

DEPARTMENT OF HEALTH AND HUMAN SERVICES

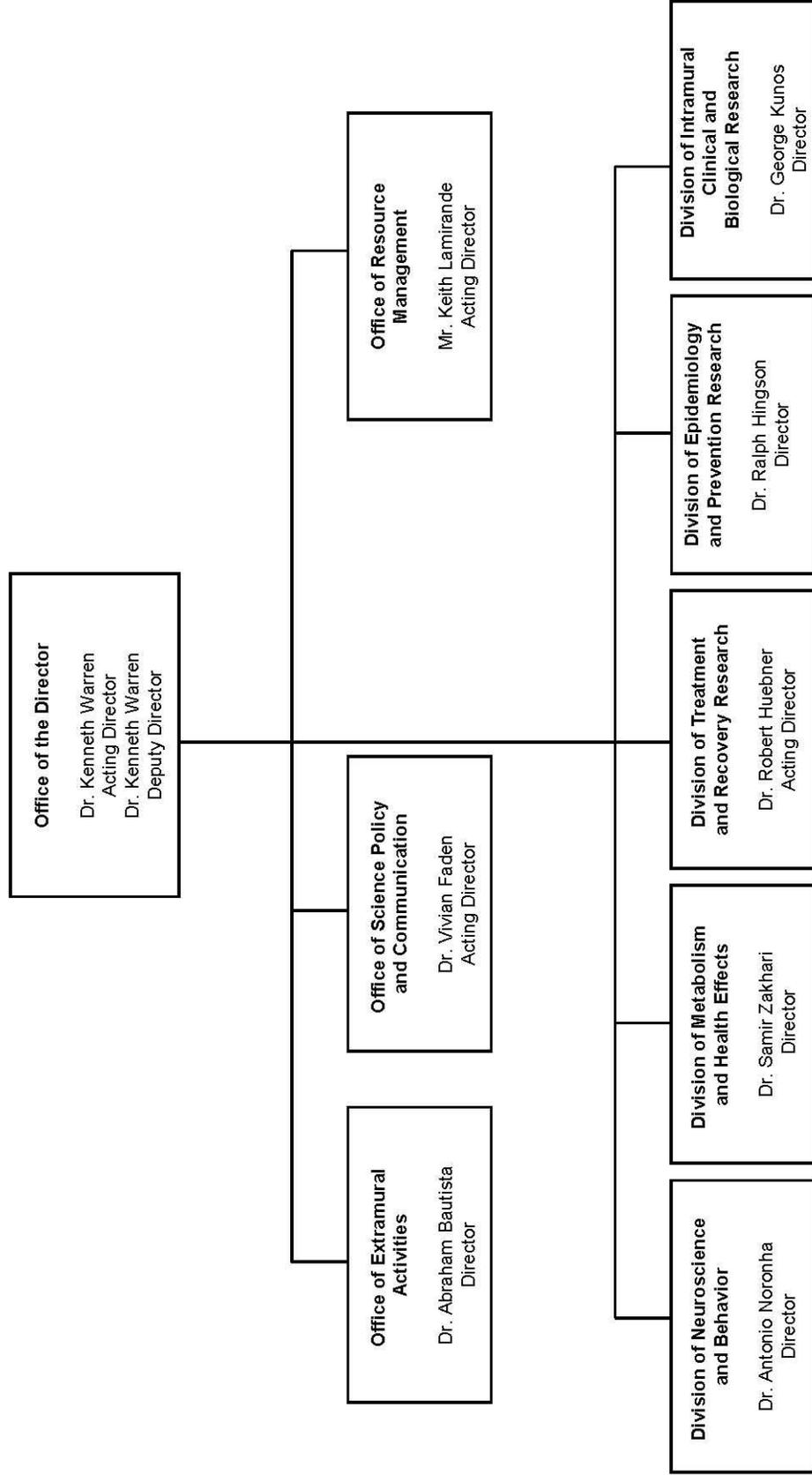
NATIONAL INSTITUTES OF HEALTH

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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# NATIONAL INSTITUTES OF HEALTH

## National Institute on Alcohol Abuse and Alcoholism



## **NATIONAL INSTITUTES OF HEALTH**

National Institute on Alcohol Abuse and Alcoholism

For carrying out section 301 and title IV of the Public Health Services Act with respect to alcohol abuse and alcoholism, [\$462,346,000], \$474,649,000 (Public Law 111-117, Consolidated Appropriations Act, 2010)

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

**Amounts Available for Obligation 1/**

Source of Funding	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Appropriation	\$450,230,000	\$462,346,000	\$474,649,000
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	450,230,000	462,346,000	474,649,000
Real transfer under Director's one-percent transfer authority (GEI)	-704,000	0	0
Comparative transfer to Public Access	-64,000	-69,000	0
Comparative transfer to National Center for Biotechnology Information	-71,000	-110,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	704,000	0	0
Subtotal, adjusted budget authority	450,095,000	462,167,000	474,649,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	450,095,000	462,167,000	474,649,000
Unobligated balance lapsing	-2,000	0	0
Total obligations	450,093,000	462,167,000	474,649,000

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

FY 2009 - \$3,830,000    FY 2010 - \$4,210,000    FY 2011 - \$4,500,000

Excludes \$9,942 in FY 2009 and \$9,865 in FY 2010 for royalties.

**NATIONAL INSTITUTES OF HEALTH**  
**National Institute on Alcoholism and Alcohol Abuse**  
(Dollars in Thousands)  
Budget Mechanism - Total

MECHANISM	FY 2009 Actual		FY 2009 Recovery Act Actual		FY 2010 Recovery Act Estimated		FY 2010 Enacted		FY 2011 PB		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:												
<u>Research Projects:</u>												
Noncompeting	530	\$192,532	\$0	\$0	\$91	\$37,220	515	\$199,024	537	\$212,865	22	\$13,841
Administrative supplements	((38))	3,038	(75)	8,003	5	948	(38)	3,038	(38)	3,114	0	76
<u>Competing:</u>												
Renewal	35	15,758	0	0	0	0	36	16,324	30	14,059	(6)	-2,265
New	156	50,600	104	44,254	0	0	157	52,110	133	44,881	(24)	-7,229
Supplements	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, competing	191	66,358	104	44,254	91	38,168	193	68,434	163	58,940	(30)	(9,494)
Subtotal, RPGs	721	261,928	104	52,257	91	38,168	708	270,496	700	274,919	(8)	4,423
SBIR/STTR	28	9,654	2	469	0	0	28	9,180	28	9,100	0	-80
Subtotal, RPGs	749	271,582	106	52,726	91	38,168	736	279,676	728	284,019	(8)	4,343
<u>Research Centers:</u>												
Specialized/comprehensive	20	27,942	12	6,632	11	6,120	20	28,371	20	29,222	0	851
Clinical research	0	0	0	0	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0	0	0	0	0
Comparative medicine	0	0	0	0	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, Centers	20	27,942	12	6,632	11	6,120	20	28,371	20	29,222	0	851
<u>Other Research:</u>												
Research careers	97	14,763	0	0	0	0	98	14,984	98	15,340	0	356
Cancer education	0	0	0	0	0	0	0	0	0	0	0	0
Cooperative clinical research	2	9,075	0	0	0	0	2	9,211	2	9,395	0	184
Biomedical research support	0	0	0	0	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0	0	0	0	0
Other	25	5,716	1	913	0	0	25	5,802	25	5,920	0	118
Subtotal, Other Research	124	29,554	1	1,228	0	0	125	29,997	125	30,655	0	658
<b>Total Research Grants</b>	<b>893</b>	<b>329,078</b>	<b>119</b>	<b>60,586</b>	<b>102</b>	<b>44,288</b>	<b>881</b>	<b>338,044</b>	<b>873</b>	<b>343,896</b>	<b>(8)</b>	<b>5,852</b>
<u>Research Training:</u>												
Individual awards	107	3,634	0	0	0	0	107	3,670	107	3,886	0	216
Institutional awards	199	8,091	0	0	0	0	199	8,173	199	8,655	0	482
Total, Training	306	11,725	0	0	0	0	306	11,843	306	12,541	0	698
<u>Research &amp; development contracts (SBIR/STTR)</u>												
	67	34,002	0	0	1	7,000	74	35,790	74	38,784	0	2,994
	(4)	(825)	(0)	(0)	(0)	(0)	(4)	(1,600)	(4)	(1,600)	(0)	(0)
<u>Intramural research</u>												
	111	48,531	0	445	0	128	112	49,260	117	50,836	5	1,576
	104	26,759	0	411	0	993	104	27,230	109	28,592	5	1,362
Construction		0						0		0		0
Buildings and Facilities		0						0		0		0
<b>Total, NIAAA</b>	<b>215</b>	<b>450,095</b>	<b>0</b>	<b>61,442</b>	<b>0</b>	<b>52,409</b>	<b>216</b>	<b>462,167</b>	<b>226</b>	<b>474,649</b>	<b>10</b>	<b>12,482</b>

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

<u>Extramural Research</u> <u>Detail:</u>	FY 2007		FY 2008		FY 2009		FY 2009		FY 2010		FY 2011		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Embryo and Fetus		\$23,412	\$27,089	\$23,815	\$23,852	\$24,543	\$25,151							608
Youth/Adolescence		59,300	65,869	62,326	62,421	64,232	65,821							1,589
Young Adult		147,152	142,875	154,315	154,548	159,031	162,967							3,936
Mid-Life/Senior Adult		134,361	128,439	133,780	133,984	137,871	141,282							3,411
<b>Subtotal, Extramural</b>		364,225	364,272	374,236	374,805	385,677	395,221							9,544
Intramural research	113	46,019	47,440	48,531	48,531	49,260	50,836	117	50,836	112	49,260	117	50,836	5
Res. management & support	107	25,341	26,157	26,759	26,759	27,230	28,592	104	26,759	104	27,230	109	28,592	5
<b>TOTAL</b>	220	435,585	437,869	449,526	450,095	462,167	474,649	226	450,095	216	462,167	226	474,649	10

## Major Changes in the Fiscal Year 2011 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 2011 budget request for NIAAA, which is \$12.482 million more than the FY 2010 Estimate, for a total of \$474.649 million.

Research Project Grants (+\$4.343 million, total \$284.019 million): NIAAA will support a total of 728 Research Project Grant (RPG) awards in FY 2011. Noncompeting RPGs will increase by 22 awards and \$13.841 million. The NIH budget policy for RPGs in FY 2011 is to provide for two percent inflationary increases in noncompeting awards and a two percent increase in average cost for competing RPGs.

Research and Development Contracts (+ \$2.994 million, total \$38.784 million): Funds are included in R&D contracts to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program (TRND), the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory, as well as increased support for other HHS agencies through the program evaluation set-aside.

Intramural Research (+\$1.576 million; total \$50.836 million): Intramural Research will receive an increase to offset the cost of pay and other costs, and to fund an additional 5 FTEs.

Research Management and Support (+\$1.362 million; total \$28.592 million): The NIAAA oversees over 800 research grants, 300 full-time training positions, and over 70 research and development contracts. The increase will be used to offset the expenses associated with pay raises and other costs and to provide for an additional 5 FTEs, 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**

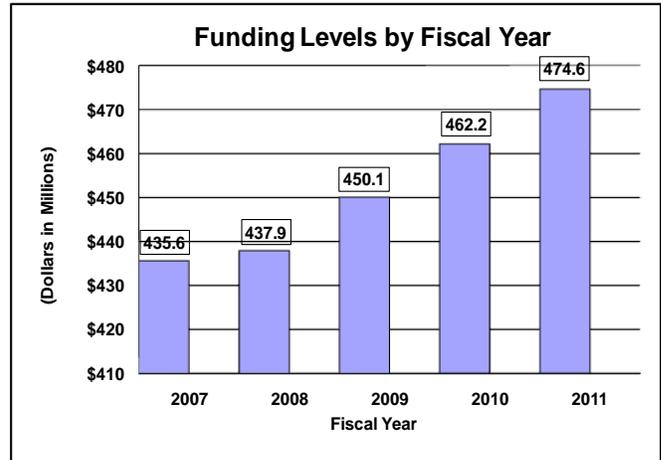
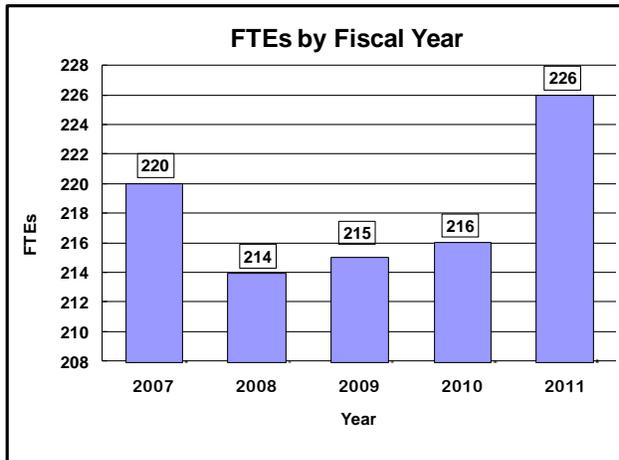
FY 2010 estimate		\$462,167,000	
FY 2011 estimated budget authority		474,649,000	
Net change		12,482,000	
CHANGES	2010 Current Estimate Base		Change from Base
	FTEs	Budget Authority	FTEs Budget Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January 2010 pay increase		\$18,795,000	\$114,000
b. January FY 2011 pay increase		18,795,000	197,000
c. Zero less days of pay (n/a for 2011)		18,795,000	0
d. Payment for centrally furnished services		7,761,000	248,000
e. Increased cost of laboratory supplies, materials, and other expenses		22,704,000	444,000
Subtotal			1,003,000
2. Research management and support:			
a. Annualization of January 2010 pay increase		\$15,557,000	\$94,000
b. January FY 2011 pay increase		15,557,000	163,000
c. Zero less days of pay (n/a for 2011)		15,557,000	0
d. Payment for centrally furnished services		1,208,000	39,000
e. Increased cost of laboratory supplies, materials, and other expenses		10,465,000	238,000
Subtotal			534,000
Subtotal, Built-in			1,537,000

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

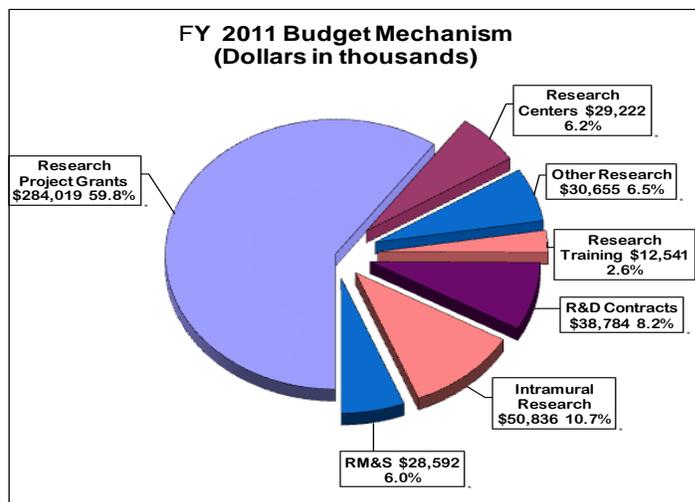
CHANGES	2010 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	515	\$202,062,000	22	\$13,917,000
b. Competing	193	68,434,000	(30)	(9,494,000)
c. SBIR/STTR	28	9,180,000	0	(80,000)
Total	736	279,676,000	(8)	4,343,000
2. Research centers	20	28,371,000	0	851,000
3. Other research	125	29,997,000	0	658,000
4. Research training	306	11,843,000	0	698,000
5. Research and development contracts	74	35,790,000	0	2,994,000
Subtotal, extramural				9,544,000
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	112	49,260,000	5	573,000
7. Research management and support	104	27,230,000	5	828,000
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program		462,167,000		10,945,000
Total changes	216		10	12,482,000

## Fiscal Year 2011 Budget Graphs

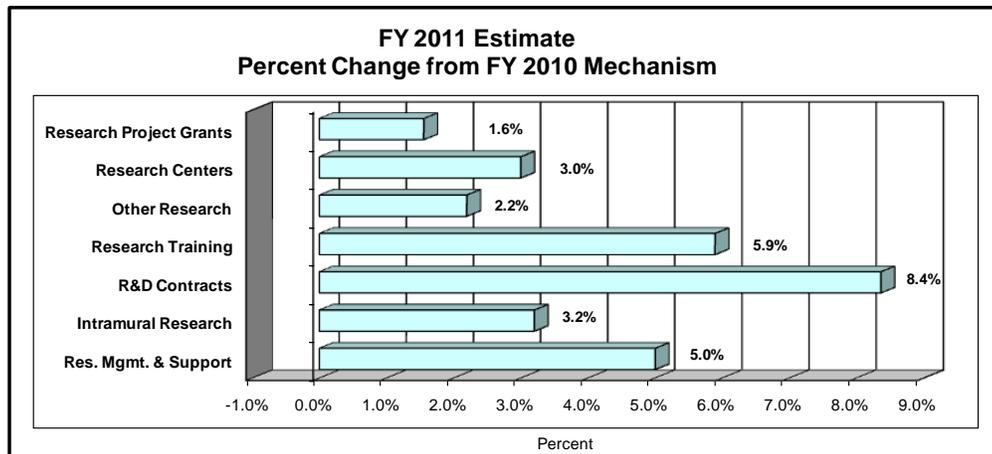
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



## Justification

### National Institute on Alcohol Abuse and Alcoholism

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

Budget Authority:

	FY 2009 Appropriation	FY 2010 Appropriation	FY 2011 President's Budget	Increase or Decrease
BA	\$450,095,000	\$462,167,000	\$474,649,000	+12,482,000
FTEs	215	216	226	+10

This document provides justification for the Fiscal Year (FY) 2011 activities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), including NIH/AIDS activities. Details of the FY 2010 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

### Director's Overview

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. Its mission is to support research, and then translate and disseminate research findings to reduce alcohol-related problems. From fetal alcohol syndrome to alcohol dependence, and from liver cirrhosis to alcohol poisoning, the consequences of alcohol misuse are widespread and costly, and affect individuals of every age, ethnic background, and socioeconomic status. In fact, alcohol use is the third leading cause of preventable death in the U.S.<sup>1</sup> Drinking too early, too fast, too much, 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). As the country looks to health care reform, it is essential to recognize that excessive alcohol use costs our nation an estimated \$235 billion annually.<sup>2</sup>

Research supported by NIAAA over the past several decades which spans prevention to treatment, and molecules to organ systems, is now being translated into new and better approaches for prevention and treatment of alcohol dependence, liver disease, and fetal alcohol syndrome. These approaches have the capacity to reduce both health care costs and alcohol's wider economic burden.

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

<sup>2</sup> Rehm J, Mathers C, Popova S, Thavorncharoensap M, Teerawattananon Y, Patra J. The Lancet 373(9682): 2223-2233, 27 June 2009-3 July 2009. <http://www.sciencedirect.com/science/article/B6T1B-4WM2BX7-16/2/a5a8694fa560c804bc8d35789d1be335>

Studies show that personalizing treatment can actually reduce health care costs. What works for whom is important and, for many, more is not better. Availability of a range of treatments, including alternatives to high cost specialty treatment and improved medical maintenance approaches, will provide treatment options for mild alcohol dependence to chronic relapsing dependence and ultimately increase the numbers of individuals who access treatment. For those engaging in harmful drinking behaviors (including those with less severe forms of dependence), making alcohol screening a part of routine primary healthcare and providing advice and/or brief interventions can prevent future more serious, and more costly problems. To facilitate alcohol screening and early intervention in primary care, NIAAA developed *The Clinician's Guide: Helping Patients Who Drink Too Much* and augmented it with online training. A similar effort is underway to produce a guide for practitioners on how to screen children and adolescents for alcohol consumption, binge drinking, and alcohol use disorders, as well as to identify those who have not initiated drinking but are at high risk for alcohol use. For adults, NIAAA seeks to capitalize on the knowledge that many individuals change harmful drinking habits without formal treatment. In order to capture the attention of those who might benefit from self-assessment of their drinking and to assist those who seek to regain and/or maintain a healthy relationship with alcohol, NIAAA developed the booklet and online interactive tool *Rethinking Drinking* <http://rethinkingdrinking.niaaa.nih.gov>. Since its release in March 2009, nearly 200,000 copies of the booklet have been distributed and almost 250,000 visitors have accessed the website.

NIAAA also supports extensive research to develop new medications and behavioral treatments to address the full spectrum of alcohol dependence, which ranges from a single episode of a few years duration to chronic relapsing disease that persists over decades. Recognizing that alcohol dependence is a complex disorder involving an array of genes and neural pathways which differentially contribute to dependence in different individuals, that different individuals seek different treatment outcomes (abstinence versus a return to moderate drinking), and that individual genetic make-up can affect treatment efficacy, NIAAA is investing in studies to identify what works for which individuals, what underlies success, and how to provide those effective elements in an affordable, accessible and appealing way so that those who need help will seek it and will adhere to the treatment offered. For example, large scale genetic studies are providing insights into the molecular mechanisms underlying dependence and identifying gene variants that may affect treatment outcomes. Collectively such studies inform the identification and use of potential drug therapies. Concurrently, studies investigating the mechanisms by which individuals change their behavior are informing development of new treatment paradigms that will also have value for addressing a range of health-related behaviors that extend beyond alcohol dependence.

To improve the ability to diagnose and treat the medical consequences of alcohol use on tissues and organs, NIAAA's research portfolio includes both studies characterizing the primary effects of alcohol on specific tissues and organs, and studies pursuing a systems biology approach, exploring how pathological changes in one organ can result in physiological aberrations in another (see gut liver brain portrait). NIAAA is exploiting high throughput technologies that permit investigators to take a comprehensive look at all molecules of a specific type such as genes, proteins or sugars within a particular cell,

tissue, or organ, under specific conditions. Such technologies are being used to identify biomarkers that enable monitoring of either alcohol consumption or the initiation and progression of damage to tissues in the liver, brain, bone, and/or developing fetus. In addition, ongoing studies are evaluating the ability of nutritional supplements and other pharmacological compounds to mitigate tissue injury early in the disease process, both for liver disease and for fetal alcohol spectrum disorders. The collective goal of these studies is to facilitate early detection and treatment of tissue injury to prevent future more serious complications which are much more difficult and expensive to treat (see medications development portrait).

Complementary to the research just described, NIAAA focuses its prevention efforts broadly, with the goal of avoiding alcohol-related problems altogether. Special attention is given to pregnant women, children and adolescents, college campuses and communities. For example, in an evaluation of the Institute of Medicine model for fetal alcohol spectrum disorders prevention, NIAAA is comparing universal, selected, and indicated prevention in five distinct communities. For children and adolescents, NIAAA has worked closely with SAMHSA to disseminate the Surgeon General's Call to Action to Prevent and Reduce Underage Drinking to states and communities. For colleges and universities, NIAAA is disseminating a recently published journal supplement summarizing a series of NIAAA funded college prevention studies and is convening a new working group of college presidents to work with NIAAA to enhance prevention efforts on college campuses.

Overall Budget Policy: Investigator-initiated research projects, new investigator research and research training are the Institute's highest priorities. In FY 2011, NIAAA will support new investigators on R01 equivalent awards at success rates equivalent to those of established investigators submitting new R01 equivalent applications. New initiatives in FY 2011 will support several key themes of the NIH, including applying genomics and other high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases, translating science into new and better treatments and putting science to work for the benefit of health care reform. Intramural Research and Research Management and Support will receive additional funds to cover the cost of pay and other increases and to provide for 10 additional FTE positions.

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

## **FY2011 Justification by Activity Detail:**

### **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. 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 prenatally to 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 consumption providing new opportunities for monitoring alcohol exposure.

Budget Policy: The FY 2011 budget estimate for the Embryo and Fetus Program is \$25.151 million, an increase of \$603 thousand or 2.5% over the FY 2010 estimate. NIAAA will continue to support research on the mechanisms by which alcohol causes damage to, as well as pharmacologic agents that lessen alcohol's adverse effects on, the developing embryo/fetus. Resources will also be directed towards the development of biomarkers, which could be used to detect alcohol exposure in pregnant women.

### **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 empirically based guidelines and recommendations for screening children and adolescents to identify risk for alcohol use especially for younger children; alcohol use, and alcohol use disorders. 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 planning an initiative for FY 2010 to study persistent 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. In addition, in 2009 NIAAA solicited applications to study decision-

making processes in adolescents as they relate to drinking behavior, and the role of neural circuitry development in adolescent decision-making and alcohol abuse and dependence.

Budget Policy: The FY 2011 budget estimate for the Youth/Adolescence Program is \$65.821 million, an increase of \$1.577 million or 2.5% over the FY 2010 estimate. In FY 2011, NIAAA will support the continuing development of a screening guide for use with children and adolescents to assess for risk of alcohol use and alcohol use disorders. NIAAA will also solicit studies that evaluate the use and effectiveness of the guide in various settings. In addition, NIAAA is planning a new research initiative on pharmacotherapy for adolescents and young adults with severe alcohol use disorders and major comorbidities, as well as behavioral interventions that target young individuals along the continuum of mild to severe alcohol related behaviors.

### **Young Adult (Ages 18-29)**

For young adults, whose drinking behavior and extent of associated problems vary widely, NIAAA focuses on risk assessment, universal and selective prevention, and early intervention and treatment. Given the pervasiveness of high-risk drinking and early 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. Recent research has demonstrated that college-aged individuals respond well to web-based screening and self-change programs, resulting in reductions in adverse alcohol-related consequences. NIAAA has released a free web-based consumer-oriented product, *Rethinking Drinking*, that can help people of all ages assess their own drinking, decide if they wish to change, and initiate and maintain change, which may be particularly appealing and accessible to young adults. The *Rethinking Drinking* booklet is a core component of a new, collaborative, national initiative to make alcohol screening and brief intervention a routine procedure in employee assistance programs (EAPs). To date, approximately 40,000 copies of the booklet have been distributed to EAPs. NIAAA also plans a major outreach initiative to primary care and mental health practitioners to make them aware of the *Rethinking Drinking* products for their patients. In addition, a wide variety of organizations including counseling centers, clinics, and hospitals; health plans; Veterans Affairs facilities; high schools, colleges, and professional schools; EAPs; drug courts and DUI rehab programs continue to put the *Rethinking Drinking* booklet to use in their programs. For those unable to change on their own, NIAAA is focusing on understanding the basic science of behavior change as well as medication treatment for younger people.

Budget Policy: The FY 2011 budget estimate for the Young Adult Activity is \$162.967 million, an increase of \$3.977 million or 2.5% over the FY 2010 estimate. Making alcohol screening and brief intervention a routine procedure in primary care and other settings is a high priority of NIAAA. In FY 2011, NIAAA will continue to promote and disseminate *Rethinking Drinking* as part of this important effort. Research has demonstrated that comprehensive community interventions that typically involve multiple levels of city government, environmental policy change and community involvement, among other factors, may reduce alcohol-related problems among

adolescents and young adults, including college students. Screening and brief intervention in primary care has also been shown effective among this population. In FY 2011 NIAAA is planning a new initiative exploring the effects of community interventions on alcohol related outcomes in young adults.

Portrait of a Program: Pharmacologic Interventions for Alcohol-Related Problems

Funding levels:

FY 2010 Level: \$3.3 million

FY 2011 Level: \$4.1 million

Change \$ .8 million

In addition to its role in alcohol dependence, excessive alcohol consumption can have toxic effects on virtually every organ system in the body resulting in liver and heart disease, pancreatitis, fetal abnormalities, brain damage, and an increased risk for esophageal and liver cancer. Liver disease in particular claims 37,000 lives annually, about 40% of which are due to excessive alcohol use. Currently the only treatment for liver cirrhosis – the end stage of alcoholic liver disease - is liver transplantation which is impacted by limited availability of matching organs, high medical costs, and increased risk for future health complications. Intervening early in the disease process continues to be an important priority of NIAAA, and research is moving us closer to developing medications that can slow or even reverse disease progression and/or mitigate health consequences. For example, preliminary research has shown that administration of the dietary supplement S-adenosylmethionine (SAME) may reverse disease symptoms in individuals with early stage liver disease and preempt cirrhosis. A phase 2 clinical trial testing the effects of this compound is currently underway. In addition, NIAAA and NIDDK are co-funding a project focused on developing small molecules to reverse alcoholic liver fibrosis, as well as liver damage resulting from obesity and metabolic syndromes; clinical trials are expected as early as 2011. Reducing or eliminating the deleterious effects of fetal alcohol exposure is also a high priority. Animal studies evaluating prenatal and early postnatal supplementation with the nutrient choline, a molecule important to the structure and function of cell membranes, have shown reduced severity of certain behavioral and physical effects of prenatal alcohol exposure. Clinical trials to determine choline's effectiveness for Fetal Alcohol Spectrum Disorders (FASD) are anticipated. For alcohol dependence, NIAAA is moving medications that promote abstinence and/or reduction in heavy drinking through the medications development pipeline via its early Phase 2 clinical trials program. These include trials for quetiapine, a mood stabilizing drug, completed in late FY 2009 and for levetiracetam, an antiepileptic medication, initiated in late FY 2009. Taken together, the use of effective medications has the potential to treat and/or preempt multiple alcohol-related health disorders and reduce the economic burden of alcohol on society and the health care system.

### **Midlife/Senior Adult**

Research has demonstrated that there is no typical alcoholic; the variation among individuals who meet criteria for alcohol dependence reflects both the subtype of dependence and individual genetic make-up. NIAAA's research focus for the midlife/senior population encompasses: 1) Identification of mechanisms by which alcohol and its metabolites cause tissue and organ pathologies; 2) Development of treatment strategies for alcohol dependence (including medications) that are tailored to specific populations; and 3) Treatment of individuals with co-existing psychiatric and medical disorders. In its ongoing efforts to deal with one of the most serious medical consequences of alcohol dependence, NIAAA supported a Phase II medication trial in FY2009 for the treatment of alcoholic liver disease and continues to seek biomarkers for liver damage. In order to better understand how alcohol causes cell and tissue damage in multiple organs in the body, NIAAA supports studies using a systems biology approach to investigate how pathological changes in one organ can also result in

physiological aberrations in another. The interactions between the gut, liver and brain are a focus of such an approach. To develop additional medications for alcohol dependence, NIAAA completed one early Phase II medication trial in FY2009 and initiated another. NIAAA also works closely with extramural investigators and industry to facilitate development of new compounds, and several have been identified. The NIAAA *Clinician's Guide* provides guidance to health care professionals on identification and treatment of heavy drinking in health care settings helping prevent both alcohol dependence and the medical consequences of chronic heavy drinking.

**Budget Policy:** The FY 2011 budget estimate for the Midlife/Senior Adult Program is \$141.282 million, an increase of \$3.387million or 2.5% over the FY 2010 estimate. The program plans for FY 2011, along with expected accomplishments, are as follows. In FY 2011, NIAAA is planning a new initiative on developing effective pharmacological and behavioral treatments for individuals who have alcohol use disorders and co-existing other drug, psychiatric and/or physical disorders. In FY 2011 NIAAA will also support studies aimed at risk reduction, early identification and diagnosis of harmful alcohol use and personalized treatment. The liver is the primary target of the toxic effects of alcohol; each year 37,000 people die from liver disease and 40% of the deaths are caused by alcohol. Additional funds will be committed for research on the underlying mechanisms of alcohol-induced liver injury and the identification of biomarkers of alcohol-induced tissue injury. These studies are expected to reveal new therapeutic targets, inform strategies for preventing tissue injury, facilitate early diagnosis and improve the prognosis for alcohol-related liver disease.

Portrait of a Program: A Systems Biology Approach: Understanding Alcohol's Effects throughout the Body

Funding levels:

FY 2010 Level: \$2.3 million

FY 2011 Level: \$2.4 million

Change               \$.1 million

Over the past four decades, numerous scientific advances have been made in identifying the pathologic effects of alcohol and its metabolic products on the brain, liver, heart, pancreas, and immune and endocrine systems. Recently, NIAAA has taken a systems biology approach, investigating how perturbation of one organ system by alcohol influences other organ systems, leading to a cascade of effects throughout the body. Based on intriguing findings described below, NIAAA is initially focusing on the intricate interplay between the gut, liver, brain and immune system. Alcohol consumption sets in motion a number of signaling processes which operate directly and indirectly on multiple systems in the body. For example, one mechanism by which alcohol negatively impacts the liver and brain is through signaling molecules released from the gut. The gut normally contains bacteria whose outer membranes consist primarily of large amounts of molecules known as lipopolysaccharides (LPS). Alcohol increases gut 'leakiness' allowing LPS to travel throughout the body, resulting in inflammation in both the brain and liver. Liver inflammation then triggers the release of cytokines, signaling molecules that promote further inflammation in the brain. Gut 'leakiness' may also be the mechanism by which alcohol disrupts immune function, although other mechanisms have also been postulated to explain alcohol's effects on the immune system. Another target of alcohol may be the hypothalamic pituitary adrenal axis (HPA axis), a major part of the neuroendocrine system that regulates reactions to stress and many body processes, including digestion, the immune system, mood and emotions, sexuality, and energy storage and expenditure. Considering the human body as a complex network in which perturbations of one organ system alters interactions with other organ systems thereby affecting the functions of each, will enable the development of treatments that address the source(s) of alcohol-induced tissue and organ damage.

## **Intramural Research**

The Intramural Research Program has made significant advances in the areas of medications development, neuroscience, genetics, epidemiology and physiology. A major focus of NIAAA in general, and of the Intramural Program specifically, has been to improve treatment of alcohol use disorders and associated problems. The approach of identifying molecular targets for treatment in experimental animals and then validating these targets in clinical research studies has been successful. 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. There has also been considerable progress in identifying genes that underlie alcohol dependence and that influence the efficacy of specific treatments. This has not yet resulted in individualized treatments, but has demonstrated that some treatments are more effective than others in individuals with particular gene variants. 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 2011 budget estimate for the Intramural Research Program is \$50.836 million, an increase of \$1.576 million or 3.2% over the FY 2010 estimate. The increase will be used to offset the expenses associated with pay raises and other costs and to provide for an additional 5 FTEs. In FY 2011, 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.

Budget Policy: The 2011 budget estimate for the Research Management and Support detail is \$28.592 million, an increase of \$1.362 million or 5.0% over the FY 2010 estimate. The increase will be used to offset the expenses associated with pay raises and other costs and to provide for an additional 5 FTEs, to provide for the effective

administrative, planning and evaluation, public information and communications, and scientific leadership of the institute.

## **NIH Common Fund**

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

## **Recovery Act Implementation**

Recovery Act Funding: \$113.851 million

In FY 2009, NIAAA received \$113.9 million under the American Recovery and Reinvestment Act (ARRA). Of this amount, \$61.4 million was obligated in FY 2009 and \$52.4 million will be obligated in FY 2010. These funds are being used to support: 1) highly meritorious research project grants (RPGs) that otherwise could not be supported under the Institute's regular appropriation; 2) supplementation of ongoing RPGs as administrative supplements, summer supplements for students and teachers, and competitive revisions; 3) faculty recruitment under the NIH ARRA P30 initiative; 4) Challenge Grants; and 5) Grand Opportunities (GO) projects, which include NIAAA's Signature Initiatives. Funds provided through the Recovery Act are allowing the creation and retention of many needed jobs, accelerating the pace of scientific research, supporting the economy through the purchase of new equipment and financing and expanding research opportunities that might otherwise be lost or delayed.

NIAAA's ARRA Signature Initiatives represent significant investments that address major challenges in alcohol research and have the potential to make important, long-term impacts for personalizing treatment and reducing healthcare costs. One Signature Initiative seeks to better characterize the mechanisms by which alcohol causes tissue and organ damage, especially liver injury, as well as to discover reliable biomarkers as noninvasive diagnostic tools of liver injury. The studies supported under this initiative are expected to reveal potential targets for treatment, inform the development of more effective prevention and treatment strategies, facilitate early diagnosis of alcohol-induced liver disease, leading to earlier medical intervention and improved outcomes, and improve monitoring of disease progression and treatment effectiveness. The goal of the second NIAAA Signature Initiative is to elucidate the mechanisms that underlie alcohol and nicotine codependence, a condition that increases the risk of developing certain diseases, such as cancer of the larynx and pharynx, due to the synergistic effects of the two substances. The studies supported under this initiative are investigating the molecular changes in the brain resulting from co-occurring alcohol and nicotine use and the mechanisms by which these substances influence dependence on one another. The findings are expected to lead to improved prevention and treatment strategies for codependence.

Through the Recovery Act, NIAAA is capitalizing on the unprecedented opportunity to help jumpstart the economy, create and save jobs and support critical scientific research.

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**Budget Authority by Object**

	FY 2010 Enacted	FY 2011 PB	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	216	226	10	4.6
Full-time equivalent of overtime and holiday hours	1	1	0	0.0
Average ES salary	\$173,503	\$175,411	\$1,908	1.1
Average GM/GS grade	12.6	12.6	0.0	0.0
Average GM/GS salary	\$102,571	\$103,699	\$1,128	1.1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$133,463	\$134,931	\$1,468	1.1
Average salary of ungraded positions	102,463	103,590	1,127	1.1
<b>OBJECT CLASSES</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>Increase or Decrease</b>	<b>Percent Change</b>
Personnel Compensation:				
11.1 Full-time permanent	\$16,366,000	\$17,418,000	\$1,052,000	6.4
11.3 Other than full-time permanent	6,786,000	7,220,000	434,000	6.4
11.5 Other personnel compensation	800,000	852,000	52,000	6.5
11.7 Military personnel	446,000	474,000	28,000	6.3
11.8 Special personnel services payments	3,174,000	3,376,000	202,000	6.4
<b>Total, Personnel Compensation</b>	<b>27,572,000</b>	<b>29,340,000</b>	<b>1,768,000</b>	<b>6.4</b>
12.0 Personnel benefits	6,410,000	6,821,000	411,000	6.4
12.2 Military personnel benefits	370,000	394,000	24,000	6.5
13.0 Benefits for former personnel	0	0	0	0.0
<b>Subtotal, Pay Costs</b>	<b>34,352,000</b>	<b>36,555,000</b>	<b>2,203,000</b>	<b>6.4</b>
21.0 Travel and transportation of persons	818,000	829,000	11,000	1.3
22.0 Transportation of things	90,000	91,000	1,000	1.1
23.1 Rental payments to GSA	0	0	0	0.0
23.2 Rental payments to others	18,000	18,000	0	0.0
23.3 Communications, utilities and miscellaneous charges	350,000	354,000	4,000	1.1
24.0 Printing and reproduction	174,000	178,000	4,000	2.3
25.1 Consulting services	268,000	275,000	7,000	2.6
25.2 Other services	5,508,000	5,586,000	78,000	1.4
25.3 Purchase of goods and services from government accounts	46,338,000	48,819,000	2,481,000	5.4
25.4 Operation and maintenance of facilities	76,000	76,000	0	0.0
25.5 Research and development contracts	19,542,000	20,762,000	1,220,000	6.2
25.6 Medical care	92,000	92,000	0	0.0
25.7 Operation and maintenance of equipment	545,000	547,000	2,000	0.4
25.8 Subsistence and support of persons	0	0	0	0.0
<b>25.0 Subtotal, Other Contractual Services</b>	<b>72,369,000</b>	<b>76,157,000</b>	<b>3,788,000</b>	<b>5.2</b>
26.0 Supplies and materials	3,806,000	3,802,000	(4,000)	-0.1
31.0 Equipment	2,857,000	2,864,000	7,000	0.2
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	347,332,000	353,800,000	6,468,000	1.9
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
<b>Subtotal, Non-Pay Costs</b>	<b>427,815,000</b>	<b>438,094,000</b>	<b>10,279,000</b>	<b>2.4</b>
<b>Total Budget Authority by Object</b>	<b>462,167,000</b>	<b>474,649,000</b>	<b>12,482,000</b>	<b>2.7</b>

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**Salaries and Expenses**

OBJECT CLASSES	FY 2010 Enacted	FY 2011 PB	Increase or Decrease	Percent Change
<b>Personnel Compensation:</b>				
Full-time permanent (11.1)	\$16,366,000	\$17,418,000	\$1,052,000	6.4
Other than full-time permanent (11.3)	6,786,000	7,220,000	434,000	6.4
Other personnel compensation (11.5)	800,000	852,000	52,000	6.5
Military personnel (11.7)	446,000	474,000	28,000	6.3
Special personnel services payments (11.8)	3,174,000	3,376,000	202,000	6.4
<b>Total Personnel Compensation (11.9)</b>	<b>27,572,000</b>	<b>29,340,000</b>	<b>1,768,000</b>	<b>6.4</b>
Civilian personnel benefits (12.1)	6,410,000	6,821,000	411,000	6.4
Military personnel benefits (12.2)	370,000	394,000	24,000	6.5
Benefits to former personnel (13.0)	0	0	0	0.0
<b>Subtotal, Pay Costs</b>	<b>34,352,000</b>	<b>36,555,000</b>	<b>2,203,000</b>	<b>6.4</b>
Travel (21.0)	818,000	829,000	11,000	1.3
Transportation of things (22.0)	90,000	91,000	1,000	1.1
Rental payments to others (23.2)	18,000	18,000	0	0.0
Communications, utilities and miscellaneous charges (23.3)	350,000	354,000	4,000	1.1
Printing and reproduction (24.0)	174,000	178,000	4,000	2.3
<b>Other Contractual Services:</b>				
Advisory and assistance services (25.1)	268,000	275,000	7,000	2.6
Other services (25.2)	5,508,000	5,586,000	78,000	1.4
Purchases from government accounts (25.3)	30,176,000	30,890,000	714,000	2.4
Operation and maintenance of facilities (25.4)	76,000	76,000	0	0.0
Operation and maintenance of equipment (25.7)	545,000	547,000	2,000	0.4
Subsistence and support of persons (25.8)	0	0	0	0.0
<b>Subtotal Other Contractual Services</b>	<b>36,573,000</b>	<b>37,374,000</b>	<b>801,000</b>	<b>2.2</b>
Supplies and materials (26.0)	3,800,000	3,796,000	(4,000)	-0.1
<b>Subtotal, Non-Pay Costs</b>	<b>41,823,000</b>	<b>42,640,000</b>	<b>817,000</b>	<b>2.0</b>
<b>Total, Administrative Costs</b>	<b>76,175,000</b>	<b>79,195,000</b>	<b>3,020,000</b>	<b>4.0</b>

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Authorizing Legislation						
PHS Act/ Other Citation	U.S. Code Citation	2010 Amount Authorized	FY 2010 Estimate	2011 Amount Authorized	FY 2011 PB	
Research and Investigation	Section 301	42§241	Indefinite	Indefinite		
			\$462,167,000	Indefinite	\$474,649,000	
National Institute on Alcohol Abuse and Alcoholism	Section 402(a)	42§281	Indefinite	Indefinite		
<b>Total, Budget Authority</b>			<b>462,167,000</b>		<b>474,649,000</b>	

**NATIONAL INSTITUTES OF HEALTH**  
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**Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	436,256,000
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	466,308,000	457,887,000	462,346,000
Rescission				0
2011	474,649,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

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

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**Details of Full-Time Equivalent Employment (FTEs)**

OFFICE/DIVISION	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Office of the Director	9	9	10
Office of Extramural Activities	15	15	16
Office of Science Policy and Communications	12	12	13
Office of Resource Management	23	23	24
Division of Epidemiology and Prevention Research	13	13	13
Division of Metabolism and Health Effects	9	9	10
Division of Neuroscience and Behavior	13	13	13
Division of Treatment Recovery Research	10	10	10
Division of Intramural Clinical and Biological Research	111	112	117
<b>Total</b>	<b>215</b>	<b>216</b>	<b>226</b>
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		
2007	12.5		
2008	12.5		
2009	12.6		
2010	12.6		
2011	12.6		

**NATIONAL INSTITUTES OF HEALTH  
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**Detail of Positions**

GRADE	FY 2009 Actual	FY 2010 Enacted	FY 2011 PB
Total, ES Positions	2	2	2
Total, ES Salary	343,230	347,006	350,823
GM/GS-15	22	22	23
GM/GS-14	37	37	39
GM/GS-13	43	43	46
GS-12	27	27	29
GS-11	9	9	10
GS-10	2	2	3
GS-9	9	9	9
GS-8	3	3	3
GS-7	2	2	2
GS-6	2	2	2
GS-5	1	1	1
GS-4	0	0	0
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	158	158	168
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	75	75	75
Total permanent positions	160	160	170
Total positions, end of year	239	240	250
Total full-time equivalent (FTE) employment, end of year	215	216	226
Average ES salary	171,615	173,503	175,411
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	101,455	102,571	103,699

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**New Positions Requested**

	FY 2011		
	Grade	Number	Annual Salary
Supervisory Public Affairs Specialist	GS-15	1	\$123,758
Health Science Administrator	GS-14	2	105,211
Health Science Administrator	GS-13	1	89,033
Laboratory Manager	GS-13	1	89,033
Biologist	GS-13	1	89,033
Staff Scientist	GS-12	2	74,872
Management Analyst	GS-11	1	62,467
Research Fellow	GS-10	1	56,857