

DEPARTMENT OF HEALTH AND HUMAN SERVICES

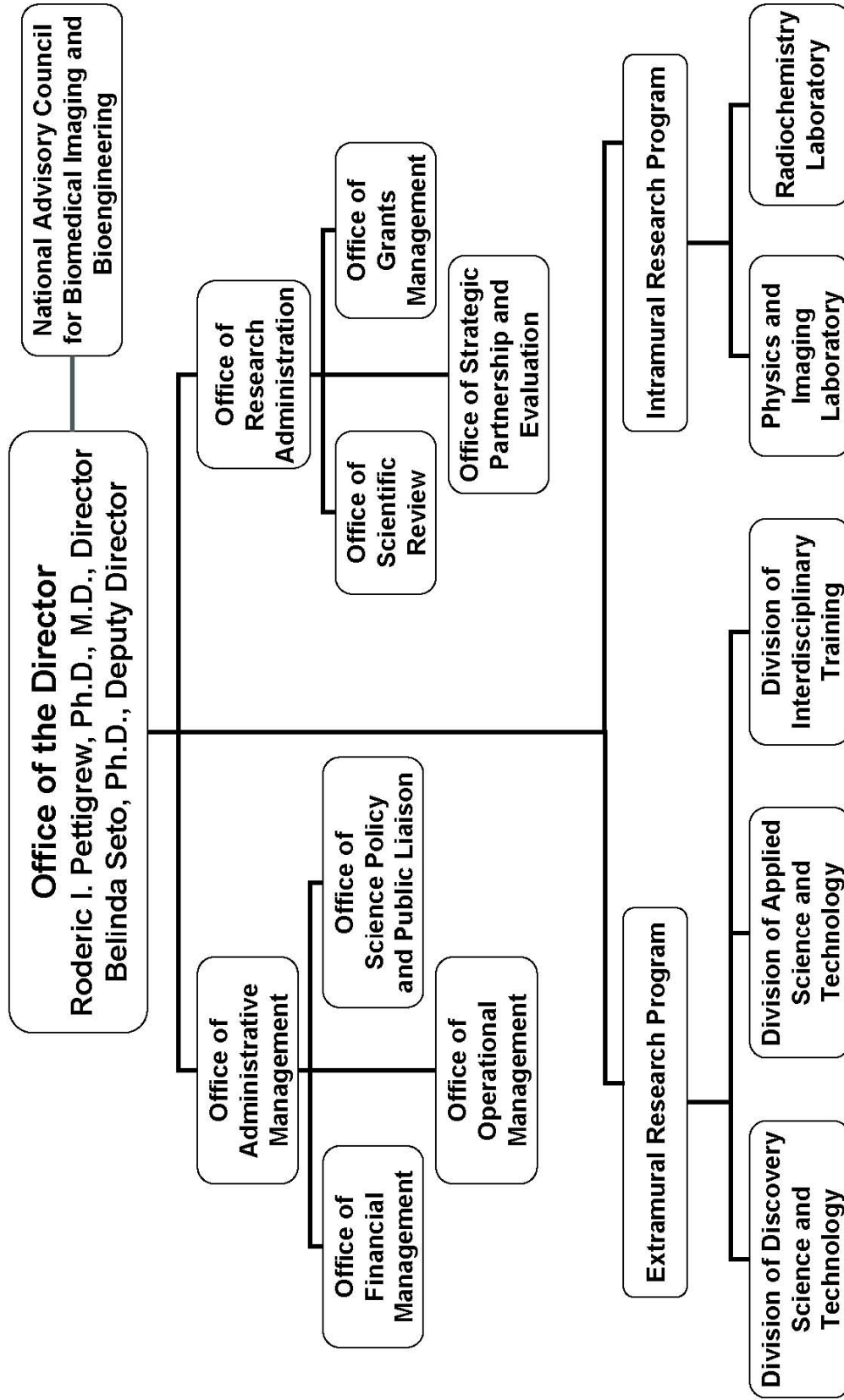
NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

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NIBIB ORGANIZATIONAL CHART



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 biomedical imaging and bioengineering research, [\$299,808,000] *\$294,850,000*.

[Department of Health and Human Services Appropriations Act, 2006]

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

Amounts Available for Obligation 1/

| Source of Funding | FY 2005 Actual | FY 2006 Appropriation | FY 2007 Estimate |
|---|-------------------|--------------------------|---------------------|
| Appropriation | \$300,647,000 | \$299,808,000 | \$294,850,000 |
| Enacted Rescissions | (2,438,000) | (2,998,000) | |
| Subtotal, Adjusted Appropriation | 298,209,000 | 296,810,000 | 294,850,000 |
| Real transfer under NIH Director's one-percent transfer authority for Roadmap | (1,885,000) | (2,652,000) | |
| Comparative transfer from OD for NIH Roadmap | 1,885,000 | 2,652,000 | |
| Subtotal, adjusted budget authority | 298,209,000 | 296,810,000 | 294,850,000 |
| Unobligated Balance, start of year | 0 | 0 | 0 |
| Unobligated Balance, end of year | 0 | 0 | 0 |
| Subtotal, adjusted budget authority | 298,209,000 | 296,810,000 | 294,850,000 |
| Unobligated balance lapsing | 0 | 0 | 0 |
| Total obligations | 298,209,000 | 296,810,000 | 294,850,000 |

1/ Excludes the following amounts for reimbursable activities carried out by this account:

FY 2005 - \$262,000 FY 2006 - \$3,000,000 FY 2007 - \$3,000,000

Justification

National Institute of Biomedical Imaging and Bioengineering

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

Budget Authority:

| FY 2005 Actual | | FY 2006 Appropriation | | FY 2007 Estimate | | Increase or Decrease | |
|-------------------|---------------|--------------------------|---------------|---------------------|---------------|-------------------------|---------------|
| <u>FTEs</u> | <u>BA</u> | <u>FTEs</u> | <u>BA</u> | <u>FTEs</u> | <u>BA</u> | <u>FTEs</u> | <u>BA</u> |
| 46 | \$298,209,000 | 53 | \$296,810,000 | 54 | \$294,850,000 | 1 | (\$1,960,000) |

This document provides justification for the Fiscal Year 2007 research activities of the National Institute of Biomedical Imaging and Bioengineering, including HIV/AIDS activities. A more detailed description of NIH-wide Fiscal Year 2007 HIV/AIDS activities can be found in the NIH section entitled “Office of AIDS Research (OAR).” Detailed information on the NIH Roadmap for Medical Research may be found in the Overview section.

INTRODUCTION

The mission of the NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care. Research in biomedical imaging and bioengineering is progressing rapidly and is becoming increasingly multidisciplinary. Recent technological advances have revolutionized the diagnosis and treatment of disease and provide unprecedented opportunities for furthering understanding of biological processes and for conducting powerful biological investigations. To capitalize on these opportunities, NIBIB is supporting a robust research program in biomedical imaging and bioengineering that focuses on developing fundamental new knowledge, fostering potent new technologies, supporting promising researchers, and facilitating cross-cutting capabilities. Ultimately, NIBIB seeks to translate research findings from the laboratory into solutions that advance human health by improving quality of life and reducing disease burden.

Technologies to Improve Health Care Delivery and Accessibility

Transitioning from a focus on hospital-based care toward the provision of services in primary care and home-based settings has the potential to improve health care delivery. Such a transition can also help address the challenges of health disparities by providing diagnostic capabilities to communities with limited access to large healthcare facilities. Point-of-care testing (POCT) technologies often combine multiple analytical functions into self-contained devices that can be used by non-specialists to detect and diagnose disease, and can guide the selection of optimal therapies. In specific cases, these systems can enable patient self-testing.

Digital Doctors and Mobile Medicine

Advances in communications, computer science, informatics, and medical technology have facilitated the practice of “telehealth” which is broadly defined as the use of communications technologies to provide and support health care at a distance. Today, the term “distance” is relative and could be as short as across town or as great as across the world. Telehealth can be as simple as two doctors talking on the phone about a patient’s care or as elegant as the use of robotic technology to perform surgery in another country. In each case the type of data transmitted can take one of many forms—videos, images, patient records, or sounds.

The National Aeronautics and Space Administration (NASA) is generally credited for the first effort in telehealth when it transmitted physiologic signals from astronauts *via* satellite in the 1960s. However, a case could be made that telecommunications-facilitated healthcare has been used since the early days of the two-way radio and the telephone. As early as 1906, Einthoven, the father of electrocardiography, first investigated electrocardiogram transmission over telephone lines! In the 1920’s, radios were used to link physicians standing watch at shore stations to assist ships at sea that had medical emergencies. By the end of World War II, telecommunications technologies were an integral part of medical care for those wounded in the battlefield. Today, if a soldier is wounded and surgical personnel are not available on the battlefield, the Army can deploy a Trauma Pod, which is a mobile operating room with robotic surgeons hooked up to real surgeons in a real-time, virtual reality link.

Improving the Quality of Care through Teleconsultation

As telehealth technologies have progressed, they have become more targeted towards specific patient needs and less expensive to adopt. As a result, more medical practitioners have engaged in telemedicine activities. For patients with complicated cases or chronic illnesses, especially those in rural or outlying areas, consultation with an appropriate specialist can vastly improve the quality and outcome of their healthcare. In certain cases, imaging technologies like magnetic resonance imaging (MRI), computerized tomography (CT) and ultrasound can be used to diagnose or monitor a disease process. To facilitate the routine use of teleconsultations for these patients, images captured locally by a physician can be incorporated in a medical record and sent to a specialist elsewhere for consultation. To hasten and streamline the process, the remote consultant should only receive relevant, high-quality information. This can be a difficult task as hundreds of images may be generated at one time; forcing the practitioner to spend considerable time reviewing information to determine what is most useful. To help focus the consultation process, one NIBIB researcher is developing and testing a “context sensitive” telehealth infrastructure that is based on automated incorporation of relevant clinical data into a single, condensed file. The method integrates two processes, natural language processing and automatic image selection. Natural language processing allows computers to “understand” statements written in human languages. In this case, the referring physician’s hypothesis about the patient’s problem is used as the information source to automatically drive image selection and summarization in a real world environment. Although the study focuses on neurological and musculoskeletal disorders, the approach can be adopted for many different diseases.

Another researcher has developed an expert visual guidance system to direct rural health care providers in acquiring diagnostic medical ultrasound images. This project builds upon the visual guidance system developed for NASA to assist flight personnel in acquiring medical ultrasound images on each other while aboard the International Space Station. The innovation lies in the fact that the new system will not just passively transmit images to an expert at a distant center, but will enable the expert to actively guide the untrained health care provider in acquiring the images. The rationale is that by providing assistance at the time of image acquisition, the expert at the receiving end can prevent difficulties in interpreting the studies due to poor diagnostic quality. The expert provides guidance through a visual and anatomic interface that projects a schematized three-dimensional image of the target organ onto a video display. The group has collected a library of anatomical images by extracting features from actual scans. The selected image is then projected onto the examiner’s screen to serve as a visual tutorial to guide image acquisition.

Remote Monitoring: Reducing Surgical Risk

Intraoperative monitoring (IOM) is a technique that allows a surgeon to perform continuous checking, recording, and testing during a sophisticated surgical procedure. In neurological surgeries IOM is used to detect potentially damaging changes in brain, spinal cord, and peripheral nerve function prior to irreversible damage. The procedure also has been effective in localizing anatomical structures, such as peripheral nerves, which helps guide the surgeon during dissection. IOM is traditionally performed in medical centers where experienced neurophysiologists are

available. In regional hospitals this type of monitoring is often difficult to perform because of lack of experts. NIBIB researchers have developed technologies for multimedia remote IOM systems capable of transmitting data, voice, and images over the Internet. However, the transmission of digital video of an acceptable quality is still somewhat of a problem, even when a broadband Internet connection (a high data-transmission rate) is used. The primary reason is lack of a high-performance algorithm (a mathematical function that is used to encrypt and decrypt information) that can adapt the special features of IOM video. The researchers have now formed an interdisciplinary team—electrical engineers, neurophysiologists and neurosurgeons—to tackle this high-tech problem. They are currently developing a special-purpose video compression algorithm that minimizes the bandwidth problem. They are also developing new methods for improved synchronization and integration of multimedia data for remote IOM.

Another NIBIB researcher is developing a high-resolution, holographic, three-dimensional (3D) color display for use in telehealth applications. Such a display would improve remote medical teaching, assist less skilled personnel in medical diagnosis, and further facilitate the sharing of 3D imaging data between networked sites. This 3D display uses “white light” illumination rather than lasers to eliminate potential concerns for eye safety. Success in this endeavor will provide an enormous boost for future medical telehealth applications.

The Electronic House Call

There is no doubt that the Internet has played a significant role in the growth and awareness of telehealth. But today’s telehealth goes beyond remote diagnosis and surgery. Preventative care and disease education and management are all being delivered virtually by medical personnel. For example, an NIBIB scientist is using cable TV technology to deliver an interactive weight loss program in patients with type 2 diabetes. Obesity and type 2 diabetes are emerging epidemics in America. Weight loss has been shown to improve diabetes outcomes, reduce the need for medication, and prevent diabetes from developing in some at-risk patients. However, implementation of behavioral weight-loss programs in a primary care setting has proven to be a challenge. Although Internet-based weight-loss programs are known to be effective, access to computers and the Internet is limited among low-income individuals and the elderly, two populations at risk for type 2 diabetes and its complications. This project demonstrates that a diet and exercise program can be delivered directly to individuals in their home using a TV and a special interactive remote control. The technology allows patients to interact with their TV set so that their blood sugar and body weight can be monitored and they can receive and respond to special notices.

Personalized Medicine: Tune In for Tomorrow’s Successes

With the advent of miniaturized devices and wireless communication, the way in which doctors care for patients has changed dramatically. The next decade will bring a new realm of precision and efficiency to the way information is transmitted and interpreted and thus the way medicine is practiced. Empowering clinicians to make decisions at the “point-of-care” has the potential to significantly impact health care delivery and to address the challenges of health disparities by providing diagnostic capabilities to communities with limited access to large healthcare facilities. The success of such a shift relies on the development of portable diagnostic and monitoring devices for near-patient testing that, when combined with suitable telehealth technologies, effectively empower clinicians or other providers to make decisions at the point-of-care. Results are immediate as samples do not have to be shipped off-site to a centralized laboratory. This is further complemented by their ability to carry out multiple assays such as blood gases, electrolytes, chemistries, coagulation, hematology, glucose, and cardiac markers simultaneously. The NIBIB has contributed to advances in this area by funding the development of sensor and microsystem technologies for point-of-care testing. These instruments combine multiple analytical functions into self-contained, portable devices that can be used by non-specialists to detect and diagnose disease, and can enable the selection of optimal therapies through patient screening and monitoring of a patient’s response to a chosen treatment. These technological advances limit the reliance on submission of samples to centralized laboratories, with results available within minutes as opposed to several hours or days, enabling clinicians to make decisions regarding treatment at a time when these decisions can have the greatest impact. In specific cases, sensors and microsystems can enable patient self-testing, and can contribute to the realization of personalized medicine by creating a link between the diagnosis of disease and the ability to tailor therapeutics to the individual.

Research Directions

Even with its recognized potential, the field of POCT is not without its challenges. A critical need within the technology community is to establish the clinical collaborations necessary to guide the selection of analyses that may benefit from a point-of-care approach, to assist with the level of device integration for a particular application, and to provide education not only on existing technologies but on the need to evaluate the efficacy of new approaches relative to existing approaches. To help overcome these challenges, the NIBIB will sponsor a workshop in April 2006 that has the broad goal of improving healthcare accessibility by fostering collaborations among technology developers, clinicians, and industry. The workshop will address merging the areas of miniaturization, imaging, and informatics with specific clinical need to advance point-of-care testing. A workshop report will be prepared that summarizes the recommendations for high-priority applications in point-of-care testing and the technological challenges that exist.

New Paradigms for Tissue Engineering and Gene and Drug Delivery

Tissue engineering offers potential for the development of human tissues to replace or repair damaged or injured tissues as well as for studying developmental biology, physiology and disease pathogenesis. Engineering principles can also be used to design new systems for advanced drug delivery applications. As pharmaceuticals have broadened to include small molecule drugs as well as peptides, proteins and genes, delivery of the larger molecules as drugs – to the proper location in the body, at the proper time, in the proper concentration, and without damage to the drug – has become increasingly important in moving new pharmaceuticals from the bench to the clinic.

Science Advance: From Silk to Bone—A Tangled Web. Scientists recently formed bone-like tissue from human adult bone marrow-derived stem cells and a silk scaffold. Cells cultured on a variety of three-dimensional silk scaffolds expressed several bone markers and accumulated a bone-like matrix. Silk scaffolds have been found to elicit a minimal immune response in humans, suggesting this material is suitable as a base for engineering synthetic tissues for applications in humans. Other researchers used a two-step process to fabricate a special biocompatible nanoporous alumina membrane for bone engineering. By altering the surface chemistry of the membrane, researchers were able to place a “cellular glue” on the membrane surface. This glue served to promote bone cell attachment and matrix formation, offering a method for controlling bone cell behavior which will assist in the development of additional implant materials.

In related research, scientists tested the effectiveness of coating implants with nitric oxide infused sol-gels in cultures to reduce potential infections at implant sites. Sol-gels are thin films that are formed from a jelly-like mass of water, alcohol, and metal oxides. This technique was found to reduce the adhesion of several bacteria known to populate implant sites. Next steps are to determine if additional nitric oxide from the implant affects wound healing since the body releases its own nitric oxide in response to injury.

Science Advance: Novel Strategies for Improving Gene and Drug Delivery. An emerging area in gene therapy (the delivery of healthy or engineered genetic material to cells with mutant or malfunctioning genetic material) research is the development of new transporters of genetic

material that are non-viral and less likely to initiate an immune response. A group of NIBIB researchers are investigating whether polymers can serve as a non-viral carrier in suicide gene therapy experiments. Suicide gene therapy is used to deliver a deadly payload of DNA to destroy tumor cells. Researchers synthesized hundreds of polymers able to carry genetic material to cancer cells and then used automated screening techniques to discover the best candidates for the task. The polymer “library” provides a new method for researchers to examine large numbers of polymers at one time and choose the most efficient ones to target cancer cells. For example, the team used this approach to identify the most effective and least toxic polymer to carry the DNA of diphtheria toxin (DT) to prostate tumor cells in a mouse model. The DT targeted both rapidly and slowly dividing tumor cells suggesting that it may be an effective therapy for aggressively growing tumors (e.g., melanoma) as well as for slower growing tumors (e.g., prostate cancer).

Ultrasound can be used to target the delivery of anti-cancer drugs to tumors. Ultrasonic chemotherapy is promising because the drugs remain within a protective carrier until activated by ultrasound, thus sparing healthy tissue from the toxic side effects of many cancer drugs. NIBIB investigators found that micelles, nanosized-droplets composed of a hydrophilic outer layer and a hydrophobic inner core, are ideal drug carriers for ultrasound chemotherapy because they decrease the amount of drug circulating throughout the body, diminishing drug uptake by normal cells. In a mouse model of ovarian cancer, micelles were injected intravenously and then activated with an ultrasonic burst, delivering the chemotherapy in high concentrations directly to the tumors. Other researchers are designing “smart” polymers for drug delivery. In order to increase a carrier’s ability to cross the cell membrane, they developed polymers that sense changes in environmental pH and alter their state to adapt to the local milieu. These polymers can cross the cellular membrane in their hydrophilic state. Once inside the more acidic environment of the cell, the polymers become less stable and release the therapeutic agent directly within the cell. Researchers can design the polymers to mimic different biological conditions to target delivery of specific drugs and doses.

Research Directions

As an emerging multidisciplinary field at the interface between the life and physical sciences, there is significant need for the NIBIB to provide continued resources to foster the science needed for these fields to mature. The NIBIB will also promote the translation of important breakthroughs from basic research to clinical studies and ultimately to patients.

Imaging Tools and Technologies for the Early Diagnosis and Treatment of Disease

Several decades of advances in the imaging sciences have demonstrated that imaging has become an important, if not critical, factor in the care of patients. Advanced imaging technologies help doctors detect, diagnose and monitor numerous diseases, including brain disorders and cancer, more accurately and earlier in the disease process.

Science Advance: Advanced Technologies. Advances in imaging technologies have spurred a variety of new minimally invasive procedures that localize human disease and injury, provide diagnostic tissue, administer treatment, and monitor responses to therapeutic interventions. In this respect, image-guided interventions are not only more efficient in terms of time and cost, but their less invasive nature has the potential to result in fewer complications and less damage to normal tissue. For example, shunt placements bypass liver blockages and relieve one of the most

serious symptoms of cirrhosis and other liver diseases. With X-rays, surgeons can generate images of the hollow needle used to penetrate the vessels, but cannot visualize the vessels themselves, often requiring multiple attempts before locating the needle within the vessel. To overcome this challenge, NIBIB researchers developed an integrated X-ray/magnetic resonance imaging (MRI) hybrid system. They modified the X-ray system so that it integrates directly into the MRI system, with minimal loss of image quality. The modified system eliminates the need to transfer a patient between X-ray and MRI facilities and increases the precision of surgeons to successfully enter the target vessel on the first attempt.

Another researcher team has developed a “Sonic Flashlight,” a handheld ultrasound display that replaces the standard monitor often used by surgeons to guide needle biopsies, confirm tumor locations, and access blood vessels. Standard ultrasound procedures limit hand-eye coordination by requiring the surgeon to look away from the operating field to see the ultrasound image on the monitor. This new system merges the patient, ultrasound image, instrument, and the surgeon’s hands into the same field of view, allowing the surgeon to operate directly on the ultrasound image.

Other researchers are developing new MRI techniques that non-invasively detect organ rejection post transplantation. By injecting study animals with a special dye that adheres to the disease fighting or immune cells, researchers can monitor the build up of these cells at the transplant site. Results from animal studies have shown a strong correlation between the strength of the MRI signal from the labeled immune cells at the transplant site and the physical changes seen in biopsy samples. This novel approach to monitoring organ rejection lays the foundation for other non-invasive techniques to detect acute rejection as well as correctly assess the extent of rejection. With additional research, this technology should help physicians detect organ rejection at early stages and improve a patient’s quality of life by reducing the need for invasive, post-transplant biopsies, the current standard for assessing organ rejection.

Science Advance: A Window into the Brain. Magnetic resonance imaging (MRI) has been used successfully for over 15 years to generate soft tissue images of the body and is the technique of choice for the routine diagnosis of many neurological diseases. Functional MRI (fMRI) is a relatively new techniques that measures quick and tiny oxygenation changes that occur with brain activity.

Findings from MRI of brain structures in elderly patients with late-onset depression suggest structural abnormalities in the brain could be responsible for the initial onset of depression in this group. Patients with late-onset depression are more likely to have a greater cognitive loss as well as an increased risk of dementia and morbidity. NIBIB researchers used brain mapping techniques to determine if decreases in gray matter in specific regions of the brain were a hallmark of late-onset depression. MRI scans coupled with an image analysis technique called cortical pattern matching imply that elderly patients with late-onset depression do possess unique brain structure abnormalities that may differ from other forms of depression and dementia. However, only long-term follow-up evaluations will be able to make this distinction, with important implications from both therapeutic and research standpoints.

Other NIBIB researchers are using fMRI to study the brain's signaling pathways related to attention deficit hyperactivity disorder (ADHD). The study was the first stringent double-blind, placebo-controlled examination of the effects of the drug methylphenidate on brain activity. It was also the first neuroimaging study to compare brain activity of ADHD individuals to that of people with another similar disorder, in this case a reading disorder. The goal was to discover which brain regions function abnormally both in individuals with ADHD and with a reading disorder. Researchers found that in the unmedicated portion of the experiment the subjects with ADHD or reading disorder had significantly less activity in the region of the brain known as the striatum than the control subjects. After receiving methylphenidate, the activity in this brain area increased to match that of the control group, but performance on the attention tasks did not improve. These results produced a new question for researchers to ponder: why do ADHD and reading disorder, which affect children in two different ways, yield imaging scans that show similar brain dysfunctions and a similar response to medication? Another new angle to explore is the primary effect of methylphenidate. Does it moderate impulsivity and hyperactivity more than it bolsters attention? Additional studies will look at potential differences in brain response to different drug treatments for ADHD.

Science Advance: Detecting and Treating Cancer. Non-invasive methods to diagnose and monitor various forms of cancer would improve patient quality of life. Numerous NIBIB researchers are studying ways to accomplish just this. For example, researchers are developing probes that can non-invasively detect tumors in animal models. One team has constructed a nanoprobe using a cell-like vehicle called a polymersome. These vesicles carry Q-dots (tiny semiconductors) or other fluorescent agents that can target markers on the surface of specific tumor cells. The polymersomes are very similar in structure to the membrane of living cells, vastly reducing the toxicity of the Q-dots and enabling their use in humans. Another group has developed a "smart enzyme sensing" probe which is a specially designed compound that binds to an enzyme and emits a signal when hit by a wavelength of light known to activate the enzyme. In breast cancer, high levels of an enzyme called cathepsin are associated with highly aggressive tumors and poor patient outcomes. Therefore, researchers employed optical imaging methods to successfully detect breast cancer cells by a cathepsin-sensing probe in a mouse model with spontaneous breast cancer. Developing a technique that can hone in on this particular enzyme should enhance breast cancer detection in a clinical setting. Further advances in both technologies will enable the non-invasive imaging of tumors and will be less costly and more accessible than MRI-based methods.

Often doctors use painful needle biopsies to detect and treat forms of cancer. This procedure has limited value in that it samples only a small area of the body. To overcome this limit researchers have developed a modified MRI technique that reveals the presence of leukemia by distinguishing between water inside and outside of a cell. This technique may also help doctors treat and monitor lymphoma and breast and prostate cancer. These diseases are hard to track as the associated tumors do not show up well on other imaging diagnostics such as X-rays and CT scans. In addition, the approach is rapid (20 minutes), non-invasive and pain-free.

Research Directions

Biomedical imaging will continue to be an area of high priority for both basic and clinical research, especially with regard to image-guided surgery, biopsies, and minimally invasive

therapies. The goal of the NIBIB program is to support research on the development of tools and technologies that can replace traditional invasive surgical procedures with minimally invasive, image-guided procedures that serve as standards of care. The NIBIB will also continue to support research on the synthesis of clinical imaging agents and molecular probes. Research in this area is expected to lead to the development of probes that can be adapted to new targets, “smart” probes that can be activated by a specific physiological process, molecular probes that enable the simultaneous imaging or detection of multiple biological processes within the body, and imaging agents that have drug delivery capabilities.

NIH ROADMAP: ACCELERATING MEDICAL RESEARCH PROGRESS

To transform the nation’s medical research capabilities and to speed the movement of research discoveries from the bench to the bedside, the NIH has laid out a series of initiatives known collectively as the NIH Roadmap for Medical Research. The NIH Roadmap provides a framework for strategic investments that NIH needs to make to optimize its entire research portfolio and builds on the tremendous progress in medical research achieved thus far. The tie between the NIBIB mission and the NIH Roadmap is direct—the Roadmap will facilitate the development of innovative, novel and multidisciplinary science and technology that has the potential to further advances in health care. Roadmap activities will improve health by providing researchers with tools and capabilities to make new discoveries and to quickly allow basic research discoveries to be translated into new therapies.

Over the last year NIBIB has organized a Roadmap initiative entitled “Innovation in Molecular Imaging Probes.” Molecular imaging approaches can be used to study biochemical abnormalities and cellular events. The major roadblocks to *in vivo* clinical applications of molecular imaging are the poor sensitivity and potential toxicity of the current molecular imaging probes. This initiative supports research programs that will circumvent these roadblocks.

Within the Bioinformatics and Computational Biology Roadmap, the NIBIB plays a significant role in managing the National Centers for Biomedical Computing. Specifically, NIBIB plays lead roles in two of the Centers that focus on imaging and computational biology.

The NIBIB also collaborates with several Institutes on the Nanomedicine Roadmap Initiative. Four new Nanomedicine Development Centers were established in FY 2005. These centers are staffed by multidisciplinary scientific teams that include biologists, physicians, mathematicians, engineers and computer scientists. The overall goal of this activity is to understand the physical properties of intracellular molecular structures and to use this information to design, develop and apply “nano” tools for the prevention, detection, diagnosis, and treatment of a wide range of diseases.

The goal of high throughput screening (HTS) is to scan thousands to millions of potential new compounds or drugs in a rapid efficient manner. This technique holds great potential for discovery by rapidly exploring a broad “chemical space” for potential activity. The NIBIB is participating in an initiative entitled “Molecular Libraries Screening Instrumentation” which is focused on developing technologies and tools for rapid HTS. The overall goal of this initiative is to build a better “toolbox” to advance our understanding of complex biological networks, with

HTS instrumentation providing the technological means to identify compounds that modulate biological processes.

NIH NEUROSCIENCE BLUEPRINT

The Neuroscience Blueprint is a framework designed to enhance cooperative activities among fifteen NIH Institutes and Centers (ICs) that support research on the nervous system. By pooling resources and expertise, the Blueprint confronts challenges too large for any single IC to tackle and develops research tools and infrastructure that will serve the entire neuroscience community. During FY 2005, NIBIB contributed to the development of a number of initiatives, leading or participating in three Blueprint project teams. In the neuroimaging area, NIBIB led a project team in concept development and implementation of two specific initiatives: better ways to image neural activity, and neuroimaging tools and database clearinghouse. These initiatives aim to support research and development of imaging technology for high resolution imaging of neural activity that is reflected in electrophysiological signals; and to develop a framework that attempts to address the critical need of neuroimaging data and software tools sharing and integration. The NIBIB also participated in the development of neuroscience training initiatives.

FY 2007 INITIATIVES: EXPANSION OF CURRENT RESEARCH AREAS

Through strategic planning retreats and group discussions, the NIBIB has identified research priorities across the programs of the Institute. To advance the science in these areas, the NIBIB is planning to expand several current research programs.

Integrated Sensors and Lab-On-A-Chip for Point-Of-Care Laboratory Tests: Sensor technology has the potential to capture the power of biological sample analysis currently performed in a clinical laboratory onto a single, miniaturized, integrated microfluidic chip. These “point-of-care” systems hold promise for bringing a large clinical laboratory to the patient, wherever the patient may be, and for providing results at the time of the visit. This initiative will support research on critical areas for the development of microsystems and microsensors, including sample concentration, amplification, separation, fouling, repeatability, reliability, specificity, assay development, and successful operation using clinical samples. These systems could reduce the cost of health care, much as integrated electronics have reduced the cost of computing, and greatly simplify and improve patient delivery of care.

Enabling Technologies for Regenerative Medicine: Regenerative medicine, sometimes also called tissue engineering, involves the functional remodeling and regeneration of tissue inside the body (*in vivo*) and the growth of functional tissues and organs in the laboratory (*in vitro*) for implantation in the body to repair, replace, maintain, or enhance tissue and organ function. To realize the potential of regenerative medicine there are significant technological obstacles that must be overcome in the field including control of cell proliferation and differentiation, bioreactor scale up for volume production of cells, cell preservation, and development of matrix to promote cell growth and differentiation. There is also a great need for non-destructive imaging and cellular process measurement techniques to monitor and control the cell and tissue development. NIBIB is committed to leading the development of enabling biomedical technologies to advance regenerative medicine. There are potential applications for regenerative medicine in many of the disease and organ specific institutes, for example nerve and fiber track

regeneration following spinal cord injury. This research effort will develop enabling technologies that can benefit all these areas.

Image-Guided Surgery for Minimally Invasive Treatment of Disease and Injury: Modern imaging techniques provide significant anatomical and functional information that is critical in the planning of a surgical procedure. However, the power of modern imaging is not utilized in the operating room because the detailed image information is not fully integrated into the modern operating room in an interactive mode. This NIBIB-supported research program will expand the applications of image guided surgery by developing technologies to allow the surgeon to seamlessly visualize the patient in three-dimensional preoperative images; track intraoperative changes with real-time imaging; and restore a normal sense of touch through new robotic tools with sensors for biofeedback. This research may lead to new minimally invasive surgical procedures with fewer complications, shorter hospital stays, and reduced costs.

ADVANCES IN OUTREACH AND EDUCATION

NIBIB Releases New Website: The recently released and improved website provides a reliable and comprehensive source of information for a wide range of audiences. The Internet is an integral part of NIBIB's plan to communicate mission-related activities, timely information, and accomplishments to Congress, researchers, advocacy groups, students, media, and the general public. This new web site makes it easy for anyone interested in the NIBIB to find information and answers to questions in a clear and user-friendly manner. Notable content changes include the addition of health information and science education resources, a searchable funding opportunities database and extensive information on the grant application process. The website also serves as a showcase for NIBIB grantees whose stunning visuals are featured throughout the site. In an effort to make information more accessible to the growing population of Spanish-speaking individuals, the web site features a comprehensive Spanish-language section, with health information, education resources and program overviews. The site is fully accessible by users with assistive technology devices, such as screen readers for the visually impaired.

NIBIB Launched Regional Grantsmanship Seminar and Toolkit: Educating new researchers in the NIH application and review process is critically important. As an institute that supports the development of emerging technologies, the NIBIB attracts many researchers new to this process. The Seminar is aimed at informing researchers, students, and others unfamiliar with the NIH about NIBIB funding opportunities and the NIH application, review, and grant-awarding processes. The one-day program includes staff presentations on the NIBIB and the NIH, NIBIB research and training programs and opportunities, the NIH peer review process, and tips for preparing NIH grant applications. The toolkit contains copies of the presentations and includes useful websites, fact sheets and a CD with sample applications and a mock review video. Host grantees will participate as well by sharing their personal perspectives and experiences with the NIH application and review system. Thus the format of the program reflects the theme of partnership between NIH and grantee institutions in research administration.

SUMMARY

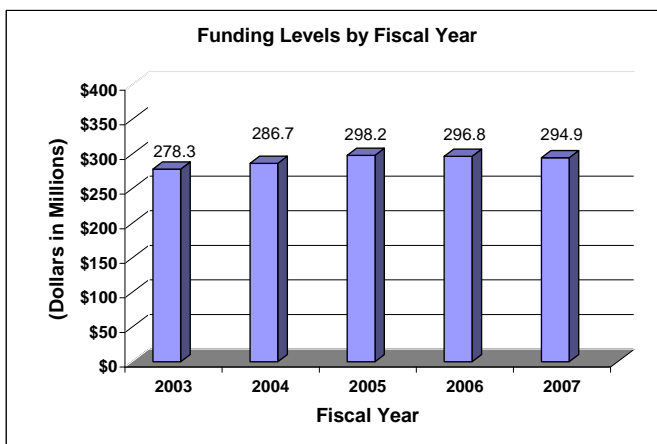
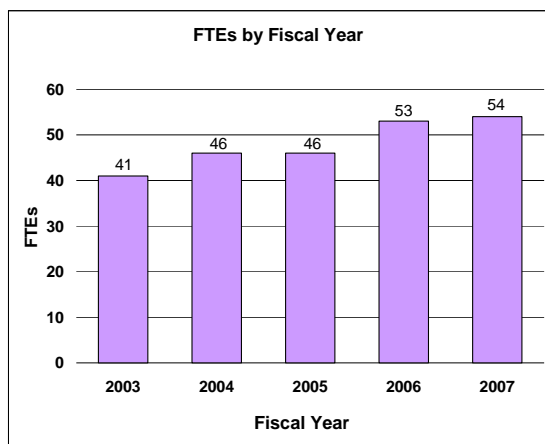
The fields of biomedical imaging and bioengineering are expanding rapidly—from the detection, diagnosis and treatment of diseases and disabilities at the level of tissues and organs to the analysis of structure and function at the molecular and genetic levels. The establishment of

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 2007 budget request for the NIBIB is \$294,850,000, a decrease of \$1,960,000 and 0.7 percent under the FY 2006 Appropriation. Included in the FY 2007 request is NIBIB's support for the trans-NIH Roadmap initiatives, estimated at 1.2% of the FY 2007 budget request. A full description of this trans-NIH program may be found in the NIH Overview.

A five year history of FTEs and Funding Levels for NIBIB are shown in the graphs below. Note that as the result of several administrative restructurings in recent years, FTE data is non-comparable.



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 pursuing new research opportunities. We estimate that the average cost of competing RPGs will be \$288,000 in FY 2007. While no inflationary increases are provided for direct recurring costs in noncompeting RPGs, where the NIBIB has committed to a programmatic increase for an award, such increases will be provided.

NIH must nurture a vibrant, creative research workforce, including sufficient numbers of new investigators with new ideas and new skills. In the FY 2007 budget request for NIBIB, \$450,000 will be used to support 5 awards for the new K/R "Pathway to Independence" program.

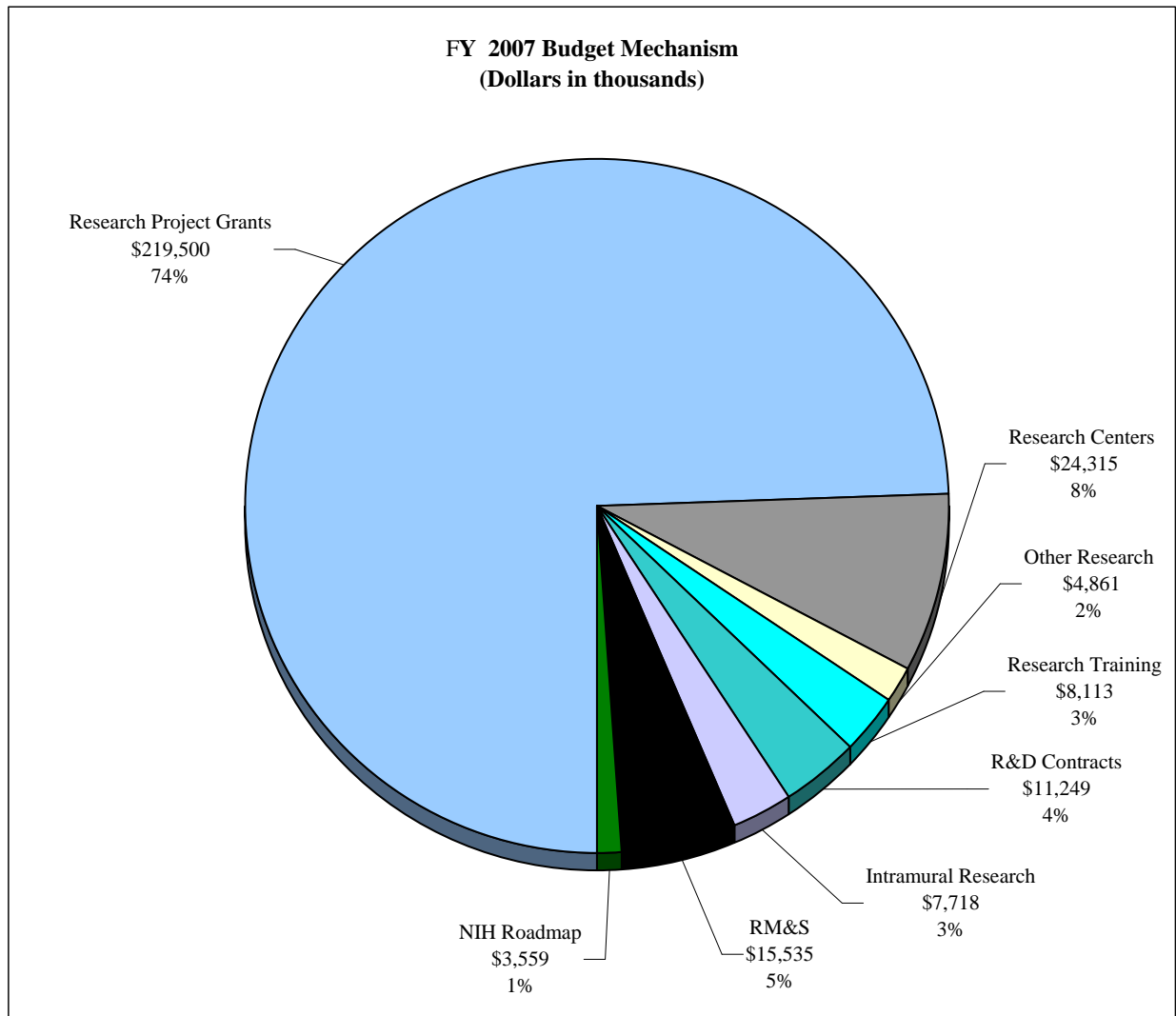
NIBIB will also support the Genes, Environment, and Health Initiative (GEHI) to: 1) accelerate discovery of the major genetic factors associated with diseases that have a substantial public health impact; and 2) accelerate the development of innovative technologies and tools to measure dietary intake, physical activity, and environmental exposures, and to determine an individual's biological response to those influences. The FY 2007 request includes \$507,000 to support this project.

In the FY 2007 request, stipend levels for trainees supported through the Ruth L. Kirschstein National Research Service Awards will remain at the FY 2006 levels.

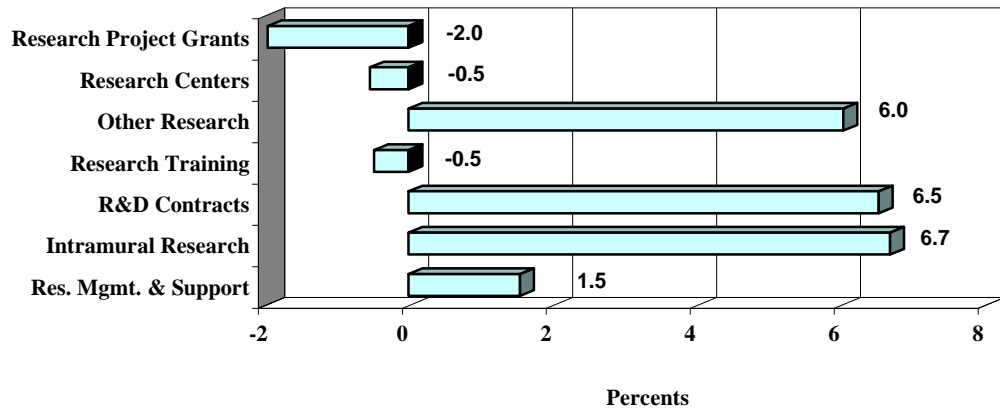
The FY 2007 request includes funding for 24 research centers, 52 other research grants, including 31 career awards, and 27 R&D contracts. Intramural Research increases by 6.7 percent. Research Management and Support increases by 1.5 percent.

Due to inflation and pay costs not being completely covered by the 1.5 percent increase in Research Management and Support, NIBIB will carefully review administrative expenditures and determine if any areas can be found to absorb these expenses without program impact.

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



**FY 2007 Estimate
Percent Change from FY 2006 Mechanism**



NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Budget Mechanism - Total

| MECHANISM | FY 2005 Actual | | FY 2006 Appropriation | | FY 2007 Estimate | |
|---|-------------------|-----------------------|--------------------------|------------------------|---------------------|------------------------|
| | No. | Amount | No. | Amount | No. | Amount |
| Research Grants: | | | | | | |
| <u>Research Projects:</u> | | | | | | |
| Noncompeting | 443 | \$168,385,000 | 473 | \$170,490,000 | 397 | \$136,460,000 |
| Administrative supplements | (12) | 588,000 | (0) | 0 | (0) | 0 |
| Competing: | | | | | | |
| Renewal | 29 | 11,506,000 | 24 | 9,559,000 | 40 | 15,914,000 |
| New | 161 | 44,439,000 | 134 | 35,961,000 | 223 | 59,866,000 |
| Supplements | 6 | 548,000 | 0 | 0 | 0 | 0 |
| Subtotal, competing | 196 | 56,493,000 | 158 | 45,520,000 | 263 | 75,780,000 |
| Subtotal, RPGs | 639 | 225,466,000 | 631 | 216,010,000 | 660 | 212,240,000 |
| SBIR/STTR | 44 | 8,913,000 | 39 | 7,875,000 | 36 | 7,260,000 |
| Subtotal, RPGs | 683 | 234,379,000 | 670 | 223,885,000 | 696 | 219,500,000 |
| <u>Research Centers:</u> | | | | | | |
| Specialized/comprehensive | 3 | 2,593,000 | 5 | 5,000,000 | 5 | 4,975,000 |
| Clinical research | 0 | 0 | 0 | 0 | 0 | 0 |
| Biotechnology | 21 | 21,247,000 | 19 | 19,446,000 | 19 | 19,340,000 |
| Comparative medicine | 0 | 0 | 0 | 0 | 0 | 0 |
| Research Centers in Minority Institutions | 0 | 0 | 0 | 0 | 0 | 0 |
| Subtotal, Centers | 24 | 23,840,000 | 24 | 24,446,000 | 24 | 24,315,000 |
| <u>Other Research:</u> | | | | | | |
| Research careers | 21 | 2,977,000 | 26 | 3,623,000 | 31 | 3,905,000 |
| 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 | 22 | 559,000 | 22 | 961,000 | 21 | 956,000 |
| Subtotal, Other Research | 43 | 3,536,000 | 48 | 4,584,000 | 52 | 4,861,000 |
| Total Research Grants | 750 | 261,755,000 | 742 | 252,915,000 | 772 | 248,676,000 |
| <u>Research Training:</u> | <u>FTEs</u> | | <u>FTEs</u> | | <u>FTEs</u> | |
| Individual awards | 23 | 852,000 | 28 | 893,000 | 28 | 888,000 |
| Institutional awards | 143 | 6,439,000 | 156 | 7,259,000 | 156 | 7,225,000 |
| Total, Training | 166 | 7,291,000 | 184 | 8,152,000 | 184 | 8,113,000 |
| Research & development contracts (SBIR/STTR) | 23 (2) | 7,999,000 (17,000) | 26 (2) | 10,559,000 (17,000) | 27 (2) | 11,249,000 (17,000) |
| Intramural research | <u>FTEs</u> 5 | 3,981,000 | <u>FTEs</u> 7 | 7,234,000 | <u>FTEs</u> 7 | 7,718,000 |
| Research management and support | 39 | 15,298,000 | 44 | 15,298,000 | 45 | 15,535,000 |
| Cancer prevention & control | 0 | 0 | 0 | 0 | 0 | 0 |
| Construction | | 0 | | 0 | | 0 |
| Buildings and Facilities | | 0 | | 0 | | 0 |
| NIH Roadmap for Medical Research | 2 | 1,885,000 | 2 | 2,652,000 | 2 | 3,559,000 |
| Total, NIBIB | 46 | 298,209,000 | 53 | 296,810,000 | 54 | 294,850,000 |
| (Clinical Trials) | | (0) | | (0) | | (0) |

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Budget Authority by Activity
(dollars in thousands)

| ACTIVITY | FY 2005 | | FY 2006 | | FY 2007 | | Change | |
|---------------------------------------|-----------|----------------|-----------|----------------|-----------|----------------|----------|----------------|
| | FTEs | Amount | FTEs | Amount | FTEs | Amount | FTEs | Amount |
| <u>Extramural Research:</u> | | | | | | | | |
| Biomedical Imaging and Bioengineering | | \$277,045 | | \$271,626 | | \$268,038 | | (\$3,588) |
| | | | | | | | | 0 |
| | | | | | | | | 0 |
| Subtotal, Extramural research | | 277,045 | | 271,626 | | 268,038 | | (3,588) |
| Intramural Research | 5 | 3,981 | 7 | 7,234 | 7 | 7,718 | --- | 484 |
| Research Management & Support | 39 | 15,298 | 44 | 15,298 | 45 | 15,535 | 1 | 237 |
| NIH Roadmap for Medical Research | 2 | 1,885 | 2 | 2,652 | 2 | 3,559 | --- | 907 |
| Total | 46 | 298,209 | 53 | 296,810 | 54 | 294,850 | 1 | (1,960) |

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Summary of Changes

| | | | | |
|--|--------------------------|---------------------|------------------|---------------------|
| FY 2006 Estimate | | \$296,810,000 | | |
| FY 2007 Estimated Budget Authority | | 294,850,000 | | |
| Net change | | (1,960,000) | | |
| CHANGES | FY 2006 Appropriation | | Change from Base | |
| | FTEs | Budget Authority | FTEs | Budget Authority |
| A. Built-in: | | | | |
| 1. Intramural research: | | | | |
| a. Within grade increase | | | | |
| | | \$1,032,000 | | \$12,000 |
| b. Annualization of January 2006 pay increase | | | | |
| | | 1,032,000 | | 8,000 |
| c. January 2007 pay increase | | | | |
| | | 1,032,000 | | 18,000 |
| d. Payment for centrally furnished services | | | | |
| | | 980,000 | | 15,000 |
| e. Increased cost of laboratory supplies, materials, and other expenses | | | | |
| | | 5,222,000 | | 115,000 |
| Subtotal | | | | 168,000 |
| 2. Research Management and Support: | | | | |
| a. Within grade increase | | | | |
| | | 6,139,000 | | 108,000 |
| b. Annualization of January 2006 pay increase | | | | |
| | | 6,139,000 | | 50,000 |
| c. January 2007 pay increase | | | | |
| | | 6,139,000 | | 107,000 |
| d. Payment for centrally furnished services | | | | |
| | | 3,361,000 | | 50,000 |
| e. Increased cost of laboratory supplies, materials, and other expenses | | | | |
| | | 5,798,000 | | 117,000 |
| Subtotal | | | | 432,000 |
| Subtotal, Built-in | | | | 600,000 |

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Summary of Changes--continued

| CHANGES | FY 2006 | | | |
|---------------------------------------|---------------|---------------|------------------|----------------|
| | Appropriation | | Change from Base | |
| | No. | Amount | No. | Amount |
| B. Program: | | | | |
| 1. Research project grants: | | | | |
| a. Noncompeting | 473 | \$170,490,000 | (76) | (\$34,030,000) |
| b. Competing | 158 | 45,520,000 | 105 | 30,260,000 |
| c. SBIR/STTR | 39 | 7,875,000 | (3) | (615,000) |
| Total | 670 | 223,885,000 | 26 | (4,385,000) |
| 2. Research centers | 24 | 24,446,000 | 0 | (131,000) |
| 3. Other research | 48 | 4,584,000 | 4 | 277,000 |
| 4. Research training | 184 | 8,152,000 | 0 | (39,000) |
| 5. Research and development contracts | 26 | 10,559,000 | 27 | 690,000 |
| Subtotal, extramural | | | | (3,588,000) |
| | <u>FTEs</u> | | <u>FTEs</u> | |
| 6. Intramural research | 7 | 7,234,000 | 0 | 316,000 |
| 7. Research management and support | 44 | 15,298,000 | 1 | (195,000) |
| 8. NIH Roadmap for Medical Research | 2 | 2,652,000 | 0 | 907,000 |
| Subtotal, program | | 296,810,000 | | (2,560,000) |
| Total changes | 53 | | 1 | (1,960,000) |

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Budget Authority by Object

| | FY 2006 Appropriation | FY 2007 Estimate | Increase or Decrease |
|---|----------------------------------|-----------------------------|---------------------------------|
| Total compensable workyears: | | | |
| Full-time employment | 53 | 54 | 1 |
| Full-time equivalent of overtime & holiday hours | 0 | 0 | 0 |
| Average ES salary | \$0 | \$0 | \$0 |
| Average GM/GS grade | 13.7 | 13.7 | 0.0 |
| Average GM/GS salary | \$89,134 | \$92,789 | \$3,655 |
| Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207) | \$0 | \$0 | \$0 |
| Average salary of ungraded positions | 148,400 | 157,312 | 8,912 |
| OBJECT CLASSES | FY 2006 Appropriation | FY 2007 Estimate | Increase or Decrease |
| Personnel Compensation: | | | |
| 11.1 Full-Time Permanent | \$3,695,000 | \$4,050,000 | \$355,000 |
| 11.3 Other than Full-Time Permanent | 1,521,000 | 1,550,000 | 29,000 |
| 11.5 Other Personnel Compensation | 194,000 | 202,000 | 8,000 |
| 11.7 Military Personnel | 0 | 0 | 0 |
| 11.8 Special Personnel Services Payments | 254,000 | 254,000 | 0 |
| Total, Personnel Compensation | 5,664,000 | 6,056,000 | 392,000 |
| 12.0 Personnel Benefits | 1,507,000 | 1,550,000 | 43,000 |
| 12.2 Military Personnel Benefits | 0 | 0 | 0 |
| 13.0 Benefits for Former Personnel | 0 | 0 | 0 |
| Subtotal, Pay Costs | 7,171,000 | 7,606,000 | 435,000 |
| 21.0 Travel & Transportation of Persons | 490,000 | 500,000 | 10,000 |
| 22.0 Transportation of Things | 17,000 | 18,000 | 1,000 |
| 23.1 Rental Payments to GSA | 0 | 0 | 0 |
| 23.2 Rental Payments to Others | 65,000 | 68,000 | 3,000 |
| 23.3 Communications, Utilities & Miscellaneous Charges | 100,000 | 105,000 | 5,000 |
| 24.0 Printing & Reproduction | 170,000 | 175,000 | 5,000 |
| 25.1 Consulting Services | 145,000 | 150,000 | 5,000 |
| 25.2 Other Services | 850,000 | 860,000 | 10,000 |
| 25.3 Purchase of Goods & Services from Government Accounts | 19,472,000 | 19,783,000 | 311,000 |
| 25.4 Operation & Maintenance of Facilities | 120,000 | 123,000 | 3,000 |
| 25.5 Research & Development Contracts | 2,626,000 | 3,205,000 | 579,000 |
| 25.6 Medical Care | 0 | 0 | 0 |
| 25.7 Operation & Maintenance of Equipment | 189,000 | 194,000 | 5,000 |
| 25.8 Subsistence & Support of Persons | 0 | 0 | 0 |
| 25.0 Subtotal, Other Contractual Services | 23,402,000 | 24,315,000 | 913,000 |
| 26.0 Supplies & Materials | 450,000 | 460,000 | 10,000 |
| 31.0 Equipment | 1,226,000 | 1,255,000 | 29,000 |
| 32.0 Land and Structures | 0 | 0 | 0 |
| 33.0 Investments & Loans | 0 | 0 | 0 |
| 41.0 Grants, Subsidies & Contributions | 261,067,000 | 256,789,000 | (4,278,000) |
| 42.0 Insurance Claims & Indemnities | 0 | 0 | 0 |
| 43.0 Interest & Dividends | 0 | 0 | 0 |
| Subtotal, Non-Pay Costs | 286,987,000 | 283,685,000 | (3,302,000) |
| NIH Roadmap for Medical Research | 2,652,000 | 3,559,000 | 907,000 |
| Total Budget Authority by Object | 296,810,000 | 294,850,000 | (1,960,000) |

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

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Salaries and Expenses

| OBJECT CLASSES | FY 2006 Appropriation | FY 2007 Estimate | Increase or Decrease |
|---|--------------------------|---------------------|-------------------------|
| Personnel Compensation: | | | |
| Full-Time Permanent (11.1) | \$3,695,000 | \$4,050,000 | \$355,000 |
| Other Than Full-Time Permanent (11.3) | 1,521,000 | 1,550,000 | 29,000 |
| Other Personnel Compensation (11.5) | 194,000 | 202,000 | 8,000 |
| Military Personnel (11.7) | 0 | 0 | 0 |
| Special Personnel Services Payments (11.8) | 254,000 | 254,000 | 0 |
| Total Personnel Compensation (11.9) | 5,664,000 | 6,056,000 | 392,000 |
| Civilian Personnel Benefits (12.1) | 1,507,000 | 1,550,000 | 43,000 |
| Military Personnel Benefits (12.2) | 0 | 0 | |
| Benefits to Former Personnel (13.0) | 0 | 0 | 0 |
| Subtotal, Pay Costs | 7,171,000 | 7,606,000 | 435,000 |
| Travel (21.0) | 490,000 | 500,000 | 10,000 |
| Transportation of Things (22.0) | 17,000 | 18,000 | 1,000 |
| Rental Payments to Others (23.2) | 65,000 | 68,000 | 3,000 |
| Communications, Utilities and Miscellaneous Charges (23.3) | 100,000 | 105,000 | 5,000 |
| Printing and Reproduction (24.0) | 170,000 | 175,000 | 5,000 |
| Other Contractual Services: | | | |
| Advisory and Assistance Services (25.1) | 145,000 | 150,000 | 5,000 |
| Other Services (25.2) | 850,000 | 860,000 | 10,000 |
| Purchases from Govt. Accounts (25.3) | 10,329,000 | 10,492,000 | 163,000 |
| Operation & Maintenance of Facilities (25.4) | 120,000 | 123,000 | 3,000 |
| Operation & Maintenance of Equipment (25.7) | 189,000 | 194,000 | 5,000 |
| Subsistence & Support of Persons (25.8) | 0 | 0 | 0 |
| Subtotal Other Contractual Services | 11,633,000 | 11,819,000 | 186,000 |
| Supplies and Materials (26.0) | 450,000 | 460,000 | 10,000 |
| Subtotal, Non-Pay Costs | 12,925,000 | 13,145,000 | 220,000 |
| Total, Administrative Costs | 20,096,000 | 20,751,000 | 655,000 |

NATIONAL INSTITUTES OF HEALTH

National Institute of Biomedical Imaging and Bioengineering

SIGNIFICANT ITEMS IN HOUSE AND SENATE APPROPRIATIONS COMMITTEE REPORTS

FY 2006 House Appropriations Committee Report Language (H. Rpt. 109-143)

Item

Imaging for autoimmune disease – The Committee is encouraged by the recent development of imaging technology being evaluated in clinical trials for detection of metastatic cancer in human patients. The Committee encourages the Institute to support the translation of imaging technologies to the detection and diagnosis of autoimmune disease, in particular juvenile diabetes and organ transplantation. Non-invasive imaging approaches are critical to the detection of progression of disease or early rejection of transplanted organs or cells. (p. 94)

Action taken or to be taken

The NIBIB recognizes the potential benefits to the diabetes community offered by advances in non-invasive imaging to 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. Further understanding of beta cell function and successful islet transplantation are important to the ultimate goal of a cure for type 1 diabetes. NIBIB-supported researchers are using nuclear magnetic resonance spectroscopy and microimaging to non-invasively assess function and viability of transplanted pancreatic islets. This technique will lead to greater understanding of beta cell function, factors influencing successful islet transplantation, and the further development of encapsulated pancreatic beta cells necessary for a bioartificial pancreas. The NIBIB also supports research on imaging methods to detect pancreatic islet beta cells *in vivo*, and measure their mass, function, or evidence of inflammation. NIBIB is participating in a new initiative, led by the NIDDK, on imaging pancreatic beta cells in humans. NIBIB is co-sponsoring a workshop on imaging the pancreatic beta cell in health and disease in April 2006. Other participating organizations include NIDDK, NCI, NIAID, and the Juvenile Diabetes Research Foundation International. Consistent with its mission, the NIBIB will continue to support the development of non-invasive imaging technologies to improve the detection and diagnosis of autoimmune diseases and to monitor the viability and early rejection of transplanted organs or cells.

Item

Bone Imaging – The Committee urges NIBIB to focus on improving musculoskeletal disease detection, monitoring and treatment through focused imaging and engineering advances. The Institute is encouraged to develop noninvasive techniques to measure bone quality and bone strength in humans. (p. 95)

Action taken or to be taken

Osteoporotic fractures occur because of a failure of bone to resist loading. “Bone quality” is an ill-defined term used to describe the diverse factors influencing skeletal health and fracture risk that go beyond bone mineral density (BMD) measurement. Although BMD measurement is among the most useful clinical tools for diagnosing osteoporosis, it does have limitations. This makes bone quality and skeletal fragility among the hottest topics for basic scientists, clinical investigators, and clinicians. NIBIB actively supports improvements in non-invasive imaging technologies (e.g., magnetic resonance imaging, computerized tomography, and optical imaging) that have the potential to significantly improve measurement of bone quality and bone strength in humans.

In May 2005, the NIBIB and the National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS) sponsored a conference entitled “Bone Quality: What Is It and Can We Measure It?” NIBIB provided a technology perspective to the conference. The meeting was also sponsored by INSERM (The French National Institute of Health and Medical Research) and the American Society for Bone and Mineral Research. The goals of this meeting were to: identify needs and future directions in this area of research; highlight basic science, clinical, regulatory and pharmaceutical perspectives; assess which established and newly developed methodologies for measurement of bone fragility are ready for inclusion into large clinical trials and how to facilitate their inclusion; and discuss novel mechanisms to bring together research efforts on bone quality to move the field forward.

The NIBIB is also an active partner in the Osteoarthritis Initiative (OAI), a public-private partnership between the NIH and industry to create a resource to hasten discovery of biological markers for osteoarthritis. Osteoarthritis, a degenerative condition whose hallmarks are joint pain and limited movement resulting from progressive loss of cartilage, is the most common type of arthritis, especially among older people. It can occur in any joint, but most often affects the hands, knees, hips, or spine.

Item

Liver imaging techniques – Consistent with NIBIB’s mission to improve all diagnostic imaging technologies, the Committee encourages NIBIB to make liver imaging techniques a primary focus, speeding the development of new modalities that better capture the early stages of various liver diseases, including cancer, as well as offering the potential for combinations of diagnosis and treatment. This is also necessary to develop less invasive diagnostics for liver disease patients. The Committee recommends that NIBIB participate actively in trans-NIH initiatives that address these priorities. (p. 95)

Action taken or to be taken

In the past century, radiologists relied on morphologic information obtained with various imaging techniques for disease detection and diagnosis, and for monitoring therapeutic responses. The techniques most commonly used for imaging liver diseases include computerized

tomography (CT), magnetic resonance imaging (MRI), and ultrasound (US), which can be used alone or in combination.

With advances in molecular techniques, and the successful mapping of the human genome, the age of molecular medicine has arrived, bringing with it important advances in both liver imaging and biotechnology. The integration of techniques from molecular biology, immunology, genetics, chemistry, and tissue engineering with imaging technologies will give unprecedented capabilities to study biochemistry and physiology in intact human organs, leading to the development of new diagnostic and therapeutic methods. Many of these novel approaches can be applied to liver diseases.

The NIBIB has been actively involved in developing an Inter-Agency “Action Plan for Liver Disease Research.” The NIBIB also serves at the NIH Institute on a Roadmap initiative entitled “Innovation in Molecular Imaging Probes.” This initiative is supporting “high-risk” development of novel molecular imaging probes for human studies. In addition, the NIBIB supports a grant portfolio related to the development of novel imaging techniques. Together, these two major areas will enhance the development of clinical molecular imaging for liver diseases.

The NIBIB held a workshop on Image-Guided Interventions in May 2004. The workshop was co-sponsored by the National Science Foundation (NSF) and the National Aeronautics and Space Administration (NASA). The purpose of this workshop was to promote interdisciplinary team science, and provide recommendations to ensure that NIH, NSF, and NASA programs address important needs and issues associated with image-guided interventions (IGI). NIBIB has sponsored a follow-up IGI Federal Inter-Agency Retreat this past winter.

FY 2006 Senate Appropriations Committee Report Language (S. Rpt. 109-103)

Item

Imaging and Engineering Advances – The Committee urges NIBIB to focus efforts on improving musculoskeletal disease detection, monitoring and treatment through focused imaging and engineering advances. The Institute is also encouraged to develop noninvasive techniques to measure bone quality and bone strength in humans. (p. 150)

Action taken or to be taken

Please refer to page NIBIB-24 (*Bone Imaging*) of this document for NIBIB’s response to this significant item regarding Imaging and Engineering Advances.

Item

Liver Imaging Techniques – Consistent with NIBIB’s mission to improve all diagnostic imaging technologies, the Committee urges NIBIB to make liver imaging techniques a primary focus, speeding the development of new modalities that better capture the early stages of various liver diseases, including cancer, as well as offering the potential for combinations of diagnosis and

treatment. This is also necessary to develop less invasive diagnostic for liver disease patients. The Committee urges NIBIB to participate actively in trans-NIH initiatives that address these priorities.

The Committee is encouraged by the potential of image-guided surgery to improve patient outcomes. The Committee supports the Institute's plans to hold a conference on image-guided surgery and looks forward to learning the results of this conference. (p. 150-151)

Action taken or to be taken

Please refer to page NIBIB-25 of this document for NIBIB's response to this significant item regarding Liver Imaging Techniques.

Item

PET and microPET scans – The Committee continues to encourage the 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. 152)

Action taken or to be taken

One of the most promising and rapidly evolving areas of diagnostic medicine is that of molecular imaging, which includes positron emission tomography (PET) and a range of optically-based technologies. Along with these are corresponding approaches devised for the study of small laboratory animals, such as microPET, microCT, and microMRI. The NIBIB continues to give these efforts high priority by supporting relevant research. For example, components of the recently established NIBIB intramural PET Radiochemistry program focus on the development of new molecular probes, and tools developed in this laboratory serve also to support research in other NIH Institutes and Centers. Development of novel specific radioligands for PET may lead to an enhanced understanding of biochemical processes and to the development of new therapeutic drugs. PET imaging agents for the study of neurological disorders and cancers have been evaluated for their potential utility for human clinical protocols. In addition, the NIBIB and the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration have established a joint Laboratory for the Assessment of Medical Imaging Systems (LAMIS). An important aspect of this joint effort is to assess and optimize molecular and other medical imaging systems.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

| | | Authorizing Legislation | | | | |
|-------------------------------------|----------------------------|--------------------------------|---------------------------|--------------------------|---------------------------|----------------------------|
| | PHS Act/ Other Citation | U.S. Code Citation | 2006 Amount Authorized | FY 2006 Appropriation | 2007 Amount Authorized | FY 2007 Budget Estimate |
| Research and Investigation | Section 301 | 42§241 | Indefinite | | Indefinite | |
| Imaging and Bioengineering | Section 41B | 42§285b | Indefinite | \$288,658,000 | Indefinite | \$286,737,000 |
| National Research Service Awards | Section 487(d) | 42§288 | a/ | 8,152,000 | | 8,113,000 |
| Total, Budget Authority | | | | 296,810,000 | | 294,850,000 |

a/ Amounts authorized by Section 301 and Title IV of the Public Health Act.

NATIONAL INSTITUTES OF HEALTH
National Institute of Biomedical Imaging and Bioengineering

Appropriations History

| Fiscal Year | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation <u>1/</u> |
|----------------|--------------------------------|--------------------|---------------------|-------------------------|
| 2002 | 40,206,000 | 39,869,000 | 140,000,000 | 111,984,000 |
| Rescission | | | | (33,000) |
| 2003 | 120,502,000 | 270,494,000 | 283,100,000 | 280,100,000 |
| Rescission | | | | (1,821,000) |
| 2004 | 282,109,000 | 282,109,000 | 289,300,000 | 288,900,000 |
| Rescission | | | | (1,771,000) |
| 2005 | 297,647,000 | 297,647,000 | 300,800,000 | 300,647,000 |
| Rescission | | | | (2,438,000) |
| 2006 | 299,808,000 | 299,808,000 | 309,091,000 | 299,808,000 |
| Rescission | | | | (2,998,000) |
| 2007 | 294,850,000 | | | |

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 2005 Actual | FY 2006 Appropriation | FY 2007 Estimate |
|--|---------------------|--------------------------|---------------------|
| Office of the Director | 3 | 4 | 4 |
| Extramural Research Program | 12 | 18 | 19 |
| Office of Research Administration | 13 | 12 | 12 |
| Office of Administrative Management | 13 | 12 | 12 |
| Intramural Science Program | 5 | 7 | 7 |
| Total | 46 | 53 | 54 |
| Includes FTEs which are reimbursed from the NIH Roadmap for Medical Research FTEs supported by funds from Cooperative Research and Development Agreements | | | |
| | (0) | (0) | (0) |
| FISCAL YEAR | Average GM/GS Grade | | |
| 2003 | 11.9 | | |
| 2004 | 12.3 | | |
| 2005 | 12.8 | | |
| 2006 | 13.7 | | |
| 2007 | 13.7 | | |

NATIONAL INSTITUTES OF HEALTH
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Detail of Positions

| GRADE | FY 2005 Actual | FY 2006 Appropriation | FY 2007 Estimate |
|---|-------------------|--------------------------|---------------------|
| ES-6 | 0 | 0 | 0 |
| ES-5 | 0 | 0 | 0 |
| ES-4 | 0 | 0 | 0 |
| ES-3 | 0 | 0 | 0 |
| ES-2 | 0 | 0 | 0 |
| ES-1 | 0 | 0 | 0 |
| Subtotal | 0 | 0 | 0 |
| Total - ES Salary | \$0 | \$0 | \$0 |
| GM/GS-15 | 4 | 9 | 10 |
| GM/GS-14 | 12 | 16 | 16 |
| GM/GS-13 | 8 | 11 | 11 |
| GS-12 | 4 | 4 | 4 |
| GS-11 | 3 | 5 | 5 |
| GS-10 | 0 | 0 | 0 |
| GS-9 | 4 | 7 | 7 |
| GS-8 | 0 | 1 | 1 |
| GS-7 | 0 | 0 | 0 |
| GS-6 | 0 | 0 | 0 |
| GS-5 | 0 | 0 | 0 |
| GS-4 | 0 | 0 | 0 |
| GS-3 | 0 | 0 | 0 |
| GS-2 | 0 | 0 | 0 |
| GS-1 | 0 | 0 | 0 |
| Subtotal | 35 | 53 | 54 |
| Grades established by Act of July 1, 1944 (42 U.S.C. 207): | | | |
| Assistant Surgeon General | | | |
| Director Grade | | | |
| Senior Grade | 0 | 0 | 0 |
| Full Grade | | | |
| Senior Assistant Grade | | | |
| Assistant Grade | | | |
| Subtotal | 0 | 0 | 0 |
| Ungraded | 20 | 22 | 22 |
| Total permanent positions | 35 | 53 | 54 |
| Total positions, end of year | 43 | 58 | 58 |
| Total full-time equivalent (FTE) employment, end of year | 46 | 53 | 54 |
| Average ES level | - | - | - |
| Average ES salary | \$0 | \$0 | \$0 |
| Average GM/GS grade | 12.8 | 13.7 | 13.7 |
| Average GM/GS salary | \$85,706 | \$89,134 | \$92,789 |

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

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

New Positions Requested

| | FY 2007 | | |
|------------------------------|---------|--------|---------------|
| | Grade | Number | Annual Salary |
| Health Science Administrator | GS-14 | 1 | \$106,000 |
| Total Requested | | 1 | \$106,000 |