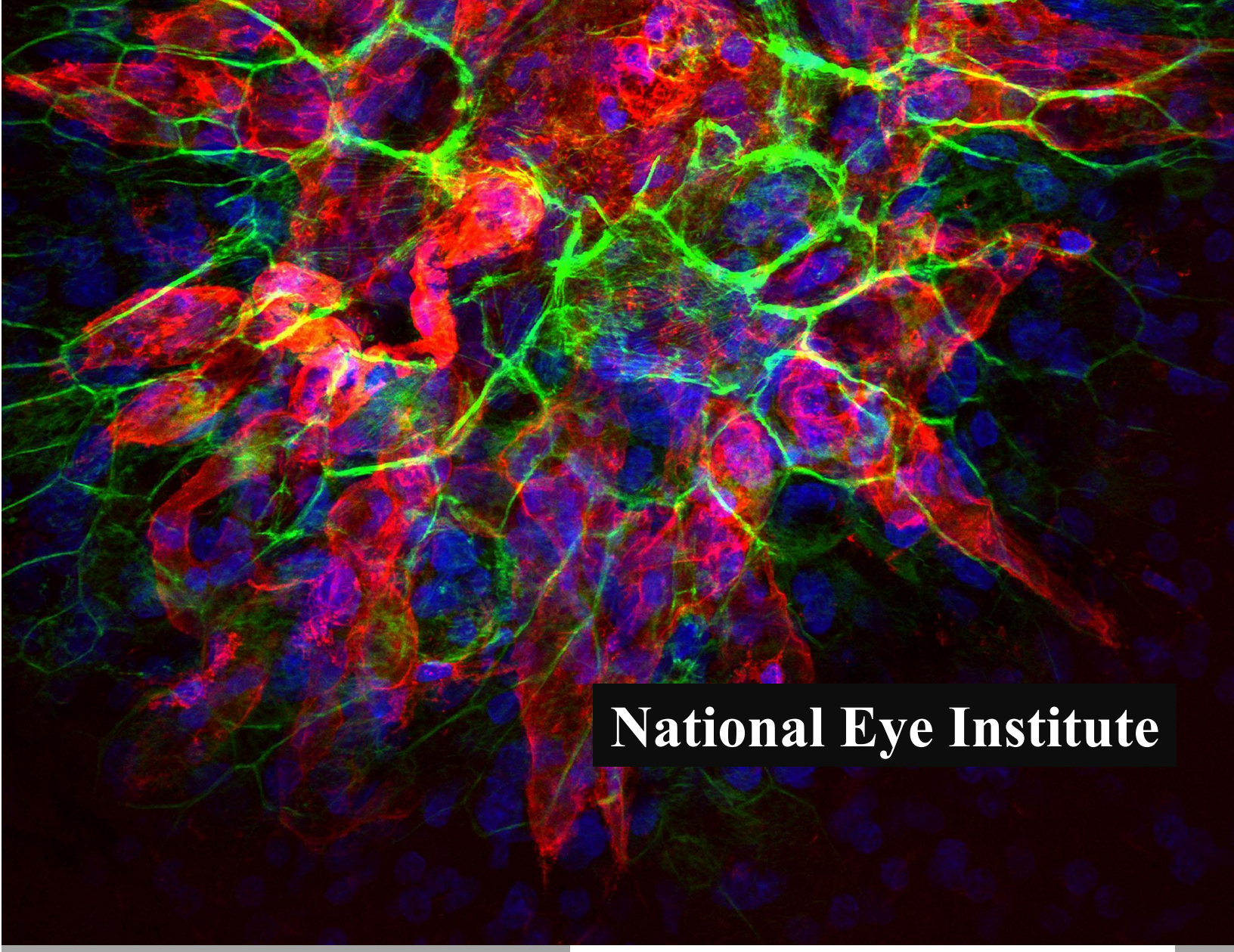

National Eye Institute

CONGRESSIONAL JUSTIFICATION
FY 2023

Department of Health and Human Services
National Institutes of Health

National Eye Institute

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Eye Institute (NEI)

FY 2023 Budget Table of Contents

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Director's Overview

Eye diseases that lead to visual impairment and blindness, such as age-related macular degeneration (AMD), diabetic retinopathy (DR), and glaucoma, affect millions of Americans of all ages, ethnicities, and backgrounds. Over 150 million Americans require eyeglasses. These and other forms of vision loss restrict career choices and can rob people of their mobility and independence, and surveys show that blindness is among the conditions that Americans fear most. As the population ages, virtually all Americans will develop a visual problem as they get older. NEI supports vision research through approximately 1,700 research grants and training awards made to scientists at more than 270 medical centers, hospitals, and universities across 44 states and around the world. NEI also conducts laboratory and patient-oriented clinical research at its facilities in Maryland.

New Mission, New Vision

As with virtually every aspect of our lives, vision care has been disrupted over the past two years. Missed vision exams and delayed treatment may have public health consequences for years. The pandemic has exposed vulnerabilities in access to vision care that exacerbate health disparities. Individuals with vision impairment have adapted to altered accessibility services and reduced transportation options. Eye care providers and patients are adjusting to increased use of telehealth.

Michael F. Chiang, M.D., Director

Meanwhile, as unprecedented advances in science and computing have occurred, we are rapidly moving into an era where knowledge discovery is no longer limited by technology, but only by creativity. Because of the evolving landscape in research, healthcare, technology, and public health, NEI refreshed its mission statement for the first time in over 50 years, with the assistance of external and internal stakeholders.

The mission of the National Eye Institute is to eliminate vision loss and improve quality of life through vision research. To achieve this mission, NEI provides leadership to:

- Drive innovative research to understand the eye and visual system, prevent and treat vision diseases, and expand opportunities for people who are blind or require vision rehabilitation
- Foster collaboration in vision research and clinical care to develop new ideas and share knowledge across other fields
- Recruit, inspire, and train a talented and diverse new generation of individuals to expand and strengthen the vision workforce
- Educate health care providers, scientists, policymakers, and the public about advances in vision research and their impact on health and quality of life

NEI Combats COVID-19 and the Impacts of the Pandemic on Vision Care
Responding to the COVID-19 health emergency, NEI researchers applied their expertise to tackle genomics, data science, and clinical safety challenges. Leveraging the resources of the NIH Clinical Center and other NIH collaborators, NEI scientists developed a faster, safer, and cheaper diagnostic test for SARS-CoV-2, the virus that causes COVID-19. Their new virus sample preparation method eliminates time-consuming steps of viral RNA extraction, while also increasing test sensitivity. NEI supports two clinical trials examining possible ocular changes due to COVID-19. Another study is comparing vision-related quality of life before and after cataract surgery during the pandemic. The presence of virus in ocular tissues provoked new guidelines for clinical care, yet research has suggested that unlike infectious Herpes Simplex or Zika viruses, SARS-CoV-2 does not appear to replicate in the human cornea.

The disruptive changes prompted by the pandemic provides an opportunity to rethink and improve quality and delivery of vision care in the future. More than ever before, the importance of equitable access to vision treatments has come to the forefront. Broader adoption of telemedicine may reduce some access barriers and improve outcomes, yet vision care is heavily reliant on imaging and specialized instruments. Traditional optical coherence tomography (OCT) imaging devices require trained operators, but a new device can be integrated into a primary care setting. NEI has advanced the field by supporting development of a fully automated, contactless OCT device, which uses light waves to image layers of the retina to detect disease. Independently, Notal Home OCT is a novel artificial intelligence (AI)-based imaging device designed to allow patients at home to scan their own retinas. In an NEI clinical study of patients with AMD, the Notal system checked fluid levels in the retina and conveyed data to the treating physician to monitor disease progression, reducing the need for regular doctor visits. Innovations in research are also making management regimens easier for patients. FDA recently approved an ocular implant for AMD that slowly releases a vision-saving drug into the eye. The device only needs to be refilled twice per year, instead of monthly eye injections at the doctor's office. Previous NEI research has shown the effectiveness of this drug for diabetic retinopathy and other retinal diseases. Primary open-angle glaucoma (POAG), a blinding disease that damages the optic nerve, disproportionately impacts Hispanic and African Americans. NEI supported development of a new long-acting drug-free therapy, which can potentially replace daily eye drops and surgery with a hydrogel injected at regular patient visits, two to three times per year. This advance coincides with results from the 20-year follow-up of a landmark NEI trial showing the benefit of treating elevated ocular pressure, the major risk factor for POAG, prior to disease onset. The study enabled clinicians to build a model predicting disease outcomes based on treatment, race, and severity index. Another change NEI innovated this year capitalizes on social media to recruit participants for clinical trials for both common diseases like AMD as well as rare diseases, like Stargardt dystrophy.

A Data Destiny
Data science extracts useful information from 'big data' and represents the future of clinical care. Vision researchers have been natural leaders pioneering and applying data science to clinical questions, from the first genomics successes identifying AMD genes to the first FDA-approved autonomous AI system in any field of medicine (to diagnose diabetic retinopathy). Yet, the frontier sometimes resembles the wild west; the reams of genetic, imaging, and electronic health record data being generated are relatively siloed and contain both structured and unstructured

data. New incentives and resources are required for investigators to collect, manage, and share data in a uniform way. In a key vision scientific journal, NEI Director Michael Chiang announced the creation of a new type of peer-reviewed, citable article, called a data science descriptor, which incentivizes data scientists to get intellectual credit for publishing data sets or software libraries (codes used to develop software programs and applications) in open-access repositories. Dr. Chiang is also co-leading the NIH Common Fund Bridge2AI Initiative which seeks to establish widespread adoption of AI in biomedical research, starting with creation of flagship data sets and best practices in AI-ready data generation. Additionally, NEI supports the NIH Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program, pursuing beneficial and coordinated partnerships to increase the participation and representation of researchers from underrepresented communities in the development of AI and machine learning models.

Starting in 2023, all NIH grantees will be required to submit a data management and sharing plan; yet, differing data standards and lack of interoperability remain significant challenges. The newly created NEI Office of Data Science and Health Informatics coordinates existing activities within the NEI and across NIH and provides a home for new trans-agency programs in data collection, data sharing, and data interoperability. NEI has called for imaging device makers to standardize their data formatting to enable communication across health care providers, improve quality of care, and enhance the creation of datasets for research. To this end, the NEI small business program supports the development of a secure data management platform, Integrated Translational Imaging™, specializing in collection, curation, sharing, and analysis of ocular images and related clinical data. Such a tool could help identify disease-specific biomarkers and develop quantitative metrics.

Large genomics studies depend on data sharing for gene discovery. For years, researchers knew glaucoma was highly heritable, but until recently, they were unable to pin down specific genes. An international collaboration including the NEI Glaucoma Human Genetics Collaboration (NEIGHBOR) genomics consortium analyzed genes in over 34,000 people with glaucoma from European, African, and Asian descent, identifying 44 new gene locations and confirming 83 previously identified ones. While earlier studies had primarily focused on European descent, the cross-ancestry comparison found most genes were consistent across groups. Similarly, an international collaboration in Mexico, Pakistan, and the U.S. conducted whole-genome sequencing of a diverse population of 409 individuals from families with rare, inherited retinal dystrophies to identify 42 new disease-causing gene variants and confirm 52 others.

Translation Success

Years of foundational research have laid the groundwork to improve vision care. An international coalition classified 25 subtypes of uveitis (inflammatory eye disease). These classification criteria are a major step forward for epidemiological, translational, and outcomes research, and clinical trials. The retina is the most accessible part of the central nervous system, and while groundbreaking imaging tools can track anatomy of individual neurons in living patients over time, measuring their function has been a challenge. A novel optoretinography

system provides an all-optical, non-invasive method to assess light-induced functional activity in retinal neurons with high-resolution and sensitivity to detect early-stage defects. While developed as a tool to assess efficacy of new therapies, it might also detect biomarkers of retinal health. NEI-funded Nanoscope, LLC used optogenetics to restore vision in blind mice—a light-sensitive protein specifically delivered to either retinal bipolar cells or retinal ganglion cells renders them intrinsically sensitive to light, even if the photoreceptor cells are non-functioning, as in retinitis pigmentosa. The company is planning a U.S. clinical trial for later this year.

AMD can cause blind spots in both eyes, impacting eye-hand coordination, face recognition, navigation, visual search, and reading. A new eye-tracking based tool overcame technical challenges to enable mapping the precise locations of blind spots on one or both eyes, a necessary first step in vision rehabilitation. The 'dry' form of AMD is currently untreatable, yet new research conducted, in part, by a high school student suggests that the antidepressant Prozac (fluoxetine) slowed progression in a mouse model, possibly by inhibiting a component of the immune system, the inflammasome, involved in triggering dry AMD. When the pandemic prevented her access to the laboratory, the student conducted a computational analysis of two insurance databases covering 100 million Americans, finding that patients taking Prozac were less likely to develop dry AMD. Repurposed FDA-approved drugs can bypass early clinical development to be tested for effectiveness in new indications. Photobiomodulation (PBM) is a potential therapy for dry AMD developed by NEI-funded LumiThera Inc. PBM uses specific wavelengths of light to target respiratory molecules within the mitochondria of cells. Mitochondrial dysfunction leads to oxidative stress, which can result in a number of diseases including AMD and diabetic retinopathy. Clinical results of PBM showed significant improvements in AMD biomarkers and functional vision after six months.

New 5-Year Strategic Plan: Vision for the Future

In November, NEI released a comprehensive strategic plan, "Vision for the Future" centered around seven cross-cutting areas of emphasis (AoE). To implement the plan, NEI created trans-NEI workgroups for each AoE to develop initiatives addressing key recommendations. Actions include workshops, strategic partnerships, training mechanisms, targeted funding opportunities and creating research consortia. NEI recently reorganized its structure creating new coordinating offices that align with the AoEs on Data Science and on Public Health and Disparities Research. The AoE on Regenerative Medicine corresponds with an existing office, which coordinates the NEI Audacious Goals Initiative (AGI) to restore vision by regenerating neurons and neural connections in the visual system. Since 2013, AGI has established three research consortia and funded $62 million in research, establishing vision as a leader in the regenerative medicine field. An external AGI Steering Committee is developing a roadmap for the next five years, building off general regenerative medicine themes identified in the strategic plan, including tools to assess transplanted tissue integration and function, increasing capacity and scale of cell manufacturing, and managing the immune response to regenerative therapies.

The NEI Anterior Segment Initiative (ASI) encompasses components from the Immune System and Eye Health AoE as well as the Biology and Neuroscience of Vision AoE. Following a workshop on the challenges in studying the ocular microbiome—the sparse populations of

microorganisms that live on the surface of the eye—NEI is preparing to release a funding initiative to develop methods to reproducibly study and manipulate the ocular microbiome, and better understand its impact on ocular disease. Another new request for applications will focus on ocular pain and itch, a significant clinical gap area. In addition to understanding corneal nerves and pain mechanisms in the brain, this initiative also explores the immune factors underlying dry eye disease, which disproportionately impacts women. In FY 2021, NEI issued a Notice of Special Interest to encourage applications developing new biomarkers and effective methods to diagnose dry eye disease.

The Public Health and Disparities Research AoE explores the intersecting fields of epidemiology, health services, and health disparities, including women's and minority health. One recommendation is to strengthen community engagement and public outreach, working with leaders in underserved and vulnerable populations to increase health literacy and to gain trust to participate in, and help design clinical studies. The plan builds on existing efforts to expand workforce diversity. In March 2021, NEI initiated a Diversity, Equity, Inclusion, and Accessibility Council to lead initiatives within the organization. NEI firmly believes that developing a talented and diverse workforce will help meet the needs of the NEI mission and lead to increased employee growth, performance, and productivity. And finally, the Individual Quality of Life AoE focuses on the individual's perspective, including patient-reported outcomes, understanding visual function, personalizing rehabilitation for different types of visual impairment and comorbidities, optimizing accessibility devices for low vision, developing resources for education, employment, and navigation, and integrating mental health and wellness into holistic vision care.

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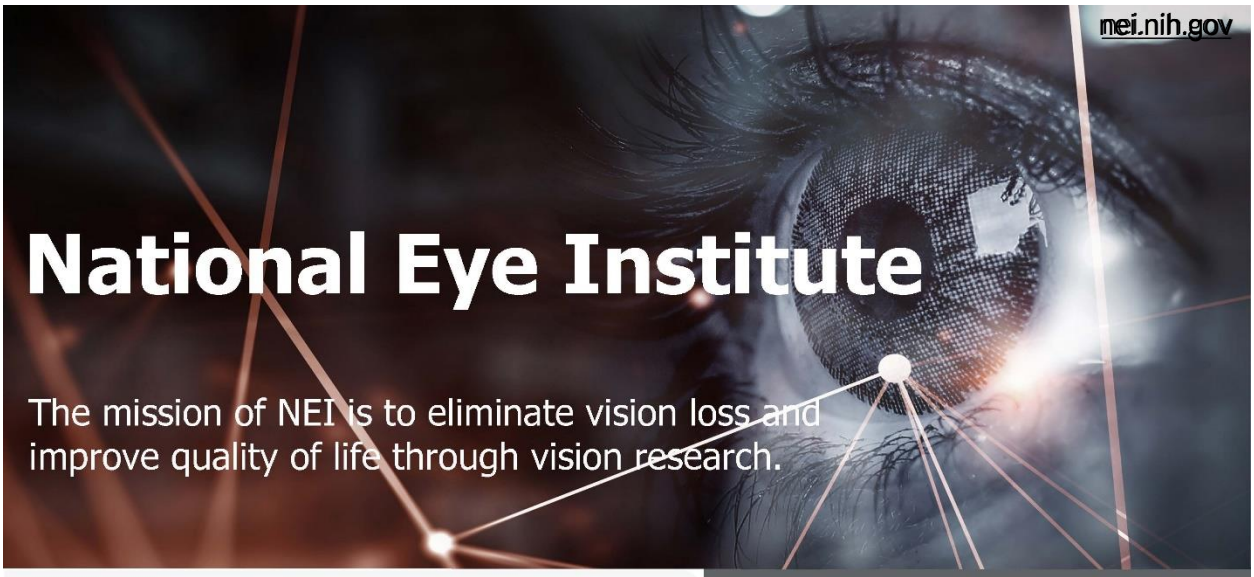
Fact Sheet



To achieve this mission, NEI provides leadership to:

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NIH National Eye Institute

Our Institute

625 NEI employees

$835,714,000
FY 2022 CR
(1.9% of the total NIH budget)

$853,355,000
FY 2023 Budget Request

Extramural Programs
(% of Total FY 2021 Extramural)

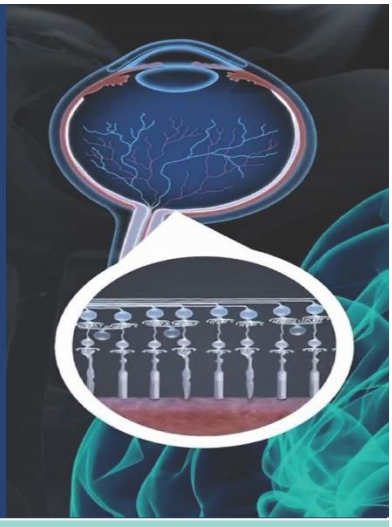
47 %	Retinal Diseases
17 %	Strabismus, Amblyopia, Visual Processing
16 %	Glaucoma and Optic Neuropathy
13 %	Corneal Diseases
4 %	Lens and Cataract
3 %	Low Vision and Blindness Rehabilitation

Intramural Research

23	Laboratories
6	Core Facilities

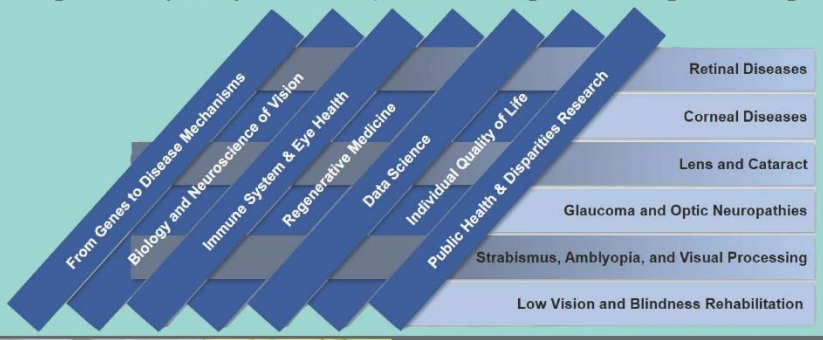
Translating Basic Research to Improve Care

- A new long-acting therapy for glaucoma can potentially replace daily eye drops and surgery with a hydrogel injected at regular patient visits 2-3 times per year.
- NEI Intramural researchers developed a faster, safer, and cheaper COVID-19 test in collaboration with NIH colleagues using a new virus sample preparation method that eliminates time-consuming steps of viral RNA extraction, while also increasing test sensitivity.
- A fully automated at-home advanced retinal imaging device enables patients with age-related macular degeneration to regularly monitor disease progression and response to therapy, greatly reducing the need for doctor visits and potentially improving outcomes. Data are conveyed to the treating physician to help guide appropriate care.



Implementing a Vision for the Future

NEI released its five-year strategic plan in November 2021, building on natural strengths and addressing key needs in seven cross-cutting areas of emphasis (pictured), which intersect with core research programs. The plan affirms the refreshed NEI mission to eliminate vision loss and improve quality of life through innovative research, translating discovery into public health, and recruiting and training the next generation of scientists.



Promoting Diversity in the Vision Research Workforce

- The Diversity In Vision Research and Ophthalmology training program hosts trainees from underrepresented groups in vision research. During the pandemic, NEI adapted a hybrid approach of providing virtual and hands-on learning to 20 NEI trainees.
- NEI launched a Diversity, Equity, Inclusion, and Accessibility Council to improve the workplace environment. Dedicated and strategic actions will help meet the NEI mission and lead to increased employee growth, performance, and productivity.

NIH National Eye Institute

For more information:
nei.nih.gov

Major Changes in the Budget Request

Major changes by budget mechanism and/or budget 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 2023 President's Budget. The FY 2023 President's Budget for NEI is $853.4 million, an increase of $17.6 million from the FY 2022 CR level.

Research Project Grants (RPGs) (+$11.9 million; total $533.3 million):
NEI will support a total of 1,245 Research Project Grants (RPGs) in FY 2023. Noncompeting RPG awards will increase by 15 awards and increase by $6.5 million. Competing RPG awards will increase by 12 awards and increase by $4.9 million.

Other Research (+$1.4 million; total $92.4 million):
Funding for Research Careers is expected to increase by 1.5 percent relative to the FY 2022 CR level, funding an additional 2 grants compared to the FY 2022 CR level of 108 awards. Both Cooperative Clinical Research and Other Research are expected to increase by 1.5 percent while holding the same number of awards.

Research & Development Contracts (+$0.8 million; total $48.2 million)
NEI will increase funding for Research & Development Contracts to accommodate increases to trans-NIH and trans-HHS initiatives for program evaluation and cybersecurity. Funding is also included to accommodate increases to centrally funded services.

Intramural Research (+$2.0 million; total $101.3 million):
NEI will increase funding for Intramural Research to accommodate costs for employee salary and benefit increases and to accommodate increases in charges for centrally funded services.

Budget Mechanism Table

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Budget Mechanism *

(Dollars in Thousands)

Mechanism	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Projects:								
Noncompeting	889	$364,796	897	$380,266	912	$386,731	15	$6,465
Administrative Supplements	*(57)*	$5,301	*(57)*	$5,301	*(57)*	$5,301	0	$0
Competing:								
Renewal	85	$39,671	77	$31,569	80	$32,977	3	$1,408
New	215	$89,794	192	$78,717	201	$82,229	9	$3,511
Supplements	0	$0	0	$0	0	$0	0	$0
Subtotal, Competing	**300**	**$129,465**	**269**	**$110,286**	**281**	**$115,206**	**12**	**$4,920**
Subtotal, RPGs	1,189	$499,562	1,166	$495,854	1,193	$507,238	27	$11,384
SBIR/STTR	51	$25,570	51	$25,570	52	$26,051	1	$481
Research Project Grants	1,240	$525,131	1,217	$521,423	1,245	$533,289	28	$11,865
Research Centers								
Specialized/Comprehensive	39	$26,723	42	$27,386	43	$27,797	1	$411
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	$146	0	$2
Research Centers in Minority Institutions	0	$0	0	$0	0	$0	0	$0
Research Centers	**39**	**$26,867**	**42**	**$27,530**	**43**	**$27,943**	**1**	**$413**
Other Research:								
Research Careers	103	$20,203	108	$21,703	110	$22,029	2	$326
Cancer Education	0	$0	0	$0	0	$0	0	$0
Cooperative Clinical Research	32	$39,876	32	$39,876	32	$40,475	0	$598
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	$30,996	22	$29,496	22	$29,939	0	$442
Other Research	**152**	**$91,076**	**162**	**$91,076**	**164**	**$92,442**	**2**	**$1,366**
Total Research Grants	1,431	$643,075	1,421	$640,029	1,452	$653,674	31	$13,644
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	125	$6,031	135	$6,781	135	$6,917	0	$136
Institutional Awards	118	$5,643	127	$7,938	127	$8,097	0	$159
Total Research Training	**243**	**$11,674**	**262**	**$14,719**	**262**	**$15,013**	**0**	**$294**
Research & Develop. Contracts	41	$46,059	41	$47,371	41	$48,185	0	$814
SBIR/STTR (non-add)	*(0)*	*($269)*	*(0)*	*($269)*	*(0)*	*($269)*	*(0)*	*($0)*
Intramural Research	202	$98,424	182	$99,334	182	$101,342	0	$2,008
Res. Management & Support	83	$33,781	108	$34,261	108	$35,141	0	$880
SBIR Admin. (non-add)	*(0)*	*($0)*	*(0)*	*($0)*	*(0)*	*($0)*	*(0)*	*($0)*
Construction		$0		$0		$0		$0
Buildings and Facilities		$0		$0		$0		$0
Total, NEI	**285**	**$833,012**	**290**	**$835,714**	**290**	**$853,355**	**0**	**$17,641**

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

Appropriations Language

NATIONAL EYE INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to eye diseases and visual disorders, $853,355,000.

Summary of Changes

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Summary of Changes
(Dollars in Thousands)

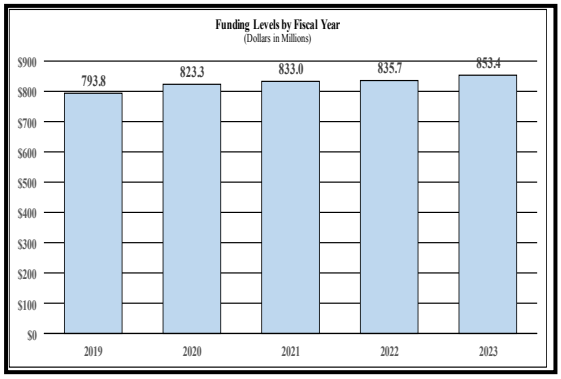
FY 2022 CR	$835,714
FY 2023 President's Budget	$853,355
Net change	$17,641

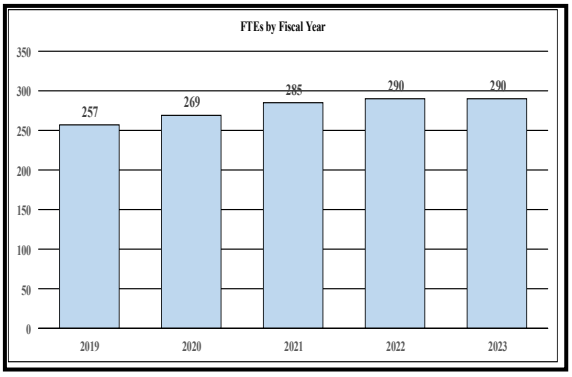
CHANGES	FY 2022 CR FTEs	FY 2022 CR Budget Authority	FY 2023 President's Budget FTEs	FY 2023 President's Budget Budget Authority	Built-In Change from FY 2022 CR FTEs	Built-In Change from FY 2022 CR Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2022 pay increase & benefits		$38,292		$39,688		$349
b. January FY 2023 pay increase & benefits		$38,292		$39,688		$1,047
c. Paid days adjustment		$38,292		$39,688		$0
d. Differences attributable to change in FTE		$38,292		$39,688		$0
e. Payment for centrally furnished services		$17,051		$17,392		$341
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$43,991		$44,262		$977
Subtotal						$2,714
2. Research Management and Support:						
a. Annualization of January 2022 pay increase & benefits		$19,133		$19,833		$175
b. January FY 2023 pay increase & benefits		$19,133		$19,833		$525
c. Paid days adjustment		$19,133		$19,833		$0
d. Differences attributable to change in FTE		$19,133		$19,833		$0
e. Payment for centrally furnished services		$4,208		$4,292		$84
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$10,920		$11,016		$240
Subtotal						$1,025
Subtotal, Built-in						$3,738

CHANGES	FY 2022 CR No.	FY 2022 CR Amount	FY 2023 President's Budget No.	FY 2023 President's Budget Amount	Program Change from FY 2022 CR No.	Program Change from FY 2022 CR Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	897	$385,567	912	$392,032	15	$6,465
b. Competing	269	$110,286	281	$115,206	12	$4,920
c. SBIR/STTR	51	$25,570	52	$26,051	1	$481
Subtotal, RPGs	1,217	$521,423	1,245	$533,289	28	$11,865
2. Research Centers	42	$27,530	43	$27,943	1	$413
3. Other Research	162	$91,076	164	$92,442	2	$1,366
4. Research Training	262	$14,719	262	$15,013	0	$294
5. Research and development contracts	41	$47,371	41	$48,185	0	$814
Subtotal, Extramural		$702,119		$716,872		$14,753
6. Intramural Research	182	$99,334	182	$101,342	0	-$706
7. Research Management and Support	108	$34,261	108	$35,141	0	-$144
8. Construction		$0		$0		$0
9. Buildings and Facilities		$0		$0		$0
Subtotal, Program	290	$835,714	290	$853,355	0	$13,903
Total built-in and program changes						$17,641

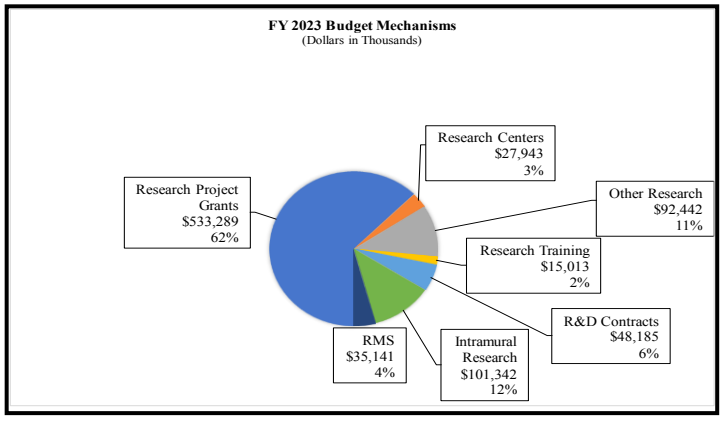
Fiscal Year 2023 Budget Graphs

History of Budget Authority and FTEs:

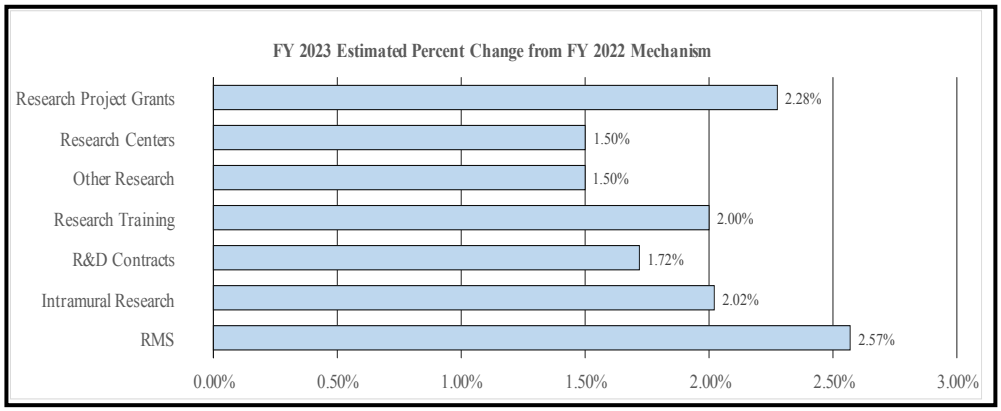




Change by Selected Mechanisms:



Distribution by Mechanism:

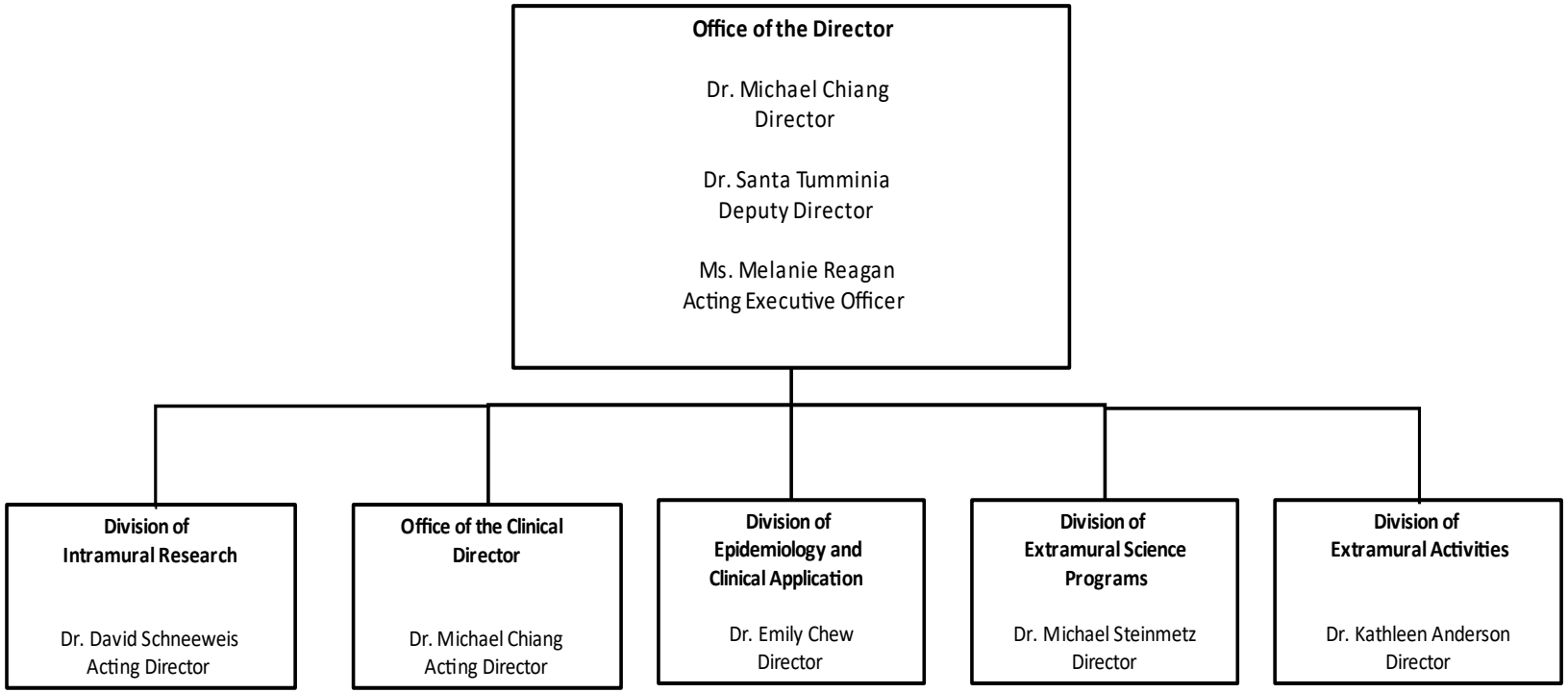


Organization Chart

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Organizational Chart



Budget Authority by Activity Table

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Budget Authority by Activity *
(Dollars in Thousands)

	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022 CR	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Retinal Diseases Research		$340,135		$340,771		$347,932		$7,160
Corneal Diseases, Cataract, and Glaucoma Research		$222,948		$223,365		$228,059		$4,693
Sensorimotor Disorders, Visual Processing, and Rehabilitation Research		$137,725		$137,983		$140,882		$2,899
Subtotal, Extramural		**$700,807**		**$702,119**		**$716,872**		**$14,753**
Intramural Research	**202**	**$98,424**	**182**	**$99,334**	**182**	**$101,342**	**0**	**$2,008**
Research Management & Support	**83**	**$33,781**	**108**	**$34,261**	**108**	**$35,141**	**0**	**$880**
TOTAL	**285**	**$833,012**	**290**	**$835,714**	**290**	**$853,355**	**0**	**$17,641**

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

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 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	833,012,000	835,714,000	853,355,000	+17,641,000
FTE	285	290	290	0

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

Overall Budget Policy: The FY 2023 President's Budget request is $853.4 million, an increase of $17.6 million or 2.1 percent compared with the FY 2022 CR level.

Program Descriptions

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 from diseases such as macular degeneration or diabetic retinopathy are among the leading causes of blindness in the United States. 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 in cell biology, physiology, neuroscience, and immunology related to the retina. Major areas addressed within the Retina Program include key causes of blindness such as:

- **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 breakdown of light sensing photoreceptor neurons; and neovascular ("wet") AMD, an abnormal growth of blood vessels underneath the retina.
- **Retinopathy.** Diabetic retinopathy is a complication of diabetes mellitus in which abnormal blood vessels grow on the surface of the retina and may swell and leak fluid. Retinopathy of Prematurity (ROP) is a potentially blinding disorder that affects premature infants with very low birthweight.
- **Retinal monogenic disorders.** Single genetic mutations cause some retinal degenerative diseases, including retinitis pigmentosa, Usher syndrome, and ocular albinism.

- **Uveitis.** Inflammatory diseases that produce swelling and destroy eye tissue, sometimes leading to severe vision loss.

Accomplishments:

- A new method to noninvasively image photoreceptors, the light-sensing neurons in the retina, selectively blocked light used to image the eye, improving image resolution by 30 percent. This advance will make it easier to monitor cell changes in retinal tissue.
- Using patient-derived stem cells and a bioengineered matrix, researchers recently developed a 3-D model of part of the human retina including small blood vessels (choriocapillaris) and the retinal pigment epithelium, the thin tissue that nourishes the photoreceptors. The interaction of these tissues underlies "wet" AMD, enabling dissection of cellular mechanisms in each layer using different genetic backgrounds.
- A gene related to retinal disease progression can provide insights towards developing drug target for diseases such as Leber congenital amaurosis. Studies found that deleting a specific gene in a mouse model that codes for a fatty acid transport protein (FATP4) can prevent photoreceptors from deteriorating. This advance provides a promising path towards mitigating vision loss in people with specific gene mutations.
- NEI has leveraged trans-NIH initiatives to translate basic biology into clinical trials. The NIH Blueprint Neurotherapeutics program developed small molecule therapies, including a trial testing a drug that potentially neutralizes toxic byproduct of the visual cycle that can lead to dry AMD. A phase 1/2 clinical trial is one of two projects testing stem cell-based therapies for AMD through the Regenerative Medicine Innovation Project, part of the 21st Century Cures Act.

Budget Policy: The FY 2023 Budget request for this program area is $347.9 million, an increase of $7.2 million or 2.1 percent compared with the FY 2022 CR level.

Corneal Diseases, Cataract, and Glaucoma Research: Corneal diseases, cataracts, and glaucoma cause more visits to ophthalmologists a year than any other vision disorder. NEI supports research to address these conditions that originate in the front of the eye.

- **Corneal disease.** Corneal injuries, infections, and diseases can be extremely painful and require immediate medical attention. The ocular surface is the front line against environmental insults, such as viruses (herpes simplex, herpes zoster), bacteria (causing trachoma and other conditions), fungus (sometimes associated with contact lens wear) and ocular inflammation (uveitis) that can be serious and lead to permanent vision loss. NEI's corneal research encompasses ocular injuries sustained from sports and other recreational activities, from workplace accidents, and from eye trauma.
- **Cataract.** Cataracts, a clouding of the lens in the eye that affects vision, are the leading cause of blindness worldwide. NEI researchers investigate strategies to prevent cataract formation and progression through research to understand the physiological basis of how the lens in the healthy eye remains transparent for much of the lifespan.

- **Glaucoma.** Glaucoma refers to a group of blinding diseases that result from damage to the optic nerve, the bundle of fibers that transmit signals from the eyes to the brain. Because there are no early symptoms, half of people with glaucoma don't know they have it, but over time individuals slowly lose side (peripheral) vision. Individuals over age 60, who are Black or Hispanic, or who have a family history have a much higher disease risk. Current therapies focus on reducing excessive fluid pressure in the eye, which causes nerve damage in the most common form of glaucoma.

Accomplishments:

- While cataracts are almost inevitable in aging eyes, even routine surgery poses risk of infection. Researchers discovered that a molecule produced by cells called itaconate can help protect the eye from abnormal inflammation during infection, acting through a pathway called the inflammasome. To reduce potential risks of acquiring infections after eye surgeries for cataract, AMD, or glaucoma, doctors can use itaconate in combination with antibiotics.
- The 21st Century Cures Act Regenerative Medicine Innovation Project has launched two stem cell trials for corneal repair. One trial is developing a stem cell therapy for Limbal Stem Cell Deficiency; limbal stem cells repair damage to cornea. The other trial captures restorative factors secreted by stem cells to create a therapeutic eye drop to accelerate corneal wound healing.
- Congenital cataract has an incidence of 2 to 6 cases per 10,000 children.[1] A recent NEI study followed infants who underwent cataract surgery and showed that the risk of developing glaucoma was substantial between ages 1 through 10, regardless of prior lens implantation. This study challenges the belief that replacing a child's lens with an implanted one protects them from developing glaucoma and underscores the need for long-term glaucoma surveillance.
- Although glaucoma is characterized by nerve damage, approved therapies generally work to reduce fluid pressure, a risk factor for some, but not all, forms of the disease. Through animal models, scientists discovered that ingesting citicoline, a compound naturally produced in the brain, can restore optic nerve signals, and reduce vision loss in a rat model of glaucoma. The molecule did not reduce fluid pressure, but instead appeared to be neuroprotective.

Budget Policy: The FY 2023 Budget request for this program area is $228.1 million, an increase of $4.7 million or 2.1 percent compared with the FY 2022 CR level.

[1] Solebo, A. L., & Rahi, J. S. Epidemiology of congenital cataract. Congenital Cataract 2017; (pp. 15-25). Springer, Cham.

Sensorimotor Disorders, Visual Processing, and Rehabilitation Research: Vision is the dominant sensory system in humans, occupying over one-third of the brain neocortex. NEI funds basic and applied research on the brain as it relates to the visual system and perception, and research on rehabilitation for individuals with low vision. NEI neuroscientists have made remarkable progress in understanding what goes on in the face-processing areas in the brain. As a leader in the trans-NIH Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative, NEI leverages neuroscience research in other fields to propel visual neuroscience, such as the development of the Orion visual cortical prosthesis system, which provides vision rehabilitation for blind individuals.

Program Portrait: Myopia— a complex public health burden and a potential therapy

Refractive errors are the most common type of vision problem, occurring when the shape of the eye results in light focusing in front of the retina, causing blurry vision. Nearsightedness, or myopia, makes it difficult to focus on distant objects. Myopia primarily begins in childhood as their eyes are still elongating—a process called emmetropization—but it can worsen with age. Because the underlying changes in the eye brought about by myopia are irreversible, identifying the environmental factors associated with myopia development has significant implications for reducing the growing public health burden associated with the disease. If undiagnosed, myopia has potentially damaging consequences, impairing vision in the classroom with lifelong learning implications; severe myopia increases risk for blinding diseases including glaucoma, cataract, and retinal detachment. Behaviors that involve 'near work' like reading or screen time may increase risks. The HHS Healthy People 2030 Initiative created a new research goal to understand the impacts of screen time on eye development and visual impairment. Epidemiological studies have shown that children who spend more time outdoors in broad sunlight reduce their risks of developing myopia. However, the underlying causes of myopia are complex and recent laboratory research found that dim light, such as those found indoors, does not cause myopia, but may contribute to impairing of the way in which the eye controls refractive errors. Children wearing therapeutic contact lenses that correct central vision but leave peripheral vision uncorrected had slower progression of their myopia, according to results from the NEI-funded Bifocal Lenses In Nearsighted Kids study. Researchers are currently following participants to investigate whether myopia progression is slowed by wearing these therapeutic contact lenses and assess whether there is a "rebound" in myopia progression after discontinued wear.

- **Sensorimotor disorders and visual processing research.** Strabismus (misalignment of the eyes) and amblyopia (commonly known as "lazy eye") are common disorders that develop during childhood and are a major cause of irreversible vision loss in children. Program goals center on gaining a better understanding of the neuromuscular control of gaze and the development of the visual system in babies and young children at high risk for these disorders. Neuroscientists working in vision research 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. Additional research is directed at trying to open the so-called "critical period" and thereby allow some recovery of visual function and stereopsis in adult amblyopia subjects.
- **Refractive errors.** Refractive errors, such as nearsightedness (myopia), farsightedness, and astigmatism, are, once diagnosed, commonly correctable with eyeglasses or contact lenses, but these conditions often worsen and therefore remain a costly, recurring

economic and personal burden to many in the United States and globally. Increases in the prevalence of these conditions are a public health concern. People with complications, such as severe nearsightedness, can also be at risk of vision loss from glaucoma or retinal detachment. The 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 with the goal of prevention of disease onset or progression.

- **Rehabilitation research.** Some causes of blindness and visual impairment are not currently treatable. Low vision is the term used to describe chronic visual conditions whose visual impairment is not correctable by eyeglasses 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 developing improved accessibility aids and devising new strategies proven to assist those without useful vision.

Accomplishments:

- The visual system handles a continuously changing stream of input; people parse that input by eye movements (i.e., saccades) to attend to different parts of a visual scene. Even before initiating an eye movement, presaccadic attention is deployed to a future gaze location which alerts the system to the information there. Subjects can overtly attend to that information by making an eye movement to that particular location, or covertly without moving their eyes. A series of psychophysics (the science of perception) experiments and model comparisons determined the degree to which these different types of visual attention can be dissociated, suggesting the perceptual modulations by overt presaccadic and covert spatial attention have different dynamics and are mediated through different computations.
- Many existing functional vision tests, including the ability to distinguish between different shades of light and dark, called contrast sensitivity function (CSF), involve lengthy procedures, and rely on verbal instruction and feedback, making it difficult to administer for many patients and excludes populations with cognitive and/or cerebral (cortical) visual impairment (CVI). NEI researchers created a nonverbal test for contrast sensitivity, called "Gradiate," that infers visibility from eye movements and manipulates stimulus appearance in real time. The new testing procedure holds potential to be adopted into mainstream optometry batteries. The current goal is to incorporate the new measure in clinical studies aiming to link specific diseases, such as CVI, to specific changes in the shape of the CSF.
- Vision impairment is common among the aging population and older drivers are prone to experience higher rates of motor vehicle accidents compared to other age groups. Researchers objectively assessed natural driving methods and identified a link between vision risk factors (e.g., impaired contrast sensitivity, slower processing speed, decreased motion perception) and traffic accidents. This type of research provides evidence for interventions that enhance both public safety and personal mobility.

Budget Policy: The FY 2023 Budget request for this program area is $140.9 million, an increase of $2.9 million or 2.1 percent compared with the FY 2022 CR level.

Intramural Research: NEI basic and clinical studies conducted on the NIH campus are focused on the cause, prevention, and treatment of eye diseases and vision disorders; cellular and molecular mechanisms of eye development, infectious diseases of the eye; inflammatory and immunological responses; mechanisms of visual perception by the brain; and sensory control of movements.

Accomplishments: NEI scientists have been applying their expertise to addressing the COVID-19 pandemic. A team of researchers from across NIH developed a faster, safer, and cheaper diagnostic test for SARS-CoV-2, the virus that causes COVID-19. Their new virus sample preparation method eliminates time-consuming steps of viral RNA extraction, while also increasing test sensitivity. NEI investigators are also collaborating with the National Library of Medicine and other scientists to examine the genome, associated proteins, and mutation patterns of SARS-CoV-2, which contributes to important foundational research and overall pandemic preparedness.

Budget Policy: The FY 2023 Budget request for this program area is $101.3 million, an increase of $2.0 million or 2.0 percent compared with the FY 2022 CR level.

Research Management and Support (RMS): RMS is a budget category that supports leadership and administrative personnel whose job it is to supply direction for the Institute, provide essential services, manage research programs, and monitor budgets. This line item includes functions and activities such as management of human resource support, training, travel, purchasing, facilities, budget, planning and oversight, information technology, and extramural grant awards. NEI currently oversees more than 1,700 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 2023 Budget request for this program area is $35.1 million, an increase of $0.9 million or 2.6 percent compared with the FY 2022 CR level.

Appropriations History

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2014	$699,216,000		$701,407,000	$682,077,000
Rescission				$0
2015	$675,168,000			$684,191,000
Rescission				$0
2016	$695,154,000	$698,108,000	$709,549,000	$715,903,000
Rescission				$0
2017 [1]	$707,998,000	$735,576,000	$740,826,000	$732,618,000
Rescission				$0
2018	$549,847,000	$743,881,000	$758,552,000	$772,317,000
Rescission				$0
2019	$711,015,000	$781,540,000	$796,955,000	$796,536,000
Rescission				$0
2020	$685,644,000	$835,465,000	$840,163,000	$824,090,000
Rescission				$0
2021	$749,003,000	$831,177,000	$850,135,000	$835,714,000
Rescission				$0
2022	$858,535,000	$877,129,000	$857,868,000	$835,714,000
Rescission				$0
2023	$853,355,000			

[1] Budget Estimate to Congress includes mandatory financing.

Authorizing Legislation

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2022 Amount Authorized	FY 2022 CR	2023 Amount Authorized	FY 2023 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$835,714,000	Indefinite	$853,355,000
National Eye Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$835,714,000		$853,355,000

Amounts Available for Obligation

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Amounts Available for Obligation [1]

(Dollars in Thousands)

Source of Funding	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation	$835,714	$835,714	$853,355
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*($0)*	*($0)*	*($0)*
Other Mandatory financing	*($0)*	*($0)*	*($0)*
Secretary's Transfer	-$2,509	$0	$0
Subtotal, adjusted appropriation	$833,205	$835,714	$853,355
OAR HIV/AIDS Transfers	-$193	$0	$0
Subtotal, adjusted budget authority	$833,012	$835,714	$853,355
Unobligated balance, start of year	$0	$0	$0
Unobligated balance, end of year (carryover)	$0	$0	$0
Subtotal, adjusted budget authority	**$833,012**	**$835,714**	**$853,355**
Unobligated balance lapsing	$0	$0	$0
Total obligations	$833,012	$835,714	$853,355

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2021 - $18,808 FY 2022 - $25,100 FY 2023 - $21,500

Budget Authority by Object Class

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022 CR
Total compensable workyears:				
	Full-time equivalent	290	290	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$201	$207	$5
	Average GM/GS grade	12.5	12.5	0.0
	Average GM/GS salary	$119	$123	$3
	Average salary, Commissioned Corps (42 U.S.C. 207)	$118	$121	$3
	Average salary of ungraded positions	$150	$154	$4
	OBJECT CLASSES	**FY 2022 CR**	**FY 2023 President's Budget**	**FY 2023 +/- FY 2022**
	Personnel Compensation			
11.1	Full-Time Permanent	23,496	24,370	875
11.3	Other Than Full-Time Permanent	12,441	12,904	463
11.5	Other Personnel Compensation	1,797	1,865	67
11.7	Military Personnel	125	130	5
11.8	Special Personnel Services Payments	5,285	5,482	198
11.9	**Subtotal Personnel Compensation**	**$43,144**	**$44,751**	**$1,607**
12.1	Civilian Personnel Benefits	14,130	14,613	483
12.2	Military Personnel Benefits	151	156	6
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$57,425**	**$59,521**	**$2,096**
21.0	Travel & Transportation of Persons	55	54	-1
22.0	Transportation of Things	78	78	0
23.1	Rental Payments to GSA	1	1	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	109	87	-22
24.0	Printing & Reproduction	34	33	-1
25.1	Consulting Services	23,033	23,488	456
25.2	Other Services	20,541	21,113	572
25.3	Purchase of Goods and Services from Government Accounts	54,945	55,096	151
25.4	Operation & Maintenance of Facilities	53	54	0
25.5	R&D Contracts	14,227	14,560	333
25.6	Medical Care	525	545	20
25.7	Operation & Maintenance of Equipment	2,826	2,844	17
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$116,150**	**$117,699**	**$1,549**
26.0	Supplies & Materials	4,224	4,281	57
31.0	Equipment	2,315	2,346	31
32.0	Land and Structures	574	566	-7
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	654,748	668,687	13,939
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$778,289**	**$793,834**	**$15,545**
	Total Budget Authority by Object Class	**$835,714**	**$853,355**	**$17,641**

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

Salaries and Expenses

NATIONAL INSTITUTES OF HEALTH

National Eye Institute

Salaries and Expenses

(Dollars in Thousands)

Object Classes	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel Compensation			
Full-Time Permanent (11.1)	$23,496	$24,370	$875
Other Than Full-Time Permanent (11.3)	$12,441	$12,904	$463
Other Personnel Compensation (11.5)	$1,797	$1,865	$67
Military Personnel (11.7)	$125	$130	$5
Special Personnel Services Payments (11.8)	$5,285	$5,482	$198
Subtotal, Personnel Compensation (11.9)	**$43,144**	**$44,751**	**$1,607**
Civilian Personnel Benefits (12.1)	$14,130	$14,613	$483
Military Personnel Benefits (12.2)	$151	$156	$6
Benefits to Former Personnel (13.0)	$0	$0	$0
Subtotal Pay Costs	**$57,425**	**$59,521**	**$2,096**
Travel & Transportation of Persons (21.0)	$55	$54	-$1
Transportation of Things (22.0)	$78	$78	$0
Rental Payments to Others (23.2)	$0	$0	$0
Communications, Utilities & Misc. Charges (23.3)	$109	$87	-$22
Printing & Reproduction (24.0)	$34	$33	-$1
Other Contractual Services			
Consultant Services (25.1)	$23,033	$23,488	$456
Other Services (25.2)	$20,541	$21,113	$572
Purchase of Goods and Services from Government Accounts (25.3)	$33,953	$34,972	$1,019
Operation & Maintenance of Facilities (25.4)	$53	$54	$0
Operation & Maintenance of Equipment (25.7)	$2,826	$2,844	$17
Subsistence & Support of Persons (25.8)	$0	$0	$0
Subtotal Other Contractual Services	**$80,406**	**$82,470**	**$2,064**
Supplies & Materials (26.0)	$4,224	$4,281	$57
Subtotal Non-Pay Costs	**$84,905**	**$87,003**	**$2,098**
Total Administrative Costs	**$142,330**	**$146,524**	**$4,194**

Detail of Full-Time Equivalent Employment (FTE)

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2021 Final			FY 2022 CR			FY 2023 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Activities									
Direct:	18	-	18	18	-	18	18	-	18
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	18	-	18	18	-	18	18	-	18
Division of Intramural Research									
Direct:	135	-	135	139	-	139	139	-	139
Reimbursable:	3	-	3	3	-	3	3	-	3
Total:	138	-	138	142	-	142	142	-	142
Office of the Director									
Direct:	98	1	99	98	1	99	98	1	99
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	98	1	99	98	1	99	98	1	99
Division of Epidemiology and Clinical Applications									
Direct:	10	-	10	10	-	10	10	-	10
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	10	-	10	10	-	10	10	-	10
Division of Extramural Science									
Direct:	20	-	20	21	-	21	21	-	21
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	20	-	20	21	-	21	21	-	21
Total	284	1	285	289	1	290	289	1	290
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
2019	12.4
2020	12.4
2021	12.5
2022	12.5
2023	12.5

Detail of Positions

NATIONAL INSTITUTES OF HEALTH
National Eye Institute

Detail of Positions[1]

GRADE	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	$199,300	$201,293	$206,728
General Schedule			
GM/GS-15	36	36	36
GM/GS-14	38	38	38
GM/GS-13	49	49	49
GS-12	34	34	34
GS-11	30	30	30
GS-10	2	2	2
GS-9	13	13	13
GS-8	2	2	2
GS-7	2	2	2
GS-6	1	1	1
GS-5	1	1	1
GS-4	2	2	2
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	211	211	211
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	1	1	1
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	1	1	1
Ungraded	79	77	77
Total permanent positions	212	212	212
Total positions, end of year	292	290	290
Total full-time equivalent (FTE) employment, end of year	285	290	290
Average ES salary	$199,300	$201,293	$206,728
Average GM/GS grade	12.5	12.5	12.5
Average GM/GS salary	$117,440	$119,311	$122,532

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