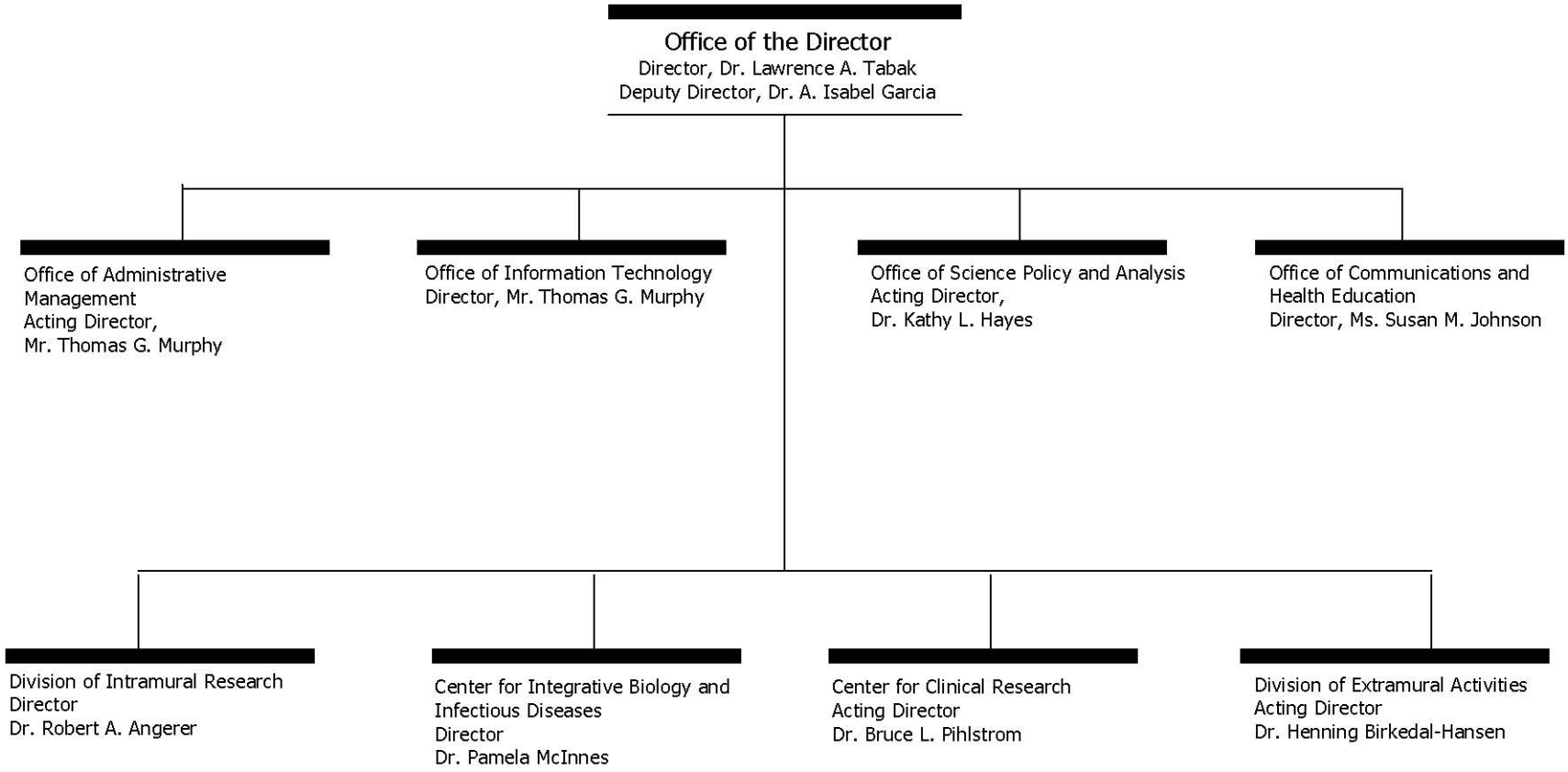
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research



FY 2008 Proposed Appropriation Language

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

For carrying out section 301 and title IV of the Public Health Services Act with respect to dental and craniofacial diseases $389,722,000

Comparison of Proposed FY 2008 Appropriation Language to Most Recently Enacted Full-Year Appropriations

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

For carrying out section 301 and title IV of the Public Health Services Act with respect to dental and craniofacial diseases [~~$386,095,000~~]**$389,722,000** (Department of Health and Human Services Appropriation Act, 2006)

National Institutes of Health
National Institute of Dental and Craniofacial Research

Amounts Available for Obligation 1/

Source of Funding	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Appropriation	$393,269,000	$389,336,000	$389,722,000
Enacted Rescissions	-3,933,000	0	0
Subtotal, Adjusted Appropriation	389,336,000	389,336,000	389,722,000
Real Transfer under Roadmap Authority	-3,479,000		
Real Transfer under Secretary's One-percent transfer authority	-267,000		
Comparative transfer from OD for NIH Roadmap	3,479,000		
Comparative Transfer to NIBIB	-33,000	-33,000	
Comparative transfer to OD	-14,000	-15,000	
Comparative Transfer to NCRR	-357,000	-284,000	
Comparative Transfers to the Office of the Assistant Secretary for Admin. And Mgmt. and to the Office of the Assistant Secretary for Public Affairs	-1,000	-1000	
Subtotal, adjusted budget authority	388,664,000	389,003,000	389,722,000
Unobligated balance lapsing	-1,000	0	0
Total obligations	388,663,000	389,003,000	389,722,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2006 - $1,075,000 FY 2007 - $755,000 FY 2008 - $755,000
Excludes $525,000 in FY 2007 and $525,000 in FY 2008 for royalties.

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2006 Actual		FY 2007 Continuing Resolution		FY 2008 Estimate		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	482	$173,486	434	$169,235	426	$179,081	-8	$9,846
Administrative supplements	(23)	4,848	(20)	2,800	(15)	2,000	-5	-800
Competing:								
Renewal	26	10,688	27	11,206	24	9,831	-3	-1,375
New	130	50,052	137	52,475	117	45,088	-20	-7,387
Supplements	2	440	2	461	2	372	0	-89
Subtotal, competing	158	61,180	166	64,142	143	55,291	-23	-8,851
Subtotal, RPGs	640	239,514	600	236,177	569	236,372	-31	195
SBIR/STTR	30	8,575	34	8,330	32	8,275	-2	-55
Subtotal, RPGs	670	248,089	634	244,507	601	244,647	-33	140
Research Centers:								
Specialized/comprehensive	10	12,453	8	17,143	8	20,100	0	2,957
Clinical research	0	88	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
Subtotal, Centers	10	12,541	8	17,143	8	20,100	0	2,957
Other Research:								
Research careers	85	11,454	77	10,408	73	9,778	-4	-630
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	24	2,130	20	1,660	20	1,660	0	0
Subtotal, Other Research	109	13,584	97	12,068	93	11,438	-4	-630
Total Research Grants	789	274,214	739	273,718	702	276,185	-37	2,467
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	35	1,466	37	1,546	37	1,546	0	0
Institutional awards	265	12,864	294	14,204	275	13,200	-19	-1,004
Total, Training	300	14,330	331	15,750	312	14,746	-6	
Research & development contracts	19	18,290	17	15,965	17	14,900	0	-1,065
(SBIR/STTR)	(0)	(19)	(0)	(0)	(0)	(0)	0	0
	FTEs		FTEs		FTEs		FTEs	
Intramural research	165	56,816	165	57,059	165	56,685	0	-374
Research management and support	80	21,535	87	21,850	91	22,075	4	225
NIH Roadmap for Medical Research	0	3,479	0	4,661	0	5,131		470
Total, NIDCR	245	388,664	252	389,003	256	389,722	4	1,723

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research
Budget Authority by Program
(Dollars in thousands)

Extramural Research	FY 2004 Actual FTEs	FY 2004 Actual Amount	FY 2005 Actual FTEs	FY 2005 Actual Amount	FY 2006 Actual FTEs	FY 2006 Actual Amount	FY 2006 Comparable FTEs	FY 2006 Comparable Amount	FY 2007 Continuing Resolution FTEs	FY 2007 Continuing Resolution Amount	FY 2008 Estimate FTEs	FY 2008 Estimate Amount	Change FTEs	Change Amount
Detail:														
Integrative Biology		$175,526		$186,666		$182,666		$182,452		$181,619		$180,190		-$1,429
Clinical		59,645		64,252		69,859		69,780		69,461		71,715		2,254
Biotechnology & Innovation		71,732		60,223		54,666		54,602		54,353		53,926		-427
Subtotal, Extramural		306,903		311,141		307,191		306,834		305,433		305,831		398
Intramural research	173	54,054	173	57,766	165	56,864	165	56,816	165	57,059	165	56,685	0	-374
Res. management & support	84	21,064	86	20,445	80	21,535	80	21,535	87	21,850	91	22,075	4	225
NIH Roadmap for Medical Research	0	1,316	0	2,477	0	3,479	0	3,479	0	4,661	0	5,131	0	470
TOTAL	257	383,337	259	391,829	245	389,069	245	388,664	252	389,003	256	389,722	4	719

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

Major Changes in the FY 2007 Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail and these highlights will not sum to the total change for the FY 2008 budget request for NIDCR, which is $0.7 million more than the FY 2007 estimate, for a total of $389.7 million.

Oral Health Disparity Centers Program (+$2.8 million; total $10 million): Within the Research Centers budget mechanism, the NIDCR currently supports five regional Centers for Research to Reduce Oral Health Disparities, which is a program categorized with NIDCR's clinical research sub-activity. The renewal of the Oral Health Disparities Centers Program in FY 2008 will further NIDCR's efforts to find ways to eliminate the persistent gaps in oral health that remain in our nation. To build on knowledge gained from the first 7 years of this centers program, NIDCR will move towards research that will involve large community-based clinical trials with the real potential of demonstrating that targeted, multi-factorial interventions can have a meaningful positive impact in specific populations including rural Americans, inner city populations of African Americans, Native Americans, and Hispanic Americans. The budget request would allow for support of this critical stage of intervention research.

Research Project Grants (+$0.2 million; total $236.4 million): NIDCR will support a total of 569 Research Project Grant (RPG) awards in FY 2008. Noncompeting RPGs will decrease by eight awards and increase by $9.8 million. Competing RPGs will decrease by 23 awards and decrease by $8.9 million.

Research Careers (-$0.6 million; total $9.8 million): NIDCR will support the Pathway to Independence program by funding an additional six awards in FY 2008. Total support for the Pathway program in FY 2008 is 11 awards and $0.9 million. The Institute will be reducing its support for the balance of its research career program by $1.2 million to enable support for other research areas, including the Oral Health Disparity Centers program. The reduction is projected to impact all research areas.

Research Training (-$1.0 million, total $14.7 million): Funding for research training awards will be reduced to bolster support for other research areas, including the Oral Health Disparity Centers program. The reduction is projected to impact all research areas.

Research and Development Contracts (-$1.1 million; total $14.9 million): Funding for research contracts will be reduced to bolster support for other research areas, including the Oral Health Disparity Centers program. The reduction is projected to impact all research areas.

NIH Roadmap for Biomedical Research (+$0.5 million; total $5.1 million): NIDCR will continue its support of the NIH Roadmap, an incubator for new ideas and initiatives that will accelerate the pace of discovery, in FY 2008.

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research
Summary of Changes

FY 2007 Continuing Resolution				$389,003,000
FY 2008 Estimated Budget Authority				389,722,000
Net change				719,000
	FY 2007 Continuing Resolution		Change from Base	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Annualization of January 2007 pay increase		$21,249,000		$140,000
b. January 2008 pay increase		21,249,000		478,000
c. Two extra days of pay		21,249,000		161,000
d. Payment for centrally furnished services		10,775,000		108,000
e. Increased cost of laboratory supplies, materials, and other expenses		25,084,000		424,000
Subtotal				1,311,000
2. Research Management and Support:				
a. Annualization of January 2007 pay increase		$11,166,000		$74,000
b. January 2008 pay increase		11,166,000		251,000
c. Two extra days of pay		11,166,000		78,000
d. Payment for centrally furnished services		7,264,000		34,000
e. Increased cost of laboratory supplies, materials, and other expenses		3,420,000		114,000
Subtotal				551,000
Subtotal, Built-in				1,862,000

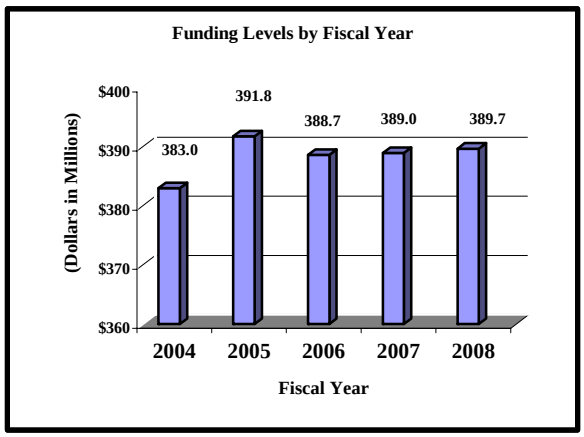
NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

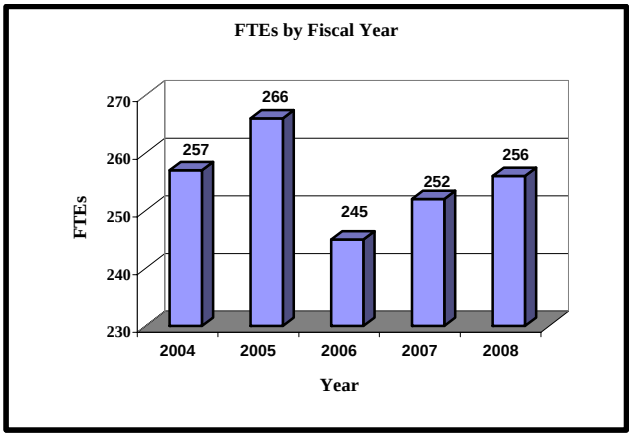
Summary of Changes--continued

CHANGES	2007 Continuing Resolution Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	434	$172,035,000	-8	$9,046,000
b. Competing	166	64,142,000	-23	-8,851,000
c. SBIR/STTR	34	8,330,000	-2	-55,000
Total	634	244,507,000	-33	140,000
2. Research centers	8	17,143,000	0	2,957,000
3. Other research	97	12,068,000	-4	-630,000
4. Research training	331	15,750,000	-19	-1,004,000
5. Research and development contracts	17	15,965,000	0	-1,065,000
Subtotal, extramural				398,000
	FTEs		FTEs	
6. Intramural research	165	57,059,000	0	-1,685,000
7. Research management and support	87	21,850,000	4	-326,000
11. NIH Roadmap for Medical Research	0	4,661,000	0	470,000
Subtotal, program		389,003,000		-1,143,000
Total changes	252		4	719,000

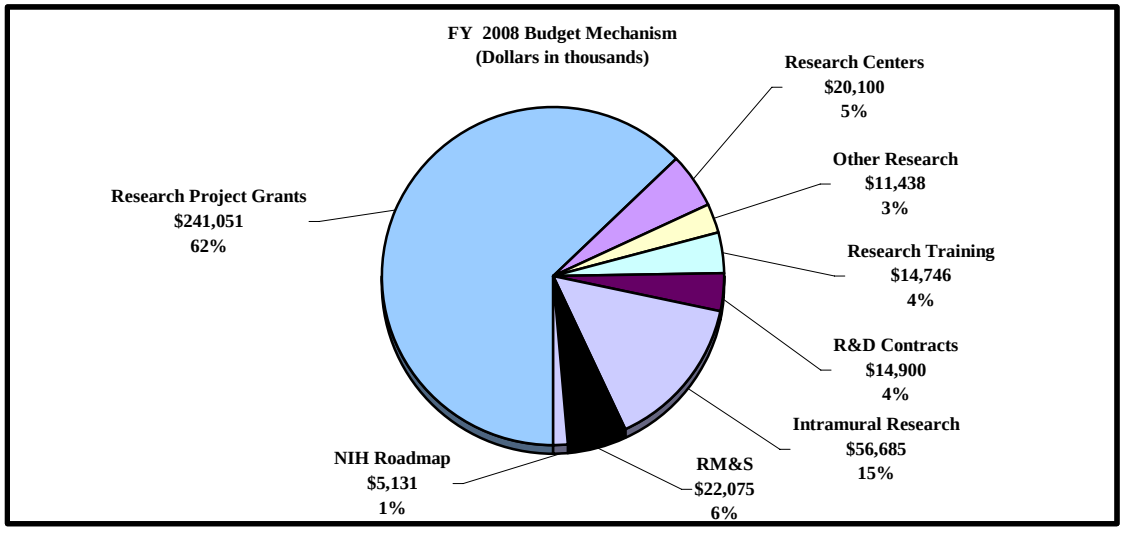
Fiscal Year 2007 Budget Graphs

History of Budget Authority and FTEs:

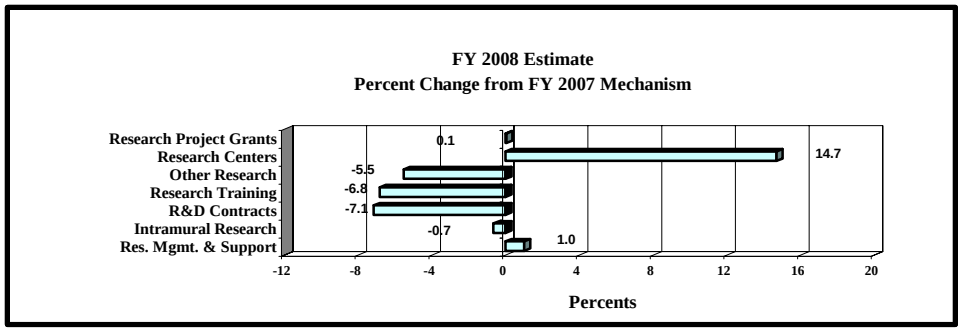




Distribution by Mechanism:



Change by Selected Mechanisms:



Justification of Budget Request

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

Budget Authority:

FY 2006 Actual		FY 2007 Continuing Resolution		FY 2008 Estimate		Increase or Decrease	
FTEs	BA	FTEs	BA	FTEs	BA	FTEs	BA
245	$388,664,000	252	$389,003,000	256	$389,722,000	4	$719,000

This document provides justification for the Fiscal Year 2008 activities of the National Institute of Dental and Craniofacial Research (NIDCR) including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2008 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR)." Details on the Roadmap/Common Fund are located in the Overview, Volume One.

DIRECTOR'S OVERVIEW

From the tube of toothpaste in the medicine cabinet to the sophisticated digital x-ray instrument in the dentist's office, advances in dental care tell a remarkable story of progress and innovation that has vastly improved the lives of the overwhelming majority of Americans. The most telling measure of this progress involves those who are edentulous (have lost all their teeth). Fifty years ago, more than 32% of American adults aged 45 and older were edentulous. Today, dental research has helped cut that rate by more than half, to less than 15%. As a result, an additional 18.5 million Americans in this age group--more than the population of Florida—are able to reap the functional and esthetic benefits of keeping some or all of their teeth for a lifetime[1,2].

As the Nation's leading supporter of dental, oral, and craniofacial research, NIDCR helped to support this success through its mission to improve oral, dental and craniofacial health through research, research training, and the dissemination of health information. The NIDCR is now sowing the seeds of a new crop of scientific advances that one day could number among its finest accomplishments for the American people. Tooth decay, periodontal disease, chronic dry mouth, oral cancer--all are en route to profound improvements in their diagnosis and/or treatment. Research on chronic oral and facial pain, bone and cartilage regeneration, salivary diagnostics, and bio-replacement teeth—all continue to yield new secrets and move ever closer to clinical applications that will benefit millions of Americans.

[1] HEW. National Center for Health Statistics, Series 11, Number 7: Selected Dental Findings in Adults by Age, Race, and Sex; United States – 1960-1962. Reprinted November 1965.

[2] Centers for Disease Control and Prevention. Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis—United States, 1988-1994 and 1999-2002. In: Surveillance Summaries, August 26, 2005. MMWR 2005:54 (No. SS-3).

Yet despite tremendous improvements in the Nation's oral health over the past decades, the benefits have not been equally shared by millions of low income and underserved Americans. The poor, underserved minorities, those living in some rural and inner-city areas, frail elderly persons living in institutional settings and people with special health care needs—all these suffer a disproportionate and debilitating amount of oral disease. Through activities such as its Centers to Eliminate Oral Health Disparities, cutting-edge research on the causes and repair of craniofacial defects and deformities, and genetic engineering to resolve the debilitating effects of radiation therapies and diseases such as Sjögren's Syndrome, NIDCR stands ready to help bring the benefits of oral health and function to all.

NIDCR's vibrant strategic planning process includes extensive vetting during plan development and finalization. The beneficial outcome is that mission-relevant priorities are clearly identified and articulated, and are used to provide guidance and inspiration to the scientific community and our own professional staff. Our strategic plan creates a framework within which high-quality research addressing important oral health problems can be organized, while providing a rational means of communicating priorities to the extramural community. Simultaneously, it allows for sufficient scientific freedom that newly emerging areas of discovery are not overlooked, and affords the opportunity for outside experts to weigh in on our current and future directions.

This FY 2008 Congressional Justification presents how the Institute will continue to plant the seeds of research and harvest the most scientifically mature of these ideas. But the process is never static. NIDCR strives to strike a delicate and appropriate balance in its commitment to the basic and clinical sciences. It does so through its comprehensive planning process that begins with NIDCR Strategic Plan and culminates in development and funding of promising new research initiatives that will round out the existing grant portfolio and bolster areas of emerging scientific opportunity, while leaving room for top quality investigator-initiated research. This document explains how we will build upon NIDCR's remarkable successes to create an even brighter and healthier future for all Americans.

Extramural Research

Integrative Biology

An excellent example of integrative biology in action exists in the arena of oral cancer detection. About 39,000 people develop head and neck cancers each year;[3] relative survival rates are among the lowest of major cancers. Only one-half the number of persons diagnosed with oral cancer are alive five years after the diagnosis.[4] The NIDCR's FY 2008 plans in this program area include continued support of a multifaceted program that will develop and integrate several new technologies and levels of care into a reliable clinical protocol to improve oral cancer detection and survival. Technologies under development include devices to aid in earlier detection, rapid genotyping of pathology samples to enhance analysis of suspicious lesions removed for biopsy, and integration of screening, diagnosis and treatment. NIDCR-supported researchers recently achieved initial success using a customized optical device that allows dentists to visualize in a completely new way whether a patient might have a developing oral cancer. Called a Visually Enhanced Lesion Scope (VELScope™), this simple, hand-held device emits a cone of blue light into the mouth that excites various molecules within our cells, causing them to absorb the light energy and re-emit it as visible fluorescence. Changes in the natural fluorescence of healthy tissue generally indicate light-scattering biochemical or structural changes caused by developing tumor cells. Health care providers shine the light onto a suspicious sore in the mouth, look through an attached eyepiece, and check for changes in color. Normal oral tissue emits a pale green fluorescence, while early tumor cells appear dark green to black. Not only would the instrument be an effective screening adjunct, it may also prove useful for helping surgeons determine how far to extend the surgical borders when removing tissue for biopsies. In 2008 NIDCR will continue to support the integration and translation of cutting edge technologies and practice protocols that hold great promise to finally improve the early detection and long term survival rates for those who suffer from oral cancer.

Budget Policy: The FY 2008 estimate for the Integrative Biology program area is $180.2 million, a decrease of $1.4 million, or 0.8 percent from the FY 2007 estimate. The program plans for FY 2008, along with expected outputs, follow. High priority will be given to support ongoing programs such as the one described above, meritorious new investigator–initiated research grants, and research training related to the mission areas described above. In addition, NIDCR will start two new initiatives in the following scientific areas:

- *Systems Biology Approach to Salivary Gland Physiology:* Saliva is a complex mixture of water, buffers, antibodies, and specialized proteins, important for maintaining oral health, function, and comfort. For example, this remarkable liquid aids in the body's immune function, digests food, remineralizes tooth enamel, protects the oral mucosa, and helps prevent oral fungal infections. Previously NIDCR-supported research projects catalogued

[3] National Cancer Institute Fact Sheet. Head and Neck Cancers: Questions and Answers. Accessed online at <http://www.cancer.gov/cancertopics/factsheet/Sites-Types/head-and-neck> in December 2006.
[4] Centers for Disease Control and Prevention. Oral Health Resources Fact Sheet series; Oral Cancer: Deadly to Ignore. Accessed online at < http://www.cdc.gov/OralHealth/factsheets/oc-facts.htm> in December 2006.

the genes and proteins that are expressed in the salivary glands. This could be thought of as similar to assembling a list of cities in the world but having little or no information about their location, culture, or neighboring communities. This initiative will build on that knowledge by putting the existing salivary gene and protein catalogues into context. That is, not only will it define when and where these genes and proteins are expressed in the salivary glands, but also how they function as parts of a fully integrated biological system. This initiative will combine the power of mathematics, biology, genomics, computer science, and other areas to assemble this information. This highly detailed information will likely translate into more precise and practical leads to treat Sjögren's Syndrome, a debilitating autoimmune disorder that affects millions of Americans. The initiative also will help in learning to use saliva as a diagnostic fluid for a variety of conditions, from AIDS to cancer to diabetes.

- *Osteoimmunology--Crosstalk between Immune System and Bone:* Osteoimmunology represents a rethinking of the traditional divide between bone and immunology research. This reconsideration results from recent work indicating that bone influences the well-being of our immune system - and vice versa. The challenge now is to define these interactions throughout the body, including the mouth. This initiative that will provide a fundamental understanding of the biological crosstalk between oral bone and the immune system. For Americans, this initiative will provide information that has a direct impact on our understanding of the nature, progression, and treatment of periodontal disease, and, most importantly, how best to prevent this condition before it erodes oral bone and causes tooth loss.

Clinical Research

Even though the Nation's oral health has never been better, a glance through today's dental or medical journals clearly shows that a long, challenging road lies ahead before our Nation achieves optimum oral health for all.[5] NIDCR will support research to expand the scientific evidence available to practitioners for current and future dental and oral health treatments. The availability of rigorous science-based information will allow practitioners to better match a patient's specific condition and personal health variables to the most efficacious treatment regimen. As the Nation's leading supporter of dental and oral health research, NIDCR is uniquely positioned to take the lead in generating this evidence base.

Budget Policy: The FY 2008 estimate for the Clinical Research Program is $71.7 million, an increase of $2.3 million, or 3.2 percent over the FY 2007 estimate. The program plans for FY 2008 include support for ongoing programs, highly meritorious new investigator–initiated research grants, and research training related to the mission.

- NIDCR will fund a competing renewal of the *Oral Health Disparities Centers Initiative* due to the promising achievements of currently funded centers, and the magnitude of the need for

[5] Centers for Disease Control and Prevention. Surveillance for dental caries, dental sealants, tooth retention, edentulism, and enamel fluorosis—United States, 1988-1994 and 1999-2002. In: Surveillance Summaries, August 26, 2005. MMWR 2005:54 (No. SS-3).

scientific advancement to eliminate disparities. Despite the remarkable improvement in the Nation's oral health over the years, not all Americans have benefited equally. Oral, dental, and craniofacial conditions remain among the most common health problems for low-income, disadvantaged, and institutionalized Americans. Unfortunately, there is no easy, one-size-fits-all solution. Much remains to be learned about the complex array of cultural, economic, genetic, and other contributory factors to these disparities and how best to overcome them. The NIDCR currently supports five regional Centers for Research to Reduce Oral Health Disparities. These centers already have devised several innovative, low-cost approaches to address early childhood tooth decay, oral cancer, poor diet, and improper tooth alignment, called malocclusion. The renewal of the Oral Health Disparities Centers Program in FY 2008 will further NIDCR's efforts to find ways to eliminate the persistent gaps in oral health that remain in our nation.

- *Practice-Based Research Networks:* Three regional dental practice-based research networks, or PBRNs, have been established through NIDCR grants. Their mission is to create networks of practicing dentists and dental hygienists to participate in clinical studies on a variety of pressing clinical issues in oral healthcare. A new activity for FY 2008 will provide an important and unanticipated benefit to the American people by expanding the evidence base on an emerging public health issue. Millions of Americans currently take a type of drug called bisphosphonates, typically to ease cancer-related pain or to prevent osteoporosis. But recent reports[6,7,8] indicate that newly formulated bisphosphonates can cause in some people a debilitating condition of the jawbone called osteonecrosis. What remains unclear is the prevalence of this unwanted side effect and, more importantly, who precisely is at risk. The NIDCR is launching the needed studies to investigate the problem and provide more meaningful data for the millions of Americans who may be at risk for osteonecrosis of the jaw.

- *Clinical studies of the potential association between maternal oral health and obstetric outcomes:* In recent years evidence has suggested that a pregnant woman with periodontal (gum) disease might be at increased risk for premature birth[9,10,11]. NIDCR-supported scientists recently completed the largest clinical trial to date to evaluate this possibility, called the Obstetrics and Periodontal Therapy Trial (OPT). Although OPT is currently the largest study to publish on the subject, NIDCR-supported *Maternal Oral Therapy to Reduce Obstetric Risk (MOTOR)* study is ongoing and will continue into FY 2008. There are some differences between the two studies. The 1,800-patient MOTOR study involves a broader

[6] Woo SB, Hellstein JW, Kalmar JR. Bisphosphonates and Osteonecrosis of the Jaws *Ann Intern Med.*2006; 144:753-761.
[7] Ruggiero SL, Mehrotra B, Rosenberg TJ, Engroff SL. Osteonecrosis of the jaws associated with the use of bisphosphonates: a review of 63 cases. J Oral Maxillofac Surg 2004;62(5):527-34.
[8] Markiewicz MR, Margarone JE 3rd, Campbell JH, Aguirre A. Bisphosphonate-associated osteonecrosis of the jaws: a review of current knowledge. JADA 2005;136(12):1669-74.
[9] Bassani DG, Olinto MTA, Kreiger N. Periodontal disease and perinatal outcomes: a case-control study. J Clin Periodontol 2007; 34: 31–39.
[10] Radnai M, Gorzo´ I, Urba´n E, Eller J, Nova´k T, Pa´l A. Possible association between mother's periodontal status and preterm delivery. J Clin Periodontol 2006; 33: 791–796.
[11] Jarjoura K et al. Markers of periodontal infection and preterm birth. American Journal of Obstetrics and Gynecology (2005) 192: 513-9

socio-economic cross section of women, provides fewer basic dental services, and includes women with slightly less severe periodontal disease. Conducting more than one large clinical trial on this important public health question will cast a wide enough investigational net to determine which, if any, women are at risk.

- *Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA):* This five-year clinical study continues into FY 2008 and will greatly accelerate the identification of better treatments to control the pain of temporomandibular muscle and joint disorders (TMJD), a group of conditions that cause pain and dysfunction in the jaw joint and muscles that control jaw movement. The OPPERA study marks one of the first, if not the first large, prospective clinical study of a chronic pain disorder. A prospective study is the "gold standard" of medical research: it looks forward in time, monitoring the health of those in the study over several years to track the onset or progression of a disease. This study will open a much needed window on these extremely complex conditions. With this five-year vantage point, it will be possible to begin identifying individual genetic, physiologic, and psychological factors that cause or contribute to TMJ disorders. In addition to our investment in OPPERA, NIDCR's continued investment in this area for FY 2008 includes several program announcements that will advance virtually all aspects of understanding and caring for these disorders.

Biotechnology and Innovation

NIDCR supports research on the next generation of breakthrough biomedical technologies that will improve oral health. To accelerate technology development, the Institute relies on interdisciplinary research approaches with an emphasis on basic and translational studies. Biomimetics (the use of biological systems as models to develop synthetic substances, devices, or systems), nanotechnology and nanoscience, diagnostic technologies, stem cell research, bioinformatics, dental materials, and biocompatibility of engineered materials—all fall within the sphere of this research area. Achievements that promise to make real what once seemed impossible loom on the horizon. However, these discoveries will improve health and quality of life only if they are incorporated into everyday practice; for that reason technology transfer is an important part of this program area. To that end, activities to fast-track small business innovation grants are planned for FY 2008, thus speeding the translation of scientific findings into practice.

Budget Policy: The FY 2008 estimate for the Biotechnology and Innovation program area is $53.9 million, a decrease of $0.4 million, or 0.8 percent from the FY 2007 estimate. Priority will be given to support of ongoing programs and highly meritorious new research projects. For this program, a significant portion of the FY 2008 budget will be targeted toward the following two areas:

- *Salivary diagnostics:* The NIDCR stands at the forefront of efforts to develop salivary diagnostics, the use of saliva as a diagnostic fluid. Several Institute grantees are now working to develop the various constituent parts required to assemble a tiny automated machine that can precisely measure levels of the various antibodies, antigens, and nucleic

acids present in saliva, all of which may indicate a developing disease or condition. In contrast to existing blood tests, salivary tests will able to be performed on the spot and require no painful needle sticks. Recently, the promise of salivary diagnostics moved closer to becoming technologically feasible. NIDCR grantees fabricated the first disposable, low-cost miniaturized diagnostic platform to process small amounts of saliva, amplify its DNA, and detect the levels of DNA sequences of interest. During FY 2008 work will proceed to integrate this back-end platform with existing front-end technologies to ultimately create a fully functional hand-held instrument for salivary diagnostic tests.

- *Biomaterials:* This field of research includes a number of promising areas of investigation—for example, engineering more biocompatible materials to act as scaffolding for replacement bone and teeth; the use of nanoparticles to increase the strength and durability of dental filling materials; and the design and development of effective bioadhesives for mineralized tissues such as dental enamel and bone, an area of investigation for FY 2008, made possible by recent progress. A waterproof, all-purpose adhesive that is secreted by mussels first intrigued biomedical and dental materials scientists a few decades ago. However, attempts to mimic mussels were slowed by an inadequate understanding of the molecular underpinnings of the adhesion. As new and more powerful research technologies emerge, these underpinnings are starting to come into focus. In a groundbreaking study, NIDCR grantees recently defined the adhesive qualities of a single amino acid called dopa that is prominent in mussel glue. This new understanding will pave the way for a new generation of bioadhesives. FY 2008 investments in the area of biomaterials will speed that progress.

Intramural Research Program

The NIDCR's Division of Intramural Research (DIR) continues to be extremely productive in an incredible array of research areas. Using the latest techniques in biomedical science - molecular biology, immunology and cell biology - researchers investigate the biochemistry, structure, function and development of bone, teeth, salivary glands and connective tissues; the role of bacteria and viruses in oral disease; genetic disorders and tumors of the oral cavity; the cause and treatment of acute and chronic pain; and the development of new and improved methods to diagnose oral disease.

Budget Policy: The FY 2008 estimate for the DIR Program area is $56.7 million, a decrease of $0.4 million, or 0.7 percent from the FY 2007 estimate. In FY 2008 NIDCR will continue to support its superlative intramural research program, building upon the outstanding progress made to date. This work will include the following FY 2008 activities:

- *Basic Science Investigating Taste Sensation:* NIDCR scientist Dr. Nicholas Ryba and his collaborators will continue pursuit of their goal to understand the organization and control of taste signaling, including not only individual pathways involved in taste transduction function, but how they interact with each other as well. Thus far, the scientists have discovered the specific proteins and cells in our mouths that detect the everyday tastes of sweet, bitter, savory, and sour, setting the stage for pursuit of their long-term goals of defining the various components and the organization required for taste responses both peripherally and centrally, and elucidating the logic of taste coding. These discoveries will

ultimately open the door to engineer better natural additives to control appetite and/or enhance or alter the flavor of our food.

- *Mechanisms of Pain:* An integral component of NIDCR's intramural program is unraveling the mystery of nociception, the sensory component of pain. It depends in part on the intricate sensory neural network within our bodies, stretching from our extremities to the spinal cord and on to the brain. But on its most fundamental level, nociception involves molecules and chemical mechanisms. An established area of intramural investigation that NIDCR will pursue further in FY 2008 is the role of the protein called cyclin-dependent kinase 5 (Cdk5). Recently, Dr. Ashok Kulkarni, along with other NIDCR scientists and their NIH colleagues reported the first direct evidence that Cdk5 plays a regulatory role in pain signaling between sensory nerves in the spinal cord and nerve ganglia. These findings point the way for additional research in FY 2008, suggesting that new analgesic drugs that alter Cdk5 activity one day may be beneficial in treating pain.

Portrait of a Program: Gene Therapy and Therapeutics Program

FY 2007: $4.7 Million
FY 2008: $4.7 Million
Change: $0.0

Salivary Gene Transfer: Gene therapy is an area of medical research that holds great promise; this year NIDCR scientist and DIR's Gene Therapy and Therapeutics Branch Chief Dr. Bruce Baum and his team are poised to move the field a giant step forward. The team has been working to address the technical difficulties related to gene transfer by employing salivary glands as the target organ. Frequently overlooked in the medical literature, salivary glands not only release saliva into the mouth, they routinely secrete digestive enzymes and other proteins into the circulatory system. Their unique ability to secrete protein in two directions makes them a potential gene-transfer depot to treat single-protein deficiencies. Dr. Baum and his colleagues have methodically moved this promising idea through the research process. As scientific hurdles arose along the way, the team benefited greatly from the wealth of scientific expertise on the NIH campus, to devise viable scientific strategies that would have been difficult or impossible to conceive at most other research institutions.

Gene transfer also might be an ideal strategy to boost salivary production for people with salivary gland disease or cancer patients whose salivary glands were damaged during radiation therapy. While radiation therapy kills cancerous cells, it frequently also destroys the acinar (fluid-producing) salivary gland cells that lie within the salivary gland in grape-like clusters. This renders the patients unable to produce adequate saliva and results in a host of long term problems including recurrent oropharyngeal infections, and difficulties with swallowing, speech, and taste. The NIDCR team has been working on a possible therapy by coaxing cells into doing what doesn't come naturally. Unlike acinar cells, ductal cells in the salivary gland (which can be thought of as the "stems" on the grapes) frequently survive irradiation. But they cannot make or secrete saliva. The scientists used gene transfer techniques to insert an aquaporin protein gene into the ductal cells; aquaporins are a family of proteins that form pores in cell membranes, through which fluid can pass. Their insertion essentially "plumps up" the stems and allows the flow of fluid into the mouth again.

In FY 2008, the team will be quite busy administering the first clinical trial of gene transfer into the salivary glands for cancer patients with dry mouth; the Food and Drug Administration has already approved the research protocol. Although the outcome of clinical trials is always hard to predict, the preclinical data have been extremely promising.

Research Management and Support

This budget category supports the scientific and administrative management structures needed to effectively lead and manage the world's largest oral health research enterprise. The Institute's extramural staff scientists and grant specialists maintain liaison with nearly 800 grantees, and provide stewardship for the Institute's $340 million investment in research and research training grants. Additionally, NIDCR conducts formal evaluations of its intramural and extramural research programs. These evaluations are designed to inform leadership and advisory bodies on scientific progress and new research directions in the quest to strengthen our Nation's health.

This budget category also supports the Institute's health communication activities. The NIDCR Office of Communications and Health Education produces and disseminates informational materials on a wide variety of topics, ranging from children's oral health, oral cancer, and periodontal disease to oral health care for people with disabilities. Some materials are geared toward patients or the general public; others are targeted to health care professionals, teachers, or caregivers for special needs patients. The Office also disseminates information about significant research advances to the media, patient support organizations, professional organizations and the research community

Budget Policy: The FY 2008 estimate for the Research Management and Support program area is $22.1 million, an increase of $0.2 million, or 1.0 percent over the FY 2007 estimate. The NIDCR will use these resources to fund the scientific and administrative management and oversight activities of the Institute to fulfill its responsibilities as a steward of funds being invested in research to better the health of the American people.

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Budget Authority by Object

	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	252	256	4
Full-time equivalent of overtime & holiday hours	0	0	0
Average ES salary	$139,838	$143,907	$4,069
Average GM/GS grade	11.0	11.0	0.0
Average GM/GS salary	$77,915	$80,182	$2,268
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$102,297	$105,274	$2,977
Average salary of ungraded positions	$107,824	$110,962	3,137

OBJECT CLASSES		FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease
	Personnel Compensation:			
11.1	Full-Time Permanent	$13,758,000	$14,567,000	$809,000
11.3	Other than Full-Time Permanent	7,953,000	8,330,000	377,000
11.5	Other Personnel Compensation	373,000	395,000	22,000
11.7	Military Personnel	876,000	933,000	57,000
11.8	Special Personnel Services Payments	3,172,000	3,289,000	117,000
	Total, Personnel Compensation	26,132,000	27,514,000	1,382,000
12.0	Personnel Benefits	5,765,000	6,064,000	299,000
12.2	Military Personnel Benefits	518,000	552,000	34,000
	Subtotal, Pay Costs	**32,415,000**	**34,130,000**	**1,715,000**
21.0	Travel & Transportation of Persons	712,000	700,000	-12,000
22.0	Transportation of Things	63,000	57,000	-6,000
23.3	Communications, Utilities & Miscellaneous Charges	364,000	317,000	-47,000
24.0	Printing & Reproduction	317,000	239,000	-78,000
25.1	Consulting Services	1,321,000	1,108,000	-213,000
25.2	Other Services	3,078,000	2,728,000	-350,000
25.3	Purchase of Goods & Services from Government Accounts	42,502,000	42,249,000	-253,000
25.4	Operation & Maintenance of Facilities	101,000	101,000	0
25.5	Research & Development Contracts	5,390,000	4,132,000	-1,258,000
25.6	Medical Care	367,000	339,000	-28,000
25.7	Operation & Maintenance of Equipment	714,000	657,000	-57,000
25.0	**Subtotal, Other Contractual Services**	**53,473,000**	**51,314,000**	**-2,159,000**
26.0	Supplies & Materials	5,412,000	4,971,000	-441,000
31.0	Equipment	2,118,000	1,932,000	-186,000
41.0	Grants, Subsidies & Contributions	289,468,000	290,931,000	1,463,000
	Subtotal, Non-Pay Costs	**351,927,000**	**350,461,000**	-1,466,000
	NIH Roadmap for Medical Research	**4,661,000**	**5,131,000**	470,000
	Total Budget Authority by Object	**389,003,000**	**389,722,000**	719,000

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Salaries and Expenses

OBJECT CLASSES	FY 2007 Continuing Resolution	FY 2008 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-Time Permanent (11.1)	$13,758,000	$14,567,000	$809,000	5.9
Other Than Full-Time Permanent (11.3)	7,953,000	8,330,000	377,000	
Other Personnel Compensation (11.5)	373,000	395,000	22,000	5.9
Military Personnel (11.7)	876,000	933,000	57,000	6.5
Special Personnel Services Payments (11.8)	3,172,000	3,289,000	117,000	3.7
Total Personnel Compensation (11.9)	**26,132,000**	**27,514,000**	**1,382,000**	**5.3**
Civilian Personnel Benefits (12.1)	5,765,000	6,064,000	299,000	5.2
Military Personnel Benefits (12.2)	518,000	552,000	34,000	
Benefits to Former Personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	**32,415,000**	**34,130,000**	**1,715,000**	**5.3**
Travel (21.0)	712,000	700,000	-12,000	-1.7
Transportation of Things (22.0)	63,000	57,000	-6,000	-9.5
Rental Payments to Others (23.2)	0	0	0	0.0
Communications, Utilities and Miscellaneous Charges (23.3)	364,000	317,000	-47,000	-12.9
Printing and Reproduction (24.0)	317,000	239,000	-78,000	-24.6
Other Contractual Services:				
Advisory and Assistance Services (25.1)	1,321,000	1,108,000	-213,000	-16.1
Other Services (25.2)	3,078,000	2,728,000	-350,000	-11.4
Purchases from Govt. Accounts (25.3)	25,261,000	24,647,000	-614,000	-2.4
Operation & Maintenance of Facilities (25.4)	101,000	101,000	0	0.0
Operation & Maintenance of Equipment (25.7)	714,000	657,000	-57,000	-8.0
Subsistence & Support of Persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	**30,475,000**	**29,241,000**	**-1,234,000**	**-4.0**
Supplies and Materials (26.0)	5,412,000	4,971,000	-441,000	-8.1
Subtotal, Non-Pay Costs	37,343,000	35,525,000	-1,818,000	-4.9
Total, Administrative Costs	**69,758,000**	**69,655,000**	**-103,000**	**-0.1**

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2007 Continuing Resolution	2008 Amount Authorized	FY 2008 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	$389,003,000	Indefinite	$389,722,000
Craniofacial Research	Section 402(a)	P.L.-109-482	Indefinite		Indefinite	
Total, Budget Authority				389,003,000		389,722,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation 1/
1999	214,559,000 2/ 3/	228,961,000	233,588,000	234,338,000
Rescission				155,000
2000	225,709,000 2/	257,349,000	267,543,000	270,253,000
Rescission				-1,442,000
2001	236,075,000 2/	309,007,000	309,923,000	306,448,000
Rescission				-173,000
2002	341,898,000	339,268,000	348,767,000	343,327,000
Rescission				-178,000
2003	374,319,000	374,319,000	374,067,000	374,067,000
Rescission				-2,431,000
2004	382,396,000	382,396,000	386,396,000	385,796,000
Rescission				-2,514,000
2005	394,080,000	394,080,000	399,200,000	395,080,000
Rescission				-3,251,000
2006	393,269,000	393,269,000	405,269,000	393,269,000
Rescission				-3,933,000
2007	386,095,000	386,095,000	389,669,000	389,669,000 4/
2008	389,722,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.
2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research
3/ Reflects a decrease of $590,000 for the budget amendment for Bioterrorism
4/ Annualized current rate

NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Office of the Director	15	15	15
Office of Administrative Management	12	13	13
Office of Information Technology	7	7	7
Office of Science Policy and Analysis	7	8	8
Office of Communications and Health Education	6	7	7
Division of Intramural Research	165	165	165
Center for Integrative Biology and Infectious Diseases	10	13	15
Center for Clinical Research	8	8	10
Division of Extramural Activities	15	16	16
Total	245	252	256
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			

FISCAL YEAR	Average GM/GS Grade
2004	10.8
2005	11.1
2006	11.0
2007	11.0
2008	11.0

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

Detail of Positions

GRADE	FY 2006 Actual	FY 2007 Continuing Resolution	FY 2008 Estimate
Total, ES Positions	0	1	1
Total, ES Salary	0	139,838	143,907
GM/GS-15	17	18	18
GM/GS-14	27	28	29
GM/GS-13	19	20	21
GS-12	25	25	26
GS-11	22	22	23
GS-10	1	1	1
GS-9	15	15	16
GS-8	6	6	6
GS-7	12	13	13
GS-6	10	8	9
GS-5	5	5	5
GS-4	1	1	1
GS-3	1	1	1
GS-2	1	1	1
GS-1	1	1	1
Subtotal	163	165	171
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	1	0	0
Director Grade	4	4	4
Senior Grade	1	1	1
Full Grade			
Senior Assistant Grade			
Assistant Grade			
Subtotal	6	5	5
Ungraded	77	81	83
Total permanent positions	174	175	176
Total positions, end of year	246	254	258
Total full-time equivalent (FTE) employment, end of year	245	252	256
Average ES salary	0	139,838	143,907
Average GM/GS grade	11.0	11.0	11.0
Average GM/GS salary	75,826	77,915	80,182

Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research.