

DEPARTMENT OF HEALTH AND HUMAN SERVICES

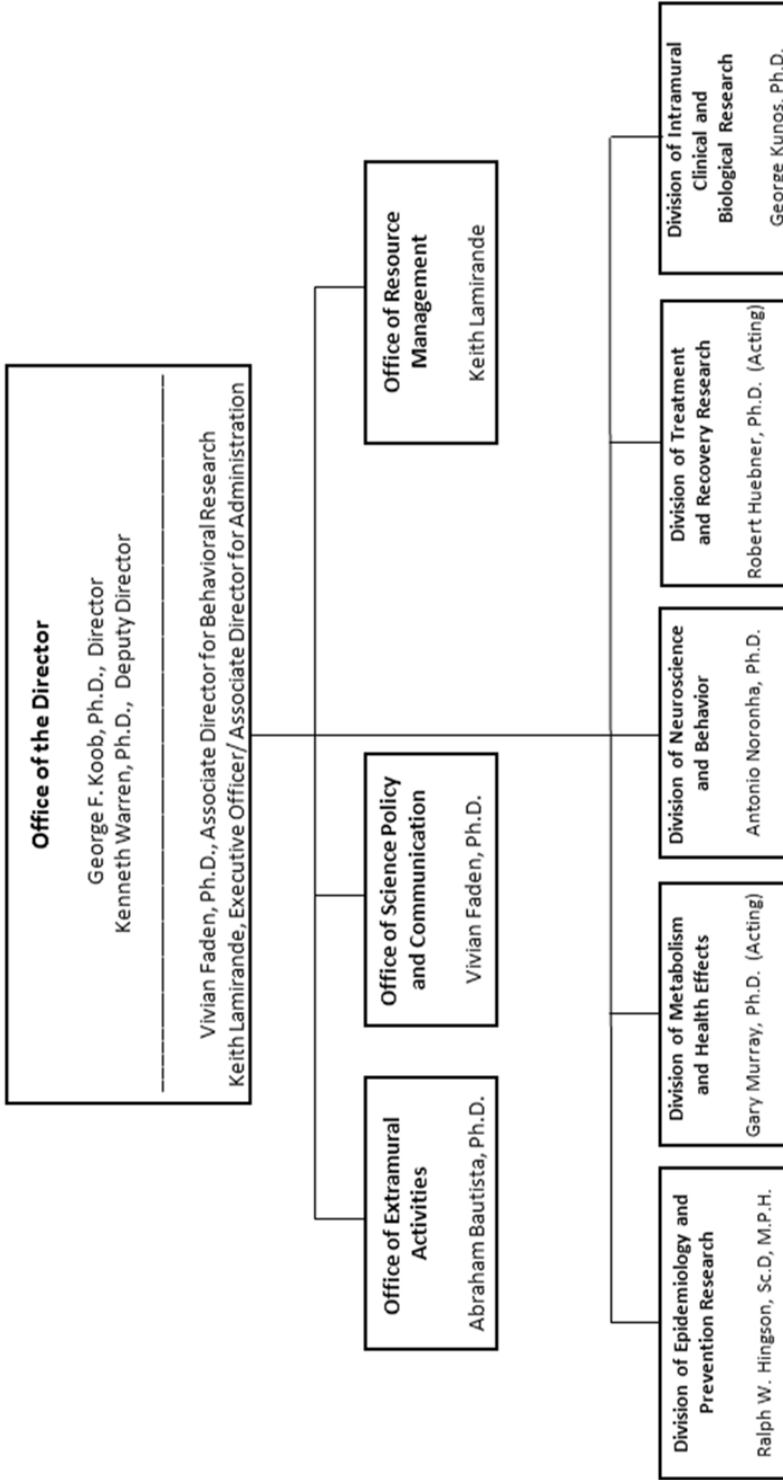
NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism



NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

For carrying out section 301 and title IV of the PHS Act with respect to alcohol abuse and alcoholism, [~~\$446,025,000~~]*\$446,017,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Appropriation	\$459,519	\$446,025	\$446,017
Type 1 Diabetes	0	0	0
Rescission	-919	0	0
Sequestration	-23,065	0	0
Subtotal, adjusted appropriation	\$435,535	\$446,025	\$446,017
FY 2013 Secretary's Transfer	-2,541	0	0
OAR HIV/AIDS Transfers	0	0	0
Comparative transfers to NLM for NCBI and Public Access	-514	-614	0
National Children's Study Transfers	369	0	0
Subtotal, adjusted budget authority	\$432,849	\$445,411	\$446,017
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$432,849	\$445,411	\$446,017
Unobligated balance lapsing	-117	0	0
Total obligations	\$432,732	\$445,411	\$446,017

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

FY 2013 - \$4,971 FY 2014 - \$7,000 FY 2015 - \$7,000

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism
Budget Mechanism - Total¹

(Dollars in Thousands)

MECHANISM	FY 2013 Actual		FY 2014 Enacted ²		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	482	\$182,889	477	\$184,633	479	\$184,407	2	-\$226
Administrative Supplements	(24)	1,269	(24)	1,269	(24)	1,269	(0)	0
<u>Competing:</u>								
Renewal	20	8,480	21	8,943	21	8,943	0	0
New	146	46,812	153	49,002	154	49,490	1	488
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	166	\$55,292	174	\$57,945	175	\$58,433	1	\$488
Subtotal, RPGs	648	\$239,450	651	\$243,847	654	\$244,109	3	\$262
SBIR/STTR	23	7,951	26	9,360	28	9,660	2	300
Research Project Grants	671	\$247,402	677	\$253,207	682	\$253,769	5	\$562
<u>Research Centers:</u>								
Specialized/Comprehensive	18	\$25,852	18	\$25,792	18	\$25,792	0	\$0
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	18	\$25,852	18	\$25,792	18	\$25,792	0	\$0
<u>Other Research:</u>								
Research Careers	95	\$14,398	95	\$14,398	95	\$14,398	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	1	6,096	1	7,500	1	7,500	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research	0	340	0	340	0	340	0	0
Other	38	14,239	39	14,826	39	14,826	0	0
Other Research	134	\$35,073	135	\$37,064	135	\$37,064	0	\$0
Total Research Grants	823	\$308,326	830	\$316,063	835	\$316,625	5	\$562
<u>Ruth L. Kirchstein Training Awards:</u>	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	106	\$4,120	106	\$4,160	106	\$4,210	0	\$50
Institutional Awards	164	7,313	164	7,483	164	7,633	0	150
Total Research Training	270	\$11,433	270	\$11,643	270	\$11,843	0	\$200
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	65 (7)	\$37,119 (2,921)	65 (6)	\$37,426 (2,340)	65 (6)	\$38,390 (2,340)	0 (0)	\$964 (0)
Intramural Research	113	46,829	113	49,144	113	49,144	0	0
Res. Management & Support	130	29,141	130	30,015	130	30,015	0	0
<i>Res. Management & Support (SBIR Admin) (non-add)</i>	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAAA	243	\$432,849	243	\$445,411	243	\$446,017	0	\$606

¹ All items in italics and brackets are non-add entries. FY 2013 and FY 2014 levels are shown on a comparable basis to FY 2015.

² The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

Major Changes in the Fiscal Year 2015 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 mechanism and activity detail and these highlights will not sum to the total change for the FY 2015 President's Budget request for NIAAA, which is \$0.606 million more than the FY 2014 Enacted level, for a total of \$446.017 million.

Research Project Grants (+\$0.562 million; total \$253.769 million):

NIAAA will support a total of 682 Research Project Grant (RPG) awards in FY 2015. Noncompeting RPGs will increase by two awards and competing awards will increase by one award and \$0.488 million.

Research Training (+\$0.200 million; total \$11.843 million):

NIAAA is committed to supporting the training and development of the next generation of scientists.

Research and Development Contracts (+\$0.964 million; total \$38.390 million):

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

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Summary of Changes¹

(Dollars in Thousands)

FY 2014 Enacted				\$445,411
FY 2015 President's Budget				\$446,017
Net change				\$606
CHANGES	FY 2015 President's Budget		Change from FY 2014	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2014 pay increase & benefits		\$19,657		\$48
b. January FY 2015 pay increase & benefits		19,657		147
c. Zero more days of pay (n/a for 2015)		19,657		0
d. Differences attributable to change in FTE		19,657		0
e. Payment for centrally furnished services		8,002		134
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		21,484		-330
Subtotal				\$0
2. Research Management and Support:				
a. Annualization of January 2014 pay increase & benefits		\$19,256		\$47
b. January FY 2015 pay increase & benefits		19,256		144
c. Zero more days of pay (n/a for 2015)		19,256		0
d. Differences attributable to change in FTE		19,256		0
e. Payment for centrally furnished services		1,234		18
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		9,525		-209
Subtotal				\$0
Subtotal, Built-in				\$0

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Summary of Changes - Continued¹

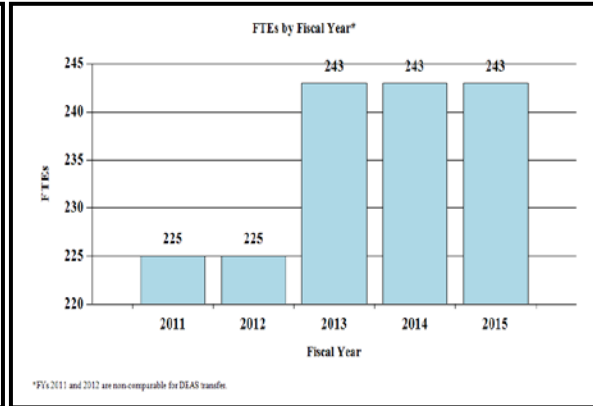
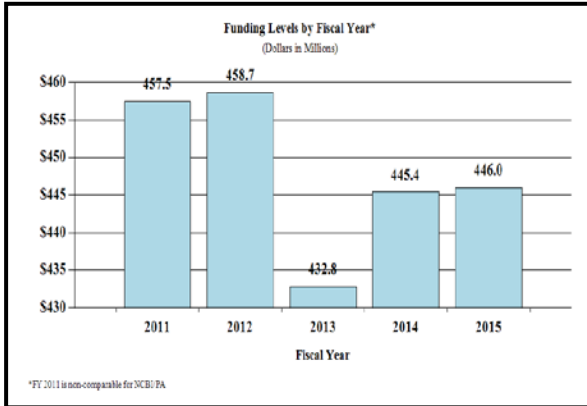
(Dollars in Thousands)

CHANGES	FY 2015 President's Budget		Change from FY 2014	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	479	\$185,676	2	-\$226
b. Competing	175	58,433	1	488
c. SBIR/STTR	28	9,660	2	300
Subtotal, RPGs	682	\$253,769	5	\$562
2. Research Centers	18	\$25,792	0	\$0
3. Other Research	135	37,064	0	0
4. Research Training	270	11,843	0	200
5. Research and development contracts	65	38,390	0	964
Subtotal, Extramural		\$366,858		\$1,726
6. Intramural Research	<u>FTEs</u> 113	\$49,144	<u>FTEs</u> 0	\$0
7. Research Management and Support	130	30,015	0	0
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	243	\$446,017	0	\$1,726
Total changes				\$606

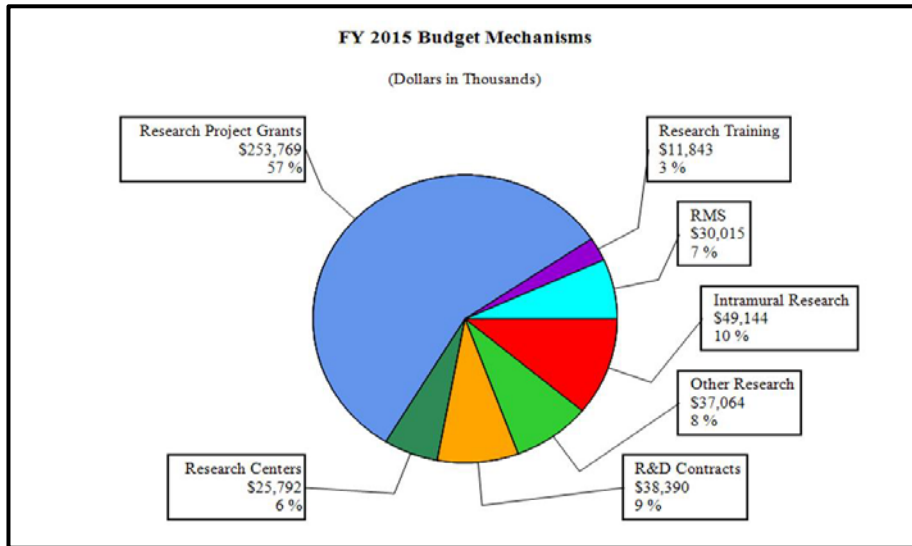
¹ The amounts in the Change from FY 2014 column take into account funding reallocations, and therefore may not add to the net change reflected herein.

Fiscal Year 2015 Budget Graphs

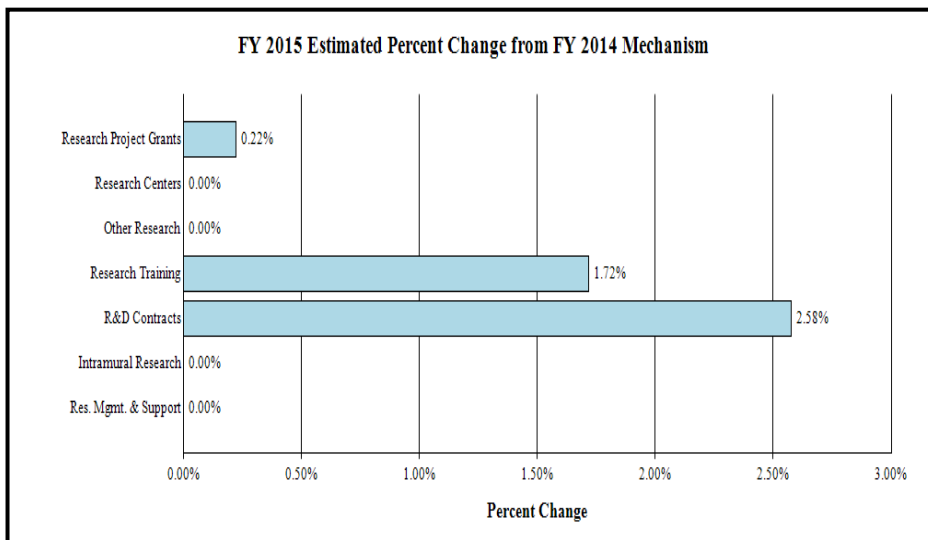
History of Budget Authority and FTEs:



Distribution by Mechanism (dollars in thousands):



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Budget Authority by Activity¹

(Dollars in Thousands)

	FY 2013 Actual		FY 2014 Enacted ²		FY 2015 President's Budget		FY 2015 +/- FY 2014	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Extramural Research</u>								
<u>Detail</u>								
Embryo and Fetus		\$15,236		\$15,642		\$15,681		\$39
Youth/Adolescence		59,819		61,412		61,566		154
Young Adult		161,609		164,661		165,886		1,225
Mid-Life/Senior Adult		120,215		123,417		123,725		308
Subtotal, Extramural		\$356,879		\$365,132		\$366,858		\$1,726
Intramural Research	113	\$46,829	113	\$49,144	113	\$49,144	0	\$0
Research Management & Support	130	\$29,141	130	\$30,015	130	\$30,015	0	\$0
TOTAL	243	\$432,849	243	\$445,411	243	\$446,017	0	\$606

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

² The amounts in the FY 2014 column take into account funding reallocations, and therefore may not add to the total budget authority reflected herein.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2014 Amount Authorized	FY 2014 Enacted	2015 Amount Authorized	FY 2015 PB
Research and Investigation	Section 301	42§241	Indefinite	\$445,411,000	Indefinite	\$446,017,000
National Institute on Alcohol Abuse and Alcoholism	Section 401(a)	42§281	Indefinite	\$445,411,000	Indefinite	\$446,017,000
Total, Budget Authority				\$445,411,000		\$446,017,000

**NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2005 Rescission	\$441,911,000	\$441,911,000	\$444,900,000	\$441,911,000 (\$3,634,000)
2006 Rescission	\$440,333,000	\$440,333,000	\$452,271,000	\$440,333,000 (\$4,403,000)
2007 Rescission	\$433,318,000	\$433,318,000	\$433,318,000	\$435,930,000 \$0
2008 Rescission Supplemental	\$436,505,000	\$436,505,000	\$436,505,000	\$436,256,000 (\$7,757,000) \$2,320,000
2009 Rescission	\$436,681,000	\$451,688,000	\$448,834,000	\$450,230,000 \$0
2010 Rescission	\$455,149,000	\$466,308,000	\$457,887,000	\$462,346,000 \$0
2011 Rescission	\$474,649,000		\$473,904,000	\$462,346,000 (\$4,059,673)
2012 Rescission	\$469,197,000	\$469,197,000	\$453,127,000	\$460,389,000 (\$870,135)
2013 Rescission Sequestration	\$457,104,000		\$458,489,000	\$459,518,865 (\$919,038) (\$23,064,687)
2014 Rescission	\$463,848,000		\$460,765,000	\$446,025,000 \$0
2015	\$446,017,000			

Justification of Budget Request

National Institute on Alcohol Abuse and Alcoholism

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

Budget Authority (BA):

	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 + / - FY 2014
BA	\$432,849,372	\$445,411,000	\$446,017,000	+\$606,000
FTE	243	243	243	0

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

Director's Overview

Excessive alcohol use cost the U.S. an estimated \$223.5 billion in 2006 and takes a tremendous toll on individuals and their families¹. Specific consequences of alcohol misuse range from physical and cognitive deficits due to alcohol exposure during embryo/fetus development to organ damage from chronic heavy drinking, and from alcohol poisonings to alcohol dependence. Over the past several decades, it has become increasingly clear that individuals are differentially susceptible to the effects of alcohol and respond differently to specific treatments. To reduce the considerable burden of illness associated with alcohol misuse, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports research focused on: identifying the underlying mechanisms of alcohol related health problems such as alcohol dependence, fetal alcohol spectrum disorders (FASD), and alcoholic liver disease (ALD); developing behavioral and pharmacological interventions; and determining which interventions work for whom and why.

Medications Development and Precision Medicine: Recognizing that medications available to treat alcohol dependence work for many, but not all individuals, NIAAA continues to make significant progress towards developing additional treatments. NIAAA's Clinical Investigations Group (NCIG) recently completed a multisite clinical trial that showed the anti-smoking medication varenicline (Chantix®) significantly reduced alcohol consumption and craving in both smokers and non-smokers with alcohol dependence. Building on its recent success, NCIG is currently testing additional compounds in collaboration with the pharmaceutical industry. Additional NIAAA-supported studies are moving us closer to making precision medicine a reality by determining what treatments will work based on an individual patient's profile. It has long been recognized that different people drink for different reasons, some being drawn to alcohol-induced euphoria, others drinking large quantities to experience any effect at all, and still others attempting to self-medicate anxiety or depression. Different molecular mechanisms likely

¹ Bouchery, EE, et al. 2011. 41(5): 516-524. *American Journal of Preventive Medicine. Economic Costs of Excessive Alcohol Consumption in the U.S., 2006.*

underlie each of these drinking behaviors, suggesting the need for different treatments and potentially explaining why certain medications differentially benefit certain individuals.

Researchers have shown that small variations in specific genes can predict effectiveness of a particular medication and virtually all clinical trials now include the collection of genetic material for analysis (see Exploring New Medication Options for Alcohol Dependence portrait).

NIAAA promotes alcohol screening for all people and brief interventions and/or treatment when appropriate; however, certain groups require special attention. Although there has been some decline in overall alcohol use by high school and college students, the prevalence of binge drinking (consuming five or more drinks on a single occasion) is still high. Blackouts and alcohol poisonings on college campuses are commonplace. NIAAA efforts are focusing on identifying effective interventions for college students as well as barriers to implementing them. Rates of binge drinking among young women are approaching those of their male counterparts, an especially worrying trend given the serious consequences such as alcohol-related sexual assault and the fact that women experience adverse health effects after fewer years of heavy drinking than men. Military personnel, veterans and their families are also vulnerable to alcohol problems, especially those suffering from post-traumatic stress disorder (PTSD), traumatic brain injury (TBI) or other mental health problems. NIAAA is investing significant resources in research to understand and treat these co-occurring disorders, including studies on the relationship between PTSD, interpersonal violence, and alcohol (see portrait).

For those who engage in chronic heavy alcohol use, genetic and environmental factors can increase susceptibility to ALD. Recent research has revealed that although ALD is similar pathologically to non-alcoholic fatty liver disease, there are distinct molecular pathways that lead to the resulting organ damage. A better understanding of these divergent pathways will inform treatment for each condition. NIAAA efforts include an intense focus on alcoholic hepatitis (AH), a severe form of liver injury which has a mortality rate as high as 60 percent within the first four weeks of diagnosis. In patients who survive an acute episode of AH, more than 50 percent go on to develop cirrhosis. NIAAA has established four research consortia to pursue new clinical approaches for the treatment of AH. Therapies targeting pathways involved in the development of AH include compounds that: 1) decrease the molecules in the gastrointestinal tract that result from disrupted gut barrier function and activate the immune response; 2) block inflammation and innate immune cell activation; and 3) reduce liver cell death and injury. In addition, combination therapies are being tested in AH patients who do not respond to standard treatment with prednisolone.

Today's Basic Science for Tomorrow's Breakthroughs: Clinical advances are underpinned by a vast amount of basic research, and current studies will ultimately lead to better treatments. For example, relapse, which is often triggered by alcohol related cues, is a significant impediment to treatment success, with most patients relapsing within the first year of abstinence. In a rodent model, the drug rapamycin disrupted alcohol associated memories triggered by alcohol's odor and taste, reduced craving, and prevented relapse. By identifying individuals who may be more likely to relapse, we could improve patient care; a recent study identified distinct patterns of brain activity associated with relapse among alcohol dependent patients in early recovery. Identifying additional therapeutic targets is also a priority. Converging evidence from humans and rodents suggests that alcohol dependence leads to deficits in the brain receptor mGluR2; restoring the receptor in the brains of rats reduced alcohol consumption. Long-term

abstinence may result in changes that enhance the brain's executive control network while decreasing the impact of the reward network thereby promoting continued abstinence. In the area of liver disease, intramural investigators developed a new animal model that mimics disease progression of human ALD revealing that the molecules E-selectin and osteopontin have a role in promoting alcoholic liver injury. Research in one disease area often leads to important findings in another; studies by intramural researchers showed that selectively inhibiting cannabinoid1 receptors reversed type-2 diabetes and its complications in animal models. Toxicology screening of the cannabinoid receptor inhibitor is underway in preparation for testing in human subjects.

Collaborative Research on Addictions at NIH (CRAN): NIAAA actively participates in CRAN, which provides a collaborative framework for NIAAA, NIDA, and the Tobacco Control Branch within NCI to integrate resources and expertise. To date CRAN has issued two funding announcements to augment existing grants to support research in cross-cutting areas of substance use, abuse, addiction and related health consequences.

Overall Budget Policy:

The FY 2015 President's Budget request is \$446.017 million, an increase of \$0.606 million or 0.1 percent above the FY 2014 Enacted level. Investigator-initiated research projects, new investigator research and research training remain the Institute's highest priorities. In FY 2014, NIAAA will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. Program plans in FY 2015 will focus on several key themes of the NIH including Investing in Basic Research, Accelerating Discovery Through Technology, Advancing Translational Sciences, and Encouraging New Investigators and New Ideas.

Program Descriptions and Accomplishments

Embryo and Fetus: The developing embryo and fetus are uniquely vulnerable to the adverse effects of alcohol. Epidemiological studies suggest that the prevalence of fetal alcohol spectrum disorders (FASD) is between two and five percent, a prevalence on par with autism spectrum disorder. NIAAA's research support for this life stage encompasses outreach to pregnant women for the identification and intervention of risky drinking, research to enhance our ability for early identification of and interventions with prenatal alcohol affected children, examination of nutritional and pharmacological agents that could lessen alcohol's adverse effects on the developing embryo/fetus or ameliorate those effects in affected children, and research on how alcohol disrupts normal embryonic and fetal development. Research has shown that the severity of alcohol-related effects on the developing fetus is affected by the timing and level of maternal alcohol consumption, maternal nutritional status and maternal hormones. One challenge facing clinicians is the ability to recognize women who are drinking during pregnancy and infants who have been exposed to alcohol prenatally. Although the facial features of fetal alcohol syndrome (FAS), the most severe form of FASD, are well defined, less is known about the full range of facial phenotypes caused by prenatal alcohol exposure. A recent study demonstrated that three-dimensional facial imaging may help identify children who have cognitive impairments caused by prenatal alcohol exposure but lack the facial features characteristic of FAS. In addition, developing behavioral markers and determining the neurological deficits underlying the

behavioral manifestations of FASD will be critical to effectively intervening with affected children. Given that alcohol appears to play a significant role in the risks of SIDS and stillbirth, NIAAA continues to collaborate with NICHD and NIDCD to support studies that investigate the interactions between prenatal alcohol exposure and other environmental and maternal factors that contribute to SIDS and stillbirth.

Budget Policy:

The FY 2015 President's Budget estimate is \$15.681 million, an increase of \$0.039 million or 0.3 percent above the FY 2014 Enacted level.

Youth/Adolescence (Ages 0-17): Adolescence is the time of life during which drinking, binge drinking (drinking five or more drinks on one occasion), and heavy drinking (binge drinking five or more times in the past 30 days) all increase dramatically. It is also a period of significant biological, social, and environmental changes. Protecting the developing body and brain from alcohol exposure is an important investment in short- and long-term health. NIAAA continues to support multisite longitudinal studies of youth ages 12-21 to assess the vulnerability of the adolescent brain to alcohol exposure. Complementary studies with animals will continue to investigate the effects of adolescent alcohol exposure on subsequent brain function and behavior into adulthood. Screening and brief interventions by health providers has been shown to be effective in reducing problem drinking in adults and a growing body of evidence supports the use of alcohol screening among adolescents. A 2010 survey of 10th grade students showed that while more than 80 percent had visited a doctor in the past year, only 54 percent of them were asked about drinking during their visit. To encourage universal screening for youth in health care settings, NIAAA developed an empirically based alcohol screener and guide for pediatricians and other clinicians who care for children and adolescents. This developmentally appropriate screening instrument is endorsed by the American Academy of Pediatrics. It was devised to identify children at elevated risk for using alcohol, children and adolescents who have already begun to experiment with alcohol, and those who are more heavily involved with alcohol. In 2013, NIAAA partnered with Medscape to develop an online training course to familiarize clinicians with the screening and brief intervention process and increase their skill and comfort level with it. To date, nearly 8,000 health care providers have been Medscape certified.

Budget Policy:

The FY 2015 President's Budget estimate is \$61.566 million, an increase of \$0.154 million or 0.3 percent above the FY 2014 Enacted level.

Young Adult (Ages 18-29): For young adults, whose drinking behavior and extent of associated problems vary widely, NIAAA focuses on risk assessment, universal and selective prevention, early intervention (before problems escalate and/or become chronic), and timely treatment for those who need it. Given the pervasiveness of high-risk drinking and alcohol dependence among young adults, efforts to alter drinking trajectories at this stage have life-changing potential and can significantly reduce the burden of illness resulting from alcohol-related problems. Incidents of alcohol poisonings and other alcohol related consequences on college campuses are commonplace. Especially worrisome is the percent of college students who report having experienced a blackout in the past year as a result of drinking. NIAAA-supported studies have shown that both individual and environmental approaches to prevention and treatment for college

students are necessary to reduce harmful drinking and its consequences. For example, a large scale trial showed that when college campuses and their surrounding communities partner on alcohol policies, alcohol-related problems in off campus settings can be reduced. Other strategies that can influence students' drinking behavior include: providing alcohol screening in the college health center; holding Friday classes; encouraging parents to communicate regularly with their college students; and being mindful of especially vulnerable periods such as the first six weeks of freshman year, spring break, and study abroad.

Budget Policy:

The FY 2015 President's Budget estimate is \$165.886 million, an increase of \$1.255 million or 0.7 percent above the FY 2014 Enacted level.

Midlife/Senior Adult: Research has demonstrated that there is no typical alcoholic; the variation among individuals who meet criteria for alcohol dependence reflects both the subtype of dependence and individual genetic make-up. NIAAA's research focus for the midlife/senior population encompasses: 1) identification of mechanisms by which alcohol and its metabolites cause tissue and organ pathologies; 2) development of treatment strategies for alcohol dependence (including medications) that are tailored to specific populations; and 3) treatment of individuals with co-existing psychiatric and medical disorders. NIAAA continues to support development of medications for the treatment of alcoholic liver disease, especially alcoholic hepatitis, and to seek biomarkers that enable detection of various stages of liver damage. Studies that take a systems biology approach are investigating how pathological changes in one organ can result in physiological aberrations in another. This approach is being used to study alcohol-induced interactions between the gut, liver, and brain. To ensure efficient testing of promising compounds for alcohol dependence and to move them more quickly through early clinical testing, NIAAA's Clinical Investigations Group (NCIG) continues to coordinate multi-site Phase II clinical trials. By taking on more of the risk for failure during early drug development, NIAAA anticipates that pharmaceutical companies will be more willing to pursue those compounds that show positive effects. NIAAA's medications development program has been especially successful at linking individual genetic variation with positive outcomes for specific medications.

Budget Policy:

The FY 2015 President's Budget estimate is \$123.725 million, an increase of \$0.308 million or 0.3 percent above the FY 2014 Enacted level.

Intramural Research: A major focus of the Intramural Program is to improve treatment of alcohol use disorders and associated problems. Identifying molecular targets for treatment in experimental animals and then validating these targets in clinical studies has been successful. Considerable progress has also been made in identifying genes that underlie alcohol dependence and that influence the efficacy of specific treatments, confirming that some treatments are more effective than others in individuals with particular gene variants. Recognizing that PTSD and alcohol use disorders frequently co-occur, intramural researchers are investigating the relationship between stress, alcohol and PTSD, including clinical studies to explore potential treatment options. While evidence indicates that alcohol may be used by some to alleviate the symptoms of PTSD, recent studies in animals suggest that chronic alcohol use prior to

experiencing a traumatic event may increase susceptibility to PTSD. The Intramural program also has a major research emphasis on understanding and preventing alcoholic liver disease. Notably, the development of a new animal model that better mimics the pathogenesis of human alcoholic hepatitis has led to identification of molecules that play critical roles in alcohol liver injury. Intramural researchers are also gaining a better understanding of the connection between alcohol-induced gut leakiness and liver inflammation and disease. NIAAA and NIDA have made significant progress in integrating their intramural research programs in substance use, abuse, and addiction, including the establishment of a single Clinical Director and the establishment of a joint genetics Intramural Research Program and a common optogenetics lab.

Budget Policy:

The FY 2015 President's Budget estimate is \$49.144 million, the same as the FY 2014 Enacted level. The request maintains continued support for NIAAA laboratories within the Division of Intramural Clinical and Biological Research as well as the Intramural Office of Laboratory Animal Science.

Research Management and Support: NIAAA 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. RMS functions also encompass strategic planning, coordination, and evaluation of the Institute's programs, regulatory compliance, international coordination, and liaison with other Federal agencies, Congress, and the public.

Budget Policy:

The FY 2015 President's Budget estimate is \$30.015 million, the same as the FY 2014 Enacted level.

Program Portrait: Exploring New Medication Options for Alcohol Dependence

FY 2014 Level: \$18.0 million

FY 2015 Level: \$18.0 million

Change: \$0.0 million

Basic and clinical advances in neuroscience and genetics, coupled with the availability of compounds already shown to be safe in humans, are increasing the speed and efficiency with which promising drugs are being evaluated for their effectiveness in treating alcohol dependence. For example, in a recently completed multisite Phase II clinical trial, NIAAA's clinical investigations group (NCIG) showed that the anti-smoking medication varenicline (Chantix®) significantly reduced alcohol consumption and craving in both non-smokers and smokers with alcohol dependence. In fact, Chantix® was at least as effective as other medications currently used to treat alcohol dependence. In a separate study, the widely prescribed anti-seizure medication gabapentin which is also used to treat pain and used off-label for migraines reduced heavy drinking and other related symptoms in alcohol dependent patients. Given that alcohol dependence is a complex disorder, it is not surprising that different subsets of individuals respond positively to different medication; therefore, determining the relationship between individual genetic variations and optimal therapeutic outcomes is an NIAAA priority. A study of the anti-nausea medication ondansetron revealed that variations in two different genes predict effectiveness in treating alcohol dependence. These findings expand the percent of individuals likely to benefit from ondansetron and also suggest that individuals who carry specific combinations of these variants are likely to benefit most. Genetic analysis from the recent NCIG varenicline study, as well as studies on naltrexone, topiramate, and other compounds, will determine if there are subsets of alcohol dependent individuals who derive greater benefit from treatment with each of these promising

medications.

Collectively, the studies described above demonstrate that it is not uncommon for a medication to be useful for treating health problems other than those for which it was developed and initially approved. Recognizing this as an opportunity, NIAAA's intramural scientists are exploiting similarities in the mechanisms driving food and alcohol consumption to investigate the role of the hormone ghrelin as a potential therapeutic target for treating alcohol dependence. In the body, ghrelin normally serves as an appetite regulator, and inhibitors of ghrelin have been used in the treatment of obesity.

Program Portrait: Addressing alcohol misuse and co-occurring disorders in military personnel and veterans

FY 2014 Level: \$7.1 million

FY 2015 Level: \$7.1 million

Change: \$0.0 million

More military personnel are in need of intervention and/or treatment for alcohol use disorders than any other substance use disorder according to a 2012 Institute of Medicine Report. Alcohol and other substance use disorders frequently co-occur with traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), depression and/or suicidal behavior in military personnel and veterans, complicating treatment for each condition. In 2012, President Obama issued an Executive Order calling for improved coordination among federal agencies to accelerate research to inform efforts for earlier diagnosis, prevention and treatment. NIAAA supports this Executive Order through research programs to more fully understand the underlying mechanisms of these co-occurring disorders. A significant number of veterans suffer from PTSD, which increases their risk for alcohol use disorders; conversely, chronic alcohol use may increase the risk for PTSD by altering the brain's ability to recover from a traumatic experience. Using an animal model of PTSD, NIAAA Intramural researchers discovered that chronic alcohol exposure altered neurons in the medial prefrontal cortex region of the brain, making the animals slower to suppress a conditioned fear response. Differences in the ability to handle fear responses could help explain differences in vulnerability to PTSD among humans, and lead to therapeutic approaches and diagnostic risk biomarkers. Understanding that PTSD and alcohol use disorders frequently co-occur and share certain symptoms, NIAAA-supported studies are exploring whether treatment targeted to either PTSD or alcohol problems in veterans with both disorders can improve outcomes for both. Additional studies with veterans are seeking to better understand the complex relationship between alcohol use, PTSD and other behavioral problems, as well as the role of gene and environment interactions. Given that many service members who need help do not receive it, NIAAA supports studies that examine barriers which prevent them from seeking treatment for comorbid PTSD and substance abuse. Researchers are also developing interventions that partners of service members can use to address their loved one's alcohol misuse.

Suicidal behavior among service members and veterans continues to be of great concern and ongoing research efforts are directed towards identifying preventive interventions. One such effort is the Department of Defense Better Resiliency Among Veterans With Omega-3s (BRAVO) study, a large randomized, placebo controlled clinical trial that is testing nutritional supplementation with omega-3 fatty acids to prevent suicidal behaviors in veterans. BRAVO is conducted collaboratively by investigators at NIAAA and the Medical College of South Carolina.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Budget Authority by Object Class¹
(Dollars in Thousands)

	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Total compensable workyears:			
Full-time employment	243	243	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$0	\$0	\$0
Average GM/GS grade	12.7	12.7	0.0
Average GM/GS salary	\$107	\$108	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$94	\$95	\$1
Average salary of ungraded positions	\$135	\$137	\$1
OBJECT CLASSES	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation			
11.1 Full-Time Permanent	\$19,008	\$19,198	\$190
11.3 Other Than Full-Time Permanent	7,043	7,113	70
11.5 Other Personnel Compensation	182	184	2
11.7 Military Personnel	485	490	5
11.8 Special Personnel Services Payments	3,422	3,456	34
11.9 Subtotal Personnel Compensation	\$30,140	\$30,441	\$301
12.1 Civilian Personnel Benefits	\$7,777	\$8,050	\$272
12.2 Military Personnel Benefits	419	423	4
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$38,336	\$38,914	\$578
21.0 Travel & Transportation of Persons	\$706	\$639	-\$67
22.0 Transportation of Things	46	42	-4
23.1 Rental Payments to GSA	2	2	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	398	361	-37
24.0 Printing & Reproduction	21	19	-2
25.1 Consulting Services	\$497	\$460	-\$38
25.2 Other Services	4,803	4,375	-428
25.3 Purchase of goods and services from government accounts	\$46,742	\$46,385	-\$358
25.4 Operation & Maintenance of Facilities	\$41	\$38	-\$4
25.5 R&D Contracts	20,456	21,163	707
25.6 Medical Care	101	92	-9
25.7 Operation & Maintenance of Equipment	906	822	-84
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal Other Contractual Services	\$73,547	\$73,334	-\$213
26.0 Supplies & Materials	\$3,636	\$3,319	-\$317
31.0 Equipment	1,013	920	-94
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	327,706	328,468	762
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	0	0	0
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$407,075	\$407,103	\$28
Total Budget Authority by Object Class	\$445,411	\$446,017	\$606

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

NATIONAL INSTITUTES OF HEALTH
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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation			
Full-Time Permanent (11.1)	\$19,008	\$19,198	\$190
Other Than Full-Time Permanent (11.3)	7,043	7,113	70
Other Personnel Compensation (11.5)	182	184	2
Military Personnel (11.7)	485	490	5
Special Personnel Services Payments (11.8)	3,422	3,456	34
Subtotal Personnel Compensation (11.9)	\$30,140	\$30,441	\$301
Civilian Personnel Benefits (12.1)	\$7,777	\$8,050	\$272
Military Personnel Benefits (12.2)	419	423	4
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$38,336	\$38,914	\$578
Travel & Transportation of Persons (21.0)	\$706	\$639	-\$67
Transportation of Things (22.0)	46	42	-4
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	398	361	-37
Printing & Reproduction (24.0)	21	19	-2
Other Contractual Services:			
Consultant Services (25.1)	497	460	-38
Other Services (25.2)	4,803	4,375	-428
Purchases from government accounts (25.3)	30,045	29,412	-633
Operation & Maintenance of Facilities (25.4)	41	38	-4
Operation & Maintenance of Equipment (25.7)	906	822	-84
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$36,293	\$35,106	-\$1,187
Supplies & Materials (26.0)	\$3,636	\$3,319	-\$317
Subtotal Non-Pay Costs	\$41,100	\$39,485	-\$1,614
Total Administrative Costs	\$79,435	\$78,399	-\$1,036

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2013 Actual			FY 2014 Est.			FY 2015 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Epidemiology and Prevention Research									
Direct:	11		11	11		11	11		11
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	11		11	11		11	11		11
Division of Intramural Research									
Direct:	100	4	104	100	4	104	100	4	104
Reimbursable:	9		9	9		9	9		9
Total:	109	4	113	109	4	113	109	4	113
Effects									
Direct:	9		9	9		9	9		9
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	9		9	9		9	9		9
Division of Neuroscience and Behavior									
Direct:	14		14	14		14	14		14
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	14		14	14		14	14		14
Division of Treatment and Recovery Research									
Direct:	10		10	10		10	10		10
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	10		10	10		10	10		10
Office of Extramural Activities									
Direct:	21		21	21		21	21		21
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	21		21	21		21	21		21
Office of Resource Management									
Direct:	36		36	36		36	36		36
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	36		36	36		36	36		36
Office of Science Policy and Communications									
Direct:	17		17	17		17	17		17
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	17		17	17		17	17		17
Office of the Director									
Direct:	12		12	12		12	12		12
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12		12	12		12	12		12
Total	239	4	243	239	4	243	239	4	243
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2011	12.6								
2012	13.0								
2013	12.7								
2014	12.7								
2015	12.7								

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Detail of Positions

GRADE	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Total, ES Positions	0	0	0
Total, ES Salary	0	0	0
GM/GS-15	28	28	28
GM/GS-14	48	48	48
GM/GS-13	43	43	43
GS-12	25	25	25
GS-11	9	9	9
GS-10	3	3	3
GS-9	5	5	5
GS-8	3	3	3
GS-7	9	9	9
GS-6	2	2	2
GS-5	1	1	1
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	176	176	176
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	2	2	2
Senior Grade	0	0	0
Full Grade	2	2	2
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	83	83	83
Total permanent positions	185	185	185
Total positions, end of year	263	263	263
Total full-time equivalent (FTE) employment, end of year	243	243	243
Average ES salary	0	0	0
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	106,377	107,175	108,247

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