I am pleased to present the Congressional Justification of the National Institutes of Health (NIH) FY 2007 Budget Request, including the Annual Performance Plan and the Annual Performance Report, as required by the Government Performance and Results Act of 1993. This budget request supports the President's and Secretary's priority initiatives and the goals and objectives in the HHS FY 2004-2009 Strategic Plan.

In formulating the FY 2007 Budget, we faced many tough choices. To best preserve our investment in biomedical research and to support research for medical advancements that will improve the length and quality of human life, we have chosen to carefully invest in several trans-NIH strategic initiatives

I strongly believe that it is more important than ever to invest in our future. NIH must nurture a vibrant, creative research workforce, including sufficient numbers of new investigators with new ideas and new skills, such as interdisciplinary research skills. In FY 2007. NIH will begin the new K/R "Bridges to independence" program to increase our support of new investigators.

Wc plan lo continue to increase NIH support for the Roadmap in FY 2007. The NIH Roadmap is an incubator for new ideas and initiatives that will accelerate the pace of discovery. These initiatives are focused on efforts that no single or small group of Institutes or Centers could conduct on their own. These initiatives are transforming; they have fostered synergies and led to other transforming initiatives within NIH.

NIH will undertake a study of Genes, Health and the Environment lo accelerate discovery of the major genetic factors for diseases that have a substantial public health impact.

NIH continues to be proactive in its efforts to transform and modernize the management of NIH, and to improve Irans-NIH scientific coordination. The Office of Portfolio Analysis and Strategic Initiatives will play a key role in ensuring that barriers to effective research programs are reduced, enhancing our scientific networking and working to reduce unnecessarily duplicative programs. Using the Roadmap as a starting base, the Office will use a common fund for activities/efforts identified through a transparent planning process.

The development of this performance budget request was consistent with the Government Performance and Results Act (GPRA). NIH used GPRA and many other performance monitoring tools, such as peer review, site visits, and performance-based contracting to continually assess program performance and lo plan future research programs. Our effectiveness has been recognized by the Office of Management and Budget through the Performance Assessment Rating Tool (PART) in four NIH programs that have been assessed to date—the AIDS Research Program, which was scored as moderately effective, and the Extramural Research Program, Intramural Research Program, and Buildings and Facilities Program, which were scored as effective.

The NIH is one of the world's foremost centers for the conduct and support of medical research, and thanks to the support of the Secretary and the President, the research NIH conducts and supports today will be the basis for countless future advances in science and improvements in health. In the upcoming budget hearings, I look forward to discussing how we can maintain the momentum of discovery, as exemplified by the Nil I Roadmap for Biomedical Research, and to working with you to enact a budget that allows NTH to best continue its mission to uncover new knowledge that will lead to better heajth for everyone through performance-based budgeting.

Elins A. Zerhouni, M.D.

Statement of the National Institutes of Health Mission

The NIH mission is to uncover new knowledge that will lead to better health for everyone.

The National Institutes of Health (NIH) accomplishes its mission through one overarching program: Research. NIH probes the unknown to gain new knowledge; communicates and transfers new knowledge to the public and health care providers; trains investigators; and manages and supports the people, systems, and facilities necessary to carry out this work. These activities are integral elements of the research enterprise with the goal of adding to the body of knowledge that will help prevent, detect, diagnose, and treat disease and disability.

The NIH research mission is pursued by an array of Institutes and Centers (ICs), which support and conduct research through an extensive extramural research community and the intramural research program.

The institutes and centers

NIH is composed of 27 institutes and centers, whose research activities extend from basic research that explores the fundamental workings of biological systems and behavior, to studies that examine disease and treatments in clinical settings, to prevention, and population-based analyses of health status and needs. The Office of the Director, NIH, provides leadership, oversight, and coordination for the enterprise.

The ICs are the NIH "visible" to most Americans. While some of the ICs focus on specific diseases (e.g., cancer, diabetes), others concentrate on organ systems (e.g., heart, eye, kidney); focus on a stage of life (e.g., children, the aging population); or address overarching opportunities (e.g., deciphering the human genome, understanding cellular biology) and technologies (e.g., biomedical imaging). ICs support research and training through extramural activities and also conduct "in-house" science and training through intramural activities.

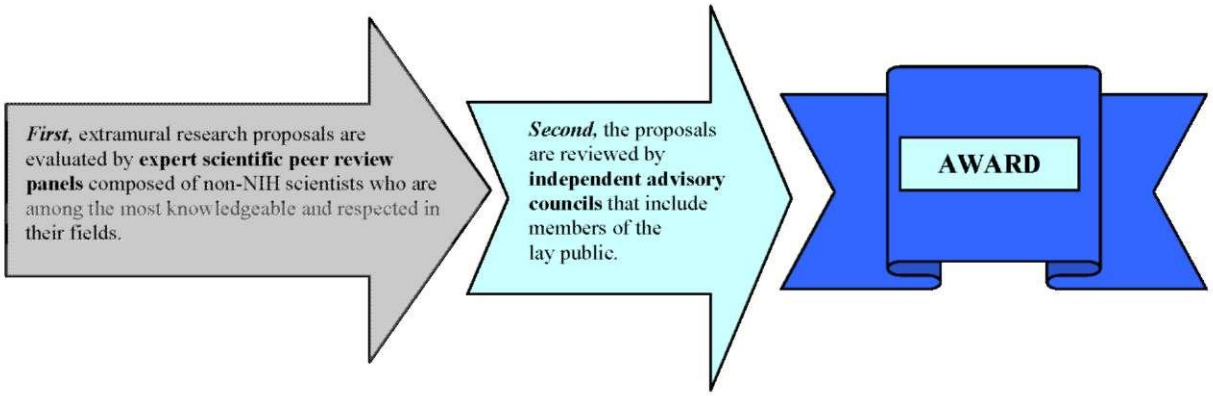
The Extramural Community

The extramural community is composed of non-Federal scientists at universities, medical centers, hospitals, and research institutions throughout the country and abroad. With NIH support, these investigators and their institutions conduct the vast majority of research that leads to improvements in the prevention, detection, diagnosis, and treatment of disease and disability. In tandem with the conduct of research, the extramural community also contributes to training the next generation of researchers, enhancing the skills and abilities of established investigators, and renewing the infrastructure for NIH-sponsored research.

More than $8 out of every $10 appropriated to NIH flows out to the scientific community at large. The extramural research community numbers more than 200,000 scientists and research personnel affiliated with over 3,100 organizations, including universities, medical schools, hospitals, and other research

facilities located in all 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad.

NIH funds are awarded through a highly competitive process to the most promising and productive scientists as illustrated below. This two-tiered independent review system is critical to ensuring that the best proposals are funded from the approximately 68,000 research and training applications NIH reviewed in FY 2005.



NIH'S Intramural Laboratories

A much smaller fraction of NIH funds, approximately 10 percent of the budget, supports a core program of basic and clinical research activities administered and staffed by NIH physicians and scientists known as the intramural research program. Approximately 1,250 principal investigators lead intramural research projects. This in-house research program includes the NIH Clinical Center, research facilities in Montana, and other resources that provide scientific, clinical, and educational benefits to citizens of the United States and the world.

NIH ensures that the research conducted in its intramural laboratories is of the highest caliber. Each IC maintains a board of scientific counselors, composed of external experts, that reviews the intramural programs and makes recommendations to the Institute Director. The intramural program enables scientists to apply the results of laboratory research to patient care and to seek answers in the laboratory to questions that arise in the clinical setting, permitting a two-way process of the translation of scientific discovery to solving clinical problems and vice versa. This national resource permits NIH to respond rapidly to critical health problems and emergencies and take advantage of emerging opportunities.

Public Input and Outreach

As the single most influential force in the U.S. biomedical research community, NIH exercises its leadership by continually surveying public health needs and the scientific landscape to identify new problems that require attention and new opportunities for progress. To develop and maintain a research portfolio that is responsive to both public health need and scientific opportunity, NIH seeks input through multiple channels, including the Advisory Committee to the Director, the NIH Council of Public Representatives, the many Institute Advisory Councils, and numerous scientific peer-review groups. NIH drew on the expertise of more than 34,048 consultants in FY 2005. These non-governmental advisors include substantial numbers of public members. For example, one-third of Advisory Council members are public representatives.

The general public has direct access to a wealth of reliable and readily understandable health information through a variety of NIH contact points, including the very popular NIH web site (www.nih.gov). A new feature of the NIH site is a talking web site with formats and topics tailored to the needs of older people (www.NIHSeniorHealth.gov). Also featured on the NIH home page is a web site providing patients, their families, and providers with convenient access to information on clinical trials. In 2004, this website (www.clinicaltrials.gov) won the prestigious Innovations in American Government Award.

Discussion of NIH Strategic Goals

Every activity at NIH is carried out in support of NIH's mission: *To uncover new knowledge that will lead to better health for everyone.* For the purpose of planning and performance assessment, the NIH achieves its mission through a single program—**Research.** Under this program, NIH carries out activities in five functional areas. They are presented below along with representative trans-NIH performance goals and budgets for each which are reported in the Detailed Performance Tables.

In addition to supporting Agency goals, the NIH budget request supports the HHS Strategic Plan, the President's Management Agenda, HHS 20 Department-Wide Objectives, and Healthy People 2010 (See Detailed Performance Tables). In particular, NIH substantially contributes to the following HHS Strategic Goals:

- Goal 2: Enhance the ability of the Nation's healthcare system to effectively respond to bioterrorism and other public health challenges.
- Goal 4: Enhance the capacity and productivity of the Nation's health science research enterprise.
- Goal 8: Achieve excellence in management practices.

One functional area is Scientific Research Outcomes. The goals in this area are representative of the full NIH portfolio and reflect a trans-NIH approach to establishing goals. The goals are presented in a matrix that reflects low- to high-risk *(risk = difficulty in obtaining the goal)* and the number of years the agency estimates that it will take to attain the goal. The other four functional areas include performance goals which are representative of activities that enable research and its management. Detailed performance goal narratives can be found in the supplement. The graphic at the end of this section shows the "drivers" or the components of each functional area. Each of the performance goals encompasses either intramural or extramural research activities or both, and they are all aligned with the agency mission.

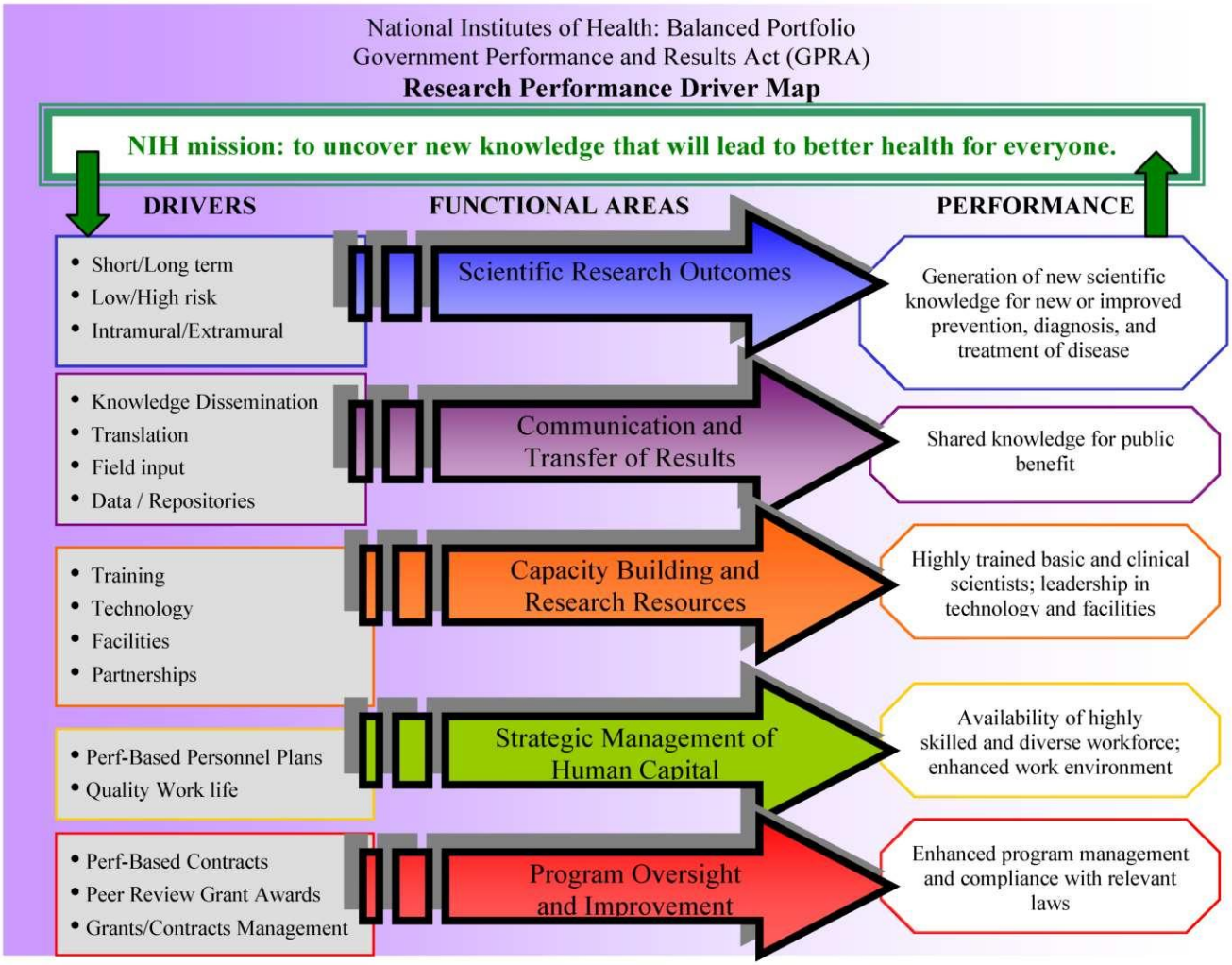
- *Scientific Research Outcomes (SRO).* NIH research encompasses the support and conduct of investigations across the full range of the health research continuum, including basic research, which may be disease oriented or related to the development and application of breakthrough technologies; observational and population-based research; behavioral research; prevention research; health services research; translational research; and clinical research. Clinical research includes research to understand both normal health and disease states, translational research which involves the application of laboratory findings to clinical interventions, as well as research on new treatments or prevention strategies.

- *Communication and Transfer of Results (CTR).* The new knowledge resulting from NIH research activities cannot benefit human health unless the information is disseminated. Thus, a core NIH function is to facilitate the communication of research findings—both in the U.S. and abroad—to clinicians, public health systems, voluntary health organizations, and the public at large. Scientific knowledge is the bedrock of evidence-based prevention and treatment programs. The diversity of the U.S. population means that effective communication requires varied approaches. Equally important is transferring knowledge to the private sector to be used in the development of new interventions, behavioral strategies, medications, biomedical technologies, and devices that lead to better health.

- *Capacity Building and Research Resources (CBRR).* The productivity of the research enterprise depends in large measure on the strength of the talent pool and on the technological and other research resources available for use in investigations. Support for pre-doctoral and postdoctoral research training replenishes and revitalizes the talent pool with new, highly trained investigators. Support for career development hones and expands the skills of those already performing research. In building capacity in the talent pool through training and career development, NIH particularly strives to augment the ranks of clinical researchers, enhance diversity, to ensure well-trained foreign collaborators, and to facilitate scientists' aptitude for multidisciplinary teamwork. Capacity building also encompasses improving and maintaining the Nation's biomedical research infrastructure. Also fundamental to the productivity of the research enterprise are the availability and accessibility of essential research tools, cutting-edge technologies, animal models, reagents, and databases and other information repositories. This is because optimal research resources set the boundaries for what questions can be investigated. Within research resources, information technology requires special notice. New technologies to share, transfer, and mine vast amounts of complex data electronically are revolutionizing the conduct of science and the management, administration, and support of the research enterprise.

- *Strategic Management of Human Capital (SMHC).* NIH recognizes human capital as one of the most important resources of the organization. A qualified workforce, working in an environment that utilizes its strengths, fosters the effective and efficient implementation of the NIH research program. NIH aims in this area include delayering, competitive sourcing, and developing a plan for strategic recruitment and retention, as well as planning for continuity and leadership succession.

- *Program Oversight and Improvement (POI).* Ensuring that NIH activities and strategies are carried out effectively and in compliance with all applicable laws and regulations requires careful oversight and thoughtful improvement in procedures, policies, and systems. Management systems need to be continually reviewed and updated to keep pace with advances in public administration, and mechanisms to ensure proper stewardship must evolve with the development of new requirements and rising thresholds for accountability. Meeting these challenges is a priority for NIH.


National Institutes of Health: Balanced Portfolio
Government Performance and Results Act (GPRA)
Research Performance Driver Map
NIH mission: to uncover new knowledge that will lead to better health for everyone.
DRIVERS
FUNCTIONAL AREAS
PERFORMANCE
• Short/Long term
• Low/High risk
• Intramural/Extramural
Scientific Research Outcomes
Generation of new scientific knowledge for new or improved prevention, diagnosis, and treatment of disease
• Knowledge Dissemination
• Translation
• Field input
• Data / Repositories
Communication and Transfer of Results
Shared knowledge for public benefit
• Training
• Technology
• Facilities
• Partnerships
Capacity Building and Research Resources
Highly trained basic and clinical scientists; leadership in technology and facilities
• Perf-Based Personnel Plans
• Quality Work life
Strategic Management of Human Capital
Availability of highly skilled and diverse workforce; enhanced work environment
• Perf-Based Contracts
• Peer Review Grant Awards
• Grants/Contracts Management
Program Oversight and Improvement
Enhanced program management and compliance with relevant laws

Links to HHS and NIH Strategic Goals

The table below presents the NIH GPRA Goals support of the HHS Strategic Goals.

	HHS Strategic Goals							
NIH GPRA Goals	Goal 1: Reduce the major threats to the health and well-being of America	Goal 2: Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges	Goal 3: Increase the percentage of the Nation's children and adults who have access to health care services, and expand consumer choices	Goal 4: Enhance the capacity and productivity of the Nation's health science research enterprise	Goal 5: Improve the quality of health care services	Goal 6: Improve the economic and social well-being of individuals, families, and communities, especially those most in need	Goal 7: Improve the stability and healthy development of our Nation's children and youth	Goal 8: Achieve excellence in management practices
Scientific Research Outcomes (SRO)								
SRO-1.1: By 2007, conduct medications development using animal models and begin conducting Phase I and II human trials of two potential treatments for alcoholism: the cannabinoid antagonist rimonabant and the corticotropin-releasing hormone antagonist antalarmin.	X			X				
SRO-1.2: By 2006, develop one or more prototypes for a low-power, highly directional hearing aid microphone to help hearing-impaired persons better understand speech in a noisy background.				X		X		
SRO-1.2.3: By 2006, develop methods that can classify at least 75% of proteins from sequenced genomes according to evolutionary origin and biological structure.				X				
SRO-2.2: By 2009, evaluate the efficacy of two novel approaches to prevent weight gain and/or treat obesity in clinical trials in humans.	X			X				
SRO-2.4: By 2009, the Laboratory of Symptom Management will develop and test multidisciplinary biobehavioral interventions to prevent/attenuate disease- and treatment-related symptoms such as pain,fatigue, and psychological distress, to reduce related symptom burden and to increase functional status and quality of life.				X				
SRO-2.3.2: By 2010, develop one universal antibiotic effective against multiple classes of biological pathogens.		X		X				
SRO-2.3.4: By 2010, develop an HIV/AIDS vaccine.	X			X				
SRO-3.1: By 2013, identify at least one clinical intervention that will delay the progression, delay the onset, or prevent Alzheimer's disease (AD).				X		X		
SRO-3.2.1: By 2015, evaluate islet transplantation in combination with immune modulation strategies for the treatment of type 1 diabetes in clinical trials.				X				
SRO-3.3: By 2013, determine the efficacy of using salivary diagnostics to monitor health and diagnose at least one systemic disease.				X				
SRO-3.5: By 2013, identify and characterize at least 2 human candidate genes that mutually influence risk for substance use disorders and risk for comorbid psychiatric disorders using high-risk family, twin, and special population studies.	X			X				
SRO-3.6: By 2012, develop and apply clinically one new imaging technique to enable tracking the mobility of stem cells within cardiovascular tissues.				X				
SRO-4.2: By 2005, develop improved animal models that best recapitulate Parkinson's disease (PD) based on emerging scientific findings of genetic or environmental influences or interactions of genes and the environment on the development of PD.				X				
SRO-4.5.1: By 2007, evaluate the efficacy of three new treatment strategies for HIV infection in clinical trials in an effort to identify agents or combinations of agents that are more effective, less toxic, and/or simpler to use than current recommended HIV treatment regimens.				X				
SRO-4.5.4: By 2007, identify 20 small molecules that are active in models of nervous system function or disease and show | | - d i l l . - -|ll_-|o l|. ,- Ml "I | ,|.|, |oo|				X				
SRO-5.2: By 2009, determine the efficacy of statins in preventing the progression of atherosclerosis in children with systemic lupus erythematosus (SLE, or lupus).				X				
SRO-5.3: By 2009, expand the range of available methods used to create, analyze, and utilize chemical libraries, which can be used to discover new medications. Specifically, use these chemical libraries to discover 10 new and unique chemical structures that could serve as the starting point for new drugs.				X				
SRO-5.5: By 2008, develop and test new evidence-based treatment approaches for drug abuse in community settings.	X		X					
SRO-5.6: By 2009, identify 1 or 2 new medication candidates to further test and develop for the treatment of tobacco addiction.				X				
SRO-5.7: By 2010, validate and compare 4 imaging methods of assessing lung cancer response to therapy.				X				
SRO-5.8: By 2010, improve device(s) to measure hot flashes and test device(s) in clinical trials.				X				
SRO-5.9: By 2010, establish the role of genetic factors in three major diseases for which health disparities are noted between populations.			X					
SRO-6.1: By 2012, identify the genes that control the risk of development of age-related macular degeneration (AMD) and glaucoma in humans.				X		X		
SRO-6.2: By 2011, assess the efficacy of at least three new treatment strategies to reduce cardiovascular morbidity/mortality in patients with type 2 diabetes and/or chronic kidney disease.	X			X				
SRO-6.3: By 2012, develop a knowledge base on chemical effects in biological systems using a systems toxicology or toxicogenomics approach.				X				
SRO-6.4: By 2014, identify and characterize two molecular pathways ofpotential clinical significance to serve as the basis for discovering new medications for preventing and treating asthma exacerbations.				X				
SRO-7.2: By 2006, integrate nanotechnology-based components into a system capable of detecting specific biomarkers (molecular signatures) to establish proof of concept for a new approach to the early detection of cancer and, ultimately, cancer preemption.				X				
SRO-7.3: By 2005, create the next-generation map of the human genome, a so-called haplotype map ("HapMap"), by identifying the patterns of genetic variation across all human chromosomes.				X				
SRO-7.8.1: By 2007, determine the genome sequences of an additional 45 human pathogens and 3 invertebrate vectors of infectious diseases.	X	X		X				
SRO-7.8.3: By 2006, build a publicly accessible Collection of Reference Sequences (RefSeq Collection) to serve as the basis for medical, functional, and diversity studies. A comprehensive RefSeq Collection will serve as a foundation for genomic research by providing a centralized, integrated, nonredundant set of sequences, including genomic deoxyribonucleic acid (DNA), ribonucleic acid (RNA) transcript, and proteome (protein product) sequences, integrated with other vital information for all major research organisms.				X				

SRO-8.2: By 2009, identify and characterize two molecular interactions of potential clinical significance between bone-forming cells and components of bone. Such interactions are defined as those having significant impact on the accrual of bone mass or the actual mechanical performance of bone (i.e., fracture resistance) in laboratory animals.				X		X		
SRO-8.4: By 2009, assess the impact of two major Institutional Development Award (IDeA) Programs on the development of competitive investigators and their capacities to compete for NIH research funding.				X				
SRO-8.5: By 2009, develop an item bank and computerized adaptive testing system available to clinical researchers to improve assessment of non-specific symptoms (e.g., pain and fatigue) and other domains of health-related quality of life in chronic disease.				X				
SRO-8.6: By 2011, develop stable national estimates of vision impairment by extending the vision component of the National Health and Nutrition Examination Survey (NHANES).				X				
SRO-8.9.1: By 2010, demonstrate through research a capacity to reduce the total years lost to disability (YLDs) in the United States by 10% by (1) developing treatment algorithms to improve the management of treatment-resistant and recurrent depression and (2) elucidating the mechanisms by which depression influences at least two comorbid physical illnesses (e.g., heart disease, cancer, Parkinson's disease, or diabetes).				X		X		
SRO-8.9.2: By 2010, identify culturally appropriate, effective stroke prevention programs for nationwide implementation in minority communities.	X		X	X				
SRO-9.3: By 2012, create a database and analytical software that illustrates the progression of normal MRI measurement of brain development in a nationally representative sample of children in the United States.				X			X	
Communication and Transfer of Results (CTR)								
CTR-1: By 2008, reduce the disparity between African American and white infants in back sleeping by 50% to further reduce the risk of sudden infant death syndrome (SIDS).			X	X			X	
CTR-2: By 2006, increase awareness among the general public about the symptoms of stroke and the need to seek treatment rapidly by partnering with providers and volunteers in at least five communities and extending the impact of the National Institute of Neurological Disorders and Stroke campaign "Know Stroke. Know the Signs. Act in Time."	X			X				
CTR-3: By 2006, through education and technical assistance, strengthen the capacity of developing countries to identify technologies and pursue their development into products.				X				
CTR-4: By 2008, increase the percentage of Small Business Innovation Research (SBIR) Program award recipients who are successful in identifying the resources and/or partners necessary to further the development of their SBIR projects toward commercialization.				X				
CTR-5: By 2013, improve marketing and management of NIH intellectual property (IP) assets by building data mining capability.				X				X
Capacity Building and Research Resources (CBRR)								
CBRR-1: Recruit, train, and retain a diverse population of highly trained scientists in biomedical, behavioral, and clinical research using research training grants, fellowships, career development awards, and student loan repayment programs.				X				
CBRR-2: Promote data sharing and provide information in real time by implementing the NIH Business System.								X
CBRR-3: Streamline business processes and automate data movement by implementing the Clinical Research Information System (CRIS).					X			X
CBRR-4: Provide greater functionality and more streamlined processes in grants administration by continuing to develop the NIH electronic research administration (eRA).								X
CBRR-5: By 2010, expand by 50% the pool of researchers trained in biomedical informatics by increasing the numbers oof informatics-trained graduates in basic biomedical sciences, clinical medicine, and public health.				X				
Strategic Management of Human Capital (SMHC)								
SMHC-3: Improve the strategic management of NIH resources by developing a comprehensive human capital plan based on the Agency's programmatic objectives and projected future needs.								X
SMHC-4: Ensure that NIH commercial functions are performed as efficiently and cost-effectively as possible by conducting competitive sourcing reviews on the required number of functions within the Agency's commercial inventory.								X
SMHC-5: Improve and monitor the use of human resource services by providing real-time access to tools via the NIH Portal.								X
Program Oversight and Improvement (POI)								
POI-1: Ensure that approved design and construction projects are executed on time, on scope, and on budget by implementing an Earned Value Analysis and Management System (EVAMS).								X
POI-2: Expand the use of Performance-Based Contracting (PBC).								X
POI-4: Ensure proper stewardship of public funding for research.								X
POI-5: By 2010, enhance NIH's ability to demonstrate benefits for extramural research investments through changes to policy and information systems.								X
POI-6: Provide responsibility stewardship over existing federally owned real property assets.								X
POI-7: Manage design and construction of capital facility projects funded by the building and facilities appropriation (B&F) so the HHS and congressionally approved scope of work is delivered within the appropriate budget.								X
POI-8: Protect NIH's interest in real property supported under the extramural construction grant program throughout each phase of the project. (ongoing)								X

Note: New goals are in italics.

HHS 20 Department-Wide Objectives

NIH supports 18 of the 20 the HHS department-wide objectives. NIH is primarily responsible for objective #5 Advance Medical Research and objective #15 Promote Quality, Relevance and Performance of Research and Development Activities. NIH's support of these objectives is represented by the NIH performance goals and other related research and management activities.

Overview of NIH Performance

NIH supports a balanced portfolio of research, and its performance goals and targets are representative of that portfolio. Given the unpredictable nature of scientific discovery, NIH continually adjusts its targets to reflect the latest developments in science. NIH reports on performance by presenting a story of scientific discovery, including the background (burden of disease), rationale for the goal, planned

implementation strategies, baseline data, summary of performance, targets and target adjustment to enhance goal achievement, and other highlights.

Although decisions regarding the development and implementation of performance goals are made at the NIH level, the development of specific goals and their administration occurs at the IC level using a formal goal replacement strategy. This strategy requires that each new performance goal be based on Research and Development Investment (R&D) criteria, be representative, measurable, trans-NIH, meaningful to researchers, public, and NIH stakeholders, and have an estimated date of completion. Also, the goal should lend itself to annual reporting, allow linkage of budget with performance, be able to appear in managers' performance plans, and tie to one of the objectives found in Healthy People 2010 (http://www.healthypeople.gov/), the FY 2004-2009 HHS Strategic Plan (http://aspe.hhs.gov/hhsplan/), and/or the President's Management Agenda (http://www.whitehouse.gov/omb/budintegration/pma_index.html). Many of the NIH performance goals also support the HHS Secretary's 500-Day Plan (http://www.hhs.gov/500DayPlan/). The selection of performance goals and targets are guided by the following criteria:

- *Research and Development (R&D) Investment Criteria.* The NIH performance goals are consistent with the OMB R&D Investment Criteria. These criteria - *relevance, quality,* and *performance* - are considered in the development of NIH performance goals and associated targets.

  The first criterion—relevance—is addressed in several ways as it relates to research. One way is in setting research priorities—by considering public health needs, as judged by the incidence, severity, and cost of specific disorders as a key factor in determining areas of research support. Relevance is also ensured by seeking the views of the public on NIH's research agenda(s). This occurs through meetings of advisory councils and/or boards that include representatives of the public, by publishing research plans for public comment, and by meeting with representatives of patient groups and presenting NIH research plans and seeking feedback. In addition, to help ensure that the results of research reach the hands of those who can put the information to practical use, relevance is also considered when developing and disseminating educational materials or implementing public education campaigns based on results from NIH-funded research.

  Quality—the second criterion—is embodied by a commitment on the part of NIH to support work of the highest scientific caliber. NIH ensures quality through the peer review process for grants, and the principles guiding this review for scientific merit are contained in the Public Health Service Scientific Peer Review regulations. Peer review takes place in multiple steps. The initial step of the peer review process takes place in Scientific Review Groups or study sections, and the second level of peer review is carried out by the National Advisory Councils. A major effort has been underway at NIH to reorganize many of these review groups to keep pace with the ever-changing landscape of science, thus helping to ensure the quality of peer review.

  The third criterion—performance—is key to each and every R&D goal set by NIH. Once priorities are set, peer review occurs, and funding decisions are made, performance on NIH grants and contracts is monitored on a regular basis. For example, grantees must submit annual progress reports which are reviewed to assess their performance, and follow-up actions are taken when necessary. In addition, there are other oversight mechanisms for reviewing progress such as site visits conducted by NIH staff. NIH also conducts state-of-the-science reviews, workshops, and

other scientific meetings where knowledge in a particular area of research is reviewed, and scientific progress and performance are assessed.

- *Balanced Portfolio of Goals (Risk and Time).* The continuum of scientific discovery affirms the need for a balanced portfolio of goals, ranging from low- to high-risk, and short- to long-term. NIH presents its scientific research outcome goals in a matrix framework (See GPRA Performance Goal Narratives by Five Functional Areas) to show the nature and extent of its portfolio.

- *Goal Selection Criteria.* NIH selected 36 specific, representative research goals as proxies for performance on the larger, research portfolio. As noted above, the goals were selected based on the following criteria:

  - The goals are representative, not comprehensive; that is, taken together the goals represent the breadth of NIH's portfolio. The goals address basic, prevention, diagnostic, and treatment research.

  - The goals are objective; that is, they permit a comparison between the actual achievement level and that targeted by the performance goal.

  - The goals are reportable; that is, they lend themselves to annual reporting, including incremental progress.

  - The goals are not obviously attainable; that is, they must be recognized as something that *could* be achieved in the future, but may not be reachable for any number of reasons—the unpredictable progress of science, funding, and/or development of new tools needed to achieve the goal.

  - The goals are as specific (e.g., to a disease or definable problem) as possible, with reference to a metric and/or a date for progress/completion, as appropriate.

  - The goals are meaningful; that is, they will be credible to the research community and the public; and they are important to the NIH and its research mission.

- *Adjusting Targets.* The target-based approach for science requires flexibility to reflect the discovery process. If a target is adjusted, it incorporates new knowledge and indicates enhanced performance to reflect progress in achieving the goal.

- *Budget/Performance Integration.* The required specific scientific focus of the performance goals does not lend itself to NIH level allocation of funds. Priority setting and funding occur below the NIH level penumbra. To achieve specificity, particular performance goals are created by program staff and funded at the Institute level with multiple contributors. Often, the specificity of the goal is not captured at the level of the multiple contributing Institutes' penumbra either, since many are supported by grants and contracts. However, every performance goal is treated as a priority, performance is diligently monitored, and budgets are adjusted to facilitate the best possible outcome.

Once a goal is created, the lead and contributing Institutes/Centers (ICs) coordinate on performance monitoring and funding throughout the duration of the goal. The ICs work closely with the NIH GPRA office and Office of Budget to report performance and funding levels.

Reporting Approach

NIH categorizes performance in the GPRA Plan under five functional areas with representative trans-NIH performance goals and annual targets for each.

ERFORMANCE GOALS BY FUNCTIONAL AREA SUMMARY TABLE

FUNCTIONAL AREA PERFORMANCE GOALS

	FY03	FY04	FY05	FY06	FY07
Scientific Research Outcomes	27	28	36	34	31
Communication and Transfer of Results	1	4	5	5	3
Capacity Building and Research Resources	2	4	5	5	5
Strategic Management of Human Capital	3	2	3	3	3
Program Oversight and Improvement	3	3	7	6	6
Totals	36	41	56	53	48

A longer narrative about each performance goal is described in the Detail Performance Analysis Tables. The goal narratives begin with background text to provide scientific context, including disease burden, and rationale for the goal. Implementation strategies are presented to demonstrate the starting point for this goal. This section highlights the budget-performance integration. A table that presents the annual target(s) and baseline(s) NIH uses to measure performance on the goal follows. When scientific discovery mandates a change in the target, the adjusted target is presented in the same box as the original. FY 2007 targets were added to each goal that is active in 2007. The year the goal ends, the goal becomes the expected annual target for that year. Rationales for adjusted FY 2006 targets are presented if applicable. The FY 2005 performance summary is provided with target achievements, and with highlights of implementation strategy advances. If a target is achieved efficiently, a short narrative description is provided and a subscript "e" on the performance summary table. Finally, at the end of the narrative, it indicates whether the goal was included in an OMB Program Assessment Rating Tool (PART). Unless stated otherwise, NIH plans to move forward with the proposed annual targets and implementation strategies within the context of the proposed budget.

Significant Accomplishments of Performance Goals

NIH has a strong track record of meeting its annual performance targets and, ultimately, of achieving its performance goals. In FY 2005, NIH had 56 active goals with 79 annual performance targets. NIH met 77 of its annual targets (including two extended FY04 targets) with 27 met efficiently as retrospectively reported. Targets that are met efficiently were met before the expected completion date, resulted in more product than expected, or required fewer funds for expected activity. Four of the FY 2005 performance targets were extended until a future date. One FY04 extended target was not met due to a sound scientific justification. Details on the annual performance targets for each performance goal can be found in the Detailed Performance Analysis Tables later in the document.

Fifteen of the current performance goals will be achieved in FY 2005, FY 2006, or FY 2007; therefore, 16 new performance goals were added to the GPRA FY 2007 performance plan. Ten of the goals are scientific research outcomes, one is a communication and transfer of results goal, one is capacity

building and research resources goal, and the remaining four are program oversight and improvement goals. These new goals begin in FY 2005, FY 2006, or FY 2007.

Specific accomplishments on current performance goals are highlighted below:

Scientific Research Outcomes

- *International HapMap Project Successfully Completed by Identifying the Patterns of Genetic Variation Across All Human Chromosomes.* A major goal of genetic research is to identify gene variants that contribute to disease. Finding these variants allows an understanding of the disease process, thus enabling development of methods for disease prevention and treatment. The human haplotype map (HapMap) is a tool that can be used by researchers studying many diseases to find, much more efficiently and comprehensively, regions with gene variants that affect health and disease risk. In FY 2005, a first-pass draft HapMap was completed with 1.007 million single nucleotide polymorphisms (SNPs), sites in the genome where individuals differ in their DNA spelling by a single letter. This is an increase of more than 400,000 SNPs over the projected total of 600,000 at the project's inception. In addition, genotyping has been attempted on an additional 4.7 million SNPs. The data have been released on the HapMap web site. A paper describing the results of this landmark study was published in the October 27, 2005 issue of the journal Nature. (See GPRA Goal SRO-7.3)

- *Using Nanotechnology to Develop New Approaches to Cancer Detection and Preemption.* Recent advances in understanding the molecular basis of cancer and the associated development of novel molecular technologies in areas such as proteomics portend a future where cancer can be detected early and preempted before it spreads, perhaps on an individual basis. Applications of nanotechnology have the potential to shift the paradigm of cancer toward earlier detection and prevention and provide a new platform for eventual high-throughput diagnostics and, ultimately, real-time monitoring of patients. NIH established the national Nanotechnology Characterization Laboratory (NCL) that will enable development of essential data about the profiles of nanoparticles in biological systems. In FY 2005, NIH-supported research integrated nanoparticles and nanosensors into a platform technology for development in an applied research setting. (See GPRA Goal SRO-7.2)

- *Directional Microphone Developed to Help Hearing-Impaired Individuals.* NIH-supported scientists successfully combined a microphone's diaphragm and electronic circuitry to produce a directional microphone, which will ultimately help hearing aid users to better understand speech in a noisy background, such as in a crowded room. This directional microphone mimics the auditory system of the parasitic fly *Ormia ochracea.* The fly's auditory system is an excellent model to imitate because its mechanically coupled ears enable it to detect the direction of sound. This biological feature suggested a way to miniaturize a directional microphone for use in hearing aids. The scientists are using silicon microfabrication technology to make a directional microphone that is small enough to be potentially incorporated into a hearing aid. (See GPRA Goal SRO-1.2)

- *Identifying New Medication Candidates to Treat Tobacco Addiction.* Tobacco addiction is a preventable cause of disease and death, and the identification and development of candidate medications for smoking cessation are critical for improving public health. NIH-supported scientists have identified four candidate medications for tobacco addiction: selegiline, nicotine

vaccine, and two compounds that enhance GABA, chemicals in the brain responsible for signaling between neurons -- CGP44532 and tiagabine. These candidate medications all have the potential to aid in smoking cessation through their ability to counteract the effects of cigarette smoking on the brain. For example, selegiline acts by inhibiting an enzyme which is thought to be involved in the development of negative mood effects during withdrawal. The GABA agonists reduce the effects of nicotine on the pleasure pathway in the brain. The nicotine vaccine would prevent nicotine from reaching the brain, thereby preventing its effects on the brain and behavior. (See GPRA Goal SRO-5.6)

- *Salivary Diagnostics Developed to Monitor Health and Diagnose Systemic Diseases.* NIH is building a rapid, efficient and cost-effective system to simultaneously analyze multiple substances found in human saliva. Scientists and engineers developed microchip immunoassays to help detect important analytes such as C-reactive protein, IL-1-beta, TNF-alpha, and IL-8 in human saliva. This past year integrated microfluidic assay systems were developed that quantify C-reactive protein in saliva. These systems have been able to detect C-reactive protein at relatively low levels, enabling researchers to compare salivary levels of C-reactive protein in healthy subjects to those in subjects with inflammatory conditions. The development of fully integrated, handheld devices for collecting and analyzing saliva will not only facilitate the detection of known biomarkers, but will also catalyze research efforts to identify new biomarkers for a wider range of oral and systemic diseases and conditions. (See GPRA Goal SRO-3.3)

- *Supporting Genome Sequencing Projects to Design Strategies for Infectious Diseases.* NIH is using genomics to understand the microbes that cause disease and to design strategies to overcome infectious disease. With microbe-specific genome information, drugs can be targeted to specific genes, and the products of specific genes can be incorporated into experimental vaccines. Furthermore, strategies can be devised to counteract genetic mutations that cause a microbe to become drug resistant. NIH made a significant investment in the large-scale DNA sequencing of the genomes of human pathogens and of the invertebrate vectors that harbor them, including microorganisms considered to be potential agents of bioterrorism. As of FY 2005, NIH supported a total of 105 genome projects to sequence pathogen and invertebrate vectors of infectious diseases that include: 88 bacteria, 6 fungi, 9 parasitic protozoan, and 2 invertebrate vectors. (See GPRA Goal SRO-7.8.1)

Communication and Transfer of Results

- *Developing Program of Technical Assistance to Translate Innovations Into Commercially Viable Products.* The Small Business Innovation Research (SBIR) program was initiated to stimulate technological innovation, use small businesses to meet Federal research/research and development (R/R&D) needs, foster participation by disadvantaged persons and women-owned small businesses in technological innovation, and increase private sector commercialization of innovations derived from Federal R/R&D. NIH developed a menu of assistance programs from which SBIR awardees may choose to enroll that will help them augment their ability to commercialize their federally-funded technologies. To achieve this end, modules expected to assist in the commercialization of SBIR products will be piloted and effective pilots will be transitioned into programs. In FY 2005, a pilot of the Niche Assessment Program, which assists with identifying the niche markets for new technologies, was completed with 100 SBIR Phase I participants. Also in FY 2005, 114 SBIR

Phase II awardees completed the trans-NIH Commercialization Assistance Program, and 68 of those presented their business opportunities at an investment forum. (See GPRA Goal CTR-4)

Capacity Building and Research Resources

- *Streamlining Grants Processes by Developing the NIH Electronic Research Administration (eRA).* The eRA is NIH's infrastructure for interactive electronic transactions for the receipt and review of applications, and the monitoring and administration of NIH awards. Converting grants administration to an electronic process will increase the efficiency and lower costs to both NIH and the submitting institutions. The development of eRA incorporates government-wide standards and will integrate with the other NIH, DHHS, and e-grants systems. At the end of FY 2005, 80% of eligible HHS OPDIVs (AHRQ, FDA, SAMHSA and CDC) were using eRA to process new research grants. Approximately 33% of the business processes are now being handled electronically. The pilot for electronic notification was implemented in FY05 and approximately 25% of the progress reports were submitted electronically, and about 75% of the Financial Status Reports were submitted electronically in FY 2005. Internet (electronic) Assisted Review is replacing the paper based review of applications. Although only a small percentage of applications were received electronically, all paper applications are converted to electronic format, and they are processed electronically. (See GPRA Goal CBRR-4)

Strategic Management of Human Capital

- *Consolidation of Human Resource Websites on the NIH Portal.* NIH developed a Human Resources (HR) Community on the NIH Portal that serves as the primary site for NIH employees to access HR information and self-service applications. Content from several websites were moved to the central HR Community Portal for easy access of HR information. Having HR information on one site is making the management of HR information more efficient for the web/portal team. HR also worked with the Center for Information Technology (CIT) to evaluate products that could measure the usage and distinct hits on HR content in the HR Community Portal. The Portal Interaction Analytics product provides statistics on the usage of the Human Resources community, collaboration on the NIH Portal, human resources portlets as well as providing metrics on the documents most accessed on the NIH Portal and key search terms. HR can use this knowledge to better direct the NIH Community to HR resources more intelligently. (See GPRA Goal SMHC-5)

Program Oversight and Improvement

- *Providing Responsible Stewardship Over Existing Federally Owned Real Property Assets.* NIH adopted a facility condition assessment protocol to assure its facilities are capable of supporting its biomedical research mission. Facility Condition Index (CI) is an industry best practice for assessing and measuring the state of individual facilities and the portfolio of facilities by objectively quantifying deferred maintenance and non-compliance with recognized codes and applicable standards. The CI is expressed mathematically as the relationship between the cost of deferred maintenance and the capital replacement value of a facility or portfolio of facilities. In FY 2005, NIH met or exceeded its targets of maintaining the average CI at 85 and having not less than 87% of occupied facility gross square feet (GSF) with a CI greater than 65, which are the criteria for optimum performance. In FY 2005, the average CI was 87, and 87% of the occupied space had a CI > 65. (See GPRA Goal POI-6)

President's Management Agenda (PMA)
Many of NIH's performance goals also support the President's Management Agenda in the areas of Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Management, Expanded Electronic Government, and Budget and Performance Integration.

10 Percent Program Improvements
A large portion of NIH funds support grants to extramural investigators and institutions conducting high quality scientific research consistent with NIH's mission. Grants are the core means of supporting extramural research. It is essential that the processes relating to grants and peer review are unbiased, effective, and efficient so that scientific discovery is not impeded by administrative burdens.

As a means to gain efficiencies in the grants process, NIH will implement *grants.gov* as its form of direct electronic submission of grant proposals, replacing the current practice of paper submission and electronic scanning. The current process averages nine months from receipt to award notification and funding availability. This long process often delays the onset of research projects and further delays reapplication for those scientists who are denied funding. A ten percent improvement is a one-month reduction in the application to award process, and the number of electronic submissions would increase by more than ten percent each year.

Electronic submission will reduce turn-around-time by reducing administrative burdens (including scanning, postage, photocopying) as well as enable NIH to categorize applications electronically, leading to more effective and rapid identification and assignment of appropriate reviewers. Thus, electronic submission will facilitate the peer review and grants management process to make more timely awards and enable supported scientists to begin important research more rapidly.

Strategies for improving program performance require a phased approach. NIH piloted and will incrementally phase-in electronic submission of grant applications by: 1) working with *grants.gov* staff at OMB to implement NIH specific forms and assure grants.gov functionality, 2) implementing the standard Federal grants application form (SF - 424) for NIH programs, 3) piloting additional programs using *grants.gov*, and 4) fully implementing electronic submission for all NIH programs.

10% PROGRAM PERFORMANCE GOAL: Electronic grants submission reduces average application-to-award turn-around-time as a means to accelerate onset of scientific discovery.				
Measure	**Baseline**	**2005**	**2006**	**2007**
Make available *grants.gov* as the method to submit NIH electronic applications in program areas	1 program	Increase by 2 program areas	Increase by 2 program areas	Increase by 2 program areas
FY 2005 Actual Performance: (MET) Increased by 3 program areas: 1) SBIR/STTR 2) R13s 3) R15s				
Monitor the average application-to-award time for those programs having implemented electronic submission	9 months	9 months	9 months	8 months
FY 2005 Actual Performance: (MET) 9 months				
Source Validation: The url for the announcement of the mechanisms is: http://era.nih.gov/ElectronicReceipt/ and the guide notice is at : http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-067.html (released in August)				

Program Assessment Rating Tool (PART)
NIH has been PARTed in 2005, 2006 and 2007 with ratings above Moderately Effective achieving *Proud to Be* goals for the Research and Development Criteria under the President's Management Agenda.

In the FY 2005 PART, AIDS Research was deemed Moderately Effective. The high score demonstrates good management and sufficient progress towards meeting its performance measures. The program has a flexible and cross-cutting design that explicitly allows NIH to plan, identify, evaluate and fund AIDS research priorities across the Institutes. For example, NIH initiated four clinical trials anti-HIV drug regimens to assess anti-retroviral regimens and prevention strategies. As a follow-up, NIH will evaluate interventions to reduce mother to child transmission of HIV.

In the FY 2006 PART, Extramural Research was deemed Effective. The high score demonstrates exemplary management and ample progress towards meeting its performance measures. Several Scientific Research Outcome goals were used to assess the program. For example, NIH launched the Alzheimer's Disease Neuroimaging Initiative test whether serial magnetic resonance imaging (MRI), positron emission tomography (PET), other biological markers and clinical and neuropsychological assessment can be combined to measure the progression of mild cognitive impairment and early Alzheimer's disease.

In the FY 2007 PART, Intramural Research was deemed Effective. The high score demonstrates exemplary management and ample progress towards meeting its performance measures. Several Scientific Research Outcome goals were used to assess the program. For example, in its goal to establish the role of genetic factors in three major diseases for which health disparities are noted between populations, nearly 6 million genotypes have already been collected for the study. By 2012, a study within the Intramural Research Program will develop one new imaging technique to enable tracking the mobility of stem cells within cardiovascular tissues for research and clinical uses.

In the FY 2007 PART, Buildings and Facilities was deemed Effective. The high score demonstrates exemplary management and plenteous progress towards meeting its performance measures. NIH managed all 21 active projects so they were completed within 100% of the final approved project cost. By 2007, the Earned Value Analysis System will be implemented to significantly improve NIH's ability to actively track capital project performance management.

A team, consisting of agency and OMB representatives, is carrying out the following activities pertaining to SBIR programs: conducting an evaluation to assess the program's impact; focusing on improving program administration and determining if legislative reform is needed; developing common long-term and annual measures; and developing a database that tracks commercialization and sales in a consistent manner.

Performance is monitored on a regular basis with course corrections occurring as needed in order to achieve the goal. Programs that perform well are sustained if funding is available. Poorly performing programs are corrected to overcome deficiencies or cut to fund other high priority projects.

Overview of FY 2007 Request for NIH

The FY 2007 Request for the NIH is $28,587 million at the total program level, the same as the FY 2006 program level. Included in this level is $78 million for the Superfund Research Program. The NIH program level also includes $150 million for the Type I Diabetes Initiative appropriated by Public Law 107-360. The FY 2007 request to the Labor, Health and Human Services, Education, and Related Agencies Subcommittee is $28,350 million.

NIH will continue implementation of the long-range strategic plan for biodefense research and support the Secretary's goal to enhance the ability of the Nation's health care system to effectively respond to bioterrorism. The total Biodefense budget is $1,891million, an increase of $110 million and 6 percent. Within this increase, NIH will direct $160 million, an increase of +$110 million to an Advanced Development fund.

The FY 2007 request includes $2,888 million to support basic research and to develop vaccines and improve treatments and prevention strategies against HIV/AIDS. This reflects a decrease of -0.5%, or -$15 million, consistent with the non-biodefense research portfolio.

NIH has chosen to carefully invest in trans-NIH strategic initiatives, similar to the investments we have made in obesity research and the NIH Blueprint for Neurosciences. In the FY 2007 Request, we have identified the following strategic priorities:

Enhanced Support for New Investigators -- NIH must sustain a vibrant, creative research workforce, including sufficient numbers of new investigators with new ideas and new skills, such as interdisciplinary research skills. In the FY 2007 Request, NIH will invest $15 million in a new program—Pathways to Independence—that will provide increased support for new investigators.

NIH Roadmap for Biomedical Research - NIH plans to continue to increase its support for the Roadmap in FY 2007. The NIH Roadmap is an incubator for new ideas and initiatives that will accelerate the pace of discovery. In FY 2007, NIH will direct $443 million towards the Roadmap initiatives, an increase of +$113 million over the FY 2006 Appropriation. Of the $443 million total, $111 million will be provided by the NIH Director's Discretionary Fund (DDF), and the remaining $332 million will be provided by the Institutes and Centers (ICs).

Genes, Environment and Health Initiative -- The Department of Health and Human Services is proposing a forward-looking initiative to benefit the health of all Americans. Recognizing that health and disease are due to the complex interplay of genetic and environmental factors, including diet and physical activity, the Initiative's two-pronged approach would lead directly to the identification of major genetic susceptibility factors for common diseases like heart disease, stroke, osteoarthritis, cancer, diabetes, and Alzheimer's disease, while simultaneously advancing the development of new technologies to assess the contribution of diet, physical activity, and environmental exposures to the causation of these illnesses. Like the Human Genome Project (the successful effort to sequence the human genome) and the International HapMap Project (the successful effort to catalog variation in the human genome) that laid the groundwork necessary for it, this new Initiative would catalyze the development of U.S. biotechnology and would make the data it generates rapidly and freely available to researchers in both the public and private sectors, speeding the development of new strategies and

tools to fight disease. To prepare effectively for this initiative, the National Institutes of Health (NIH) has planned several pilot studies, which begin in FY 2006. In FY 2007, NIH will direct $68 million towards this multi-year initiative.

Clinical and Translational Sciences - In order to accelerate the benefits of the major research investment of the past several years, NIH will undertake a bold new program to reshape our support for clinical and translational sciences. This program will take elements of existing NIH programs for clinical research, primarily the General Clinical Research Centers in the National Center for Research Resources (NCRR), as well as Roadmap initiatives in the Reengineering the Clinical Research theme and combine them in a way that we hope will create better and faster bridges between research findings and clinical practice. In FY 2007, NIH has increased the request for the National Center for Research Resources by an additional $3 million for this high-priority program.

The FY 2007 Request would support an estimated 9,337 competing RPGs, for $3.3 billion, an increase of 275 competing RPGs over the FY 2006 Appropriation. In the FY 2007 Request for NIH, the average cost of a competing RPG will not increase over the FY 2006 Appropriation. The apparent decrease in average cost in FY 2007 is the result of an extremely large cohort of AIDS clinical trials and G-8 HIV Vaccine awards cycling from competing into noncompeting status. While no inflationary increases are provided for direct, recurring costs in non-competing RPG's, where the NIH has committed to a programmatic increase in an award, such increases will be provided.

The FY 2007 request would support 1,373 Research Centers, for $2.8 billion, an increase of $62 million, or 2.3 percent.

Other Research increases by 1.2 percent. Within the Other Research mechanism, Research Careers increases by $21 million, including $15 million for a new program to support new investigators.

In the FY 2007 Request for NIH, stipends for trainees supported by the Ruth L. Kirschstein National Research Service Award (NRSA) will remain at the FY 2006 Appropriation levels. No increases are provided for other components of the NRSA training programs, such as tuition or health benefits. In the FY 2007 request, training remains at approximately the same level as the FY 2006 Appropriation. The FY 2007 Level will support 17,499 Full-Time Training Positions (FTTPs), approximately the same as the FY 2006 Appropriation.

Research and Development (R&D) contracts increase by $44 million and 1.6 percent compared to the FY 2006 Appropriation. This increase is the result of the $40 million increase in the Genes, Health and Environment initiative and increases in the Program Evaluation set-aside.

Intramural Research decreases in total by -0.3 percent. Research Management and Support increases by $14 million, or 1.3 percent. NIH must have the necessary resources to ensure good stewardship of its research portfolio, including improvements in data management and security systems.

In FY 2007, NIH is requesting a total of $25 million to construct additional BSL-3 laboratories and to renovate existing laboratories to meet current BSL-3 standards, including providing the capacity to support Good Laboratory Practice (GLP) research processes within selected BSL-3 laboratories.

Consistent with the FY 2006 Appropriation, no funds are provided for non-biodefense extramural construction.

The Buildings and Facilities mechanism remains at $89 million, with the Buildings and Facilities appropriation at $81 million, the same as the FY 2006 Appropriation. These funds will allow NIH to fund ongoing programs for essential safety and regulatory compliance, as well as Repairs and Improvements, in order to maintain valuable research capacity and to ensure the safety of NIH facilities and their occupants. Funds for the NCI-Frederick facility remain at $8 million, also the same as the FY 2006 Appropriation.

In FY 2007, the appropriation level for the Office of the Director (OD) increases by $140 million, or 27 percent, for a total of $668 million. Of this amount, $111 million has been reserved in the NIH Director's Discretionary Fund for the NIH Roadmap for Medical Research, an increase of +$29 million over the FY 2006 Appropriation. NIH will also direct an additional $1 million to the Office of Portfolio Analysis and Strategic Initiatives. Support for Advanced Development for biodefense countermeasures will increase by +$110 million over the FY 2006 Appropriation, for a total of $160 million. Funding for Nuclear/Radiological and Chemical Countermeasures research will remain at $96 million, the same as the FY 2006 Appropriation.

In support of the Department's Pandemic Influenza Preparedness Plan, the FY 2007 President's Budget requests an additional $17 million to support specific initiatives in pandemic influenza research. Research activities that will be supported by these funds include assisting in the development and testing of candidate vaccines and drugs produced by Vietnam and other countries with endemic avian influenza, expanding the clinical trials infrastructure and research in Southeast Asia, and conducting human-animal interface studies, including the surveillance of diseases in animals in SE Asia. Overall NIH spending on influenza in FY 2007 is estimated to increase to $199 million, $35 million over the FY 2006 estimate.

Program Assessment Rating Tool (PART) Summary Table FY 2004 – FY 2007

Program Assessment Rating Tool (PART) Summary
National Institutes of Health
FY 2004-2007
(Dollars in Millions)

	FY 2006 Conference/Enacted	FY 2007 Request	FY 2007 +/- FY 2006	Narrative Rating
FY 2004 PARTs				
No programs PARTed				
FY 2005 PARTs				
HIV/AIDS Research	$2,903	$2,888	-$15	Moderately Effective
FY 2006 PARTs				
Extramural Research	$21,223	$21,249	$26	Effective
FY 2007 PARTs				
Intramural Research	$2,956	$2,946	-$10	Effective
Buildings & Facilities	$89	$89	0	Effective

NIH has undergone the PART for FY 2005, 2006, and FY 2007, as described below.

YEAR	PROGRAM	NARRATIVE
FY 05	HIV/AIDS Research	The HIV/AIDS Research Program was deemed Moderately Effective. Improvements based on PART included a scientific update to the deadline for the end target, and an increase in the number of program evaluations submitted for the planning and budget development process.
FY 06	Extramural Research	The Extramural Research Program was deemed Effective. The PART resulted in integrating the CJ and GPRA Plans/Reports and led to discussions addressing budget performance alignment.
FY 07	Intramural Research	The Intramural Research Program received a rating of Effective from OMB.
FY 07	Buildings & Facilities	The Buildings & Facilities Program received a rating of Effective from OMB.

HIV/AIDS Research - This program was rated Moderately Effective in FY 2005. Increases for HIV/AIDS are consistent with the development of the NIH budget. At the FY 2007 Request for NIH, the AIDS research program would decrease by -0.5 percent or -$15 million, for a total of $2,888 million.

Extramural Research - This program, comprising over 70 percent of the total NIH budget, was rated Effective in FY 2006. In the FY 2007 request, the extramural research program increases by $26 million over the FY 2006 Level.

Intramural Research - This program, reviewed for FY 2007, was rated Effective. At the FY 2007 request level, Intramural research decreases by -0.3 percent, or -$10 million.

Buildings and Facilities - This program, reviewed for FY 2007, was rated Effective. At the FY 2007 request level, B&F is funded at $89 million, the same as the FY 2006 Appropriation.

Additional information on NIH PART reviews can be found at www.ExpectMore.gov.