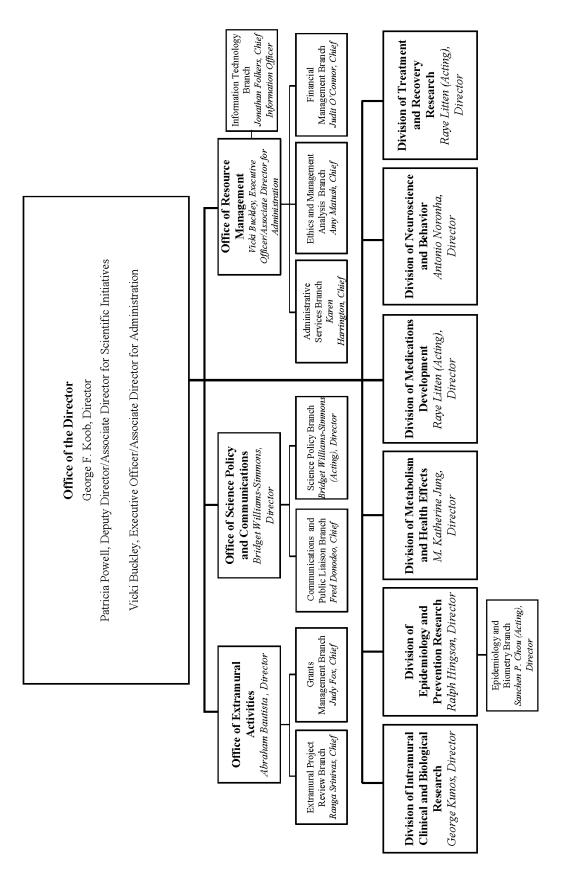
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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National Institute on Alcohol Abuse and Alcoholism



NATIONAL 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, [\$545,373,000]\$497,346,000.

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	\$525,591	\$545,373	\$497,346
Mandatory Appropriation: (non-add)	·	·	·
Type 1 Diabetes	(0)	(0)	(0)
Other Mandatory financing	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-1,805	0	0
Subtotal, adjusted appropriation	\$523,786	\$545,373	\$497,346
OAR HIV/AIDS Transfers	1,530	1,323	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$525,316	\$546,696	\$497,346
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$525,316	\$546,696	\$497,346
Unobligated balance lapsing	-34	0	0
Total obligations	\$525,282	\$546,696	\$497,346

 $^{^1}$ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2019 - \$5,850 FY 2020 - \$6,000 FY 2021 - \$6,000

Budget Mechanism - Total¹

(Dollars in Thousands)

MECHANISM	FY	FY 2019 Final		Final FY 2020 Enacted		FY 2021 President's Budget		2021 +/- 2020 acted
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Research Flojects.								
Noncompeting	580	\$226,217	576	\$227,620	567	\$219,467	-9	-\$8,153
Administrative Supplements	(23)	2,985	(23)	3,000	(22)	2,730	(-1)	-270
Competing:								
Renewal	14	6,195	15	6,691	12	4,410	-3	-2,281
New	145	60,223	156	64,853	109	42,874	-47	-21,979
Supplements	0	0	1	195	0	0	-1	-195
Subtotal, Competing	159	\$66,417	172	\$71,739	121	\$47,284	-51	-\$24,455
Subtotal, RPGs	739	\$295,619	748	\$302,359	688	\$269,481	-60	-\$32,878
SBIR/STTR	21	13,380	24	14,034	20	12,736	-4	-1,298
Research Project Grants	760	\$308,999	772	\$316,393	708	\$282,217	-64	-\$34,176
Research Centers:								
Specialized/Comprehensive	21	\$31,622	21	\$31,622	21	\$29,408	0	-\$2,214
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	\$31,622	21	\$31,622	21	\$29,408	0	-\$2,214
Other Research:								
Research Careers	124	\$20,173	129	\$21,173	120	\$19,691	-9	-\$1,482
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	1	7,500	2	10,000	2	9,300	0	-700
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	500	0	500	0	465	0	-35
Other	57	17,386	59	17,908	53	16,654	-6	-1,254
Other Research	182	\$45,559	190	\$49,581	175	\$46,110	-15	-\$3,471
Total Research Grants	963	\$386,179	983	\$397,596	904	\$357,735	-79	-\$39,861
Ruth L Kirchstein Training Awards:	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	113	\$5,030	116	\$5,200	105	\$4,830	-11	-\$370
Institutional Awards	213	9,939	215	10,350	198		-17	-846
Total Research Training	326	\$14,969	331	\$15,550		, ,	-28	-\$1,216
Research & Develop. Contracts	70	\$34,173	82	\$39,900	74	\$36,309	-8	-\$3,591
(SBIR/STTR) (non-add)	(7)	(2,371)	(7)	(2,378)	(6)	(2,040)	(-1)	(-338)
Intramural Research	89	54,359	94	56,500	94	53,675	0	-2,825
Res. Management & Support	136	35,635	144	37,150	144	35,293	0	-1,857
Res. Management & Support (SBIR Admin) (non-add)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAAA	225	\$525,316	238	\$546,696	238	\$497,346	0	-\$49,350
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¹ All items in italics and brackets are non-add entries.

Major Changes in the Fiscal Year 2021 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 2021 President's Budget request for NIAAA, which is \$49.4 million below the FY 2020 Enacted level, for a total of \$497.3 million.

Research Project Grants (-\$34.2 million; total \$282.2 million): NIAAA will support a total of 708 Research Project Grant (RPG) awards in FY 2021. Noncompeting RPGs will decrease by 9 awards and competing awards will decrease by 51 awards and \$24.5 million.

Research Centers and Other Research Grants (-\$5.7 million; total \$75.5 million): NIAAA will support a total of 21 Research Centers and 175 Other Research Grants in FY 2021.

Research and Development Contracts (-\$3.6 million; total \$36.3 million): Funds are included in R&D contracts to support the expansion of clinical trials to test promising therapeutic agents for alcohol use disorders.

Intramural Research and Research Management and Support (-\$4.7 million; total \$89.0 million): This funding level will support NIAAA laboratories within the Division of Intramural Clinical and Biological Research as well as the Intramural Office of Laboratory Animal Science.

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

Summary of Changes

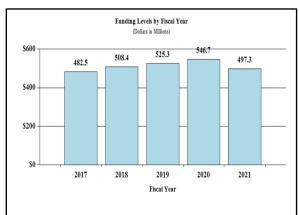
(Dollars in Thousands)

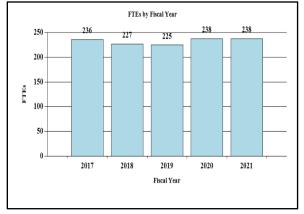
FY 2020 Enacted		\$546,696
FY 2021 President's Budget		\$497,346
Net change		-\$49,350
	FY 2021 President's Budget	Change from FY 2020 Enacted
CHANGES	FTEs Budget Authority	FTEs Budget Authority
A. Built-in:		
1. Intramural Research:		
a. Annualization of January 2020 pay increase & benefits	\$18,965	\$124
b. January FY 2021 pay increase & benefits	18,965	275
c. Paid days adjustment	18,965	-71
d. Differences attributable to change in FTE	18,965	0
e. Payment for centrally furnished services	8,696	-19
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	26,014	-230
Subtotal		\$80
2. Research Management and Support:		
a. Annualization of January 2020 pay increase & benefits	\$26,987	\$173
b. January FY 2021 pay increase & benefits	26,987	405
c. Paid days adjustment	26,987	-101
d. Differences attributable to change in FTE	26,987	0
e. Payment for centrally furnished services	283	-15
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	8,024	-17
Subtotal		\$445
Subtotal, Built-in		\$525

	FY 2021 Pro Budget	esident's	Change from I	FY 2020
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	567	\$222,197	-9	-\$8,423
b. Competing	121	47,284	-51	-24,455
c. SBIR/STTR	20	12,736	-4	-1,298
Subtotal, RPGs	708	\$282,217	-64	-\$34,176
2. Research Centers	21	\$29,408	0	-\$2,214
3. Other Research	175	46,110	-15	-3,471
4. Research Training	303	14,334	-28	-1,216
5. Research and development contracts	74	36,309	-8	-3,591
Subtotal, Extramural		\$408,378		-\$44,668
	FTEs		<u>FTEs</u>	
6. Intramural Research	94	\$53,675	0	-\$2,905
7. Research Management and Support	144	35,293	0	-2,302
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	238	\$497,346	0	-\$49,875
Total changes				-\$49,350

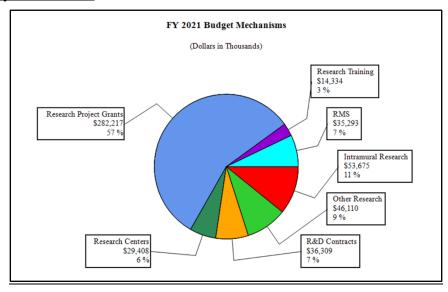
Fiscal Year 2021 Budget Graphs

History of Budget Authority and FTEs:

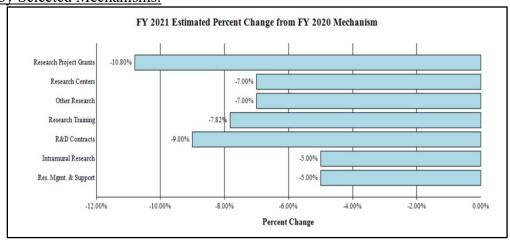




Distribution by Mechanism:



Change by Selected Mechanisms:



NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

Budget Authority by Activity¹ (Dollars in Thousands)

	FY 20	FY 2019 Final		FY 2020 Enacted		esident's	FY 2021 +/- FY2020		
Extramural Research	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount	
<u>Detai</u> l									
Embryo and Fetus		\$17,413		\$18,122		\$16,335		-\$1,787	
Youth/Adolescence		43,532		45,305		49,005		3,700	
Young Adult		200,248		203,870		179,687		-24,183	
Mid-Life/Senior Adult		174,129		185,749		163,351		-22,398	
Subtotal, Extramural		\$435,322		\$453,046		\$408,378		-\$44,668	
Intramural Research	89	\$54,359	94	\$56,500	94	\$53,675	0	-\$2,825	
Research Management & Support	136	\$35,635	144	\$37,150	144	\$35,293	0	-\$1,857	
TOTAL	225	\$525,316	238	\$546,696	238	\$497,346	0	-\$49,350	

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

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Authorizing Legislation

	PHS Act/	U.S. Code	2020 Amount	FY 2020 Enacted	2021 Amount	2021 Amount FY 2021 President's Budget
	Other Citation	Citation	Authorized		Authorized	
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute on Alcohol Abuse and Alcoholism	Section 401(a)	42 § 281	Indefinite	\$546,696,000	Indefinite	\$497,346,000
Total, Budget Authority				\$546,696,000		\$497,346,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2012	\$469,197,000	\$469,197,000	\$453,127,000	\$460,389,000
Rescission				\$870,135
2013	\$457,104,000		\$458,489,000	\$459,518,865
Rescission				\$919,038
Sequestration				(\$23,064,687)
2014	\$463,848,000		\$460,765,000	\$446,025,000
Rescission				\$0
2015	\$446,017,000			\$447,408,000
Rescission				\$0
2016	\$459,833,000	\$456,012,000	\$469,355,000	\$467,700,000
Rescission				\$0
20171	\$467,445,000	\$480,330,000	\$488,782,000	\$483,363,000
Rescission				\$0
2018	\$361,356,000	\$490,796,000	\$500,491,000	\$509,573,000
Rescission				\$0
2019	\$469,109,000	\$515,658,000	\$525,867,000	\$525,591,000
Rescission				\$0
2020	\$452,419,000	\$551,278,000	\$556,010,000	\$545,373,000
Rescission				\$0
2021	\$497,346,000			

¹ Budget Estimate to Congress includes mandatory financing.

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 2021	
	FY 2019	FY 2020	President's	FY 2021 +/-
_	Final	Enacted	Budget	FY 2020
BA	\$525,316,000	\$546,696,000	\$497,346,000	-\$49,350,000
FTE	225	238	238	0

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

Director's Overview

Alcohol misuse has profound effects on the health and well-being of individuals, families, and communities. Nearly 88,000 people die each year from alcohol-related causes, and approximately 15 million people in the United States have alcohol use disorder (AUD). 1,2 Alcohol plays a prominent role in deaths of despair, contributing to liver disease; suicides; alcohol, opioid and other drug overdoses; and a broad range of other disease states that lead to mortality. Alcohol misuse imposes a massive economic burden; the most recent estimate indicates that alcohol misuse costs the country \$249 billion a year.³ Although effective options are available, fewer than 10 percent of individuals with AUD receive treatment.⁴ NIAAA's mission is to generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being and to apply that knowledge to improve the diagnosis, prevention, and treatment of alcohol-related problems, including AUD, across the lifespan. In 2020, the Institute celebrates its 50-year history of supporting cutting-edge research that has expanded our understanding of alcohol's effects on the brain and body and yielded interventions to prevent and treat alcohol misuse and related conditions. NIAAA is building on this progress to bring us closer to improved, individualized, and accessible preventive and treatment interventions.

Advancing Basic Research

For many years, AUD was viewed as a moral failing or character flaw. Today, advances in neuroscience have revolutionized our understanding of AUD as a chronic brain disease with the potential for recovery and recurrence like other chronic medical conditions. This major shift in perspective is enabling a deeper understanding of the pathological mechanisms in the brain that underlie AUD, particularly at the neurocircuit level. Several recent NIAAA-supported studies in

² https://www.samhsa.gov/data/

¹ www.cdc.gov/ARDI

³ https://pubmed.ncbi.nlm.nih.gov/26477807/

⁴ https://www.samhsa.gov/data/

animals have identified brain circuitry that may regulate negative emotional states that occur during alcohol withdrawal and contribute to relapse. These findings could pave the way for future pharmacotherapy approaches to prevent relapse in humans. Neuroscience advances also allow for a deeper understanding of the relationships between alcohol misuse and commonly co-occurring conditions such as chronic pain and sleep dysregulation. As part of the NIH Helping to End Addiction Long-term (HEAL) initiative, NIAAA is encouraging studies that develop and validate biomarkers of comorbid alcohol use and pain and that address alcohol misuse in the context of pain management. NIAAA also established an initiative to encourage research examining the mechanisms that underlie the reciprocal relationships between chronic alcohol use and sleep disruption and how those mechanisms contribute to relapse.

Developmental neuroscience research continues to illuminate our understanding of fetal alcohol spectrum disorders (FASD). It is now recognized that prenatal alcohol exposure can cause a spectrum of lifelong developmental, behavioral, and emotional deficits that extend beyond fetal alcohol syndrome and the associated facial abnormalities that were first described in the 1970s. A recent study found that more children may have FASD than previously thought, with conservative estimates ranging from one to five percent among a sample of four U.S. communities. These findings suggest that FASD is often under-diagnosed or misdiagnosed. Improved diagnostics that are widely accessible to health care providers could facilitate earlier diagnosis and intervention. NIAAA research efforts are focused on improving prevention, screening, diagnosis, and treatment of FASD (see Embryo/Fetus program description below and program portrait: "Improving screening, diagnosis, prevention, and treatment of FASD").

Research on adolescent brain development has flourished over the past 20 years, demonstrating that the human brain continues to develop into the mid-twenties. NIAAA supports numerous research programs, including multi-site longitudinal studies, that are characterizing the effects of alcohol on the developing adolescent brain (described below in the Youth/Adolescence program description). The research findings will inform future strategies to prevent the initiation and escalation of underage drinking and to treat alcohol-related problems among youth.

NIAAA also supports studies focused on elucidating how alcohol misuse contributes to agerelated changes in the brain and cognitive decline among senior adults. With the increasing population of senior adults in the United States and recent data indicating that 1 in 10 adults age 65 and older engage in binge drinking,⁶ this emerging area of research remains a significant Institute priority. To encourage studies on the neurobiological mechanisms that underlie the influence of alcohol on the onset and progression of Alzheimer's disease and related dementias, NIAAA is partnering with the National Institute on Aging on an initiative to expand research in this area.

In addition to effects on the brain, alcohol misuse can lead to a broad spectrum of alcohol-associated liver diseases (AALD) including fatty liver, steatohepatitis, fibrosis, cirrhosis, and hepatocellular carcinoma and now accounts for nearly half of liver disease deaths in the United States. NIAAA supports basic research on AALD, including studies investigating the pathological mechanisms that lead to the development of AALD and exploring diverse

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⁵ https://pubmed.ncbi.nlm.nih.gov/29411031/

⁶ https://pubmed.ncbi.nlm.nih.gov/31364159/

therapeutic targets to prevent or treat AALD. A recent NIAAA-supported study demonstrated that cenicriviroc, a compound that inhibits immune receptors involved in liver inflammation and fibrosis, was effective in preventing and reversing alcohol-induced liver damage in animal models.⁷

Advancing Epidemiology and Prevention Research

Significant changes in patterns of drinking behavior and consequences have occurred over the past 20 years. Rates of underage drinking have been cut in half since 1998 and continue to decline. Rates of alcohol-impaired driving fatalities have also dramatically decreased, particularly among individuals under age 21. Despite these promising trends, other harmful patterns of alcohol use have emerged. For example, over 10 percent of college-age individuals engage in high-intensity drinking⁸ – alcohol intake at levels twice or more the gender-specific thresholds for binge drinking. Identifying or developing interventions that target high-risk alcohol consumption in this population remains a high priority for the Institute. Accordingly, NIAAA developed a resource to assist college and university officials in addressing harmful patterns of alcohol use on their campuses, the College Alcohol Intervention Matrix (*CollegeAIM*). CollegeAIM was updated in 2019 to reflect recent research (see program portrait: "Translating NIAAA research into evidence-based resources").

Epidemiological data have also indicated that alcohol use, misuse, and related consequences such as emergency department (ED) visits have increased over the past decade among women and adults over age 55. ¹⁰ Alcohol-related ED visits also increased among young adults aged 25-34, a group that has experienced a significant increase in AALD such as cirrhosis over the past 10 years. ¹¹ Interventions to prevent alcohol misuse and associated consequences exist and are under-utilized. NIAAA continues to promote alcohol screening and brief intervention in primary care and other settings to facilitate earlier intervention with problem drinking and alcohol-related problems, and supports research on innovative and integrated preventive interventions that can be easily accessed and implemented. This includes studies to develop and test mobile health technologies to prevent and reduce alcohol misuse among adolescents, college students, pregnant women, and older adults.

Advancing Clinical Research on Diagnosis and Treatment

The clinical diagnosis of AUD and AUD treatment options have also evolved over the past 20 years. Separate diagnoses of "alcohol abuse" and "alcohol dependence" are now folded into a single spectrum disorder that ranges from mild to severe. This new diagnostic classification of AUD as a spectrum disorder mirrors other chronic diseases and demonstrates that distinct symptoms of AUD can vary among individuals. An increasing focus on precision medicine will likely improve AUD diagnosis and enable individualized treatment in the future. Twenty years ago, there were only two FDA-approved medications for AUD (disulfiram and naltrexone);

⁷ https://pubmed.ncbi.nlm.nih.gov/30179264/

⁸ http://www.monitoringthefuture.org//pubs/monographs/mtf-vol2 2018.pdf

⁹ www.collegedrinkingprevention.gov/collegeaim/

¹⁰ https://pubmed.ncbi.nlm.nih.gov/29293274/

¹¹ https://www.ncbi.nlm.nih.gov/pubmed/30021785

today there are three (acamprosate) as well as an extended-release version of naltrexone. Ongoing basic, translational, and clinical research aims to identify and evaluate novel neurobiological targets to pave the way for a broader menu of effective AUD medications in the future. Efforts are also underway to identify outcomes, in addition to abstinence, that define success in alcohol clinical trials and could increase the number of effective medications.

Although numerous behavioral therapies (such as outpatient cognitive behavioral therapy and motivational interviewing) and three FDA-approved medications are currently available, many people still believe that 12-step programs or residential treatment are their only options. In order to raise awareness about treatment options and connect individuals with treatment near them, NIAAA developed the Alcohol Treatment Navigator[®], ¹² an online resource supported by funding increases from FY 2015 to 2018. Developing resources, like the Alcohol Treatment Navigator[®], is a key strategy for translating NIAAA research into accessible materials that can be used by both healthcare professionals and the public (see program portrait: "Translating NIAAA research into evidence-based resources"). NIAAA will continue to work to close the treatment gap by supporting the integration of AUD screening and treatment into routine health care.

NIAAA has made efforts to foster a paradigm shift over recent years to integrate research on treatment of AALD with behavioral and pharmacological treatment of AUD – a "whole person" treatment approach. As an example, a recent NIAAA-funded study of patients recovering from alcoholic hepatitis, a severe form of AALD, revealed that participation in alcohol rehabilitation shortly after hospital discharge was associated with improved outcomes including reduced hospital readmission rates, alcohol relapse, and mortality. ¹³ A greater understanding of the treatment and recovery process and factors that influence relapse will also help inform future interventions and strategies for sustained recovery. The NIAAA Data Archive, ¹⁴ a repository recently established to collect and share clinical data from NIAAA-supported studies, will facilitate advances in AUD and AALD clinical research while promoting rigor and reproducibility.

Cultivating the Next Generation of Alcohol Researchers

The cultivation of a diverse and trained biomedical workforce will be instrumental for continued advancement in the field of alcohol research. NIAAA promotes research training through individual pre- and postdoctoral fellowships, institutional training grants, and career development awards across all areas of alcohol research. Increased funding in recent years has permitted NIAAA to invest in more career development awards. The Institute also makes funding decisions designed to sustain the pipeline of alcohol researchers. For example, NIAAA funds grant applications scoring in the top 25th percentile for early stage investigators and gives special consideration to promising mid-career investigators who are at risk of losing all sources of funding. With technological advances, collaborative science, and a rapidly expanding body of knowledge, the next generation of alcohol researchers is poised to advance basic, epidemiologic, prevention, and treatment findings to the next frontier.

13 https://www.ncbi.nlm.nih.gov/pubmed/31042580

¹² alcoholtreatment.niaaa.nih.gov/

¹⁴ www.niaaa.nih.gov/research/niaaa-data-archive

Overall Budget Policy:

The FY 2021 President's Budget request is \$497.3 million, a decrease of \$49.4 million or 9.0 percent compared with the FY 2020 Enacted level. NIAAA will continue to focus on spreading knowledge about the effects of alcohol misuse and to improve the diagnosis, prevention, and treatment of alcohol-related problems, including AUD.

Program Descriptions and Accomplishments

NIAAA's extramural programs are organized by stage of life to encourage consideration of how changes in biology, behavior, and environmental inputs over time influence the emergence and progression of drinking behavior, and prevention/treatment of alcohol misuse and associated health consequences.

Embryo/Fetus

The prenatal stage of development is particularly vulnerable to harm from alcohol. Indeed, alcohol exposure during embryonic and fetal development is a leading preventable cause of birth defects and can result in fetal alcohol spectrum disorders (FASD). Individuals with FASD may experience damage to the brain and other organs, growth retardation, facial abnormalities, and a range of neurobiological deficits that can result in physical, cognitive, behavioral, and social challenges throughout a person's life. NIAAA's Collaboration on FASD Prevalence Initiative aims to establish more precise and representative FASD prevalence estimates among schoolaged children across the United States. NIAAA supports the Collaborative Initiative on Fetal Alcohol Spectrum Disorders, a multidisciplinary international consortium of basic, translational, and clinical FASD research projects to understand the mechanisms of FASD and to improve approaches for prevention and treatment. For more information, see program portrait below entitled: "Improving screening, diagnosis, prevention, and treatment of FASD."

<u>Budget Policy</u>: The FY 2021 President's Budget request is \$16.3 million, a decrease of \$1.8 million or 9.9 percent compared with the FY 2020 Enacted level. FASD will continue to be a focus for NIAAA.

Youth/Adolescence (Ages 0-17)

Alcohol use is commonly initiated during adolescence, and the prevalence of drinking and binge drinking increases dramatically during this period. Not only are adolescents at increased risk of injuries and accidents while under the influence, but those who begin drinking early are at increased risk of alcohol problems later in life. Moreover, preclinical and clinical research indicate that alcohol exposure during adolescence can affect brain development and compromise cognitive function in both the short- and long-term. To promote the continued advancement of our understanding of the consequences of adolescent alcohol consumption and development of prevention efforts informed by adolescent neurobiology, NIAAA supports multiple research consortia that study the effects of alcohol exposure on the developing brain. The National Consortium on Alcohol and Neurodevelopment in Adolescence and the Adolescent Brain Cognitive Development (ABCD; see trans-NIH initiatives) study are two longitudinal studies

examining brain structure and function in youth before and after they begin using alcohol or other drugs. Complementing these human research consortia, NIAAA's Neurobiology of Adolescent Drinking in Adulthood consortium is enabling investigators to examine, in animal models, the mechanisms by which adolescent drinking affects brain structure and function and how the changes observed during this critical period persist into adulthood. By elucidating the specific consequences of adolescent alcohol exposure and the factors that confer vulnerability to these effects, these initiatives could lead to improvements in early intervention.

Alcohol screening is an important step for identifying and preventing alcohol-related problems among youth. A recent NIAAA-supported study demonstrated the predictive validity of NIAAA's two-question youth alcohol screening guide in accurately characterizing risk for future AUD. ¹⁵ Another NIAAA-supported study found that, relative to usual care, adolescent patients (ages 12-18) subjected to screening, brief intervention, and referral to treatment in pediatric primary care settings had improved health, mental health, and substance use outcomes over a three-year follow up period. ¹⁶

<u>Budget Policy</u>: The FY 2021 President's Budget request is \$49.0 million, an increase of \$3.7 million or 8.2 percent compared with the FY 2020 Enacted level. Researching effects of adolescent drinking, as well as prevention and reduction of adolescent drinking will continue to be a focus for NIAAA.

Young adult (Ages 18-29)

The prevalence of binge drinking and heavy alcohol use (binge drinking five or more times during past month) increase and peak during young adulthood. Among college-age young adults (ages 18-20), 24.1 percent of individuals report current binge drinking, with about 6 percent reporting heavy alcohol use. For young adults ages 21-25, 42 percent of individuals report current binge drinking, with 11 percent reporting heavy alcohol use. These patterns of drinking increase risks for blackouts, assault, unsafe sexual behavior, alcohol overdose, injuries, death, and AUD. Furthermore, effects of alcohol exposure on the developing brain extend into young adulthood. A recent NIAAA-funded study found that heavy alcohol exposure during the transition from late adolescence to young adulthood was associated with reduced rates of brain growth. Disseminating information about interventions that target harmful patterns of alcohol consumption among college students remains a high priority for the Institute. NIAAA also invests in research to develop mobile health interventions for students at four-year and community colleges as well as for young adults in other settings.

NIAAA encourages studies on alcohol screening and brief intervention for young adults and the development and implementation of individual-, family-, community-, and policy-level interventions. A recent study demonstrated that individuals under age 40 suffer twice as many aggression-related and driving-related harms due to alcohol use by others ("secondhand" effects)

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¹⁵ https://www.ncbi.nlm.nih.gov/pubmed/30783022

¹⁶ https://pubmed.ncbi.nlm.nih.gov/31018988/

¹⁷ https://www.samhsa.gov/data/report/2018-nsduh-detailed-tables

¹⁸ https://www.ncbi.nlm.nih.gov/pubmed/30993181

compared to those over age 40. 19 State policies that reduce binge drinking or alcohol-impaired driving were linked to lower levels of reported experiences of secondhand harms in the under-40 age group.

<u>Budget Policy</u>: The FY 2021 President's Budget request is \$179.7 million, a decrease of \$24.2 million or 11.9 percent compared with the FY 2020 Enacted level. Research aimed at preventing, reducing, and treating alcohol misuse and its consequences, in addition to assisting colleges and universities, will continue to be a focus for NIAAA.

Midlife (Ages 30-59)

Midlife is the time when individuals with AUD are most likely to seek treatment. Pharmacotherapy is an important component of treatment for AUD, and NIAAA has taken several steps to advance potential medications through the development pipeline. Through the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs, NIAAA supports research on promising, early-stage compounds to enable researchers to submit an investigational new drug application to the FDA prior to human testing. NIAAA's Human Laboratory Program was initiated to screen candidate compounds for potential effectiveness before embarking on more expensive and time-consuming clinical trials. Human laboratory studies also allow researchers to better understand treatment responses by using experimental manipulations designed to probe mechanisms underlying alcohol use. Through the NIAAA Clinical Investigations Group, NIAAA supports a network of research sites for conducting Phase II clinical trials of promising compounds. NIAAA also supports research examining the utility of alternative outcomes other than abstinence or the absence of heavy drinking days for alcohol clinical trials. Two recent NIAAA-supported studies demonstrated the potential utility of reductions in the World Health Organization drinking risk levels as clinical trial outcomes. Alternative outcomes are useful given that many individuals are able to reduce their drinking to less harmful levels during treatment, resulting in improvements in how they feel and function.

The heterogeneous nature of AUD drives the need for precision diagnosis and treatment, and recent advances in precision medicine may ultimately change the way AUD is diagnosed and lead to individualized treatment strategies. NIAAA intramural researchers have developed the Addictions Neuroclinical Assessment, a framework that utilizes neuropsychological data based on the addiction cycle with the goal of providing individualized AUD treatment once a diagnosis has been made.

Health consequences of chronic alcohol use such as alcohol-associated liver disease (AALD) typically emerge in midlife. Nearly half of U.S. liver disease deaths are attributable to alcohol misuse, and AALD is the most common alcohol-related cause of death as well as the leading cause of liver transplantation due to chronic liver disease. To accelerate research on alcoholic hepatitis, a severe form of AALD, NIAAA consolidated its alcoholic hepatitis research consortia into an Alcoholic Hepatitis Clinical and Translational Network that is maximizing the use of research resources and promoting the sharing of research expertise.

¹⁹ https://pubmed.ncbi.nlm.nih.gov/31166048/

Senior Adult (Age 60+)

Over the past two decades, the prevalence of alcohol use has steadily increased in the population age 60 and above, particularly among women.²⁰ These trends are concerning as senior adults are generally more sensitive to the sedative (sleep-inducing) effects of alcohol, as well as its effects on balance, coordination, attention, and driving skills. For these reasons, older adults are at heightened risk for falls, car crashes, and other unintentional injuries that may result from drinking. Research by NIAAA suggests that 4 out of 5 people age 65 and over who drink alcohol also take a medication that could interact with alcohol,²¹ emphasizing the need to educate this population about potential drug interactions.

NIAAA encourages research to increase understanding of the effects of alcohol use/misuse in older adults and the factors that promote alcohol misuse in this population. Ongoing NIAAA-supported research includes studies to examine the contributions of advanced age to vulnerability to alcohol-induced brain damage, the relationship between alcohol and inflammaging (i.e., aging-related changes in immune function that increase risk for infections), and the role of social networks in influencing alcohol misuse. Social isolation has been associated with adverse health outcomes among older adults and NIAAA is also exploring ways to expand research in this area.

<u>Budget Policy</u>: The FY 2021 President's Budget request for midlife and senior adult research is \$163.4 million, a decrease of \$22.4 million or 12.1 percent compared with the FY 2020 Enacted level. Research aimed at preventing, reducing, and treating alcohol misuse and its consequences will continue to be a focus for NIAAA.

Intramural Research

The goal of NIAAA's Intramural Research Program (IRP) is to use highly innovative research to improve understanding of the biological and behavioral basis of AUD, the impact of alcohol on brain structure and function, processes underlying the effects of alcohol on the body, and to develop treatments for AUD and other alcohol-related conditions. The NIAAA IRP provides a unique environment for cutting-edge basic, translational, and clinical alcohol research and for training young investigators. Intramural researchers recently shed light on the mechanisms that contribute to liver cancer in people with chronic liver disease who drink heavily and have an inactive form of aldehyde dehydrogenase 2 (ALDH2), an enzyme that detoxifies a harmful byproduct of alcohol metabolism.²² Elucidating these pathological mechanisms could reveal new pharmacotherapy targets to prevent alcohol-associated liver cancer. Advancing evidencebased treatment for AUD is a major focus of the IRP's clinical program. One such study is investigating the role of ghrelin, a hormone that regulates appetite and food intake, in alcoholrelated behaviors such as alcohol craving and seeking, and its potential in the treatment of AUD. Intramural scientists also developed the Addictions Neuroclinical Assessment, a framework for classifying individual differences in AUD based on neuropsychological measures, and recently validated the framework with data from a large, diverse group of research participants in NIAAA's research program at the NIH Clinical Center. In addition, NIAAA intramural

²⁰ https://onlinelibrary.wiley.com/doi/full/10.1111/acer.13365

²¹ https://onlinelibrary.wiley.com/doi/10.1111/acer.12633

²² https://pubmed.ncbi.nlm.nih.gov/31279903/

researchers collaborate with scientists across NIH on a broad range of alcohol-related topics and lead the NIH Center for Compulsive Behavior which comprises intramural investigators from NIAAA as well as many other NIH institutes.

<u>Budget Policy</u>: The FY 2021 President's Budget request is \$53.7 million, a decrease of \$2.8 million or 5.0 percent compared with the FY 2020 Enacted level. The support and success of alcohol research will continue to be a focus for IR at NIAAA.

Research Management and Support

Research Management and Support provides for administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of grants, training awards, and contracts; strategic planning, coordination, and evaluation of the NIAAA's programs; regulatory compliance; and liaison with other Federal agencies, Congress, and the public.

<u>Budget Policy</u>: The FY 2021 President's Budget request is \$35.3 million, a decrease of \$1.9 million or 5.0 percent compared with the FY 2020 Enacted level. The support and success of alcohol research will continue to be a focus for RMS at NIAAA.

Program Portrait: Improving screening, diagnosis, prevention, and treatment of FASD

FY 2020 Level: \$30.1 million FY 2021 Level: \$27.4 million Change: -\$2.7 million

Recent research suggests that many children in need of FASD screening and treatment are not receiving it. Improved diagnostic techniques for FASD would enable more accurate diagnosis and earlier intervention. NIAAA-funded researchers have developed three-dimensional photography and computerized image analysis that can enhance the detection of a broad range of alcohol-induced facial characteristics in children who were prenatally exposed to alcohol. This approach is being refined and could potentially facilitate widespread FASD screening and early diagnosis, including for children who do not have access to a clinician with the expertise to diagnose FASD.

To further advance research on FASD diagnosis and early intervention, NIAAA supports studies to refine the understanding of the neurobehavioral traits associated with FASD and which distinguish individuals with FASD from those with other neurodevelopmental conditions. Researchers are adapting these neurobehavioral findings to develop a web-based screening tool for mobile use. Other research in this area is exploring maternal immune profiles as biomarkers of prenatal alcohol exposure and risk of neurodevelopmental delay in infants. In addition, NIAAA is leading an effort to develop a single system for classifying the range of FASD subtypes for use in research worldwide. The adoption of a single classification system by researchers could accelerate progress on diagnosis, prevention, and treatment of FASD.

Developing culturally-appropriate approaches for the prevention of alcohol-exposed pregnancies continues to be an important focus of NIAAA research. Studies have shown that screening, brief intervention, and referral to treatment (SBIRT) approaches are a significant tool for addressing alcohol and other substance use in primary and prenatal care settings. Ongoing research supported by NIAAA on computer-delivered brief interventions is beginning to show promising effects in the area of alcohol

misuse. These approaches could ultimately enable efficient and low-cost SBIRT in community settings such as those that provide prenatal care.

Effective interventions to mitigate the health and behavioral effects of FASD continue to be needed. NIAAA-supported scientists recently showed that dietary supplementation with the essential nutrient choline provides beneficial effects on learning, memory, and other cognitive measures in alcohol-exposed animals. More recent exploratory research has found evidence that a high dose of choline administered early in pregnancy can mitigate adverse effects of heavy prenatal alcohol exposure on postnatal growth and cognition in human infants.

Program Portrait: Translating NIAAA research into evidence-based resources

FY 2020 Level: \$4.3 million FY 2021 Level: \$3.9 million Change: -\$0.4 million

Alcohol misuse is the third leading preventable cause of death in the nation. Despite the advances made in alcohol research, many people, including health care professionals, are not aware of the full range of evidence-based options for prevention and treatment of alcohol-related problems. Equally apparent is the lack of implementation of evidence-based prevention and treatment strategies for alcohol misuse. NIAAA is working to raise awareness of the availability of prevention and treatment options and to translate evidence-based information into resources for the general public, schools, communities, and health care professionals to promote their widespread implementation.

Underage drinking is a serious public health problem in the United States. Adolescent alcohol exposure can impair brain development, compromise cognitive functioning, and increase the likelihood of developing alcohol-related problems later in life. NIAAA developed Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide²³ to help health care professionals identify youth who are at risk for alcohol use, are using alcohol, or have AUD, and to intervene as appropriate. To address underage drinking at the high school level and below, NIAAA is currently developing a lay-friendly online core prevention resource that distills and synthesizes evidence-based information about underage drinking preventive interventions for schools and communities. NIAAA developed CollegeAIM²⁴ to assist colleges and universities in choosing from more than 60 evidence-based college drinking interventions based on their effectiveness, anticipated costs, and barriers to implementation. CollegeAIM was recently revised to reflect new research findings. Seven new interventions were added and some interventions received updated ratings of effectiveness.

Rethinking Drinking, 25 NIAAA's most popular resource for the public, is an interactive website and accompanying booklet that offers research-based information to help individuals who use alcohol assess their drinking habits and find ways to make a change. Rethinking Drinking also provides information about the amount of alcohol that constitutes a U.S. standard drink (or alcoholic-drink equivalent) and an online calculator for determining the number of standard drinks in mixed alcoholic beverages to help individuals understand how much alcohol they may be consuming.

²³ https://www.niaaa.nih.gov/sites/default/files/publications/YouthGuide.pdf

https://www.collegedrinkingprevention.gov/collegeaim/
 https://www.rethinkingdrinking.niaaa.nih.gov/

While some people are able to change their drinking habits or stop drinking on their own, others need professional support but may not be aware of the variety of treatment options or know how to find qualified treatment providers. NIAAA developed the *Alcohol Treatment Navigator*^{®26} to help people understand treatment options for AUD and search for professionally-led, evidence-based alcohol treatment near them. NIAAA recently added a clinician's portal²⁷ to the Navigator to assist health care professionals in making effective referrals to evidence-based alcohol treatment. NIAAA is also developing a clinician's core resource to provide health care professionals with essential information to help them better recognize the effects of alcohol in their patients and deliver improved care for those whose drinking may be affecting their health. This resource will help inform efforts to improve clinician training in addiction medicine, from professional school through post-graduate studies including internships, residencies, fellowships, and beyond.

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²⁶ https://alcoholtreatment.niaaa.nih.gov/

²⁷ https://alcoholtreatment.niaaa.nih.gov/healthcare-professionals

Budget Authority by Object Class¹ (Dollars in Thousands)

		FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total cor	mpensable work years:			2020
	Full-time equivalent	238	238	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	\$195	\$197	\$2
	Average GM/GS grade	12.9	12.9	0.0
	Average GM/GS salary	\$128	\$128	\$1
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$144	\$145	\$1
	Average salary of ungraded positions	\$111	\$112	\$0
	OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
	Personnel Compensation			
11.1	Full-Time Permanent	23,186	23,453	267
11.3	Other Than Full-Time Permanent	7,916	8,007	91
11.5	Other Personnel Compensation	599	606	7
11.7	Military Personnel	159	163	4
11.8	Special Personnel Services Payments	2,886	2,919	33
11.9	Subtotal Personnel Compensation	\$34,746	,	\$402
12.1	Civilian Personnel Benefits	10,249	10,649	400
12.2	Military Personnel Benefits	151	155	4
13.0	Benefits to Former Personnel	0	0	0
21.0	Subtotal Pay Costs	\$45,146	\$45,952	\$806
21.0	Travel & Transportation of Persons	600	348	-252
22.0 23.1	Transportation of Things	59	42	-17
23.1	Rental Payments to GSA Rental Payments to Others	0	0	0
23.2	Communications, Utilities & Misc. Charges	212	134	-77
24.0	Printing & Reproduction	3	2	-1
25.1	Consulting Services	243	143	-100
25.2	Other Services	7,584	5,023	-2,561
25.3	Purchase of goods and services from government	53,066	53,354	288
25.4	accounts	· ·	ŕ	
25.4	Operation & Maintenance of Facilities	71	46 15 254	-25
25.5	R&D Contracts	19,513	15,354	-4,159
25.6	Medical Care	100	73	-28
25.7 25.8	Operation & Maintenance of Equipment Subsistence & Support of Persons	719	477 0	-242 0
25.8 25.0	Subtotal Other Contractual Services	\$81,296		-\$6,827
26.0	Supplies & Materials	3,987	2,860	-1,127
31.0	Equipment	2,247	2,800 1,469	-1,127 -778
32.0	Land and Structures	2,247	0.	-776
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	413,146	372,069	-41,077
42.0	Insurance Claims & Indemnities	0	0	(
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	Ö
	Subtotal Non-Pay Costs	\$501,550	\$451,394	-\$50,156
	Total Budget Authority by Object Class	\$546,696		-\$49,350

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

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation			
Full-Time Permanent (11.1)	\$23,186	\$23,453	\$267
Other Than Full-Time Permanent (11.3)	7,916	8,007	91
Other Personnel Compensation (11.5)	599	606	7
Military Personnel (11.7)	159	163	4
Special Personnel Services Payments (11.8)	2,886	2,919	33
Subtotal Personnel Compensation (11.9)	\$34,746	\$35,148	\$402
Civilian Personnel Benefits (12.1)	\$10,249	\$10,649	\$400
Military Personnel Benefits (12.2)	151	155	4
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$45,146	\$45,952	\$806
Travel & Transportation of Persons (21.0)	\$600	\$348	-\$252
Transportation of Things (22.0)	59	42	-17
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	212	134	-77
Printing & Reproduction (24.0)	3	2	-1
Other Contractual Services:			
Consultant Services (25.1)	243	143	-100
Other Services (25.2)	7,584	5,023	-2,561
Purchases from government accounts (25.3)	39,794	39,698	-96
Operation & Maintenance of Facilities (25.4)	71	46	-25
Operation & Maintenance of Equipment (25.7)	719	477	-242
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$48,412	\$45,386	-\$3,025
Supplies & Materials (26.0)	\$3,987	\$2,860	-\$1,127
Subtotal Non-Pay Costs	\$53,272	\$48,773	-\$4,499
Total Administrative Costs	\$98,418	\$94,725	-\$3,693

Detail of Full-Time Equivalent Employment (FTE)

	1	FY 2019 Final		F	Y 2020 Enacto	ed	FY 202	1 President's	Budget
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Epidemiology and Prevention Research	17		17	10		10	10		10
Direct:	17	-	17	18	-	18	18	-	18
Reimbursable:	17	-	17	-	-	-	- 10	-	1.0
Total:	17	-	17	18	-	18	18	-	18
Division of Intramural Research Program									
Direct:	78	1	79	87	1	88	87	1	88
Reimbursable:	10	-	10	8	-	8	8	-	8
Total:	88	1	89	95	1	96	95	1	96
Division of Medications Development									
Direct:	5	_	5	6	_	6	6	_	6
Reimbursable:	_	_	_	-	_	-	_	_	
Total:	5	-	5	6	-	6	6	-	6
Division of Metabolism and Health Effects									
Direct:	10	-	10	10	-	10	10	-	10
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	10	-	10	10	-	10	10	-	10
Division of Neuroscience and Behavior									
Direct:	15	-	15	16	-	16	16	-	16
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	15	-	15	16	-	16	16	-	16
Division of Treatment and Recovery Research									
Division of Treatment and Recovery Research Direct:	5		5	6		6	6		6
Reimbursable:	3		3	0	_	0	-	-	
Total:	5	_	5	6	-	6	6	_	6
Office of Extramural Activities									
Direct:	21	-	21	21	-	21	21	-	21
Reimbursable:	-	-	-	-	-	-	-	-	
Total:	21	-	21	21	-	21	21	-	21
Office of Resource Management									
Direct:	38	-	38	39	-	39	39	-	39
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	38	-	38	39	-	39	39	-	39
Office of Science Policy and Communications									
Direct:	15	_	15	16	_	16	16	_	16
Reimbursable:	_	_	_	-	_	-	-	_	_
Total:	15	-	15	16	-	16	16	-	16
Office of the Director	4.0		4.0			4.0	4.0		
Direct:	10	-	10	10	-	10	10	-	10
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	10	-	10	10	-	10	10	-	10
Total	224	1	225	237	1	238	237	1	238
Includes FTEs whose payroll obligations are supported by the	NIH Common	Fund.							•
FTEs supported by funds from Cooperative Research and	0	0	0	0	0	0	0	0	0
Development Agreements.	, o	U	Ü	-	•		Ü	0	U
FISCAL YEAR				Av	erage GS Gra	ade			
2017					12.8				
2018					12.9				
2019					12.9				
2020					12.9				
2021					12.9				

NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

Detail of Positions¹

Detail of	1 USITIONS		777.0004
GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	190,995	194,815	196,763
GM/GS-15	26	29	29
GM/GS-14	54	58	58
GM/GS-13	41	44	44
GS-12	20	22	22
GS-11	9	10	10
GS-10	1	1	1
GS-9	6	6	6
GS-8	4	4	4
GS-7	5	5	5
GS-6	0	0	0
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	166	179	179
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	1	1	1
Ungraded	75	75	75
Total permanent positions	171	184	184
Total positions, end of year	243	256	256
Total full-time equivalent (FTE) employment, end of year	225	238	238
Average ES salary	190,995	194,815	196,763
Average GM/GS grade	12.9	12.9	12.9
Average GM/GS salary	123,688	127,522	128,032

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