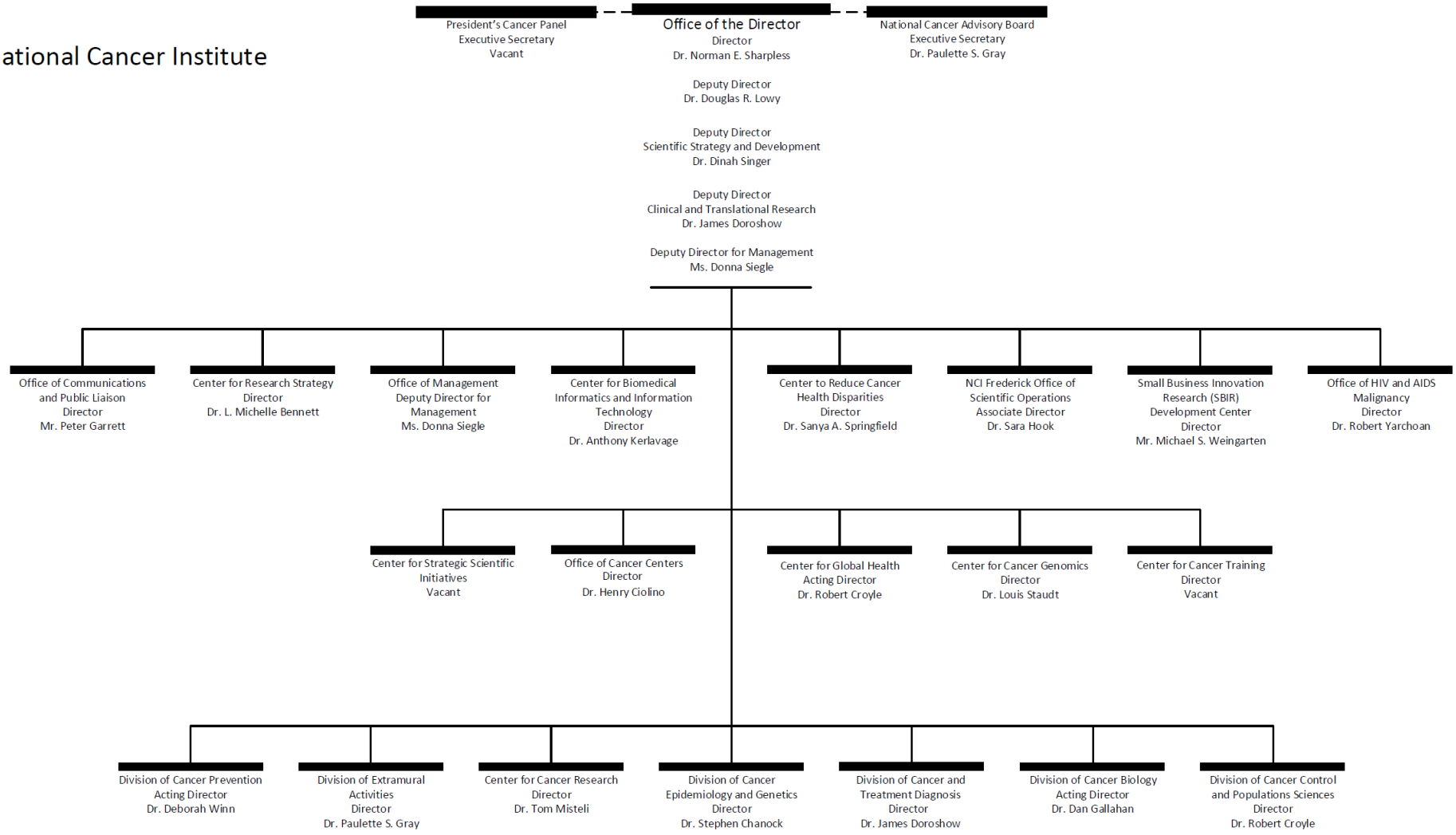
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute (NCI)

National Cancer Institute



NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, [$6,245,442,000]*$5,686,173,000*, of which up to $30,000,000 may be used for facilities repairs and improvements at the National Cancer Institute-Frederick Federally Funded Research and Development Center in Frederick, Maryland.

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, **[**$492,000,000**]***$404,000,000*, 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 Cancer Institute

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation[2,3]	$6,143,892	$6,440,442	$5,881,173
Secretary's Transfer	-19,730	0	0
Subtotal, adjusted appropriation	$6,124,162	$6,440,442	$5,881,173
OAR HIV/AIDS Transfers	-2,874	-4	0
Subtotal, adjusted budget authority	$6,121,288	$6,440,438	$5,881,173
Unobligated balance, start of year[4]	38,686	166,121	0
Unobligated balance, end of year[5]	-166,121	0	0
Subtotal, adjusted budget authority	$5,993,853	$6,606,559	$5,881,173
Unobligated balance lapsing	-253	0	0
Total obligations	$5,993,600	$6,606,559	$5,881,173

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2019 - $22,479 FY 2020 - $25,000 FY 2021 - $22,000

[2] Of which $400.0 million in FY 2019, $195.0 million in FY 2020, and $195.0 million in FY 2021 is derived by transfer from the NIH Innovation Account under the 21st Century Cures Act

[3] Of which $50.0 million is included for the Childhood Cancer Data Initiative (CCDI) in FY 2020 and FY 2021

[4] In FY 2019, reflects 21st Century Cures Act carried over from FY 2017 and FY 2018 into FY 2019

[5] Reflects 21st Century Cures Act funding from FY 2017 through FY 2019 not obligated in FY 2019, and carried over into FY 2020

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Budget Mechanism - Total[1]
(Dollars in Thousands)

MECHANISM	FY 2019 Final[2]		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY 2020 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	3,561	$1,801,598	3,846	$1,947,293	3,885	$1,990,022	39	$42,729
Administrative Supplements	*(268)*	30,715	*(346)*	39,901	*(258)*	29,748	*(-88)*	-10,152
Competing:								
Renewal	94	63,912	108	73,710	110	70,025	2	-3,686
New	1,097	567,192	1,199	538,742	1,219	489,058	20	-49,683
Supplements	7	1,611	7	4,275	3	1,667	-4	-2,608
Subtotal, Competing	1,198	$632,716	1,314	$616,727	1,332	$560,750	18	-$55,977
Subtotal, RPGs	4,759	$2,465,029	5,160	$2,603,920	5,217	$2,580,520	57	-$23,400
SBIR/STTR	245	136,670	271	151,480	260	145,285	-11	-6,195
Research Project Grants	5,004	$2,601,700	5,431	$2,755,400	5,477	$2,725,805	46	-$29,595
Research Centers:								
Specialized/Comprehensive	255	$667,891	247	$599,325	217	$520,742	-30	-$78,583
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	75	0	75	0	65	0	-11
Comparative Medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Research Centers	255	$667,966	247	$599,400	217	$520,807	-30	-$78,593
Other Research:								
Research Careers	446	$84,991	459	$87,560	437	$83,182	-22	-$4,378
Cancer Education	77	20,459	101	26,890	96	25,546	-5	-1,345
Cooperative Clinical Research	104	290,137	114	316,281	100	277,062	-14	-39,219
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	97	0	98	0	84	0	-14
Other	192	112,079	215	123,286	187	109,493	-28	-13,793
Other Research	819	$507,763	889	$554,114	820	$495,367	-69	-$58,748
Total Research Grants	6,078	$3,777,429	6,567	$3,908,915	6,514	$3,741,979	-53	-$166,936
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	585	$25,589	585	$27,473	556	$26,099	-29	-$1,374
Institutional Awards	1,004	61,388	1,004	65,907	954	62,612	-50	-3,295
Total Research Training	1,589	$86,978	1,589	$93,380	1,510	$88,711	-79	-$4,669
Research & Develop. Contracts	428	$814,093	471	$885,275	356	$669,756	-115	-$215,519
(SBIR/STTR) (non-add)	*(49)*	*(34,201)*	*(36)*	*(24,721)*	*(35)*	*(24,016)*	*(-1)*	*(-705)*
Intramural Research	1,684	974,901	1,770	1,036,280	1,770	947,282	0	-88,998
Res. Management & Support	1,204	449,887	1,265	486,588	1,265	418,445	0	-68,143
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(3,000)*	*(0)*	*(3,000)*	*(0)*	*(2,865)*	*(0)*	*(-135)*
Construction		0		0		0		0
Buildings and Facilities		18,000		30,000		15,000		-15,000
Total, NCI	2,888	$6,121,288	3,035	$6,440,438	3,035	$5,881,173	0	-$559,265

[1] Of which $400.0 million in FY 2019, $195.0 million in FY 2020, and $195.0 million in FY 2021 is derived by transfer from the NIH Innovation Account under the 21st Century Cures Act

[2] Reflects 21st Century Cures Act funding not obligated in FY 2019, and carried over into FY 2020

** 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 or budget activity are briefly described below. Note that there may be overlap between budget mechanisms and activity detail, and the highlights on this page will not sum to the total change for the FY 2021 President's Budget for NCI, which is $559.3 million less than the FY 2020 Enacted level, for a total of $5,881.2 million, a decrease of 8.7 percent. This level includes $50.0 million for the Childhood Cancer Data Initiative (CCDI) and $195.0 million to support the ongoing 21st Century Cures Act Cancer Moonshot℠ efforts. The FY 2021 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NCI will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds. Reductions will occur in nearly every budget mechanism; however, strategic prioritization, the CCDI, and funding plans for the Cancer Moonshot℠ will lessen reductions to some program areas. The 21st Century Cures Act funding will continue to support Cancer Moonshot℠ projects that implement the Blue Ribbon Panel recommendations. This budget reflects NCI's plans to address fluctuating 21st Century Cures Act funding levels resulting in fewer new Cancer Moonshot℠ initiatives beginning in FY 2020.

Research Project Grants (-$29.6 million; total $2,725.8 million): During FY 2021, NCI will issue new competing Research Project Grants (RPGs) and support the NCI commitment base for noncompeting RPGs at reduced levels, consistent with the overall budget request. Funding for RPGs will decline by 1.1 percent compared to the FY 2020 Enacted level. For noncompeting grants, NCI will continue to honor grants awarded in previous years that remain active in FY 2021. Funding for noncompeting RPGs will increase by 2.2 percent compared to the FY 2020 Enacted level. Due to an anticipated average cost reduction of -7.0 percent for competing RPGs, NCI estimates that it will issue 1,332 competing RPG awards, 18 more than in FY 2020.

NCI intends to give priority to competing and noncompeting awards issued to new and early stage investigators and thereby support cancer research conducted by early-career scientists who are poised to become future leaders. Grant awards to these investigators will also experience reductions, but at a lesser rate compared to other grant types. NCI will support SBIR/STTR awards at levels consistent with the statutory formula for FY 2021.

Research Centers (-$78.6 million; total $520.8 million): Within the Research Centers budget mechanism, the overall funding reduction will be 13.1 percent. This will result in reductions to the NCI-designated Cancer Centers program and Specialized Programs of Research Excellence (SPOREs) program, although reductions to individual research centers will not be at a single, uniform level.

Other Research (-$58.7 million; total $495.4 million): Within the Other Research budget mechanism, the overall funding reduction will be 10.6 percent. However, NCI made the strategic decision to minimize reductions to education and training within this mechanism. Given these priorities, other programs within this budget mechanism will experience reductions that exceed 10.6 percent.

Historically, more than 30,000 patients are annually enrolled in large-scale treatment trials through participating institutes that collaborate in the Cooperative Clinical Research Program.

For this reason, NCI considers the Cooperative Clinical Research Program to be a high value to cancer science and a priority for FY 2021.

Similarly, NCI made the strategic decision to prioritize funding related to education and training. This includes funding for the Cancer Research Education Grants program which supports activities that enhance workforce training to meet the nation's research needs. In addition, NCI will maintain the funding level of the Career Development Awards program which supports early-career scientists and clinicians to develop independent careers in cancer research.

Research & Development Contracts (-$215.5 million; total $669.8 million): During FY 2021, NCI will reduce research contracts by 24.3 percent. NCI will reduce its contract profile to ensure that funding is available for other cancer research priorities.

Intramural Research (-$89.0 million; total $947.3 million): During FY 2021, NCI will reduce intramural cancer research by 8.6 percent. Intramural science remains an important priority within the overall NCI cancer research portfolio. As in the past, NCI intramural research will emphasize high-risk, high-reward cancer research that would otherwise not be conducted by other entities.

Training Awards (-$4.7 million; total $88.7 million): During FY 2021, NCI will reduce research training awards by 5.0 percent. Programs to train and retain a diverse workforce of researchers with the skills required to conduct demanding and sophisticated cancer research will remain a high priority for NCI. NCI training programs help maintain a strong cadre of future researchers capable of delivering important research results for the patients we serve. During FY 2021, NCI will prioritize support for training mechanisms that emphasize progress towards research independence.

Buildings and Facilities (-$15.0 million; total $15.0 million): The NCI Federally Funded Research and Development Center in Frederick has many buildings that are over 50 years old. During FY 2021, NCI will use these funds to replace aging building infrastructure, modify laboratories to install new state-of-the-art research instrumentation and equipment, reconfigure laboratory space to support emerging cancer research needs, and provide new infrastructure to protect mission-critical operations of the Frederick National Laboratory for Cancer Research. NCI will move forward with the highest priority infrastructure and modernization projects. The FY 2021 amount of $15 million is an estimate and may increase up to the $30 million allowable by law as needs are evaluated.

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Summary of Changes
(Dollars in Thousands)

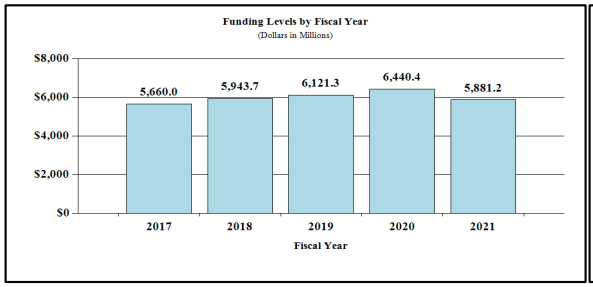
FY 2020 Enacted	$6,440,438
FY 2021 President's Budget	$5,881,173
Net change	-$559,265

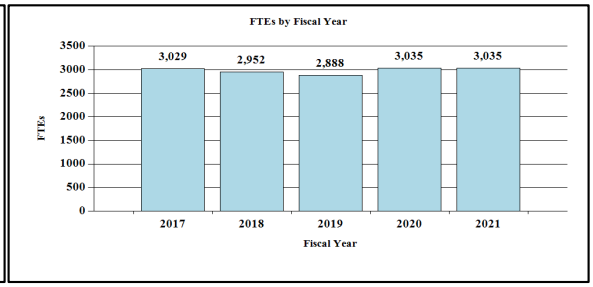
CHANGES	FY 2021 President's Budget FTEs	FY 2021 President's Budget Budget Authority	Change from FY 2020 Enacted FTEs	Change from FY 2020 Enacted Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2020 pay increase & benefits		$382,124		$2,475
b. January FY 2021 pay increase & benefits		382,124		5,681
c. Paid days adjustment		382,124		-1,427
d. Differences attributable to change in FTE		382,124		0
e. Payment for centrally furnished services		150,380		-7,915
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		414,777		-600
Subtotal				-$1,786
2. Research Management and Support:				
a. Annualization of January 2020 pay increase & benefits		$243,048		$1,561
b. January FY 2021 pay increase & benefits		243,048		3,693
c. Paid days adjustment		243,048		-907
d. Differences attributable to change in FTE		243,048		0
e. Payment for centrally furnished services		32,606		-1,716
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		142,791		-2,615
Subtotal				$16
Subtotal, Built-in				-$1,770

CHANGES	FY 2021 President's Budget No.	FY 2021 President's Budget Amount	Change from FY 2020 Enacted No.	Change from FY 2020 Enacted Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	3,885	$2,019,770	39	$32,577
b. Competing	1,332	560,750	18	-55,977
c. SBIR/STTR	260	145,285	-11	-6,195
Subtotal, RPGs	5,477	$2,725,805	46	-$29,595
2. Research Centers	217	$520,807	-30	-$78,593
3. Other Research	820	495,367	-69	-58,748
4. Research Training	1,510	88,711	-79	-4,669
5. Research and development contracts	356	669,756	-115	-215,519
Subtotal, Extramural		$4,500,446		-$387,124
	FTEs		FTEs	
6. Intramural Research	1,770	$947,282	0	-$87,212
7. Research Management and Support	1,265	418,445	0	-68,158
8. Construction		0		0
9. Buildings and Facilities		15,000		-15,000
Subtotal, Program	3,035	$5,881,173	0	-$557,495
Total changes				-$559,265

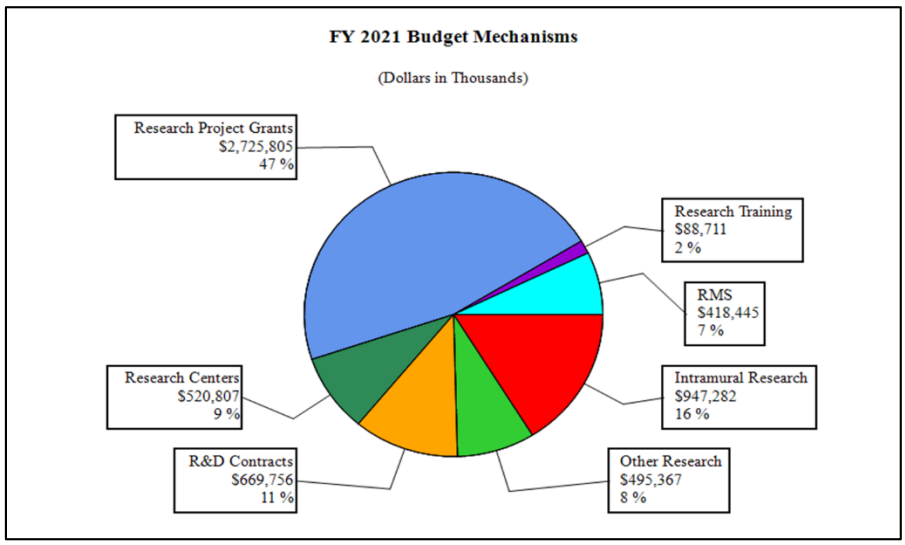
Fiscal Year 2021 Budget Graphs

History of Budget Authority and FTEs:

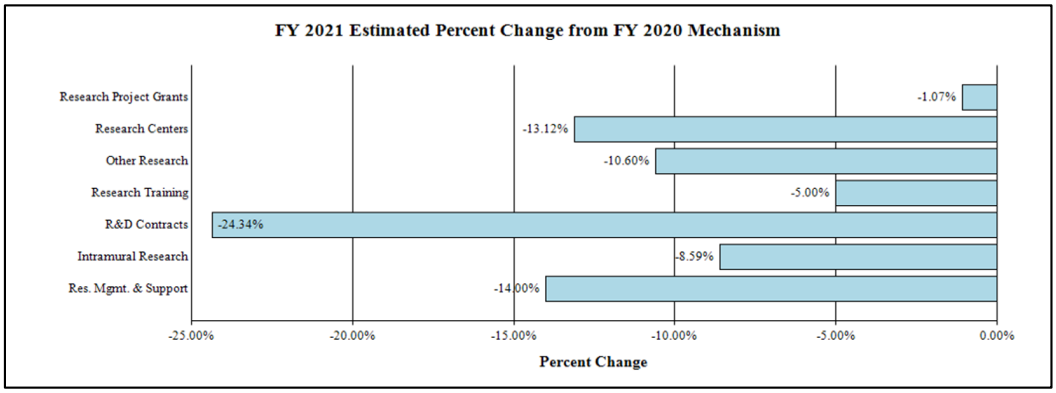




Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Budget Authority by Activity
(Dollars in Thousands)

	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY2020	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Understanding How Cancer Develops		$898,231		$921,212		$854,703		-$66,508
Understanding the Causes of Cancer		980,027		1,025,042		949,640		-75,402
Detecting and Diagnosing Cancer		545,207		595,504		549,964		-45,540
Treating Cancer and Improving Survivorship		1,092,242		1,193,004		1,101,772		-91,232
Improving Cancer Prevention and Control		228,892		249,931		230,823		-19,108
Cancer Centers		655,966		599,400		520,807		-78,593
Research Workforce Development		192,428		207,830		197,439		-10,392
Repairs and Improvements		18,000		30,000		15,000		-15,000
Childhood Cancer Data Initiative (CCDI)		0		50,000		50,000		0
Subtotal, Extramural		**$4,696,500**		**$4,917,570**		**$4,515,446**		**-$402,124**
Intramural Research	**1,684**	**$974,901**	**1,770**	**$1,036,280**	**1,770**	**$947,282**	**0**	**-$88,998**
Research Management & Support	**1,204**	**$449,887**	**1,265**	**$486,588**	**1,265**	**$418,445**	**0**	**-$68,143**
TOTAL	**2,888**	**$6,121,288**	**3,035**	**$6,440,438**	**3,035**	**$5,881,173**	**0**	**-$559,265**

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2020 Amount Authorized	FY 2020 Enacted	2021 Amount Authorized	FY 2021 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$6,440,438,000	Indefinite	$5,881,173,000
National Cancer Institute	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$6,440,438,000		$5,881,173,000

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Appropriations History[1]

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2012	$5,196,136,000	$5,196,136,000	$5,001,623,000	$5,081,788,000
Rescission				$9,604,579
2013	$5,068,864,000		$5,084,227,000	$5,072,183,421
Rescission				$10,144,367
Sequestration				($254,588,730)
2014	$5,125,951,000		$5,091,885,000	$4,923,238,000
Rescission				$0
2015	$4,930,715,000			$4,950,396,000
Rescission				$0
2016	$5,098,479,000	$5,081,812,000	$5,204,058,000	$5,214,701,000
Rescission				$0
2017[2]	$5,893,509,000	$5,388,444,000	$5,429,769,000	$5,689,329,000
Rescission				$0
2018	$4,474,222,000	$5,771,181,000	$5,858,270,000	$5,964,800,000
Rescission				$0
2019	$5,626,312,000	$6,136,037,000	$6,147,125,000	$6,143,892,000
Rescission				$0
2020	$5,246,737,000	$6,444,165,000	$6,351,863,000	$6,440,442,000
Rescission				$0
2021	$5,881,173,000			

[1] Includes funds derived by transfer from the NIH Innovation Account under the 21st Century Cures Act
[2] Budget Estimate to Congress includes mandatory financing

FY 2021 Justification of Budget Request

National Cancer Institute

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

	FY 2019 Actual	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	$6,121,288,000	$6,440,438,000	$5,881,173,000	-$559,265,000
FTE	2,888	3,035	3,035	0

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

NCI Director's Overview

The Long Arc of Cancer Research
Basic research is vital to progress in cancer. Virtually all major advances in cancer originate with discoveries in the basic sciences. Basic research reveals fundamental new concepts about the causes of cancer and how cancer develops, progresses, and responds to therapy. The knowledge that flows from investment in basic research is essential to discovering new ways to prevent, detect, and treat cancer.

The National Cancer Institute (NCI) is investing in basic research and the broad, deep progress it delivers. Examples of important clinical advances that emerged from basic research findings include molecular tests to detect cancer, precision oncology, cancer vaccines, and immunotherapy – all of which were virtually unimaginable 20 years ago.

Enthusiasm for Investigator-Initiated Research
NCI is witnessing unprecedented enthusiasm within the cancer research community, as evidenced by a 50 percent increase in grant applications to NCI during the past five years. Clearly, researchers see tremendous scientific opportunity to make advances and meet the needs of cancer patients. This enthusiasm is driving the abundance of promising ideas in the research applications NCI receives.

Knowledge gained from research that NCI funds today will drive tomorrow's advances, helping all patients with cancer and those at risk of cancer. Therefore, NCI funds meritorious applications to ensure that NCI doesn't sacrifice opportunities for future breakthroughs, diminish the momentum that drives progress, and cause a new generation of talented researchers to lose heart and abandon cancer research as a career.

Remarkable Return on Research Investment
The results of the NCI research investment are tangible. Thanks to advances in prevention, screening, diagnosis, and treatment, and with the benefit of new tools such as genomics and breakthroughs such as immunotherapy, cancer mortality declined 27 percent between 1991 and 2016. The rewards of this research include major advances in understanding cancer and how it

progresses, and the volume of new cancer drugs approved by the U.S. Food and Drug Administration (FDA), almost all of which have relied on the results of basic research. In 2018 alone, FDA approved 18 new oncology drugs and six new biosimilars to treat different types of cancer.

Prevention and Screening
Public health initiatives that encourage individuals to adopt proven cancer prevention and screening strategies have been central to the decline in cancer incidence and mortality. Tobacco control efforts have led to reduced smoking and lowered lung cancer rates. Lung cancer screening of heavy current and former smokers offers the potential to save additional lives. Screening has reduced incidence and lowered mortality rates for other cancers, such as colorectal, cervical, and breast cancer.

One of NCI's foremost priorities is uncovering new and better ways to detect and diagnose precancers and cancers at the earliest possible stage. With this priority in mind, NCI is making significant investments to develop new strategies for cancer prevention and screening, and to promote increased use of evidence-based practices so fewer people will be diagnosed with advanced cancer and suffer its physical, financial, social, and psychological harms.

Therapeutic Resistance
One vexing challenge is the too-common experience of a treatment initially working, but resistance eventually emerging, causing the cancer to grow and spread. Such acquired therapeutic resistance, as well as primary resistance where the tumor fails to respond to treatment, are the main reasons many patients eventually succumb to cancer. Understanding the basis for primary and acquired resistance is a central theme for NCI's drug development program and clinical trials networks. One example of this priority is the NCI Drug Resistance and Sensitivity Network (DRSN), a Cancer Moonshot^{SM} investment. DRSN supports preclinical research to identify innovative strategies for combating mechanisms of tumor resistance.

Pediatric Cancer
Not long ago, only half of children diagnosed with cancer survived five years or more. Thanks to strong progress in the intervening years, more than 80 percent of children now survive. But, the improvement is not consistent across all pediatric cancers. Too many children, adolescents, and young adults still die from their disease. Many survivors endure lifelong adverse effects from their disease and treatment.

The Administration's FY 2020 budget proposed $50.0 million for the first year of a planned 10 year initiative to speed progress against childhood cancer. Known as the Childhood Cancer Data Initiative (CCDI), the effort is an opportunity to leverage new technologies to gather and integrate data, and to build a framework that ensures data are accessible and usable in meaningful ways by researchers and the clinicians who treat young cancer patients. CCDI will yield insights into questions that previously were unanswerable. CCDI will serve as a cornerstone supporting many other programs in our pediatric portfolio, such as the promising Pediatric Molecular Analysis for Therapy Choice (MATCH) study, the Childhood Cancer Survivor Study, and the Pediatric Brain Tumor Consortium. CCDI will enhance the ability to link data across research to advance future childhood cancer discovery.

CCDI also complements other, ongoing NCI initiatives to share, aggregate, and analyze the large volume of data generated across the continuum of cancer research, surveillance, and clinical care. One example is the Cancer Research Data Commons, NCI's cloud-based informatics infrastructure to foster data aggregation and sharing, and thereby accelerate cancer discovery.

Health Disparities
In recent decades, cancer death rates decreased within the overall population. Yet, some populations have higher incidence and mortality than the general population for some cancers, such as liver and kidney cancer and multiple myeloma. Thus, cancer disparities remain a serious public health challenge. Not everyone benefits equally from advances in cancer research, although there has been substantial narrowing of the gap for some groups.

Cancer survival also varies widely by geographic area. For example, cancer patients in many rural areas suffer poorer outcomes. Although many of these disparities can be attributed to differences in access to cancer screening and care, NCI seeks to better understand the complex interplay between genetics and lifestyle and how they influence outcomes.

With these concerns in mind, NCI is committing more research to understand and mitigate the factors – biological and non-biological – that contribute to cancer disparities. Our goal is to ensure that cancer research, screening, and treatment broadly benefits the entire nation and its many ethnic and racial populations, urban and rural.

The Path Ahead
Cancer patients today have a far better chance of living longer and enjoying an improved quality of life. Yet, despite our progress in preventing, diagnosing, and treating cancers, too many Americans face a cancer diagnosis, and far too many die from the disease. Mortality rates for certain cancers have increased, while cancer health disparities remain a serious challenge.

Thus, much work remains to meet the needs of those diagnosed with cancer, those at risk of cancer, and the growing population of cancer survivors. The NCI budget justification that follows highlights some of the many areas where NCI expects to make new progress and deliver results for the patients that NCI serves.

Overall Budget Policy:
The FY 2021 President's Budget request is $5,881.2 million, a decrease of $559.3 million or 8.7 percent compared with the FY 2020 Enacted level. The Budget includes $50.0 million for the Childhood Cancer Data Initiative and $195.0 million to support the ongoing 21st Century Cures Act Cancer Moonshot efforts. For FY 2021, NCI made strategic choices that prioritize how it allocates funding to NCI research programs. For example, NCI will prioritize research training programs during FY 2021, and research in the area of pediatric cancer will be maintained at a level equal to or above FY 2020 level.

Program Descriptions and Accomplishments

NCI conducts basic and applied research that advances five broad scientific goals:

- Understanding How Cancer Develops
- Understanding the Causes of Cancer
- Detecting and Diagnosing Cancer
- Treating Cancer and Improving Survivorship
- Improving Cancer Prevention and Control

To pursue these goals, NCI issues grants to support investigator-initiated research, conducts clinical trials, and finances a range of other research programs. NCI selects and supports NCI-designated Cancer Centers, conducts basic, clinical, and population research through its intramural program, manages research contracts, including a Federally Funded Research and

Development Center (FFRDC) for operations of the Frederick National Laboratory for Cancer Research, and operates research facilities to support NCI intramural and FFRDC activities.

NCI uses these and other mechanisms to support research and advance NCI scientific goals. Investigator-initiated research project grants constitute a large portion of the research investment for all five goals. During FY 2019, NCI issued 6,053 grant awards across all grant mechanisms, including 3,127 traditional research project (R01) and 359 exploratory (R21) grants. These grant awards include 88 grants through the 21st Century Cures Act.

The FY 2019 total for grant awards also includes 17 Outstanding Investigator (R35) Awards (OIA), which provide seven years of funding to investigators with outstanding records in cancer research. OIA grants are an opportunity for researchers to test high-risk hypotheses supported by a higher award level and for more years than under a traditional research project grant. In the five years since NCI began the OIA program, NCI has issued 144 competing OIAs.

NCI also has a long-standing priority of developing and supporting the next generation of talented cancer researchers. Our goal is to maintain a robust pipeline of scientists who can provide future leadership in basic, translational, and clinical research. An important component of this priority is supporting researchers early in their careers. Early Stage Investigators (ESIs) are researchers who completed a terminal research degree or medical residency within the past ten years and have not previously competed successfully for a substantial NIH research grant.

NCI is also identifying ways to enhance the research environment for ESIs. This includes reducing the administrative burden of grant applications to ensure that young scientists do not become discouraged and leave to pursue other careers. During FY 2021, as in prior years, NCI will rely on an existing grant mechanism, the Method to Extend Research in Time (MERIT) R37 Award to extend the length of time that ESIs can receive funding under their first substantial independent grant. Using this approach, NCI can convert the most meritorious ESI applications to R37 grants, which will provide a sixth and seventh year of support for these investigators.

During FY 2019, more than 30,000 new patients enrolled in clinical trials that NCI sponsored or supported. Two-thirds of these patients enrolled in trials supported through the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Network (NCORP).

The narratives that follow highlight some of NCI's programs and identify recent progress, as well as ongoing and future activities in each scientific area. However, it is important to appreciate that virtually all NCI research under one scientific goal influences the approaches used to advance goals in the other scientific areas. The breadth and complexity of NCI research precludes a complete review of all NCI programs in this budget document. Further details appear on the NCI web site, www.cancer.gov. The examples that follow offer a meaningful overview of NCI accomplishments and initiatives, but they understate the vast amount of valuable NCI work to advance the National Cancer Program.

I. Understanding How Cancer Develops

Cancer is driven by alterations of a cell's genome (DNA) and the proteins that its DNA encodes. During this process, abnormal types and amounts of proteins emerge that lead to a variety of molecular abnormalities. These abnormalities cause a normal cell to transform into a tumor cell and lead to a diminished ability to control growth and other hallmarks of cancer. Precision medicine, in all its forms, depends on a deeper understanding of the genetic and functional changes that occur in cancer cells and the tumor microenvironment.

To better understand how cancer develops, NCI supports large-scale, high-throughput studies of the genes, proteins, and pathways altered in cancer. In addition, NCI funds studies of basic cell biology, cell interactions, angiogenesis (blood vessels that form to support a tumor), immune responses, and other essential research to understand the mechanisms of how cancer develops and progresses. NCI also supports laboratory studies in a variety of model systems, including animal and computational models, to investigate the functions of these systems and their relationship to cancer. Examples of initiatives under this NCI research goal include:

Metastasis Research Network: No therapeutic strategies effectively treat cancer metastases. We lack sufficient understanding of how, when, and why metastasis develops. To address these gaps, NCI is developing a Metastasis Research Network to understand –

- why in some cancers, cells break away before the cancer fully develops or is detected;
- how these cancer cells disseminate and travel;
- how cancer cells establish residence, yet can sometimes remain dormant and clinically undetectable for months or years;
- what triggers dormant cells to grow and develop into metastatic disease; and
- how treatments influence these processes.

By expanding scientific knowledge in these areas, NCI hopes to uncover new ways to intervene and treat metastasis.

Early-Onset Cancers in Underrepresented Populations: Individuals from certain ethnic and racial populations are at increased risk of developing cancers at an early age. With this concern in mind, NCI supports an Early-Onset Malignancies Initiative (EOMI) to collect patient specimens and associated patient clinical information. NCI then genomically characterizes the specimens to understand disease mechanisms, genetic variation, and risk factors. Special attention is given to populations of African Americans, Hispanics, and Native American patients. By enrolling patients at 11 community practice sites, EOMI is focusing on breast, colon, liver, multiple myeloma, prostate, and kidney cancers to better understand the biology of early disease and response to treatment.

Leveraging Innate Immunity to Fight Cancer: Most current immunotherapies harness the adaptive immune system to fight cancer. Recent research advances demonstrate that innate immune pathways within the body are also critically important. The innate immune system provides the first line of defense. Once an innate response is activated, an adaptive immune response is also stimulated. Then, both work together to eliminate infections or other threats. Innate pathways may either enhance anti-tumor immunity or block pathways that suppress tumors. Through research on these pathways, NCI hopes to use the new knowledge of innate immunity to develop immunotherapies that offer more strategies to treat cancers.

Reducing Cancer Disparities: Certain populations experience higher incidence and mortality rates for some cancers compared to the general population. NCI strives to understand the causes of these disparities and to reduce them. As an example, NCI is supporting two major research studies addressing cancer disparities in African American populations. In addition, NCI has three research programs that support basic and translational studies investigating cancer disparities among diverse populations.

Budget Policy: The FY 2021 President's Budget request is $854.7 million, a decrease of $66.5 million or 7.2 percent compared with the FY 2020 Enacted level.

II. Understanding the Causes of Cancer

Cancer develops through a complex interplay of genetics, factors such as lifestyle decisions, environmental exposures, and changes that occur through aging. These factors probably influence the likelihood of developing almost all cancers. In some cases, cancer risk is more strongly influenced by inheriting a mutation or a variant of a gene or a combination of genes. In other cases, cancer risk is determined principally by external factors, such as exposure to tobacco or infectious agents.

Understanding the interactions among genetic background, environmental, and lifestyle factors will improve the ability of scientists to prevent as well as detect, diagnose, and treat cancers at the earliest possible time. NCI-funded studies on the causes of cancer range from small-scale laboratory-based research to large-scale studies that use population cohorts or case-controlled comparisons of subpopulations. The studies may also involve modeling to determine cancer risk for individuals or within populations. Through such studies, NCI research strives to identify the causes of cancer. Examples of initiatives under this NCI research goal include:

Interdisciplinary Approaches to Support Cancer Research: NCI is using interdisciplinary approaches such as bioengineering to detect cancer earlier and increase the effectiveness of treatments. These efforts include engineered drug delivery, nanotherapy, and high-resolution imaging. The techniques may employ synthetic biology and computational modeling to design medical probes and devices, gather insights into the origins of cancer, and develop new diagnosis and treatment options.

Inherited Cancer Syndromes: Although genetic testing is often performed in some family members identified at high risk of cancer, many individuals with inherited cancer syndromes are not identified and thus do not benefit from the strategies available to prevent and detect these cancers. To address this concern, NCI funded four research projects through the Cancer Moonshot^{SM}. NCI also launched a longitudinal cohort study to examine the incidence of these syndromes, analyze associated tumors, better understand these rare conditions, and identify potential treatments.

Budget Policy: The FY 2021 President's Budget request is $949.6 million, a decrease of $75.4 million or 7.4 percent compared with the FY 2020 Enacted level.

III. Detecting and Diagnosing Cancer

Many deaths occur because cancers are diagnosed at late stages when treatment is often less effective. NCI-supported researchers are working on techniques to image tumors earlier and identify molecules, nucleic acids, proteins, metabolites, and other substances, that may improve early detection and diagnosis. This often involves uncovering the distinct molecular signatures of cancers and developing and refining molecular tests to detect cancer.

NCI has an array of programs to advance many aspects of early cancer detection and diagnosis:

- Developing new technologies and improving existing methods of noninvasive imaging to support cancer diagnosis, to identify disease subsets in patients, to determine the stage of disease, and to monitor the progress of cancer treatment;
- Coordinating efforts to obtain high-quality tissue specimens and data for the research community, and developing databases of molecularly characterized specimens; and
- Maintaining infrastructure and programs such as the Genomic Data Commons, the Cancer

Genome Characterization Initiative, and The Cancer Genome Atlas (with the National Human Genome Research Institute) to improve cancer detection and diagnosis.

Investigator-initiated research project grants are one mechanism NCI relies on to support and improve early detection and diagnosis of cancer. In addition, as examples listed above illustrate, other larger research programs also play important roles. Initiatives under this goal include:

Big Data and Artificial Intelligence (AI): Big data and AI can revolutionize cancer research and care. To cite one example, an NCI-led team developed an AI approach to advance cervical cancer screening. In other examples, NCI supports training on big data through a partnership with the Department of Veterans Affairs and is developing extreme-scale predictive models with the Department of Energy to accelerate precision oncology. NCI scientific infrastructure such as the Cancer Research Data Commons acts as a foundation to foster data sharing and to advance AI for oncology.

Biomarkers and Imaging for Early Detection: Accurately identifying early-stage aggressive cancers – to distinguish lesions that are life-threatening from those that are not – is an NCI priority. For example, NCI's Consortium for Imaging and Biomarkers is integrating imaging strategies with biomarkers to identify false positives and reduce the significant problem of overdiagnosis. NCI is also supporting academic and industry partnerships to plan, design, and engineer novel imaging technologies that can improve the accuracy of detecting cancers.

Early Detection of Pancreatic Cancer: NCI is advancing on multiple fronts to improve detection of resectable pancreatic cancer. Investigators from four NCI consortia are evaluating biomarkers, imaging characteristics, and clinical information. Specific projects include –

- validating biomarkers to distinguish aggressive from nonaggressive pancreatic cysts;
- building a multi-institutional imaging repository of pre-diagnostic and early-stage pancreatic cancers to allow researchers to develop artificial intelligence detection tools; and
- following high-risk cohorts and prospectively collecting biospecimens for analysis.

Other NCI investments include a Small Business Innovative Research (SBIR) award to develop an ultrasound contrast agent that may better detect early-stage pancreatic ductal adenocarcinoma. NCI is also collaborating with the National Institute of Diabetes and Digestive and Kidney Diseases to study individuals with new-onset diabetes (NOD), a condition that can occur before pancreatic cancer patients become symptomatic. Researchers will estimate the probability of cancer in the NOD group, establish a specimen reference set, and use imaging and clinical data to identify those at higher risk of pancreatic cancer who could benefit from careful monitoring.

New Technologies for Cancer Discovery: Cancer initiates and progresses due to changes within a complex interplay of molecular pathways in cells and surrounding tissue. Our ability to understand – and ultimately influence – these events requires technologies, techniques, and advanced computing and algorithms to generate, distill, and interpret research data. NCI supports focused programs that connect cancer biologists and oncologists with engineers, computer scientists, physicists, and mathematicians to stimulate multi-disciplinary approaches and develop innovative technologies to advance cancer research.

HPV Antibodies Detected Years Before Cancer Diagnosis: There has been an alarming increase in the number of head and neck cancers, especially cancer of the oropharynx (part of the throat), attributable to human papillomavirus (HPV) infection. HPV16 causes the vast majority

of these tumors. Research from NCI has shown that antibodies associated with HPV16 can be detected in the blood of individuals with HPV-positive oropharyngeal cancer ten years or more before diagnosis. This observation highlights an opportunity to use the biomarker for research to understand how these cancers develop and as a potential screening tool for early detection of a cancer that has been increasing in the United States.

Enhancing Colorectal Cancer Screening: A long-standing impediment to reducing the incidence and mortality of colorectal cancer is making effective screening available, while addressing the challenges of cultural differences and access. NCI addresses these concerns by working through community health educators at NCI-designated Cancer Centers, implemented Screen-to-Save (S2S). S2S focuses on reaching racial and ethnically diverse populations and communities through culturally sensitive, evidenced based education and outreach. In FY 2019, S2S reached more than 3,000 participants in underserved communities through 347 educational events.

Budget Policy: The FY 2021 President's Budget request is $550.0 million, a decrease of $45.5 million or 7.6 percent compared with the FY 2020 Enacted level.

IV. Treating Cancer and Improving Survivorship

Research on cancer therapy has many facets that go beyond developing and testing drugs, radiotherapy, immunotherapy, and surgery. These include controlling symptoms, improving care, and enhancing long-term survivorship and quality of life. Developing new therapies and the means to monitor cancers before and during treatment are central to successfully treating cancer. Increasingly, progress is linked to knowledge about molecular fingerprints of tumors, the structure of cancer-associated molecules and how to target them with new drugs, how cancer cells interact with the host environment and the immune system, and the altered behaviors of cancer cells.

To develop and improve cancer treatments, NCI invests in basic, translational, and clinical research. These investments identify therapeutic targets and strategies, and commercial interests frequently validate these targets and develop interventions against them. NCI also supports clinical research to develop and test interventions at many sites across the country. Examples of current NCI priorities include:

Improving Quality of Life for Cancer Survivors: There are nearly 17 million cancer survivors in the United States today, and the number will likely exceed 20 million by 2026. During FY 2019, NCI issued two Cancer Moonshot^{SM} solicitations to address issues confronting survivors. One encourages research to implement key elements of the Survivorship, Treatment, Access, and Research (STAR) Act enacted by Congress in 2018, improving outcomes for pediatric, adolescent, and young adult cancer survivors. The second focuses on adult cancer survivors, stimulating research to enhance communication, engagement, and coordination between oncologists and non-oncology care providers as a means of optimizing follow-up care.

NCI Program Portrait: Childhood Cancer Data Initiative

FY 2020 Budget Level: $50.0 million
FY 2021 Budget Level: $50.0 million
Change $ 0.0 million

Each year, 16,000 children and adolescents are diagnosed with cancer in the United States, or about one of every hundred new cancer cases.

Care for these young patients is generally more networked – that is, interconnected and relying on multiple specialists, sometimes in remote locations – than for adult cancer patients. Given the number of young patients and the need for cohesion among institutions providing care, we have a genuine opportunity to provide state-of-the-art clinical care to each child and to learn, in a focused and organized way, from every patient with childhood cancer.

The system-wide knowledge of childhood cancer cases, spanning the spectrum from basic biology to clinical outcomes, to survivorship, offers an opportunity to change the course of cancer in all children. However, to accelerate progress, knowledge from individual cancer cases must be freed from institutional siloes, appropriately curated, and made broadly available to cancer researchers. The Childhood Cancer Data Initiative (CCDI) provides a blueprint for this bold vision and for establishing similar data resources for adult cancers and other diseases. Through the CCDI, NCI will connect data repositories and registries, collect standardized, high-quality data on childhood cancers, and promote efficient data sharing to accelerate research and discovery.

By building an integrated, connected data framework for pediatric cancer, NCI will connect multiple existing and new data repositories and offer software tools to analyze and share the data. The data repositories will include comprehensive and standardized patient information featuring some or all of the following: genomics, proteomics, metabolomics, imaging, pathology, side effects, and outcomes reported by patients and caregivers.

Putting these pieces together – interconnecting data repositories with better data collection – will create a data ecosystem for childhood and adolescent cancers that ensures data are more broadly accessible and interoperable. This will allow us to answer many questions that, to date, have been difficult or impossible to address, either because we have not collected the necessary information or because we lacked universal access to the data. Making data available in this powerful way will accelerate our ability to transform the childhood and adolescent cancer landscape with earlier diagnoses, less-toxic and more-effective treatments, and ultimately, better outcomes for these patients.

CCDI will not only be a marquee feature within the NCI childhood cancer program, it will complement and inform other, ongoing pediatric cancer research. To cite one example, as a component of the Cancer Moonshot[SM], NCI created an engagement network for pediatric and young adult patients. By working with the NCI Intramural Research and Clinical Center programs, the network seeks to better understand rare tumors and develop more effective therapies for these tumors in children and young adults.

Another example of ongoing high-priority research is the partnership between the Children's Brain Tumor Tissue Consortium and NCI's Clinical Proteomics Tumor Analysis Consortium. By using proteogenomics – a method that analyzes both the protein and genome profiles of tumors – to comprehensively characterize the landscape of pediatric tumors across many subtypes, researchers can better understand the biology of pediatric tumors and thereby identify treatment options.

Combination Precision Oncology Trials: Precision medicine in cancer offers an opportunity to tailor therapy to specific genetic changes that often emerge in the course of a cancer. Initial NCI trials focused on single drugs to respond to these genetic changes. However, studies supported by NCI suggest that combinations of drugs may be more likely to overcome resistance than treatment with a single drug. Based on this understanding, NCI plans to give new focus to drug

combination trials within the NCI National Clinical Trials Program. To test this approach, NCI will support a central, network laboratory for generating the analysis to allow clinicians to recommend a combination therapy based on molecular targets.

Imaging Cancer Inflammation: Thanks to advances in cancer imaging, researchers can better understand the role that inflammation plays as an underlying cause of cancer and how inflammation drives how cancer behaves in individual patients. With these principles in mind, NCI established the Cancer Imaging Program to incorporate advanced imaging techniques into research and thereby improve outcomes for cancer patients. NCI's Cancer Imaging Program is also benefiting from a trans-NIH initiative focusing on Inflammation and its Impact on Disease and from workshops on this topic that NCI co-sponsored in 2017 and 2019.

SBIR – STTR: Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are a longstanding priority. Examples of recent SBIR awards include:

- **First Treatment for Rare Adrenal Cancers.** In July 2018, FDA approved Azedra (iobenguane I 131) to treat adults and adolescents age 12 and older with rare tumors of the adrenal gland which cannot be surgically removed. Patients with adrenal cancer often suffer severe hypertension, affecting quality and length of life. After favorable clinical trial results, FDA granted the Azedra new drug application Fast Track, Breakthrough Therapy, Priority Review, and Orphan Drug designations in advance of the July 2018 approval.
- **Device to Better Select Immunotherapies for Patients.** NCI is providing SBIR support to develop a device to evaluate the potential toxicity of CAR-T cells before the immunotherapy is given to the patient. CAR-T cells are a new and powerful type of personalized immunotherapy used to treat difficult cancers. However, CAR-T therapy can also produce severe patient toxicities. The device being developed enables oncologists to predict if the personalized CAR-T cells will produce a response in a patient and whether there is a likelihood that toxicities may also emerge.

Budget Policy: The FY 2021 President's Budget request is $1,101.8 million, a decrease of $91.2 million or 7.6 percent compared with the FY 2020 Enacted level.

V. Improving Cancer Prevention and Control

Cancer prevention research focuses on actions that individuals can take to lower their risk of getting cancer. Such actions include maintaining a healthy lifestyle, avoiding exposure to cancer-causing substances, and taking medicines or vaccines to prevent cancer from developing. Prevention should ideally be tailored to an individual's underlying risk of developing cancer. Cancer prevention draws on our growing knowledge of the mechanisms and causes of cancer. Prevention also relies on population-based surveys to obtain epidemiological information, such as the incidence of specific types of cancers and factors that may cause a specific cancer. Through education, behavior modification, vaccination or preventive medications, and policies that limit exposures to carcinogens, 30 to 50 percent of all cancers could be prevented.

Cancer control science relies on basic and applied research in behavioral, social, and population sciences to enhance interventions that reduce cancer risk, incidence, morbidity and mortality, and improve quality of life. Cancer control seeks to understand the causes and distribution of cancer throughout the population, identify and implement effective healthcare practices to reduce cancer incidence, and monitor and explain cancer trends and health disparities in the population. Cancer control research aims to generate basic knowledge about how to monitor and change individual and collective behavior and translate that knowledge into practice.

To improve cancer prevention and control, NCI supports research to understand the factors that influence cancer outcomes, quality of care, and quality of life. Other research focuses on the best ways to integrate proven, effective interventions into routine health care. NCI also promotes studies in underserved communities to advance the goal of controlling cancer more effectively for all populations. Examples of initiatives under this NCI research goal include:

Tobacco Control for a New Generation: Tobacco use remains the leading cause of preventable death in the United States. Research is needed to address a myriad of factors, including the changing landscape of tobacco products on the market, use of electronic nicotine delivery systems (ENDS), and evolving patterns of how individuals initiate and use tobacco products. An example of ways NCI is addressing this research need is a funding opportunity titled, "Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research" to conduct research on ENDS. This new research opportunity will expand our understanding of population-based disease prevention and tobacco use and behavior.

Improving Cancer Control in Rural Communities: Compared to urban counties, rural areas have higher average death rates for all cancers. To better understand this phenomenon, NCI awarded 40 administrative supplements to NCI designated Cancer Centers to develop greater capacity for rural cancer control research. These supplements support teams at Cancer Centers that, in collaboration with rural communities and clinics, will develop rural cancer control programs for low-income and underserved populations. Additionally, in NCI's Partnerships to Advance Cancer Health Equity program – a unique partnership program between minority-serving institutions and NCI-designated Cancer Centers – four of the current 16 partnerships are conducting research, research education, and community outreach to address rural disparities.

Enhancing NCI SEER to Support Precision Medicine: In the era of patient-specific precision medicine, population-based cancer surveillance must be capable of rapidly expanding the capture of data in new categories and from a range of sources. To meet this priority, NCI's Surveillance, Epidemiology, and End Results (SEER) Program expanded its capability to include real-time case eligibility assessment for cohort studies, clinical trials, and other research studies. SEER also added features such as Virtual Linked Biorepository and the Virtual Pooled Registry. In addition, in FY 2019, NCI posted a solicitation to further expand SEER registries by increasing population coverage.

Improving HPV Vaccine Development: NCI's HPV Serology Standards Laboratory is working with international partners to standardize serological assays used to measure antibody responses to HPV vaccination. The serology effort targets a primary endpoint for clinical trials that evaluate new vaccines and new indications, including the ongoing one-dose trials. If one dose of an HPV vaccine is sufficient to prevent HPV infection and reduce the incidence of cervical cancer, more widespread, lower cost vaccination programs may be possible for preventing HPV-related cancers. The Serology Lab is also developing procedures and standardizing reagents that, in conjunction with other data, will allow HPV vaccine trials of the future to be immunogenicity trials, which can be smaller, shorter, and less expensive to conduct than efficacy trials, thus helping to foster new HPV vaccines that could be lower cost.

Aggressive Versus Indolent Early Lesion Biology: Overdiagnosis and overtreatment of cancer is an ongoing challenge. Screening for cancer often identifies early lesions (pre-cancer or pre-cancerous lesions), and there is currently no definitive way to determine which lesions are likely to progress to invasive cancer. NCI supports research to expand our understanding of what cell types and molecular defects drive early lesions to either become aggressive or remain indolent (slow growing). Studies conducted through the Molecular and Cellular Characterization of Screen-Detected Lesions Consortium are characterizing the cell types and molecular defects that

may distinguish aggressive versus indolent lesions to identify ways to reduce this important public health burden.

New Technologies in Cancer Epidemiology: Technology that collects patient-specific data is an increasingly important aspect of cancer prevention research. NCI is establishing an analytic infrastructure to integrate various data sources, such as wearable sensors, electronic medical records, and genomics. The analytical infrastructure NCI is developing will support a new generation of cohort studies that will capitalize on these research innovations to investigate the causes of cancer and inform new approaches for precision cancer prevention and early detection.

Novel Ways to Deliver Chemopreventive Agents: Delivering chemopreventive agents locally is one way to reduce the toxicity of agents while maintaining clinical benefit. A localized chemoprevention approach may be ideal for individuals at high risk or who have premalignant disease because the agent can provide high drug concentrations at specific locations where early disease may originate and thereby limit systemic toxicity. Research projects include topical gels to prevent breast cancer, a vaginal cream to prevent cervical cancer, and an inhaled aerosol agent to prevent lung cancer. Either a clinician or patient could administer these agents. To advance this area of research, NCI issued an SBIR contract solicitation to develop new delivery devices and other approaches for bringing these agents to patients.

Budget Policy: The FY 2021 President's Budget request is $230.8 million, a decrease of $19.1 million or 7.6 percent compared with the FY 2020 Enacted level.

VI. Cancer Centers

The NCI Cancer Centers program is a key component of the nation's cancer research efforts. Together with their community partners, the 71 NCI-designated Cancer Centers, located in 35 states and the District of Columbia, form the backbone of NCI's extramural program for studying and controlling cancer. NCI-designated Cancer Centers are the nation's single most important source of new insights into the causes of cancer and strategies to prevent, diagnose, and treat cancer. Research proposals from Cancer Center investigators account for about three-quarters of successful NCI investigator-initiated grants.

Examples of the important research at NCI Cancer Centers include:

- At the University of Texas Southwestern Harold C. Simmons Comprehensive Cancer Center, researchers led an international, randomized phase III clinical trial for patients with advanced kidney cancer. The trial demonstrated significantly higher response rates and improved survival compared to the standard therapy for patients with intermediate and highly aggressive kidney cancers. Based on this information, FDA approved the combination of two checkpoint inhibitors, ipilimumab and nivolumab, to treat metastatic kidney cancer.

- At the Ohio State University Comprehensive Cancer Center, researchers are combining the latest digital imaging technologies, computational image analysis, and big data to convert traditional pathology slides into high resolution digital images for clinical, educational, and research purposes. When combined with other clinical information, physicians gain a unified picture of each person's cancer.

- At the Fred Hutchinson Cancer Research Center, cancer outcome researchers published data on cancer patients covered by Washington state's largest public and commercial

insurance providers. The report shows quality metrics and associated costs across the spectrum of cancer care, from initial treatment, to surveillance, to end of life care. The report shares best practices for delivering innovative quality cancer care at lower costs.

In addition to designated Cancer Centers, NCI supports more than 100 other specialized centers.

Budget Policy: The FY 2021 President's Budget request is $520.8 million, a decrease of $78.6 million or 13.1 percent compared with the FY 2020 Enacted level.

VII. Research Workforce Development

NCI has a long-standing commitment to train, develop, and support a strong workforce of cancer researchers spanning the career continuum. The NCI investment in early stage investigators helps attract talented scientists to ensure the strength of future cancer research. In addition to NCI's direct support for training, support for established investigators – scientists who have proven their ability to conduct robust science – fosters mentoring for the next generation of cancer researchers.

NCI also supports programs designed to develop a cancer research workforce that reflects the nation that NCI serves. The NCI Center to Reduce Cancer Health Disparities (CRCHD) is NCI's focal point for this important goal. Examples of CRCHD programs include:

- Continuing Umbrella of Research Experiences (CURE)
- Intramural Continuing Umbrella of Research Experiences (iCURE)
- Supplements to Support Training in Tribal Communities
- Youth Enjoy Science (YES) Research Education Program
- Partnerships to Advance Cancer Health Equity (PACHE)

Training Cancer Researchers of the Future

NCI has a broad array of training opportunities to develop cancer researchers of the future. Through formal training, individual fellowships, and career development awards, NCI supports opportunities for training in basic, clinical, and behavioral research at universities and other institutions across the country. Grant recipients include pre-doctoral candidates, postdoctoral fellows, and new faculty in independent research positions. In addition, NCI supports research experiences for high school, college, graduate, and medical school students, and postdoctoral fellows working in NCI intramural research programs.

NCI is committed to supporting a well-defined career path to research independence for scientists. During FY 2019, NCI funded the fourth round of a new mechanism, the F99/K00 award, to support the transition from graduate research to postdoctoral training. This new mechanism positions awardees to be competitive for a second NCI transition mechanism to advance their independence, the K99/R00 award, which supports the transition from postdoctoral training to serving as a tenure-track investigator. These mechanisms provide recipients with resources and a meaningful pathway to smoothly achieve these challenging transitions. More than 94 percent of the first cohort of F99 awardees successfully transitioned to the K00 phase, securing postdoctoral positions in top laboratories.

NCI continues to explore new approaches to attract and support physician-scientists to conduct research during clinical training. NCI is one of four NIH institutes participating in the R38 Stimulating Access to Research in Residency (StARR) program, and in FY 2019, the K38 Stimulating Access to Research in Residency Transition Scholar (StARRTS) Program. Together, these programs recruit and retain outstanding early-career health professionals who have

demonstrated potential and interest in pursuing careers as clinician-investigators.

Budget Policy: The FY 2021 President's Budget request is $197.4 million, a decrease of $10.4 million or 5.0 percent compared with the FY 2020 Enacted level.

VIII. Intramural Research

The activities of NCI's intramural research program complement all aspects of the National Cancer Program. The scientists, physicians, and clinicians who make up the NCI intramural research program conduct basic, clinical, genomic, and population-based research. NCI intramural research emphasizes high-risk, high-reward cancer research that would otherwise not be conducted. The many accomplishments of the intramural research program appear within the program descriptions for the five NCI scientific goals of this budget document.

Budget Policy: The FY 2021 President's Budget request is $947.3 million, a decrease of $89.0 million or 8.6 percent compared with the FY 2020 Enacted level.

IX. Research Management and Support

NCI research management and support personnel serve an indispensable role by supporting and enabling the success of all NCI-funded programs. This staff conducts activities that include but are not limited to central administration, overall program direction, grant and contract administration, human resources, program coordination, and financial management.

Budget Policy: The FY 2021 President's Budget request is $418.4 million, a decrease of $68.1 million or 14.0 percent compared with the FY 2020 Enacted level.

X. Repairs and Improvements

Funding for Repairs and Improvements allows NCI to operate the Frederick National Laboratory for Cancer Research (FNLCR) as a modern research enterprise and to maintain essential infrastructure at the Frederick research campus.

Budget Policy: The FY 2021 President's Budget request is $15.0 million, a decrease of $15.0 million or 50.0 percent compared with the FY 2020 Enacted level. The FY 2021 amount of $15 million is an estimate and may increase up to the $30 million allowable by law as needs are evaluated.

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total compensable workyears:				
	Full-time equivalent	3,035	3,035	0
	Full-time equivalent of overtime and holiday hours	6	6	0
	Average ES salary	$189	$194	$5
	Average GM/GS grade	12.6	12.6	0.0
	Average GM/GS salary	$121	$122	$1
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$102	$105	$3
	Average salary of ungraded positions	$121	$122	$1
	OBJECT CLASSES	**FY 2020 Enacted**	**FY 2021 President's Budget**	**FY 2021 +/- FY 2020**
	Personnel Compensation			
11.1	Full-Time Permanent	248,433	251,254	2,822
11.3	Other Than Full-Time Permanent	136,982	138,532	1,551
11.5	Other Personnel Compensation	13,592	13,748	156
11.7	Military Personnel	3,467	3,559	92
11.8	Special Personnel Services Payments	66,627	67,309	683
11.9	**Subtotal Personnel Compensation**	**$469,100**	**$474,403**	**$5,303**
12.1	Civilian Personnel Benefits	142,547	148,092	5,545
12.2	Military Personnel Benefits	2,608	2,677	69
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$614,255**	**$625,172**	**$10,917**
21.0	Travel & Transportation of Persons	18,760	13,282	-5,478
22.0	Transportation of Things	1,407	955	-451
23.1	Rental Payments to GSA	24,069	19,399	-4,670
23.2	Rental Payments to Others	69	41	-28
23.3	Communications, Utilities & Misc. Charges	7,341	4,310	-3,032
24.0	Printing & Reproduction	71	37	-35
25.1	Consulting Services	44,784	29,261	-15,523
25.2	Other Services	631,912	421,434	-210,478
25.3	Purchase of goods and services from government accounts	730,330	689,159	-41,171
25.4	Operation & Maintenance of Facilities	12,785	8,553	-4,232
25.5	R&D Contracts	249,862	160,307	-89,555
25.6	Medical Care	5,172	4,263	-909
25.7	Operation & Maintenance of Equipment	28,989	22,754	-6,235
25.8	Subsistence & Support of Persons	275	219	-56
25.0	**Subtotal Other Contractual Services**	**$1,704,110**	**$1,335,951**	**-$368,159**
26.0	Supplies & Materials	50,085	39,728	-10,357
31.0	Equipment	17,975	14,127	-3,847
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	4,002,295	3,828,170	-174,125
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$5,826,183**	**$5,256,001**	**-$570,182**
	Total Budget Authority by Object Class	**$6,440,438**	**$5,881,173**	**-$559,265**

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

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation			
Full-Time Permanent (11.1)	$248,433	$251,254	$2,822
Other Than Full-Time Permanent (11.3)	136,982	138,532	1,551
Other Personnel Compensation (11.5)	13,592	13,748	156
Military Personnel (11.7)	3,467	3,559	92
Special Personnel Services Payments (11.8)	66,627	67,309	683
Subtotal Personnel Compensation (11.9)	**$469,100**	**$474,403**	**$5,303**
Civilian Personnel Benefits (12.1)	$142,547	$148,092	$5,545
Military Personnel Benefits (12.2)	2,608	2,677	69
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$614,255**	**$625,172**	**$10,917**
Travel & Transportation of Persons (21.0)	$18,760	$13,282	-$5,478
Transportation of Things (22.0)	1,407	955	-451
Rental Payments to Others (23.2)	69	41	-28
Communications, Utilities & Misc. Charges (23.3)	7,341	4,310	-3,032
Printing & Reproduction (24.0)	71	37	-35
Other Contractual Services:			
Consultant Services (25.1)	25,767	16,648	-9,119
Other Services (25.2)	631,912	421,434	-210,478
Purchases from government accounts (25.3)	556,851	498,383	-58,468
Operation & Maintenance of Facilities (25.4)	6,537	4,370	-2,167
Operation & Maintenance of Equipment (25.7)	28,989	22,754	-6,235
Subsistence & Support of Persons (25.8)	275	219	-56
Subtotal Other Contractual Services	**$1,250,331**	**$963,809**	**-$286,523**
Supplies & Materials (26.0)	$50,085	$39,728	-$10,357
Subtotal Non-Pay Costs	**$1,328,065**	**$1,022,161**	**-$305,904**
Total Administrative Costs	**$1,942,320**	**$1,647,333**	**-$294,987**

NATIONAL INSTITUTES OF HEALTH
National Cancer 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 Cancer Research									
Direct:	1,258	16	1,274	1,317	16	1,333	1,317	16	1,333
Reimbursable:	7	-	7	7	-	7	7	-	7
Total:	1,265	16	1,281	1,324	16	1,340	1,324	16	1,340
Division of Cancer Biology									
Direct:	50	-	50	54	-	54	54	-	54
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	50	-	50	54	-	54	54	-	54
Division of Cancer Control and Population Sciences									
Direct:	162	2	164	171	2	173	171	2	173
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	164	2	166	173	2	175	173	2	175
Division of Cancer Epidemiology and Genetics									
Direct:	159	3	162	170	2	172	170	2	172
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	159	3	162	170	2	172	170	2	172
Division of Cancer Prevention									
Direct:	100	1	101	103	1	104	103	1	104
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	100	1	101	103	1	104	103	1	104
Division of Cancer Treatment and Diagnosis									
Direct:	213	4	217	226	4	230	226	4	230
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	213	4	217	226	4	230	226	4	230
Division of Extramural Activities									
Direct:	91	1	92	92	1	93	92	1	93
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	91	1	92	92	1	93	92	1	93
Office of the Director									
Direct:	813	5	818	860	6	866	860	6	866
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	814	5	819	861	6	867	861	6	867
Total	2,856	32	2,888	3,003	32	3,035	3,003	32	3,035
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	**Average GS Grade**								
2017	12.4								
2018	12.5								
2019	12.6								
2020	12.6								
2021	12.6								

NATIONAL INSTITUTES OF HEALTH
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Detail of Positions[1]

GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	2	3	4
Total, ES Salary	366,306	566,492	774,961
GM/GS-15	293	289	289
GM/GS-14	493	502	502
GM/GS-13	527	546	546
GS-12	408	394	394
GS-11	158	154	154
GS-10	10	10	10
GS-9	94	97	97
GS-8	49	51	51
GS-7	42	38	38
GS-6	12	14	14
GS-5	7	6	6
GS-4	3	4	4
GS-3	5	6	6
GS-2	2	4	4
GS-1	0	1	1
Subtotal	2,103	2,116	2,116
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	10	12	12
Senior Grade	8	6	6
Full Grade	7	7	7
Senior Assistant Grade	7	7	7
Assistant Grade	0	0	0
Subtotal	32	32	32
Ungraded	917	965	965
Total permanent positions	2,066	2,153	2,153
Total positions, end of year	3,054	3,116	3,117
Total full-time equivalent (FTE) employment, end of year	2,888	3,035	3,035
Average ES salary	183,153	188,831	193,740
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	116,999	120,626	121,567

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