

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

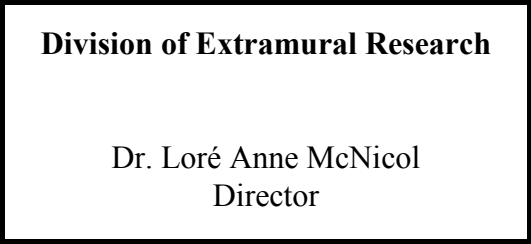
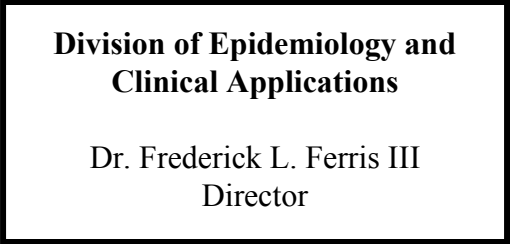
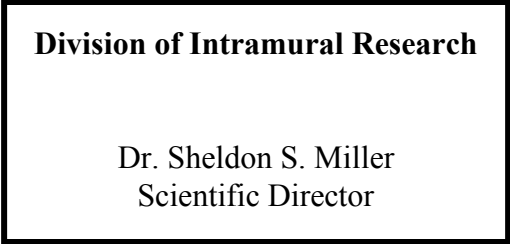
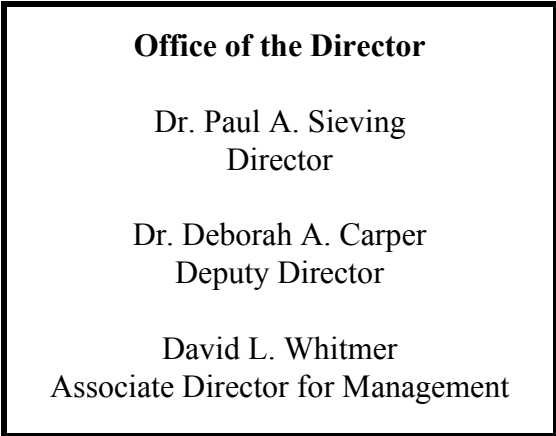
National Eye Institute (NEI)

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NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Organization Chart



NEI-2

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, \$699,216,000.

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Amounts Available for Obligation ¹
(Dollars in Thousands)

Source of Funding	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Appropriation	704,043	707,013	699,216
Rescission	(1,331)	0	0
Subtotal, adjusted appropriation	702,712	707,013	699,216
Secretary's Transfer for Alzheimer disease (AD)	(463)	0	0
Secretary's Transfer for AIDS authorized by PL 112-74, Section 206	(200)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(642)	(832)	0
Subtotal, adjusted budget authority	701,407	706,181	699,216
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	701,407	706,181	699,216
Unobligated balance lapsing	(57)	0	0
Total obligations	701,350	706,181	699,216

¹ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2012 - \$15,697 FY 2013 - \$17,020 FY 2014 - \$17,020

NATIONAL INSTITUTES OF HEALTH
National Eye Institute
Budget Mechanism - Total ¹
(Dollars in Thousands)

MECHANISM	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
<u>Research Projects</u>								
Noncompeting	754	\$299,295	757	\$311,294	770	\$320,965	16	\$21,670
Administrative Supplements	(97)	14,236	(80)	11,522	(33)	4,810	-(64)	-9,426
Competing:								
Renewal	130	56,305	128	55,387	115	46,482	-15	-9,823
New	165	63,318	163	62,286	146	59,191	-19	-4,127
Supplements	1	49	0	0	0	0	-1	-49
Subtotal, Competing	296	\$119,673	291	\$117,673	261	\$105,673	-35	-\$14,000
Subtotal, RPGs	1,050	\$433,203	1,048	\$440,489	1,031	\$431,448	-19	-\$1,755
SBIR/STTR	46	17,997	48	18,829	50	19,466	4	1,469
Research Project Grants	1,096	\$451,200	1,096	\$459,318	1,081	\$450,914	-15	-\$286
<u>Research Centers</u>								
Specialized/Comprehensive	40	30,169	40	30,169	38	29,169	-2	-1,000
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	144	0	0	0	0	0	-144
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	40	\$30,313	40	\$30,169	38	\$29,169	-2	-\$1,144
<u>Other Research</u>								
Research Careers	67	13,203	67	13,204	67	13,203	0	0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	38	47,884	35	41,884	35	41,885	-3	-5,999
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	14	10,472	17	12,473	17	12,472	3	2,000
Other Research	119	\$71,560	119	\$67,561	119	\$67,560	0	-\$4,000
Total Research Grants	1,255	\$553,074	1,255	\$557,048	1,238	\$547,643	-17	-\$5,431
<u>Ruth L. Kirschstein Training Awards</u>	<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>	
Individual	70	3,387	70	3,387	70	3,495	0	108
Institutional	178	7,543	178	7,543	178	7,543	0	0
Total Research Training	248	\$10,930	248	\$10,930	248	\$11,038	0	\$108
Research & Development Contracts	43	39,869	43	40,668	40	43,000	-3	3,131
<i>SBIR/STTR (non-add)</i>	<i>(0)</i>	<i>(38)</i>	<i>(0)</i>	<i>(25)</i>	<i>(0)</i>	<i>(25)</i>	<i>(0)</i>	<i>-(13)</i>
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural Research	180	72,960	184	72,960	184	72,960	4	0
Research Management and Support	83	24,575	93	24,575	93	24,575	10	0
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NEI	263	\$701,407	277	\$706,181	277	\$699,216	14	-\$2,191

¹ All items in italics and brackets are "non-adds."

Major Changes in the Fiscal Year 2014 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanisms and activity detail and these highlights will not sum to the total change for the FY 2014 President's Budget for NEI, which is \$2.2 million less than the FY 2012 level, for a total of \$699.2 million.

Research Project Grants (-\$0.286 million, total \$450.914 million):

NEI will support a total of 1,081 Research Project Grants (RPGs) in FY 2014. Noncompeting RPGs will increase by 16 awards and increase by \$21.670 million. Competing RPG awards will decrease by 35 awards and decrease by \$14.0 million. SBIR/STTR RPGs will increase by 4 awards and increase by \$1.469 million. NIH budget policy for RPGs in FY 2014, continues FY 2012 policy of eliminating inflationary increases for future year commitments. However, adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.

Other Research (-\$4.000 million, total \$67.560 million):

The NIH Office of AIDS Research has supported a series of NEI-sponsored clinical trials known collectively as the Studies of the Ocular Complications of AIDS (SOCA). These trials established the efficacy of combination antiviral drug therapy in treating cytomegalovirus (CMV) retinitis, a sight-threatening complication of advanced AIDS. With the advent of Highly Active Antiretroviral Therapy (HAART) for AIDS, the incidence of CMV retinitis dropped drastically. Further SOCA studies established that patients presenting with advanced AIDS can stop CMV retinitis treatment once HAART treatment has improved immune function. The successful development of drug therapies for CMV retinitis and the further elimination of this ocular infection due to HAART end a successful chapter in the fight against AIDS. With the conclusion of SOCA studies, the Office of AIDS Research will no longer need to contribute to NEI AIDS studies.

Research Training (+\$0.108 million, total \$11.038 million):

Support for NRSA training mechanism will be increased by \$0.108 million to cover the cost of increased stipends. The Ruth L. Kirschstein NRSA budget reflects a stipend increase to \$42,000 for the entry level postdoctoral trainees and fellows along with 4 percent increases for each subsequent level of experience. These increases are consistent with stipend increases recommended by the Advisory Committee to the NIH Director and the National Research Council. In addition, this increase is consistent with 42 USC 288(b)(5), which anticipates periodic adjustments in stipends to reflect increases in the cost of living.

Research and Development Contracts (+\$3.131 million, total \$43.000 million):

Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

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

FY 2012 Actual				\$701,407
FY 2014 President's Budget				\$699,216
Net change				-\$2,191
CHANGES	2014 President's Budget		Change from FY 2012	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of March 2013 pay increase & benefits		\$29,885		\$77
b. January FY 2014 pay increase & benefits		29,885		220
c. One more day of pay		29,885		113
d. Differences attributable to change in FTE		29,885		0
e. Payment for centrally furnished services		12,466		223
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		30,609		82
Subtotal				\$715
2. Research Management and Support:				
a. Annualization of March 2013 pay increase & benefits		\$13,967		\$38
b. January FY 2014 pay increase & benefits		13,967		103
c. One more day of pay		13,967		53
d. Differences attributable to change in FTE		13,967		0
e. Payment for centrally furnished services		3,474		70
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		7,134		2
Subtotal				\$267
Subtotal, Built-in				\$982

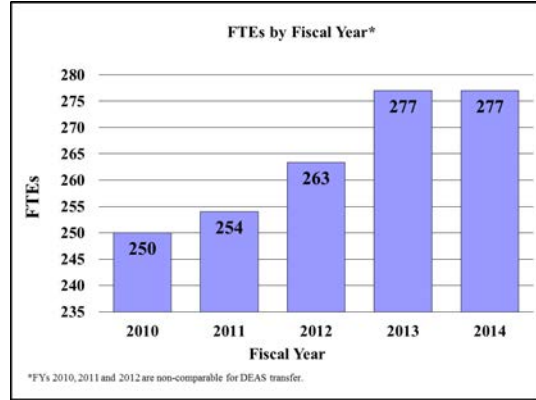
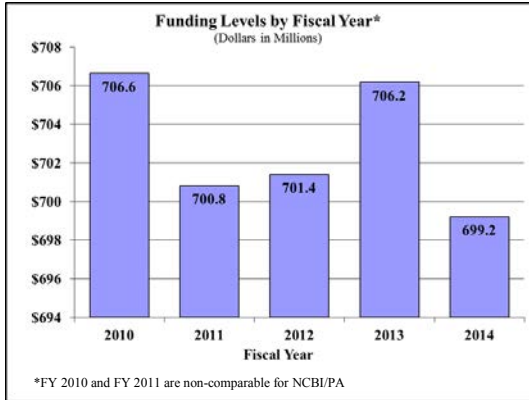
**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Summary of Changes--continued

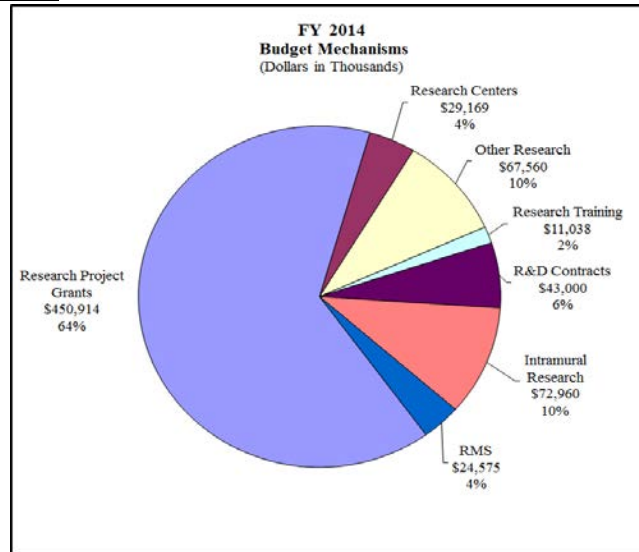
CHANGES	2014 President's Budget		Change from FY 2012	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	770	\$325,775	16	\$12,244
b. Competing	261	105,673	-35	-14,000
c. SBIR/STTR	50	19,466	4	1,469
Total	1,081	\$450,914	-15	-\$287
2. Research Centers	38	\$29,169	-2	-\$1,144
3. Other Research	119	67,560	0	-4,000
4. Research Training	248	11,038	0	108
5. Research and development contracts	40	43,000	-3	3,131
Subtotal, Extramural		\$601,681		-\$2,192
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural Research	184	\$72,960	4	-\$715
7. Research Management and Support	93	24,575	10	-266
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	277	\$699,216	14	-\$3,173
Total changes				-\$2,191

Fiscal Year 2014 Budget Graphs

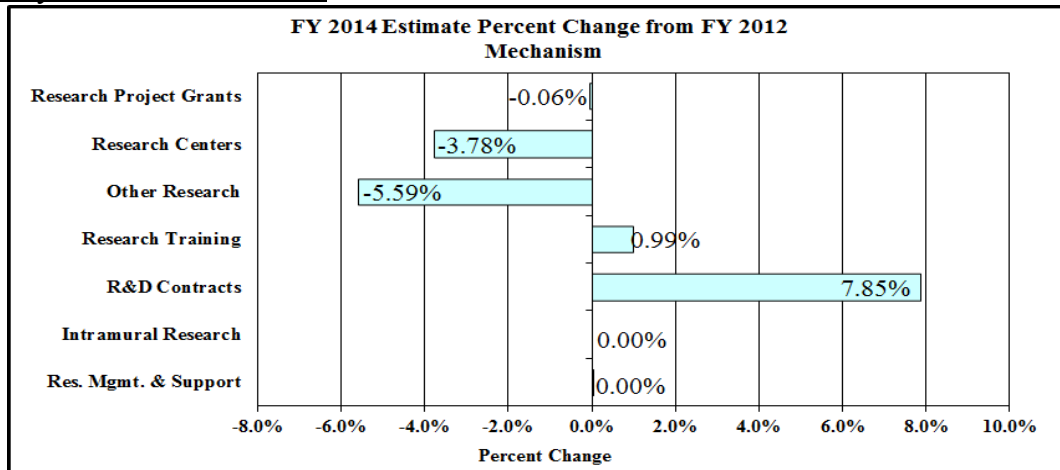
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Eye Institute
Budget Authority by Activity^{1,2}
(Dollars in Thousands)

	FY 2012 Actual		FY 2013 CR		FY 2014 PB		Change vs. FY 2012	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research								
<u>Detail:</u>								
Retinal Diseases Research		\$285,195		\$287,450		\$284,161		-\$1,034
Corneal Diseases, Cataract, and Glaucoma Research		173,319		174,689		172,689		-\$630
Sensorimotor Disorders and Rehabilitation Research		145,358		146,507		144,831		-\$527
Subtotal, Extramural		\$603,872		\$608,646		\$601,681		(\$2,191)
Intramural Research	180	\$72,960	184	\$72,960	184	\$72,960	4	\$0
Research Management & Support	83	\$24,575	93	\$24,575	93	\$24,575	10	\$0
TOTAL	263	\$701,407	277	\$706,181	277	\$699,216	14	(\$2,191)

¹ Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

² Includes Transfers and Comparable Adjustments as detailed in the "Amounts Available for Obligation" table.

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Authorizing Legislation

NEI-11

	PHS Act/ Other Citation	U.S. Code Citation	2013 Amount Authorized	FY 2013 CR	2014 Amount Authorized	FY 2014 PB
Research and Investigation	Section 301	42§241	Indefinite	\$706,181,000	Indefinite	\$699,216,000
National Eye Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$706,181,000		\$699,216,000

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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				-
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				-
2010	\$695,789,000	\$713,072,000	\$700,158,000	\$707,036,000
Rescission				-
2011	\$724,360,000	-	\$723,220,000	\$707,036,000
Rescission				(\$6,208,198)
2012	\$719,059,000	\$719,059,000	\$692,938,000	\$704,043,000
Rescission				(\$1,330,641)
2013	\$693,015,000	-	\$695,115,000	-
Rescission				-
2014	\$699,216,000	-	-	-

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 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 +/- FY 2012
BA	\$701,407,000	\$706,181,000	\$699,216,000	-\$2,191,000
FTE	263	277	277	+14

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

Director's Overview

Blinding eye diseases, such as age-related macular degeneration (AMD), diabetic retinopathy, and glaucoma, affect millions of Americans of all ages and ethnicities. These and other less common diseases disable productive careers and rob people of their mobility and independence. NEI supports vision research through over 1,500 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.

Laying the Groundwork for Tomorrow's Medical Breakthroughs

NEI-supported research has made encouraging progress in developing stem cell therapies for common and rare eye diseases. Investigators recently isolated immune cells from human blood samples and created induced pluripotent stem (iPS) cells. The stem cells were manipulated to form structures resembling eye tissues, such as the neural retina and the retinal pigment epithelium (RPE). Since many blinding eye diseases are caused by degeneration of RPE and retinal neurons, it may one day be possible to generate replacement tissues for damaged eyes. Adult, human RPE can also be a source of stem cells. Biologists showed that a subpopulation of RPE cells from donor eyes could be induced to multiply and turn into other cell types, not just eye cells, but also brain, fat, and blood tissues.

The eye is filled with fluid, which is filtered and drained by a tissue at the base of the cornea called the trabecular meshwork. Blocked drainage can lead to elevated intraocular pressure—a key risk factor for glaucoma. Cochlin, a protein of unknown origin, was found in the trabecular meshwork and was shown to aggregate and change physical properties when fluid pressure increased. Using animal models of glaucoma, NEI researchers found that raising or lowering cochlin levels in trabecular cell membranes correlated with changes in intraocular pressure.

These observations suggest that cochlin functions as an ocular mechanical stress sensor to regulate intraocular pressure, and that cochlin is a potential therapeutic target for glaucoma.

Translating Research Into Therapies

NEI-supported investigators have developed a potential new treatment to prevent the most common complication of retinal detachment, a sight-threatening condition that requires prompt surgical treatment. Proliferative retinopathy (PVR) occurs in about 10 percent of retinal detachments, resulting in permanent scarring of the retina. In this condition, RPE cells migrate through the retinal detachment where they rapidly multiply on the surface of the retina. The RPE cells next contract and pull at the retina creating another detachment that results in heavy scarring of the retina and potential blindness. NEI investigators identified seven classes of biological growth factors and regulatory proteins that promote the proliferation and contraction of RPE cells in an animal model of PVR. By inhibiting the expression of these biological factors, the investigators prevented PVR, demonstrating proof-of-concept for a treatment to prevent this serious, sight-threatening complication of retinal detachment.

The cornea, the outer protective layer of the eye, is amazingly resilient to infection. Exposing cultured human corneal cells to bacteria led researchers to identify cytokeratin 6A-derived peptides, previously known to serve only as structural support, as important in corneal defense of bacterial infection. Blocking these peptides in a rodent model led to a marked increase in corneal infections. Synthetic variations of these peptides effectively killed bacteria that lead to flesh-eating disease and strep throat, staph infections, diarrhea, and cystic fibrosis lung infections. The findings could lead to a powerful new class of low-cost antibiotics.

A device that provides sight to the blind may sound like science fiction, but in October 2012 the Argus II Retinal Prosthesis System took a key step toward market approval when an FDA advisory panel voted unanimously (19-0) in favor of the system. Argus II consists of a miniature video camera that is inconspicuously mounted on a pair of sunglasses. A processing unit worn on a belt converts images captured by the camera into electrical impulses that are wirelessly transmitted to a 60-electrode grid implanted in the eye. Users perceive the electrical impulses as patterns of light that produce visual information. The device restores ambulatory vision to people who are blind from retinitis pigmentosa, a retinal degenerative disease. The Argus II, developed by Second Sight, Inc., was made possible through a decade of support from the Department of Energy and NEI.

The Power of Bioinformatics to Solve Vision Science Questions

The surge in high powered computing has enabled scientists to analyze immense amounts of data. Increased computing capacity, coupled with faster and cheaper methods of sequencing DNA, has revolutionized the search for factors that cause complex disease. NEI initiated an institutional research training program in Statistical Genetics and Genome Informatics to help meet a growing need for investigators trained in ophthalmologic computational genomics. Two institutions were awarded grants in FY 2011, and two more grants will be added to the program in FY 2013.

AMD is the leading cause of blindness in the U.S. NEI is proposing a new initiative in FY 2014 that will build on recent advances in genetics, imaging, and clinical testing techniques to identify distinct subgroups and the corresponding molecular mechanisms that cause this complex disease.

Current evidence suggests that there are multiple biologic pathways that lead to the final stage of advanced AMD and vision loss (e.g., vascular, immunologic, and cholesterol). NEI proposes to use new high resolution imaging and visual function measurements combined with patient genetic information to identify AMD subgroups at various stages of the disease. These patients will be eligible to for expedited recruitment into prevention clinical trials and will help clinicians develop appropriate treatment strategies and personalized medicine.

Primary Open Angle Glaucoma (POAG) affects more than 2 million Americans and is the leading cause of blindness among Hispanic and African Americans. This year the NEI Glaucoma Human genetics collaboration (NEIGHBOR) published results from the largest ever glaucoma genome-wide association study, which identified two genetic regions associated with POAG. Current POAG drugs target intraocular pressure, a risk factor that leads to degeneration of the optic nerve in many patients. Significantly, the new genes are associated with neurodegeneration, the common endpoint of different types of glaucoma, opening the door to new avenues of therapy. NEI is now creating the NEIGHBOR Heritable Overall Operational Database consortium, whose goals are to expand the collection of glaucoma cases, to collect exacting clinical data for detailed classifications of POAG phenotypes, and to correlate them with genetic variations of the disease.

Audacious Goals for Vision Research

In 2012, NEI released a new strategic planning report titled *Vision Research: Needs, Gaps, and Opportunities*. The report provides a clear view of the state of vision research and identifies the breadth of the work needed to improve eye health. The plan is useful to clinicians and scientists who are considering applying for NEI support, and it provides confidence to the vision research community, patients, patient-advocacy organizations, and Congress that NEI stewardship of vision research is well-placed. Building on this report, NEI has embarked on a novel strategic planning initiative, *The NEI Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation*. This initiative was created to forge new approaches to persistent challenges in vision research. An audacious goal would fundamentally change research or vision care by closing critical knowledge gaps, opening developmental bottlenecks, or providing key elements to translate scientific discoveries into clinical applications. NEI solicited ideas for audacious goals, not just from vision researchers, but from all scientists, clinicians, and the public through the new prize competition authority, the America COMPETES Reauthorization Act of 2010. Ten winning ideas were selected for further development at the *NEI Audacious Goals Development Meeting* in February, 2013. After two days of discussion and debate, this gathering of more than 150 scientific and clinical experts recommended a set of specific goals for the NEI to consider in establishing a national vision research agenda and inform NEI's research priorities in the coming decade.

Overall Budget Policy: The FY 2014 President's Budget request is \$699.216 million, a decrease of \$2.191 million or 0.3 percent below the FY 2012 Actual level. This budget estimate incorporates an \$8.902 million reduction by the NIH Office of AIDS Research to address trans-NIH strategic planning priorities and evolving scientific advances. NEI will continue to support new investigators and the highest quality of investigator-initiated research as evaluated through the peer review system.

Funds are included in R&D contracts to support trans-NIH initiatives, such as the Basic Behavioral and Social Sciences Opportunity Network (OppNet).

Program Descriptions and Accomplishments

Corneal Diseases, Cataract, and Glaucoma Research: Corneal diseases, cataract, and glaucoma cause more visits to ophthalmologists than any other vision disorders. NEI supports research to address all three conditions.

- *Corneal disease research.* 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.
- *Cataract research.* 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 research.* Glaucoma is a blinding disease that 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.

Budget Policy: The FY 2014 President's Budget estimate for these activities is \$172.70 million, a decrease of \$0.6 million or 0.4 percent below the FY 2012 Actual level. Program plans for FY 2014 include evaluating the possible use of anti-neovascular agents in the treatment of neovascular corneal disease. Results of the 10-year follow-up from Cornea Donor Study, which is comparing the viability of younger and older donor tissue, will be published in the spring of 2013. NEI grantees are studying the role of highly enriched proteins in the ocular lens (crystallins, connexins, and aquaporins) with particular focus on their role in cataract development. NEI-supported 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 the differential response of individuals to glaucoma medications. Other projects include optic nerve regeneration and functional re-connection of the injured optic nerve to the brain.

Sensorimotor Disorders, Visual Processing, and Rehabilitation Research: NEI supports important research in sensorimotor control, visual processing, and rehabilitation for individuals with low vision.

- *Sensorimotor disorder 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.
- *Visual processing research.* Refractive errors, such as nearsightedness, farsightedness, and astigmatism, are commonly correctable with eye glasses or contact lenses in the U.S. 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. NEI-supported vision scientists seek to understand how the brain processes the visual information that floods our eyes, how neural activity is related to visual perception, and how the visual system interacts with cognitive and motor systems.

- *Rehabilitation research.* 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.

Budget Policy: The FY 2014 President's Budget estimate for these activities is \$144.8 million, a decrease of \$0.5 million or 0.4 percent below the FY 2012 Actual level. FY 2014 program plans include pursuing research to identify genetic risk factors for strabismus, myopia, and other ocular diseases. The program also supports the Neuro-Ophthalmology Research Disease Investigator Consortium, a clinical trials network dedicated to diseases of the optic nerve. The Consortium is conducting a clinical trial to evaluate a drug therapy and weight loss in the treatment of idiopathic intracranial hypertension (IIH), which is common in obese women, causes severe headaches and vision loss due to increased pressure on the optic nerve. More than 100,000 Americans suffer with IIH. NEI-supported investigators are also uncovering the neural basis of facial recognition which will ultimately provide an understanding of face-blindness, a condition associated with autism spectrum disorders. Finally, LookTel, an NEI-supported Small Business Innovation Research grantee, has leveraged the power and portability of smart phones to develop and release a novel product that allows the blind and visually impaired to recognize everyday objects by using their iPhone camera. Users capture an image of an item and record an audio description. The LookTel Recognizer will then immediately recognize the item and play the audio description the next time the phone camera is pointed at it.

Retinal Diseases Research: The light-sensitive retina is susceptible to many sight-threatening conditions, including age-related macular degeneration (AMD), diabetic retinopathy, retinopathy of prematurity, retinitis pigmentosa, Usher's syndrome, ocular albinism, retinal detachment, and uveitis (inflammation). 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.

Budget Policy: The FY 2014 President's Budget estimate for these activities is \$284.2 million, a decrease of \$1.0 million or 0.4 percent below the FY 2012 Actual level. In FY 2014, NEI will support projects that address the possible restoration of vision in common and rare retinal degenerative diseases by building on recent advances in gene transfer, stem cell biology, photosensitive replacement molecules, and visual prostheses. NEI plans to host a workshop in 2013 on the role of the complement factor H (CFH) gene in AMD. Variants in this gene, which regulates inflammatory responses to pathogens, are associated with half of all AMD cases and

are also linked to some kidney diseases. Therapies that more tightly regulate CFH expression could prevent vision loss in this common, blinding eye disease. This workshop will help unite kidney and eye researchers and immunologists. In addition, results from 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, will be published in the spring of 2013. Results from the second year of the Comparison of AMD Treatments Trials (CATT), published in 2012, found that Lucentis and Avastin, two common drugs used in the treatment of AMD, were equally effective. Additional results found that monthly injections were no better than less frequent, as-needed injections, allowing patients to avoid the discomfort of unneeded eye injections of the drugs. NEI-supported investigators have developed a digitally automated diagnostic algorithm that screens for early signs of diabetic retinopathy with a high degree of accuracy. This technology will expand access to diabetic retinopathy screening in rural and underserved areas.

Program Portrait: Translational Research Program

FY 2012 Level: \$10.0 million

FY 2014 Level: \$10.0 million

Change: +\$0.0 million

NEI investigators have made significant progress in understanding disease mechanisms that result in vision loss and have established proof-of-concept in animal models for several novel therapies. In 2013, NEI will enhance its translational research program by increasing support of a grant mechanism, the R24, which is specifically designed to support collaborative, multidisciplinary research programs focused on translational research such as development of pharmacologic, gene-, and cell-based therapies and delivery systems.

Current research is evaluating a novel agent that inhibits neovascularization. The growth of abnormal blood vessels is a common cause of severe vision loss in diabetic retinopathy, age-related macular degeneration, and retinopathy of prematurity. Two other R24 awards are evaluating small molecules to treat Stargardt disease, an early onset form of macular degeneration. Another grant is evaluating novel drug delivery methods to the retina. NEI also supports grants to develop gene-based therapies for a common form of retinitis pigmentosa and Leber Hereditary Optic Neuropathy. Still another project is developing novel therapies to control the expression of the complement factor H gene. Variants in this gene account for half of all cases of AMD.

Program Portrait: Stem Cell Approaches to Developing New Therapies for Ocular Diseases

FY 2012 Level: \$0.0 million

FY 2014 Level: \$0.8 million

Change: +\$0.8 million

The regenerative potential of human stem cells offers a promising way to restore vision lost to injury and disease. Many of the leading causes of visual and ocular disorders are due in part to the loss of photoreceptors, inner retinal neurons, or corneal epithelial cells. Preliminary studies demonstrate that stem cell-based therapies may have the potential to treat common and rare ophthalmic conditions including corneal degeneration and inflammation, glaucoma, age-related macular degeneration, diabetic retinopathy, and retinal degenerative diseases.

Critical to the transplantation of stem cell-derived therapeutics is the question of tissue integration. For example, can retinal progenitor cells integrate and interact with the established neural circuitry of the retina by receiving incoming signals and processing such information to restore vision.

NEI issued a funding opportunity (RFA) encouraging the submission of proposals to use human stem cells (adult, induced pluripotent, or embryonic) to develop methods for generating replacement cells and transplantation techniques for the treatment of ocular diseases and disorders that promote tissue integration. The RFA generated 24 applications that were reviewed through peer-review in fall 2012 and presented to the NEI Advisory Council for funding approval in January 2013.

Program Portrait: NEI Regulatory Assistance Program

FY 2012 Level: \$0.1 million

FY 2014 Level: \$0.1 million

Change: +\$0.0 million

The Small Business Innovation Research (SBIR) Program is a grant program for companies to convert innovative ideas into medical devices or other products that help people. Many of the companies are developing drugs or medical devices that require regulatory approval from FDA. This is a major hurdle for small companies, most of which do not have any experience navigating the FDA approval process. To improve the likelihood of success, NEI implemented a new regulatory assistance program. Companies that have developed promising products are selected to receive 30 hours of high quality regulatory consulting, provided by a well-established regulatory consulting firm, to assist them in developing a step-by-step plan for receiving FDA approval. The program is modeled on a pilot program established by the National Cancer Institute. Close collaboration with NCI allowed NEI to benefit from their experience in rolling out the program and to save time and costs. NEI awarded 10 companies in the first round of the program in FY 2012. NEI is optimistic that this program will help small companies with the FDA approval process to insure that the government's research investments result in new and effective treatments for eye disease.

Intramural Research: NEI conducts world-class research that explores 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; mechanisms of visual perception by the brain; and the 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 U.S., has expanded its operations by collecting more than 4,000 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. X-linked retinitis pigmentosa (XLRP) is an early onset and severe form of the rare disease, retinitis pigmentosa. In early 2012, intramural investigators were part of a large collaboration which used gene therapy to robustly restore vision in a canine model of XLRP. The treatment not only restored photoreceptor function but also greatly improved nerve connections with inner retinal cells that relay photoreceptor signals to the optic nerve. This proof-of-concept study opens the opportunity to pursue pre-clinical work necessary to conduct clinical trials. Ocular albinism is characterized by a lack of pigmentation in the skin and retinal pigment epithelial cells, which support the function of photoreceptor cells. Ocular albinism results from defects in the tyrosinase gene. NEI investigators working in the NIH clinical center increased pigmentation in a mouse model of ocular albinism using nitisinone, an FDA approved drug that was found to boost tyrosinase production. Children with ocular albinism have varying degrees of visual impairment, including blindness. Although it was not possible to evaluate visual function in the mouse model, this approach suggests that nitisinone may have benefit for children with this condition.

Budget Policy: The FY 2014 President's Budget estimate for these activities is \$72.960 million, the same level as FY 2012. The newly created Ocular Stem Cells and Translational Research (OSCTR) program within the NEI intramural program is evaluating the use of induced pluripotent stem cells to treat degenerative eye diseases. In collaboration with the NEI clinic, OSCTR investigators are generating iPS retinal cells from skin biopsies of patients with degenerative eye diseases to study disease initiation and progression. OSCTR investigators are also working with investigators in the National Center for Advancing Translational Sciences to use high throughput technologies to screen potential therapeutic agents stem cell based models of disease. Lastly, in collaboration with the new NIH Center for Regenerative Medicine, intramural investigators are developing iPS RPE cells under Good Manufacturing Practices for use in cell-based therapies. This work represents a cutting-edge model to translate iPS cell technologies to clinical use.

Research Management and Support: Research Management and Support (RMS) sustains, guides, and monitors the extramural and intramural research programs. Included in these funds is 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 1,300 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 2014 President's Budget estimate is \$24.575 million, the same as the FY 2012 Actual level. The apparent increase in estimated FY 2014 FTE compared to the FY 2012 actual FTE usage level is due to the effect of transferring positions previously funded from a centralized support operation (Division of Extramural Activities Support) to individual ICs as of year-end 2012. As a result of the DEAS transfer, estimated salaries and benefits for FY 2014 are proportionately higher than those identified for FY 2012 and previous years. The research management plans for FY 2014 include the continued prudent use of RMS funds while implementing strategic changes through continuous improvement and business process reengineering to promote efficient spending.

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

**Budget Authority by Object Class
(Dollars in Thousands)**

	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	263	277	14
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary (in whole dollars)	\$167,411	\$167,411	\$0
Average GM/GS grade	12.3	12.2	(0.1)
Average GM/GS salary (in whole dollars)	\$101,291	\$101,718	\$427
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) (in whole dollars)	\$99,552	\$102,006	\$2,454
Average salary of ungraded positions (in whole dollars)	\$124,490	\$125,894	\$1,404
OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Personnel Compensation:			
11.1 Full-time permanent	\$15,612	\$17,022	\$1,410
11.3 Other than full-time permanent	12,382	12,998	616
11.5 Other personnel compensation	741	784	43
11.7 Military personnel	402	431	29
11.8 Special personnel services payments	3,104	3,234	130
Total, Personnel Compensation	\$32,242	\$34,469	\$2,227
12.0 Personnel benefits	\$8,516	\$9,112	\$596
12.2 Military personnel benefits	257	271	14
13.0 Benefits for former personnel	0	0	0
Subtotal, Pay Costs	\$41,014	\$43,852	\$2,838
21.0 Travel and transportation of persons	\$787	\$588	(\$199)
22.0 Transportation of things	114	115	1
23.1 Rental payments to GSA	0	0	0
23.2 Rental payments to others	23	24	1
23.3 Communications, utilities and miscellaneous charges	565	565	(0)
24.0 Printing and reproduction	17	15	(2)
25.1 Consulting services	497	532	35
25.2 Other services	8,037	6,461	(1,576)
25.3 Purchase of goods and services from government accounts	56,973	60,461	3,488
25.4 Operation and maintenance of facilities	68	69	1
25.5 Research and development contracts	18,312	17,398	(914)
25.6 Medical care	181	181	0
25.7 Operation and maintenance of equipment	3,847	3,647	(200)
25.8 Subsistence and support of persons	0	0	0
25.0 Subtotal, Other Contractual Services	\$87,914	\$88,749	\$835
26.0 Supplies and materials	\$4,427	\$4,427	\$0
31.0 Equipment	2,541	2,200	(341)
32.0 Land and structures	0	0	0
33.0 Investments and loans	0	0	0
41.0 Grants, subsidies and contributions	564,003	558,681	(5,322)
42.0 Insurance claims and indemnities	0	0	0
43.0 Interest and dividends	0	0	(0)
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	\$660,393	\$655,364	(\$5,029)
Total Budget Authority by Object Class	\$701,407	\$699,216	(\$2,191)

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

**Salaries and Expenses
(Dollars in Thousands)**

OBJECT CLASSES	FY 2012 Actual	FY 2014 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	\$15,612	\$17,022	\$1,410
Other than full-time permanent (11.3)	12,382	12,998	616
Other personnel compensation (11.5)	741	784	43
Military personnel (11.7)	402	431	29
Special personnel services payments (11.8)	3,104	3,234	130
Total Personnel Compensation (11.9)	\$32,241	\$34,469	\$2,228
Civilian personnel benefits (12.1)	\$8,516	\$9,112	\$596
Military personnel benefits (12.2)	257	271	14
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	\$41,014	\$43,852	\$2,838
Travel (21.0)	\$787	\$588	(\$199)
Transportation of things (22.0)	114	115	1
Rental payments to others (23.2)	23	24	1
Communications, utilities and miscellaneous charges (23.3)	565	565	0
Printing and reproduction (24.0)	17	15	(2)
Other Contractual Services:			
Advisory and assistance services (25.1)	497	532	35
Other services (25.2)	8,037	6,461	(1,576)
Purchases from government accounts (25.3)	38,386	38,057	(329)
Operation and maintenance of facilities (25.4)	68	69	1
Operation and maintenance of equipment (25.7)	3,847	3,647	(200)
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$50,835	\$48,766	(\$2,069)
Supplies and materials (26.0)	\$4,380	\$4,380	\$0
Subtotal, Non-Pay Costs	\$56,721	\$54,453	(\$2,268)
Total, Administrative Costs	\$97,735	\$98,305	\$570

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2012 Actual			FY 2013 CR			FY 2014 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	81	3	84	84	3	87	84	3	87
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	82	3	85	85	3	88	85	3	88
Division of Intramural Research									
Direct:	133	-	133	137	-	137	137	-	137
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	135	-	135	139	-	139	139	-	139
Division of Epidemiology and Clinical Applications									
Direct:	13	-	13	14	-	14	14	-	14
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	13	-	13	14	-	14	14	-	14
Division of Extramural Research									
Direct:	29	1	30	35	1	36	35	1	36
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	29	1	30	35	1	36	35	1	36
Total	259	4	263	273	4	277	273	4	277
Includes FTEs whose payroll obligations are supported by the NIH Common Fund. FTEs supported by funds from Cooperative Research and Development Agreements.									
FISCAL YEAR	Average GS Grade								
2010	12.1								
2011	12.1								
2012	12.3								
2013	12.2								
2014	12.2								

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Detail of Positions

GRADE	FY 2012 Actual	FY 2013 CR	FY 2014 PB
Total, ES Positions	1	1	1
Total, ES Salary	\$ 167,411	\$ 167,411	\$ 167,411
GM/GS-15	32	33	33
GM/GS-14	21	22	22
GM/GS-13	32	33	33
GS-12	30	33	33
GS-11	37	38	38
GS-10	1	1	1
GS-9	3	5	5
GS-8	7	7	7
GS-7	3	4	4
GS-6	4	5	5
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	170	181	181
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	2	2	2
Full Grade	1	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	94	97	97
Total permanent positions	172	186	186
Total positions, end of year	269	283	283
Total full-time equiv (FTE) at YE	263	277	277
Average ES salary	\$ 167,411	\$ 167,411	\$ 167,411
Average GM/GS grade	12.3	12.2	12.2
Average GM/GS salary	\$ 101,291	\$ 100,836	\$ 101,718

Includes FTEs whose payroll obligations are supported by the NIH Common Fund.