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

For carrying out section 301 and title IV of the PHS Act with respect to environmental health sciences, \$691,348,000.

Amounts Available for Obligation 1

(Dollars in Thousands)

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	686,869	689,767	691,348
Rescission	(1,298)	0	0
Subtotal, adjusted appropriation	685,571	689,767	691,348
Real transfer under Secretary's transfer authority	(195)	0	0
Secretary's Transfer for Alzheimer's disease (AD)	(452)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	0	0	0
Comparative Transfers to NLM for NCBI and Public Access	(626)	(812)	0
Subtotal, adjusted budget authority	684,297	688,955	691,348
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	684,297	688,955	691,348
Unobligated balance lapsing	(107)	0	0
Total obligations	684,190	688,955	691,348

¹ Excludes the following amounts for reimbursable activities carried out by this account: FY 2012 - \$1,288 FY 2013 - \$1,293 FY 2014 - \$1,293

Excludes \$293 in FY 2012 and \$357 in FY 2013 for royalties.

Budget Mechanism - Total ¹ (Dollars in Thousands)

MECHANISM	FY 2	2012 tual	FY 2			2014 B	Change vs	. FY 2012
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects								
Noncompeting	449	\$192,627	458	\$182,136	515	\$194,279	66	\$1,652
Administrative Supplements	(41)	3,151	(39)	3,151	(39)	3,151	-(2)	0
Competing:								
Renewal	21	7,905	23	8,520	20	7,529	- 1	-376
New	153	47,812	183	57,268	144	44,765	-9	-3,047
Supplements	3	1,174	6	2,353	5	2,000	2	826
Subtotal, Competing	177	\$56,891	212	\$68,141	169	\$54,294	-8	-\$2,597
Subtotal, RPGs	626	\$252,669	670	\$253,428	684	\$251,724	58	-\$945
SBIR/STTR	38	13,856	39	14,512	42	15,247	4	1,391
Research Project Grants	664	\$266,524	709	\$267,940	726	\$266,971	62	\$447
Research Centers								
Specialized/Comprehensive	26	34,083	26	34,083	26	34,083	0	0
1 *	0	34,083	0				0	0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	0	-	0	0	0	0	0
Research Centers in Minority Institutions	_	Ü		Ü			0	\$0
Research Centers	26	\$34,083	26	\$34,083	26	\$34,083	0	\$0
Other Research								
Research Careers	45	5,961	51	6,799	49	6,399	4	438
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	33	3,060	33	3,060	33	3,060	0	0
Other Research	78	\$9,022	84	\$9,859	82	\$9,459	4	\$437
Total Research Grants	768	\$309,629	819	\$311,882	834	\$310,513	66	\$884
Ruth L. Kirschstein Training Awards	FTTPs		FTTPs		FTTPs		FTTPs	
Individual	44	1,896		1,896	43	1,896	-1	0
Institutional	420	17,094	420	17,094	416	17,094	-4	0
Total Research Training	464	\$18,990		\$18,990	459	\$18,990	-5	\$0
Passageh & Davidanment Contracts	138	147,133	138	149.078	138	152,600	0	5,467
Research & Development Contracts		,		- ,				,
SBIR/STTR (non-add)	(0)	(34)	(0)	(34)	(0)	(36)	(0)	+(2)
	FTEs		<u>FTEs</u>		FTEs		<u>FTEs</u>	
Intramural Research	543	184,771	543	184,771	543	184,771	0	0
Research Management and Support	133	23,773	144	24,234	144	24,474	11	701
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIEHS	676	\$684,297	687	\$688,955	687	\$691,348	11	\$7,051

 $^{^{\}rm 1}$ All items in italics and brackets are "non-adds."

Major Changes in the Fiscal Year 2014 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 2014 President's Budget for NIEHS, which is \$7.1 million above the FY 2012 Actual level, for a total of \$691.3 million.

<u>Fundamental Research (+\$6.292 million; total \$207.163 million):</u> New grants in this program will potentially increase our mechanistic understanding of how environmental exposures affect the proteins and components of the genome involved in establishing and maintaining gene expression patterns.

Exposure Research (-\$7.607 million; total \$43.693 million): The decrease in this program is largely due to the completion of the Disease Investigation through Specialized Clinically-Oriented Ventures in Environmental Research (DISCOVER) program. Also, our previous investment in new tools for exposure assessment technology is reaching its planned termination.

Translational Research and Special Populations (+\$6.134 million; total \$100.483 million): Additional funding in this program will be used to support a larger number of Children's Environmental Health and Disease Prevention Research Centers, which are transdisciplinary programs examining the effects of environmental factors on children's health and well-being and encouraging strong links to translate findings between basic, applied, clinical and public health sciences to prevent disease and promote health in children. NIEHS is also devoting some additional resources to its program in Climate Change and Health: Assessing and Modeling Population Vulnerability to Climate Change.

NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences Summary of Changes

(Dollars in Thousands)

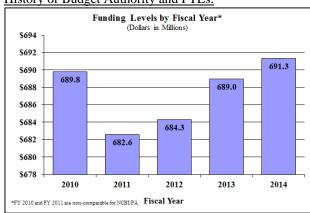
FY 2012 Actual				\$684,297
FY 2014 President's Budget				\$691,348
Net change				\$7,051
	_	2014		
	Preside	nt's Budget	Change fr	om FY 2012
		Budget		Budge
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of March				
2013 pay increase & benefits		\$79,015		\$204
b. January FY 2014 pay increase & benefits		79,015		582
c. One more day of pay		79,015		300
d. Differences attributable to change in FTE		79,015		(
e. Payment for centrally furnished services		22,695		424
f. Increased cost of laboratory supplies, materials,				
other expenses, and non-recurring costs		83,061		185
Subtotal				\$1,695
2. Research Management and Support:				
a. Annualization of March				
2013 pay increase & benefits		\$17,651		\$50
b. January FY 2014 pay increase & benefits		17,651		13
c. One more day of pay		17,651		6
d. Differences attributable to change in FTE		17,651		
e. Payment for centrally furnished services		1,867		4
f. Increased cost of laboratory supplies, materials,		·		
other expenses, and non-recurring costs		4,956		,
Subtotal				\$29
Subtotal, Built-in				\$1,992

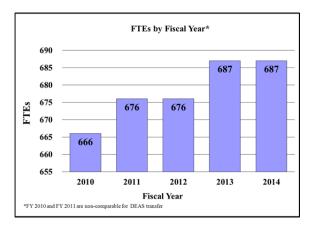
Summary of Changes--continued

		2014		
	Preside	nt's Budget	Change fi	rom FY 2012
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research Project Grants:				
a. Noncompeting	515	\$197,430	66	\$1,652
b. Competing	169	54,294	-8	-2,597
c. SBIR/STTR	42	15,247	4	1,391
Total	726	\$266,971	62	\$446
2. Research Centers	26	\$34,083	0	\$0
3. Other Research	82	9,459	4	437
4. Research Training	459	18,990	-5	0
5. Research and development contracts	138	152,600	0	5,467
Subtotal, Extramural		\$482,103		\$6,350
6. Intramural Research	<u>FTEs</u> 543	\$184,771	FTEs 0	-\$1,695
7. Research Management and Support	144	24,474	11	404
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	687	\$691,348	11	\$5,059
Total changes				\$7,051

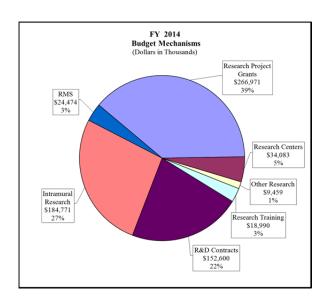
Fiscal Year 2014 Budget Graphs

History of Budget Authority and FTEs:

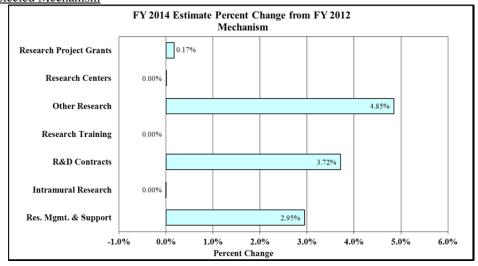




Distribution by Mechanism



Change by Selected Mechanism



NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Sciences

Budget Authority by Activity

(Dollars in Thousands)

		2012 ctual		7 2013 CR		Z 2014 PB		nge vs. 7 2012
Extramural Research Detail:	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	Amount	FTEs	Amount	FTEs	<u>Amount</u>
Fundamental Research		\$200,871		\$203,432		\$207,163		\$6,292
Exposure Research		51,300		46,301		43,693		-\$7,607
Translational Research and Special Populations		94,349		100,091		100,483		6,134
Predictive Toxicology		88,167		88,167		88,167		0
Training and Education		41,066		41,959		42,597		1,531
Subtotal, Extramural		\$475,753		\$479,950		\$482,103		\$6,350
Intramural Research	543	\$184,771	543	\$184,771	543	\$184,771	0	(\$0)
Research Management & Support	133	\$23,773	144	\$24,234	144	\$24,474	11	\$701
TOTAL	676	\$684,297	687	\$688,955	687	\$691,348	11	\$7,051

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

^{2.} Includes Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2013 Amount Authorized	FY 2013 CR	2014 Amount Authorized	FY 2014 PB
Research and Investigation	Section 301	42\$241	Indefinite		Indefinite	
National Institute of Environmental Health Sciences	Section 401(a)	42\$281	Indefinite	- \$688,955,000	Indefinite	\$691,348,000
Total, Budget Authority				\$688,955,000		\$691,348,000

Appropriations History

Fiscal	Budget Estimate to			
Year	Congress	House Allowance	Senate Allowance	Appropriation
2005	\$650,027,000	\$650,027,000	\$655,100,000	\$650,027,000
Rescission				(\$5,522,000)
2006	\$647,608,000	\$647,608,000	\$667,372,000	\$647,608,000
Rescission				(\$6,476,000)
2007	\$637,323,000	\$637,323,000	\$641,292,000	\$642,002,000
Rescission				-
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				-
Supplemental				\$3,416,000
2010	\$684,257,000	\$695,497,000	\$683,149,000	\$689,781,000
Rescission				-
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	-
Rescission				-
2014	\$691,348,000	-	-	-

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 2014	
	FY 2012	FY 2013	President's	FY 2014 +/-
	Actual	CR	Budget	FY 2012
BA	\$684,297,000	\$688,955,000	\$691,348,000	+\$7,051,000
FTE	676	687	687	+11

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

Director's Overview

The mission of the NIEHS, rearticulated this year in the Institute's 2012-2017 strategic plan, *Advancing Science, Improving Health: A Plan for Environmental Health Research*, is to discover how the environment affects people in order to promote healthier lives. The vision that will guide implementation of this plan is to "provide global leadership for innovative research that improves public health by preventing disease and disability." It is this focus on public health and prevention that distinguishes NIEHS. Diseases and disorders are caused by a combination of three factors: genetics, age, and environment. Of these, the only one at present that can be changed or avoided is exposure to hazardous agents in the environment. To this end, this strategic plan renews and reemphasizes the NIEHS commitment to the tandem goals of understanding those exposures in our environment that contribute to the development of disease and impair health, and developing interventions to avoid or eliminate them.

The NIEHS mission and vision will be carried out through six core themes that were developed during a 15-month process of scientific and stakeholder engagement: Fundamental Research, Exposure Research, Translational Science, Global Health and Health Disparities, Training and Education, and Communications and Engagement. These themes represent the continuum of actions required to protect and improve the public's environmental health, and as such, each offers distinct scientific and prevention opportunities. Crosscutting these themes are the issues of Collaborative and Integrative Approaches and Knowledge Management. These core and crosscutting themes reflect and intersect with the thematic focus areas articulated by the NIH Director: Today's Basic Science for Tomorrow's Breakthroughs (NIEHS Fundamental Research and Exposure Research), Translational Science, and Recruiting and Retaining Diverse Scientific Talent and Creativity. These joint themes are underpinned by a set of strategic goals for NIEHS that will define focus areas, measure progress, and provide a framework for innovation for the field of environmental health sciences. NIEHS research investments have made significant, measurable impacts on public and global health by providing the data to inform decision making. For example, studies of developmental effects on children of exposure to the plastic component bisphenol A, used in food can liners, storage containers, and water bottles, has led manufacturers

to reformulate products without the toxic chemical. NIEHS-supported research on engineered nanomaterials continues to broaden our understanding of how such particles interact in the body and specific organs, in both beneficial and harmful ways. This new strategic plan will enable the Institute to continue its global leadership role and build on these efforts to provide new tools and understanding for some of the nation's and the world's most difficult and confounding public health problems.

The continuum from basic research through translation to development of interventions for protection of public health is demonstrated by a set of research and policy activities surrounding the developmental origins of health and disease (DOHAD) and epigenetics.

DOHAD is the concept that diseases in adulthood are influenced not only by genetic and adult lifestyle factors, but also by environmental factors acting in early life, including prenatally, and indirectly on DNA function. The extent of the later effects is determined by toxicant properties, dosage amount, timing in regard to windows of vulnerability, and possible epigenetic changes brought about by toxicant exposure that may be heritable. NIEHS has been the leader in supporting DOHAD research that has established, for example, that environmental exposures to arsenic in prenatal and early life are linked to development of COPD and lung cancer³, and exposures to tobacco smoke and diethylstilbestrol (DES) are linked to obesity. There is suggestive evidence that epigenetic mechanisms are responsible for the deleterious health effects associated with the exposure to various environmental agents: arsenic, air pollutants, benzene and other aromatic hydrocarbons, and tobacco smoke, in addition to other types of exposures such as dietary micronutrients, shiftwork, and stress. NIEHS is initiating new research efforts that will uncover the interactions between environmental agents and epigenetic processes, leading to more effective targets for diagnosis, treatment, and prevention of environmentally related diseases.

Early life exposures also are increasingly linked to development of chronic non-communicable diseases (NCDs), which present a global epidemic that is causing immeasurable human suffering and threatening to swamp healthcare systems. NCDs, including diabetes, cardiovascular disease, metabolic syndrome, and chronic lung diseases account for 63 percent of global deaths, including nine million preventable deaths before the age of 60, and 50 percent of global

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¹ U.S. Department of Health and Human Services, NTP (National Toxicology Program), CERHR (Center for the Evaluation of Risks to Human Reproduction). 2000. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. NIH (National Institutes of Health) Publication No. 08-5994.

² Nazarenko Y, Zhen H, Han T, Lioy PJ, Mainelis G. 2012. Potential for inhalation exposure to engineered nanoparticles from nanotechnology-based cosmetic powders. Environ Health Perspect 120(6):885-892.

³ Tokar EJ, Qu W, Waalkes MP. 2010. Arsenic, stem cells and the developmental basis of adult cancer. Toxicol Sci; doi: 10.1093/toxsci/kfq342 [Online 11 November 2010]

⁴ Cupul-Uicab LA, Skjaerven R, Haug K, Melve KK, Engel SM, Longnecker MP. 2011. In utero exposure to maternal tobacco smoke and subsequent obesity, hypertension, and gestational diabetes among women in the MoBa cohort. Environ Health Perspect; doi:10.1289/ehp.1103789 [Online 29 November 2011].

⁵ Fleisch AF, Wright RO, Baccarelli AA. 2012. Environmental epigenetics: a role in endocrine disease? J Mol Endocrinol October 1, 2012 49 R61-R67

⁶ Lovinsky-Desir S, Miller RL. 2012. Epigenetics, asthma, and allergic diseases: a review of the latest advancements. Curr Allergy Asthma Rep Volume 12, Number 3 (2012), 211-220, DOI: 10.1007/s11882-012-0257-4 ⁷ Baccarelli A, Ghosh S. 2012. Environmental exposures, epigenetics and cardiovascular disease. Curr Opin Clin Nutr Metab Care 2012, 15:323-329, DOI:10.1097/MCO.0b013e328354bf5c

disability cases. Currently, there are an estimated 366 million people with diabetes worldwide.⁸ It is estimated that treatment of NCDs will cost the global economy \$47 trillion over the next 20 years.⁹

The NIEHS took an important step toward addressing these issues by convening a meeting in May that brought international DOHAD researchers together with global public health experts battling NCDs to broaden the discussion of primary prevention to include the developmental origins of non-communicable disease. Research shows that certain populations are particularly vulnerable to both environmental exposures and unhealthy behaviors that can combine to increase their risk for NCDs. For example, lower levels of education are associated with unhealthy diet, which may lead to a cycle of obesity. Discussions such as this meeting are critical to developing policy, community, and individual interventions to break the cycle of NCDs being passed from one generation to the next.

Activities of the last step in the continuum actually form a loop back to basic research through feedback and engagement of affected populations in community based participatory research, which helps to translate research to refine and target efforts to understand effects of environmental exposures on the most vulnerable populations. The NIEHS continues to lead such efforts through the Partnerships for Environmental Public Health Program and efforts in the fight for environmental justice. In July, the NIEHS hosted a stakeholder meeting that was a key component of the implementation of the *HHS 2012 Environmental Justice Strategy*. ¹¹

This meeting is just one part of the Institute's ongoing commitment to integrating diversity across all of our research activities. Through our Office of Science Education and Diversity, we conduct a broad range of activities to further this goal, recognizing that developing, recruiting, and retaining a diverse scientific workforce is critical to creating the innovation that will be required to solve environmental health problems going forward.

Overall Budget Policy: The FY 2014 President's Budget request is \$691.348 million, an increase of \$7.051 million, or 1.0 percent above the FY 2012 Actual level. NIEHS will continue to support new investigators and maintain the number of competing RPGs. In FY 2014, no inflationary increase will be provided for non-competing grants and they will increase by 0.9 percent above the FY 2012 Actual level. NIEHS will maintain the average cost of competing grants at the FY 2012 Actual level.

Support for NRSA training mechanism will remain constant reflecting a reduction in the number of trainees supported. The Ruth L. Kirschstein NRSA budget reflects a stipend increase to \$42,000 for the entry level postdoctoral trainees and fellows along with 4.0 percent increases for each subsequent level of experience. These increases are consistent with stipend increases

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⁸ International Diabetes Foundation, retrieved at http://www.idf.org/.

⁹ World Economic Forum, The Global Burden of Non-Communicable Diseases, 2011. Retrieved from: http://www.weforum.org/reports/global-economic-burden-non-communicable-diseases.

¹⁰ National Institute of Environmental Health Sciences and World Health Organization, Primary Prevention: Avoiding Non-Communicable Diseases by Reducing Early Life Exposure, May 13, 2012, Université Paris Descartes, Paris, France.

¹¹ http://www.hhs.gov/environmentaljustice/

recommended by the Advisory Committee to the NIH Director and the National Research Council. In addition, this increase is consistent with 42 USC 288(b)(5), which anticipates periodic adjustments in stipends "to reflect increases in the cost of living."

Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

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

Perfluorinated compounds are widely found in food packaging and textiles, but their impact on human health is not fully understood. Research funded by NIEHS has shown that elevated exposure to perfluorinated compounds is associated with reduced immune responses in children. A prospective study assessed prenatal exposure of children in the Faroe Islands by measuring perfluorinated compounds in the mother's serum during pregnancy, and later checked for the compounds in samples from the children at age five. Investigators found that children with elevated exposure to perfluorinated compounds had lower antibody responses to childhood immunizations, which reflects how well the immune system is functioning.¹²

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$207.163 million, an increase of \$6.292 million, or 3.1 percent over the FY 2012 Actual level. The focus of this research on basic biological processes that are susceptible to the effects of environmental stressors continues as affirmed in the goals of the NIEHS Strategic Plan. New grants in this program will potentially increase our mechanistic understanding of how environmental exposures affect the proteins and components of the genome involved in establishing and maintaining gene expression patterns.

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¹² Grandjean P, Anderson EW, Budtz-Jorgensen E, Nielsen F, Molbak K, Weihe P, Heilmann C. 2012. Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. JAMA 307(4):391-397.

Program Portrait: Understanding the Role of Environmental Exposures on Obesity and Diabetes

FY 2012 Level: \$32.1 million FY 2014 Level: \$32.3 million Change: +\$0.2 million

In the United States, one in three adults and nearly 17 percent of children are obese, putting them at increased risk for cardiovascular disease, stroke, cancers, liver disease, Type 2 diabetes, and osteoarthritis, among others. Type 2 diabetes affects nearly one in 12 people in the United States and is the seventh leading cause of death; some 79 million people are pre-diabetic. Research increasingly shows strong links between environmental exposures such as toxic contaminants as well as food components and the development of obesity and Type 2 diabetes. NIEHS has a strong portfolio of fundamental research aimed at uncovering the mechanisms by which these exposures are related to the development of disease, which in turn may lead to potential interventions. Studies under the Role of Environmental Chemical Exposures in the Development of Obesity, Type 2 Diabetes, and Metabolic Syndrome initiative are looking, for example, at the effects of exposure to endocrine disrupting chemicals (EDCs), such as bisphenol A and its role in affecting metabolism and insulin resistance. Studies on pregnant mothers and the developing fetus are examining the role of environmental exposures and epigenetic programming during development and the risk of obesity and diabetes later in life. Other research is focused on examining the relationship between exposure to contaminants such as arsenic, PCBs, DDT, and air pollution on the development of obesity. NIEHS-supported studies also are underway to investigate the synergistic effects of exposure to environmental pollutants on people's overall health when they already have a co-morbidity such as obesity or diabetes. Obesity and Type 2 diabetes are strongly associated with health disparities and disproportionately affect minorities including Hispanic/Latino, African American, American Indian, and Pacific Islander Americans, as well as those who are socioeconomically disadvantaged. Studies conducted under the Partnerships for Environmental Public Health program are engaging these communities in research to determine potential underlying genetic susceptibilities to obesity, Type 2 diabetes, and metabolic syndrome, and to tease out the contribution of societal and lifestyle factors that may be modified to prevent or minimize the risk of these diseases and disorders and improve health.

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 or other organisms, including biological markers, sensor and detector tools, remote exposures detection, better analytical methods, and informatics technologies.

University of California at Berkeley researchers, working in the NIH Randomized Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE) trial which included 534 rural Guatemala households with a pregnant woman or young infant, have found that rates of severe childhood pneumonia were reduced by 30 percent in households given cooking stoves with chimneys to use rather than using open, indoor wood cooking fires. The findings suggest that interventions that lower exposure to wood smoke may help reduce childhood deaths from pneumonia in areas of the world where indoor open fires are commonly used. The researchers also found that carbon monoxide exposure levels in the homes equipped with chimneys were, on average, half that of the households with the open fires.¹³

¹³ Smith K, McCracken J, Weber M, Hubbard A, Jenny A, Thompson L, Balmes J, Diaz A, Arana B, Bruce N. Effect of reduction in household air pollution on childhood pneumonia in Guatemala (RESPIRE): a randomised controlled trial. 2011 Nov 12. The Lancet 378(9804): 1717-1726.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$43.693 million, a decrease of \$7.607 million, or 14.8 percent below the FY 2012 Actual level. The decrease in this program is largely due to the completion of the Disease Investigation through Specialized Clinically-Oriented Ventures in Environmental Research (DISCOVER) program. Also, our previous investment in new tools for exposure assessment technology is reaching its planned termination.

Program Portrait: Expanding Understanding of Engineered Nanomaterials and Health

FY 2012 Level: \$21.4 million FY 2014 Level: \$21.6 million Change: +\$0.2 million

Engineered nanomaterials (ENMs) are increasingly in use in a variety of applications and are now found in many common products, including sunscreens, drugs, medical devices, cosmetics, clothing, and building materials. The same properties that make them so attractive for multiple uses in the marketplace—the fact that they can be engineered to behave differently from their "bulk" analogs—also make it difficult to ascertain risk from exposure. As part of its role in supporting the National Nanotechnology Initiative, NIEHS has developed an integrated, strategic research program "ONE Nano" to increase our fundamental understanding of how ENMs interact with living systems, develop predictive models for quantifying ENM exposure and assessing ENM health impacts, and guide the design of second-generation ENMs to minimize adverse health effects. NIEHS's research investments in ENM health and safety include extramural grants and grantee consortia, intramural research activities, and toxicology studies being conducted by the National Toxicology Program (NTP). The flagship extramural program in ENM health impacts is the NIEHS Centers for Nanotechnology Health Implications Research (NCNHIR) consortium. Launched in 2010 with an overarching goal of enhancing our fundamental understanding of how ENM interact with biological systems, the consortium brings together 20 NIEHS grantees to facilitate meaningful interchange, enhance collaboration within the nanotechnology field, and produce valuable scientific insights such as toxicological profiles for selected ENMs, as well as improved methods and protocols for conducting studies to assess ENM health effects. In the NIEHS Clinical Research Unit, researchers are investigating the health effects of two types of environmentally relevant nanoparticles: cerium dioxide nanoparticles (diesel fuel additive) and multi-walled carbon nanotubes (electronic and other applications). The studies focus on lung effects and the interplay with pre-existing disease (asthma, COPD), as well as co-exposure (diesel particles), using primary human cells for ex vivo work. Next year, the plan is to start the first human controlled exposure to cerium dioxide with diesel particles, as well as evaluate respiratory effects in individuals with occupational exposure to multi-walled carbon nanotubes.

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.

Non-coding DNA variants may link early environmental exposures with later health problems. Researchers supported by the NIH Common Fund report that genetic differences linked to a variety of diseases influence how genes are activated during fetal development. These findings could help explain why some early environmental exposures increase risk of diseases years or even decades later. Understanding how and when environmental exposures affect gene

regulation may provide insights into ways to prevent disease by reducing exposures early in life. 14

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$100.483 million, an increase of \$6.134 million, or 6.5 percent over the FY 2012 Actual level. Additional funding in this program will be used to support additional Children's Environmental Health Centers.

Predictive Toxicology: This program comprises the NIEHS extramural research investment of the National Toxicology Program (NTP), whose mission 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.

Program Portrait: Transforming Public Health Protection through Tox21

FY 2012 Level: \$5.5 million FY 2014 Level: \$5.0 million Change: \$5.5 million \$5.0 million \$0.5 million

The National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP), the U.S. Environmental Protection Agency's (EPA) National Center for Computational Toxicology (NCCT), the National Center for Advancing Translational Science (NCATS)/NIH Chemical Genomics Center (NCGC), and the Food and Drug Administration have developed a vision and implementation strategy, termed Tox21, to shift the assessment of chemical hazards from traditional experimental animal toxicology studies to target specific, mechanism-based, biological observations largely obtained using in vitro assays. Developing a comprehensive compound library is critical to the ultimate ability of Tox21 to develop relevant prioritization schemes and prediction models. The Tox21 compound library includes approximately 11,000 structurally defined compounds intended to broadly capture chemical and toxicological "space." At the NCGC, compounds are screened at multiple concentrations to yield concentration-response curves that define compound activity. Selected assays include chemicals that induce stress response pathways and interact with nuclear receptors, based on the premise that compounds that induce one or more stress response pathway are likely to exhibit in vivo toxicity. Human nuclear receptor assays were selected because of the key roles they play in endocrine and metabolism pathways. The collection of Tox21 data will be used to create a systematic view of the biological network that responds to chemical perturbations, which will then be linked to toxicological effects in animals and humans. To aid in interpreting these data, Tox21 researchers are designing an online resource database called NCGC BioPlanet that will host information from manually curated and publicly available data. This user interface is intended to allow easy browsing, visualization, and analysis of the universe of nearly 1,100 human pathways to help assess assay coverage and identify where new assays might be most useful.

Recent notable research achievements from the new National Toxicology laboratory include the finding that human prostate epithelial cells transformed to malignancy by exposure to inorganic arsenic, a human carcinogen, can release diffusible factors that convert normal prostate stem

¹⁴ Maurano MT, Humbert R, Rynes E, Thurman RE, Haugen E, Wang H, Reynolds AP, Sandstrom R, Qu H, Brody J, Shafer A, Neri F, Lee K, Kutyavin T, Stehling-Sun S, Johnson AK, Canfield TK, Giste E, Diegel M, Bates D, Hansen RS, Neph S, Sabo PJ, Heimfeld S, Raubitschek A, Ziegler S, Cotsapas C, Sotoodehnia N, Glass I, Sunyaev SR, Kaul R, Stamatoyannopoulos JA. Systematic localization of common disease-associated variation in regulatory DNA. Science. 2012 Sep 7;337(6099):1190-5.

cells into cancer stem cells. This important finding accounts for the high prevalence of cancer stem cells observed in several models of arsenic induced prostate cancer, and furthers our understanding of how cancer progresses.¹⁵

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$88.167 million, the same as the FY 2012 Actual level.

Training and Education: This program's goal is to attract the brightest students and scientists into the environmental health sciences field 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).

Recently, a recipient of an NIEHS training award using her experience to study the effects of prenatal exposure to bisphenol A, reported that mice exposed to low doses of BPA in the womb had both immediate and long-lasting changes in the brain (decreases in mRNA levels of neuropeptides vasopressin and oxytocin) and social behaviors (fewer social interactions), some of which persisted into the fourth generation. The levels of BPA present in the blood plasma of the female mice that received BPA were in a range similar to those measured in exposed humans. These findings have implications for complex neurological disease.¹⁶

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$42.597 million, an increase of \$1.531 million, or 3.7 percent over the FY 2012 Actual level.

Intramural Research: The mission of the NIEHS intramural research program is to 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 longer-term and comprise unique components, such as NIEHS contribution to the NTP, epidemiological studies of environmentally associated diseases and exposures (including the study of individuals exposed by the Gulf oil spill), and intervention and prevention studies in humans to reduce the effects of exposures to hazardous environments. The NIEHS Clinical Research Unit provides opportunities for clinical and basic scientists in the Intramural Program to collaborate and learn how environmental exposures influence human health and disease.

A recent intramural study is the first to report the presence of a bacterial protein called flagellin in common household dust, and show that it can boost human allergic responses to indoor allergens. These findings suggest that individuals exposed to high amounts of flagellin might be at increased risk for developing asthma.¹⁷

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¹⁵ Xu et al, 2012. Environmental Health Perspectives, 120(6): 865871.

¹⁶ Wolstenholme JT, Edwards M, Shetty SR, Gatewood JD, Taylor JA, Rissman EF, Connelly JJ. 2012. Gestational exposure to bisphenol A produces transgenerational changes in behaviors and gene expression. Endocrinology 153(8):3828-3838.

¹⁷ Wilson RH, Maruoka S, Whitehead GS, Foley J, Flake GP, Sever ML, Zeldin, DC, Kraft M, Garantziotis S, Nikano H, Cook DN. The Toll-like receptor 5 ligand flagellin promotes asthma by priming allergic responses to indoor allergens. Nature Medicine. 2012 Oct 14, doi:10.1038/nm.2920.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$184.771 million, the same as the FY2012 Actual level. Resources will continue to support intramural research in basic science and environmental epidemiology as well as the demand for bioinformatics in high throughput screening, epigenomics, systems biology and database integration.

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 834 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.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate for this program is \$24.474 million, an increase of \$0.701 million, or 2.9 percent above the FY 2012 Actual level. Resources continue to support liaison functions with other government agencies and non-government organizations to improve interagency collaboration and efficiency and optimize use of resources. Resources are also devoted to implementation planning and tracking of progress in addressing the goals of the new NIEHS Strategic Plan. The apparent increase in estimated FY 2014 FTE compared to the FY 2012 actual FTE usage level is due to the effect of transferring positions previously funded from a centralized support operation (Division of Extramural Activities Support) to individual ICs as of year-end 2012. As a result of the DEAS transfer, estimated salaries and benefits for FY 2014 are proportionately higher than those identified for FY 2012 and previous years.

Budget Authority by Object Class

(Dollars in Thousands)

	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	676	687	11
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary (in whole dollars)	\$168,286	\$169,969	\$1,683
Average GM/GS grade	11.5	11.5	0.0
Average GM/GS salary (in whole dollars)	\$92.097	\$85,251	\$1.264
Average Givi/GS salary (in whole dollars) Average salary, grade established by act of	\$83,987	\$65,251	\$1,264
July 1, 1944 (42 U.S.C. 207) (in whole dollars)	\$0	\$0	\$0
Average salary of ungraded positions (in whole dollars)	\$0 \$0	\$0 \$0	\$0 \$0
Average salary of diffraced positions (in whole dollars)	φυ	φ0	ΨΟ
	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$41,404	\$43,044	\$1,640
11.3 Other than full-time permanent	21,346	21,821	475
11.5 Other personnel compensation	838	869	31
11.7 Military personnel	1,088	1,126	38
11.8 Special personnel services payments	8,735	8,880	145
Total, Personnel Compensation	\$73,410	\$75,740	\$2,330
12.0 Personnel benefits	\$19,446	\$20,073	\$627
12.2 Military personnel benefits	818	853	35
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$93,674	\$96,666	\$2,992
21.0 Travel and transportation of persons	\$1,777	\$1,748	(\$29)
22.0 Transportation of things	396	396	0
23.1 Rental payments to GSA	0	0	(0)
23.2 Rental payments to others	53	53	0
23.3 Communications, utilities and	1.075	1.075	(0)
miscellaneous charges 24.0 Printing and reproduction	1,075 20	1,075 20	(0)
24.0 Printing and reproduction 25.1 Consulting services	429	428	(1)
25.2 Other services	31,839	31,019	(820)
25.3 Purchase of goods and services from	31,037	31,017	(020)
government accounts	103,353	105,441	2,088
25.4 Operation and maintenance of facilities	5,502	5,502	(0)
25.5 Research and development contracts	103,396	105,130	1,734
25.6 Medical care	229	229	(0)
25.7 Operation and maintenance of equipment	3,686	3,686	(0)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	\$248,434	\$251,435	\$3,001
26.0 Supplies and materials	\$10,001	\$9,813	(\$188)
31.0 Equipment	5,386	5,285	(101)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	323,479	324,857	1,378
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	0	0	(0)
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	\$590,622	\$594,682	\$4,060
Total Budget Authority by Object Class	\$684,297	\$691,348	\$7,051

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

Salaries and Expenses

(Dollars in Thousands)

	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$41,404	\$43,044	\$1,640
Other than full-time permanent (11.3)	21,346	21,821	475
Other personnel compensation (11.5)	838	869	31
Military personnel (11.7)	1,088	1,126	38
Special personnel services payments (11.8)	8,735	8,880	145
Total Personnel Compensation (11.9)	\$73,411	\$75,740	\$2,329
Civilian personnel benefits (12.1)	\$19,446	\$20,073	\$627
Military personnel benefits (12.2)	818	853	35
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$93,675	\$96,666	\$2,991
Travel (21.0)	\$1,777	\$1,748	(\$29)
Transportation of things (22.0)	396	396	0
Rental payments to others (23.2)	53	53	0
Communications, utilities and			
miscellaneous charges (23.3)	1,075	1,075	0
Printing and reproduction (24.0)	20	20	0
Other Contractual Services:			
Advisory and assistance services (25.1)	429	428	(1)
Other services (25.2)	31,839	31,019	(820)
Purchases from government accounts (25.3)	65,793	64,555	(1,238)
Operation and maintenance of facilities (25.4)	5,502	5,502	0
Operation and maintenance of equipment (25.7)	3,686	3,686	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$107,249	\$105,190	(\$2,059)
Supplies and materials (26.0)	\$9,996	\$9,808	(\$188)
Subtotal, Non-Pay Costs	\$120,566	\$118,290	(\$2,276)
Total, Administrative Costs	\$214,241	\$214,956	\$715

Details of Full-Time Equivalent Employment (FTEs)

		FY 2012			FY 2013			FY 2014	
		Actual			CR			PB	
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	50	2	52	50	2	52	50	2	52
Reimbursable:	1	-	1	1	2	1	1	2	1
Total:	51	2	53	51	2	53	51	2	53
Division of Intramural Research									
Direct:	332	4	336	332	4	336	332	4	336
Reimbursable:	2	4	2	2	4	2	2		2
Total:	334	4	338	334	4	338	334	4	338
Division of National Toxicology Program									
Direct:	108	2	110	109	1	110	109	1	110
Reimbursable:	100	_	110	102	_	110	105	-	110
Total:	108	2	110	109	1	110	109	1	110
Division of Extramural Research and Training									
Direct:	57	_	57	68	_	68	68	_	68
Reimbursable:	1	_	1	1	_	1	1	_	1
Total:	58	-	58	69	-	69	69	-	69
Office of Management									
Direct:	115	2	117	115	2	117	115	2	117
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	115	2	117	115	2	117	115	2	117
Total	666	10	676	678	9	687	678	9	687
Includes FTEs whose payroll obligations are supported by								-	
the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and									
Development Agreements.									
FISCAL YEAR				Av	erage GS Gra	ade			
2010									
2010					11.3				
2011					11.4				
2012					11.5				
2013					11.5				
2014					11.5				

Detail of Positions

	FY 2012		FY 2013		FY 2014	
GRADE	Actual		CR		PB	
Total, ES Positions		1		1		1
Total, ES Salary	\$	168,286	\$	169,127	\$	170,818
GM/GS-15		41		41		41
GM/GS-14		53		53		53
GM/GS-13		96		96		96
GS-12		98		98		98
GS-11		100		100		100
GS-10		1		1		1
GS-9		59		60		60
GS-8		16		16		16
GS-7		24		24		24
GS-6		2		2		2
GS-5		1		1		1
GS-4		7		7		7
GS-3		2		2		2
GS-2		0		0		0
GS-1		0		0		0
Subtotal		500		501		501
Grades established by Act of						
July 1, 1944 (42 U.S.C. 207):						
Assistant Surgeon General		1		0		0
Director Grade		5		5		5
Senior Grade		2		2		2
Full Grade		2		2		2
Senior Assistant Grade		0		0		0
Assistant Grade		0		0		0
Subtotal		10		9		9
Ungraded		203		204		204
Total permanent positions		505		516		516
Total positions, end of year		714		725		725
Total full-time equiv (FTE) at YE		676		687		687
Average ES salary	\$	168,286	\$	169,127	\$	169,969
Average GM/GS grade		11.5		11.5		11.5
Average GM/GS salary	\$	83,987	\$	84,407	\$	85,251

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