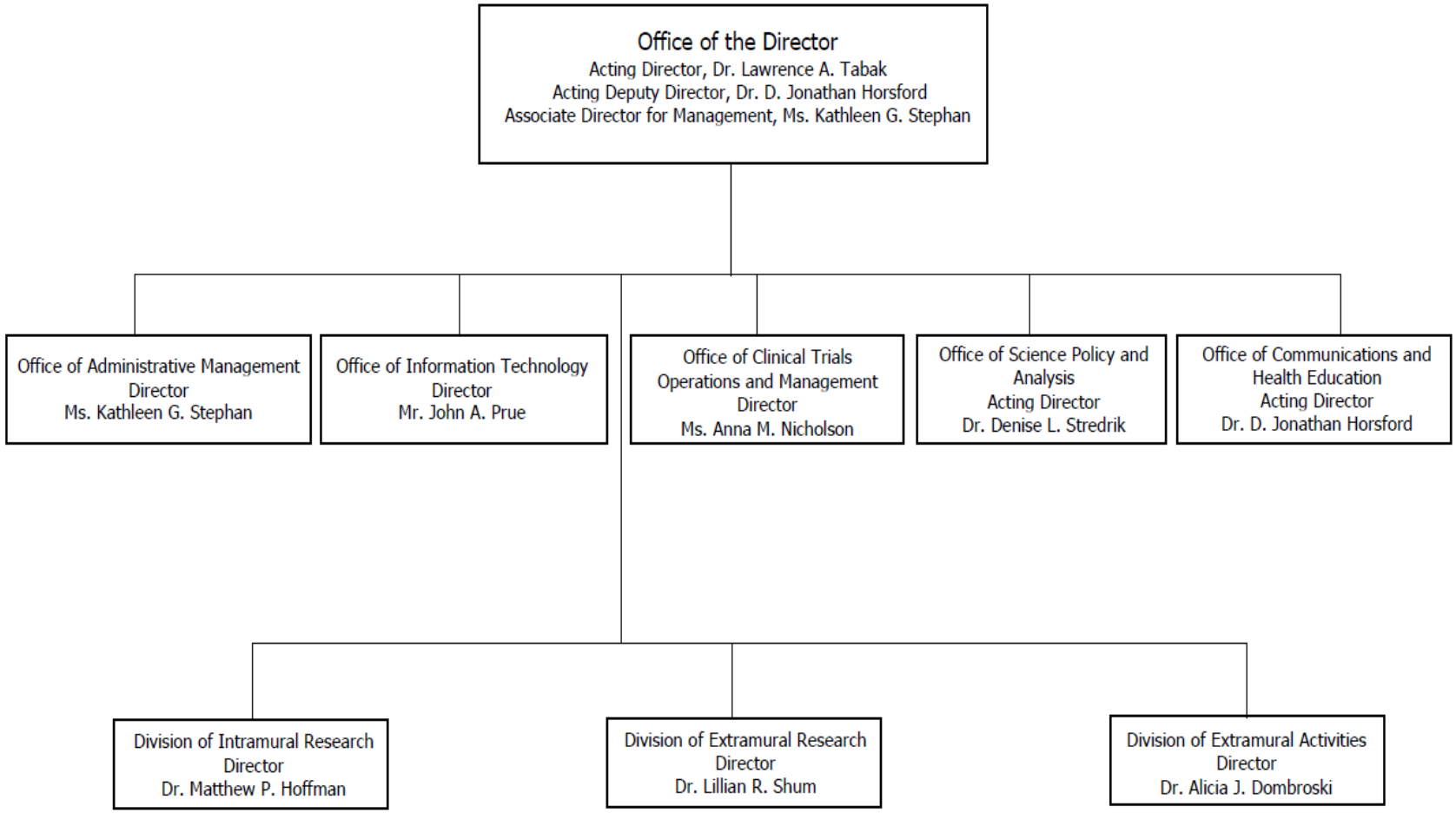
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Dental and Craniofacial Research



NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

For carrying out section 301 and title IV of the PHS Act with respect to dental and craniofacial diseases, [$477,429,000]*$434,559,000*.

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Amounts Available for Obligation[1]
(Dollars in Thousands)

Source of Funding	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	$461,781	$477,429	$434,559
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	-1,586	0	0
Subtotal, adjusted appropriation	$460,195	$477,429	$434,559
OAR HIV/AIDS Transfers	449	250	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	$460,644	$477,679	$434,559
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$460,644	$477,679	$434,559
Unobligated balance lapsing	-31	0	0
Total obligations	$460,613	$477,679	$434,559

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2019 - $3,019 FY 2020 - $3,100 FY 2021 - $3,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY 2020 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	447	$205,348	470	$219,106	473	$208,035	3	-$11,070
Administrative Supplements	*(0)*	5,004	*(0)*	4,000	*(0)*	3,720	*(0)*	-280
Competing:								
Renewal	27	12,180	27	12,217	22	9,281	-5	-2,936
New	166	69,131	173	69,336	141	52,673	-32	-16,662
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	193	$81,311	200	$81,552	163	$61,954	-37	-$19,598
Subtotal, RPGs	640	$291,664	670	$304,658	636	$273,709	-34	-$30,949
SBIR/STTR	24	12,964	25	13,429	23	12,146	-2	-1,283
Research Project Grants	664	$304,628	695	$318,087	659	$285,855	-36	-$32,232
Research Centers:								
Specialized/Comprehensive	1	$4,042	1	$4,042	1	$3,678	0	-$364
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	1	$4,042	1	$4,042	1	$3,678	0	-$364
Other Research:								
Research Careers	58	$8,507	60	$8,766	55	$7,977	-5	-$789
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	97	0	97	0	97	0	0
Other	18	9,071	19	10,455	17	9,514	-2	-941
Other Research	76	$17,675	79	$19,317	72	$17,588	-7	-$1,730
Total Research Grants	741	$326,345	775	$341,446	732	$307,120	-43	-$34,326
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	108	$4,990	108	$5,140	98	$4,677	-10	-$463
Institutional Awards	126	7,139	126	7,317	115	6,659	-11	-659
Total Research Training	234	$12,129	234	$12,457	213	$11,336	-21	-$1,121
Research & Develop. Contracts	17	$22,543	16	$20,515	16	$20,272	0	-$242
(SBIR/STTR) (non-add)	*(0)*	*(140)*	*(0)*	*(144)*	*(0)*	*(131)*	*(0)*	*(-13)*
Intramural Research	139	70,363	146	72,826	146	66,916	0	-5,909
Res. Management & Support	86	29,265	89	30,436	89	28,914	0	-1,522
Res. Management & Support (SBIR Admin) (non-add)	*(0)*	*(2)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NIDCR	225	$460,644	235	$477,679	235	$434,559	0	-$43,120

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

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

Major changes by budget mechanism and/or budget detail are briefly described below. The FY 2021 President's Budget for NIDCR is $434.6 million, a decrease of $43.1 million from the FY 2020 Enacted level.

Research Project Grants (RPGs) (-$32.2 million; total $285.9 million):
NIDCR will cut funding for non-competing RPGs by 5.1 percent, a reduction of $11.1 million reduction from the FY 2020 Enacted level. Individual noncompeting awards in FY 2021 will be reduced by 7.0 percent relative to their full funding level in order to free up funding within research project grants for competing awards. Competing RPGs will decrease by 37 grants compared to the FY 2020 enacted level of 200 awards, and the amount to support competing awards will decrease by $19.6 million from the FY 2020 enacted level, a 24.0 percent reduction.

Other Research (-$1.7 million; total $17.6 million):
NIDCR will reduce funding by 9.0 percent for Other Research. These reductions will be distributed across all programmatic areas.

Research Training (-$1.1 million; total $11.3 million):
NIDCR will reduce funding by 9.0 percent for Research Training.

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Summary of Changes

(Dollars in Thousands)

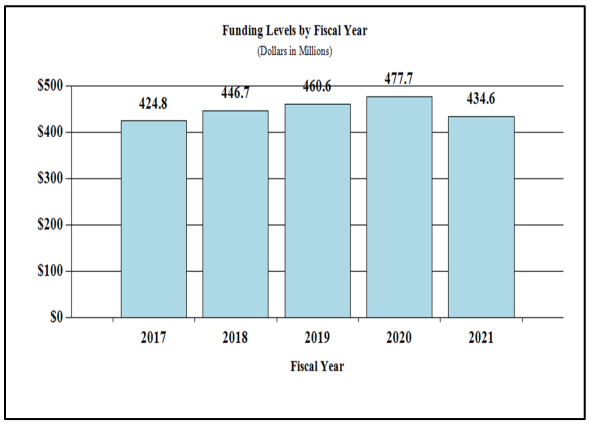
FY 2020 Enacted	$477,679
FY 2021 President's Budget	$434,559
Net change	-$43,120

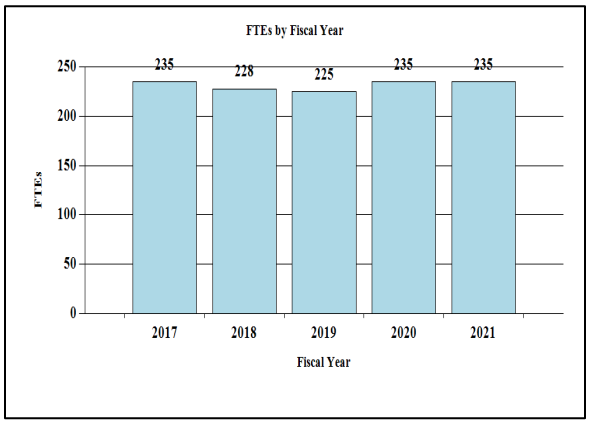
CHANGES	FY 2021 President's Budget FTEs	FY 2021 President's Budget Budget Authority	Change from FY 2020 Enacted FTEs	Change from FY 2020 Enacted Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2020 pay increase & benefits		$25,624		$166
b. January FY 2021 pay increase & benefits		25,624		399
c. Paid days adjustment		25,624		-97
d. Differences attributable to change in FTE		25,624		0
e. Payment for centrally furnished services		11,288		-806
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		30,004		146
Subtotal				-$192
2. Research Management and Support:				
a. Annualization of January 2020 pay increase & benefits		$15,033		$96
b. January FY 2021 pay increase & benefits		15,033		233
c. Paid days adjustment		15,033		-56
d. Differences attributable to change in FTE		15,033		0
e. Payment for centrally furnished services		2,690		-213
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		11,191		132
Subtotal				$192
Subtotal, Built-in				$0

CHANGES	FY 2021 President's Budget No.	FY 2021 President's Budget Amount	Change from FY 2020 Enacted No.	Change from FY 2020 Enacted Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	473	$211,755	3	-$11,350
b. Competing	163	61,954	-37	-19,598
c. SBIR/STTR	23	12,146	-2	-1,283
Subtotal, RPGs	659	$285,855	-36	-$32,232
2. Research Centers	1	$3,678	0	-$364
3. Other Research	72	17,588	-7	-1,730
4. Research Training	213	11,336	-21	-1,121
5. Research and development contracts	16	20,272	0	-242
Subtotal, Extramural		$338,729		-$35,689
	FTEs		FTEs	
6. Intramural Research	146	$66,916	0	-$5,717
7. Research Management and Support	89	28,914	0	-1,714
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	235	$434,559	0	-$43,120
Total changes				-$43,120

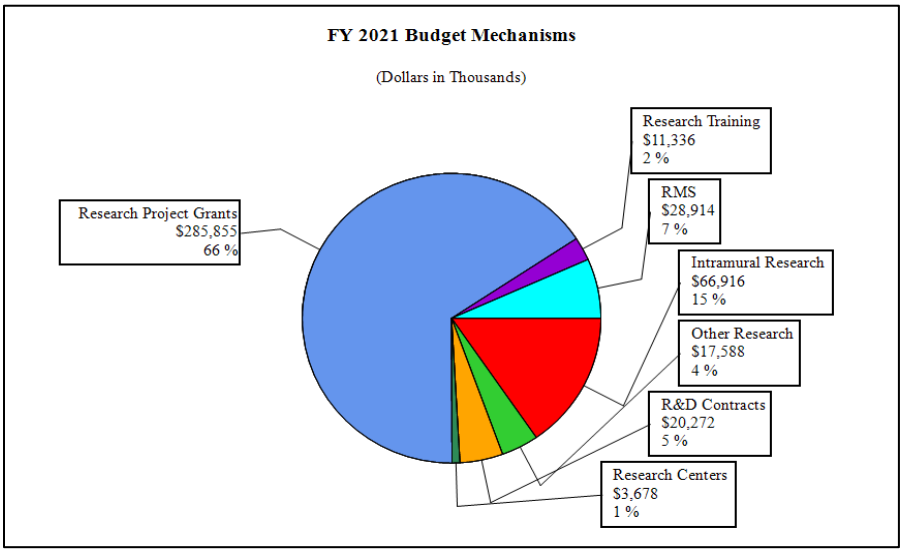
Fiscal Year 2021 Budget Graphs

History of Budget Authority and FTEs:

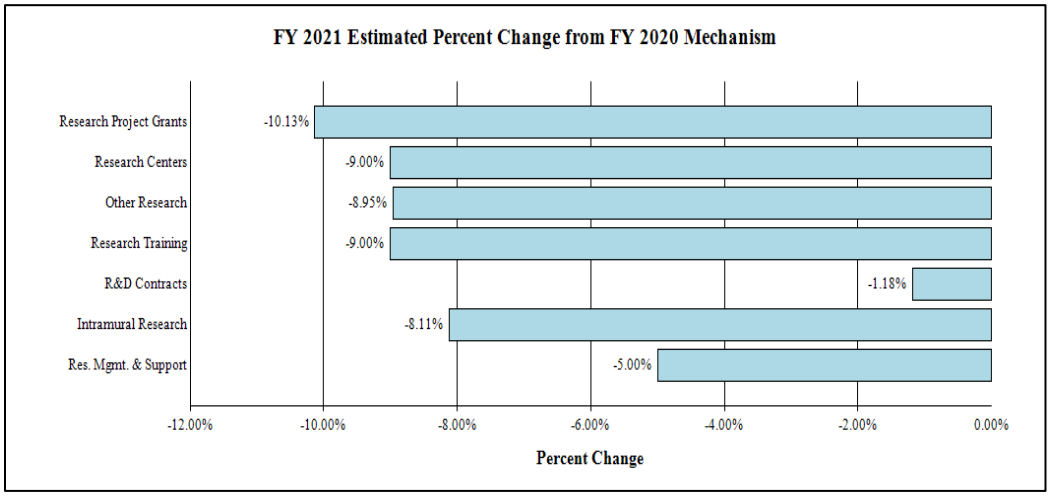




Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Budget Authority by Activity[1]
(Dollars in Thousands)

	FY 2019 Final		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 +/- FY2020	
Extramural Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Oral and Craniofacial Biology		$220,293		$228,471		$206,693		-$21,778
Clinical Research		69,803		72,394		65,494		-6,901
Behavioral and Social Sciences		16,879		17,506		15,837		-1,669
Genetics and Genomics		54,041		56,047		50,705		-5,342
Subtotal, Extramural		**$361,016**		**$374,418**		**$338,729**		**-$35,689**
Intramural Research	**139**	**$70,363**	**146**	**$72,826**	**146**	**$66,916**	**0**	**-$5,909**
Research Management & Support	**86**	**$29,265**	**89**	**$30,436**	**89**	**$28,914**	**0**	**-$1,522**
TOTAL	**225**	**$460,644**	**235**	**$477,679**	**235**	**$434,559**	**0**	**-$43,120**

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2020 Amount Authorized	FY 2020 Enacted	2021 Amount Authorized	FY 2021 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$477,679,000	Indefinite	$434,559,000
National Institute of Dental and Craniofacial Research	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$477,679,000		$434,559,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2012	$420,369,000	$420,369,000	$404,997,000	$411,488,000
Rescission				$777,712
2013	$408,212,000		$409,449,000	$410,710,288
Rescission				$821,421
Sequestration				($20,614,832)
2014	$411,515,000		$409,947,000	$398,650,000
Rescission				$0
2015	$397,131,000			$399,886,000
Rescission				$0
2016	$406,746,000	$404,847,000	$415,169,000	$415,582,000
Rescission				$0
2017[1]	$413,396,000	$425,578,000	$430,544,000	$425,751,000
Rescission				$0
2018	$320,749,000	$432,363,000	$439,738,000	$447,735,000
Rescission				$0
2019	$413,196,000	$453,082,000	$462,024,000	$461,781,000
Rescission				$0
2020	$397,493,000	$484,350,000	$486,756,000	$477,429,000
Rescission				$0
2021	$434,559,000			

[1] Budget Estimate to Congress includes mandatory financing.

Justification of Budget Request

National Institute of Dental and Craniofacial Research

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

Budget Authority (BA):

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
BA	$460,644,000	$477,679,000	$434,559,000	-$43,120,000
FTE	225	235	235	0

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

Director's Overview

The National Institute of Dental and Craniofacial Research (NIDCR) is taking the lead Federal role in a newly commissioned Surgeon General's Report on Oral Health. The Report will document 20 years of progress since the first Oral Health Report in 2000 and identify challenges and opportunities to transform how NIDCR prioritizes research, promotes oral health, treats disease, and overcomes health disparities for all Americans. The framework for prioritizing the work ahead is found in NIDCR 2030, a strategic plan that examines Dental, Oral and Craniofacial health and disease in the context of the whole body.

Oral Health in the Context of Overall Health

Results from research studies, funded, in part, by NIDCR, have shown poor oral health is associated with systemic diseases such as diabetes, stroke, and heart disease. NIDCR-supported researchers are now pinpointing common biological mechanisms that may underly these associations. One study identified a specific protein modification that is common between periodontal (gum) disease and rheumatoid arthritis. This may represent a causative link between the two diseases.[1] Other scientists showed that a bacterium involved in the formation of dental plaque accelerates growth of human colorectal cancer cells in vitro and increases the number of spontaneous tumors in a mouse model of colon cancer.[2]

Most common oral diseases are multifactorial in nature, involving biological, environmental, behavioral, and social factors. NIDCR-funded investigators are testing a behavioral intervention targeting both parents and medical providers to increase dental visits and reduce untreated caries (tooth decay) in children. In addition, NIDCR will continue to support successful examples of

[1] https://www.ncbi.nlm.nih.gov/pubmed/27974664
[2] https://www.ncbi.nlm.nih.gov/pubmed/30833345

integrated dental and medical care in clinical settings and disseminate those findings to improve clinical environments. Ultimately, by continuing to encourage collaborative research among academia, industry, clinicians, advocacy groups, and community members, NIDCR will ensure that oral health is always considered in the context of overall health.

Advancing the Promise of Regenerative Medicine

Regenerative medicine exploits the potential of stem cells and other biomaterials to repair or replace damaged and diseased tissues, including those within the Dental Oral and Craniofacial complex. NIDCR-funded researchers are employing single-cell analysis to study variations among individual cells within a tissue. By studying the expression of genes and proteins (genomics, proteomics) in thousands of individual cells simultaneously, signaling pathways and mediators in the regenerative process that have not been previously identified are defined.

To realize the full potential of regenerative medicine, there must be enhanced synergy between basic and translational science to bring treatments to the clinic. In 2015, recognizing the lag between basic research and their translation into treatments, NIDCR launched the Dental, Oral, and Craniofacial Tissue Regeneration Consortium (DOCTR-C) to accelerate the movement of innovative ideas into preclinical products capable of becoming successful treatments. The first two phases of DOCTR-C created two multidisciplinary research teams and supported many projects. For example, a small business is optimizing a novel organic-bone mineral biomaterial for improved bone grafting. This product may also prove to be useful in the delivery of non-opioid medication to treat pain and is receiving funding from the NIH HEAL (Helping to End Addiction Long-term) Initiative. The third phase of the effort focuses on the validation, manufacturing, and preclinical testing of the most promising products to ready them for submission for Food and Drug Administration (FDA) approval.

NIDCR is the lead NIH Institute on the National Academy of Medicine Forum on regenerative medicine. The Forum brings together experts from diverse backgrounds and organizations to identify strategies to overcome barriers and accelerate development of new cures. NIDCR continues to pioneer regenerative medicine, for example, by investing in a promising research field called autotherapies, which are treatments that take advantage of the body's innate ability to repair and regenerate damaged or diseased dental, oral, and craniofacial tissues.

Identifying Clues to Oral Diseases in the Oral Microbiome

Communities of microbes, such as bacteria, viruses, and fungi, make up the microbiome, which play important roles in the maintenance of health and the pathogenesis of disease. NIDCR has been a leader in microbiome research and was originally co-lead of the 2007 NIH Common Fund supported Human Microbiome Project. NIDCR now supports the Human Oral Microbiome Database to catalog the genetic material of microorganisms in the oral cavity and makes this information freely available to the research community. Encouraging collaborations among different research disciplines is another way in which NIDCR is advancing the field. For example, biomedical researchers and engineers collaborated to build microscopic nanorobots, a remarkable new technology, to target and destroy dental plaque, the community (or microbiome) of bacteria that grow on teeth and can cause caries (tooth decay). The nanorobots, which contain

an anti-bacterial compound, are controlled using tiny magnets to perform micro-scale precision cleaning. This technology could be used to prevent dental caries and periodontal disease, in addition to cleaning other surfaces susceptible to biofilms, such as metal implants or hospital equipment. Other investigators are developing an oral probiotic rinse that would maintain optimal balance between healthy and harmful microbiota in the mouth and prevent biofilm formation. Exploiting the oral microbiome to take advantage of its significant influence on health will give scientists exciting opportunities to use the body's protective mechanisms to prevent and treat disease.

NIDCR has increased its investment in early-stage and mid-career investigators and continued strengthening the foundation of future oral health researchers. The benefits are described in more detail below.

Overall Budget Policy: The FY 2021 President's Budget request for NIDCR is $434.6 million, a decrease of $43.1 million or 9.0 percent below the FY 2020 Enacted level.

Program Descriptions and Accomplishments

The breadth of NIDCR research precludes a complete review of all the Institute's program areas in this budget document. The narratives that follow highlight just some of the Institute's research areas, programs, and initiatives.

Oral and Craniofacial Biology

NIDCR supports a comprehensive dental, oral, and craniofacial biology research portfolio which provides the scientific evidence for advancing prevention, diagnosis, and treatment of diseases affecting these structures. Basic research in this program enables development of improved dental restorative materials and novel oral biodevices, a better understanding of the genetics underlying dental, oral, and craniofacial diseases, insights into connections between oral health and overall health, advances in data collection and analysis, and multidisciplinary investigations into the causes of the transition from acute to chronic orofacial pain and overlapping pain conditions.

Developing Tissue Chips to Accelerate Pre-clinical Research

New candidate drugs often work well in the laboratory in mice and rats, but then fail in costly and time consuming human clinical trials. To help address this obstacle, scientists are creating a drug-screening tool called tissue chips, 3D platforms that support living human cells grown to become miniature models that mimic the structure and function of human organs. In a collaboration with the National Center for Advancing Translational Sciences (NCATS) and the Food and Drug Administration (FDA), NIDCR-funded investigators are building a salivary gland tissue chip to identify drugs that protect against salivary gland damage – to prevent complications like dry mouth – when radiotherapy is used to treat head and neck cancers. One group is focused on understanding how different cell types form during salivary gland

development,[3] while another is taking the essential first step in making a salivary gland tissue chip by stimulating the different cell types to organize into a functional salivary gland.[4] These collaborative efforts will help improve drug screening to reduce the number of new drugs that fail during clinical trials, ultimately accelerating translational research.

Understanding the Biological Effects of Electronic Cigarettes on Oral Health

E-cigarette use is on the rise among teenagers, increasing from 12 to 21 percent among high school students.[5] Although often thought of as a safer alternative to conventional cigarettes, evidence of their harmful effects is quickly accumulating, as demonstrated by over 30 deaths due to lung injury associated with vaping.[6] In 2016, NIDCR launched an initiative to determine the effects of e-cigarettes on oral health. Initial findings suggest they may have negative health effects similar to those of conventional cigarettes, such as increasing the risk of developing oral cancer. By comparing oral cells from the mouths of e-cigarette users, conventional cigarette smokers, and non-smokers, researchers found that more than 60 percent of the abnormally expressed genes from e-cigarette users' oral cells were associated with certain cancers. For example, the levels of two genes that keep cells from becoming cancerous, called NOTCH1 and HERC2, were found expressed at lower levels in both e-cigarette users and conventional cigarette smokers. Although genes associated with cancer showed the most severe aberrant expression, scientists also found genes associated with gastrointestinal and neurological disease to be abnormally expressed.[7] Given the importance of this public health crisis, NIDCR continues to build on its investments to understand how e-cigarettes contribute to oral diseases and support research to establish novel strategies to reduce their use, especially among young adults.

Program Portrait: Building Research Capacity with Investments in Early-Stage and Mid-Career Investigators

NIDCR recognizes the vital importance of having a well-trained and diverse cadre of scientists to tackle the research and clinical challenges of the future. Accordingly, the Institute has invested in initiatives for early-stage and mid-career investigators. NIDCR's Pathway to Independence awards and support for early-stage investigators (ESIs) help early-career scientists overcome challenges as they set up their research labs as independent faculty. As a result, early-career researchers are making valuable contributions to dental, oral, and craniofacial research and health. For example, one awardee showed that a bacterium found in periodontal lesions contributes to formation of harmful oral biofilms such as dental plaque by gliding over surfaces to transport other types of harmful bacteria that cannot move on their own.[8] In FY2019 NIDCR funded approximately one third of the ESIs who submitted applications, helping the NIH to exceed its Next Generation Researchers Initiative goal of supporting 1,100 ESIs.

NIDCR is committed to supporting high-achieving mid-career researchers through the Sustaining Outstanding Achievement in Research (SOAR) program, which provides exceptional mid-career investigators longer-term support to tackle ambitious projects of extraordinary potential. For example, one SOAR grantee is studying how stem cells in the salivary duct behave after radiation therapy for head

[3] www.ncbi.nlm.nih.gov/pubmed/30713042, www.ncbi.nlm.nih.gov/pubmed/29335337; www.ncbi.nlm.nih.gov/pubmed/30305288
[4] www.ncbi.nlm.nih.gov/pubmed/?term=30384153
[5] www.cdc.gov/vitalsigns/youth-tobacco-use/index.html
[6] www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html
[7] www.ncbi.nlm.nih.gov/pubmed/30744164
[8] www.ncbi.nlm.nih.gov/pubmed/30082394

and neck cancer, which cause salivary dysfunction and dry mouth. They have identified several groups of cells that could potentially be manipulated to regenerate salivary tissue to treat this agonizing condition.

As part of building a stronger, more dynamic research environment by bringing different perspectives to address complex scientific problems, NIDCR's intramural program awarded its first fully funded fellowship for postdoctoral scientists from diverse backgrounds. The trainee is characterizing the molecular signaling pathways of ribosomes, cellular machines that translate genetic messages into proteins, to understand how craniofacial malformations develop. Such investments in early- and mid-career scientists ensure NIDCR has the kind of well-trained, diverse investigators needed for scientific advancement of the dental, oral, and craniofacial research field.

Developing Immunotherapies for Oral Cancer

Investments in cancer research have resulted in improved treatments and an overall increase in cancer survival rates. However, some cancers such as those in the head and neck region, remain a challenge because they respond poorly to standard treatments such as surgery, radiation, and chemotherapy. NIDCR-supported researchers are building on advances in immunotherapies, which use a person's own immune system to attack cancer cells, to develop novel treatments for head and neck cancers (HNC). These investigators generated an HNC-targeting therapeutic cancer nanovaccine to activate the immune system as part of treatment, rather than for disease prevention. The vaccine not only results in greater anti-tumor activity by promoting the survival of specific immune cells called T-cells, its nanoparticles enhance uptake by immune cells to increase effectiveness compared to standard vaccines. In mice, this anti-HNC nanovaccine reduced tumor size, improved survival, and was even more effective when combined with a commonly used immunotherapy.[9] These encouraging results suggest that therapeutic vaccines can be combined with other therapies to improve HNC treatment and suggest that nanovaccines have great potential to treat many cancer types.

Designing Dental Materials to Last a Lifetime

Restoring (filling) cavities with synthetic dental materials or capping a tooth following a routine root canal are standard treatments. However, dental materials often crack or detach from the tooth and need to be replaced over time. For fillings to last a lifetime, they must remain strong enough to prevent cracking after decades of chewing. Equally important, they must bind very tightly to the tooth surface to prevent water and bacteria from seeping underneath and causing new decay. One NIDCR-funded group of scientists has shown that by adding a safe and non-toxic compound called thiourethane, fillings were made two times more resistant to breakage as compared to a standard filling.[10] Further, the non-toxic polymer methacrylamide renders filling materials more resistant to degradation by bacterial enzymes. After six months, this novel dental material remained attached to the tooth more strongly than the original material.[11] Building on these advances, NIDCR investments in dental materials could lead to a future where fillings last a lifetime, dramatically reducing oral health costs and dental visits.

[9] www.ncbi.nlm.nih.gov/pubmed/29769207
[10] www.ncbi.nlm.nih.gov/pubmed/30783177
[11] www.ncbi.nlm.nih.gov/pubmed/30826074

Budget Policy: The FY 2021 President's Budget estimate for this program is $206.7 million, a decrease of $21.8 million or 9.5 percent compared to the FY 2020 Enacted level.

Clinical Research

To complement investments in basic dental, oral, and craniofacial research, NIDCR supports a broad range of clinical research activities, including clinical trials, epidemiological studies, practice- and community-based research, and studies of oral health disparities.

Reducing Health Disparities and Improving Oral Health in Rural America

Preventive oral health services, such as fluoride varnish application, dental screening, and oral health behavior education, promote good oral health, and reduce dental caries (decay) and periodontal (gum) disease. As of 2018, all States in the U.S. offer Medicaid-supported delivery of preventive health services for children, including oral health, in medical offices. This is especially important in rural areas where there are fewer dentists, particularly pediatric dentists, and rates of poor oral health are higher than in urban areas. To help address this problem, NIDCR-funded researchers investigated the use of Medicaid-supported preventive oral health services for children to see if there were differences in delivery in rural versus urban areas. The scientists found that children in rural counties were half as likely to receive these preventive oral health services in medical offices than children in counties with urban areas[12]. The reduced use of preventive oral health services in rural medical offices suggests there is a pressing need for strategies to increase the number of young children receiving these services, and that there may be opportunities to improve the integration of oral health into primary care. With this evidence in hand, researchers will focus on understanding the role of parents in accessing childhood oral preventative services to implement strategies to increase the usage of this Medicaid service.

Program Portrait: TMD – The Pain That Won't Go Away

Experts estimate that at least 10 million Americans are affected by temporomandibular disorders (TMD), a group of conditions that cause pain and dysfunction in the jaw joint and muscles. NIDCR is a long-time investor in research to understand the causes of TMD, why it sometimes becomes a chronic disorder, and how to treat it. The Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) study, launched in 2005, has yielded a wealth of information on the role of behavioral, genetic, and psychological factors in TMD pain. Currently, the study is identifying genetic variations that affect TMD development, transition from acute to chronic TMD, and TMD's relationship to other chronic pain conditions such as headache, low back pain, and irritable bowel syndrome. Scientists identified several pain-related clinical symptoms and designed a mathematical model that strongly predicts greater risk of progressing from acute to chronic TMD. These predictive clinical signs and symptoms may help clinicians identify the most at-risk patients and take steps to prevent or provide earlier treatment for chronic painful TMD.

NIDCR works with the NIH Pain Consortium, which brings researchers together from multiple NIH Institutes and Centers to identify and understand common biomechanisms underlying chronic pain syndromes such as TMD, and to advance pain prevention, diagnoses, and treatment. To help determine the next phases of TMD research, NIDCR and the NIH are sponsoring an independent committee under

[12] www.ncbi.nlm.nih.gov/pubmed/30537073

the auspices of the National Academies of Science, Engineering, and Medicine to address the current state of TMD research and treatment. The findings of this multidisciplinary panel will help inform the development of research priorities and strategies to improve treatment and clinical management of TMD patients.

Because TMD can become a chronic pain condition, finding safe and non-addictive alternatives to opioid treatment is a high priority. Through the HEAL (Helping to End Addiction Long-term) Initiative, launched by NIH in 2018, NIDCR is playing an important role in accelerating scientific solutions for new pain management therapies for TMD. In 2019, several TMD-related HEAL projects were awarded, including research to discover and validate biomarker signatures as a predictor of TMD pain severity and duration. NIDCR will continue to push forward to improve prevention, diagnosis, and treatment for TMD and other pain conditions.

Protecting Teeth with Fluoride Varnish: A Public Health Success Story

It is important for all people to have access to prevention, therapies, and cures that result from biomedical research, regardless of socioeconomic status or other defining characteristics. NIDCR investments in fluoride research helped demonstrate the value of fluoride varnish – a coating applied to children's teeth – to prevent dental caries, but many underserved populations did not have adequate access to fluoride varnish and its preventive benefits. To address this problem, NIDCR launched the Centers for Research to Reduce Disparities in Oral Health more than a decade ago to change clinical practice by helping to remove barriers preventing vulnerable populations from receiving equal care. Because of this research, all 50 State Medicaid programs support application of fluoride varnish to children's teeth by primary care physicians. NIDCR-funded investigators have validated that Medicaid-supported fluoride varnish policies are associated with better oral health and that children were much more likely to have very good or excellent teeth four or more years after the policies were enacted.[13] Building on the successful implementation of fluoride varnish in community settings, NIDCR invests in research to improve fluoride varnish, such as adding antimicrobial agents to provide enhanced protection against dental caries.[14]

Budget Policy: The FY 2021 President's Budget estimate for this program is $65.5 million, a decrease of $6.9 million or 9.5 percent compared to the FY 2020 Enacted level.

Behavioral and Social Sciences

NIDCR's investments in behavioral and social sciences research are leading to the development and implementation of evidence-based strategies to improve oral and overall health across the lifespan. NIDCR-supported studies help us understand how behavioral and social factors impact oral health, and what methods work best to influence decision-making and behavior.

Developing Mobile Oral Health Technologies

The development of digital tools and technologies, such as mobile health technology (mHealth), which include using mobile devices as activity trackers, is transforming health care, including oral

[13] www.ncbi.nlm.nih.gov/pubmed/?term=30032444
[14] www.ncbi.nlm.nih.gov/pubmed/28667230

health. Oral mHealth is a powerful tool that enhances health promotion and prevention by helping optimize oral health behaviors such as tooth brushing and flossing. NIDCR-supported researchers have created mORAL, a computational model that uses data from wrist-worn sensors to reliably and accurately detect oral health behaviors in people using manual toothbrushes.[15] Scientists are building on current technologies and computational models to advance personalized digital interventions that include electronic toothbrushes and mobile apps.[16] Other scientists are developing a mobile device-based infrared imaging tool that allows dentist-guided self-measuring of periodontal disease. This device could be linked to additional intraoral diagnostic and therapeutic devices to transform management of periodontal diseases, as well as other conditions, and would be especially useful in medically underserved, resource-limited areas.[17]

Reducing Health Disparities in American Indian/Alaska Native Populations

Early Childhood Caries is a form of dental caries that develops in the primary teeth of children. It is more severe and occurs earlier in the lifespan in American Indian/Alaska Native (AI/AN) children compared to other demographic groups in the United States. Many strategies to improve oral health in AI/AN populations have not produced promising results. However, because storytelling is an important method of transferring knowledge and communicating core values and belief systems in many Native communities, NIDCR-funded researchers experimented with a caries prevention story to increase oral health knowledge and positive oral health behaviors in AI/AN mothers and pregnant women.[18] The story incorporated oral health messages and was told by traditional storytellers in a talking circle. The investigators found improved oral health practices were maintained for at least six months after the storytelling sessions, suggesting traditional storytelling may be an effective way to promote good oral health behaviors in AI/AN communities. Future studies will test the success of the technique in additional communities and determine if it can be adapted to address other diseases or conditions disproportionally affecting AI/AN populations.

Budget Policy: The FY 2021 President's Budget estimate for this program is $15.8 million, a decrease of $1.7 million or 9.5 percent compared to the FY 2020 Enacted level.

Genetics and Genomics

The Genetics and Genomics program supports the translation of discoveries in genetics, genomics, and developmental biology into improved prevention, diagnosis, and treatment of dental, oral, and cranofacial disorders. The program also supports research in data science fields that require development of tools and technologies to collect, integrate, disseminate, and analyze large sets of phenotypic, clinical, and -omics (large families of cellular molecules like proteins or genes) data. This portfolio includes studies that range from uncovering molecular mechanisms in model organisms and humans to population-level studies, all with the aim of translating basic science into clinical practice.

[15] https://dl.acm.org/citation.cfm?id=3314388
[16] www.projectreporter.nih.gov/project_info_description.cfm?aid=9741950&icde=46654171
[17] www.projectreporter.nih.gov/project_info_description.cfm?aid=9856694&icde=46653932
[18] www.ncbi.nlm.nih.gov/pubmed/31012105

Reinforcing the Importance of Considering Oral Health in the Context of the Whole Body

The genetic contributions to dental caries and periodontitis have been poorly characterized. An international group of researchers, including several funded by NIDCR, carried out the largest-ever genome-wide association study to date[19] – more than 500,000 participants – and found 47 genomic regions linked to these diseases. These dental diseases also share common genetic signatures with a wide range of health including smoking, obesity, cardiovascular complications, cancers, and personality traits – highlighting the importance of considering oral health in the context of the whole body. Further identification and characterization of the genes associated with oral diseases may increase diagnostic efficiency and guide development of targeted therapies to treat these conditions and improve overall health.

Deducing Oral Microbiome Relationships and the Impact on Oral Health

Dental caries is the second most common infectious disease in the United States and the most common chronic disease of children and adolescents.[20] Two bacterium, S. mutans and S. sobrinus are most responsible for dental decay. To help elucidate the synergistic destructive relationship between these microorganisms, NIDCR-supported researchers sequenced the complete genome of S. sobrinus. Most bacteria have proteins that allow them to interact with neighboring bacteria; however, S. sobrinus's DNA sequence suggests it is missing these proteins.[21] It is possible that S. sobrinus uses missing proteins from nearby S. mutans to inflict more damage to tooth enamel. Future studies will confirm these initial results and potentially identify new approaches to prevent and treat dental caries by disrupting partnerships between harmful oral bacteria.

Budget Policy: The FY 2021 President's Budget estimate for this program is $50.7 million, a decrease of $5.3 million or 9.5 percent compared to the FY 2020 Enacted level.

Intramural Research

Scientists in NIDCR's intramural research division conduct cutting-edge basic, translational, and clinical dental, oral, and craniofacial research. Taking advantage of the NIH Clinical Center and collaborations with extramural investigators, intramural scientists study the biology of pain, itch, and taste; oral and craniofacial genetics and development; immunology of the mucosal system; salivary gland development and function; and stem cell biology and tissue regeneration.

Program Portrait: Itching: It's Not Just Skin Deep

Itch is an unpleasant sensation that most people relieve by scratching, but when itch is a chronic condition, constant itching and scratching becomes devastating not just to the skin, but also to mental health, as it negatively impacts quality of life. Treatments for chronic itch, which can accompany a number of skin, systemic, or neurological diseases, are few and only partly effective. As a result of decades of support for somatosensory (pressure, pain, and temperature) research, NIDCR scientists have begun to identify potential targets for interventions to relieve the agony of chronic itch.

[19] www.ncbi.nlm.nih.gov/pubmed/31235808
[20] www.cdc.gov/healthywater/hygiene/disease/dental_caries.html
[21] www.ncbi.nlm.nih.gov/pubmed/30533864

Clustered just beneath our skin are sensory nerves that detect pressure, texture, temperature, and vibration. The signals these nerves generate have a long trip from the skin to nerve cells in the spinal cord and then on to sensory processing neurons in the brain. Understanding how these signals make that trip is one focus of the NIDCR Division of Intramural Research, whose investigators began studying a receptor called TrpV1 on sensory cells that mediate the perception of heat. Early studies established that distinct subsets of cells responded specifically to different types of sensory stimuli such as heat, touch, and itch. Following this lead, further studies revealed that itch sensory signals were received and transmitted by a small group of dedicated receptors and transmitters.

The group is now characterizing ways to interfere with itch signal transmission. Their tactic exploits the relationship between the nerve cell receptor Npr1, which acts like a locked door, and the signaling molecule associated with itch, called Nppb, which acts as a molecular key unlocking the door to let the itch signal pass through into the cell. Working with the National Center for Advancing Translational Sciences (NCATS), researchers used high throughput drug screening to identify compounds that could block Nppb from unlocking Npr1, thus stopping the itch signal from entering the cell. In mouse models, a number of these compounds relieved chronic itch with no adverse effects. Fine-tuning the compounds and testing them in humans comes next. If successful, this treatment could break apart the painful itch-scratch cycle to offer permanent relief from the daily torment of chronic itch.

Characterizing the Link Between High-Sugar Diets and Autoimmune diseases

Diets high in sugar are known contributors to a myriad of chronic conditions such as dental caries, obesity, type 2 diabetes, and cardiovascular diseases. NIDCR intramural researchers have demonstrated that autoimmune diseases – for example, Crohn's disease and multiple sclerosis (MS) – should be added to this growing list of health conditions associated with a high sugar diet. Autoimmune diseases are caused by the immune system mistakenly attacking and destroying healthy cells throughout the body. The incidence of autoimmune diseases has risen along with increasing sugar consumption, suggesting a link between diet and these diseases. To understand the biological basis of this association, NIDCR investigators fed sugar-sweetened water, similar to soda and fruit juices, to mouse models of MS and Crohn's disease and noticed that the symptoms of the diseases worsened. The scientists found an increase in a molecule called transforming growth factor-beta, along with elevated levels of specific immune cells called T helper-17 cells that play a role in tissue destruction in autoimmune diseases.[22] These findings are further examples of the negative effects high sugar consumption has on health and emphasize the importance of reducing sugar intake to maintain health and prevent oral and systemic disease.

Insights from the Mouth Could Help Skin Wounds Heal Faster

Why is it that a bitten lip heals more quickly than a cut finger? As part of the intramural program, scientists at NIDCR and the National Institute of Arthritis and Musculoskeletal and Skin Diseases have discovered biological mechanisms that help explain why wounds in the mouth heal faster and with less scarring than wounds in other locations on the body. The researchers performed a common biopsy technique on the tissue lining the inside of the mouth, called oral mucosa, and skin in human subjects and compared the molecular signatures. They found that the genes required for wound healing are always turned on in oral mucosa, while in

[22] www.ncbi.nlm.nih.gov/pubmed/31451397

skin tissues those same genes are not turned on until after a wound occurs. These results suggest that oral mucosa wounds heal faster, in part, because they get a head start on the healing process. The investigators then tested whether activating this genetic program in skin could mimic oral wound healing by focusing on two genes, called SOX2 and PITX1, that were not expressed in skin. When SOX2 was added to skin cells in mice, wound healing was faster than in mice without SOX2.[23] These data demonstrate how studying novel aspects of oral biology give insights into overall health and disease and offer opportunities to develop more effective therapies for treating skin and other tissue wounds to improve healing and reduce recovery time from injuries and surgery.

Budget Policy: The FY 2021 President's Budget estimate for this program is $66.9 million, a decrease of $5.9 million or 8.1 percent compared to the FY 2020 Enacted level.

Research Management & Support

NIDCR research management and support (RMS) personnel enable the success of all NIDCR-funded programs. The Institute uses a data-driven approach to decision-making, which improves administrative efficiency by streamlining and harmonizing RMS activities. RMS personnel serve as liaisons with grantees, provide stewardship for research training and career development programs, analyze and advance science policy, coordinate program planning and evaluation, lead stakeholder outreach and communications, and oversee NIDCR's fellowship in oral health informatics.

Budget Policy: The FY 2021 President's Budget estimate for this program is $28.9 million, a decrease of $1.5 million or 5.0 percent compared to the FY 2020 Enacted level.

[23] www.ncbi.nlm.nih.gov/pubmed/30045979

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Budget Authority by Object Class[1]

(Dollars in Thousands)

	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Total compensable workyears:			
Full-time equivalent	235	235	0
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	$196	$200	$4
Average GM/GS grade	11.9	11.9	0.0
Average GM/GS salary	$109	$111	$2
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$105	$107	$2
Average salary of ungraded positions	$147	$150	$3

	OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
	Personnel Compensation			
11.1	Full-Time Permanent	15,248	15,424	175
11.3	Other Than Full-Time Permanent	10,706	10,829	123
11.5	Other Personnel Compensation	663	671	8
11.7	Military Personnel	228	234	6
11.8	Special Personnel Services Payments	3,365	3,064	-302
11.9	**Subtotal Personnel Compensation**	**$30,211**	**$30,221**	**$10**
12.1	Civilian Personnel Benefits	9,890	10,275	386
12.2	Military Personnel Benefits	157	161	4
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$40,257**	**$40,657**	**$400**
21.0	Travel & Transportation of Persons	711	652	-58
22.0	Transportation of Things	64	59	-5
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	251	230	-21
24.0	Printing & Reproduction	0	0	0
25.1	Consulting Services	2,003	1,838	-164
25.2	Other Services	9,355	7,902	-1,453
25.3	Purchase of goods and services from government accounts	54,431	49,177	-5,255
25.4	Operation & Maintenance of Facilities	813	732	-81
25.5	R&D Contracts	7,301	6,966	-335
25.6	Medical Care	148	138	-10
25.7	Operation & Maintenance of Equipment	1,178	1,081	-97
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$75,229**	**$67,835**	**-$7,394**
26.0	Supplies & Materials	4,269	3,919	-350
31.0	Equipment	2,995	2,749	-246
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	353,903	318,456	-35,447
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$437,422**	**$393,902**	**-$43,520**
	Total Budget Authority by Object Class	**$477,679**	**$434,559**	**-$43,120**

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Salaries and Expenses
(Dollars in Thousands)

OBJECT CLASSES	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel Compensation			
Full-Time Permanent (11.1)	$15,248	$15,424	$175
Other Than Full-Time Permanent (11.3)	10,706	10,829	123
Other Personnel Compensation (11.5)	663	671	8
Military Personnel (11.7)	228	234	6
Special Personnel Services Payments (11.8)	3,365	3,064	-302
Subtotal Personnel Compensation (11.9)	**$30,211**	**$30,221**	**$10**
Civilian Personnel Benefits (12.1)	$9,890	$10,275	$386
Military Personnel Benefits (12.2)	157	161	4
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$40,257**	**$40,657**	**$400**
Travel & Transportation of Persons (21.0)	$711	$652	-$58
Transportation of Things (22.0)	64	59	-5
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	251	230	-21
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	2,003	1,838	-164
Other Services (25.2)	9,355	7,902	-1,453
Purchases from government accounts (25.3)	54,431	49,177	-5,255
Operation & Maintenance of Facilities (25.4)	813	732	-81
Operation & Maintenance of Equipment (25.7)	1,178	1,081	-97
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$67,780**	**$60,731**	**-$7,049**
Supplies & Materials (26.0)	$4,269	$3,919	-$350
Subtotal Non-Pay Costs	**$73,075**	**$65,591**	**-$7,484**
Total Administrative Costs	**$113,332**	**$106,249**	**-$7,083**

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2019 Final			FY 2020 Enacted			FY 2021 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Extramural Activities									
Direct:	17	-	17	18	-	18	18	-	18
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	18	-	18	19	-	19	19	-	19
Division of Extramural Research									
Direct:	26	-	26	25	-	25	25	-	25
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	26	-	26	25	-	25	25	-	25
Division of Intramural Research									
Direct:	128	1	129	135	1	136	135	1	136
Reimbursable:	10	-	10	10	-	10	10	-	10
Total:	138	1	139	145	1	146	145	1	146
Office of Administrative Management									
Direct:	12	-	12	14	-	14	14	-	14
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12	-	12	14	-	14	14	-	14
Office of Clinical Trial Operations and Management									
Direct:	2	-	2	2	-	2	2	-	2
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	2	-	2	2	-	2	2	-	2
Office of Communication and Health Education									
Direct:	7	-	7	7	-	7	7	-	7
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	7	-	7	7	-	7	7	-	7
Office of Information Technology									
Direct:	8	-	8	8	-	8	8	-	8
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	8	-	8	8	-	8	8	-	8
Office of Science Policy and Analysis									
Direct:	6	1	7	8	-	8	8	-	8
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	1	7	8	-	8	8	-	8
Office of the Director									
Direct:	6	-	6	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	6	-	6
Total	223	2	225	234	1	235	234	1	235
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2017	11.8
2018	11.8
2019	11.9
2020	11.9
2021	11.9

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Detail of Positions[1]

GRADE	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	192,254	196,099	200,021
GM/GS-15	12	14	14
GM/GS-14	24	27	27
GM/GS-13	42	44	44
GS-12	37	39	39
GS-11	10	12	12
GS-10	0	0	0
GS-9	11	12	12
GS-8	6	7	7
GS-7	5	5	5
GS-6	3	4	4
GS-5	0	0	0
GS-4	0	0	0
GS-3	3	3	3
GS-2	0	0	0
GS-1	0	0	0
Subtotal	153	167	167
Grades established by Act of July 1, 1944 (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	2	1	1
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	2	1	1
Ungraded	83	87	87
Total permanent positions	153	167	167
Total positions, end of year	239	256	256
Total full-time equivalent (FTE) employment, end of year	225	235	235
Average ES salary	192,254	196,099	200,021
Average GM/GS grade	11.9	11.9	11.9
Average GM/GS salary	107,022	109,162	111,345

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