

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

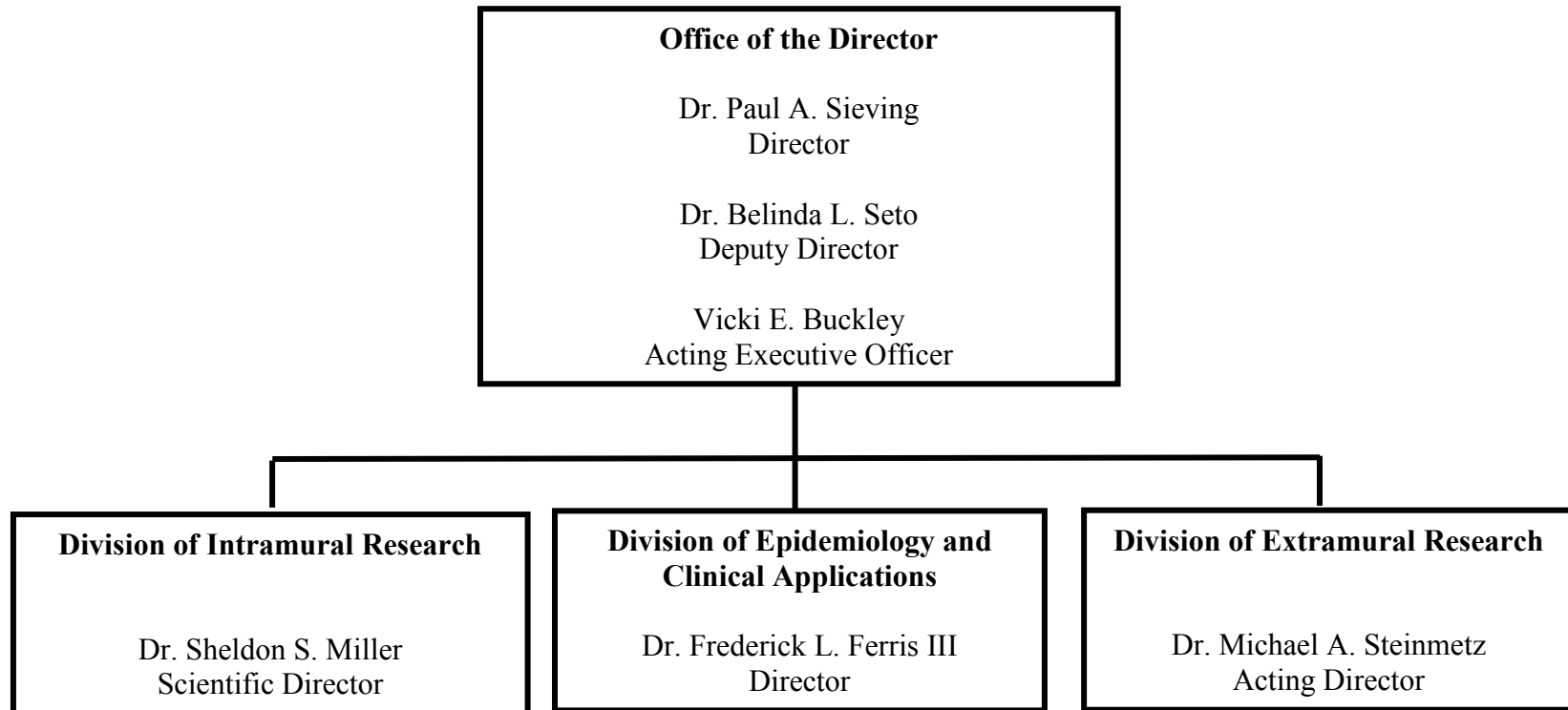
National Eye Institute (NEI)

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**NATIONAL INSTITUTES OF HEALTH**

**National Eye Institute**

Organization Chart



**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, [~~\$684,191,000~~]*\$695,154,000*.

**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

**Amounts Available for Obligation<sup>1</sup>  
(Dollars in Thousands)**

Source of Funding	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Appropriation	\$682,077	\$684,191	\$695,154
Type 1 Diabetes	0	0	0
Rescission	0	0	0
Sequestration	0	0	0
FY 2014 First Secretary's Transfer	-1,712	0	0
FY 2014 Second Secretary's Transfer	-134	0	0
Subtotal, adjusted appropriation	\$680,231	\$684,191	\$695,154
OAR HIV/AIDS Transfers	-6,890	-7,427	0
National Children's Study Transfers	2,242	0	0
Subtotal, adjusted budget authority	\$675,583	\$676,764	\$695,154
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$675,583	\$676,764	\$695,154
Unobligated balance lapsing	-32	0	0
Total obligations	\$675,551	\$676,764	\$695,154

<sup>1</sup> Excludes the following amounts for reimbursable activities carried out by this account:

FY 2014 - \$17,020    FY 2015 - \$17,020    FY 2016 - \$17,020

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

MECHANISM	FY 2014 Actual		FY 2015 Enacted		FY 2016 President's Budget		FY 2016 +/- FY 2015	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	758	\$304,489	767	\$316,827	722	\$305,897	-45	-\$10,930
Administrative Supplements	(33)	2,934	(31)	2,718	(34)	2,957	(3)	239
<u>Competing:</u>								
Renewal	123	52,809	108	46,415	130	51,833	22	5,418
New	167	62,826	147	55,219	181	72,349	34	17,130
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	290	\$115,634	255	\$101,634	311	\$124,182	56	\$22,548
Subtotal, RPGs	1,048	\$423,057	1,022	\$421,179	1,033	\$433,036	11	\$11,857
SBIR/STTR	56	18,589	58	19,191	62	20,617	4	1,426
Research Project Grants	1,104	\$441,646	1,080	\$440,370	1,095	\$453,653	15	\$13,283
<u>Research Centers:</u>								
Specialized/Comprehensive	38	\$25,363	38	\$25,363	39	\$25,962	1	\$599
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	0	144	0	144	0	144	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	38	\$25,507	38	\$25,507	39	\$26,106	1	\$599
<u>Other Research:</u>								
Research Careers	75	\$16,455	70	\$15,255	70	\$15,255	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	41	35,515	41	35,515	41	35,515	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	17	11,493	17	11,493	17	11,493	0	0
Other Research	133	\$63,463	128	\$62,263	128	\$62,263	0	\$0
Total Research Grants	1,275	\$530,616	1,246	\$528,140	1,262	\$542,022	16	\$13,882
<u>Ruth L Kirchstein Training Awards:</u>	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	66	\$3,436	66	\$3,505	66	\$3,575	0	\$70
Institutional Awards	189	8,326	189	8,492	189	8,662	0	170
Total Research Training	255	\$11,762	255	\$11,997	255	\$12,237	0	\$240
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	40 <i>(0)</i>	\$37,549 <i>(93)</i>	42 <i>(0)</i>	\$39,057 <i>(93)</i>	42 <i>(0)</i>	\$41,374 <i>(93)</i>	0 <i>(0)</i>	\$2,317 <i>(0)</i>
Intramural Research	178	71,703	179	73,137	179	74,600	0	1,463
Res. Management & Support	83	23,953	83	24,433	83	24,921	0	488
<i>Res. Management &amp; Support (SBIR Admin) (non-add)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>	<i>(0)</i>
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NEI	261	\$675,583	262	\$676,764	262	\$695,154	0	\$18,390

\*All items in italics and brackets are non-add entries.

## **Major Changes in the Fiscal Year 2016 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 2016 President's Budget for NEI, which is \$18.4 million more than the FY 2015 Enacted level, for a total of \$695.2 million.

### Research Project Grants (+\$13.283 million, total \$453.653 million):

NEI will support a total of 1,095 Research Project Grants (RPGs) in FY 2016. Noncompeting RPGs will decrease by 45 awards and decrease by \$10.930 million. Competing RPG awards will increase by 56 awards and increase by \$22.548 million. SBIR/STTR RPGs will increase by 4 awards and increase by \$1.426 million.

### Research Training (+\$0.240 million, total \$12.237 million):

Support for NRSA training mechanism will be increased by \$0.240 million to cover the cost of increased stipends. The Ruth L. Kirchstein NRSA budget reflects a 2 percent stipend increase. 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 (+\$2.317 million, total \$41.374 million):

Funds are included in R&D contracts to support trans-NIH and trans-HHS initiatives, such as the Best Pharmaceuticals for Children Act and Program Evaluation.

**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

**Summary of Changes  
(Dollars in Thousands)**

<b>FY 2015 Enacted</b>				\$676,764
<b>FY 2016 President's Budget</b>				\$695,154
<b>Net change</b>				\$18,390
CHANGES	FY 2016 President's Budget		Change from FY 2015	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2015 pay increase & benefits		\$30,448		\$75
b. January FY 2016 pay increase & benefits		30,448		225
c. One more day of pay (n/a for 2015)		30,448		90
d. Differences attributable to change in FTE		30,448		0
e. Payment for centrally furnished services		11,866		290
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		32,286		112
Subtotal				\$792
2. Research Management and Support:				
a. Annualization of January 2015 pay increase & benefits		\$12,648		\$31
b. January FY 2016 pay increase & benefits		12,648		93
c. One more day of pay (n/a for 2015)		12,648		38
d. Differences attributable to change in FTE		12,648		0
e. Payment for centrally furnished services		3,362		82
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		8,911		38
Subtotal				\$282
Subtotal, Built-in				\$1,074

**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

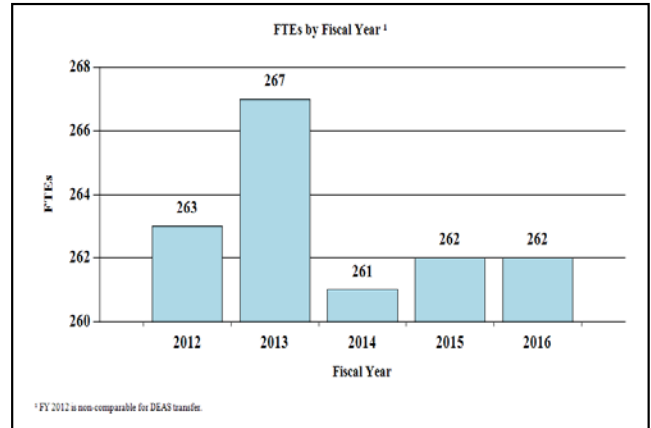
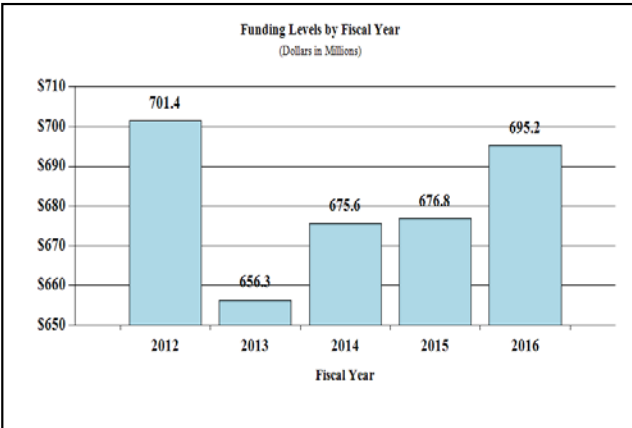
**Summary of Changes - Continued  
(Dollars in Thousands)**

CHANGES	FY 2016 President's Budget		Change from FY 2015	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	722	\$308,854	-45	-\$10,691
b. Competing	311	124,182	56	22,548
c. SBIR/STTR	62	20,617	4	1,426
Subtotal, RPGs	1,095	\$453,653	15	\$13,283
2. Research Centers	39	\$26,106	1	\$599
3. Other Research	128	62,263	0	0
4. Research Training	255	12,237	0	240
5. Research and development contracts	42	41,374	0	2,317
Subtotal, Extramural		\$595,633		\$16,439
6. Intramural Research	<u>FTEs</u> 179	\$74,600	<u>FTEs</u> 0	\$671
7. Research Management and Support	83	24,921	0	206
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	262	\$695,154	0	\$17,316
Total changes				\$18,390

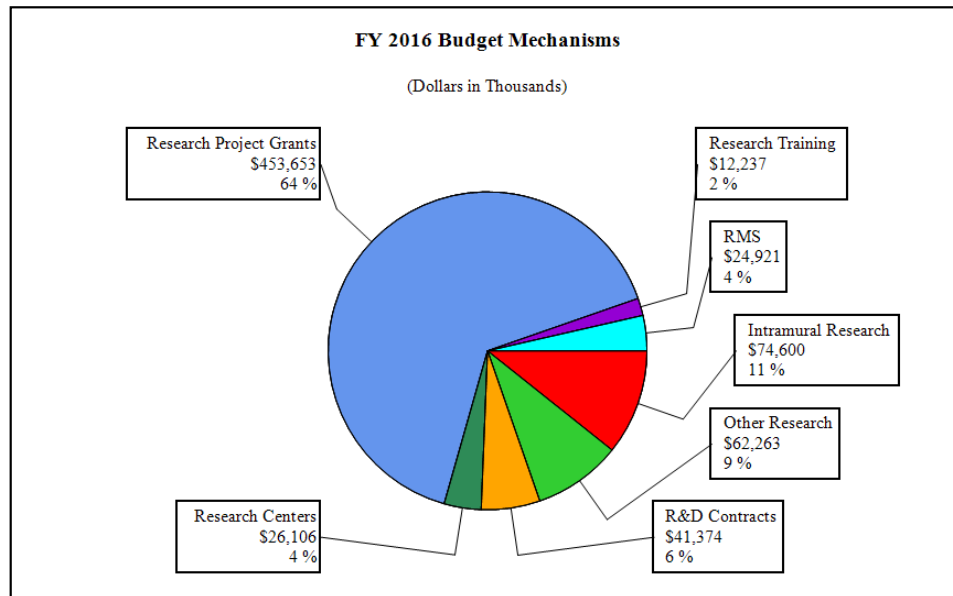


## Fiscal Year 2016 Budget Graphs

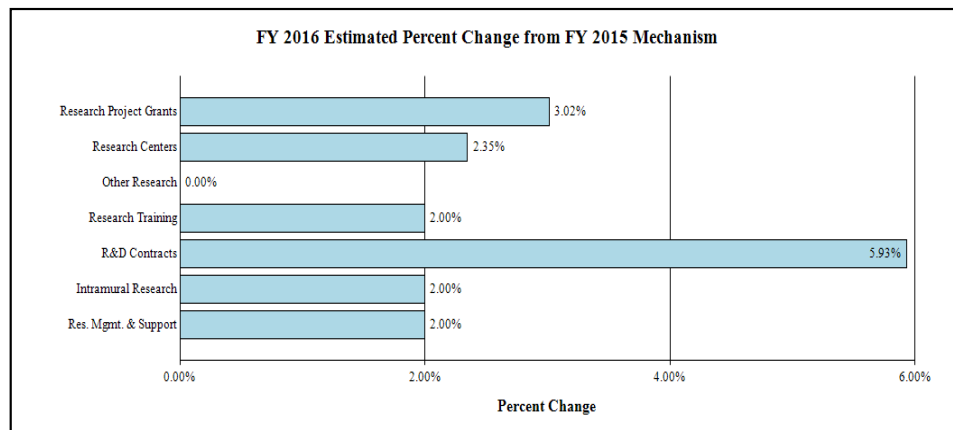
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:



**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

**Budget Authority by Activity<sup>1</sup>**  
(Dollars in Thousands)

	FY 2014 Actual		FY 2015 Enacted		FY 2016 President's Budget		FY 2016 +/- FY 2015	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
<b><u>Extramural Research</u></b>								
<u>Detail</u>								
Retinal Diseases Research		\$266,222		\$265,885		\$273,432		\$7,547
Corneal Diseases, Cataract, and Glaucoma Research		174,766		174,546		179,500		4,954
Sensorimotor Disorders, Visual Processing, and Rehabilitation Research		138,939		138,763		142,701		3,938
<b>Subtotal, Extramural</b>		<b>\$579,927</b>		<b>\$579,194</b>		<b>\$595,633</b>		<b>\$16,439</b>
<b>Intramural Research</b>	<b>178</b>	<b>\$71,703</b>	<b>179</b>	<b>\$73,137</b>	<b>179</b>	<b>\$74,600</b>	<b>0</b>	<b>\$1,463</b>
<b>Research Management &amp; Support</b>	<b>83</b>	<b>\$23,953</b>	<b>83</b>	<b>\$24,433</b>	<b>83</b>	<b>\$24,921</b>	<b>0</b>	<b>\$488</b>
<b>TOTAL</b>	<b>261</b>	<b>\$675,583</b>	<b>262</b>	<b>\$676,764</b>	<b>262</b>	<b>\$695,154</b>	<b>0</b>	<b>\$18,390</b>

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2015 Amount Authorized</b>	<b>FY 2015 Enacted</b>	<b>2016 Amount Authorized</b>	<b>FY 2016 President's Budget</b>
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Eye Institute	Section 401(a)	42§281	Indefinite	\$676,764,000	Indefinite	\$695,154,000
<b>Total, Budget Authority</b>				<b>\$676,764,000</b>		<b>\$695,154,000</b>

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**NATIONAL INSTITUTES OF HEALTH  
National Eye Institute**

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2006 Rescission	\$673,491,000	\$673,491,000	\$693,559,000	\$673,491,000 (\$6,735,000)
2007 Rescission	\$661,358,000	\$661,358,000	\$666,898,000	\$667,166,000 \$0
2008 Rescission Supplemental	\$667,820,000	\$677,039,000	\$681,962,000	\$678,978,000 (\$11,862,000) \$3,548,000
2009 Rescission	\$667,764,000	\$690,721,000	\$687,346,000	\$688,276,000 \$0
2010 Rescission	\$695,789,000	\$713,072,000	\$700,158,000	\$707,036,000 \$0
2011 Rescission	\$724,360,000		\$723,220,000	\$707,036,000 (\$6,208,198)
2012 Rescission	\$719,059,000	\$719,059,000	\$692,938,000	\$704,043,000 (\$1,330,641)
2013 Rescission Sequestration	\$693,015,000		\$695,115,000	\$702,712,359 (\$1,405,425) (\$35,271,328)
2014 Rescission	\$699,216,000		\$701,407,000	\$682,077,000 \$0
2015 Rescission	\$675,168,000			\$684,191,000 \$0
2016	\$695,154,000			

## 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 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
BA	\$675,582,692	\$676,764,000	\$695,154,000	+\$18,390,000
FTE	261	262	262	0

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 (DR), 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) supports vision research through approximately 1,500 research grants and training awards made to scientists at more than 200 medical centers, hospitals, and universities across the United States and around the world. NEI also conducts laboratory and patient-oriented research at its own facilities located on the NIH campus in Bethesda, Maryland.

#### Research to Improve Patient Care

Treatment of DR underwent a paradigm shift five years ago, when an NEI clinical trial network demonstrated that the drug Lucentis not only prevents vision loss, but actually improves vision for about half of affected patients, providing the first new DR therapy in 25 years. A complication of diabetes and a leading cause of blindness in working age adults, DR leads to growth and leakiness of abnormal blood vessels that damage the retina, the neural tissue that detects light. The trial network has just concluded a new trial that compares Lucentis with two other drugs, Avastin and Eylea, in the treatment of DR. Lucentis and Eylea were developed to treat (AMD) and Avastin is a cancer drug, but all three drugs target the same protein, VEGF, which spurs blood vessel growth. The results of this study, expected to be published later this month, will demonstrate the comparative effectiveness and safety for various treatment options for patients with diabetic retinopathy.

Another form of retinopathy, retinopathy of prematurity (ROP), is a sight-threatening disease in infants born severely premature. In ROP, as with DR, abnormal growth of blood vessels injures the retina. The condition is treatable if discovered early. Some degree of ROP appears in more than half of all premature infants born at 30 weeks or younger, but only about 5 to 8 percent of cases become severe enough to require treatment. Additionally, many rural and underserved

populations lack access to a point-of-care doctor who can make treatment decisions for ROP. A recent NEI clinical trial found that telemedicine is an effective diagnostic tool for ROP. Trained technicians reviewing retinal images electronically sent to an off-site center accurately identified patients in need of treatment in 98 percent of cases. This study holds promise for other diseases for which telemedicine may improve patient care, where access to specialists is limited.

AMD, the leading cause of blindness in the United States, causes significant impairment of central vision, making activities of daily living very difficult, if not impossible. AMD can often lead to severe depression. The Low Vision Depression Trial found that low-vision rehabilitation training along with behavioral support from social workers or psychologists reduced the incidence of depression by 50 percent compared to patients without behavioral interventions. These results suggest that collaborative care between eye care professionals, low-vision therapists, and mental health practitioners will be important to prevent or reduce depression that accompanies AMD.

### **Translating Basic Research into Therapy**

Vision research has been leading the way in gene therapy, replacing mutant genes with functional ones in patients with rare retinal degenerative diseases. Now researchers are developing gene therapy to prevent a common form of AMD. About half of all cases of the disease result from an alteration in complement factor H (CFH), a gene that regulates immune responses, causing a chronic state of inflammation in the eye. In the advanced stage of AMD, abnormal blood vessels that leak fluid and blood develop, leading to severe central vision loss, a process known as choroidal neovascularization (CNV). In a mouse model of AMD, gene delivery of PRELP, a gene known to inhibit CFH protein expression, greatly reduced CNV. Although preliminary, this approach could provide a treatment to prevent severe vision loss for many with AMD.

While gene therapy is promising, other therapies are based on a re-engineering approach. Photoreceptors (PRs) are retinal neurons that convert light into a visual signal. When diseases such as AMD and retinitis pigmentosa (RP) cause PRs to die, the eye is unable to detect light, even though the other retinal cells remain intact. To bypass PRs, NEI scientists, funded in partnership with the NIH Common Fund Nanomedicine Initiative, have synthesized molecules that are chemically sensitive to light and can control neuronal activity in response to lights turning on and off. In pre-clinical studies these “photoswitches” were inserted into mice and showed no adverse toxicity. Successful development of this small-molecule approach could offer a path to restore ambulatory vision to the profoundly blind.

The cornea is the transparent, self-renewing, outside surface of the eye that protects the eye from the environment. Limbal stem cells, resident in the cornea, are key to wound healing and repair. While stem cells regenerate, limbal stem cell deficiencies are a growing consequence of long-term contact lens wear, corneal surface diseases, injury, and congenital defects. Currently, corneal grafts are the only treatment for these conditions. However, it is unknown whether grafts contain an adequate supply of stem cells. NEI investigators identified ABCB5 as a gene central to renewal of corneal stem cells. Mice models lacking ABCB5 could not develop viable stem cells. Transplanting ABCB5-enhanced stem cells in mice lacking ABCB5 increased viable stem cell populations. With this advance it will now be possible to use ABCB5 as a stem cell marker

for donor tissue to improve corneal transplant surgeries. In a complementary advance, a separate team of NEI investigators was able to manipulate skin cells to become corneal stem cells. Transplanting these new stem cells led to corneal repair in a rabbit model of injury. Together, these advances hold promise to transform treatment of corneal stem cell deficiencies.

### **NEI Audacious Goals Initiative Targets Regenerating Neurons in the Retina**

NEI's Audacious Goal Initiative (AGI) seeks to regenerate neurons and neural connections in the eye and visual system. In 2014, NEI selected photoreceptors and retinal ganglion cells, two important neuronal cell types, which, when damaged, account for the majority of blinding diseases. The first challenge to achieve this goal was to address technical needs and opportunities to better image cells in the visual system. In soliciting applications, NEI reached out to diverse scientific expertise, including physical scientists and engineers to recruit their talents to vision research; grants will be awarded in early 2015. NEI established an AGI Steering Committee of experts to monitor progress and guide strategic planning, in conjunction with the National Advisory Eye Council and NEI staff. The Committee held a state-of-the-science workshop in November 2014: Restoring Vision: Regenerating the Optic Nerve.

The ultimate goal of regenerative medicine is to create cells, tissue, and organs to replace lost function due to disease and injury. As the AGI Steering Committee generates a roadmap for achieving the program's goals, NEI investigators are already reporting major advances in the field. One team was able to create whole retinal structures complete with functional PR cells from induced pluripotent stem cells (iPSCs). These cells are created by removing some adult skin cells from a living human and then genetically manipulating them so that they can be converted into any cell type. The developmental steps of these retinal structures, through iPSCs technology, mirrored studies of retinal development in animal models. Not only does this advance allow scientists to compare development of the eye in healthy and diseased patients, it brings us one step closer to regenerating functional neurons connections in the eye.

### **Program Descriptions and Accomplishments**

**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 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 2016 budget estimate for these activities is \$273.432 million, an increase of \$7.547 million or 2.8 percent over the FY 2015 Enacted level. In one research highlight, researchers discovered a role for dopamine (DA) in early diabetic retinopathy and identified potential therapies to prevent vision loss. DA is a chemical synthesized in neurons and used as a messenger to communicate between cells. Lack of dopamine production is associated with

multiple neurologic disorders including Parkinson's disease. Investigators have previously found diabetes leads to loss of dopamine in the retina but its significance for diabetic retinopathy was not well understood. Using rodent models of diabetes, NEI investigators found the drop in DA levels correlated with the onset of damage to the retina. Furthermore, they were able to reverse visual deficits by treating with drugs that supplemented the low DA.

**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 these conditions that originate in the front (anterior) of the eye.

- **Corneal disease research.** Corneal injuries, infections, and diseases can be extremely painful and require immediate medical attention. NEI grantees are exploring the molecular mechanisms which spur ocular pain, and promote or deter corneal wound healing.
- **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 investigate strategies to prevent cataract formation and progression.
- **Glaucoma research.** Glaucoma is a family of blinding diseases that result from damage to the optic nerve, the bundle of fibers that transmit signals from the eyes to the brain. Current therapies focus on reducing excessive fluid pressure in the eye, which causes nerve damage in the most common form of glaucoma. NEI investigators study the complex genetic and biological factors that cause the disease to develop early detection strategies and treatments that protect optic nerves and prevent vision loss. The Audacious Goal Initiative seeks to regenerate connections in damaged optic nerves.

Budget Policy: The FY 2016 budget estimate for these activities is \$179.500 million, an increase of \$4.954 million or 2.8 percent over the FY 2015 Enacted level. In a key 2014 advance, NEI scientists developed a contact lens that offers long-term, chronic administration of pressure-reducing drugs to control glaucoma. This approach overcomes the challenge of treatment compliance in glaucoma patients who require daily oral medications. NEI's new cross-cutting program area exploring the intersection of aging and biological mechanisms of eye disease will promote research on environmental factors of aging affecting corneal dysfunction and cataract formation.



**Program Portrait: NEI Expands Gene Therapy Program to Include Mitochondrial Disease.**

FY 2015 Level: \$ 1.5 million

FY 2016 Level: \$ 1.5 million

Change: \$ 0.0 million

In 2014, NEI launched the first-ever gene therapy clinical trial for a mitochondrial eye disorder. Mitochondria are the parts of a cell that convert sugar into energy. While most genes in a cell are found in the DNA of the cell nucleus, mitochondria contain their own DNA with their own genes. One of the more common mitochondrial diseases, Leber hereditary optic neuropathy (LHON), results from a mutation in one of these mitochondrial genes that interferes with energy transfer leading to degeneration of retinal ganglion cells (RGCs) and subsequent deterioration of the optic nerve. RGCs relay visual information from the eye to the brain. Vision loss in LHON first occurs in one eye, providing a window to treat the unaffected eye with gene therapy. To date, all efforts in gene therapy have focused on DNA in the nucleus, but not mitochondrial DNA. In preclinical work, NEI investigators developed a novel gene therapy vector that delivers corrected DNA to the mitochondria in RGCs. In rodent models, this vector was safe and prevented degeneration and subsequent vision loss. This work paved the way for regulatory approval to test the treatment in clinical trials. First-year safety results in patients who have chronic severe vision loss should be available in late 2015. In FY 2016, the study will test efficacy of the therapy in preventing vision loss in recently diagnosed LHON patients.

**Sensorimotor Disorders, Visual Processing, and Rehabilitation Research:** NEI funds basic and applied brain research, and research on rehabilitation for individuals with low vision.

- **Sensorimotor disorders and visual processing 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. Vision neuroscientists 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.
- **Refractive errors.** 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.
- **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 to improve the quality of life for people 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 2016 budget estimate for these activities is \$142.701 million, an increase of \$3.938 million or 2.8 percent over the FY 2015 Enacted level. NEI investigators are developing visual rehabilitation therapies using a tool called perceptual learning. In one study, patients previously treated for amblyopia, in which their brain favors one eye, were trained successfully to judge depth perception using both eyes. Another team designed a perceptual learning video game, which improved vision perception in normally sighted subjects. In FY 2016, the investigators will test the game in people with low vision.

**Program Portrait: BRAIN Initiative: Vision Virtual Consortium**

FY 2015 Level: \$ 1.0 million

FY 2016 Level: \$ 4.0 million

Change: \$ 3.0 million

Over one quarter of the human brain is involved in visual processing. Thus, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative will pay many dividends for visual neuroscience. In FY 2015, NEI is investing \$1 million in BRAIN. The FY 2016 Budget provides funding for an NIH-wide increase of \$70 million to expand the BRAIN Initiative, including an expected increase of \$3 million at NEI. Mapping and understanding the circuitry that relays signals from the retina, to the optic nerve, and ultimately to the brain, will answer fundamental questions about development, plasticity, memory formation and how neurologic diseases impact the brain. The BRAIN Initiative synergizes with NEI's Audacious Goal Initiative, which seeks to regenerate neurons and neural connections in the eye and visual system. For example, one BRAIN grantee is using cutting edge tools to stimulate, image, and classify individual retinal ganglion neurons and to map their connectomes – a circuit diagram of a neuron's connections with other neurons in the eye and brain. BRAIN also aligns with the NEI research mission. Thus, NEI National Eye Advisory Council recommended that NEI form a "virtual consortium" among BRAIN grantees working in vision research to foster collaborations and coordinate their research progress. NEI is developing two scientific consortia, one focused on mammalian retinal circuitry, the other on the brain visual cortex. A combination of large annual meetings and smaller retreats will provide an informal setting for direct interactions. Each will function as virtual centers for exchange of methods, information, and resources across laboratories working on these circuits.

**Intramural Research:** NEI clinical studies are focused on 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 the ability to guide movements under sensory control. Increasing diversity in the biomedical research workforce is a hallmark of Dr. Francis Collins' leadership as NIH director. The NEI intramural program created the Diversity in Vision Research and Ophthalmology (DIVRO), a summer internship which has successfully increased the number of African-American, Latino, and Native American scientists in vision research by providing career development opportunities for students interested in pursuing a career in research. DIVRO interns get hands-on training from leading scientists that will prepare them to continue their studies, and advance their careers in basic and clinical research. It is hoped that early exposure to research will motivate underserved students to pursue a scientific career.

**Budget Policy:** The FY 2016 budget estimate for these activities is \$74.600 million, an increase of \$1.463 million or 2 percent over the FY 2015 Enacted level. In a unique program that leverages the NIH Common Fund with the NIH Eye Clinic, NEI scientists are generating retinal tissue from patients with AMD using induced pluripotent stem (iPS) cell technology. This technological breakthrough has resulted in patient-specific disease models in a dish, to understand causes of disease, to screen for drugs, and to develop cell-based therapies. NEI recently awarded a contract to Cellular Dynamics International to manufacture clinically compatible iPS cell derived human retinal tissue, which, upon FDA-approval for use in humans, will be used in the first U.S. clinical trial to treat patients using stem cells derived from their own

tissue. 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 5,000 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.

**Program Portrait: Adaptive Optics**

FY 2015 Level: \$ 0.5 million

FY 2016 Level: \$ 0.5 million

Change: \$ 0.0 million

When the microscope was invented in the 17<sup>th</sup> Century, scientists discovered that living tissue was comprised of tiny individual cells. Similarly, adaptive optics retinal imaging (AO) is a game-changing technology that now permits eye doctors to examine living cells during a patient’s eye exam using a “microscope”. Prior to this technology, imaging was limited by distortions caused when structures in the eye bent light waves. But now, AO sensors measure the curvature of the eye and correct for distortions, providing the unprecedented opportunity to view clear, non-invasive, real-time images of retinal cells and sub-cellular structures in human eyes. AO is central to diagnosing and treating retinal disease. AO can also measure therapy responses at the cellular level, which may shorten clinical trials, or help personalize medicine for standard of care.

Recognizing the critical importance of this technology, the NIH eye clinic purchased cutting-edge AO technology in FY 2014 and recruited an expert to its scientific staff to integrate AO into clinical research and patient care. By developing an adaptive optics program, NEI is harnessing data and technology to improve health.

**Research Management and Support:** Research Management and Support (RMS) sustains, guides, and monitors NEI 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 1,500 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 2016 budget estimate for these activities is \$24.921 million, an increase of \$0.488 million or 2 percent over the FY 2015 Enacted level.

**NATIONAL INSTITUTES OF HEALTH**  
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**Budget Authority by Object Class<sup>1</sup>**

(Dollars in Thousands)

	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Total compensable workyears:			
Full-time employment	262	262	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$175	\$177	\$2
Average GM/GS grade	12.3	12.3	0.0
Average GM/GS salary	\$104	\$105	\$1
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$94	\$95	\$1
Average salary of ungraded positions	\$124	\$125	\$1
<b>OBJECT CLASSES</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>	<b>FY 2016 +/- FY 2015</b>
Personnel Compensation			
11.1 Full-Time Permanent	\$17,242	\$17,481	\$238
11.3 Other Than Full-Time Permanent	11,137	11,291	154
11.5 Other Personnel Compensation	862	874	12
11.7 Military Personnel	253	257	4
11.8 Special Personnel Services Payments	3,800	3,853	53
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$33,295</b>	<b>\$33,755</b>	<b>\$461</b>
12.1 Civilian Personnel Benefits	\$9,059	\$9,150	\$91
12.2 Military Personnel Benefits	188	190	3
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$42,542</b>	<b>\$43,096</b>	<b>\$554</b>
21.0 Travel & Transportation of Persons	\$720	\$732	\$12
22.0 Transportation of Things	91	93	1
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	11	11	0
23.3 Communications, Utilities & Misc. Charges	495	502	8
24.0 Printing & Reproduction	6	6	0
25.1 Consulting Services	532	541	9
25.2 Other Services	7,927	8,258	331
25.3 Purchase of goods and services from government accounts	56,380	59,911	3,530
25.4 Operation & Maintenance of Facilities	52	52	0
25.5 R&D Contracts	17,103	16,678	-425
25.6 Medical Care	212	217	5
25.7 Operation & Maintenance of Equipment	4,659	4,808	150
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$86,865</b>	<b>\$90,464</b>	<b>\$3,599</b>
26.0 Supplies & Materials	\$4,152	\$4,218	\$66
31.0 Equipment	1,744	1,771	28
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	540,137	554,259	14,121
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	1	1	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$634,222</b>	<b>\$652,058</b>	<b>\$17,836</b>
<b>Total Budget Authority by Object Class</b>	<b>\$676,764</b>	<b>\$695,154</b>	<b>\$18,390</b>

<sup>1</sup>Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

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

OBJECT CLASSES	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$17,242	\$17,481	\$238
Other Than Full-Time Permanent (11.3)	11,137	11,291	154
Other Personnel Compensation (11.5)	862	874	12
Military Personnel (11.7)	253	257	4
Special Personnel Services Payments (11.8)	3,800	3,853	53
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$33,295</b>	<b>\$33,755</b>	<b>\$461</b>
Civilian Personnel Benefits (12.1)	\$9,059	\$9,150	\$91
Military Personnel Benefits (12.2)	188	190	3
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$42,542</b>	<b>\$43,096</b>	<b>\$554</b>
Travel & Transportation of Persons (21.0)	\$720	\$732	\$12
Transportation of Things (22.0)	91	93	1
Rental Payments to Others (23.2)	11	11	0
Communications, Utilities & Misc. Charges (23.3)	495	502	8
Printing & Reproduction (24.0)	6	6	0
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	461	469	7
Other Services (25.2)	7,927	8,258	331
Purchases from government accounts (25.3)	38,871	38,536	-335
Operation & Maintenance of Facilities (25.4)	52	52	0
Operation & Maintenance of Equipment (25.7)	4,659	4,808	150
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$51,970</b>	<b>\$52,123</b>	<b>\$153</b>
Supplies & Materials (26.0)	\$4,152	\$4,218	\$66
<b>Subtotal Non-Pay Costs</b>	<b>\$57,445</b>	<b>\$57,685</b>	<b>\$240</b>
<b>Total Administrative Costs</b>	<b>\$99,987</b>	<b>\$100,781</b>	<b>\$794</b>

**NATIONAL INSTITUTES OF HEALTH  
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**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2014 Actual			FY 2015 Est.			FY 2016 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Epidemiology and Clinical Applications									
Direct:	12		12	12		12	12		12
Reimbursable:			-			-			-
Total:	12		12	12		12	12		12
Division of Extramural Research									
Direct:	32		32	32		32	32		32
Reimbursable:			-			-	0		-
Total:	32		32	32		32	32		32
Division of Intramural Research									
Direct:	133		133	134		134	134		134
Reimbursable:	2		2	2		2	2		2
Total:	135		135	136		136	136		136
Office of the Director									
Direct:	79	2	81	79	2	81	80	2	82
Reimbursable:	1		1	1		1			-
Total:	80	2	82	80	2	82	80	2	82
Total	259	2	261	260	2	262	260	2	262
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2012	12.3								
2013	12.2								
2014	12.3								
2015	12.3								
2016	12.3								

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**Detail of Positions<sup>1</sup>**

<b>GRADE</b>	<b>FY 2014 Actual</b>	<b>FY 2015 Enacted</b>	<b>FY 2016 President's Budget</b>
Total, ES Positions	1	1	1
Total, ES Salary	174,139	175,445	177,199
GM/GS-15	36	36	36
GM/GS-14	21	21	21
GM/GS-13	34	34	34
GS-12	29	29	29
GS-11	32	32	32
GS-10	1	1	1
GS-9	5	5	5
GS-8	5	5	5
GS-7	4	4	4
GS-6	4	4	4
GS-5	0	0	0
GS-4	2	2	2
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
<b>Subtotal</b>	<b>173</b>	<b>173</b>	<b>173</b>
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	2	2	2
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
<b>Subtotal</b>	<b>2</b>	<b>2</b>	<b>2</b>
Ungraded	86	87	87
Total permanent positions	0	0	0
Total positions, end of year	261	262	262
Total full-time equivalent (FTE) employment, end of year	261	262	262
Average ES salary	174,139	175,445	177,199
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	103,010	103,783	104,821

<sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.