DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

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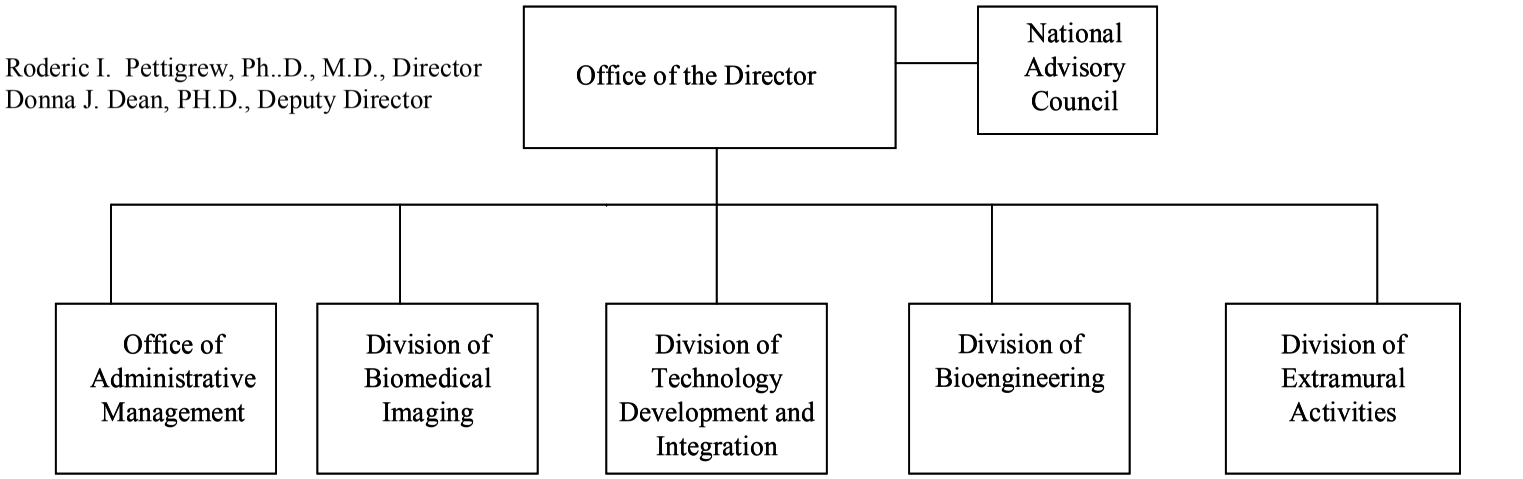


NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

For carrying out section 301 and title IV of the Public Health Service Act with respect to National Institute of Biomedical Imaging and Bioengineering, $282,109,000.

National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering

Amounts Available for Obligation 1/

Source of Funding	FY 2002 Actual	FY 2003 Amended President's Budget	FY 2004 Estimate
Appropriation	$111,984,000	$120,502,000	$282,109,000
Enacted Rescissions	(123,000)	---	---
Subtotal, Adjusted Appropriation	111,861,000	120,502,000	282,109,000
Real transfer to:			
Other HHS Agencies through Secretary's one-percent transfer authority	(121,000)	---	---
Comparative transfer to:			
Office of the Director for program changes	(7,000)	(8,000)	---
Comparative transfer from:			
Various NIH Institutes and Centers for Biomedical Imaging and Bioengineering Activities	150,000,000	150,000,000	---
Subtotal, adjusted budget authority	261,733,000	270,494,000	282,109,000
Subtotal, adjusted budget authority	261,733,000	270,494,000	282,109,000
Unobligated balance lapsing	---	---	---
Total obligations	261,733,000	270,494,000	282,109,000

1/ Excludes the following amounts for reimbursable activities carried out by this account:
FY 2002 - $15,000 FY 2003 - $3,000,000 FY 2004 - $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:

FY 2002 Actual		FY 2003 Amended President's Budget		FY 2004 Estimate		Increase or Decrease	
FTEs	BA	FTEs	BA	FTEs	BA	FTEs	BA
15	$261,733,000	35	$270,494,000	34	$282,109,000	(1)	$11,615,000

This document provides justification for the Fiscal Year 2004 activities of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2004 HIV/AIDS activities can be found in the NIH section entitled "Office of AIDS Research (OAR).

Introduction

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by supporting and conducting interdisciplinary research and training in biomedical imaging and bioengineering. This is achieved through supporting the development and translation of emerging technologies that enable fundamental biomedical discoveries and facilitate early disease detection and management. More specifically, the NIBIB plans, conducts and supports an integrated and coordinated program of research and research training that can be applied to an individual or a broad spectrum of biological processes, disorders, and diseases and across organ systems. The research promoted and supported by NIBIB is strongly synergistic with the other NIH Institutes and Centers as well as across government agencies, and has the potential for direct positive medical application. Ultimately, NIBIB seeks to translate research findings from the laboratory into practical solutions that will benefit the public health. Research in biomedical imaging and bioengineering is progressing rapidly and is becoming more and more interdisciplinary. Recent technological advances have revolutionized the diagnosis and treatment of disease and provided unprecedented opportunities for improving our understanding of biological processes and for conducting powerful biological investigations. To capitalize on these opportunities, the NIBIB is developing a robust research program in biomedical imaging and bioengineering that will focus on developing fundamental new

knowledge, fostering potent new technologies, nurturing and supporting promising researchers, and facilitating cross-cutting capabilities.

NIBIB is also planning activities in FY 2003 that will provide further guidance in setting a future research agenda in biomedical imaging and bioengineering. For example, in December 2002, NIBIB held a workshop designed to obtain input from the biomedical community on future research focus areas appropriate for the NIBIB as well as on potential large-scale projects that support these focus areas. The overall objectives of the workshop were to ensure that NIBIB's research programs are relevant to national interests, address community needs, and are focused on high scientific priority areas. Examples of additional planned workshops include a Biomedical Technology Research Symposium, a Biomaterials Advisory Meeting, a Biomedical Imaging Informatics Advisory Meeting, a Telemedicine Advisory Meeting, and several NIBIB Grantee Grantsmanship Workshops.

Another important goal of the NIBIB is to nurture a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research. Researchers trained in biomedical imaging and bioengineering must be able to exhibit technical competency in multiple fields as well as have the capacity to think independently, communicate ideas effectively, work in teams, and contribute to a strong vision that transcends a narrow discipline. To this end, the NIBIB will capitalize on existing NIH training mechanisms, collaborate on trans-agency training programs, and work with the community to develop new programs that cross-train research scientists in the biological and quantitative sciences. The Institute also plans to help build on an inclusive base human capital by supporting the training of aspiring minority students and new minority investigators, and identifying established minority investigators who would benefit from supplemental funding to their bioimaging or bioengineering research.

SCIENCE ADVANCES

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is the newest of the research institutes within the National Institutes of Health, and was established by law in December 2000. NIBIB received its first appropriation and grant funding authority in fiscal year (FY) 2002. Although scientific accomplishments often take years to unfold into new diagnostic technologies and methods to treat and prevent disease, the NIBIB is pleased to report that the confluence of our generous appropriation with scientific opportunity has already begun to yield significant results.

New High Resolution Imaging Technique for Eye Tissue. Diseases and disorders of the eye, including glaucoma, affect an enormous number of Americans every year. Currently, the mechanisms responsible for damage associated with glaucoma are not fully understood. While drug therapies are assumed to control the disease by reducing inner–eye pressure, methods to evaluate or quantify changes in blood flow in the anterior portion of the eye have not previously existed. New high-frequency ultrasound scanning systems developed by NIH investigators now provide an unprecedented opportunity to image blood flow in the anterior segment of the eye. The resolution power of this novel technique represents an order of magnitude in improvement

over existing techniques and provides the first non-invasive opportunity to evaluate blood flow in opaque tissues. A key aspect of this technique is the development of new contrast agents that are acoustically activated. This technique allows researchers to develop a two-dimensional map of blood flow in the anterior segment of the eye, providing crucial information in the staging and diagnosis of various eye diseases and disorders, such as in glaucoma. The ability to diagnose and monitor the physiology of the eye will also help to combat major causes of blindness. In addition, information about normal eye physiology, as well as age-dependent variations, will be paramount to fully understanding the mechanisms of all eye diseases and disorders.

New Brain Imaging Techniques Allow Insight into Neuronal Functioning. It is well established that brain activity alters optical properties of tissue near the surface of the brain, due to both changes in blood flow and scattering from brain cells. It has also been shown that near-infrared light can pass easily through the skull and reach the surface of the brain. Therefore, measurements of slow changes in blood flow can be readily measured by near infrared spectroscopy (NIRS), a non-invasive and inexpensive imaging modality capable of measuring changes in the optical properties in the surface of the brain. However, measurements of fast neuronal activity have yet to be demonstrated. The recent development of a new sensor technology by NIH investigators may make this type of observation not only possible, but widely affordable and accessible. Researchers have also proven that this new NIRS methodology correlates well with traditional functional magnetic resonance imaging (fMRI) techniques. The development of such multimodality devices (combining fMRI with NIRS) significantly increases the researchers' and clinicians' ability to resolve high-resolution images of brain function and opens the door to a new approach for observing brain function. It also has the potential to provide a wealth of new knowledge about the progression and treatment of a wide range of neurological disorders. In addition, this technique could be expanded beyond the realm of neurology to applications in cardiology and vascular biology. The development of non-invasive imaging techniques affordable to a wide range of medical centers, clinics, and health facilities is vital to the wide translation and adoption of new advancements for diagnosing and treating disease. As high resolution imaging methods provide greater insight into a wider range of physiological functions, researchers will be better poised to further decipher the mysteries of illnesses such as Parkinson's and Alzheimer's diseases.

New Digital Tools to Evaluate Child Development Across Ethnic Boundaries. Bone age assessment is a common diagnostic procedure performed on children to evaluate normal growth and to identify possible growth disorders, malformations and bone abnormalities. NIH researchers have recently developed a digital atlas containing a large set of normal hand and wrist images of children from four ethnic groups. This atlas is comprised of over 1,100 reference images compiled from computed radiography and digitized film and contains computer-extracted bone objects and quantitative features that can be used to more thoroughly evaluate skeletal development. Images in the database are evenly distributed across a wide range of healthy children, including infants and adolescents; males and females; and children of European, African, Hispanic, and Asian descent. The digital atlas format also supports both Web-based access and automated diagnosis, allowing measurements taken from a patient's hand image to be directly compared with patterns from the atlas database to assess bone age. This

new resource will allow physicians to more accurately assess skeletal development in children and adolescents across various ethnicities, enhancing the diagnosis and management of a variety of metabolic and growth disorders and can also be used in planning orthopedic procedures. Furthermore, the development of a digitized and automated diagnostic tool represents a significant contribution to practices in imaging sciences, enabling many medical advances in the upcoming years.

Real-time, Ultra-high Resolution Imaging. The increasing number of laser-based eye surgeries in the United States creates a critical need for ultra-high resolution imaging capable of displaying information in real-time. While there are many techniques available, these methods cannot resolve the time and depth information necessary to verify current procedures. Laser irradiation is also becoming widely used to treat a variety of vascular disorders, but the treatments are often incomplete due to an inability to accurately assess the effectiveness of a given therapy. A new ultra-high resolution imaging method called Optical Coherence Tomography (OCT) may be able to overcome many of the limitations of the current techniques used to monitor the anterior portion of the eye. Recent technological advancements by NIH researchers have led to the development of a real-time, high-resolution imaging system that reduces imaging flaws attributed to patient motion and device misalignment. In addition, hand-held OCT systems have been developed to allow more convenient imaging of the anterior segment of the eye during routine clinical examinations. The existence of portable, non-invasive, ultra-high resolution imaging devices will be invaluable in the rapid diagnosis and treatment of patients with a variety of disorders. For example, OCT systems will be important for the early detection of cancers of the lung, stomach, and intestines; outcome assessment of laser eye surgeries; evaluation of common eye disorders; and monitoring of patients with vascular complications associated with diabetes, glaucoma, and age-related diseases and disorders.

Ultrasound-mediated Transdermal Drug Delivery. Transdermal drug delivery has been used in recent years as an efficient and effective method for administering drugs from the surface of the skin--through its layers--into the circulatory system. Researchers have previously shown that the application of low-frequency ultrasound enhances drug transport through the skin, a phenomenon referred to as low-frequency sonophoresis, or LFS. It has recently been proposed that LFS-induced skin permeabilization results from the direct mechanical impact of gas bubbles collapsing on the surface of the skin, a process referred to as cavitation. Researchers funded by the NIH have now demonstrated definitively that ultrasound-induced cavitation is the key mechanism through which LFS enhances skin permeability. The ability to administer a drug into the circulatory system via the skin allows patients to administer uniform doses of a particular drug over a specified period of time. This technique also reduces, and may even eliminate, side effects commonly associated with the passage of a drug through a person's gastrointestinal tract. Future research leading to an increased understanding of the mechanisms of LFS holds great potential for the bioengineering of novel transdermal drug delivery mechanisms applicable to the treatment of many diseases and disorders, including hypertension, postmenopausal syndrome, and hormone replacement.

SQUID: A Technique for Assessing Uterine Activity During Labor. Currently, knowledge of the physiological mechanisms of uterine contraction during labor is incomplete. Therefore, physicians are often unable to accurately predict the onset of labor and to differentiate between true and false labor, for both full-term and pre-term patients. The lack of an effective method for the diagnosis of labor contractions suggests a strong need for deeper investigation into the physiological features of uterine activity. To address this need, researchers funded by the NIH examined the feasibility of measuring and recording both spatial and temporal electrical activity of the uterus using a newly developed device called SQUID, a superconducting quantum interference device array. Using this tool, researchers were able to determine regions of localized activation, propagation velocity, and the direction and spread of uterine activity as a function of distance. When correlated with anatomical data obtained from a three-dimensional ultrasound, physicians were more accurately able to assess the onset of term labor and the presence of pre-term contractions. Adoption of this innovative technique will allow physicians to reliably monitor labor progression, avoiding unnecessary hospital stays and medical treatment. Future research efforts will focus on obtaining data that will allow physicians to differentiate between false and true labor, leading to potential breakthroughs in the treatment of abnormal labor.

Engineering Technologies Improve Surgical Outcome In Patients With Epilepsy. Researchers funded by the NIH are developing new strategies that capitalize on the combination and integration of advanced magnetic resonance technologies, allowing researchers to directly map changes in the brain that correspond to certain aspects of brain function. Epilepsy is a chronic medical condition produced by temporary changes in the electrical function of the brain. These changes can cause seizures that affect awareness, movement, or sensation. Severe seizures that resist treatment are associated with a shortened life span, risk of intellectual impairment and a sharply reduced quality of life. Seizures that cannot be controlled with drug therapy may be successfully treated with neurosurgical procedures. Initial developments have already been applied to surgical procedures that are designed to either remove brain regions that generate the seizures or to disconnect epileptic brain regions from other areas and prevent the spread of seizure activity. In one case, an early form of surgery employing magnetic resonance imaging (MRI) mapping developed under this project was used to treat a patient suffering from as many as 100 seizures daily. Post-surgery, the patient's seizures have almost completely stopped and the patient is experiencing a significant increase in quality of life.

Q-dots: Development of a Novel Probe Technology. Biomedical research on the cellular and molecular structures responsible for regulating biological processes is fundamental to understanding, diagnosing, and treating disease. NIH researchers have recently developed a novel probe technology, called Q-dots, which has unique optical, physical, and chemical properties. This technology offers new possibilities for labeling biomolecules involved in various molecular pathways. For example, researchers are currently using Q-dots to study protein trafficking and assembly in living cells. Further development of this technology will provide biomedical researchers with better tools for studying both normal and altered biological processes.

Data Processing for Magnetic Resonance Spectroscopy. Information on tissue metabolites obtained by proton magnetic resonance spectroscopy (H-MRS) offers potential for assessing disease state or response to treatment for disorders such as multiple sclerosis, epilepsy, Alzheimer's disease, and stroke. Currently, the evaluation of MRS data is based primarily on the comparison of the levels of three primary metabolites in regions of pathology with corresponding healthy regions. However, to objectively and confidently evaluate such changes, it is first necessary to establish how reproducible the measured levels are in normal controls. To address the issue of reproducibility, NIH researchers used H-MRS to evaluate brain metabolite levels in eight healthy volunteers. They found that measurement uncertainties could be reliably reduced by either increasing spatial resolution or by performing serial follow-ups. These data lend support for ongoing clinical studies investigating changes in brain metabolites associated with Alzheimer's disease and aging, epilepsy, and multiple sclerosis.

NEW INITIATIVES

As the NIBIB enters its second year, we are beginning to identify and define, in consultation with the extramural community and our constituency groups, emerging program areas that warrant Institute focus. In FY 2004, the NIBIB is planning a number of new and compelling initiatives in these emerging areas, including initiatives in tissue engineering and regenerative medicine; functional cell imaging; and *in vivo* monitoring and imaging applications. One key goal of the NIBIB is to catalyze team science through training and collaborative research. Therefore, planned initiatives will cut across NIH Institutes and Centers, as well as other Federal agencies, academia, and industry and will serve to integrate multiple scientific disciplines. Four initiatives planned for FY 2004 are described below.

Tissue Engineering: Revolutionizing the Practice of Medicine. Tissue engineering is an emerging field that is broadly defined as the development and manipulation of laboratory-grown molecules, cells, tissues, or organs to replace defective or injured body parts. Tissue engineering and regenerative medicine are interdisciplinary fields that apply the principles of engineering and the life sciences to the development of viable biological substitutes. Many current medical therapies may be improved through tissue engineering principles with significant medical savings. For example, until recently, most damaged or diseased human tissue could only be replaced by donor transplants or with totally artificial parts. Today, tissue engineering and regenerative medicine promise to revolutionize the treatment of patients who need new vital structures. The field has already made headway in the synthesis and regeneration of structural tissues such as skin, cartilage, and bone. Furthermore, bladder tissue has been successfully bioengineered for use in humans. Thus, progress to date predicts future success in the bioengineering of more complex internal organs, such as blood vessels and cardiac valves, and the field is now poised for moving in that direction. As the field continues to evolve, rapid development of procedures and techniques to produce functional tissues in the laboratory will bring us to the next challenge--that of translating this research into large-scale production of safe, reproducible tissues that are clinically appropriate. Critical to this translational step will be the development and application of engineering design principles. Therefore, goals of this initiative are to:

- Develop bioengineering strategies to promote vascularization of tissue constructs
- Exploit externally applied mechanical stimuli to regulate the development of engineered tissues
- Evaluate the mechanical properties of native tissues and determine the minimum values of native tissue mechanical properties required of an engineered tissue
- Adapt bioreactor technology for large-scale cell expansion and three-dimensional tissue production
- Identify appropriate techniques for preserving, storing, and shipping engineered cells and tissues so that these products can be used off the shelf and can reach a world-wide market
- Develop improved monitoring devices to assess tissue function from the site of production to the transplant clinic
- Develop methodologies, such as imaging, to noninvasively track the fate of and allow for the functional assessment of implanted tissue.

Research and technology development in tissue engineering promises to revolutionize current methods of health care treatment and significantly improve the quality of life for millions of patients. Tissue-engineered products hold the promise for true functional replacement. The development and application of rational engineering design criteria is expected to improve the success of tissue engineered products, and the NIBIB is in a unique position to foster research in this area.

Understanding Cell and Molecular Processes In Complex Environments. The successful translation and application of the tools used by molecular and cell biologists *in vitro* to investigate cell function *in vivo* relies on the development of devices and molecular probes capable of imaging biological processes in small cell populations deep within the tissues of the body. This approach involves sensing molecular changes through observation of processes at the cellular level, including gene expression, enzyme activity, and metabolism. Also of interest are tracking of immune and stem cells to their sites of action and monitoring the location and function of transplanted cells, such as engrafted islet cells and engineered tissue constructs. These molecular changes precede the anatomic changes currently utilized for disease assessment, potentially enabling intervention when it can be most effective. As many of these approaches relate to the imaging of small cell populations, such as insulin-producing pancreatic cells, there exist many technological challenges that must be overcome before these techniques reach clinical utility. Challenges are related to image resolution, sensitivity, quantification in deep tissues, and probe specificity. Additionally, imaging approaches that enable the noninvasive monitoring of molecular events may allow for *in vivo* identification of molecular targets and assist with image-guided collection of tissue samples for target validation. Specific goals of this initiative include:

- Identification and validation of molecular targets that potentially play a role in several disease processes, especially when the identification is coupled with the use of image-guided tissue analysis

- Design of molecular probes and imaging agents that report on the function or microenvironment of the cell, or enable cell tracking, with an emphasis on specificity, low toxicity, labeling, and probe stability and delivery
- Improvements in ligand discovery technology, for example, combinatorial approaches to enable high throughput generation and screening of probes
- Development of amplification strategies for detection of small cell populations or low receptor concentrations
- Development of molecular probes and methods that enable the simultaneous imaging of multiple biological processes *in vivo*, including the use of multi-modality imaging
- Development of devices and methods that enable the quantification and real-time monitoring of molecular probes in deep tissues, including multiphoton and confocal fluorescence microscopy, fluorescence tomography, and nuclear and MRI/MRS approaches
- Development of improved methods for assessment of localization and function of engrafted cells and engineered tissue constructs.

The successful translation to *in vivo*, and ultimately to clinical application, of the tools used by molecular and cell biologists to investigate cell function *in vitro* relies on the development of devices and molecular probes capable of imaging biological processes in small cell populations within deep tissues in the body. This requires high-resolution and sensitive devices able to image probes that demonstrate high specificity for the disease of interest. With an emphasis on imaging of biological processes *in vivo*, molecular and cellular imaging offers the potential for early-stage diagnosis and treatment of disease, with the potential to combine diagnostics and therapeutics tailored to the individual patient.

Application of Optical Technologies to Biomedical Research. Optical technologies hold great promise for applications in biomedical research and in the diagnosis, monitoring and treatment of disease. Applications of optical technologies to *in vivo* biomedical research include brain imaging using near-infrared technology, tissue surface assessment using optical coherence tomography, cancer diagnosis using molecular signatures of tissue as measured by fluorescence and Raman spectroscopy, and blood component monitoring using spectroscopic approaches. Advances in these areas include the application of optical coherence tomography with near-cellular-level resolution to the endoscopic imaging of cancer, with the potential to extend the technology to the characterization of atherosclerotic plaques. Optical technologies have also been recognized as having potential to provide complementary information relative to conventional imaging modalities, such as functional magnetic resonance imaging (fMRI) and positron emission tomography (PET), for brain oxygenation measurements and metabolic studies, or to replace invasive procedures that require tissue and blood collection. As many technical hurdles exist to extending the capabilities of these technologies beyond current applications, the ultimate goal of this initiative is to facilitate the improvement of existing optical systems, as well as the development of new instrumentation and methods, for *in vivo* imaging, monitoring, and therapeutic intervention. Specific objectives include:

- Miniaturization of imaging and spectroscopic devices to improve portability and enhance clinical utility

- Development of portable, inexpensive light sources with suitable power and spectral characteristics in the near-infrared for deep tissue imaging
- Development of detectors with fast responses for time-dependent studies and high sensitivity for low-light applications
- Development of optical probes and imaging agents with improved targeting and signal transduction capabilities for evaluation of biological processes in vivo
- Development of multi-band approaches for the simultaneous detection of multiple probes
- Improved modeling of light propagation through tissue for quantification of blood and tissue components
- Improvements to existing signal processing methods to enable the extraction of molecule-specific information from a high background, such as glucose concentration.

Advances in these areas are necessary to move the technology into clinical application, where the emphasis is on providing real-time information on the structure and function of human systems, particularly at the molecular level for early detection and diagnosis of disease.

Bioengineering and Biomedical Imaging Research Training. A high priority of the NIBIB is to nurture a new generation of researchers equipped to meet the modern needs of interdisciplinary and transdisciplinary research in biomedical imaging and bioengineering. To this end, NIBIB recently sponsored two workshops aimed at obtaining scientific input into multidisciplinary research training needs. Meeting summaries served as the basis for the training initiative described below.

A supply of highly trained professionals capable of conducting multidisciplinary, integrative research is necessary to realize the substantial benefits associated with bioengineering and biomedical imaging. Collaborative efforts between the quantitative and biomedical sciences are required to facilitate this training and address previous institutional barriers. In addition, to ensure a continuum of talent for future research, training at all career levels--from the undergraduate level through the senior career level--must be considered. Specific goals of this initiative include:

- Attract quantitative science students and investigators at all career levels to biomedical research careers
- Address institutional issues such as support for program coordinators, curriculum development, equipment, and infrastructure
- Provide competitive stipends to attract graduate-level students to biomedical fields
- Support mentor-development programs
- Utilize funded research projects as training venues by providing training supplements for research grants
- Provide opportunities for biological and medical students and post-doctoral staff to obtain training in the quantitative sciences and biomedical research
- Provide training for integrative, systems-based approaches to biomedical research

- Partner with other Federal agencies to ensure that appropriate communities are aware of new and existing training opportunities.

Proposed novel training programs will differ from traditional NIH training opportunities in that they will support institutional needs, equipment, curriculum and faculty development, and student costs in order to make the programs viable and attractive for universities.

INNOVATIONS IN MANAGEMENT AND ADMINISTRATION

Building on planning efforts that took place in the previous fiscal year, management and administrative structures continue to be established by the NIBIB. Consistent with the Institute's area of expertise, we will continue to use state-of-the-art technology and be a leader in technology development.

Infrastructure and Staffing. The NIBIB successfully met its recruitment targets for FY 2002 and in FY 2003 is actively recruiting for additional staff. FY 2003 recruitment is targeting those scientific disciplines and specialties necessary to support the development of new initiatives, promote scientific collaborations and advances, and review and evaluate new grant applications. Minimal additional hiring for FY 2003 will be in the areas of information technology and grant review and management. A major management initiative in FY 2003 will be to develop a performance measurement and reporting system for use in assessing NIBIB's progress toward achieving its program goals. From efforts initiated in FY 2002, office space has been secured both on and off the NIH campus and is being placed in service to coincide with the arrival of additional staffing.

Grant Tracking System. NIBIB has instituted an electronic barcoding system that will provide easy tracking of files and facilitate an annual inventory of NIBIB grants. Each grant file, both funded and pending, has been assigned a unique barcode. The barcode is tracked using the Records Management System, a software program that corresponds with IMPAC II and eGRANTS. The NIBIB eGRANTS system will provide staff with a wealth of information required for administrative, planning, reporting, and financial processes. Electronic information will also allow NIBIB quick and easy access to scientific content of a grant for a variety of purposes. Implementation of the eGRANTS system meets goals set forth in the Government Paperwork Elimination Act (P.L. 105-277), enables rapid transmission and retrieval of information, facilitates a reduction in storage space requirements, and will result in significant cost savings to the Institute. Bar coding will also provide easy tracking of files and facilitate an annual inventory of NIBIB grant files.

Continued Administration of the NIH Bioengineering Consortium. On September 19, 2001, the administration of the Bioengineering Consortium (BECON) transitioned from the Office of Extramural Research, Office of the NIH Director, 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 and centers

plus representatives of other Federal agencies concerned with biomedical research and development. In its administrative role, the NIBIB is committed to maintaining the successful coordination of trans-NIH bioengineering research, training, and related programs. For example, in FY 2002, the NIBIB, in coordinating with BECON members, sponsored a symposium entitled "Sensors for Biological Research and Medicine" as well as the Second Annual Bioengineering Partnership grantee meeting. In FY 2003, NIBIB will sponsor the annual BECON with this years topic being "catalyzing team science."

Establishment of the National Advisory Council for Biomedical Imaging and Bioengineering. In FY 2002, NIBIB established its National Advisory Council for Biomedical Imaging and Bioengineering. The Council consists of 12 members appointed by the Secretary and 8 nonvoting ex officio members. The NIBIB held its first Council meeting on January 16-17, 2003. Tentative dates for meetings through FY 2004 have also been determined.

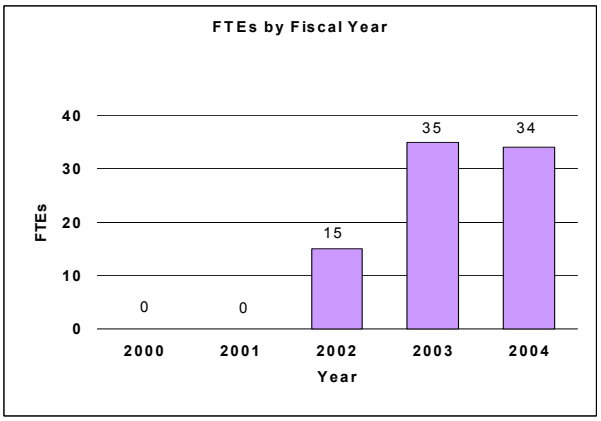
Planning for an Intramural Research Program. The NIBIB has begun gathering the necessary information required for the development of an intramural research and training program. The focus of this program will be on emerging biomedical technologies, with particular emphasis on those technologies that cut across multiple disciplines and applications.

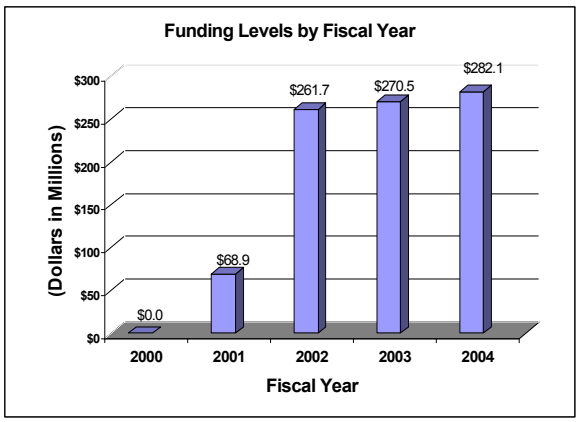
SUMMARY

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 capitalize on emerging scientific areas where biomedical imaging and bioengineering approaches can be used to explore promising new directions.

BUDGET POLICY

The Fiscal Year 2004 budget request for the NIBIB is $282,109,000, including AIDS, an increase of $11,615,000 and 4.3 percent over the FY 2003 amended President's Budget Request. A five year history of FTEs and Funding Levels for NIBIB are shown in the graphs below. Note that Fiscal Years 2001 and 2000 FTEs are not comparable for the NIH Human Resources functional consolidation.



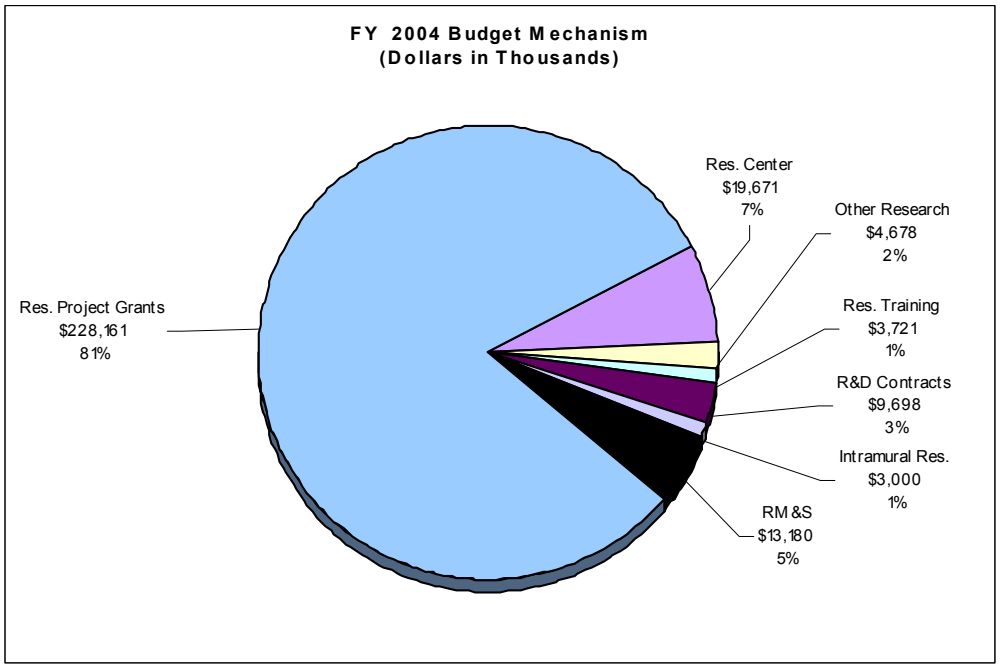


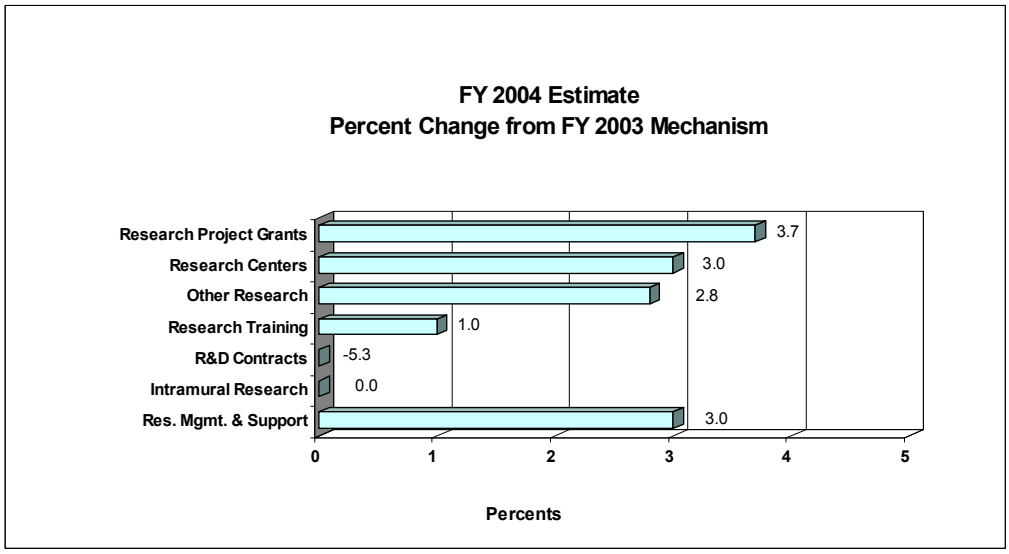
NIH's highest priority is the funding of medical research through research project grants (RPGs). Support for RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while providing new research opportunities. NIBIB will provide an aggregate average cost increase of 6.4 percent for Research Project Grants.

Also in FY 2004, NIBIB will fully fund two grants. These are expected to be Academic Research Enhancement Awards.

Promises for advancement in medical research are dependent on maintaining the supply of new investigators with new ideas. In the Fiscal Year 2004 request, NIBIB will support 73 pre- and postdoctoral trainees in full-time training positions, one more than in FY 2003. Stipend levels for NRSA trainees will increase by 4 percent over Fiscal Year 2003 levels for predoctoral fellows, and from 4-1 percent, based on years of experience, for postdoctoral fellows.

The Fiscal Year 2004 request includes funding for 19 research centers, 18 other research grants, including 9 clinical career awards, and 7 R&D contracts. An Intramural Research Program will be initiated and Research Management and Support receives an increase of 3 percent over FY 2003.


FY 2004 Budget Mechanism
(Dollars in Thousands)
Res. Center
$19,671
7%
Other Research
$4,678
2%
Res. Training
$3,721
1%
R&D Contracts
$9,698
3%
Intramural Res.
$3,000
1%
RM&S
$13,180
5%
Res. Project Grants
$228,161
81%


FY 2004 Estimate
Percent Change from FY 2003 Mechanism
Research Project Grants
Research Centers
Other Research
Research Training
R&D Contracts
Intramural Research
Res. Mgmt. & Support
3.7
3.0
2.8
1.0
-5.3
0.0
3.0
0
1
2
3
4
5
Percents

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

Budget Mechanism - Total

MECHANISM	FY 2002 Actual		FY 2003 Amended President's Budget		FY 2004 Estimate	
Research Grants:	No.	Amount	No.	Amount	No.	Amount
Research Projects:						
Noncompeting	268	$89,059,000	336	$124,952,000	463	$191,335,000
Administrative supplements	(1)	33,000	(0)	0	(0)	0
Full funded	N/A	N/A	N/A	N/A	2	300,000
Single year	249	103,020,000	196	82,637,000	68	29,180,000
Subtotal, competing	249	103,020,000	196	82,637,000	70	29,480,000
Subtotal, RPGs	517	192,112,000	532	207,589,000	533	220,815,000
SBIR/STTR	62	18,983,000	35	12,526,000	20	7,346,000
Subtotal, RPGs	579	211,095,000	567	220,115,000	553	228,161,000
Research Centers:						
Specialized/comprehensive	20	19,935,000	19	19,098,000	19	19,671,000
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	20	19,935,000	19	19,098,000	19	19,671,000
Other Research:						
Research careers	9	1,501,000	9	1,503,000	9	1,548,000
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	7	3,597,000	5	3,047,000	9	3,130,000
Subtotal, Other Research	16	5,098,000	14	4,550,000	18	4,678,000
Total Research Grants	615	236,128,000	600	243,763,000	590	252,510,000
Research Training:	FTTPs		FTTPs		FTTPs	
Individual awards	16	723,000	16	725,000	17	732,000
Institutional awards	54	2,906,000	56	2,959,000	56	2,989,000
Total, Training	70	3,629,000	72	3,684,000	73	3,721,000
Research & development contracts	9	10,246,000	9	10,246,000	7	9,698,000
(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)
	FTEs		FTEs		FTEs	
Intramural research	0	0	0	0	0	3,000,000
Research management and support	15	11,730,000	35	12,801,000	34	13,180,000
Total, NIBIB	15	261,733,000	35	270,494,000	34	282,109,000
(Clinical Trials)		(0)		(0)		(0)

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Budget Authority by Activity
(dollars in thousands)

ACTIVITY	FY 2002 Actual FTEs	FY 2002 Actual Amount	FY 2003 Amended President's Budget FTEs	FY 2003 Amended President's Budget Amount	FY 2004 Estimate FTEs	FY 2004 Estimate Amount	Change FTEs	Change Amount
Extramural Research:								
Biomedical Imaging and Bioengineering		$250,003		$257,693		$265,929		$8,236
Subtotal, Extramural research		250,003		257,693		265,929		8,236
Intramural research						3,000		3,000
Res. management & support	15	11,730	35	12,801	34	13,180	(1)	379
Total	15	261,733	35	270,494	34	282,109	(1)	11,615

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Summary of Changes

2003 Amended President's Budget				$270,494,000
2004 Estimated Budget Authority				282,109,000
Net change				11,615,000
	2003 Amended President's Budget Base		Change from Base	
CHANGES	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:				
1. Intramural research:				
a. Within grade increase		$0		$0
b. Annualization of January 2003 pay increase		0		0
c. January 2004 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		3,875,000		66,000
b. Annualization of January 2003 pay increase		3,875,000		32,000
c. January 2004 pay increase		3,875,000		60,000
d. One extra day of pay		3,875,000		15,000
e. Payment for centrally furnished services		1,591,000		32,000
f. Increased cost of laboratory supplies, materials, and other expenses		7,335,000		112,000
Subtotal				317,000
Subtotal, Built-in				317,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Summary of Changes--continued

CHANGES	2003 Amended President's Budget Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research project grants:				
a. Noncompeting	336	$124,952,000	127	$66,383,000
b. Competing	196	82,637,000	(126)	(53,157,000)
c. SBIR/STTR	35	12,526,000	(15)	(5,180,000)
Total	567	220,115,000	(14)	8,046,000
2. Research centers	19	19,098,000	0	573,000
3. Other research	14	4,550,000	4	128,000
4. Research training	72	3,684,000	1	37,000
5. Research and development contracts	9	10,246,000	(2)	(548,000)
Subtotal, extramural				8,236,000
	FTEs		FTEs	
6. Intramural research	0	0	0	3,000,000
7. Research management and support	35	12,801,000	(1)	62,000
Subtotal, program		257,693,000		11,298,000
Total changes	35		(1)	11,615,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Budget Authority by Object

	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease
Total compensable workyears:			
Full-time employment	35	34	(1)
Full-time equivalent of overtime & holiday hours	0	0	0
Average ES salary	$129,874	$133,800	$3,926
Average GM/GS grade	12.0	12.0	0.0
Average GM/GS salary	$67,323	$68,412	$1,089
Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$115,782	$118,098	$2,316
Average salary of ungraded positions	158,211	161,375	3,164
OBJECT CLASSES	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	$2,910,000	$3,050,000	$140,000
11.3 Other than Full-Time Permanent	15,000	15,000	0
11.5 Other Personnel Compensation	100,000	103,000	3,000
11.7 Military Personnel	120,000	124,000	4,000
11.8 Special Personnel Services Payments	0	0	0
Total, Personnel Compensation	3,145,000	3,292,000	147,000
12.1 Civilian Personnel Benefits	700,000	725,000	25,000
12.2 Military Personnel Benefits	30,000	31,000	1,000
13.0 Benefits for Former Personnel	0	0	0
Subtotal, Pay Costs	**3,875,000**	**4,048,000**	**173,000**
21.0 Travel & Transportation of Persons	264,000	300,000	36,000
22.0 Transportation of Things	150,000	150,000	0
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	10,000	10,000	0
23.3 Communications, Utilities & Miscellaneous Charges	110,000	110,000	0
24.0 Printing & Reproduction	54,000	54,000	0
25.1 Consulting Services	100,000	100,000	0
25.2 Other Services	1,897,000	3,495,000	1,598,000
25.3 Purchase of Goods & Services from Government Accounts	6,872,000	7,029,000	157,000
25.4 Operation & Maintenance of Facilities	130,000	500,000	370,000
25.5 Research & Development Contracts	8,543,000	8,503,000	(40,000)
25.6 Medical Care	0	0	0
25.7 Operation & Maintenance of Equipment	50,000	70,000	20,000
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	**17,592,000**	**19,697,000**	**2,105,000**
26.0 Supplies & Materials	150,000	272,000	122,000
31.0 Equipment	842,000	1,237,000	395,000
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	247,447,000	256,231,000	8,784,000
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	**266,619,000**	**278,061,000**	**11,442,000**
Total Budget Authority by Object	**270,494,000**	**282,109,000**	**11,615,000**

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Salaries and Expenses

OBJECT CLASSES	FY 2003 Amended Pres. Budget	FY 2004 Estimate	Increase or Decrease
Personnel Compensation:			
Full-Time Permanent (11.1)	$2,910,000	$3,050,000	$140,000
Other Than Full-Time Permanent (11.3)	15,000	15,000	0
Other Personnel Compensation (11.5)	100,000	103,000	3,000
Military Personnel (11.7)	120,000	124,000	4,000
Special Personnel Services Payments (11.8)	0	0	0
Total Personnel Compensation (11.9)	**3,145,000**	**3,292,000**	**147,000**
Civilian Personnel Benefits (12.1)	700,000	725,000	25,000
Military Personnel Benefits (12.2)	30,000	31,000	1,000
Benefits to Former Personnel (13.0)	0	0	0
Subtotal, Pay Costs	**3,875,000**	**4,048,000**	**173,000**
Travel (21.0)	264,000	300,000	36,000
Transportation of Things (22.0)	150,000	150,000	0
Rental Payments to Others (23.2)	10,000	10,000	0
Communications, Utilities and Miscellaneous Charges (23.3)	110,000	110,000	0
Printing and Reproduction (24.0)	54,000	54,000	0
Other Contractual Services:			
Advisory and Assistance Services (25.1)	100,000	100,000	0
Other Services (25.2)	1,897,000	3,495,000	1,598,000
Purchases from Govt. Accounts (25.3)	4,245,000	4,834,000	589,000
Operation & Maintenance of Facilities (25.4)	130,000	500,000	370,000
Operation & Maintenance of Equipment (25.7)	50,000	70,000	20,000
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**6,422,000**	**8,999,000**	**2,577,000**
Supplies and Materials (26.0)	150,000	272,000	122,000
Subtotal, Non-Pay Costs	7,160,000	9,895,000	2,735,000
Total, Administrative Costs	**11,035,000**	**13,943,000**	**2,908,000**

NATIONAL INSTITUTES OF HEATH

National Institute of Biomedical Imaging and Bioengineering

SIGNIFICANT ITEMS IN SENATE APPROPRIATIONS COMMITTEE REPORTS

The following section represents FY 2003 Congressional requirements for reports and significant items derived from Senate Report 107-216. These actions discussed below are contingent on inclusion of similar language and funding in the final FY 2003 appropriation and related reports. Additional items may be transmitted at a later date as a result of the final Conference report.

Item

Juvenile diabetes **–** The Committee is aware that imaging and bioengineering technologies could have widespread applications for the treatment and prevention of diseases and conditions such as juvenile diabetes. The Committee encourages the NIBIB to collaborate with the **National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)** on the development and application of imaging technologies to evaluate and track the progress of biologic events noninvasively, specifically the investigation and monitoring of beta cell destruction during the onset of juvenile diabetes and indications of graft rejection following the transplantation of whole organs, tissue, or cells. The Committee also encourages the Institute to collaborate with the NIDDK to develop non-invasive metabolic sensor technologies for the monitoring of glucose and metabolism in individuals with juvenile diabetes. (p. 141)

Action taken or to be taken

The NIBIB recognizes the potential benefits to the diabetes community offered by advances in noninvasive imaging and bioengineering technologies to noninvasively detect and treat this devastating disease. Diabetes results when insulin release is insufficient, and plasma glucose rises above normal. Diabetes treatments take many forms, but they all have the same goal, that of regulating blood glucose levels in patients whose bodies cannot control glucose levels on their own. Continuous glucose monitoring helps physicians prescribe insulin therapies and dietary programs better suited to individual needs. Glucose monitoring using sensor technology is an area of diabetes research that is progressing rapidly and has the potential to for dramatic impact on the way in which diabetes is treated. To further facilitate glucose sensor development, the NIBIB, in collaboration with NIDDK, **the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute on Deafness and Other Communication Disorders (NIDCD) and the National Human Genome Research Institute (NHGRI)**, released an initiative entitled "Sensor Development and Validation." As a result of this initiative, applications were supported that specifically related to glucose sensor development as well as to basic sensor technology development applicable to the treatment of diabetes. Also in accordance with its mission, the NIBIB, in collaboration with the NIDDK, plans to enhance research on beta cell imaging. This initiative will focus on imaging

methods to detect pancreatic islet beta cells *in vivo*, and measure their mass, function, or evidence of inflammation, or to monitor engraftment of transplanted isolated pancreatic islets. Advances in noninvasive imaging technology would allow high-risk individuals to be monitored prior to the onset of diabetes; patients could be monitored over the course of their disease to determine the exact stage of their disease; and it would also allow monitoring responses to therapy.

Item

Molecular imaging technologies **–** The Committee encourages the Institute to provide increased funding for 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 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 supported by the NIH. (p. 141)

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. The NIBIB plans to devote significant resources to support the development and application of molecular imaging, including PET and microPET. In July 2002, the NIBIB, along with the Institute of Electrical and Electronics Engineers (IEEE), conducted a joint international conference on biomedical imaging technologies and applications. Topics covered included potential modalities for both molecular imaging and improvements in clinical diagnostic imaging. The conference served as a means to identify future research directions for the NIBIB imaging program. To this end, the NIBIB has planned initiatives in "Cellular and Molecular Imaging", "Small Animal Imaging", and "Improvements to Imaging Methods and Technologies". The NIBIB also collaborated with the National Center for Research Resources on an initiative entitled "Technology Development for Biomedical Applications." To further the development of disease-specific biomedical imaging and bioengineering research, NIBIB has also collaborated with other NIH Institutes on Bioengineering Research Partnerships and Bioengineering Research Grants.

Item

Temporomandibular joint disorders (TMJ) **–** The Committee is mindful of the dismal history of failures in the case of plastic and other materials used in implants to replace parts of the temporomandibular joint. The Committee urges the Institute to make studies of the TM joint and related structures a high priority. (p. 141)

Action taken or to be taken

The NIBIB recognizes the significance of diseases and disorders of joint and related structures including the TMJ. To advance research on normal and abnormal structural and functional features of the joint and related structures, the NIBIB will support research in tissue engineering, on the development of advanced molecular and diagnostic imaging technologies, and on the application of advanced sensor technologies to measure mechanical parameters associated with joint function. NIBIB will also support research dedicated to the development and assessment of biomaterials such as TMJ implants. Consistent with these goals, NIBIB has conducted several meetings on imaging modalities and has plans for future meetings. To identify advanced imaging technologies for specific biomedical applications, including TMJ research, NIBIB sponsored a workshop entitled, "Thermographic Approaches to Medical Diagnosis and Therapy," with the Department of Energy (DOE) in December 2001 and held 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, NIBIB conducted a biosensor symposium coordinated by the NIBIB administered NIH Bioengineering Consortium. With regards to biomaterials development, NIBIB was also a co-sponsor of the "Medical Implant Information Performance and Policies" workshop in September 2002. Several initiatives addressing TMJ, as well as other medical implants, will be undertaken as a result of the recommendations from this workshop. In addition, NIBIB participates on the NIH Temporomandibular Disorders Interagency Working Group and will collaborate with the NIDCR on an initiative entitled "Research Registries and Repositories for the Evaluation of the Temporomandibular Joint Implants." Examples of future NIBIB initiatives include a Broad Biomaterial announcement and Tissue Engineering announcement. NIBIB has also collaborated with other Institutes at the NIH on Bioengineering Research Partnerships and Bioengineering Research Grants.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2003 Amount Authorized	2003 Amended President's Budget	2004 Amount Authorized	2004 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	$266,810,000	Indefinite	$278,388,000
Imaging and Bioengineering	Section 41B	42§285b	Indefinite		Indefinite	
National Research Service Awards	Section 487(d)	42§288	a/	3,684,000	b/	3,721,000
Total, Budget Authority				270,494,000		282,109,000

a/ Amounts authorized by Section 301 and Title IV of the Public Health Act.
b/ Reauthorizing legislation will be submitted.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Appropriations 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	120,502,000			
2004	282,109,000			

1/ Reflects enacted supplementals, rescissions, and reappropriations.

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

Detail of Full-Time Equivalent Employment (FTEs)

OFFICE/DIVISION	FY 2002 Actual	FY 2003 Amended Pres. Budget	FY 2004 Estimate
Office of the Director, NIH (pre-NIBIB)	9		
Office of the Director	1	6	6
Office of Administrative Management	2	7	7
Division of Biomedical Imaging	1	4	4
Division of Bioengineering	0	3	3
Division of Technology Development & Integration	0	1	1
Division of Extramural Activities	2	14	13
Total	15	35	34

FISCAL YEAR	Average GM/GS Grade
2002	12.3
2003	12.0
2004	12.0

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Detail of Positions

GRADE	FY 2002 Actual	FY 2003 Amended Pres. Budget	FY 2004 Estimate
ES-6			
ES-5			
ES-4			
ES-3			
ES-2			
ES-1		1	1
Subtotal	0	1	1
Total - ES Salary	$0	$129,874	$133,800
GM/GS-15	4	4	4
GM/GS-14	4	7	7
GM/GS-13	10	7	7
GS-12	2	3	3
GS-11			
GS-10			
GS-9	1	2	2
GS-8	1	1	1
GS-7	2	7	6
GS-6			
GS-5			
GS-4			
GS-3			
GS-2			
GS-1			
Subtotal	24	31	30
Grades established by Act of July 1, 1944 (42 U.S.C. 207):			
Assistant Surgeon General			
Director Grade	1	1	1
Senior Grade			
Full Grade			
Senior Assistant Grade			
Assistant Grade			
Subtotal	1	1	1
Ungraded	1	3	3
Total permanent positions	25	35	34
Total positions, end of year	26	35	34
Total full-time equivalent (FTE) employment,end of year	15	35	34
Average ES level		1	1
Average ES salary		$129,874	$133,800
Average GM/GS grade	12.3	12.0	12.0
Average GM/GS salary	$75,770	$67,323	$68,412