

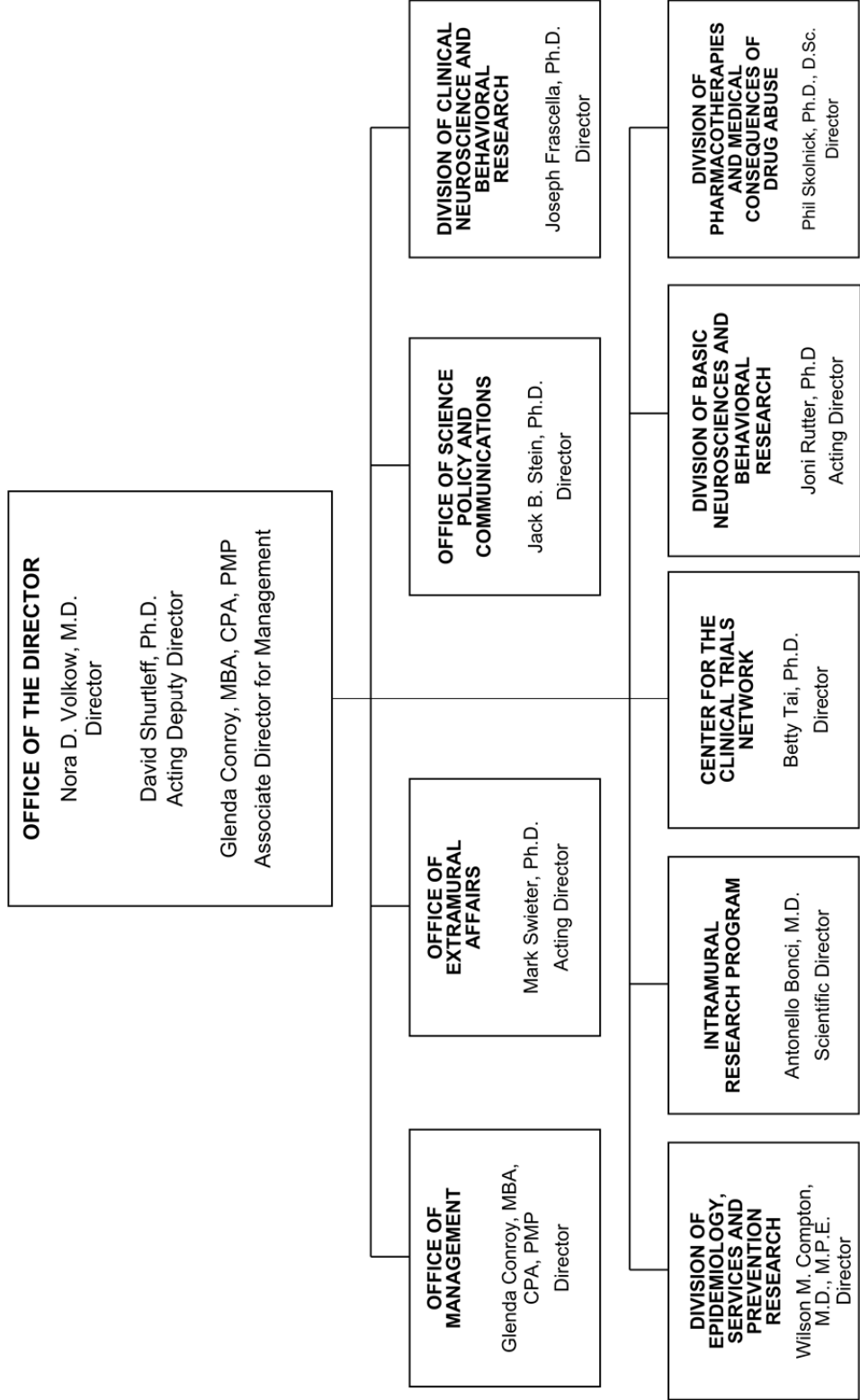
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute on Drug Abuse (NIDA)

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National Institutes of Health National Institute on Drug Abuse Organizational Structure



NATIONAL INSTITUTES OF HEALTH

National Institute on Drug Abuse

*For carrying out section 301 and title IV of the PHS Act with respect to drug abuse,
\$1,071,612,000.*

NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse

Amounts Available for Obligation ¹
(Dollars in Thousands)

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	1,055,362	1,059,814	1,071,612
Rescission	(1,995)	0	0
Subtotal, adjusted appropriation	1,053,367	1,059,814	1,071,612
Secretary's Transfer for Alzheimer's disease (AD)	(694)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	(300)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(963)	(1,247)	0
Subtotal, adjusted budget authority	1,051,410	1,058,567	1,071,612
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	1,051,410	1,058,567	1,071,612
Unobligated balance lapsing	(5)	0	0
Total obligations	1,051,405	1,058,567	1,071,612

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

FY 2012 - \$37,125 FY 2013 - \$80,444 FY 2014 - \$87,443

National Institute on Drug Abuse
Budget Mechanism - Total ¹
(Dollars in Thousands)

MECHANISM	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	1,041	\$459,924	1,049	\$461,848	1,060	\$476,169	19	\$16,245
Administrative Supplements	(102)	6,974	(79)	5,200	(79)	5,200	(-23)	-1,774
Competing:								
Renewal	51	27,471	51	27,471	51	27,471	0	0
New	347	134,353	388	139,684	371	132,282	24	-2,071
Supplements	1	113	1	113	1	113	0	0
Subtotal, Competing	399	\$161,937	440	\$167,268	423	\$159,866	24	-\$2,071
Subtotal, RPGs	1,440	\$628,835	1,489	\$634,316	1,483	\$641,235	43	\$12,400
SBIR/STTR	56	20,241	59	21,404	63	23,106	7	2,865
Research Project Grants	1,496	\$649,076	1,548	\$655,720	1,546	\$664,341	50	\$15,265
<u>Research Centers</u>								
Specialized/Comprehensive	38	63,546	38	63,546	35	63,546	-3	0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	38	\$63,546	38	\$63,546	35	\$63,546	-3	\$0
<u>Other Research</u>								
Research Careers	211	34,638	211	34,638	211	34,638	0	0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	13	33,291	13	33,291	13	33,291	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	1,366	0	1,366	0	1,366	0	0
Other	73	14,821	73	14,821	73	14,821	0	0
Other Research	297	\$84,116	297	\$84,116	297	\$84,116	0	\$0
Total Research Grants	1,831	\$796,738	1,883	\$803,382	1,878	\$812,003	47	\$15,265
<u>Ruth L. Kirschstein Training Awards</u>	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Individual	164	6,428	164	6,428	162	6,428	-2	0
Institutional	393	18,806	393	18,806	386	18,806	-7	0
Total Research Training	557	\$25,234	557	\$25,234	548	\$25,234	-9	\$0
Research & Development Contracts	169	79,496	169	79,212	169	83,636	0	4,140
<i>SBIR/STTR (non-add)</i>	(19)	(6,437)	(19)	(6,437)	(19)	(6,437)	(0)	(-0)
Intramural Research	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Research Management and Support	124	87,853	128	88,649	128	88,649	4	796
Construction	258	62,090	283	62,090	283	62,090	25	0
Buildings and Facilities		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIDA	382	\$1,051,410	411	\$1,058,567	411	\$1,071,612	29	\$20,202

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 there may be overlap between budget mechanisms and activity detail and these highlights will not sum to the total change for the FY 2014 President's Budget for NIDA, which is \$20.2 million more than the FY 2012 level, for a total of \$1,071.6 million.

Research Project Grants (+\$15.265 million; total \$664.3 million): NIDA will support a total of 1,546 Research Project Grant (RPG) awards in FY 2014. Non-competing RPGs will increase by 19 awards and \$16.245 million. Competing RPGs will increase by 24 awards and decrease in the amount of \$2.071 million. Within the total, research priorities include those that position the Institute to advance the development of medications, using innovative genetics tools and technologies, and translating the results of evidence-based findings to improve drug abuse interventions and promote greater access to them worldwide. NIDA will also continue to make the support of new and early stage investigators a priority.

HIV/AIDS Research (+\$12.994 million; total \$332.3 million): NIDA plans to support targeted HIV/AIDS research in FY 2014. Efforts will center on particularly vulnerable populations such as ethnic minorities, homeless populations, and aging drug users. NIDA will also support HIV/AIDS research to advance proven interventions and their integration into primary medical systems.

NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse
Summary of Changes
(Dollars in Thousands)

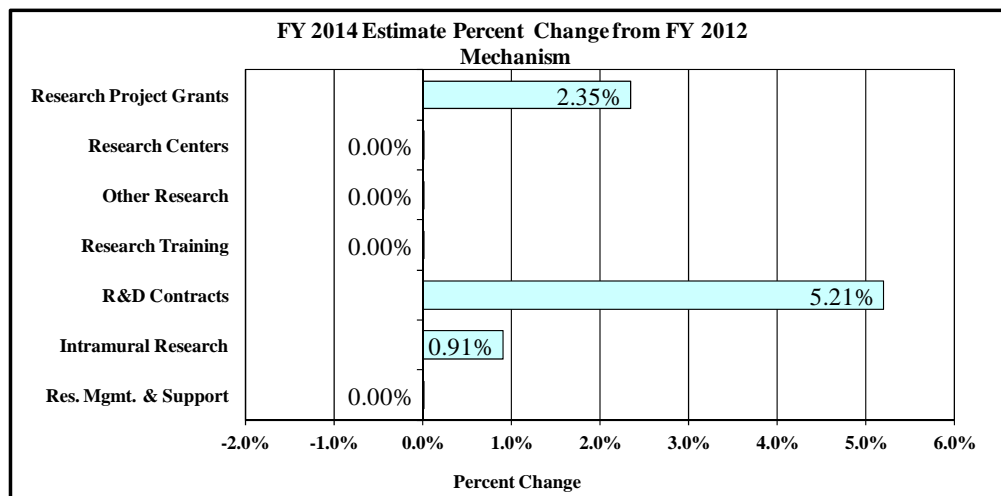
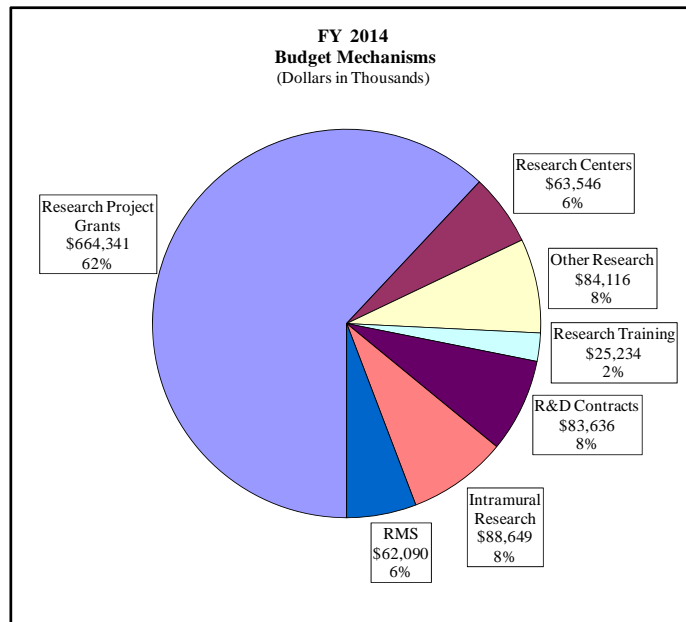
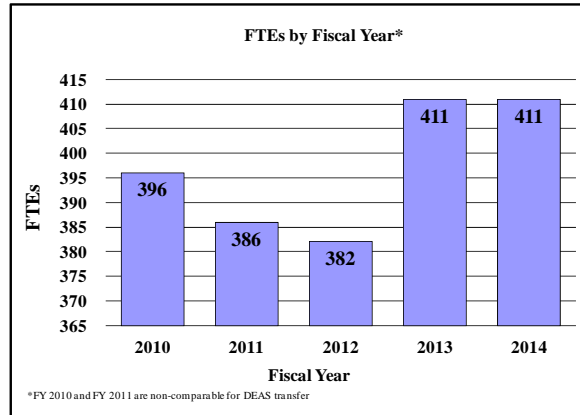
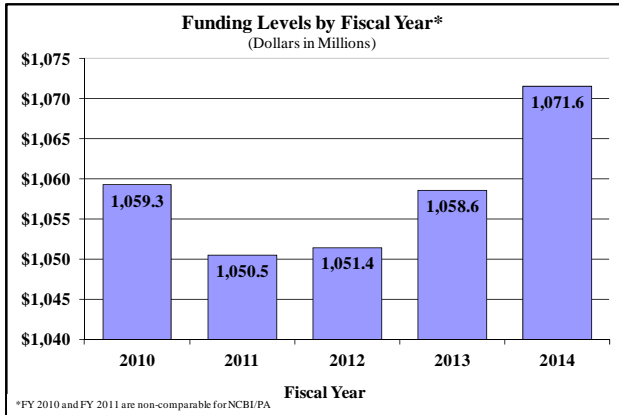
FY 2012 Actual				\$1,051,410
FY 2014 President's Budget				\$1,071,612
Net change				\$20,202
CHANGES	2014 President's Budget		Change from FY 2012	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of March				
		\$24,346		\$66
		24,346		178
		24,346		92
		24,346		0
		11,229		203
		53,074		70
Subtotal				\$609
2. Research Management and Support:				
a. Annualization of March				
		\$38,637		\$105
		38,637		286
		38,637		146
		38,637		0
		4,316		82
		19,137		3
Subtotal				\$622
Subtotal, Built-in				\$1,231

NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse

Summary of Changes--continued

CHANGES	2014 President's Budget		Change from FY 2012	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	1,060	\$481,369	19	\$14,471
b. Competing	423	159,866	24	-2,071
c. SBIR/STTR	63	23,106	7	2,865
Total	1,546	\$664,341	50	\$15,265
2. Research Centers	35	\$63,546	-3	\$0
3. Other Research	297	84,116	0	0
4. Research Training	548	25,234	-9	0
5. Research and development contracts	169	83,636	0	4,140
Subtotal, Extramural		\$920,873		\$19,405
6. Intramural Research	<u>FTEs</u> 128	\$88,649	<u>FTEs</u> 4	\$187
7. Research Management and Support	283	62,090	25	-622
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	411	\$1,071,612	29	\$18,970
Total changes				\$20,202

Fiscal Year 2014 Budget Graphs



NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse
Budget Authority by Activity ^{1,2}
(Dollars in Thousands)

	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research								
<u>Detail:</u>								
Basic and Clinical Neuroscience and Behavioral Research		\$459,075		\$462,342		465,342		\$6,267
Epidemiology, Services and Prevention Research		255,536		257,338		264,383		\$8,847
Pharmacotherapies and Medical Consequences		137,540		138,537		\$141,537		\$3,997
Clinical Trials Network		49,316		49,611		49,611		\$295
Subtotal, Extramural		\$901,467		\$907,828		\$920,873		\$19,406
Intramural Research	124	\$87,853	128	\$88,649	128	\$88,649	4	\$796
Research Management & Support	258	\$62,090	283	\$62,090	283	\$62,090	25	\$0
TOTAL	382	\$1,051,410	411	\$1,058,567	411	\$1,071,612	29	\$20,202

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.

NATIONAL INSTITUTES OF HEALTH National Institute on Drug Abuse 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 on Drug Abuse	Section 401(a)	42§281	Indefinite	\$1,058,567,000	Indefinite	\$1,071,612,000
Total, Budget Authority				\$1,058,567,000		\$1,071,612,000

**NATIONAL INSTITUTES OF HEALTH
National Institute on Drug Abuse**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2005	\$1,019,060,000	\$1,019,060,000	\$1,026,200,000	\$1,014,760,000
Rescission				(\$8,341,000)
2006	\$1,010,130,000	\$1,010,130,000	\$1,035,167,000	\$1,010,130,000
Rescission				(\$10,101,000)
2007	\$994,829,000	\$994,829,000	\$1,000,342,000	\$1,000,621,000
Rescission				-
2008	\$1,000,365,000	\$1,015,559,000	\$1,022,594,000	\$1,018,493,000
Rescission				(\$17,793,000)
Supplemental				\$5,322,000
2009	\$1,001,672,000	\$1,035,997,000	\$1,029,539,000	\$1,032,759,000
Rescission				-
2010	\$1,045,384,000	\$1,069,583,000	\$1,050,091,000	\$1,059,848,000
Rescission				-
2011	\$1,094,078,000	-	\$1,092,369,000	\$1,059,848,000
Rescission				(\$9,306,097)
2012	\$1,080,018,000	\$1,080,018,000	\$1,038,714,000	\$1,055,362,000
Rescission				(\$1,994,634)
2013	\$1,054,001,000	-	\$1,057,196,000	-
Rescission				-
2014	\$1,071,612,000	-	-	-

Justification of Budget Request

National Institute on Drug Abuse

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

Budget Authority (BA):

	FY 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 +/- FY 2012
BA	\$1,051,410,000	\$1,058,567,000	\$1,071,612,000	+\$20,202,000
FTE	382	411	411	-29

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

Director's Overview

Enlarging Our View of Addiction

The societal impact of substance abuse (alcohol, tobacco, illicit, and nonmedical use of prescription drugs) in this country is daunting, exceeding \$600 billion a year in health care, crime-related, and productivity losses. To provide a comprehensive public health response, the National Institute on Drug Abuse (NIDA) will build on science advances from investments in genetics, pharmacotherapy, neuroscience, and behavioral and health services research that have led to innovative strategies for preventing and treating substance abuse and addiction.

NIDA will also pursue a "functional integration" or collaborative framework to enhance and expand activities related to substance use, abuse, and addiction research across the NIH, especially with the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Significant progress has already been made in the integration of NIDA's and NIAAA's intramural research programs and in the initiation of joint National Advisory Council meetings. This functional integration provides an important opportunity to pool resources and expertise to more effectively capitalize on synergies in addiction research, address scientific opportunities, and meet public health needs, while maintaining the unique research contributions of each IC.

The scope of both licit and illicit substance abuse is broad in this country. Prescription drug abuse, for example, remains a major concern across age groups and causes thousands of needless overdose deaths each year.¹ Rates of marijuana use also hover at unacceptably high levels, even

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012.*

as new research reveals it can disrupt learning circuitry and lower IQ.² Drugs compromise our young people's potential and the competitiveness of a nation that depends on them.

Basic Science for Tomorrow's Breakthroughs

Stunning discoveries in addiction research have enhanced understanding of the genetic, developmental, structural, and environmental factors that influence brain function in health and disease. Epigenetics—the study of how environmental factors can persistently alter gene expression (but not the DNA sequence) and thereby influence brain function and behavior—seeks to understand such phenomena. Animal studies have shown that factors like stress, drug exposure, and parenting behavior can influence addiction risk long-term through chemical modifications (i.e., epigenetic marks) in specific genes that may persist across generations: a recent study found that paternal cocaine exposure caused reduced body weight and changes in the brain systems governing mood regulation in the offspring. Epigenetics, combined with genetic information, will improve our ability to prevent, identify, diagnose, and treat addiction.

NIDA's multipronged strategy has helped usher in progress on several fronts. For one, it has led to innovation in medications development, such as anti-drug enzymes or antibodies to sequester the psychoactive ingredient of an abused substance in the bloodstream, slowing or preventing its entry into the brain (see Program Portrait on gene therapy). Also important is the search for predictive biomarkers to help clinicians select and monitor a therapeutic course of action and to help researchers evaluate and refine new therapeutic interventions. A recent advance showed, for example, that a person's response to treatment using a dopamine receptor drug can be predicted by individual differences in the levels of an enzyme (catecholamine o-methyl transferase) or of dopamine receptor type 3 expressed in white blood cells. Further, imaging studies of the brain at rest are revealing reproducible changes in brain structure and connectivity in addicted individuals—advances to help realize the promise of personalized medicine, allow for earlier identification and treatment of addicted patients, and reveal new targets for pharmacotherapies, desperately needed for addiction.

Public Health Impact: Translating Research to Real-World Practice

Translating findings from basic science into intervention strategies is not only key to exploring new approaches, but also to ensuring that evidence-based practices work in real-world settings, including a variety of health care venues and the criminal justice system. NIDA's National Drug Abuse Clinical Trials Network (CTN) and Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS) enhance the rapid deployment of research-based interventions in multiple settings, undertaking studies that lead to more effective and cost-effective treatment approaches. To help integrate addiction services across the healthcare continuum, NIDA supports studies to identify barriers to and facilitators for integrating these services in diverse primary care settings.

Healthcare reform legislation portends needed change in this regard, presenting opportunities to study how innovations in service delivery, organization, and financing can be used to improve

² Meier et al. *Persistent cannabis users show neuropsychological decline from childhood to midlife*. *PNAS USA* 109(40):E2657-64, 2012. PMID: 22927402.

access to and use of effective prevention and treatment interventions (see Program Portrait on HIV). One area primed for change is screening, brief intervention, and referral to treatment (SBIRT) for substance use; NIDA will build on the success of screening for alcohol and tobacco use in primary care settings and continue to evaluate and expand SBIRT for other drugs of abuse and for special populations, including polydrug users and adolescents.

Another urgent public health issue pertains to substance abuse and associated comorbidities among military personnel, veterans, and their families. In collaboration with the Departments of Defense (DoD) and Veteran's Affairs (VA), NIAAA, and National Institute of Child Health and Human Development (NICHD), NIDA is launching a new initiative to develop and test interventions to prevent the onset and progression of drug abuse and comorbid conditions.

Other critical target populations for NIDA research include at-risk adolescents, such as those in the criminal justice system, with rates of substance abuse (or mental illness) that exceed 50 percent.³ In response, NIDA will support research to discover how juvenile justice systems can effectively implement a continuum of evidence-based substance abuse prevention and treatment services so as to reach every juvenile in the system and link them appropriately.

The Research Workforce: Encouraging Innovation

Attracting and retaining scientists can be challenging. NIDA will support the training and career development of a diverse pool of scientists to address all aspects of substance abuse and its health consequences. To meet the needs of modern science, NIDA will continue to create programs to attract researchers from physics, bioinformatics, and computational neuroscience—scientists who can create the needed language, tools, expertise, and infrastructure for researchers and clinicians to harmonize and analyze complex systems and large datasets. In this regard NIDA has taken the lead on several training initiatives supported through the NIH Neuroscience Blueprint—including Institutional grants in Computational Neuroscience and Neuroimaging. NIDA also offers special funding opportunities to facilitate the entry of much needed chemists into the drug abuse field through a program known as E-Chem, designed to help new-to-NIH researchers conduct exploratory research.

Overall Budget Policy: The FY 2014 President's Budget request for NIDA is \$1.072 billion, an increase of \$20 million or 1.9 percent above the FY 2012 Actual level. Research priorities include those that position the Institute to advance the development of medications, taking advantage of innovative genetics tools and technologies, and translating the results of evidence-based findings to improve drug abuse interventions and promote greater access to them worldwide. HIV prevention and treatment is another top NIDA research priority, including research on the interactions between HIV, substance abuse, and other comorbid psychiatric disorders, linking vulnerable populations to HIV prevention, testing, and treatment services, addressing HIV/AIDS-related health disparities, and integrating the treatment of substance abuse and HIV. Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

³ Wasserman et al. *Psychiatric disorder, comorbidity, and suicidal behavior in juvenile justice youth. Criminal Justice and Behavior* 37:1362, 2010.

Program Descriptions and Accomplishments

Basic and Clinical Neuroscience: The Basic and Clinical Neuroscience programs work together to expand understanding of the neurobiological, genetic/epigenetic, and behavioral factors that underlie drug abuse and addiction. Specifically, they examine which variables influence risk of drug abuse, addiction, and drug-related disorders; how addiction works in the brain, including the effects of drugs on the expression or silencing of genes; and how resultant changes affect brain function and consequent behaviors. Research provides critical information to develop and test novel prevention and treatment interventions for drug abuse and addiction. New research will build on the growing recognition of the many essential roles played by non-neuronal cells (collectively called glia) in neurotransmission, inflammation, neuroprotection, and brain energy management. Recent findings suggest that glia can influence behavioral responses to drugs, including their rewarding or aversive effects. Also, HIV infection can undermine glial cells' vital role as supporters of neuronal physiology. NIDA is encouraging research to investigate the molecular and cellular correlates and consequences of substance abuse, HIV infection, and their interactions with glial cells in the central nervous system.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$465.3 million, an increase of \$6.3 million, or 1.4 percent above the FY 2012 Actual level.

Epidemiology, Services, and Prevention Research: This NIDA Division supports integrated approaches to understand and address the interactions between individuals and environments that contribute to drug abuse problems. It supports large surveys (e.g., the annual Monitoring the Future Survey, which tracks drug use and related attitudes among teens) and surveillance networks (e.g., the Community Epidemiology Work Group) to monitor drug-related issues and trends locally, nationally, and internationally; guide development of responsive interventions for a variety of populations; and encourage optimal service delivery in real-world settings (see Program Portrait). Key program areas include epidemiological studies on topics of special concern to better tailor prevention and treatment programs and adapt evidence-based interventions for target populations, such as youth, military, and the homeless. Runaways and other homeless young people are highly vulnerable and at greater risk for HIV infection and substance abuse. To address this critical public health gap, NIDA plans to support research to better understand the extent of HIV infection among homeless youth, the factors driving it, and how optimally to link these youth to HIV prevention, testing, care and treatment services.

In addition, this NIDA Division oversees partnering initiatives, including the first large-scale NIH-U.S. Food and Drug Administration (FDA) collaboration on tobacco regulatory research since Congress granted FDA the authority to regulate tobacco products. The Population Assessment of Tobacco and Health (PATH) Study, a national, longitudinal cohort study, will follow an estimated 59,000 adults and youth ages 12 to 18 to assess susceptibility to tobacco use, risk perceptions, use patterns, and resultant health impacts. Data collection is slated to begin in fall 2013, with plans for four or more annual data collection waves. Outcomes will inform current and future regulatory options for the FDA to protect public health, including setting tobacco product standards and communicating the risks of tobacco use to the general public.

Program Portrait: Potential of Healthcare Reform to Better Integrate HIV and Substance Abuse Treatment

FY 2012 Level: \$10.1 million

FY 2014 Level: \$11.6 million

Change: +\$ 1.5 million

The stubbornly high incidence of new HIV infections in the United States (<http://www.cdc.gov/hiv/topics/surveillance/basic.htm#incidence>) belies the overwhelming evidence showing that sustained antiretroviral therapy (ART) provided to HIV+ individuals can improve the health of the infected individual and also prevent the spread of HIV to others. Moreover, in HIV+ substance users, widespread use of ART has been shown to reduce viral load and HIV incidence at the population level. Substance users contribute to HIV infection rates through injection drug use and high-risk sexual behaviors. Approximately one-third of the estimated 1.2 HIV-infected Americans currently use drugs or binge on alcohol (<http://www.samhsa.gov/data/2k10/HIV-AIDS/HIV-AIDS.htm>). These individuals often do not receive ART treatment—partly because of concerns about possible non-compliance with the treatment regimens, or because they remain largely out of the treatment and care system. To reverse such trends will require a sustained and focused effort to seek, test, treat, and retain in care hard-to-reach substance users and to integrate substance abuse treatment with HIV treatment programs.

The Affordable Care Act of 2010 (ACA) and other healthcare reform legislation has the potential to lead needed change by providing medical insurance to a large percentage of currently uninsured persons with substance use disorders and by creating structural changes in the health care system that facilitate integration of substance abuse treatment with HIV programs. NIDA is exploring efficient and cost-effective models to test strategies to improve early HIV identification and immediate treatment for those who test positive—along with long-term HIV care—among drug users in both general medical and substance treatment settings.

Because of the high co-occurrence of substance abuse and infectious diseases such as HIV and Hepatitis C (HCV), infectious disease specialists also have a role to play in ensuring that their HIV+/HCV+ patients receive treatment for their substance use disorders. NIDA plans to support research to address this critical gap by understanding both the barriers to and opportunities for engaging infectious disease specialists in implementing screening, brief intervention, and referral to treatment in their practices. Identifying problems and starting and sustaining patients on needed treatment—for HIV *and* substance abuse—would have a significant impact on these intertwined epidemics in our country.

Budget Policy: The FY 2014 President’s Budget estimate for this program is \$264.4 million, an increase of \$8.8 million, or 3.5 percent over the FY 2012 Actual level.

Pharmacotherapies and Medical Consequences: This program area is responsible for medications development aimed at helping people recover from drug abuse and addiction and sustain abstinence, and includes development of pain medications with less potential for abuse and addiction (see Program Portrait below). It capitalizes on research showing the involvement of different brain systems in drug abuse and addiction, beyond the pleasure pathway (the brain circuits engaged by activities that are pleasurable and that promote survival—e.g., eating, sex—and so tend to be repeated), to develop medications in response to a variety of newly defined targets. Joint efforts with the NIAAA will help NIDA expand its medication development efforts to exploit common addiction circuitry and address polysubstance abuse.

To get innovative compounds and delivery systems into the marketplace more quickly, NIDA works closely with industry and the FDA and supports public-private partnerships to advance effective addiction medications. The goal is to leverage the strengths of public (government agencies and institutes), non-profit (academia, NGOs, philanthropic institutions), and private sector entities to incentivize a steady flow of compounds that can more rapidly progress from

“molecules to medicine.” A related strategy to this end is a new funding paradigm (e.g., “GO-MD” grants) aimed at “de-risking” medications in the early stages of discovery. This approach provides greater up-front support to closely monitored grantees for a shorter period of time, so that they can produce results quicker—whether for new compounds or repurposed medications—or change direction as needed.

This Division also supports innovative technological approaches to medication monitoring and delivery. For example, studies are being sought to develop and validate a reliable remote, real-time monitoring system to detect and measure cocaine ingestion in cocaine-dependent clinical trials participants. Such technology will be valuable for researchers testing and verifying treatments for cocaine addiction. This Division also includes programs to address the medical consequences of drug abuse and addiction, including Hepatitis C and HIV.

Program Portrait: Developing Pain Relievers with Less Abuse Liability

FY 2012 Level: \$42.3 million

FY 2014 Level: \$43.0 million

Change: +\$0.7 million

Commonly prescribed for treating severe and/or chronic pain, opioid pain medications are beneficial when used appropriately. But since they act on the same receptors as heroin, they are also prone to abuse, with potentially dire consequences: CDC reports that since 1999, unintentional overdose deaths involving prescription opioid pain relievers have more than quadrupled in the United States.⁴ As the following examples illustrate, NIDA takes a multipronged approach to this problem that includes: (a) research to identify new analgesic compounds, targets, and drug combinations with reduced abuse, tolerance, and dependence risk; and (b) working with industry and government to devise alternative delivery systems and drug formulations that minimize diversion [use of a drug in a way that is not medically prescribed to obtain a “high” (e.g., inhaling or injecting crushed pills designed for oral treatment)] and prevent overdose deaths.

- **Drugs that target the toll-like receptor 4 (TLR-4).** TLR-4 is a type of immune detector located on non-neuronal cells called glia, which initiate an inflammatory response when activated. Recently these receptors were also shown to cause the loss of opioids’ pain-relieving capacity with repeated use (i.e., tolerance) and to be involved in opioids’ rewarding effects. Medications that block TLR-4 could both reverse opioid tolerance (and the need for higher doses) and negate rewarding effects. Clinical confirmation could result in a novel strategy to enhance the efficacy and reduce the addictiveness of pain medications.
- **A pro-drug opioid medication.** A pro-drug is one that is inactive in the bloodstream until it is cleaved by specific enzymes in the digestive system. It also does not readily cross the blood-brain barrier, thereby preventing abuse via non-oral routes (e.g., injection or inhalation). A pro-drug technology for an opioid medication has already sparked the interest of a small biotechnology company, which has begun pursuing its development, thereby positioning NIDA to partner with industry in supporting needed clinical studies.
- **A drug formulation to reverse overdose from opioid drugs.** Although naloxone (an opioid antagonist) is an effective medication for reversing overdose, it can only be administered by health care professionals. To broaden its availability and save lives, new formulations need to be approved for over-the-counter sale. NIDA will support research to advance the development of intranasal naloxone administration—specifically a clinical study to define doses that correspond to alternatively administered (e.g., injected) doses already approved by the FDA.

Given the scope of the prescription opioid abuse problem, developing analgesics, overdose treatments, and innovative methods of delivering them can and must quickly be translated into real-world use.

⁴ Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012.*

Program Portrait: Gene Therapy for Treating Stimulant Addiction

FY 2012 Level: \$23.1 million

FY 2014 Level: \$23.2 million

Change: +\$0.1 million

Stimulant use disorders (e.g., cocaine, methamphetamine, prescription stimulants) remain a major public health concern. In 2011, over 1.8 million individuals currently (within the past month) abused either cocaine or methamphetamine.⁵ Unfortunately, no approved medications yet exist to treat addiction to stimulants. NIDA is funding a promising approach to treat stimulant and other substance use disorders that uses anti-drug enzymes or antibodies to neutralize the substance while it is still in the bloodstream, keeping it from entering the brain. The commercial feasibility of these approaches hinges on overcoming significant technical obstacles, one of which was addressed by two recent NIDA-supported preclinical studies that developed an attractive strategy based on the use of non-infective viruses modified to deliver (harmlessly) a gene that codes for the desired enzyme or antibody.

Preliminary results show that, once expressed in the body after a single injection of the virus carrier, these gene products can interfere with the pharmacological effects of the target drug for a long time. One study used an adeno-associated virus (AAV) to deliver a gene that encoded a high-affinity anti-cocaine monoclonal antibody to mice. The introduction of this gene stimulated the animals to produce high levels of cocaine-specific antibodies, which prevented cocaine from entering their brains and rendered them impervious to cocaine's behavioral effects for at least for 4 months after the injection. The second study used the same adenovirus system to deliver a gene that encodes for an enhanced version of a naturally occurring cocaine-metabolizing enzyme called butyrylcholinesterase. In rodents injected a single time with a virus carrying the gene for this enzyme, cocaine's effects in the body and central nervous system were completely blocked for at least 6 months.

These results suggest that using an adenovirus "shuttle" to deliver an efficient anti-cocaine antibody or cocaine-metabolizing enzyme is feasible and could be used to treat cocaine addiction. NIDA proposes to extend the findings described, first to non-human primates and then via translation to the clinic. If successful, the AAV-based monoclonal antibody strategy could also be applied to other drugs of abuse (e.g., methamphetamine, heroin) where the feasibility of producing high-affinity monoclonal antibodies has already been demonstrated. If it proves successful, this delivery mechanism would obviate the need for patient adherence with frequent medication regimens or multiple vaccine injections.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$141.5 million, an increase of \$4.0 million, or 2.9 percent over the FY 2012 Actual level.

Clinical Trials Network: NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) now comprises 13 research nodes and more than 240 individual community treatment programs in 38 States, plus the District of Columbia and Puerto Rico. The CTN works to develop treatment protocols for drug abuse and addiction and related conditions, such as comorbid mental health disorders and HIV, testing their real-world effectiveness with diverse patient populations and community treatment providers. It also serves as a research and training platform to help NIDA respond to emerging public health threats.

Since 1999, the CTN has increased the adoption of research-based treatments in community treatment practice. For example, CTN trials have shown that buprenorphine/naloxone is a safe and effective treatment for opioid addiction in young adults and in those abusing prescription opioid pain relievers. Buprenorphine/naloxone, which can be prescribed by qualified office-based physicians, is an alternative to methadone that can expand the reach of effective treatment for opioid addiction. Additionally, a CTN trial has shown that rapid HIV testing can be

⁵ SAMHSA, *Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2011.*

implemented in community-based drug abuse treatment centers, thus contributing to more comprehensive health care for patients with substance use disorders.

The CTN is currently at the final stage of completing (1) a multi-site study to evaluate Web-delivery of evidence-based psychosocial treatment for substance use disorders, (2) a trial of the safety and effectiveness of buprenorphine plus naltrexone for the treatment of cocaine addiction in patients also dependent on or abusing opioids, and (3) a trial evaluating the impact of adding smoking-cessation to standard treatment for stimulant addiction among patients who also smoke. Ongoing studies are evaluating the effect of screening, brief intervention, and referral to treatment (SBIRT) in emergency departments on substance use and substance-related outcomes, and a new study is comparing extended-release naltrexone (Vivitrol) to buprenorphine for patients addicted to heroin or other opioids, including prescription medications.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$49.6 million, an increase of \$0.3 million, or 0.6 percent above the FY 2012 Actual level.

Intramural Research Program (IRP): The Intramural program performs cutting edge research within a coordinated multidisciplinary framework. The IRP attempts to (1) elucidate the nature of the addictive process; (2) determine the potential use of emerging new therapies for substance abuse, both pharmacological and psychosocial; and (3) establish the long-term consequences of drugs of abuse on systems and organs, with particular emphasis on the brain and its development, maturation, function, and structure. In addition, the IRP supports an HIV/AIDS Pathophysiology and Medications Discovery Program, focusing on, among other things, the development of compounds to block the destructive effects of HIV on immune system cells. IRP investigators are working on varied potential targets for addiction medications, many of which are being pursued through collaborative efforts with NIDA's extramural medications development program, an approach that should speed up the progress of selected targets along the NIDA medications development pipeline. In addition, NIDA and NIAAA together have made significant progress at integrating their intramural research programs in substance use, abuse, and addiction, including the appointment of a single Clinical Director for NIAAA and NIDA and the establishment of a joint genetics Intramural Research Program and a common optogenetics lab.

Budget Policy: The FY 2014 President's Budget estimate for this program is \$88.6 million, an increase of \$0.8 million, or 0.9 percent above the FY 2012 Actual level.

Research Management and Support (RMS): RMS activities provide administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research and development contracts. Additionally, the functions of RMS encompass strategic planning, coordination, and evaluation of NIDA's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public. NIDA currently oversees more than 1,800 research grants and more than 190 research and development contracts. In addition to the infrastructure required to support research and training, NIDA also strives to educate the public about drug abuse and addiction and to raise awareness of the science addressing it.

Indeed, physicians are a key target for NIDA’s outreach efforts. In October 2012, the Office of National Drug Control Policy (ONDCP) and NIDA launched two online continuing medical education courses, using the “test-and-teach” model—one focused on safe prescribing for pain, the other on managing patients who abuse prescription opioids—in partnership with Medscape, a free web resource for physicians and other health professionals that features peer-reviewed original medical journal articles; medical news, major conference coverage, and drug information; and a customized version of the National Library of Medicine's MEDLINE database, among other things. After just 2 months, nearly 25,000 physicians and registered nurses have already completed these courses. In 2013, NIDA will publish a new NIDA *Principles of Effective Treatment for Adolescents*, intended to provide parents, referring clinicians, treatment practitioners, youth, and others with an evidence-based guide to the principles of effective substance abuse treatment for youth. This booklet complements *Principles of Drug Addiction Treatment: A Research-Based Guide*, highly regarded by the field. Like its parent, the new booklet offers FAQs, proven approaches, descriptions of multiple treatment modalities and settings, and a listing of other resources.

Budget Policy: The FY 2014 President’s Budget estimate for this program is \$62.1 million flat to the FY 2012 Actual level. 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.

NIH Collaborative Activities: NIDA actively participates in a variety of trans-NIH activities. NIDA has a lead role for the Common Fund–supported Epigenomics Program and additionally will be administering a request for application (RFA) to support a data management center for the new Common Fund Extracellular RNA Communication Program. NIDA participates in the NIH Neuroscience Blueprint—a collaboration between 15 NIH Institutes, Centers, and Offices that fund neuroscience research. It aims to accelerate neuroscientific discovery by pooling resources and expertise to address research challenges too large for any single institute or center. NIDA is the lead for the NIH Blueprint–supported Institutional Training Grants on Computational Neuroscience and Neuroimaging and the Neuroscience Information Framework (a dynamic inventory of Web-based neuroscience resources, data, and tools for scientists and students). NIDA also participates in the Basic Behavioral and Social Sciences Opportunity Network (OppNet) and in an OppNet-supported RFA titled the Effects of the Social Environment on Health, which will fund research to investigate structural, behavioral, sociocultural, environmental, cognitive, emotional, and/or biological mechanisms by which the social environment affects health outcomes. Additionally, NIDA collaborates and provides support for the HIV Prevention Trials Network (HPTN), funded by the Division of AIDS within the National Institute of Allergy and Infectious Diseases. HPTN focuses on the use of ART for HIV prevention and treatment, as well as treatment and prevention of sexually transmitted infections and substance abuse (particularly injection drug use) to reduce HIV transmission and acquisition.

NIDA has taken the lead, working with 20 NIH ICs and the Office of the Director, in supporting Centers of Excellence in Pain Education (CoEPEs). In May 2012, 12 CoEPEs were awarded to develop pain management curriculum resources for medical, dental, nursing, and pharmacy schools to advance the assessment, diagnosis, and safe treatment of pain, which will include a focus on minimizing risks of addiction to and diversion of opioid pain medications.

NATIONAL INSTITUTES OF HEALTH
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Budget Authority by Object Class
(Dollars in Thousands)

	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	382	411	29
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary (in whole dollars)	\$177,884	\$180,112	\$2,228
Average GM/GS grade	12.8	12.7	(0.1)
Average GM/GS salary (in whole dollars)	\$110,974	\$108,133	(\$2,841)
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) (in whole dollars)	\$110,901	\$112,010	\$1,109
Average salary of ungraded positions (in whole dollars)	\$140,659	\$142,066	\$1,407
OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$30,229	\$32,072	\$1,843
11.3 Other than full-time permanent	10,921	11,432	511
11.5 Other personnel compensation	813	849	36
11.7 Military personnel	1,173	1,214	41
11.8 Special personnel services payments	4,222	4,275	53
Total, Personnel Compensation	\$47,359	\$49,842	\$2,483
12.0 Personnel benefits	\$11,771	\$12,292	\$521
12.2 Military personnel benefits	691	715	24
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$59,821	\$62,849	\$3,028
21.0 Travel and transportation of persons	\$938	\$1,210	\$272
22.0 Transportation of things	75	75	0
23.1 Rental payments to GSA	5	5	0
23.2 Rental payments to others	26	26	0
23.3 Communications, utilities and miscellaneous charges	1,222	1,222	0
24.0 Printing and reproduction	13	13	0
25.1 Consulting services	2,909	2,067	(842)
25.2 Other services	3,704	3,241	(463)
25.3 Purchase of goods and services from government accounts	107,750	110,461	2,711
25.4 Operation and maintenance of facilities	2,100	1,931	(169)
25.5 Research and development contracts	43,263	44,638	1,375
25.6 Medical care	1,931	1,728	(203)
25.7 Operation and maintenance of equipment	1,496	1,496	(0)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	\$163,153	\$165,562	\$2,409
26.0 Supplies and materials	\$3,522	\$4,374	\$852
31.0 Equipment	5,411	4,821	(590)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	817,225	831,455	14,230
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	\$991,589	\$1,008,763	\$17,174
Total Budget Authority by Object Class	\$1,051,410	\$1,071,612	\$20,202

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

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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$30,229	\$32,072	\$1,843
Other than full-time permanent (11.3)	10,921	11,432	511
Other personnel compensation (11.5)	813	849	36
Military personnel (11.7)	1,173	1,214	41
Special personnel services payments (11.8)	4,222	4,275	53
Total Personnel Compensation (11.9)	\$47,358	\$49,842	\$2,484
Civilian personnel benefits (12.1)	\$11,771	\$12,292	\$521
Military personnel benefits (12.2)	691	715	24
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$59,820	\$62,849	\$3,029
Travel (21.0)	\$938	\$1,210	\$272
Transportation of things (22.0)	75	75	0
Rental payments to others (23.2)	26	26	0
Communications, utilities and miscellaneous charges (23.3)	1,222	1,222	0
Printing and reproduction (24.0)	13	13	0
Other Contractual Services:			
Advisory and assistance services (25.1)	2,909	2,067	(842)
Other services (25.2)	3,704	3,241	(463)
Purchases from government accounts (25.3)	70,922	67,846	(3,076)
Operation and maintenance of facilities (25.4)	2,100	1,931	(169)
Operation and maintenance of equipment (25.7)	1,496	1,496	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$81,131	\$76,581	(\$4,550)
Supplies and materials (26.0)	\$3,001	\$3,852	\$851
Subtotal, Non-Pay Costs	\$86,406	\$82,979	(\$3,427)
Total, Administrative Costs	\$146,226	\$145,828	(\$398)

NATIONAL INSTITUTES OF HEALTH
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Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2012 Actual			FY 2013 CR			FY 2014 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	23	-	23	24	-	24	23	-	23
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	23	-	23	24	-	24	23	-	23
Office of Extramural Activities									
Direct:	17	-	17	22	-	22	22	-	22
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	17	-	17	22	-	22	22	-	22
Office of Management									
Direct:	50	-	50	55	-	55	55	-	55
Reimbursable:	23	-	23	26	-	26	28	-	28
Total:	73	-	73	81	-	81	83	-	83
Office of Science Policy and Communication									
Direct:	28	-	28	28	-	28	28	-	28
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	28	-	28	28	-	28	28	-	28
Division of Epidemiology, Services & Prevention Research									
Direct:	26	3	29	28	2	30	28	2	30
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	26	3	29	28	2	30	28	2	30
Division of Basic Neuroscience & Behavioral Research									
Direct:	28	-	28	32	-	32	32	-	32
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	29	-	29	33	-	33	33	-	33
Division of Pharmacotherapies & Medical Consequences of Drug Abuse									
Direct:	29	-	29	32	-	32	32	-	32
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	29	-	29	32	-	32	32	-	32
Center for the Clinical Trials Network									
Direct:	13	2	15	16	1	17	16	1	17
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	13	2	15	16	1	17	16	1	17
Division of Clinical Neuroscience & Behavioral Research									
Direct:	15	-	15	16	-	16	15	-	15
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	15	-	15	16	-	16	15	-	15
Intramural Research Program									
Direct:	116	6	122	120	6	126	120	6	126
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	118	6	124	122	6	128	122	6	128
Total	371	11	382	402	9	411	402	9	411
Includes FTEs whose payroll obligations are supported by the NIH Common Fund. FTEs supported by funds from Cooperative Research and Development Agreements.									
FISCAL YEAR	Average GS Grade								
2010	13.0								
2011	13.0								
2012	12.8								
2013	12.7								
2014	12.7								

**NATIONAL INSTITUTES OF HEALTH
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Detail of Positions

GRADE	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Total, ES Positions	1	1	1
Total, ES Salary	\$ 177,884	\$ 178,329	\$ 180,112
GM/GS-15	66	66	66
GM/GS-14	87	87	87
GM/GS-13	58	58	58
GS-12	38	39	39
GS-11	13	13	13
GS-10	1	1	1
GS-9	16	16	16
GS-8	13	17	17
GS-7	4	17	17
GS-6	0	3	3
GS-5	2	3	3
GS-4	4	4	4
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	303	325	325
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	8	7	7
Full Grade	0	0	0
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	9	8	8
Ungraded	70	70	70
Total permanent positions	306	335	335
Total positions, end of year	383	412	412
Total full-time equiv (FTE) at YE	382	411	411
Average ES salary	\$ 177,884	\$ 178,329	\$ 180,112
Average GM/GS grade	12.8	12.7	12.7
Average GM/GS salary	\$ 110,974	\$ 107,062	\$ 108,133

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