DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

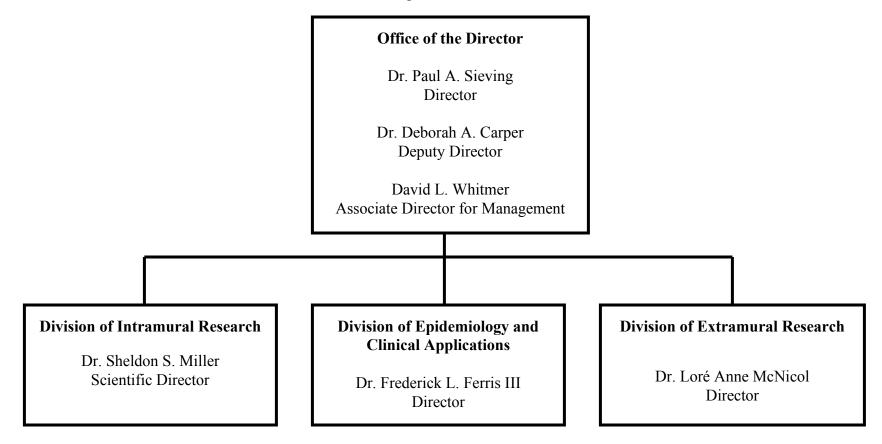
National Eye Institute

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NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Organization Chart



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 \$719,059,000.

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2010 Actual	FY 2011 CR	FY 2012 PB
Appropriation	707,036	707,036	719,059
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	707,036	707,036	719,059
Real transfer under Director's one-percent transfer authority (GEI)	-1,130	0	0
Real transfer under Secretary's one-percent transfer authority	-106	0	0
Comparative Transfers to NLM for NCBI and Public Access	-288	-601	0
Comparative transfer under Director's one-percent transfer authority (GEI)	1,130	0	0
Subtotal, adjusted budget authority	706,642	706,435	719,059
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	706,642	706,435	719,059
Unobligated balance lapsing	0	0	0
Total obligations	706,642	706,435	719,059

¹ Excludes the following amounts for reimbursable activities carried out by this account: FY 2010 - \$16,007 FY 2011 - \$17,060 FY 2012 - \$17,060

Excludes \$3,250 in FY 2010 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Budget Mechanism - Total¹ (Dollars in Thousands)

MECHANISM		2010 ctual		2011 CR		2012 PB	Channer	s. FY 2010
MECHANISM							8	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects	054	¢225.220	014	6217 520	765	\$200 (2 0	(00)	(*********
Noncompeting	854	\$335,229	814	\$317,520	765	\$308,620	(89)	(\$26,609)
Administrative Supplements	30	3,267	30	3,280	31	3,390	1	123
Competing: Renewal	115	48,938	130	51 411	143	57 205	28	0 457
New	115	,		51,411	-	57,395	28 33	8,457
	133	47,470 0	150 0	59,458 0	166 0	66,224 0	55 0	18,754
Supplements	-		-	-	-	÷	-	0
Subtotal, Competing	248	\$96,408	280	\$110,869	309	\$123,619	61	\$27,211
Subtotal, RPGs	1,102	\$434,904	1,094	\$431,669	1,074	\$435,629	(28)	\$725
SBIR/STTR	51	\$17,302	51	\$17,248	52	\$17,554	1	\$252
Research Project Grants	1,153	\$452,206	1,145	\$448,917	1,126	\$453,183	(27)	\$977
Research Centers								
	40	\$27 (04	40	\$27.604	40	\$27.990	0	\$276
Specialized/Comprehensive Clinical Research	40	\$27,604 0	40	\$27,604 0	40	\$27,880	0	\$270
	-	0	-		-	0	0	
Biotechnology	0		0	0	0	0	0	0
Comparative Medicine	-	150	-	150		150		
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	40	\$27,754	40	\$27,754	40	\$28,030	0	\$276
Other Research								
Research Careers	64	\$12,797	64	\$13,053	65	\$13,184	1	\$387
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	33	50,127	33	50,127	33	50.628	0	501
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	18	12,059	18	12,059	18	12,180	0	121
Other Research	115	\$74,983	115	\$75,239	116	\$75,992	1	\$1.009
Total Research Grants	1,308	\$554,943	1,300	\$551,910	1,282	\$557,205	(26)	\$2,262
			,		,			
Research Training	FTTPs		FTTPs		FTTPs			
Individual Awards	67	\$3,042	67	\$3,103	67	\$3,227	0	\$185
Institutional Awards	187	7,368	187	7,515	187	7,816	0	448
Total Research Training	254	\$10,410	254	\$10,618	254	\$11,043	0	\$633
Research & Development Contracts	43	\$45,900	44	\$46,371	44	\$52,299	1	\$6,399
(SBIR/STTR)	43	\$43,900 \$34	0	\$185	0	\$185	0	\$151
(SDIN/STTK)	0	\$54	0	\$105	0	\$105	0	<i>\$151</i>
	FTEs		FTEs		FTEs		FTEs	
Intramural Research	169	\$71,529	169	\$72,960	169	\$73,690	0	\$2,161
Research Management and Support	81	23,860	82	24,576	82	24,822	1	962
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NEI	250	\$706,642	251	\$706,435	251	\$719,059	1	\$12,417

1. All items in italics are "non-adds"; items in parenthesis are subtractions

Major Changes in the Fiscal Year 2012 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 2012 budget request for NEI, which is \$12.417 million more than the FY 2010 level, for a total of \$719.059 million.

<u>Research Project Grants (+\$0.977 million, total \$453.183 million):</u> NEI will support a total of 1,126 Research Project Grants (RPGs) in FY 2012. Noncompeting RPGs will decrease by 89 awards and decrease by \$26.609 million. Competing RPGs will increase by 61 awards and increase by \$27.211 million. The NIH budget policy for RPGs in FY 2012 includes 1% inflationary increases in noncompeting awards and in the average cost for competing RPGs.

<u>Research Training (+\$0.633 million, total \$11.043 million):</u> NIH will provide an increase of 4% for stipends levels under the Ruth L. Kirschstein National Research Service Award training program to continue efforts to attain the stipend levels recommended by the National Academy of Sciences. This will build on the 2% increase in stipend levels for FY 2011. Stipend levels were largely flat for several years, and the requested increase will help to sustain the development of a highly qualified biomedical research workforce.

<u>Research and Development Contracts (+\$6.399 million, total \$52.299 million):</u> Funds are included in R&D contracts to reflect NEI's share of NIH-wide funding required to support several trans-NIH initiatives, such as the Therapies for Rare and Neglected Diseases program, the Basic Behavioral and Social Sciences Opportunity Network (OppNet), and support for a new synchrotron at the Brookhaven National Laboratory. For example, each IC that will benefit from the new synchrotron will provide funding to total NIH's commitment to support this new technology--\$10 million.

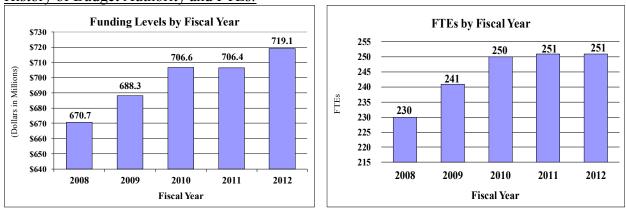
NATIONAL INSTITUTES OF HEALTH National Eye Institute Summary of Changes (Dollars in Thousands)

FY 2010 Actual FY 2012 Estimate				\$706,642 719,059
Net change				\$12,417
0		2012 timate	Change fi	rom FY 2010
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January				
2010 pay increase		\$27,393		\$165
b. January FY 2012 pay increase		27,393		0
c. One less day of pay (n/a for 2011)		27,393		(106)
d. Payment for centrally furnished services		11,246		111
e. Increased cost of laboratory supplies,				
materials, and other expenses		35,051		344
Subtotal				\$514
2. Research Management and Support:				
a. Annualization of January				
2010 pay increase		\$11,346		\$68
b. January FY 2012 pay increase		11,346		0
c. One less day of pay (n/a for 2011)		11,346		(44)
d. Payment for centrally furnished services		4,165		41
e. Increased cost of laboratory supplies,				
materials, and other expenses		9,311		91
Subtotal				\$156
Subtotal, Built-in				\$670

Summary of Changes--continued

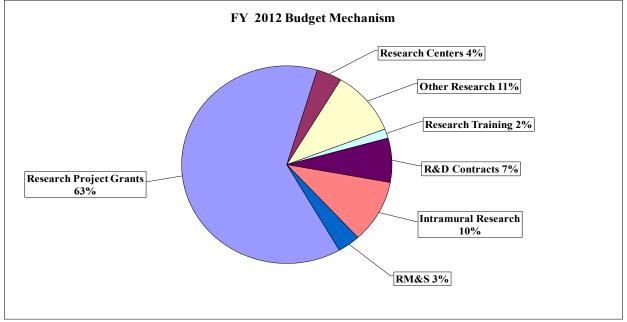
		2012 stimate	Change from FY 2010		
CHANGES	No.	Amount	No.	Amount	
B. Program:			1.00	111104110	
1. Research Project Grants:					
a. Noncompeting	765	\$312,010	(89)	(\$26,486)	
b. Competing	309	123,619	61	27,211	
c. SBIR/STTR	52	17,554	1	252	
Total	1,126	\$453,183	(27)	\$977	
2. Research Centers	40	\$28,030	0	\$276	
3. Other Research	116	75,992	1	1,009	
4. Research Training	254	11,043	0	633	
5. Research and development contracts	44	52,299	1	6,399	
Subtotal, Extramural		\$620,547		\$9,294	
	<u>FTEs</u>		<u>FTEs</u>		
6. Intramural Research	<u>11123</u> 169	\$73,690	0	1,647	
7. Research Management and Support	82	24,822	1	806	
8. Construction		0		0	
9. Buildings and Facilities		0		0	
Subtotal, program	251	\$719,059	1	\$11,747	
Total changes		\$719,059		\$12,417	

Fiscal Year 2012 Budget Graphs

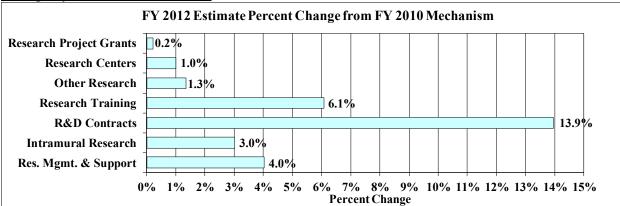


History of Budget Authority and FTEs:

Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Budget Authority by Activity (Dollars in thousands)

	FY 2010 Actual			2011 CP		2012 PD	Chan FY 2	0
	А	ctual	CR		PB		FY 2	.010
Extramural Research	FTEs	Amount	FTEs	Amount	<u>FTEs</u>	<u>Amount</u>	FTEs	Amount
Detail:								
Retinal Disease Research		\$272,317		\$271,268		\$276,458		\$4,141
Corneal Diseases, Cataract,								
and Glaucoma Research		174,370		173,698		177,020		2,650
Sensorimotor Disorders, Visual Processing,								
and Rehabilitation Research		164,566		163,933		167,069		2,503
Subtotal, Extramural		\$611,253		\$608,899		\$620,547		\$9,294
Intramural Research	169	\$71,529	169	\$72,960	169	\$73,690	0	\$2,161
Research Management & Support	81	\$23,860	82	\$24,576	82	\$24,822	1	\$962
TOTAL	250	\$706,642	251	\$706,435	251	\$719,059	1	\$12,417

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2011 Amount Authorized	FY 2010 Estimate	2012 Amount Authorized	FY 2012 PB
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
	Section 401(a)	42§281	Indefinite	\$706,642,000	Indefinite	\$719,059,000
National Eye Institute						
Total, Budget Authority				\$706,642,000		\$719,059,000

NEI-11

Appropriations History

Fiscal	Budget Estimate to			
Year	Congress	House Allowance	Senate Allowance	Appropriation
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	\$667,166,000
Rescission				\$0
2008	\$667,820,000	\$677,039,000	\$681,962,000	\$678,978,000
Rescission				(\$11,862,000)
Supplemental				\$3,548,000
2009	\$667,764,000	\$690,721,000	\$687,346,000	\$688,276,000
Rescission				\$0
2010	\$695,789,000	\$713,072,000	\$700,158,000	\$707,036,000
Rescission				\$0
2011	\$724,360,000		\$723,220,000	
Rescission				
2012	\$719,059,000			

Justification of Budget Request

National Eye Institute

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

Budget Authority (BA):

		FY 2011	FY 2012	
	FY 2010	Continuing	Budget	FY 2012 + / -
	Actual	Resolution	Request	FY 2010
BA	\$706,642,000	\$706,435,000	\$719,059,000	\$12,417,000
FTE	250	251	251	1

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The National Eye Institute (NEI) was established by Congress in 1968 to protect and prolong the vision of the American people. NEI research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages. NEI supports vision research through approximately 1,600 research grants and training awards made to scientists at more than 250 medical centers, hospitals, and universities across the country and around the world. NEI also conducts laboratory and patient-oriented research at its own facilities located on the NIH campus in Bethesda, Maryland.

Accelerating Discovery with New Technologies

The causes of common diseases are complex in that there are potentially many different environmental factors and genetic variants that can contribute to disease. New technologies such as genome-wide association studies (GWAS) allow investigators to scan the genomes of patients to identify genetic risk variants for common diseases. Individually, each of these variants may only contribute to a small percentage of cases, so GWAS often require many subjects to identify low frequency risk variants. In the largest GWAS study in vision research to date, NEI investigators recently sequenced DNA from over 18,000 patients and control subjects and identified three new genes associated with age-related macular degeneration (AMD), the most common cause of vision loss in older Americans. Two of these genes are involved with highdensity lipoprotein cholesterol metabolism, implicating a new biochemical pathway involved in the pathogenesis of AMD. These findings will allow researchers to better understand the disease mechanisms underlying AMD and develop therapies that address the root cause of vision loss.

In FY 2010, NEI established the NEI Glaucoma Human Genetics Collaboration (NEIGHBOR), a consortium of clinicians and geneticists at 12 institutions throughout the U.S. dedicated to identifying the genetics of glaucoma. NEIGHBOR has collected and is now sequencing 6000

DNA samples for large-scale GWAS. The data from these DNA samples are expected to be released to the vision research community in 2011.

Refractive errors (nearsightedness and farsightedness) are the leading cause of vision impairment in the world, affecting an estimated two billion people and growing. Severe nearsightedness increases the risk of other sight-threatening conditions such as retinal detachment, macular degeneration, cataract, and glaucoma. Although refractive error is heritable, no genes have been identified yet. Two recent GWAS studies involving over 15,000 subjects identified a susceptibility locus for refractive errors on chromosome 15 that may harbor regulatory elements for two genes expressed in the retina. The next step is to study the role of these genes in refractive error with the ultimate goals of understanding the causes of refractive error and developing preventative treatments.

Therapeutic Development Pipeline

Positive results of ongoing clinical trials of gene therapy for Leber congenital amaurosis, a severe, early onset retinal disease, have encouraged applications of this approach to many other eye diseases. In the past year, NEI investigators demonstrated proof-of-concept of gene therapy in animal models of AMD, achromatopsia, Leber's hereditary optic neuropathy, retinitis pigmentosa, and red-green color blindness. Previous work has established the utility of gene therapy in juvenile retinoschisis, optic neuritis, and Stargardt disease. These studies now allow investigators to conduct the pre-clinical work necessary to pursue regulatory approval for clinical trials. In addition, novel gene delivery systems, such as the use of nanoparticles, have shown promise in animal models. Such vectors will be helpful in expanding the reach of gene therapy to target a variety of ocular tissues such as ganglion and photoreceptor cell layers.

Clinical Trials of Comparative Effectiveness

Diabetic macular edema (DME) is a common sight-threatening complication of diabetes in which fluid from leaky blood vessels causes the retina to swell. For the past 25 years, DME has been treated with a laser to destroy abnormal blood vessels. Although laser therapy slows disease progression, the effects are temporary, and repeated treatments can damage healthy retinal tissue and impair vision. In recent years, ophthalmologists have been supplementing laser treatment with ocular injections of either ranibizumab, a drug that prevents blood vessel growth, or triamcinolone, a corticosteroid to reduce inflammatory complications. An ongoing clinical trial comparing the safety and efficacy of these two drugs is being conducted by the NEI-supported Diabetic Retinopathy Clinical Research Network (DRCR.net). After one year, ranibizumab + laser treatment was superior in both safety and efficacy to triamcinolone + laser or to laser alone. The triamcinolone treatment group also experienced a far greater incidence of cataract and glaucoma. This landmark clinical trial identified the first new safe and effective treatment regimen for DME in more than two decades. In addition, the study demonstrated that intravitreal triamcinolone, which had been used in 60 percent of patients with DME, had significant side effects and was not better than laser alone. These results are already being used by community ophthalmologists to greatly improve the quality of life for people living with diabetes.

The treatment of cataracts in infants is challenging for pediatric ophthalmologists and parents. Removing and substituting for the opaque lens is critical to preventing permanent loss of vision in the eye. Contact lenses have been the preferred method to overcome the loss of the natural lens. However, it is difficult and stressful for parents to insert a contact lens into an infant's eye. Surgical implantation of intraocular lenses (IOLs) in adults is common but had not been fully characterized in infants. An NEI-supported clinical trial found no difference in visual acuity with contact lenses compared to IOLs at one year after cataract removal. However, IOLs caused significant numbers of surgical complications. Based on these results, the use of contact lenses has been determined to be the safest effective treatment for infants with cataract.

New Ideas and New Investigators in Vision Research

In 2011, NEI will renew its national plan to identify current needs, gaps, and opportunities in research to improve eye health. NEI is reinvigorating its strategic planning process which consists of three new components: 1) assembling expert panels in all six major program areas to develop a national plan; 2) developing an implementation guide to describe NEI operations, policies, and priorities; and 3) periodically convening workshops that address emerging needs and opportunities in vision research. A recent multidisciplinary NEI workshop on Ocular Pain and Sensitivity was the first in this series. Experts in ocular surface disease met with experts in pain and sensitivity in more thoroughly studied non-ocular tissues (e.g., itch in skin; headache pain; burning mouth) in order to gain knowledge about the neural mechanisms of pain. A workshop report has been posted to the NEI Web site. These workshops will draw attention to emerging scientific and clinical needs, identify emerging biomedical research areas, and attract new investigators into vision research.

<u>Overall Budget Policy</u>: The FY 2012 request for NEI is \$719.059 million, an increase of \$12.417 million or 1.8% over the FY 2010 Actual level. NEI will continue to support new investigators and to maintain an adequate number of competing RPGs. NEI will provide a 1% inflationary increase for non-competing and competing grants, and continue funding the highest quality investigator-initiated research as evaluated through the peer review system.

Program Descriptions and Accomplishments

Retinal Diseases Research: The light-sensitive retina 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 are to increase the understanding of 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. NEI investigators have identified gene variants for many of these diseases and have made significant progress in discovering the underlying biological mechanisms of vision loss. With this knowledge, efforts are now increasingly focused on translational research to advance novel gene-based therapies to clinical trials.

<u>Budget Policy</u>: The FY 2012 budget estimate for these activities is \$276.458 million, an increase of \$4.141 million or 1.5% over the FY 2010 Actual. FY 2012 program plans will focus on an acceleration of research on the genetic and environmental basis for AMD, including the role of possible immunological factors. This effort will include meta-analysis 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 gene transfer, stem cell biology, photosensitive replacement molecules, and visual prostheses. Research will continue in efforts to control abnormal blood vessel growth (angiogenesis) in several eye diseases. Program plans also include the continuation of the Age-Related Eye Disease Study 2 (AREDS2), a multi-center study to evaluate the use of additional oral supplements for the treatment of AMD and cataract. NEI will also support an ocular follow-up study of patients in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial to gain important information on the long-term progression of diabetic retinopathy.

Program Portrait: Translational Research Expansion

FY 2010 Level: \$5.4 million FY 2012 Level: <u>\$6.3 million</u> Change: \$0.9 million

NEI investigators have made significant progress in understanding underlying disease mechanisms that result in vision loss and have established proof-of-concept in animal models for several novel therapies. NEI is enhancing its translational research program by increasing support of a grant mechanism, the R24, specifically designed to support collaborative, multidisciplinary research programs focused on new therapeutic approaches such as gene therapy, pharmacological approaches, and development of appropriate delivery systems.

New blood vessel growth, or neovascularization, is an important developmental process, but abnormal neovascularization is a common cause of vision loss in diabetic retinopathy and age-related macular degeneration. Inhibition of neovascularization in these diseases prevents catastrophic vision loss by preventing complications such as ocular hemorrhage and edema. NEI investigators have discovered a naturally occurring enzyme with potent anti-neovascularization as well as to develop a drug delivery system for use in clinical trials. Work supported by two other R24 awards will be evaluating small molecules to treat Stargardt disease, an early onset form of macular degeneration. Stargardt disease results from a defect in the visual cycle, the set of chemical interactions that convert light into an electrical signal that is then processed by the brain. This defect leads to accumulation of harmful vitamin A by-products in the retina. One grant is evaluating a compound that slows the visual cycle to limit the accumulation of vitamin A metabolites. It is thought that this approach could result in long-term preservation of vision. A second grant proposes to screen small molecules for their therapeutic potential and to develop a gene transfer technique for treatment of Stargardt disease.

Corneal Diseases, Cataract, and Glaucoma Research: Corneal diseases, cataract, and glaucoma cause more visits to ophthalmologists than any other vision disorders. Corneal injuries, infections, and diseases can be extremely painful and require immediate medical attention. NEI grantees are exploring how infectious, inflammatory, and immunological processes affect the cornea, and how the cornea heals after a wound. Important proteins that promote and deter wound healing have been identified, providing an opportunity to develop therapies that prevent or ameliorate corneal disease. Worldwide, cataracts are the leading cause of blindness. NEI cataract research seeks to understand the physiological basis of lens transparency at the cellular and molecular levels and investigates strategies to prevent cataract formation and progression. Glaucoma is a blinding disease that most often results from increased intraocular pressure. NEI investigators aim 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.

<u>Budget Policy</u>: The FY 2012 budget estimate for these activities is \$177.020 million, an increase of \$2.650 million or 1.5% over the FY 2010 Actual. FY 2012 program plans 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. NEI will continue to fund projects that study the cellular, biochemical, biophysical and molecular bases of lens transparency and its relation to cataractogenesis. Furthermore, proteins highly enriched in the ocular lens (such as crystallins, connexins, and aquaporins) will continue to be investigated with a particular focus on their role in cataract development. NEI expects to fund new projects to identify therapeutic approaches to limit and/or reduce corneal pain. Projects will be funded to examine the possible contribution of defects in gap junctions in the development of cataracts. Genome wide association studies and related bioinformatics efforts will continue to explore the role of genetics and the environment on the development of glaucoma and to understand better the differential response of individuals to glaucoma medications. Other projects will relate to optic nerve regeneration and functional re-connection of the injured optic nerve to the brain.

Program Portrait: Pluripotent Stem Cells in Ocular Regenerative Medicine

FY 2010 Level: \$0.0 million FY 2012 Level: <u>\$1.0 million</u> Change: \$1.0 million

Regenerative medicine is an emerging field that holds promise to restore lost vision due to injury or disease. Many of the leading causes of visual impairment and blindness are due in part to the loss of photoreceptor cells in the retina or either a loss of cells or opacities in the normally transparent cornea. While there is some evidence that embryonic retinal cells can differentiate into photoreceptors, thus far they do not integrate well with the host retina and are not yet suitable for therapeutic use. Likewise, although stem cells derived from the outer ring of the corneal epithelium have had limited success in replacing damaged corneal tissue, more research is needed to expand the utility of stem cells in generating replacements for the corneal epithelium and other layers of the cornea.

NEI plans to augment its existing regenerative medicine portfolio. Applications will be solicited to 1) encourage research to better understand the factors that promote differentiation of pluripotent stem cells into retinal and corneal cells; 2) promote methods to create *in vitro* cell cultures that facilitate self-renewal and differentiation of these stem cells as possible sources for transplantation; and 3) foster the discovery of factors that direct stem cells to the target tissue and promote their integration in order to repair/treat the retina or the cornea.

Sensorimotor Disorders, Visual Processing, and Rehabilitation Research: Strabismus (misalignment of the eyes) and amblyopia (known as "lazy eye") are common disorders that develop during childhood. Program goals center on gaining a better understanding of the neuromuscular control of gaze and the development of the visual system in children at high risk for these disorders. Refractive errors, such as nearsightedness, farsightedness, and astigmatism, are commonly correctable with eye glasses or contact lenses in the United States, but remain a tremendous economic and personal burden globally. Major goals of this program are to discover 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 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. Low vision is the term used to describe chronic visual conditions that are not correctable by eye glasses or contact lenses. 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.

<u>Budget Policy</u>: The FY 2012 budget estimate for these activities is \$167.069 million, an increase of \$2.503 million or 1.5% over the FY 2010 Actual. FY 2012 program plans include pursuing research to identify genetic risk factors for strabismus, myopia, and other ocular diseases. Gene therapy trials are underway for treating Leber's Hereditary Optic Neuropathy, an inherited disease that frequently results in a substantial loss of central vision. The Neuro-Ophthalmology Research Disease Investigator consortium will expand to include many new sites in order to facilitate patient recruitment and the conduct of clinical trials. Investigators will also pursue new findings about how the activity of certain brain cells allows us to perceive faces and objects and allow us to provide a stable view of our surroundings despite constant head and eye movements. A better understanding of the rules of visual system development will lead to new strategies for improving binocular vision in amblyopia and for stimulating the recovery of function in other ocular diseases. Further advances are expected in the development of retinal implants and other neural interfaces to provide artificial stimulation of visual pathways and the use of brain electrical activity to control computer displays and robotic arms.

Intramural Research: NEI conducts world-class research programs that explore clinical and translational studies concerned with the cause, prevention, and treatment of major eye diseases and vision disorders; cellular and molecular mechanisms of eye development, including the expression and function of genes within the eye; immunology and infectious diseases of the eye; the mechanisms of visual perception by the brain; and developing a better understanding of our ability to guide movements under sensory control. The National Ophthalmic Disease Genotyping Network (eyeGENE), an NEI intramural collaboration with patients, clinicians, and investigators throughout the United States, has expanded its operations by collecting more than 2200 patient DNA samples. eyeGENE enables patients to receive a genetic diagnosis for many rare eye diseases in exchange for donating DNA samples for research and participating in a clinical trial registry Through this unique collaboration, eyeGENE is enhancing patient care, education and research.

<u>Budget Policy</u>: The FY 2012 budget estimate for these activities is \$73.690 million, an increase of \$2.161 million or 3% over the FY 2010 Actual. In FY 2012, NEI will continue recruiting investigators for the Laboratory of Neurobiology, Neurodegeneration and Repair to integrate basic, pre-clinical, and translation research in developing and testing therapeutic interventions in neurodegenerative eye diseases. NEI is building its capacity in pre-clinical animal model evaluation and development, expanding its Genetic Engineering Facility in support of a new initiative to develop human embryonic stem cells for therapeutic use in retinal degenerative and other ocular diseases, and developing a new animal Visual Function Facility with expertise in electroretinography and optical coherence tomography. NEI is also recruiting for a new laboratory in computational medicine and plans to enhance electroretinography and optical coherence tomography to assess patients in the Ophthalmic Genetics and Visual Function Branch. NEI continues to expand the eyeGENE network to facilitate research on the genetic causes of ocular diseases.

Program Portrait: Bioinformatics Support and Resource Center for Vision Research

FY 2010 Level: \$0.0 million FY 2012 Level: <u>\$3.0 million</u> Change: \$3.0 million

New medical research technologies are evolving rapidly, leading to an exponential increase in the volume of data generated from genomics, proteomics, and metabolomics studies. These data need to be matched to genetic information (genotype) and disease characteristics from patients (phenotype) with eye diseases. The immense quantity of information will require novel and sophisticated mathematical and statistical methods to help uncover the nature of these complex interactions in health and disease.

To meet these challenges, NEI initiated a three-pronged approach this past year with a new institutional training grant that partners vision researchers with statistical and mathematical scientists to train the next generation of vision researchers in computational methods. NEI is also soliciting applications from investigators to develop novel computational and bioinformatics approaches and tools to analyze large data sets of genomic and phenotypic data. To increase availability and accessibility of these data sets, in the coming year NEI plans to establish a bioinformatics resource center for sharing diverse sets of biological data and research tools for vision research. The infrastructure developed under this program will support the various needs and activities of both intramural and extramural vision research scientists and will facilitate computational biology/bioinformatics efforts.

Research Management and Support: Research Management and Support (RMS) sustains, guides, and monitors 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 1,600 grants and contracts, including research project grants, core center grants, research career development awards, cooperative clinical research agreements, and research and development contracts.

<u>Budget Policy</u>: The FY 2012 budget estimate for these activities is \$24.822 million, an increase of \$0.962 million or 4% over the FY 2010 Actual to continue to enhance the activities described above.

Budget Authority by Object

(Dollars in Thousands)

		FY 2010 Actual	FY 2012 PB	Increase or Decrease	Percent Change
Total c	ompensable workyears:				
	Full-time employment	250	251	1	0.4%
	Full-time equivalent of overtime and holiday hours	0	0	0	0.0%
	Average ES colory	\$167	\$167	\$0	0.0%
	Average ES salary	\$167	-	\$0	0.0%
	Average GM/GS grade	12.4	12.4	0.0	0.0%
	Average GM/GS salary	\$102	\$102	\$0	0.0%
	Average salary, grade established by act of				
	July 1, 1944 (42 U.S.C. 207)	\$90	\$90	\$0	0.0%
	Average salary of ungraded positions	123	123	0	0.0%
		FY 2010	FY 2012	Increase or	Percent
	OBJECT CLASSES	Actual	Estimate	Decrease	Change
	Personnel Compensation:				
	Full-time permanent	\$15,038	\$15,164	\$126	0.8%
11.3	·····	11,111	11,149	38	0.3%
11.5	1 1	978	983	5	0.5%
11.7	Military personnel	253	262	9	3.6%
11.8	Special personnel services payments	3,251	3,258	7	0.2%
	Total, Personnel Compensation	\$30,631	\$30,816	\$185	0.6%
	Personnel benefits	\$7,691	\$7,731	\$40	0.5%
12.2	J F	192	192	0	0.0%
13.0	1	0	0	0	0.0%
	Subtotal, Pay Costs	\$38,514	\$38,739	\$225	0.6%
21.0	1 1	\$857	\$935	\$78	9.1%
22.0	Transportation of things	77	83	6	7.8%
23.1	Rental payments to GSA	0	0	0	0.0%
23.2	Rental payments to others	9	9	0	0.0%
23.3	,	505	502	50	11.00/
24.0	miscellaneous charges	525	583	58	11.0%
	Printing and reproduction	70	77 52	7	10.0%
25.1 25.2	Consulting services Other services	46 7,030	52 7,641	6 611	13.0% 8.7%
25.2		7,030	7,041	011	0./70
25.5	government accounts	57,008	64,368	7,360	12.9%
25.4	Operation and maintenance of facilities	1,085	1,189	104	9.6%
	Research and development contracts	24,595	24,687	92	9.070 0.4%
	Medical care	138	24,087	92	8.0%
	Operation and maintenance of equipment	4,434	4,828	394	8.9%
	Subsistence and support of persons	0	.,020	0	0.0%
25.0	Subtotal, Other Contractual Services	\$94,336	\$102,914	\$8,578	9.1%
26.0		\$4,383	\$4,738	\$355	8.1%
	Equipment	2,516	2,731	215	8.5%
	Land and structures	0	0	0	0.0%
	Investments and loans	0	0	0	0.0%
41.0	Grants, subsidies and contributions	565,353	568,248	2,895	0.5%
42.0		0	0	0	0.0%
43.0	Interest and dividends	2	2	0	0.0%
44.0	Refunds	0	0	0	0.0%
	Subtotal, Non-Pay Costs	\$668,128	\$680,320	\$12,192	1.8%
	Total Budget Authority by Object	\$706,642	\$719,059	\$12,417	1.8%

Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2010 Actual	FY 2012 PB	Increase or Decrease	Percent Change
Personnel Compensation:	Actual	ſD	Decrease	Change
Full-time permanent (11.1)	\$15,038	\$15,164	\$126	0.8%
Other than full-time permanent (11.3)	11,111	11,149	38	0.8%
Other personnel compensation (11.5)	978	983	50	0.5%
Military personnel (11.7)	253	983 262	5 9	0.3% 3.6%
Special personnel services payments (11.8)	3,251	3,258	9 7	0.2%
	,		,	
Total Personnel Compensation (11.9)	\$30,631	\$30,816	\$185	0.6%
Civilian personnel benefits (12.1)	\$7,691	\$7,731	\$40	0.5%
Military personnel benefits (12.2)	192	192	0	0.0%
Benefits to former personnel (13.0)	0	0	0	0.0%
Subtotal, Pay Costs	\$38,514	\$38,739	\$225	0.6%
Travel (21.0)	\$857	\$935	\$78	9.1%
Transportation of things (22.0)	77	83	6	7.8%
Rental payments to others (23.2)	9	9	0	0.0%
Communications, utilities and				
miscellaneous charges (23.3)	525	583	58	11.0%
Printing and reproduction (24.0)	70	77	7	10.0%
Other Contractual Services:				
Advisory and assistance services (25.1)	46	52	6	13.0%
Other services (25.2)	7,030	7,641	611	8.7%
Purchases from government accounts (25.3)	37,773	39,114	1,341	3.6%
Operation and maintenance of facilities (25.4)	1,085	1,189	104	9.6%
Operation and maintenance of equipment (25.7)	4,434	4,828	394	8.9%
Subsistence and support of persons (25.8)	0	0	0	0.0%
Subtotal Other Contractual Services	\$50,368	\$52,824	\$2,456	4.9%
Supplies and materials (26.0)	\$4,330	\$4,681	\$351	8.1%
Subtotal, Non-Pay Costs	\$56,236	\$59,192	\$2,956	5.3%
Total, Administrative Costs	\$94,750	\$97,931	\$3,181	3.4%

Details of Full-Time Equivalent Employment (FTEs)

		FY 2010			FY 2011			FY 2012	
		Actual			CR			PB	
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director	79	3	82	80	3	83	80	3	83
Division of Intramural Research Programs	125	0	125	125	0	125	125	0	125
Division of Epidemiology and Clinical Applications	12	0	12	12	0	12	12	0	12
Division of Extramural Research	31	0	31	31	0	31	31	0	31
Total	247	3	250	248	3	251	248	3	251
Includes FTEs which are reimbursed from the NIH Common Fu	nd for Medica	l Research							
FTEs supported by funds from Cooperative Research and Development Agreements	0	0							0
Development Agreements	0	0							0
FISCAL YEAR				Av	erage GS Gra	ade			
2008					12.0				
2009					12.1				
2010		12.4							
2011					12.4				
2012					12.4				

Detail of Positions

GRADE	FY 2010	FY 2011	FY 2012 PB
Total, ES Positions	Actual 1	CR	ГБ
Total, ES Salary	167	167	167
GM/GS-15	35	36	36
GM/GS-14	18	18	18
GM/GS-13	29	29	29
GS-12	26	26	26
GS-11	35	35	35
GS-10	0	0	0
GS-9	10	10	10
GS-8	5	5	5
GS-7	4	4	4
GS-6	1	1	1
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	163	164	164
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	2	2	2
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	3	3	3
Ungraded	87	87	87
Total permanent positions	165	166	166
Total positions, end of year	254	255	255
Total full-time equivalent (FTE)			
employment, end of year	250	251	251
Average ES salary	167	167	167
Average GM/GS grade	12.4	12.4	12.4
Average GM/GS salary	102	102	102

New Positions Requested

		FY 2012		
	Grade	Number	Annual Salary	
Health Science Administrator, Translational Research	GS-15	1	\$150,000	
Total Requested		1	\$150,000	