

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Eye Institute (NEI)

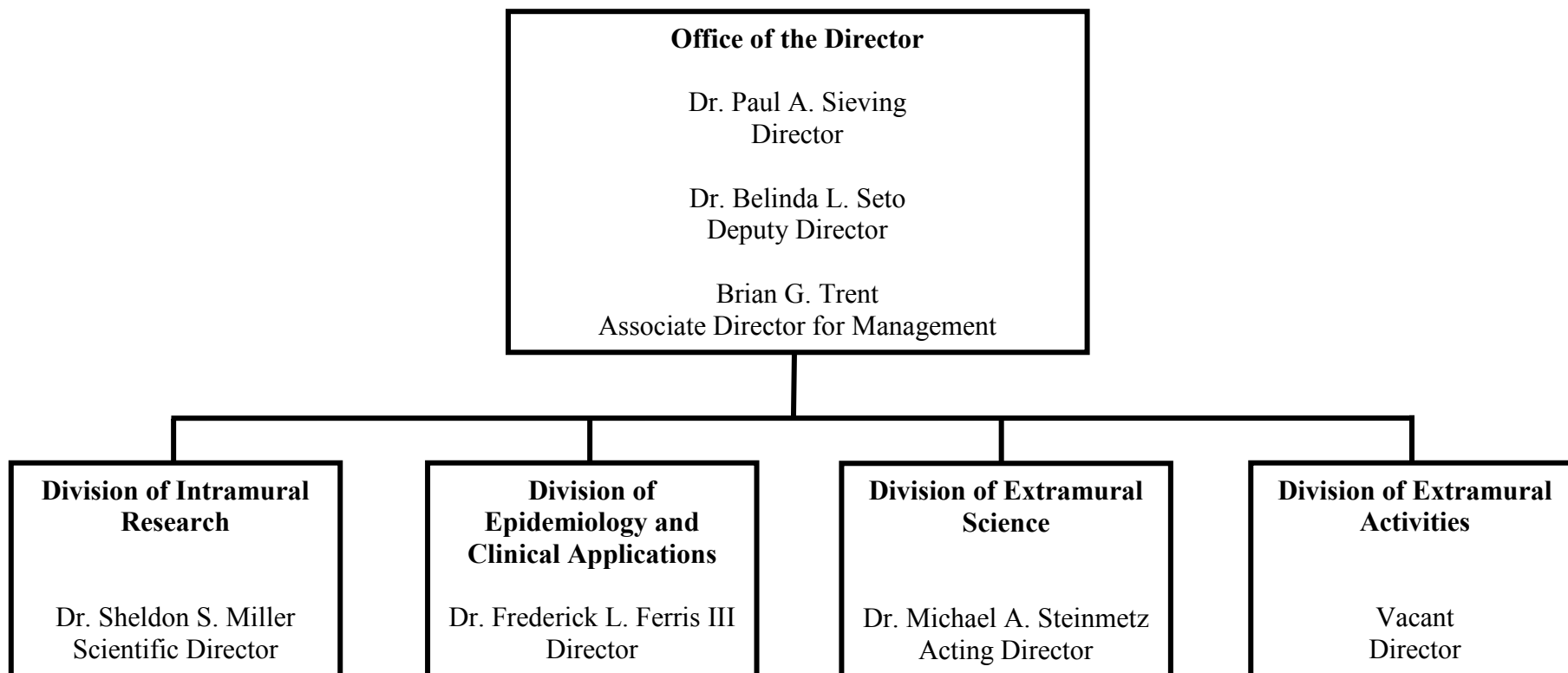
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NOTE: The FY 2016 Enacted funding amounts cited throughout this chapter reflect the effects of OAR HIV/AIDS Transfers.

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, [~~\$715,903,000~~]*\$687,249,000*.

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	\$684,191	\$715,903	\$707,998
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(20,749)
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	\$684,191	\$715,903	\$707,998
OAR HIV/AIDS Transfers	-7,427	-7,905	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	\$676,764	\$707,998	\$707,998
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$676,764	\$707,998	\$707,998
Unobligated balance lapsing	-38	0	0
Total obligations	\$676,726	\$707,998	\$707,998

¹ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2015 - \$16,464 FY 2016 - \$20,020 FY 2017 - \$20,020

NATIONAL INSTITUTES OF HEALTH
National Eye Institute
Budget Mechanism - Total¹
(Dollars in Thousands)

MECHANISM	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget ²		FY 2017 +/- FY 2016	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	770	\$313,053	745	\$312,367	775	\$322,085	30	\$9,718
Administrative Supplements	(30)	2,092	(47)	3,259	(29)	2,026	(-18)	-1,233
<u>Competing:</u>								
Renewal	88	38,750	105	46,073	94	41,185	-11	-4,888
New	185	68,261	220	81,163	196	72,551	-24	-8,612
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	273	\$107,010	325	\$127,236	290	\$113,736	-35	-\$13,500
Subtotal, RPGs	1,043	\$422,155	1,070	\$442,862	1,065	\$437,847	-5	-\$5,015
SBIR/STTR	47	19,128	51	20,894	54	21,982	3	1,088
Research Project Grants	1,090	\$441,283	1,121	\$463,756	1,119	\$459,829	-2	-\$3,927
<u>Research Centers:</u>								
Specialized/Comprehensive	37	\$25,363	38	\$25,963	38	\$25,963	0	\$0
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	37	\$25,507	38	\$26,107	38	\$26,107	0	\$0
<u>Other Research:</u>								
Research Careers	78	\$14,953	78	\$14,953	78	\$14,953	0	\$0
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	43	35,748	43	37,748	43	37,748	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	15	10,934	15	10,934	15	10,934	0	0
Other Research	136	\$61,636	136	\$63,635	136	\$63,635	0	\$0
Total Research Grants	1,263	\$528,425	1,295	\$553,498	1,293	\$549,571	-2	-\$3,927
<u>Ruth L. Kirchstein Training Awards:</u>								
	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	76	\$3,775	76	\$3,850	76	\$3,927	0	\$77
Institutional Awards	175	7,937	175	8,096	175	8,258	0	162
Total Research Training	251	\$11,712	251	\$11,946	251	\$12,185	0	\$239
Research & Develop. Contracts	43	\$39,057	42	\$41,326	41	\$43,889	-1	\$2,563
<i>(SBIR/STTR) (non-add)</i>	<i>(0)</i>	<i>(161)</i>	<i>(0)</i>	<i>(223)</i>	<i>(0)</i>	<i>(273)</i>	<i>(0)</i>	<i>(50)</i>
Intramural Research	172	73,137	172	76,062	172	76,937	0	875
Res. Management & Support	76	24,433	78	25,166	78	25,416	0	250
<i>Res. Management & 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>
<i>Office of the Director - Appropriation²</i>								
<i>Office of the Director - Other</i>								
<i>ORIP/SEPA (non-add)²</i>								
<i>Common Fund (non-add)²</i>								
<i>Buildings and Facilities</i>								
<i>Appropriation</i>								
<i>Type 1 Diabetes</i>								
<i>Program Evaluation Financing</i>								
<i>Cancer Initiative Mandatory Financing</i>								
<i>Other Mandatory Financing</i>								
Subtotal, Labor/HHS Budget Authority		\$676,764		\$707,998		\$687,249		-\$20,749
<i>Interior Appropriation for Superfund Res.</i>								
Total, NIH Discretionary B.A.		\$676,764		\$707,998		\$687,249		-\$20,749
<i>Type 1 Diabetes</i>								
<i>Proposed Law Funding</i>								
<i>Cancer Initiative Mandatory Financing</i>								
<i>Other Mandatory Financing</i>								
Total, NIH Budget Authority		\$676,764		\$707,998		\$707,998		
<i>Program Evaluation Financing</i>								
Total, Program Level		\$676,764		\$707,998		\$707,998		

¹ All Subtotal and Total numbers may not add due to rounding.

² All numbers in italics and brackets are non-add.

³ Includes mandatory financing.

Major Changes in the Fiscal Year 2017 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 2017 President's Budget for NEI, which is the same as the FY 2016 Enacted level, for a total of \$708.0 million.

Research Project Grants (-\$3.927 million, total \$459.829 million):

NEI will support a total of 1,119 Research Project Grants (RPGs) in FY 2017. Noncompeting RPGs will increase by 30 awards and increase by \$9.718 million. Competing RPG awards will decrease by 35 awards and decrease by \$13.500 million. SBIR/STTR RPGs will increase by 3 awards and increase by \$1.088 million.

Research Training (+\$0.239 million, total \$12.185 million):

Support for NRSA training mechanism will be increased by \$0.239 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 (+\$2.563 million, total \$43.889 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 the Human Frontier Science Program.

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Summary of Changes
(Dollars in Thousands)

FY 2016 Enacted				\$707,998
FY 2017 President's Budget				\$707,998
Net change				\$0
CHANGES	FY 2017 President's Budget¹		Change from FY 2016	
	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2016 pay increase & benefits		\$30,832		\$171
b. January FY 2017 pay increase & benefits		30,832		343
c. Two less days of pay		30,832		-201
d. Differences attributable to change in FTE		30,832		0
e. Payment for centrally furnished services		11,906		562
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		34,199		0
Subtotal				\$875
2. Research Management and Support:				
a. Annualization of January 2016 pay increase & benefits		\$12,148		\$72
b. January FY 2017 pay increase & benefits		12,148		143
c. Two less days of pay		12,148		-90
d. Differences attributable to change in FTE		12,148		0
e. Payment for centrally furnished services		2,127		125
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		11,141		0
Subtotal				\$250
Subtotal, Built-in				\$1,125

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

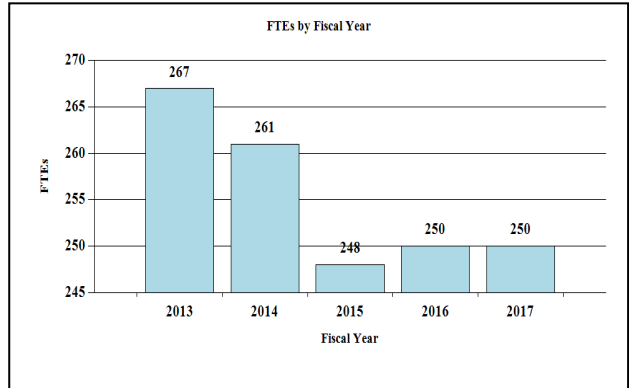
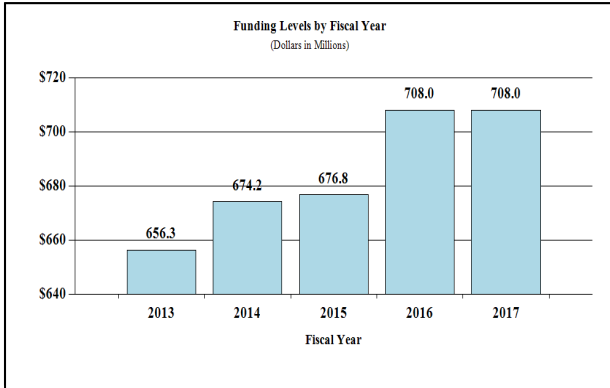
**Summary of Changes - Continued
(Dollars in Thousands)**

CHANGES	FY 2017 President's Budget ¹		Change from FY 2016	
	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	775	\$324,111	30	\$8,485
b. Competing	290	113,736	-35	-13,500
c. SBIR/STTR	54	21,982	3	1,088
Subtotal, RPGs	1,119	\$459,829	-2	-\$3,927
2. Research Centers	38	\$26,107	0	\$0
3. Other Research	136	63,635	0	0
4. Research Training	251	12,185	0	239
5. Research and development contracts	41	43,889	-1	2,563
Subtotal, Extramural		\$605,645		-\$1,125
6. Intramural Research	<u>FTEs</u> 172	\$76,937	<u>FTEs</u> 0	\$0
7. Research Management and Support	78	25,416	0	0
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	250	\$707,998	0	-\$1,125
Total changes				\$0

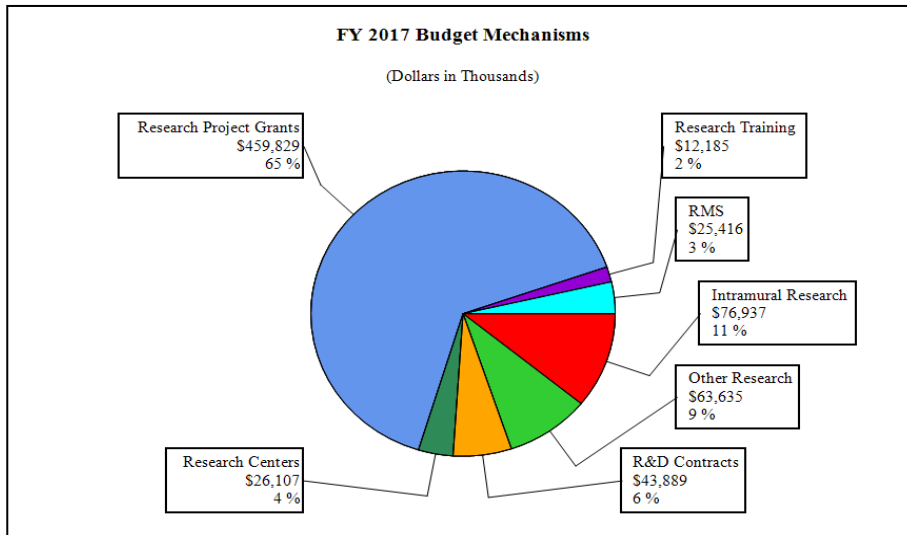
¹ Includes mandatory financing.

Fiscal Year 2017 Budget Graphs

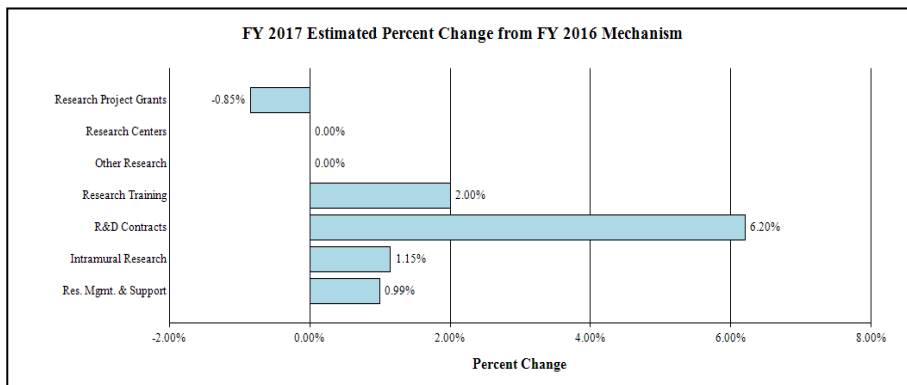
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanism:



**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

**Budget Authority by Activity¹
(Dollars in Thousands)**

	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget ²		FY 2017 +/- FY2016	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
<u>Extramural Research</u>								
<u>Detail</u>								
Retinal Diseases Research		\$261,682		\$274,141		\$273,634		-\$507
Corneal Diseases, Cataract, and Glaucoma Research		175,201		183,543		183,202		-341
Sensorimotor Disorders, Visual Processing, and Rehabilitation Research		142,311		149,086		148,809		-277
Subtotal, Extramural		\$579,194		\$606,770		\$605,645		-\$1,125
Intramural Research	172	\$73,137	172	\$76,062	172	\$76,937	0	\$875
Research Management & Support	76	\$24,433	78	\$25,166	78	\$25,416	0	\$250
TOTAL	248	\$676,764	250	\$707,998	250	\$707,998	0	\$0

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

² Includes mandatory financing.

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget¹
Research and Investigation	Section 301	42§241	Indefinite	\$707,998,000	Indefinite	\$687,249,000
National Eye Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$707,998,000		\$687,249,000

¹Excludes mandatory financing.

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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 Rescission	\$695,154,000	\$698,108,000	\$709,549,000	\$715,903,000 \$0
2017 ¹	\$707,998,000			

¹Includes mandatory financing.

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 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
BA	\$676,764,000	\$707,998,000	\$707,998,000	0
FTE	248	250	250	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.

Vision is the key to unlocking the human brain

Of the many complex activities of the human brain, vision is the largest coherent function, involving over one third of the brain, allowing us to integrate information on form, motion, color, and visual memories. For decades, neuroscientists have studied the visual system to understand brain organization and development. Loss of neurons in the retina or the brain can cause visual impairment. To address this crucial problem, NEI launched the Audacious Goals Initiative (AGI) in 2013 to restore vision through regenerating neurons and their connections in the eye and visual system. AGI addresses challenges like converting stem cells into neurons and then integrating these cells in the eye or guiding neuronal wiring over long distances to form proper connections in the brain. Five AGI grants awarded last April focused on developing novel imaging technologies to help clinicians observe the function of individual neurons in human patients and follow them over subsequent visits as they test new therapies. NEI is assembling multi-disciplinary consortia to share data, technology and early results. To foster stewardship, NEI has established an external committee of topic experts for each consortium, and an AGI Steering Committee to provide overarching direction. NEI has just received applications for the second AGI funding opportunity to identify new factors that control regeneration and to

compare the regenerative process among model organisms, rodents, and non-human primates. AGI is leading the charge for neuroregenerative medicine that will not only advance vision research but also may provide insights to advance the research for other neurodegenerative diseases.

The President's interagency Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative seeks to revolutionize understanding of the brain by developing new technologies to record and modulate brain circuit activity. In NIH's first round of BRAIN projects, 41 percent focused on vision or were awarded to NEI grantees; in the second round, an additional 21 percent of new projects went to NEI grantees. The President's FY 2017 Budget for NIH overall requests \$195 million overall for the BRAIN initiative, an increase of \$45 million, to continue progress on this promising research. While independent from AGI, the two initiatives have already synergized. In a BRAIN enterprise to create a census of every subtype of neuron, one BRAIN/NEI grantee has used computational tools to parse big data from molecular, functional, and new imaging methods that trace the shape and connections of neurons in unprecedented details. His team calculates there are an astounding 30 different subtypes of retinal ganglion cells (RGCs), the neurons which carry signals from the eye to the brain, with each subtype carrying different messages about features of the visual world, such as motion or color. Furthermore, when the RGC connections to the brain were damaged, such as in glaucoma, some subtypes regenerated and others did not. The team identified promising molecular factors for promoting regeneration within these subtypes of cells, which may unlock general principles behind neuron regeneration.

Revolutionizing the Field of Gene Therapy

The science of precision medicine involves identifying disease-causing genes and manipulating them, with tools such as gene therapy. Gene therapy is built on understanding the function of specific genes, their linkage to disease states, and tools to modulate them as needed. Vision research has a jump start, having identified over 500 genes with disease-causing mutations that affect sight and vision. The field of gene therapy – in which a DNA sequence is inserted to overcome a patient's mutations – celebrated a marquee success by restoring sight in young patients with an acute, early onset retinal disease called Leber congenital amaurosis (LCA). The gene that was later implicated in a form of LCA was discovered in 1993 by researchers in the NEI intramural program, and NEI has supported development of the gene delivery system including both preclinical studies in animal models, and clinical trials. In 2015, start-up company Spark Therapeutics, Inc. announced it was applying for FDA approval to commercialize gene therapy for LCA and make it widely available. In addition to LCA, gene therapies for other eye diseases are at various stages within the translational pipeline. In 2015, NEI Director Dr. Paul Sieving enrolled the first patients in a gene therapy trial for another severe, early onset retinal disease called X-linked retinoschisis, another severe, early onset retinal disease. NEI is also funding a range of studies to test gene therapies for other rare disorders and more common, complex diseases such as AMD and glaucoma.

Treating diseases in which light-sensitive photoreceptor cells in the eye have already been destroyed requires a different approach. A novel application of gene therapy delivers light-sensing proteins directly to retinal bipolar neurons, the next layer of healthy cells, bypassing the destroyed photoreceptor cells and effectively converting the bipolar cells from relay cells into

light-sensing cells. This approach could have widespread application for many retinal diseases which destroy photoreceptor cells but leave the rest of the retina intact. Other researchers are expanding the capabilities of gene therapy by developing new ways of delivering larger amounts of genetic material into cells using DNA nanoparticles. These studies are also fine-tuning gene therapy by incorporating DNA-based instructions regarding how much therapeutic protein cells should produce.

Improving patient care

The emergence of Ebola virus disease (EVD) in western Africa has mobilized the health community. One complication in EVD survivors is a vision-threatening inflammation in the eye, uveitis, possibly due to immune reaction to the virus. As part of the Partnership for Research on Ebola Vaccines in Liberia clinical partnership, NEI sent a research team to Liberia to establish a vision clinic to treat survivors. They will determine incidence and extent of EVD eye disease, risk factors contributing to its development, and optimal treatment strategies.

Retinopathy of prematurity (ROP) is a disorder that can cause blindness in preterm infants if not treated in time. Unfortunately, rural and underserved community hospitals do not always have immediate access to a retina specialist. An NEI clinical trial demonstrated that telemedicine could be used to send retina images to specialists remotely to make treatment decisions. This trial also identified a list of factors for predicting which infants are at greatest risk for ROP, including gender, race, gestational age, damage to the retina, and weight gain. Low birth weight infants with ROP have low levels of a protein made by fat tissue called adiponectin, which could be used as a biomarker to help determine which infants are at risk. Another NEI study in an animal model of ROP showed that dietary intake of omega-3 fatty acids could reduce the growth of abnormal blood vessels, providing a safe supplementary therapy.

Of the nearly eight million Americans with diabetic retinopathy, 1.5 percent have an advanced stage called proliferative diabetic retinopathy (PDR), in which lack of blood flow in the retina increases production of a signaling molecule called vascular endothelial growth factor (VEGF). VEGF stimulates the growth of abnormal, leaky blood vessels. Since the 1970s, doctors have treated PDR with a laser therapy, but this treatment can damage night and side vision, so researchers have sought improved therapies. Lucentis is one of several drugs that block VEGF and has been shown to be effective in other eye diseases. A recent NEI clinical trial found that Lucentis is highly effective in treating PDR, reversing some vision loss without affecting side vision. By comparison, laser treatment merely preserves existing central vision without reversing losses, and leads to substantial loss of side vision after two years. The findings demonstrate the first major therapy advance for PDR in nearly 40 years.

Overall Budget Policy:

The FY 2017 President's Budget request is \$707.998 million, which is the same as the FY 2016 Enacted Level. The most important priority is to support the highest quality research that will achieve the mission of the NEI. NEI recognizes that the main engine for scientific discovery is investigator-initiated research project grants (RPGs). As such, these RPGs comprise the majority of the NEI portfolio. In FY 2015, NEI funded the first Audacious Goals Initiative (AGI) consortium awards to develop and refine new imaging technologies. The AGI is ramping up, establishing a new consortium in FY 2016 to identify new factors controlling regeneration, while planning future workshops and funding opportunities for FY 2017.

Program Descriptions and Accomplishments

Retinal Diseases Research: The retina is the light-sensitive neural tissue that lines the inside of the eye and sends visual messages through the optic nerve to the brain. Damage to the retina through disease or retinal detachment can lead to severe vision loss. 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, neuroscience, and immunology of the retina.

- **Age-related Macular Degeneration.** A leading cause of vision loss, AMD is a disease that blurs the sharp, central vision required for reading, driving, and face recognition. There are two forms of advanced AMD: geographic atrophy (“dry” AMD), a gradual breakdown of the light-sensing photoreceptor neurons cause vision loss; neovascular AMD (“wet” AMD), when abnormal blood vessels grow underneath the retina.
- **Retinopathy.** Diabetic retinopathy is a complication of diabetes in which abnormal blood vessels grow on the surface of the retina and may swell and leak fluid. Retinopathy of Prematurity is a potentially blinding disorder that affects premature infants with very low birthweight.
- **Retinal monogenic disorders.** Some retinal degenerative diseases are caused by single genetic mutations, including retinitis pigmentosa, Usher syndrome, and ocular albinism.
- **Uveitis.** Inflammatory diseases that produce swelling and destroy eye tissue can lead to severe vision loss.

Budget Policy:

The FY 2017 budget estimate for these activities is \$273.634 million, which is a \$0.507 million or 0.2 percent decrease compared to the FY 2016 estimate. With many retinal diseases sharing a common problem of neurodegeneration, the retina program has supported research applying new technologies to protect retinal neurons from death. Accomplishments include developing small molecule and gene therapies that reduce oxidative stress, reduce inflammation, prevent abnormal blood vessel growth, or block pathways that lead to death. These strategies may help preserve the retina from a variety of genetic and environmental insults.

Program Portrait: Transformative 3D Retina Organoids to Recapitulate Function and Model Disease

FY 2016 Level: \$0.075 million

FY 2017 Level: \$1.000 million

Change: +\$0.925 million

The report that accompanied H.R. 114-195 directed NEI to create a challenge program to accelerate cures related to retina disease. In response to the request, NEI plans to launch a challenge targeted to bioengineers, materials scientists, chemists, and vision scientists in industry and academia to develop retina organoids—miniature, self-assembling multi-layered tissue cultures that model the structure and function of a full-scale retina. These organoids will serve as models to provide new insights into the development, biology, or disease pathology of retinal diseases and to test pharmaceutical, gene transfer, and regenerative therapies. The potential to create disease models from retina organoids is emerging from a number of converging technological advances such as the creation of optic cups from stem cells; development of microfluidic based tissue chips for other organs; advanced imaging capabilities; innovations in 3D bioprinting of cells; and neuroregenerative medicine initiatives. The \$1 million challenge will consist of two phases – Phase I: Ideation, in which a development strategy is mapped out and feasibility is established; Phase II: Proof-of-concept, in which awards are made based on models that best satisfy technical requirements. Specific details of the challenge will be finalized following a technical planning meeting in the spring of 2016. It is hoped this effort will lead to a valuable resource to be shared by the vision research community.

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 of the eye.

- **Corneal disease research.** Corneal injuries, infections, and diseases can be extremely painful and require immediate medical attention. NEI grantees have developed nanoparticle drug delivery devices to deliver therapeutic molecules that prevent the abnormal growth of blood vessels into the cornea and promote wound healing. Another advance in drug delivery for patients with dry eye syndrome combines a protein from human tears, lacritin, which stimulates tear secretion, with a polymer that changes properties at different temperatures. In animal models, the treatment created a stable drug reserve that was not quickly washed away.
- **Cataract research.** Cataracts, a clouding of the lens in the eye that affects vision, are the leading cause of blindness worldwide. NEI investigates strategies to prevent cataract formation and progression through research to understand the physiological basis of how the lens in the eye remains transparent at the cellular and molecular levels. A recent NEI study identified molecules that restore transparency to the lens in animal models. These agents could be delivered via eye drops, potentially eliminating the need for costly surgical removal.
- **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. In FY 2015, NEI investigators used induced pluripotent stem cells to develop functional retinal ganglion cells (RGCs), which could one day replace the cells damaged in glaucoma.

Budget Policy:

The FY 2017 budget estimate for these activities is \$183.202 million, which is a \$0.341 million or 0.2 percent decrease compared to the FY 2016 estimate. NEI's cross-cutting program area exploring the intersection of aging and biological mechanisms of eye disease supports research on environmental factors of aging affecting corneal dysfunction and cataract formation.

Sensorimotor Disorders, Visual Processing, and Rehabilitation Research: NEI funds basic and applied brain research, and research on and 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 2017 budget estimate for these activities is \$148.809 million, which is a \$0.277 million or 0.2 percent decrease compared to the FY 2016 estimate. Treating amblyopia in children typically requires patching the stronger eye, but that does not always restore normal binocular vision. NEI researchers have developed eye exercises for the iPad designed to improve vision in children with amblyopia. In a clinical trial, children with recurrent amblyopia had rapid and lasting improvement in visual acuity in the weaker eye, and the benefits appear to be long-term.

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.

Budget Policy:

The FY 2017 budget estimate for these activities is \$76.937 million, which is a \$0.875 million or 1.2 percent increase compared to the FY 2016 estimate. Our microbiome – the diverse population of microorganisms living in our body including our gut and on the surface of our eye – influences the immune system and is involved in a host of biological functions. While ocular inflammation impacts diseases such as uveitis and AMD, the role of the microbiome is not known. Studies by NEI intramural basic science investigators and clinicians have identified microbiome patterns correlating to immune dysfunction and inflammatory eye diseases; in uveitis patients, initial results have identified a microbiome signature, which, if confirmed could provide a new way to test for patients at risk for disease. They are planning a study to evaluate altering patients’ immune responses with oral feeding of probiotics in an attempt to prevent AMD.

Program Portrait: Testing a stem-cell-derived therapy for age-related macular degeneration (AMD)

FY 2016 Level: \$1.500 million

FY 2017 Level: \$1.500 million

Change: \$0.000 million

In FY 2017, researchers in the NEI intramural research program are preparing to file the first Investigational New Drug application to launch the first human clinical trial using a therapy derived from induced pluripotent stem cells (iPSCs) to treat a form of AMD. The retinal pigment epithelium (RPE) layer nourishes and supports the photoreceptors in the retina. In this form of AMD, RPE cells start to die, leading to photoreceptor cell loss and visual impairment. Replacing RPE prevents vision loss in animal models of retinal degeneration. The team has developed a clinical-grade manufacturing process to derive iPSCs from patients and convert them into RPE tissue on a biodegradable 3D scaffold for transplantation within 142 days after a blood draw from an AMD patient. Patient-derived iPSCs are less likely to be rejected by the immune system as compared to tissues from mismatched donors. A world-renowned retina surgeon has helped optimize a surgery in pig models. The NEI team has demonstrated that transplanted tissue integrates in the retina and restores lost function in pig models of retinal degeneration. Current efforts are directed toward optimizing this treatment in pre-clinical work. They have also developed partnerships with industry to help scale up production with Good Manufacturing Practices suitable for FDA-approved human use.

Research Management and Support (RMS): 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 2017 budget estimate for these activities is \$25.416 million, which is a \$0.250 million or 1.0 percent increase compared to the FY 2016 estimate.

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Budget Authority by Object Class¹
(Dollars in Thousands)

	FY 2016 Enacted	FY 2017 President's Budget²	FY 2017 +/- FY 2016
Total compensable workyears:			
Full-time employment	250	250	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$186	\$188	\$3
Average GM/GS grade	12.3	12.3	0.0
Average GM/GS salary	\$106	\$107	\$2
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$106	\$108	\$2
Average salary of ungraded positions	\$133	\$135	\$2
OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget²	FY 2017 +/- FY 2016
Personnel Compensation			
11.1 Full-Time Permanent	\$17,078	\$17,208	\$130
11.3 Other Than Full-Time Permanent	10,676	10,758	81
11.5 Other Personnel Compensation	924	931	7
11.7 Military Personnel	213	215	2
11.8 Special Personnel Services Payments	4,146	4,178	32
11.9 Subtotal Personnel Compensation	\$33,038	\$33,290	\$252
12.1 Civilian Personnel Benefits	\$9,330	\$9,514	\$185
12.2 Military Personnel Benefits	174	176	1
13 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$42,542	\$42,980	\$438
21 Travel & Transportation of Persons	\$842	\$857	\$15
22 Transportation of Things	56	57	1
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	9	9	0
23.3 Communications, Utilities & Misc. Charges	485	494	9
24 Printing & Reproduction	8	8	0
25.1 Consulting Services	\$445	\$453	\$8
25.2 Other Services	12,817	12,691	-126
25.3 Purchase of goods and services from government accounts	58,943	63,175	4,232
25.4 Operation & Maintenance of Facilities	\$174	\$177	\$3
25.5 R&D Contracts	16,047	14,970	-1,077
25.6 Medical Care	191	197	5
25.7 Operation & Maintenance of Equipment	3,439	3,501	62
25.8 Subsistence & Support of Persons	0	0	0
25 Subtotal Other Contractual Services	\$92,056	\$95,163	\$3,107
26 Supplies & Materials	\$4,217	\$4,293	\$76
31 Equipment	2,337	2,379	42
32 Land and Structures	0	0	0
33 Investments & Loans	0	0	0
41 Grants, Subsidies & Contributions	565,444	561,756	-3,688
42 Insurance Claims & Indemnities	0	0	0
43 Interest & Dividends	2	2	0
44 Refunds	0	0	0
Subtotal Non-Pay Costs	\$665,456	\$665,018	-\$438
Total Budget Authority by Object Class	\$707,998	\$707,998	\$0

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

² Includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	\$17,078	\$17,208	\$130
Other Than Full-Time Permanent (11.3)	10,676	10,758	81
Other Personnel Compensation (11.5)	924	931	7
Military Personnel (11.7)	213	215	2
Special Personnel Services Payments (11.8)	4,146	4,178	32
Subtotal Personnel Compensation (11.9)	\$33,038	\$33,290	\$252
Civilian Personnel Benefits (12.1)	\$9,330	\$9,514	\$185
Military Personnel Benefits (12.2)	174	176	1
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$42,542	\$42,980	\$438
Travel & Transportation of Persons (21.0)	\$842	\$857	\$15
Transportation of Things (22.0)	56	57	1
Rental Payments to Others (23.2)	9	9	0
Communications, Utilities & Misc. Charges (23.3)	485	494	9
Printing & Reproduction (24.0)	8	8	0
Other Contractual Services:			
Consultant Services (25.1)	241	246	4
Other Services (25.2)	12,817	12,691	-126
Purchases from government accounts (25.3)	38,968	39,683	715
Operation & Maintenance of Facilities (25.4)	174	177	3
Operation & Maintenance of Equipment (25.7)	3,439	3,501	62
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$55,638	\$56,297	\$659
Supplies & Materials (26.0)	\$4,217	\$4,293	\$76
Subtotal Non-Pay Costs	\$61,255	\$62,015	\$760
Total Administrative Costs	\$103,798	\$104,995	\$1,197

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2015 Actual			FY 2016 Est.			FY 2017 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Epidemiology and Clinical Applications									
Direct:	11		11	11		11	11		11
Reimbursable:									
Total:	11		11	11		11	11		11
Division of Extramural Activities									
Direct:	15		15	15		15	15		15
Reimbursable:									
Total:	15		15	15		15	15		15
Division of Extramural Science									
Direct:	15		15	15		15	15		15
Reimbursable:									
Total:	15		15	15		15	15		15
Division of Intramural Research									
Direct:	130		130	130		130	130		130
Reimbursable:	2		2	2		2	2		2
Total:	132		132	132		132	132		132
Office of the Director									
Direct:	73	2	75	75	2	77	75	2	77
Reimbursable:									
Total:	73	2	75	75	2	77	75	2	77
Total	246	2	248	248	2	250	248	2	250
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
FISCAL YEAR	Average GS Grade								
2013	12.3								
2014	12.2								
2015	12.3								
2016	12.3								
2017	12.3								

**NATIONAL INSTITUTES OF HEALTH
National Eye Institute**

Detail of Positions¹

GRADE	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	183,300	185,555	188,394
GM/GS-15	32	34	34
GM/GS-14	21	21	21
GM/GS-13	36	36	36
GS-12	29	29	29
GS-11	34	34	34
GS-10	1	1	1
GS-9	5	5	5
GS-8	4	4	4
GS-7	3	3	3
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
Subtotal	171	173	173
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	2	2	2
Ungraded	77	77	77
Total permanent positions	0	0	0
Total positions, end of year	251	253	253
Total full-time equivalent (FTE) employment, end of year	248	250	250
Average ES salary	183,300	185,555	188,394
Average GM/GS grade	12.3	12.3	12.3
Average GM/GS salary	104,022	105,568	107,183

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