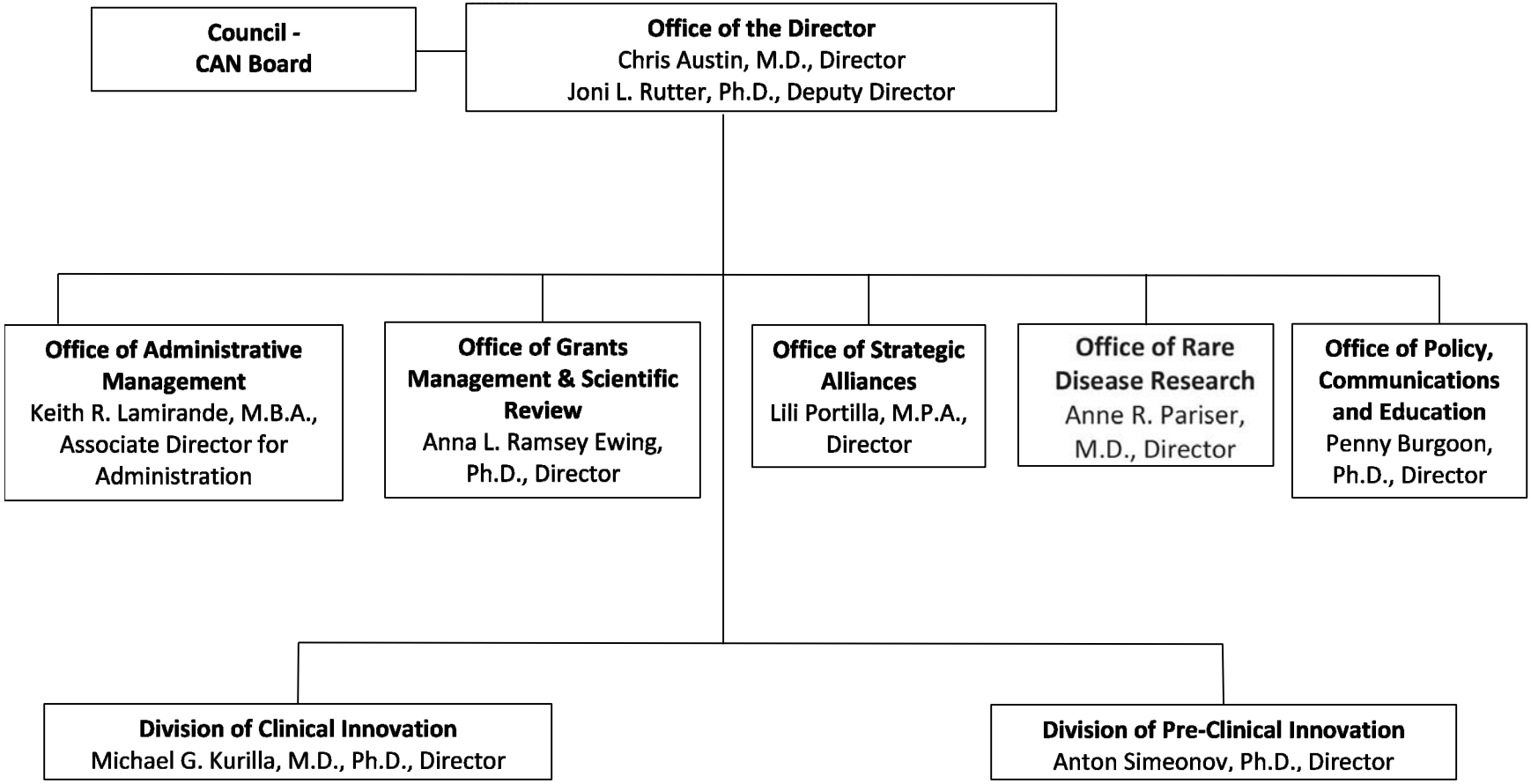
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences



For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, **[**$806,373,000**]***$694,112,000*: *Provided*, That up to **[**$80,000,000**]***10 percent of the amount available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network[: Provided further, That at least $559,736,000 is provided to the Clinical and Translational Sciences Awards program].

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation	$742,354	$806,373	$694,112
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(0)*
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-1,744	0	0
Subtotal, adjusted appropriation	$740,610	$806,373	$694,112
OAR HIV/AIDS Transfers	0	0	0
HEAL Initiative Transfer	20,100		
Subtotal, adjusted budget authority	$760,710	$806,373	$694,112
Unobligated balance, start of year[2]	0	6,603	0
Unobligated balance, end of year[2]	-6,603	0	0
Subtotal, adjusted budget authority	$754,107	$812,976	$694,112
Unobligated balance lapsing	-27	0	0
Total obligations	$754,080	$812,976	$694,112

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2018 - $16,815 FY 2019 - $65,000 FY 2020 - $57,000

[2] Reflects HEAL Initiative funding not obligated in FY 2018, and carried over into FY 2019.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Budget Mechanism Table[1]
(Dollars in Thousands)

MECHANISM	FY 2018 Final[2]		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY 2019 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	38	$33,130	45	$41,024	68	$58,383	23	$17,360
Administrative Supplements	*(13)*	2,889	*(1)*	347	*(0)*	0	*(-1)*	-347
Competing:								
Renewal	0	0	0	0	0	0	0	0
New	23	17,511	35	28,150	8	5,732	-27	-22,418
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	23	$17,511	35	$28,150	8	$5,732	-27	-$22,418
Subtotal, RPGs	61	$53,531	80	$69,520	76	$64,115	-4	-$5,405
SBIR/STTR	35	20,729	38	22,455	30	17,677	-8	-4,778
Research Project Grants	96	$74,260	118	$91,975	106	$81,791	-12	-$10,184
Research Centers:								
Specialized/Comprehensive	0	$9,951	0	$10,000	0	$9,000	0	-$1,000
Clinical Research	58	397,388	58	405,794	58	348,079	0	-57,715
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	58	$407,339	58	$415,794	58	$357,079	0	-$58,715
Other Research:								
Research Careers	58	$55,043	60	$57,861	58	$49,626	-2	-$8,235
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	0	0	0	0	0	0	0
Biomedical Research Support	0	0	0	0	0	0	0	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	28	36,396	30	35,934	23	23,607	-7	-12,327
Other Research	86	$91,439	90	$93,795	81	$73,233	-9	-$20,563
Total Research Grants	240	$573,038	266	$601,565	245	$512,103	-21	-$89,462
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	449	29,610	455	30,034	392	25,849	-63	-4,186
Total Research Training	449	$29,610	455	$30,034	392	$25,849	-63	-$4,186
Research & Develop. Contracts	126	$30,619	130	$39,102	120	$37,193	-10	-$1,909
(SBIR/STTR) (non-add)	*(0)*	*(3,045)*	*(2)*	*(3,045)*	*(2)*	*(3,000)*	*(0)*	*(-45)*
Intramural Research	48	87,847	45	93,580	45	81,084	0	-12,496
Res. Management & Support	124	39,597	122	42,092	122	37,883	0	-4,209
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(0)*	*(0)*	*(315)*	*(0)*	*(0)*	*(0)*	*(-315)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NCATS	172	$760,710	167	$806,373	167	$694,112	0	-$112,261

[1] All items in italics and brackets are non-add entries.
[2] Includes $6.6 million of HEAL Initiative funding not obligated in FY 2018, and carried over into FY 2019.

Major Changes in the Fiscal Year 2020 President's Budget Request

The budget request for NCATS of $694.1 million represents a $112.3 million dollar or 13.9 percent decrease from the FY 2019 level. At this budget level, NCATS would develop funding strategies to allow for continuation of priority research programs. NCATS would pay most non-competing grant awards at 10 percent below committed levels in order to provide funding for high priority new awards. For example, NCATS would fund a total of 58 CTSA hub center awards, the same number funded as in both FY 2018 and FY 2019.

Research Project Grants (-$5.4 million; total $64.1 million):
While the total number funded would drop from 80 to 74 awards, the number of non-competing awards funded would increase from 45 to 68 because of the need to pay the out-years of grants awarded as new in prior years (grant cycling).

Summary of Changes

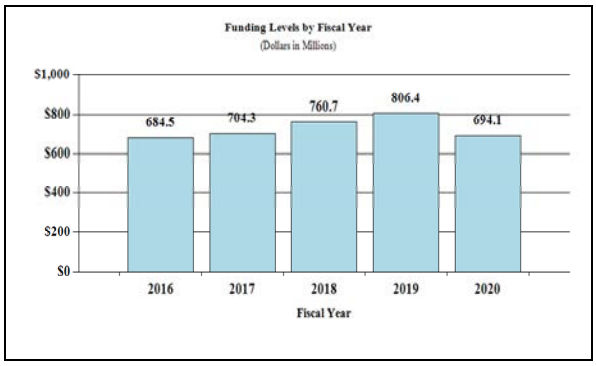
(Dollars in Thousands)

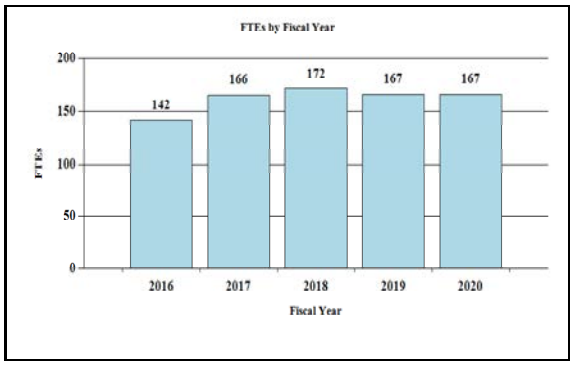
FY 2019 Enacted	$806,373
FY 2020 President's Budget	$694,112
Net change	-$112,261

CHANGES	FY 2020 President's Budget FTEs	FY 2020 President's Budget Budget Authority	Change from FY 2019 Enacted FTEs	Change from FY 2019 Enacted Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2019 pay increase & benefits		$9,120		$8
b. January FY 2020 pay increase & benefits		9,120		27
c. Paid days adjustment		9,120		34
d. Differences attributable to change in FTE		9,120		0
e. Payment for centrally furnished services		3,551		-60
f. Cost of laboratory supplies, materials, other expenses,		68,413		0
Subtotal				$9
2. Research Management and Support:				
a. Annualization of January 2019 pay increase & benefits		$18,980		$18
b. January FY 2020 pay increase & benefits		18,980		56
c. Paid days adjustment		18,980		72
d. Differences attributable to change in FTE		18,980		0
e. Payment for centrally furnished services		339		-38
f. Cost of laboratory supplies, materials, other expenses,		18,564		0
Subtotal				$109
Subtotal, Built-in				$117

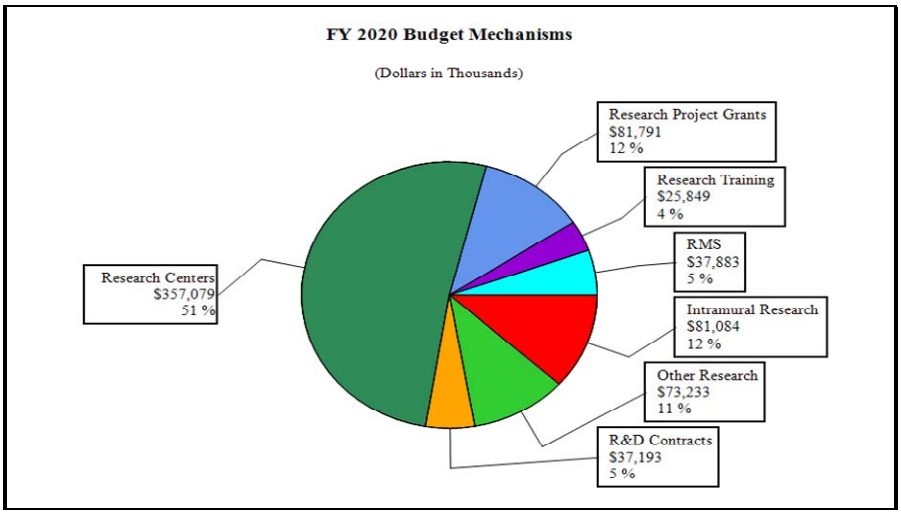
CHANGES	FY 2020 President's Budget No.	FY 2020 President's Budget Amount	Change from FY 2019 Enacted No.	Change from FY 2019 Enacted Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	68	$58,383	23	$17,013
b. Competing	8	5,732	-27	-22,418
c. SBIR/STTR	30	17,677	-8	-4,778
Subtotal, RPGs	106	$81,791	-12	-$10,184
2. Research Centers	58	$357,079	0	-$58,715
3. Other Research	81	73,233	-9	-20,563
4. Research Training	392	25,849	-63	-4,186
5. Research and development contracts	120	37,193	-10	-1,909
Subtotal, Extramural		$575,145		-$95,556
	FTEs		FTEs	
6. Intramural Research	45	$81,084	0	-$12,505
7. Research Management and Support	122	37,883	0	-4,318
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	167	$694,112	0	-$112,378
Total changes				-$112,261

History of Budget Authority and FTEs:

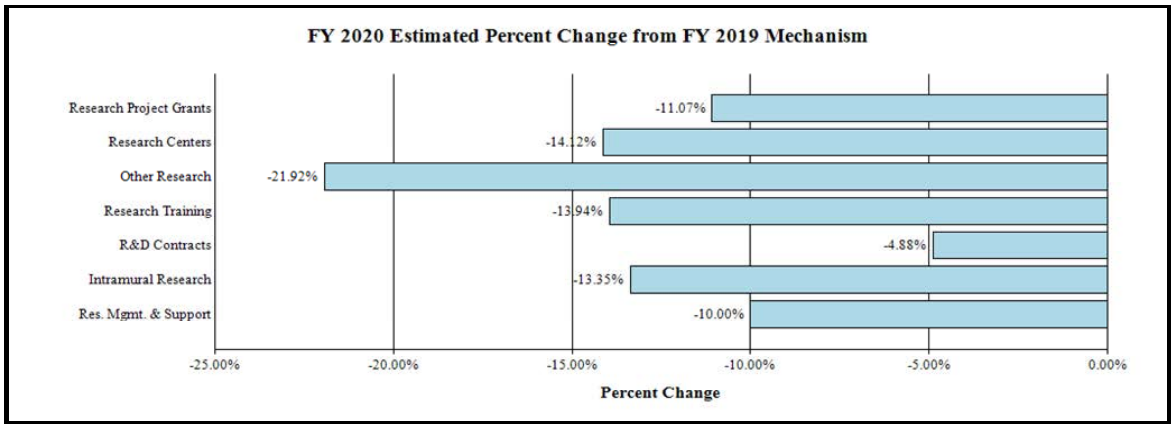




Distribution by Mechanism:



Change by Selected Mechanism:



Budget Authority by Activity[1]

(Dollars in Thousands)

Research	FY 2018 Final FTE	FY 2018 Final Amount	FY 2019 Enacted FTE	FY 2019 Enacted Amount	FY 2020 President's Budget FTE	FY 2020 President's Budget Amount	FY 2020 +/- FY2019 FTE	FY 2020 +/- FY2019 Amount
Detail								
Clinical and Translational Science Activities		$541,504		$559,736		$481,811		-$77,925
Program Leadership and Oversight (non-add) [2]		*(5,421)*		*(5,500)*		*(4,950)*		*-(550)*
Rare Disease Research and Therapeutics		49,580		58,337		51,054		-7,283
Reengineering Translational Sciences		71,047		83,601		69,497		-14,104
Cures Acceleration Network[4]		25,773		49,000		42,169		-6,831
Program Leadership and Oversight (non-add) [2]		*(588)*		*(592)*		*(533)*		*-(59)*
Translational Research Resources		19,378		19,699		17,181		-2,518
Helping End Addiction Long-term		20,100		0		0		0
Program Leadership and Oversight (non-add) [2]		*(260)*		*(0)*		*(0)*		*(0)*
Subtotal, Research		**$727,382**		**$770,373**		**$661,712**		**-$108,661**
Intramural Research (non-add) [2]	**48**	***($87,847)***	**45**	***($93,580)***	**45**	***($81,084)***	**0**	***-($12,496)***
Research Management & Support[3]	**124**	**$33,328**	**122**	**$36,000**	**122**	**$32,400**	**0**	**-$3,600**
TOTAL	**172**	**$760,710**	**167**	**$806,373**	**167**	**$694,112**	**0**	**-$112,261**

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

[2] All items in italics and brackets are non-add entries.

[3] Research Management & Support excludes $6.3 million in FY 2018, $6.1 million in FY 2019, and $5.5 million in FY 2020 for CTSA, CAN, and HEAL Program Leadership and Oversight.

[4] Includes $6.0 million for FY 2019 Rare Disease "Vector" project, $5.5 million for FY 2020.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2019 Amount	FY 2019 Enacted	2020 Amount	FY 2020 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$806,373,000	Indefinite	$694,112,000
National Center for Advancing Translational Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$806,373,000		$694,112,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2011				
Rescission				$0
2012	$721,601,000		$582,326,000	$576,456,000
Rescission				$1,089,502
2013	$639,033,000		$631,346,000	$575,366,498
Rescission				$1,150,733
Sequestration				($28,879,442)
2014	$665,688,000		$661,264,000	$633,267,000
Rescission				$0
2015	$657,471,000			$635,230,000
Rescission				$0
2016	$660,131,000	$643,111,000	$699,319,000	$685,417,000
Rescission				$0
2017[1]	$685,417,000	$707,335,000	$713,849,000	$705,903,000
Rescission				$0
2018	$557,373,000	$718,867,000	$729,094,000	$742,354,000
Rescission				$0
2019	$685,087,000	$751,219,000	$806,787,000	$806,373,000
Rescission				$0
2020	$694,112,000			

[1] Budget Estimate to Congress includes mandatory financing.

Justification of Budget Request

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended, and Section 480 of the PHS Act, relating to the Cures Acceleration Network

Budget Authority (BA):

	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
BA	$760,710,000	$806,373,000	$694,112,000	- $112,261,000
FTEs	172	167	167	-

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

Director's Overview

Nationwide, we have witnessed unprecedented advances in basic and fundamental science; however, the translation of research discoveries into treatments and interventions that improve human health continues to be a slow and failure-prone process. The National Center for Advancing Translational Sciences (NCATS) was created to directly address this issue by improving the translation of discovery to health for the benefit of all biomedical research. While most of the NIH Institutes and Centers are focused on research for specific diseases or disorders, NCATS is focused on improving the scientific and operational processes for refining and accelerating *translation*, the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

For FY 2020, NCATS is placing priority in the following areas of translation:

Advancing and accelerating treatments for rare diseases: There are about 7,000 diseases officially defined as "rare," or affecting fewer than 200,000 people in the United States; only a few hundred of these diseases have any approved treatment. Added together, rare diseases are anything but rare; they affect 25 million people in our country alone, and approximately 50 percent of these patients are children. Families generally must cope with a years-long odyssey to a correct diagnosis, only to find that 95 percent of the time there is no effective available treatment. These too-often disabling and fatal diseases are devastating and costly for patients, their families, and the Nation.

NCATS is applying its collaborative translational science model to transform understanding, diagnosis, and treatment of rare diseases. The time is right for this effort since the basic research

community has successfully identified the molecular causes of more than 90 percent of rare diseases in the past few decades, making translation possible and urgent. NCATS' fundamental approach is to shift from considering each rare disease in isolation to identifying and developing treatments for rare diseases based on their commonalities — essential given the thousands of diseases that urgently need addressing. NCATS, therefore, invests resources and expertise at the points where research is most difficult and therefore often abandoned.

The Center develops innovative technologies and operational models that catalyze treatment development for many rare diseases simultaneously. For example, NCATS' Therapeutics for Rare and Neglected Diseases (TRND) program has created a breakthrough collaborative science model which is unprecedented in its efficiency in developing rare disease treatments to the point at which biopharmaceutical companies will adopt them for clinical trials and regulatory approval. Through TRND, NCATS works specifically and intentionally in the "valley of death" — the unpredictable prototype development stage of therapy development that is particularly expensive and prone to failure. Many research projects are abandoned at this stage because they are deemed too risky for industry investment, thus preventing potentially life-saving treatments from reaching patients. TRND supports a collaborative team-based approach wherein NCATS scientists work closely with academic and small company investigators to develop interventions. Importantly, each project is chosen not only based on scientific potential and medical need, but also on the project's ability to establish a new scientific or operational principle that can be published and applied to other projects, thereby making the process less risky and continually more efficient and effective. Now that the TRND program has enabled outstanding success in the development of many new rare disease therapies, the program needs to be scaled up to apply NCATS' innovative TRND model to many more potential therapeutics that are ready for translation and remain without Food and Drug Administration (FDA) approval.

Most rare diseases are genetic, caused by "misspellings" in DNA that are passed from one generation to the next. Advances in gene delivery and gene editing have recently re-invigorated gene therapy as a potential approach to treating genetically-based diseases. Unlike small molecule drugs, genes cannot enter cells, so they need to be transported in the body and into the diseased cell type by a "vector" carrier, most often a modified cold virus. While effective, this requirement for a vector greatly increases the experimental, regulatory, safety, clinical complexity, and cost of gene therapy, since both the carried gene and the vector are different in every development program. This significantly hinders gene therapy being expanded or "scaled up" to address the many diseases that potentially could be treated. To tackle this problem, and thus simplify gene therapy and make it more efficient and effective, NCATS is developing a Collaborative Rare Disease Platform Vector Gene Therapy Trial program. Viral vectors will be well-characterized for their capacity and safety as gene delivery vehicles and tested as platforms to carry a variety of genes to treat multiple diseases. Initially, NCATS will support the testing of vectors as gene delivery vehicles for the treatment of at least three rare genetic diseases that share a therapeutic target tissue or cell type. If successful, NCATS will expand this strategy to provide rare diseases researchers with a palette of vectors to treat many, and potentially all, rare genetic diseases.

Leveraging NCATS programs to advance NIH's efforts to address the opioid epidemic: NCATS' Clinical and Translational Science Awards (CTSA) Program supports a translational

research network of pre-eminent biomedical research institutions across the country with experts who are well-positioned and ready to work together to address the opioid epidemic. These institutions have access to affected populations as well as clinical trials expertise and resources in place. This network of investigators will participate in NIH's Helping to End Addiction Long-term (HEAL) Initiative in a new NCATS-led HEAL Pain Management-Effectiveness Research Network (Pain Management-ERN), through which researchers will test the effectiveness of existing and novel approaches for prevention and management of pain while reducing risk of addiction. Leveraging the CTSA Program Trial Innovation Network and the CTSA Program hubs, the HEAL Pain Management-ERN also will test innovative clinical trial designs and use other CTSA Program resources such as the Streamlined, Multisite, Accelerated Resources for Trials (SMART) Institutional Review Board (IRB) Reliance Platform, and patient and community engagement expertise.

NCATS' Stem Cell Translation Laboratory, 3-D Bioprinting, Tissue Chips for Drug Screening, A Specialized Platform for Innovative Research Exploration (ASPIRE), Assay Development and Screening Technology, and Therapeutics Development Branch programs are being leveraged by NIH HEAL Initiative to identify and develop new compounds to treat pain, addiction, and overdose. Through its HEAL Human Cell-Based Screening Platforms initiative, NCATS is developing models of pain, addiction, and overdose using bioengineered human cells, tissues, and organs which hold promise to be more predictive of responses in people than previously used animal models. Through its HEAL Novel Drugs to Treat Pain, Addiction, and Overdose initiative, the Center is teaming its pre-clinical translation resources and expertise with experts in these conditions to identify and develop new therapies that can be tested in the clinic via other HEAL initiatives. More details about NCATS' role in the HEAL Initiative are provided in the NCATS program descriptions that follow.

Importantly, the ability for NCATS to respond rapidly to pressing public health priorities is built on its successful framework and past accomplishments. By applying innovation in new ways to address common scientific and organization problems, NCATS is advancing and accelerating the translation of discoveries to improve health.

Overall Budget Policy: The FY 2020 President's Budget request is $694.1 million, a decrease of $112.3 million or 13.9 percent compared with the FY 2019 enacted level. Reductions are distributed across all programmatic areas and reflect payment of most non-competing awards at 10 percent below committed levels. The FY 2020 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NCATS will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

Program Descriptions and Accomplishments

NCATS Clinical Innovation: Improving the efficiency and effectiveness of clinical testing and implementation of interventions that prevent and treat disease

NCATS' flagship **Clinical and Translational Sciences Award Program** comprises a suite of initiatives focused on understanding and reversing the causes of clinical translational failure, which prevent new interventions from being successfully tested in and made available to patients. The Center works collaboratively with more than 50 biomedical research institutions nationwide to improve clinical translation and to develop a cadre of trained investigators through sustainable translational science career development pathways.

For FY 2018, NCATS funded an additional hub institution, while also providing supplements to existing hubs to support priority research areas and operations such as the opioid crisis, education and training, critical research software applications, informatics, research methods and processes, community engagement, and rare diseases. NCATS also has been working closely with CTSA Program hub investigators to have the CTSA Program Trial Innovation Network (TIN) ready to help the biomedical research community conduct their multisite clinical studies more efficiently and effectively. Some general statistics regarding the efficiency of conducting NIH clinical trials include:

- It can easily take two years from the time a clinical study grant is funded to the time the study actually can begin and another three to five years to recruit participants for a study.
- A large percentage of clinical studies ultimately fail due to an inability to recruit enough participants and/or results being irrelevant by the time the study is completed.

These delays and failures represent enormous losses to the health and lives of patients, the careers of investigators, and the advancement of science and medicine. The TIN focuses on understanding and developing scientific and operational solutions to the causes of multisite clinical trial inefficiency and uses the network and its resources as a national laboratory to innovate clinical trial processes. With the participation of the CTSA Program hubs, Trial Innovation Centers, and Recruitment Innovation Center, through the TIN, NCATS is developing, demonstrating the effectiveness of, and disseminating scientific and operational innovations to dramatically increase the efficiency and effectiveness of clinical studies. The TIN works via proposal submissions from investigators across the biomedical community — both within and outside of the CTSA Program — to collaboratively design and conduct trials that require a scientific and/or operational innovation to be successful. These innovations could include novel recruitment and participant engagement strategies, data-driven approaches to participant identification utilizing anonymized electronic health records as a site selection tool, and testing of new statistical or trial designs such as for adaptive trials. As of November 2018, the TIN has received more than 150 proposals from 56 different institutions across the United States.

NCATS appreciates the language accompanying the FY 2019 appropriation encouraging the Center to apply its innovative translational science paradigm to rural health, health disparities, and special populations. In FY 2019-2020, the CTSA Program will focus special attention on the translational science of health disparities, rural health outcomes,

and underserved and vulnerable populations. In FY 2019, NCATS will utilize available funding mechanisms to support promising approaches and test their applicability to a variety of geographic settings and populations. Also, in FY 2019, NCATS will conduct a workshop on rural and health disparities research to identify systemic roadblocks to progress and potential solutions. The Center will build on these efforts with the development of a new CTSA Program funding opportunity for FY 2020 funding, which will develop and test clinical and translational research solutions to health disparities, including rural health outcomes, underserved, and vulnerable populations. While plans for the funding opportunity are still in development, the Center anticipates that this new opportunity will include innovative strategies such as community engagement, telemedicine, and partnering with programs focusing on special populations and geographic areas, such as the National Institute of General Medical Sciences' Institutional Development Award (IDeA) Program Infrastructure for Clinical and Translational Research.

Program Portrait: CTSA Program Researchers Partner with Barbershops to Cut High Blood Pressure

FY 2019 Level: $559.7 million
FY 2020 Level: $481.1 million
Change: -$77.9 million

When is a haircut more than a haircut? When it is also the first step to cutting high blood pressure.

Black men are more likely to die from complications of high blood pressure than any other group in the United States. Overwhelmed primary care offices, hesitation to take a new medication, and other barriers prevent many men from monitoring and getting treatment for high blood pressure.

To tackle this disparity, researchers from the Smidt Heart Institute at Cedars-Sinai and the University of California, Los Angeles (UCLA), paired pharmacists with barbershops to offer high blood pressure care for customers. Instead of sending barbershop patrons to pharmacists, they sent pharmacists to barbershops. The goal was to overcome yet another obstacle for black men: They are less likely than other groups to visit a doctor. Barbershops are often the cornerstone of African American communities, where barbers and patrons develop a trusting relationship.

The Community Engagement Unit at UCLA's Clinical and Translational Science Institute worked with the research team at Smidt Heart Institute at Cedars-Sinai to recruit an initial group of barbershop owners, who then reached out to other colleagues to recruit a total of 52 barbershops in the study. On average, the barbers had cut the men's hair every two weeks for the past 10 years and could provide a powerful endorsement for the pharmacists. Barbers encouraged patrons with high blood pressure to meet with a pharmacist at the shop, and the pharmacists provided high blood pressure medications as appropriate and then followed up with the participants at future haircut appointments.

The research team tracked participants' blood pressure over the next six months. Men in the control group, who were encouraged to see their doctor, had slight improvements in blood pressure, although on average their blood pressure was still high after six months. But men in the test group, who met with a pharmacist at a barbershop, had large decreases in their blood pressure. The findings, published in the April 5, 2018, issue of the *New England Journal of Medicine*, offer valuable lessons on the potential impact of directly engaging communities and using alternative health care delivery, through pharmacists, in non-traditional settings. For FY 2019, NCATS will support additional funding to the project team to test whether this model of community engagement is transferable to other community settings.

The **Rare Diseases Clinical Research Network (RDCRN)** advances the understanding, diagnosis, and treatment of rare diseases by supporting clinical studies and facilitating collaboration and data sharing. NCATS directs the RDCRN in partnership with several NIH ICs and Offices. The RDCRN consists of 22 distinct clinical research consortia and a Data Management and Coordinating Center (DMCC), all of which comprise physician scientists and their multidisciplinary teams. They collaborate with patient advocacy groups and NIH content experts who work cooperatively to study more than 280 rare diseases at sites across the nation. Each consortia focuses on at least three related rare diseases, participates in multisite studies, supports rare disease research training, and includes patient support organizations as research partners. Since its launch, nearly 40,000 patients have been enrolled in RDCRN-associated clinical studies.

In FY 2019, funding for the RDCRN is being recompeted with an emphasis on clinical translation research (e.g., no animal studies will be allowed) and clinical trial readiness (e.g., use of single IRB will be required), as well as an increased focus on incorporation of input from patients and other stakeholders. To address the need for information on the progression of rare diseases, all applicants must propose a natural history study as one of their clinical research projects. Data sharing is a critical RDCRN goal because this can help identify commonalities across diseases that were previously considered unrelated. To enable this sharing, NCATS will provide centralized "cloud" computing services for the RDCRN and the DMCC. Using this computing platform, the DMCC will provide clinical research and data management support, coordinate activities across the RDCRN, and serve as a conduit of information related to rare diseases research being conducted by the network.

Program Portrait: Paving the Way for New Treatments for Lysosomal Diseases

FY 2019 Level: $26.5 million
FY 2020 Level: $23.7 million
Change: -$2.8 million

Lysosomal diseases affect about one in 6,000 people worldwide. These disorders are characterized by an abnormal buildup of various toxic materials in the body's cells. A pair of rare, inherited lysosomal diseases, Hurler and Hunter syndromes, can cause enlarged facial features, heart and other organ damage, bone and joint problems, developmental delays, brain damage, and early death.

Investigators supported through the RDCRN's Lysosomal Disease Network (LDN) worked with scientists from Sangamo Therapeutics, Inc. to find out whether Sangamo's novel gene editing technique could prevent or reverse Hurler and Hunter syndromes. The project team conducted clinical studies of affected children and adults. The studies captured data that revealed how these diseases progress over time and gathered promising results using Sangamo's gene editing technique, tested in mouse models of Hunter syndrome. In November 2017, Sangamo made headlines when scientists made the first attempt to edit a gene inside the human body in a patient with Hunter syndrome.

The LDN researchers worked with Sangamo to develop the current clinical trial and recruit participants. The project team will gauge the safety of the gene editing technique in patients and will also watch for signs of effectiveness by using LDN-developed tools, including brain imaging. In addition, LDN investigators will help study and evaluate the effects of the gene editing therapy on patients' thinking and learning abilities. In the meantime, LDN researchers continue to examine how these diseases and treatments affect the brain over time.

Clinical Innovation (-$80.7 million; total $503.7 million):
The FY 2020 President's Budget request is a decrease of $80.5 million or 13.8 percent compared with the FY 2019 Enacted Level. This amount includes an FY 2020 request of $481.8 million for the Clinical and Translational Science Awards program, a decrease of $77.9 million or 13.9 percent compared with the FY 2019 Enacted Level. NCATS would develop funding strategies in order to maintain the same number of CTSA hubs as funded in FY 2019, which is 58 hubs, and the same number of Rare Disease centers.

NCATS Pre-Clinical Innovation: Accelerating the transformation of basic research discoveries into promising therapeutics that are ready for clinical testing

Discovering New Therapeutics Uses for Existing Molecules (NTU): NTU accelerates development of new treatments by finding new uses for existing therapies that already have cleared several key steps along the development path. Establishment of public-private partnerships between academia, foundations, and industry and are facilitated with NCATS template legal agreements that academic institutions and pharmaceutical companies use as a launching point for negotiations facilitating the negotiation process.

NTU's *NIH-Industry Partnerships* initiative enabled agreements between a single company and a single investigator or biomedical research institution. A key feature of this program is the involvement of multiple pharmaceutical companies and the potential for any U.S. researcher to participate. Companies provide most if not all of the data

needed by the FDA for the NCATS-funded investigators to conduct clinical trials in a new disease. That investment represents millions of dollars invested by the companies. As the NTU program has evolved, other roadblocks to repurposing are being realized. Experimental drugs that often are no longer being pursued by the company typically do not have a clinical supply available. In other words, there are not bottles of pills sitting on their shelves, waiting to be tested for a new indication. As a result, NCATS is exploring avenues to address this manufacturing issue, which may also result in a subsequent increase in the number of assets that companies will make available.

Program Portrait: Speeding the Formation of Public-Private Partnerships

FY 2019 Level: $11.4 million
FY 2020 Level: $8.9 million
Change: -$2.5 million

Public-private partnerships are an important way to accelerate translational science, but establishing this kind of partnership can be its own challenge. Through its Discovering New Therapeutic Uses for Existing Molecules (NTU) program, NCATS has developed and disseminated an innovative public-private partnership model that is now being widely used in the research community.

Translational roadblocks are equally scientific and operational, and NTU illustrates this approach: The scientific problem is how to accelerate development of new treatments by finding new uses for existing therapies, while the operational problem is the cumbersome and time-consuming process of public-private partnership agreement negotiation. The scientific solution was to bring together partners from the pharmaceutical industry and academic institutions to crowdsource ideas for new disease indications for investigational drugs. The operational solution was to create template legal agreements that academic institutions and pharmaceutical companies can use as a launching point for negotiations. Most NTU project agreements are now formed within four months instead of the typical one year or more.

These NCATS solutions have now been widely adopted. The scientific approach has now been implemented independently by a number of companies and academic institutions, freeing NTU to innovate in other areas of drug repurposing. The collaborative agreement templates are freely available on the NCATS' website for researchers and companies to adapt to their own needs and have been adapted by NIH for use in a wide range of innovative research initiatives including the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the Common Fund's Stimulating Peripheral Activity to Relieve Conditions (SPARC) program.

Through the NTU's Bench-to-Clinic Repurposing initiative, NCATS explores a potential new use of an existing investigational therapy, FDA-approved drug, or licensed biologic. The Center will support pre-clinical studies, clinical feasibility studies, or proof-of-concept clinical trials to test the utility of an independent crowdsourcing effort or computational algorithm to predict new uses of a drug or biologic.

Therapeutics for Rare and Neglected Diseases (TRND) and Bridging Interventional Development Gaps (BrIDGs) programs: transforming the therapeutic development "Valley of Death"

The most challenging, failure-prone, and expensive stage of pre-clinical translation is transforming a prototype therapeutic that works in cell or animal models into a drug that can be tested in humans. Most prototype therapies never survive this stage of translation, earning it the moniker "Valley of Death." Given the disproportionate need for innovation in this translational stage, NCATS devotes considerable resources to it.

Through its TRND and BrIDGs programs, NCATS works collaboratively with partners in the public and private sectors to improve scientific understanding and operational efficiencies in this stage of translation, in the context of developing candidate therapeutics for both rare and common diseases. Both programs are designed to "de-risk" the intervention such that it will be adopted by a biopharmaceutical company for clinical testing. The operational model is as innovative as the science: investigators with a prototype and NCATS translational experts form a joint project team that progressively adapts the prototype to be suitable for human testing and generates the data required for Investigational New Drug (IND) applications to the FDA.

For example, NCATS' TRND program and Agilis Biotherapeutics, which is a startup biotechnology company in Boston, partnered to successfully develop a gene therapy technology for a devastating and untreatable disease of children called Aromatic Amino Acid Decarboxylase (AADC) Deficiency. The resulting de-risked project was recently acquired by PTC Therapeutics, which will take on further development steps, registration, and marketing of the therapy. Building on this success, TRND scientists currently are developing platform technologies to catalyze the application of gene therapy to many rare diseases simultaneously. And BrIDGs, in collaboration with the National Cancer Institute (NCI) and Northwestern University, is developing a potential therapy to stop the spread of pancreatic cancers.

Toxicology in the 21st Century (Tox21). A major reason for pre-clinical translational failure is unanticipated adverse effects from a new drug in humans that were not seen in animal models. As with other areas of translation, the science of what causes a drug to be toxic is poorly understood, and the methods to study and determine toxicity are largely the same as they were in the 1950s. As a result, NCATS has prioritized the systematic understanding of toxicity and the development of new non-animal testing systems. The Tissue Chip, 3-D Bioprinting, and Tox21 programs all reflect this priority.

The Tox21 program is a four-Federal agency collaboration among NCATS, the National Toxicology Program at NIH's National Institute of Environmental Health Sciences, the Environmental Protection Agency, and the FDA. Now in its 10th year, through Tox21, scientists have catalyzed a major shift in how testing is done to identify potential harmful effects of drugs and environmental chemicals. Tox21 researchers have developed new testing paradigms, a public database of more than 100 million test results on over 10,000 drugs and chemicals, and computational algorithms that are remarkably accurate in predicting the potential toxicity of a new compound. These publicly available data are now beginning to inform regulatory decisions about safety. In March 2018, the Tox21 partners released a new strategic and operational plan, which directly addresses the set of

challenges, identified in a National Academy of Sciences report, that continue to hinder the realization of the ultimate Tox21 vision of automated human cell- and tissue-based testing with sufficient reliability, efficiency, and predictive capability to replace animal testing entirely. Tox21 has launched new cross-partner research projects to address these challenges.

Pre-Clinical Innovation (-$14.0 million; total $78.0 million):
The FY 2020 President's Budget request is a decrease of $14.0 million or 15.2 percent compared with the FY 2019 Enacted Level. NCATS would develop funding strategies to continue priority research programs at this budget level.

NCATS Cures Acceleration Network: Investing in activities to accelerate the development of high-need cures

The Cures Acceleration Network (CAN) is an authority within the Public Health Service Act that provides NCATS with some innovative funding mechanisms, including Flexible Research Authority — also known as Other Transactions (OT) Authority — and the ability for eligible entities to contribute matching, non-Federal funds to an award. CAN authorities support "revolutionary advances" in research and translational science discoveries while reducing the barriers to their development. NCATS greatly appreciates the FY 2019 increase in CAN funding, which will support the initiation or expansion of several transformational programs, each addressing a major limitation in our ability to develop high-need cures.

ASPIRE (Automated Synthesis Platform for Innovative Research Exploration) addresses the currently very limited types of chemical molecules that can be made, which inevitably greatly limits the development of drugs for untreatable diseases. Currently, less than 10 percent of potential targets in the human genome can be altered or modulated by a small molecule compound, and less than 0.1 percent of potential small molecule compounds have been developed. This represents both an enormous roadblock to drug developers and a significant opportunity to break open entirely new areas of disease treatment, if these problems can be solved. With CAN funding, in FY 2018, NCATS launched ASPIRE, an ambitious multi-disciplinary initiative to innovate and integrate chemistry, biological activity testing, robotic engineering, and machine learning/artificial intelligence. Through ASPIRE, the Center is developing a recursive, automated research platform in which novel chemical compounds are rapidly synthesized and tested for their potential to influence disease processes, with the results analyzed by machine learning algorithms that lead automatically to the design and synthesis of the next round of compounds. Such a system promises to revolutionize our ability to create novel drugs for currently unreachable targets and diseases.

3-D Bioprinting addresses the limited ability of current testing systems to correctly identify compounds that will be effective in humans. "Screening" of thousands of compounds for a desired effect is often the first translational step toward making a new drug and is frequently misleading due to the rudimentary nature of human cellular screening systems. To address this challenge, NCATS' 3-D Bioprinting program is bringing together iPSC (induced pluripotent stem cell) differentiation technologies, 3-D

printer engineering, and advanced imaging to rapidly print miniature mimics of human tissues. This bioprinting initiative is currently printing miniature skin, retina, and blood vessel tissues that promise to mimic human function and disease and, thus, provide a much more accurate way to screen large numbers of compounds in the critical first step of drug development.

Tissue Chips for Drug Screening addresses the inaccuracy and high cost of "toxicity testing" in which drugs are assessed for their safety prior to human testing. This process currently utilizes multiple species of animals and frequently does not predict adverse effects of drugs in humans. The Tissue Chip program's network of academic and small company laboratories has created microfluidic-engineered systems made of many different types of human cells that represent all major human organs. Program-supported scientists work closely with the FDA and pharmaceutical companies to validate their use in drug development. NCATS' efforts have stimulated interest in this rapidly developing field, which holds great promise for making toxicity testing more efficient and accurate. The successes of the Tissue Chip for Drug Screening effort have now led to scientific and technological expansion of the program to explore additional translational applications for these chips. NCATS is collaborating with many other NIH Institutes and Centers to support the development of more than a dozen "organs-on-chip" disease models that promise to yield new understanding of diseases and provide platforms for testing of new drugs to treat them. In addition, NCATS is supporting the standardization, validation, commercialization, and dissemination of the chips that will make the technology broadly accessible to non-experts.

- **Tissue Chip Testing Centers:** Initially funded in October 2016, testing center scientists independently validate tissue chip platforms and make all data publicly available to promote adoption of this technology by the broad research community. NextGen Tissue Chip Testing Centers, awarded in September 2018, advance the wider adoption of tissue chip technologies by the pharmaceutical and biotechnology industries, as well as regulatory agencies, to transition this technology into commercialization.
- **Tissue Chips for Disease Modeling and Efficacy Testing** supports development of tissue chip models of human disease that mimic the pathology in major human organs and tissues. NCATS partnered with nine NIH Institutes, Centers, and Offices to support 14 awards in February 2018.
- **Tissue Chips in Space** is a partnership with the Center for Advancement of Science in Space, National Aeronautics and Space Administration, and National Institute of Biomedical Imaging and Bioengineering to advance knowledge of human disease using the unique microgravity environment of the International Space Station U.S. National Laboratory (ISS-NL). In addition to producing insights into bone, muscle, immune, and kidney diseases, the program is greatly accelerating the simplification and miniaturization of tissue chip systems, which will further their wider adoption. The first of three launches of tissue chips to the ISS-NL occurred on December 5, 2018.
- **"Clinical Trials on a Chip"** is a new initiative planned for FY 2019. This is a potentially "game changing" effort to explore how tissue chips could be used to

facilitate clinical trial planning and execution. Collection of tissue chip data in a study designed to run in parallel with a human clinical trial will generate needed information regarding the potential of tissue chips in predicting clinical outcomes. If successful, this initiative also has potential value for clinical trials for rare diseases through expanding the small patient population sizes with tissue-chip surrogates.

Biomedical Data Translator (Translator) addresses the rapidly changing categorization, data connecting, and linguistic issues that inhibit the free flow of information and understanding. When applied across the many stages of translation, integration of information and data becomes a major barrier to translational efficiency. Translator is an unprecedented effort to create an open-source computational platform that connects disparate categories of biomedical information from many sources to help translational researchers generate new ideas for preventing, diagnosing, and treating diseases. Once completed, Translator will be able to draw on data sources ranging from gene information to cell type categories, to disease names to air quality measurements, to clinical data from electronic health records. It will be able to provide answers to researchers' queries such as "What are all the diseases that aspirin (or any other drug) could possibly treat?" or "What are all the genetic conditions that reduce risk for osteoporosis?" and subsequently ask, "How is it doing that?"

While the task of bringing together and making connections among all these data types is ongoing, the next big step for Translator is the development of a "Reasoning Tool" that will "think like a doctor and a scientist" — envision a computational version of Dr. Gregory House from the American television medical drama "House." Translator not only needs to be able to comprehend a user's query, it must then be able to find the relevant knowledge sources, extract the right information, and piece the information together into a narrative that the user can understand. Creating an effective Reasoning Tool requires convening people with diverse expertise, each with their own idiosyncratic medical or scientific languages. Not only was this a difficult scientific problem, but the typical NIH grant/contract mechanisms were not well-suited to supporting this kind of endeavor. So NCATS took an entirely unconventional scientific management approach and utilized the CAN OT authority to design a decidedly non-traditional funding opportunity approach to identify suitable applicants for the Reasoner. Candidates interested in applying for Translator funding first had to solve a series of difficult computational puzzles before they could access the funding opportunity announcement (FOA). The idea behind the FOA puzzles was to have teams demonstrate they had the skills to build a Reasoning Tool before they could apply for funding. Solving the puzzles required candidates to pull together relevant expertise and, at the same time, familiarized them with the Translator initiative. The puzzle approach generated a tremendous amount of "buzz" in the computational community and attracted many applicants who previously had never been supported by NIH.

Collaborative Rare Disease Platform Vector Gene Therapy Trials is a new rare diseases initiative to begin in FY 2019 with CAN funds and may include the first use of CAN's matching funds authority. The goal is to accelerate the benefit of gene therapy for

rare diseases by moving from the current "one disease at a time" to a "many diseases at a time" approach. Through the initiative, NCATS will develop a toolbox of well-characterized, modified viruses which can be utilized as vehicles, or "vectors," that can deliver disease-related genes to treat specific cells and tissue types that are affected in multiple different rare genetic diseases. This revolutionary approach has great potential for shortening the time of therapeutics development for rare diseases and, if successful, is an approach that is likely to be transferable to other more common genetically-based diseases.

Cures Acceleration Network (-$6.8 million; total $42.2 million):
The FY 2020 President's Budget request is a decrease of $6.8 million or 13.9 percent compared with the FY 2019 Enacted Level. NCATS would develop funding strategies to continue priority research programs at this budget level.

NCATS' Role in the NIH's Helping to End Addiction Long-term (HEAL) initiative

To address the opioid epidemic, new, safe interventions are needed to combat opioid addiction, overdose, and pain. At the basic research to pre-clinical research phases of the translational spectrum,[1] research models that more accurately predict how potential new drugs will affect humans are needed, and new-mechanism therapeutics need to be developed and tested. At the public health end of the translational spectrum, doctors treating pain need better data about what non-opioid treatments work most effectively in "real world" settings. Using HEAL funds transferred to NCATS, the Center is leveraging its pre-clinical and clinical expertise programs to address these needs and thus advance the goals of the NIH HEAL Initiative.

Through pre-clinical translation, NCATS is developing new human cell-based platforms of cells, tissues, and organs designed for high throughput screening of potential treatments. These platforms will be utilized to identify compounds that act on novel addiction, overdose, and pain targets for the development of investigational new drugs suitable for clinical testing. All projects will follow NCATS' signature collaboration model, composed of NCATS' translational experts and disease and biology experts from the external research and development community, as well as with other scientists at the NIH. These joint project teams are anticipated to make progress much more rapidly than either could accomplish alone.

For its HEAL Human Cell-Based Screening Platform Development program, NCATS will apply the accumulated expertise and resources of its Stem Cell Translation Laboratory, 3-D Bioprinting, and Tissue Chip programs to develop human cell-based models of opioid addiction, overdose, and pain which promise to be more accurate and predictive than previously-used simple cell or animal models. Neurons and other cell types that carry pain and addiction signals will be produced from induced pluripotent stem cells and used to produce both 3-D bioprinted tissues for screening and tissue chips for efficacy and toxicity testing. The goal is to be able to rapidly and reproducibly make these cells, tissues, and tissue chip models available as platforms to enable high throughput testing of candidate drugs.

[1] https://ncats.nih.gov/translation/spectrum.

For its HEAL Development of Novel Mechanism Compounds and Candidate Drugs for Clinical Testing program, NCATS will apply its chemical synthesis, robotic screening, and therapeutic development expertise and resources to accelerate the identification and testing of existing and potential new drugs for pre-clinical development. The following three initiatives are focused on facilitating the testing needed to bring promising drug candidates to first-in-human studies:

- NCATS will issue a competition to stimulate the research community to propose concepts in designing novel chemicals that have potential for addressing pain, addiction, and overdose. Promising ideas for new chemical structures will be carried forward for development and testing through NCATS'ASPIRE, which supports applied automation in synthesizing novel chemical compounds to accelerate the creation of new chemical compounds.

- For research experts who have identified compounds that act on biological targets of opioids and pain, NCATS will provide access to assay development, high-throughput screening, and medicinal chemistry resources and expertise to advance the pre-clinical development of these compounds and further their development into pharmacological or drug-like compounds which will allow new mechanism hypotheses to be tested in iPSC-derived cells, tissue chips, or animal models.

- If these or other new-mechanism compounds show promise in early testing, the NCATS Therapeutics Development Branch will perform the next stages of biological, chemical, and drug development research to determine if these compounds can be turned into candidate drugs suitable for testing in humans. The Branch provides medicinal chemistry, pharmacology, testing of the metabolic properties of compounds, safety testing, optimal drug formulation for administration in humans, and chemistry manufacturing of potential drugs, which are all areas of pre-clinical therapeutics development needed before a drug can be tested in humans.

In clinical translation, NCATS is leveraging the expertise and operational infrastructure of its CTSA Program to rapidly create a clinical network that will test the effectiveness of treatments for pain, including drugs and non-pharmacologic interventions, which are in current clinical use but do not have adequate data on their effectiveness or applicability to particular pain conditions.

This **HEAL Pain Management-Effectiveness Research Network (HEAL Pain Management-ERN)** will utilize the CTSA Program Hubs and the CTSA Program Trial Innovation Network (TIN). NCATS will work with the NIH Institutes and Centers to design multi-site clinical trials to test the comparative effectiveness of existing therapies or effectiveness of novel approaches for prevention and management of pain while reducing risk of addiction. The studies must address questions within the mission and research interests of participating NIH Institutes and Centers and evaluate preventive strategies or interventions including medications, biologics, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, rehabilitation strategies, complementary therapies, integrated approaches, and delivery system strategies in well controlled trials in specific pain conditions. The goal is to inform clinicians about the effectiveness of interventions or management strategies that reduce opioid

use and will improve functional outcomes and reduce acute to chronic pain associated with many types of diseases or conditions. By using HEAL funds transferred to NCATS, grant supplements will be used to supplement existing grants within the CTSA Program. By leveraging the CTSA TIN, the HEAL Pain Management-ERN also will test innovative clinical trial designs to conduct the trials more efficiently, and will include access to all CTSA Trial Innovation Centers to streamline clinical trial operations such as SMART IRB and master contracting; the CTSA Recruitment Innovation Center for access to informatics and patient engagement resources and expertise to facilitate study recruitment; and the CTSA Program hubs for access to clinical trial and pain experts, study populations, and potential study sites.

Budget Authority by Object Class[1]

(Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total compensable workyears:				
	Full-time equivalent	167	167	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$192	$192	$0
	Average GM/GS grade	12.8	12.8	0.0
	Average GM/GS salary	$115	$115	$0
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$118	$118	$0
	Average salary of ungraded positions	$172	$172	$0
	OBJECT CLASSES	**FY 2019 Enacted**	**FY 2020 President's Budget**	**FY 2020 +/- FY 2019**
	Personnel Compensation			
11.1	Full-Time Permanent	12,759	12,808	48
11.3	Other Than Full-Time Permanent	6,513	6,538	25
11.5	Other Personnel Compensation	777	780	3
11.7	Military Personnel	238	246	8
11.8	Special Personnel Services Payments	1,077	1,081	4
11.9	**Subtotal Personnel Compensation**	**$21,365**	**$21,453**	**$88**
12.1	Civilian Personnel Benefits	6,272	6,391	119
12.2	Military Personnel Benefits	247	255	8
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$27,884**	**$28,099**	**$215**
21.0	Travel & Transportation of Persons	525	489	-36
22.0	Transportation of Things	47	47	0
23.1	Rental Payments to GSA	65	65	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	142	142	0
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	576	576	0
25.2	Other Services	50,504	43,103	-7,401
25.3	Purchase of goods and services from government accounts	53,207	47,762	-5,445
25.4	Operation & Maintenance of Facilities	663	663	0
25.5	R&D Contracts	15,270	13,517	-1,752
25.6	Medical Care	1,668	1,668	0
25.7	Operation & Maintenance of Equipment	3,817	3,817	0
25.8	Subsistence & Support of Persons	16	16	0
25.0	**Subtotal Other Contractual Services**	**$125,720**	**$111,122**	**-$14,598**
26.0	Supplies & Materials	10,791	8,690	-2,101
31.0	Equipment	9,599	7,505	-2,094
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	631,599	537,952	-93,647
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$778,489**	**$666,013**	**-$112,476**
	Total Budget Authority by Object Class	**$806,373**	**$694,112**	**-$112,261**

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

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	$12,759	$12,808	$48
Other Than Full-Time Permanent (11.3)	6,513	6,538	25
Other Personnel Compensation (11.5)	777	780	3
Military Personnel (11.7)	238	246	8
Special Personnel Services Payments (11.8)	1,077	1,081	4
Subtotal Personnel Compensation (11.9)	**$21,365**	**$21,453**	**$88**
Civilian Personnel Benefits (12.1)	$6,272	$6,391	$119
Military Personnel Benefits (12.2)	247	255	8
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$27,884**	**$28,099**	**$215**
Travel & Transportation of Persons (21.0)	$525	$489	-$36
Transportation of Things (22.0)	47	47	0
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	142	142	0
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	576	576	0
Other Services (25.2)	50,504	43,103	-7,401
Purchases from government accounts (25.3)	33,007	27,633	-5,374
Operation & Maintenance of Facilities (25.4)	663	663	0
Operation & Maintenance of Equipment (25.7)	3,817	3,817	0
Subsistence & Support of Persons (25.8)	16	16	0
Subtotal Other Contractual Services	**$88,582**	**$75,807**	**-$12,775**
Supplies & Materials (26.0)	$10,791	$8,690	-$2,101
Subtotal Non-Pay Costs	**$100,087**	**$85,176**	**-$14,912**
Total Administrative Costs	**$127,972**	**$113,275**	**-$14,697**

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2018 Final			FY 2019 Enacted			FY 2020 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Clinical Innovation									
Direct:	23	1	24	23	-	23	23	-	23
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	23	1	24	23	-	23	23	-	23
Division of Pre-Clinical Innovation									
Direct:	42	1	43	40	-	40	40	-	40
Reimbursable:	5	-	5	5	-	5	5	-	5
Total:	47	1	48	45	-	45	45	-	45
Office of Administrative Management									
Direct:	32	-	32	32	-	32	32	-	32
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	32	-	32	32	-	32	32	-	32
Office of Grants Management and Scientific Review									
Direct:	20	-	20	19	-	19	19	-	19
Reimbursable:	9	-	9	9	-	9	9	-	9
Total:	29	-	29	28	-	28	28	-	28
Office of Policy, Communications, and Education									
Direct:	11	-	11	11	-	11	11	-	11
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	11	-	11	11	-	11	11	-	11
Office of Rare Diseases Research									
Direct:	6	-	6	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	6	-	6
Office of Strategic Alliances									
Direct:	6	-	6	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	6	-	6
Office of the Director									
Direct:	16	-	16	16	-	16	16	-	16
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	16	-	16	16	-	16	16	-	16
Total	170	2	172	167	-	167	167	-	167
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
2016	12.8
2017	12.6
2018	12.6
2019	12.8
2020	12.8

Detail of Positions[1]

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	189,120	191,767	191,767
GM/GS-15	18	18	18
GM/GS-14	27	27	27
GM/GS-13	45	45	45
GS-12	12	14	14
GS-11	10	8	8
GS-10	0	0	0
GS-9	6	6	6
GS-8	3	3	3
GS-7	2	2	2
GS-6	0	0	0
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	123	123	123
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	1	1	1
Ungraded	45	45	45
Total permanent positions	127	127	127
Total positions, end of year	172	172	172
Total full-time equivalent (FTE) employment, end of year	172	167	167
Average ES salary	189,120	191,767	191,767
Average GM/GS grade	12.8	12.8	12.8
Average GM/GS salary	113,732	115,324	115,324

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