DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

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NATIONAL INSTITUTES OF HEALTH

National Eye Institute

For carrying out section 301 and title IV of the Public Health Services Act with respect to eye diseases and visual disorders \$678,978,000 **\$667,764,000** (Department of Health and Human Services Appropriation Act, 2008)

National Institutes of Health National Eye Institute

Amounts Available for Obligation 1/

	FY 2007	FY 2008	FY 2009
Source of Funding	Actual	Enacted	Estimate
Appropriation	\$666,756,000	\$678,978,000	\$667,764,000
Pay cost add-on	360,000	0	0
Rescission	0	-11,862,000	0
Subtotal, adjusted appropriation	667,116,000	667,116,000	667,764,000
Real transfer under Director's one-percent			
transfer authority (GEI)	-1,130,000	0	0
Comparative transfer to NIBIB	-33,000	0	0
Comparative transfer to OD	-15,000	0	0
Comparative transfer to NCRR	-392,000	0	0
Comparative transfers to the Office of the Assistant Secretary for Admin. and Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-1,000	0	0
Comparative transfer under Director's one-percent			
transfer authority (GEI)	1,130,000	0	0
Subtotal, adjusted budget authority	666,675,000	667,116,000	667,764,000
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	666,675,000	667,116,000	667,764,000
Unobligated balance lapsing	-123,000	0	0
Total obligations	666,552,000	667,116,000	667,764,000

 <u>1</u>/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2007 - \$13,900,000 FY 2008 - \$17,500,000 FY 2009 - \$17,500,000 Excludes \$1,822,400 in FY 2007 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

(Dollars in Thousands)

	Buc	lget Mechar	nism - Tot	al				
	FY	2007	FY	2008	FY	´ 2009		
MECHANISM	A	ctual	Er	nacted	Es	timate	C	hange
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	835	\$303,948	778	\$295,345	807	\$310,617	29	\$15,272
Administrative supplements	(58)	5,934	(59)	6,000	(59)	6,000	(0)	0
Competing	262	95,181	276	101,302	232	85,274	-44	-16,028
Subtotal, RPGs	1,097	405,063	1,054	402,647	1,039	401,891	-15	-756
SBIR/STTR	58	18,980	48	15,782	47	15,760	-1	-22
Subtotal, RPGs	1,155	424,043	1,102	418,429	1,086	417,651	-16	-778
Research Centers:								
Specialized/comprehensive	39	25,844	39	25,844	39	25,844	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	190	0	190	0	190	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	C
Subtotal, Centers	39	26,034	39	26,034	39	26,034	0	0
Other Research:								
Research careers	68	15,187	74	16,607	74	16,607	0	0
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	63	49,079	63	49,619	63	49,619	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	27	12,340	27	12,476	27	12,476	0	0
Subtotal, Other Research	158	76,606	164	78,702	164	78,702	0	0
Total Research Grants	1,352	526,683	1,305	523,165	1,289	522,387	-16	-778
Research Training:	<u>FTTPs</u>		<u>FTTPs</u>		FTTPs			
Individual awards	62	2,812	67	3,017	72	3,258	5	241
Institutional awards	205	7,794	200	7,591	195	7,403	-5	-188
Total, Training	267	10,606	267	10,608	267	10,661	0	53
Research & development contracts	52	39,553	52	41,826	52	41,826	0	C
(SBIR/STTR)	(0)	(38)	(0)	(38)	(0)	(38)	(0)	(0)
	FTEs		FTEs		<u>FTEs</u>		<u>FTEs</u>	
Intramural research	145	67,249	145	68,594	146	69,623	1	1,029
Research management and support	69	22,584	69	22,923	70	23,267	1	344
Total, NEI	214	666,675	214	667,116	216	667,764	2	648

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

NATIONAL INSTITUTES OF HEALTH National Eye Institute BA by Program (Dollars in thousands)

	Ъ	2005	FY	2006	Γ	2007	FΥ	2007	Ę	2008	FΥ	2009		
	Ă	tual	Ă	ctual	Ā	ctual	Com	parable	ш	acted	Est	imate	Char	oge
Extramural Research	<u>FTEs</u>	Amount	FTEs	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	<u>Amount</u>	<u>FTEs</u>	Amount	FTES	Amount	FTEs A	mount
<u>Detail:</u>														
Retinal Disease Research		257,986		266,534		263,438		263,547		262,979		262,648		-\$331
Comeal Diseases, Cataract, and														
Glaucoma Research		171,620		166,543		168,110		168,448		168,085		167,873		-212
Sensorimotor Disorders and						¢.		2		9		ć		
Rehabilitation Research		151,524		144,031		144,556		144,847		144,535		144,353		-182
Subtotal, Extramural		581,130		577,108		576,104		576,842		575,599		574,874		-725
Intramural research	152	67,487	143	67,029	145	67,298	145	67,249	145	68,594	146	69,623	٢	1,029
Res. management & support	60	20,453	64	22,161	69	22,584	69	22,584	69	22,923	70	23,267	~	344
TOTAL	212	669,070	207	666,298	214	665,986	214	666,675	214	667,116	216	667,764	2	648
														Ī

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

Major Changes in the Fiscal Year 2009 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2009 budget request for NEI, which is \$.6 million more than the FY 2008 Estimate, for a total of \$667.8 million.

<u>Research Project Grants (-\$.8 million; total \$417.7 million):</u> The NIH Budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs. NEI will continue to support new investigators and to maintain an adequate number of competing RPGs. NEI will support 1,039 Research Project Grant (RPG) awards in FY 2009. Noncompeting RPGs will increase by 29 awards and increase by \$15.3 million. Competing RPGs will decrease by 44 awards and decrease by \$16.0 million. Intramural Research and Research Management and Support receive modest increases to help offset the cost of pay and other increases.

Intramural Research (+\$1.0 million; total \$69.6 million): NEI will support a new laboratory to integrate basic, pre-clinical, and translational research to develop and test therapeutic interventions in neurodegenerative eye diseases.

NATIONAL INSTITUTES OF HEALTH National Eye Institute Summary of Changes

				·
FY 2008 Enacted				\$667,116,000
FY 2009 Estimated Budget Authority				667,764,000
Net change				648,000
	200)8 Current		
	Estir	mate Base	Char	nge from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January				
2008 pay increase		\$23,356,000		\$262,000
b. January FY 2009 pay increase		23,356,000		508,000
c. One less day of pay		23,356,000		(89,000)
d. Payment for centrally furnished services		11,293,000		169,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		33,945,000		658,000
	<u> </u>			
Subtotal				1,508,000
0. Descerch management and supports				
2. Research management and support.				
a. Annualization of January		ኖር ርዕድ በበበ		¢101 000
2006 pay increase		Φ9,005,000		φτυτ,000 406.000
D. January F i 2009 pay increase		9,005,000		190,000
c. One less day of pay		9,005,000		(34,000)
d. Payment for centrally turnished services		4,493,000		67,000
e. Increased cost of laboratory supplies,		0 425 000		192 000
		9,420,000		102,000
Subtotai				512,000
Subtotal Built-in				2.020.000

Summary of Changes--continued

	20 5 -	008 Current	Ohar	
	ES	timate Base	Chan	ige from Base
CHANGES	NO.	Amount	NO.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	778	\$301,345,000	29	\$15,272,000
b. Competing	276	101,302,000	(44)	(16,028,000)
c. SBIR/STTR	48	15,782,000	(1)	(22,000)
Total	1,102	418,429,000	(16)	(778,000)
2. Research centers	39	26,034,000	(0)	0
3. Other research	164	78,702,000	(0)	0
4. Research training	267	10,608,000	(0)	53,000
5. Research and development contracts	52	41,826,000	0	0
Subtotal. extramural				(725.000)
	FTEs		<u>FTEs</u>	(-,,
6. Intramural research	145	68,594,000	1	(479,000)
7. Research management and support	69	22,923,000	1	(168,000)
Subtotal, program	214	667,116,000		(1,372,000)
Total changes			2	648,000

History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Justification of Budget Request

National Eye Institute

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

Budget Authority:

	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate	Inc De	rease or ecrease
<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	<u>FTEs</u>	<u>BA</u>	FTEs	<u>BA</u>
214	\$666,675,000	214	\$667,116,000	216	\$667,764,000	2	\$(648,000)

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Eye Institute including HIV/AIDS activities. Details of the FY 2009 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" section of the Overview. Details on the NIH Common Fund are located in the Overview, Volume I. Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The National Eye Institute's (NEI) mission is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of individuals who are visually impaired. Inherent in this mission is clinical research across the spectrum of eye diseases and vision disorders, as well as the investigation of the normal tissue and normal visual processes that will help gain a more complete understanding of abnormal circumstances that lead to these conditions. These investigations are conducted in hundreds of laboratories and clinics throughout the U.S. and in NEI's own intramural research facilities in Bethesda, Maryland.

NEI has continued to reinvigorate its intramural research program (IRP) to better leverage new scientific opportunities. The newly established Laboratory of Neurobiology, Neurodegeneration and Repair will be expanded further in FY 2009. This laboratory integrates basic, pre-clinical, and translational research to develop and test therapeutic interventions in neurodegenerative eye diseases such as macular degeneration, glaucoma and retinitis pigmentosa. Interventions including gene therapy, small molecules, neurotrophic factors, and cell-based systems, will be explored and assessed in combination with a variety of treatment delivery technologies. A senior scientist was recruited in FY 2008 to head the laboratory and additional laboratory sections will be added in FY 2009 following national recruitment searches.

FY 2009 will also bring enhancements to the Ophthalmic Genetics and Visual Function Branch within the IRP. NEI established eyeGENE, a partnership involving the IRP and laboratories across the vision research community, to enhance diagnostic genetic testing for eye diseases. eyeGENE provides genotyping information to participating patients and their doctors that will help to predict an individual's risk of developing eye disease while also creating a centralized repository of genetic material and diagnostic information for research purposes. The eyeGENE network will add several additional genotyping tests and testing sites in FY 2009.

The first patients have been entered into a phase I clinical trial to evaluate gene transfer therapy for a rare but severe retinal degenerative disease, Leber's congenital amaurosis (LCA), that causes blindness in children. The clinical trial includes a dose escalation study, a re-dosing study and evaluation of the treatment in adults and adolescents with the disease. Data generated from the proposed studies will test the hypothesis that this vector is safe and warrants consideration for use in larger clinical trials assessing efficacy. Gene transfer is particularly well-suited to the treatment of retinal degenerative diseases. Nearly 200 single gene defects have been implicated in these diseases. This clinical trial is an important step in treating LCA and in establishing proof-of-concept for gene transfer as a viable therapy for an entire family of eye diseases.

NIH developed the **d**ata**b**ase of **G**enotype **a**nd **P**henotype (dbGaP) program to archive and distribute genetic sequences and disease information from large clinical trials and epidemiology studies. The intent of this program is to disseminate genetic data and clinical information to qualified investigators to accelerate the pace of discovery. These data sets are pivotal to understanding genetic and environmental interactions in disease. The dbGAP program was launched with data from NEI's Age-Related Eye Diseases Study (AREDS), a landmark study of the clinical course of age-related macular degeneration (AMD) and cataracts. NEI anticipates that additional datasets will be added to the dbGAP during FY 2009.

AMD, the leading cause of blindness in the elderly in the United States, will impose an increasing burden in future years based on demographics. The original AREDS clinical trial, completed in 2005, demonstrated that antioxidant vitamin and mineral supplements reduced the progression to advanced AMD by 25 percent on average. Building on these landmark findings, AREDS2 is assessing additional supplements (lutein, zeaxanthin, and long-chain omega-3 fatty acids) as a treatment for AMD and cataracts. AREDS2 is also evaluating effects of eliminating beta-carotene and/or reducing zinc in the original AREDS formulation on AMD progression. Additionally, AREDS2 investigators will be exploring gene-environment interactions in the development of these conditions, as well as investigating how these interactions influence cognitive function, and cardiovascular health. NEI anticipates completion of enrollment of the 4000 participants in this large, multi-center trial by FY 2009.

The NEI extramural research program recently implemented a new initiative to investigate the role of inflammation in degenerative eye diseases such as AMD, uveitis, and other chronic disorders of the eye. This initiative will expand in FY 2009 to leverage the latest knowledge of the molecular and cellular aspects of inflammation and to study the development and progression of degenerative eye diseases. A second emphasis is to expand our knowledge of how the inflammatory process is kept under tight control using the eye as a model system. This knowledge will be pivotal to the development of new diagnostic and intervention strategies to halt and reverse the progression of degenerative eye diseases.

Justification of the FY 2009 Budget by Activity Detail

Program Descriptions and Accomplishments

Retinal Diseases Research:

The light-sensitive retina of the eye is susceptible to many sight-threatening conditions including age-related macular degeneration, diabetic retinopathy, retinopathy of prematurity, retinitis pigmentosa, Usher's syndrome, ocular albinism, retinal detachment, uveitis (inflammation), and eye cancer. The goals of this program area are to understand the disease mechanisms that cause vision loss and to develop improved methods of prevention, diagnosis, and treatment. To meet these goals, NEI supports research on the cell biology, physiology, and immunology of the retina and on the role of gene expression, gene regulation, and the environment in retinal health and disease.

Recent accomplishments include the successful launch of a phase I clinical trial to assess the safety of gene transfer in treating people with a form of Leber congenital amaurosis (LCA). People with LCA are born with severe visual impairment or develop vision loss early in childhood.

Budget Policy:

The FY 2009 budget estimate for Retinal Diseases Research activities is \$262.6 million, a change of -\$.3 million or -.1% from the FY 2008 estimate. The program plans for FY 2009 and accomplishments expected include an acceleration of research on the genetic and environmental basis for AMD, including the role of possible immunological factors. This will include an expansion of genome wide association studies and related efforts in bioinformatics. NEI will support projects that address the possible restoration of vision in retinal degenerative diseases by building on recent advances in cell transplantation and precursor cell biology, including the use of bone marrow stem cell transplantation, and on "re-engineering" the production of light-sensitive proteins in retinal neurons. Research will continue in efforts to control abnormal new blood vessel growth (angiogenesis) in a number of eye diseases, and will include the conduct of clinical trials in this area. These areas were among those designated as research priorities in NEI's latest strategic plan. The program plans for FY 2009 also include the conclusion of the remarkably productive Age-Related Eye Disease Study (AREDS), a multicenter study of cataract and AMD. AREDS demonstrated that high-dose antioxidant supplements (beta-carotene, vitamins C and E, and zinc) can slow the progression of AMD, and added to our understanding of the epidemiology of cataract and AMD, including the demonstration of new genetic associations. NEI will expand the activities of AREDS 2 to evaluate the use of additional oral supplements for the treatment of AMD and cataract. NEI also plans to continue collaborating with the National Heart Lung and Blood Institute on the follow-up ocular component of the Multi-Ethnic Study of Atherosclerosis (MESA) study. The study is attempting to identify factors that predict the development of symptoms and progression to overt cardiovascular disease in different ethnic groups in diverse geographical locations.

Corneal Diseases, Cataract, and Glaucoma Research:

Portrait of a Program: Gene Transfer Therapy for Childhood-Onset Blindness

FY 2008 Level:\$1.5 millionFY 2009 Level:\$2.0 millionChange\$0.5 million

NEI has launched a clinical trial to assess the safety and efficacy of gene transfer in treating people with a form of childhood blindness called Leber congenital amaurosis (LCA). NEI scientists discovered RPE65, a protein within the retina that is critical for regeneration of photoreceptor cell visual pigment following exposure to light. One form of LCA is caused by mutations in the RPE65 gene. Proof-of-concept for gene transfer as a treatment for LCA was demonstrated by NEI-supported investigators both in extensive studies using a dog breed that has LCA and in studies using other animal models. Restoration of visual function in these affected dogs following a single treatment has been remarkable, and has persisted for more than five years.

NEI-supported scientists conducted rigorous pre-clinical safety studies in animals and received approval by the NIH Recombinant DNA Advisory Committee and the FDA to begin human safety studies. The first volunteers with LCA were treated in late 2007. If successful, the clinical trial will continue and expand through FY 2009 to assess the efficacy of this approach. The expectation and hope is that transferring the RPE65 gene will restore useful visual function in people with LCA. An independent data and safety monitoring board is providing careful oversight for all aspects of this trial.

Portrait of a Program: Role of Inflammation in Age Related Macular Degeneration

FY 2008 Level:\$2.0 millionFY 2009 Level:\$2.5 millionChange\$0.5 million

Recognition that inflammation may play an important role in the pathogenesis of age-related macular degeneration (AMD) has led to a major paradigm shift in our understanding of this disease. Investigators now hypothesize that the underlying mechanism that leads to AMD is immune driven, perhaps sharing some of the characteristics of atherosclerosis and other degenerative disorders. NEI funding has provided crucial support for these discoveries. A phase II clinical trial, with supporting laboratory investigations, has been initiated within the NEI clinic. Participants with AMD are randomized to receive one of three immunomodulatory agents or to be observed in conjunction with their standard anti-angiogenic therapy. A second clinical trial based on promising preliminary results will begin in FY 2008 and be expanded during FY 2009.

Corneal diseases, cataract, and glaucoma are among the most prevalent disorders of the eye. Corneal injuries, infections, and diseases can be extremely painful, requiring immediate medical attention. NEI grantees are exploring how infectious, inflammatory, and immunological processes affect the cornea, and how the cornea heals following a wound. The cornea, tear film, eyelids, and conjunctiva form a highly-integrated biological system.

By 2020 researchers estimate that about 40 million Americans will be affected by cataracts¹. The economic burden of cataract will only worsen as the American population ages. NEI cataract research seeks to understand the physiological basis of lens transparency at the cellular and molecular levels and seeks strategies to prevent cataract formation and progression.

Approximately 2.2 million Americans have glaucoma and the prevalence of the disease will rise to a projected 3 million by 2020². Glaucoma is the leading cause of blindness in African Americans. Glaucoma research aims to understand the complex genetic and biological factors that cause the disease and to develop treatments that protect optic nerves from the damage that leads to vision loss.

Recent accomplishments include new findings that may explain how glaucoma causes blindness and may provide new drug targets for protecting the optic nerve. In animal models of glaucoma, increased levels of an inflammatory molecule (TNF-alpha) was found to activate microglia, cells that are part of the eye's immune system. These activated microglia in turn killed many of the cells (oligodendrocytes) that ordinarily support the optic nerve fibers. The unsupported optic nerves then began to die, and vision was lost, reproducing the hallmark clinical features of clinical glaucoma.

Budget Policy:

The FY 2009 budget estimate for Corneal Diseases, Cataract, and Glaucoma Research activities is \$167.9 million, a change of -\$.2 million or -.1% from the FY 2008 estimate. The program plans for FY 2009 and accomplishments expected include following up on a recent finding that certain receptors that bind to vascular endothelial growth factor may play an important role in maintaining the normal transparency of the cornea by blocking the formation of new blood vessel growth. Research will continue to explore the role of precursor cells in accelerating corneal wound healing. The cornea is the most densely innervated tissue in the body and is extremely painful when subjected to trauma; however, relatively little is known of interventions, which could limit and/or reduce corneal pain. NEI expects to fund new projects to identify therapeutic approaches. A growing body of evidence suggests that movement of nutrients through small channels between cells in the lens, known as gap junctions, plays a significant role in maintaining the function of lens epithelial cells. Projects will be funded to examine the possible contribution of defects in the gap junctions in the development of cataracts. Genome wide association studies and related bioinformatics efforts will be launched to explore further the role of genetics and the environment on the development of glaucoma and to understand better the differential response of individuals to glaucoma medications. Research will also be conducted to follow up on the surprising finding in an animal model of glaucoma that death of retinal ganglion

¹ Prevalence of cataract and pseudophakia/aphakia among adults in the United States. <u>Arch</u> <u>Ophthalmol</u> 122: 487-494, 2004.

² Prevalence of open-angle glaucoma among adults in the United States. <u>Arch Ophthalmol</u> 122: 532-538, 2004.

cells, a hallmark of the disease, may be initiated by the immunologic destruction of certain cells that normally surround and support the optic nerve. NEI will expand its collaborative participation in the Age Gene/Environment Susceptibility Study with the National Institute on Aging and several other participating institutes. NEI will fund the follow-up ocular component of this study, which is investigating the contribution of candidate genes and the environment in diseases that are common in old age.

Sensorimotor Disorders and Rehabilitation Research:

Strabismus (misalignment of the eyes) and amblyopia (commonly known as "lazy eye") occur during development and affect 2-4 percent of the U.S. population^{3 4}. Program goals center on gaining a better understanding of the development of the visual system in children at high risk for these conditions, and of the neuromuscular control of gaze.

Refractive errors, such as nearsightedness (myopia), farsightedness (hyperopia) and astigmatism are the most common, correctable visual disorders. A major goal of this program is to prevent refractive error by discovering the biochemical pathways that govern eye growth and uncovering the risk factors associated with refractive errors.

Much of the cerebral cortex is devoted to processing the visual information that floods our eyes. Vision scientists seek to understand how the brain processes visual information, how neural activity is related to visual perception, and how the visual system interacts with cognitive and motor systems.

Three million Americans now have low vision, a term used to describe chronic visual conditions that are not correctable by eye glasses or contact lenses⁵. The NEI supports rehabilitation research on improving the quality of life of persons with visual impairments by helping them maximize the use of remaining vision and by devising improved aids and strategies to assist those without useful vision.

Recent accomplishments include the discovery of a protein, expressed as a gradient during development, which controls the proper guidance of nerves from the two eyes to the brain, a process that is critical for normal visual function.

Budget Policy:

The FY 2009 budget estimate for Sensorimotor Disorders and Rehabilitation Research activities is \$144.4 million, a change of -\$.1 million or -.1% from the FY 2008 estimate. The program plans for FY 2009 and accomplishments expected include pursuing the research finding of several genes involved in Leber's Hereditary Optic Neuropathy, a genetic disease that frequently results in a substantial loss of central vision. The

³ The evolving concept of amblyopia: a challenge to epidemiologists. <u>Am J Epidemiol</u> 118(2): 192-205, 1983.

⁴ Baltimore Vision Screening Project. <u>Ophthalmology</u> 103(1): 105-109, 1996.

⁵ Blindness and Visual Impairment in an American Urban Population. <u>Arch Ophthalmol</u> 108: 286-290, 1990.

development of animal models carrying these mutations could lead to successful genebased therapy for this disease. Research will also pursue remarkable new findings about how the activity of certain brain cells allows us to perceive a stable view of our surroundings despite constant head and eye movements, as highlighted in NEI's strategic plan. This research will help us to understand better the neural control of eye movements and associated disorders, and may have applicability in other sensory systems.

Intramural Research:

The program conducts vision research in its laboratories and clinic located on the NIH campus in Bethesda and other facilities in Rockville, Maryland. Program activities include: clinical studies concerned with the cause, prevention, and treatment of major eye diseases and vision disorders; basic research on cellular and molecular mechanisms of eye development, including the expression and function of genes within the eye; research in immunology and infectious diseases of the eye; and, developing a better understanding of our critical ability to guide movements under sensory control.

Recent accomplishments include the release of initial Age-Related Eye Disease Study (AREDS) genotype and clinical phenotype data into dbGaP, the new NIH database designed to archive and facilitate data sharing from NIH genome wide association studies.

Budget Policy:

The FY 2009 budget estimate for Intramural Research activities is \$69.6 million, a change of \$1.0 million or +1.5% from the FY 2008 estimate. The program plans for FY 2009 and accomplishments expected include the expansion of the recently established Laboratory of Neurobiology, Neurodegeneration and Repair to integrate basic, preclinical, and translation research in developing and testing therapeutic interventions in neurodegenerative eye diseases. These therapeutic approaches will include gene therapy, small molecules, neurotrophic factors, and cell based systems, in combination with a variety of treatment delivery technologies. NEI will also enhance the Ophthalmic Genetics and Visual Function Branch and expand the eyeGENE network to facilitate research on the discovery of the genetic causes of ocular diseases.

Research Management and Support:

Provides support to sustain, guide, and monitor the extramural and intramural research programs. Included in these funds are the support necessary for personnel to carry out leadership and management functions, human resource support, training, travel, purchasing, facilities, budget, planning, information technology, and extramural grant award and management. NEI currently oversees more than 1,400 grants and contracts, including research project grants, core center grants, research career development

awards, cooperative clinical research agreements, and research and development contracts.

Budget Policy:

The FY 2009 budget estimate for Research Management and Support activities is \$23.3 million, a change of \$.3 million or 1.5% from the FY 2008 estimate. The management plans for FY 2009 and accomplishments expected include the continued prudent use of RMS funds while implementing strategic change through continuous improvement, business process reengineering, and other change strategies to meet NEI goals. For example, as part of its strategic planning process, NEI scientific programs undergo regular portfolio review at its National Advisory Eye Council meetings. NEI is participating in a variety of trans-NIH objectives such as using Knowledge Management to implement a transparent coding and disease reporting system and embracing the electronic submission of grant applications to replace previous paper applications. NEI will develop a Risk Management Program that will align with that of the NIH to standardize the risk management process and implement this risk management methodology, approach, tools, and procedures across NEI organizations.

The NEI is the lead institute for the Nanomedicine Initiative supported through the NIH Common Fund.

Budget Authority by Object

	EV 2008	EX 2000	Increase or
	Enacted	Estimate	Decrease
Total compensable workyears:		20111010	200.0000
Full-time employment	214	216	2
Full-time equivalent of overtime and holiday hour	0	0	0
	• · · · · · · ·	• · · · · · · ·	
Average ES salary	\$161,400	\$166,000	\$4,600
Average GM/GS grade	12.2	12.2	0.0
Average GM/GS salary	\$97 100	\$99 900	\$2 800 0
Average salary, grade established by act of	<i>\</i> \\\\\\\\\\\\\	<i><i><i>vcc,ccc</i></i></i>	<i>4</i> <u></u> , 60000
July 1, 1944 (42 U.S.C. 207)	\$70.100	\$72.200	\$2,100
Average salary of ungraded positions	\$134.100	\$138.000	\$3.900
	<i> </i>	+ ··· · ,···	+-,
	FY 2008	FY 2009	Increase or
OBJECT CLASSES	Estimate	Estimate	Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$16,022,000	\$16,647,000	\$625,000
11.3 Other than full-time permanent	6,029,000	6,258,000	229,000
11.5 Other personnel compensation	961,000	998,000	37,000
11.7 Military personnel	408,000	423,000	15,000
11.8 Special personnel services payments	2,591,000	2,685,000	94,000
Total, Personnel Compensation	26,011,000	27,011,000	1,000,000
12.0 Personnel benefits	6,065,000	6,299,000	234,000
12.2 Military personnel benefits	285,000	295,000	10,000
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	32,361,000	33,605,000	1,244,000
21.0 Travel and transportation of persons	790,000	785,000	(5,000)
22.0 Transportation of things	122,000	122,000	0
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	29,000	29,000	0
zs.s Communications, utilities and	532 000	524 000	(8,000)
24.0 Printing and reproduction	401 000	397,000	(4,000)
25.1 Consulting services	351.000	349,000	(2,000)
25.2 Other services	6.378.000	6.336.000	(42,000)
25.3 Purchase of goods and services from	-,,	-,,	(,,-,
government accounts	58,417,000	59,238,000	821,000
25.4 Operation and maintenance of facilities	462,000	460,000	(2,000)
25.5 Research and development contracts	21,116,000	20,529,000	(587,000)
25.6 Medical care	312,000	311,000	(1,000)
25.7 Operation and maintenance of equipment	3,904,000	3,888,000	(16,000)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	90,940,000	91,111,000	171,000
26.0 Supplies and materials	4,630,000	4,615,000	(15,000)
31.0 Equipment	3,525,000	3,515,000	(10,000)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	522 042 000	(725.000)
41.0 Grants, subsidies and contributions	533,773,000	533,048,000	(125,000)
42.0 Insurance claims and indeminities	13 000	13 000	0
44.0 Refunds	13,000 ∩	13,000	0
Subtotal Non-Pay Costs	634 755 000	634 159 000	(596.000)
Total Budget Authority by Object	667 116 000	667 764 000	642 000
Total Budget Authonity by Object	007,110,000	001,104,000	040,000

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

Salaries and Expenses

	FY 2008	FY 2009	Increase or
OBJECT CLASSES	Enacted	Estimate	Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$16,022,000	\$16,647,000	\$625,000
Other than full-time permanent (11.3)	6,029,000	6,258,000	229,000
Other personnel compensation (11.5)	961,000	998,000	37,000
Military personnel (11.7)	408,000	423,000	15,000
Special personnel services payments (11.8)	2,591,000	2,685,000	94,000
Total Personnel Compensation (11.9)	26,011,000	27,011,000	1,000,000
Civilian personnel benefits (12.1)	6,065,000	6,299,000	234,000
Military personnel benefits (12.2)	285,000	295,000	10,000
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	32,361,000	33,605,000	1,244,000
Travel (21.0)	790,000	785,000	(5,000)
Transportation of things (22.0)	122,000	122,000	0
Rental payments to others (23.2)	29,000	29,000	0
Communications, utilities and			
miscellaneous charges (23.3)	532,000	524,000	(8,000)
Printing and reproduction (24.0)	401,000	397,000	(4,000)
Other Contractual Services:			
Advisory and assistance services (25.1)	351,000	349,000	(2,000)
Other services (25.2)	6,378,000	6,336,000	(42,000)
Purchases from government accounts (25.3)	40,151,000	40,393,000	242,000
Operation and maintenance of facilities (25.4)	462,000	460,000	(2,000)
Operation and maintenance of equipment (25.7)	3,904,000	3,888,000	(16,000)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	51,246,000	51,426,000	180,000
Supplies and materials (26.0)	4,622,000	4,607,000	(15,000)
Subtotal, Non-Pay Costs	57,742,000	57,890,000	148,000
Total, Administrative Costs	90,103,000	91,495,000	1,392,000

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NATIONAL INSTITUTES OF HEAL	National Eye Institute	Authorizing Legislation

	PHS Act/	U.S. Code	2007 Amount	FY 2008	2008 Amount	FY 2009
	Other Citation	Citation	Authorized	Enacted	Authorized	Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
		POCSCE		\$667,116,000		\$667,764,000
Ivalional Eye Inslitute	Section 402(a)	- 07874				
Total, Budget Authority				667,116,000		667,764,000

Fiscal	Budget Estimate	House	Senate		
Year	to Congress	Allowance	Allowance	Appropriation	<u>1/</u>
2000	395,935,000 <u>2</u> /	428,594,000	445,172,000	452,706,000	
Rescission				(2,406,000)	
2001	462,776,000 <u>2</u> /	514,673,000	516,605,000	510,611,000	
Rescission				(153,000)	
2002	571,126,000 <u>2</u> /	566,725,000	614,000,000	581,366,000	
Rescission				(653,000)	
2003	625,666,000	625,666,000	637,290,000	637,290,000	
Rescission				(4,142,000)	
2004	652,738,000	648,299,000	657,199,000	657,199,000	
Rescission				(4,147,000)	
2005	671,578,000	671,578,000	680,300,000	674,578,000	
Rescission				(5,508,000)	
2006	673,491,000	673,491,000	693,559,000	673,491,000	
Rescission				(6,735,000)	
2007	661,358,000	661,358,000	666,898,000	667,116,000	
2008	667,820,000	677,039,000	681,962,000	678,978,000	
Rescission				(11,862,000)	
2009	667,764,000				

Appropriations History

<u>1</u>/ Reflects enacted supplementals, rescissions, and reappropriations.
<u>2</u>/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

	FY 2007	FY 2008	FY 2009	
OFFICE/DIVISION	Actual	Enacted	Estimate	
Office of the Director	44	44	44	
Division of Intramural Research	105	105	106	
Division of Epidemiology and Clinical Research	40	40	40	
Division of Extramural Research	25	25	26	
Total	214	214	216	
ncludes FTEs which are reimbursed from the NIH Roadmap for Medical Research				
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)	
FISCAL YEAR	Average GM/GS Grade			
2005	12.4			
2006	12.5			
2007	12.2			
2008	12.2			
2003	12.2			

Details of Full-Time Equivalent Employment (FTEs)

			FV 0000
	FY 2007	FY 2008	FY 2009
GRADE	Actual	Enacled	Estimate
Total, ES Positions	2	2	2
Total, ES Salary	\$308,855	\$322,800	\$332,000
GM/GS-15	33	33	33
GM/GS-14	16	16	16
GM/GS-13	25	25	25
GS-12	29	29	29
GS-11	20	20	22
GS-10	2	2	2
GS-9	11	11	11
GS-8	8	8	8
GS-7	3	3	3
GS-6	2	2	2
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	150	150	152
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	1	1	1
Full Grade	3	3	3
Senior Assistant Grade	0	0	0
Assistant Grade	1	1	1
Subtotal	5	5	5
Ungraded	79	79	79
Total permanent positions	176	176	178
Total positions, end of year	236	236	238
Total full-time equivalent (FTE)			
employment, end of year	214	214	216
Average ES salary	154,428	161,400	166,000
Average GM/GS grade	12.2	12.2	12.2
Average GM/GS salary	92,958	97,100	99,900

Detail of Positions

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