

National Institute of Neurological Disorders and Stroke

National Institute of Neurological Disorders and Stroke

CONGRESSIONAL JUSTIFICATION FY 2025

Department of Health and Human Services National Institutes of Health [THIS PAGE INTENTIONALLY LEFT BLANK]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological Disorders and Stroke (NINDS)

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General Notes

- 1. FY 2024 funding levels cited in this document are based on the Continuing Resolution in effect at the time of budget preparation (Public Law 118-35) and do not include HIV/AIDS transfers.
- 2. Detail in this document may not sum to the subtotals and totals due to rounding.

Cover Page

A cluster of neurons in a mouse hippocampus colored green and blue with a few active neurons colored red. 2021 First Place Photo Winner, Show Us Your BRAINs! Photo & Video Contest (braininitiative.nih.gov/news-events/show-us-your-brains-photo-video-contest). By Sahar Ahmad, Ye Wu, and Pew-Thian Yap, The University of North Carolina at Chapel Hill [THIS PAGE INTENTIONALLY LEFT BLANK]

DIRECTOR'S OVERVIEW

Director's Overview

The mission of the National Institute of Neurological Disorders and Stroke (NINDS) is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people. 2025 will mark our 75th anniversary as a leader in neuroscience research, a milestone and opportunity to celebrate our accomplishments and envision progress still to come. Although the sheer complexity of the nervous system and its sensitivity to injury present formidable challenges, decades of basic, translational, and clinical research



Walter J. Koroshetz, M.D., *Director*

have led to therapies for previously untreatable conditions and new tools for studying brain development and function across scales from cells to circuits and to behavior. Our achievements give us hope even as the needs remain daunting: neurological disorders are the leading cause of disability and the second leading cause of death worldwide,¹ and the impact of conditions such as stroke and neurodegenerative diseases will continue to grow as the population ages. To meet these needs, and guided by the NINDS Strategic Plan, we are investing in innovative and rigorous research, fostering a robust and inclusive research workforce, and working closely with our many partners, including people with lived experience of neurological disorders.

Fueling new approaches to treating neurological disorders

When NINDS was established in 1950, we knew little about stroke, and doctors could do virtually nothing for people who had one. As research identified treatable risk factors such as high blood pressure, stroke mortality began to decline,² falling 77 percent between 1969 and 2013. Another major advance was the clot-dissolving medicine tissue plasminogen activator (tPA), the first life-saving treatment for acute ischemic stroke. NINDS played a central role in tPA's success,³ funding early studies providing a rationale for its use and leading pivotal clinical trials supporting Food and Drug Administration (FDA) approval in 1996. NINDS also launched a public campaign to promote urgent treatment for stroke and pioneered protocols for rapid patient assessment and treatment that revolutionized stroke care. This momentum in advancing stroke care has continued, bolstered by research to develop and apply new brain imaging methods and surgical approaches. In 2016, a clinical trial through our stroke trials network (NIH StrokeNet) drove updates to treatment guidelines to expand the use of endovascular thrombectomy (EVT), or surgical clot removal.⁴

Despite this progress, nearly 800,000 people in the United States have a stroke each year,⁵ and after decades of decline, stroke mortality rates have plateaued in recent years,⁶ with concerning

¹ pubmed.ncbi.nlm.nih.gov/31813850/

² pubmed.ncbi.nlm.nih.gov/26505597/

³ www.ninds.nih.gov/about-ninds/impact/ninds-contributions-approved-therapies/tissue-plasminogen-activatoracute-ischemic-stroke-alteplase-activaser

⁴ www.ninds.nih.gov/about-ninds/impact/ninds-contributions-approved-therapies/optimizing-endovascular-therapyischemic-stroke

⁵ <u>www.cdc.gov/stroke/facts.htm</u>

 $[\]label{eq:constraint} ^{6} \underline{health.gov/healthypeople/objectives-and-data/browse-objectives/heart-disease-and-stroke/reduce-stroke-deaths-hds-03/data} \\$

increases in some groups and regions. Too few people who experience a stroke meet eligibility requirements for current treatments, and stroke continues to be a leading cause of disability. Looking ahead, a new platform within StrokeNet will simultaneously test several interventions to further optimize EVT, and the Stroke Preclinical Assessment Network (SPAN) is testing candidate drugs that may protect brain tissue and improve outcomes when used with therapies like tPA or EVT to restore blood flow. NINDS also focuses on primary and secondary stroke prevention and on novel approaches to stroke rehabilitation and recovery.

One thousand or more diseases affect the nervous system, including a large number of genetic conditions. Beginning in the 1980s and accelerated by the Human Genome Project, we witnessed an explosion of discoveries pinpointing genetic causes of neurological disorders, enabling faster and more accurate diagnoses and transforming research to understand disease mechanisms and develop targeted therapies. For many neurological diseases, both common and rare, current medications may not achieve their desired outcomes without unintended, off-target side effects. We are now starting to realize the promise of gene-based approaches, such as gene therapies and antisense oligonucleotides (ASO), as more effective and more precise treatments that directly modify disease mechanisms in affected cells and tissues. For example, NINDS-funded research made important contributions to an ASO and a gene therapy for spinal muscular atrophy (SMA),^{7,8} the first FDA-approved therapies for this rare and often fatal condition affecting motor neurons. Gene-based therapies are also approved or in development for other neurological disorders, including muscular dystrophy, and amyotrophic lateral sclerosis (ALS).

To stimulate further advances, NINDS established the Ultra-Rare Gene Therapy Network (URGenT) to support the development of gene-based therapies for ultra-rare diseases, affecting no more than 1 in 50,000 people. Few ultra-rare neurological diseases have effective treatments, and the small number of people affected presents challenges for research, commercial investment, and regulatory approval. Yet, most of these diseases are caused by variations in a single gene, making them excellent candidates for gene-based therapies. In FY 2023, URGenT launched three new projects to develop gene-based therapies for prion disease, Menkes disease, and aspartylglucosaminuria, and a new gene therapy consortium will facilitate clinical trials for ultra-rare diseases as a collaboration within our Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT). URGenT complements NINDS leadership and participation in other genetic therapy initiatives, including the NIH Common Fund's Somatic Cell Genome Editing and the Bespoke Gene Therapy Consortium through the Accelerating Medicines Partnership (AMP®) managed by the Foundation for the National Institutes of Health (FNIH). These programs have also launched new projects on neurological disorders.

Focusing on gene-based therapies for rare diseases through URGenT and other programs is a first step, and we hope that successes and lessons learned will lead to broader applications for more common neurological conditions as well as diseases that are still unknown. Elusive medical conditions that have not been diagnosed despite extensive clinical evaluation present difficult problems for patients, families, and physicians who may spend years seeking diagnosis and treatment. Leveraging advances in medical and genomic research, the NIH Undiagnosed

⁷ <u>ninds.nih.gov/about-ninds/impact/ninds-contributions-approved-therapies/nusinersen-spinrazar-spinal-muscular-atrophy-sma</u>

⁸ directorsblog.nih.gov/2017/11/21/clinical-trials-bring-hope-to-kids-with-spinal-muscular-atrophy/

Diseases Network (UDN) has established exemplary clinical practices, standards, and pipelines for genomics-based diagnoses that can inform patient care. Since its launch by the NIH Common Fund in 2013, the UDN has made over 670 diagnoses including new diseases and syndromes and identified hundreds of disease-linked genes and genomic variants. NINDS has played a major part in the UDN, given that many cases have neurologic involvement, and in FY 2023, the UDN transitioned to NINDS leadership with NIH-wide collaboration to sustain and expand the program to reach a greater number and diversity of participants.

In 1950, neuroscience was a young discipline, and researchers were just beginning to uncover basic principles about how neurons and neural connections work. Mapping of brain circuits and functions was rudimentary, as tools were not available to observe brain structure and activity with sufficient resolution in time or space. Fast-forward to today, and new tools allow research to identify and map individual cell types across the brain.⁹ monitor thousands of cells in a circuit in real time, precisely manipulate cells' activity, and non-invasively observe and stimulate the human brain with increasing precision. Made possible by decades of basic neuroscience research, the NIH Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative-supported by NINDS, the National Institute on Mental Health (NIMH), and eight other NIH partners-has propelled many of these innovations. Researchers are using BRAINfunded technologies to answer fundamental questions about brain function and disease mechanisms and to develop new diagnostic tools and therapies. Exciting advances include new prosthetics for speech and movement disorders and brain and spinal cord stimulation therapies for chronic pain, Parkinson's disease, depression, and obsessive compulsive disorder, and motor impairment after stroke. Three large-scale transformative BRAIN projects will build on this progress, including the recently launched BRAIN Initiative Connectivity Across Scales (BRAIN CONNECTS) Network, which will generate brain-wide wiring diagrams.

Partnerships strengthen NINDS research

The challenges and opportunities before us to advance neuroscience research and tackle neurological diseases are too complex for NINDS alone. We rely on the expertise and creativity of the scientific community, and we know that working with our many partners to bring in diverse resources, knowledge, and perspectives will only strengthen and expand the reach of our research. In addition to our roles in the BRAIN Initiative® and the NIH Blueprint for Neuroscience, we bring NINDS leadership and support to NIH-wide activities addressing urgent public health priorities. NINDS co-leads the Researching COVID to Enhance Recovery (RECOVER) Initiative with the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Allergy and Infectious Diseases (NIAID); collaborates with the National Institute on Aging (NIA) to drive research on Alzheimer's Disease Related Dementias (ADRD); and directs pain management research activities within the Helping to End Addiction Long-term® (HEAL) Initiative, co-led with the National Institute on Drugs and Addiction (NIDA).¹⁰ Through the FNIH's AMP® initiative, we engage in public-private partnerships with industry and non-profit organizations to speed therapy development. AMP® Parkinson's Disease is working to identify and validate biomarkers for use in diagnosis and prognosis and as tools to aid

⁹ <u>nimh.nih.gov/news/science-news/2023/scientists-unveil-detailed-cell-maps-of-the-human-brain-and-the-nonhuman-primate-brain</u>

¹⁰ The FY 2025 President's Budget proposes to rename the National Institute on Drug Abuse to the National Institute on Drugs and Addiction.

clinical trials. A new AMP program on ALS will begin soon; this program is one component of a larger partnership established by NIH and the FDA under the Accelerating Access to Critical Therapies for ALS (ACT for ALS) Act, which also includes a new clinical research consortium supported by NINDS to collect natural history data and biospecimens.

We also know that listening to and working with people affected by neurological disorders will lead us to more meaningful progress through research. Consistent with a cross-cutting strategy in the NINDS Strategic Plan, we continue to expand opportunities for community engagement across all stages of research. People with lived experience provide valuable perspectives into AMP® programs and other initiatives; they are informing priorities for a new research roadmap for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS); and they have served on review committees for research using data from expanded access to investigational therapies, a provision of the ACT for ALS. NINDS-funded clinical research studies and networks are also building more community and patient engagement into study development and execution.

Our commitments to diversity, equity, inclusion, and accessibility

NINDS has long recognized that all of neuroscience benefits if we can engage all segments of society in our efforts. The NINDS Strategic Plan includes goals to ensure a vibrant, talented, and diverse neuroscience workforce and to create and sustain a supportive work culture, and it emphasizes overall that diversity, equity, inclusion, and accessibility (DEIA) are essential to the way we work to fund, conduct, and support research. In alignment with these goals, we are working to promote DEIA at NINDS, in research study inclusion, and in other interactions to broaden public participation and community engagement in research. We also take a comprehensive approach to enhancing diversity in the neuroscience workforce across the research career pipeline through programs designed to overcome barriers to participation and inclusion of underrepresented or disadvantaged groups and individuals with disabilities.

Moreover, we are committed to research that will improve health outcomes for every person, and that means doing more to overcome persistent disparities in the prevalence, care, and outcomes, of neurological disorders. In the United States, the risk of stroke is nearly twice as high for Black people as for White people. Despite overall declines in stroke mortality, Black people have the highest rate of death due to stroke, and Hispanic and American Indian/Alaska Native populations have seen the least improvement over time.¹¹ In addition, health disparities exist for other neurological disorders including traumatic brain injury (TBI), pain, epilepsy, and ADRDs, and we do not yet understand the contributing factors. Guided by the NINDS Health Equity Strategic Plan, NINDS is investing in research to understand and eliminate health inequities across neurological disorders, whether associated with race, ethnicity, religion, socioeconomic status, age, mental health, disability, gender, sexual orientation, gender identity, geographic location, or other characteristics historically linked to discrimination, stigmatization, or exclusion. Our new Community-Engaged Health Equity Research in Neuroscience Initiative (HERN) is a multi-pronged approach to understand drivers of health disparities and barriers to equity; develop sustainable interventions; and build capacity to conduct rigorous communityengaged research. NINDS also supports research to address health disparities related to pain and dementia through HEAL and ADRD programs, respectively.

¹¹ Source: National Vital Statistics Sample 2008-2018 (latest data available as of Oct 2020)



National Institute of Neurological Disorders and Stroke

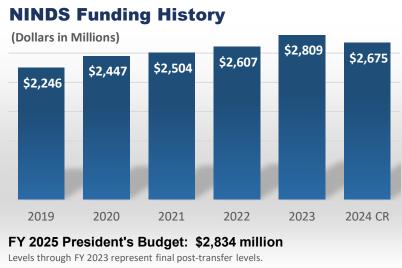
Our mission

To seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people.

Neurological disorders include common and rare conditions that affect people of all ages. By some measures, they account for a greater burden than any other group of diseases.

What we do

- □ Support and perform basic, translational, and clinical neuroscience research to understand the nervous system in health and disease and to develop new and improved therapies.
- □ Fund and conduct research training and career development programs to ensure a vibrant, talented, and diverse neuroscience workforce.
- Disseminate neuroscience discoveries and their implications for health to the public, health professionals, researchers, and policymakers.



All amounts include Cures Act funding.

Facts and Figures FY 2023

650 Full-Time Equivalent (FTE) Employment
932 Research Project Grants¹
1,205 Extramural Principal Investigators²

150 Extramural Early Stage Investigators^{1,3}

50 Intramural Principal Investigators

Research Highlights

Research supported and conducted by NINDS has contributed to:

- □ Decades of decline in stroke deaths, due to advances in prevention and treatment including the clot-busting drug t-PA, clot retrieval devices, and innovative acute stroke imaging methods.
- □ New therapies for diseases such as epilepsy, multiple sclerosis, migraine, spinal muscular atrophy, amyotrophic lateral sclerosis (ALS), muscular dystrophy, and others, including the first gene-directed therapies for neurological disorders.
- Devices that connect to the nervous system to treat disease or restore function, including brain stimulation therapies and brain-computer interfaces for movement disorders, stroke recovery, epilepsy, and spinal cord injury.
- Growing evidence for vascular contributions to dementia, which is informing approaches to prevent cognitive decline and promote healthy brain aging.
- Biomarkers for neurodegenerative diseases that may allow earlier diagnosis and intervention designed to prevent or modify the progressive course of these conditions.
- Cutting-edge tools for neuroscience research allowing studies to classify the many cell types in the human brain, map complex neural circuits, and observe brain activity in unprecedented detail.

¹ Competing awards only. ² Includes Principal Investigators and Multiple Principal Investigators. ³ Early Stage Investigators are within 10 years of their final research degree or end of post-graduate clinical training and have not received a substantial independent research grant from NIH.





National Institute of Neurological Disorders and Stroke

Recent successes

Brain and spinal cord stimulation therapies may aid stroke recovery

Each year, nearly 800,000 people in the United States have a stroke, and about half of survivors have persistent disabilities. Two small studies supported by the BRAIN Initiative[®] showed that devices for stimulating the nervous system may provide a new way to help people recover impaired hand and arm function after stroke. One study used deep brain stimulation in the cerebellum, and another used spinal cord stimulation. Improvements remained even after turning stimulation off, suggesting the potential for lasting beneficial changes, or plasticity, in neural circuits.

Brain activity signatures for chronic pain

For the first time, researchers supported by the NIH BRAIN Initiative® and HEAL Initiative® recorded pain-related brain activity directly from people with chronic pain. In three people with post-stroke pain and one with phantom limb pain after amputation, researchers surgically implanted electrodes in brain regions important for processing pain signals. Using machine learning to analyze participants' pain ratings and brain activity data, researchers identified objective biomarkers of chronic pain, an exciting step toward future therapies that modulate brain activity to relieve pain.



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Donny Bliss/NIH

Understanding brain tumor growth

Glioblastoma is a fast-growing, hard to treat brain cancer. A basic research study discovered that glioblastoma cells steal cellular powerhouses called mitochondria from healthy surrounding cells. The acquired mitochondria boost energy production in cancer cells, fueling tumor growth. The study also found that this mitochondrial transfer requires a protein called GAP43, together suggesting a mechanism behind glioblastoma's aggressive growth and a new target for trying to halt it.

Future Initiatives

- □ The Community-Engaged Health Equity Research in Neuroscience Initiative (HERN) supports and builds capacity for rigorous community-engaged research to understand and address health disparities across neurological disorders.
- □ A new Accelerating Medicines Partnership® (AMP) program on ALS and a new clinical research consortium will launch as part of the public private partnership established by NIH and the FDA under the ACT for ALS.
- □ The Sustainable Transformation of Institutional Research Rigor (STIRR) initiative supports programs to enhance research rigor and transparency practices within academic and research institutions.
- New projects through NINDS and NIH programs aim to develop gene-based therapies for rare and ultra-rare neurological disorders, and a new gene therapy consortium will facilitate clinical trials.

Neuroscience research across NIH

NINDS is a leader in NIH-wide initiatives, reflecting the nervous system's broad role in human health.

- The Researching COVID to Enhance Recovery (RECOVER) Initiative aims to understand, prevent, and treat Long COVID, including persistent neurological effects.
- □ The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® is an ambitious effort to develop and use new technologies to study brain circuits, and ultimately to understand and treat brain diseases.
- Within the NIH Helping to End Addiction Long-term® (HEAL) Initiative, NINDS focuses on non-addictive treatments for pain. NINDS also leads the NIH Pain Consortium.
- Through the NIH Blueprint for Neuroscience Research, NIH Institutes, Centers, and Offices collaborate on cross-cutting needs for neuroscience research and research training.

- NINDS leads the NIH Undiagnosed Diseases Network (UDN), to sustain and expand this successful program initiated through the NIH Common Fund.
- NINDS and NIA are partners in research on Alzheimer's Disease and Alzheimer's Disease-Related Dementias (ADRD), including the Center for Alzheimer's and Related Dementias at NIH.
- NINDS and the National Institute of Allergy and Infectious Diseases (NIAID) lead the trans-NIH ME/CFS working group.
- NINDS helps to lead innovative programs of the NIH Common Fund and Foundation for the NIH.



Major Changes in the Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail, and these highlights will not sum to the total change for the FY 2025 President's Budget request for the National Institute of Neurological Disorders and Stroke (NINDS), which is \$2,833.8 million, an increase of \$24.4 million from the FY 2023 Final level. The request includes \$45.5 million provided by the 21st Century Cures Act. Within the President's Budget request level, NINDS will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Research Project Grants (RPGs) (+\$41.8 million; total \$2,072.5 million):

The NINDS budget reflects an increase of \$41.8 million in the Research Project Grants portfolio, including Small Business Innovation Research and Small Business Technology Transfer Research (SBIR/STTR) awards, compared to the FY 2023 Final level. RPG awards are expected to increase by 112 grants in FY 2025 compared to the FY 2023 Final level of awards.

Research Centers (-\$0.6 million; total \$27.6 million):

The NINDS budget reflects a decrease of \$0.6 million in the Research Centers portfolio with a reduction of 1 grant in FY 2025 compared to the FY 2023 Final level.

Other Research (-\$9.0 million; total \$172.7 million):

The NINDS budget reflects a decrease of \$9.0 million in the Other Research portfolio, including Research Careers awards. Other Research awards are expected to decrease by 11 awards in FY 2025 compared to the FY 2023 Final level.

Research and Development Contracts (+\$13.2 million; total \$175.2 million):

The NINDS budget reflects an increase of \$13.2 million in Research and Development Contracts including SBIR/STTR awards. NINDS plans to increase R&D contract funding to accommodate new and expanded contracts within translational research programs to develop new drugs, biologic therapies, and devices, including the Blueprint Neurotherapeutics programs.

Intramural Research (-\$20.9 million; total \$233.4 million):

The NINDS budget reflects a decrease of \$20.9 million in Intramural Research. In FY 2023, a catastrophic flood occurred in the Porter Neuroscience Building, resulting in one-time FY 2023 and FY 2024 costs to repair damage and restore lost capital equipment and supplies for 18 NINDS laboratories. This one-time cost is now removed from the Intramural budget for FY 2025.

<u>Research Management and Support (RMS) (-\$1.3 million; total \$114.7 million):</u> The NINDS budget reflects a decrease of \$1.3 million in RMS to reflect decreased contracting costs and reduced staffing levels for the Helping to End Addiction Long-term (HEAL) Initiative.

BUDGET MECHANISM TABLE

Budget Mechanism ^{*,1}	
(Dollars in Thousands)	

Mechanism	FY 2	023 Final ²	FY 2024 CR		-	5 President's Budget	FY 2025 +/- FY 2023		
	Number	Amount	Number	Amount	Number	Amount	Number	Amount	
Research Projects:									
Noncompeting	2,327	\$1,265,229		\$1,358,426		\$1,481,302		\$216,073	
Administrative Supplements	(272)	\$24,427	(230)	\$16,300	(277)	\$18,977	(5)	-\$5,450	
Competing:									
Renewal	90	\$60,562	80	\$43,568		\$36,058		-\$24,504	
New	841	\$584,132	743	\$415,827	678	\$442,147		-\$141,985	
Supplements	1	\$480	0	\$0	0	\$0	-1	-\$480	
Subtotal, Competing	932	\$645,175	823	\$459,394		\$478,205	-184	-\$166,970	
Subtotal, RPGs	3,259	\$1,934,831	3,279	\$1,834,120	3,368	\$1,978,483	109	\$43,652	
SBIR/STTR	121	\$95,840		\$85,493	124	\$93,971	3	-\$1,869	
Research Project Grants	3,380	\$2,030,671	3,389	\$1,919,613	3,492	\$2,072,454	112	\$41,783	
Research Centers									
Specialized/Comprehensive	17	\$28,083	21	\$34,215	16	\$27,638	- 1	-\$444	
Clinical Research	0	\$0	~	\$0	0	\$0	0	\$0	
Biotechnology	0	\$0	-	\$0	0	\$0	0	\$0	
Comparative Medicine	0	\$137	0	\$0	0	\$0	0	-\$137	
Research Centers in Minority Institutions	0	\$0	*	\$0	0	\$0	0	\$0	
Research Centers	17	\$28,220	21	\$34,215	16	\$27,638	-1	-\$582	
Other Research:									
Research Careers	299	\$57,696	_	\$62,226	311	\$66,615	12	\$8,920	
Cancer Education	0	\$0	-	\$0	0	\$0		\$0	
Cooperative Clinical Research	8	\$1,774	0	\$1,102	0	\$0	-8	-\$1,774	
Biomedical Research Support	0	\$0	0	\$0	0	\$0	0	\$0	
Minority Biomedical Research Support	0	\$0	-	\$0		\$0	0	\$0	
Other	258	\$122,161	249	\$104,605	243	\$106,048	-15	-\$16,113	
Other Research	565	\$181,631	541	\$167,933	554	\$172,663	-11	-\$8,967	
Total Research Grants	3,962	\$2,240,523	3,951	\$2,121,761	4,062	\$2,272,756	100	\$32,234	
Ruth L Kirschstein Training Awards:	<u>FTTPs</u>		FTTPs		<u>FTTPs</u>		<u>FTTPs</u>		
Individual Awards	341	\$15,597	360	\$16,893		\$17,167		\$1,570	
Institutional Awards	312	\$20,837	350	\$20,559	345	\$20,559	33	-\$277	
Total Research Training	653	\$36,434	710	\$37,452	715	\$37,726	62	\$1,292	
	120	¢1(2,012	1.50	¢166.042	165	¢175 017	20	¢12.205	
Research & Develop. Contracts	139	\$162,012		\$166,943		\$175,217		\$13,205	
SBIR/STTR (non-add)	<i>(9)</i> 224	(\$1,294)	(6) 244	(\$1,333)	(5)	(\$1,311)	-(4)	(\$17)	
Intramural Research	334	\$254,413	344 369	\$235,318		\$233,419	14	-\$20,994	
Res. Management & Support	316	\$116,036	369	\$113,451	381	\$114,709	65	-\$1,328	
SBIR Admin. (non-add)		(\$837)		(\$870)		(\$0)		-(\$837)	
Construction		\$0		\$0		\$0		\$0	
Buildings and Facilities		\$0		\$0		\$0		\$0	
Total, NINDS	650	\$2,809,418	713	\$2,674,925	729	\$2,833,827	79	\$24,409	

² Reflects FY 2023 21st Century Cures Act funding not obligated in FY 2023, and carried over into FY 2024.

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

For carrying out section 301 and title IV of the PHS Act with respect to neurological disorders and stroke, \$2,788,327,000.

NIH INNOVATION ACCOUNT, CURES ACT (INCLUDING TRANSFER OF FUNDS)

For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, \$127,000,000, to remain available until expended: Provided, That such amounts are appropriated pursuant to section 1001(b)(3) of such Act, are to be derived from amounts transferred under section 1001(b)(2)(A) of such Act, and may be transferred by the Director of the National Institutes of Health to other accounts of the National Institutes of Health solely for the purposes provided in such Act: Provided further, That upon a determination by the Director that funds transferred pursuant to the previous proviso are not necessary for the purposes provided, such amounts may be transferred back to the Account: Provided further, That the transfer authority provided under this heading is in addition to any other transfer authority provided by law.

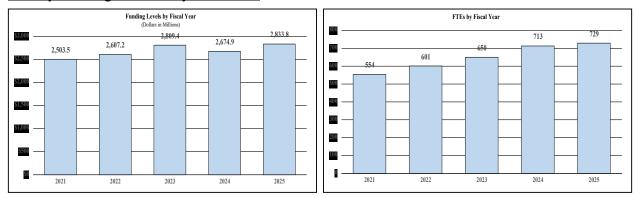
NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Summary of Changes

(Dollars in Thousands)

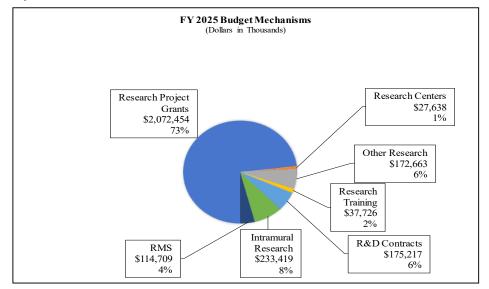
	FY 2	023 Final		5 President's Budget		Change from 2023 Final
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budge Authority
1. Intramural Research:						
A. Built-in cost changes:						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$66,853		\$75,117		\$790
b. FY 2024 effect of FY 2024 pay & benefits increase		\$66,853		\$75,117		\$2,60
c. FY 2024 paid days adjustment		\$66,853		\$75,117		\$257
d. Differences attributable to FY 2024 change in FTE		\$66,853		\$75,117		\$2,110
e. FY 2025 effect of FY 2024 pay & benefits increase		\$66,853		\$75,117		\$883
f. FY 2025 effect of FY 2025 pay & benefits increase		\$66,853		\$75,117		\$1,199
g. FY 2025 paid days adjustment		\$66,853		\$75,117		\$
h. Differences attributable to FY 2025 change in FTE		\$66,853		\$75,117		\$87
i. Payment for centrally furnished services		\$34,851		\$37,369		\$2,51
j. Cost of laboratory supplies, materials, other expenses, and non-		\$152,701		\$120,932		\$10,37
recurring costs		\$152,701		\$120,952		
Subtotal, IR built-in cost changes						\$21,61
2. Research Management and Support:						
A. Built-in cost changes:						
a. FY 2024 effect of FY 2023 pay & benefits increase		\$55,754		\$64,642		\$65
b. FY 2024 effect of FY 2024 pay & benefits increase		\$55,754		\$64,642		\$2,16
c. FY 2024 paid days adjustment		\$55,754		\$64,642		\$21
 d. Differences attributable to FY 2024 change in FTE 		\$55,754		\$64,642		\$9,92
e. FY 2025 effect of FY 2024 pay & benefits increase		\$55,754		\$64,642		\$75
f. FY 2025 effect of FY 2025 pay & benefits increase		\$55,754		\$64,642		\$1,01
g. FY 2025 paid days adjustment		\$55,754		\$64,642		\$
h. Differences attributable to FY 2025 change in FTE		\$55,754		\$64,642		\$2,33
i. Payment for centrally furnished services		\$6,047		\$6,484		\$43
j. Cost of laboratory supplies, materials, other expenses, and non		\$54,231		\$43,583		\$3,08
recurring costs		\$54,251		\$45,585		
Subtotal, RMS built-in cost changes						\$20,592
	FY 2	023 Final		5 President's Budget		Change from 2023 Final
CHANGES	No.	Amount	No.	Amount	No.	Amoun
B. Program:						
 Research Project Grants: 						
a. Noncompeting	2,327	\$1,289,656	2,620	\$1,500,279	293	\$210,622
b. Competing	932	\$645,175	748	\$478,205	-184	-\$166,970
c. SBIR/STTR	121	\$95,840	124	\$93,971	3	-\$1,869
Subtotal, RPGs	3,380	\$2,030,671	3,492	\$2,072,454	112	\$41,78
2. Research Centers	17	\$28,220	16	\$27,638	-1	-\$58
3. Other Research	565	\$181,631	554	\$172,663	-11	-\$8,96
4. Research Training	653	\$36,434	715	\$37,726	62	\$1,29
5. Research and development contracts	139	\$162,012	165	\$175,217	26	\$13,20
Subtotal, Extramural	139	\$2,438,969	105	\$2,485,699	20	\$46,73
6. Intramural Research	334	\$254,413	348	\$233,419	14	-\$42,61
7. Research Management and Support	316	\$116,036	381	\$114,709	65	-\$21,92
8. Construction		\$0		\$0		\$
Buildings and Facilities		\$0		\$0		-\$17,79
Subtotal, program changes	1					
Subtotal, program changes						ψ17,75

BUDGET GRAPHS

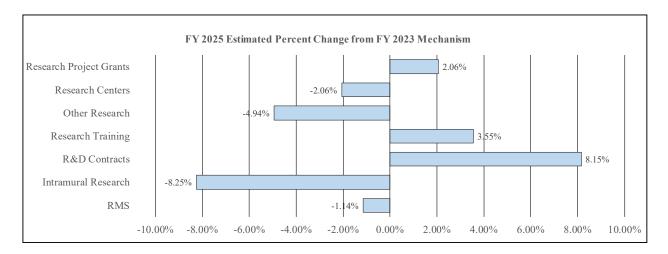


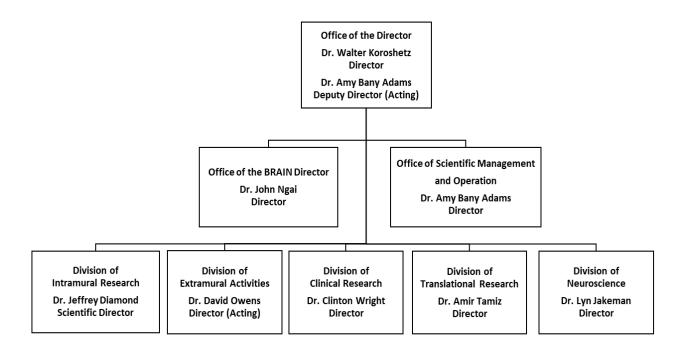
History of Budget Authority and FTEs:

Distribution by Mechanism:



Change by Selected Mechanisms:





BUDGET AUTHORITY BY ACTIVITY TABLE

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Budget Authority by Activity^{*} (Dollars in Thousands)

	FY 2023 Final FY 2024 CR			President's dget	FY 2025 +/- FY 2023 Final			
Extramural Research	<u>FTE</u>	<u>Amount</u>	FTE	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Detail</u>								
Division of Neuroscience		\$1,728,133		\$1,627,202		\$1,752,583		\$24,450
Division of Clinical Research		\$139,983		\$131,808		\$141,964		\$1,981
Division of Translational Research		\$219,373		\$206,560		\$222,477		\$3,104
Division of Extramural Activities		\$106,779		\$100,542		\$108,289		\$1,511
Opioid/Pain Research ¹		\$244,700		\$260,044		\$260,386		\$15,686
Subtotal, Extramural		\$2,438,969		\$2,326,156		\$2,485,699		\$46,731
Intramural Research	334	\$254,413	344	\$235,318	348	\$233,419	14	-\$20,994
Research Management & Support	316	\$116,036	369	\$113,451	381	\$114,709	65	-\$1,328
TOTAL	650	\$2,809,418	713	\$2,674,925	729	\$2,833,827	79	\$24,409

^{*} Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
 ¹ Total for HEAL Initiative including IR and RMS is (in thousands) \$280,295 in FY 2023, \$280,295 in FY 2024, and \$280,295 in FY 2025.

JUSTIFICATION OF BUDGET REQUEST

National Institute of Neurological Disorders and Stroke (NINDS)

Authorizing Legislation: Section 301 and Title IV of the Public Health Service Act, as amended. Budget Authority (BA):

			FY 2025	
			President's	FY 2025 +/-
	FY 2023 Final	FY 2024 CR	Budget	FY 2023
BA	\$2,809,418,000	\$2,674,925,000	\$2,833,827,000	\$24,409,000
FTE	650	713	729	79

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

<u>Overall Budget Policy</u>: The FY 2025 President's Budget request for NINDS is \$2,833.8 million, an increase of \$24.4 million or 0.9 percent compared to the FY 2023 Final level. The NINDS request includes 21st Century Cures Act authorized funding of \$45.5 million for the BRAIN Initiative, reflecting the Cures Act authorized level for the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN)® Initiative, which is a reduction of \$179.5 million from the authorized level in FY 2023. To offset this decrease, the request also includes an increase of \$179.5 million in non-Cures Act funding for the BRAIN Initiative to offset the Cures Act reduction and maintain the total FY 2023 Enacted level for the program. Funding for the Helping to End Addiction Long-term (HEAL) Initiative within NINDS is equal to the FY 2023 Final level of \$280.3 million. In addition, the request includes an increase of \$16.0 million to base funding to support the Undiagnosed Diseases Network (UDN) for a total funding level of \$18.0 million within NINDS, in order to complete the transition of the program that started in FY 2023 due to Common Fund policy limiting the duration of its programs.

Program Descriptions

Extramural Research

Investigator-initiated research driven by scientific ingenuity and opportunity is the mainstay of NINDS extramural research and has consistently proven essential to fueling breakthroughs. In addition, specific initiatives focus on priorities that warrant a more targeted approach. NINDS Extramural divisions also support research training, resources, and scientific conferences.

Division of Neuroscience (DON)

As the largest part of the NINDS extramural program, DON supports research on the normal brain, spinal cord, and nerves of the body; mechanisms of neurological injury and disease; and early development of treatments and diagnostics. DON also leads NINDS efforts to promote and leverage data sharing and data science approaches in neuroscience. DON program areas include:

OPTIMIZING ANTI-AMYLOID PASSIVE IMMUNOTHERAPIES FOR DEMENTIA

As the first disease-modifying drugs approved for Alzheimer's disease (AD), Aduhelm® and Leqembi® represent significant medical progress. However, a high number (>20%) of participants in clinical trials for these anti-amyloid immunotherapies developed amyloid-related imaging abnormalities (ARIA), which are adverse events observed on brain imaging that may indicate fluid retention and microbleeds. Most ARIA cases were asymptomatic; but about a quarter showed clinical symptoms, and several patients experienced brain bleeds and swelling.

A leading hypothesis is that ARIA results from antiamyloid antibodies attaching to amyloid in blood vessel walls, which triggers inflammation. Given safety concerns, patients with known cerebrovascular pathology have been excluded from clinical trials of anti-amyloid therapies, which could limit their use as more than half of people over 85 with confirmed AD have extensive cerebrovascular damage. Research is needed to understand if these therapies can be modified to be safer, and if they can be effective in people with cerebrovascular and other dementia-related pathologies.

To fill in knowledge gaps for anti-amyloid immunotherapies in AD/ADRD, NINDS is investing in basic, translational, and clinical research to: 1) understand how and why these therapies can damage brain blood vessels, 2) develop strategies that can protect the brain when anti-beta-amyloid immunotherapy is delivered, and 3) support clinical trials of anti-amyloid therapy in unstudied populations, such as patients with vascular pathologies, Lewy bodies, or high levels of betaamyloid in the brain – patients previously excluded from clinical trials. Clinical trials will be required to include patient and community engagement cores and determine effectiveness in diverse populations.

Patients are already receiving these diseasemodifying immunotherapies, yet it is not currently possible to identify or distinguish between patients who may benefit and patients who may be harmed. This research will hopefully provide much needed basic and clinical data and result in strategies to optimize their use. Basic neuroscience: Gaps in understanding nervous system development and function hinder progress in treating and preventing neurological disorders. Basic research to fill those gaps does not receive sustained private sector support and is therefore a critical component of the NINDS mission. NINDS works with other NIH Institutes, Centers, and Offices (ICOs) to support all facets of basic neuroscience research, including through the NIH BRAIN Initiative® and the NIH Blueprint for Neuroscience Research. A working group of the National Advisory Neurological Disorders and Stroke Council recently recommended new priorities for fundamental neuroscience research.

Neurodegeneration: NINDS leads NIH research support for many neurodegenerative diseases, including Alzheimer's Disease Related Dementias (ADRD), amyotrophic lateral sclerosis (ALS), Parkinson's disease, movement disorders, and others. This research is making exciting progress toward identifying targets for modifying disease and biomarkers to aid early detection and treatment. Programs include the Morris K. Udall Centers of Excellence in Parkinson's Disease Research and Accelerating Medicines Partnerships for Parkinson's disease and ALS.

Stroke and cerebrovascular disease: Among NINDS research on stroke and strategies for neuroprotection and recovery, the Stroke Preclinical Assessment Network (SPAN) rigorously tests potential neuroprotective therapies in rodent models of acute ischemic stroke with replication across multiple labs. SPAN's first results showed promise for intravenous uric acid, and tests of more candidate therapies are ongoing.¹²

Vascular contributions to dementia also are a major focus, including studies on white matter

¹² www.ninds.nih.gov/news-events/press-releases/researchers-develop-new-method-identify-potential-stroketherapies

disease and on vascular factors involved in a serious side effect of new anti-amyloid therapies for Alzheimer's disease.

Rare, genetic, and unknown diseases:

Research on the many rare diseases that affect the nervous system meets a critical need and yields insights into other diseases with shared mechanisms. NINDS leads the Undiagnosed Diseases Network (UDN), with plans to expand its reach to include more sites and greater diversity. NINDS initiatives aim to fill gaps in clinical trial readiness for rare neurological and neuromuscular diseases, and NINDS is a partner in the NIH Rare Diseases Clinical Research Network, supporting consortia on lysosomal disorders, mitochondrial diseases, dystonia, neuropathies, and others.

Other disorders: DON research is informing new treatments and diagnostics for epilepsy, hydrocephalus, spinal cord injury, and traumatic brain injury (TBI), among others. In addition to a leading role in the NIH HEAL Initiative®, NINDS leads pain and headache research and the NIH Pain Consortium (with 21 ICOs). NINDS also collaborates across NIH on areas including developmental conditions like cerebral palsy and autism; muscular dystrophies; autoimmune disorders like multiple sclerosis; nervous system infections including COVID-19; myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS); and brain cancers. Among advances are new insights for treating aggressive brain tumors and growing evidence linking ME/CFS to disruptions in mitochondria and the gut microbiome.

Budget Policy: The FY 2025 President's Budget request for the Division of Neuroscience is \$1,752.6 million, an increase of \$24.5 million, or 1.4 percent, from the FY 2023 Final level.

THE NIH BRAIN RESEARCH THROUGH <u>ADVANCING INNOVATIVE</u> <u>NEUROTECHNOLOGIES®</u> (BRAIN) INITIATIVE

The BRAIN Initiative® is revolutionizing understanding of the human brain by accelerating the development and application of innovative technologies and ultimately, inspiring new treatments for brain diseases. Spanning 10 NIH Institutes and Centers, the BRAIN Initiative is uniquely positioned for cross-cutting and accelerated discoveries in neuroscience that go beyond the mission of any single ICO. The NIH BRAIN Initiative has invested more than \$3 billion in over 1,300 projects that have enabled researchers to understand the brain at unprecedented levels of detail and improve how we treat, prevent, and cure brain disorders. Precise and effective interventions for relieving epilepsy, depression, stroke injury, spinal cord injury, retinal degeneration, pain, opioid use disorder, Parkinson's disease, and Alzheimer's disease, for example, are emerging from discoveries about how brain circuits are altered in disease.

The BRAIN Initiative's focus on accelerating the development and application of innovative technologies is not only laying the foundation for future cures, but also contributing to results in clinical settings today.

- Supported by the BRAIN Initiative and HEAL Initiative, researchers recorded, for the first time, pain-related data from inside the brain of individuals with chronic pain disorders, providing a target for the development of new therapies for chronic pain.¹
- The Initiative has fueled the application of deep brain stimulation (DBS) therapy to treat various brain conditions. For example, using DBS therapy, researchers identified a pattern of brain activity, or biomarker, related to the clinical signs of recovery in treatment-resistant depression.² This is a pivotal step towards using brain data to standardize care, moving promising therapies closer to clinical use.

The BRAIN Initiative launched awards for its third transformative project—the Brain Initiative Connectivity Across Scales (BRAIN CONNECTS) program—which aims to develop a bold, high-resolution wiring diagram of the human brain, helping decipher its neural code. Together with two previously launched transformative projects (the BRAIN Initiative Cell Atlas Network and the Armamentarium for Precision Brain Cell Access), BRAIN CONNECTS promises to transform neuroscience research, illuminating foundational principles governing the circuit basis of behavior and informing new approaches for treating human brain disorders.

¹ www.ninds.nih.gov/news-events/press-releases/brainsignatures-chronic-pain-identified-small-groupindividuals

² www.nih.gov/news-events/news-releases/researchersdiscover-biomarker-tracking-depression-recovery

Division of Translational Research (DTR)

DTR leads NINDS extramural development of drugs, devices, and biologic therapies through milestone-driven programs and resources spanning preclinical studies to first-in-human clinical trials. Translational research is prone to failure, and DTR programs help to reduce risks by moving therapies to a point of readiness sufficient for industry interest, or for testing in NINDS-funded clinical trials. Major DTR programs include:

The **Office of Neural Exposome and Toxicology (ONETOX)** focuses on non-inherited contributions to neurological diseases, including toxic exposures, social factors, diet, and the microbiome. ONETOX directs the NIH Countermeasures Against Chemical Threats program (**CounterACT**), part of NIAID's Chemical Countermeasures Research Program.

NINDS Small Business Innovation Research (SBIR) and Small Business Technology Transfer programs (STTR) support research by small businesses on therapies, diagnostics, and research tools, as well as resources to help businesses transition to private funding and commercialization. Recent successes include a new steroid therapy for muscular dystrophy¹³ and a clinical trial testing a variation of the blood cancer immunotherapy CAR-T to treat myasthenia gravis.¹⁴ Many programs in DTR, BRAIN, and HEAL include SBIR/STTR components.

The **NINDS Biomarkers Program** supports development and validation of biomarkers for use in clinical trials to aid therapy development or to help guide patient care decisions. Biomarker projects are in advanced validation stages for multiple sclerosis (MS), traumatic brain injury (TBI), and different forms of Parkinsonism.

For early stage development of drug or biologic therapies, the **Innovation Grants to Nurture Initial Translational Efforts (IGNITE)** program funds assay validation, model system development for testing, and proof of concept sufficient for further study. The **Epilepsy Therapy Screening Program (ETSP)** tests compounds from academic institutions and industry in well-characterized models of epilepsy and has contributed to 11 approved epilepsy drugs.

For later stage development, the **Blueprint Neurotherapeutics Network (BPN)**, led by NINDS for the NIH Blueprint for Neuroscience Research, supports small molecule drug development, and the **Blueprint Neurotherapeutics Network for Biologics (BPN-Biologics)** advances biological therapies, including large biological molecules, cell therapies, and gene-targeted therapies. The NINDS **Ultra-rare Gene Therapy (URGenT)** Network supports precision medicine therapy development for serious ultra-rare neurological diseases affecting no more than 1 in 50,000 people. These diseases represent an important medical need with few available treatments, and they offer promise for advancing genetic therapies for neurological diseases. In FY 2023, URGenT launched three projects to develop new gene-based therapies.

¹³ ninds.nih.gov/news-events/highlights-announcements/ninds-small-business-funding-leads-new-therapy-duchennemuscular-dystrophy

¹⁴ <u>ninds.nih.gov/news-events/press-releases/potential-treatment-rare-autoimmune-disorder-adapted-car-t-therapy</u>

The NINDS Translational Neural Devices

program supports therapeutic and diagnostic device development for nervous system disorders, from preclinical studies through early clinical trials. NINDS also helps to lead NIH-wide support for neural device development through the BRAIN and HEAL initiatives and the **Blueprint MedTech** program. Since 2015, researchers across these programs filed 39 investigational device exemptions with the FDA to allow clinical studies.

Budget Policy: The FY 2025 President's Budget request for the Division of Translational Research is \$222.5 million, an increase of \$3.1 million, or 1.4 percent, from the FY 2023 Final level.

Division of Clinical Research (DCR)

DCR supports large-scale clinical research and infrastructure, including early and advanced phase clinical trials, epidemiological studies of neurological conditions across the lifespan, comparative effectiveness research, and resources such as the NINDS Common Data Elements, which foster data sharing and data quality. NINDS clinical research networks enable efficient multi-site clinical trials, convene expert communities to promote highquality research, enable partnerships with industry and people with lived experience, and help train future clinical trial researchers. Major DCR programs include:

The Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) supports Phase

II clinical trials to test investigational treatments prior to larger late-stage trials, as well as studies to discover and validate biomarkers. NeuroNEXT will also provide clinical sites and support to facilitate clinical testing of gene-based therapeutics through the NINDS URGenT program. The **NIH StrokeNet** supports trials on stroke treatment,

ADVANCING ALS RESEARCH

Approximately 30,000 people in the United States¹ have amyotrophic lateral sclerosis (ALS), a rapidly progressive, invariably fatal neurological disease in which motor neurons gradually degenerate, causing progressive weakness and loss of the ability to walk, talk, move, swallow, and eventually breathe. Most people die within three to five years of symptom onset. FDA-approved drugs may slow clinical decline or extend life by several months, and one new therapy targets disease mechanisms in a specific genetic form of ALS. However, no treatments currently stop, reverse, or prevent ALS.

In 2022, the NINDS convened the ALS lived experience and research communities to establish Strategic Research Priorities for ALS. These priorities, which focus on basic, translational, clinical, and quality of life research as well as opportunities for partnerships and collaborations, are guiding programmatic decisions within NINDS and the ALS research community.

With specific appropriations in FY 2022 and 2023 for implementing Accelerating Access to Critical Therapies (ACT) for ALS Act, NIH funded four grants for research utilizing data from expanded access to investigational therapies for ALS and will release new funding opportunities for this program in FY 2024, 2025, and 2026, if funds are available. Additionally, NIH is collaborating with the FDA, industry, nonprofits, and people with lived experience to establish the HHS Public Private Partnership (PPP) for Rare Neurodegenerative Diseases, which is designed to advance research on ALS that will lead to new potential therapies and to build clinical research infrastructure to test those therapies in diverse groups of people with ALS and at risk for ALS. The PPP consists of the Critical Path for Rare Neurodegenerative Diseases (CP-RND) launched in 2022, and the ALS Clinical & Expanded Access Research Consortia and Accelerating Medicines Partnership (AMP®) for ALS launched in 2023. These activities will continue past FY 2025.

Building upon the research priorities identified in the NIH Strategic Priorities for ALS, NIH has commissioned a study from the National Academy of Science, Engineering, and Medicine (NASEM) to recommend actions for the public, private, and non-profit sectors to undertake to make ALS a livable disease within a decade. The study will be completed before October 2024. prevention, and recovery and rehabilitation. StrokeNet research provided key evidence for updated stroke treatment guidelines expanding the use of mechanical clot removal, or endovascular thrombectomy (EVT). StrokeNet has added a new mechanism for platform trials to efficiently and simultaneously test several interventions to further optimize or enhance EVT. **Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN),** led by NINDS and the National Heart, Lung, and Blood Institute (NHLBI), conducts trials in emergency care for neurologic, cardiac, respiratory, and hematologic conditions.

Guided by the NINDS Health Equity Strategic Plan, the **Office of Global Health and Health Disparities** in DCR issued two new funding opportunities for the Community-Engaged Health Equity Research in Neuroscience Initiative (HERN), a multi-pronged approach to advance and build capacity for health equity research across neurological diseases.

Budget Policy: The FY 2025 President's Budget request for the Division of Clinical Research is \$142.0 million, an increase of \$2.0 million, or 1.4 percent, from the FY 2023 Final level.

Division of Extramural Activities (DEA)

DEA leads NINDS extramural research training and career development, workforce diversity, and efforts to enhance research rigor, that together enable innovative neuroscience research for generations to come. Major DEA programs include:

The **Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN)** promotes the inclusion of underrepresented or historically underserved groups and individuals with disabilities in the neuroscience research workforce. Programs span career stages from K-12 outreach to mentoring networks and initiatives targeting career transitions. For example, OPEN leads the NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (DSPAN) program to facilitate the transition of graduate students from diverse backgrounds to postdoctoral positions through career development, peer mentoring, and the support of a diverse scientific network. DSPAN has awarded 152 scholars since 2017, and so far, 77 have transitioned to postdoctoral positions and 11 to independent researcher roles.

The **Office of Training and Workforce Development** directs NINDS extramural research training and career development, including fellowships, mentored awards, and programs at academic institutions. NINDS initiatives complement NIH-wide programs to address unique training needs across neuroscience research career stages and include national research training programs for neurosurgeons and pediatric neurologists, career development awards for advanced trainees launching independent projects, and workshops focused on strengthening mentorship in neuroscience research. A recent outcomes analysis of the NINDS Research Education Programs for Residents and Fellows in Neurological Disorders and Stroke found that the program increases program graduates' success in obtaining NIH career development awards (K awards).

The **Office of Research Quality** promotes rigor and transparency in neuroscience research and has been instrumental to NIH and research journal policies to improve rigor in experimental design and transparent reporting in publications. A new initiative, Sustainable Transformation of Institutional Research Rigor (STIRR), supports programs to enhance research rigor and

transparency practices within academic and research institutions, engaging the research community directly to promote a culture of high-quality neuroscience research.

Budget Policy: The FY 2025 President's Budget request for the Division of Extramural Activities is \$108.3 million, an increase of \$1.5 million, or 1.4 percent, from the FY 2023 Final level.

NIH Helping to End Addiction Long-term (HEAL) Initiative®

The NIH HEAL Initiative® is a trans-agency effort to speed scientific solutions to stem the national opioid crisis. As the NIH lead for pain research, NINDS directs HEAL research to develop effective, non-addictive pain treatments that may reduce reliance on opioids for pain management. NINDS works closely with NIDA on overall HEAL management and on cross-cutting areas, such as addressing opioid use disorder in people with pain; increasing participant diversity and reducing stigma; and leveraging real-time opioid and pain management data. HEAL activities supported through NINDS include other NIH ICOs as partners, and they build on and integrate with NINDS programs for basic, translational, and clinical research.

A suite of milestone-driven translational research programs, including the Pain Therapeutic Development Program, support the discovery, optimization, and development of non-addictive small molecule and biologic therapies for pain. In addition, the Preclinical Screening Platform for Pain tests and characterizes promising therapeutic candidates in animal models that mimic human pain conditions. Parallel programs support development of device-based approaches for pain management, including exciting new technologies to reveal changes in brain activity with chronic pain and use that knowledge to reduce pain through neural stimulation.¹⁵ NINDS also leads a HEAL program to identify biomarkers that can aid in diagnosing and monitoring pain conditions and improve clinical trials by predicting who might respond to a new therapy.

In clinical research within HEAL, NINDS directs the Early Phase Pain Investigation Network (EPPIC-Net), which provides infrastructure for the rapid design and performance of Phase II clinical trials to test promising pain therapeutics, as well as phenotyping and biomarker studies in people with specific pain conditions. NINDS also plays a lead role in the Pain Management Effectiveness Research Network, which supports clinical trials on the effectiveness of pharmacological and non-pharmacological therapies for pain management. Furthermore, NINDS is a key partner in HEAL programs to reduce health inequities in pain care, with studies to develop, test, and implement interventions to improve outcomes and access to quality pain care in populations that experience health disparities.

For more information, see the section on Chronic Pain and Substance Use Disorder in the Cross-Cutting Initiatives chapter of the NIH Congressional Justification Overview volume.

Budget Policy: The FY 2025 President's Budget request for NINDS HEAL is \$280.3 million, equal to the FY 2023 Final level. NINDS HEAL funding for FY 2025 includes \$260.4 million

¹⁵ <u>heal.nih.gov/news/stories/carpal-tunnel-pain-relief</u>

for extramural research, \$8.0 million for intramural research, and \$11.9 million for research management and support (RMS).

NINDS Intramural Research Program (IRP)

The NINDS IRP conducts research and research training on the NIH campus. The IRP spans basic, translational, and clinical research in neuroscience, neurology, and neurosurgery and hosts core facilities providing state-of-the-art research technologies. Over 180 labs from NINDS and other Institutes conduct neuroscience research at NIH, including many co-located in the Porter Neuroscience Research Center, creating a rich environment for collaboration that also benefits from the NIH Clinical Center and connections with local hospitals and extramural scientists. NINDS investigators conduct multidisciplinary studies to answer fundamental questions about the nervous system, focusing for example, on the cell biology of neurons, muscle, and glia; neural development and plasticity; and synapses and circuits. Intramural research also includes studies on diseases of the nervous system and early trials for drugs, devices, and gene therapy. Topics of ongoing studies include Gulf War Illness¹⁶ (with the Veterans Health Administration), ME/CFS, Long COVID, stroke, neurodegenerative diseases, MS, TBI, epilepsy, brain tumors, movement disorders, and rare genetic disorders. The Roy Blunt Center for Alzheimer's and Related Dementias (CARD) established by the National Institute on Aging (NIA) and NINDS is a collaborative initiative to initiate, stimulate, accelerate, and support research leading to improved treatment and preventions for these diseases. NINDS investigators also identify causes of puzzling neurological disorders through the Undiagnosed Diseases Program, the intramural component of the UDN.

Among recent advances, NINDS research on ME/CFS and persistent neurological symptoms of Long COVID is pointing to new targets for treating these debilitating and poorly understood conditions. For example, a comprehensive analysis of patients with lasting neurological symptoms after SARS-CoV-2 infection showed broad immune dysregulation in the central nervous system;¹⁷ and a detailed examination of post exertional malaise, a key feature of ME/CFS and Long COVID, showed that high levels of a protein called WASF3 disrupt energy production in muscle cells of people with ME/CFS.¹⁸ In addition, new findings from studies of vascular injury and repair in the brain identify pathways that might be harnessed for improved outcomes after infections, injury, stroke, neurodegeneration, and autoimmune disease.¹⁹

Budget Policy: The FY 2025 President's Budget request for the Intramural Research Program is \$233.4 million, a decrease of \$21.0 million, or 8.3 percent, from the FY 2023 Final level.

Research Management and Support (RMS)

RMS comprises administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants, training awards, and research contracts. RMS also includes strategic planning, program evaluation, regulatory compliance, enhanced patient and community

¹⁶ www.ninds.nih.gov/news-events/press-releases/va-nih-launch-study-gulf-war-illness

¹⁷ www.ninds.nih.gov/news-events/press-releases/nih-study-identifies-features-long-covid-neurological-symptoms

¹⁸ www.nih.gov/news-events/nih-research-matters/protein-may-be-linked-exercise-intolerance-me-cfs

¹⁹ pubmed.ncbi.nlm.nih.gov/37248420

engagement activities, internal diversity, equity, inclusion, and accessibility (DEIA) efforts, communication about neurological disorders and NINDS research, and liaison with other agencies, Congress, and the public.

Budget Policy: The FY 2025 President's Budget request for Research Management and Support is \$114.7 million, a decrease of \$1.3 million, or 1.1 percent, from the FY 2023 Final level.

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Fiscal Year	Budget Estimate	House	Senate	Appropriation
Fiscal I cal	to Congress	Allowance	Allowance	Appropriation
2016	\$1,660,375,000	\$1,656,334,000	\$1,694,758,000	\$1,696,139,000
Rescission				\$0
2017 1	\$1,695,180,000	\$1,751,049,000	\$1,803,306,000	\$1,783,654,000
Rescission				\$0
2018 ²	\$1,355,998,000	\$1,853,011,000	\$1,904,666,000	\$2,188,149,000
Rescission	\$1,555,776,000	\$1,000,011,000	\$1,704,000,000	\$2,100,149,000
Rescission				\$U
2019 ²	\$1,838,556,000	\$2,228,780,000	\$2,275,580,000	\$2,274,413,000
Rescission		. , , , ,		\$0
2020 ²	\$2,026,031,000	\$2,385,571,000	\$2,490,494,000	\$2,444,687,000
Rescission				\$0
2021 3	¢2 245 110 000	#2 465 110 000	¢2,526,245,000	¢0, 510, 200, 000
2021 ²	\$2,245,110,000	\$2,465,110,000	\$2,526,245,000	\$2,513,393,000
Rescission				\$0
2022 ²	\$2,783,300,000	\$2,799,515,000	\$2,786,096,000	\$2,611,370,000
Rescission	\$2,703,300,000	\$2,799,515,000	\$2,700,090,000	\$2,011,570,000
				ψŪ
2023 ²	\$2,768,043,000	\$2,833,590,000	\$2,765,918,000	\$2,813,925,000
Rescission				\$0
2024 2	\$2,825,418,000	\$2,674,925,000	\$2,849,925,000	\$2,674,925,000
Rescission				\$0
2025	¢2 022 027 000			
2025	\$2,833,827,000			

Appropriations History

¹ Budget Estimate to Congress includes mandatory financing.

² Includes funds derived by transfer from the NIH Innovation Account under the 21st Century Cures Act.

AUTHORIZING LEGISLATION

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2024 Amount Authorized	FY 2024 CR	2025 Amount Authorized	FY 2025 President's Budget
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				\$2,674,925,000		\$2,833,827,000
National Institute of			>		>	
Neurological Disorders and	Section 401(a)	42§281	Indefinite		Indefinite	
Stroke						
Total, Budget Authority				\$2,674,925,000		\$2,833,827,000

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Appropriation ²	\$2,813,925	\$2,674,925	\$2,833,827
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(\$0)	(\$0)	(\$0)
Other Mandatory financing	(\$0)	(\$0)	(\$0)
Subtotal, adjusted appropriation	\$2,813,925	\$2,674,925	\$2,833,827
OAR HIV/AIDS Transfers	-\$4,507	\$0	\$0
Subtotal, adjusted budget authority	\$2,809,418	\$2,674,925	\$2,833,827
Unobligated balance, start of year	\$33,120	\$70,249	\$0
Unobligated balance, end of year (carryover) ³	\$70,249	\$0	\$0
Subtotal, adjusted budget authority	\$2,912,787	\$2,745,174	\$2,833,827
Unobligated balance lapsing	\$0	\$0	\$0
Total obligations	\$2,912,787	\$2,745,174	\$2,833,827

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account: FY 2023 - \$36,274 FY 2024 - \$38,501 FY 2025 - \$40,943

 2 Of which \$225.0 million in FY 2023, \$86.0 million in FY 2024, and \$45.5 million in FY 2025 is derived by transfer from the NIH Innovation Account under the 21st Century Cures Act.

³ Reflects 21st Century Cures Act funding not obligated in FY 2023, and carried over into FY 2024.

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Budget Authority by Object Class¹ (Dollars in Thousands)

		FY 2024 CR	FY 2025 President's Budget
Total co	mpensable workyears:		
	Full-time equivalent	713	729
	Full-time equivalent of overtime and holiday hours	0	0
	Average ES salary	\$201	\$201
	Average GM/GS grade	13.0	12.9
	Average GM/GS salary	\$140	\$144
	Average salary, Commissioned Corps (42 U.S.C. 207)	\$0	\$0
	Average salary of ungraded positions	\$203	\$209
	OBJECT CLASSES	FY 2024 CR	FY 2025 President's Budget
	Personnel Compensation		
11.1	Full-Time Permanent	\$51,547	\$54,979
11.3	Other Than Full-Time Permanent	\$30,407	\$32,363
11.5	Other Personnel Compensation	\$3,808	\$4,062
11.7	Military Personnel	\$0	\$0
11.8	Special Personnel Services Payments	\$13,118	\$13,485
11.9	Subtotal Personnel Compensation	\$98,880	\$104,889
12.1	Civilian Personnel Benefits	\$32,571	\$34,870
12.2	Military Personnel Benefits	\$0	\$0
13.0	Benefits to Former Personnel	\$0	\$0
	Subtotal Pay Costs	\$131,452	\$139,760
21.0	Travel & Transportation of Persons	\$3,966	\$4,053
22.0	Transportation of Things	\$267	\$273
23.1	Rental Payments to GSA	\$0	\$0
23.2	Rental Payments to Others	\$94	\$96
23.3	Communications, Utilities & Misc. Charges	\$138	\$141
24.0	Printing & Reproduction	\$8	\$8
25.1	Consulting Services	\$59,129	\$60,965
25.2	Other Services	\$51,697	\$40,939
25.3	Purchase of Goods and Services from Government Accounts	\$182,741	\$189,999
25.4	Operation & Maintenance of Facilities	\$154	\$154
25.5	R&D Contracts	\$50,762	\$51,879
25.6	Medical Care	\$732	\$761
25.7	Operation & Maintenance of Equipment	\$8,840	\$9,035
25.8	Subsistence & Support of Persons	\$0	\$0
25.0	Subtotal Other Contractual Services	\$354,056	\$353,732
26.0	Supplies & Materials	\$10,490	\$10,721
31.0	Equipment	\$7,964	\$6,140
32.0	Land and Structures	\$5,049	
33.0	Investments & Loans	\$0	\$0
41.0	Grants, Subsidies & Contributions	\$2,161,424	\$2,313,726
42.0	Insurance Claims & Indemnities	\$0	\$0
43.0	Interest & Dividends	\$19	\$19
44.0	Refunds	\$0	\$0
	Subtotal Non-Pay Costs	\$2,543,473	\$2,694,067
	Total Budget Authority by Object Class	\$2,674,925	\$2,833,827

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

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological Disorders and Stroke

Salaries and Expenses

(Dollars in Thousands)

Object Classes	FY 2024 CR	FY 2025 President's Budget
Personnel Compensation		
Full-Time Permanent (11.1)	\$51,547	\$54,979
Other Than Full-Time Permanent (11.3)	\$30,407	\$32,363
Other Personnel Compensation (11.5)	\$3,808	\$4,062
Military Personnel (11.7)	\$0	\$0
Special Personnel Services Payments (11.8)	\$13,118	\$13,485
Subtotal, Personnel Compensation (11.9)	\$98,880	\$104,889
Civilian Personnel Benefits (12.1)	\$32,571	\$34,870
Military Personnel Benefits (12.2)	\$0	\$0
Benefits to Former Personnel (13.0)	\$0	\$0
Subtotal Pay Costs	\$131,452	\$139,760
Travel & Transportation of Persons (21.0)	\$3,966	\$4,053
Transportation of Things (22.0)	\$267	\$273
Rental Payments to Others (23.2)	\$94	\$96
Communications, Utilities & Misc. Charges (23.3)	\$138	\$141
Printing & Reproduction (24.0)	\$8	\$8
Other Contractual Services	· · ·	
Consultant Services (25.1)	\$59,062	\$60,898
Other Services (25.2)	\$51,697	\$40,939
Purchase of Goods and Services from Government Accounts (25.3)	\$107,895	\$109,830
Operation & Maintenance of Facilities (25.4)	\$154	\$154
Operation & Maintenance of Equipment (25.7)	\$8,840	\$9,035
Subsistence & Support of Persons (25.8)	\$0	\$0
Subtotal Other Contractual Services	\$227,649	\$220,856
Supplies & Materials (26.0)	\$10,490	\$10,721
Subtotal Non-Pay Costs	\$242,610	\$236,146
Total Administrative Costs	\$374,062	\$375,906

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT (FTE)

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

Detail of Full-Time Equivalent Employment (FTE)

Civilian Military Total Division of Clinical Research 26 - 26 28 - 28 28 - 2 Division of Extramural Activities 90 - 90 96 - 96 99 - 29 Division of Intramural Research 90 - 90 - 90 - 96 - 96 99 - 99 Division of Intramural Research 316 - 316 326 - 326 330 - 33 Division of Neuroscience 0 - - 55 - 55 63 - 63 63 - 6 Division of Translational Research 0 - - 44 -	Office	F	Y 2023 Fin	al	FY 2024 CR			FY 2025 President's Budget		
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Total650-650713-713729-72Includes FTEs whose payroll obligations are supported by the NIH Common Fund.FTEs supported by funds from Cooperative Research and Development Agreements.00000000FISCAL YEAR202113.8202212.8202313.0	Direct:	77	-	77	104	-	104	113	-	113
Includes FTEs whose payroll obligations are supported by the NIH Common Fund. FTEs supported by funds from Cooperative Research and Development Agreements. 0	Total:	77	-	77	104	-	104	113	-	113
FTEs supported by funds from Cooperative Research and Development Agreements. 0 0 0 0 0 0 0 FISCAL YEAR Average GS Grade 2021 13.8 2022 12.8 2023 13.0					713	-	713	729	-	729
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2023 13.0										
2025										

NATIONAL INSTITUTES OF HEALTH National Institute of Neurological Disorders and Stroke

CRADE			FY 2025
GRADE	FY 2023 Final	FY 2024 CR	President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	\$201,135	\$201,135	\$201,135
General Schedule			
GM/GS-15	84	86	86
GM/GS-14	116	122	124
GM/GS-13	145	155	160
GS-12	71	76	80
GS-11	30	32	35
GS-10	1	1	1
GS-9	15	16	18
GS-8	4	4	4
GS-7	4	5	5
GS-6	2	2	2
GS-5	1	1	1
GS-4	3	3	3
GS-3	1	1	1
GS-2	0	0	0
GS-1	0	0	0
Subtotal	477	504	520
Commissioned Corps (42 U.S.C.			
207)			
Assistant Surgeon General	0	0	0
Director Grade	0	0	0
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Junior Assistant	0	0	0
Subtotal	0	0	÷
Ungraded	207	208	208
Total permanent positions	685	713	729
Total positions, end of year	685	713	729
Total full-time equivalent (FTE)	(50)	710	700
employment, end of year	650	713	729
Average ES salary	\$201,135	\$201,135	\$201,135
Average GM/GS grade	13.0	13.0	12.9
Average GM/GS salary	\$133,449	\$140,388	\$144,319

Detail of Positions 1

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