



National Cancer Institute

CONGRESSIONAL JUSTIFICATION
FY 2023

Department of Health and Human Services
National Institutes of Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
National Cancer Institute (NCI)

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Cover Photo: The image on the cover displays nanotechnology particles (shown in green) in a culture of blood cells. These nano particles were developed by a research team at the University of North Carolina at Charlotte. The particles are being investigated as a vaccine adjuvant, a substance that enhances the body’s ability to produce an immune response.

The NCI Nanotechnology Characterization Program (NCL) at the Frederick National Laboratory for Cancer Research serves as a national resource for advancing nanoscale particles into clinical application. At NCL, NCI assists cancer researchers to study and characterize nanotechnology particles such as these for cancer vaccines, other cancer therapeutics, and diagnostics.

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Director's Overview

On behalf of scientists, clinicians, and patients who contribute to the National Cancer Program in countless ways, I am pleased to present the FY 2023 President's Budget request for the National Cancer Institute (NCI). We are in a dynamic era of cancer discovery, and there is much to report.

Biden Cancer Initiative: In February 2022, President Biden announced a bold new goal for making progress toward ending cancer as we know it: cutting America's age-adjusted death rate due to cancer by at least 50 percent over the next 25 years and improving the experience of people, families, and caregivers through living with and surviving cancer. From the East Room of the White House – joined by First Lady Jill Biden and Vice President Kamala Harris, and surrounded by patients, caregivers, advocates, cancer researchers, health care providers, and leaders in Congress and the Administration – the President defined actionable steps for reaching these ambitious, achievable goals, while also setting defined priorities for the Cancer Moonshot.



NCI Director Norman E. "Ned" Sharpless, M.D.

In 2016, as part of the bipartisan 21st Century Cures Act, Congress created the *Beau Biden Cancer Moonshot*, a 7-year, \$1.8 billion initiative at the NCI to speed progress against cancer. The February 2022 White House announcement builds on that landmark 2016 initiative, igniting a new phase of the Cancer Moonshot. The priorities include –

- *Diagnose cancer sooner*, by increasing access to screening and advancing new testing technologies
- *Prevent cancer*, identify, develop and implement additional ways to prevent cancer, including the development vaccines that prevent cancer, like the HPV vaccine
- *Address inequities* that lead to disparities in access to care and patient outcomes
- *Target treatments to patients*, through research to learn which therapies work best for each patient
- *Speed progress* against the deadliest and rarest cancers, including childhood cancers
- *Support patients, caregivers, and survivors* as they navigate cancer and its aftermath
- *Learn from more patients*, which includes building unified systems to collect, integrate, and broadly share data to speed cancer science.

These priorities demonstrate the broad scale and scope of the President's vision, and the full context of his commitment to ending cancer as we know it. NCI will play a central role in achieving this vision and will continue to lead the National Cancer Program. However, the President also summoned a whole-of-government approach to addressing the challenges before us, convening a Cancer Cabinet of White House leadership and federal departments and agencies, including NCI.

Cancer Moonshot Delivers Results – Enacted in 2016 as Title I of the 21st Century Cures Act, the *Beau Biden Cancer Moonshot* was a bold action on behalf of cancer patients. The initiative funds a range of promising science to accelerate cancer discovery, foster collaboration, and increase data sharing to speed advances.

This seven-year program enters its final funding year in FY 2023. To maximize the opportunity for advances, Congress enacted Moonshot appropriations as “no-year” funding. This increased NCI’s flexibility to design initiatives and make research awards. Prominent, ongoing Moonshot priorities include –

- ***Improving Immunotherapy*** – Moonshot investments are expanding the reach of immunotherapy. This includes discovering new immune targets and developing novel cell-based therapies for cancer treatments through research networks dedicated to children and adults with cancer.
- ***Childhood Cancer*** – Since childhood cancers are very different from those that arise in adults, the therapies that can yield an effective response in children are also different. To address this challenge, several Moonshot initiatives focus on pediatric cancers. These include research to target rare pediatric cancers and research on fusion oncoproteins, the fusion of genes that drive some childhood cancers.
- ***Cancer Prevention and Early Detection*** – Other Moonshot initiatives seek to reduce cancer risks and diminish health disparities. Moonshot funds are delivering proven prevention and detection strategies to underserved, rural, and minority populations. They are also deploying evidence-based approaches to expand colorectal cancer screening and sustain tobacco cessation. Additionally, federal agencies, led by the NCI, will develop a focused program to expeditiously study and evaluate multicancer detection tests, as we did for COVID-19 diagnostics, which could help detect cancers at a time when there may be more effective treatment options for patients.
- ***Cancer Implementation Science*** – Implementation science strives to maximize the use of proven cancer prevention and early detection strategies and to incorporate them into standards of care. There is an urgent need to expand the use of proven strategies, especially among underserved, rural, and minority populations. To cite one example, a Moonshot-funded effort is applying artificial intelligence technology to detect cervical cancer. The technology may be an important advance in rural areas where the incidence of cervical cancer is greater than elsewhere and access to care is limited.

NCA at 50 – Throughout 2021, NCI honored the 50th anniversary of the National Cancer Act of 1971 (NCA), a watershed event that sparked five decades of remarkable progress in cancer discovery. The contributions of two prominent NCA priorities – NCI-designated cancer centers and NCI-sponsored clinical trials networks – highlight some of the many advances in science that the NCA inspired. These two programs remain cornerstones of NCI research to this day.

Each year, more than 75,000 new patients enroll in NCI-sponsored and NCI-supported clinical trials. Half of these patients enroll in trials supported by the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Program (NCORP). In addition, NCI also enrolls patients in observational studies to observe and assess outcomes.

Through the NCTN and NCORP networks, patients participate in testing new ways to screen, prevent, diagnose, and treat cancer. These trials yield important results. Foremost among them is evidence to demonstrate the safety and effectiveness of new therapies, evidence that leads to new U.S. Food and Drug Administration (FDA)-approved drugs, vaccines, and devices, and allows patients with cancer and those at risk of cancer to lead longer, healthier lives.

In many cases, these trials are conducted at one or more of NCI's 71 Designated Cancer Centers. In addition to conducting these trials, NCI Cancer Centers engage in the full spectrum of basic, clinical, and translational research to advance and expand knowledge about cancer. From its origins in the NCA 50 years ago, the Cancer Centers Program has grown into a dynamic engine of discovery, serving as the nation's single most important source of new insights into the causes of cancer and strategies to prevent and treat cancer.

Long Legacy of the NCA – These and other achievements are an enduring legacy of the NCA. They represent five decades of cancer progress that has delivered dramatic declines in cancer mortality. Since 1990, the rate of cancer mortality has dropped by 30 percent. The average annual rate of decline is 1.5 percent, a decline that has been accelerating in recent years.

NCI-sponsored clinical trials offer another compelling example of NCA progress. An analysis released in September 2021 documented that during the past 40 years, U.S. cancer patients gained 14 million years of additional life, thanks to the results of clinical trials that NCTN conducts.¹ This budget is an opportunity to sustain and extend the decades of progress.

Diversifying the Research Workforce – In addition to sponsoring a range of programs designed to reduce cancer disparities, NCI is also focused on diversity within the research workforce. Working with the NIH Common Fund and other institutes, NCI played a leadership role in establishing an innovative program to diversify the biomedical research workforce and provide support to research faculty from underrepresented groups.

This initiative – Faculty Institutional Recruitment for Sustainable Transformation (FIRST) – seeks to establish, enhance, and sustain cultures of inclusive excellence throughout the biomedical research community. To achieve this, FIRST relies on evidence-based practices to promote diversity and inclusion within biomedical faculties and prepare early-stage faculty to thrive as NIH-funded researchers. In September of 2021, NIH issued FIRST awards through the NIH Common Fund. NCI supplemented the NIH funding to increase the number of FIRST awards, and we expect to issue additional awards in future funding cycles.

NCI Extramural Grants – Despite continuing challenges within the research community caused by the COVID-19 pandemic, FY 2020 and FY 2021 funding from Congress supported strong growth for competing and continuing NCI grants. In this two-year period, NCI–

- increased total funding for competing and continuing grants by \$250 million;
- increased the payline for investigator-initiated R01 grants by 37 percent; and
- funded 362 more investigator-initiated R01 and R37 awards than in prior years.

¹ Annals of Oncology (2021) 32 (suppl_5): S1102-S1110. 10.1016/annonc/annonc711

Basic research is vital to progress in cancer, and the NCI grants portfolio reflects this reality. 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 emerges from the NCI investment in basic research is essential to discovering new ways to prevent, detect, and treat cancer.

Report to the Nation – Each year, NCI, the Centers for Disease Control and Prevention, and cancer organizations issue a *Report to the Nation* on cancer incidence and mortality. A companion analysis accompanying the 2021 report focused on the financial burden that U.S. cancer patients face. The analysis revealed that direct costs to cancer patients, such as out-of-pocket costs and patient time, exceed \$21 billion per year. To put this amount in perspective, the \$21 billion direct cost to U.S. cancer patients –

- exceeds the gross domestic product of 90 nations and
- is equivalent to the combined annual research budgets of the 10 largest NIH Institutes.

The analysis spotlights the acute financial toxicity and hardship that many cancer patients and their families experience due to the cost of treatment. In addition to these direct patient costs, the overall cost of cancer care in the United States is estimated at \$209 billion in 2020, while the cost of lost productivity accounts for a further \$148 billion.

Building on Our Accomplishments – As this overview emphasizes, cancer patients today have a better chance of living longer and enjoying improved quality of life, thanks to investments in NCI cancer science. 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.

Thus, much work remains. The FY 2023 NCI budget justification highlights some of the many areas where NCI expects to make new progress and deliver important results for those diagnosed with cancer, those at risk of cancer, and the growing population of cancer survivors.



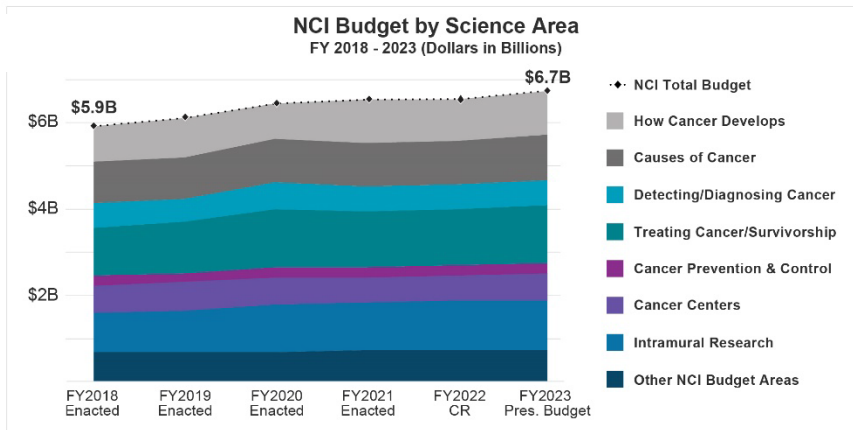
IC Fact Sheet

NCI History: Established under the National Cancer Act of 1937, NCI is the Federal Government’s principal agency for cancer research, training, and education. In 2021, NCI celebrated the 50th anniversary of the National Cancer Act of 1971. The 1971 statute expanded NCI’s scope and responsibilities, and included a requirement that NCI submit an annual plan and professional judgment budget directly to the President, and thereafter to Congress.

NCI Mission & Budget: NCI leads, conducts, and supports cancer research to advance scientific knowledge and help all people live longer, healthier lives. To perform its mission, NCI funds basic and applied cancer research to advance the scientific priorities highlighted in Fig. 1.



Norman E. “Ned” Sharpless, M.D., was sworn in as the 15th director of NCI on October 17, 2017. Dr. Sharpless also served as Acting Commissioner of the U.S. Food and Drug Administration for 7 months during 2019.



NCI Intramural Research: More than 300 principal investigators (PIs) perform research within the intramural program, which complements all aspects of the national cancer program. As of October 2020, NCI intramural researchers had on-going collaborations with more than 2,000 extramural investigators at more than 800 academic institutions in 46 states, the District of Columbia, and 66 countries around the world.

NCI Extramural Grants: NCI uses an array of programs and financial mechanisms to support cancer science and the NCI mission. Foremost among these are extramural grants to fund investigator-initiated research, as Fig. 2 illustrates. Extramural grants support research by more than 7,000 PIs, yielding new insights to understand, prevent, diagnose, and treat cancer.

There is unprecedented enthusiasm for cancer research within the science community. For example, between 2013 and 2019 grant applications to NCI rose by 50 percent, based on analysis of NIH grants data (data not displayed).

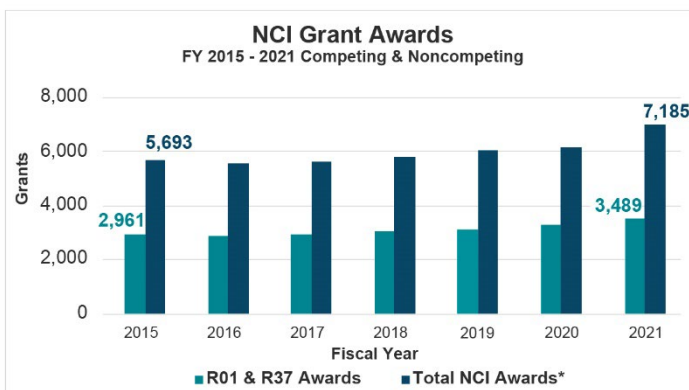


Fig. 2 * Data excludes Nat. Research Service Training Awards¹
¹ These grant counts include grants awarded from Cures funding carried over from previous years, and exclude grants anticipated to be awarded from Cures funding carried over into future years.

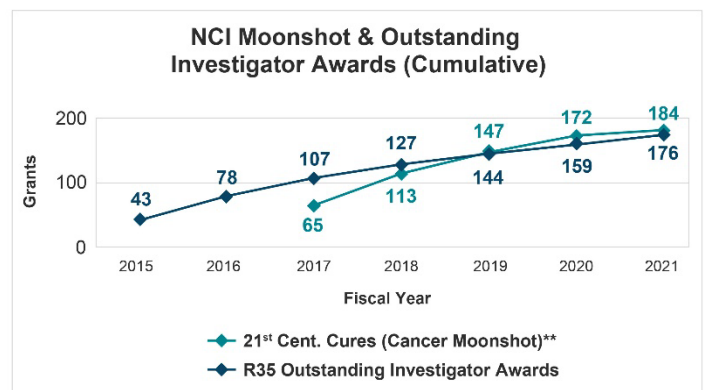


Fig. 3 **NCI received its first Moonshot funding in FY 2017

Cancer Moonshot / Outstanding Investigators – Fig. 3 displays the history of Moonshot and Outstanding Investigator Awards (OIA) grant awards. In December 2016, Congress enacted the Cancer Moonshot, which authorizes \$1.8 billion across seven fiscal years to accelerate the pace of cancer discovery. Another innovation is NCI’s OIA Program, which provides seven years of funding to investigators with outstanding records in cancer research. OIA researchers test high-risk hypotheses supported by a higher award level and for more years of funding than NCI typically provides.

Current Activities and Accomplishments

Cancer Moonshot Progress – In 2016, Congress enacted the Cancer Moonshot, a bold and visionary program to speed cancer discovery, collaboration, and implementation. To date, NCI has invested more than \$1 billion in Moonshot funding to support over 240 research projects across more than 70 cancer science initiatives. This investment produced important advances tied to many Moonshot research priorities, from improving cancer immunotherapies, to addressing treatment resistance, to identifying new targets for pediatric cancer.

Examples of other Moonshot accomplishments include:

MyPART – The My Pediatric and Adult Rare Tumor (MyPART) network includes scientists, patients, families, advocates, and healthcare providers searching for treatments for childhood, teen, and young adult solid rare tumors that have no cures. MyPART accomplishments include:

- 5 new treatment trials for rare cancers launched
- 8 trials in the pipeline for other rare cancers
- A protocol for a natural history study for all rare tumor types in the MyPART database.

Cancer Screening – Despite challenges due to the COVID-19 pandemic, the American Indian Colorectal Cancer (AI-CRC) Consortia is increasing CRC screening for American Indian adults. The program is delivering culturally appropriate CRC education and screening reminders to the American Indian community through telehealth visits and is partnering with clinics and pharmacies to distribute CRC screening kits.

PACT – The Moonshot-funded Partnership for Accelerating Cancer Therapies (PACT) is identifying, developing, and validating biomarkers to advance new therapies that harness the immune system to attack cancer.

FDA Approvals – The rewards of research include FDA-approved cancer drugs that rely on the results of NCI-supported basic science and clinical trials. During the 5-year period of 2017-2021, FDA approved 98 new drugs and 11 biosimilars to treat cancer. FDA also approved 184 expanded uses for previously approved oncology drugs and biologics.

Nobel Awards – Between 2009 and 2018, five Nobel Prizes in Physiology or Medicine were awarded to scientists who received NCI R01 grants.

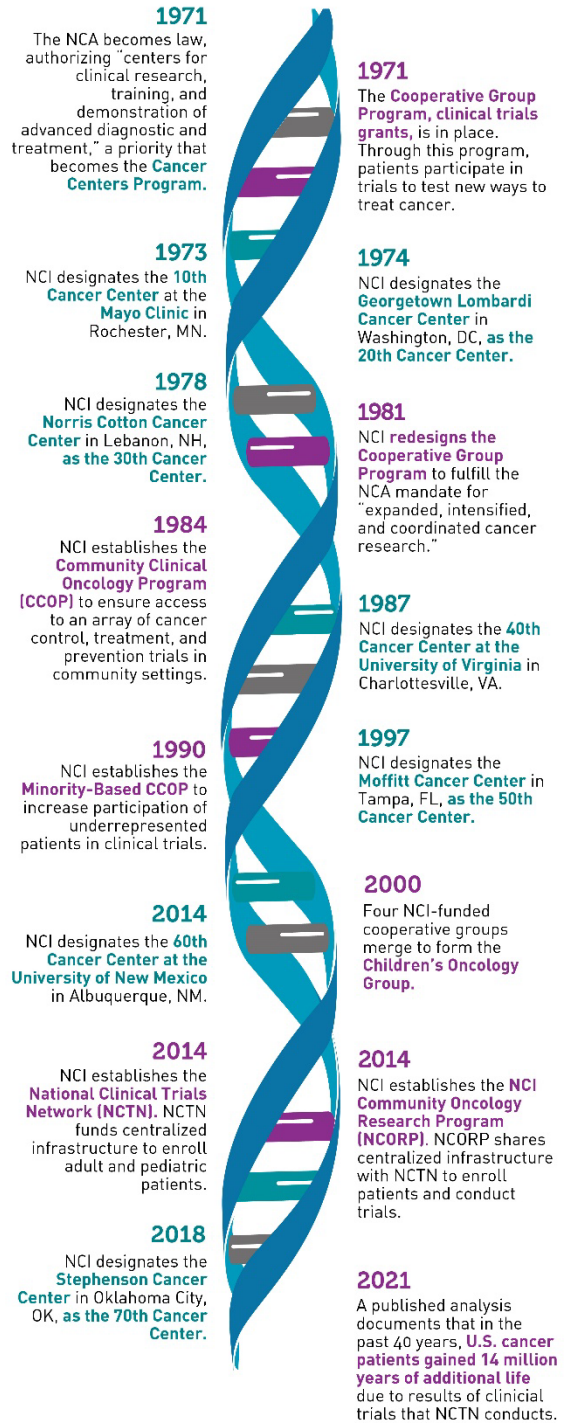
NCI Future Research

Cutting the Cancer Death Rate – In February 2022, President Biden announced a bold new goal for achieving progress against cancer: cutting America's age-adjusted death rate due to cancer by 50 percent over the next 25 years.

To achieve this goal, NCI will support a range of compelling priorities that include diagnosing cancer sooner, addressing inequities that lead to disparities in cancer outcomes, and providing comprehensive support to cancer patients, survivors, and caregivers. These and other priorities will fulfill our commitment to end cancer as we know it.

NCI — SELECTED MILESTONES

Throughout 2021, NCI honored the 50th anniversary of the National Cancer Act (NCA), a watershed event that prompted five decades of remarkable cancer discovery. The timeline below spotlights two prominent NCA achievements – the NCI-designated Cancer Centers Program and national clinical trials networks.



Major Changes in the Fiscal Year 2023 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 2023 President's Budget for NCI, which is \$154.0 million more than the FY 2022 Continuing Resolution (CR) level, for a total of \$6,713.9 million, an increase of 2.3 percent. This level includes \$50.0 million for the Childhood Cancer Data Initiative (CCDI) and \$216.0 million to support the ongoing 21st Century Cures Act Cancer MoonshotSM efforts. The FY 2023 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.

Research Project Grants (+\$51.4 million; total \$2,887.9 million): Increased funding in FY 2023 will allow NCI to pay continuing non-competing Research Project Grants (RPGs) at 96 percent of the commitment levels. In addition to increased costs to support the commitment base, NCI will support an increased number of competing RPGs and SBIR/STTR awards compared to the FY 2022 CR level. Funding additional meritorious research proposals will allow NCI to act on more opportunities to prevent, detect, and treat cancer. NCI intends to maintain the payline for investigator initiated R01 awards at the 9th percentile, similar to the FY 2022 CR level, while supporting additional competing awards issued to new and early-stage investigators. Support for early-stage investigators attracts talented scientists and ensures the future strength of cancer research.

Research Centers (+\$37.2 million; total \$617.0 million): The increase will support costs for any competitively awarded new centers and renewing centers in the NCI-designated Cancer Centers and Specialized Programs of Research Excellence (SPOREs) programs. The NCI Cancer Centers program is a cornerstone of the nation's cancer research program. Together with their community partners, the 71 NCI-designated Cancer Centers form the backbone of NCI's extramural program for studying and controlling cancer.

Other Research (+\$44.9 million; total \$638.6 million): The increase will support NCI efforts to establish a network for direct patient involvement and develop a 3D cancer atlas. A core effort of the Cancer Moonshot, these networks for patient involvement will support the Human Tumor Atlas Network and increasing patient engagement with cancer genome sequencing. The increase will also support clinical research projects as they increase participation after the impact of COVID-19.

Research & Development Contracts (+\$6.9 million; total \$814.9 million): Continued funding will support critical shared infrastructure across NIH, enhanced information technology, and continued funding of the Federally Funded Research and Development Center (FFRDC) that manages the Frederick National Laboratory for Cancer Research (FNLRCR). NCI's FNLRCR is a national asset and a unique resource. FNLRCR brings public and private partners together to address the most difficult cancer research challenges. Information technology accelerates cancer research by empowering scientists and clinicians with the data and tools they need to drive their research

Intramural Research (+\$2.3 million; total \$1,152.6 million): The increase will support critical NIH shared infrastructure and high priority intramural science that remains an important priority within the overall NCI cancer research portfolio. NCI intramural research will emphasize high-risk, high-reward cancer research that would otherwise not be conducted by other entities.

Training Awards (+\$1.8 million; total \$96.1 million): The increase will be used to support stipend increases and childcare allowances. 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 NCI serves. During FY 2023, NCI will prioritize support for training mechanisms that emphasize progress towards research independence.

Buildings and Facilities (+\$0.0 million; total \$30.0 million): The NCI Federally Funded Research and Development Center in Frederick has many buildings that are over 50 years old. During FY 2023, 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.

Budget Mechanism Table

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Budget Mechanism ^{*,1}

(Dollars in Thousands)

Mechanism	FY 2021 Final ²		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Projects:								
Noncompeting	3,641	\$1,982,735	3,670	\$2,048,117	3,691	\$2,086,681	21	\$38,564
Administrative Supplements	(283)	\$40,531	(267)	\$38,750	(232)	\$33,760	-35	-\$4,990
Competing:								
Renewal	118	\$71,408	106	\$64,294	114	\$66,283	8	\$1,990
New	1,215	\$579,545	1,098	\$526,342	1,174	\$536,667	76	\$10,325
Supplements	9	\$2,875	14	\$4,723	16	\$5,693	2	\$970
Subtotal, Competing	1,342	\$653,827	1,218	\$595,359	1,304	\$608,643	86	\$13,284
Subtotal, RPGs	4,983	\$2,677,094	4,888	\$2,682,225	4,995	\$2,729,083	107	\$46,858
SBIR/STTR	238	\$158,269	231	\$154,260	238	\$158,793	7	\$4,532
Research Project Grants	5,221	\$2,835,363	5,119	\$2,836,486	5,233	\$2,887,876	114	\$51,390
Research Centers								
Specialized/Comprehensive	252	\$586,148	247	\$579,804	269	\$616,970	22	\$37,165
Clinical Research	0	\$0	0	\$0	0	\$0	0	\$0
Biotechnology	0	\$0	0	\$0	0	\$0	0	\$0
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	252	\$586,148	247	\$579,804	269	\$616,970	22	\$37,165
Other Research:								
Research Careers	524	\$102,655	537	\$105,046	544	\$106,500	7	\$1,454
Cancer Education	68	\$17,633	25	\$17,650	30	\$21,439	5	\$3,789
Cooperative Clinical Research	106	\$300,690	103	\$292,204	109	\$309,331	6	\$17,127
Biomedical Research Support	0	\$0	0	\$0	0	\$0	0	\$0
Minority Biomedical Research Support	0	\$1,497	0	\$1,500	0	\$1,500	0	\$0
Other	224	\$173,334	254	\$177,300	246	\$199,811	-8	\$22,511
Other Research	922	\$595,810	919	\$593,700	929	\$638,581	10	\$44,880
Total Research Grants	6,395	\$4,017,321	6,285	\$4,009,991	6,431	\$4,143,427	146	\$133,436
Ruth L Kirschstein Training Awards:	FTEPs		FTEPs		FTEPs		FTEPs	
Individual Awards	696	\$31,872	696	\$32,318	696	\$32,932	0	\$614
Institutional Awards	932	\$61,123	932	\$61,979	932	\$63,157	0	\$1,178
Total Research Training	1,628	\$92,995	1,628	\$94,297	1,628	\$96,089	0	\$1,792
Research & Develop. Contracts	436	\$831,685	436	\$807,954	434	\$814,903	-2	\$6,949
<i>SBIR/STTR (non-add)</i>	<i>(44)</i>	<i>(\$20,917)</i>	<i>(52)</i>	<i>(\$24,481)</i>	<i>(53)</i>	<i>(\$24,853)</i>	<i>(1)</i>	<i>(\$372)</i>
Intramural Research	1,766	\$1,104,819	1,857	\$1,150,293	1,900	\$1,152,600	43	\$2,307
Res. Management & Support	1,331	\$462,877	1,388	\$467,317	1,420	\$476,832	32	\$9,515
<i>SBIR Admin. (non-add)</i>	<i>(0)</i>	<i>(\$3,057)</i>	<i>(0)</i>	<i>(\$3,057)</i>	<i>(0)</i>	<i>(\$3,000)</i>	<i>(0)</i>	<i>-\$57)</i>
Construction		\$0		\$0		\$0		\$0
Buildings and Facilities		\$30,000		\$30,000		\$30,000		\$0
Total, NCI	3,097	\$6,539,696	3,245	\$6,559,852	3,320	\$6,713,851	75	\$153,999

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

¹ Of which \$195.0 million in FY 2021, \$195.0 million in FY 2022, and \$216.0 million in FY 2023 are derived by transfer from the NIH Innovation Account under the 21st Century Cures Act.

² Includes 21st Century Cures Act funding not obligated in FY 2021, and carried over into FY 2022.

Appropriations Language

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

For carrying out section 301 and title IV of the PHS Act with respect to cancer, \$6,497,851,000, 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, \$1,085,000,000, 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.

Summary of Changes

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

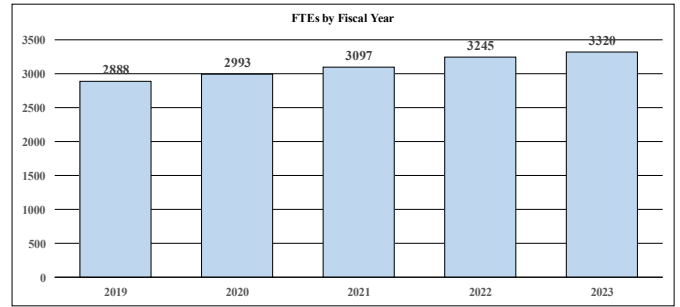
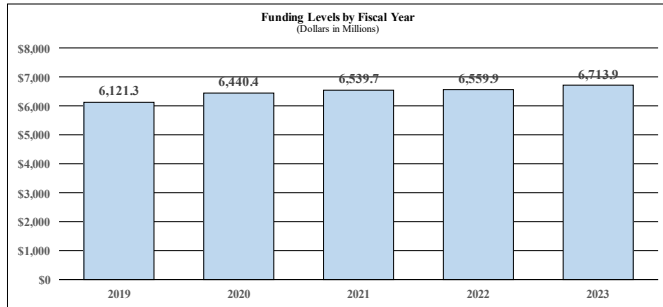
Summary of Changes (Dollars in Thousands)

FY 2022 CR	\$6,559,852
FY 2023 President's Budget	\$6,713,851
Net change	\$153,999

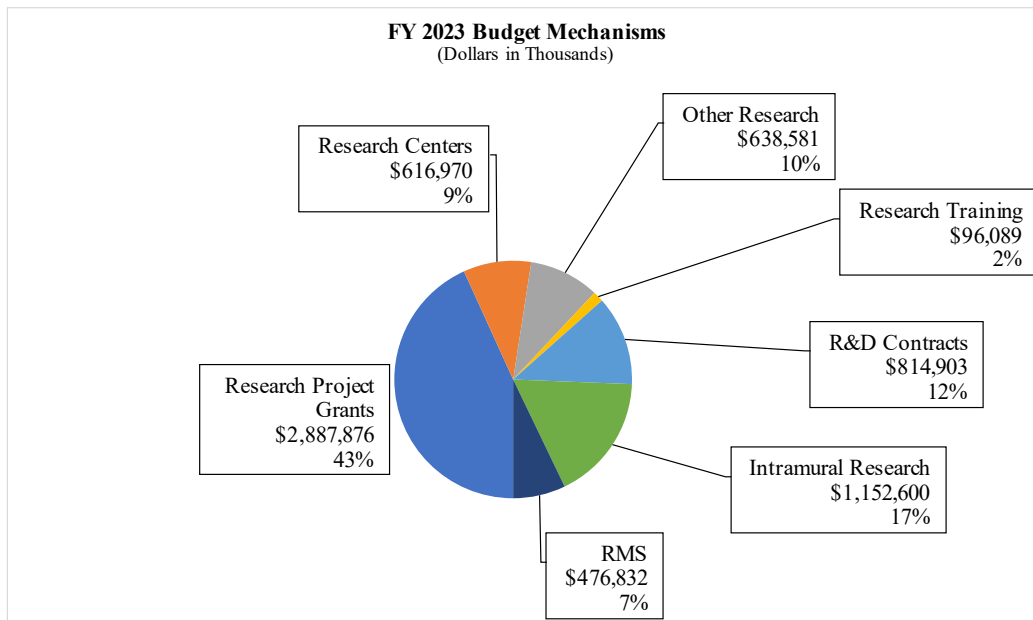
CHANGES	FY 2022 CR		FY 2023 President's Budget		Built-In Change from FY 2022 CR	
	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2022 pay increase & benefits		\$408,570		\$425,334		\$12,076
b. January FY 2023 pay increase & benefits		\$408,570		\$425,334		\$16,529
c. Paid days adjustment		\$408,570		\$425,334		-\$1,565
d. Differences attributable to change in FTE		\$408,570		\$425,334		\$9,461
e. Payment for centrally furnished services		\$182,972		\$186,631		\$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		\$558,751		\$540,635		\$15,868
Subtotal						\$52,369
2. Research Management and Support:						
a. Annualization of January 2022 pay increase & benefits		\$259,338		\$270,170		\$7,718
b. January FY 2023 pay increase & benefits		\$259,338		\$270,170		\$10,486
c. Paid days adjustment		\$259,338		\$270,170		-\$993
d. Differences attributable to change in FTE		\$259,338		\$270,170		\$5,979
e. Payment for centrally furnished services		\$28,827		\$29,404		\$0
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		\$179,151		\$177,259		\$4,380
Subtotal						\$27,570
Subtotal, Built-in						\$79,938
CHANGES	FY 2022 CR		FY 2023 President's Budget		Program Change from FY 2022 CR	
	No.	Amount	No.	Amount	No.	Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	3,670	\$2,086,867	3,691	\$2,120,440	21	\$33,574
b. Competing	1,218	\$595,359	1,304	\$608,643	86	\$13,284
c. SBIR/STTR	231	\$154,260	238	\$158,793	7	\$4,532
Subtotal, RPGs	5,119	\$2,836,486	5,233	\$2,887,876	114	\$51,390
2. Research Centers	247	\$579,804	269	\$616,970	22	\$37,165
3. Other Research	919	\$593,700	929	\$638,581	10	\$44,880
4. Research Training	1,628	\$94,297	1,628	\$96,089	0	\$1,792
5. Research and development contracts	436	\$807,954	434	\$814,903	-2	\$6,949
Subtotal, Extramural		\$4,912,242		\$5,054,419		\$142,176
6. Intramural Research	1,857	\$1,150,293	1,900	\$1,152,600	43	-\$50,061
7. Research Management and Support	1,388	\$467,317	1,420	\$476,832	32	-\$18,054
8. Construction		\$0		\$0		\$0
9. Buildings and Facilities		\$30,000		\$30,000		\$0
Subtotal, Program	3,245	\$6,559,852	3,320	\$6,713,851	75	\$74,061
Total built-in and program changes						\$153,999

Budget Graphs

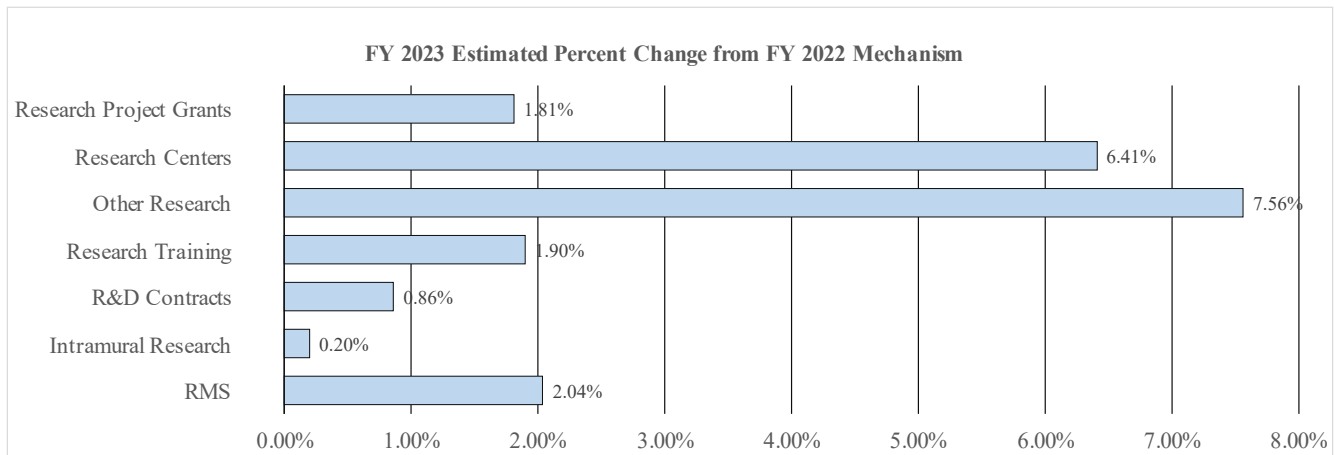
History of Budget Authority and FTEs:



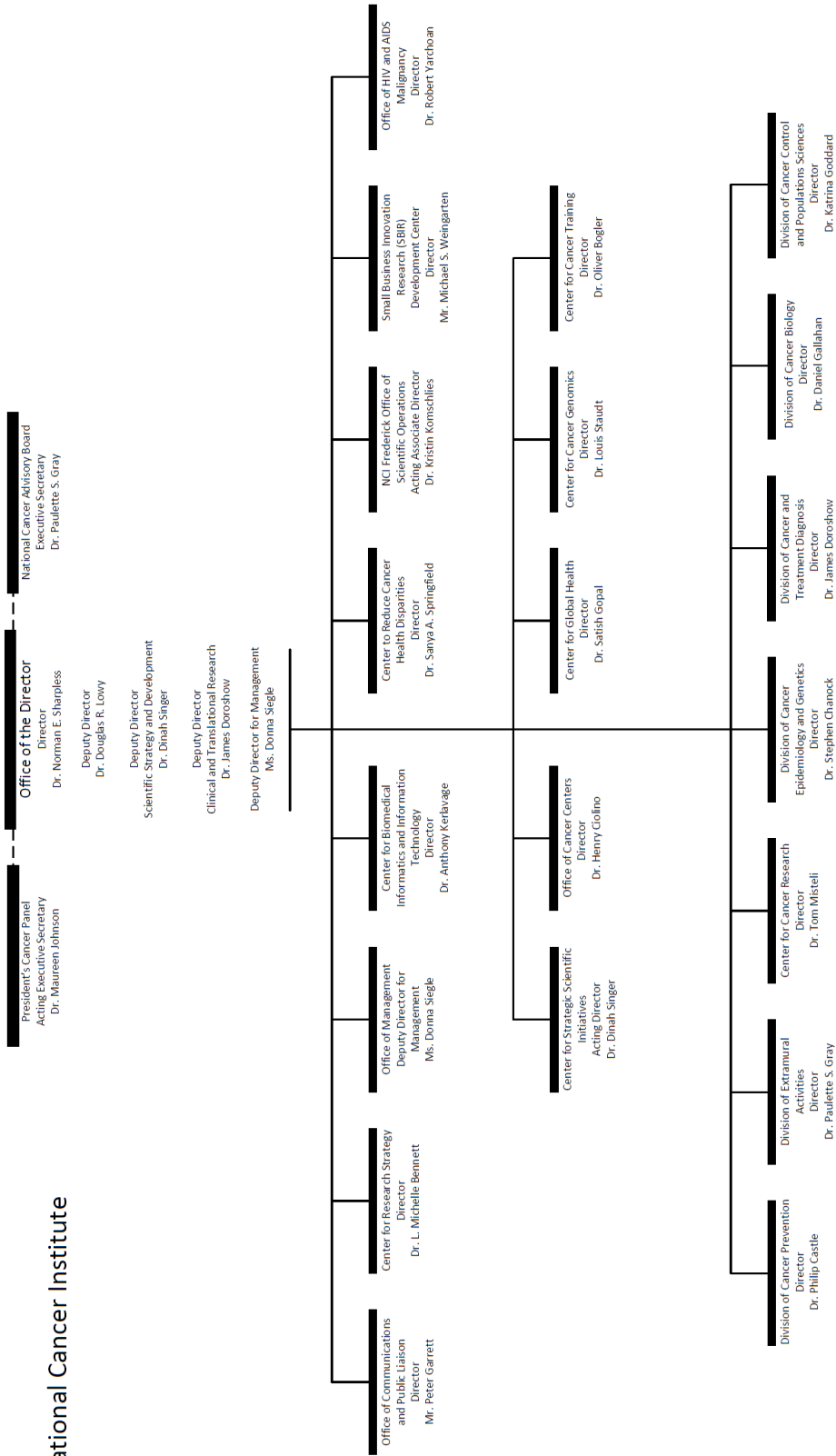
Distribution by Mechanism:



Change by Selected Mechanism



Organization Chart



National Cancer Institute

Budget Authority by Activity Table

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

Budget Authority by Activity * (Dollars in Thousands)

	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022 CR	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
<u>Extramural Research</u>								
<u>Detail</u>								
Understanding How Cancer Develops		\$975,992		\$966,119		\$989,313		\$23,194
Understanding the Causes of Cancer		\$1,040,935		\$1,029,576		\$1,054,806		\$25,230
Detecting and Diagnosing Cancer		\$571,294		\$566,905		\$580,358		\$13,454
Treating Cancer and Improving Survivorship		\$1,283,730		\$1,272,414		\$1,302,774		\$30,360
Improving Cancer Prevention and Control		\$237,105		\$235,177		\$240,770		\$5,593
Cancer Centers		\$576,521		\$579,558		\$616,870		\$37,312
Research Workforce Development		\$211,125		\$216,994		\$224,028		\$7,034
Repairs and Improvements		\$30,000		\$30,000		\$30,000		\$0
Childhood Cancer Data Initiative (CCDI) ¹		\$45,300		\$45,500		\$45,500		\$0
Subtotal, Extramural		\$4,972,001		\$4,942,242		\$5,084,419		\$142,176
Intramural Research	1,766	\$1,104,819	1,857	\$1,150,293	1,900	\$1,152,600	43	\$2,307
Research Management & Support	1,331	\$462,877	1,388	\$467,317	1,420	\$476,832	32	\$9,515
TOTAL	3,097	\$6,539,696	3,245	\$6,559,852	3,320	\$6,713,851	75	\$153,999

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

¹ Includes CCDI extramural program costs. Total CCDI costs, including intramural research, are \$50.0 million in each year from FY 2021 through FY 2023.

Justification of Budget Request

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	\$6,539,696,000	\$6,559,852,000	\$6,713,851,000	\$153,999,000
FTE	3,097	3,245	3,320	75

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

Overall Budget Policy: The FY 2023 President's Budget request is \$6,713.9 million, an increase of \$154.0 million or 2.3 percent compared with the FY 2022 Continuing Resolution (CR) level. The Budget includes \$216.0 million to support the ongoing 21st Century Cures Act Cancer Moonshot efforts including outyear commitments for existing projects. The overall increase for NCI in FY 2023 includes \$20.0 million for increased research in the area of health disparities.

Program Descriptions

NCI supports 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 advance these goals, NCI issues grants for investigator-initiated research, conducts clinical trials, and finances a broad range of other science programs. NCI selects and supports NCI-designated Cancer Centers, and conducts basic, clinical, and population research through its intramural program. NCI also manages research contracts, including a Federally Funded Research and Development Center (FFRDC) that serves the Frederick National Laboratory for Cancer Research, and operates research facilities to support NCI FFRDC and intramural science.

Investigator-initiated research project grants constitute a large portion of the research investment for all five scientific goals. During FY 2021, NCI issued 7,185 grant awards across all grant mechanisms, including 3,269 traditional research project (R01) and 299 exploratory (R21) grants.² These grant awards include 103 grants through the 21st Century Cures Act. Also during FY 2020, more than 50,000 new patients enrolled in over 750 clinical trials that NCI sponsored

² Grant counts include grants awarded in FY 2021 from Cures funding carried over from previous years, and exclude grants anticipated to be awarded from FY 2021 Cures funding carried over into future years.

or supported. Half of these patients are enrolled in trials supported by the National Clinical Trials Network (NCTN) and the NCI Community Oncology Research Network (NCORP). NCI sponsored trials include trials coordinated by NCTN, NCORP, and other networks, where NCI funds infrastructure and other costs to support the networks and the trials. NCI-supported trials are trials that investigators conduct with NCI grant funding other than the awards to networks. Support for these trials often comes from R01 grants.

The narratives that follow highlight NCI programs and progress in each scientific area, as well as future activities. However, virtually all NCI research under one scientific goal influences the approaches used to advance other areas of science. The breadth and complexity of NCI research precludes a complete review of all NCI programs in this document. Further details appear at www.cancer.gov. Examples that follow offer an overview of initiatives and accomplishments but understate the vast amount of NCI work that advances and contributes to the National Cancer Program.

I. Understanding How Cancer Develops

Cancer is driven by alterations of a cell's genome (DNA) as well as the RNAs and 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, epigenetic, and non-genetic changes that occur in cancer cells and the surrounding tumor microenvironment.

To better understand how cancer develops, NCI supports large-scale, high-throughput studies of the genes, RNAs, proteins, and pathways altered in cancer. In addition, NCI funds studies of basic cell biology, cell interactions, tumor angiogenesis (blood vessels that form to support a tumor), immune responses, and related research to understand the mechanisms that cause cancer to develop and progress. NCI also supports laboratory studies in 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:

Basic Research Builds Understanding of Cancer Health Disparities – To understand why certain populations experience unequal burden from cancer, NCI supports studies to investigate the biological and genetic causes of cancer health disparities. These studies are yielding insights into the molecular basis for disparities, especially in underrepresented populations that more often experience health disparities. Identifying such differences may offer new opportunities to develop targeted early screening, detection, prevention, and treatment strategies that can reduce disparities. One example of NCI efforts to understand and address cancer health disparities is a new research program that seeks to identify best practices for increasing participation of underrepresented populations in NCI-supported clinical trials.

Genomics of Lung Cancer in Never Smokers – Ten to twenty percent of lung cancers occur in patients who never smoked. Expanding our knowledge of the causes of lung cancer in those who never smoked offers the potential to improve how we detect and treat lung cancer in both smokers and non-smokers. To advance this priority, in 2021, NCI scientists analyzed tumor genomes of never smokers to identify cancers that were either rapid or slow growing. The NCI analysis of the slow-growing tumors revealed novel stem cell-like features. The mutational

signatures of the slow growing tumors were associated with damage that occurred due to endogenous changes, that is, changes originating from within the body. A further finding was that, for patients who reported exposure to secondhand tobacco smoke, researchers found no mutational signatures associated with smoking. NCI plans further research to verify this finding.

Human Tumor Atlas Network (HTAN) – Through HTAN, investigators have constructed comprehensive analyses of six human tumors: colon, lung, breast, pancreas, melanoma, and pediatric leukemia. The atlases for these tumors range from pre-cancer specimens to metastatic disease. NCI is also working to develop seven other HTAN atlases. Recent advances in imaging and the maturity of an array of ‘omics technologies (genomics, proteomics, microbiomics, etc.) now serve as the foundation for HTAN and the research that HTAN supports. The full breadth of these technologies has allowed HTAN to produce molecularly defined, single-cell atlases of tumors as they progress from pre-cancer to cancer, as they transition from locally invasive to metastatic disease, and as they respond or resist therapy. HTAN serves as a powerful resource for the cancer research community. In a parallel development, NCI also has established a new Single Cell Analysis Facility to map tumors and gain insights into their mechanisms.

Research to Understand and Inhibit Metastasis – Many cancer treatments are effective in patients with primary tumors (tumors found in the original, first site in the body), but not in patients with metastatic disease. Using advanced genetic analysis to compare a patient’s primary tumor and metastatic tissue, investigators discovered that cells can metastasize before the primary tumor is detected. This discovery has transformed our understanding of how and when tumors metastasize. As part of the new Metastasis Research Network (MRN) launched in 2021, NCI funded four diverse teams to build on these findings and discover the mechanisms by which cells metastasize to different organs, how other cells and tissues either promote or inhibit these processes, and how such insights can be used to address or prevent metastatic cancers. NCI plans to fund additional MRN research teams in 2022.

Budget Policy: The FY 2023 President’s Budget request for this area is \$989.3 million, an increase of \$23.2 million or 2.4 percent compared with the FY 2022 CR level.

II. Understanding the Causes of Cancer

Cancer develops through a complex interplay of factors, including genetics, environmental exposure, 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, a variant of a gene, or a combination of genes. In other cases, cancer risk is influenced by external factors, such as exposure to tobacco or infectious agents.

Understanding the interactions among genetic, environmental, and lifestyle factors will improve the ability of scientists to prevent, detect, diagnose, and treat cancers at the earliest possible time. NCI-funded studies on the causes of cancer range from 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 continues to strive to identify the causes of cancer.

Examples include:

Blood Samples Identify Environmental Factors that Cause Cancer – Biological samples collected decades ago are now revealing markers of environmental exposure that may be linked to future cancer risk. In 2021, NCI conducted the first study of general population exposure to perfluorooctanoic acid (PFOA), a ubiquitous and highly persistent chemical. NCI found that for each doubling in blood serum concentrations of PFOA, there was an estimated 70 percent increase in the risk of kidney cancer. By identifying links between environmental contaminants and cancer, NCI research can safeguard public health and inform the decision making of regulatory agencies.

Impact of Diet on Cancer, Tumor Metabolism, and Immunity – The public faces a barrage of choices and misinformation about diet and its relationship to cancer. Nutritional deficiencies and some nutritional excesses have been shown to affect cancer initiation, development, treatment, and survivorship. Studies suggest that healthy diets may improve cancer outcomes, especially in populations with below normal ranges of dietary intake. Clinical investigations have also shown that supplementing diet with specific nutrients often fails to have benefit. NCI is supporting research to gain a deeper understanding of the basic biology underlying diet and cancer to improve our ability to measure dietary effects and to identify areas of research for further study.

Genetic and Genomic Effects of Ionizing Radiation – The radioactive fallout from the 1986 Chernobyl nuclear power plant accident caused an unprecedented increase in thyroid cancer among exposed children. Since 2000, NCI has supported the Chernobyl Tissue Bank to foster global research on carefully collected and preserved samples of thyroid cancers. NCI researchers recently used next-generation DNA sequencing of the tumors to discover the genetic changes due to ionizing radiation exposure that causes cancer. This research also examined inherited DNA of children born to exposed adults and found no evidence of increased genetic changes in these children compared to either parent.

Budget Policy: The FY 2023 President’s Budget request for this area is \$1,054.8 million, an increase of \$25.2 million or 2.5 percent compared with the FY 2022 CR 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 – including 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 early cancer detection and diagnosis. These include –

- 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.
- Maintaining infrastructure and programs such as the Genomic Data Commons, the Cancer Genome Characterization Initiative, and The Cancer Genome Atlas (a collaboration with the National Human Genome Research Institute) to support the cancer research enterprise.

Investigator-initiated research project grants are one mechanism NCI relies on to support and improve early detection and diagnosis of cancer. Other initiatives under this goal include:

Identifying Families at High Risk of Cancer – There is currently limited use of genetic testing in those diagnosed with hereditary cancers, such as hereditary breast, ovarian, endometrial (cancer that forms in the tissue lining the uterus) and colon cancers. This constitutes a missed opportunity to assess risk and offer preventive options to family members who may be at high risk of developing these cancers. To improve how we identify these high-risk families, NCI is funding a program called Traceback, which uses medical records and community outreach to find and test tumors gathered from previously diagnosed cases, including those from under-represented populations. Traceback is also assessing the ethical considerations for communicating genetic results to patient and family members.

Reducing Prostate Cancer Over-Diagnosis and Over-Treatment – Despite advances in imaging and growing acceptance of active surveillance for patients who do not need immediate therapy, over-diagnosis and over-treatment of prostate cancer are continuing challenges. NCI is supporting research to refine the precision and targeting of technologies that detect aggressive cancers and distinguish them from indolent, slow-growing disease. NCI is also conducting research on interventions to slow or prevent disease progression during active surveillance.

Treatment Implementation and De-Implementation – Evidence-based practices can improve cancer outcomes at every stage of the care continuum. Conversely, there is a benefit to ending the use of interventions that are ineffective, low-value, or harmful. Working with other NIH institutes and centers, NCI joined the trans-NIH research funding announcement, “Dissemination and Implementation (D&I) Research in Health.” Separately, through the Cancer Moonshot, NCI is also funding a series of centers to support research to improve how clinicians adopt, implement, and sustain evidence-based cancer care across diverse practice settings.

Cancer Technologies for Low-Resource Settings – Many established cancer control technologies are not suitable for low-resource settings due to their cost or because they require extensive medical infrastructure that is not readily available. Since 2014, the NCI Affordable Cancer Technologies (ACTs) program has supported testing and validating resource-appropriate technologies suitable for low- and middle-income countries. These technologies are designed for use by health workers at the clinical point-of-need for use in a diverse range of health care settings. ACTs is advancing global cancer control by commercializing suitable technologies. These technologies are generating data that are influencing international practice guidelines.

Data to Support Cancer Discovery – To understand the multiple risk factors for cancer and to improve cancer outcomes, collecting and sharing data are essential, especially for discovery related to rare cancers. NCI broadly supports sharing, aggregating, and analyzing the large amount of data generated throughout the continuum of cancer research, surveillance, and clinical care. This includes a cancer data ecosystem known as the Cancer Research Data Commons (CRDC). CRDC aggregates and shares data from studies including data on genomics, proteomics, imaging, immuno-oncology, trials, and canine models. Future plans for the CRDC include a new coordinating center and a data commons for clinical data and population science.

NCI also facilitates collaboration and drives research across the cancer control continuum by supporting programs such as the NCI Cohort Consortium, which pools data to address critical scientific questions. Another program, the NCI Surveillance, Epidemiology, and End Results (SEER) Program, collects and shares cancer incidence and survival data representing nearly 50 percent of the U.S. population. SEER data are the basis for key reports to the nation on cancer trends. Progress in understanding the causes of cancer and improving cancer outcomes requires sharing data to leverage other NCI research investments.

Advancing Cancer Research with Artificial Intelligence (AI) – To date, AI has shown greatest promise where it can outperform clinical experts in detecting features in medical images that predict cancer stage and outcome. However, AI also has potential to accelerate discoveries and advances across the cancer research continuum. To advance this field, NCI is partnering with the Department of Energy and the FDA to curate large, well-characterized datasets to support cancer discovery and to provide the computational infrastructure necessary to develop AI-driven research. NCI is further leveraging these activities by fostering trans-disciplinary networks to accelerate the strategic use of AI to address other compelling challenges in cancer research.

Budget Policy: The FY 2023 President’s Budget request for this area is \$580.4 million, an increase of \$13.5 million or 2.4 percent compared with the FY 2022 CR 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 patients. 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 supports basic, translational, and clinical research to identify therapeutic targets and strategies. Commercial entities frequently validate these targets and develop interventions against them. NCI also supports clinical research to develop and test interventions at sites across the country. Examples of these priorities include:

COVID Immunity in Cancer Patients – NCI is using COVID-19 supplemental appropriations to support the Serological Sciences Network (SeroNet), a national research network dedicated to studying all aspects of the immune response to SARS-CoV-2 infection and vaccination. The research is especially relevant for cancer patients who are immunosuppressed due to their disease or treatment, and are more likely to have worse outcomes from COVID-19. SeroNet is providing critical data to cancer clinicians and the overall population on questions such as the breath and duration of the immune response to COVID-19 infection and vaccination, and whether or when a vaccine booster is needed.

NCI Childhood Cancer Data Initiative (CCDI) – With so few patients for each type of childhood cancer, NCI must optimize how researchers collect, analyze, and share research results and clinical care data for children, adolescents, and young adults diagnosed with cancer. In its initial years, CCDI sought to maximize data sharing from childhood cancer research and build a foundation of infrastructure and tools for further CCDI work. Future activities include –

- Gathering data from every child, adolescent, and young adult diagnosed with cancer, regardless of where they receive their care
- Developing a federated platform of repositories and analytical tools for clinical care and research data that allows researchers and clinicians to improve cancer prevention, diagnosis, treatment, and survivorship for all childhood cancers
- Creating a national strategy for appropriately characterizing clinical and molecular data on childhood cancers and implementing this strategy to speed diagnosis and provide insights on optimum treatment for all types of childhood cancers.

The FY 2023 President’s Budget request for CCDI, including both extramural and intramural costs, is \$50.0 million, held flat at the the FY 2022 CR level.

Improving Outcomes for Cancer Survivors – Adverse cardiovascular outcomes due to cancer treatments affect the quality, functionality, and longevity of pediatric, adolescent and young adult (AYA), and adult cancer survivors. Studies suggest that more than 60 percent of pediatric and AYA cancer survivors suffer adverse outcomes months or years after completing treatment. To address this challenge, NCI is implementing the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act, which advances research to improve survivorship for pediatric and AYA populations. Developing feasible and scalable interventions that minimize cardiotoxicity in young patients is one example of a STAR Act priority.

Working with the National Heart, Lung, and Blood Institute (NHLBI), NCI is also supporting research on adult treatment-related cardiotoxicity to understand the mechanisms of toxicity on the heart and vascular system, identify those at risk, and prevent cardiac damage before it occurs. Through this research, NCI seeks to improve the lives of pediatric and adult cancer survivors.

Addressing Tolerability of Cancer Treatment – Cancer clinical trials assess safety and toxicity, but not toxicity over time. A Cancer Moonshot-funded consortium of investigators is developing methods to combine clinician reported adverse events with patient reported symptomatic events and other data to assess how patients tolerate cancer treatment. In addition, NCI intramural researchers are using patient reported outcomes to understand the enduring impact of cancer and treatments throughout the course of disease. The researchers are also exploring ways to use patient reported outcomes in early phase and precision medicine trials.

Community and Patient Engagement (COE) in Cancer Research – COE promotes an understanding of cancer that is holistic, transdisciplinary, culturally sensitive and inclusive. In FY 2020, NCI provided funding to 23 NCI-designated cancer centers for programs that engage with communities and coalitions to disseminate evidence-based interventions, public education, and public health recommendations on COE, and to demonstrate how COE contributes to scientific outcomes. NCI also supports COE in clinical trials and in Cancer Moonshot programs.

Increasing Diversity in Clinical Trials – NCI seeks to enhance diversity in clinical trials by supporting research sites that serve diverse communities. For example, the NCI CATCH-UP initiative – Create Access to Targeted Cancer Therapy for Underserved Populations – supports eight NCI-designated cancer centers as they develop programs to enhance access by minority and underserved populations to early phase precision medicine cancer trials.

Broadening Eligibility in Clinical Trials – Trials with narrow eligibility criteria that exclude patients with co-morbidities are a major barrier to enrolling diverse populations. Through its clinical trials network, NCI is evaluating ways to broaden eligibility criteria. This includes identifying eligibility criteria that may require more focused clinical review and engaging with investigators as they design trials to ensure broad patient access to these trials.

Cancer Models for Disparities Research – Developing new models for research using tissues from patients whose characteristics are underrepresented among individuals participating in clinical trials helps to ensure that advances in precision cancer treatment reflect and benefit all segments of the U.S. population. Emphasizing diversity when planning pre-clinical cancer studies improves the design, recruitment, and outcomes of early phase clinical trials in ways that generate new insights into the causes of cancer disparities.

MyeloMATCH Clinical Trial – Launched in 2015, the NCI MATCH precision medicine clinical trial matched the molecular mutations of patient’s tumors with targeted therapies, without regard to the site of the cancer. NCI enrolled and screened more than 6,000 patients with advanced relapsed cancers for possible assignment to MATCH treatments.

In 2021, building on the success of this approach, NCI commenced MyeloMATCH, a precision medicine initiative in myeloid cancers to study patients from initial diagnosis and throughout their course of treatment. MyeloMATCH employs advanced tumor genomics to change the treatment paradigm for acute myeloid leukemia and myelodysplastic syndromes. The standard approach, which has not changed in decades, involved treating patients, then carefully monitoring them for relapse. In contrast, MyeloMATCH uses the NCI MATCH trial design to assess whether clinicians can prevent relapse by precision targeting of any residual cancer.

Budget Policy: The FY 2023 President’s Budget request is \$1,302.8 million, an increase of \$30.4 million or 2.4 percent compared with the FY 2022 CR level.

V. Improving Cancer Prevention and Control

Cancer prevention and control research focuses on identifying ways to reduce cancer risk and improve cancer outcomes at the individual and population levels. NCI supports a broad range of research, including studies to characterize molecular changes associated with how cancer initiates and progresses, that can become the basis for developing therapies and other interventions to target these mechanisms. NCI research also focuses on ways to reduce exposures to cancer-causing substances and increase healthy behaviors. Other research focuses on integrating proven, effective interventions into routine care. NCI also funds studies in underserved communities to advance the goal of controlling cancer more effectively for all populations. Through education, behavior modification, vaccination and other preventive treatments, and through policies that limit exposures to carcinogens, 30 to 50 percent of cancers could be prevented.

Cancer control science relies on basic and applied research in behavioral, social, and population sciences to reduce cancer risk, incidence, morbidity, and mortality, and improve quality of life. Cancer control seeks to understand the causes and distribution of cancer in the population, identify and implement effective healthcare practices to reduce cancer incidence, and monitor and explain cancer trends and disparities in the population. Cancer control research generates basic knowledge about monitoring and changing behavior and translates 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. 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:

Persistent Poverty and Cancer Mortality – Populations living in persistent poverty face higher rates of cancer morbidity and mortality. This underscores the need to identify and implement evidence-based cancer prevention and control practices to serve these populations. With this goal in mind, in FY 2021, NCI awarded research supplements to NCI-designated cancer centers. The supplements support multidisciplinary research teams that collaborate with clinics serving populations living in areas of persistent poverty. Each team will plan, implement, and sustain a cancer prevention and control program focused on low-income and underserved populations.

Vaccines for Precision Cancer Prevention in Lynch Syndrome (LS) – LS is the most common hereditary cancer syndrome, causing genetic mutations that can be passed to offspring. LS patients have significantly increased risk of developing colon, endometrial, and other cancers. Cancers occurring in LS patients express specific mutant peptides, known as neoantigens, due to LS-driven genetic defects. In preclinical studies, NCI demonstrated that vaccines that precisely target the neoantigens can significantly boost immune response and slow cancer growth. NCI is using this knowledge to develop vaccine strategies for LS patients.

Cancer Grand Challenges – In August 2020, NCI joined with Cancer Research U.K. to launch Cancer Grand Challenges (CGC), an initiative funding research to address some of the most profound, unresolved questions in cancer. By joining forces, NCI and Cancer Research U.K. seek to accelerate the pace of cancer science, stimulate scientific creativity of the highest caliber, and make bold progress to understand, prevent, detect, and treat cancer.

CGC posed nine cancer challenges to the research community, seeking compelling ideas from multidisciplinary, multi-national teams to solve these research challenges. In the spring of 2022, NCI and Cancer Research U.K. will issue awards to support the most promising research proposals. The successful teams will then commence their research, striving to advance cancer science and improve outcomes for people affected by cancer.

Promoting of Global Cancer Control – By 2040 an estimated 69 percent of cancer deaths will occur in low resource settings – countries or regions that experience infrastructure limits or other constraints. Many advances in cancer prevention and control have failed to enter clinical practice due to resource constraints in these settings. To respond to this challenge, NCI facilitates knowledge exchange across the scientific community and among policymakers to strengthen global cancer control. One such engagement is the International Cancer Control Partnership, a coalition of 25 international organizations founded by NCI that advise countries as they develop, implement, and evaluate data-driven national cancer control plans.

Budget Policy: The FY 2023 President’s Budget request is \$240.8 million, an increase of \$5.6 million or 2.4 percent compared with the FY 2022 CR level.

VI. Cancer Centers

The NCI Cancer Centers program is a cornerstone of the nation’s cancer research program. Together with their community partners, the 71 NCI-designated Cancer Centers form the backbone of NCI’s extramural program for studying and controlling cancer. NCI 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 the investigator-initiated grants NCI issues.

Examples of the cancer center clinical trials that led to recent FDA approvals include:

- Based on research led by a team at the Lurie Cancer Center of Northwestern University, FDA approved the drug olaparib (Lynparza) for men with metastatic prostate cancer that showed certain genetic changes where the cancer progressed following previous therapies, including hormone therapy. Patients who received this olaparib showed longer overall survival when compared to other therapies.
- Based on research led by a team at the Fred Hutchinson - University of Washington Cancer Consortium, FDA approved the drug avelumab (Bavencio) for patients with advanced urothelial cancer. The study by this cancer center demonstrated that patients who received the immune-boosting drug following chemotherapy lived longer than those who did not receive the therapy.

Budget Policy: The FY 2023 President’s Budget request is \$616.9 million, an increase of \$37.3 million or 6.4 percent compared with the FY 2022 CR level.

VII. Research Workforce Development

NCI has a longstanding commitment to train, develop, and support a strong and diverse workforce of researchers spanning the career continuum. Support for early-stage investigators attracts talented scientists and ensures the future strength of cancer research. In addition to direct support for training, NCI grants awarded to established investigators – scientists with a proven ability to conduct robust science – fosters mentoring for a new generation of cancer researchers.

Center to Reduce Cancer Health Disparities – NCI supports programs to develop and maintain a robust cancer research workforce that reflects the nation NCI serves. At NCI, the Center to Reduce Cancer Health Disparities (CRCHD) plays a vital role to advance this goal. Examples of the breadth of CRCHD programs in health disparities include:

Continuing Umbrella of Research Experiences (CURE) provides research training and career development to middle school students through early stage investigators for those from underrepresented backgrounds, supporting their progress along the academic pathway to achieve research independence.

Intramural Continuing Umbrella of Research Experiences (iCURE) provides mentored research experience for post-baccalaureate and graduate students and postdoctoral fellows, many from underrepresented backgrounds, who are engaged in intramural research at NCI.

Youth Enjoy Science (YES) Research Education Program promotes cancer research careers among underrepresented students by supporting institution-level, early intervention education for grades 6-12 and for undergraduate students, as well as training to support teachers and faculty.

Partnerships to Advance Cancer Health Equity (PACHE) supports partnerships between NCI-designated Cancer Centers and institutions serving underserved populations and underrepresented students, with special focus on cancer health disparities, research education, and community outreach.

Training Cancer Researchers of the Future – NCI supports a broad array of training to develop cancer researchers of the future. Through formal training, individual fellowships, and career development awards, NCI supports training in basic, clinical, and behavioral research at institutions across the country. Those receiving training grants include pre-doctoral candidates, postdoctoral fellows, and new faculty in independent research positions. NCI also supports research training experiences for high school, college, graduate, and medical school students, and postdoctoral fellows working in NCI intramural research programs.

NCI continues to advance new approaches to strengthen the cancer research workforce. In FY 2020, NCI initiated the NCI Awardee Skills Development Consortium (NASDC) to support training and mentorship for junior faculty. These faculty investigators are at a critical point in their careers. They are expected to survive in a hyper-competitive funding climate and become academic leaders who teach, mentor, and manage research programs. Through NASDC, NCI delivers a suite of courses to teach skills in areas critical to achieving an independent career in academic research. The NASDC network is an opportunity for grantees serving as junior faculty to improve their professional, research, and clinical skills, and enhance their cancer research careers.

NCI is committed to supporting a well-defined career path to research independence for scientists. During FY 2020, NCI funded the fifth F99/K00 training award cohort, supporting the transition from pre-doctoral research to postdoctoral training. This positions awardees to be competitive for a second transition award to advance their research independence, the K99/R00, supporting the transition to tenure-track investigators. Collectively, these mechanisms offer a smoother pathway for making these challenging transitions. Ninety percent of the first two cohorts of F99 awardees successfully transitioned to the K00 phase, securing postdoctoral positions in top laboratories.

Budget Policy: The FY 2023 President's Budget request is \$224.0 million, an increase of \$7.0 million or 3.2 percent compared with the FY 2022 CR level.

VIII. Intramural Research

NCI intramural research complements all aspects of the National Cancer Program. The scientists, physicians, and clinicians in the NCI Intramural Research Program conduct basic, clinical, genomic, and population research. NCI intramural research emphasizes high-risk, high-reward

research that would otherwise not occur. 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 2023 President's Budget request is \$1,152.6 million, an increase of \$2.3 million or 0.2 percent compared with the FY 2022 CR level.

IX. Research Management and Support

NCI research management and support staff serve an indispensable role by enabling the success of all NCI programs. Their activities include central administration, program direction, grant and contract administration, human resources, program coordination, and financial management.

Budget Policy: The FY 2023 President's Budget request is \$476.8 million, an increase of \$9.5 million or 2.0 percent compared with the FY 2022 CR level.

X. Repairs and Improvements

Funding for Repairs and Improvements allows NCI to operate facilities at the Frederick National Laboratory for Cancer Research at Fort Detrick, Maryland, as a modern research enterprise.

Budget Policy: The FY 2023 President's Budget request is \$30.0 million, held flat at the FY 2022 CR level.

Appropriations History

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

Appropriations History¹

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	\$6,494,155,000	\$6,722,656,000	\$6,559,852,000
Rescission				\$0
2022	\$6,733,302,000	\$6,994,056,000	\$6,772,469,000	\$6,559,852,000
Rescission				\$0
2023	\$6,713,851,000			

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.

Authorizing Legislation

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2022 Amount Authorized		FY 2022 CR	2023 Amount Authorized	FY 2023 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	}	\$6,559,852,000	Indefinite	\$6,713,851,000
National Cancer Institute	Section 401(a)	42§281	Indefinite			Indefinite	
Total, Budget Authority					\$6,559,852,000		\$6,713,851,000

Amounts Available for Obligation

**NATIONAL INSTITUTES OF HEALTH
National Cancer Institute**

Amounts Available for Obligation¹
(Dollars in Thousands)

Source of Funding	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation ^{2,3}	\$6,559,852	\$6,559,852	\$6,713,851
Secretary's Transfer	-\$19,109	\$0	\$0
OAR HIV/AIDS Transfers	-\$1,047	\$0	\$0
Subtotal, adjusted budget authority	\$6,539,696	\$6,559,852	\$6,713,851
Unobligated balance, start of year ⁴	\$196,342	\$185,106	\$0
Unobligated balance, end of year (carryover) ⁵	-\$185,106	\$0	\$0
Subtotal, adjusted budget authority	\$6,550,932	\$6,744,958	\$6,713,851
Unobligated balance lapsing	-\$289	\$0	\$0

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2021 - \$24,295 FY 2022 - \$25,000 FY 2023 - \$25,000

² Of which \$195.0 million in FY 2021, \$195.0 million in FY 2022, and \$216.0 million in FY 2023 are 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 2022 and FY 2023.

⁴ In FY 2021, reflects 21st Century Cures Act funding carried over from FY 2017, FY 2018, FY 2019, and FY 2021 into FY 2021. In FY 2022, reflects 21st Century Cures Act funding carried over from FY 2017 through FY 2021 into FY 2022.

⁵ Reflects 21st Century Cures Act funding carried over from FY 2017 through FY 2021 into FY 2022.

Budget Authority by Object Class

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

Budget Authority by Object Class¹ (Dollars in Thousands)

	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Total compensable workyears:			
Full-time equivalent	3,245	3,320	75
Full-time equivalent of overtime and holiday hours	3	3	0
Average ES salary	\$199	\$199	\$0
Average GM/GS grade	12.7	12.7	0.0
Average GM/GS salary	\$126	\$131	\$5
Average salary, Commissioned Corps (42 U.S.C. 207)	\$110	\$115	\$5
Average salary of ungraded positions	\$159	\$165	\$7
OBJECT CLASSES	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel Compensation			
11.1 Full-Time Permanent	\$256,514	\$267,391	\$10,877
11.3 Other Than Full-Time Permanent	\$150,193	\$156,494	\$6,301
11.5 Other Personnel Compensation	\$17,544	\$18,287	\$743
11.7 Military Personnel	\$2,916	\$3,039	\$123
11.8 Special Personnel Services Payments	\$70,076	\$73,016	\$2,941
11.9 Subtotal Personnel Compensation	\$497,243	\$518,228	\$20,985
12.1 Civilian Personnel Benefits	\$168,224	\$174,732	\$6,508
12.2 Military Personnel Benefits	\$2,442	\$2,544	\$102
13.0 Benefits to Former Personnel	\$0	\$0	\$0
Subtotal Pay Costs	\$667,908	\$695,504	\$27,595
21.0 Travel & Transportation of Persons	\$3,739	\$3,816	\$76
22.0 Transportation of Things	\$1,672	\$1,621	-\$52
23.1 Rental Payments to GSA	\$31,448	\$30,013	-\$1,436
23.2 Rental Payments to Others	\$63	\$60	-\$3
23.3 Communications, Utilities & Misc. Charges	\$5,221	\$5,078	-\$143
24.0 Printing & Reproduction	\$28	\$28	-\$0
25.1 Consulting Services	\$338,785	\$341,535	\$2,750
25.2 Other Services	\$500,870	\$505,826	\$4,957
25.3 Purchase of Goods and Services from Government Accounts	\$591,363	\$587,099	-\$4,264
25.4 Operation & Maintenance of Facilities	\$5,559	\$5,478	-\$81
25.5 R&D Contracts	\$298,844	\$303,101	\$4,257
25.6 Medical Care	\$9,628	\$9,524	-\$103
25.7 Operation & Maintenance of Equipment	\$29,301	\$28,013	-\$1,288
25.8 Subsistence & Support of Persons	\$4	\$4	-\$0
25.0 Subtotal Other Contractual Services	\$1,774,353	\$1,780,580	\$6,228
26.0 Supplies & Materials	\$49,069	\$47,154	-\$1,915
31.0 Equipment	\$14,683	\$14,046	-\$637
32.0 Land and Structures	\$2,118	\$2,083	-\$36
33.0 Investments & Loans	\$0	\$0	\$0
41.0 Grants, Subsidies & Contributions	\$4,007,611	\$4,131,961	\$124,350
42.0 Insurance Claims & Indemnities	\$0	\$0	\$0
43.0 Interest & Dividends	\$3	\$3	-\$0
44.0 Refunds	\$0	\$0	\$0
Subtotal Non-Pay Costs	\$5,891,944	\$6,018,347	\$126,404
Total Budget Authority by Object Class	\$6,559,852	\$6,713,851	\$153,999

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

Salaries and Expenses

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Salaries and Expenses

(Dollars in Thousands)

Object Classes	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
<u>Personnel Compensation</u>			
Full-Time Permanent (11.1)	\$256,514	\$267,391	\$10,877
Other Than Full-Time Permanent (11.3)	\$150,193	\$156,494	\$6,301
Other Personnel Compensation (11.5)	\$17,544	\$18,287	\$743
Military Personnel (11.7)	\$2,916	\$3,039	\$123
Special Personnel Services Payments (11.8)	\$70,076	\$73,016	\$2,941
Subtotal, Personnel Compensation (11.9)	\$497,243	\$518,228	\$20,985
Civilian Personnel Benefits (12.1)	\$168,224	\$174,732	\$6,508
Military Personnel Benefits (12.2)	\$2,442	\$2,544	\$102
Benefits to Former Personnel (13.0)	\$0	\$0	\$0
Subtotal Pay Costs	\$667,908	\$695,504	\$27,595
Travel & Transportation of Persons (21.0)	\$3,739	\$3,816	\$76
Transportation of Things (22.0)	\$1,672	\$1,621	-\$52
Rental Payments to Others (23.2)	\$63	\$60	-\$3
Communications, Utilities & Misc. Charges (23.3)	\$5,221	\$5,078	-\$143
Printing & Reproduction (24.0)	\$28	\$28	-\$0
<u>Other Contractual Services</u>			
Consultant Services (25.1)	\$279,394	\$281,204	\$1,810
Other Services (25.2)	\$500,870	\$505,826	\$4,957
Purchase of Goods and Services from Government Accounts (25.3)	\$439,928	\$434,797	-\$5,131
Operation & Maintenance of Facilities (25.4)	\$5,559	\$5,478	-\$81
Operation & Maintenance of Equipment (25.7)	\$29,301	\$28,013	-\$1,288
Subsistence & Support of Persons (25.8)	\$4	\$4	-\$0
Subtotal Other Contractual Services	\$1,255,055	\$1,255,323	\$268
Supplies & Materials (26.0)	\$51,004	\$49,060	-\$1,944
Subtotal Non-Pay Costs	\$1,316,782	\$1,314,984	-\$1,798
Total Administrative Costs	\$1,984,691	\$2,010,488	\$25,797

Detail of Full-Time Equivalent Employment (FTE)

NATIONAL INSTITUTES OF HEALTH National Cancer Institute

Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2021 Final			FY 2022 CR			FY 2023 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Activities									
Direct:	90	2	92	95	2	97	97	2	99
Total:	90	2	92	95	2	97	97	2	99
Office of the Director									
Direct:	859	4	863	894	4	898	915	4	919
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	860	4	864	895	4	899	916	4	920
Center for Cancer Research									
Direct:	1,384	14	1,398	1,461	13	1,474	1,496	13	1,509
Reimbursable:	7	-	7	7	-	7	7	-	7
Total:	1,391	14	1,405	1,468	13	1,481	1,503	13	1,516
Division of Cancer Biology									
Direct:	48	-	48	51	-	51	52	-	52
Total:	48	-	48	51	-	51	52	-	52
Division of Cancer Treatment and Diagnosis									
Direct:	231	2	233	242	2	244	248	2	250
Total:	231	2	233	242	2	244	248	2	250
Division of Cancer Prevention									
Direct:	99	1	100	100	1	101	102	1	103
Total:	99	1	100	100	1	101	102	1	103
Division of Cancer Control and Population Sciences									
Direct:	174	3	177	184	2	186	188	2	190
Reimbursable:	2	-	2	2	-	2	2	-	2
Total:	176	3	179	186	2	188	190	2	192
Division of Cancer Epidemiology and Genetics									
Direct:	174	2	176	182	2	184	186	2	188
Total:	174	2	176	182	2	184	186	2	188
Total	3,069	28	3,097	3,219	26	3,245	3,294	26	3,320
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0
FISCAL YEAR	Average GS Grade								
2019	12.6								
2020	12.6								
2021	12.7								
2022	12.7								
2023	12.7								

Detail of Positions
NATIONAL INSTITUTES OF HEALTH
National Cancer Institute

Detail of Positions¹

GRADE	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Total, ES Positions	2	3	3
Total, ES Salary	\$398,600	\$597,900	\$597,900
General Schedule			
GM/GS-15	318	316	316
GM/GS-14	503	498	510
GM/GS-13	604	622	637
GS-12	396	404	414
GS-11	166	168	173
GS-10	8	8	7
GS-9	98	103	106
GS-8	40	37	37
GS-7	40	41	41
GS-6	9	9	9
GS-5	9	8	8
GS-4	7	6	6
GS-3	5	4	4
GS-2	3	3	3
GS-1	0	0	0
Subtotal	2,206	2,227	2,271
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	13	12	12
Senior Grade	2	2	2
Full Grade	7	7	7
Senior Assistant Grade	6	5	5
Assistant Grade	0	0	0
Subtotal	28	26	26
Ungraded	1,007	1,118	1,149
Total permanent positions	2,152	2,233	2,285
Total positions, end of year	3,243	3,374	3,449
Total full-time equivalent (FTE) employment, end of year	3,097	3,245	3,320
Average ES salary	\$199,300	\$199,300	\$199,300
Average GM/GS grade	12.7	12.7	12.7
Average GM/GS salary	\$122,802	\$125,602	\$130,789

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