

DEPARTMENT OF HEALTH AND HUMAN SERVICES

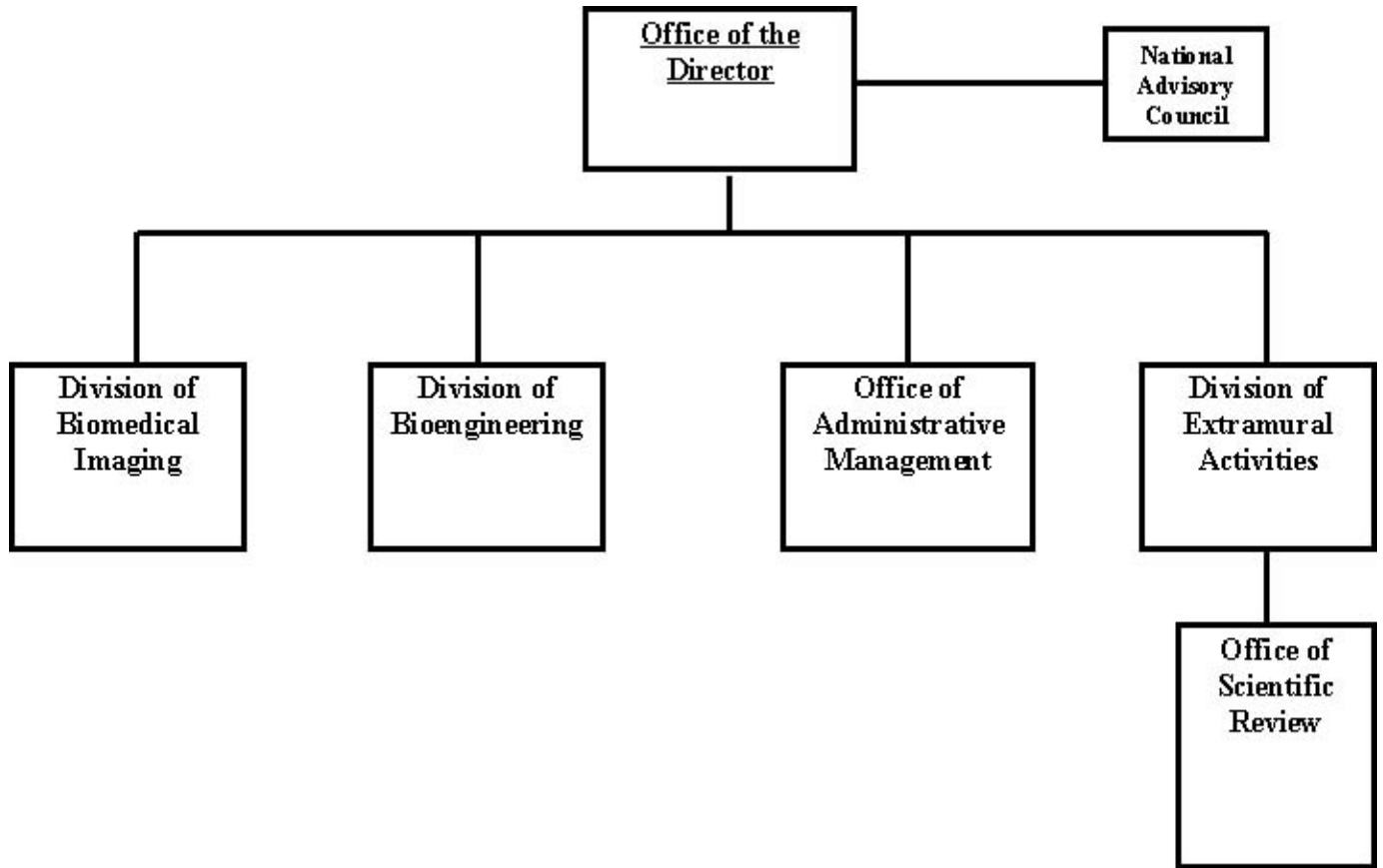
NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

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National Institute of Biomedical Imaging and Bioengineering

Organizational Structure



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National Institute of Biomedical Imaging and Bioengineering

Appropriation Language

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the Public Health Service Act with respect to biomedical imaging and bioengineering, \$40,206,000.

Language Analysis

Language Provision	Explanation
For carrying out section 301 and title IV of the Public Health Service Act with respect to biomedical imaging and bioengineering \$40,206,000	Language appropriating funds for the National Institute of Biomedical Imaging and Bioengineering.

**NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering**

**National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering**

Amounts Available for Obligation (1/)

Source of Funding	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
Appropriation	\$0	\$0	\$40,206,000
Enacted Rescission	(0)	(0)	---
Subtotal, Adjusted Appropriation	0	0	40,206,000
Comparative transfer from: Office of the Director for Biomedical Imaging and Bioengineering activities	200,000	1,975,000	---
Subtotal, adjusted budget authority	200,000	1,975,000	40,206,000
Unobligated balance lapsing	---	---	---
Total obligations	200,000	1,975,000	40,206,000

1/ Excludes the following amounts for reimbursable activities carried out by this account: FY 2000 - \$0
FY 2001 - \$0 FY 2002 - \$4,000,000

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National Institute of Biomedical Imaging and Bioengineering

Justification
National Institute of Biomedical Imaging and Bioengineering

Authorizing Legislation:

Sections 401(b)(1) and 464z and Title IV of the Public Health Service Act, as amended by the National Institute of Biomedical Imaging and Bioengineering Establishment Act of 2000 (P.L.106-580).

Budget Authority:

FY 2000 Actual		FY 2001 Estimate		FY 2002 Estimate		Increase or Decrease	
FTEs	BA	FTEs	BA	FTEs	BA	FTEs	BA
0	\$200,000	4	\$1,975,000	21	\$40,206,000	17	\$38,231,000

This document provides justification for the FY 2002 activities of the National Institute of Biomedical Imaging and Bioengineering (NIBIB).

INTRODUCTION

The foundations of tomorrow's medicine will continue to be built on the emergence of new methods and technologies. Advances in the imaging sciences can change the face of medicine, making it possible to detect, diagnose, and guide therapy for a large variety of diseases without the use of invasive procedures. Bioengineering improves quality of life through its contribution to advances in science and technology related to human health. It is unique in its ability to integrate principles from a diversity of fields, and crosses the boundaries of academia, science, medicine and industry

Most of the revolutionary changes in biology and medicine over the past decades were rooted in fundamental discoveries in many different fields, such as the role of nuclear physics in producing radioisotopes essential for much of modern medical science. Engineering and physics were central to development of key tools of common clinical practice today-x-rays, CAT scans, fiber optic viewing, laser surgery, echocardiography and fetal sonograms. Materials science provides new joints, heart valves, and other tissue mimetics. Understanding of nuclear magnetic resonance and positron emissions was required for the imaging experiments that have allowed the study of location and timing of brain activities that accompany thought, motion, sensation, speech, or drug use. Now, as never before, the boundaries are disappearing between biology and biomedical engineering, resulting in increased and expanded opportunities for new scientific and technological approaches as well as sophisticated and clinical tools and devices.

The recently established National Institute of Biomedical Imaging and Bioengineering (NIBIB) will promote fundamental discoveries, design and development, and translation of technological capabilities

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in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science, and computer sciences. The research supported by NIBIB will be multidisciplinary in nature and strongly synergistic with the other NIH research Institutes and Centers. NIBIB will meet the challenge of training a new generation of investigators with a vision transcending previous narrow disciplines.

Research Directions and Activities

The focus of NIBIB will be on developing fundamental new knowledge, creating potent new technologies, and nurturing researchers able to fully integrate the quantitative sciences with biomedical research. The creation of programs on the cutting edge of research and innovation will pose complex scientific challenges and require multidisciplinary strategies. A critical component of the Institute's inaugural year will be the formulation of a strategic long-range plan for research in biomedical imaging and bioengineering. One basis for developing research programs in biomedical imaging and bioengineering will be key areas of opportunity highlighted in the series of four research symposia sponsored by NIH:

- "Bioengineering: Building the Future of Biology and Medicine" (February 1998)
- "Biomedical Imaging: Visualizing the Future of Biology and Medicine" (June 1999)
- "Nanoscience and Nanotechnology: Shaping Biomedical Research" (June 2000)
- "Reparative Medicine: Growing Tissues and Organs" (scheduled for June 2001)

Bioengineering is rooted in physics, mathematics, chemistry, and the life sciences. It is the application of a systematic, quantitative, and integrative method of thinking about and approaching solutions to problems important to biology, medical research, and clinical and population studies. In support of its mission, NIBIB will support an integrated and coordinated program of research and research training that can be applied to a broad spectrum of biological processes, disorders and diseases and across organ systems. Strong coordination will be fostered with the other NIH Institutes and programs of Federal agencies which support imaging and engineering research having potential specific medical applications. These partnerships will facilitate the translation of fundamental discoveries into research and applications for specific diseases, disorders, or biological processes. Training and career development programs will be pivotal to NIBIB's approach to its mission. Increasing the pool of individuals uniquely positioned to bring innovative concepts and approaches to research in biomedicine and health will benefit the entire NIH biomedical portfolio.

Selected examples are described below to indicate research areas providing rich opportunities in fostering new basic understandings and collaborations among the biological, medical, engineering, physical and computational sciences which are consistent with NIBIB's mission.

Nanotechnology: The creation and characterization of functional materials, devices, and systems at a scale of 1 to 100 nanometers (a nanometer is one-billionth of a meter), as well as the exploitation of novel properties and phenomena developed at that scale for application to biomedical studies.

Biomaterials and tissue engineering: Research on approaches to creating new, perhaps "smart" or self-monitoring materials designed specifically for therapies which are cell-based, chemical (drug)-based, or

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gene-based. Development of (1) efficient methods to assess acceptance of biomaterials by the human body, (2) predictive, low-cost in vivo and in vitro models that permit assessment of reliability and reproducibility, (3) methodology for accelerated testing, analysis, and evidence of failure, and (4) approaches for improved understanding of the biology-biomaterial interface. Research on the processing and manufacture of well-characterized materials, including biostable materials as well as bioresorbable and scaffold materials.

Implant science: Research to create design principles and approaches; exploratory research of next generation concepts; studies to prevent adverse events (i.e. chronic inflammation); development of tools for accessing loads and stresses on an implant in the everyday environment; rapid simulation and prototyping methods; life-time predictive methods and rigorous analysis of technologies both at the time of design and at the time of dysfunction and failure.

Development of imaging devices: Research and development of generic biomedical imaging technologies before specific applications are demonstrated.

Contrast agents: Research on the design, synthesis, calibration and standardization of contrast agents and molecular probes that link an imaging device to the processes related to a specific disease by selectively targeting a specific region, tissue, lesion, or cell based on some novel aspect of its particular biology or some specific physical property that it has.

Image exploitation: Development, design, and implementation of algorithms for image processing and information analysis, including advanced methodology for acquisition, storage, and display of images; research and development on image-guided procedures; and techniques for using multidimensional images to understand physiology and normal and abnormal function.

Assessment of imaging technology: Research on and development of methods for the evaluation and comparison of new and existing imaging technologies so as to establish their effectiveness, robustness, and range of applicability.

Minimally invasive technologies: Basic research involving the use of robotics technologies of actuation, sensing, control, programming, human/machine interface, and the design of mechanisms to determine research endpoints such as diagnosis and automated or remote treatment of disease.

Biosensors: Research and development of basic biosensor technology including the design, fabrication, and characterization of biocompatible sensors to be used in biomedical research and medicine.

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Summary

The leadership role of NIBIB in developing cross-cutting research and training in biomedical imaging and bioengineering will be fostered by strong partnerships and collaborations with other Institutes and Centers of the National Institutes of Health, with the ultimate goal of improving human health and well-being. The Institute is poised to identify challenges in biomedical research that can benefit from bioengineering and bioimaging approaches, facilitate inter-institute cooperation, and promote transdisciplinary research training.

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Budget Policy

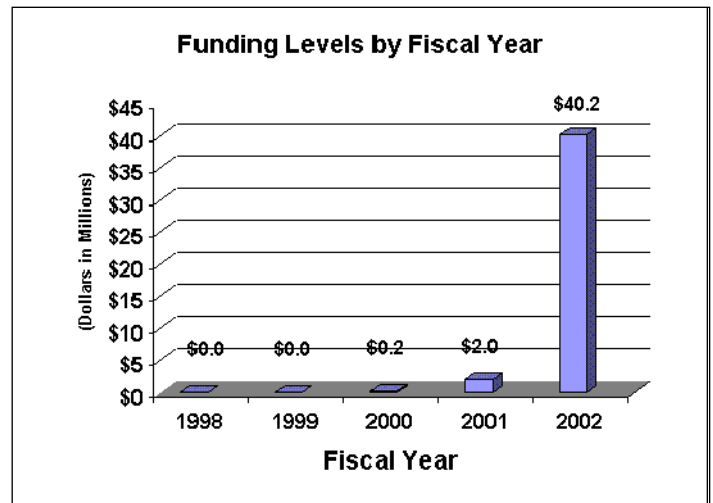
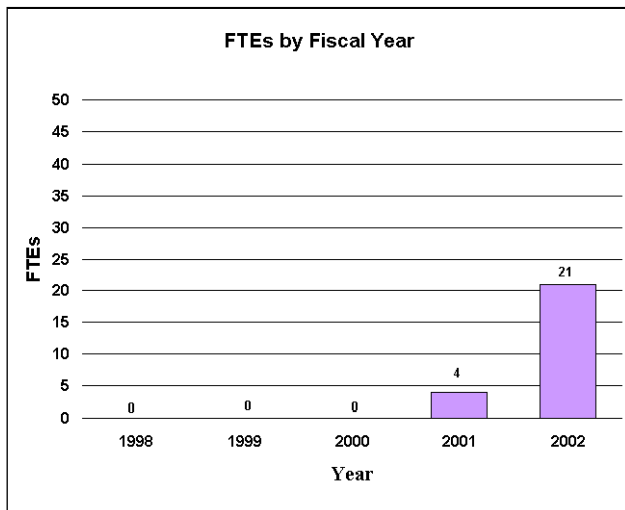
The Fiscal Year 2002 budget request for the NIBIB is \$40,206,000, an increase of \$38,231,000 over the comparable FY 2001 level.

One of NIH's highest priorities is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while providing new research opportunities. A trans-NIH review committee is conducting an analysis of bioengineering and biomedical imaging research portfolios. The committee anticipates that its analysis will recommend that some current projects be moved to NIBIB in the future. In FY 2002, NIBIB will fund 49 new RPGs and 43 SBIR/STTR awards.

Promises for advancement in medical research are dependent on a continuing supply of new investigators with new ideas. In the Fiscal Year 2002 request, NIBIB will support 74 pre- and postdoctoral trainees in full-time training positions.

The Fiscal Year 2002 request includes funding for 12 other research grants and 7 R&D contracts.

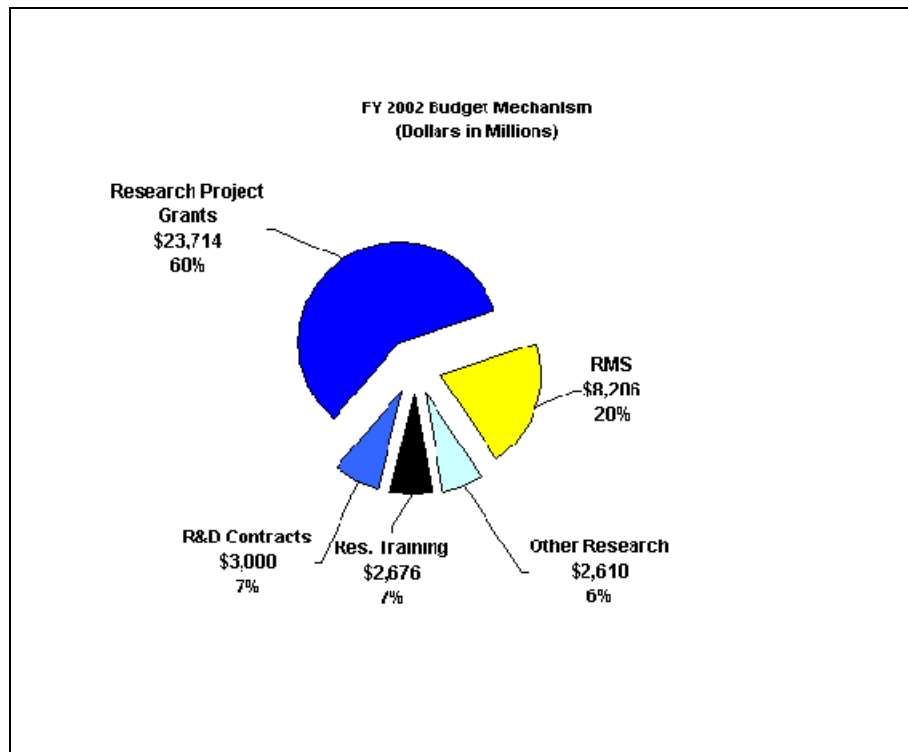
A five year history of FTEs and Funding Levels for NIBIB are shown in the graphs below:



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In its inaugural year, NIBIB is directing \$8,206,000 to Research Management and Support to finance an efficient and effective foundation for its subsequent operations. Given this funding level, the NIBIB will recruit and hire 14 new employees to meet both the scientific and administrative needs of this new Institute. The NIBIB will establish a national advisory council to meet peer review requirements and will engage in advisory workshops and meetings to develop a long-range research strategic plan. To build new extramural research and research training programs, emphasis will be on hiring specialists to manage portfolios for development of (a) new imaging technologies, probes and contrast agents, (b) biomaterials and tissue engineering, and (c) biosensors and nanoscale systems. Beyond this, the NIBIB will engage in partnerships with other Institutes/Centers at NIH to foster transdisciplinary research in biomedical imaging and bioengineering. The NIBIB will purchase furniture, supplies and materials for newly hired staff. To obtain new services quickly, the NIBIB will become a participant in the NIH competitive service centers. NIBIB will use the Center for Scientific Review's Scientific Review Evaluation Award Check Writing Competitive Service Center and the National Institute of Child Health and Human Development's Committee Management Competitive Service Center. Beyond this, NIBIB will need to coordinate with other service centers to obtain critical administrative support and service in areas such as information technology, web development and design, grants management, EEO, and ethics oversight. NIBIB will need to take advantage of these "best practices" until it is fully established. The Institute will establish the Public Information and Liaison Office to reflect the Institute's commitment to communicating with the public. NIBIB will be interacting with advocacy groups and will jointly sponsor conferences and meetings on topics of mutual interest. NIBIB will rent off-campus office space to house additional staff as programs move toward full implementation.

The mechanism distribution by dollars is displayed below:



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Budget Mechanism

MECHANISM	FY 2000 Actual		FY 2001 Estimate		FY 2002 Estimate	
	No.	Amount	No.	Amount	No.	Amount
Research Grants:						
<u>Research Projects:</u>						
Noncompeting	0	\$0	0	\$0	0	\$0
Administrative supplements	(0)	0	(0)	0	(0)	0
Competing:						
Renewal	0	0	0	0	0	0
New	0	0	0	0	49	16,375,000
Supplements	0	0	0	0	0	0
Subtotal, competing	0	0	0	0	49	16,375,000
Subtotal, RPGs	0	0	0	0	49	16,375,000
SBIR/STTR	0	0	0	0	43	7,339,000
Subtotal, RPGs	0	0	0	0	92	23,714,000
<u>Research Centers:</u>						
Specialized/comprehensive	0	0	0	0	0	0
Clinical research	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0
Comparative medicine	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0
Subtotal, Centers	0	0	0	0	0	0
<u>Other Research:</u>						
Research careers	0	0	0	0	5	720,000
Cancer education	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0
Other	0	0	0	0	7	1,890,000
Subtotal, Other Research	0	0	0	0	12	2,610,000
Total Research Grants	0	0	0	0	104	26,324,000
<u>Training:</u>	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual awards	0	0	0	0	16	704,000
Institutional awards	0	0	0	0	58	1,972,000
Total, Training	0	0	0	0	74	2,676,000
Research & development contracts	0	0	0	0	7	3,000,000

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(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)
	<u>FTEs</u>		<u>FTEs</u>		<u>FTEs</u>	
Intramural research	0	0	0	0	0	0
Research management and support	0	200,000	4	1,975,000	21	8,206,000
Cancer prevention & control	0	0	0	0	0	0
Construction		0		0		0
Total, NIBIB	0	200,000	4	1,975,000	21	40,206,000
(Clinical Trials)		0		0		0

Budget Authority by Activity
(dollars in thousands)

ACTIVITY	FY 2000		FY 2001		FY 2002		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
<u>Extramural Research:</u>								
Biomedical Imaging and Bioengineering		\$0		\$0		\$32,000		\$32,000
Subtotal, Extramural research		0		0		32,000		32,000
Intramural research	0	0	0	0	0	0	0	0
Research management and support	0	200	4	1,975	21	8,206	17	6,231
Total	0	200	4	1,975	21	40,206	17	38,231

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Summary of Changes

2001 Estimated budget authority					\$1,975,000
2002 Estimated budget authority					40,206,000
Net change					38,231,000
		2001 Current			
		Estimate Base		Change from Base	
		Budget		Budget	
CHANGES		FTEs	Authority	FTEs	Authority
A. Built-in:					
1. Intramural research:					
a. Within grade increase			\$0		\$0
b. Annualization of January 2001 pay increase			0		0
c. January 2002 pay increase			0		0
d. One extra day of pay			0		0
e. Payment for centrally furnished services			0		0
f. Increased cost of laboratory supplies, materials, and other expenses			0		0
Subtotal					0
2. Research Management and Support:					
a. Within grade increase			443,000		7,000
b. Annualization of January 2001 pay increase			443,000		4,000
c. January 2002 pay increase			443,000		12,000
d. One extra day of pay			443,000		2,000
e. Payment for centrally furnished services			0		0
f. Increased cost of laboratory supplies, materials, and other expenses			1,532,000		32,000
Subtotal					57,000
B. Program:					
1. Research project grants:					
a. Noncompeting		0	0	0	0
b. Competing		0	0	49	16,375,000
c. SBIR/STTR		0	0	43	7,339,000
Total		0	0	92	23,714,000

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2. Centers	0	0	0	0
3. Other research	0	0	12	2,610,000
4. Research training	0	0	74	2,676,000
5. Research and development contracts	0	0	7	3,000,000
Subtotal, extramural				32,000,000
6. Intramural research	<u>FTEs</u> 0	<u>FTEs</u> 0	<u>FTEs</u> 0	0
Subtotal, intramural	0	0	0	0
7. Research management and support	4	1,975,000	17	6,174,000
Subtotal, program		1,975,000		38,174,000
Total changes	4		17	38,231,000

Budget Authority by Object

	FY 2001 Estimate	FY 2002 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	4	21	17
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$126,981	\$133,152	\$6,171
Average GM/GS grade	12.1	11.5	(0.6)
Average GM/GS salary	\$64,038	\$60,794	(\$3,244)
Average salary, grades established by act of July 1, 1944	\$0	\$0	\$0
Average salary of ungraded positions	\$180,000	\$185,400	\$5,400
	FY 2001	FY 2002	Increase or

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OBJECT CLASSES		Estimate	Estimate	Decrease
	Personnel Compensation:			
11.1	Full-Time Permanent	\$337,000	\$1,592,000	\$1,255,000
11.3	Other than Full-Time Permanent	0	0	0
11.5	Other Personnel Compensation	22,000	78,000	56,000
11.8	Special Personnel Services Payments	0	0	0
11.9	Total Personnel Compensation	359,000	1,670,000	1,311,000
12.0	Personnel Benefits	84,000	398,000	314,000
13.0	Benefits for Former Personnel	0	0	0
	Subtotal, Pay Costs	443,000	2,068,000	1,625,000
21.0	Travel & Transportation of Persons	40,000	132,000	92,000
22.0	Transportation of Things	7,000	23,000	16,000
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	1,328,000	1,328,000
23.3	Communications, Utilities & Miscellaneous Charges	16,000	36,000	20,000
24.0	Printing & Reproduction	15,000	54,000	39,000
25.1	Consulting Services	236,000	236,000	0
25.2	Other Services	685,000	1,857,000	1,172,000
25.3	Purchase of Goods & Services from Government Accounts	358,000	4,953,000	4,595,000
25.4	Operation & Maintenance of Facilities	0	0	0
25.5	Research & Development Contracts	0	0	0
25.6	Medical Care	0	0	0
25.7	Operation & Maintenance of Equipment	5,000	9,000	4,000
25.8	Subsistence & Support of Persons	0	0	0
25.0	Subtotal, Other Contractual Services	1,284,000	7,055,000	5,771,000
26.0	Supplies & Materials	25,000	198,000	173,000
31.0	Equipment	145,000	312,000	167,000
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	0	29,000,000	29,000,000
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	0
	Subtotal, Non-Pay Costs	1,532,000	38,138,000	36,606,000
	Total Budget Authority by Object	1,975,000	40,206,000	38,231,000

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Salaries and Expenses

OBJECT CLASSES	FY 2001 Estimate	FY 2002 Estimate	Increase or Decrease
Personnel Compensation:			
Full-Time Permanent (11.1)	\$337,000	\$1,592,000	\$1,255,000
Other Than Full-Time Permanent (11.3)	0	0	0
Other Personnel Compensation (11.5)	22,000	78,000	56,000
Special Personnel Services Payments (11.8)	0	0	0
Total Personnel Compensation (11.9)	359,000	1,670,000	1,311,000
Civilian Personnel Benefits (12.0)	84,000	398,000	314,000
Benefits to Former Personnel (13.0)	0	0	0
Subtotal, Pay Costs	443,000	2,068,000	1,625,000
Travel (21.0)	40,000	132,000	92,000
Transportation of Things (22.0)	7,000	23,000	16,000
Rental Payments to Others (23.2)	0	1,328,000	1,328,000
Communications, Utilities and Miscellaneous Charges (23.3)	16,000	36,000	20,000
Printing and Reproduction (24.0)	15,000	54,000	39,000
Other Contractual Services:			
Advisory and Assistance Services (25.1)	236,000	236,000	0
Other Services (25.2)	685,000	1,857,000	1,172,000
Purchases from Govt. Accounts (25.3)	358,000	1,280,000	922,000
Operation & Maintenance of Facilities (25.4)	0	0	0
Operation & Maintenance of Equipment (25.7)	5,000	9,000	4,000
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	1,284,000	3,382,000	2,098,000
Supplies and Materials (26.0)	25,000	198,000	173,000
Subtotal, Non-Pay Costs	1,387,000	5,153,000	3,766,000
Total, Administrative Costs	1,830,000	7,221,000	5,391,000

**NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2000 Amount Authorized	2001 Estimate	2002 Amount Authorized	2002 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
				\$1,975,000		\$37,530,000
National Institute of Biomedical Imaging and Bioengineering	Section 481	42§285	Indefinite		Indefinite	
National Research Service Awards	Section 487(d)	42§288	a/	0	b/	2,676,000
Total, Budget Authority				1,975,000		40,206,000

a/ Funding provided under the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2001 (P.L. 106-554).

b/ Reauthorizing legislation will be submitted.

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Appropriation History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2002	40,206,000 1/			

1/ Prior to the FY 2002 budget estimate to Congress, comparable NIBIB activities were funded through the OD Appropriation.

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OD Appropriation

Detail of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
Office of the Director		1	3
Division of Biomedical Imaging		1	3
Division of Bioengineering		1	3
Division of Extramural Activities			2
Office of Administrative Management		1	9
Office of Scientific Review			1
Total, NIBIB	0	4	21
FTEs supported by funds from Cooperative Research and Development Agreements	(0)	(0)	(0)
FISCAL YEAR	Average GM/GS Grade		
1998	0.0		
1999	0.0		
2000	0.0		
2001	12.1		
2002	11.5		

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Program Administration

Detail of Positions

GRADE	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
ES-6			
ES-5			
ES-4		1	1
ES-3			1
ES-2			
ES-1		1	1
Subtotal	0	2	3
Total - ES Salary	\$0	\$253,961	\$385,576
GM/GS-15		2	3
GM/GS-14		2	5
GM/GS-13		1	4
GS-12		0	1
GS-11		0	0
GS-10		0	1
GS-9		0	2
GS-8		0	0
GS-7		2	3
GS-6		0	1
GS-5		0	0
GS-4		0	0
GS-3		0	0
GS-2		0	0
GS-1		0	0
Subtotal	0	7	20
Grades established by Act of July 1, 1944 (42 U.S.C. 207): Assistant Surgeon General			

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Director Grade			
Senior Grade			
Full Grade			
Senior Assistant Grade			
Assistant Grade			
Co-Step			
Subtotal	0	0	0
Ungraded	0	1	1
Total permanent positions	0	10	24
Total positions, end of year	0	10	24
Total full-time equivalent (FTE) employment, end of year	0	4	21
Average ES level	ES-	ES-2	ES-2
Average ES salary	\$0	\$126,981	\$133,152
Average GM/GS grade	0.0	12.1	11.5
Average GM/GS salary	\$0	\$64,038	\$60,794

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New Positions Requested

	FY 2002		
	Grade	Number	Annual Salary
Senior Advisor	ES-3	1	136,353
Program Analysis Officer	GS-15	1	91,027
Health Scientist Administrator	GS-14	2	77,386
Legislative/Public Affairs Officer	GS-14	1	77,386
Health Scientist Administrator	GS-13	1	65,487
Human Resources Officer	GS-13	1	65,487
Program Analyst	GS-13	1	65,487
Budget Analyst	GS-12	1	55,070
Secretary	GS-10	1	41,820
Budget Analyst	GS-9	1	37,976
Human Resources Specialist	GS-9	1	37,976
Secretary	GS-7	1	31,045
Secretary	GS-6	1	27,937
Total Requested		14	