

DEPARTMENT OF HEALTH AND HUMAN SERVICES

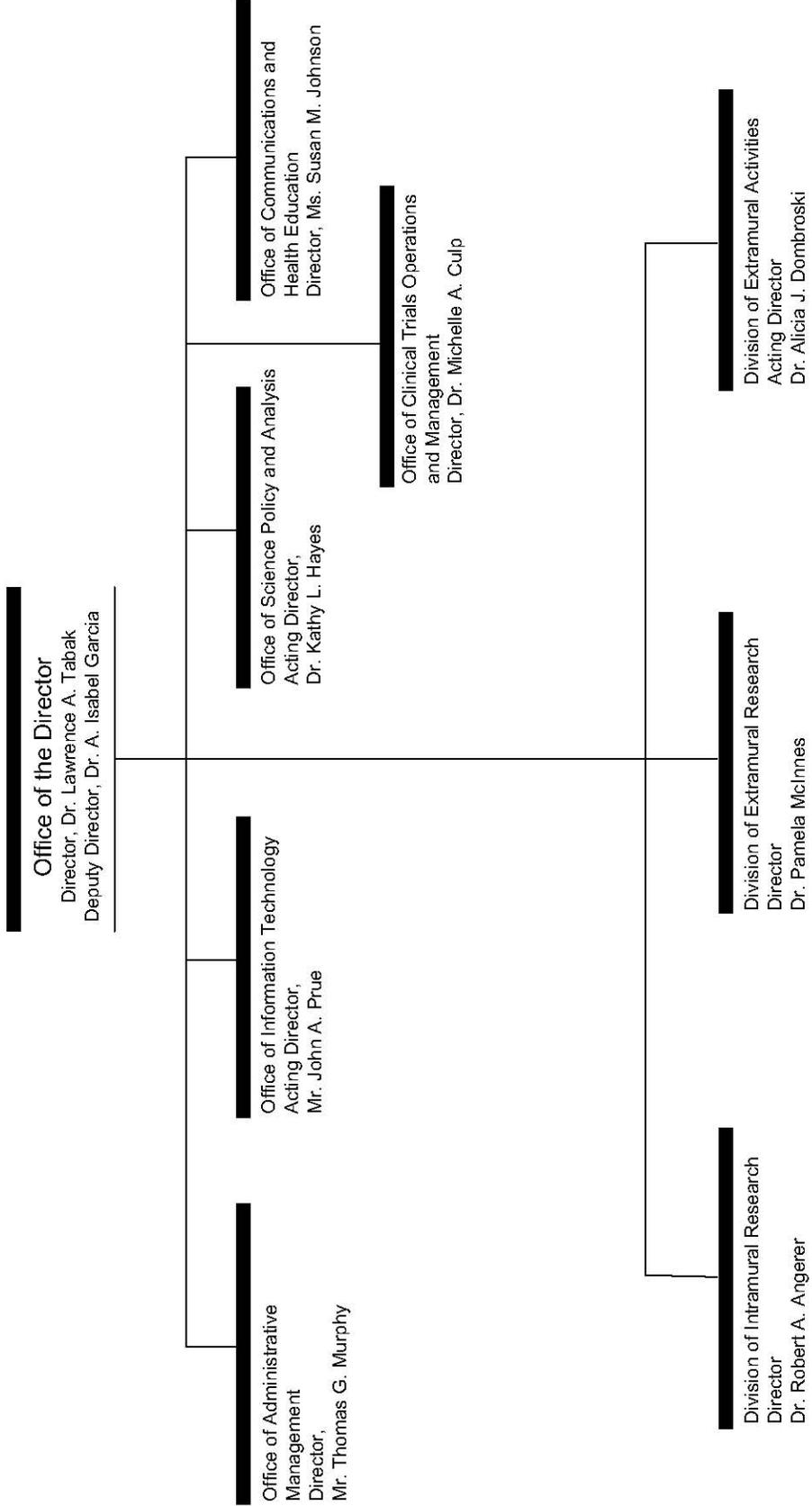
NATIONAL INSTITUTES OF HEALTH

National Institute of Dental and Craniofacial Research

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NATIONAL INSTITUTES OF HEALTH

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 Public Health Services Act with respect to dental and craniofacial diseases ~~\$396,632,000~~ **\$390,535,000** (Department of Health and Human Services Appropriation Act, 2008)

**National Institutes of Health
National Institute of Dental and Craniofacial Research**

Amounts Available for Obligation 1/

Source of Funding	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Appropriation	\$389,703,000	\$396,632,000	\$390,535,000
Pay cost add-on	0	0	0
Rescission	0	-6,929,000	0
Subtotal, adjusted appropriation	389,703,000	389,703,000	390,535,000
Real transfer under Director's one-percent transfer authority (GEI)	-637,000	0	0
Comparative transfer to NIBIB	-33,000	0	0
Comparative transfer to OD	-15,000	0	0
Comparative transfer to NCRR	-284,000	0	0
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	0	0
Comparative transfer to NIDCR	437,000	455,000	0
Comparative transfer under Director's one-percent transfer authority (GEI)	637,000	0	0
Subtotal, adjusted budget authority	389,807,000	390,158,000	390,535,000
Unobligated balance lapsing	-6,000	0	0
Total obligations	389,801,000	390,158,000	390,535,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2007 - \$992,000 FY 2008 - \$1,400,000 FY 2009 - \$ 1,100,000
Excludes \$1,384,000 in FY 2008 and \$1,384,000 in FY 2009 for royalties.

NATIONAL INSTITUTES OF HEALTH
National Institute of Dental and Craniofacial Research

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Grants:								
<u>Research Projects:</u>								
Noncompeting	433	\$169,040	468	\$180,619	468	\$175,903	0	-\$4,716
Administrative supplements	(26)	6,003	(3)	600	(16)	3,600	(13)	3,000
Competing:								
Renewal	33	12,885	28	10,917	29	11,092	1	175
New	165	47,369	138	40,133	140	40,776	2	643
Supplements	1	176	1	149	1	151	0	2
Subtotal, competing	199	60,430	167	51,199	170	52,019	3	820
Subtotal, RPGs	632	235,473	635	232,418	638	231,522	3	-896
SBIR/STTR	30	8,520	30	8,520	30	8,529	0	9
Subtotal, RPGs	662	243,993	665	240,938	668	240,051	3	-887
<u>Research Centers:</u>								
Specialized/comprehensive	8	17,940	8	17,519	6	14,050	(2)	-3,469
Clinical research	0	87	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	8	18,027	8	17,519	6	14,050	(2)	-3,469
<u>Other Research:</u>								
Research careers	80	9,667	83	10,366	83	10,366	0	0
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	18	1,862	19	1,932	19	1,932	0	0
Subtotal, Other Research	98	11,529	102	12,298	102	12,298	0	0
Total Research Grants	768	273,549	775	270,755	776	266,399	1	-4,356
<u>Research Training:</u>	<u>FTEPs</u>		<u>FTEPs</u>		<u>FTEPs</u>			
Individual awards	36	1,629	45	2,019	55	2,476	10	457
Institutional awards	268	11,985	311	13,915	299	13,458	(12)	-457
Total, Training	304	13,614	356	15,934	354	15,934	(2)	0
Research & development contracts (SBIR/STTR)	17 (0)	21,872 (20)	22 (0)	21,183 (0)	22 (0)	24,652 (0)	0 (0)	3,469 (0)
Intramural research	<u>FTEs</u> 163	<u>FTEs</u> 58,319	<u>FTEs</u> 163	<u>FTEs</u> 59,485	<u>FTEs</u> 164	<u>FTEs</u> 60,400	<u>FTEs</u> 1	<u>FTEs</u> 915
Research management and support	77	22,453	77	22,801	78	23,150	1	349
Total, NIDCR	240	389,807	240	390,158	242	390,535	2	377

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

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

Extramural Research	FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2007 Comparable		FY 2008 Enacted		FY 2009 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Integrative Biology		\$187,854		\$183,828		\$186,516		\$186,729		\$186,026		\$185,490		-\$536
Clinical		64,661		70,303		61,367		61,437		61,206		61,030		-176
Biotechnology & Innovation		60,606		55,014		60,799		60,869		60,640		60,465		-175
Subtotal, Extramural		313,121		309,145		308,682		309,035		307,872		306,985		-887
Intramural research	173	58,133	165	57,226	163	58,367	163	58,319	163	59,485	164	60,400	1	915
Res. management & support	86	20,575	80	22,698	77	22,017	77	22,453	77	22,801	78	23,150	1	349
TOTAL	259	391,829	245	389,069	240	389,066	240	389,807	240	390,158	242	390,535	2	377

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

Major Changes in the FY 2009 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 2009 budget request for NIDCR, which is \$0.4 million more than the FY 2008 estimate, for a total of \$390.5 million.

Research Project Grants: The NIH Budget policy for RPGs in FY 2009 is to provide no inflationary increases in noncompeting awards and no increase in average cost for competing RPGs.

Specialized Centers for Oral, Dental, and Craniofacial Research (-\$3.5 million; total \$0 million): Within the Research Centers budget mechanism, the NIDCR supports two specialized research centers categorized within the integrative biology research sub-activity. This centers program will have completed its funding cycle.

Research and Development Contracts (+\$3.5 million; total \$24.7 million): Funding for research contracts will be increased to bolster support for several research areas, including support for clinical trials oversight and management activities, and for genome wide association studies (integrative biology).

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

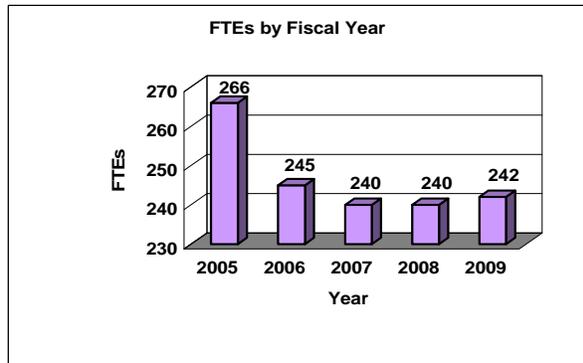
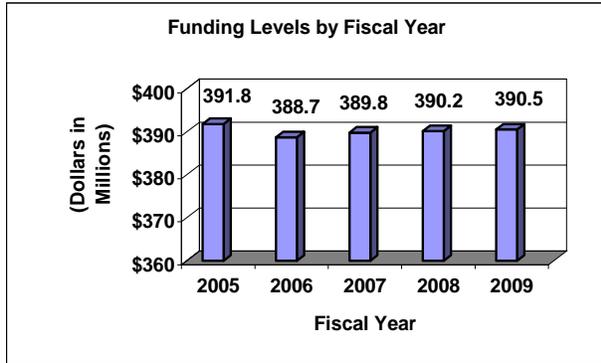
FY 2008 Enacted		\$390,158,000	
FY 2009 estimated budget authority		390,535,000	
Net change		377,000	
CHANGES	FY 2008		
	Enacted Base	Change from Base	
	Budget	Budget	
	FTEs	FTEs	Authority
A. Built-in:			
1. Intramural research:			
a. Annualization of January			
2008 pay increase	\$22,823,000		\$256,000
b. January FY 2009 pay increase	22,823,000		496,000
c. One less day of pay	22,823,000		(86,000)
d. Payment for centrally furnished services	10,437,000		157,000
e. Increased cost of laboratory supplies, materials, and other expenses	26,225,000		513,000
Subtotal			1,336,000
2. Research management and support:			
a. Annualization of January			
2008 pay increase	\$10,179		\$114,000
b. January FY 2009 pay increase	10,179		221,000
c. One less day of pay	10,179		(36,000)
d. Payment for centrally furnished services	3,751,000		56,000
e. Increased cost of laboratory supplies, materials, and other expenses	8,871,000		177,000
Subtotal			532,000
Subtotal, Built-in			1,868,000

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

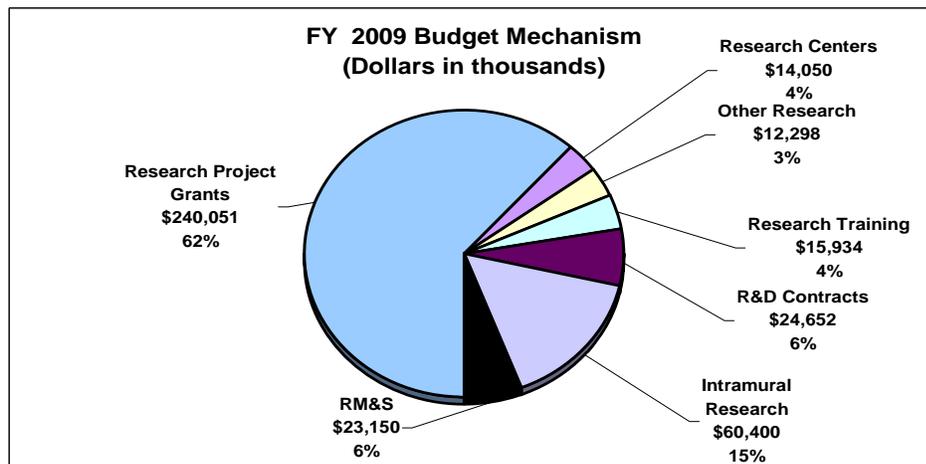
CHANGES	FY 2008			
	Enacted Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	468	\$181,219,000	0	(\$1,716,000)
b. Competing	167	51,199,000	3	820,000
c. SBIR/STTR	30	8,520,000	0	9,000
Total	665	240,938,000	3	(887,000)
2. Research centers	8	17,519,000	(2)	(3,469,000)
3. Other research	102	12,298,000	0	0
4. Research training	356	15,934,000	(2)	0
5. Research and development contracts	22	21,183,000	0	3,469,000
Subtotal, extramural				(887,000)
	<u>FTEs</u>		<u>FTEs</u>	
6. Intramural research	163	59,485,000	1	(421,000)
7. Research management and support	77	22,801,000	1	(183,000)
Subtotal, program		390,158,000		(1,491,000)
Total changes	240		2	377,000

Fiscal Year 2009 Budget Graphs

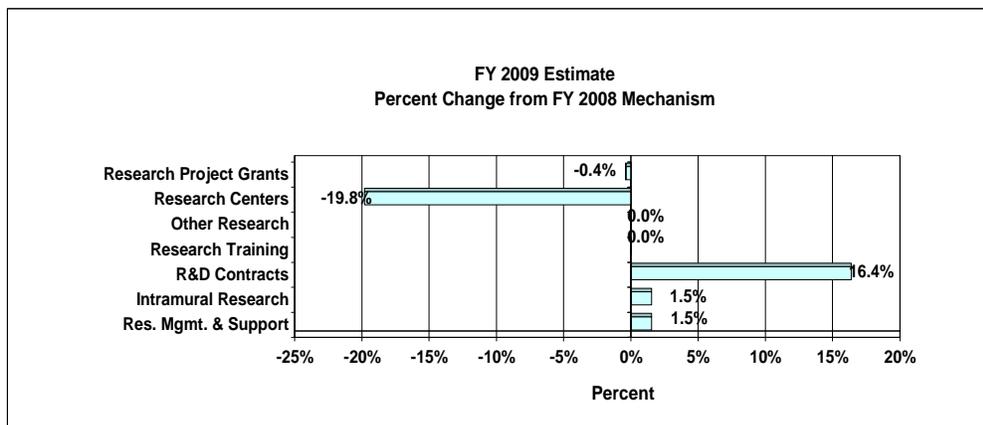
History of Budget Authority and FTEs:



Distribution by Mechanism:



Change by Selected Mechanisms:



Justification of Budget Request

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

Budget Authority:

FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Increase or Decrease	
<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>	<u>FTE</u>	<u>BA</u>
240	\$389,807,000	240	\$390,158,000	242	\$390,535,000	2	\$377,000

This document provides justification for the Fiscal Year (FY) 2009 activities of the National Institute of Dental and Craniofacial Research (NIDCR), including NIH/AIDS activities. Details of the FY 2009 HIV/AIDS activities are in the “Office of AIDS Research (OAR)” Section of the Overview. Details on the Common Fund are located in the Overview, Volume One. 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 the lead agency in the nation’s ongoing efforts to improve oral, dental, and craniofacial health. The NIDCR pursues its mission through research, research training, and the dissemination of health information to the public and practitioners.

Established in 1948, NIDCR has long supported the research of individual scientists through its multi-faceted research programs. The Institute’s research has traditionally cut across diverse fields of scientific disciplines in order to address the numerous complex diseases and conditions that fall under its mission. As more powerful new technologies and sophisticated biomedical research tools become available, NIDCR’s research is evolving to include large-scale projects that meld the investigative strengths of two or more often unrelated scientific disciplines. These collaborative projects have the potential to generate novel strategies that more readily work through old problems and transform areas of research in unexpected ways.

NIDCR recently has expanded its clinical research portfolio and engaged in several “big science” projects. These large-scale projects attempt to assemble a more detailed snapshot of the biological topography of a given tissue or disease process. With this more comprehensive view of the biological landscape, scientists can search more systematically for new diagnostic and therapeutic leads and move them more rapidly into clinical testing. A good example is a consortium of scientists that recently

completed a parts list of the proteins that are at work in the salivary glands. This first-ever catalogue, like a Webster's dictionary to a writer, provides an essential resource to design future saliva-based tests for human diseases.

Another exciting example is in the area of craniofacial development. As noted below in this year's budget request, NIDCR is launching an initiative that brings together various research disciplines to explore the developmental programming that creates the structures of the human face and head. This initiative represents an unprecedented opportunity for the institute's traditional research communities. Scientists now can begin to unravel more systematically how nature assembles the myriad parts of the head and face, from tooth to jawbone to cranial vault. This initiative will help to define the genetic programs of the various craniofacial structures and will provide the first working blueprints to build three-dimensional replacement tissues or more naturally repair a damaged tooth or cleft palate.

The NIDCR continues to set the scientific bar high. The diverse array of tools in the research toolbox has never been better, and the opportunities have never been more profound in their potential impact. As highlighted in the following pages, the discoveries that are being seeded and harvested will have a transforming effect now and in the years to come on the nation's public health.

2009 JUSTIFICATION BY ACTIVITY DETAIL

Program Descriptions and Accomplishments

Extramural Research

Integrative Biology

This program integrates scientists from diverse professional backgrounds to solve seemingly intractable research problems by generating more creative hypotheses and potential solutions than could be envisioned by a single discipline working alone. An example of integrative biology is the emergence of genome-wide association studies, or GWAS, which meld the investigative power of genetics, computer science, mathematics, and other research disciplines to scan the breadth of human DNA for inherited “misspellings” in the genetic code that are linked to a given disease.

The NIDCR recently began support of GWAS studies that focus on tooth decay and orofacial clefts. Still a major public health problem among certain communities in this country, tooth decay is the most prevalent of all dental diseases. Cleft lip and/or cleft palate is one of the most common of all birth defects.^{1,2} The expectation is this powerful and proven research approach will generate unexpected new leads into the basic biology of these conditions that may have otherwise remained elusive. This information will greatly solidify the scientific foundation that supports research in these fields, while also accelerating new discoveries to improve their diagnosis and potentially their treatment.

Budget Policy: The FY 2009 estimate for the Integrative Biology program area is \$185.5 million, a decrease of \$0.5 million, or 0.3 percent from the FY 2008 estimate. The program plans for FY 2009, along with expected outputs, follow. High priority will be given to support ongoing programs, such as the ones described above, meritorious new investigator-initiated research grants, and research training related to the institute’s mission areas. These include investments into the prevention, detection, diagnosis and treatment of craniofacial, oral and dental diseases and disorders, such as periodontitis, caries, head and neck cancer, craniofacial birth defects, orofacial pain disorders and xerostomia. In FY 2009, this program will launch two new initiatives.

- *The FaceBase Project.* More than half of all birth defects are associated with some form of craniofacial malformation. Although scientists have had success identifying individual genes and mutations that contribute to an oral cleft or a tooth

¹ U.S. Department of Health and Human Services, 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”, Morbidity and Mortality Weekly Report, August 25, 2005.

² U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. “Improved National Prevalence Estimates for 18 Selected Major Birth Defects – 1999-2001”, Morbidity and Mortality Weekly Report, January 6, 2006.

malformation, it has become increasingly clear that the story is more complex. Indeed, many of these conditions are caused not by one altered gene but the interplay of myriad genes and their protein products and environmental elements during craniofacial development. To tap more directly into this dynamic developmental process, NIDCR will launch the FaceBase Project. This initiative will help to establish consortia of various collaborative research projects that focus on specific sequences of events of craniofacial development and associated disorders. Two central resources will support the consortia.

- The first is a data coordination and bioinformatics component. It will ensure that the large amounts of new data generated from the initiative are properly and seamlessly stored, analyzed, and made available for sharing.
- The second is a technology development component that will hammer out new tools to broadly observe or read the developmental process as it unfolds. Taken together, these projects and resources will yield a more complete understanding of the molecular machinery that nature employs to build a human head, face, and mouth. Assembling this detailed information is absolutely critical as scientists begin to devise improved strategies that prevent expensive and often demoralizing malformations of the face.
- *Harnessing Inflammation for Reconstruction of Oral and Craniofacial Tissues:* Many people have noticed a puffy redness, or inflammation, of their gums; others may have had a swelling in their jaw. Such symptoms involve an acute, highly complex interplay of immune cells that actively thwart infection and promote healing. However, the inflammatory process can go awry. Acute inflammation can progress to chronic inflammation, setting in motion a destructive cycle of tissue degradation and disease. To better control the chronic inflammation associated with various oral and craniofacial conditions, scientists must learn to decipher the molecular cross talk involved in the inflammatory process, from its onset to its resolution. This new knowledge is clinically important, as the tools of modern biotechnology and nanotechnology in recent years have laid the scientific foundation to one day re-engineer damaged oral and craniofacial tissues and make them whole again. Recognizing both a need and an opportunity, NIDCR has launched an initiative to fill in the knowledge gaps that are interspersed throughout the inflammatory process and that disrupt our understanding of its progression. Identifying these gaps will provide a complete picture of the normal resolution of acute inflammation and the aberrant transition into chronic inflammation. Strategies also will be developed to introduce genes and proteins that overcome inflammation and promote the reconstruction of damaged tissues. This initiative, like all research in the Integrative Biology Program, places a premium on teamwork and assembling a diversity of scientific expertise to develop novel approaches and creative solutions.

Clinical Research

The NIDCR began nearly four years ago to invest more of its resources to support large, randomized Phase III clinical trials; such trials are the final investigative step in the clinical development process, and test the safety and efficacy of an investigational treatment against the standard of care in a well-defined group of patients. Each will yield high quality data that have the potential to change healthcare practice and policy and improve the nation's public health. Currently, the Institute supports four ongoing Phase III trials and has plans to launch several additional studies during FY 2008 and FY 2009.

In FY2007, two large, NIDCR-supported clinical trials (the Obstetrics and Periodontal Therapy study and the Trial to Enhance Elderly Teeth) published their results. The first study found that periodontal therapy was not effective in reducing adverse birth outcomes in pregnant women with periodontal disease; however, it did show that dental care provided during pregnancy was safe and effective in reducing the burden of periodontal disease. These findings are of immense value to both the practicing obstetrical and dental community because there has been a reluctance to provide dental care to expectant mothers due to concerns about the safety of providing such care during pregnancy. The second study was designed to assess the clinical effectiveness of a daily chlorhexidine (CHX) mouth rinse for reducing the incidence of dental caries in community-dwelling elders. Previous studies suggested that CHX could reduce caries in at-risk children, but evidence for its effectiveness against caries in adult populations was inconclusive. This study demonstrated no effect on the preservation of sound tooth structure in low-income older adults with irregular access to professional dental care and a history of poor home care. These results are important because the older adults in this study represent the broader population of community-dwelling adults who lack dental insurance or who are irregular dental attendees in North America.

A very important case-control study will be completed in FY2008. It is a collaborative project of all three NIDCR-supported Practice-Based Research Networks that will identify dental risk factors for osteonecrosis of the jaws (ONJ). Many adult dental patients take oral and intravenous bisphosphonates for treatment of osteoporosis and complications of certain cancers. Unfortunately, some of these patients develop ONJ. This case-controlled study is designed to identify factors that may contribute to the development of this serious complication.

Budget Policy: The FY 2009 estimate for the Clinical Research Program is \$61.0 million, a decrease of \$0.2 million, or 0.3 percent from the FY 2008 estimate. The program plans for FY 2009 include support for the new initiatives and ongoing programs described below, as well as meritorious new investigator-initiated research grants, and research training related to its mission.

- *Developing Complex Models of Oral Health and Behavior:* Traditional models assume that behavior is driven by people carefully weighing the risks and benefits of their choices. The models lay out a rational, linear, unidirectional set

of causes and effects. While helpful, these models fail to capture adequately the complexity of the decision-making process for most Americans. This shortcoming has led groups ranging from funding agencies to policy makers to call for new approaches that better capture the complexity of the process. To meet this need, NIDCR will actively encourage research that builds on the existing models and identifies new ways to conceptualize the numerous behavioral and social contributors to oral health. The initiative's long-term goal is to use these models to identify potential targets for more efficient interventions to help more people achieve and maintain good oral health.

- *Practice-Based Research Networks:* In 2005, the institute began supporting three regional dental practice-based research networks, or PBRNs. Their mission is to create large networks of practicing dentists and dental hygienists to participate in conducting clinical studies on various issues in oral healthcare. This initiative grew out of the recognition that dental professionals frequently lack high quality research data to guide their treatment decisions. The PBRNs seek to provide that needed data and to greatly facilitate the translation of these findings into clinical practice. After an initial planning and organizational process, the PBRNs have begun to develop their first clinical protocols. The first round of studies include evaluations of how dentists currently diagnose and treat tooth decay in both mildly and heavily affected teeth. Other studies will include randomized, controlled trials evaluating computer-assisted learning for the treatment of dental needle phobics and comparisons of the outcomes of two different techniques frequently used when treating deep dental decay. The three PBRNs are presently engaged collaboratively in a study to assess the dental risk factors for osteonecrosis of the jaw in patients treated with bisphosphonates. Larger and more complicated randomized clinical trials are planned and will be highlighted in subsequent years.
- *Oral Health Disparities Centers Initiative:* In 2001, NIDCR initiated five Oral Health Disparities Centers, located in various regions of the country. These centers have worked to design innovative, science-based strategies to improve the oral health of low income and minority Americans. Funding for these centers will conclude in mid 2008 and to maintain this research momentum, NIDCR re-issued a Request for Applications, or RFA. This RFA was an open competition, meaning previous funding as an oral health disparities center was not a prerequisite. New centers will be required to conduct interventional trials designed to determine the best methods for disease prevention and translation of research findings in communities with health disparities. During FY 2008, grant applications will be reviewed and the most meritorious selected for award. These centers will require NIDCR funding support for several fiscal years.

Biotechnology and Innovation

The NIDCR continues to support high quality research to produce cutting edge devices for oral health. Toward this end, the Institute employs interdisciplinary research

strategies that emphasize basic and translational studies. A nice example of this strategy at work is in the program's funding of biomimetics - copying the secrets of nature to design better synthetic materials.

Recently, NIDCR grantees combined biomimetics, nanotechnology, and various existing technologies to develop a new medical adhesive that combines the natural adhesive strategies of the lizard gecko and the marine mussel. Another program accomplishment brings us closer to annotating the salivary proteome. NIDCR-supported scientists and their teams have finished compiling a comprehensive roster of the more than 1,100 proteins that are normally present in saliva. Most of the proteins are not yet fully characterized. A database that lays out for the research community the raw data from these projects is now available online. The next step in the process is to create technologies and methodologies to establish a community-based annotation server for the human salivary proteome in order to assist those who study the salivary glands and accelerate their searches for better ways to treat Sjögren's syndrome and other chronic conditions that affect normal saliva production. The software is under development and should be online in the near future.

Budget Policy: The FY 2009 estimate for the Biotechnology and Innovation Program area is \$60.5 million, a decrease of \$0.2 million, or 0.3 percent from the FY 2008 estimate. Priority will be given to support ongoing programs and highly meritorious new research projects. In the FY 2009 budget, NIDCR will continue to support innovative projects such as the one described below:

- *Annotation of the Salivary Proteome:* NIDCR supported scientists and their teams have finished compiling a comprehensive roster of the proteins that are normally present in saliva from the major salivary glands. The roster contains more than 1,100 distinct proteins, most of which are not fully characterized. The database that lays out for the research community the raw data from these projects is available online. The next step in the process is to create technologies and methodologies to establish community-based annotation server for the human salivary proteome. For instance, scientists might click on a particular uncharacterized protein and submit their own research data demonstrating that the protein also is present in the brain, where it functions in a specific way. In this way, raw data can become detailed entries that assist those who study the salivary glands and accelerate their searches for better ways to treat Sjögren's syndrome and other chronic conditions that affect normal saliva production. The software is under development and should be online in the near future.

Portrait of a Program: Salivary Diagnostics

FY 2008: \$7.7 million
FY 2009: \$7.7 million
Change: \$0

Over the last several decades, scientists have begun to talk more actively about using a person's saliva to detect a range of oral and systemic diseases. Unlike blood, which involves a painful needle stick, must be carefully processed, and often sent elsewhere for analysis, saliva could be collected quickly and painlessly and then analyzed right there in a dentist or doctor's office. The test results could be delivered within minutes, allowing patient and health professional to consult immediately and develop a plan of follow up care.

But as part of creating the scientific infrastructure, the researchers needed to catalogue the genes and protein content of normal saliva, giving them a point of comparison to detect the other molecules that might appear and be indicative of a developing disease. Toward this end, NIDCR supported large collaborative projects that created the first complete record of the genes and proteins found in saliva. No longer must researchers look to see if a disease-linked protein also happens to be found in saliva. Now they could cast a wide analytical net and look for patterns of protein content in people who have oral or autoimmune diseases. Recently, showing the diagnostic power of this approach for the first time, an NIDCR grantee identified 43 proteins and 16 peptides that were present at abnormally higher or lower levels in the saliva of people with primary Sjögren's syndrome. This surpasses previous efforts to identify protein biomarkers for this condition. Primary Sjögren's disease affects roughly two million Americans³, primarily women, and can be difficult to diagnose. Collaborations have begun between scientists in the United States and Europe to validate the most informative of these proteins as telltale signs of Sjögren's syndrome. Diagnostic tests for various cancers also are being developed. With this parts list of salivary genes and proteins now in place, similar findings should emerge in the years ahead and lay the scientific foundation for point-of-care salivary diagnostics in the future.

Intramural Research Program

The NIDCR's Division of Intramural Research (DIR) conducts basic, translational, and clinical research that covers a variety of areas relevant to oral health. These areas include investigations into 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 improved methods to diagnose disease.

NIDCR scientists have played an important role in organizing the Head and Neck Tissue Array Initiative, a consortium developed to overcome the longstanding problem that research on head and neck cancer has been inhibited by a lack of communication and sharing of tissue samples among scientists. The consortium consists of scientists from eight countries. To help alleviate this problem, Consortium scientists recently dissected the protein interactions in a key signaling pathway that is frequently deregulated in carcinomas of the head and neck. The NIDCR scientists will take part in

³ Sjögren's Foundation website. Accessed on 19 October 2007 at <http://www.sjogrens.org/syndrome/>

conducting a clinical trial to evaluate the benefit of targeting treatment to that specific pathway. Another recent accomplishment was in the field of connective tissue regeneration. NIDCR scientists and colleagues discovered recently a small subset of previously unknown adult stem cells embedded in tendon. The discovery points to a natural source of tendon-producing cells in adults and raises the possibility that, with further research, these cells one day could help to mend torn or degenerating tendons that are slow to heal.

Budget Policy: The FY 2009 estimate for the DIR Program area is \$60.4 million, an increase of \$0.9 million, or 1.5 percent over the FY 2008 estimate to help offset the cost of pay and other increases. In FY 2009, NIDCR will continue to support its outstanding research program and ensure its continued progress. This work will include the following FY 2009 activities:

- *Head and Neck Cancer:* Carcinomas of the head and neck are the sixth most frequent cancer in the United States. For years, research on head and neck cancer has been inhibited to some degree by a lack of communication and sharing of tissue samples among scientists. To help alleviate this problem, NIDCR scientists have played an important role in recent years to organize the Head and Neck Tissue Array Initiative. The consortium consists of scientists from eight countries, ranging from Argentina, China, Japan, India, Mexico, South Africa, Thailand, and the United States. Consortium scientists have recently dissected the protein interactions in a key signaling pathway, called Akt-mTOR, which is frequently deregulated in carcinomas of the head and neck. As an outgrowth of this work, the NIDCR scientists will take part in conducting a clinical trial to evaluate the benefit of targeting treatment to the Akt-mTOR pathway. The NIDCR scientists also continue to make progress in dissecting other signaling pathways that are frequently inactivated in head and neck cancers.
- *Connective Tissue Regeneration:* NIDCR scientists and colleagues discovered recently that tendon, the cord-like tissue that connects muscle to bone, contains a small subset of previously unknown adult stem cells. The cells are embedded between layers of extracellular matrix (ECM), the chain-like coils of protein that give tendon its elasticity and contain relatively few cells or blood vessels. To date, most known adult stem cells occupy cell rich environments with a ready source of nutrients. The discovery points to a natural source of tendon-producing cells in adults and raises the possibility that, with further research, these cells one day could help to mend torn or degenerating tendons that are slow to heal. The NIDCR scientists are now attempting to determine whether other adult stem cells could be prompted in similar niches to form tendon. If so, they could create a more plentiful supply of tendon-producing stem cells, which would better enable additional work to characterize their responses to conditions in the ECM.

Portrait of a Program: Decoding the Biochemistry of Taste

FY 2008: \$1.9 million
FY 2009: \$1.9 million
Change: \$0

Although a gourmet chef might disagree on principle, scientists have determined that human taste comes in five sensations: sweet, bitter, sour, salty, and savory (sometimes called umami). Over the past 10 years, NIDCR scientist Dr. Nicholas Ryba and collaborator Dr. Charles Zucker, a scientist at the University of California at San Diego, have identified and characterized two types of protein receptors that activate the sensations of sweet, savory, and bitter. The scientists also have identified a cellular channel through which certain small molecules pass that likely serves as the receptor for sour tastes.

These discoveries make it theoretically possible to map out the connectivity pathways for each of the five taste qualities, starting at the tongue and ending within the cortex of the brain. It is also theoretically possible to understand not only where the signals go, but where and how they combine in the neural circuitry to choreograph the experience of taste and flavor. As this information amasses, Dr. Ryba notes that it will be possible to take the next step and evaluate in fine detail the biochemical effects of taste on behavior. This fundamental information will be invaluable in helping to advance various research fields ranging from neuroscience to food science. Potential applications include more rational designs of taste enhancers that might reduce a person's dietary sugar or salt intake. It may also be possible to take the bitterness out of medicines that currently leave patients with a lingering and unpleasant taste in their mouths.

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 investment in research and research training grants. The NIDCR participates in the support of the Interdisciplinary Research Consortia funded through the NIH Common Fund. 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 2009 estimate for the Research Management and Support program area is \$23.1 million, an increase of \$0.3 million, or 1.5 percent over the FY 2008 estimate to help offset the cost of pay and other increases. 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.

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Budget Authority by Object

	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease	Percent Change
Total compensable workyears:				
Full-time employment	240	242	2	0.8
Full-time equivalent of overtime and holiday hour	1	1	0	0.0
Average ES salary	\$143,790	\$148,531	\$4,741	3.3
Average GM/GS grade	11.2	11.2	0.0	0.0
Average GM/GS salary	\$82,208	\$84,919	\$2,711	3.3
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	\$103,455	\$106,866	\$3,411	3.3
Average salary of ungraded positions	112,747	116,464	3,717	3.3
OBJECT CLASSES	FY 2008 Estimate	FY 2009 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
11.1 Full-time permanent	\$14,144,000	\$14,686,000	\$542,000	3.8
11.3 Other than full-time permanent	7,297,000	7,564,000	267,000	3.7
11.5 Other personnel compensation	691,000	717,000	26,000	3.8
11.7 Military personnel	568,000	591,000	23,000	4.0
11.8 Special personnel services payments	3,905,000	4,043,000	138,000	3.5
Total, Personnel Compensation	26,605,000	27,601,000	996,000	3.7
12.0 Personnel benefits	6,045,000	6,272,000	227,000	3.8
12.2 Military personnel benefits	352,000	366,000	14,000	4.0
13.0 Benefits for former personnel	0	0	0	0.0
Subtotal, Pay Costs	33,002,000	34,239,000	1,237,000	3.7
21.0 Travel and transportation of persons	718,000	764,000	46,000	6.4
22.0 Transportation of things	48,000	47,000	(1,000)	-2.1
23.1 Rental payments to GSA	0	0	0	0.0
23.2 Rental payments to others	0	0	0	0.0
23.3 Communications, utilities and miscellaneous charges	490,000	465,000	(25,000)	-5.1
24.0 Printing and reproduction	343,000	325,000	(18,000)	-5.2
25.1 Consulting services	1,312,000	1,169,000	(143,000)	-10.9
25.2 Other services	2,277,000	2,152,000	(125,000)	-5.5
25.3 Purchase of goods and services from government accounts	46,470,000	47,836,000	1,366,000	2.9
25.4 Operation and maintenance of facilities	138,000	107,000	(31,000)	-22.5
25.5 Research and development contracts	9,336,000	11,907,000	2,571,000	27.5
25.6 Medical care	304,000	302,000	(2,000)	-0.7
25.7 Operation and maintenance of equipment	626,000	618,000	(8,000)	-1.3
25.8 Subsistence and support of persons	0	0	0	0.0
25.0 Subtotal, Other Contractual Services	60,463,000	64,091,000	3,628,000	6.0
26.0 Supplies and materials	5,456,000	5,389,000	(67,000)	-1.2
31.0 Equipment	2,949,000	2,882,000	(67,000)	-2.3
32.0 Land and structures	0	0	0	0.0
33.0 Investments and loans	0	0	0	0.0
41.0 Grants, subsidies and contributions	286,689,000	282,333,000	(4,356,000)	-1.5
42.0 Insurance claims and indemnities	0	0	0	0.0
43.0 Interest and dividends	0	0	0	0.0
44.0 Refunds	0	0	0	0.0
Subtotal, Non-Pay Costs	357,156,000	356,296,000	(860,000)	-0.2
Total Budget Authority by Object	390,158,000	390,535,000	377,000	0.1

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

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Salaries and Expenses

OBJECT CLASSES	FY 2008 Enacted	FY 2009 Estimate	Increase or Decrease	Percent Change
Personnel Compensation:				
Full-time permanent (11.1)	\$14,144,000	\$14,686,000	\$542,000	3.8
Other than full-time permanent (11.3)	7,297,000	7,564,000	267,000	3.7
Other personnel compensation (11.5)	691,000	717,000	26,000	3.8
Military personnel (11.7)	568,000	591,000	23,000	4.0
Special personnel services payments (11.8)	3,905,000	4,043,000	138,000	3.5
Total Personnel Compensation (11.9)	26,605,000	27,601,000	996,000	3.7
Civilian personnel benefits (12.1)	6,045,000	6,272,000	227,000	3.8
Military personnel benefits (12.2)	352,000	366,000	14,000	4.0
Benefits to former personnel (13.0)	0	0	0	0.0
Subtotal, Pay Costs	33,002,000	34,239,000	1,237,000	3.7
Travel (21.0)	718,000	764,000	46,000	6.4
Transportation of things (22.0)	48,000	47,000	(1,000)	-2.1
Rental payments to others (23.2)	0	0	0	0.0
Communications, utilities and miscellaneous charges (23.3)	490,000	465,000	(25,000)	-5.1
Printing and reproduction (24.0)	343,000	325,000	(18,000)	-5.2
Other Contractual Services:				
Advisory and assistance services (25.1)	1,312,000	1,169,000	(143,000)	-10.9
Other services (25.2)	2,277,000	2,152,000	(125,000)	-5.5
Purchases from government accounts (25.3)	25,155,000	26,047,000	892,000	3.5
Operation and maintenance of facilities (25.4)	138,000	107,000	(31,000)	-22.5
Operation and maintenance of equipment (25.5)	626,000	618,000	(8,000)	-1.3
Subsistence and support of persons (25.8)	0	0	0	0.0
Subtotal Other Contractual Services	29,508,000	30,093,000	585,000	2.0
Supplies and materials (26.0)	5,456,000	5,389,000	(67,000)	-1.2
Subtotal, Non-Pay Costs	36,563,000	37,083,000	520,000	1.4
Total, Administrative Costs	69,565,000	71,322,000	1,757,000	2.5

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2007 Amount Authorized	FY 2008 Enacted	2008 Amount Authorized	FY 2009 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	\$390,158,000	Indefinite	\$390,535,000
Craniofacial Research	Section 402(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority					390,158,000	390,535

NATIONAL INSTITUTES OF HEALTH
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Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation <u>1/</u>
2000	225,709,000 <u>2/</u>	257,349,000	267,543,000	270,253,000
Rescission				(1,442,000)
2001	236,075,000 <u>2/</u>	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	389,699,000	389,703,000
2008	389,722,000	395,753,000	398,602,000	396,632,000
Recission				(6,929,000)
2009	390,535,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

2/ Excludes funds for HIV/AIDS research activities consolidated in the NIH Office of AIDS Research.

NATIONAL INSTITUTES OF HEALTH
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Details of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Office of the Director	11	9	9
Office of Administrative Management	12	13	13
Office of Information Technology	7	7	7
Office of Science Policy and Analysis	7	7	7
Office of Communications and Health Education	6	6	6
Division of Intramural Research	163	163	164
Division of Extramural Activities	16	17	18
Division of Extramural Research	18	18	18
Total	240	240	242
Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research			
FISCAL YEAR	Average GM/GS Grade		
2005	11.1		
2006	11.0		
2007	11.2		
2008	11.2		
2009	11.2		

NATIONAL INSTITUTES OF HEALTH
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Detail of Positions

GRADE	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate
Total, ES Positions	0	1	1
Total, ES Salary	0	143,790	148,531
GM/GS-15	17	19	19
GM/GS-14	27	30	30
GM/GS-13	19	16	17
GS-12	28	30	29
GS-11	20	20	25
GS-10	2	2	2
GS-9	15	20	15
GS-8	6	6	6
GS-7	14	15	15
GS-6	8	5	5
GS-5	2	4	4
GS-4	2	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	160	168	168
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General	0	0	0
Director Grade	4	4	4
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	4	4	4
Ungraded	80	83	83
Total permanent positions	176	177	178
Total positions, end of year	244	245	247
Total full-time equivalent (FTE) employment, end of year	240	240	242
Average ES salary	0	143,790	148,531
Average GM/GS grade	11	11	11
Average GM/GS salary	79,025	82,208	84,919

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