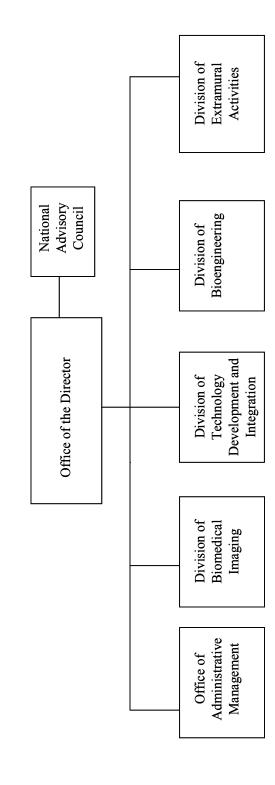
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# NATIONAL INSTITUTES OF HEALTH

# National Institute of Biomedical Imaging and Bioengineering

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National Institute of Biomedical Imaging and Bioengineering



# 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 [\$111,984,000] \$118,842,000.

Departments of Labor, Health and Human Services, Education and Related Agencies Appropriations

Act for Fiscal Year 2002 (P.L. 107-116)]

# National Institute of Biomedical Imaging and Bioengineering Amounts Available for Obligation 1/

	FY 2001	FY 2002	FY 2003
Source of Funding	Actual	Estimate	Estimate
Appropriation	\$0	\$111,984,000	\$118,664,000
Enacted Rescission	(0)	(33,000)	
Subtotal, Adjusted Appropriation	0	111,951,000	118,664,000
Comparable adjustment for legislative proposal for			
accrued retirement costs	55,000	71,000	178,000
Comparative transfer from: Office of the Director for Biomedical Imaging and			
Bioengineering activities	1,975,000		
Various Institutes and Centers for Biomedical Imaging and Bioengineering activities	66,848,000		
National Cancer Institute for research activities			2,536,000
Subtotal	68,878,000	112,022,000	121,378,000
Subtotal, adjusted budget authority	68,878,000	112,022,000	121,378,000
Unobligated balance, lapsing			
Total obligations	68,878,000	112,022,000	121,378,000

<sup>1/</sup> Excludes the following amounts for reimbursable activities carried out by this account: FY 2001 - \$0; FY 2002 - \$3,000,000; FY 2003 - \$3,000,000

# Justification

# National Institute of Biomedical Imaging and Bioengineering

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

Reauthorizing legislation will be submitted.

## **Budget Authority:**

	2001 Actual	2002 Appropriation	2002 Current Estimate	2003 Estimate	Increase or Decrease
Current Law BA	\$68,823,000	\$111,984,000	\$111,951,000	\$121,200,000	\$9,249,000
Accrued Costs	55,000	71,000	71,000	178,000	107,000
Proposed Law BA	68,878,000	112,055,000	112,022,000	121,378,000	9,356,000
FTE	0	21	21	30	9

This document provides justification for the Fiscal Year 2003 activities of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2003 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR)."

The President's appropriation request of \$121,378,000 for this account includes current law adjusted by assuming Congressional action on the proposed Managerial Flexibility Act of 2001.

#### INTRODUCTION

Important breakthroughs in biomedical imaging have revolutionized the diagnosis and treatment of disease and increased knowledge about the function and structure of the normal brain and other organs. At the same time, exciting discoveries in bioengineering have introduced innovative approaches in the areas of biologics, materials, processes, implants, devices and informatics. These recent discoveries signaled a "coming of age" of biomedical imaging and bioengineering, and set the stage for the formation and early development of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the National Institutes of Health (NIH). The creation of NIBIB offers great potential to expand the research frontiers of these disciplines to unparalleled heights.

The mission of the NIBIB is to improve health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of physics, chemistry, mathematics, materials science, information science, and computer sciences. In carrying out its mission, the Institute will be actively planning, conducting, fostering, and supporting an integrated and coordinated program of research grants and research training that can be applied to a broad

spectrum of biological processes, disorders, diseases and organ systems. The research promoted and supported by NIBIB will be multidisciplinary and strongly synergistic with the other NIH Institutes and Centers (ICs) as well as across government agencies, and will have the potential for direct positive medical application. Ultimately, NIBIB will seek to translate research findings from the laboratory into practical solutions that will benefit the public health.

Efforts to create a robust research program at NIBIB will focus on developing fundamental new knowledge, fostering potent new technologies, nurturing and supporting promising researchers, and facilitating cross-cutting capabilities. At the invitation of several ICs with overlapping research areas, NIBIB formed partnerships during Fiscal Year (FY) 2002, and continues to work collaboratively with scientific staff in other ICs. The following examples of collaborative projects demonstrate the range of activities: development of novel technologies for *in vivo* imaging with the National Cancer Institute; ligand development for Positron Emission Tomography (PET) and Single-Photon Emission Computed Tomography (SPECT) with the National Institute of Mental Health; development of imaging technology with the National Institute on Drug Abuse and the National Institute of Deafness and Other Communication Disorders; development of functional tissues and organs with the National Heart, Lung and Blood Institute; and technology development for biomedical applications with the National Center for Research Resources. In addition, NIBIB will participate in trans-NIH announcements for Bioengineering Research Grants and Bioengineering Research Partnerships.

An additional step in building NIBIB's research portfolio was achieved with the transfer of already funded grants relevant to biomedical imaging and bioengineering from several NIH ICs. NIBIB staff are monitoring the peer review process for grant applications submitted to NIH that would be appropriate for funding by NIBIB, and implementing referral guidelines and procedures for new applications during FY 2002. In addition, NIBIB is supporting activities in FY 2002 that will provide guidance in setting the research agenda, including two workshops with the Department of Energy (DOE), "Applications of Thermography in Medical Diagnosis and Therapy" in December 2001, and "Sensor Technologies" in February 2002, the annual NIH-sponsored bioengineering conference "Sensors for Biological Research and Medicine" in June 2002, and the "International Symposium on Biomedical Imaging: Macro to Nano" with the Institute of Electrical and Electronics Engineers (IEEE) in July 2002.

The NIBIB portfolio will be further expanded by initiating new projects that are related to the discovery, design, development, translation and physical assessment of new knowledge in biomedical imaging and bioengineering. The Institute has been organized and will operate initially with three scientific divisions to provide leadership for NIBIB's emerging extramural research program. The Divisions are Biomedical Imaging, Bioengineering, and Technology Development and Integration.

Advances in the imaging sciences are changing the face of medicine, making it possible to non-invasively detect, diagnose, and guide therapy for a large variety of diseases. The Division of Biomedical Imaging will support research that is focused on the following areas: development of imaging devices for evaluation of all levels of biological material; improvement of imaging techniques including image reconstruction, image processing and image display; design and synthesis of target-specific contrast agents to enhance images; and study of informatics and computer sciences related to imaging.

Bioengineering can improve the quality of life through its contribution to advances in science and technology related to human health. The field is unique in its ability to integrate principles and enhancements from a diversity of fields and meshes the boundaries of academia, science, medicine, industry, and government. The Division of Bioengineering will support research that is focused on the following areas: development of biomaterials including implants, prostheses, and artificial organs; enhancement of biosensor technology; exploitation of novel properties and phenomena at the nanoscale level for the eventual application to nanotechnology; and improvement of bioinformatic capability.

Some science areas and organization mandates are cross-cutting and complementary in bioengineering and biomedical imaging. Related issues are encompassed by the Division of Technology Development and Integration which focuses on activities in the following areas: facilitation of communication and cooperation with other NIH ICs and government agencies, establishment of trans-disciplinary research training programs, conduct of technology transfer activities, coordination of NIBIB administration of the NIH Bioengineering Consortium and other inter-organizational committees, and support for the general scientific community in areas concerning existing and emerging health technologies and issues.

The mission of NIBIB includes the training, education and career development for the next generation of scientists that will carry out research in biomedical imaging and bioengineering. New training programs are needed to create a cadre of scientists for whom the principles of mathematics, chemistry, optics, computer science, physics, bioengineering, molecular biology, physiology, pharmacology, and pathophysiology form an intellectual continuum. The Institute plans to help build human capital by supporting the training of aspiring minority students and new minority investigators, and identifying established minority investigators that would benefit from supplemental funding to their bioimaging or bioengineering research. Supporting the training of new researchers in the areas of biomedical imaging and bioengineering will be a priority for NIBIB.

We are in the process of building a structure for the Institute to provide leadership, guidance, planning and evaluation for the overall management of NIBIB scientific research areas. At this time, we are actively recruiting for talented individuals both inside and outside NIH to join the NIBIB. We have on board now a small, and growing, science-based nucleus of staff who can promote biomedical imaging and bioengineering, foster strong partnerships within the other institutes and centers of NIH, and meet with and expand the pool of potential grantee institutions. The creation of programs on the cutting edge of research and innovation poses complex scientific challenges and requires multidisciplinary strategies. Our goal is to create an Institute that will proactively and significantly accelerate the pace of biomedical imaging and bioengineering research and medical advances.

#### SCIENCE ADVANCES

In this first full year of existence for NIBIB, the research projects reported in this section were begun with initial funding from existing NIH Institutes and Centers. These funded projects

relevant to the NIBIB mission were transferred from the NIH IC's in FY 2002, and funding will be provided by NIBIB in FY 2003.

#### **BIOMEDICAL IMAGING**

**Integrated Functional Brain Imaging.** Neuroimaging studies help us to understand which aspects of brain structure and function are responsible for some brain disorders. One major area of advancement in neuroimaging has been the development of functional magnetic resonance imaging (fMRI) which provides functional information on the brain during cognitive and physical task activations. From these studies we are learning about the human brain and its development in normal and diseased states.

There is increasing interest in the neuroscience community in the use of fMRI in conjunction with other techniques, including electroencephalography (EEG) and transcranial magnetic stimulation (TMS) methods. NIBIB is providing support through a Biomedical Research Partnership (BRP) grant to researchers at Yale University to explore the integration of several different brain mapping techniques. This BRP allows integration of information obtained from high field fMRI, near infrared optical encephalography, EEG, TMS, and computer data analysis in non-invasive and comprehensive mapping of the human brain. The integration of these various methods provides a unique and valuable new resource for neuroscience research whose capabilities will far exceed the sum of its separate components. This new resource will be applied to study development in infants and children, as well as the neurobiological basis of various psychiatric, developmental, and neurological disorders. It is expected that this BRP will ultimately allow development and monitoring of new therapeutic regimens for certain neuropsychiatric disorders.

Improvements in Single-Photon Emission Computed Tomography (SPECT) Imaging. SPECT is a nuclear medicine technique which uses radioactively labeled contrast agents to study organ function. Despite being less expensive, as compared to Positron Emission Tomography (PET), SPECT is not widely used in routine clinical practice. Two studies are ongoing that may lead to expanded use of SPECT imaging.

One factor limiting the use of SPECT is image quality. The lack of sophisticated image acquisition hardware and comprehensive reconstruction algorithms cause SPECT images to be degraded by poor spatial and temporal resolution, scatter and attenuation in the patient's body, and image noise arising from poor counting statistics. Thus, it is often difficult to detect subtle lesions or to obtain quantitative information using SPECT imaging. NIBIB is supporting research to address these problems from a total systems engineering approach. The goal of the research is to develop a rigorous theoretical and experimental framework for objective assessment of image quality and apply it to the development and optimization of reconstruction algorithms and imaging systems for SPECT. This work, begun with NIH funding ten years ago, ranges from revolutionizing imaging hardware, developing new mathematical formulations for image reconstruction, object and image simulation, image quality assessment, image statistical analysis, system optimization, and comprehensive theory of image artifacts. Significant results include the design and implementation of a parallel computing system based on a workstation cluster, and the development and validation of the theoretical formulation of digital imaging

systems. The investigators developed a comprehensive theory for objective assessment of image quality using task-specific measures based on mathematical models of the human observer, which has been widely used for image assessment by other prominent groups working in the field. They have also developed innovative statistical descriptions of objects and reconstructed images that accurately account for scattered radiation. Results of this research expanded the theoretical understanding of image quality and its relation to reconstruction algorithms and system design. This research, directed at both basic image science and practical clinical applications, will allow SPECT to be used as a more effective imaging device for the study of organ function.

The successful development of specific contrast agents would enable SPECT imaging to demonstrate serotonin receptors (SERT) in the brain. Serotonin (5-HT) is an essential neurotransmitter in the brain which controls various important behaviors, including sleep-awake cycle, mood, temperature, and appetite. Imaging SERT is particularly important since serotonin receptors are implicated in a number of neurological disorders such as depression and anxiety. Scientists supported by NIBIB are working to develop specific radioactive iodinated (I-123) tracers for imaging SERT in the brain. This research group reported the development of Technetium (Tc-99m) labeled dopamine transporter ligand which may be used to evaluate patients with Parkinson's disease, and a novel radioiodinated agent, IDAM, which demonstrated an excellent selectivity, good brain penetration and a high affinity to SERT. Further investigations will be targeted to study the structure-activity relationship by making a series of derivatives from the basic structure, labeling and testing selected compounds for *in vivo* biodistribution, and applying these iodinated compounds for the *in vivo* study of SPECT imaging in animals and humans. These investigations will make it possible to image SERT non-invasively in the human brain.

**Development of Low-Cost, High Quality Magnetic Resonance Imaging (MRI) Head Scanner.** MRI is the method of choice for diagnosis of soft tissue tumors; however, the high cost of MRI examinations can be somewhat prohibitive. A significant component of the cost is associated with the MRI scanner hardware. Alternative design and construction of the scanner hardware would significantly reduce the overall cost of such systems, while maintaining the high quality of diagnostic images that are produced. The successful development of such innovative technology requires the application of several principles of engineering and science. With support from NCI and NIBIB, researchers are working to design and build a low-cost dedicated MRI head scanner that is capable of generating images that are comparable to those of low-field commercially available systems. To date, they have reported several significant physics and engineering advances toward achieving their goal of designing a low-cost head scanner. They have also been able to obtain a one-dimensional image of a test object from a prototype low-cost MRI system and obtained three US patents related to this research. Future research goals are to design and build other low-cost MRI systems, such as a dedicated breast or extremity scanner, as

well as whole body MRI systems. If these efforts prove successful, MRI may be able to be used for studies that are currently too costly to be feasible, including screening of high-risk patients and minimally-invasive image-guided therapy.

#### BIOENGINEERING

Enhanced Drug Delivery Systems. Delivery of drugs to a specific location in the body will allow for lower drug dosages, therapies that are more effective and tailored to a specific disease, and fewer side effects. However, the potential of designer-delivery systems has not been realized. With support from NIBIB, scientists are addressing two new methods for drug delivery. The first method involves delivery of a drug via the lung by suspending a specific protein in ethanol, allowing the delivery of a reproducible dosage of drug without loss of biological activity of the drug or toxic effect of the suspending agent on the tissue. In the second method, a new gene vector approach, the vector is composed of polymers, which cause the DNA to condense into nanostructures. This nontoxic delivery system can lead to high levels of protein (drug) expression. Both methods for drug delivery have opened new opportunities for administration of therapeutic agents. These involve a range of clinical applications and will enable more efficient, less toxic drugs in the future.

Metallic Barcodes Enable Multi-assay Design. Many assays used in research and clinical diagnoses are being miniaturized to reduce the cost and time and yet maintain resolution of the results. With this miniaturization, the need for processing several different assays simultaneously (multi-assay design) has become apparent. A limited number of spectrally distinguishable fluorescent probes are available that can be used to differentiate assays and to quantify results. As the result of a collaboration between academia and industry, and with funding from NIBIB, this problem has been overcome with the development of metallic barcodes. The barcodes are striped, cylindrically shaped metal nanoparticles that can be identified by the pattern of differential optical reflectivity of adjacent stripes. These striping patterns will increase the number of patterns by several orders of magnitude. Thus, comprehensive analyses can be determined with very high-level multiplexing in small sample volumes. Solution arrays of highly encodable and chemically diverse bars offer an innovative solution to these requirements. Application of this technology will enable analyses of research and clinical samples more rapidly and less expensively.

**Cell Separation by Rolling Adhesion**. Normally as blood flows through a blood vessel, cells adhere to the vessel wall via adhesion molecules. Initially the cell is tethered to these adhesion molecules but then the cell rolls along the vessel (rolling adhesion) and finally firmly adheres. This rolling adhesion can be employed as a novel separation that exploits differences in rolling adhesion between populations of cells. Researchers supported by NIBIB have defined a new method for separating cell types which utilizes the cell's adherence to different adhesion molecules, e.g. selectins or integrins. Their data, using mathematical models and spheres coated with leukocyte adhesion molecules, demonstrate that a separation procedure is attainable. Thus, cell separation such as the separation of hematopoietic stem and progenitor cells can be used to restore the blood and immune systems of cancer patients and to treat autoimmune, metabolic, and genetic diseases. Separation of these cell types can be accomplished in several different ways. However, with each step in the process, the yield is decreased, while time, cost, and the possibility of contamination are increased. The rolling adhesion approach can be applied to the separation of any cell population according to the surface density of a particular surface protein or antigen, to which an antibody is available. Development of this technology will have implications for many areas of medicine including tissue engineering, for the separation of progenitor cells, and reconstitution of normal bone marrow following therapeutic ablation.

#### **NEW INITIATIVES**

In FY 2003, NIBIB will continue to expand the research portfolio through a variety of activities. The Institute will pursue several important areas in future initiatives, including the development of micro-analytical systems to facilitate ultra-high throughput screening and rapid medical diagnostic tests, a systemized approach to information systems to create an information infrastructure for use throughout the healthcare industry, the development of small animal imaging systems, and integrated systems approaches and imaging methods for multi-modality imaging. In addition, NIBIB will launch specific initiatives in FY 2003. These are described below.

Nanoparticle Materials for Drug Production, Discovery and Delivery. Advances in the nanoscale science and technology will enable the creation and application of materials, devices and systems and the understanding and utilization of properties and phenomenon at the atomic and molecular scale (1 to 100 nanometers). A potential application of nanotechnology to medical therapy is the development of nanoparticle materials for drug production, discovery and delivery. Since cellular- and molecular-level interactions occur on the nanometer scale, such technologies have the potential to offer significant improvements over current treatment options. NIBIB plans to solicit applications in this area to meet the following research goals: to develop scalable fabrication methods, including milling, crystallization and coating techniques, controlled particle aggregation, to effectively manufacture materials on a large-scale; to develop nanostructured biomaterials to replace hard and soft skeletal tissue, lipids for gene therapy vectors and biocompatible materials for tissue genesis; and to develop biocompatible biocapsules for cellular therapy and delivery.

**Biomedical Imaging Technology Development.** Recent discoveries present a significant opportunity to foster the development of new biomedical imaging technologies including molecular probes and contrast agents that are the tools for linking imaging to specific biological processes. Recognizing the multidisciplinary nature of the research required to realize the potential benefits of these new technologies, a new initiative in biomedical imaging technology development will be launched in FY 2003 to support the research and development of molecular probes and contrast agents for biomedical imaging. The NIBIB initiative will facilitate collaboration among experts in chemistry, physics, molecular biology, pharmacology, and bioengineering and cooperation among universities, national laboratories and industry.

Real Time and Multi-Measurement Sensors for Research and Medicine. Real time sensors can offer the clinical setting enormous advantages in reducing the time and cost of stabilizing patients during surgery, during an emergency, or in critical care facilities. Protein chemistry, physical characteristics and chemical modifications have been exploited to determine and measure new targets. These technologies are available, and more are in the planning stages, to extend the prospect for the application of sensors in the biological arena, but research into the capabilities of these sensor systems in clinical settings is required. NIBIB plans an initiative to increase the variety of detected samples, the number of measurements on a sensor, the validity of a sensor and the development of transducers and actuators to utilize the sensor as a closed-loop or control system.

Informatics in Biomedical Imaging. The rapid evolution of medical procedures in general, and medical imaging in particular, has created a gap between the mass of clinical information a health care professional must synthesize and the technology for integrating it into a coherent, rapidly interpretable picture. This new initiative will support research and development in the application of informatics to biomedical imaging. The goals of this initiative are: to encourage interdisciplinary collaborations in developing new informatics-based systems models that integrate clinical and biomedical imaging data for support of medical decision-making; to design compatible databases that contain both biomedical images and pathology or other outcome and clinical data; to develop computer-aided image analysis methods for increasing the specificity of current clinical imaging methods; and to design biostatistics components for all image analysis programs to better quantify the results of imaging tests.

**Training**. Progress in biomedical engineering, imaging and informatics on a steady supply of young scientists, engineers and mathematicians who are well-educated in the fundamentals and research methods of their disciplines. Training this next generation of researchers is a high priority for NIBIB. The development of trained professionals in these areas requires opportunities and support all along the career continuum including the undergraduate, predoctoral, postdoctoral, junior career, and senior career levels. Because of the nature of the fields of biomedical imaging and bioengineering, training and education programs require transor cross-disciplinary interaction between the engineering, physical, and computational sciences and the biological and medical sciences across all career levels.

In June 2001, NIH and the National Science Foundation (NSF) conducted a joint workshop on bioengineering research training and education to identify gaps in related training opportunities from high school through undergraduate, predoctoral, postdoctoral, and career levels. To address one of the recommendations identified in the workshop, the NIBIB plans to develop a joint program with NSF that will provide a summer biomedical research experience for students majoring in the quantitative sciences. The program, targeted to rising junior undergraduates through second year graduate students, would introduce science and biology students to engineering and computer science concepts, and engineering and computer science students to concepts in biology. In this program, students will work on multidisciplinary research teams and be exposed to the role of engineering in clinical medicine at an early educational stage.

Another initiative is being developed that will provide support to early career (postdoctoral) professionals. The initiative will support postdoctoral training opportunities for persons trained in the quantitative sciences to receive up to five years of mentored training in the biomedical sciences and for persons trained in the biomedical sciences to receive training in the quantitative sciences. This program will promote the involvement of faculty in multidisciplinary and interdepartmental training and research which are typically unsupported by traditional engineering and basic science departments.

# INNOVATIONS IN MANAGEMENT AND ADMINISTRATION

Building on initial planning efforts that took place in the previous fiscal year, management and administrative structures are continuing to be established at NIBIB. With no structure in existence, we had numerous opportunities to try innovative strategies. Consistent with the

Institute's areas of expertise, we expect to continue using state-of-the-art technology and being a leader in technology development.

Launch of Official Website for the NIBIB. On October 1, 2001 the National Institute of Biomedical Imaging and Bioengineering (NIBIB) announced the launch of the official website at www.nibib.nih.gov. Information on all aspects of NIBIB operations and on activities related to biomedical imaging and bioengineering in general is available on this site. The site is divided into six main sections: About NIBIB, For Investigators, For Students, News & Events, General Information and BECON. The About NIBIB portion of the site contains information about the history, mission, legislative activities, budget, staff, vacancy announcements, and administration of the new Institute. Lists and links to NIBIB and BECON research and training opportunities, NIH extramural grant requirements and information, data on current grants, and opportunities from other Federal agencies are contained in the For Investigators and For Students portions of the site. Articles describing breaking news and events associated with the NIBIB, a list of reports and articles issued by the NIBIB, and a calendar of events for biomedical imaging and bioengineering activities (symposia, application deadlines, national and international conferences, workshops, etc.) are contained in the News and Events section. The General Information section provides links to reports and publications concerned with biomedical imaging and bioengineering and links to related Web sites (other Federal agencies, foundations, societies, and academic programs). Information about the history, mission, meetings, membership, and activities of the NIH's Bioengineering Consortium (BECON) is provided in the BECON portion of the site. The BECON, which was formerly administered by the Office of Extramural Research at the NIH, is now administered by the NIBIB. The NIBIB website is updated on a regular basis to provide current news and research opportunities to the general public and scientific community.

Administration of the Bioengineering Consortium. On September 19, 2001, the administration of the Bioengineering Consortium (BECON) transitioned from the Office of Extramural Research to the NIBIB. Since its establishment in 1997, the Bioengineering Consortium has been the focus of bioengineering activities at the NIH. The Consortium consists of senior-level representatives from all of the NIH institutes, centers, and divisions plus representatives of other Federal agencies concerned with biomedical research and development. The NIBIB will join the BECON as an additional institute representative. In its administrative role, the NIBIB will be committed to maintaining the successful coordination of trans-NIH bioengineering research, training, and related programs.

Membership in the Biomedical Information Science and Technology Initiative Consortium.

The NIBIB has joined the Biomedical Information Science and Technology Initiative Consortium (BISTIC) as an additional institute representative. The BISTIC was established in May 2000 to serve as the focus of biomedical computing issues at the NIH and to facilitate implementation of the BISTI recommendations. The Consortium is composed of senior-level representatives from the NIH centers and institutes and representatives of other Federal agencies concerned with bioinformatics and computational applications. The mission of the NIBIB will support the development of research in the areas of biomedical computing such as computer modeling and simulation, computer-assisted surgery, telemedicine and image processing, storage, analysis and retrieval.

Infrastructure and Staffing. The NIBIB has intensified its recruitment efforts to have on board by late Spring 2002, a cadre of health scientist administrators, biomedical engineers, and other key staff. While NIBIB is still in its infancy, it has been in the process of planning and building the Institute and identifying key goals and objectives to guide its growth and value. Space for the Institute has been secured both on and off the NIH main campus to house its projected growth in staff. The NIBIB plans to create unique research opportunities for the development of specialized instruments and devices that will emerge from the bioimaging and bioengineering research community.

Grant Application Scanning. The NIBIB continues to support efforts by the NIH to migrate from a paper-based system towards electronic systems. In concert with the electronic research administration (eRA) efforts at the NIH, the NIBIB has begun to scan full versions of all incoming grants and applications that are assigned to the institute for review, monitoring and administration. Active grants will be available through the NIH IMPAC (Information for Management, Planning, Analysis, and Coordination) II system in the portable document format (PDF). The NIBIB scanning effort is one of several pilot activities being conducted at the NIH. The scanning of grant applications is the first step towards accepting electronic application submissions by FY2003 as mandated by federal law. The Bioengineering Consortium, which will be administered by the NIBIB, has successfully participated in the scanning pilots for several years. The BECON has also offered the applications on compact discs (CDs) for NIH staff and peer reviewers, resulting in significant cost-savings in human resources and reproduction. The NIBIB is committed to the efforts of the eRA, while maintaining applicant confidentiality, conflict of interest protections and secure transmission of information.

## **SUMMARY**

The fields of biomedical imaging and bioengineering are expanding rapidly from the detection, diagnosis and treatment of diseases and disabilities at the level of tissues and organs, to the analysis of structure and function at the molecular and genetic levels. The establishment of NIBIB was predicated on present and potential advances in these exciting fields. As the Institute evolves in the coming years, our research mission will allow us to find areas where biomedical imaging and bioengineering approaches can be used to explore promising new directions.

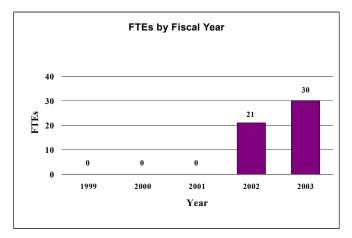
# **Budget Policy**

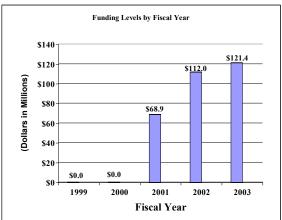
The Fiscal Year 2003 budget request for the NIBIB is \$121,378,000, including AIDS, an increase of \$9,356,000 and 8.4 percent over the FY 2002 level.

A five year history of FTEs and Funding Levels for NIBIB are shown in the graphs below. Note that Fiscal Years 2000 and 1999 are not comparable for the Managerial Flexibility Act of 2001 legislative proposal.

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. The Fiscal Year 2003 request provides average cost increases for competing RPGs equal to the Biomedical Research and Development Price Index (BRDPI), estimated at 4.0 percent. Noncompeting RPGs will be funded at committed levels which include increases of 3 percent on average for recurring direct costs.

Future promises for advancement in medical research rest in part with new investigators with new ideas. In the Fiscal Year 2003 request, NIBIB will support an estimated 74 pre- and

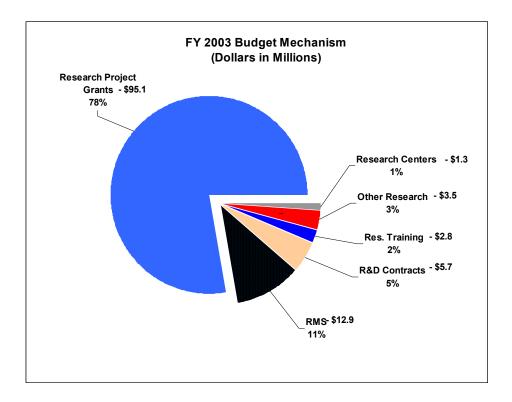


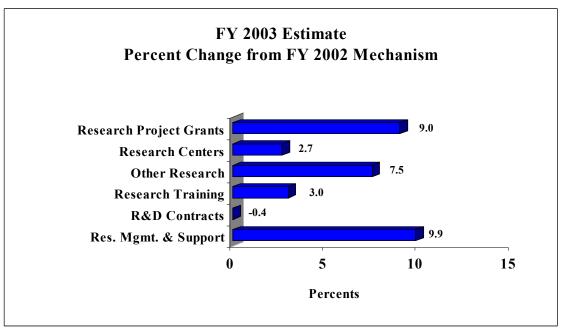


postdoctoral trainees in full-time training positions, the same number as in FY 2002. Stipend levels for NRSA trainees will increase by 4 percent over Fiscal Year 2002 levels.

The Fiscal Year 2003 request includes funding for 2 research centers, 14 other research grants, including 6 clinical career awards, and 9 R&D contracts. Research Management and Support receives an increase of close to 9.9 percent over FY 2002.

The mechanism distribution by dollars and percent change are displayed below:





#### National Institute of Biomedical Imaging and Bioengineering TOTAL - Current Law Budget Mechanism

MECHANISM		Y 2001 Actual	FY 2002 Appropriation			Y 2002 ent Estimate		Y 2003 Estimate
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects: Noncompeting Administrative supplements	207 (0)	\$44,590,000 0	116 (0)	\$35,716,000 0	116 (0)	\$35,716,000 0	188 (0)	\$64,738,000 0
Competing: Renewal New Supplements	0 13 0	0 2,632,000 0	28 100 0	7,889,000 36,348,000 0	28 100 0	7,889,000 36,348,000 0	28 49 0	9,823,000 17,860,000 0
Subtotal, competing	13	2,632,000	128	44,237,000	128	44,237,000	77	27,683,000
Subtotal, RPGs	220	47,222,000	244	79,953,000	244	79,953,000	265	92,421,000
SBIR/STTR	85	15,024,000	30	7,339,000	30	7,339,000	11	2,727,000
Subtotal, RPGs	305	62,246,000	274	87,292,000	274	87,292,000	276	95,148,000
Research Centers: Specialized/comprehensive Clinical research Biotechnology	2 0 0	1,257,000 0 0	2 0 0	1,281,000 0 0	2 0 0	1,281,000 0 0	2 0 0	1,315,000 0 0
Comparative medicine	0	0	0	0	0	Ö	0	0
Research Centers in Minority Institution	0	0	ő	ő	0	0	0	0
Subtotal, Centers	2	1,257,000	2	1,281,000	2	1,281,000	2	1,315,000
Other Research: Research careers Cancer education Cooperative clinical research Biomedical research support Minority biomedical research support Other Subtotal, Other Research	2 0 0 0 0 4	282,000 0 0 0 0 0 2,291,000 2,573,000	4 0 0 0 0 4	720,000 0 0 0 0 2,510,000 3,230,000	4 0 0 0 0 4	720,000 0 0 0 0 2,510,000 3,230,000	6 0 0 0 0 8	1,139,000 0 0 0 2,333,000 3,472,000
Total Research Grants	313	66,076,000	284	91,803,000	284	91,803,000	292	99,935,000
<u>Training:</u> Individual awards Institutional awards	FTTPs 0 0	0	FTTPs 16 58 74	704,000 1,972,000	FTTPs 16 58 74	704,000 1,972,000	<u>FTTPs</u> 16 58 74	725,000 2,031,000
Total, Training  Research & development contracts (SBIR/STTR)	3 (0)	1,202,000 (0)	9 (0)	2,676,000 5,754,000 (0)	9 (0)	2,676,000 5,721,000 (0)	9	2,756,000 5,700,000 (0)
Intramural research	FTEs 0	0	FTEs 0	0	FTEs 0	0	FTEs 0	0
Research management and support	0	1,545,000	21	11,751,000	21	11,751,000	30	12,809,000
Total. NIBIB	0	68.823.000	21	111,984,000	21	111,951,000	30	121,200,000
(Clinical Trials)	U	(0)	۷1	(0)	۷1	(0)		(0)

# National Institute of Biomedical Imaging and Bioengineering TOTAL - Accrued Costs for Retirement and Health Benefits Budget Mechanism

MECHANISM	FY 2 Act			Y 2002 ropriation		Y 2002 nt Estimate		FY 2003 Estimate
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects: Noncompeting Administrative supplements Competing: Renewal New Supplements Subtotal, competing Subtotal, RPGs SBIR/STTR Subtotal, RPGs Research Centers: Specialized/comprehensive Clinical research	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Biotechnology Comparative medicine Research Centers in Minority Institution Subtotal, Centers	ns I							
Other Research: Research careers Cancer education Cooperative clinical research Biomedical research support Minority biomedical research support Other Subtotal, Other Research								
Total Research Grants <u>Training:</u> Individual awards Institutional awards	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Total, Training  Research & development contracts (SBIR/STTR)								
Intramural research	FTEs 0	0	FTEs 0	0	FTEs 0	0	FTEs 0	0
Research management and support	0	55,000	0	71,000	0	71,000	0	178,000
Total, NIBIB	0	55,000	0	71,000	0	71,000	0	178,000
Clinical Trials)	1	(0)	_	(0)	-	(0)		(0

#### National Institute of Biomedical Imaging and Bioengineering TOTAL - Proposed Law Budget Mechanism

MECHANICM		Y 2001		Y 2002		Y 2002		FY 2003	
MECHANISM		Actual		propriation		ent Estimate		stimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount	
Research Projects:									
Noncompeting	207	\$44,590,000	116	\$35,716,000	116	\$35,716,000	188	\$64,738,000	
Administrative supplements	(0)	0 0	(0)	\$33,7 TO,000 0	(0)	φ33,7 10,000	(0)	0	
·	(0)	U	(0)	U	(0)	U	(0)	U	
Competing:	0	0	20	7 000 000	20	7 000 000	20	0.000.000	
Renewal	0	0	28	7,889,000	28	7,889,000	28	9,823,000	
New	13 0	2,632,000	100	36,348,000	100	36,348,000	49	17,860,000	
Supplements		0.000.000	0	0	0	0	0	0	
Subtotal, competing	13	2,632,000	128	44,237,000	128	44,237,000	77	27,683,000	
Subtotal, RPGs	220	47,222,000	244	79,953,000	244	79,953,000	265	92,421,000	
SBIR/STTR	85	15,024,000	30	7,339,000	30	7,339,000	11	2,727,000	
Subtotal, RPGs	305	62,246,000	274	87,292,000	274	87,292,000	276	95,148,000	
Research Centers:									
Specialized/comprehensive	2	1,257,000	2	1,281,000	2	1,281,000	2	1,315,000	
Clinical research	0	0	0	0	0	0	0	0	
Biotechnology	0	0	0	0	0	0	0	0	
Comparative medicine	0	0	0	0	0	0	0	0	
Research Centers in Minority Institution	0	0	0	0	0	0	0	0	
Subtotal, Centers	2	1,257,000	2	1,281,000	2	1,281,000	2	1,315,000	
Other Research:									
Research careers	2	282,000	4	720,000	4	720,000	6	1,139,000	
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	4	2,291,000	4	2,510,000	4	2,510,000	8	2,333,000	
Subtotal, Other Research	6	2,573,000	8	3,230,000	8	3,230,000	14	3,472,000	
Total Research Grants	313	66,076,000	284	91,803,000	284	91,803,000	292	99,935,000	
Training:	FTTPs		FTTPs		FTTPs		FTTPs		
Individual awards	0	0	16	704.000	16	704.000	16	725.000	
Institutional awards	0	0	58	1,972,000	58	1,972,000	58	2,031,000	
Total, Training	0	0	74	2,676,000	74	2,676,000	74	2,756,000	
Bassanda O davidas de la del	_	4 000 000	_	F 75 4 00 5	_	F 704 005		F 700 000	
Research & development contracts	3	1,202,000	9	5,754,000	9	5,721,000	9	5,700,000	
(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	
	<u>FTEs</u>		<u>FTEs</u>		FTEs		FTEs		
Intramural research	0	0	0	0	0	0	0	0	
Research management and support	0	1,600,000	21	11,822,000	21	11,822,000	30	12,987,000	
Total NIDID	^	60 070 000	04	110 055 000	04	110 000 000	20	101 270 000	
Total, NIBIB	0	68,878,000	21	112,055,000	21	112,022,000	30	121,378,000	
(Clinical Trials)		(0)		(0)		(0)		(0)	

# National Institute of Biomedical Imaging and Bioengineering <u>Budget Authority by Activity</u> 1/ (dollars in thousands)

ACTIVITY	FY 2001 Actual		FY 2002 Estimate		FY 2003 Estimate		Change	
	FTEs	Amount	FTEs	Amount	FTEs	Amount	FTEs	Amount
Extramural Research:								
Biomedical Imaging and Bioengineering		\$67,278		\$100,200		\$108,391		\$8,191
Subtotal, extramural research		67,278		100,200		108,391		8,191
Research management and support	0	1,600	21	11,822	30	12,987	9	1,165
Total	0	68,878	21	112,022	30	121,378	9	9,356

 $<sup>\</sup>underline{1}$ / Please see the following tables for the crosswalk from current law to proposed law to reflect the administration's proposal for full accrued retirement and health benefits.

# National Institute of Biomedical Imaging and Bioengineering

# 2001 Crosswalk for Accrued Retirement and Health Benefit Costs (Dollars in thousands)

Extramural December	2001 Actual Current Law	2001 Additional <u>Accrual Costs</u>	2001 Actual <u>Proposed Law</u>
Extramural Research: Biomedical Imaging and	\$67,278	\$0	\$67,278
Bioengineering			
Subtotal, extramural research	67,278	0	67,278
Research management and support	1,545	55	1,600
Total	68,823	55	68,878
Total	00,023		00,070

# National Institute of Biomedical Imaging and Bioengineering

# 2002 Crosswalk for Accrued Retirement and Health Benefit Costs (Dollars in thousands)

	2002	2002	2002
	Current Estimate	Additional	Appropriation
Fisher was I Dana a male.	Current Law	Accrual Costs	Proposed Law
Extramural Research:			
Biomedical Imaging and Bioengineering	\$100,200	\$0	\$100,200
Subtotal, extramural research	100,200	0	100,200
Research management and support	11,751	71	11,822
Total	111,951	71	112,022

# National Institute of Biomedical Imaging and Bioengineering

# 2003 Crosswalk for Accrued Retirement and Health Benefit Costs (Dollars in thousands)

Extramural Research:	2003 Estimate <u>Current Law</u>	2003 Additional <u>Accrual Costs</u>	2003 Estimate <u>Proposed Law</u>
Biomedical Imaging and Bioengineering	\$108,391	\$0	\$108,391
Subtotal, extramural research	108,391	0	108,391
Research management and support	12,809	178	12,987
Total	121,200	178	121,378

# National Institute of Biomedical Imaging and Bioengineering Summary of Changes

2002 Estimated budget authority				\$112,022,000
2003 Estimated budget authority				121,378,000
Net change				9,356,000
		02 Current	0.1	. 5
	Est	mate Base	Chan	ge from Base
		Budget		Budget
CHANGES	FTEs	Authority	FTEs	Authority
A. Built-in:				
Intramural research:      Within and do in an account.	0	<b>#</b> 0		
a. Within grade increase		\$0		
b. Annualization of January 2002 pay increase		0		
c. January 2003 pay increase		0		
d. Payment for centrally furnished services		0		
e. Increased cost of laboratory supplies,		· ·		
materials, and other expenses		0		
f. Accrued costs for retirement and health		•		
benefits		0		
Subtotal				0
Research Management and Support:				
a. Within grade increase		2,114,000		36,000
b. Annualization of January		2, ,		00,000
2002 pay increase		2,114,000		24,000
c. January 2003 pay increase		2,114,000		42,000
d. Payment for centrally furnished services		357,000		32,000
<ul> <li>e. Increased cost of laboratory supplies,</li> </ul>				
materials, and other expenses		9,351,000		183,000
f. Accrued costs for retirement and health				
benefits		3,000		107,000
Subtotal				424,000
Subtotal, Built-in				424,000

# National Institute of Biomedical Imaging and Bioengineering Summary of Changes--continued

	20	02 Current		
	Est	imate Base	Chang	ge from Base
CHANGES	No.	Amount	No.	Amount
B. Program:				
Research project grants:				
a. Noncompeting	116	35,716,000	72	29,022,000
b. Competing	128	44,237,000	(51)	-16,554,000
c. SBIR/STTR	30	7,339,000	(19)	-4,612,000
Total	274	87,292,000	2	7,856,000
2. Centers	2	1,281,000	0	34,000
3. Other research	8	3,230,000	6	242,000
4. Research training	74	2,676,000	0	80,000
5. Research and development		5 704 000	0	04.000
contracts	9	5,721,000	0	-21,000
Subtotal, extramural		100,200,000		8,191,000
	<u>FTEs</u>		<u>FTEs</u>	
6. Research management and support	21	11,822,000	9	741,000
Subtotal, program		112,022,000		8,932,000
Total changes	21		9	9,356,000

## National Institute of Biomedical Imaging and Bioengineering Budget Authority by Object

	FY 2002	FY 2002	FY 2003	Increase or
	Appropriation	Current Estimate	Estimate	Decrease
Total compensable workyears:				
E II Constant	0.4	0.4	00	•
Full-time employment Full-time equivalent of overtime and holiday hours	21	21 0	30 0	9
i dil-time equivalent of overtime and nonday hours	0	U	U	0
Average ES salary	\$130,000	\$130,000	\$136,240	\$6,240
Average GM/GS grade	12.9	12.9	10.4	(2.5
Average CM/CS colony	\$70,543	\$70,543	\$48,758	(¢01 70E
Average GM/GS salary Average salary, grades established by act of	\$70,543	\$70,543	φ <del>4</del> 0,736	(\$21,785
July 1, 1944 (42 U.S.C. 207)	\$0	\$0	\$0	\$0
Average salary of ungraded positions	\$0	\$0	\$0	\$0
	FY 2002	FY 2002	FY 2003	Increase or
OBJECT CLASSES	Appropriation	Estimate	Estimate	Decrease
Personnel Compensation:				
11.1 Full-Time Permanent	\$1,592,000	\$1,592,000	\$1,688,000	\$96,000
11.3 Other than Full-Time Permanent	43,000	43,000	43,000	(
11.5 Other Personnel Compensation	78,000	78,000	78,000	(
11.8 Special Personnel Services Payments	0	0	0	(
11.9 Total Personnel Compensation	1,713,000	1,713,000	1,809,000	96,000
12.1 Personnel Benefits	398,000	398,000	422,000	24,000
12.1 Personnel Benefits, Accrued Retirement Costs	3,000	3,000	107,000	104,000
13.0 Benefits for Former Personnel	0	0	0	(
Subtotal, Pay Cost, Current Law	2,111,000		2,231,000	120,000
Subtotal, Pay Cost, Proposed Law	2,114,000	, ,	2,338,000	224,000
21.0 Travel and Transportation of Persons	132,000	· · · · · · · · · · · · · · · · · · ·	132,000	(
22.0 Transportation of Things	23,000	23,000	24,000	1,000
23.1 Rental Payments to GSA	0	0	0	(
23.2 Rental Payments to Others	1,328,000	1,328,000	1,407,000	79,000
23.3 Communications, Utilities and				
Miscellaneous Charges	36,000	· · · · · · · · · · · · · · · · · · ·	50,000	14,000
24.0 Printing and Reproduction	54,000	· · · · · · · · · · · · · · · · · · ·	60,000	6,000
25.1 Consulting Services	392,000	,	440,000	48,000
25.2 Other Services	2,990,000	2,990,000	3,378,000	388,000
25.3 Purchase of Goods and Services from	5 004 000	5 000 000	5 540 000	245.00
Government Accounts 25.3 Accrued Retirement Costs	5,261,000		5,543,000	315,000
25.3 Accrued Retirement Costs 25.4 Operation and Maintenance of Facilities	68,000 0	68,000	71,000	3,000
I	4,521,000	4 524 000	4 504 000	
25.5 Research and Development Contracts 25.6 Medical Care	4,521,000	4,521,000	4,521,000	
25.7 Operation and Maintenance of Equipment	9,000	9,000	10,000	1,000
25.8 Subsistence and Support of Persons	9,000	9,000	0,000	1,000
25.0 Subtotal, Other Contractual Services,	•	,		
Current Law	13,173,000	13,140,000	13,892,000	752,000
25.0 Subtotal, Other Contractual Services,	1	., .,,	.,,	,
Proposed Law	13,241,000		13,963,000	755,000
26.0 Supplies and Materials	198,000	· · · · · · · · · · · · · · · · · · ·		20,000
31.0 Equipment	450,000		495,000	45,000
32.0 Land and Structures	0	_	0	(
33.0 Investments and Loans	0	0		()
41.0 Grants, Subsidies and Contributions	94,479,000	94,479,000	102,691,000	8,212,000
42.0 Insurance Claims and Indemnities		0	0	',
43.0 Interest and Dividends 44.0 Refunds	0	0	0	
	109,873,000	109,840,000	118,969,000	9,129,000
Subtotal, Non-Pay Costs, Current Law Subtotal, Non-Pay Costs, Proposed Law	109,967,000	109,934,000	119,080,000	9,146,000
Subtotal, Non-Pay Costs, Proposed Law	103,307,000	100,004,000	110,000,000	3, 140,000
Total Budget Authority by Object Comment	111,984,000	111,951,000	121,200,000	9,249,000
Total Budget Authority by Object, Current		112,048,000	121,200,000	
Total Budget Authority by Object, Proposed Total Accrued Retirement Costs	112,081,000			9,370,000
Total Accrued Retirement Costs	71,000	71,000	178,000	107,000

# National Institute of Biomedical Imaging and Bioengineering Salaries and Expenses

	FY 2002	FY 2002	FY 2003	Increase or
OBJECT CLASSES	Appropriation	Current Estimate	Estimate	Decrease
Personnel Compensation:				
Full-Time Permanent (11.1)	\$1,592,000	\$1,592,000	\$1,688,000	\$96,000
Other Than Full-Time Permanent (11.3)	43,000	43,000	43,000	0
Other Personnel Compensation (11.5)	78,000	78,000	78,000	0
Special Personnel Services Payments (11.8)	0	0	0	0
Total Personnel Compensation (11.9)	1,713,000	1,713,000	1,809,000	96,000
Civilian Personnel Benefits (12.1)	398,000	398,000	422,000	24,000
Accrued Costs of Retirement Benefits (12.1)	3,000	3,000	107,000	104,000
Benefits to Former Personnel (13.0)	0	0	0	0
Subtotal, Pay Costs, Current Law	2,111,000	2,111,000	2,231,000	120,000
Subtotal, Pay Costs, Proposed Law	2,114,000	2,114,000	2,338,000	224,000
Travel (21.0)	132,000	132,000	132,000	0
Transportation of Things (22.0)	23,000	23,000	24,000	1,000
Rental Payments to Others (23.2)	1,328,000	1,328,000	1,407,000	79,000
Communications, Utilities and				
Miscellaneous Charges (23.3)	36,000	36,000	50,000	14,000
Printing and Reproduction (24.0)	54,000	54,000	60,000	6,000
Other Contractual Services:				
Advisory and Assistance Services (25.1)	392,000	392,000	440,000	48,000
Other Services (25.2)	2,990,000	2,990,000	3,378,000	388,000
Purchases from Govt. Accounts (25.3)	3,525,000	3,525,000	3,855,000	330,000
Accrued Retirement Costs (25.3)	68,000	68,000	71,000	3,000
Operation & Maintenance of Facilities (25.4)	0	0	0	0
Operation & Maintenance of Equipment (25.7)	9,000	9,000	10,000	1,000
Subsistence & Support of Persons (25.8)	0	0	0	0
Subtotal, Other Contractual Services, Current Law	6,916,000	6,916,000	7,683,000	767,000
Subtotal, Other Contractual Services, Proposed Law	6,984,000		7,754,000	770,000
Supplies and Materials (26.0)	198,000		218,000	20,000
Subtotal, Non-Pay Costs, Current Law	7,114,000	7,114,000	9,474,000	2,360,000
Subtotal, Non-Pay Costs, Proposed Law	7,182,000	7,182,000	9,545,000	2,363,000
Total, Administrative Costs, Current Law	9,225,000	9,225,000	11,705,000	2,480,000
Total, Accrued Costs	71,000		178,000	107,000
Total, Administrative Costs, Proposed Law	9,296,000	9,296,000	11,883,000	2,587,000

# National Institute of Biomedical Imaging and Bioengineering

# SIGNIFICANT ITEMS IN HOUSE, SENATE, AND CONFERENCE APPROPRIATIONS COMMITTEE REPORTS

FY 2002 House Appropriations Committee Report Language (H. Rpt. 107-229)

#### Item

Joint replacement - An estimated 500,000 joint replacements are performed in the U.S. each year, a number of which fail and require additional surgery. Patients who require additional surgery are typically elderly. The failure of the replacement joint is usually caused by wear of the weight-bearing surfaces, the surgery is often more complex and expensive than the original procedure, and the failure rate is several times greater. The Committee encourages NIBIB to enhance research to identify the causes of wear in prosthetic joints and find solutions to the problem, such as new materials through all available mechanisms as appropriate. (p. 93)

## Action taken or to be taken

The NIBIB plans to enhance research to identify the causes of wear in prosthetics and to address the problems through approaches such as the development of new materials or device designs. Research to identify the causes and locations of wear in prosthetics will require appropriate mechanical in-vivo or non-invasive ex-vivo biosensors. To facilitate the development of the designs and technologies needed for these biosensors, the NIBIB and the Department of Energy conducted a joint workshop in December 2001 focused on identifying related biomedical and technological gaps and actions to address them. The NIH's Bioengineering Consortium, which is administered by the NIBIB, will conduct a major symposium on biosensors in June 2002 to determine needs and directions for research in mechanical, biological, and optical sensors that could be used in all aspects of biomedical research including prosthetics and devices. The research portfolio of NIBIB is starting off with over \$65 million in funded grants transferred from other Institutes, some of which relate to research on joint replacement. With regard to materials development for prosthetic applications, the NIBIB recognizes the multidisciplinary nature of the required research and plans to support such efforts through two Program Announcements. The Bioengineering Research Grant program (PA-02-011) will award grants for research to be performed in a single laboratory or by a small number of investigators. The Bioengineering Research Partnership program (PAR-02-010) will award grants for scientists working in multidisciplinary research teams from several laboratories or organizations.

FY 2002 Senate Appropriations Committee Report Language (S. Rpt. 107-84)

#### <u>Item</u>

Imaging technologies - The Committee encourages this new Institute to devote significant resources to molecular imaging technologies such as positron emission tomography (PET) and microPET to take advantage of the capacities of molecular imaging to detect disease process at the molecular level and to monitor the effectiveness of targeted gene therapies now under development. The Committee also encourages the new Institute to develop its research agenda in close collaboration with other disease-specific Institutes at NIH, so that new imaging technologies are closely tied to the research projects being undertaken by the various other institutes of NIH. (p. 172)

#### Action taken or to be taken

The NIBIB recognizes the significant potential associated with molecular imaging technologies to detect disease genesis and process at the earliest stages and to monitor the efficacy of targeted gene therapies and novel pharmaceuticals. Consistent with its mission, the NIBIB plans to devote significant resources to support the development and application of molecular imaging including PET and microPET. To ensure that related NIBIB programs are based on state-of-the-art technologies and community resources, the Institute, along with the Institute of Electrical and Electronics Engineers (IEEE), will conduct a joint international conference on biomedical imaging technologies and applications in June 2002. The conference will encompass molecular imaging in addition to diagnostic imaging modalities, and the results will be used to identify directions for NIBIB imaging programs.

The research portfolio of NIBIB is starting off with over \$65 million in funded grants transferred from other Institutes, some of which relate to imaging technologies. The NIBIB plans to build its imaging research agenda in close collaboration with other institutes at the NIH to ensure that new imaging technologies are closely tied to research projects being undertaken by other institutes. Examples of NIBIB collaboration with other NIH institutes on new initiatives include a joint announcement with the National Cancer Institute (NCI) to support innovative research on molecular imaging technologies (RFA-CA-01-014), and a joint announcement concerning brain function imaging with the National Institute of Mental Health to support the development of PET probes for molecular targets and new technologies for radiotracer development (RFA-MH-02-003). In addition, to provide multi-Institute perspectives, scientific staff from other NIH Institutes will join NIBIB on temporary duty assignments to support the initial development of the Institute's molecular imaging programs.

#### Item

**Joint replacement wear** – Average life expectancy has at least doubled over the past century, presenting new challenges in our efforts to reduce disability. For example, an estimated 500,000 joint replacements are performed in the United States each year, many of which fail and require additional surgery. Because the patients are typically elderly and frail, the failed implant is

often difficult to remove. The required surgery is much more complex, dangerous, and expensive than the original procedure, and the failure rate is several times greater. It is widely recognized that the majority of failures of artificial joints are caused by wear of the weight-bearing surfaces. In light of demographic projections of a rapid increase in the elderly population, the Committee expects the Institute to assign a high priority to research identifying the causes of wear in prosthetic joints as well as to finding solutions to the problem, such as new materials. (p. 172)

## Action taken or to be taken

The NIBIB plans to address research to identify the causes of wear in prosthetics and to search for solutions to the problems through approaches such as the development of materials or device design. The research portfolio of NIBIB is starting off with over \$65 million in funded grants transferred from other Institutes, some of which relate to research on joint replacement. Additional research will be needed to identify the causes and locations of wear in prosthetics which will require appropriate mechanical in-vivo or non-invasive ex-vivo biosensors. To facilitate the development of the designs and the technologies needed for these biosensors, the NIBIB and the Department of Energy will conduct a joint workshop in February 2002 focused on identifying related biomedical and technological needs and actions to address the gaps. The NIH's Bioengineering Consortium, which is administered by the NIBIB, will conduct a major symposium on biosensors in June 2002 to determine needs and directions for research in mechanical, biological, and optical sensors that could be used in all aspects of biomedical research including prosthetics and devices. With regard to materials development for prosthetic applications, the NIBIB recognizes the multidisciplinary nature of the research and plans to support such efforts through two Program Announcements, the Bioengineering Research Grants (PA-02-011), and Bioengineering Research Partnerships (PAR-02-010).

#### Item

**Non-destructive evaluation** - The Committee is encouraged by the possible use of non-destructive evaluation research for the improvement of diagnostic capabilities in medicine. It also recognizes that the initial parts of many clinical studies will proceed more quickly on living animals. Research on developing quantitative measurement techniques in the areas of radiography, CT, ultrasound, magnetic resonance, and many others should be investigated, with experiments on animals being a vehicle for early clinical studies. (p. 173)

#### Action taken or to be taken

The NIBIB recognizes the potential benefits offered by non-destructive evaluation technologies to diagnostic medicine. To investigate possible applications of non-destructive techniques to medical diagnosis and therapy, the NIBIB and the Department of Energy (DOE) conducted a joint workshop in December 2001, focused on acoustic, magnetic resonance, and optical (microwave and infrared) modalities and image-guided therapy. In July 2002, the NIBIB and IEEE will conduct an international conference that will include an investigation of possible applications of non-destructive evaluation technologies to biomedical imaging based on input from the quantitative science and engineering community. The use of living animals as a possible vehicle

for early clinical studies is also recognized by the NIBIB and was considered during the December 2001 joint NIH/DOE workshop.

# <u>Item</u>

**Temporomandibular joint disorders (TMJ)** - The Committee is aware that the research portfolio on temporomandibular diseases and disorders has extensively studied psychological and behavioral factors in the etology or chronicity of TMJ diseases and disorders. The Committee urges the Institute to broaden its scientific base for TMJ research by putting greater emphasis on basic and clinical research on normal and abnormal structural and functional features of the joint and related structures, using the tools of cell and molecular biology as well as advanced imaging techniques. (p. 173)

## Action taken or to be taken

The NIBIB recognizes the significance of diseases and disorders of joint and related structures including the TMJ. To facilitate research on normal and abnormal structural and functional features of the joint and related structures, the NIBIB will support the development of advanced molecular and diagnostic imaging technologies and the application of advanced sensor technologies to measure mechanical parameters associated with joint function. Consistent with these goals, NIBIB has conducted some meetings and has plans for several future meetings. To identify advanced imaging technologies for specific biomedical applications, including TMJ research, NIBIB sponsored a workshop with the Department of Energy (DOE) in December 2001, and is planning a major international conference with the IEEE in July 2002. To identify advanced biosensor technologies for biomedical research applications including mechanical sensing appropriate for TMJ research, we will jointly sponsor a workshop on sensor technology with the DOE in February 2002, and conduct a biosensor symposium coordinated by the NIH's Bioengineering Consortium (which is administered by the NIBIB). This emphasis on imaging and sensor technology development and applications will facilitate basic and clinical research on joints and related structures.

# National Institute of Biomedical Imaging and Bioengineering Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2002 Amount Authorized	2002 Estimate	2003 Amount Authorized	2003 Budget Estimate 1/
Research and Investigation  National Institute of Blomedical Imaging and Bioengineering	Section 301 Section 417B	42§241 42§285	Indefinite Indefinite	\$109,346,000	Indefinite Indefinite	\$118,622,000
National Research Service Awards	Section 487(d)	42§288	a/	2,676,000	b/	2,756,000
Total, Budget Authority				112,022,000		121,378,000

a/ Funding provided under the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2002 (P.L. 107-116).

b/ Reauthorizing legislation will be submitted.

<sup>1/</sup> Reflects proposed transfer from the National Cancer Institute

# National Institute of Biomedical Imaging and Bioengineering Appropriation History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation 1/
2002	40,206,000	39,869,000	140,000,000	111,984,000
Rescission	, ,	, ,	, ,	(33,000)
2003	121,378,000			

<sup>1/</sup> Reflects enacted supplementals, rescissions and reappropriations.

# National Institute of Biomedical Imaging and Bioengineering Detail of Full-Time Equivalent Employment (FTEs)

	FY 2001	FY 2002	FY 2003
OFFICE/DIVISION	Actual	Estimate	Estimate
Office of the Director		4	5
Division for Biomedical Imaging		4	5
Division of Bioengineering		4	5
Division of Technology Development and Integration		3	4
Division of Extramural Activities		2	4
Office of Review		1	3
Office of Administration		3	4
Total, NIBIB	0	21	30

Funds to support these FTEs are provided by Cooperative Research and Development

Agreements

FISCAL YEAR	Average GM/GS Grade		
1999	0.0		
2000	0.0		
2001	0.0		
2002	12.9		
2003	10.4		

# National Institute of Biomedical Imaging and Bioengineering Detail of Positions

GRADE	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
SIVADE	Actual	Louinate	Lotimate
ES-6	0	0	0
ES-5	0	0	0
ES-4		1	1
	0	1	
ES-3	0	0	0
ES-2	0	1	1
ES-1	0	1	5
Subtotal	0	3	7
Total - ES Salary	\$0	\$401,600	\$930,624
GM/GS-15		3	6
GM/GS-14		5	7
GM/GS-13		5	8
GS-12		2	5
GS-11			
GS-10		1	1
GS-9		2	5
GS-8		_	5
GS-7			1
GS-6			'
GS-5			
GS-4			
GS-3			
GS-2			
GS-1			
Subtotal	0	18	38
Grades established by Act of			
July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General			
Director Grade			
Senior Grade			
Full Grade			
Senior Assistant Grade			
Some ricolotant Grade			
Subtotal	0	0	0
Ungraded			
T-11-1 1 :::		<u> </u>	
Total permanent positions		21	45
Total positions, end of year		21	45
Total full-time equivalent (FTE)			
employment,end of year		21	30
Average ES level	ES-0	ES-2	ES-2
Average ES salary	\$0	\$130,000	\$136,240
Average GM/GS grade	0.0	12.9	10.4
Average GM/GS salary	\$0	\$70,543	\$48,758
Average Givi/GO Salary	φU	φ10,543	φ <del>4</del> 0,130

# National Institute of Biomedical Imaging and Bioengineering New Positions Requested

		FY 2003		
	Grade	Number	Annual Salary	
Senior Advisor Division Director Health Science Administrator Senior Science Program Analyst Health Science Administrator Scientific Review Administrator Scientific Review Administrator Program Analyst Grants Management Specialist Grants Technical Assistant Secretary Program Assistant Secretary Administrative Technician	ES-1 ES-1 GS-15 GS-14 GS-13 GS-12 GS-12 GS-9 GS-9 GS-9	1 3 3 2 2 1 2 1 2 1 2 3 1	127,436 127,436 109,344 92,957 78,661 78,661 66,149 45,614 45,614 41,301 41,301 32,904	
Total Requested		24		