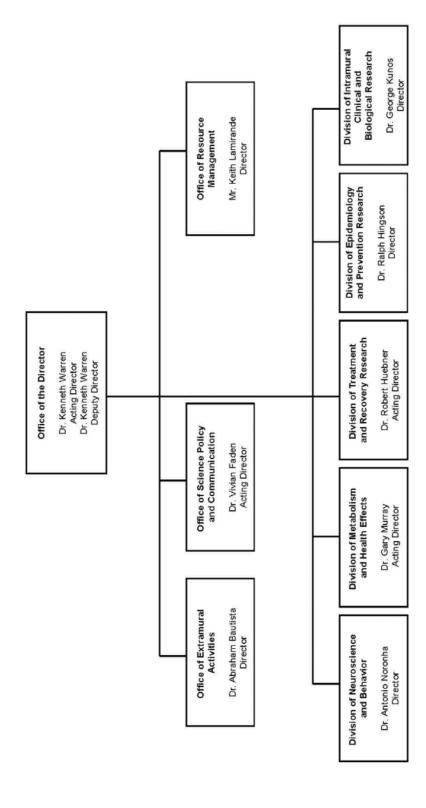
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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National Institute on Alcohol Abuse and Alcoholism



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, \$463,848,000.

Amounts Available for Obligation ¹

(Dollars in Thousands)

	FY 2012	FY	FY
Source of Funding	Actual	2013	2014
Appropriation	460,389	462,331	463,848
Rescission	(870)	0	0
Subtotal, adjusted appropriation	459,519	462,331	463,848
		0	0
Secretary's Transfer for Alzheimer's disease (AD)	(303)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	(131)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(420)	(544)	0
Subtotal, adjusted budget authority	458,665	461,787	463,848
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	458,665	461,787	463,848
Unobligated balance lapsing	(6)	0	0
Total obligations	458,659	461,787	463,848

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

FY 2012 - \$4,750 FY 2013 - \$6,000 FY 2014 - \$6,500

National Institute on Alcohol Abuse and Alcoholism

Budget Mechanism - Total ¹ (Dollars in Thousands)

	FY	2012	FY 2013			2014		
MECHANISM		Actual		CR	PB		Change vs	. FY 2012
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects	450	0100 171	40.4	#107.102	404	#105.00 5		#2.712
Noncompeting	472	\$192,174	484	\$197,193	481	\$195,887	9	\$3,713
Administrative Supplements	(28)	1,491	(28)	1,491	(28)	1,491	(0)	0
Competing: New	136	47,830	134	47,088	142	49,752	6	1,922
Supplements	1 130	130	134	128	142	130	0	1,922
Subtotal, Competing	167	\$60.881	164	\$59,936	173	\$62.972	6	\$2.091
Subtotal, RPGs	639	\$254,546	648	\$258,620	654	\$260,350	15	\$5,804
SBIR/STTR	24	9,802	21	8,680	22	9,214	-2	-588
Research Project Grants	663	\$264,347	669	\$267,300	676	\$269,564	13	\$5,217
		720 1,0 11		+===,,===		+===,===		++,=
Research Centers								
Specialized/Comprehensive	21	27,421	21	27,421	21	27,421	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	21	\$27,421	21	\$27,421	21	\$27,421	0	\$0
Other Research Research Careers								
	94	14,817	94	14,817	94	14,817	0	0
Cancer Education	0	0	0	6.555	0	6.555	0	0
Cooperative Clinical Research	1 0	6,565	1 0	6,555	1 0	6,555	0	-10
Biomedical Research Support Minority Biomedical Research Support	1	320	1	320	1	320	0	0
Other	37	14,938	37	14,938	37	14,938	0	0
Other Research	133	\$36,640	133	\$36,630	133	\$36,630	0	-\$10
Total Research Grants	817	\$328,408	823	\$331,351	830	\$333,615	13	\$5,207
		++0,100		+,		+,		++,=
Ruth L. Kirschstein Training Awards	FTTPs		FTTPs		FTTPs		FTTPs	
Individual	108	4,159	108	4,159	108	4,199	0	40
Institutional	179	7,888	179	7,888	179	7,901	0	13
Total Research Training	287	\$12,047	287	\$12,047	287	\$12,100	0	\$53
Research & Development Contracts	65	40,176	69	39,658	69	39,402	4	-774
SBIR/STTR(non-add)	(6)	(1,408)	(6)	(3,024)	(6)	(3,095)	(0)	+(1,687)
	-		POPE.		FFF			
Intropoural Passarch	FTEs	40 701	FTEs	10 701	<u>FTEs</u>	10 701	FTEs 0	0
Intramural Research	109	48,781	109	48,781 29,950	109	48,781 29,950	10	697
Research Management and Support Construction	116	29,253	126	29,950	126	29,930	10	097 0
Buildings and Facilities		0		0		0		0
Total, NIAAA	225	\$458,665	235	\$461,787	235	\$463,848	10	\$5,183

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 mechanism and activity detail and these highlights will not sum to the total change for the FY 2014 President's Budget request for NIAAA, which is \$5.2 million more than the FY 2012 Actual level, for a total of \$463.8 million.

Research Project Grants (+\$5.217 million; total \$269.564 million): NIAAA will support a total of 676 Research Project Grant (RPG) awards in FY 2014. Noncompeting RPGs will increase by nine awards and \$3.713 million and competing awards will increase by six awards and \$2.091 million. NIH budget policy for RPGs in FY 2014, continues FY 2012 policy of eliminating inflationary increases for future year commitments. However adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.

Research Training (+\$0.053 million; total \$12.100 million): The success of biomedical research is dependent upon the robustness of NIH training programs for the next generation of scientists. NIH will provide an across-the-board increase in FY 2014 of 2.0 percent for stipends levels under the Ruth L. Kirschstein National Research Service Award training program to continue efforts to attain the stipend levels recommended by the National Academy of Sciences. The requested increase will help to sustain the development of a highly qualified biomedical research workforce.

Research and Development Contracts (-\$0.774 million; total \$39.402 million): Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

Intramural Research and Research Management and Support (+\$0.697 million; total \$78.731 million): Intramural Research will be funded at the same level as in FY 2012. This funding level will maintain 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 funding will be increased by \$0.697 million to support the transfer of the 10 FTEs to the NIAAA from the DEAS. The 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.

National Institute on Alcohol Abuse and Alcoholism Summary of Changes

(Dollars in Thousands)

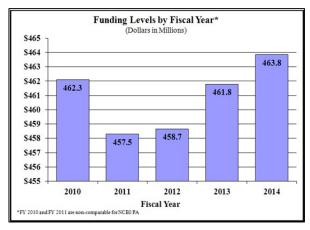
FY 2012 Actual				\$458,665
FY 2014 President's Budget				\$463,848
Net change				\$5,183
		014		TTT 0010
+	FTEs	t's Budget Budget	Change from	m FY 2012 Budget
CHANGES	TILS	Authority	11123	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of March 2013 pay increase & benefits		\$18,893		\$52
b. January FY 2014 pay increase & benefits		18,893		136
c. One more day of pay		18,893		72
d. Differences attributable to change in FTE		18,893		0
e. Payment for centrally furnished services		7,692		138
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		22,196		83
Subtotal				\$482
Research Management and Support:				
a. Annualization of March 2013 pay increase & benefits		\$20,540		\$56
b. January FY 2014 pay increase & benefits		20,540		152
c. One more day of pay		20,540		7
d. Differences attributable to change in FTE		20,540		0
e. Payment for centrally furnished services		1,219		22
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		8,191		1
Subtotal		•		\$309
Subtotal, Built-in				\$791

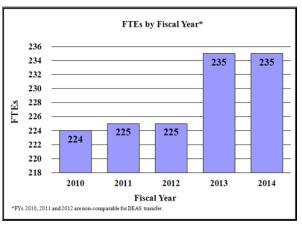
Summary of Changes--continued

		2014 nt's Budget	Change from FY 2012		
CHANGES	No.	Amount	No.	Amount	
B. Program:					
Research Project Grants:					
a. Noncompeting	481	\$197,378	9	\$3,713	
b. Competing	173	62,972	6	2,091	
c. SBIR/STTR	22	9,214	-2	-588	
Total	676	\$269,564	13	\$5,217	
2. Research Centers	21	\$27,421	0	\$0	
3. Other Research	133	36,630	0	-10	
4. Research Training	287	12,100	0	53	
5. Research and development contracts	69	39,402	4	-774	
Subtotal, Extramural		\$385,117		\$4,486	
6. Intramural Research	<u>FTEs</u> 109	\$48,781	FTEs 0	-\$482	
0. Initaliata Research	109	\$40,781	U	-9402	
7. Research Management and Support	126	29,950	10	388	
8. Construction		0		0	
9. Buildings and Facilities		0		0	
Subtotal, program	235	\$463,848	10	\$4,392	
Total changes				\$5,183	

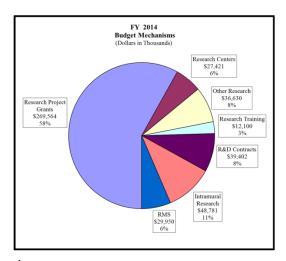
Fiscal Year 2014 Budget Graphs

History of Budget Authority and FTEs

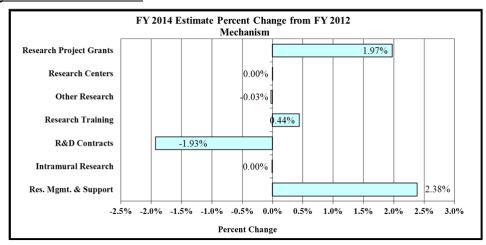




Distribution by Mechanism



Change by Selected Mechanism



Budget Authority by Activity 1, 2

(Dollars in Thousands)

	FY 2012 Actual			Z 2013 CR	FY 2014 PB		Change FY 2	vs. 012
Extramural Research	FTEs	Amount	FTEs	<u>Amount</u>	FTEs	Amount	<u>FTEs</u>	Amount
<u>Detail</u> :								
Embryo and Fetus		\$15,560		\$15,659		15,743		\$183
Youth/Adolescence		65,793		66,212		66,568		\$775
Young Adult		171,239		172,330		173,257		\$2,018
Mid-Life/Senior Adult		128,039		128,855		129,549		\$1,510
Caldadal Estamonal		\$290 <i>6</i> 21		\$292.05 <i>C</i>		¢205 117		¢4.496
Subtotal, Extramural		\$380,631		\$383,056		\$385,117		\$4,486
Intramural Research	109	\$48,781	109	\$48,781	109	\$48,781	0	(\$0)
Research Management & Support	116	\$29,253	126	\$29,950	126	\$29,950	10	\$697
TOTAL	225	\$458,665	235	\$461,787	235	\$463,848	10	\$5,183

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 Institute on Alcohol Abuse and Alcoholism

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	\$461,787,000	Indefinite	\$463.848,000
	Section 401(a)	42§281	Indefinite	\$461,787,000	Indefinite	\$463.848,000
National Institute on Drug Abuse						
Total, Budget Authority				\$461,787,000		\$463.848,000

Appropriations History

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

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 2014	
	FY 2012	FY 2013	President's	FY 2014 + / -
	Actual	CR	Budget	FY 2012
BA	\$458,665,000	\$461,787,000	\$463,848,000	+\$5,183,000
FTE	225	235	235	+10

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 2006¹ and takes a tremendous toll on individuals and their families. Specific consequences of alcohol misuse range from physical and cognitive deficits due to alcohol exposure of the developing embryo/fetus to organ damage from chronic heavy drinking, and from alcohol poisonings to alcohol dependence. To reduce the considerable burden of illness associated with alcohol misuse, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is working to prevent the onset and escalation of drinking during childhood and adolescence and intervene for problem alcohol use at all ages.

Building on recent progress in the coordination of addiction research with the National Institute on Drug Abuse (NIDA), NIAAA will pursue a "functional integration," which is a collaborative framework to enhance and expand activities across all ICs that participate in substance use, abuse, and addiction related research. This functional integration provides an important opportunity to advance addictions research while maintaining the unique research contributions of each IC. Already, significant progress has been made in the integration of NIAAA's and NIDA's intramural research programs in substance use, abuse, and addiction, including the appointment of a single Clinical Director. NIAAA and NIDA have also initiated joint Council meetings. The ICs will continue to pool resources and expertise to more effectively capitalize on synergies in addiction research, address scientific opportunities, and meet public health needs. For example, the two ICs are expanding joint efforts on medications development for diseases of addiction, an area where NIAAA can share its extensive expertise and success. In addition, delivery of screening, brief intervention, and referral to treatment (SBIRT) for alcohol has been successful in primary care; NIAAA and NIDA will collaborate to explore SBIRT for other drugs for both adults and adolescents.

Science is becoming progressively more interdisciplinary. Primarily because alcohol affects nearly every organ in the body and is a commonly used substance, NIAAA-supported research

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.

has been at the forefront of this interdisciplinary trend. NIAAA's research covers a broad spectrum of diseases and disorders including: alcohol, tobacco, and other drug dependence; fetal alcohol spectrum disorders (FASD); liver and cardiovascular disease; breast, pancreatic, head, and neck cancers; and it employs an extensive menu of methodologies from high tech imaging to optogenetics and from cognitive behavioral studies to medications development. To optimize addictions related research, NIAAA will expand the integration of alcohol with tobacco and other drugs in studies when appropriate, recognizing that the complexity of such studies sometimes necessitates starting with investigation of the effects of, or intervention for, a single substance before broadening studies to include other licit or illicit substances. An integrated model can also be applied to NIAAA supported research not directly related to addiction.

Given the exploratory nature of basic scientific investigation, it is not surprising that research in one area may reveal opportunities in a seemingly unrelated area. For example, NIAAA's focus on the endocannabinoid system and its role in alcohol-related effects in both the brain and liver led to development of a compound that may be effective in treating obesity. Similarly, research on the cardioprotective effects of moderate drinking resulted in identification of a compound that may improve outcomes following ischemic stroke. Maintaining the individual research perspective of each IC is critical to scientific progress across the entire disease spectrum.

Today's Basic Science for Tomorrow's Breakthroughs: The brain is a major target of alcohol's effects. Studies are assessing the effects of alcohol exposure on the structure and function of the brain at various life stages and how these changes influence behavior. Research is focused on key questions such as what are the underlying cognitive deficits in FASD and what interventions can best address them. Other studies are utilizing neuroimaging as well as neuropsychological and behavioral measures to determine the effects of alcohol initiation, escalation of use, and recovery on the developing adolescent brain. NIAAA is also exploring alcohol's association with other psychiatric and substance use disorders. A recent study in mice suggests that chronic alcohol use may increase the risk for post-traumatic stress disorder by altering neural circuits that mediate recovery from trauma. A major focus of NIAAA basic research continues to be the identification of receptors, signaling pathways, and neurocircuits underlying alcohol dependence and preclinical medications targeting them (see Program Portrait).

The liver is also a major target of alcohol's adverse effects. Building on systems biology studies demonstrating a link between pathology in the gut, liver, and brain, NIAAA is supporting several consortia to test novel compounds for treatment of alcoholic hepatitis, one of the most serious forms of alcohol-induced liver disease. Forty percent of patients with alcoholic hepatitis die within six months of onset of the clinical syndrome. Compounds to be tested include agents that: enhance gut integrity to prevent leaking of material from the gut, prevent or reduce inflammation, inhibit cell death, or inhibit bile metabolism, among others.

Public Health Impact: Translating Research to Real-World Practice: Smoking and heavy drinking often co-occur, and nicotine dependence is the most common co-occurring substance use disorder for individuals with an alcohol use disorder. Following a study suggesting that the smoking cessation medication varenicline (Chantix[®]) may decrease alcohol consumption in heavy drinking smokers, NIAAA initiated a Phase II clinical trial to assess varenicline's efficacy in alcohol abusers who do <u>not</u> smoke and to ascertain the relationship between its effects on

smoking and drinking. In collaboration with NICHD and NIDCD, NIAAA is investigating the association between prenatal alcohol exposure and the risk of Sudden Infant Death Syndrome (SIDS) and stillbirth and interactions with other factors, including tobacco exposure.

NIAAA also has a strong focus on alcohol screening for all ages. NIAAA is evaluating its youth screening guide as a predictor of alcohol risk, alcohol use, and alcohol problems, and as an initial screen for other behavioral health problems such as drug use or smoking. In addition, NIAAA will track changes in state policies on marijuana, expanding research to assess how these changes affect underage drinking, poisoning deaths and other drug related outcomes (see Program Portrait).

Recognizing that alcohol is a significant problem for returning veterans, NIAAA will participate with NIDA to accelerate research to reduce the onset and progression of substance use and abuse and associated mental and physical problems in military personnel, veterans and their families.

The Research Workforce: Encouraging Innovation: NIAAA will support the training and career development of a diverse pool of scientists to: address both the unique and common aspects of addiction; integrate biological and behavioral research; exploit new technologies for analyzing complex systems; and analyze vast amounts of data. For example, pooling data at the observation level across multiple drug studies (which would increase statistical power and enhance the types of analyses that could be performed) will require specialized training in the development, application and analysis of common data items across studies.

Overall Budget Policy: The FY 2014 President's Budget request is \$463.848 million an incresase of \$5.183 million or 1.1 percent above the FY 2012 Actual 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 2014 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. Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

Program Descriptions and Accomplishments

Embryo and Fetus: The developing embryo and fetus are uniquely vulnerable to the adverse effects of alcohol. Recent epidemiological studies demonstrate that the prevalence of fetal alcohol spectrum disorders is between two and five percent. This is substantially higher than previous estimates derived using less sophisticated techniques. This makes prenatal alcohol exposure a significant contributor to neurodevelopmental disorders in children, with a prevalence on par with autism spectrum disorder. NIAAA's research support for this life stage encompasses outreach to pregnant women for 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 of the key challenges facing clinicians is the ability to recognize women who are drinking during pregnancy and infants who have been exposed to alcohol prenatally. Complicating diagnosis is the lack of facial features characteristic of a subset of children with more severe forms of FASD. Developing behavioral markers and determining the neurological deficits underlying the behavioral manifestations of FASD will be critical to effectively intervening with affected children. Alcohol also appears to play a significant role in the risks of SIDS and stillbirth. In collaboration with NICHD and NIDCD, NIAAA is supporting studies to investigate the association with prenatal alcohol exposure as well as the interactions between prenatal alcohol exposure and other environmental and maternal factors.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate is \$15.743 million, an increase of \$0.183 million or 1.2 percent above the FY 2012 Actual 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. To address the pervasive use of alcohol among young people, 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, endorsed by the American Academy of Pediatrics, was devised to identify children at elevated risk for using alcohol as well as those children and adolescents who have already begun to experiment or are more heavily involved with alcohol. Protecting the developing body and brain from alcohol exposure is an important investment in short- and long-term health. NIAAA also has a significant research investment targeting this period of life.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate is \$66.568 million, an increase of \$0.775 million or 1.2 percent above the FY 2012 Actual level.

In FY 2012, NIAAA funded four five year studies to evaluate its youth alcohol screening guide, one in a network of emergency departments, one in a juvenile justice setting, one in primary care, and one with youth who have a chronic condition (e.g. asthma, diabetes), and added a study to evaluate the guide in schools. The brief, two question screener is being assessed in youth ages 9 to 18 both: as a predictor of alcohol risk, alcohol use, and alcohol problems including alcohol use disorders; and as an initial screen for other behavioral health problems, for example other drug use, smoking, or conduct disorder. In FY 2012 NIAAA also initiated a multisite longitudinal study to address the following: 1) what are the effects of both long and shorter-term child and adolescent alcohol exposure on the developing human brain; 2) what is the effect of timing, dose, and duration of alcohol exposure on brain development; 3) to what extent do these effects resolve or persist; 4) how do key covariates factor into alcohol's effects on the brain; and 5) potentially identify early neural, cognitive, and affective markers that may predict alcohol abuse and dependence and onset or worsening of mental illness during adolescence and/or adulthood.

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. Blackouts are periods of memory loss for events that transpired while a person was drinking and fully conscious, and that result from alcohol's disruption of activity in the brain's hippocampus. In one study at a major university, forty percent of students surveyed who drank in the past year reported a blackout in that period, with an average of 3.2 blackouts per year each.² For this study a blackout was defined as "waking in the morning after a night of drinking not able to remember places that you went or things that you did." 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. Strategies that can influence students' drinking behavior include: providing alcohol screening in the college health center; ensuring colleges partner with surrounding communities on alcohol policies; holding Friday classes; encouraging parents to communicate regularly with their college students especially on weekends; and being mindful of especially vulnerable periods such as the first six weeks of freshman year, spring break, and study abroad.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate is \$173.257 million, an increase of \$2.018 million or 1.2 percent above the FY 2012 Actual level.

In FY2014 NIAAA will continue to fund projects in response to a funding announcement issued in FY2013 to encourage research grant applications that explore whether and how alcohol and other drugs illicit or illicitly used prescription drugs interact to contribute to unintentional and intentional injuries and poisonings and to prevent and/or reduce such use of alcohol or drugs singly or in combination. NIAAA will also continue to fund studies solicited in collaboration with the VA, NIDA and other ICs to reduce the onset and progression of alcohol, tobacco, and other drug use and abuse and associated mental and physical health problems among active-duty or recently separated (e.g., Iraq and Afghanistan) military troops, Veterans, and their families. In FY 2014 NIAAA will launch a new initiative to characterize the role of non coding RNAs (ncRNAs) in the complex regulatory networks mediating alcohol's effects on the brain. This program aims to characterize the expression, the cellular signaling capacity, and determine the function of ncRNAs in acute intoxication, alcohol tolerance, chronic alcohol dependence, and the neurotoxic effects of alcohol on development.

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

NIAAA-17

² White AM et. al. 2002. 51(3):117-9, 122-31. Journal of American College Health. Prevalence and correlates of alcohol-induced blackouts among college students: results of an e-mail survey.

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. In its ongoing efforts to deal with one of the most serious medical consequences of alcohol dependence, NIAAA continues to support medications development for the treatment of alcoholic liver disease and continues to seek biomarkers for liver damage. In order to better understand how alcohol causes cell and tissue damage in multiple organs in the body, NIAAA supports studies using a systems biology approach to investigate how pathological changes in one organ can also result in physiological aberrations in another. Such an approach is being used to study the 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, the Institute established the NIAAA Clinical Investigations Group (NCIG). By conducting early clinical trials itself, NIAAA anticipates that pharmaceutical companies will be more willing to pursue those compounds shown to be effective. In its medications development program, NIAAA has been especially successful at linking individual genetic variation with positive outcomes for specific medications.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate is \$129.549 million, an increase of \$1.510 million or 1.2 percent above the FY 2012 Actual level.

In FY 2014 NIAAA will continue to fund medications development through the NIAAA clinical investigations group (NCIG). In addition medications are being tested in understudied populations, such as those with comorbid psychiatric disorders, comorbid substance abuse, comorbid medical disorders, as well as in adolescents and young adults. In FY 2014 NIAAA will continue to support translational research on alcoholic hepatitis (AH) which causes substantial early mortality (up to 40%) within 6 months after the onset of the clinical syndrome. In the long-term, patients who survive an episode of AH have a 70 percent probability of developing cirrhosis. The major goal of this research initiative is to expedite the translation of promising emerging findings as well as to find new molecules using combinatorial chemistry to advance the development of new treatments for AH.

Program Portrait: The Role of Non-coding RNAs in the Neuroadaptation to Alcohol Dependence

FY 2012 Level: \$1.662 million **FY 2014 Level:** \$2.000 million **Change:** +\$0.338 million

It is well established that alcohol affects nearly every organ and system in the body, including the brain where it causes neuroadaptations – changes in neuronal circuitry in response to environmental stimuli – that can lead to alcohol tolerance and ultimately alcohol dependence. At the physiological level, tolerance to alcohol involves: neuroadaptive changes in ion channels, such as the BK calcium channel; neurotransmitters; and other signaling molecules. These neuroadaptations are thought to occur through changes in gene expression in the brain. Recent advances have revealed a role for RNA molecules called non-coding RNAs (ncRNAs) in regulating gene expression. ncRNAs are transcribed from DNA but do not code for protein. They typically alter gene expression by binding to RNAs from specific genes, but they have also been shown to serve as signaling molecules, particularly in the nervous system. Previous research has implicated ncRNAs in the neuroadaptive changes that produce alcohol tolerance. For example, animal studies have demonstrated that levels of the ncRNA miR-9 rapidly increase in brain neurons in response to acute alcohol exposure. miR-9 binds to specific mRNA transcripts that encode proteins that comprise the BK calcium channel, thus determining the composition of this channel in response to alcohol. This elegant finding shows the exquisite rapid regulation of the structural composition of the BK channel, which itself is a target of alcohol action and a mediator of alcohol sensitivity. In this study, ten additional alcohol relevant miR-9 targets were also identified in the brain, suggesting a mechanism for an integrated neuronal response to alcohol in which miR-9 plays a pivotal role. Importantly, it may be possible to generalize this mechanism to neuronal alterations beyond adaptation to drugs of abuse. In FY 2014, NIAAA will launch a new initiative to characterize the role of ncRNAs in the complex regulatory networks that mediate alcohol's effects on the brain. Specifically, this program will focus on characterizing the expression and the cellular signaling capacity of ncRNAs, in addition to determining their function in acute intoxication, alcohol tolerance, alcohol dependence, and in the neurotoxic effects of alcohol on development. Determining the role of ncRNAs in complex neuronal regulatory networks will elucidate how the brain adapts to a wide range of stimuli including alcohol. This will enhance our understanding of a broad range of brain disorders and provide insights into how to treat them.

Program Portrait: Functional Integration of Policy Research on Alcohol and Marijuana

FY 2012 Level: \$1.336 million **FY 2014 Level:** \$2.000 million **Change:** +\$0.664 million

Recent policy changes legalizing recreational and/or medical marijuana use in a number of states (making its status in those states more similar to that of alcohol) provide an unprecedented opportunity to systematically examine how these changes affect alcohol and other drug use and misuse, including adverse outcomes due to alcohol only, marijuana only, or a combination of the two. In addition, recent changes in drug and driving laws, e.g., per se laws that make it illegal to drive after drug use, present a similar opportunity. Relevant outcomes for which data is currently collected include: traffic injuries and fatalities; overdoses or poisonings; binge drinking and marijuana and other drug use in young people and adults; and involvement with the criminal justice system. To capitalize on this opportunity, NIAAA will expand its Alcohol Policy Information System, which currently tracks state and local alcohol policies to also include marijuana policies. NIAAA will also issue a funding opportunity announcement to solicit studies on the effects of such policy changes on various behaviors and outcomes.

According to the National Epidemiologic Survey of Alcohol and Related Conditions (NESARC), marijuana is the most commonly used illicit substance in the U.S. NESARC also showed that among U.S. adults aged 18 and older

who have ever had an alcohol use disorder, 22.8 percent also have had a marijuana use disorder; of those who ever had a marijuana use disorder, 81.5 percent also have had an alcohol use disorder. Findings such as these underscore the need to understand whether legalizing marijuana for recreational or medical use affects alcohol and/or marijuana use in general as well as how such policy changes affect the numbers of individuals who have a problem with either substance or both.

Research has shown that individuals who use multiple substances may be at higher risk for negative outcomes. For example, data from the National Highway Traffic Safety Administration (NHTSA) Fatality Analysis Reporting System for nine states in 2008-2009, in which more than 80 percent of fatally injured drivers were tested for both alcohol and other drugs, indicate that 47 percent tested negative for both alcohol and drugs, 27 percent were positive for alcohol only, 15 percent for drugs only and 12 percent were positive for both. Further, in its most recent national roadside survey (2007), NHTSA for the first time collected both driver breath alcohol samples and saliva and blood samples for drug testing. At night, the percent that tested positive was 14 percent for drugs and 12 percent for alcohol. For the first time collected both driver breath alcohol samples and saliva and blood samples for drug testing. At night, the percent that tested positive was 14 percent for drugs and 12 percent for alcohol.

Findings from these studies will be useful to policy makers as additional states confront decisions around marijuana policies and to healthcare providers who treat individuals with alcohol and marijuana related problems.

Intramural Research: The Intramural Research Program has made significant advances in the areas of medications development, neuroscience, genetics, epidemiology and physiology. A major focus of NIAAA in general, and of the Intramural Program specifically, has been to improve treatment of alcohol use disorders and associated problems. The approach of identifying molecular targets for treatment in experimental animals and then validating these targets in clinical research studies has been successful. There has also been considerable progress 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. The Intramural Research Program also focuses on understanding and preventing alcoholic liver disease. Studies have revealed that endocannabinoids - endogenous marijuana-like substances – are necessary in a specific type of liver cell for the development of alcoholinduced fatty liver, a forerunner of more serious liver diseases, such as cirrhosis and liver cancer. A novel medication that targets endocannabinoid action in peripheral tissues, such as the liver, without causing adverse neuropsychiatric side effects is currently under development. Other studies have demonstrated that dietary supplements can prevent the development of alcohol-induced fatty liver and mitochondrial dysfunction in animal models. In addition, the Intramural Program continues to conduct large scale studies that provide information on the extent of alcohol and other drug dependence and co-occurring mental disorders in the U.S. population (see portrait). Treatment studies on alcohol dependence and co-occurring psychiatric disorders are also underway.

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³ National Institute on Alcohol Abuse and Alcoholism, Rockville, MD. Drug Use Disorders Are Rare Among Persons with Alcohol Use Disorders, unpublished data.

⁴ National Institute on Alcohol Abuse and Alcoholism, Rockville, MD. Prevalence of Lifetime Alcohol Use Disorders Among Individuals with Selected Lifetime Drug Use Disorders and in the General Population, unpublished data.

⁵ Hingson, RW. Preventing Drug-Impaired Driving: Lessons from Alcohol-Impaired Driving, Society for Prevention Research, May 29 – June 1, 2012, Washington, DC.

⁶ National Highway Traffic Safety Administration, Washington, DC. 2007 National Roadside Survey of Alcohol and Drug Use: Drug Prevalence Rates.

⁷ National Highway Traffic Safety Administration, Washington, DC. 2007 National Roadside Survey of Alcohol and Drug Use: Alcohol Prevalence Rates.

<u>Budget Policy:</u> The FY 2014 President's Budget estimate is \$48.781 million, the same as the FY 2012 Actual 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.

<u>Budget Policy</u>: The FY 2014 President's Budget estimate is \$29.950 million, an increase of \$0.697 or 2.4 percent above 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.

Budget Authority by Object Class (Dollars in Thousands)

FY 2012 FY 2014 Increase or Actual PB Decrease Total compensable work years: Full-time employment 225 225 10 Full-time equivalent of overtime and holiday Average ES salary (in whole dollars) \$179,700 \$179,700 \$0 Average GM/GS grade 13.0 13.0 0.0 \$113,287 \$109,459 Average GM/GS salary (in whole dollars) \$3,828 Average salary, grade established by act of July \$109,459 \$132,113 \$1,528 1 1944 (42 U.S.C. 207) (in whole dollars) Average salary of ungraded positions (in whole \$114,918 \$109,459 \$1,329 dollars) FY 2014 **OBJECT CLASSES** FY 2012 Increase or Actual PB Decrease Personnel Compensation: \$18,105 11.1 Full-time permanent \$20,177 \$2,072 11.3 Other than full-time permanent 6,556 6,709 153 11.5 Other personnel compensation 453 490 37 429 11.7 Military personnel 431 (2)3,282 3,273 11.8 Special personnel services payments (9 Total, Personnel Compensation \$31,07 \$28,82 \$2,25 12.0 Personnel benefits \$7,218 \$7,81 \$601 12.2 Military personnel benefits 538 536 (2)13.0 Benefits for former personnel 0 0 Subtotal, Pay Costs \$36,58 \$39,43 \$2,85 21.0 Travel and transportation of persons \$760 \$585 (\$175 22.0 Transportation of things 59 54 (5)23.1 Rental payments to GSA 1 1 0 23.2 Rental payments to others 9 9 (0)23.3 Communications, utilities and miscellaneous charges 320 252 (68)24.0 Printing and reproduction 131 75 (56)25.1 Consulting services 276 215 (61)25.2 Other services 5,956 4,756 (1,20)25.3 Purchase of goods and services from 42,642 44,95 government accounts 2,316 Operation and maintenance of facilities 588 364 (224)25.5 Research and development contracts 23,407 20,26 (3,141)25.6 Medical care 179 178 (1)25.7 Operation and maintenance of equipment 789 670 (119)25.8 Subsistence and support of persons 0 0 0 25.0 Subtotal, Other Contractual Services \$73,83 \$71,40 (\$2,43Supplies and materials \$4,442 \$4.35 (\$91)31.0 Equipment 2,068 1,966 (102)32.0 Land and structures 0 0 0 33.0 Investments and loans 0 0 0 41.0 Grants, subsidies and contributions 340,45 345,71 5,260 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 \$422,08 \$424,41 \$2,33 **Total Budget Authority by Object Class** \$463.84

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

Salaries and Expenses

(Dollars in Thousands)

	FY 2012	FY 2014	Increase or
OBJECT CLASSES	Actual	PB	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$18,105	490	\$2,072
Other than full-time permanent (11.3)	6,556	6,709	153
Other personnel compensation (11.5)	453	490	37
Military personnel (11.7)	431	429	(2)
Special personnel services payments (11.8)	3,282	3,273	(9)
Total Personnel Compensation (11.9)	\$28,827	\$31,078	\$2,251
Civilian personnel benefits (12.1)	\$7,218	\$7,819	\$601
Military personnel benefits (12.2)	538	536	(2)
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$36,583	\$39,433	\$2,85
Travel (21.0)	\$760	\$585	(\$175)
Transportation of things (22.0)	59	54	(5)
Rental payments to others (23.2)	9	9	0
Communications, utilities and			
Miscellaneous charges (23.3)	320	252	(68)
Printing and reproduction (24.0)	131	75	(56)
Other Contractual Services:			
Advisory and assistance services (25.1)	276	215	(61)
Other services (25.2)	5,956	4,756	(1,200)
Purchases from government accounts (25.3)	28,932	29,022	90
Operation and maintenance of facilities (25.4)	588	364	(224)
Operation and maintenance of equipment (25.7)	789	670	(119)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$36,541	\$35,027	(\$1,514)
Supplies and materials (26.0)	\$4,434	\$4,344	(\$90)
Subtotal, Non-Pay Costs	\$42,254	\$40,346	(\$1,908)
Total, Administrative Costs	\$78,837	\$79,779	\$942

Details of Full-Time Equivalent Employment (FTEs)

		FY 2012		FY 2013			FY 2014		
OFFICE/DIVISION	Civilian	Actual Military	Total	Civilian	CR Military	Total	Civilian	PB Military	Total
Office of the Director									
	0		0	0		0	0		0
Direct Reimbursable:	9	-	9	9	-	9	9	-	9
Total:	9	-	9	9	-	9	9	-	9
Office of Extramural Activities									
Direct:	14	-	14	20	-	20	20	-	20
Reimbursable: Total:	14	-	14	20	-	20	20	-	20
Office of Science Policy and Communications									
Direct:	15	-	15	15	-	15	15	-	15
Reimbursable: Total:	15	-	15	15	-	15	15	-	15
Office of Resource Management									
Direct:	35	-	35	36	-	36	36	-	36
Reimbursable: Total:	35	-	35	36	-	36	36	-	36
Division of of Epidemiology and Prevention									
Direct:	10	-	10	11	-	11	11	-	11
Reimbursable:	10	-	- 10	- 11	-	- 11	- 11	-	- 11
Total:	10	-	10	11	-	11	11	-	11
Division of Metabolism and Health Effects Direct:	11	_	11	12	_	12	12		12
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	11	-	11	12	-	12	12	-	12
Division of Neuroscience and Behavior Direct:	1.4		1.4	1.5		15	1.5		1.5
Reimbursable:	14	-	14	15	-	-	15	-	15
Total:	14	-	14	15	-	15	15	-	15
Division of Treatment and Recovery Research						0			
Direct: Reimbursable:	8	-	8	8	-	8	8	-	8
Total:	8	-	8	8	-	8	8	-	8
Division of Intramural Research Program									
Direct: Reimbursable:	97 8	4	101 8	97 8	4	101 8	97 8	4	101 8
Total:	105	4	109	105	4	109	105	4	109
	_	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-
Total	221	4	225	231	4	235	231	4	235
Includes FTEs whose payroll obligations are									
supported by the NIH Common Fund. FTEs supported by funds from Cooperative									
Research and Development Agreements.									
FISCAL YEAR				Ave	rage GS G	rade			
2010					12.6				
2011		12.6 12.6							
2012 2013					13.0 13.0				
2014		13.0 13.0							

Detail of Positions

	FY 2012	FY 2013	FY 2014
GRADE	Actual	CR	PB
Total, ES Positions	1	1	1
Total, ES Salary	\$179,700	\$179,700	\$179,700
GM/GS-15	27	27	27
GM/GS-14	49	49	49
GM/GS-13	41	42	42
GS-12	27	27	27
GS-11	6	6	6
GS-10	3	3	3
GS-9	8	8	8
GS-8	0	1	1
GS-7	2	9	9
GS-6	0	0	0
GS-5	2	4	4
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	165	176	176
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	2	2	2
Senior Grade	1	1	1
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	81	81	81
Total permanent positions	175	185	185
Total positions, end of year	251	261	261
Total full-time equiv (FTE) at YE	225	235	235
Average ES salary	\$179,700	\$179,700	\$179,700
Average GM/GS grade	13.0	13.0	13.0
Average GM/GS salary	\$109,459	\$110,554	\$113,287

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