson's disease (PD), end stage renal disease, depression, respiratory disease, and many types of cancer. For example, one study found a positive association between pesticide exposure and depression, including associations with several specific pesticides.¹⁰ More recently, the researchers examined whether protective glove use and hygiene could modify the association with a specific health outcome, and found that protective glove use and hygiene practices appeared to be important modifiers of the association between pesticides and PD and may reduce risk of PD associated with certain pesticides.¹¹

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$194.240 million, an increase of \$1.932 million or 1.0 percent compared to the FY 2016 Enacted level. Additional funds will cover pay related costs, including the 1.6 percent 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 827 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.

A core function of Research Management and Support is evaluation of NIEHS's research investment. In 2015, NIEHS completed a major report and evaluation of its flagship Environmental Health Sciences Core Centers program. This evaluation focused on the extent to which the Centers foster and produce complex, emerging, and translational environmental health research, the strategies they use to facilitate this research, and the impacts of the research. The evaluation also addressed the strategies by which the Centers support career development and the NIEHS strategic plan.

¹⁰ Beard JD, Umbach DM, Hoppin JA, Richards M, Alavanja MC, Blair A, Sandler DP, Kamel F. Pesticide exposure and depression among male private pesticide applicators in the agricultural health study. *Environ Health Perspect*. 2014 Sep;122(9):984-91. doi: 10.1289/ehp.1307450. Epub 2014 Jun 6.

Furlong M, Tanner CM, Goldman SM, Bhudhikanok GS, Blair A, Chade A, Comyns K, Hoppin JA, Kasten M, Korell M, Langston JW, Marras C, Meng C, Richards M, Ross GW, Umbach DM, Sandler DP, Kamel F. Protective glove use and hygiene habits modify the associations of specific pesticides with Parkinson's disease. Environ Int. 2015 Feb;75:144-50. doi: 10.1016/j.envint.2014.11.002. Epub 2014 Nov 21

Budget Policy:

The FY 2017 President's Budget estimate for this program is \$26.562 million, an increase of \$0.368 million or 1.4 percent compared to the FY 2016 Enacted level. Additional funds will cover pay related costs, including the 1.6 percent pay raise, the increase in retirement contributions, and the increase in federal employee health benefit premiums.

Budget Authority by Object Class¹

		FY 2016 Enacted	FY 2017 President's Budget ²	FY 2017 +/- FY 2016
Total cor	mpensable workyears:			
	Full-time employment	662	662	0
	Full-time equivalent of overtime and holiday hours	1	1	0
	Average ES salary	\$186	\$188	\$3
	Average GM/GS grade	11.8	11.8	0.0
	Average GM/GS salary	\$91	\$92	\$1
	Average salary, grade established by act of July 1,	·		
	1944 (42 U.S.C. 207)	\$101	\$102	\$2
	Average salary of ungraded positions	\$140	\$142	\$2
	OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget ²	FY 2017 +/- FY 2016
	Personnel Compensation			
11.1	Full-Time Permanent	\$43,120	\$43,448	\$328
11.3	Other Than Full-Time Permanent	23,018	23,193	175
11.5	Other Personnel Compensation	946	953	7
11.7	Military Personnel	827	833	6
11.8	Special Personnel Services Payments	7,873	7,933	60
11.9	Subtotal Personnel Compensation	\$75,783	\$76,360	\$577
12.1	Civilian Personnel Benefits	\$22,238	\$22,679	\$440
12.2	Military Personnel Benefits	499	503	4
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	\$98,521	\$99,542	\$1,021
21.0	Travel & Transportation of Persons	\$1,753	\$1,784	\$32
22.0	Transportation of Things	571	581	10
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	52	52	1
23.3	Communications, Utilities & Misc. Charges	1,099	1,119	20
24.0	Printing & Reproduction	13	13	0
25.1	Consulting Services	\$667	\$679	\$12
25.2	Other Services	48,330	45,973	-2,357
25.3	Purchase of goods and services from government accounts	98,468	100,116	1,648
25.4	Operation & Maintenance of Facilities	\$5,837	\$5,942	\$105
25.5	R&D Contracts	96,081	97,301	1,220
25.6	Medical Care	436	447	12
25.7	Operation & Maintenance of Equipment	4,544	4,626	82
25.8	Subsistence & Support of Persons	0	0	0
25.0	Subtotal Other Contractual Services	\$254,362	\$255,084	\$722
26.0	Supplies & Materials	\$10,579	\$10,769	\$190
31.0	Equipment	6,340	6,343	3
32.0	Land and Structures	0,5 .0	0,5 .5	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	320,242	318,242	-2,000
42.0	Insurance Claims & Indemnities	1	1	0
43.0	Interest & Dividends	2.	2	(
44.0	Refunds	0	0	ĺ
	Subtotal Non-Pay Costs	\$595,012	\$593,991	-\$1,021
	Total Budget Authority by Object Class	\$693,533		\$0

 $^{^{\}mbox{\scriptsize 1}}$ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

² Includes mandatory financing.

Salaries and Expenses

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	\$43,120	\$43,448	\$328
Other Than Full-Time Permanent (11.3)	23,018	23,193	175
Other Personnel Compensation (11.5)	946	953	7
Military Personnel (11.7)	827	833	6
Special Personnel Services Payments (11.8)	7,873	7,933	60
Subtotal Personnel Compensation (11.9)	\$75,783	\$76,360	\$577
Civilian Personnel Benefits (12.1)	\$22,238	\$22,679	\$440
Military Personnel Benefits (12.2)	499	503	4
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$98,521	\$99,542	\$1,021
Travel & Transportation of Persons (21.0)	\$1,753	\$1,784	\$32
Transportation of Things (22.0)	571	581	10
Rental Payments to Others (23.2)	52	52	1
Communications, Utilities & Misc. Charges (23.3)	1,099	1,119	20
Printing & Reproduction (24.0)	13	13	0
Other Contractual Services:			
Consultant Services (25.1)	667	679	12
Other Services (25.2)	48,330	45,973	-2,357
Purchases from government accounts (25.3)	66,305	67,527	1,222
Operation & Maintenance of Facilities (25.4)	5,837	5,942	105
Operation & Maintenance of Equipment (25.7)	4,544	4,626	82
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$125,682	\$124,747	-\$936
Supplies & Materials (26.0)	\$10,579	\$10,769	\$190
Subtotal Non-Pay Costs	\$139,748	\$139,065	-\$683
Total Administrative Costs	\$238,269	\$238,608	\$339

Detail of Full-Time Equivalent Employment (FTE)

	FY	Y 2015 Actu	al	I	Y 2016 Est		I	FY 2017 Est	
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Research									
Direct:	70		70	70		70	70		70
Reimbursable:	1		1	1		1	1	_	1
Total:	71	-	71	71	-	71	71	-	71
Division of Intramural Research									
Direct:	329	3	332	335	3	338	335	3	338
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	330	3	333	336	3	339	336	3	339
Division of National Toxicology Program									
Direct:	106	1	107	106	1	107	106	1	107
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	106	1	107	106	1	107	106	1	107
Office of Management									
Direct:	89	2	91	89	2	91	89	2	91
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	89	2	91	89	2	91	89	2	91
Office of the Director									
Direct:	52	2	54	52	2	54	52	2	54
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	52	2	54	52	2	54	52	2	54
Total	648	8	656	654	8	662	654	8	662
Includes FTEs whose payroll obligations ar	e supported	by the NIH	Common F	und.					
FTEs supported by funds from									
Cooperative Research and Development	0	0	0	0	0	0	0	0	0
Agreements.									
FISCAL YEAR		,		Ave	rage GS Gr	ade		,	
2012					11.5				
2013					11.5				
2014					11.5				
2015					11.8				
2016					11.8				
2017					11.8				

Detail of Positions¹

GRADE	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	183,300	185,555	188,394
GM/GS-15	41	41	41
GM/GS-14	52	52	52
GM/GS-13	102	103	103
GS-12	115	116	116
GS-11	94	95	95
GS-10	1	1	1
GS-9	35	35	35
GS-8	17	17	17
GS-7	23	23	23
GS-6	3	3	3
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	483	486	486
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	185	188	188
Total permanent positions	487	493	493
Total positions, end of year	677	683	683
Total full-time equivalent (FTE) employment, end of year	656	662	662
Average ES salary	183,300	185,555	188,394
Average GM/GS grade	11.8	11.8	11.8
Average GM/GS salary	89,841	90,946	92,337

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