

DEPARTMENT OF HEALTH AND HUMAN SERVICES

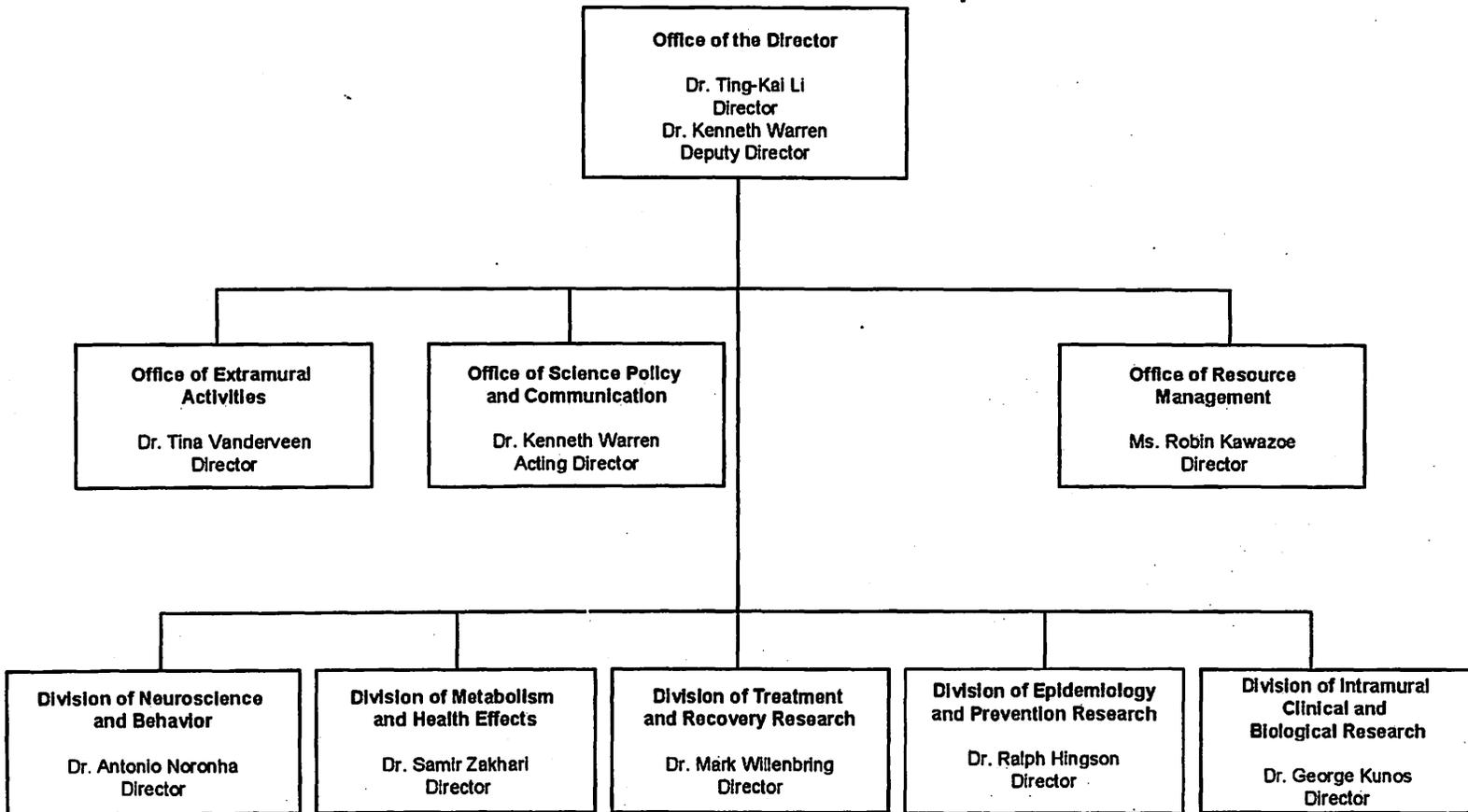
NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

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NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism



NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism

For carrying out section 301 and title IV of the Public Health Services Act with respect to alcohol abuse and alcoholism, [~~\$444,016,000~~], **\$436,681,000** (Department of Health and Human Services Appropriation Act, 2008)

**National Institutes of Health
National Institute on Alcohol Abuse and Alcoholism**

Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$435,930,000	\$444,016,000	\$436,681,000
Pay cost add-on	329,000	0	0
Rescission	0	-7,757,000	0
Subtotal, adjusted appropriation	436,259,000	436,259,000	436,681,000
Real transfer under Director's one-percent transfer authority (GEI)	-674,000	0	0
Real transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	0	0	0
Real transfer to the Office of Public Health Emergency Preparedness	0	0	0
Comparative transfer to NIBIB	-22,000	0	0
Comparative transfer to OD	-10,000	0	0
Comparative transfer to NCRR	-169,000	0	0
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-1,000	0	0
Comparative transfer to (specify)	0	0	0
Comparative transfer under Director's one-percent transfer authority (GEI)	674,000	0	0
Comparative transfer to the Global Fund to fight HIV/AIDS, Malaria and Tuberculosis	0	0	0
Comparative transfer from DHHS	0	0	0
Comparative transfer to DHHS for PHS historian	0	0	0
Subtotal, adjusted budget authority	436,057,000	436,259,000	436,681,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	436,057,000	436,259,000	436,681,000
Unobligated balance lapsing	-219,000	0	0
Total obligations	435,838,000	436,259,000	436,681,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2007 - \$2,513,000 FY 2008 - \$3,320,000 FY 2009 - \$3,399,000
Excludes \$1,437 in FY 2008 and \$2,043 in FY 2009 for royalties.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism
(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects:								
Noncompeting	537	\$187,539	543	\$194,056	526	\$189,605	(17)	-\$4,451
Administrative supplements	(20)	1,090	(20)	1,000	(20)	1,147	(0)	147
Competing:								
Renewal	41	17,883	39	17,399	42	18,463	3	1,064
New	162	49,113	141	42,601	149	45,205	8	2,604
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	203	66,996	180	60,000	191	63,668	11	3,668
Subtotal, RPGs	740	255,625	723	255,056	717	254,420	(6)	-636
SBIR/STTR	32	9,890	27	8,315	27	8,284	0	-31
Subtotal, RPGs	772	265,515	750	263,371	744	262,704	(6)	-667
Research Centers:								
Specialized/comprehensive	17	27,590	17	27,280	17	27,280	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
Subtotal, Centers	17	27,590	17	27,280	17	27,280	0	0
Other Research:								
Research careers	83	11,670	86	11,940	86	11,940	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	2	8,695	2	8,765	2	8,765	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	26	6,591	26	6,507	26	6,507	0	0
Subtotal, Other Research	111	26,956	114	27,212	114	27,212	0	0
Total Research Grants	900	320,061	881	317,863	875	317,196	(6)	-667
Research Training:	FTEs		FTEs		FTEs			
Individual awards	86	3,052	86	3,052	85	3,052	(1)	0
Institutional awards	204	8,293	204	8,293	202	8,293	(2)	0
Total, Training	290	11,345	290	11,345	287	11,345	(3)	0
Research & development contracts (SBIR/STTR)	22 (2)	33,354 (358)	22 (4)	34,454 (1,550)	22 (4)	34,454 (1,550)	0 (0)	0 (0)
Intramural research	FTEs		FTEs		FTEs		FTEs	
Intramural research	107	46,019	107	46,940	108	47,644	1	704
Research management and support	113	25,278	113	25,657	114	26,042	1	385
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAAA	220	436,057	220	436,259	222	436,681	2	422

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism
BA by Program
(Dollars in thousands)

	FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2007 Comparable		FY 2008 Enacted		FY 2009 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research														
<u>Detail:</u>														
Embryo and Fetus		\$20,930		\$20,732		\$23,412		\$23,446		\$23,345		\$23,302		-43
Youth/Adolescence		55,740		55,213		59,300		59,392		59,213		59,104		-109
Young Adult		155,157		153,688		147,152		147,368		146,924		146,655		-269
Mid-Life/Senior Adult		137,361		136,062		134,361		134,554		134,180		133,934		-246
Subtotal, Extramural		369,188		365,695		364,225		364,760		363,662		362,995		-667
Intramural research	117	45,346	117	45,574	113	46,019	113	46,019	113	46,940	114	47,644	1	704
Res. management & support	116	23,743	108	24,361	107	25,341	107	25,278	107	25,657	108	26,042	1	385
TOTAL	233	438,277	225	435,630	220	435,585	220	436,057	220	436,259	222	436,681	2	422

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

Major Changes in the Fiscal Year 2009 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 2009 budget request for NIAAA, which is \$0.422 million more than the FY 2008 Estimate, for a total of \$436.505 million.

Research Project Grants (-\$0.7 million, total \$262.7 million). The NIH budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs. NIAAA will support a total of 191 Research Project Grant (RPG) awards in FY 2009. Noncompeting RPGs will decrease by 17 awards and \$4.5 million. Competing RPGs will increase by 11 awards and \$3.7 million.

Research Careers (+\$0.0 million; total \$11.940 million): NIAAA will support the Pathway to Independence program by continuing to fund 3 new K99 awards annually. Total support for the Pathway program in FY 2009 is 9 awards and \$1.4 million.

Neuroscience Blueprint (+0.0 million; total \$1.0 million): NIAAA will continue its support for the NIH Neuroscience blueprint which was inspired by recognition that unifying themes in neuroscience research are fundamental to understanding the normal and disordered nervous system and to developing better prevention and treatment therapies.

Intramural Research (+\$0.7 million; total \$47.6 million): NIAAA supports an Intramural Research Program of ten Intramural Laboratories encompassing 108 FTEs and approximately 100 additional non-FTE staff including research fellows and visiting scientists, among others. The increase will be used to partially offset the expenses associated with pay raises and other cost increases necessary to provide for the effective operations of the NIAAA Intramural Program.

Research Management and Support (+\$0.4 million; total \$26.0 million): NIAAA oversees almost 900 research grants, 22 research and development contracts, and more than 280 full-training positions. The increase will be used to partially offset the expenses associated with pay raises and other cost increases necessary to provide for the effective administrative, planning and evaluation, public information and communications, and scientific leadership of the Institute.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism
Summary of Changes

FY 2008 Enacted		\$436,259,000		
FY 2009 estimated budget authority		436,681,000		
Net change		422,000		
CHANGES	2008		Change from Base	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2008 pay increase				
		\$17,508,000		\$197,000
		17,508,000		381,000
		17,508,000		(67,000)
		7,403,000		111,000
		22,029,000		432,000
Subtotal				1,054,000
2. Research management and support:				
a. Annualization of January 2008 pay increase				
		\$14,929,000		\$168,000
		14,929,000		325,000
		14,929,000		(57,000)
		3,197,000		48,000
		7,531,000		142,000
Subtotal				626,000
Subtotal, Built-in				1,680,000

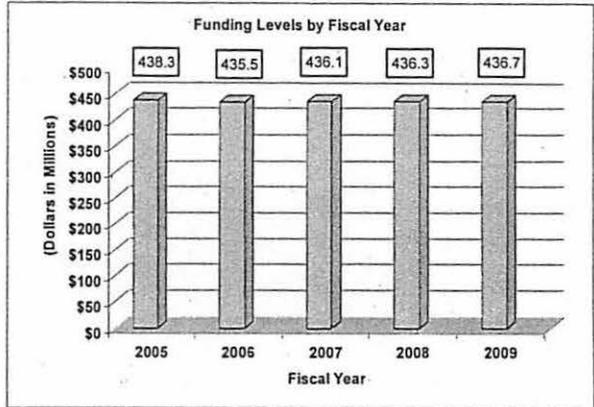
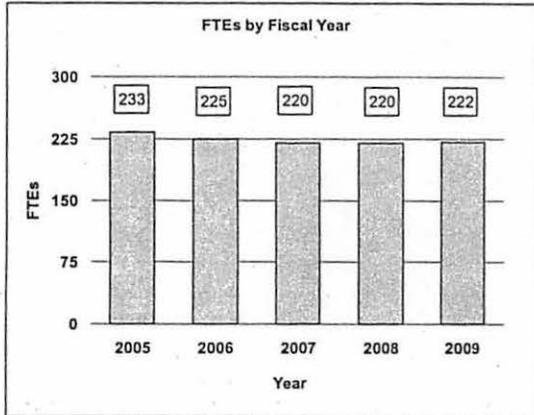
**NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism**

Summary of Changes--continued

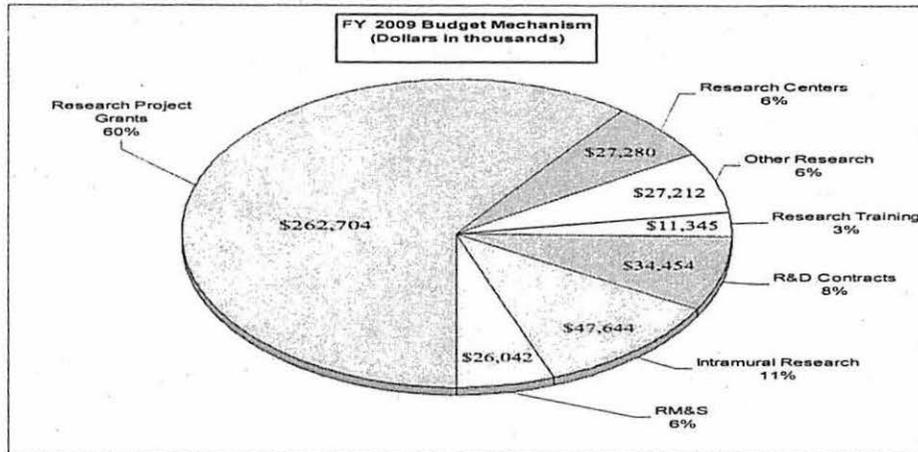
CHANGES	2008 Enacted Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	543	\$195,056,000	(17)	(\$4,304,000)
b. Competing	180	60,000,000	11	3,668,000
c. SBIR/STTR	27	8,315,000	0	(31,000)
Total	750	263,371,000	(6)	(667,000)
2. Research centers	17	27,280,000	0	0
3. Other research	114	27,212,000	0	0
4. Research training	290	11,345,000	(3)	0
5. Research and development contracts	22	34,454,000	0	0
Subtotal, extramural				(667,000)
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	107	46,940,000	1	(350,000)
7. Research management and support	113	25,657,000	1	(241,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		436,259,000		(1,258,000)
Total changes	220		2	422,000

Fiscal Year 2008 Budget Graphs

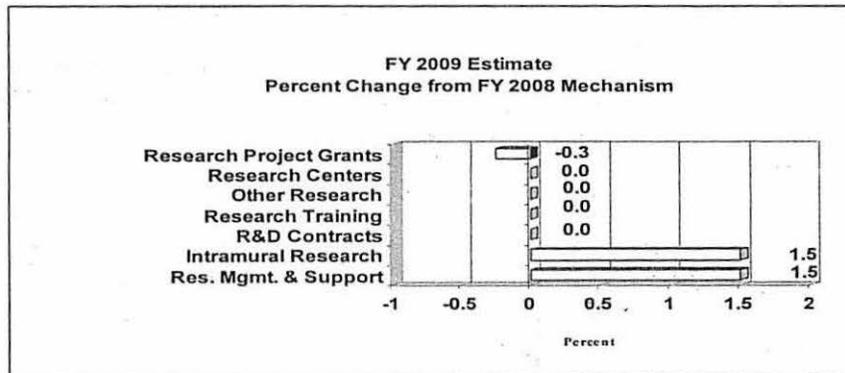
History of Budget Authorities and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Justification

National Institute on Alcohol Abuse and Alcoholism

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

Budget Authority:

FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Increase or Decrease	
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>
220	\$436,057,000	220	\$436,259,000	222	\$436,681,000	2	+\$422,000

This document provides justification for the Fiscal Year 2009 activities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), including HIV/AIDS activities. Details of the FY 2008 HIV/AIDS activities are in the Office of AIDS Research (OAR) section of the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

Alcohol is the third leading cause of preventable death in the U.S.¹ Drinking too early, too much, too fast, and/or too often can lead to acute and chronic consequences for the drinker as well as to outcomes that extend beyond the individual, affecting the health and well-being of others and society-at-large. Excessive alcohol use also comes with an economic cost to our nation estimated at \$185 billion annually.² In the U.S. in 2006 there were over 18 million people ages 12 years and older suffering from alcohol abuse or dependence with less than 7 percent receiving any form of treatment³.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is the lead agency for U.S. research on alcohol abuse, alcoholism, and other health and developmental effects of alcohol. NIAAA's goal is to support and promote the best science on alcohol and health for the benefit of all by: increasing the understanding of normal and abnormal biological functions and behavior relating to alcohol use; improving the diagnosis, prevention, and treatment of alcohol use disorders; reducing alcohol-related health disparities; and enhancing access to quality health care for alcohol-related problems.

¹ Mokdad AH, Marks JS, Stroup DF, Gerberding JL. JAMA. 2004. 29: 1238-45.

² Harwood, H. Updating Estimates of the Economic Costs of Alcohol Abuse in the United States: Estimates, Update Methods and Data (2000). <http://pubs.niaaa.nih.gov/publications/economic-2000/>

³ Source: Office of Applied Studies, SAMHSA. Detailed tabulations from the 2006 National Survey on Drug Use and Health, Table 5.1A and 5.26A.

NIAAA's mission is broader than just preventing alcoholism, encompassing the prevention and reduction of: prenatal alcohol exposure; risk for early drinking; escalation of drinking; engagement in hazardous patterns of drinking; and the acute and chronic consequences of alcohol use, which include alcoholism. To address this broad agenda, NIAAA has taken a life span approach, examining the most significant vulnerabilities to alcohol's negative effects at each stage of life (embryo/fetus, youth/adolescent, young adult, and mid life/senior adult) as well as the opportunities for intervention.

Complementing NIAAA's emphasis on periods of enhanced vulnerability is a focus on individuals and sub-populations who may be at increased risk for alcohol dependence and other adverse alcohol-related outcomes due to genetic and environmental factors, and the interplay among them. For example, NIAAA continues to support research to identify genes and biomarkers that are associated with an increased risk for alcohol dependence. Studies are also exploring how environmental factors including chronic alcohol exposure, can affect gene expression resulting in damage to cells, tissues and organs. In addition, research is ongoing to determine how sex, including hormonal differences, factors into the escalation of drinking, development of dependence, and tissue and organ damage.

In parallel with NIAAA supported research studies designed to address alcohol-related vulnerabilities across the lifespan, recent studies are increasing our understanding of the entire spectrum of alcohol disorders including the transition from controlled, voluntary alcohol use to compulsive, involuntary use, i.e. addiction. A recent study has given us new insight into the face of alcoholism in the U.S. While clinicians and researchers have long recognized the variation within the alcohol dependent population, the public perception of a 'typical alcoholic' remains that of a dysfunctional individual affected by the chronic relapsing subtype of the disorder. In fact, this subtype occurs in a relatively small percentage of the alcohol-dependent population. Recent analyses of data from NIAAA's National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) have identified distinct subtypes of alcohol dependence. Because these analyses were performed on data representing the general population, and not specifically on data from people in alcohol treatment settings, they provide a much broader and more accurate picture of the range of individuals who suffer from alcohol dependence and the multi-faceted nature of their disorder. Certain subtypes of alcoholics have emerged that were previously undetected, or at least significantly underestimated, because few individuals with these subtypes of alcohol disorder access treatment. For example, young adults rarely seek any kind of help for their drinking but comprise the largest group of alcoholics in this country. In addition, nearly 20 percent of alcoholics are highly functional and well-educated with good incomes and stable families; less than 1/5 of this group seeks treatment. Individuals in other subtypes, although variable in age and other characteristics, make up the more severe end of the spectrum. They are more likely to have other psychiatric disorders and other substance abuse problems, are more likely to seek treatment and therefore have been well characterized in treatment focused studies.

Our increased understanding of alcohol dependence has brought about a significant paradigm shift in alcohol research. Given studies that show that the majority of individuals who meet diagnostic criteria for alcohol dependence do not access treatment, NIAAA supported research is evaluating screening and brief intervention in venues other than specialty treatment facilities. For example, despite the high burden of illness associated with alcohol abuse and dependence, screening and diagnosis of alcohol problems are not standard components of primary health care for most individuals. Whereas virtually every physical examination for people of all ages includes measurement of blood pressure to assess risk for hypertension, relatively few physicians routinely ask patients about their drinking. NIAAA is working to integrate alcohol screening and treatment into routine health care. In addition, NIAAA supported research is exploring other settings for screening and intervention including emergency departments, trauma centers, college health centers and community venues. See portrait for details.

This new information defining the subtypes of alcoholic dependence, in conjunction with the accumulating knowledge base on the influence of genetic makeup, epigenetic changes in gene expression, and life stage is enabling us to increasingly personalize treatment including both behavioral interventions and medications. See portrait for details on medications development. In addition, NIAAA continues to support research into how people change their drinking behavior both with and without treatment.

FY 2008 Justification by Activity Detail:

Overall Budget Policy: Investigator-initiated research projects and new investigator research and career development are the Institute's highest priorities. The NIAAA carefully evaluates investigator-initiated requests to all its programs, conducts scientific review, and presents results to the NIAAA Advisory Council to determine the level of recommended support. The level of support provided for Institute-initiated projects (e.g. RFAs) is also evaluated. The Institute maintains a balance between solicitations issued to the extramural community in areas that need stimulation and funding made available to support investigator-initiated projects. NIAAA's Program Funding Table comprises the primary building blocks used to manage NIAAA's portfolio and parallels closely the objectives identified in NIAAA's Strategic Plan. Intramural Research and Research Management and Support receive modest increases to help offset the cost of pay and other increases. NIAAA will continue to support new investigators and to maintain an adequate number of competing RPGs.

The following narrative includes representative NIAAA activities that highlight program plans and expected accomplishments.

Embryo and Fetus

The developing embryo and fetus is very vulnerable to the adverse effects of alcohol. 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, exploring nutritional and pharmacological agents that could lessen alcohol's adverse effects on the developing embryo/fetus; and research on how alcohol disrupts normal embryonic and fetal development.

In February 2007, NIAAA convened a panel of distinguished experts to review research progress on Fetal Alcohol Spectrum Disorders (FASD) and to identify key areas for future research.

Budget Policy: The FY 2009 budget estimate for the Embryo and Fetus Program is \$23.3 million, a decrease of \$.043 million (unchanged in percentage) from the FY 2008 estimate. The Program plans for 2009, along with expected accomplishments are as follows. NIAAA will continue to support research to prevent and intervene with FASD, including the investigation of nutritional supplements to ameliorate the effects of alcohol exposure in utero. To better understand how alcohol exerts its deleterious effects on the developing embryo, NIAAA will be funding a new initiative (\$1.5 million in FY 2009) focused on the disruption of early embryonic gene expression by alcohol in animal models, to be funded from turnover of non-competing RPG awards. Research studies under this program will provide important insights into which cells within the developing embryo and fetus are most vulnerable to alcohol and at what stages of development.

Portrait of a Program: Effects of Alcohol on Early Embryonic Genes

Funding levels:

FY 2008 Level:	\$2.8 million
FY 2009 Level:	<u>\$4.3 million</u>
Change	\$1.5 million

In the developing embryo timing is everything. Development unfolds as a precise sequence of events with early gene expression and cell signaling laying the foundation for later events throughout the organism. For example, a fully functional brain requires that positional cues within the very early stage embryo define regions that have the potential to produce specific cell types. Along with additional molecular signals these cues establish the proper patterning of cells that will eventually become neurons. Integration of information within the embryo that governs its development is achieved by the selective activation and inactivation of a variety of molecules in specific cells at specific times during development. A vast array of signaling molecules moves among cells at any given time. For communication to occur correctly, cells sending signals must be precisely timed with target cells which are only able to receive and respond to specific signaling molecules within a certain window of time. The target cells respond by setting into place a cascade of developmental events of their own influencing neighboring cell development and formation of cell networks as well as their own specification. Therefore later developmental events are dependent on the fidelity of those that precede them. In fact, disruption of very early embryonic events may result in the failure of a specific organ or tissue to develop properly if at all leading to physical abnormalities and functional deficits. Alcohol is known to interfere with a number of molecules involved in signaling and cell type specification during embryogenesis including Pax 6, Otx 6, Sox 3, and NCAM. Disruption of early embryonic gene expression in animal models by doses of alcohol equivalent to binge or heavy drinking produces developmental deficits that resemble those in individuals with Fetal Alcohol Syndrome (FAS). NIAAA will expand studies on the effects of alcohol on early embryonic genes to better understand which cells within the embryo and fetus are most vulnerable to alcohol and at what stages of development.

Youth/Adolescence (Ages 0-17)

Adolescence is the time of life in 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 ramp up dramatically. Adolescence is also a period of dramatic biological, social and environmental changes. NIAAA's research portfolio targeting this period of life focuses on 1) the effects of alcohol use on the developing body and brain, and 2) the interplay of development, genes and environment on adolescent alcohol use.

In 2007, NIAAA initiated several pilot projects that will set the stage for a larger scale initiative assessing the short- and long-term effects of alcohol exposure on the developing adolescent brain. In addition, NIAAA convened two expert panels to clarify issues relevant to adolescent screening (June 2007) and diagnosis (April 2006) including: the need for developmentally appropriate screening and diagnostic questions for a wide range of ages and levels of comprehension; consideration of the pharmacological effects of alcohol on adolescents compared with adults; and recognition that adolescents drink more opportunistically (less frequently, but higher volume per occasion) than adults. These meetings mark the beginning of NIAAA's effort to promote alcohol screening among young people as standard practice in multiple settings including routine primary and mental healthcare.

Budget Policy: The FY 2009 budget estimate for the Youth/Adolescence detail is \$59.1 million, a decrease of \$0.1 million (unchanged in percentage) from the FY 2008 estimate. The Program plans for FY 2009, along with expected accomplishments are as follows. In response to recent findings showing the high prevalence of binge drinking among adolescents and the high prevalence of alcohol dependence in young adults, NIAAA is working to ensure that pediatricians, primary care physicians and other health care professionals have and use optimal tools to detect early and hazardous alcohol use by children and adolescents. NIAAA is developing guidance for the field and is committing \$2.0 million dollars in funds made available from turnover of non-competing RPG awards for research to support studies on alcohol screening and diagnosis in children, adolescents and young adults.

Young Adult (Ages 18-29)

For young adults, whose drinking behavior and extent of associated problems vary widely, NIAAA's focus on risk assessment, prevention, and reduction has the potential to significantly reduce adverse alcohol-related outcomes. Given the pervasiveness of high-risk drinking and the high prevalence of alcohol dependence occurring 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.

Recognizing that the primary care and mental health care systems provide an existing structure through which effective treatment could be made available to large numbers of patients with alcohol dependence, NIAAA has widely promoted and disseminated its recently updated *Clinicians Guide: Helping Patients Who Drink Too Much* and the related online training, to encourage physicians to make alcohol screening part of routine primary and mental healthcare, the first step to providing care. For young adults who drink heavily but do not see a primary care physician, NIAAA continues to explore other venues to provide intervention such as trauma centers, emergency departments, and college health centers. In 2007, NIAAA funded 12 pilot studies to better understand the mechanisms by which individuals change their drinking behavior.

Budget Policy: The FY 2009 budget estimate for the Young Adult detail is \$146.7 million, a decrease of \$0.3 million (unchanged in percentage) from the FY 2008 estimate. The Program plans for FY 2009, along with expected accomplishments are as follows. In FY2008 NIAAA will continue its efforts to encourage primary care and mental health providers to implement screening and brief intervention as part of routine healthcare. In addition, given the considerable variation within the alcohol dependent population, NIAAA has committed \$2.0 million in FY 2009 of funds made available from turnover of non-competing RPG awards for research on the development and progression of the various subtypes of alcohol dependence. A better understanding of the causes underlying each of the subtypes of alcohol dependence will facilitate the design of more specific and effective prevention and intervention practices for the range of individuals who may develop the disorder.

Portrait of a Program: Screening and Brief Intervention

Funding levels:

FY 2008 Level:	\$6.2 million
FY 2009 Level:	<u>\$8.2 million</u>
Change	\$2.0 million

In 2006, more than 18 million Americans 12 years and older met the criteria for alcohol abuse or dependence. Many others do not meet these criteria, yet their drinking behavior puts them at significant risk for alcohol-related problems, including dependence. Despite the high burden of illness associated with alcohol abuse and dependence, relatively few physicians routinely ask patients about their drinking; and the majority of individuals who are alcohol dependent do not access treatment. NIAAA's goal is to make screening and diagnosis of alcohol problems a standard component of primary healthcare, thereby reducing risks for alcohol-related problems and providing treatment to a large number of patients who would not otherwise receive it.

To facilitate the dialog about alcohol and health between patients and primary care or mental health physicians, NIAAA updated its publication *Helping Patients Who Drink Too Much: A Clinician's Guide* in 2007. The guide provides tools for rapid screening, assessment and management of at-risk drinking and alcohol use disorders, including information on pharmacotherapy and how to provide brief behavioral support to such patients. NIAAA has disseminated and promoted the guide widely through professional organizations. In 2008, NIAAA will launch an online, interactive program based on the Clinician's Guide featuring four video scenarios that demonstrate screening, assessment, and management of at-risk and dependent patients in different states of readiness to change. As an added incentive, NIAAA is working to provide continuing education credits for physicians and nurses who participate in this online training. In

January 2008, two new Current Procedural Terminology (CPT) Codes were established by the American Medical Association that allow primary care physicians to report services they provide to screen patients for alcohol problems and to provide an office based behavioral intervention for high risk drinking. This is important because it endorses the value of screening, diagnosis and intervention in primary care settings. The establishment of these codes is based on the strong body of evidence accrued from studies over the past twenty years on the reliability and validity of structured screening instruments, as well as from clinical trials of brief alcohol interventions in primary care settings that have been supported in large part by NIAAA. In addition, NIAAA supported research is evaluating the effectiveness of screening and brief intervention (SBI) in other settings such as emergency departments, trauma centers, college health centers and community venues, as well as among other populations including children and adolescents. By bringing assessment of alcohol use and risk for dependence into mainstream healthcare we will not only underscore the significant health implications of harmful patterns of alcohol use but may also help to destigmatize alcohol use disorders thereby encouraging those who need professional help with alcohol problems to access it.

Midlife/Senior Adult

Research has demonstrated that there is no typical alcoholic; the variation among individuals who meet criteria for alcohol dependence reflects both the subtype of dependence and individual genetic make-up. NIAAA's research focus for the midlife/senior population encompasses: 1) identification of mechanisms by which alcohol causes tissue and organ pathologies; 2) development of treatment strategies (including medications) that are tailored to specific populations; and 3) identification of a range of desirable treatment outcomes in addition to complete abstinence.

In 2007, statistical analysis of data from NIAAA's National Epidemiological Survey on Alcohol and Related Conditions (NESARC) revealed and categorized the considerable heterogeneity within the alcohol dependent population. This information will inform the design, selection of participants and target outcomes, and analysis of results of clinical trials. As part of NIAAA's efforts to uncover the mechanisms by which chronic alcohol exposure damages tissues and organs, the Institute convened a panel of experts in August 2007 to explore using immortalized cell lines from well-characterized alcohol-consuming human populations.

Budget Policy: The FY 2009 budget estimate for the Midlife/Senior Adult detail is \$133.9 million, a decrease of \$0.2 million (unchanged in percentage) from the FY 2008 estimate. The Program plans for FY 2009, along with expected accomplishments are as follows. NIAAA continues its investment in medications development, moving promising compounds through the development pipeline. Mid-life is when the physiological consequences of heavy alcohol use become manifest and the routes by which alcohol causes organ pathologies continue to be of great interest. Alcohol may cause tissue and organ injury via many mechanisms, and researchers in recent years have gained an increased understanding of several factors contributing to the development of these conditions. NIAAA is continuing to explore the effects of alcohol on mitochondria, the organelles responsible for energy production within individual cells. In addition, for FY 2009 NIAAA has committed \$2.0 million of funds made available from turnover of non-competing RPG awards for a new initiative exploring the use of.

immortalized cell lines from well-characterized alcohol-consuming human populations. These cell lines will provide insights about the interaction of alcohol within the typical relationship of genes, proteins, post-translational and metabolic events.

Portrait of a Program: NIAAA Medications Development Program

Funding levels:

FY 2008 Level: \$28.5 million

FY 2009 Level: \$30.1 million

Change \$1.6 million

Medications development continues to be a strong focus of NIAAA. Emerging data are changing the way we look at alcohol dependence, thereby guiding us to be more strategic about the medications we test, the way we test and design medications, and how we determine the subpopulations of patients who are most likely to benefit from them. For example, knowledge of an individual's subtype of alcohol dependence (see Director's Overview) may be used to guide treatment strategies and predict medications that may be effective in treating a specific subtype of dependence. Additionally, individual genetic makeup may be used to predict those who will respond positively to a medication. For example, sequence variations in genes linked to an increased vulnerability for alcohol dependence, e.g., *mu* opioid receptor and dopamine D4 receptor, have been associated with the efficacy of certain medications. Desired treatment outcomes, such as abstinence or a reduction in heavy drinking, are also influencing the medications that are being tested as well as how they are tested. For example, some clinical trials are measuring the efficacy of medications in not only individuals who abstain from drinking prior to entering the trial but also in those who continue to drink when they enter clinical studies. Human laboratory paradigms also are being developed to screen lead compounds to determine their efficacy and mechanism of action. These models may make it possible to detect whether or not a drug is successful at modifying a specific aspect of alcohol dependence, such as reducing the positive reinforcing effects of alcohol in heavy drinkers. The results from these studies will also be used to identify clinical indicators that predict treatment success. Finally, alcohol research continues to unravel the biological mechanisms that underlie alcohol dependence, facilitating the discovery and preclinical development of novel compounds as well as investigating the efficacy of compounds in use for other disorders. This includes agents that target drinking mediated by stress and anxiety systems. These important research findings are guiding the Institute in its efforts to expand the repertoire of medications available to patients and to develop medications targeted to the best candidates in a cost-effective and timely manner. Expanding and targeting drug treatment options will give hope to the affected 18 million Americans as well as their families, and reduce the myriad and costly medical, psychological, social, economic, and personal problems associated with alcohol use disorders.

NIAAA Intramural Research Program

The Intramural Research Program has made important inroads in neurobiology, physiology and epidemiology relevant to understanding the biological basis of alcoholism and to developing novel forms of therapy. These include: 1) understanding the link between variations in genes associated with stress and alcohol dependence, including relapse; 2) revealing a role for endocannabinoids – endogenous marijuana-like substances – in alcohol-induced fatty liver, a forerunner of more serious liver diseases, such as cirrhosis and liver cancer; and 3) conducting large scale studies that will permit a more accurate assessment of the role of chronic alcohol use with or without

comorbid diseases in affecting disability adjusted as well as quality adjusted life years (DALYs and QALYs) in the United States.

Budget Policy: The FY 2009 budget estimate for the Intramural Research Program is \$47.6 million, an increase of \$0.7 million or 1.5 percent from the FY 2008 estimate. The Program plans for FY 2009, along with expected accomplishments are as follows. NIAAA will continue support for the ten Laboratories within DICBR, as well as the Office of Laboratory Animal Science and the Office of Research and Information Technology.

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. The Institute currently oversees nearly 900 research grants and centers, as well as 22 research and support contracts. More than 550 NIAAA research projects involve human subjects, including 121 clinical trials.

Budget Policy: The 2009 budget estimate for the Research Management and Support detail is \$26.0 million, an increase of \$0.4 million or 1.5 percent from the FY 2008 estimate. The Program plans for 2008, along with expected accomplishments, are as follows. NIAAA will satisfactorily administer the review, processing, award, and scientific performance appraisal of approximately 900 research grants, 125 training awards, and 22 contracts in alcohol abuse and alcoholism program areas.

NIH Common Fund

The NIAAA participates in the support of the Interdisciplinary Research initiative funded through the NIH Common Fund.

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National Institute on Alcohol Abuse and Alcoholism

Budget Authority by Object

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	220	222	2
Full-time equivalent of overtime and holiday hour	1	1	0
Average ES salary	\$497,841	\$507,797	\$9,956
Average GM/GS grade	12.5	12.5	0.0
Average GM/GS salary	\$95,031	\$96,932	\$1,901
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$92,195	\$94,040	\$1,845
Average salary of ungraded positions	93,168	95,031	1,863
OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$15,313,000	\$16,163,000	\$850,000
11.3 Other than full-time permanent	6,802,000	7,180,000	378,000
11.5 Other personnel compensation	545,000	576,000	31,000
11.7 Military personnel	735,000	776,000	41,000
11.8 Special personnel services payments	2,536,000	2,652,000	116,000
Total, Personnel Compensation	25,931,000	27,347,000	1,416,000
12.0 Personnel benefits	5,983,000	6,314,000	331,000
12.2 Military personnel benefits	524,000	553,000	29,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	32,438,000	34,214,000	1,776,000
21.0 Travel and transportation of persons	648,000	644,000	(4,000)
22.0 Transportation of things	87,000	88,000	1,000
23.1 Rental payments to GSA	1,000	1,000	0
23.2 Rental payments to others	9,000	9,000	0
23.3 Communications, utilities and miscellaneous charges	1,013,000	1,025,000	12,000
24.0 Printing and reproduction	58,000	58,000	0
25.1 Consulting services	604,000	597,000	(7,000)
25.2 Other services	3,566,000	3,549,000	(17,000)
25.3 Purchase of goods and services from government accounts	48,443,000	48,606,000	163,000
25.4 Operation and maintenance of facilities	1,260,000	1,282,000	22,000
25.5 Research and development contracts	11,979,000	11,061,000	(918,000)
25.6 Medical care	70,000	71,000	1,000
25.7 Operation and maintenance of equipment	1,127,000	1,119,000	(8,000)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	67,049,000	66,285,000	(764,000)
26.0 Supplies and materials	3,499,000	3,556,000	57,000
31.0 Equipment	2,243,000	2,255,000	12,000
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	329,208,000	328,541,000	(667,000)
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	6,000	5,000	(1,000)
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	403,821,000	402,467,000	(1,354,000)
Total Budget Authority by Object	436,259,000	436,681,000	422,000

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Salaries and Expenses

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$15,313,000	\$16,163,000	\$850,000
Other than full-time permanent (11.3)	6,802,000	7,180,000	378,000
Other personnel compensation (11.5)	545,000	576,000	31,000
Military personnel (11.7)	735,000	776,000	41,000
Special personnel services payments (11.8)	2,536,000	2,652,000	116,000
Total Personnel Compensation (11.9)	25,931,000	27,347,000	1,416,000
Civilian personnel benefits (12.1)	5,983,000	6,314,000	331,000
Military personnel benefits (12.2)	524,000	553,000	29,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	32,438,000	34,214,000	1,776,000
Travel (21.0)	648,000	644,000	(4,000)
Transportation of things (22.0)	87,000	88,000	1,000
Rental payments to others (23.2)	9,000	9,000	0
Communications, utilities and miscellaneous charges (23.3)	1,013,000	1,025,000	12,000
Printing and reproduction (24.0)	58,000	58,000	0
Other Contractual Services:			
Advisory and assistance services (25.1)	542,000	534,000	(8,000)
Other services (25.2)	3,566,000	3,549,000	(17,000)
Purchases from government accounts (25.3)	15,910,000	15,628,000	(282,000)
Operation and maintenance of facilities (25.4)	1,260,000	1,282,000	22,000
Operation and maintenance of equipment (25.5)	1,127,000	1,119,000	(8,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	22,405,000	22,112,000	(293,000)
Supplies and materials (26.0)	3,497,000	3,554,000	57,000
Subtotal, Non-Pay Costs	27,717,000	27,490,000	(227,000)
Total, Administrative Costs	60,155,000	61,704,000	1,549,000

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2008 Enacted	2008 Amount Authorized	FY 2009 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	\$436,259,000	Indefinite	\$436,681,000
National Institute on Alcohol Abuse and Alcoholism	Section 402(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				436,259,000		436,681,000

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
2000	248,916,000 <u>2/</u>	265,497,000	265,497,000	293,935,000
Rescission				(1,566,000)
2001	308,661,000 <u>2/</u>	346,216,000	336,848,000	340,678,000
Rescission				(154,000)
2002	381,966,000	379,026,000	390,761,000	384,238,000
Rescission				(623,000)
2003	416,773,000	401,933,000	418,773,000	418,773,000
Rescission				(2,722,000)
2004	430,121,000	430,121,000	431,521,000	431,471,000
Rescission				(2,802,000)
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
2008	436,505,000	436,505,000	436,505,000	436,259,000
Rescission				(7,757,000)
2009	436,681,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

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

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	14	14	14
Office of Extramural Activities	14	14	14
Office of Science Policy and Communications	13	13	13
Office of Resource Management	24	24	25
Division of Epidemiology and Prevention Research	12	12	12
Division of Metabolism and Health Effects	9	9	9
Division of Neuroscience and Behavior	11	11	11
Division of Treatment and Recovery Research	10	10	10
Division of Intramural Clinical and Biological Research	113	113	114
Total	220	220	222
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
2005	12.1		
2006	12.1		
2007	12.5		
2008	12.5		
2009	12.5		

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

Detail of Positions

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	3	3	3
Total, ES Salary	\$488,079	\$497,841	\$507,797
GM/GS-15	19	19	19
GM/GS-14	36	36	36
GM/GS-13	43	43	45
GS-12	24	24	24
GS-11	11	11	11
GS-10	2	2	2
GS-9	9	9	9
GS-8	4	4	4
GS-7	4	4	4
GS-6	0	0	0
GS-5	1	1	1
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	153	153	155
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	4	4	4
Senior Grade	3	3	3
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	7	7	7
Ungraded	70	70	70
Total permanent positions	166	166	168
Total positions, end of year	233	233	235
Total full-time equivalent (FTE) employment, end of year	220	220	222
Average ES salary	\$488,079	\$497,841	\$507,797
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	93,168	95,031	96,932

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.

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

New Positions Requested

	FY 2009		
	Grade	Number	Annual Salary
Health Scientist Administrator (HSA)	GS-13	1	\$80,000
Investigator (Tenure Track)	GS-13	1	\$80,000
Total Requested		2	