

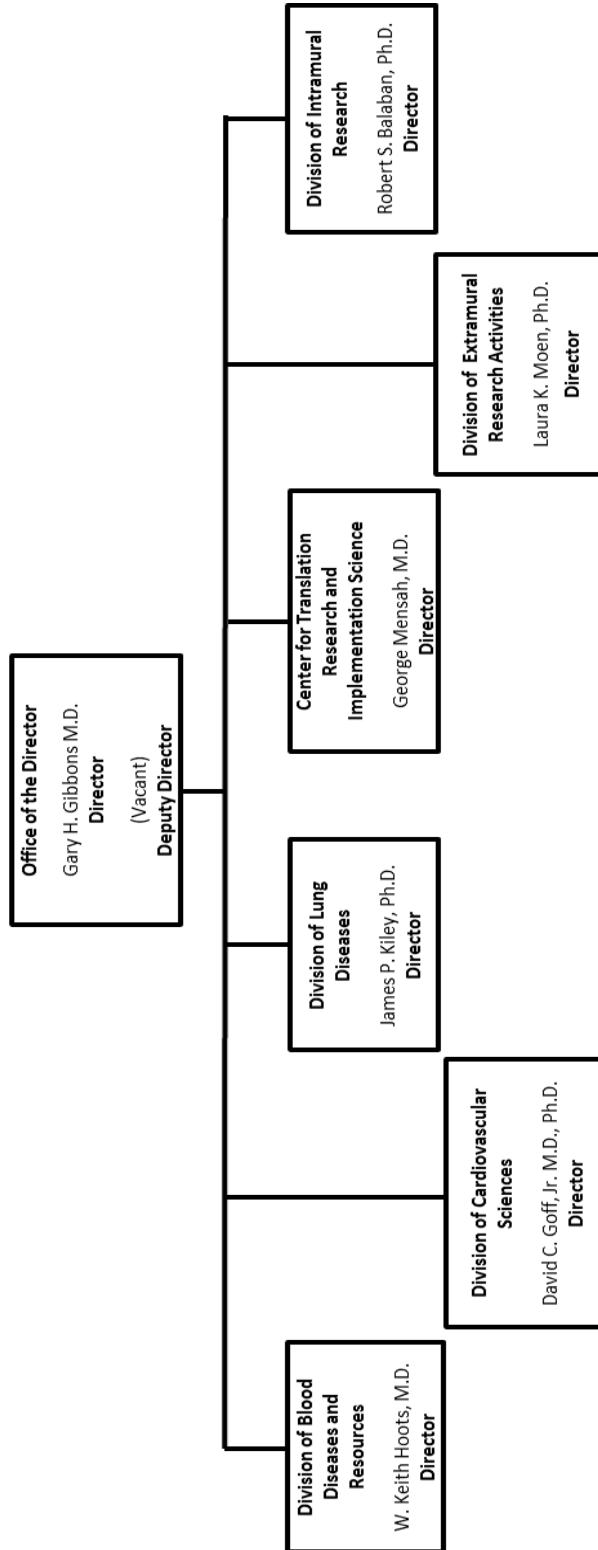
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute (NHLBI)

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**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood, Institute**



**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

For carrying out section 301 and title IV of the PHS Act with respect to cardiovascular, lung, and blood diseases, and blood and blood products, [~~\$3,624,258,000~~]*\$3,298,004,000*.

**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**

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

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	\$3,488,335	\$3,624,258	\$3,298,004
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-11,982	0	0
Subtotal, adjusted appropriation	\$3,476,353	\$3,624,258	\$3,298,004
OAR HIV/AIDS Transfers	6,024	1,000	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$3,482,377	\$3,625,258	\$3,298,004
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$3,482,377	\$3,625,258	\$3,298,004
Unobligated balance lapsing	-140	0	0
Total obligations	\$3,482,237	\$3,625,258	\$3,298,004

<sup>1</sup> Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:  
FY 2019 - \$13,267    FY 2020 - \$14,100    FY 2021 - \$15,306

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Budget Mechanism - Total<sup>1</sup>**

(Dollars in Thousands)

MECHANISM	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY 2020 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	2,779	\$1,705,468	2,788	\$1,769,513	2,792	\$1,658,171	4	-\$111,342
Administrative Supplements	(113)	27,882	(98)	24,267	(20)	3,177	(-78)	-21,090
<u>Competing:</u>								
Renewal	144	102,920	154	110,008	139	99,007	-15	-11,001
New	820	493,446	851	512,248	758	455,901	-93	-56,347
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	964	\$596,366	1,005	\$622,256	897	\$554,908	-108	-\$67,348
Subtotal, RPGs	3,743	\$2,329,716	3,793	\$2,416,036	3,689	\$2,216,256	-104	-\$199,779
SBIR/STTR	203	106,113	212	110,627	197	102,883	-15	-7,744
Research Project Grants	3,946	\$2,435,829	4,005	\$2,526,663	3,886	\$2,319,139	-119	-\$207,523
<u>Research Centers:</u>								
Specialized/Comprehensive	8	\$15,899	7	\$14,839	6	\$13,059	-1	-\$1,781
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	1,017	0	806	0	749	0	-56
Comparative Medicine	0	455	0	455	0	455	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	8	\$17,371	7	\$16,100	6	\$14,263	-1	-\$1,837
<u>Other Research:</u>								
Research Careers	768	\$138,068	784	\$144,540	692	\$127,542	-92	-\$16,999
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	39	12,531	39	12,847	35	11,562	-4	-1,285
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	154	94,157	158	98,158	139	85,397	-19	-12,761
Other Research	961	\$244,756	981	\$255,545	866	\$224,501	-115	-\$31,044
Total Research Grants	4,915	\$2,697,955	4,993	\$2,798,308	4,758	\$2,557,903	-235	-\$240,405
<u>Ruth L. Kirchstein Training Awards:</u>								
Individual Awards	FTTPs 473	\$22,194	FTTPs 527	\$25,296	FTTPs 464	\$22,261	FTTPs -63	-\$3,036
Institutional Awards	2,021	95,097	2,064	99,055	1,816	87,168	-248	-11,887
Total Research Training	2,494	\$117,291	2,591	\$124,351	2,280	\$109,429	-311	-\$14,922
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	743 <i>(0)</i>	\$307,931 <i>(7,927)</i>	794 <i>(0)</i>	\$329,031 <i>(7,900)</i>	722 <i>(0)</i>	\$289,548 <i>(6,900)</i>	-72 <i>(0)</i>	-\$39,484 <i>(-1,000)</i>
Intramural Research	406	220,596	467	229,420	467	204,184	0	-25,236
Res. Management & Support <i>Res. Management &amp; Support (SBIR Admin) (non-add)</i>	434 <i>(0)</i>	138,604 <i>(1,710)</i>	495 <i>(0)</i>	144,148 <i>(1,800)</i>	495 <i>(0)</i>	136,941 <i>(900)</i>	0 <i>(0)</i>	-7,207 <i>(-900)</i>
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NHLBI	840	\$3,482,377	962	\$3,625,258	962	\$3,298,004	0	-\$327,254

<sup>1</sup> All items in italics and brackets are non-add entries.

## **Major Changes in the Fiscal Year 2021 President's Budget Request**

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanisms and activity detail; and these highlights may not sum to the total change for the FY 2021 budget request for the NHLBI, which is \$3,298.0 million, a decrease of \$327.3 million from the FY 2020 Enacted level. In FY 2021, the overall reductions of 9.0 percent are distributed across multiple programmatic areas including basic, translational, and clinical research. NHLBI is committed to the continuous support for key strategic priorities along with other scientific areas of the Institute's research portfolio. Within the framework of the Administration's fiscal policy goals for the Federal Government, NHLBI will pursue its highest research priorities through strategic investments and careful stewardship of the appropriated funds.

### Research Project Grants (RPGs) (-\$207.5 million; total \$2,319.1 million):

NHLBI will make dollar adjustments to both competing and non-competing RPGs which result in a 8.2 percent reduction to fund 897 competing RPGs and approximately 2,792 noncompeting RPG awards in FY 2021. Adjustments for special circumstances will be accommodated.

### Research Centers (-\$1.8 million; total \$14.3 million):

A shift in the receipt of research applications that are normally supported under this mechanism to other Program Announcements and/or Funding Opportunity Announcements for research projects will reduce funding requirements in this mechanism and increase other research mechanisms.

### Other Research (-\$31.0 million; total \$224.5 million):

NHLBI will reduce funding for Other Research by 12.1 percent, which is a \$31.0 million decrease compared to the FY 2020 Enacted level of \$255.5 million. The number of competing grant awards will also decrease. The reductions are distributed across all programmatic areas and basic, translational or clinical research.

### Research and Development (R&D) Contracts (-\$39.5 million; total \$289.5 million):

NHLBI will reduce funding for Research and Development Contracts by 12.0 percent, which is a \$39.5 million decrease compared to the FY 2020 Enacted level of \$329.0 million. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

### Intramural Research (IR) (-\$25.2 million; total \$204.2 million):

NHLBI will reduce funding for Intramural Research by 11.0 percent, which is a \$25.2 million decrease compared to the FY 2020 Enacted level of \$229.4 million. These reductions are distributed across all programmatic areas and basic, translational or clinical research.

### Research Management and Support (RMS) (-\$7.2 million; total \$136.9 million):

NHLBI will reduce funding for Intramural Research by 5.0 percent, which is a \$7.2 million decrease compared to the FY 2020 Enacted level of \$144.1 million. These reductions are distributed across all programmatic areas of RMS.

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Summary of Changes**

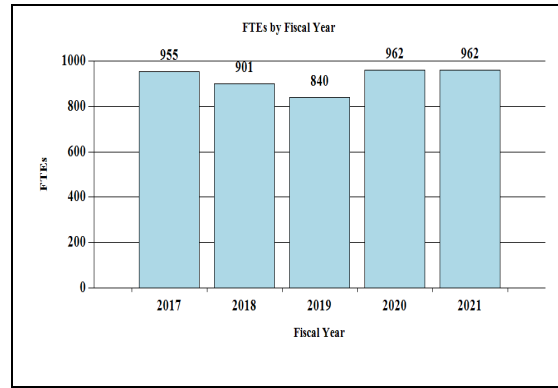
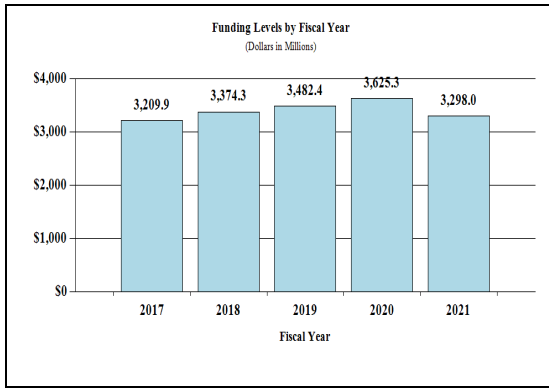
(Dollars in Thousands)

<b>FY 2020 Enacted</b>					\$3,625,258
<b>FY 2021 President's Budget</b>					\$3,298,004
<b>Net change</b>					-\$327,254
CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted		
	FTEs	Budget Authority	FTEs	Budget Authority	
<b>A. Built-in:</b>					
<b>1. Intramural Research:</b>					
a. Annualization of January 2020 pay increase & benefits		\$87,135			\$565
b. January FY 2021 pay increase & benefits		87,135			837
c. Paid days adjustment		87,135			-325
d. Differences attributable to change in FTE		87,135			0
e. Payment for centrally furnished services		28,555			-1,503
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		88,494			1,415
Subtotal					\$989
<b>2. Research Management and Support:</b>					
a. Annualization of January 2020 pay increase & benefits		\$73,227			\$470
b. January FY 2021 pay increase & benefits		73,227			722
c. Paid days adjustment		73,227			-273
d. Differences attributable to change in FTE		73,227			0
e. Payment for centrally furnished services		3,314			-174
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		60,416			842
Subtotal					\$1,585
Subtotal, Built-in					\$2,574

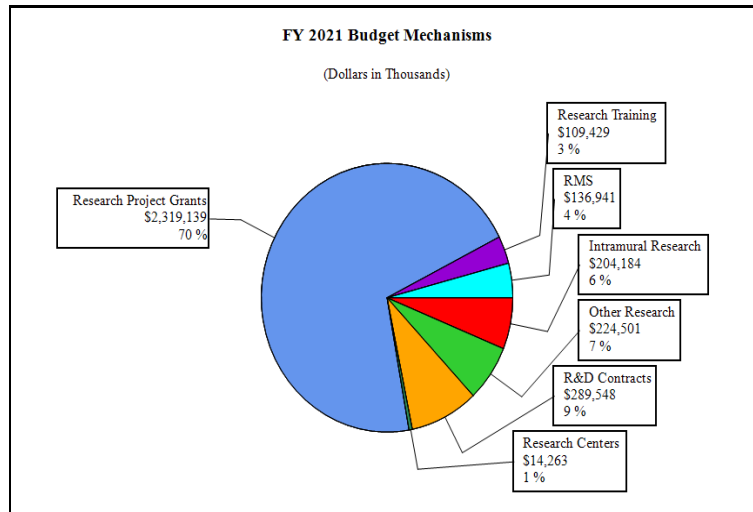
CHANGES	FY 2021 President's Budget		Change from FY 2020 Enacted		
	No.	Amount	No.	Amount	
<b>B. Program:</b>					
<b>1. Research Project Grants:</b>					
a. Noncompeting	2,792	\$1,661,348	4		-\$132,431
b. Competing	897	554,908	-108		-67,348
c. SBIR/STTR	197	102,883	-15		-7,744
Subtotal, RPGs	3,886	\$2,319,139	-119		-\$207,523
2. Research Centers	6	\$14,263	-1		-\$1,837
3. Other Research	866	224,501	-115		-31,044
4. Research Training	2,280	109,429	-311		-14,922
5. Research and development contracts	722	289,548	-72		-39,484
Subtotal, Extramural		\$2,956,879			-\$294,810
6. Intramural Research	FTEs 467	\$204,184	FTEs 0		-\$26,225
7. Research Management and Support	495	136,941	0		-8,793
8. Construction		0			0
9. Buildings and Facilities		0			0
Subtotal, Program	962	\$3,298,004	0		-\$329,828
Total changes					-\$327,254

## Fiscal Year 2021 Budget Graphs

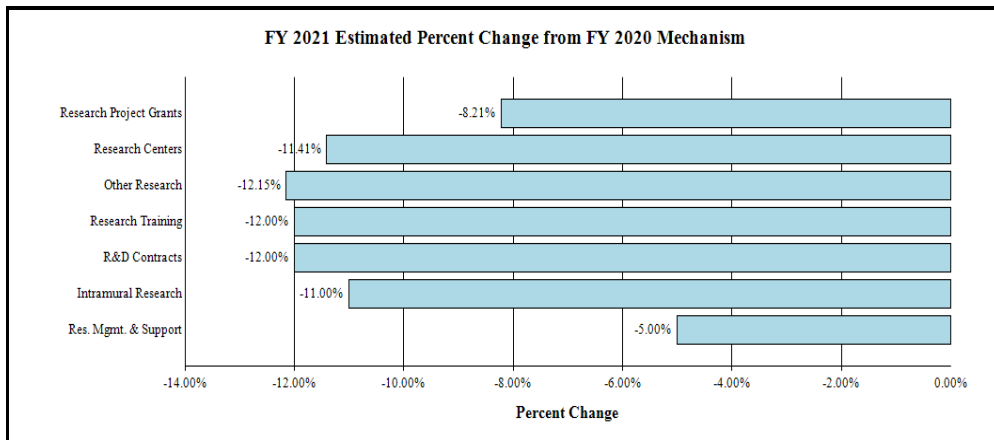
### History of Budget Authority and FTEs:



### Distribution by Mechanism:



### Change by Selected Mechanism:





**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

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

	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY2020	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<b><u>Extramural Research</u></b>								
<u>Detail</u>								
Center for Translation, Implementation Sciences		\$27,369		\$28,496		\$25,913		-\$2,584
Heart and Vascular Diseases		1,865,252		1,941,945		1,765,881		-176,064
Lung Diseases		740,036		770,521		700,663		-69,858
Blood Diseases and Resources		490,520		510,727		464,423		-46,304
<b>Subtotal, Extramural</b>		<b>\$3,123,177</b>		<b>\$3,251,690</b>		<b>\$2,956,879</b>		<b>-\$294,810</b>
<b>Intramural Research</b>	<b>406</b>	<b>\$220,596</b>	<b>467</b>	<b>\$229,420</b>	<b>467</b>	<b>\$204,184</b>	<b>0</b>	<b>-\$25,236</b>
<b>Research Management &amp; Support</b>	<b>434</b>	<b>\$138,604</b>	<b>495</b>	<b>\$144,148</b>	<b>495</b>	<b>\$136,941</b>	<b>0</b>	<b>-\$7,207</b>
<b>TOTAL</b>	<b>840</b>	<b>\$3,482,377</b>	<b>962</b>	<b>\$3,625,258</b>	<b>962</b>	<b>\$3,298,004</b>	<b>0</b>	<b>-\$327,254</b>

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

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Authorizing Legislation**

	<b>PHS Act/ Other Citation</b>	<b>U.S. Code Citation</b>	<b>2020 Amount Authorized</b>	<b>FY 2020 Enacted</b>	<b>2021 Amount Authorized</b>	<b>FY 2021 President's Budget</b>
Research and Investigation	Section 301	42§241	Indefinite	\$3,625,258,000	Indefinite	\$3,298,004,000
National Heart, Lung, and Blood Institute	Section 401(a)	42§281	Indefinite		Indefinite	
<b>Total, Budget Authority</b>				<b>\$3,625,258,000</b>		<b>\$3,298,004,000</b>

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

**Appropriations History**

<b>Fiscal Year</b>	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
2012	\$3,147,992,000	\$3,147,992,000	\$3,036,189,000	\$3,084,851,000
Rescission				\$5,830,368
2013	\$3,076,067,000		\$3,085,390,000	\$3,079,020,632
Rescission				\$6,158,041
Sequestration				(\$154,545,663)
2014	\$3,098,508,000		\$3,077,916,000	\$2,988,605,000
Rescission				\$0
2015	\$2,987,685,000			\$2,997,870,000
Rescission				\$0
2016	\$3,071,906,000	\$3,035,062,000	\$3,135,519,000	\$3,115,538,000
Rescission				\$0
2017 <sup>1</sup>	\$3,113,533,000	\$3,190,474,000	\$3,242,685,000	\$3,206,589,000
Rescission				\$0
2018	\$2,534,803,000	\$3,256,521,000	\$3,322,774,000	\$3,383,201,000
Rescission				\$0
2019	\$3,112,032,000	\$3,423,604,000	\$3,490,171,000	\$3,488,335,000
Rescission				\$0
2020	\$3,002,696,000	\$3,658,822,000	\$3,694,771,000	\$3,624,258,000
Rescission				\$0
2021	\$3,298,004,000			

<sup>1</sup> Budget Estimate to Congress includes mandatory financing.

## Justification of Budget Request

### National Heart, Lung, and Blood Institute

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

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	\$3,482,377,000	\$3,625,258,000	\$3,298,004,000	-\$327,254,000
FTE	840	962	962	0

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

### Director's Overview

The National Heart, Lung, and Blood Institute (NHLBI) is committed to fueling the scientific discoveries needed to improve the health of the nation. Over the past seven decades, by forming partnerships with communities, patients, and researchers, NHLBI's research programs have helped improve longevity and quality of life for people across the globe. Among adults in the United States, deaths from cardiovascular disease (CVD) decreased by nearly 19 percent between 2006-2016 and from coronary heart disease by almost 32 percent.<sup>1</sup> While congenital heart disease and sickle cell disease (SCD) once meant a death sentence in childhood, children with these diseases are now living and thriving into adulthood; young people with SCD have even been cured through state-of-the-art cell- and gene-based therapies.

To continue these encouraging trends, in FY 2021, NHLBI will pursue the priorities set forward in its Strategic Vision,<sup>2</sup> with an emphasis on advancing fundamental discovery research, expanding the biomedical use of artificial intelligence (AI), reducing heart disease deaths for women of all races and ethnicities, improving the health of rural and underserved populations, and nurturing a diverse, talented biomedical workforce.

**Advancing Fundamental Discovery Science for Public Health Impact.** Decades of fundamental research into life's dependence on oxygen shows how long-term investments in basic research can have unexpected payoffs.<sup>3</sup> In work recognized with the 2019 Nobel Prize in Medicine, NHLBI grantee Gregg Semenza explored how the body responds to oxygen deprivation. It was known that low oxygen leads to increased production of red blood cells, but how the body senses low oxygen was unknown. More than 20 years ago, Semenza's research established that a protein called hypoxia-inducible factor-1 (HIF-1) plays a key role in oxygen

<sup>1</sup> [www.ahajournals.org/doi/full/10.1161/CIR.0000000000000659](http://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000659)

<sup>2</sup> [www.nhlbi.nih.gov/about/strategic-vision](http://www.nhlbi.nih.gov/about/strategic-vision)

<sup>3</sup> [www.nobelprize.org/prizes/medicine/2019/press-release/](http://www.nobelprize.org/prizes/medicine/2019/press-release/)

sensing. His later work in models of heart disease showed that when arteries to the heart are clogged, HIF-1 can stimulate the growth of blood vessels around the blockage.<sup>4</sup> This knowledge about blood cell production and blood vessel remodeling may lead to new therapies for anemia, heart disease, and even cancers, which all depend on a robust blood supply to thrive.

Other Nobelists honored in 2017 helped to define the genetic and molecular pathways underlying the circadian rhythm—the body’s internal clock—opening new doors to understanding sleep and sleep disorders.<sup>5</sup> Years of basic research have established that the brain regulates sleep and wakefulness in part by releasing a hormone called hypocretin. In 2019, a study in mice found that undisturbed sleep maintains the brain’s proper release of hypocretin, which in turn helps quiet inflammatory signals that can contribute to atherosclerosis.<sup>6</sup> Sleep-deprived mice had lower levels of circulating hypocretin and higher rates of atherosclerosis, which could be prevented by giving them infusions of hypocretin—suggesting that this pathway could be leveraged to develop new therapies for atherosclerosis.

**Using Big Data and AI to Predict, Prevent, and Preempt Disease.** As new data emerges on complex biological pathways, there are growing opportunities for researchers to connect insights from one field, or one disease, to another. To enhance data sharing and deep analyses that will help make precision medicine a reality, NHLBI is launching a new data science platform.<sup>7</sup> As part of the NIH STRIDES Initiative,<sup>8</sup> this cloud-based platform will enable researchers to securely find, access, share, store, cross-link, and analyze large-scale datasets, with appropriate privacy protections. Among the rich data available from NHLBI-funded research will be more than 20,000 chest images from the COPDGene Study<sup>9</sup> and more than 150,000 whole genome sequences collected through NHLBI’s Trans-Omics for Precision Medicine (TOPMed)<sup>10</sup> program from participants in more than 80 diverse studies, including the Framingham Heart Study, Jackson Heart Study, and Women’s Health Initiative.

To propel further growth in data science, NHLBI also supports research on transformational AI tools, which rapidly sift through vast amounts of data to identify patterns that can help researchers make new discoveries and aid clinicians in improving care. For example, NHLBI’s COPDGene Study used AI principles to predict acute respiratory events in smokers with chronic obstructive pulmonary disease (COPD),<sup>11</sup> and another study used AI to distinguish malignant and benign lung nodules (swellings).<sup>12</sup> An ongoing study is evaluating whether an AI “chat bot” can improve adherence to medication for high blood pressure, coronary heart disease, and other

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<sup>4</sup> [www.ncbi.nlm.nih.gov/pmc/articles/PMC4696033/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4696033/)

<sup>5</sup> [www.nhlbi.nih.gov/news/2017/wake-call-2017-nobel-prize-medicine-awarded-studies-bodys-internal-clock](http://www.nhlbi.nih.gov/news/2017/wake-call-2017-nobel-prize-medicine-awarded-studies-bodys-internal-clock)

<sup>6</sup> [www.ncbi.nlm.nih.gov/pubmed/30760925](http://www.ncbi.nlm.nih.gov/pubmed/30760925)

<sup>7</sup> [www.nhlbi.datastage.org/](http://www.nhlbi.datastage.org/)

<sup>8</sup> [www.datascience.nih.gov/strides](http://www.datascience.nih.gov/strides)

<sup>9</sup> [www.copdgene.org/](http://www.copdgene.org/)

<sup>10</sup> [www.nhlbiwgs.org/](http://www.nhlbiwgs.org/)

<sup>11</sup> [www.ncbi.nlm.nih.gov/pubmed/28892454](http://www.ncbi.nlm.nih.gov/pubmed/28892454)

<sup>12</sup> [www.ncbi.nlm.nih.gov/pubmed/31087332](http://www.ncbi.nlm.nih.gov/pubmed/31087332)

conditions.<sup>13</sup> The hope is that in the years ahead, the combination of AI, large accessible datasets, and robust analytics will lead to more precise diagnostic tools and therapies.

### **Reducing Maternal Mortality and Improving Women’s Heart Health across the Lifespan.**

Maternal mortality and morbidity are rising in the United States even as they decrease globally. Each year, about 700 American women die from pregnancy or delivery complications. Cardiovascular conditions, including gestational hypertension and preeclampsia (which is marked by hypertension and elevated protein in urine), cardiomyopathy (heart muscle weakness), and venous thromboembolism (a clot that starts in a vein) are among the leading causes.<sup>14</sup> Moreover, these conditions disproportionately affect women of color, and Black and American Indian/Alaska Native women aged 30 and over are four to five times more likely to die during childbirth than White women.<sup>15</sup>

With rising rates of obesity, diabetes, and high blood pressure among young people, many women are coming into their pregnancies at higher risk for CVD. Additionally, pregnancy is a risk factor for future CVD. There is an urgent need to improve women’s heart health across the entire lifespan, and to use implementation science to bring proven interventions into practice to reduce racial/ethnic disparities in CVD. NHLBI supports research to understand and reduce women’s risk of CVD, including during vulnerable windows of time before, during, and after pregnancy. For example, an ongoing trial is examining whether pregnant women with mild chronic hypertension, the most common medical disorder in pregnancy, will benefit from treatment to lower their blood pressure to a target often used for non-pregnant adults (<140/90 mmHg), without a harmful reduction in blood flow to the womb.<sup>16</sup> In collaboration with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NHLBI is supporting research to better understand how sleep disturbance affects pregnancy outcomes. A recent analysis from the nuMoM2b Sleep-Disordered Breathing Study revealed that sleep apnea during pregnancy is associated with an increased risk of gestational hypertension and diabetes.<sup>17</sup> The nuMoM2b Heart Health Study<sup>18</sup> is now looking at how sleep apnea and other pregnancy complications, such as preeclampsia and hypertension, affect a woman’s long-term health. Another NHLBI-funded study focuses on how to best manage blood clots in pregnant women.<sup>19</sup> Researchers are also working to determine the most effective ways to improve pregnancy-related outcomes in obese and overweight pregnant women. A recent study found that lifestyle interventions can help.<sup>20</sup>

**Addressing Disparities to Improve the Health of All Populations.** In addition to reducing disparities in maternal health, NHLBI will continue its long-standing commitment to address the

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<sup>13</sup> [https://projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9750927&icde=46475566](https://projectreporter.nih.gov/project_info_description.cfm?aid=9750927&icde=46475566)

<sup>14</sup> [www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm](http://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm)

<sup>15</sup> [www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s\\_cid=mm6835a3\\_w](http://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w)

<sup>16</sup> [www.nhlbi.nih.gov/news/2019/chronic-hypertension-pregnancy-treat-or-not-treat](http://www.nhlbi.nih.gov/news/2019/chronic-hypertension-pregnancy-treat-or-not-treat)

<sup>17</sup> [www.ncbi.nlm.nih.gov/pubmed/27926645](http://www.ncbi.nlm.nih.gov/pubmed/27926645)

<sup>18</sup> [www.clinicaltrials.gov/ct2/show/NCT02231398](http://www.clinicaltrials.gov/ct2/show/NCT02231398)

<sup>19</sup> [https://projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9676403&icde=46918786](https://projectreporter.nih.gov/project_info_description.cfm?aid=9676403&icde=46918786)

<sup>20</sup> [www.ncbi.nlm.nih.gov/pubmed/31292531](http://www.ncbi.nlm.nih.gov/pubmed/31292531)

disparate burden of CVD and chronic lung disease in underserved minority, low-income, and rural communities. Recognizing that unique communities can face unique barriers and challenges to health over the lifespan, NHLBI will expand its cohort studies to better understand and address chronic disease risk factors and outcomes across diverse populations.

For COPD, which disproportionately affects people living in rural areas, NHLBI is working with Federal agencies and non-governmental partners to implement the COPD National Action Plan, released in 2017.<sup>21</sup> For example, funding opportunities driven by the Action Plan are supporting researchers to develop innovative ways to deliver pulmonary rehabilitation to patients in hard-to-reach settings, which can help them breathe better and may even slow disease progression.

To address the high burden of chronic disease in America's heartland, NHLBI established a new study in 2019, the Risk Underlying Rural Areas Longitudinal (RURAL) cohort study,<sup>22</sup> that will include 4,000 people in 10 low-income counties in the South. NHLBI also continues to advance research to improve the health of American Indian communities. In 2019, NHLBI renewed its commitment to the Strong Heart Study, the largest study of CVD and its risk factors in American Indians. The study involves a partnership with 12 Tribal Nations, and since its inception in 1988, has followed more than 8,000 participants, many of whom live in low-income, rural areas of Arizona, Oklahoma, and the Dakotas. This new study phase includes more funding for community-driven pilot projects, and continued emphasis on training and development.

**Sustaining a Diverse and Inclusive Scientific Workforce.** Investigator-initiated research remains the cornerstone of the biomedical research enterprise. NHLBI has prioritized investigator-initiated science and support for early-stage investigators (ESI); over the past five years, the success rate for NHLBI ESIs improved by 78 percent. The Institute also has invested in programs to sustain a workforce that reflects the diversity of the Nation. Examples include the availability of NHLBI supplemental awards to grantees who diversify their research team, and NHLBI's Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE), which prepares junior faculty from underrepresented backgrounds for successful research careers. An analysis of the PRIDE program found that from 2006 to 2018, the success rate for NIH grant applications submitted by PRIDE graduates was 63 percent, compared to 19 percent for NIH applications overall—evidence that the program has been successful in strengthening the skills of underrepresented investigators and helping to diversify the NIH-funded workforce.<sup>23</sup>

Ensuring the long-term stability of an inclusive workforce is also a priority. NHLBI leadership and program staff make every effort to identify and retain tomorrow's scientific leaders; to support them on a path to independence; and to prepare them to train the next generation. One researcher with early support from an NHLBI training award is now helping cultivate a new

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<sup>21</sup> [www.nhlbi.nih.gov/health-topics/education-and-awareness/COPD-national-action-plan](http://www.nhlbi.nih.gov/health-topics/education-and-awareness/COPD-national-action-plan)

<sup>22</sup> [www.theruralstudy.org/](http://www.theruralstudy.org/)

<sup>23</sup> [www.ncbi.nlm.nih.gov/pubmed/30975303](http://www.ncbi.nlm.nih.gov/pubmed/30975303)

cadre of physician-scientists through a medical residency program,<sup>24</sup> and recently discovered a new lung cell type that could lead to new treatment strategies for cystic fibrosis.<sup>25</sup> A Native American researcher who did her graduate work with the Strong Heart Study under a training grant is now the principal investigator leading the study's field center in North and South Dakota, and is working with research trainees from the affiliated American Indian communities.<sup>26</sup> Yet another former NHLBI-funded trainee in hematology went on to transform the understanding of how blood-clotting cells regenerate and to lead a program for early medical students to gain research experience.<sup>27</sup> NHLBI will continue this commitment to support talented scientists throughout their careers, helping them succeed not only as investigators, but as teachers and mentors for a future globally competitive workforce.

### **Program Portrait: Supporting Native American Students to Lead in Native Health Research**

A racially and ethnically diverse biomedical workforce is essential for addressing racial and ethnic health disparities, such as those that affect American Indian and Alaska Native (AI/AN) populations. Rates of heart disease and asthma are higher in AI/AN people than in whites, yet AI/AN researchers represent less than one percent of the biomedical work force.<sup>1</sup> To address this issue, NHLBI and other Institutes established the Native American Research Internship (NARI) nearly one decade ago to provide culturally relevant research training and experience for AI/AN students.<sup>2</sup> NARI supports undergraduate AI/AN students from across the country in paid summer research internships at the University of Utah. Students also receive cultural and professional mentorship from community members and renowned biomedical scientists working in many areas including heart, lung, blood, and sleep disorders. Through program development in partnership with AI/AN elders, faculty, students, and community organizations, NARI has been highly successful. Since 2010, NHLBI funding for the program has supported 65 students from 36 tribal nations. Of those, 47 have received a health-related bachelor's degree, 14 have gone to graduate school, and 10 have gone to medical school.

<sup>1</sup> [www.ncbi.nlm.nih.gov/pubmed/25588950](http://www.ncbi.nlm.nih.gov/pubmed/25588950)

<sup>2</sup> <https://medicine.utah.edu/pediatrics/research/education/nari.php>

### **Overall Budget Policy:**

The FY 2021 President's Budget request is \$3,298.0 million, a decrease of \$327.3 million or 9.0 percent compared with the FY 2020 Enacted level. Reductions are distributed across all programmatic, basic, epidemiologic, translation, and clinical research areas.

### **Program Descriptions and Accomplishments**

**Cardiovascular Diseases:** The cardiovascular disease (CVD) program supports research aimed at diagnosing, preventing and treating pediatric and adult cardiovascular diseases, including heart attack, heart failure, vascular dementia, stroke, and congenital heart disease. The program also supports the development of innovative technologies to diagnose, prevent, and treat CVD and offers research training and career development opportunities. In FY 2021, NHLBI will continue

<sup>24</sup> [www.ncbi.nlm.nih.gov/pubmed/29878132](http://www.ncbi.nlm.nih.gov/pubmed/29878132)

<sup>25</sup> [www.ncbi.nlm.nih.gov/pubmed/30069044](http://www.ncbi.nlm.nih.gov/pubmed/30069044)

<sup>26</sup> [www.nhlbi.nih.gov/nhlbi-celebrates-women-scientists/amanda-fretts-phd-mpd](http://www.nhlbi.nih.gov/nhlbi-celebrates-women-scientists/amanda-fretts-phd-mpd)

<sup>27</sup> [www.projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9672557](http://www.projectreporter.nih.gov/project_info_description.cfm?aid=9672557)



supporting innovative and novel research ideas submitted by new investigators.

The CVD program's portfolio supports research to understand and improve heart and vascular health across the lifespan. Since 1948, NHLBI's Framingham Heart Study (FHS) has continued to amass knowledge about CVD risk factors, and to guide prevention and treatment strategies. Many studies modeled after FHS are exploring chronic disease risk in diverse populations, including the Jackson Heart Study of African Americans in Mississippi, and the Atherosclerosis Risk in Communities Study (ARIC) study of Black and White middle-aged adults.

FHS investigators were also among the first to recognize that a high burden of CVD might contribute to the increasing burden of dementia in older Americans. The FHS and NHLBI's diverse cohort studies have thus expanded over the years to include cognitive testing, and to examine how cardiovascular risk factors affect cognitive outcomes. For example, new findings from ARIC add to the growing evidence base that physical activity is not only good for the heart, but also for the brain. The researchers found that after 17 years of follow-up, participants who engaged in persistent moderate-to-high physical activity in midlife had about a 40 percent reduced incidence of dementia than their sedentary peers.<sup>28</sup>

NHLBI is also working with the National Institute on Aging and other Institutes to refine this emerging knowledge about vascular causes of dementia. In FY 2019 and 2020, NHLBI made nearly 30 supplemental awards to existing projects with potential relevance to dementia. For example, one group of researchers has been examining reductive stress—a harmful process that can occur with excess exposure to antioxidants—and its potential role in some types of heart failure. With their supplemental award, these researchers are now also studying whether reductive stress contributes to dementia in people with heart failure.<sup>29</sup>

The CVD program continues to support innovative research toward new treatments for the full spectrum of cardiovascular disease in people of all ages. For example, many Americans have a cardiac arrhythmia (an abnormal heart rate); the most common type—atrial fibrillation (AFib)—affects 3 to 7 million adults and is a risk factor for strokes. One NHLBI-funded team is working with patients, their caregivers, health care providers and computer programmers to develop, validate and test a new smartphone application that can monitor and detect AFib in people at risk for a first-time or recurrent stroke.<sup>30</sup> In a study of ventricular tachycardia (a fast rhythm), researchers are developing a noninvasive catheter-free method for mapping and treating the area of the heart where the abnormal rhythm originates. The procedure combines cardiac imaging and electrocardiography (EKG) with stereotactic body radiation therapy—originally developed to deliver precise, high-dose radiation to tumors.<sup>31</sup> Others are working to improve cardiac interventions for pediatric patients. In one study, magnetic resonance imaging (MRI) images were overlaid with standard live X-ray images to help guide cardiac catheterization for children with congenital heart disease. The combined procedure was faster and reduced the children's exposure to X-rays.<sup>32</sup>

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<sup>28</sup> [www.ncbi.nlm.nih.gov/pubmed/30321503](http://www.ncbi.nlm.nih.gov/pubmed/30321503)

<sup>29</sup> [www.projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9596809&icde=45602328](http://www.projectreporter.nih.gov/project_info_description.cfm?aid=9596809&icde=45602328)

<sup>30</sup> [www.clinicaltrials.gov/ct2/show/NCT03761394](http://www.clinicaltrials.gov/ct2/show/NCT03761394)

<sup>31</sup> [www.ncbi.nlm.nih.gov/pubmed/29236642](http://www.ncbi.nlm.nih.gov/pubmed/29236642)

<sup>32</sup> [www.ncbi.nlm.nih.gov/pubmed/31062506](http://www.ncbi.nlm.nih.gov/pubmed/31062506)

Since it began in 2001, NHLBI's Pediatric Heart Network (PHN) has been working to improve evidence-based treatment for congenital heart disease. The PHN includes more than 30 children's hospitals with specialized heart disease teams that collaborate to support both state-of-the-art care and research. For example, through a collaborative review of surgeries for two common heart defects—tetralogy of Fallot (TOF) and coarctation (narrowing) of the aorta—network researchers developed new postsurgical guidelines that cut the amount of time infants spent on a breathing tube by 80 percent.<sup>33</sup> These new guidelines also reduced the cost of TOF surgery by 27 percent.<sup>34</sup>

NHLBI is leveraging the PHN and other resources, including its Pediatric Cardiac Genomics Consortium (PGCC), as part of the trans-NIH project, Investigation of Co-occurring Conditions Across the Lifespan to Understand Down syndrome (INCLUDE). Through INCLUDE, NHLBI-funded researchers are increasing the number of individuals with both Down syndrome and congenital heart disease in the PGCC to investigate the genetic factors that could link Down syndrome with congenital heart disease. The PHN is also supporting career development awards for four emerging clinician-scientists to help them gain expertise in treating patients with congenital heart disease and Down syndrome.

#### Budget Policy:

The FY 2021 President's Budget request is \$1,765.9 million, a decrease of \$176.1 million or 9.0 percent compared with the FY 2020 Enacted level.

**Lung Diseases:** Since its inception in 1969, NHLBI's Division of Lung Diseases has focused on translating basic scientific research into more effective treatments and patient care. The lung program supports research on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders, while also supporting the researchers of the future. Some areas covered include asthma, COPD, cystic fibrosis, sleep-disordered breathing, acute lung injury, pulmonary complications of HIV/AIDS, pediatric lung diseases, pulmonary fibrosis and other rare lung disorders, including lymphangiomyomatosis (LAM).

NHLBI's lung program is committed to reducing the burden of COPD, which is among the leading causes of death in the United States and has a disproportionate impact on rural communities. As part of the COPD National Action Plan, NHLBI has been working with other Federal health agencies and non-governmental partners to intensify research and outreach efforts to address this disparity. One high priority area for NHLBI is finding new ways to increase the use of pulmonary rehabilitation (PR) for COPD patients, especially in rural areas. Despite proven benefits, a very small proportion of COPD patients receive PR during hospitalization, and of those, only about four percent adhere to it after discharge, perhaps due to the challenge of regular travel to distant PR facilities. Researchers are thus testing the effectiveness of a home-

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<sup>33</sup> [www.ncbi.nlm.nih.gov/pubmed/27513600](http://www.ncbi.nlm.nih.gov/pubmed/27513600)

<sup>34</sup> [www.ncbi.nlm.nih.gov/pubmed/30458158](http://www.ncbi.nlm.nih.gov/pubmed/30458158)

based PR program that includes a health coach.<sup>35</sup> Another group is analyzing the records of Medicare beneficiaries to identify factors and strategies that enable some hospitals to achieve higher rates of PR participation than others.<sup>36</sup>

In 2019, NHLBI funded two new population studies that will also help address the burden of COPD and other lung diseases nationwide and in rural communities. The American Lung Association (ALA) Lung Health Cohort is the first national adult cohort focused on respiratory health and will follow 4,000 healthy millennials (aged 25-35) to identify early risk factors and signs of lung disease, to allow for earlier and more effective intervention. This cohort may help researchers better understand the long-term impact of potentially harmful exposures such as nicotine products and e-cigarettes or vaping on adult lungs. The RURAL Cohort Study will investigate what causes the high rates of COPD and other chronic diseases in southern rural communities. The study will use a mobile clinic to collect health data from about 4,000 residents aged 35-64 in 10 rural counties in Alabama, Kentucky, Louisiana, and Mississippi.

The lung program is also committed to reducing the burden of asthma, the most prevalent chronic respiratory disease worldwide. Poorly controlled or uncontrolled asthma is associated with reduced quality of life, increased hospitalizations and healthcare costs, and high rates of missed school and work. There is a need for timely clinical practice guidelines that can be used by frontline practitioners to diagnose, treat, and manage asthma. NHLBI is taking a leadership role in updating the 2007 national asthma guidelines for adults and children. The new guidelines are expected to be released for public comment in early 2020 and completed by fall 2020.

As part of its commitment to translational research and precision medicine, NHLBI's lung program is beginning to enroll patients with severe asthma at 30 locations nationwide as part of its PrecISE clinical trial network.<sup>37</sup> PrecISE will evaluate novel and approved treatments for asthma by targeting them to defined groups of patients, for example, patients who share certain genetic factors or biomarkers. Recent NHLBI-funded research illustrates the benefits of tailoring asthma interventions based on patient characteristics. For example, one study found that patients with high levels of eosinophils—a cell type that can contribute to airway inflammation—are more likely to respond to inhaled corticosteroid medications, a standard treatment for asthma, than are patients with low eosinophils.<sup>38</sup> Another recent study examined how African Americans with poorly controlled asthma respond to more intensive treatment options—either a higher corticosteroid dose or addition of a bronchodilator (a drug to open the airway). While the latter option tends to work best for most African Americans over age 12 and for White children, in this study, the two options were about equally likely to work for African American children under 12.<sup>39</sup>

NHLBI's leadership in precision medicine for lung disease can also be seen in its Pulmonary Vascular Disease Phenomics (PVDOMICS) program, which focuses on pulmonary hypertension

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<sup>35</sup> [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=9786816&icde=46788170](https://projectreporter.nih.gov/project_info_details.cfm?aid=9786816&icde=46788170)

<sup>36</sup> [www.ncbi.nlm.nih.gov/pubmed/30417670](http://www.ncbi.nlm.nih.gov/pubmed/30417670)

<sup>37</sup> [www.preciseasthma.org/preciseweb/](http://www.preciseasthma.org/preciseweb/)

<sup>38</sup> [www.ncbi.nlm.nih.gov/pubmed/31112384](http://www.ncbi.nlm.nih.gov/pubmed/31112384)

<sup>39</sup> [www.ncbi.nlm.nih.gov/pubmed/31553835](http://www.ncbi.nlm.nih.gov/pubmed/31553835)

(PH)—a type of high blood pressure in the lungs and heart. There are clinically defined subtypes of PH that can help refine diagnosis and treatment—but many patients have a mix of subtypes and face poor outcomes. Via deep analysis of disease mechanisms and biomarkers, PVDOMICS is achieving new molecularly defined subtypes of PH that will inform more precise treatments.

The Institute is also committed to stimulating precision medicine approaches for pulmonary fibrosis (PF), a progressive disease that scars the lungs. For example, new projects in calendar year 2020 will focus on developing better model systems to understand the disease and conduct preclinical studies of potential new therapies. In addition, based on an earlier retrospective analysis suggesting that the TOLLIP gene influences patients' responses to the antioxidant N-acetylcysteine (NAC), the new PRECISIONS trial will enroll only those patients who carry a certain TOLLIP gene variation to determine if they benefit from NAC.<sup>40</sup>

The lung program also administers NIH's National Center on Sleep Disorders Research, established by Congress in 1993.<sup>41</sup> In its early years, the Center facilitated programs to raise public awareness about sleep and health, including a collaboration with the Department of Transportation to call attention to the perils of drowsy driving. In its second decade, the Center commissioned an Institute of Medicine review concluding that sleep deprivation and disorders remain an unmet challenge to public health, and in follow-up, NHLBI established novel training programs in sleep research and public health education. Today, the Center supports state-of-the-art science in the biology of sleep, circadian rhythms, and sleep disorders, and their contributions to heart, lung, and blood health, and the risk of chronic disease.

#### Budget Policy:

The FY 2021 President's Budget request is \$700.7 million, a decrease of \$69.9 million or 9.0 percent compared with the FY 2020 Enacted level.

**Blood Diseases:** Blood diseases affect millions of people worldwide each year. NHLBI's blood program is a leader in research on the causes, prevention, and treatment of congenital and acquired blood diseases, including anemias, venous thromboembolism, hemophilia, malaria, and other bleeding disorders. The program also helps ensure the safety of the world's blood supply and supports stem cell biology and new gene and cell-based therapies to repair and regenerate human tissues.

The blood program has a long history of supporting research on sickle cell disease (SCD), a genetic blood disorder that afflicts about 100,000 African Americans with disabling pain and life-threatening complications. A legacy of research support on SCD provided a scientific foundation for the Cure Sickle Cell Initiative<sup>42</sup>, a public-private partnership of patients, researchers, Federal health agencies, biotechnology firms, and other private sector partners.

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<sup>40</sup> [www.projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9822535&icde=46909809](http://www.projectreporter.nih.gov/project_info_description.cfm?aid=9822535&icde=46909809)

<sup>41</sup> [www.ncbi.nlm.nih.gov/pubmed/31125417](http://www.ncbi.nlm.nih.gov/pubmed/31125417)

<sup>42</sup> [www.nhlbi.nih.gov/science/cure-sickle-cell-initiative](http://www.nhlbi.nih.gov/science/cure-sickle-cell-initiative)

Launched in 2018, the initiative aims to bring state-of-the-art gene- and cell-based therapies for SCD into first-in-human trials within the next several years. Recent progress includes funding of several preclinical studies of emerging therapies. For example, one project awarded in 2019 focuses on clustered regularly interspaced short palindromic repeats (CRISPR) gene-editing technology, which can precisely cut out and insert small pieces of DNA to repair a defective gene. The researchers have devised an approach that uses CRISPR to repair the sickle cell mutation in blood-forming stem cells, and are performing the studies needed to prepare for an early phase clinical trial in adults with severe SCD.<sup>43</sup>

Also, as part of The Cure Initiative, a funding opportunity released in May 2019 will support the development of new assays to evaluate SCD gene therapy and gene editing approaches in clinical trials, as well as new technology and methods to support manufacture of validated therapeutics. An analysis is also being conducted to better understand both the clinical and economic benefits and risks of new intervention strategies compared to more established treatment strategies.

Since data show that many patients with SCD do not receive interventions proven to reduce pain and the risk of stroke, the blood program also supports research to identify barriers to care for SCD. The SCD Implementation Consortium consists of eight geographically diverse centers that are testing new approaches to enhance delivery of evidence-based care for SCD and improve health outcomes. The first three protocols have begun, including one that focuses on improving emergency department (ED) care of patients in severe acute pain, or sickle cell crisis. NHLBI supports global research efforts in SCD that are expected to benefit patients in the United States and in other parts of the world. For example, sub-Saharan Africa is home to more than 75 percent of SCD births worldwide, and more than half of infants born with SCD die before age 5. NHLBI supports major programs in the region, including the Sickle Pan-African Research Consortium, that are working to build research capacity and develop an infrastructure to enhance disease surveillance and delivery of care. NHLBI is also part of a new NIH collaboration with the Bill & Melinda Gates Foundation to develop affordable, gene-based cures for SCD that will be made available in low-resource communities globally.

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<sup>43</sup> [www.projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9935897&icde=45533387](http://www.projectreporter.nih.gov/project_info_description.cfm?aid=9935897&icde=45533387)

## Program Portrait: Leveraging Genetic Discoveries and Technologies to Improve Health

The NHLBI has been a leader in defining the genetic causes of rare, inheritable diseases, and in developing gene-based therapies. For example, in 1993, NHLBI intramural scientists discovered the gene that causes X-linked severe combined immunodeficiency (XSCID), in which the body fails to develop essential immune cells, causing a high risk of recurrent and potentially fatal infections.<sup>1</sup> This discovery paved the way for a recent NIH-funded gene therapy trial that successfully reconstituted the immune systems of eight infants with XSCID.<sup>2</sup> Today, NHLBI supports a robust portfolio of projects focused on gene-based therapies, including gene editing, a technology that works like molecular scissors to repair a defective gene. An NHLBI-sponsored workshop held in 2018, “Advancing Gene Editing Technologies for the Treatment of Cystic Fibrosis Lung Disease,” is helping inform strategic research in this area.<sup>3</sup> NHLBI also support the development of gene editing tools that are highly precise yet versatile enough to target a wide range of mutations, such as those that can cause Duchenne muscular dystrophy (DMD). In one recent study, researchers used a gene editing tool called CRISPR-Cas9 to “cut out” a variety of DMD mutations—including large deletions and single-letter changes in the DNA code—in heart muscle cells derived from patients.<sup>4</sup> Every advance for each disease is helping set the stage for new treatments, and ultimately cures, for a vast array of diseases. Indeed, NHLBI’s Cure Sickle Cell Initiative, launched in 2018, is building on these kinds of advances to bring gene-based therapies for sickle cell disease into clinical trials in the next several years.

<sup>1</sup> [www.ncbi.nlm.nih.gov/pubmed/8462096](http://www.ncbi.nlm.nih.gov/pubmed/8462096)

<sup>2</sup> [www.ncbi.nlm.nih.gov/pubmed/30995372](http://www.ncbi.nlm.nih.gov/pubmed/30995372)

<sup>3</sup> <https://www.nhlbi.nih.gov/events/2018/nhlbicff-workshop-advancing-gene-editing-technologies-treatment-cystic-fibrosis-lung>

<sup>4</sup> [www.ncbi.nlm.nih.gov/pubmed/29404407](http://www.ncbi.nlm.nih.gov/pubmed/29404407)

In addition to SCD, NHLBI supports research on many other blood disorders, including hemophilia, a rare genetic disorder that can cause severe bleeding from a minor cut. People with hemophilia A are deficient for blood-clotting protein called Factor VIII (FVIII); those with hemophilia B are deficient for Factor IX. NHLBI-funded research helped lead to the development of factor replacement therapy—the infusion of these proteins into the blood—which can prevent dangerous bleeding. However, approximately 30 percent of individuals with hemophilia A develop antibodies against FVIII that can render the therapy ineffective. In 2018, NHLBI launched a five-year multi-center program to understand how anti-FVIII antibodies arise, and to guide development of new therapies that avoid triggering them. Researchers are also working to develop gene therapy approaches with the potential to avoid the antibody response to FVIII.<sup>44</sup>

Ensuring the safety of the blood supply is a public health priority, particularly when the Nation is threatened by new infectious diseases with the potential for blood transmission. NHLBI’s Recipient Epidemiology and Donor Study (REDS) program was established in 1989 during the AIDS epidemic to reduce the transmission of HIV/AIDS through blood. REDS investigators began monitoring the blood supply and developed a screening method, nucleic acid testing (NAT), that can rapidly detect HIV in donated blood and is still being used today.

<sup>44</sup> [https://projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9738975&icde=47058833](https://projectreporter.nih.gov/project_info_description.cfm?aid=9738975&icde=47058833)

When the mosquito-borne Zika virus emerged as a public health threat in 2016, the Recipient Epidemiology and Donor Evaluation Study (REDS)<sup>45</sup> program began surveillance of the virus in blood donations, and established a biorepository of blood samples from consenting Zika-positive donors in the United States from 2016-2018. Although the Zika outbreak has fortunately waned, these blood samples have been shared broadly with researchers who are studying the virus and developing better tests to detect it. In 2019, the REDS program expanded its scope to address transfusion safety in infants and children—a group that is understudied in transfusion research and highly vulnerable to adverse outcomes. REDS is also working with the Department of Defense and academic centers to establish guidelines for use of blood-clotting products in injured soldiers.

**Budget Policy:**

The FY 2021 President’s Budget request is \$464.4 million, a decrease of \$46.3 million or 9.0 percent compared with the FY 2020 Enacted level.

**Implementation Science:** The Center for Translation Research and Implementation Science<sup>46</sup> was established in 2014 to serve as a focal point within the Institute for coordinating and advancing late-stage translational research implementation science—which describes research to improve the adoption of evidence-based approaches to treat and prevent disease and promote health. As an important part of this focus, the Center supports research on health disparities and inequities, and on global health, as well as research training and career development in implementation science.

The program is at the leading edge of using implementation science and predictive analytics to translate discovery into real-world health impact. For example, the program is supporting a new field of study called Modeling and Systems Science (SMSS), in which researchers simulate how a specific intervention might work in different populations and settings, with the ability to adjust and refine the intervention prior to actually implementing it in the real world. A current project is using SMSS to project the 10- and 30-year impact of 6 evidence-based obesity interventions at the national level and in 6 socioeconomically diverse states—Alaska, Hawaii, Mississippi, New York, West Virginia, and Washington.<sup>47</sup>

To better address the high burden of chronic disease faced by many communities in the United States, the Center is working in collaboration with the National Institute on Minority Health and Health Disparities to analyze health data at the county level, stratified by race/ethnicity, socioeconomic status, sex, and age. These data are expected to help identify what drives high rates of disease in some communities, and to reveal potential targets for intervention. In collaboration with NIH’s Fogarty International Center, the program is working to address the increasing global burden of chronic diseases that affect people living with HIV.<sup>48</sup> Even with

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<sup>45</sup> <https://www.nhlbi.nih.gov/science/recipient-epidemiology-and-donor-evaluation-study-reds-program>

<sup>46</sup> <https://www.nhlbi.nih.gov/about/divisions/center-translation-research-and-implementation-science>

<sup>47</sup> [https://projectreporter.nih.gov/project\\_info\\_description.cfm?aid=9714056&icde=46850057](https://projectreporter.nih.gov/project_info_description.cfm?aid=9714056&icde=46850057)

<sup>48</sup> [www.grants.nih.gov/grants/guide/rfa-files/RFA-HL-20-026.html](http://www.grants.nih.gov/grants/guide/rfa-files/RFA-HL-20-026.html)

effective drug therapy to suppress HIV, people with HIV have a high risk of developing chronic heart, lung, blood, and sleep disorders, compared to people who are HIV-negative. The Heart, Lung, and Blood Co-morbidities Implementation Models in People Living with HIV (HLB-SIMPLE) initiative supports implementation science research to understand and reduce these HIV-related comorbidities in low- and middle-income countries. The goal is to achieve earlier detection and prevention of these comorbidities, and the strategies and findings are expected to benefit Americans with HIV living in low-and middle-income regions of the United States.

Budget Policy:

The FY 2021 President's Budget request is \$25.9 million, a decrease of \$2.6 million or 9.1 percent compared with the FY 2020 Enacted level.

**Intramural Research:** The NHLBI intramural program, located on the NIH Campus in Bethesda, Maryland, conducts innovative basic and clinical research and has a strong training program. The research portfolio is broad, ranging from basic research on molecules and cells to clarifying disease mechanisms, to establishing new therapies for human diseases through population studies and clinical trials.

Intramural researchers studying psoriasis, a chronic inflammatory skin disease, recently made a discovery with potential implications not only for treating psoriasis but for heart disease. Based on prior research showing that people with psoriasis have a higher risk of coronary artery disease, the researchers wondered if newer therapies for psoriasis would also reduce heart disease risk in these patients. In a study of 134 patients, they used a novel imaging technique to determine that patients who received biologic therapy had a significant reduction in coronary artery plaque after one year, compared to patients who elected to receive only topical skin treatments.<sup>49</sup> This work highlights the potential significance of inflammation—and efforts to treat it— in all patients with coronary artery disease.

Other researchers continue to work toward curative strategies for SCD. For more than a decade, an intramural team has been working to improve genetic therapy approaches for the disease, with a focus on higher efficiency methods to insert therapeutic genes into bone marrow stem cells that could then be delivered to patients. These researchers recently developed an improved vector, or virus-based delivery system, that is 10 times more efficient at incorporating corrective genes into bone marrow stem cells than the most common vectors used in this research.<sup>50</sup> The new vector will soon be tested in human trials.

Intramural scientists continue to be innovative leaders in biological imaging, which has earned them recognition from major scientific professional organizations. One scientist set out to achieve better views of the lung using MRI, which has been problematic because the images are distorted by air. Her solution was to combine older, lower magnetic-field MRI technology with

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<sup>49</sup> [www.ncbi.nlm.nih.gov/pubmed/31365032](http://www.ncbi.nlm.nih.gov/pubmed/31365032)

<sup>50</sup> [www.ncbi.nlm.nih.gov/pubmed/31578323](http://www.ncbi.nlm.nih.gov/pubmed/31578323)



contemporary high-performance hardware. This approach enabled high-quality lung images, and earned a BEAR Cage (Building Education to Advance Research) prize at the 2019 American Thoracic Society conference.<sup>51</sup> Another intramural scientist was recently inducted into the National Academy of Sciences<sup>52</sup> for her pioneering work in understanding the movement of cells. She invented an advanced microscopic imaging method that has increased the field's knowledge of the molecular and biophysical basis of cell movement, a critical aspect of many processes including growth, development, wound healing, and regeneration.

Budget Policy:

The FY 2021 President's Budget request is \$204.2 million, a decrease of \$25.2 million or 11.0 percent compared with the FY 2020 Enacted level.

**Research Management and Support (RMS):** RMS activities include administrative and technical functions that support and enhance the effectiveness of the Institute's research investments. This includes providing administrative, budgetary, logistical, and scientific support in the review, award, and monitoring of research grants and clinical trials, training awards, and research and development contracts. RMS functions also encompass strategic planning, trans-NHLBI and NIH coordination, evaluation of the Institute's programs, regulatory compliance, international coordination, interactions with other Federal agencies and Congress, and dissemination of research findings to the public.

Budget Policy:

The FY 2021 President's Budget request is \$136.9 million, a decrease of \$7.2 million or 5.0 percent compared with the FY 2020 Enacted level.

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<sup>51</sup> <https://www.nhlbi.nih.gov/nhlbi-celebrates-women-scientists/adrienne-campbell-washburn-phd>

<sup>52</sup> [www.nasonline.org/member-directory/members/20044138.html](http://www.nasonline.org/member-directory/members/20044138.html)

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

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

	<b>FY 2020 Enacted</b>	<b>FY 2021 President's Budget</b>	<b>FY 2021 +/- FY 2020</b>
Total compensable workyears:			
Full-time equivalent	962	962	0
Full-time equivalent of overtime and holiday hours	1	1	0
Average ES salary	\$194	\$197	\$3
Average GM/GS grade	12.8	12.8	0.0
Average GM/GS salary	\$124	\$126	\$2
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$107	\$110	\$3
Average salary of ungraded positions	\$132	\$134	\$2
<b>OBJECT CLASSES</b>	<b>FY 2020 Enacted</b>	<b>FY 2021 President's Budget</b>	<b>FY 2021 +/- FY 2020</b>
Personnel Compensation			
11.1 Full-Time Permanent	65,707	66,463	756
11.3 Other Than Full-Time Permanent	35,056	35,459	403
11.5 Other Personnel Compensation	4,877	4,933	56
11.7 Military Personnel	2,277	2,338	60
11.8 Special Personnel Services Payments	11,122	11,250	128
<b>11.9 Subtotal Personnel Compensation</b>	<b>\$119,039</b>	<b>\$120,442</b>	<b>\$1,403</b>
12.1 Civilian Personnel Benefits	36,544	37,969	1,425
12.2 Military Personnel Benefits	1,901	1,952	50
13.0 Benefits to Former Personnel	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$157,484</b>	<b>\$160,363</b>	<b>\$2,879</b>
21.0 Travel & Transportation of Persons	3,609	3,681	72
22.0 Transportation of Things	193	196	4
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	648	661	13
24.0 Printing & Reproduction	6	6	0
25.1 Consulting Services	2,967	3,026	59
25.2 Other Services	95,320	57,727	-37,593
25.3 Purchase of goods and services from government accounts	315,322	266,760	-48,562
25.4 Operation & Maintenance of Facilities	4,817	4,817	0
25.5 R&D Contracts	144,190	105,380	-38,811
25.6 Medical Care	1,198	1,245	47
25.7 Operation & Maintenance of Equipment	21,515	21,875	360
25.8 Subsistence & Support of Persons	0	0	0
<b>25.0 Subtotal Other Contractual Services</b>	<b>\$585,329</b>	<b>\$460,829</b>	<b>-\$124,500</b>
26.0 Supplies & Materials	16,192	16,504	312
31.0 Equipment	10,308	10,509	201
32.0 Land and Structures	1,663	1,696	33
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	2,849,820	2,643,552	-206,268
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	6	6	0
44.0 Refunds	0	0	0
<b>Subtotal Non-Pay Costs</b>	<b>\$3,467,774</b>	<b>\$3,137,641</b>	<b>-\$330,133</b>
<b>Total Budget Authority by Object Class</b>	<b>\$3,625,258</b>	<b>\$3,298,004</b>	<b>-\$327,254</b>

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

**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**

**Salaries and Expenses**

(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
<b>Personnel Compensation</b>			
Full-Time Permanent (11.1)	\$65,707	\$66,463	\$756
Other Than Full-Time Permanent (11.3)	35,056	35,459	403
Other Personnel Compensation (11.5)	4,877	4,933	56
Military Personnel (11.7)	2,277	2,338	60
Special Personnel Services Payments (11.8)	11,122	11,250	128
<b>Subtotal Personnel Compensation (11.9)</b>	<b>\$119,039</b>	<b>\$120,442</b>	<b>\$1,403</b>
Civilian Personnel Benefits (12.1)	\$36,544	\$37,969	\$1,425
Military Personnel Benefits (12.2)	1,901	1,952	50
Benefits to Former Personnel (13.0)	0	0	0
<b>Subtotal Pay Costs</b>	<b>\$157,484</b>	<b>\$160,363</b>	<b>\$2,879</b>
Travel & Transportation of Persons (21.0)	\$3,609	\$3,681	\$72
Transportation of Things (22.0)	193	196	4
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	648	661	13
Printing & Reproduction (24.0)	6	6	0
<b>Other Contractual Services:</b>			
Consultant Services (25.1)	2,967	3,026	59
Other Services (25.2)	95,320	57,727	-37,593
Purchases from government accounts (25.3)	229,388	167,076	-62,312
Operation & Maintenance of Facilities (25.4)	4,817	4,817	0
Operation & Maintenance of Equipment (25.7)	21,515	21,875	360
Subsistence & Support of Persons (25.8)	0	0	0
<b>Subtotal Other Contractual Services</b>	<b>\$354,007</b>	<b>\$254,521</b>	<b>-\$99,485</b>
Supplies & Materials (26.0)	\$16,192	\$16,504	\$312
<b>Subtotal Non-Pay Costs</b>	<b>\$374,655</b>	<b>\$275,571</b>	<b>-\$99,084</b>
<b>Total Administrative Costs</b>	<b>\$532,139</b>	<b>\$435,933</b>	<b>-\$96,205</b>

**NATIONAL INSTITUTES OF HEALTH**  
**National Heart, Lung, and Blood Institute**

**Detail of Full-Time Equivalent Employment (FTE)**

OFFICE/DIVISION	FY 2019 Final			FY 2020 Enacted			FY 2021 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Translation Research and Implementation Science									
Direct:	12	1	13	20	2	22	20	2	22
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12	1	13	20	2	22	20	2	22
Division of Blood and Resources									
Direct:	27	1	28	32	1	33	32	1	33
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	27	1	28	32	1	33	32	1	33
Division of Cardiovascular Sciences									
Direct:	116	1	117	131	2	133	131	2	133
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	116	1	117	131	2	133	131	2	133
Division of Extramural Research Activities									
Direct:	91	-	91	103	1	104	103	1	104
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	91	-	91	103	1	104	103	1	104
Division of Intramural Research									
Direct:	392	15	407	437	15	452	437	15	452
Reimbursable:	12	-	12	15	-	15	15	-	15
Total:	404	15	419	452	15	467	452	15	467
Division of Lung Diseases									
Direct:	33	-	33	43	-	43	43	-	43
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	33	-	33	43	-	43	43	-	43
Office of the Director									
Direct:	137	2	139	156	4	160	156	4	160
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	137	2	139	156	4	160	156	4	160
<b>Total</b>	<b>820</b>	<b>20</b>	<b>840</b>	<b>937</b>	<b>25</b>	<b>962</b>	<b>937</b>	<b>25</b>	<b>962</b>
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
<b>FISCAL YEAR</b>	<b>Average GS Grade</b>								
2017	12.6								
2018	12.7								
2019	12.7								
2020	12.8								
2021	12.8								

**NATIONAL INSTITUTES OF HEALTH  
National Heart, Lung, and Blood Institute**

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

GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	2	2	2
Total, ES Salary	376,126	388,087	393,908
GM/GS-15	87	102	102
GM/GS-14	155	180	180
GM/GS-13	185	214	214
GS-12	57	67	67
GS-11	42	47	47
GS-10	0	0	0
GS-9	33	36	36
GS-8	5	5	5
GS-7	7	8	8
GS-6	2	2	2
GS-5	1	1	1
GS-4	5	5	5
GS-3	3	3	3
GS-2	1	1	1
GS-1	2	2	2
Subtotal	585	673	673
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	1	1	1
Director Grade	7	7	7
Senior Grade	6	6	6
Full Grade	6	6	6
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	21	21	21
Ungraded	232	266	266
Total permanent positions	608	696	696
Total positions, end of year	840	962	962
Total full-time equivalent (FTE) employment, end of year	840	962	962
Average ES salary	188,063	194,044	196,954
Average GM/GS grade	12.7	12.8	12.8
Average GM/GS salary	117,684	123,803	125,660

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