DEPARTMENT OF HEALTH AND HUMAN SERVICES

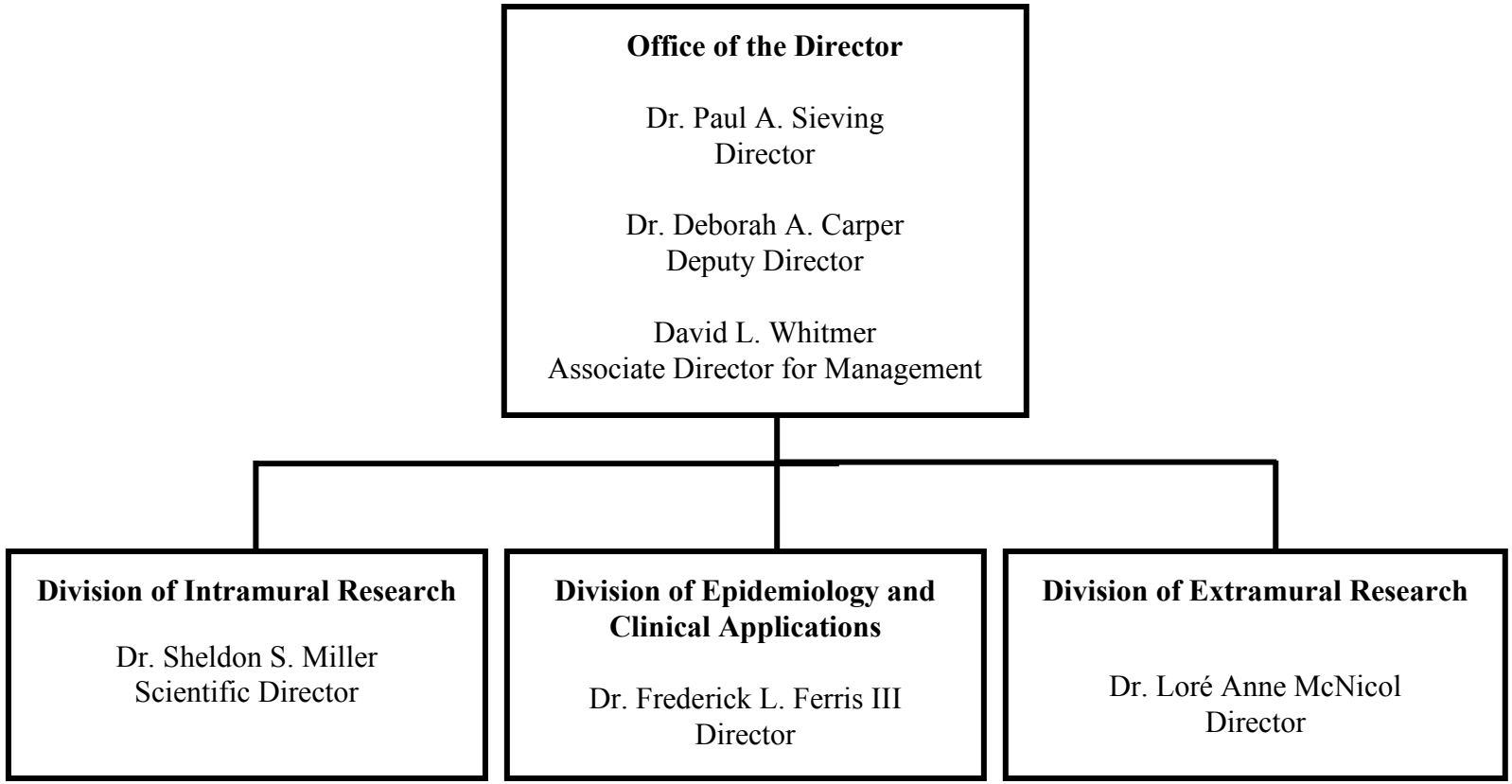
NATIONAL INSTITUTES OF HEALTH

National Eye Institute

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 PHS Act with respect to eye diseases and visual disorders, [$704,043,000] *$693,015,000. (Department of Health and Human Services Appropriations Act, 2012.)*

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Amounts Available for Obligation [1]
(Dollars in Thousands)

Source of Funding	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Appropriation	707,036	704,043	693,015
Type 1 Diabetes	0	0	0
Rescission	(6,208)	(1,331)	0
Supplemental	0	0	0
Subtotal, adjusted appropriation	700,828	702,712	693,015
Real transfer under Secretary's transfer authority	0	(200)	0
Comparative Transfers for NCATS reorganization	0	0	0
Comparative Transfers to NCATS for Therapeutics and Rare and Neglected Diseases (TRND)	(577)	0	0
Comparative Transfers to NLM for NCBI and Public Access	(601)	(636)	0
Subtotal, adjusted budget authority	699,650	701,876	693,015
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	699,650	701,876	693,015
Unobligated balance lapsing	(47)	0	0
Total obligations	699,603	701,876	693,015

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2011 - $16,484 FY 2012 - $17,060 FY 2013 - $17,060

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Budget Mechanism - Total [1/]

(Dollars in Thousands)

MECHANISM	FY 2011 Actual		FY 2012 Enacted		FY 2013 PB		Change vs. FY 2012	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants								
Research Projects								
Noncompeting	815	$314,416	747	$296,006	775	$315,235	28	$19,229
Administrative Supplements	*40*	6,078	*43*	6,600	*14*	2,173	*(29)*	(4,427)
Competing:								
Renewal	126	54,307	139	59,738	126	53,998	(12)	(5,740)
New	151	59,224	166	65,146	152	58,886	(15)	(6,260)
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	277	$113,531	305	$124,884	278	$112,884	(27)	($12,000)
Subtotal, RPGs	1,092	$434,025	1,052	$427,490	1,053	$430,292	1	$2,802
SBIR/STTR	42	$17,073	44	$18,087	45	$18,413	1	$326
Research Project Grants	1,134	$451,098	1,096	$445,577	1,098	$448,705	2	$3,128
Research Centers								
Specialized/Comprehensive	40	$28,850	40	$28,850	40	$27,408	0	($1,442)
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	147	0	146	0	146	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	40	$28,997	40	$28,996	40	$27,554	0	($1,442)
Other Research								
Research Careers	67	$14,301	72	$15,301	72	$15,301	0	$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	34	48,626	34	48,626	31	40,626	(3)	(8,000)
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	15	9,137	15	9,137	15	8,954	0	(183)
Other Research	116	$72,064	121	$73,064	118	$64,881	(3)	($8,183)
Total Research Grants	1,290	$552,159	1,257	$547,637	1,256	$541,140	(1)	($6,497)
Research Training	FTTPs		FTTPs		FTTPs			
Individual Awards	62	$2,880	63	$2,938	62	$2,938	(1)	$0
Institutional Awards	179	7,011	208	8,211	179	7,211	(29)	(1,000)
Total Research Training	241	$9,891	271	$11,149	241	$10,149	(30)	($1,000)
Research & Development Contracts	43	$40,064	43	$45,555	41	$44,191	(2)	($1,364)
SBIR/STTR	*0*	*$25*	*0*	*$25*	*0*	*$25*	*0*	*$0*
	FTEs		FTEs		FTEs		FTEs	
Intramural Research	172	$72,960	172	$72,960	171	$72,960	(1)	$0
Research Management and Support	82	24,576	82	24,575	81	24,575	(1)	0
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NEI	254	$699,650	254	$701,876	252	$693,015	(2)	($8,861)

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

Major Changes in the Fiscal Year 2013 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 mechanism and activity detail and these highlights will not sum to the total change for the FY 2013 budget request for NEI, which is $8.861 million less than the FY 2012 level, for a total of $693.015 million.

Research Project Grants (+$3.128 million, total $448.705 million):
NEI will support a total of 1,098 Research Project Grants (RPGs) in FY 2013. Noncompeting RPGs will increase by 28 awards and increase by $19.229 million. Competing RPGs awards will be funded approximately at the FY 2011 level. NIH budget policy for RPGs in FY 2013 discontinues inflationary allowances and reduces the average cost of noncompeting and competing RPGs by one percent below the FY 2012 level.

Other Research (-$8.183 million, total $64.881):
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 (-$1.000 million, total $10.149 million):
NIH will provide a two percent increase 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 two percent increase in stipend levels for FY 2012. Stipend levels have been relatively flat for several years, and increases are necessary to sustain the development of a highly-qualified biomedical research workforce.

Research and Development Contracts (-$1.364 million, total $44.191 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 Enacted			**$701,876**
FY 2013 Estimate			**693,015**
Net change			**($8,861)**
	2013 Estimate		**Change from FY 2012**
CHANGES	**FTEs**	**Budget Authority**	**FTEs**	**Budget Authority**
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2012 pay increase & benefits		$27,611		$1
b. January FY 2013 pay increase & benefits		27,611		85
c. One more day of pay		27,611		106
d. Annualization of PY net hires		27,611		0
e. Payment for centrally furnished services		11,832		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		33,517		0
Subtotal				$192
2. Research Management and Support:				
a. Annualization of January 2012 pay increase & benefits		$11,825		$0
b. January FY 2013 pay increase & benefits		11,825		36
c. One more day of pay		11,825		46
d. Annualization of PY net hires		11,825		0
e. Payment for centrally furnished services		4,421		0
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		8,329		0
Subtotal				$83
Subtotal, Built-in				$275

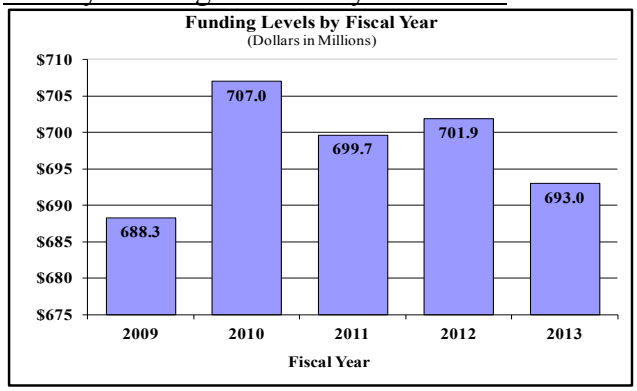
NATIONAL INSTITUTES OF HEALTH
National Eye Institute

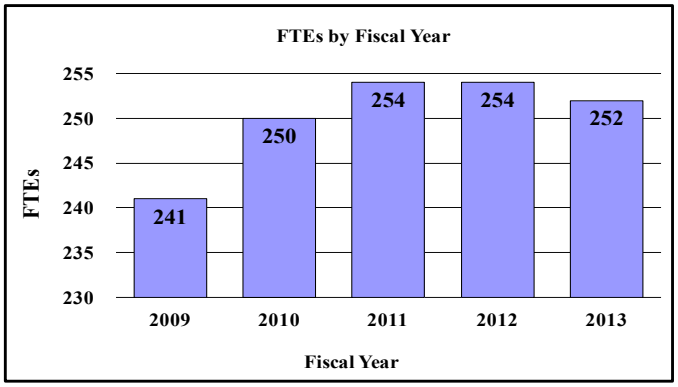
Summary of Changes--continued

CHANGES	2013 Estimate		Change from FY 2012	
	No.	**Amount**	**No.**	**Amount**
B. Program:				
1. Research Project Grants:				
a. Noncompeting	775	$317,408	28	$14,802
b. Competing	278	112,884	(27)	(12,000)
c. SBIR/STTR	45	18,413	1	326
Total	1,098	$448,705	2	$3,128
2. Research Centers	40	$27,554	0	($1,442)
3. Other Research	118	64,881	(3)	(8,183)
4. Research Training	241	10,149	(30)	(1,000)
5. Research and development contracts	41	44,191	(2)	(1,364)
Subtotal, Extramural		$595,480		($8,861)
	FTEs		FTEs	
6. Intramural Research	171	$72,960	(1)	($192)
7. Research Management and Support	81	24,575	(1)	(83)
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, program	252	$693,015	(2)	($9,136)
Total changes				($8,861)

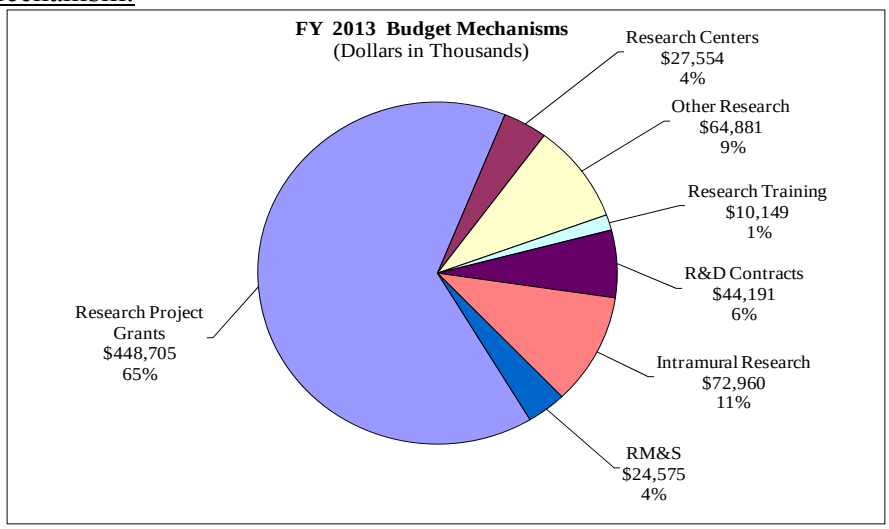
Fiscal Year 2013 Budget Graphs

History of Budget Authority and FTEs:

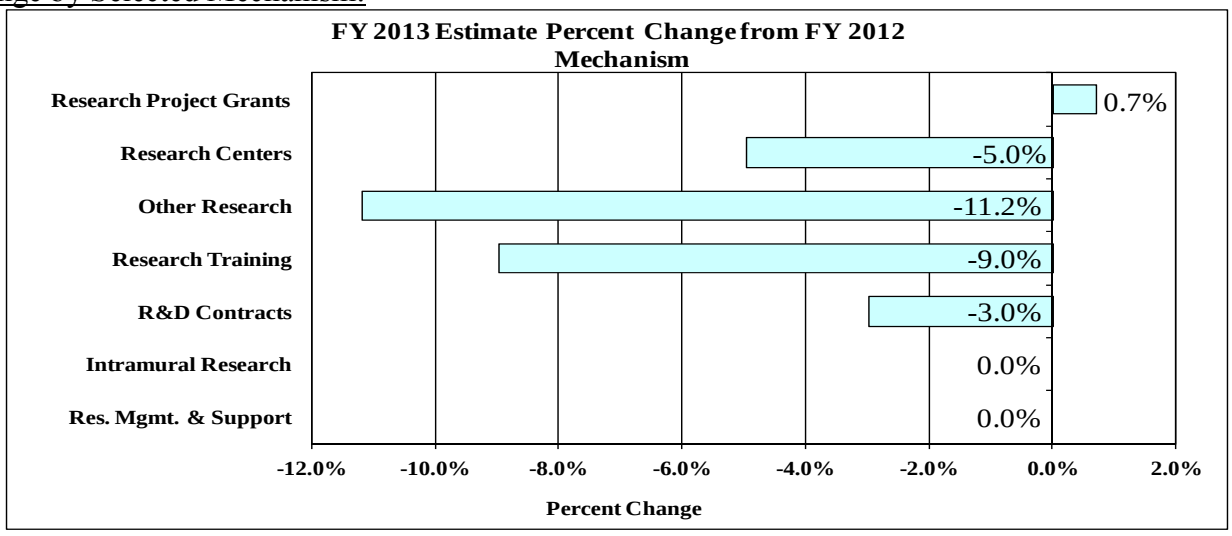




Distribution by Mechanism:



Change by Selected Mechanism:



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

	FY 2011 Actual		FY 2012 Enacted		FY 2013 PB		Change vs. FY 2012 Enacted	
Extramural Research	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**	**FTEs**	**Amount**
Detail:								
Retinal Diseases Research		$270,250		$271,251		$267,274		(3,977)
Corneal Diseases, Cataract, and Glaucoma Research		176,073		176,723		174,132		(2,591)
Sensorimotor Disorders and Rehabilitation Research		155,791		156,367		154,074		(2,293)
Subtotal, Extramural		$602,114		$604,341		$595,480		($8,861)
Intramural Research	172	$72,960	172	$72,960	171	$72,960	(1)	$0
Research Management & Support	82	$24,576	82	$24,575	81	$24,575	(1)	$0
TOTAL	254	$699,650	254	$701,876	252	$693,015	(2)	($8,861)

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2012 Amount Authorized	FY 2012 Enacted	2013 Amount Authorized	FY 2013 PB
Research and Investigation	Section 301	42§241	Indefinite	$701,876,000	Indefinite	$693,015,000
National Eye Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$701,876,000		$693,015,000

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	$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			

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 Actual	FY 2012 Enacted	FY 2013 President's Budget	FY 2013 + / - FY 2012
BA	$699,650,000	$701,876,000	$693,015,000	-$8,861,000
FTE	254	254	252	-2

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. The National Eye Institute (NEI) has made a considerable investment in basic research that is now creating unprecedented opportunities to develop new treatments that address the root causes of vision loss. NEI investigators have identified over 500 genes associated with both common and rare eye diseases. In many cases, the disease mechanisms that lead to vision loss are becoming known, which is critical to developing effective therapies. Translational research efforts by NEI have led to pioneering clinical trials of gene therapy and innovative treatments for diabetic eye disease and AMD, the two most common causes of vision loss. Stem cell research is beginning to show great promise in replacing tissue lost to disease or injury. In fact, the first stem cell clinical trials are being conducted in patients with AMD. NEI also encourages new research approaches which led to the development of the first prosthetic device to restore sight to people with retinal diseases. All of these innovative treatments are the result of basic research and the fostering of novel research ideas.

Investing in Basic Research

NEI created the AMDGene Consortium in 2010 to identify the remaining risk variants for AMD, the leading cause of blindness in older Americans. The consortium consolidates 15 international Genome Wide Association Studies (GWAS) representing over 8,000 patients with AMD and 50,000 controls. Uniting these data sets provides a highly powered sample size to conduct meta-analysis studies. Thus far, the AMDGene Consortium has validated eight gene variants that were previously identified in GWAS studies. It has also identified 19 new gene variants. The genes identified in these studies function in the immune system, cholesterol transport and metabolism, and formation and maintenance of connective tissue. Identification of the biologic pathways where these genes function will greatly increase the understanding of this complex disease and allow researchers to further pinpoint the underlying mechanisms of AMD. As a complement to the analysis by the

AMDGene Consortium, NEI recently funded a grant to discover and validate rare and/or moderately common genetic variants. These efforts will provide a nearly complete genetic heritability picture for AMD. NEI's effort to unite the international research community to share GWAS data sets made it possible to solve a common goal in our understanding of this blinding disease.

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 collected and sequenced 6,000 DNA samples and is the largest GWAS of glaucoma. Thus far, NEIGHBOR investigators identified a risk variant in the gene CDKNB2. This gene is thought to play a role in the development of the optic nerve head, where retinal ganglion cell axons, which degenerate in glaucoma, converge to form the optic nerve. NEI will make GWAS data from NEIGHBOR available to the vision research community for further evaluation in 2012.

NEI intramural investigators have begun using genetic markers and physiological assays to authenticate cells of the retinal pigment epithelium (RPE) that are derived from induced pluripotent stem cells (iPSCs). The RPE is a highly specialized layer of cells adjoining the retina that support photoreceptor cell function. AMD and retinitis pigmentosa, two blinding retinal disorders, are known to result from a diseased RPE. Efforts to develop healthy RPE cells from stem cells for use in RPE transplantation have shown some promise. However, these cells, derived from either embryonic stem cells or from iPSCs, have not been entirely validated at the molecular or functional level. The NEI investigation will identify the genetic pathways involved in differentiating RPE cells and will identify regulatory molecules of these pathways to generate fully functional RPE cells.

Advancing Translational Sciences

In 2008, NEI-supported investigators reported results from a phase I clinical trial of gene therapy in three patients with Leber congenital amaurosis (LCA), a blinding, early onset retinal disease. Initially, with only three patients, the investigators demonstrated that the treatment was well-tolerated and provided objective evidence of modest visual improvement in all three study subjects. To date, 15 participants have been treated and all have experienced visual improvements. Two participants achieved clinically significant gains in visual acuity, defined as the ability to read an additional three lines (15 letters) or more on an eye chart. These results have bolstered the case for research in ocular gene therapy. Clinical trials for AMD, choroideremia, Leber's hereditary optic neuropathy, Stargardt disease, and Usher syndrome were launched this past year. Pre-clinical safety studies for juvenile retinoschisis, achromatopsia, and retinitis pigmentosa are also underway. All of these trials were made possible by sustained NEI support to develop and refine gene therapy techniques.

Encouraging New Investigators and New Ideas

In 2011, NEI awarded a grant to support *Project Prakash,* which combines an extraordinary scientific opportunity with a humanitarian mission. Understanding how the human brain learns to perceive objects remains a fundamental challenge in neuroscience. It has long been held that the development of the visual system is limited to a window of time, called the critical period, during which the brain learns to recognize objects. This work was in part based on pioneering experiments by Nobel Laureates David H. Hubel and Torsten N. Wiesel in which they demonstrated that the visual system of young cats did not develop normally if one eye was sewn shut. The critical period

suggests that neuroplasticity, the ability of the brain and nervous system to change in response to input from the environment, may be enhanced during the critical period. Although NEI has a history of funding work on neuroplasticity and the critical period, progress is limited by the inherent difficulties of working with animal models or very young children to define or characterize the critical period.

The humanitarian side of this story resides in India, which accounts for nearly 30 percent of the world's blindness. Many are poor children with treatable congenital eye disorders, but most never receive medical attention because they live in rural areas far from urban medical centers. Tragically, it is estimated that 60 percent of India's blind children die before reaching adulthood. The goal of *Project Prakash* is to treat children born blind and, in so doing, their sight restoration will permit scientists to address fundamental questions in neuroscience. *Project Prakash* treats these children and then uses various visual testing and brain imaging techniques to study visual development in children. *Project Prakash* will help refine our understanding of plasticity in the brain and visual system and provide important clinical insights that will inform visual rehabilitation. *Project Prakash* is a truly unique merger of humanitarian medical aid and cutting-edge science. (http://web.mit.edu/bcs/sinha/prakash_science.html)

Overall Budget Policy: The FY 2013 President's Budget request is $693.015 million, a decrease of $8.861 million or 1.26 percent under the FY 2012 Enacted level. NEI will continue to support new investigators and the highest quality of investigator-initiated research as evaluated through the peer review system. Also, NEI will fund the same number of competing RPGs funded in FY 2011.

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

FY 2013 Justification by Program

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 has supported 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 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.

Budget Policy: The FY 2013 President's Budget request is $174.132 million, a decrease of $2.591 million or 1.47 percent less than the FY 2012 Enacted level. Program plans for 2013 include following up on a recent finding that certain receptors that bind to vascular endothelial growth factor (VEGF) may play an important role in maintaining the normal transparency of the cornea. VEGF is a protein that spurs blood vessel growth and is a known culprit in several neovascular eye diseases. Knowledge gained from this work may have implications for a broad array of eye diseases. NEI will continue to fund projects that study the cellular, biochemical, biophysical, and molecular bases of lens transparency and its relation to cataractogenesis. 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. Projects to examine the possible contribution of defects in gap junctions in the development of cataracts also continue. In late FY 2012, NEI created a new program for ocular pain and funded new projects to identify therapeutic approaches to limit and/or reduce corneal pain, the most common cause of emergency room visits. 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: Ocular Pain and Sensitivity

FY 2012 Level: $00.0 million
FY 2013 Level: $00.9 million
Change: $00.9 million

Ocular pain and sensitivity, particularly resulting from corneal injuries and diseases, are the most frequent cause of eye-related emergency room visits. However, the neural mechanisms underlying ocular pain and sensitivity are not well understood, and available treatments are only marginally effective. Severe cases of chronic ocular pain are extremely debilitating and may be associated with emotional fear, anxiety, depression, cognitive impairments, and ideations of suicide. In late 2010, NEI hosted a multidisciplinary workshop on ocular pain and sensitivity. Experts in ocular surface disease met with experts in pain and sensitivity in more thoroughly studied non-ocular tissues (e.g., inflammatory joint pain, itch in skin, headache pain, burning mouth, and facial pain) to share existing knowledge and its application to the eye. The workshop helped draw attention to the scientific opportunities to characterize and treat ocular pain and sensitivity, and a report was developed that outlined a wide assortment of understudied areas in both the peripheral and central nervous system (http://www.nei.nih.gov/strategicplanning/pain_workshop.asp).

As a result of the workshop, NEI funded two new grant applications submitted by workshop participants. The new grants are examining the neurons and pathways that monitor tear film and control blood flow in the eye. Disruption of these pathways may contribute to pain associated with dry eye syndrome and other conditions. To further address the gaps in the knowledge and the opportunities outlined in the workshop report, NEI created a new grant program in ocular pain. The program will consist of a diverse portfolio of grants in both basic science and translational studies.

Sensorimotor Disorders, Visual Processing, and Rehabilitation Research: NEI also 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 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. 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 2013 President's Budget request is $154.074 million, a decrease of $2.293 million or 1.47 percent less than the FY 2012 Enacted level. FY 2013 program plans include pursuing research to identify genetic risk factors for strabismus, myopia, and other ocular diseases. Gene therapy has shown promise in the laboratory for Leber's Hereditary Optic Neuropathy, an inherited disease that frequently results in a substantial loss of central vision. Efforts continue to complete pre-clinical work to gain regulatory approval for clinical trials. 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 for diseases that affect the optic nerve. 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 electrical activity in the brain to control computer displays and robotic arms.

Retinal Diseases Research: The light-sensitive retina is susceptible to many sight-threatening conditions, including 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. With this knowledge, efforts are now increasingly focused on translational research to advance novel gene-based therapies to clinical trials. In 2011, NEI investigators completed the Multicenter Uveitis Steroid Treatment (MUST) Trial, which found that systemic or local treatment with an implantable device are equally effective in treating severe forms of uveitis.

Program Portrait: Abnormal Neovascularization in Eye Disease

FY 2012 Level: $70.2 million
FY 2013 Level: $70.2 million
Change: $00.0 million

The development of anti-neovascular agents, such as Lucentis and Avastin, has dramatically improved visual outcomes for the millions of Americans with AMD and diabetic retinopathy. First year results from the NEI-sponsored Comparison of AMD Treatments Trials (CATT) established the equivalency of these two drugs, giving patients (in consultation with their ophthalmologists) a choice in effective treatment options for the disease. Two year results from CATT will be released in the spring of 2012, providing further follow-up regarding safety and longer-term efficacy.

Despite the substantial improvement in the treatment of neovascular eye disease, these drugs require rigorous patient monitoring and chronic eye injections. Moreover, about 30 percent of patients do not respond to either of the drugs. Lastly, these drugs do not prevent the disease. A better understanding of the causes and mechanisms of neovascularization will lead to more effective, less burdensome treatments. NEI remains dedicated to the ultimate goal of preventing these diseases from occurring and maintains a rich portfolio of grants to better understand the underlying mechanisms. Recent NEI-sponsored research has established that bone marrow stem cells stabilize a diseased vasculature in animal models. This finding may have particular application to premature infants who develop retinopathy of prematurity, a devastating neovascular condition that leads to life long blindness. Harvesting bone marrow stem cells from an at-risk infant's umbilical cord blood at the time of birth would insure a ready treatment. At the basic research front, AMD GWAS studies have implicated multiple genes in the immune system and cholesterol transport pathway, giving investigators important insights into the early, underlying disease mechanisms that eventually lead to neovascularization in AMD.

Program Portrait: Adult-derived Induced Pluripotent Stem Cell (iPSC) Resource for the Vision Research Community

FY 2012 Level: $01.0 million
FY 2013 Level: $01.0 million
Change: $00.0 million

The initial phase of the adult-derived iPSC resource for vision research is an intramural collaborative effort with the National Human Genome Research Institute (NHGRI) to create a set of iPSC lines for the vision research community. NHGRI has begun a large-scale genome sequencing and clinical study (ClinSeq) of 1,500 local healthy volunteers. NEI will conduct comprehensive ocular exams at the NIH Clinical Center that will match genetic information obtained in ClinSeq with visual function analysis for each individual. Ocular tests, such as intraocular pressure measurements as a risk factor for glaucoma or imaging of retinal drusen plaques for age related macular degeneration, will allow researchers to distinguish a set of "normal" volunteers from those with clinical risk factors for these and other ocular disorders. In collaboration with the NIH Center for Regenerative Medicine, NEI will create iPSC lines from tissue samples obtained from each volunteer. This new method for creating stem cells non-invasively from adult tissue samples will provide cells that have the potential to form any cell type of the body. Information will be de-identified, i.e., the genetic and ocular measurements cannot be traced back to any individual. NEI expects to obtain several hundred distinct iPSC lines that will be made available to the entire NIH research community.

The second, longer-term aspect of this program will be the solicitation of grant applications from the extramural vision research community to use these iPSC lines to produce (differentiate) specific ocular cells, such as photoreceptors and other ocular neuronal and epithelial cells, that can then be studied either as the isolated, differentiated cell, or studied after further development into multicellular tissues. The iPSC lines will be derived from individuals with known ocular traits, genetic architecture, and ocular disease risk factors. This will enable a wide range of studies to compare the characteristics of specific cell types differentiated from iPSCs that lack or contain identified genetic variants. Other studies will compare cell types differentiated from iPSC lines derived from volunteers with or without known risk factors for ocular diseases. These comparisons will lead to a better understanding of how specific genetic variants affect the disease risk factors and functional properties of differentiated cell types and tissues. This program bridges genetic and clinical studies at the cellular level, leads to a mechanistic understanding of disease pathogenesis, and provides the basis for therapeutic interventions.
ClinSeq (http://www.genome.gov/25521306)

Budget Policy: The FY 2013 President's Budget request is $267.274 million, a decrease of $3.977 million or 1.47 percent less than the FY 2012 estimate. In FY 2013, 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. Stem cell therapies are currently being evaluated in phase I clinical trials for AMD and Stargardt disease. NEI continues to work to improve this translational therapy. Thanks to robust support from NEI, Second Sight, the developer of the Argus II, a visual prosthesis, received regulatory approval to market the device in Europe. Work continues to improve and test this technology with the next generation device, the Argus III. NEI plans to host a workshop on the role of the complement factor H (CFH) gene in AMD. Variants in this gene, which regulate inflammatory responses to pathogens, account for half of all AMD cases. Therapies that regulate CFH expression more closely could prevent vision loss in this common, blinding eye disease. The proposed workshop will help identify gaps and opportunities to accelerate translational research in AMD. Also, Program plans 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.

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 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 2,200 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.

Budget Policy: The FY 2013 President's Budget request is $72.960 million, the same as the FY 2012 Enacted level. In FY 2013, NEI will recruit new investigators for the Ophthalmic Genetics and Visual Function Branch (OGVFB) to enhance translational research at NEI. OGVFB will build capacity for pre-clinical animal model evaluation and development, and expand its Genetic Engineering Facility in support of a new initiative to develop adult human stem cells for therapeutic use in retinal degenerative and other ocular diseases. Also, NEI has developed a new animal Visual Function Facility with expertise in electroretinography, optical coherence tomography, and visual behavior. In addition, NEI enhanced its clinical analysis using state of the art tools in electroretinography, optical coherence tomography, and adaptive optics to assess therapeutic interventions. These therapeutic interventions are being generated in clinical trials initiated from NEI scientists and clinicians within the OGVFB. NEI continues to expand the eyeGENE network to facilitate research on the genetic causes of ocular diseases.

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 2013 President's Budget request is $24.575 million, the same as the FY 2012 Enacted level. The research management plans for FY 2013 include the continued prudent use of RMS funds while implementing strategic changes, through continuous improvement and business process reengineering, to meet the President's Executive Order to cut waste and promote efficient spending.

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Budget Authority by Object
(Dollars in Thousands)

	FY 2012 Enacted	FY 2013 PB	Increase or Decrease
Total compensable workyears:			
Full-time employment	254	252	(2)
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary (*in dollars*)	$167	$168	$1
Average GM/GS grade	12.3	12.3	0.0
Average GM/GS salary (*in dollars)*	$101	$101	$0
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) *(in dollars)*	$95	$97	$2
Average salary of ungraded positions (*in dollars*)	125	126	1

	OBJECT CLASSES	FY 2012 Enacted	FY 2013 PB	Increase or Decrease
	Personnel Compensation:			
11.1	Full-time permanent	$15,188	$15,090	($98)
11.3	Other than full-time permanent	11,730	11,779	49
11.5	Other personnel compensation	1,015	1,017	2
11.7	Military personnel	375	381	6
11.8	Special personnel services payments	2,894	2,908	14
	Total, Personnel Compensation	**$31,202**	**$31,175**	**($27)**
12.0	Personnel benefits	$8,032	$8,025	($7)
12.2	Military personnel benefits	236	236	0
13.0	Benefits for former personnel	0	0	0
	Subtotal, Pay Costs	**$39,470**	**$39,436**	**($34)**
21.0	Travel and transportation of persons	$903	$893	($10)
22.0	Transportation of things	134	134	0
23.1	Rental payments to GSA	0	0	0
23.2	Rental payments to others	4	4	0
23.3	Communications, utilities and miscellaneous charges	552	552	0
24.0	Printing and reproduction	69	48	(21)
25.1	Consulting services	266	260	(6)
25.2	Other services	7,088	7,084	(4)
25.3	Purchase of goods and services from government accounts	59,641	64,336	4,695
25.4	Operation and maintenance of facilities	393	393	0
25.5	Research and development contracts	23,547	17,563	(5,984)
25.6	Medical care	217	217	0
25.7	Operation and maintenance of equipment	4,554	4,554	0
25.8	Subsistence and support of persons	0	0	0
25.0	**Subtotal, Other Contractual Services**	**$95,706**	**$94,407**	**($1,299)**
26.0	Supplies and materials	$3,723	$3,723	$0
31.0	Equipment	2,529	2,529	0
32.0	Land and structures	0	0	0
33.0	Investments and loans	0	0	0
41.0	Grants, subsidies and contributions	558,786	551,289	(7,497)
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	**$662,406**	**$653,579**	**($8,827)**
	Total Budget Authority by Object	**$701,876**	**$693,015**	**($8,861)**

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

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Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2012 Enacted	FY 2013 PB	Increase or Decrease
Personnel Compensation:			
Full-time permanent (11.1)	$15,188	$15,090	($98)
Other than full-time permanent (11.3)	11,730	11,779	49
Other personnel compensation (11.5)	1,015	1,017	2
Military personnel (11.7)	375	381	6
Special personnel services payments (11.8)	2,894	2,908	14
Total Personnel Compensation (11.9)	**$31,202**	**$31,175**	**($27)**
Civilian personnel benefits (12.1)	$8,032	$8,025	($7)
Military personnel benefits (12.2)	236	236	0
Benefits to former personnel (13.0)	0	0	0
Subtotal, Pay Costs	**$39,470**	**$39,436**	**($34)**
Travel (21.0)	$903	$893	($10)
Transportation of things (22.0)	134	134	0
Rental payments to others (23.2)	4	4	0
Communications, utilities and miscellaneous charges (23.3)	552	552	0
Printing and reproduction (24.0)	69	48	(21)
Other Contractual Services:			
Advisory and assistance services (25.1)	266	260	(6)
Other services (25.2)	7,088	7,084	(4)
Purchases from government accounts (25.3)	40,449	40,378	(71)
Operation and maintenance of facilities (25.4)	393	393	0
Operation and maintenance of equipment (25.7)	4,554	4,554	0
Subsistence and support of persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$52,750**	**$52,669**	**($81)**
Supplies and materials (26.0)	$3,615	$3,615	$0
Subtotal, Non-Pay Costs	$58,027	$57,915	($112)
Total, Administrative Costs	**$97,497**	**$97,351**	**($146)**

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Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2011 Actual			FY 2012 Enacted			FY 2013 PB		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	76	3	79	77	3	80	76	3	79
Reimbursable:	2	0	2	1	0	1	1	0	1
Total:	78	3	81	78	3	81	77	3	80
Division of Intramural Research									
Direct:	128	0	128	128	0	128	127	0	127
Reimbursable:	2	0	2	2	0	2	2	0	2
Total:	130	0	130	130	0	130	129	0	129
Division of Epidemiology and Clinical Applications									
Direct:	13	0	13	13	0	13	13	0	13
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	13	0	13	13	0	13	13	0	13
Division of Extramural Research									
Direct:	29	1	30	29	1	30	29	1	30
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	29	1	30	29	1	30	29	1	30
Total	250	4	254	250	4	254	248	4	252
Includes FTEs which are reimbursed from the NIH Common Fund for Medical Research									
FTEs supported by funds from Cooperative Research and Development Agreements	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2009	12.1
2010	12.4
2011	12.3
2012	12.3
2013	12.3

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Detail of Positions

GRADE	FY 2011 Actual	FY 2012 Enacted	FY 2013 PB
Total, ES Positions	1	1	1
Total, ES Salary	167	167	168
GM/GS-15	31	31	31
GM/GS-14	18	18	18
GM/GS-13	27	27	27
GS-12	29	29	29
GS-11	37	37	36
GS-10	1	1	1
GS-9	6	6	6
GS-8	7	7	7
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	161	161	160
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	93	93	92
Total permanent positions	164	164	162
Total positions, end of year	259	259	257
Total full-time equivalent (FTE) employment, end of year	254	254	252
Average ES salary	167	167	168
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	101	101	101

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