#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### NATIONAL INSTITUTES OF HEALTH

#### National Eye Institute

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# Division of Extramural Research Dr. Loré Anne McNicol Director NATIONAL INSTITUTES OF HEALTH Associate Director for Management Division of Epidemiology and Dr. Jack A. McLaughlin Office of the Director National Eye Institute Dr. Frederick L. Ferris III Dr. Paul A. Sieving Organization Chart David L. Whitmer Deputy Director Clinical Research Director Director Division of Intramural Research Dr. Sheldon S. Miller Scientific Director

#### **Primary Exhibit**

#### **FY 2008 Proposed Appropriation Language**

#### 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 \$667,820,000

#### **Supplementary Exhibit**

#### Comparison of Proposed FY 2008 Appropriation Language to Most Recently Enacted Full-Year Appropriations

#### 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 [\$673,491,000] \$667,820,000 (Department of Health and Human Services Appropriation Act, 2006)

#### National Institutes of Health National Eye Institute

#### Amounts Available for Obligation 1/

Source of Funding	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Appropriation	\$673,491,000	\$666,756,000	667,820,000
Enacted Rescissions	-6,735,000	0	0
Subtotal, Adjusted Appropriation	666,756,000	666,756,000	667,820,000
Real Transfer under Roadmap Authority	-5,958,000		
Real Transfer under Secretary's One-percent transfer authority	-458,000		
Comparative transfer from OD for NIH Roadmap	5,958,000		
Comparative Transfer to NIBIB	-32,000	-33,000	
Comparative transfer to OD	-14,000	-15,000	
Comparative Transfer to NCRR	-483,000	-392,000	
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	-1,000	
Subtotal, adjusted budget authority	665,768,000	666,315,000	667,820,000
Subtotal, adjusted budget authority	665,768,000	666,315,000	667,820,000
Unobligated balance lapsing	0	0	0
Total obligations	665,768,000	666,315,000	667,820,000

<sup>1/</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2006 - \$14,023,000 FY 2007 - \$17,500,000 FY 2008 - \$17,500,000 Excludes \$1,482,000 in FY 2006 for royalties.

#### NATIONAL INSTITUTES OF HEALTH

#### **National Eye Institute**

(Dollars in Thousands)

Budget Mechanism - Total

			FY	2007				
	FY	2006		itinuing	FY	7 2008		
MECHANISM	Α	ctual		olution	Es	timate	Cł	nange
Research Grants:	No.	Amount	No.	Amount	No.	Amount		Amount
Research Projects:								
Noncompeting	890	\$307,204	838	\$303,564	771	\$288,211	-67	-\$15,353
Administrative supplements	(23)	2,181	(12)	1,170	(51)	4,938	(39)	3,768
Competing:	258	92,941	257	92,730	288	103,555	31	10,825
Subtotal, RPGs	1,148	402,326	1,095	397,464	1,059	396,704	-36	-760
SBIR/STTR	62	16,303	60	15,726	59	15,486	-1	-240
Subtotal, RPGs	1,210	418,629	1,155	413,190	1,118	412,190	-37	-1,000
Research Centers:								
Specialized/comprehensive	40	27,075	38	25,840	38	25,840	0	0
Clinical research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative medicine	0	195	0	194	0	194	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	40	27,270	38	26,034	38	26,034	0	0
Other Research:								
Research careers	63	14,249	69	15,726	75	17,146	6	1,420
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	75	57,413	75	57,777	75	57,777	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	28	11,459	28	11,402	28	11,402	0	0
Subtotal, Other Research	166	83,121	172	84,905	178	86,325	6	1,420
Total Research Grants	1,416	529,020	1,365	524,129	1,334	524,549	-31	420
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	69	3,133	67	3,117	67	3,117	0	0
Institutional awards	197	6,114	194	6,083	194	6,083	0	0
Total, Training	266	9,247	261	9,200	261	9,200	0	
Research & development contracts	57	32,400	59	35,530	59	36,057	0	527
(SBIR/STTR)	(0)	(36)	(0)	(36)	(0)	(36)	(0)	0
`	FTEs	,	FTEs	` '	FTEs	, ,	FTEs	
Intramural research	143	66,982	150	66,980	152	66,511	2	-469
Research management and support	62	22,161	61	22,493	61	22,718	0	225
Cancer prevention & control	0	0	0	0	0	0	0	0
Construction		0	l	0		0		0
Buildings and Facilities		0		0		0		0
NIH Roadmap for Medical Research	2	5,958	2	7,983	2	8,785		802
Total, NEI	207	665,768	213	666,315	215	667,820	2	1,505

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

# NATIONAL INSTITUTES OF HEALTH National Eye Institute Budget Authority by Program (Dollars in thousands)

									FY	FY 2007				
	FY	7 2004	FY	FY 2005	FY	FY 2006	FY	FY 2006	Con	Continuing	FY	FY 2008		
	A	Actual	Ą	Actual	Ą	Actual	Com	Comparable	Res	Resolution	Est	Estimate	Change	nge
Extramural Research	FTES	Amount	FTEs	FTEs Amount	FTEs	Amount	FTES	FTEs Amount	FTES	Amount	FTES	Amount	FTEs Amount	rmount
Detail:														
Retinal Disease Research		251,696		256,108		263,889		263,665		262,830		263,268		438
Corneal Diseases, Cataract, and														
Glaucoma Research		168,345		170,371		164,783		164,644		164,122		164,395		273
Sensorimotor Disorders and														
Rehabilitation Research		146,607		150,421		142,478		142,358		141,907		142,143		236
Subtotal, Extramural		566,648		576,900		571,150		570,667		568,859		569,806		947
Intramural research	165	64,496	152	67,487	143	62,029	143	66,982	150	086'99	152	66,511	2	-469
Res. management & support	57	17,574	59	20,453	62	22,161	62	22,161	61	22,493	61	22,718	0	225
NIH Roadman for Medical Recearch		2.243	Ţ	4.230	6	5 958	C	5 958	c	7 983	C	8 785	U	802
	re	181	É		1	2,2,5	1	2000	1	50,267	1	3		700
TOTAL	223	650,961	212	669,070	207	666,298	207	665,768	213	666,315	215	667,820	7	1,505

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

#### Major Changes in the Fiscal Year 2008 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 2008 budget request for NEI which is \$1.5 million more than the FY 2007 Estimate, for a total of \$667.8 million.

Research Project Grants (-\$0.1 million, total \$396.7 million). NEI will support a total of 1,059 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPGs will decrease by 67 awards and decrease by \$15.4 million. Competing RPGs will increase by 31 awards and increase by \$10.8 million.

Research Careers (+\$1.4 million; total \$17.1 million): NEI will support the Pathway to Independence program, by funding an additional 4 awards in FY 2008. Total support for the Pathway program in FY 2008 is 8 awards and \$1.3 million.

NIH Roadmap for Biomedical Research (+\$.8 million; total \$8.785 million): NEI will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

<u>R&D Contracts (+\$.5 million; total \$36.1 million):</u> Program Evaluation increases 3.5% in FY 2008.

#### NATIONAL INSTITUTES OF HEALTH

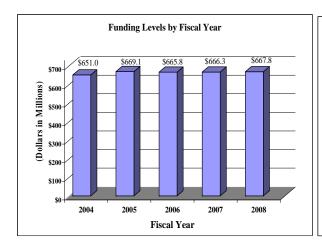
#### **National Eye Institute Summary of Changes**

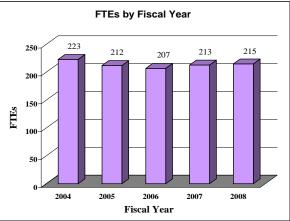
FY 2007 Continuing Resolution				\$666,315,000
FY 2008 Estimated Budget Authority				667,820,000
Net change				1,505,000
		FY 2007		
	Continu	ing Resolution	Chang	ge from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January				
2007 pay increase		\$24,003,000		\$158,000
b. January 2008 pay increase		24,003,000		540,000
c. Two extra days of pay		24,003,000		185,000
d. Payment for centrally furnished services		11,292,000		112,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		31,685,000		701,000
Subtotal				1,696,000
Research Management and Support:				
a. Annualization of January				
2007 pay increase		\$7,728,000		\$51,000
b. January 2008 pay increase		7,728,000		174,000
c. Two extra days of pay		7,728,000		59,000
d. Payment for centrally furnished services		4,609,000		46,000
e. Increased cost of laboratory supplies,				
materials, and other expenses		10,156,000		225,000
Subtotal				555,000
Subtotal, Built-in				2,251,000

#### **Summary of Changes--continued**

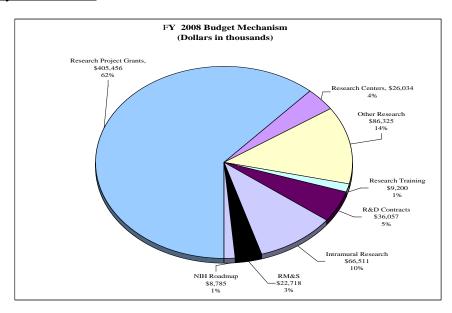
		FY 2007		
	Contin	uing Resolution	Chang	ge from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	838	\$304,734,000	-67	-11,585,000
b. Competing	257	92,730,000	31	10,825,000
c. SBIR/STTR	60	15,726,000	-1	-240,000
Total	1,155	413,190,000	-37	-1,000,000
2. Research centers	38	26,034,000	0	0
3. Other research	172	84,905,000	6	1,420,000
4. Research training	261	9,200,000	0	0
5. Research and development contracts	59	35,530,000	0	527,000
Subtotal, extramural				947,000
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	150	66,980,000	2	-2,165,000
7. Research management and support	61	22,493,000	0	-330,000
8. NIH Roadmap for Medical Research	2	7,983,000	0	802,000
Subtotal, program	213	666,315,000	2	-746,000
Total changes			2	1,505,000

#### History of Budget Authority and FTEs:

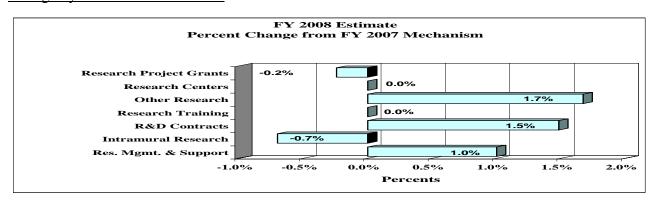




#### Distribution by Mechanism:



#### Change by Selected Mechanisms:



#### **Justification of Budget Request**

#### **National Eye Institute**

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

#### **Budget Authority:**

	FY 2006	H	FY 2007	I	FY 2008	Inc	rease or
	Actual	Continu	ing Resolution	I	Estimate	De	ecrease
<u>FTEs</u>	$\underline{BA}$	<u>FTEs</u>	$\underline{BA}$	<u>FTEs</u>	$\underline{BA}$	<u>FTEs</u>	$\underline{BA}$
207	\$665,768,000	213	\$666,315,000	215	\$667,820,000	2	\$1,505,000

This document provides justification for the Fiscal Year (FY) 2008 activities of the National Eye Institute including HIV/AIDS activities. Details of the FY 2008 HIV/AIDS activities are in the "Office of AIDS Research (OAR)" section of the Overview. Details on the Roadmap/Common Fund are located in the Overview, Volume One.

#### **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 diseases of the eye and disorders of vision, as well as the investigation of the normal tissue and normal visual processes that will help gain a more complete understanding of the abnormal processes that lead to these conditions. These investigations are conducted in hundreds of extramural laboratories and clinics throughout the U.S. and in NEI's own intramural research facilities in Bethesda, Maryland.

The NEI's research programs constantly evolve to meet new challenges. To make decisions to initiate new or expand existing research programs, NEI is guided by its strategic plan. This plan, developed through a process involving NEI program staff, outstanding vision researchers, and leading scientists from other disciplines, identified and prioritized scientific opportunities that NEI should consider for funding. Several new research projects and initiatives were undertaken in FY 2007 consistent with that plan, and some of these activities will be expanded in FY 2008.

NEI investigators have made significant discoveries to understand and treat common retinal disorders like age-related macular degeneration (AMD) and diabetic retinopathy. These findings have spurred NEI to further enhance the already productive efforts of the extramural and intramural investigators. In 2008, NEI will reinvigorate its intramural program to increase ophthalmic genetics research to further elucidate the genetics of retinal diseases. Several new

principal investigators will be hired to advance the research. The enhancement of the intramural program allows the NEI to augment existing extramural resources to develop treatments for retinal diseases.

The Age-Related Eye Disease Study (AREDS), a multicenter study of cataract and AMD originally launched in 1992, will end in FY 2008. This study, which included a clinical trial, demonstrated that high-dose antioxidant supplements (beta-carotene, vitamins C and E, and zinc) can slow the progression of AMD. More than 20 manuscripts have been published based on the results of this study with more in preparation.

As AREDS winds down, NEI will significantly expand AREDS 2. This multi-center study (up to 100 clinical sites) is a randomized, controlled clinical trial of oral supplementation lutein/zeaxanthin and omega-3 long chain polyunsaturated fatty acids for the prevention of advanced AMD and cataract. This study has started recruitment and will follow patients for 5 years.

In FY 2007, the NEI extramural program created 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 2008 to leverage the latest knowledge of the molecular and cellular aspects of inflammation and 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.

Diabetic retinopathy, a complication of diabetes, is a leading cause of vision loss among Americans. Diabetic retinopathy is characterized by the growth of abnormal blood vessels that damage the retina. Recent progress has led to a number of promising investigational therapies that are poised to enter clinical trials in FY 2008. A large clinical trial network of experienced clinicians is essential to the conduct of these trials. Therefore, NEI has developed the Diabetic Retinopathy Clinical Research Network, a cooperative research group that includes clinicians from academic and private practice. The network will continue to expand its activities in FY 2008.

The NEI extramural program began funding a phase I clinical trial in FY 2007 to evaluate gene transfer therapy for a rare but severe retinal degenerative disease called Leber's congenital amaurosis (LCA). It will expand in FY 2008 and represents a classic example of translational research, the effort to "translate" laboratory findings into investigational therapies. NEI-supported researchers first cloned a gene for LCA in humans and dogs in 1997. In 2000, a group of NEI extramural investigators restored vision in dogs with LCA using a single injection of gene therapy. Since that time investigators have completed pre-clinical work and have received regulatory approval to evaluate this promising therapy in patients.

#### Justification of the FY 2008 Budget by Activity Detail

#### **Overall Budget Policy:**

The first priority has been and continues to be funding the highest quality investigator-initiated research applications that help achieve the goals and objectives outlined in the strategic plan. To that end, the principle factor considered in determining which applications are funded continues to be the scientific and technical merit of the application, as evaluated through the peer review system, combined with the programmatic considerations of NEI, and recommendations of the National Advisory Eye Council.

#### **Retinal Diseases Research:**

The retina is the light-sensitive neural tissue lining the back of the eye. The retina is susceptible to a variety of 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 overarching goals of the retinal disease research area are to understand the disease mechanisms that cause vision loss and to develop therapies that overcome the underlying pathology. To meet these goals, NEI supports research to isolate retinal disease genes, determine the function and structure of the resultant proteins in health and disease, and evaluate potential new therapies.

#### **Budget Policy**:

The FY 2008 budget estimate for Retinal Diseases Research activities is \$263.3 million, a change of +\$0.4 million or +0.2% from the FY 2007 estimate. The program plans for FY 2008 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 2008 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 followup 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.

Portrait of a Program: Age-Related Eye Diseases Study 1 and 2

FY 2007 Level: \$4.1 million FY 2008 Level: \$5.3 million Change \$1.2 million

Previous epidemiologic studies have suggested that antioxidant vitamins and minerals might prevent or delay the progression of AMD. Acting on those findings, NEI initiated a large study called the Age-Related Eye Disease Study (AREDS) in 1992. AREDS included a clinical trial that found antioxidant supplementation was beneficial in delaying the progression to the more severe stage of the disease. AREDS also added to our understanding of the epidemiology of AMD and cataract. DNA samples from AREDS participants were crucial in uncovering genetic associations for the disease. Data from AREDS and other studies suggested that lutein/zeaxanthin and omega-3 long chain polyunsaturated fatty acids might also have benefit in AMD and cataract. Leveraging these findings, NEI began AREDS 2, a multicenter study that will include up to 100 clinical sites. AREDS 2 will be greatly expanded in 2008 to evaluate these nutrients in the prevention of advanced AMD and cataract. Additional arms of the study will evaluate different formulations than the one used in the original AREDS. The AREDS 2 study will run through 2012.

#### Corneal Diseases, Cataract, and Glaucoma Research:

Corneal diseases, cataract, and glaucoma are among the most prevalent disorders of the eye. The cornea is the transparent tissue at the front of the eye that directs incoming light onto the lens and retina. Corneal diseases and injuries can be extremely painful, requiring immediate medical attention. NEI corneal research is focused on understanding the biology of the cornea as part of a physiological system that includes tear film, eyelids, conjunctiva and other ocular tissues. NEI grantees are also exploring how the cornea promotes wound healing while still maintaining transparency and the molecular causes of corneal dystrophies. Cataract, an opacity of the lens of the eye, interferes with vision and is the leading cause of blindness in developing countries. In the U.S., cataract is also a major public health problem. An estimated 27 million Americans over age 40 have cataract or have had surgery to remove the lens opacification. By 2020 researchers estimate that about 40 million Americans will be affected by cataract<sup>1</sup> The enormous economic burden of cataract will only worsen as the American population ages. NEI cataract research area seeks to understand the physiological basis of lens transparency at the cellular and molecular levels and seeks strategies to prevent cataract formation and progression. Glaucoma is a group of eye disorders that share a distinct type of optic nerve damage, which can lead to blindness. Glaucoma is a major public health problem and the leading cause of blindness in African Americans. Approximately 2.2 million Americans have been diagnosed with glaucoma and the prevalence of the disease will rise to a projected 3 million by 2020<sup>2</sup>. Glaucoma research aims to understand the complex genetic factors that lead to common forms of the disease and to develop treatments that protect ganglion cells from the damage that leads to vision loss.

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

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

#### **Budget Policy:**

The FY 2008 budget estimate for Corneal Diseases, Cataract, and Glaucoma Research activities is \$164.4 million, a change of +\$0.3 million or +0.2% from the FY 2007 estimate. The program plans for FY 2008 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 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:**

Sensorimotor disorders such as 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<sup>3 4</sup>. The correction of strabismus is one of the most frequently-performed ophthalmic surgical procedures. NEI's sensorimotor research goals center on gaining a better understanding of the development of the visual system in children at high risk for strabismus and amblyopia, and to understand the neural circuitry and muscular mechanisms that control gaze. Refractive errors, such as nearsightedness (myopia), farsightedness (hyperopia) and astigmatism are the most common, correctable visual disorders. A major goal of understanding how to prevent refractive error is to articulate the biochemical pathways that govern eye growth and to uncover the risk factors associated with refractive errors. Much of the cerebral cortex is devoted to processing the images that flood our eyes. The visual cortex also connects with many regions of the brain that govern memory, language, movement, and a myriad of other cognitive abilities. NEI's visual processing grant portfolio is prioritized to understand how the brain processes visual information, how neural activity is related to visual perception, and how the visual system

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

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

interacts with other cognitive 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 lenses<sup>5</sup>. 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 to assist those without useful vision.

#### **Budget Policy:**

The FY 2008 budget estimate for Sensorimotor Disorders and Rehabilitation Research activities is \$142.1 million, a change of +\$0.2 million or +0.2% from the FY 2007 estimate. The program plans for FY 2008 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 development of animal models carrying these mutations could lead to successful gene-based 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 NEI intramural research program conducts research on diseases of the eye and disorders of vision in its laboratories and clinic located on the NIH campus in Bethesda and in other facilities in Rockville, Maryland. Among the research activities supported within NEI intramural program are: planning, developing, and conducting human population studies concerned with the cause, prevention, and treatment of eye disease and vision disorders, with emphasis on the major causes of blindness; conducting basic research on cellular and molecular mechanisms of the eye development, including the expression and function of genes within the eye; conducting research in immunology and infectious diseases of the eye to better understand the normal physiologic state and the processes which perturb it, with special emphasis on inflammatory mechanisms in the eye as a model system; and, developing a better understanding of the fundamental brain mechanisms that allow one of the most critical of human abilities, i.e., the ability to guide our eye movements under neurosensory control.

#### Budget Policy:

The FY 2008 budget estimate for Intramural Research activities is \$66.5 million, a change of -0.7% from the FY 2007 estimate. The program plans for FY 2008 and accomplishments expected include the closure of several research Sections and one Laboratory due to a shift in program emphasis. A recruitment effort is underway that will result in the launch or expansion of several new research activities of higher priority. These activities will include the development of a new program on retinal neurodegeneration research that will combine fundamental, pre-clinical, and translational research, designed to accelerate the introduction of

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

therapeutic interventions in various 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 develop clinical neuroscience research capabilities within the Laboratory of Sensorimotor Research that will build on an already very strong fundamental research program focused on the experimental and theoretical analysis of normal and abnormal eye movements and visual perception.

Portrait of a Program: National Ophthalmic Disease Genotyping Network (eyeGENE)

FY 2007 Level: \$2.2 million FY 2008 Level: \$2.8 million Change \$0.6 million

Centralized genetic repositories are crucial to the understanding and treatment of rare diseases. The availability of detailed genetic information from patients with eye disease allows investigators to isolate genes that cause disease and to better understand the relationship between a gene defect and the resultant pathology or phenotype. A genetic repository can also serve as a registry to identify suitable candidates for clinical studies. In FY 2007, the NEI began eyeGENE, a genotyping program to facilitate the study of eye diseases. This program will be enhanced in FY 2008. The eyeGENE includes a DNA repository, laboratories to sequence the genes in patient DNA, and a research database of genotype data for researchers to access.

#### **Research Management and Support:**

Research management and support (RMS) funds are used to sustain, guide, and monitor the extramural and intramural research program activities of NEI. Included in these funds are the amounts necessary to provide personnel to carry out these management functions, as well as the funds to provide human resource support, training, travel, purchasing, facilities, budget, research planning, information technology, extramural grant award and program management. The Institute currently oversees more than 1,400 grants and contracts, including research project grants, centers, research career awards, cooperative clinical research awards, and research and development contracts.

#### Budget Policy:

The FY 2008 budget estimate for Research Management and Support activities is \$22.7 million, a change of \$.2 million or 1.0% from the FY 2007 estimate. The management plans for FY 2008 and accomplishments expected include the continued use of RMS funds both efficiently and effectively. For example, as part of its strategic planning process, NEI scientific programs undergo regular portfolio review at its National Advisory Eye Council meetings. NEI recently created the Management Policy and Analysis Branch (MPAB) in part to perform management reviews of Divisions and Branches, which focus on setting and measuring short term targets and long term goals. Additionally, 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 which will replace previous paper applications.

**Budget Authority by Object** 

Budget Authorit	y by Object			
	FY 2007			
	Continuing	FY 2008	Increase or	Percent
	Resolution	Estimate	Decrease	Change
Total compensable workyears:				
Full-time employment	213	215	2	0.9
Full-time equivalent of overtime & holiday hours	0	0	0	0.0
1				
Average ES salary	\$155,800	\$160,500	\$4,700	3.0
Average GM/GS grade	12.5	12.5	0.0	0.0
Average GM/GS salary	\$94,300	\$97,100	\$2,800	3.0
Average salary, grade established by act of				
July 1, 1944 (42 U.S.C. 207)	\$62,200	\$64,050	\$1,850	3.0
Average salary of ungraded positions	\$124,800	\$128,600	\$3,800	3.0
	FY 2007			
	Continuing	FY 2008	Increase or	Percent
OBJECT CLASSES	Resolution	Estimate	Decrease	Change
Personnel Compensation:				
11.1 Full-Time Permanent	\$14,994,000	\$15,683,000	689,000	4.6
11.3 Other than Full-Time Permanent	6,790,000	7,118,000	328,000	4.8
11.5 Other Personnel Compensation	698,000	730,000	32,000	4.6
11.7 Military Personnel	144,000	151,000	7,000	4.9
11.8 Special Personnel Services Payments	2,964,000	3,114,000	150,000	5.1
Total, Personnel Compensation	25,590,000	26,796,000	1,206,000	4.7
12.0 Personnel Benefits	5,922,000	6,201,000	279,000	4.7
12.2 Military Personnel Benefits	219,000	230,000	11,000	5.0
13.0 Benefits for Former Personnel	0	0	0	0.0
Subtotal, Pay Costs	31,731,000	33,227,000	1,496,000	4.7
21.0 Travel & Transportation of Persons	813,000	776,000	-37,000	-4.6
22.0 Transportation of Things	72,000	68,000	-4,000	-5.6
23.1 Rental Payments to GSA	72,000	08,000	0	0.0
23.2 Rental Payments to Others	4,000	4,000	0	0.0
23.2 Rental Payments to Others 23.3 Communications, Utilities &	4,000	4,000	U	0.0
*	5.42.000	524,000	0.000	1.7
Miscellaneous Charges	543,000	534,000	-9,000	-1.7
24.0 Printing & Reproduction	380,000	374,000	-6,000	-1.6
25.1 Consulting Services	468,000	440,000	-28,000	-6.0
25.2 Other Services	5,479,000	5,185,000	-294,000	-5.4
25.3 Purchase of Goods & Services from				
Government Accounts	56,004,000	55,979,000	-25,000	0.0
25.4 Operation & Maintenance of Facilities	165,000	155,000	-10,000	-6.1
25.5 Research & Development Contracts	18,637,000	18,464,000	-173,000	-0.9
25.6 Medical Care	174,000	163,000	-11,000	
25.7 Operation & Maintenance of Equipment	3,350,000	3,166,000	-184,000	-5.5
25.8 Subsistence & Support of Persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	84,277,000	83,552,000	-725,000	-0.9
26.0 Supplies & Materials	4,229,000	3,964,000	-265,000	-6.3
31.0 Equipment	2,948,000	2,781,000	-167,000	-5.7
32.0 Land and Structures	0	0	0	0.0
33.0 Investments & Loans	0	0	0	0.0
41.0 Grants, Subsidies & Contributions	533,329,000	533,749,000	420,000	0.1
42.0 Insurance Claims & Indemnities	0	0	0	0.0
43.0 Interest & Dividends	6,000	6,000	0	0.0
44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	626,601,000	625,808,000	-793,000	-0.1
NIH Roadmap for Medical Research	7,983,000	8,785,000	802,000	10.0
Total Budget Authority by Object	666,315,000	667,820,000	1,505,000	0.2
Lotal Rudget Authority by Object				

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

#### **Salaries and Expenses**

<b></b>	-			
OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				680
Full-Time Permanent (11.1)	\$14,994,000	\$15,683,000	689,000	4.6
Other Than Full-Time Permanent (11.3)	6,790,000	7,118,000	328,000	4.8
Other Personnel Compensation (11.5)	698,000	730,000	32,000	4.6
Military Personnel (11.7)	144,000	151,000	7,000	4.9
Special Personnel Services Payments (11.8)	2,964,000	3,114,000	150,000	5.1
Total Personnel Compensation (11.9)	25,590,000	26,796,000	1,206,000	4.7
Civilian Personnel Benefits (12.1)	5,922,000	6,201,000	279,000	4.7
Military Personnel Benefits (12.2)	219,000	230,000	11,000	5.0
Benefits to Former Personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	31,731,000	33,227,000	1,496,000	4.7
Travel (21.0)	813,000	776,000	-37,000	-4.6
Transportation of Things (22.0)	72,000	68,000	-4,000	-5.6
Rental Payments to Others (23.2)	4,000	4,000	0	0.0
Communications, Utilities and				
Miscellaneous Charges (23.3)	543,000	534,000	-9,000	-1.7
Printing and Reproduction (24.0)	380,000	374,000	-6,000	-1.6
Other Contractual Services:				
Advisory and Assistance Services (25.1)	468,000	440,000	-28,000	-6.0
Other Services (25.2)	5,479,000	5,185,000	-294,000	-5.4
Purchases from Govt. Accounts (25.3)	38,070,000	37,476,000	-594,000	-1.6
Operation & Maintenance of Facilities (25.4)	165,000	155,000	-10,000	-6.1
Operation & Maintenance of Equipment (25.7)	3,350,000	3,166,000	-184,000	-5.5
Subsistence & Support of Persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	47,532,000	46,422,000	-1,110,000	-2.3
Supplies and Materials (26.0)	4,184,000	3,922,000	-262,000	-6.3
Subtotal, Non-Pay Costs	53,528,000	52,100,000	-1,428,000	-2.7
Total, Administrative Costs	85,259,000	85,327,000	68,000	0.1

8		Authorizing Legislation	Legislation			65
	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2007 Continuing Resolution	2008 Amount Authorized	Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Eye Institute	Section 402(a)	P.L.109-482	Indefinite	\$666,315,000	Indefinite	\$667,820,000
Total, Budget Authority				666,315,000		667,820,000

**Appropriations History** 

Fiscal	Budget Estimate	House	Senate	
Year	to Congress	Allowance	Allowance	Appropriation <u>1/</u>
1999	\$373,198,000 <u>2/</u>	\$383,447,000	\$395,261,000	395,857,000
Rescission	0	0	0	-262,000
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	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	666,756,000 3/
2008	667,820,000			

 $<sup>\</sup>underline{1}$ / Reflects enacted supplementals, rescissions, and reappropriations.  $\underline{2}$ / Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research

<sup>3/</sup> Annualized current rate

#### NATIONAL INSTITUTES OF HEALTH

#### **National Eye Institute**

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

OFFICE/DIVISION	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Office of the Director	40	40	40
Division of Intramural Research	107	107	109
Division of Epidemiology and Clinical Research	35	38	38
Division of Extramural Research	25	28	28
Total	207	213	215
Includes FTEs which are reimbursed from the NI FTEs supported by funds from Cooperative	H Roadmap fo	or Medical Re	search
Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Aver	age GM/GS (	Grade
2004		12.4	
2005		12.4	
2006		12.5	
2007		12.5	
2008		12.5	

#### **Detail of Positions**

Detail of 1 os	TUOIIS	
FY 2006	FY 2007	FY 2008
	•	Estimate
3	3	3
\$455,373	\$467,400	\$481,500
35	35	35
16	17	17
27	27	27
26	26	26
22	23	23
2	2	2
7	9	10
6	6	6
4	5	5
1	1	1
146	151	152
1	1	1
1 2	1 2	1 2
1 2 2	1 2 2	1 2 2
	_	1 2 2
	_	1 2 2 5
2	2	
5	5	5
5 75	5 76	5 77
5 75 176	5 76 181	5 77 183
5 75 176	5 76 181	5 77 183 237
5 75 176 229	5 76 181 235	5 77 183
2 5 75 176 229 207	5 76 181 235	5 77 183 237 215
	FY 2006 Actual  3 \$455,373  35 16 27 26 22 7 6 4 1	FY 2006 Actual  3 \$455,373  \$467,400  35 16 17 27 26 26 22 23 2 2 7 9 6 4 5 1 1

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