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DEPARTMENT OF HEALTH AND HUMAN SERVICES

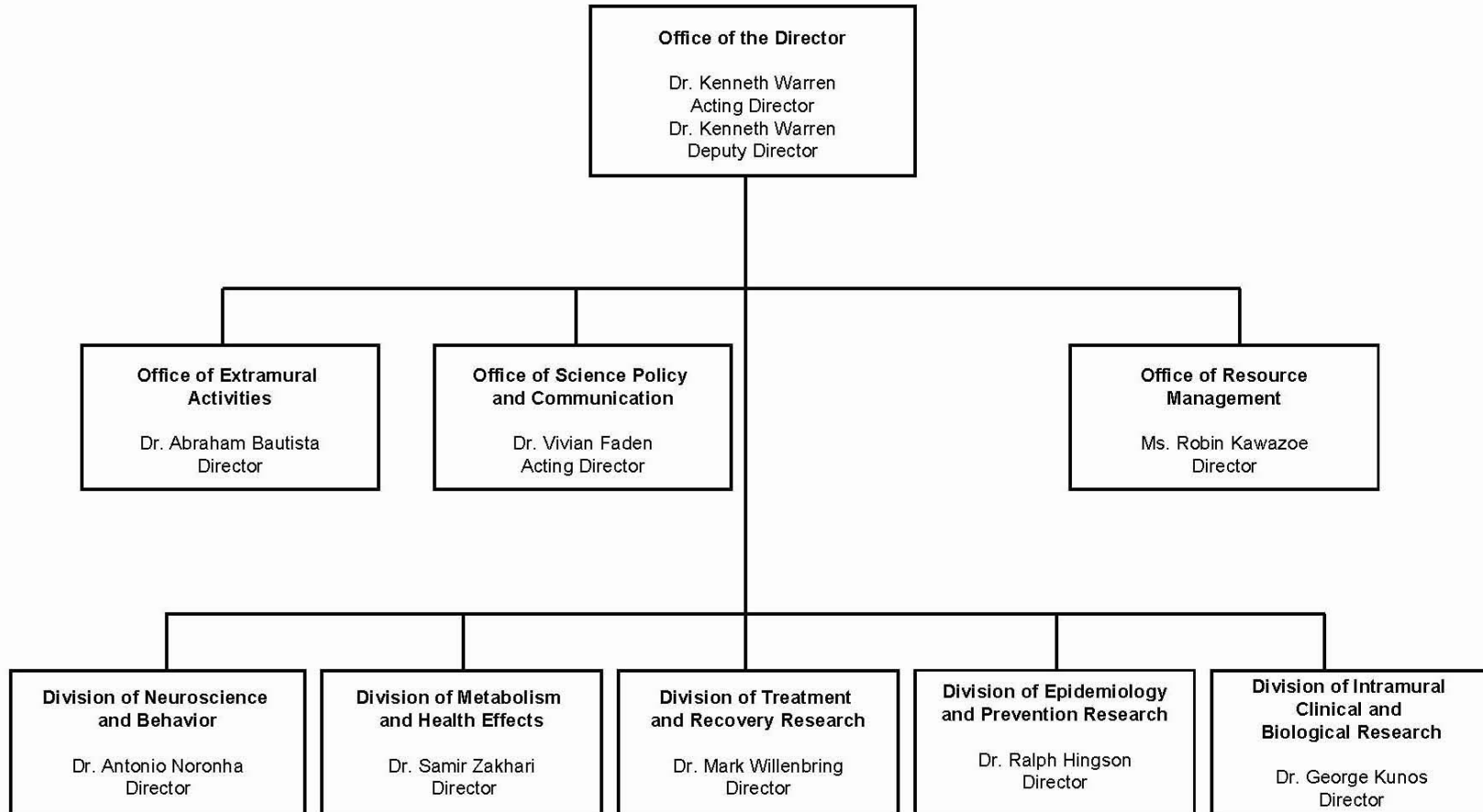
NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism



NIAAA-2

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, [\$450,230,000], **\$455,149,000** (Department of Health and Human Services Appropriation Act, 2009)

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

Amounts Available for Obligation 1/

Source of Funding	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Appropriation	\$444,016,000	\$450,230,000	\$455,149,000
Type 1 Diabetes	0	0	0
Rescission	-7,757,000	0	0
Supplemental	2,320,000	0	0
Subtotal, adjusted appropriation	438,579,000	450,230,000	455,149,000
Real transfer under Director's one-percent transfer authority (GEI)	-704,000	0	0
Comparative transfer under Director's one-percent transfer authority (GEI)	704,000	0	0
Subtotal, adjusted budget authority	438,579,000	450,230,000	455,149,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	438,579,000	450,230,000	455,149,000
Unobligated balance lapsing	-36,000	0	0
Total obligations	438,543,000	450,230,000	455,149,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2008 - \$3,173,000 FY 2009 - \$3,250,000 FY 2010 - \$3,292,000
Excludes \$6,217 in FY 2009 and \$7,303 in FY 2010 for royalties.

NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2008 Actual		FY 2009 Estimate		FY 2010 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
Research Projects:								
Noncompeting	542	\$192,681	530	\$192,433	537	\$198,606	7	\$6,173
Administrative supplements	(37)	2,539	(37)	2,608	(37)	1,468	(0)	(1,140)
Competing:								
Renewal	34	15,452	37	17,147	35	16,416	(2)	-731
New	160	45,755	172	50,773	161	48,608	(11)	-2,165
Supplements	0	0	0	0	0	0	0	0
Subtotal, competing	194	61,207	209	67,920	196	65,024	(13)	(2,896)
Subtotal, RPGs	736	256,427	739	262,961	733	265,098	(6)	2,137
SBIR/STTR	25	8,933	25	8,967	25	9,068	0	101
Subtotal, RPGs	761	265,360	764	271,928	758	274,166	(6)	2,238
Research Centers:								
Specialized/comprehensive	19	27,084	19	27,815	19	28,232	0	417
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	139	0	139	0	139	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	19	27,223	19	27,954	19	28,371	0	417
Other Research:								
Research careers	95	13,767	96	14,139	98	14,351	2	212
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	2	8,993	2	9,236	2	9,375	0	139
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	25	5,668	25	5,821	25	5,908	0	87
Subtotal, Other Research	122	28,428	123	29,196	125	29,634	2	438
Total Research Grants	902	321,011	906	329,078	902	332,171	(4)	3,093
Research Training:								
Individual awards	91	3,239	91	3,262	92	3,294	1	32
Institutional awards	209	8,396	209	8,464	209	8,549	0	85
Total, Training	300	11,635	300	11,726	301	11,843	1	117
Research & development contracts (SBIR/STTR)	30 (6)	32,336 (1,203)	30 (6)	34,136 (1,203)	30 (6)	34,648 (1,203)	0 (0)	512 (0)
Intramural research								
Research management and support	111	47,440	110	48,531	112	49,259	2	728
Research management and support	103	26,157	102	26,759	104	27,228	2	469
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIAAA	214	438,579	212	450,230	216	455,149	4	4,919

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)

9-VVAA-6

	FY 2006 Actual		FY 2007 Actual		FY 2008 Actual		FY 2008 Comparable		FY 2009 Estimate		FY 2010 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research														
<u>Detail:</u>														
Embryo and Fetus		\$20,732		\$23,412		27,089		27,143		27,884		28,161		277
Youth/Adolescence		55,213		59,300		65,869		65,997		67,798		68,471		673
Young Adult		153,688		147,152		142,875		143,153		147,058		148,518		1,460
Mid-Life/Senior Adult		136,062		134,361		128,439		128,689		132,200		133,512		1,312
Subtotal, Extramural		365,695		364,225		364,272		364,982		374,940		378,662		3,722
Intramural research	117	45,574	113	46,019	111	47,440	111	47,440	110	48,531	112	49,259	2	728
Res. management & support	108	24,361	107	25,341	103	26,157	103	26,157	102	26,759	104	27,228	2	469
TOTAL	225	435,630	220	435,585	214	437,869	214	438,579	212	450,230	216	455,149	4	4,919

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

Major Changes in the Fiscal Year 2010 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 2010 budget request for NIAAA, which is \$4.919 million more than the FY 2009 Estimate, for a total of \$455.149 million.

Research Project Grants (+\$2.238 million, total \$274.166 million). The NIH budget policy for RPGs in FY 2010 is to provide for two percent inflationary increases in noncompeting awards and a two percent increase in average cost for competing RPGs. NIAAA will support a total of 758 Research Project Grant (RPG) awards in FY 2010. Noncompeting RPGs will increase by 7 awards and \$6.173 million. Competing RPGs will decrease by 13 awards and \$2.896 million.

Screening and Intervention Across the Lifespan (+\$2.000 million; total \$10.200 million): This initiative will support, through Competing RPG awards, the development of a practitioner's guide to provide guidance that is acceptable to practitioners on how to screen for risk for alcohol use.

Medications Development (+\$2.500 million; total \$4.700 million): NIAAA will support, under contract, a Phase 2 clinical trial network to develop and test the effectiveness of potential medications in treatment of alcohol dependence and alcohol-induced tissue damage.

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

FY 2009 estimate		\$450,230,000	
FY 2010 estimated budget authority		455,149,000	
Net change		4,919,000	
CHANGES	2009 Current Estimate Base		Change from Base
	FTEs	Budget Authority	FTEs Budget Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January 2009 pay increase			
		\$18,647,000	\$223,000
b. January FY 2010 pay increase			
		18,647,000	280,000
c. Payment for centrally furnished services			
		7,346,000	147,000
d. Increased cost of laboratory supplies, materials, and other expenses			
		22,538,000	383,000
Subtotal		1,033,000	
2. Research management and support:			
a. Annualization of January 2009 pay increase			
		\$15,172,000	\$181,000
b. January FY 2010 pay increase			
		15,172,000	228,000
c. Payment for centrally furnished services			
		1,354,000	27,000
d. Increased cost of laboratory supplies, materials, and other expenses			
		10,233,000	179,000
Subtotal		615,000	
Subtotal, Built-in		1,648,000	

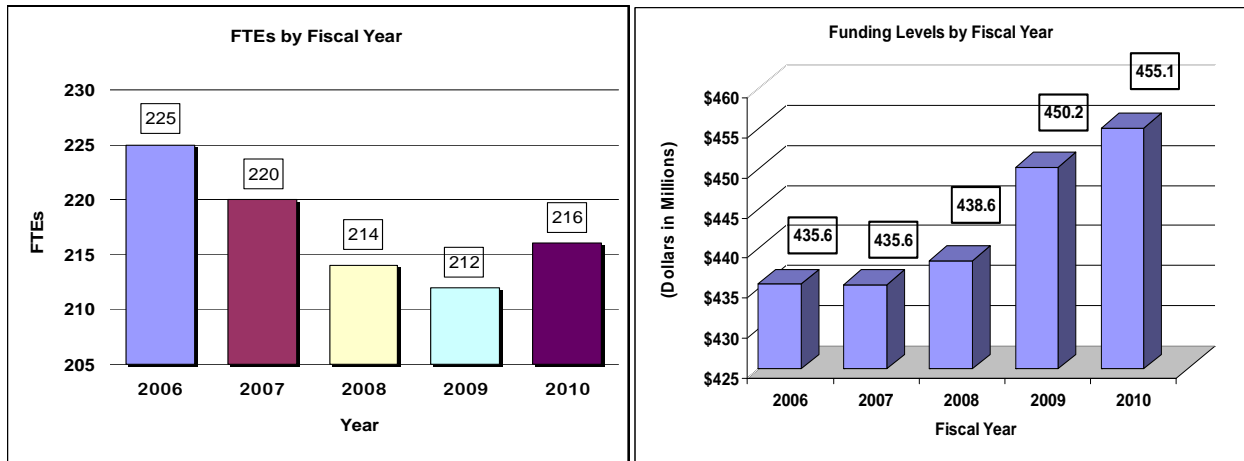
NATIONAL INSTITUTES OF HEALTH
National Institute on Alcohol Abuse and Alcoholism

Summary of Changes--continued

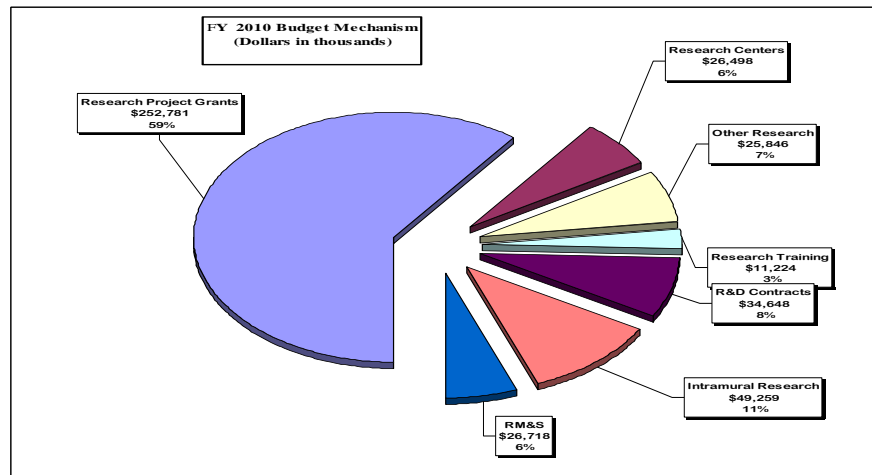
CHANGES	2009 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	530	\$195,041,000	7	\$5,033,000
b. Competing	209	67,920,000	(13)	(2,896,000)
c. SBIR/STTR	25	8,967,000	0	101,000
Total	764	271,928,000	(6)	2,238,000
2. Research centers	19	27,954,000	0	417,000
3. Other research	123	29,196,000	2	438,000
4. Research training	300	11,726,000	1	117,000
5. Research and development contracts	30	34,136,000	0	512,000
Subtotal, extramural				3,722,000
6. Intramural research	<u>FTEs</u> 110	48,531,000	<u>FTEs</u> 2	(305,000)
7. Research management and support	102	26,759,000	2	(146,000)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		450,230,000		3,271,000
Total changes	212		4	4,919,000

Fiscal Year 2010 Budget Graphs

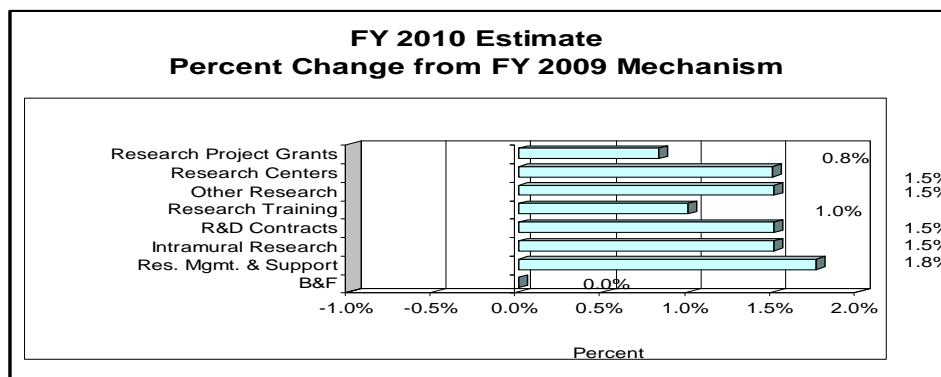
History of Budget Authorities and FTEs:



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 2008	FY 2009	FY 2009	FY 2010	FY 2010 +/-
	<u>Appropriation</u>	<u>Omnibus</u>	<u>Recovery Act</u>	<u>President's Budget</u>	<u>2009 Omnibus</u>
BA	\$438,579,000	\$450,230,000	\$113,851,000	\$455,149,000	+\$4,919,000
<u>FTE</u>	<u>214</u>	<u>212</u>		<u>216</u>	<u>4</u>

This document provides justification for the Fiscal Year 2010 activities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), including HIV/AIDS activities. Details of the FY 2010 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.

In FY 2009, a total of \$113,851,000 American Recovery and Reinvestment Act (ARRA) funds were transferred from the Office of the Director. These funds will be used to support scientific research opportunities that help support the goals of the ARRA. The ARRA allows NIH to execute these funds via any NIH funding mechanism. Funds are available until September 30, 2010. These funds are not included in the FY 2009 Omnibus amounts reflected in this document

Director's Overview

Alcohol use 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 outcomes extending beyond the individual, (i.e., 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 2006,

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/>

there were over 18 million people ages 12 years and older suffering from alcohol abuse or dependence with fewer than 7 percent of them 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 use. Whereas the Institute name implies a mission focused on alcohol abuse and dependence, and a considerable investment is made into understanding the etiology, progression, heterogeneity, prevention and treatment of alcohol use disorders, the Institute's mission is much broader, including research on alcohol use as it relates to health across the entire lifespan of an individual.

Alcohol is a chemically simple substance that has a broad range of effects on a variety of cells, tissues and organs. Moreover, it produces different consequences at different stages of life and in different individuals at the same life stage. Alcohol use affects and is affected by behavior. At all life stages, a complex interplay between an array of genetic and environmental factors influences alcohol-related health outcomes. For example, research has shown that the severity of birth defects resulting from exposure of the developing embryo or fetus to alcohol is determined by multiple factors, including genetic background, timing and level of alcohol exposure, and nutritional status. Likewise, the degree of tissue and organ damage seen in mid-life that results from chronic, heavy drinking varies across individuals whose drinking patterns are similar, suggesting that intrinsic and environmental factors, and not just the level, frequency, and duration of alcohol consumption, play a role in the progression of alcohol-related disease. Importantly, biological and environmental factors change over time and these factors not only affect drinking behavior and its consequences, but also can affect one's response to treatment.

While research has provided clues about the role of individual genetic and environmental factors in the onset and progression of alcohol-related health problems, from fetal alcohol syndrome to alcohol dependence, it has not explained how the intersection of these factors leads to these adverse health outcomes. Recent advances in the burgeoning field of epigenetics have provided a new lens through which to view the molecular mechanisms by which the environment influences the expression of genes and their products leading to different biological and behavioral outcomes in different individuals. Epigenetic modifications are stable changes that do not alter the DNA sequence itself but change the expression of a gene either by modifying the overarching structure of the region of the chromosome in which the gene is embedded or by interfering with the gene product. Changes to the DNA conformation that permit or prevent gene expression can occur by chemical modifications to the DNA itself or to histone proteins that bind to DNA. In addition, small non-coding RNAs regulate expression of genes that are integral to human development as well as genes that contribute to the onset and progression of disease. Alcohol can disrupt and/or co-opt normal developmental processes that are regulated epigenetically, including integral steps in the development of the embryo and fetus, and potentially those processes that

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.

bestow exquisite adaptability on the developing adolescent brain. Alcohol can also initiate processes that promote tissue damage. NIAAA's current and future investments in epigenetics will enhance the development of biomarkers that indicate an underlying physiological state to determine risk for a range of alcohol-related problems from fetal alcohol syndrome to alcohol dependence and to track disease progression, as well as to identify additional targets for medications development.

More than three decades of research has firmly established that the development of alcohol dependence is the product of the interplay of genes (accounting for slightly more than half the risk) and environmental factors (accounting for the remainder of the risk). NIAAA has made a significant investment over this period of time in identifying such genes that contribute to the development of alcohol dependence, and medications targeting molecules identified in these studies are now in preclinical and clinical testing. Moreover, pharmacogenetic studies have demonstrated that the effectiveness of medications varies among individuals, depending in part upon which variants of specific genes they carry. Information from these studies will enable health care providers to personalize the treatment they offer their patients. NIAAA is also capitalizing on the NIH's substantial investment in groundbreaking genetic approaches, including haplotype mapping and genome-wide association studies, to uncover additional genes and specific gene variants that play a role in alcohol dependence.

The Institute is now poised to exploit the recent advances in epigenetics to further our understanding of individual susceptibility to alcohol dependence and alcohol-related tissue and organ damage. For example, studies have shown that epigenetic modifications contribute to the anxiety experienced by individuals undergoing withdrawal that often undermines their efforts to change their drinking behavior. Other studies have shown that alcohol is a causative agent for a number of different cancers, including liver, esophageal, colon, and breast cancer. Consistent with the NIH policy to double NIH-wide cancer research spending, NIAAA will expand its support of the epigenetics of alcohol-induced cancer through investigator-initiated research projects throughout the Nation and through the work of basic and clinical scientists in the Institute's Intramural Research Program. In the area of autism research, NIAAA will continue collaborations with NINDS on the underlying cellular and molecular neurobiological causes of autism.

FY 2010 Justification by Activity Detail:

Overall Budget Policy: Investigator-initiated research projects and new investigator research and career development are the Institute's highest priorities. Intramural Research and Research Management and Support will receive increases to help cover 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. Ongoing interactions between NIAAA and France's Institut National de la Santé et de la Recherche Médicale (INSERM) in 2008 have resulted in collaborations between U.S. and French investigators on fetal alcohol syndrome. Research has shown that the severity of alcohol-related effects on the developing fetus is affected by the timing and level of maternal alcohol consumption, maternal nutritional status and maternal hormones. One of the key challenges facing clinicians is the ability to recognize women who are drinking in pregnancy and the infant who has been exposed to significant prenatal alcohol during pregnancy. Recently there have been advances in methodologies for the measurement of non-oxidative metabolites of alcohol. Unlike the alcohol molecule itself these metabolites persist in various tissues such as blood, urine and hair for multiple days to weeks following alcohol exposure providing new opportunities for monitoring alcohol exposure.

Budget Policy: The FY 2010 budget estimate for the Embryo and Fetus Program is \$28.161 million, an increase of \$288 thousand or 1.0% over the FY 2009 estimate. The Program plans for 2010, along with expected accomplishments are as follows. In FY2010, NIAAA is committing \$1.000 million of funds made available from turnover of non-competing RPG awards for a new initiative to further study the development of methodologies for the detection of prenatal alcohol exposure. In FY2010, NIAAA will also solicit and support studies on the effects of paternal alcohol use on long-term health and behavioral outcomes of offspring.

Youth/Adolescence (Ages 0-17)

Adolescence is the time of life during which drinking, binge drinking (drinking five or more drinks on one occasion) and heavy drinking (binge drinking five or more times in the past 30 days) all 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. Given that alcohol use is pervasive among adolescents and the association between early initiation and future alcohol problems, NIAAA is developing guidelines for screening children and adolescents. In 2008 and 2009 NIAAA convened an expert panel to develop these guidelines with considerations of the need: for developmentally appropriate screening for a wide range of ages and levels of comprehension; to identify risk for alcohol use especially for younger children; and to identify appropriate venues for screening. NIAAA is also supporting studies to integrate intervention for underage alcohol use into primary health care.

Research has shown that during adolescence, the brain undergoes significant growth and remodeling. This finding, coupled with the results of multiple studies showing a strong association between early initiation of alcohol use and future alcohol dependence, raises concerns about alcohol's effects on the developing adolescent brain. Specifically, the issues are whether persistent changes in neural and behavioral function result from adolescent alcohol use, and whether processes that confer adaptability of the adolescent brain to its environment also make it more vulnerable to alcohol-induced changes in structure and/or function, especially in terms of setting it up for future dependence. Complementing NIAAA's ongoing pilot studies with humans to determine if alcohol can disrupt, co-opt and/or alter normal developmental processes in the brain, NIAAA is also developing an initiative for FY2010 to study alcohol-induced changes in the brain in animal models. Together these human and animal studies will set the stage for a larger scale initiative supporting longitudinal human studies to differentiate between direct effects of alcohol and common underlying mechanisms in alcohol dependence, as well as to more fully assess other short- and long-term effects of alcohol exposure on the developing adolescent brain.

Budget Policy: The FY 2010 budget estimate for the Youth/Adolescence detail is \$68.471 million, an increase of \$673 thousand or 1.0% over the FY 2009 estimate. In FY2010, NIAAA is committing \$2.500 million dollars in funds made available from turnover of non-competing RPG awards for development of the screening guide for use with children and adolescents to assess risk for alcohol use, alcohol consumption and binge drinking, and alcohol use disorders, and to solicit and support studies that will evaluate the use and effectiveness of the guide in a variety of settings. NIAAA is also committing \$4.000 million in FY 2010 for an initiative to study alcohol-induced changes in the brain in animal models.

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. To promote screening and intervention in primary care and mental health settings, NIAAA has produced online training for physicians and nurses that includes videos demonstrating how to effectively use *The Clinician's Guide: Helping Patients Who Drink Too Much*.

Budget Policy: The FY 2010 budget estimate for the Young Adult detail is \$148.518 million, an increase of \$1.460 million or 1.0% over the FY 2009 estimate. The Program plans for FY 2010, along with expected accomplishments are as follows. Young adulthood is the heaviest drinking period of the lifespan. While the majority of individuals reduce their drinking significantly by the time they enter their thirties, a

significant number continue to drink heavily compromising their future health and well-being. Understanding the factors that underlie this difference in drinking trajectories will inform prevention and treatment, particularly for those people who are less likely to change their behavior in the absence of intervention. In FY2010, NIAAA is committing \$2.000 million in funds made available from turnover of non-competing RPG awards for development of a new initiative to investigate the biological and environmental factors that influence these disparate drinking pathways in young adulthood.

Portrait of a Program: Screening and Intervention Across The Lifespan

Funding levels:

FY 2009 Level: \$8.200 million
FY 2010 Level: \$10.200 million
Change \$2.000 million

Although approximately 18 million Americans 12 years and older meet the criteria for alcohol abuse or dependence, the vast majority do not fit the description of the stereotypic dysfunctional alcoholic. In fact, the chronic, relapsing subtype of alcohol dependence occurs in a relatively small percentage of people with an alcohol use disorder. Perhaps even more surprising is that, by far, the age group with the highest percentage of alcohol dependence in the population is 18 to 24 year olds. Collectively, this knowledge is transforming the way health care providers address alcohol use with their patients. NIAAA is actively engaging the medical community to increase the number of primary care and mental health clinicians who advise, counsel, and treat their patients regarding harmful patterns of alcohol use, including alcohol dependence. In partnership with the American Medical Association, NIAAA is promoting and disseminating *The Clinician's Guide: Helping Patients Who Drink Too Much* and the associated online training modules. For individuals with milder forms of dependence, who are much less likely to seek any form of alcohol treatment, the integration of alcohol screening and brief intervention into primary care is a cost-effective way to ensure that they receive appropriate care early in the course of their disease. For individuals with more severe forms of alcohol dependence, specialty care remains an important option. Until recently, the extent of alcohol problems among young people has been underestimated. Research showing that early alcohol use is associated with future dependence coupled with survey data showing that by the end of eighth grade approximately half of young people have experience with alcohol, many of them with binge drinking, underscores the need for health care providers to address alcohol issues with children and adolescents as well as adults. NIAAA recently convened a working group of experts to develop a practitioner's guide, modeled after the well-received *Clinician's Guide*, for screening children and adolescents for alcohol involvement. The goal for this document is to provide simple, easy to use guidance that is acceptable to practitioners on how to screen for risk for alcohol use, for alcohol consumption and binge drinking, and for alcohol use disorders in a developmentally diverse population.

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 2008,

NIAAA continued to move forward with medications development initiating a Phase II clinical trial, moving additional promising compounds through the drug development pipeline, and developing human laboratory paradigms to screen lead compounds and test specific treatment outcomes. In order to better understand how alcohol causes cell and tissue damage, NIAAA funded eight new studies on the effects of alcohol on mitochondria, the organelles responsible for energy production within individual cells.

Budget Policy: The FY 2010 budget estimate for the Midlife/Senior Adult detail is \$133.512 million, an increase of \$1.312 million or 1.0% over the FY 2009 estimate. The Program plans for FY 2010, along with expected accomplishments are as follows. In FY2010, NIAAA is committing \$2.000 million of funds made available from turnover of non-competing RPG awards to support studies that expand our understanding of the interactions between the gut, liver and brain that influence alcohol consumption. An additional \$2.000 million will be used to support a new initiative to expand our understanding of the mechanisms by which interactions between the gut, brain and liver contribute to alcohol-related tissue damage. In FY2010 NIAAA is also committing \$2.000 million of funds made available from turnover of non-competing RPG awards to expand medications development, an activity central to NIAAA's mission. Currently there are 21 compounds in pre-clinical or clinical trials with NIAAA support. As additional targets are identified for potential medications both for alcohol dependence and to prevent or reduce alcohol-related tissue damage, and as promising compounds move through the testing process, NIAAA anticipates that the cost of medications development will increase.

Portrait of a Program: NIAAA Medications Development Program

Funding levels:

FY 2009 Level: \$2.200 million
FY 2010 Level: \$4.700 million
Change \$2.500 million

Pharmacotherapy holds much promise for treating alcohol dependence and alcohol-related disorders, and for offering more treatment options to a wider spectrum of alcohol dependent individuals. NIAAA is building on its investment in pharmacotherapy research and becoming more strategic in: 1) designing and selecting medications that merit drug development; 2) advancing lead compounds through the drug development process; 3) identifying/defining the characteristics of, and most appropriate outcomes for, patients who are most likely to benefit; and 4) disseminating guidance for medication use to primary care providers. NIAAA continues to support basic research on the fundamental mechanisms underlying alcohol dependence, facilitating the discovery and development of compounds that target these mechanisms. For example, research has shown that stress mechanisms in the brain are a major contributor to relapse to heavy drinking. The results of recent early clinical studies have demonstrated that compounds which target these mechanisms successfully reduce craving and concomitant relapse in humans. Research on mechanisms of alcohol-related tissue damage also remains a priority. New studies in animal models have shown that compounds which inhibit cannabinoid receptors provide protection from fatty liver, the forerunner of alcohol-induced liver damage. In general, as compounds move through the medications development process they may encounter "bottlenecks" which slow their

development. Recently, NIAAA established the infrastructure to more rapidly advance lead compounds to Phase 2 clinical trials and, in FY 2008, launched such a trial of quetiapine (which targets dopamine and serotonin receptors) to test its effect on heavy drinking. NIAAA's goal in demonstrating the preliminary effectiveness of a compound is that the pharmaceutical industry will then take the lead in the more extensive clinical trials required to develop it as an alcohol medication. Expanding desired treatment outcomes beyond abstinence to include reductions in heavy drinking is also impacting the development and testing of medications. For example, studies have shown the drug topiramate (which targets glutamate and GABA neurotransmitter systems) both reduces heavy drinking and promotes abstinence. Importantly, it also reduces both the physical consequences (e.g., abnormal liver function) and psychosocial consequences (e.g., compulsions about using alcohol) of alcohol dependence. As more medications become available, it will be increasingly important to compare treatment options and characterize the patients for whom specific therapies are most effective. For example, COMBINE was the first study of this kind to compare the effectiveness of medications, behavioral therapy and various combinations of them in treating alcohol dependence and, has become the paradigm for future studies. Finally, NIAAA continues to provide guidance to primary health care providers on the range of treatment options available and the appropriate use of medications through the *Clinician's Guide* and its companion online training. Getting the most effective medications to the right patients and providing health care practitioners guidance on their use will ensure that more alcohol dependent individuals receive the treatment they need.

NIAAA Intramural Research Program

The Intramural Research Program has made significant advances in the areas of neuroscience, genetics, epidemiology and physiology. A major focus of NIAAA in general, and of the Intramural Program specifically, has been to identify genes that underlie alcohol dependence and influence treatment. Recently, a number of studies have demonstrated a link between alcohol preference, dependence, and/or relapse with specific molecules and circuits in the brain that modulate stress. Studies are also uncovering how variations in genes affect treatment efficacy. The Intramural Research Program also focuses on understanding and preventing alcohol-related liver disease. Studies have revealed that endocannabinoids – endogenous marijuana-like substances – are necessary in a specific type of liver cell for the development of alcohol-induced fatty liver, a forerunner of more serious liver diseases, such as cirrhosis and liver cancer. Other studies have demonstrated that dietary supplements can prevent the development of alcohol-induced fatty liver and mitochondrial dysfunction in animal models. In addition, the Intramural Program continues to conduct large scale studies that provide information on the extent of dependence and co-occurring mental disorders in the U.S. population.

Budget Policy: The FY 2010 budget estimate for the Intramural Research Program is \$49.259 million, an increase of \$728 thousand or 1.5% over the FY 2009 estimate. The Program plans for FY 2010, along with expected accomplishments are as follows. NIAAA will continue support for the ten Laboratories within its Division of Intramural Clinical and Biological Research, as well as the intramural 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 2010 budget estimate for the Research Management and Support detail is \$27.228 million, an increase of \$469 thousand or 1.8% over the FY 2009 estimate. NIAAA will administer the review, processing, award, and scientific performance appraisal of approximately 900 research grants, 125 training awards, and 30 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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Budget Authority by Object

	FY 2009 Estimate	FY 2010 Estimate	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	212	216	4	1.9
Full-time equivalent of overtime and holiday hours	1	1	0	0.0
Average ES salary	\$166,910	\$168,579	\$1,669	1.0
Average GM/GS grade	12.7	12.7	0.0	0.0
Average GM/GS salary	\$98,093	\$99,074	\$981	1.0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$124,800	\$126,048	\$1,248	1.0
Average salary of ungraded positions	95,320	96,273	953	1.0
OBJECT CLASSES	FY 2009 Estimate	FY 2010 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	\$15,132,000	\$15,828,000	\$696,000	4.6
11.3 Other than full-time permanent	7,257,000	7,587,000	330,000	4.5
11.5 Other personnel compensation	677,000	708,000	31,000	4.6
11.7 Military personnel	506,000	529,000	23,000	4.5
11.8 Special personnel services payments	3,397,000	3,551,000	154,000	4.5
Total, Personnel Compensation	26,969,000	28,203,000	1,234,000	4.6
12.0 Personnel benefits	6,456,000	6,752,000	296,000	4.6
12.2 Military personnel benefits	394,000	412,000	18,000	4.6
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	33,819,000	35,367,000	1,548,000	4.6
21.0 Travel and transportation of persons	819,000	790,000	(29,000)	-3.5
22.0 Transportation of things	132,000	127,000	(5,000)	-3.8
23.1 Rental payments to GSA	15,000	15,000	0	0.0
23.2 Rental payments to others	0	0	0	0.0
23.3 Communications, utilities and miscellaneous charges	739,000	719,000	(20,000)	-2.7
24.0 Printing and reproduction	97,000	92,000	(5,000)	-5.2
25.1 Consulting services	442,000	426,000	(16,000)	-3.6
25.2 Other services	5,590,000	5,396,000	(194,000)	-3.5
25.3 Purchase of goods and services from government accounts	44,304,000	44,502,000	198,000	0.4
25.4 Operation and maintenance of facilities	101,000	99,000	(2,000)	-2.0
25.5 Research and development contracts	19,341,000	19,793,000	452,000	2.3
25.6 Medical care	46,000	45,000	(1,000)	-2.2
25.7 Operation and maintenance of equipment	385,000	374,000	(11,000)	-2.9
25.8 Subsistence and support of persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	70,209,000	70,635,000	426,000	0.6
26.0 Supplies and materials	3,274,000	3,198,000	(76,000)	-2.3
31.0 Equipment	2,697,000	2,614,000	(83,000)	-3.1
32.0 Land and structures	0	0	0	0.0
33.0 Investments and loans	0	0	0	0.0
41.0 Grants, subsidies and contributions	338,428,000	341,591,000	3,163,000	0.9
42.0 Insurance claims and indemnities	0	0	0	0.0
43.0 Interest and dividends	1,000	1,000	0	0.0
44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	416,411,000	419,782,000	3,371,000	0.8
Total Budget Authority by Object	450,230,000	455,149,000	4,919,000	1.1

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

NATIONAL INSTITUTES OF HEALTH
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Salaries and Expenses

OBJECT CLASSES	FY 2009 Estimate	FY 2010 Estimate	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$15,132,000	\$15,828,000	\$696,000
Other than full-time permanent (11.3)	7,257,000	7,587,000	330,000
Other personnel compensation (11.5)	677,000	708,000	31,000
Military personnel (11.7)	506,000	529,000	23,000
Special personnel services payments (11.8)	3,397,000	3,551,000	154,000
Total Personnel Compensation (11.9)	26,969,000	28,203,000	1,234,000
Civilian personnel benefits (12.1)	6,456,000	6,752,000	296,000
Military personnel benefits (12.2)	394,000	412,000	18,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	33,819,000	35,367,000	1,548,000
Travel (21.0)	819,000	790,000	(29,000)
Transportation of things (22.0)	132,000	127,000	(5,000)
Rental payments to others (23.2)	0	0	0
Communications, utilities and miscellaneous charges (23.3)	739,000	719,000	(20,000)
Printing and reproduction (24.0)	97,000	92,000	(5,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	442,000	426,000	(16,000)
Other services (25.2)	5,590,000	5,396,000	(194,000)
Purchases from government accounts (25.3)	29,835,000	29,978,000	143,000
Operation and maintenance of facilities (25.4)	101,000	99,000	(2,000)
Operation and maintenance of equipment (25.7)	385,000	374,000	(11,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	36,353,000	36,273,000	(80,000)
Supplies and materials (26.0)	3,270,000	3,194,000	(76,000)
Subtotal, Non-Pay Costs	41,410,000	41,195,000	(215,000)
Total, Administrative Costs	75,229,000	76,562,000	1,333,000

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National Institute on Alcohol Abuse and Alcoholism

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2009 Amount Authorized	FY 2009 Estimate	2010 Amount Authorized	FY 2010 PB
Research and Investigation	Section 301	42§241	Indefinite	\$450,230,000	Indefinite	\$455,149,000
	Section 402(a)	42§281	Indefinite		Indefinite	
National Institute on Alcohol Abuse and Alcoholism						
Total, Budget Authority				450,230,000	455,149,000	

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National Institute on Alcohol Abuse and Alcoholism

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
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
Rescission				0
2008	436,505,000	436,505,000	436,505,000	436,259,000
Rescission				(7,757,000)
Supplemental				2,320,000
2009	436,681,000	451,688,000	448,834,000	450,230,000
Rescission				0
2010	455,149,000			

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 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Office of the Director	10	10	10
Office of Extramural Activities	15	15	15
Office of Science Policy and Communications	14	14	14
Office of Resource Management	23	22	24
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 Recovery Research	9	9	9
Division of Intramural Clinical and Biological Research	111	110	112
Total	214	212	216
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		
2006	12.1		
2007	12.5		
2008	12.5		
2009	12.5		
2010	12.7		

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

Detail of Positions

GRADE	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Total, ES Positions	2	2	2
Total, ES Salary	165,257	166,910	168,579
GM/GS-15	17	17	17
GM/GS-14	35	34	36
GM/GS-13	39	38	40
GS-12	26	26	26
GS-11	12	12	12
GS-10	2	2	2
GS-9	7	7	7
GS-8	3	3	3
GS-7	1	1	1
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	143	141	145
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	3	3	3
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	77	77	77
Total permanent positions	154	154	154
Total positions, end of year	227	225	229
Total full-time equivalent (FTE) employment, end of year	214	212	216
Average ES salary	165,257	166,910	168,579
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	97,122	98,093	99,074

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

**NATIONAL INSTITUTES OF HEALTH
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New Positions Requested

	FY 2010		
	Grade	Number	Annual Salary
Health Science Administrator	GS-13	1	\$87,000
Health Science Administrator	GS-14	1	102,000
Research Fellow	GS-13	1	87,000
Investigator (Tenure Track)	GS-13	1	87,000
Total Requested		4	