Government Performance and Results Act (GPRA)

Final FY 2001 GPRA Annual Performance Plan
Revised Final FY 2000 GPRA Annual Performance Plan
and
FY 1999 GPRA Annual Performance Report

National Institutes of Health
Government Performance and Results Act

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INTRODUCTION

In 1993, Congress passed and the President signed into law the Government Performance and Results Act (GPRA), P.L. 103-62. This legislation's broad intent is to enhance the effectiveness, efficiency, and accountability of government programs by directing federal agencies to more sharply focus their management efforts on the results that program spending yields. With better information on spending and program effectiveness, federal managers are expected to be better able to improve program performance. GPRA is also expected to make information on program performance more readily available to the Congress for policymaking, spending decisions, and program oversight.

This document presents the National Institutes of Health's (NIH's) GPRA Annual Performance Plan and Report. The Report is integrated into the Plan to eliminate redundancy and improve overall understanding of program strategies and accomplishments across multiple years.

The planning elements of this document describe NIH's mission and long term goals, resources available to NIH, and the programs and program strategies used by NIH to accomplish its goals. Within each program the plan describes expected outcomes of the program and the means used to achieve these outcomes. Also provided are annual performance goals and targets that NIH intends to achieve to improve performance and produce results for FYs 1999 – 2001.

The reporting elements of this document describe NIH accomplishments for each FY 1999 goal and target. Within each goal is identified the level of target achievement, sources of data to support target assessment, and an overall assessment of goal accomplishment.

The result is a NIH Performance Plan and Report that presents a three year picture, spanning FYs 1999 - 2001, of program plans, performance expectations and accomplishments at NIH.

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Part I
Agency Context for Performance Measurement

1.1 NIH Mission and Long Term Goals

The NIH mission is to uncover new knowledge about the prevention, detection, diagnosis, and treatment of disease and disability. NIH works toward this mission by conducting research in its own laboratories; supporting the research of non-federal scientists in universities, medical centers, hospitals, and research institutions throughout the country and abroad; helping to train research investigators; and fostering communication of medical information.

Medical innovation is one of the principal foundations on which America's past successes in improving healthcare have been built. It is where hope for the future resides. History provides abundant evidence that medical progress rarely occurs without the sustained pursuit of advances in basic and behavioral science. Through the conduct and support of medical research, the NIH seeks to expand fundamental knowledge about the nature and behavior of living systems; to improve and develop new strategies for the diagnosis, treatment, and prevention of disease; and to reduce the burdens of disease and disability.

The NIH invests the public's resources and support for medical science in three basic and interrelated ways. First and foremost, the NIH conducts and supports medical research. Second, it contributes to the development and training of the pool of scientific talent. And third, it participates in the support, construction, and maintenance of the laboratory facilities necessary for conducting cutting-edge research.

The NIH's long term goals encompass each of these important domains of agency activity:

- ***Increase understanding of normal and abnormal biological functions and behavior.***
- ***Improve prevention, diagnosis, and treatment of diseases and disabilities.***
- ***Promote the development of an appropriate talent base of well qualified, highly trained, and diverse investigators capable of yielding the scientific discoveries of the future.***
- ***Secure facilities for research that are modern, efficient, and safe.***

The agency activities and strategies discussed throughout this plan are directed at realizing all of these overarching goals.

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1.2 Organization, Programs, Operations, Strategies, and Resources

Organizational Overview

The NIH is comprised of twenty five Institutes and Centers (ICs, or "Institutes") 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 to population-based analyses of health status and needs (see Appendix 5).

The NIH "visible" to most Americans encompasses the research institutes focused on diseases (e.g., cancer, diabetes), primary organ systems (e.g., heart, eye, kidney), or a stage of life (e.g., children, the aging). Yet, no less essential to the nation's health are NIH programs that address overarching scientific needs and opportunities. Included here are such efforts as deciphering the human genome, understanding cellular and tissue biology and physiology, training investigators in relevant scientific fields, and developing the array of technologies dictated by the needs of cutting-edge research. All are scientific innovations that move into clinical practice and enhance the capabilities and quality of routine medical treatment.

The Extramural Research Community. More than $8 out of every $10 dollars appropriated to NIH flows out to the scientific community at large -- of which the lion's share supports individual scientists. This "extramural" system is premised on *independence*, embodied in "investigator- initiated" research; on *self-governance*, embodied in peer review of scientists by scientists as the primary basis for judging the merits of research proposals and awarding funds; and on the powerful incentive of *competition* among the most highly trained scientists in the world. The extramural research community numbers an estimated 50,000 scientists affiliated with some 2,000 university, hospital, and other research facilities located in all 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad.

Research at NIH's Intramural Laboratories. A much smaller fraction of the funds -- approximately 11 percent of the budget -- supports a core program of basic and clinical research activities administered and staffed by NIH's own physicians and scientists. This in-house, or intramural, research program includes the NIH Clinical Center and other resources that provide scientific, clinical, and educational benefits to the citizens of the U.S. and the world.

GPRA Programs

For purposes of GPRA planning and assessment, NIH undertakes its mission through activities in three Core Programs: 1) *Research*, 2) *Research Training and Career Development*, and 3) *Research Facilities*.

The ***Research Program*** represents all aspects of the medical research continuum, including basic research, which may be disease-oriented; observational and population-based research; behavioral research; clinical research, including research to understand both normal health and disease states, to move laboratory findings into medical applications, to assess new treatments or to compare different treatment approaches; and health services research. In addition, the timely dissemination of medical and scientific information is a key component of the Program, as is the expeditious transfer of the results of its medical research to provide benefits to human health.

The ***Research Training and Career Development Program*** addresses the need for creative and capable personnel to conduct medical research. The primary goal of the support that NIH provides for graduate training and career development is to produce new, highly trained investigators who are likely to perform research that will benefit the nation's health. Our ability to maintain the momentum of recent scientific progress and our international leadership in medical research depends upon the continued development of new, highly trained investigators.

The ***Research Facilities Program*** focuses on ensuring that the scientists we support have adequate facilities in which to conduct their work. In fact, many of the advances in medical research that are leading to more effective treatments for illnesses reflect stunning innovations in sophisticated, but often costly, research technologies that are far beyond the capacity of all but a handful of institutions to purchase, construct, or maintain. NIH recognizes that ensuring broad access to these research resources creates efficiencies that make the research dollar go farther, while providing critical resources to all scientists. Often, access to the needed tools by the largest possible number of scientists determines the pace of research on many devastating illnesses.

In general, NIH's Core Program are aggregates of the numerous specific programs and activities conducted across the agency. This is done due to the cross-cutting nature of disease and scientific discovery. By aggregating activities that are intrinsically collaborative and complementary, NIH neither omits nor minimizes the significance of any particular activity that contributes to a major function or operation for the agency as a whole.

For example, with respect to medical research, although each of the ICs has a specific research orientation, there are many commonalties. Most obvious are the shared technical approaches to medical research. Also important, but perhaps less well-understood, is the fact that multiple ICs often address different aspects of the major health problems faced by our citizens. Disease is typically systemic, influenced by multiple factors and affects more than one organ or body system. Diverse expertise is usually required to fully understand a disease's etiology, diagnosis, treatment and prevention. Thus, the efforts of many ICs need to be brought to bear on a particular disease or disability. As a result, collaboration and coordination are fundamental tenets of multi-disciplinary medical research. For these reasons, reporting on NIH research

outcomes by ICs rather than by research topics would yield overlapping and confusing information. Consequently, the NIH aggregates the research activities of its component ICs into a comprehensive Research Program for GPRA evaluation purposes. This approach will allow for an inclusive and comprehensive assessment of the strategies NIH uses to accomplish its research mission.

Aggregation is also essential for providing meaningful reporting and assessment of NIH's research training and career development activities. Performance assessment of training and career development activities at the level of the component ICs would not appropriately capture the comprehensive strategies implemented by NIH to meet its goal of maintaining an adequate supply of research talent. Many ICs conduct and support training and career development activities. The need for a pool of well-trained scientists is not unique to any particular Institute or Center. As such, NIH has adopted a coordinated agency-wide strategy for ensuring this need is met.

And, with respect to research facilities, construction, expansion, and renovation activities are also coordinated across the NIH, rather than at the IC level. Ensuring that physical infrastructure is available for the conduct of cutting-edge medical research is a goal of the entire NIH, not simply of an individual IC. Accordingly, NIH also aggregates its Research Facilities activities for assessment and reporting purposes.

Operations and Broad Strategy

NIH's mission to advance medical knowledge and sustain the nation's medical research capacity is accomplished by sustained federal stewardship. It is achieved through a number of fundamental principles that underlie NIH's broad planning and management of its programs and resources. These principles comprise the basic context in which NIH's goal setting and strategic planning operate.

Provide scientific leadership and establish research priorities. Establishing research priorities is essential to ensure that science meets national public health needs and efficiently uses limited resources. The NIH uses a multi-level system to establish and review research priorities. The NIH Director, in collaboration with IC directors and their respective advisory councils and boards and the biomedical research community, guides the priority-setting process. Additional input is sought from the Department of Health and Human Services (DHHS), Congress, and the public. Reflecting the research priorities identified through this process, ICs examine research initiatives and public health needs to ensure that the NIH is committing federal resources to projects and programs that will achieve the greatest yield from the nation's medical research investment.

Public health need and scientific opportunity are the primary drivers in the allocation of resources. In general, the NIH sponsors research that addresses public health needs – to find ways to prevent, treat, or cure disease and to minimize pain and suffering. But public health need alone is not enough; there must also be some real opportunity for success.

How do we identify areas of increased scientific opportunity? New knowledge comes from the pursuit of answers to new questions. The rate-limiting step in the generation of new knowledge is not the number of experiments conducted, but rather the number of new hypotheses or questions. When an arena of research is enjoying an exponential increase in the number of new questions, it is, indeed, an area of scientific opportunity. New questions emerge as a result of several converging factors, including the creativity of individual investigators, the emergence of new methods and tools that allow previously unanswered questions to be addressed, and what is already known about a problem. It is imperative that the NIH capitalize by investing funds in areas of scientific opportunity.

Fund the best research. Research Project Grants (RPGs) are the core mechanism for NIH support for the individual investigator. Other mechanisms include Program Project Grants, which support multi-disciplinary projects conducted by several collaborating investigators, and Center Grants, which are used to fund multi-disciplinary programs of medical research. Research proposals are submitted to the NIH by scientists working at universities, medical, dental, nursing and pharmacy schools, schools of public health, non-profit research foundations, and private industry. NIH support for a project includes the salaries of the scientists and technicians; the cost of equipment such as lasers or computers; the cost of supplies such as chemicals and test tubes; the cost of procedures conducted with research subjects; and the indirect costs associated with doing research, such as maintenance of buildings, electricity, library services, and cost of administrative support. Part of the NIH budget is also spent on research and development contracts which are awarded to non-profit and commercial organizations for work requested and overseen by the NIH.

NIH funds are awarded through a highly competitive process to the most promising and productive scientists. Extramural research proposals are first evaluated by expert scientific peer review panels composed of non-NIH scientists who are among the most knowledgeable and respected in their fields. The proposals are then reviewed by independent advisory councils that include members of the lay public. This two-tiered independent review system is critical to ensuring that the best research proposals are funded from the more than 40,000 grant applications NIH receives each year.

Conduct leading-edge research in NIH laboratories. The NIH also conducts basic and clinical research in its own (intramural) laboratories. Projects are selected on the basis of scientific merit and public health need. Each institute 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. This national resource permits the NIH to respond rapidly to critical health problems and emergencies and to take advantage of emerging opportunities.

Effectively disseminate scientific results and research-based health information. The NIH develops and disseminates informational materials to individuals and groups, including medical and scientific organizations, industry, the media, and volunteer and patient organizations. Information dissemination efforts have expedited the translation of NIH's scientific advances and technologies into important diagnostic, preventive, and therapeutic products. In addition,

they have brought about major health-enhancing changes in public attitudes and behaviors, such as reduction of smoking and better control of high blood pressure and high cholesterol levels. To effectively reach diverse audiences, whose knowledge of science and health differ, the NIH disseminates information ranging from highly technical research advances to the steps individuals can take to improve their own health.

NIH disseminates information on scientific findings and technologies to scientific and other health professionals through various avenues: scientific publications, workshops and symposia, scientific meetings, consensus development conferences, press releases, special physician education programs, and clinical alerts concerning immediate health and safety issues. NIH also provides access to information about scientific articles, NIH research grants, clinical trials and treatment through extensive electronic databases.

To respond to the public, Congress, and the media, NIH employs information offices, clearinghouses, electronic databases, Internet-based information services, public education programs, publications and press releases, as well as direct responses by letter and telephone. These provide information regarding participation in research protocols; the best current information on disease prevention and health promotion, diagnosis, and treatment of specific diseases and disorders; information about ongoing research; and referrals to other sources of information.

Facilitate the development of health-related products through technology transfer. The NIH has a statutory mandate to transfer new biomedical technologies to the private sector for further development and commercialization. NIH's technology transfer programs ensure that the public investment in NIH research leads rapidly to beneficial health-related products, including preventives, diagnostics, therapeutics, and vaccines.

Many NIH research results are converted into commercial medical products, typically through the publicly available knowledge base created by NIH-supported research. The public also benefits from NIH technology transfer activities, including Cooperative Research and Development Agreements (CRADAs) with the private sector and the licensing to industry of intellectual property rights arising out of CRADAs and other NIH research. Virtually all NIH licenses negotiated with industry are royalty-bearing.

Ensure a continuing supply of well-trained laboratory and clinical investigators. Whereas supporting research is essential, it is equally important to ensure the availability of well-trained investigators who reflect our nation’s diversity and who have specialized knowledge, methodological expertise, and creativity. The NIH’s research training grant portfolio covers all the career stages that are key to the recruitment, training, and retention of productive medical researchers.

One of the goals of research training is to teach pre- and post-doctoral students how to conduct innovative, high-quality science, including how to identify problems, develop hypotheses, design experiments, choose model systems, and see connections among different fields that allow a scientist to make quantum leaps in understanding a problem. Mentors are a critical training

resource, serving as role models and providing guidance that ensures trainees develop into successful investigators.

Sustain the nation's research facilities. The NIH must continually support the development, maintenance, and renewal of physical resources that are vital to the rapid pace of scientific discovery. The past achievements of medical research have required access to state-of-the-art laboratories. Up-to-date and safe research facilities are essential to assuring continued progress in the medical sciences. To support intramural research, NIH constructs new facilities and renovates existing ones to meet the ever-changing needs of biomedical research. The NIH also provides support to extramural grantees through research facilities construction grants designed to assist in the construction and modernization of non-federal research facilities.

Collaborate and coordinate with others. The NIH collaborates and coordinates on an ongoing basis with other federal agencies and research organizations where research interests intersect and when joint efforts will enhance the individual activities of each entity. Medical research benefits from multiple perspectives being brought to bear on a particular problem. Collaborative efforts bring diverse domains of expertise together and can facilitate a more rapid response to emerging opportunities. In addition, collaborative efforts work to produce the best possible science while making the most economical use of the resources available.

These collaborative endeavors frequently involve the NIH's sister agencies in DHHS, including the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and the Agency for Health Care Policy and Research (AHCPR). Nonetheless, the full scope of the NIH's collaborative activities -- both in the past and those contemplated for the future -- is far wider, including many other federal agencies, government bodies, non-governmental organizations, and industry.

Performance Goals for Outcomes and Means

The performance goals in NIH's Annual Performance Plans address both "Outcomes" and "Means":

> "Outcomes" refer to the tangible results of NIH program activities -- the intended result, effect, or consequence from the activities carried out under each of NIH's three Core Programs. For the most, "Outcomes" embody NIH's long-term goals (see table below).
>
> "Means" are management activities (e.g., research priority setting, grants peer review) and administrative processes (e.g., information technology planning, property management) that NIH undertakes to conduct its program activities and seek to achieve its goals. (NIH's "Means" areas are discussed in greater detail in Part II.)

Core Program	Outcomes (Anticipated Results)
Research	***Increased understanding of normal and abnormal biological functions and behavior.*** ***Improved prevention, diagnosis, and treatment of diseases and disabilities.***
Research Training and Career Development	***An appropriate talent base of well qualified, highly trained and diverse investigators capable of yielding the scientific discoveries of the future.***
Research Facilities	***Facilities and related systems to conduct medical research which are modern, efficient and safe.***

Importantly, all performance goals are instrumental for NIH to achieve its desired outcomes. Some performance goals (e.g., those identified in the "Research" section of the Research Program) *directly* embody NIH's long-term goals, while other performance goals reflect the key "Means" of each of the Core Programs.

Resources

The FY 2001 President's budget request provides funding to support NIH staff (i.e., Full Time Equivalents), including approximately 2,000 Intramural scientists, funding to support research efforts from a pool of extramural scientists, and funding to support the facilities (i.e., universities, research centers and the buildings on the NIH campus) necessary in the conduct of science. The combination of dollars, human capital, and physical facilities available for research make up the resources by which NIH accomplishes its program performance goals.

The dollar resources are distributed to NIH's programs through budget mechanisms that direct the funding to intramural and extramural researchers, contractors, NIH staff, universities and research centers. Ultimately, all funds are used to support NIH's mission and long-term goals.

NIH's highest priority is the funding of biomedical research. Funding is provided to the Research Program through a variety of budget mechanisms that includes: Research Project Grants (RPGs), Research Centers, Other Research, R&D Contracts, Intramural Research, Research Management and Support, Cancer Control, Library of Medicine and Office of the Director. RPGs are the major mechanism for this support. The emphasis on RPGs allows NIH to sustain the scientific momentum of investigator-initiated research while providing new research opportunities.

NIH continues to be a leader in the training of biomedical and behavioral researchers. Through the Research Training and Career Development Program, NIH provides the biomedical research enterprise with a steady flow of highly-trained researchers equipped to conduct the nation's

research mission. Funds are provided to this program through the Research Training, Other Research, Research Management and Support, and Office of the Director mechanisms. NIH provides facilities support for the NIH campus and to universities and research centers by providing funds through the Buildings and Facilities, Construction, Research Management and Support, and Office of the Director mechanisms.

Under NIH's aggregated approach, performance goals are grouped under the three NIH Core Programs: Research, Research Training and Career Development, and Research Facilities. Within these three program areas, NIH has defined a crosswalk for how each budget mechanism (e.g., Research Project Grant, Research Management and Support, Construction, etc.) links to the three core programs. Further information on NIH budget policy can be found in the NIH FY 2001 Congressional Justification.

Resources	Budget Mechanisms	Core Program	Program Areas
$ 17.8 Billion in FY 2000 NIH Staff Extramural Scientists Contractors Universities, Research Centers and NIH Facilities	• Research Project Grants • Research Centers • Other Research • Research Training • R&D Contracts • Intramural Research • Research Management and Support • Cancer Control • Construction • Library of Medicine • Office of the Director • Buildings and Facilities	Research	Research
			Communication of Results
			Technology Transfer
			Priority Setting
			Grants Administration and Review
			Management and Administration
		Research Training and Career Development	Training Support
			Outreach
		Research Facilities	Intramural Modernization and Maintenance
			Extramural Assistance

1.3 Partnerships and Coordination

NIH collaborates with numerous organizations to pursue its longer-term goals in all of its major program areas. Such partnerships include competitively-funded grants to the universities, medical schools, and other research entities that comprise the Extramural Research community. There are also joint efforts with other federal agencies, both within DHHS, with other departments, and with private industry.

Where research and related interests intersect and joint efforts can enhance individual activities, the reasons for such collaboration are many. Research benefits from the multiple perspectives and more diverse expertise that can be brought to bear on a particular problem. Collaboration works to produce the best possible science while making more economical use of the resources available. And, importantly, partnering can facilitate more rapid response to emerging opportunities.

Partnership with the Extramural Research Community

Research grants to the Extramural Research community comprise the main body of NIH research -- and these scientists are NIH's principal "partners" in the research enterprise. Currently, this research community numbers an estimated 50,000 scientists, affiliated with some 2,000 university, hospital, and other research facilities located in all 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad. In recent years, Extramural Research has accounted for more than 80 percent of NIH's overall annual budget appropriation.

Work by Extramural scientists encompasses virtually all aspects of NIH's research interests. This ranges from basic research that explores the fundamental workings of biological systems, to studies that examine disease and treatments in clinical settings, to prevention and population-based analyses of health status and needs.

An example of NIH's partnership with Extramural researchers that goes beyond the awarding of grants and contracts can be seen in NIH' s current activities in the *Federal Demonstration Partnership (FDP).* The FDP is a cooperative initiative among federal agencies and institutional recipients of federal funds. The FDP was established to increase research productivity by streamlining the administrative process and minimizing the administrative burden on principal investigators while maintaining effective stewardship of federal funds. In its current phase, the FDP boasts sixty-five institutional members, eleven federal agencies, and five professional organizations.

Collaboration with Other Federal Agencies

NIH conducts research in partnerships with other federal agencies, in areas of mutual interest or where the benefits from cooperation are strong. These collaborative endeavors often involve the NIH's sister agencies in HHS, such as the Centers for Disease Control and Prevention (CDC)

and the Agency for Health Care Policy and Research (AHCPR) and other agencies such as the Department of Energy (DOE) and the National Aeronautics & Space Administration (NASA).

A sampling of NIH's diverse research collaborations with other federal agencies is as follows:

-- *Human Genome Project*. NIH is currently working with the Department of Energy (and with other international collaborators) on the major effort to sequence the large and complex human genome. This endeavor is widely regarded as the single most important project currently in biology and biomedical science.

-- *DNA Polymorphism Discovery Resource*. In one of numerous related studies, NIH worked recently with CDC and several independent scientists to assemble DNA samples from several hundred U.S. residents with ancestry from all the major regions of the world. This material will provide a resource of immense value for identifying human genetic variations, through which other studies can seek to relate to health and disease.

-- *National Emphysema Treatment Trial*. NIH is collaborating with the Health Care Financing Administration (HCFA) and the Agency for Health Care Policy and Research (ACHPR) in a multi-center clinical trial designed to determine the role, safety, and effectiveness of bilateral lung volume reduction surgery in the treatment of emphysema.

-- *Managing Pfiesteria and other harmful algal blooms*. In 1997, NIH worked collaboratively with a number of major federal agencies – National Oceanic and Atmospheric Administration (NOAA), Environmental Protection Agency (EPA), CDC, U.S. Department of Agriculture (USDA), Department of the Interior (DOI), and Federal Drug Administration (FDA) -- to develop a coordinated research strategy to identify ways to manage the health and environmental threats associated with *Pfiesteria* and other harmful algal blooms.

Relationships with Private Industry

NIH also works with private industry in a number of ways, where there are opportunities to further NIH's research mission and to facilitate the flow of new biomedical knowledge and technologies to the private sector for further development and commercialization.

Among the various kinds of relationships possible, direct collaboration on research projects -- such as in the areas of vaccines, medical imaging, or other diagnostic tools -- is one important approach. Another is NIH's substantial efforts to facilitate the transfer of publicly funded research findings and technologies to the private sector. Additionally, NIH undertakes clinical trials on new drugs and therapies that may have considerable commercial interest to the private sector.

Some examples of these relationships with the private sector include:

-- *Vaccine research and development.* Most currently available vaccines, as well as those in the development pipeline, have resulted from collaborations between partners in the public and

private sector, including federal and state governments, small and large corporations, academic research institutions and non-governmental organizations.

-- *Technology Transfer through Cooperative Research and Development Agreements (CRADAs).* CRADAs are one major technology transfer mechanism used by NIH to enable private companies to work collaboratively with federal laboratory scientists and technologists in activities with the promise of yielding new technologies. (The CRADA mechanism was established by the Congress in 1986.)

-- *Clinical Trials*. For example, NIH conducted a Phase I/II trial of recombinant methionyl human stem cell factor in patients diagnosed with acquired aplastic anemia. This trial was sponsored by Amgen, Inc., the private industry producer of the recombinant methionyl human stem cell factor.

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1.4 Summary FY 1999 Performance Report: Accountability Through Performance Measurement

This is the third Annual Performance Plan submitted by NIH under GPRA. This is the first year that the Annual Plan includes an Annual Report assessing performance for a prior year's (FY 1999) performance goals. NIH has been largely successful in achieving the performance set out by the goals and targets in its FY 1999 Annual Plan. The associated activities and accomplishments have made significant contributions toward NIH's mission and long-term goals.

These successes are discussed in more detail in Part II of this document and in the accompanying ***Report of the GPRA Assessment Working Group of the Advisory Committee to the Director, NIH: Assessment of NIH Research Program Outcomes.*** An illustration of NIH's many accomplishments in FY 1999 can be seen in the following results:

Research

- Adding to the body of knowledge about normal and abnormal biological functions by succeeding in creating human cancer cells in the laboratory by altering the expression of a defined set of genes and affecting at least four cellular pathways.

- Continuing development of critical genomic resources by achieving a U.S. annual production rate of human genomic sequence of 173 million base-pairs and completing the sequence of the 97 million base-pairs of the *C. elegans* genome.

- Development of a promising new technique for detecting lung cancer at an earlier and potentially more curable stage.

- Development of an improved approach for preventing mother-to-child transmission of HIV.

- Development of a new test for diagnosing a particularly devastating aggressive cancer that can involve the brain, spinal cord, and the eye.

- Identification of an effective non-surgical treatment for fistulas, a serious complication associated with the chronic inflammatory bowel disease known as Crohn's disease.

- Progress towards the President's goal of developing an AIDS vaccine by 2007 by increasing the number and dollar value of awards made for vaccine discovery.

- Development and implementation of the Clinical Trials Database, a consolidated source of information related to federally and privately funded clinical trials for drugs for serious or life threatening diseases and conditions.

- Increased collaboration between commercial entities and federal laboratory personnel by increasing the number of executed Cooperative Research and Development Agreements by 10 percent.

- Improved oversight of and public involvement in NIH's priority setting process through Institute and Center development and review of multi-year strategic plans which include input from varied NIH constituents.

- Enhanced Electronic Research Administration (ERA) and communications with the extramural research community through the continued development of the NIH Era Commons, a Web-based client/server environment where the NIH and grantee community will conduct research administration business electronically.

- Improved relations with the vendor community and compliance with the Prompt Pay Act by paying 94% of invoices on time.

Research Training and Career Development

- Increasing the pool of clinical researchers who can conduct patient-oriented research by issuing 85 Mentored Patient-Oriented Research Career Development awards, 83 Mid-career Investigator Awards In Patient-Oriented Research, and 35 curriculum development awards.

- Encouraging interest in scientific research careers by making information on training and career development opportunities widely available to students and postdoctorates (e.g., Independent Scientist Award, Minority and Disability Research Supplements, Mentored Clinical Scientist Development Award).

Research Facilities

- Completed design and over 66% of construction for the Dale and Betty Bumpers Vaccine Research Center

- Made major progress in the design and site work for the Mark O. Hatfield Clinical Research Center.

Processes to respond to GPRA annual requirements for planning, performance assessment, and associated reporting are now well established at NIH. They reflect NIH's scientific research effort and research program management, key functions such as communications and technology transfer, and investments in infrastructure as scientific workforce training, new research facilities, and information technology. In many respects, these processes have grown out of existing mechanisms to manage and sustain the dynamic research enterprise in productive ways.

NIH recognizes the principles inherent in GPRA to set goals, produce, and then measure results. This report is intended to communicate the agency's goals for FY 2000 and 2001 and provide a report on what has been accomplished in FY 1999.

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Part II.
Program Planning and Assessment

The material in this part of the Annual Plan describes NIH's performance goals and targets for FY 2001 and FY 2000 (as revised). Performance assessment reporting on the FY 1999 goals is also integrated. The presentation is organized principally by the three Core Programs that NIH identifies for GPRA purposes: Research, Research Training and Career Development, and Research Facilities. Performance goals for these Programs are subsequently divided according to the major functional areas involved.

A detailed description of the performance goals, along with a discussion of the measures and data which underlie performance assessment is provided for each functional area. Summary charts placed early in each of these sections provide an overview of the performance goals and assessment findings. Several appendices provide additional details on NIH activities, the agency's approach to GPRA, and other essential supporting material.

GPRA Program	Budget (000's)		
	FY 1999 Actual	FY 2000 Estimate	FY 2001 Estimate
Research	$ 14,852,726	$ 16,648,940	$ 17,625,885
Research Training and Career Development	$ 811,120	$ 913,352	$ 954,153
Research Facilities	$ 239,343	$ 250,443	$ 232,697
All Programs	$ 15,633,189	$ 17,812,735	$ 18,812,735

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2.1 Research Program

2.1.1 Program Description, Context, and Summary of Performance

Program Description and Context. NIH's research activities range widely across the medical research continuum -- including basic and disease-oriented research; observational and population-based research; behavioral research; and clinical research, including research to understand both normal health and disease states, to move laboratory findings into medical applications, to assess new treatments or compare different treatment approaches; and health services research.

While the specific research activities undertaken by the numerous Institutes and Centers -- through the intramural labs or grants to the extramural medical research community -- are many, the agency's long-term goals are 1) to increase understanding of normal and abnormal biological functions and 2) to utilize this new knowledge in developing improved prevention, diagnosis, and treatment options for diseases, disabilities, and other adverse human conditions.

Scientific research probes and seeks to understand the unknown. The scientific insights that provide a basis for solutions usually accumulate over many years, and often are derived from the efforts of diverse investigators working on and communicating about differing facets of the problem. Medical discovery is marked by stops and starts, and a vital interplay between theory, experimental evidence, and clinical observations. It is very hard -- if not impossible -- to predict what discoveries will arise or to anticipate the opportunities that such new knowledge will provide. Accordingly, NIH must support research along a broad, and, of necessity, expanding program. NIH's medical research program is a diverse and continually evolving portfolio that reflects the agency's obligation to respond to public health needs, a commitment to support research of the highest scientific caliber, and judgment as to the scientific opportunities that offer the best prospects for new knowledge and better health.

Successful outcomes from the research program mean a continuing flow of high quality research, discoveries of new fundamental knowledge, applications in new therapies, diagnostics, prevention, and new research tools -- from extramural grantees and the intramural laboratories. It also means timely dissemination of scientific results and research-based health information and expeditious transfer of the results of its medical research for further development and commercialization of products of immediate benefit to improved health as an important mandate.

As the strategic principles that broadly guides NIH's research program activities indicate (see prior discussion in Part I), success in mission achievement also involves effective implementation in key management/process ("means") areas: notably, leadership in setting research priorities, effective mechanisms for grants management and identifying high quality projects for the portfolio, and effective management/administrative support.

GPRA Research Program			
Budget (000's)	**FY 1999 Actual**	**FY 2000 Estimate**	**FY 2001 Estimate**
	$ 14,852,726	**$ 16,648,940**	**$ 17,625,885**
Program Areas	**Research** -- NIH's ongoing scientific enterprise. This includes research conducted through grant awards and contracts to individual investigators and organizations in the Extramural Research community. It also includes research conducted at NIH's Intramural labs. The intended long-run outcomes of all these activities are increased understanding of normal and abnormal biological functions and behavior and improved prevention, diagnosis, and treatment of diseases and disabilities.		
	Communication of Results -- Communicate scientific results and health information to the medical research community, health care providers, patients, and the general public.		
	Technology Transfer -- Promote the efficient transfer of the new technology forthcoming from NIH research to the private sector to facilitate the development of new drugs and other products of benefit to human health.		
	Priority Setting -- Continue decision making mechanisms and policies that ensure NIH research is responsive to public health needs, scientific opportunities, and new technologies.		
	Grants Administration and Peer Review -- Maintain effective and efficient grants administration and a high quality of peer review to ensure the most meritorious research projects are considered for funding.		
	Management and Administration -- Carry out management and administrative functions which support the agency's mission.		

Summary of Performance. NIH established 38 performance goals with 60 corresponding performance targets for the Research Program in FY 1999. A snapshot of these targets shows the following:

- 100 percent (12 of 12) research area targets were met or exceeded.
- 90 percent (54 of 60) of all targets were partially met, met or exceeded.
  - 20 percent (12 of 60) targets were exceeded.
  - 67 percent (40 of 60) of all targets were met.
  - 3 percent (2 of 60) targets were partially met (targets with multiple performance elements where some elements were met).

In the pages that follow, specific details are provided for each FY 1999 goal and target of the Research program.

2.1.2 Goal-by-Goal Presentation of Performance Goals and Results

2.1.2.1 Research

NIH's research Institutes and Centers (ICs) maintain extensive medical research programs on a variety of topics in their areas of focus. In addition to providing grant support to the extramural research community through a competitive proposals process, most of these ICs also conduct their own research through NIH's intramural laboratories. Each year, NIH receives some 40,000 proposals to initiate new research from the most promising and productive scientists at universities and research centers throughout the country - and, where special opportunities exist, from scientists abroad.

NIH identifies goals and a budget strategy annually to maximize support for basic biomedical research, to promote health, and to better understand the biological and behavioral basis for disease to improve prevention and treatment of human disorders. The nation's investment in medical research has a long history of success. In recent years, NIH has been able to report annually on advances that represent outstanding achievements in science. Typically, these achievements are the result of past investments made with the belief that medical research will lead to improvements in the nation's health. The federal effort devoted to medical research, combined with private sector efforts, can and does, improve the length and quality of our lives.

As discussed earlier (in Part I), NIH's numerous research activities are aggregated for GPRA planning and assessment purposes. This is done due to the cross-cutting nature of disease and scientific discovery. By aggregating activities that are intrinsically collaborative and complementary, the significance of any particular activity that contributes in a major way to the whole is neither omitted nor minimized. Although each of the ICs has a specific research orientation, there are many commonalties. Most obvious are the shared technical approaches to medical research. Also important, but perhaps less well understood, is the fact that multiple ICs often address different aspects of the major health problems faced by our citizens. Disease is typically systemic, influenced by multiple factors and affects more than one organ or body system. Diverse expertise is usually required to fully understand a disease's etiology, diagnosis, treatment and prevention -- and the efforts of many ICs need to be brought to bear on a particular disease or disability. Reporting on NIH research outcomes by ICs rather than by research topics would yield overlapping and confusing information.

Scientific research is an enterprise for the long run – reflecting the difficulties and uncertainties of probing the unknown. Discoveries and significant advances typically prove uneven over time and are practically impossible to predict. But, once in hand, progress can often proceed rapidly. Accordingly, NIH's performance goals for the Research Program focus on broad and long-run achievement in key areas that reflect the agency's mission.

Performance Goals Summary Table – Research

Performance Goal	FY Targets	Actual Performance	Details
a) Add to the body of knowledge about normal and abnormal biological functions and behavior.	***Annual Target*** Progress in advancing scientific understanding in key fields bearing on our knowledge of biological functions and behavior in their normal and abnormal states.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target exceeded.**	Page 31
b) Develop new or improved instruments and technologies for use in research and medicine.	***Annual Target*** Progress in developing new instrumentation or technologies that enhance capabilities for investigating biological functions and diagnosing and treating diseases and disorders.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target exceeded.**	Page 35
c) Develop new or improved approaches for preventing or delaying the onset or progression of disease and disability.	***Annual Target*** Progress in developing (or facilitating the private sector's development of) new or improved approaches for preventing or delaying the onset of diseases and disabilities – and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 39
d) Develop new or improved methods for diagnosing disease and disability.	***Annual Target*** Progress in developing (or facilitating the private sector's development of) new or improved diagnostic methods that are more accurate, less invasive, and/or more cost-effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target exceeded**	Page 43
e) Develop new or improved approaches for treating disease and disability.	***Annual Target*** Progress in developing (or facilitating the private sector's development of) new or improved treatments that expand therapy options; improve the length and quality of life; and/or are more cost effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target exceeded.**	Page 47

Performance Goal	FY Targets	Actual Performance	Details
f) Develop critical genomic resources, including the DNA sequences of the human genome and the genomes of important model organisms and disease-causing microorganisms.	***FY 2001 Targets*** (1) Worldwide effort completes "full shotgun" of human genome sequence (95% complete, 99.9% accurate). (2) Finish one-third of human genome (accuracy of at least 99.99%). (3) Identify 60,000 human single nucleotide polymorphisms (SNPs). ***FY 2000 Targets*** (1) Worldwide effort completes "working draft" of human genome sequence (90% complete, 99% accurate). U.S. contributes two-thirds of that amount, and NIH contributes 85% of U.S. total. (2) Finish the sequence of at least one human chromosome. (3) Complete sequence of the genome of Drosophila melanogaster (excluding heterochromatin). ***FY 1999 Targets*** (1) U.S. annual production rate of human genomic sequence: 90 million base-pairs. (2) Worldwide annual production rate of human genomic sequence: 220 million base-pairs. (3) Total human genomic sequence completed worldwide at the end of FY 1999: 400 million base-pairs. (4) Complete the sequence of the *C.elegans* genome.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) exceeded**. **FY 1999 target (2) exceeded.** **FY 1999 target (3) exceeded.** **FY 1999 target (4) met.**	Page 51
g) Work towards the President's goal of developing an AIDS vaccine by 2007.	***FY 2001 Targets*** (1) Progress in the design and development of new or improved vaccine strategies and delivery/production technologies. (2) Progress in characterization, standardization, and utilization of animal models for evaluating candidate vaccines. (3) Progress in collaborating with industry to enhance opportunities for vaccine development.	FY 2001: To be reported in January 2002.	Page 56

Performance Goal	FY Targets	Actual Performance	Details
	(4) Progress in (a) completion of ongoing trials and (b) initiation of additional trials of new or improved concepts and designs, including the progression of promising candidates to larger trials testing vaccine candidates.		
	FY 2000 Targets (1) Progress in the design and development of new or improved vaccine strategies and delivery/production technologies.	FY 2000: To be reported in January 2001.	
	(2) Progress in characterization, standardization, and utilization of animal models for evaluating candidate vaccines.		
	(3) Progress in collaborating with industry to enhance opportunities for vaccine development.		
	(4) Progress in (a) completion of ongoing trials and (b) initiation of additional trials of new or improved concepts and designs, including the progression of promising candidates to larger trials testing vaccine candidates.		
	FY 1999 Targets (1) Increases in the research portfolio supporting innovative vaccine discovery.	**FY 1999 target (1) met.**	
	(2) Increased interactions between academic investigators and industry, to enhance opportunities for vaccine discovery and product development.	**FY 1999 target (2) met.**	
	(3) Progress in completion of ongoing trials and initiation of additional trials of new vaccine concepts and designs.	**FY 1999 target (3) met.**	

Performance Goal Details - Research

Goal a) Add to the body of knowledge about normal and abnormal biological functions and behavior.

Much of health care today still involves treating the symptoms of disease without understanding its underlying causes and the precise mechanisms by which disease develops (pathogenesis). In order to effectively and systematically attack the diseases of today such as cancer, heart disease, AIDS, arthritis, diabetes, and addiction, we need a broad base of knowledge about normal living systems. We need to understand how living systems operate at both a "micro" level -- the structure and function of proteins, nucleic acids (DNA and RNA), carbohydrates, and fats -- and as well as at more "macro" levels -- how these molecules organize and function together as living units, i.e., cells, tissues, organs, whole organisms, and even communities. As important, we need to understand how disease, genetic alterations, and environmental factors affect the function of these molecules, cells, tissues, organs, and organisms, and their consequences for human health.

All organisms are made of the same basic materials, and many share similar genetics and physiologic processes, so researchers seeking to understand both normal and disease processes in humans can learn a great deal by studying similar systems in simpler "model organisms" like bacteria, slime molds, yeast, fruit flies, zebrafish, and rodents. Model systems have proven essential tools for understanding a wide array of human conditions, providing critical new insights into mechanisms associated with cardiovascular, gastrointestinal, neurological, structural, and other defects that may have counterparts in human disorders. Animal models can be used for studying the physiological course of a disease, determining the identity and function of the genes and proteins involved in health and human disease, testing new treatments, and developing and testing methods for preventing disease and disability.

At first glance, this goal may appear to focus on laboratory research, but it actually encompasses clinical research as well. The aim is to be able to put all the parts together to understand normal biological activities and how they malfunction in disease and disability. This, in turn, will provide the fundamental theories and concepts for more disease-oriented investigations that lead to new methods for diagnosing, treating, and preventing disease and disability. It may take years, however, after a new discovery is made for the potential health applications to become clear. Thus, just as no one can predict what researchers will discover in the future, neither can the eventual clinical applications of today's results be known. As productive as the past has been, the future promises to be still more exciting as researchers gain an even greater understanding of living systems and apply that understanding to questions of health and disease.

Annual Target: **Progress in advancing scientific understanding in key fields bearing on our knowledge of biological functions and behavior in their normal and abnormal states.**

Basis and Data: Data will be reported on the new findings and theories forthcoming from the various research projects the NIH conducts and supports. Narrative descriptions of research accomplishments (e.g., scientific advances and stories of discovery) will place a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; the potential applications of knowledge from the research, if known; and the potential economic implications of the advance, if known. This information will provide perspective on where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health. These narrative descriptions will be augmented with science capsules that are short paragraphs that summarize an advance and its significance and brief descriptions of scientific awards/honors received by NIH scientists and grantees. Assessment of NIH's progress toward meeting this goal will be conducted by a working group of the Advisory Committee to the Director (ACD), NIH. This Assessment Working Group, composed of members of the ACD, the Director's Council of Public Representatives, and other standing NIH advisory committees, will assess NIH's progress in meeting this goal. The Assessment Working Group will use the following criteria in the assessment process. (See also Appendix 1.)

- The NIH biomedical research enterprise "*has successfully met this" goal* when its research yields new findings related to biological functions and behavior, and the new findings are published and/or disseminated.

- The NIH biomedical research enterprise "*has substantially exceeded this goal"* when, in addition to fulfilling the above criteria, any of the following apply:

  - Discoveries result in significant new understanding of a particular biologic or behavioral process. Such new understanding may open up new avenues of research or be applicable to other disciplines, other areas of research, or other diseases.

  - Research yields answers to long-standing, important biological and behavioral questions, or provides novel investigative approaches for addressing such questions.

  - Genomic information about humans, model organisms, and/or disease-causing agents is translated into new understanding of the role of genes and/or the environment in human health, disease, and behavior.

  - Discoveries have potential for translation into new or improved technologies, diagnostics, treatments, and preventive strategies.

Validation/Verification: Narrative descriptions of research accomplishments will be accompanied by citations of publications that relate to the accomplishment. The

narratives and copies of the publications will be available for review for verification and validation purposes.

Assessment of FY 1999 Performance

FY 1999 Target: Progress in advancing scientific understanding in key fields bearing on our knowledge of biological functions and behavior in their normal and abnormal states.

FY 1999 Achievement Summary:

- The annual target was substantially exceeded, per an independent assessment by a Working Group of the Advisory Committee of the Director, NIH. Specifically, the Working Group concluded that the outcomes demonstrated that NIH had sustained the excellence and responsiveness of the research system–an important achievement–while demonstrating willingness to take research risks necessary to advancing biomedical knowledge, and ultimately human health. In their discussion, members of the Working Group identified a number of important themes or categories of research outcomes, discussed the significance of these types of findings, and highlighted a number of research outcomes that they judged to be especially noteworthy.

- Illustrative examples of research outcomes identified by the Working Group as evidence of having exceeded the goal:

  Scientists succeeded in creating human cancer cells in the laboratory by altering the expression of a defined set of genes and affecting at least four cellular pathways. The ability to introduce specific genetic alterations to transform normal cells paves the way for more precisely defining the biochemical pathways in the cell that must be disrupted in the development of cancer. This information will open new avenues for exploring the roles of various cellular pathways that become disrupted and for determining the sequence of events that must occur as cancer develops.

  Investigators obtained the first evidence, from studies in rodents, that adult neural stem cells can be used to repair damage from a broad array of brain where cell dysfunction is "global" or spread throughout the brain. Other researchers demonstrated that bone marrow stem cells could give rise to liver cells and that neural stem cells became blood-forming cells. This new knowledge changes the way we think about the brain and treatment for brain disease and injury and has obvious implications for the development of new treatment modalities for a number of devastating illnesses and injuries.

  The discovery of a family of proteins (toll-like receptors) that are involved in the body's immune response to bacteria is another significant outcome. When these proteins detect and signal the presence of the bacteria, they trigger a severe immune reaction that can lead to septic shock. This new knowledge could facilitate development of new vaccine strategies

and new approaches to the treatment of septic shock. Drugs that could interfere with the activation of Toll-like receptors by bacteria during an acute infection could save thousands of lives by blocking the septic shock signaling cascade.

- The Assessment Report of the Working Group is attached separately. The Report describes the independent assessment process developed and implemented by the NIH; provides a detailed overview of the research outcomes submitted to the Working Group for assessment; sets forth the assessment criteria developed and applied by the Working Group; and summarizes the Working Group's discussion of the research outcomes and their rationale for concluding that the target was substantially exceeded.

Sources of FY 1999 Assessment Data: Nearly 300 descriptions of research outcomes published in FY 1999 were provided to the Working Group as examples of how NIH has been successful in meeting the annual target. The research outcomes were presented in the form of science advances, science capsules, and stories of discovery, with relevant citations as appropriate. The assessment report of the Working Group contains an overview of the FY 1999 research outcomes provided for this goal, as well as a table listing the titles of the narratives.

Discussion of Performance: FY 1999 research outcomes have significantly contributed to the knowledge base about normal and abnormal biological functions and behavior. This new knowledge will underpin the development of new and improved diagnostics, treatments, and preventive strategies that will ultimately improve human health and quality of life.

Next Steps: This annual target is sufficiently broad so that it is appropriate for future years.

Goal b) Develop new or improved instruments and technologies for use in research and medicine.

Recent advances in medical research and health care are closely linked to the development of new instruments and technologies. Improvements in the early detection of cancers, technologies to better visualize the living body in both normal health and disease states, and new ways to identify and target abnormal cells and tissues will provide a wealth of knowledge that can lead to new and improved diagnostics, treatments, and prevention strategies.

Many of the advances in medical science today, including the mapping of the human genome and brain imaging, have been the result of the development of advanced technologies and instruments that permit investigators to explore the human body in ways previously undreamed. The continued development of new technologies and instruments is vital to sustain the pace of medical discovery.

Instrumentation also includes computers and computer programs. The information generated by researchers, the information needed to conduct clinical trials, and the information required for the optimal practice of medicine have long ago exceeded the capacity of pre-computer methods. Now it is essential that we continue to improve methods for storing, disseminating, and using new information in all the areas of biology and medicine. It is critical that we have the capacity to integrate the vast array of emerging genetic information into formats that are accessible to scientists worldwide, to establish new databases for visualizing 3-dimensional protein structures, to catalog the "molecular fingerprints" of genes that are turned on during the development of particular cancers, and to disseminate in a timely fashion critical information regarding public health and medical research.

Bioengineering encompasses a number of exciting technologies with enormous potential for improving the quality of life. One of the strengths of bioengineering as a discipline is that it integrates principles from diverse arenas, crossing the boundaries of biology, chemistry, mathematics, engineering, and physics, as well as medicine, academia, and industry. Research in biomaterials science, for example, expands our knowledge of how synthetic materials interact with body tissues, leading to development of new and enhanced implantable devices, improved therapeutic procedures, and more accurate delivery of drugs to particular body sites. Research on acoustic, electric, and magnetic field effects and how they can be used to produce images has led to developments in bioimaging that have revolutionized diagnostic procedures. Research on imaging and signal processing have resulted in devices that have made it possible to scale up human DNA sequencing, which in turn is transforming the way biotechnology and pharmaceutical companies approach therapeutic drug development. And progress in chip manufacturing and micro fabrication are providing tools for biologic discovery that will forever change research on the cause and treatment of most diseases.

Annual Target: **Progress in developing new instrumentation or technologies that enhance capabilities for investigating biological functions and diagnosing and treating diseases and disorders.**

Basis and Data: Data will be reported on the new findings, theories, and technologies forthcoming from the various research projects the NIH conducts and supports. Narrative descriptions of research accomplishments (e.g., scientific advances and stories of discovery) will place a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; the potential applications of knowledge from the research, if known; and the potential economic implications of the advance, if known. This information will provide perspective on where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health. These narrative descriptions will be augmented with science capsules that are short paragraphs that summarize an advance and its significance and brief descriptions of scientific awards/honors received by NIH scientists and grantees. Assessment of NIH's progress toward meeting this goal will be conducted by a working group of the Advisory Committee to the Director (ACD), NIH. This Assessment Working Group, composed of members of the ACD, the Director's Council of Public Representatives, and other standing NIH advisory committees, will assess NIH's progress in meeting this goal. The Assessment Working Group will use the following criteria in the assessment process. (See also Appendix 1.)

- The NIH biomedical research enterprise "*has successfully met this" goal* when its research yields new findings related to biological functions and behavior, and the new findings are published and/or disseminated.

- The NIH biomedical research enterprise "*has substantially exceeded this goal"* when, in addition to fulfilling the above criteria, any of the following apply:

  - Instruments and technologies improve quality of life. This includes new or improved ways to ameliorate/manage symptoms, relieve suffering, and restore/increase physical function/activity.

  - Technical barriers are overcome so that investigations that were previously impossible are now possible.

  - Instruments and technologies enable novel approaches to answering important biological and behavioral questions.

  - Instruments and technologies are applicable to other disciplines, areas of research, or diseases.

  - New/improved methods for generating, organizing, and disseminating genomic and other biological and behavioral information are developed.

Validation/Verification: Narrative descriptions of research accomplishments will be accompanied by citations of publications that relate to the accomplishment. The narratives and copies of the publications will be available for review for verification and validation purposes.

Assessment of FY 1999 Performance

FY 1999 Target: Progress in developing new instrumentation or technologies that enhance capabilities for investigating biological functions and diagnosing and treating diseases and disorders.

FY 1999 Achievement Summary:

- The annual target was substantially exceeded, per an independent assessment by a Working Group of the Advisory Committee of the Director, NIH. Specifically, the Working Group concluded that FY99 research outcomes have significantly contributed to progress in developing new or improved instruments and technologies. The new or improved instruments/technologies, as well as new applications of existing instruments/technologies, are enabling researchers to answer important biological questions. Knowledge gained from the use of these instruments/technologies will underpin the development of new and improved diagnostics, treatments, and preventive strategies that will ultimately improve human health and quality of life. In their discussion, members of the Working Group identified a number of important themes or categories of research outcomes, discussed the significance of these types of findings, and highlighted a number of research outcomes that they judged to be especially noteworthy.

- Illustrative examples of research outcomes identified by the Working Group as evidence of having exceeded the goal:

  A promising new technique has been developed and is being tested as a screening tool for lung cancer--low radiation dose spiral computed tomography (spiral CT). Spiral CT can scan the entire lungs, form the neck to the diaphragm, in less than 20 seconds. Researchers found that, compared to chest X-ray, spiral CT is a considerably more effective tool for detecting small non-calcified lung nodules and thus, for detecting lung cancer at an earlier and potentially more curable stage.

  Researchers have developed a rapid, selective process--called direct analysis of large protein complexes (DALPC)--that is capable of rapidly identifying individual proteins in macromolecular complexes in the cell without first purifying each protein component. DALPC was used to analyze a ribosome of yeast and detected a previously unknown ribosomal protein. This new method can accomplish in a very short period of time what used to take years of intensive labor. It will provide crucial insights into complex biological phenomena and will greatly contribute to biological investigations in the post-genomic era.

Scientists developed novel tissue engineering methods to grow functional blood vessels that have an improved capacity to remain open to blood flow. Surgeons may one day be able to use blood vessels grown from a patient's own cells to replace clogged arteries. Similar techniques could lead to the production of whole organs for replacement of damaged ones.

- The Assessment Report of the Working Group is attached separately. The Report describes the independent assessment process developed and implemented by the NIH; provides a detailed overview of the research outcomes submitted to the Working Group for assessment; sets forth the assessment criteria developed and applied by the Working Group; and summarizes the Working Group's discussion of the research outcomes and their rationale for concluding that the target was substantially exceeded.

Sources of FY 1999 Assessment Data: More than 70 descriptions of research outcomes published in FY 1999 were provided to the Working Group as examples of how NIH has been successful in meeting the annual target. The research outcomes were presented in the form of science advances, science capsules, and stories of discovery, with relevant citations as appropriate. The assessment report of the Working Group contains an overview of the FY 1999 research outcomes provided for this goal, as well as a table listing the titles of the narratives.

Discussion of Performance: FY 1999 research outcomes have significantly contributed to progress in developing new or improved instruments/technologies. The new or improved instruments/technologies, as well as new applications of existing instruments/technologies, are enabling researchers to answer important biological questions. Knowledge gained from the use of these instruments/technologies will underpin the development of new and improved diagnostics, treatments, and preventive strategies that will ultimately improve human health and quality of life.

Next Steps: This annual target is sufficiently broad so that it is appropriate for future years.

Goal c) Develop new or improved approaches for preventing or delaying the onset or progression of disease and disability.

Disease and disability exact enormous tolls on our society, both economic and personal. Rising health care costs highlight the importance of research that seeks to prevent disease and disability, or to delay and/or minimize its impact. In the quest for effective and efficient means of disease prevention, knowledge about basic mechanisms of illness and health must be complemented by public education programs aimed at health-promoting lifestyles and practices.

The development of preventive, delaying, or disease-halting strategies requires a multi-disciplinary approach. Epidemiological studies provide a necessary foundation for any disease prevention program by identifying the magnitude, and possibly the variability, of a disease within any given population. The epidemiological patterns of targeted diseases may identify subpopulations that are at risk for developing specific diseases, as well as provide information about the course of disease development in different environments and in different age, ethnic and socioeconomic groups. Prevention and disease-halting strategies also require a solid understanding of disease mechanisms. For example, it is important to know what causes the disease, how the disease affects specific cells or organs, if there is a genetic basis or predisposition for developing the disease, and whether a person's immune system plays a role in the disease process. A solid understanding of the disease mechanism facilitates the development of effective ways to prevent or delay the disease. Evaluating any new therapies or behavioral approaches requires clinical research and often clinical trials. Behavioral studies are also needed. Effective strategies for prevention or control of a disease may include a new medication, or an alteration in behavior or lifestyle. Strategies are needed to both educate the public as well as encourage the public to take advantage of these findings.

Targeting preventive and disease- or disability-delaying health interventions to at-risk individuals, as opposed to the general population, permits efficient use of health care dollars, a consideration that will assume increasing importance as baby boomers age and as the ability to identify at-risk populations increases. Researchers understandably are assigning high priority to studies that will identify risk factors for disability, predict disabling events, sharpen screening processes to identify target populations, and design and evaluate interventions specifically for individuals at risk for disability and disease.

Annual Target: **Progress in developing (or facilitating the private sector's development of) new or improved approaches for preventing or delaying the onset of diseases and disabilities -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.**

Basis and Data: Data will be reported on the new concepts and capabilities forthcoming from across the various research projects the NIH conducts and supports. Narrative descriptions of research accomplishments (e.g., scientific advances and stories of discovery) will place a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; the potential applications of knowledge from the research, if known; and the potential economic implications of the advance, if known. This information will provide perspective on where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health. These narrative descriptions will be augmented with science capsules that are short paragraphs that summarize an advance and its significance and brief descriptions of scientific awards/honors received by NIH scientists and grantees. Assessment of NIH's progress toward meeting this goal will be conducted by a working group of the Advisory Committee to the Director (ACD), NIH. This Assessment Working Group, composed of members of the ACD, the Director's Council of Public Representatives, and other standing NIH advisory committees, will assess NIH's progress in meeting this goal. The Assessment Working Group will use the following criteria in the assessment process. (See also Appendix 1.)

- The NIH biomedical research enterprise "*has successfully met this" goal* when its research yields new findings related to biological functions and behavior, and the new findings are published and/or disseminated.

- The NIH biomedical research enterprise "*has substantially exceeded this goal"* when, in addition to fulfilling the above criteria, any of the following apply:

  - Findings demonstrate potential to lead/contribute to the development of preventive measures or strategies for delaying the onset/progression of disease and disability.

  - Research-based advances and public health campaigns result in broad health impacts–such as reductions in morbidity and mortality, changes in health-related behavior, amelioration of health disparities.

  - Prevention strategies are applicable to other disciplines, areas of research, or diseases and conditions.

  - Discoveries improve quality of life by preventing or delaying the onset/progression of symptoms, suffering, loss of function, and/or injury.

Validation/Verification: Narrative descriptions of research accomplishments will be accompanied by citations of publications that relate to the accomplishment. The narratives and copies of the publications will be available for review for verification and validation purposes.

Assessment of FY 1999 Performance

FY 1999 Target: **Progress in developing (or facilitating the private sector's development of) new or improved approaches for preventing or delaying the onset of diseases and disabilities -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.**

FY 1999 Achievement Summary:

- The annual target was successfully met, per an independent assessment by a Working Group of the Advisory Committee of the Director, NIH. In an initial general discussion, the Working Group acknowledged the importance of considering burden of illness in identifying especially noteworthy outcomes. They emphasized the importance of delaying the onset of disability and the tremendous implications this has for society in terms of health care costs and the toll on caregivers. The number of people that might be affected by an intervention is equally significant, and simple interventions that have an impact on large populations are especially meaningful. The Working Group also highlighted a number of especially noteworthy outcomes that, in the judgment of the members, fulfilled the criteria for having substantially exceeded the goal. These advances fell into a number of broad categories: longitudinal studies; studies related to the prevention and treatment of mental illness across the life span; therapeutic interventions that also prevent or slow disease progression; behavioral interventions; and community-based interventions.

- Illustrative examples of research outcomes identified by the Working Group as evidence of having met the goal:

  Major depression has generally been considered an adult illness, but investigators found that depression that begins in adolescence is likely to continue into adulthood and often leads to suicide, suicide attempts, or a high degree of long-term disability. With this new awareness, it becomes critically important that depression among adolescents is detected early and treated appropriately.

  Researchers developed and validated a method to determine proper placement of feeding tubes that is quicker and less costly than the current use of x-rays. The method successfully identified all instances of improper placement of the feeding tube in the respiratory tract, an event which has consequences of high morbidity and mortality.

  Scientists demonstrated the safety and effectiveness of the anti-AIDS viral drug Nevirapine for preventing mother-to-child transmission of HIV. Nevirapine is 70 times less expensive and much easier to administer than AZT, the standard of care in the United States. It offers new hope for reducing maternal-child HIV transmission in developing countries and may be useful for further reducing mother-to-child transmission of AIDS in the U.S.

- The Assessment Report of the Working Group is attached separately. The Report describes the independent assessment process developed and implemented by the NIH; provides a detailed overview of the research outcomes submitted to the Working Group for assessment; sets forth the assessment criteria developed and applied by the Working Group; and summarizes the Working Group's discussion of the research outcomes and their rationale for concluding that the target was successfully met or substantially exceeded.

Sources of FY 1999 Assessment Data: Approximately 90 descriptions of research outcomes published in FY 1999 were provided to the Working Group as examples of how NIH has been successful in meeting the annual target. The research outcomes were presented in the form of science advances, science capsules, and stories of discovery, with relevant citations as appropriate. The assessment report of the Working Group contains an overview of the FY 1999 research outcomes provided for this goal, as well as a table listing the titles of the narratives.

Discussion of Performance: FY 1999 research outcomes have significantly contributed to progress in developing new or improved approaches for preventing or delaying the onset of disease and disability. The FY 1999 research outcomes demonstrate NIH responsiveness to health needs and scientific opportunities and innovative uses of new and improved instruments and technologies. The new or improved preventive strategies that have and will arise from this research will ultimately improve human health and quality of life and have the potential to reduce health care costs.

Next Steps: This annual target is sufficiently broad so that it is appropriate for future years.

Goal d) Develop new or improved methods for diagnosing disease and disability.

Early diagnosis and detection of disease is often a key requisite for effective treatment and prevention of disease and disability. Some of the most life-threatening diseases and disabilities can only be controlled or cured if they are diagnosed and treated in the earliest stages. Diagnostic methods include a broad array of biomedical technology, e.g., machines that directly visualize the body, cells, and tissues; instruments that can measure specific body functions; and tests that detect minute quantities of biological and inorganic materials. Despite the extreme variability, diagnostic tools must be accurate and safe. It is also advantageous if they are inexpensive, noninvasive, easy to use and pain-free.

Research to create new diagnostic tools is closely intertwined with basic disease research; diagnostic tools are most commonly developed after the mechanisms of the specific disease process are understood. Studying the efficacy and accuracy of diagnostic tools requires clinical research. It must be shown that a given test is both reliable and effective.

Annual Target: **Progress in developing (or facilitating the private sector's development of) new or improved diagnostic methods that are more accurate, less invasive, and/or more cost-effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies**.

Basis and Data: Data will be reported on the new concepts and technologies forthcoming from across the various research projects the NIH conducts and supports. Narrative descriptions of research accomplishments (e.g., scientific advances and stories of discovery) will place a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; the potential applications of knowledge from the research, if known; and the potential economic implications of the advance, if known. This information will provide perspective on where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health. These narrative descriptions will be augmented with science capsules that are short paragraphs that summarize an advance and its significance and brief descriptions of scientific awards/honors received by NIH scientists and grantees. Assessment of NIH's progress toward meeting this goal will be conducted by a working group of the Advisory Committee to the Director (ACD), NIH. This Assessment Working Group, composed of members of the ACD, the Director's Council of Public Representatives, and other standing NIH advisory committees, will assess NIH's progress in meeting this goal. The Assessment Working Group will use the following criteria in the assessment process. (See also Appendix 1.)

- The NIH biomedical research enterprise "*has successfully met this" goal* when its research yields new findings related to biological functions and behavior, and the new findings are published and/or disseminated.

- The NIH biomedical research enterprise "*has substantially exceeded this goal"* when, in addition to fulfilling the above criteria, any of the following apply:

  - New findings demonstrate potential to lead/contribute to the development of new and improved diagnostics.

  - Diagnostics improve health care and/or quality of life. This includes new or improved diagnostic methods that are more sensitive and accurate; allow diagnosis or detection at an early/earlier stage; enable early/earlier treatment or preventive interventions; predict future susceptibility to disease/disability; and/or are less invasive, painful, and/or costly than current techniques.

  - Diagnostic methods are applicable to other disciplines, areas of research, or diseases.

Validation/Verification: Narrative descriptions of research accomplishments will be accompanied by citations of publications that relate to the accomplishment. The narratives and copies of the publications will be available for review for verification and validation purposes.

The aim of much of NIH research is the development of new and improved therapeutics. This pathway to our ultimate goal of better health requires a strong foundation of understanding disease mechanisms and normal and abnormal biological functions. Searches for new therapies depend on advances in chemistry, bioengineering, enzymology, structural biology, genetics, immunology, cellular and molecular biology, and pharmacology.

New techniques to rapidly screen chemical compounds are now greatly expanding the pool from which possible therapeutic substances can be drawn. The study of molecular structures by x-ray crystallography has yielded detailed understanding of many molecules critical to health, as well as therapeutic molecules specifically tailored to "fit" the structures and thus alter their chemical activity. In addition, the science of synthetic chemistry has yielded many improved ways to design new therapeutic substances.

Clinical research is the final common pathway to the development of new therapeutics. New approaches, be they drugs, devices or changes in behavior, must ultimately be evaluated in humans. This usually requires clinical trials. In addition, health services research is needed to study the ultimate effect of any new approach on the burden of a disease, both to the individual and to society.

Assessment of FY 1999 Performance

FY 1999 Target: **Progress in developing (or facilitating the private sector's development of) new or improved diagnostic methods that are more accurate, less invasive, and/or more cost-effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies**.

FY 1999 Achievement Summary:

- The annual target was substantially exceeded, per an independent assessment by a Working Group of the Advisory Committee of the Director, NIH. Specifically, the Working Group concluded that the outcomes demonstrated that NIH had significantly contributed to the development of new or improved methods for diagnosing disease. The research outcomes demonstrate new or improved diagnostic methodologies that are more accurate, less invasive, and/or more cost-effective, and are responsive to emerging health needs, scientific opportunities, and new technologies. The new or improved diagnostics that have or will arise from this research will ultimately improve human health and quality of life. For example, earlier and/or more accurate diagnosis can lead to earlier and more informed treatment decisions, and this may contribute to more positive health outcomes .In their discussion, members of the Working Group identified a number of important themes or categories of research outcomes related to diagnosis, discussed the significance of these types of findings, and highlighted a number of research outcomes that they judged to be especially noteworthy.

- Illustrative examples of research outcomes identified by the Working Group as evidence of having exceeded the goal:

  The Brain Tumor Genome Anatomy Project (BTGAP) is developing a comprehensive molecular profile of primary brain tumors at progressive levels of malignancy. The first focus of BTGAP has been the genes that are active in gliomas, the most serious and prevalent form of primary brain tumor. Already over 1000 unique genes have been detected. This new knowledge will contribute to new understanding of how tumor cells arise and to the development of more effective ways to prevent, diagnose, and treat tumors of the nervous system.

  About 5 years ago, researchers figured out how to use helical computed tomography scans to acquire detailed images of a large body region during a single breathhold, and to convert these images into elaborate three-dimensional models of the interior of anatomic structures in a way that simulated conventional endoscopy. Researchers have now developed a method to use these simulated endoscopies to automatically locate tumors in the air passages of the lungs. This may allow physicians to diagnose tumors of the airway without the need to pass an instrument down a patient's throat to see the tumor directly.

  Investigators have developed a test for diagnosing a form of an aggressive cancer called primary central nervous system lymphoma (PCNSL) that can involve the brain, spinal

cord, and the eye. The scientists identified genes and proteins which are altered in the tumor cells of PCNSL and also found that the form of PCNSL that involves only the eyes is associated with high levels of certain proteins known as cytokines. This knowledge will allow a more precise diagnosis of the disease, leading to earlier detection and more adequate treatment.

- The Assessment Report of the Working Group is attached separately. The Report describes the independent assessment process developed and implemented by the NIH; provides a detailed overview of the research outcomes submitted to the Working Group for assessment; sets forth the assessment criteria developed and applied by the Working Group; and summarizes the Working Group's discussion of the research outcomes and their rationale for concluding that the target was substantially exceeded.

FY 1999 Data Summary: More than 50 descriptions of research outcomes published in FY 1999 were provided to the Working Group as examples of how NIH has been successful in meeting the annual target. The research outcomes were presented in the form of science advances, science capsules, and stories of discovery, with relevant citations as appropriate. The assessment report of the Working Group contains an overview of the FY99 research outcomes provided for this goal, as well as a table listing the titles of the narratives.

Discussion of Performance: FY 1999 research outcomes have significantly contributed to the development of new or improved methods for diagnosing disease. The research outcomes demonstrate new or improved diagnostic methodologies that are more accurate, less invasive, and/or more cost-effective. The new or improved diagnostics that have or will arise from this research will ultimately improve human health and quality of life. For example, earlier and/or more accurate diagnosis can lead to earlier and more informed treatment decisions, and this may contribute to more positive health outcomes.

Next Steps: This annual target is sufficiently broad so that it is appropriate for future years.

Goal e) Develop new or improved approaches for treating disease and disability.

The aim of much of NIH research is the development of new and improved therapeutics. This pathway to our ultimate goal of better health requires a strong foundation of understanding disease mechanisms and normal and abnormal biological functions. Searches for new therapies depend on advances in chemistry, bioengineering, enzymology, structural biology, genetics, immunology, cellular and molecular biology, and pharmacology.

New techniques to rapidly screen chemical compounds are now greatly expanding the pool from which possible therapeutic substances can be drawn. The study of molecular structures by x-ray crystallography has yielded detailed understanding of many molecules critical to health, as well as therapeutic molecules specifically tailored to "fit" the structures and thus alter their chemical activity. In addition, the science of synthetic chemistry has yielded many improved ways to design new therapeutic substances.

Clinical research is the final common pathway to the development of new therapeutics. New approaches, be they drugs, devices or changes in behavior, must ultimately be evaluated in humans. This usually requires clinical trials. In addition, health services research is needed to study the ultimate effect of any new approach on the burden of a disease, both to the individual and to society.

Annual Target: **Progress in developing (or facilitating the private sector's development of) new or improved treatments that expand therapy options; improve the length and quality of life; and/or are more cost effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.**

Basis and Data: Data will be reported on the new findings, theories, and technologies forthcoming from across the various research projects the NIH conducts and supports. Narrative descriptions of research accomplishments (e.g., scientific advances and stories of discovery) will place a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; the potential applications of knowledge from the research, if known; and the potential economic implications of the advance, if known. This information will provide perspective on where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health. These narrative descriptions will be augmented with science capsules that are short paragraphs that summarize an advance and its significance and brief descriptions of scientific awards/honors received by NIH scientists and grantees. Assessment of NIH's

progress toward meeting this goal will be conducted by a working group of the Advisory Committee to the Director (ACD), NIH. This Assessment Working Group, comprised of members from standing NIH advisory committees, will assess NIH's progress in meeting this goal. The Assessment Working Group will use the following criteria in the assessment process. (See also Appendix 1.)

- The NIH biomedical research enterprise "*has successfully met this" goal* when its research yields new findings related to biological functions and behavior, and the new findings are published and/or disseminated.

- The NIH biomedical research enterprise "*has substantially exceeded this goal"* when, in addition to fulfilling the above criteria, any of the following apply:

  - New findings demonstrate potential to lead/contribute to the development of new and improved treatments.

  - New or improved treatments improve health care and/or quality of life. This includes treatments that are more effective or have fewer side effects; relieve suffering; are more cost-effective; are less invasive, painful, and/or costly than current methods; effect a cure or remission of disease; and/or restore/increase physical function/activity.

  - Treatment approaches are applicable to other disciplines, areas of research, or diseases.

Validation/Verification: Narrative descriptions of research accomplishments will be accompanied by citations of publications that relate to the accomplishment. The narratives and copies of the publications will be available for review for verification and validation purposes.

Assessment of FY 1999 Performance

FY 1999 Target: **Progress in developing (or facilitating the private sector's development of) new or improved treatments that expand therapy options; improve the length and quality of life; and/or are more cost effective -- and which reflect NIH responsiveness to emerging health needs, scientific opportunities, and new technologies.**

FY 1999 Achievement Summary:

- The annual target was substantially exceeded, per an independent assessment by a Working Group of the Advisory Committee of the Director, NIH. Specifically, the Working Group concluded that the outcomes demonstrated significant progress in the development of new or improved approaches for treating disease and disability. The research outcomes also signify

NIH's responsiveness to health needs, scientific opportunities, and development and utilization of new technologies. The new or improved approaches to treatment that have or will arise from this research offer new or expanded treatment options and improved length and/or quality of life for patients. In addition, they may provide more cost-effective strategies for treating disease and disability. In their discussion, members of the Working Group identified a number of important themes or categories of research outcomes relating to treatments, discussed the significance of these types of findings, and highlighted a number of research outcomes that they judged to be especially noteworthy.

- Examples of research outcomes identified by the Working Group as evidence of having exceeded the goal:

  In animal studies, scientists found that the common antibiotic gentamicin restored the function of a defective protein known as dystrophin, involved in Duchenne muscular dystrophy. Furthermore, the treatment afforded the muscles protection against injury. This discovery may pave the way for a treatment in some human patients with this devastating disease.

  Investigators determined that infliximab--a monoclonal antibody that is the first approved treatment for the chronic inflammatory bowel disease known as Crohn's disease--was also effective for the treatment of fistulas, a serious complication affecting one-third of patients with Crohn's disease. Fistulas rarely heal spontaneously and, until now, required surgery. This new use for infliximab is a major advance for a condition that affects 500,000 people in the U.S., and it also foreshadows renewed interest in monoclonal antibodies.

  Behavioral therapy holds a prominent place in the armamentarium of effective treatments. Scientists demonstrated that a stand-alone educational workshop which provides information and behavioral management techniques for caregivers and families of caregivers can lead to reduced caregiver stress and burden. Information provided in this workshop enabled caregivers of persons with dementia to provide sophisticated care tasks. The public policy outcomes of reduced caregiver stress and burden include delayed institutionalization of care recipients, reduced caregiver health needs and reduced caregiver mental health needs. Chronic diseases of other types which may involve long-term caregiving also may benefit from the intervention.

- The Assessment Report of the Working Group is attached separately. The Report describes the independent assessment process developed and implemented by the NIH; provides a detailed overview of the research outcomes submitted to the Working Group for assessment; sets forth the assessment criteria developed and applied by the Working Group; and summarizes the Working Group's discussion of the research outcomes and their rationale for concluding that the target was substantially exceeded.

FY 1999 Data Summary: Nearly 100 descriptions of research outcomes published in FY 1999 were provided to the Working Group as examples of how NIH has been successful in meeting the annual target. The research outcomes were presented in the form of science advances, science capsules, and stories of discovery, with relevant citations as appropriate. The assessment

report of the Working Group contains an overview of the FY 1999 research outcomes provided for this goal, as well as a table listing the titles of the narratives.

Discussion of Performance: FY 1999 research outcomes have significantly contributed to the development of new or improved approaches for treating disease and disability. The FY 1999 research outcomes demonstrate NIH's responsiveness to health needs and scientific opportunities. The new or improved approaches to treatment that have or will arise from this research offer new or expanded treatment options and improved length and/or quality of life for patients. In addition, they may provide more cost-effective strategies for treating disease and disability

Next Steps: This annual target is sufficiently broad so that it is appropriate for future years.

Goal f) Develop critical genomic resources, including the DNA sequences of the human genome and the genomes of important model organisms and disease-causing microorganisms.

The Human Genome Project (HGP) was started in 1990 and has, from its beginning, enjoyed significant success. A major goal of the Human Genome Project is to sequence, or read, each of the approximately 3 billion bases in the human genetic instruction book. Determining the complete genetic blueprint of humans will greatly accelerate the identification of the genes embedded in this genetic code that underlie many human diseases, including complex diseases that represent the greatest health burden to the U.S. population. Identifying those genes is the first step to a more profound understanding of the biological basis of disease and this, in turn, will lead to much more effective and inexpensive ways to diagnosis, treat and prevent disease.

Many of the project's initial goals have been achieved, including building maps to localize and order the position of genes in both the human and mouse genomes, and sequencing the genomes of model organisms including the bacterium *E. coli*, baker's yeast, and the roundworm *C. elegans*. In addition, sequencing the genome of the fruit fly (*Drosophila melanogaster*) is nearly complete. The ability to compare the sequence of genes across multiple species and develop model systems in simpler organisms will significantly enhance the ability of researchers to identify the functional roles of the encoded proteins and thereby contribute to a better understanding of the molecular basis for human health and disease.

The basic building block of DNA is the nucleotide, and DNA consists of a string of the four nucleotides adenine, cytosine, guanine and thymine (A, C, G, T). Human genes may exist in many different forms, some of them differing only by a single A, C, G, or T. When such minor variations, known as mutations, occur in regions that instruct the production of a specific protein, an altered protein may be formed which may lead to a change in the normal functioning of the human body and which may manifest itself as disease. Additional research efforts will focus on determining the location and function of these genetic variations, with the goal of correlating specific mutations with clinical disease manifestations. Such information is invaluable to medical research and practice—allowing the identification of those at risk for disease, and contributing to the development of rational treatment and preventive strategies. Such precise genetic information may also permit the development of individualized therapies, a burgeoning field known as pharmacogenomics which utilizes genetic information to predict which patients will be most likely to respond favorably to a particular therapeutic drug.

Based on the success of a three-year pilot project, in March 1999, an international consortium, with the U.S. taking the lead, launched the full-scale effort to sequence the human genome. On November 17, 1999, the consortium deposited the one-billionth base pair of the human genome into the public database, GenBank. Achieving this important milestone marks the success of the transition from the pilot to the full-scale production sequencing. The consortium expects to produce at least 90 percent of the human genome sequence in a "working draft" form by the

spring of 2000, years earlier than initially expected, and is on track to complete the final, high quality genome sequence by 2003 or earlier.

FY 2001 Targets: **(1) Worldwide effort completes "full shotgun" of human genome sequence (95% complete, 99.9% accurate).**

(2) Finish one-third of human genome (accuracy of at least 99.99%).

(3) Identify 60,000 human single nucleotide polymorphisms (SNPs).

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) Worldwide effort completes "working draft" of human genome sequence (90% complete, 99% accurate). U.S. contributes two- thirds of that amount, and NIH contributes 85% of U.S. total.**

(2) Finish the sequence of at least one human chromosome.

(3) Complete sequence of the genome of Drosophila melanogastes (excluding heterochromatin).

Basis and Data: Demonstrated increases in the pace and progress of genome sequencing, as scheduled in the targets above. Other assessment measures will include the number of sequence records added to GenBank, the number of GenBank searches, development of genomic libraries of the rat, and completion of genome sequences of infectious pathogens, and progress in sequencing full-length human cDNAs. (The FY 1998 baseline for the U.S. annual production rate of human genomic sequence was 50 million base-pairs. The FY 1998 baseline for the worldwide annual production rate of human genomic sequence was 90 million base-pairs. The FY 1998 baseline for total human genomic sequence completed worldwide was 180 million base-pairs. The FY 1998 baseline for completing the sequence of the *C.elegans* genome was 90 million of the total genome of 97 million base-pairs. The current long range plan for 1998-2003 calls for the production rate to reach 500 million base-pairs of finished sequence annually by FY 2003. Under this plan, one-third of the human genome will be sequenced by the end of 2001 and completed by the end of 2003.)

Validation/Verification: Both finished and draft sequence data are deposited into GenBank and totals reported on an NIH Website. Production rates are reported weekly on the Website. September 1, 1999 sequence information submitted to GenBank by the major participants in the Human Genome Project has included quantitative, 'per nucleotide' quality estimates provided by appropriate analytical software; this quality information is also available publicly. Independent assessment of the quality of the sequence data produced under NHGRI funding will be done by a Quality Assessment

Center separately supported for that purpose by NHGRI. The results of the Quality Assessment Center's evaluations will be publicly available through a Web site and publication.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) U.S. annual production rate of human genomic sequence: 90 million base-pairs.**

(2) Worldwide annual production rate of human genomic sequence: 220 million base-pairs.

(3) Total human genomic sequence completed worldwide at the end of FY 1999: 400 million base-pairs.

(4) Complete the sequence of the *C.elegans* genome.

FY 1999 Achievement Summary:

- Targets (1), (2), and (3) have been exceeded.

  Target (1): U.S. annual production rate of human genomic sequence: 173 million base-pairs.

  Target (2): Worldwide annual production rate of human genomic sequence: 265 million base-pairs.

  Target (3): Total human genomic sequence completed worldwide at the end of FY 1999: 442 million base-pairs.

  The numbers reported represent finished, high quality (an error rate of less than 1 in 10,000 base pairs) sequence data that is deposited and available to anyone in the U.S. public database, GenBank.

- Target (4) was achieved early in FY 1999. The complete sequence of the 97 million base-pairs of the *C. elegans* genome was published in the journal Science on December 11, 1998 (*Science* 282:2012-2018, 1998)

Sources of FY 1999 Assessment Data: The major venue for primary publication of genomic data is public databases. Indeed, all sequence data produced by the international Human Genome Project consortium are deposited in public databases for free access within 24 hours. It should also be noted that the insistence on high accuracy which characterizes the consortium's work makes certain that the position of the sequence on a human chromosome is precisely known, and

each base is actually sequenced five to ten times to ensure accuracy. Thus the one billion base-pairs of deposited sequence actually represent about eight billion base-pairs of raw sequence.

The international Human Genome Project consortium has agreed that the finished sequence should have no more than 1 error in 10,000 base pairs, all finished stretches of DNA should be at least 30,000 base-pairs, and the sequence should have no gaps except regions that are intractable to current technology. It is expected that the standard for contiguity will be increased as the project progresses.

To ensure that this standard is being met, samples of data were exchanged between sequencing groups and assessed for quality. The most recent quality assurance (QA) exercise established that all of the publicly funded U.S. centers sequencing the human genome are meeting, and in many cases exceeding, the established standards. In the near future, an independent QA center will be established to continue to monitor the rapidly increasing amount of genomic sequence being deposited in public databases.

Further information on the content of these data sources can be found at:
http://www.nhgri.nih.gov:80/Grant_info/Funding/Statements/RFA/quality_standard.html
Felsenfeld A, Peterson J, Schloss J, Guyer M. Assessing the quality of the DNA sequence from the Human Genome Project. Genome Research 9:1-4, 1999.

Discussion of Performance: The Human Genome Project experienced a remarkably successful year in FY 1999, meeting or exceeding all of its goals. This was due in large part to the success of pilot projects, completed in March 1999, which tested new technologies and strategies for high throughput production sequencing.

Public funding of the Human Genome Project is predicated on the belief that public availability of the human sequence in the shortest possible time will lead to the greatest public good. NHGRI continues to endorse strongly the policy for human sequence data release adopted by the international sequencing community. This policy states that sequence assemblies 1-2 kilobases in size, as well as finished sequence, should be released into public databases within 24 hours. This information is maintained in the U.S. by the National Center for Biotechnology Information in the database, GenBank http://www.ncbi.nlm.nih.gov/Genbank/GenbankOverview.html.

The completion of sequencing the first genome of an animal, that of the roundworm *C. elegans*, marked a historic accomplishment for the Human Genome Project. This achievement, published in December 1998 (*Science* 282:2012-2018, 1998) provides biologists with a powerful tool to experiment with and learn how whole genomes function. The ability to compare the sequence of genes across multiple species and develop model systems in simpler organisms will significantly enhance the ability of researchers to identify the functional roles of the encoded proteins and thereby contribute to a better understanding of the molecular basis for human health and disease.

Next Steps: The success realized by the Human Genome Project in FY 1999 has resulted in a hastening of the goals. The Project now sets the ambitious goal of a 90% complete "working draft" of human genome sequence information by the Spring of 2000 and has advanced the target date for completion of the final, high quality genome sequence to 2003 or earlier.

In addition, the Human Genome Project is ahead of schedule with plans to sequence the complete genomes of two other important model organisms, the fruit fly and the mouse. Completion of the fruit fly genome is anticipated in early 2000. The mouse genome is targeted for completion of a working draft by 2003 and a finished, high quality form by 2005.

Goal g) Work towards the President's goal of developing an AIDS vaccine by 2007.

A vaccine works by sensitizing the body's immune system to a particular disease-causing bacterium, virus, toxin, or a component of a pathogenic organism. When the infectious agent subsequently invades the body, the immune system recognizes it and mounts an immediate and robust response to destroy the invader before it can cause disease. The many successes of traditional vaccines are well known, but other serious and fatal diseases still have proven stubbornly resistant to vaccines, demanding new approaches.

A safe and effective AIDS vaccine is a global public health imperative. As of December 1998, more than 33 million people were living with HIV/AIDS worldwide, with almost 6 million new infections occurring during 1998 alone. AIDS is now the fourth leading cause of death and is the leading cause of disease burden in the developing world. Without an effective vaccine, the pandemic will continue unchecked. In the U.S., the rate of new infections, approximately 44,000 per year, remains unacceptably high.

To complement the extramural AIDS vaccine effort, the NIH has established an intramural Vaccine Research Center (VRC) to focus on AIDS vaccines. When President Clinton announced the initiation of the VRC in May 1997, he also challenged the NIH and the scientific community to produce an AIDS vaccine within the next 10 years. As part of the effort to meet this challenge, the VRC is a joint venture between two NIH components -- the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID). The primary focus for the VRC is to stimulate multi-disciplinary research, from basic and clinical immunology and virology through to vaccine design and production. Currently, the VRC is a "laboratory without walls," including established intramural labs focused on this area of research. NIH is completing a building on the campus to eventually house scientists recruited for the VRC. In FY99, NIH hired a director for the Center.

FY 2001 Targets:

(1) Progress in the design and development of new or improved vaccine strategies and delivery/production technologies.

(2) Progress in characterization, standardization, and utilization of animal models for evaluating candidate vaccines.

(3) Progress in collaborating with industry to enhance opportunities for vaccine development.

(4) Progress in (a) completion of ongoing trials and (b) initiation of additional trials of new or improved concepts and designs, including the progression of promising candidates to larger trials testing vaccine candidates.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) Progress in the design and development of new or improved vaccine strategies and delivery/production technologies.**

(2) Progress in characterization, standardization, and utilization of animal models for evaluating candidate vaccines.

(3) Progress in collaborating with industry to enhance opportunities for vaccine development.

(4) Progress in (a) completion of ongoing trials and (b) initiation of additional trials of new or improved concepts and designs, including the progression of promising candidates to larger trials testing vaccine candidates.

Basis and Data: Narrative science advances will be used to document progress in vaccine strategies, delivery/production technologies, and animal models. The increase in interactions between academic investigators and industry will be inferred on the basis of activities to promote such interaction. Information from the Multi-Access Coding System (MACS) will be used to compile a record of the completion of ongoing new vaccine trials and the initiation of additional trials also will be taken from MACS.

Validation/Verification: All science advances will be supported by citations. MACS is a database that draws on IMPAC, NIAID financial data, and other sources.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Increases in the research portfolio supporting innovative vaccine discovery.**

(2) Increased interactions between academic investigators and industry, to enhance opportunities for vaccine discovery and product development.

(3) Progress in completion of ongoing trials and initiation of additional trials of new vaccine concepts and designs.

FY 1999 Achievement Summary:

- Targets (1), (2) and (3) have been met. The portfolio of innovative vaccine discovery has increased; actions were taken to increase the interaction of academic investigators and industry; four new trials began and, of the seven clinical trials that started in prior fiscal years, two more completed accrual.

  Target (1) The number and dollar value of awards made for vaccine discovery increased. The percent of the increases will be available in February 2000. NIH achieved this increase by enhancing opportunities for vaccine discovery and expanding efforts to move vaccine concepts from basic research to clinical trial initiation. The ground work for the increase was laid in prior years when NIH issued several solicitations with the express intention of stimulating more discovery research (e.g., the Innovation Grant Program for Approaches in HIV Vaccine Research and the Integrated Preclinical/Clinical AIDS Vaccine Development Program). Moreover, to ensure that the vaccine discovery effort continues to increase, in FY 1999 NIH launched an expanded and modified HIV Vaccine Research and Design Program and a new HIV Vaccine Design and Development Teams Program.

  Target (2) Interaction between academic investigators and industry was promoted when NIAID and the AIDS Vaccine Research Committee (AVRC) co-sponsored a May 3-5, 1999 workshop that brought together over 700 researchers from academia and industry to discuss new research findings in HIV vaccine development. Additionally, 19 companies collaborate with NIAID and NIAID-supported academic investigators in clinical testing of candidate vaccines through the HIV Vaccine Research and Design Program, the AIDS Vaccine Evaluation Group, and/or through clinical trials agreements. In addition, NIAID-supported resources (e.g., the Simian Vaccine Evaluation Units and a reagent program) are made available for use by industry in order to enhance opportunities for vaccine discovery and product development in that sector.

  Target (3) Since 1987, more than 3,000 non-HIV-infected volunteers have enrolled in 52 NIAID-supported preventive vaccine studies involving 27 vaccines (50 Phase-1 safety studies; two Phase 2 safety and immunogenicity studies). In FY 1999, NIAID made progress both (a) toward completion of on-going clinical trials and (b) in initiating new trials.

  - (a) As illustrated in Table 1, seven HIV vaccine clinical trials were on-going at the start of FY99. Of those, three already had completed accrual and continued to follow their protocols, two completed subject accrual in FY99, and two more progressed toward complete accrual.

Table 1 Trials Ongoing in FY 1999 (10/98 – 9/99)			
Study	**Accrual**	**Accrual Completed**	**Trial Status**
AVEG 027	11/97	10/98	Ongoing
AVEG 028	12/97	5/99	Ongoing
AVEG 033	1/98	6/98	Ongoing
AVEG 034	6/98	8/98	Ongoing
AVEG 202	5/97	1/98	Ongoing
AVEG 402	6/97	In progress	Ongoing
HIVNET 007	2/99	In progress	Ongoing

- (b) As illustrated in Table 2, NIAID initiated four new trials in FY99. Accrual of subjects has been completed for three of the four trials.

Table 2 Trials Initiated in FY 1999 (10/98 – 9/99)			
Study	**Accrual**	**Accrual Completed**	**Trial Status**
AVEG 031	11/98	2/99	Ongoing
AVEG 032	8/99	9/99	Ongoing
AVEG 034 A	9/99	In progress	Ongoing
AVEG 036	11/98	3/99	Ongoing

The total dollars to support HIV vaccine clinical trials in FY 1999, and the percentage increase this represents of FY 1998 will be available in February 2000.

Sources of FY 1999 Assessment Data:

The sources used for the assessment data used above are as follows:

Target (1) The percentages used to document performance on Target 1 will be calculated using baseline (FY 1998) and target year (FY 1999) data on the number and dollar value of awards made for vaccine discovery that is maintained in the MACS database. MACS draws on IMPAC, NIAID financial data, and other sources. NIH will select data from MACS using the OAR ARIS codes 4A, 4B, and 4C, which designate preclinical vaccine research in the OAR Plan. As indicated above, NIAID expects FY 1999 funding and award data to be available in late January.

Target (2) The agenda for and a videocast of the AVRC Workshop "New Concepts in HIV Vaccine Development" can be found on the World Wide Web at www.niaid.nih.gov/daids/vaccine/meetings/mayavrc.htm.

Target (3) The lists of clinical trials supported in FY 1999 (Tables 1 and 2 above) come from the MACS database (described under Target 1 above). FY 1999 funding data will be compiled using OAR ARIS codes 4D, 4E and 4F, which code for clinical vaccine research in the OAR Plan. The figures will include the vaccine-related work of AVEG and HINVET. Yet again, we expect this data to be available in late January.

Additional sources of FY 1999 assessment data for this goal – data that do not directly address the three targets but are highly significant in term of the goal – are the science advances and science capsules provided in Research Assessment Report in support of the NIH's five general research outcome goals. (See the advance titled Progress Toward Development of a Broadly Effective HIV Vaccine, the advance titled Combination HIV Vaccine Induces Diverse Immune Responses in High-HIV Risk Population, the capsule titled Weakened Virus Still Causes Disease in Primates, and the capsule titled Cellular Immunity may be Key to HIV/AIDS Vaccine.)

Discussion of Performance: As measured by the three targets, NIH made significant progress toward achieving the President's goal of developing an AIDS vaccine by 2007. However, the targets measure the resources (the number of dollar value of discovery awards) and processes (academic/industry interaction, clinical trial initiation and completion) used to achieve the goal. They do not evaluate the significance of the research conducted with those resources and processes. That is, the data provided to document performance targets only indicate that a vigorous effort is being made; they do not indicate whether the scientific findings provide hope that a vaccine can be developed. Fortunately, some findings do provide encouragement. For example, one of the biggest barriers to development of an HIV vaccine is existence of multiple strains of HIV coupled with the high frequency of mutation. Hope that development of a broadly protective vaccine for HIV is possible arrived in FY 1999 with the publishing of NIH supported research findings on a vaccine candidate that targets HIV surface proteins that are transiently exposed. (For a fuller description of this finding, see the science advance titled Progress Toward Development of a Broadly Effective HIV Vaccine.)

Next Steps: NIAID will provide data to substantiate the assessments of Targets 1 and 3. Also, NIH has revised the targets for FY 2000 and FY 2001 to broaden the focus of the progress evaluation to encompass research outcomes. These targets are the starting point for a dialogue on the development of outcome-oriented measures of progress toward an AIDS vaccine.

2.1.2.2 Communication of Results

Communicating about health and science has long been recognized as a key NIH function. The Public Health Service Act of 1944, which defined the responsibilities of the Public Health Service (and the NIH) with respect to research, specifically authorized the PHS and NIH to "collect and make available through publications, and other appropriate means, information as to, and the practical applications of, such research and other activities." [Title III Sec. 301 (1)]

All of the NIH Institutes and Centers (ICs) conduct programs to collect, disseminate, and exchange information on medical and biological science, medicine, and health. The National Library of Medicine (NLM) is a congressionally-mandated central resource for published biomedical information, which serves health care professionals, researchers, and the public worldwide.

The legislation that enables and directs the development of NIH programs has consistently emphasized the importance of informing the public about the results of health-related research. The authorizing legislation for all ICs includes "dissemination of health information" as an integral part of each Institute's basic mission. Information dissemination ensures that the science NIH conducts and supports is appropriately applied--whether by other scientists, health care providers, patients, or the public. Without the flow of information, the important results of research would languish at the researcher's bench.

Among NIH's most critical challenges in the realm of communicating research results are:

- Improving access to and use of NIH-based information within an increasingly competitive information environment
- Ensuring access to appropriate health information among health care providers and facilitating the use of research-based innovation so that research advances translate into improved patient care
- Ensuring access to appropriate health information among minority and other at-risk audiences
- Increasing public and provider awareness, understanding, and willingness to participate in clinical research (clinical trials).

To meet these challenges, NIH works to improve outreach and access to health information. In some cases, NIH reaches out directly to health care providers and the public. In other cases, collaboration with organizations is initiated to increase attention to NIH-based information within the competitive information environment.

NIH is addressing access to information within a competitive information environment by working with organizations that have more direct access to providers (such as the American Academy of Family Practice), using techniques such as telehealth technology and consolidated databases, and improving customer services. NIH also is addressing improvements in awareness of NIH-sponsored research among health care providers, in addition to developing targeted

campaigns and educational activities on significant health problems for patients and their families, and for minority, high risk, and low-access publics. Efforts also are under way to improve public and provider understanding of, access to, and support for clinical trials.

Performance Goals Summary Table – Communication of Results

Performance Goals	FY Targets	Actual Performance	Details
a) Increase awareness of NIH-sponsored research among health care providers to promote research application.	***FY 2001 Targets*** (1) Create a partnership with the American Academy of Family Physicians to increase the knowledge of primary care physicians about the diagnosis and treatment of mental disorders. (2) Disseminate and encourage use of clinical practice guidelines on asthma through the use of continuing medical education programs on the Web-based Asthma Management Model System. ***FY 2000 Targets*** (1) Disseminate and encourage the use of clinical practice guidelines for the treatment of high blood pressure, high blood cholesterol, and other conditions by physicians who provide care to African-American patients. (2) Fund a series of demonstration projects applying telemedicine and other technology to improve the speed of reaching heart attack victims with lifesaving treatment. (3) Use telehealth technology and TV cable networks for education projects with nursing organizations and academic institutions: broadcast select conferences and workshops to nursing organizations and academic institutions and add Web site components that will allow users to interact on-line with live discussions, conferences, and other types of meetings. (4) Expand the "Not Just Once, But for A Lifetime" mammography campaign to reach health professional organizations, physicians, nurses, and other health and medical practitioners to increase awareness of the importance of mammography screening and the Medicare mammography benefit, and referrals for women, particularly those aged 65 and older. Develop and disseminate motivational messages related to breast and cervical cancer screening targeted to African American, Hispanic, and Asian communities. (5) Complete the evaluation of selected NIH outreach programs: a) the use of clinical	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 71

Performance Goals	FY Targets	Actual Performance	Details
	practice guidelines on the treatment of high blood pressure and high blood cholesterol by physicians who provide care to African-American patients, and b) the use of clinical practice guidelines on high blood pressure and obesity. ***FY 1999 Target*** Evaluate several selected NIH outreach programs: a) the use of clinical practice guidelines on the treatment of high blood pressure and high blood cholesterol by physicians who provide care to African-American patients, and b) the use of clinical practice guidelines on high blood pressure and obesity.	**FY 1999 target not met.**	
b) Increase awareness of NIH-sponsored research results among high risk, under-served, and/or affected publics.	***FY 2001 Target*** (1) Develop and implement an AIDS vaccine communication campaign to increase awareness of AIDS vaccines before the initiation of a large efficacy trial. (2) Expand the dissemination of diabetes information to target audiences, and increase understanding about the seriousness of diabetes and importance of blood glucose control. (3) Increase focus on osteoporosis across the age spectrum; and develop and implement information and education on sports injuries (particularly for women), and provide information related to autoimmunity (particularly as it relates to rheumatoid arthritis, lupus, scleroderma, and alopecia areata). ***FY 2000 Targets*** (1) Increase the available information on the benefits of exercise to older people. (2) Develop and disseminate motivational messages related to breast and cervical screening to African American, Hispanic, and Asian communities. (3) Expand programs on anxiety disorders and depression to audiences for whom language or literacy are challenges. (4) Develop and disseminate easy-to-read and Spanish language health education materials on health issues to targeted special populations.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 75

Performance Goals	FY Targets	Actual Performance	Details
	(5) Develop and implement diabetes awareness campaigns that target minority populations and their health care providers. (6) As an activity of the NIH Hispanic Communications Initiative (HCI), conduct a Spanish-language "media summit" that will detail strategies for developing continuous and sustainable working partnerships between NIH information offices, national Spanish-language media outlets, and national Hispanic intermediary organizations. (7) Pursue new outreach and collaboration initiatives to disseminate information and resources on rheumatic diseases in minority populations. ***FY 1999 Targets*** (1) Develop and implement NIH information, education, and outreach programs on specific health issues: Breast Cancer and Mammography Education Program. (2) Develop and implement NIH information, education, and outreach programs on specific health issues: extend the Back to Sleep Campaign to target minority populations. (3) Evaluate several selected NIH outreach programs: cardiovascular health outreach activities for Latinos. (4) Establish a centralized site on the NIH Home Page for access to NIH materials in Spanish.	**FY 1999 target (1) met.** **FY 1999 target (2) met.** **FY 1999 target (3) partially met.** **FY 1999 target (4) met.**	
c) Increase awareness of NIH-sponsored research results among the general public.	***FY 2001 Targets*** (1) Produce and disseminate a comprehensive report on college drinking and related problems that includes review and evaluation of current knowledge and recommendations about research needs to more than 2,000 college and university presidents, program planners, communities, and policy makers. (2) Complete a seven-year, 22 city tour of the traveling science museum exhibit VISION, one component of a nationwide public education program to promote achievements of publicly-funded vision research.	FY 2001: To be reported in January 2002.	Page 80

Performance Goals	FY Targets	Actual Performance	Details
	(3) Develop strategic alliances with youth-related organizations that result in the integration of calcium messages from the "milk matters" campaign into their sports, fitness, and health education programming. (4) Provide information and education on sports injuries (particularly to women), and provide information and education related to autoimmunity (particularly as it relates to rheumatoid arthritis, lupus, scleroderma, and alopecia areata.) (5) Disseminate information and education programs on stroke to increase the number of people who know the symptoms and seek treatment rapidly. (6) Update existing resources and develop a comprehensive and interactive Website component of "Cancer Research: Because Lives Depend on It," a multi-year educational initiative designed to increase the public's understanding of cancer research, advances, and opportunities. (7) Implement the WISE EARS! communications program by developing a coalition of more than 70 groups representing government, industry, the worker, children and older individuals as well as organizations directly committed to preventing noise-induced hearing loss and providing them with resources in order to reach children under 17, adults in mid-life, and older Americans as a means to provide information about how to prevent fully preventable noise-induced hearing loss with messages in all 50 states and territories by 2002. ***FY 2000 Targets*** (1) Generate a minimum of 30 million media impressions through placements in newspapers and magazines nationwide and on national and local television and radio programs to raise awareness among all Americans of the importance of eating at least 5 servings of fruit and vegetables a day. (2) Expand the outreach of the "milk matters" campaign beyond parents and health professionals to focus directly on activities and	FY 2000: To be reported in January 2001.	

Performance Goals	FY Targets	Actual Performance	Details
	products that help children and teens recognize the benefit of calcium in building strong bones. (3) Increase collaboration with professional associations of journalists, science writers, and health communicators to increase their coverage of NIH-funded research results. (4) Implement WISE EARS! communications program by developing a coalition of more than 70 groups representing government, industry, the worker, children and older individuals as well as organizations directly committed to preventing noise-induced hearing loss and providing them with resources in order to reach children under 17, adults in mid-life, and older Americans as a means to provide information about how to prevent fully preventable noise-induced hearing loss with messages in at least 50% of states by 2001. ***FY 1999 Targets*** (1) Develop and implement NIH information, education, and outreach programs on specific health issues: Low Vision. (2) Increase the availability of consumer health information, publications, and reports under NIH's Centralized Consumer Health Information area by 20 percent. (3) Complete the restructuring of NIMH's mental health education and information dissemination programs--as recommended by reviewers and the National Advisory Mental Health Council. (4) Strengthen relationships with universities, voluntary health associations, and other organizations that communicate health and scientific information--to expand the options for communicating NIH research results.	**FY 1999 target (1) met.** **FY 1999 target (2) exceeded.** **FY 1999 target (3) met.** **FY 1999 target (4) met.**	
d) Increase awareness of clinical research and support participation in clinical trials.	***FY 2001 Targets*** (1) Continue to develop materials and methods to educate the public about the importance of clinical research and to interest individuals and their families in participating in clinical studies (supported by NIMH). (2) Increase the number and diversity of individuals who contact the NIH Clinical	FY 2001: To be reported in January 2002.	Page 86

Performance Goals	FY Targets	Actual Performance	Details
	Center by 20% over FY 2000 figures. (3) Initiate a communication and outreach program to reach physicians, community groups, and the general public that will result in a 15% increase in initial contacts to the Patient Recruitment and Public Liaison Office (PRPL) over FY 2000 figures. (4) Improve NCI efforts to increase participation and retain minorities, underserved populations, and the elderly in clinical trials. (5) Develop Web-based clinical trials tools that will improve the development, conduct, and ease of participation in NCI-sponsored clinical trials. (6) Strengthen relationships with and outreach to target audiences through more than 60 constituency groups nationwide to help deliver the latest scientific information about drug abuse and addiction prevention and treatment and to provide feedback on emerging grassroots issues.		
	FY 2000 Targets (1) Build and maintain networks of communication and support for clinical research between NIMH and consumer and advocacy organizations and professional groups nationally, regionally, and locally. (2) Develop methods and materials to improve communication with minorities and ethnic groups and to encourage them to participate in (NIMH-sponsored) clinical research, thus meeting a critical public health need. (3) Develop simplified and easy-to-understand informed consent forms to help patients better understand a study's treatments and tests and their possible benefits and risks before deciding whether or not to participate. (4) Increase visitors to NCI's *cancerTrials* Web Site and the amount of information about cancer trials to patients, health professionals, the public and the media in all areas including prevention, detection, diagnosis, and treatment.	FY 2000: To be reported in January 2001.	
	FY 1999 Target Initiate a broad-based communications and	**FY 1999 target met.**	

Performance Goals	FY Targets	Actual Performance	Details
	public outreach program to reach physicians, and eventually, community groups and the general public.		
e) Establish a Clinical Trials Database, as required by the FDA Modernization Act.	***FY 2001 Target*** (1) Implement an outreach program to promote the database as a resource for patients, physicians, researchers, community health groups and others. (2) Implement, at least on a pilot basis, toll-free telephone access to information in the Clinical Trials Database. ***FY 2000 Targets*** (1) Expand the Clinical Trials Database to include trials from other federal agencies and the private sector. (2) Develop options for implementation of toll-free telephone access to information in the Clinical Trials Database. ***FY 1999 Targets*** Develop and implement the Clinical Trials Database.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 89
f) Improve the National Library of Medicine's customer service and information services for individuals seeking medical information.	***FY 2001 Target*** Expand the NLM's consumer health information program to ensure that a medical library in every state and major metropolitan area is working with public libraries and community organizations to improve the public's access to health information. ***FY 2000 Targets*** (1) Ensure that no less than 85 percent of respondents to a customer feedback instrument rate NLM services at least satisfactory. (2) Increase the usage of NLM's existing catalog-based databases for books, serials, and audiovisuals by 15 percent. (3) Increase the number of "health topics" in the Web-based MEDLINE *plus* to 300. ***FY 1999 Targets*** (1) Provide a single toll-free telephone number to reach customer service staff.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met.**	Page 91

Performance Goals	FY Targets	Actual Performance	Details
	(2) Implement a system to track customer service interactions, measure response times, and record customer feedback on NLM products and services.	**FY 1999 target (2) met.**	

Performance Goal Details - Communication of Results

Goal a) Increase awareness of NIH-sponsored research among health care providers to promote research application.

NIH's research mission--to develop new knowledge that leads to better health--is dependent upon the translation of research advances into improved patient care. This goal significantly contributes to that translation by helping ensure that health care providers learn about the latest research findings.

FY 2001 Targets:

(1) Create a partnership with the American Academy of Family Physicians to increase the knowledge of primary care physicians about the diagnosis and treatment of mental disorders.

(2) Disseminate and encourage use of clinical practice guidelines on asthma through the use of continuing medical education programs on the Web-based Asthma Management Model System.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets:

(1) Disseminate and encourage the use of clinical practice guidelines for the treatment of high blood pressure, high blood cholesterol, and other conditions by physicians who provide care to African-American patients.

(2) Fund a series of demonstration projects applying telemedicine and other technology to improve the speed of reaching heart attack victims with lifesaving treatment.

(3) Use telehealth technology and TV cable networks for education projects with nursing organizations and academic institutions: broadcast select conferences and workshops to nursing organizations and academic institutions and add Web site components that will allow users to interact on-line with live discussions, conferences, and other types of meetings.

(4) Expand the "Not Just Once, But for A Lifetime" mammography campaign to reach health professional organizations, physicians, nurses, and other health and medical practitioners to increase awareness of the importance of mammography screening and the Medicare

mammography benefit, and referrals for women, particularly those aged 65 and older. Develop and disseminate motivational messages related to breast and cervical cancer screening targeted to African American, Hispanic, and Asian communities.

(5) Complete the evaluation of selected NIH outreach programs: a) the use of clinical practice guidelines on the treatment of high blood pressure and high blood cholesterol by physicians who provide care to African-American patients, and b) the use of clinical practice guidelines on high blood pressure and obesity.

Basis and Data: The principal measures of achievement for each of these targets is implementing the project and tracking and measuring the effects of the outreach, education, and informational activities. Where relevant, the use and usefulness of communication materials, telemedicine, and Web technology will be assessed.

Validation/Verification: Written documentation confirming project implementation and impact findings will be provided.

Assessment of FY 1999 Performance

FY 1999 Target: **Evaluate several selected NIH outreach programs: (1) the use of clinical practice guidelines on the treatment of high blood pressure and high blood cholesterol by physicians who provide care to African-American patients, and (2) the use of clinical practice guidelines on high blood pressure and obesity.**

FY 1999 Achievement Summary:

- Target has not been met. Both evaluation efforts continue to be underway.

- Status of each effort:

Target (1) Since the outreach effort is scheduled to run an additional year, the evaluation is still under way. Preliminary data are being submitted regularly. Once the outreach effort has been concluded at the end of calendar year 2000, the final evaluation will be finished. The preliminary data suggest, however, that the National Physicians Network has been revitalized and is beginning to meet expectations.

Target (2) An evaluation of physician practices in hypertension treatment began in the summer of 1999 with a series of 8 focus groups with physicians, patients, and allied health professionals. Because of weather and unanticipated travel problems physician recruitment proved more difficult than anticipated. It is now planned that the focus groups will be completed in the Spring of 2000. Because the focus groups conducted to date have provided

new information on how physicians are using the guidelines, the survey design will be reconsidered as soon as the last of the focus groups are completed in the Spring of 2000.

Sources of FY 1999 Assessment Data:
Target (1) Data on such factors as Web site hits, number of presentations made by targeted physicians, numbers of public audience members reached through these presentations are being collected on a quarterly basis.

Target (2) Study topics include initial clinical encounter for hypertension; preference for hypertension education materials, management strategy, facilitators, and barriers to successful treatment; and provider responsibilities.

Discussion of Performance:
Target (1) The National Heart, Lung, and Blood Institute (NHLBI) awarded a two-year contract to the Association of Black Cardiologists (ABC) to provide continuing education opportunities and other information to health professionals who serve primarily African-American patients. In 1999, the first year of the project, ABC took over the leadership responsibility for the National Physicians Network, a multidisciplinary group of physicians formed by the NHLBI in 1995 to carry out community-based heart health education for professionals, patients, and the public.

As of the first year, members of the network had presented information on heart health to a cumulative audience of approximately 18,5000 professional and lay individuals, compared with an audience of only about 4,000 individuals in the prior 4 years.

Also, a videotaped presentation was aired on a Fox Network affiliate, which has a subscribed audience of 175,000 people in New Orleans, Jefferson, and St. Charles, LA. In 1999, ABC also established a professional education Web site on heart health. One of the items most frequently downloaded from the Web site is a heart health education Speakers Kit. Close to 20,000 kits have been ordered during the past 6 months. In addition, the kit has been incorporated into the curricula of the four historically black medical schools-- Drew, Howard, Meharry, and Morehouse. It also is being promoted through the ABC project to nursing schools in seven historically black colleges and universities.

Target (2) The clinical practice guidelines on high blood pressure were disseminated widely in 1998 through direct mail, presentations at professional conferences, programs, and the NHLBI Web Site. In addition to the planned focus groups, originally the evaluation was to have included a national survey of primary care physicians regarding their attitudes, beliefs, and reported behaviors. The survey design and instrument was to be developed based on what was learned from the focus groups, as well as from the literature. Because the focus groups conducted to date have provided new information on how physicians are using the guidelines, the survey design will be re-thought once the focus groups are completed.

Next Steps:
Target (1) Data collection will continue for another year.

Target (2) Focus groups will be completed and planning for a national survey continued. The work on the Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity is near completion. A working group has considered the evaluations provided by 50 health care practitioners working in primary care who reviewed and subsequently revised the document. The final document should be available in early 2000 and will be disseminated through the various associations working on the guide as well as by the NHLBI.

Goal b) Increase awareness of NIH-sponsored research results among high risk, underserved, and/or affected publics.

Many research results apply to particular segments of the public, such as those at greater risk of contracting a specific disease, or those who may not be regularly encountering a health care provider. This goal contributes to ensuring that the individuals who are most likely to benefit are specifically targeted with information resulting from pertinent research results.

FY 2001 Targets:

(1) Develop and implement an AIDS vaccine communication campaign to increase awareness of AIDS vaccines before the initiation of a large efficacy trial.

(2) Expand the dissemination of diabetes information to target audiences, and increase understanding about the seriousness of diabetes and importance of blood glucose control.

(3) Increase focus on osteoporosis across the age spectrum; develop and implement information and education on sports injuries (particularly for women); and provide information related to autoimmunity (particularly as it relates to rheumatoid arthritis, lupus, scleroderma, and alopecia areata).

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets:

1) Increase the available information on the benefits of exercise to older people.

2) Develop and disseminate motivational messages related to breast and cervical screening to African American, Hispanic, and Asian communities.

(3) Expand programs on anxiety disorders and depression to audiences for whom language or literacy are challenges.

(4) Develop and disseminate easy-to-read and Spanish language health education materials on health issues to targeted special populations.

(5) Develop and implement diabetes awareness campaigns that target minority populations and their health care providers.

(6) As an activity of the NIH Hispanic Communications Initiative (HCI), conduct a Spanish-language "media summit" that will detail strategies for developing continuous and sustainable working partnerships between NIH information offices, national Spanish-language media outlets, and national Hispanic intermediary organizations.

(7) Pursue new outreach and collaboration initiatives to disseminate information and resources on rheumatic diseases in minority populations.

Basis and Data: The principal measures of achievement for each of these targets is implementing the project and tracking and measuring the effects of the outreach, education, and informational activities. Where relevant, the use and usefulness of communication materials, telemedicine, and Web technology will be assessed.

Validation/Verification: Written documentation confirming project implementation and impact findings will be provided.

Assessment of FY 1999 Performance

FY 1999 Targets:

(1) Develop and implement NIH information, education, and outreach programs on specific health issues: Breast Cancer and Mammography Education Program.

(2) Develop and implement NIH information, education, and outreach programs on specific health issues: extend the "Back to Sleep" Campaign to target minority populations.

(3) Evaluate several selected NIH outreach programs: cardiovascular health outreach activities for Latinos.

(4) Establish a centralized site on the NIH Home Page for access to NIH materials in Spanish.

FY 1999 Achievement Summary:

- Target (1) was met. The National Cancer Institute (NCI) continued to implement this program, increasing outreach to include Cancer Information Service offices and HCFA partners.

- Target (2) was met with implementation of the "Back to Sleep Campaign." Major accomplishments this fiscal year contributing to this have been:

-- Completed video featuring a series of vignettes of minority families overcoming some of the barriers to placing an infant on their back to sleep.

-- Implemented outreach to day care facilities.

-- Created coalition of African American organizations who made a commitment to devote the resources of their organizations to promoting back sleeping in African American communities.

- Target (3) was partially met. Only the evaluation of "Salud para Su Corazon" (Health for Your Heart) was completed.

- Target (4) was met. A centralized site on the NIH Home Page for access to NIH materials in Spanish was established and launched in FY 1999, on October 4, 1998.

Sources of FY 1999 Assessment Data:
Target (1) Breast cancer and mammography brochures, bookmarks, posters, and other materials were developed by NCI in conjunction with HCFA. These materials were distributed through the Cancer Information Service's toll free number and partnership program, as well as through HCFA offices. To ensure that the Breast Cancer and Mammography Education Program would best reach its intended audience, consumer research was conducted. This included a nationwide telephone survey of women ages 65 and older to gather information on the knowledge, attitudes, and behaviors of older women concerning breast cancer, mammography screening, and Medicare coverage for mammography, as well as testing of mammography messages through focus groups with women ages 40 and older.

Target (2) The video was distributed to 2,750 organizations and individuals involved with SIDS education. All of the approximately 230,000 licensed day care facilities in 49 states were reached with information about placing infants on their backs to sleep. (California State Health Department distributed State-developed materials to day care centers in California.)

Target (3) A report on the "Salud" model is scheduled for publication in the October 1999 issue of Journal of Community Health. The data from the complete evaluation are now being finalized for posting on the NHLBI Web Site and publication in public health journals.

Target (4) Data to support this includes logs on the NIH Web Server and documents on file announcing the launch of the site.

Discussion of Performance:
Target (1) As a result of NCI-sponsored research, there is ever-increasing knowledge about the importance of early detection of breast cancer and the options for its successful treatment. To ensure that this knowledge is applied to save women's lives, NCI developed this program to motivate women, especially those least likely to be getting mammograms, to seek regular screening. During FY 1999, a nationwide survey of women aged 65 and older found that 25% more women reported ever having a mammogram than in a similar survey in 1992, and that whereas more than

75% were aware that Medicare helps pay for mammograms, only 58% had actually used the benefit. During FY 1999, working with the Cancer Information Service (CIS) resulted in 20,500 outreach contacts with partners about breast cancer, helping to prompt 82,500 calls to the CIS toll-free number (1-800-4-CANCER). About 1.15 million publications, posters, and bookmarks on breast cancer were distributed. Related information and educational activities are designed to help women who have suspicious mammograms understand the full range of diagnostic and treatment options.

Target (2) Research demonstrated that the simple act of shifting an infant to back sleeping could substantially lower the incidence of SIDS (Sudden Infant Death Syndrome). A critical element needed to instigate this change was the widespread dissemination of this message to parents and other caregivers of infants. Minority outreach has been a part of the Back to Sleep campaign since the inception of the campaign. Nevertheless, the incidence of SIDS in African American babies has not dropped in the same way as among whites, and the incidence of SIDS in this population is more than double that of white babies. Therefore, achieving message placement in day care centers and securing the commitments of African American organizations to promote the message within African American communities were important to further reduce deaths due to SIDS.

The minority-focused video was completed and distributed to community organizations such as the SIDS Alliance, the Association of SIDS and Infant Mortality Programs, and community health centers. The video was also promoted to appropriate chapters/sections within the American Academy of Pediatrics, and through the Maternal and Child Health Bureau of HRSA. The video has been used in small discussion groups to promote person-to-person information exchange and counseling.

In a new major emphasis to involve leading African American community organizations to reduce SIDS, DHHS Secretary Shalala and Mrs. Tipper Gore announced the NICHD/National Black Child Development Institute initiative to involve community-based organizations in developing and implementing community-based approaches to eliminate the disparity in SIDS rates affecting African American communities.

Target (3) “Salud para su Corazon” (Health for your Heart) is a community-based outreach initiative of the National Heart, Lung, and Blood Institute (NHLBI), designed to increase awareness and knowledge of cardiovascular disease risk factors and promote heart-health behaviors among low income, low acculturated, and less educated Latinos 18-54 years of age. Program strategies include the dissemination of educational materials through the media and community channels; “charlas,” or community group discussions; and other community outreach events.

To measure the programs reach and impact on the target population, as well as satisfaction with the program's educational materials and modes of dissemination, surveys were administered to Spanish-speaking respondents before the campaign began and 6 months after the primary intervention period. Pre- and post-test samples were comparable in demographics and recruitment locations.

Pre-test responses showed low awareness of cardiovascular (CVD) risk factors and actions for prevention. Post-test responses showed significant gains in awareness and knowledge of CVD prevention, as well as increased availability of sources of information in Spanish. For example,

without prompting, 19.5% of respondents in the post-test could cite at least 3 of the 5 modifiable risk factors highlighted in the campaign, compared with 11.0% in the pre-test. The proportion of people able to recall CVD risk factors increased across both gender and age groups. There was knowledge of prevention behaviors to reduce CVD.

While changes in CVD awareness among Latinos could be explained in part by secular trends, the "Salud para Su Corazon" campaign was recalled frequently as a source of information on CVD by post-test respondents. Further, the specific messages recalled and the sources of information cited at post-test were similar to those promoted in the campaign, indicating that it was successful in reaching the target audience.

Target (4) The site has been integrated into the structure of the NIH home page and new resources are being added as they become available. Providing access to Spanish language materials from various NIH sources in one place will facilitate access to these materials, furthering the aim of widely disseminating information resulting from NIH research. Log records show the site is actively used.

Next Steps:
Target (1) NCI's efforts will focus on increasing the number of providers who refer women for screening mammograms. NCI, in partnership with HCFA and other agencies, will work with professional medical organizations to increase awareness among providers and will develop materials that facilitate communications between providers and patients about mammography and breast cancer.

Target (2) Extending the Back to Sleep outreach campaign to minority populations, and particularly to African American communities is an activity that will span more than one year. In 1999, specific activities in support of the goal were achieved. In addition, the NICHD/NBCDI collaboration began building an infrastructure that will involve major segments of the African American community in activities designed to promote back sleeping and reduce the incidence of SIDS.

Target (3) Based on the need to move toward behavior change strategies, the NHLBI has produced *Bringing Heart Health to Latinos: A Guide for Building Community Programs* to instruct communities in how to implement "Salud" activities. In addition, it has developed a partnership with the National Council of La Raza, which will fund three community-based organizations that agreed to implement the "Salud" messages and strategies at the local level. This project also will be evaluated.

Target (4) As with many Web sites, the challenge is now to maintain the site and keep pace with developments associated with the Hispanic Initiative.

Goal c) Increase awareness of NIH-sponsored research results among the general public.

This goal contributes to ensuring that new knowledge resulting from research is broadly disseminated to reach as many individuals who can benefit as possible. Often, the general public can use the results of NIH-sponsored research to improve their health and the health of their families.

FY 2001 Targets:

(1) Produce and disseminate a comprehensive report on college drinking and related problems that includes review and evaluation of current knowledge and recommendations about research needs to more than 2,000 college and university presidents, program planners, communities, and policy makers.

(2) Complete a seven-year, 22 city tour of the traveling science museum exhibit "VISION," one component of a nationwide public education program to promote achievements of publicly-funded vision research.

(3) Develop strategic alliances with youth-related organizations that result in the integration of calcium messages from the "Milk Matters" campaign into their sports, fitness, and health education programming.

(4) Provide information and education on sports injuries (particularly to women), and provide information and education related to autoimmunity (particularly as it relates to rheumatoid arthritis, lupus, scleroderma, and alopecia areata.)

(5) Disseminate information and education programs on stroke to increase the number of people who know the symptoms and seek treatment rapidly.

(6) Update existing resources and develop a comprehensive and interactive Website component of "Cancer Research: Because Lives Depend on It," a multi-year educational initiative designed to increase the public's understanding of cancer research, advances, and opportunities.

(7) Implement the "WISE EARS!" communications program by developing a coalition of more than 70 groups representing government, industry, the worker, children and older individuals as well as organizations directly committed to preventing noise-induced hearing

loss and providing them with resources in order to reach children under 17, adults in mid-life, and older Americans as a means to provide information about how to prevent fully preventable noise-induced hearing loss with messages in all 50 states and territories by 2002.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets:

(1) Generate a minimum of 30 million media impressions through placements in newspapers and magazines nationwide and on national and local television and radio programs, to raise awareness among all Americans of the importance of eating at least 5 servings of fruit and vegetables a day.

(2) Expand the outreach of the "Milk Matters" campaign beyond parents and health professionals to focus directly on activities and products that help children and teens recognize the benefit of calcium in building strong bones.

(3) Increase collaboration with professional associations of journalists, science writers, and health communicators to increase their coverage of NIH-funded research results.

(4) Implement "WISE EARS!" communications program by developing a coalition of more than 70 groups representing government, industry, the worker, children and older individuals as well as organizations directly committed to preventing noise-induced hearing loss and providing them with resources in order to reach children under 17, adults in mid-life, and older Americans as a means to provide information about how to prevent fully preventable noise-induced hearing loss with messages in at least 50% of states by 2001.

Basis and Data: NIH will track, document, and measure the effects of outreach, education, and information activities. Use and usefulness of communication materials will be evaluated. Participation in and usefulness of telemedicine and Web technology will be documented.

Validation/Verification: Written documentation confirming project implementation and impact findings will be provided.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Develop and implement NIH information, education, and outreach programs on specific health issues: Low Vision.**

(2) Increase the availability of consumer health information, publications, and reports under NIH's Centralized Consumer Health Information area by 20 percent.

(3) Complete the restructuring of NIMH's mental health education and information dissemination programs--as recommended by reviewers and the National Advisory Mental Health Council.

(4) Strengthen relationships with universities, voluntary health associations, and other organizations that communicate health and scientific information--to expand the options for communicating NIH research results.

FY 1999 Achievement Summary:

- Target (1) was met. Completed development of the Low Vision Education Program; implementation began with a program launch on October 15, 1999. Mass media materials were produced and distributed to the print media and by satellite to television and radio stations in all 50 states. A special emphasis was placed on the top 25 markets, plus markets with a large population of people aged 65 and older who are more likely to experience vision loss.

- Target (2) was exceeded. The number of on-line publications increased from 144 in 1998 to 253 in 1999. This represents an increase of approximately 76%.

- Target (3) was met. A new position with new responsibilities was created at the Associate Director level, with a joint appointment as Office Director. This position was filled in June 1998. A new mission statement for the Office was developed, and the new Associate Director made a presentation to the National Advisory Mental Health Council on her vision and goals for the Institute's communications program.

- Target (4) was met. As one example, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has established relationships with 375 public and private organizations to support the National Diabetes Education Program. For NIDDK, organizations working with the Institute are regularly kept up-to-date about information and education activities. Materials are prepared to help interested organizations "get the message out" to their constituents and the general public. One measure of the intentions of these organizations to promote NIDDK messages is whether they order campaign kits. In 1999, partner organizations ordered 1,594 copies of the Campaign Guide for Partners. Other specialty campaign kits (the Medicare Benefits Campaign Kit, General Audience Campaign Kit, African American Media Kit, Asian American/Pacific Islander Media Kit, Hispanic/Latino Media Kit, American Indian

Media Kit) became available in August 1999. By October 1999, nearly 2,500 of these specialty kits already had been requested from partner organizations.

Sources of FY 1999 Assessment Data:
Target (1) The target was achieved through the launch of the program on October 19, 1999. Data on program implementation was unavailable because launch was conducted in early FY 2000.

Target (2) Data is based on an analysis of archived records of the older versions of the health information index as well as the log of the Web editor.

Target (3) Evidence of these changes can be found on the NIMH Web Site http://www.nimh.nih.gov. The Institute organizational chart provided on the Web Site shows the new communications office at http://www.nimh.gov/about/compon.cfm and the new mission statement for the office, along with contact information for the new Associate Director, can be found at http://www.nimh.gov/ocpl/index.htm. Examples of newly developed materials such as the new series *Research Facts About NIMH* located at http://www.nimh.gov/publicat/soms.cfm is the new *Science on Our Minds*, a series of brief fact sheets highlighting advances in the treatment of mental illnesses and covering areas of NIMH research. These brief fact sheets were initially distributed at the White House Conference on Mental Health, June 7, 1999, and at a Mental Health Forum on Rural Mental Health held in Anchorage, Alaska, August 10, 1999.

Target (4) A variety of sources of data are used to track relationships, including numbers of activities, numbers of requests, and numbers of materials.

Discussion of Performance:
Target (1) Low vision affects 14 million people, causing significant interference with their activities every day. (Low vision is a visual impairment, not correctable by standard glasses, contact lenses, medicine, or surgery.)

In some cases of vision loss, treatment is not effective. However, NEI-supported research has demonstrated that vision rehabilitation can help individuals maintain their independence, thus improving their quality of life. Therefore, it is important that people understand the resources that are available to help when they experience vision loss. This low vision information program was developed to translate the research findings into information that can help individuals experiencing vision loss; success to date has helped ensure that the results of NIH-sponsored research reach those who can most benefit from it.

Target (2) To increase awareness of NIH-sponsored research results among the general public, NIH has made use of the Web as a means of increasing the availability of health information stemming from advances in medical research. This goal seeks to measure the relative advances in efforts to make use of this new technology in furthering our goal of disseminating research-based health information. The conversion of paper-based information products to on-line data files can be expensive and time-consuming. To ensure that NIH is providing users with new and expanded on-line information resources, data were collected to measure the rate at which new information was posted in the consumer health information area. Data collected for this target reflects both NIH's commitment to improving this resource as well as the fact that more Institutes are making their

documents available in this format. As a result, more consumer health information is available to the public.

Target (3) A new position with new responsibilities was created at the Associate Director level, with joint appointment as Office Director. The position was filled June 1998, a new mission statement for the Office developed, and the vision and goals for the Institute's restructured communications program presented at the National Advisory Mental Health Council. Since then, the NIMH mental health education and information functions have been undergoing a searching review, with subsequent revisions in staff roles and office strategy. All contracts have been examined and adjusted; new research fact sheets have been developed; the Institute Web Site has been modified to better serve scientists, the press and the public; and public education materials are being systematically reviewed. To reflect these changes, an NIMH logo has been developed and incorporated into all Institute communications to foster a unified image. In addition, the communications office has been renamed the "Office of Communications and Public Liaison."

Target (4) The National Diabetes Education Program (NDEP) is a joint program of the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH and the Centers for Disease Control and Prevention (CDC). The program's purpose is to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and ultimately to prevent the onset of the disease. It is conducted as a partnership among more than 375 public and private organizations that are concerned about the health of their constituents.

Enlisting the cooperation of universities, voluntary health, and other organizations enables NIH to use organizations' communication channels to their constituents, increasing both the number of health messages to the public, and the saliency of messages endorsed by a trusted, familiar source. Further, consistent, repetitive messages funneled through as many routes as possible increase the number of people who both pay attention to and use the vital health information conveyed.

Next Steps:
Target (1) This program will be incorporated as an ongoing activity of the National Eye Health Education Program, coordinated by NEI with 60 national partner organizations. Future strategies will include working with the media, providing materials and technical assistance to organizations and agencies, working with professional organizations to educate their members, providing information through the NEI Web Site, and coordinating a new traveling exhibit with local communities.

Target (2) As the number of Americans with access to the Internet increases, the value of posting public documents on-line increases. To the extent possible, NIH will to continue to expand this area as more publications become available.

Target (3) A strategic plan for communications is being developed. New information materials continue to be written, including materials for low literacy and Hispanic audiences. Partnerships with organizations such as the American Academy of Family Physicians will be developed to disseminate research-based information on the diagnosis and treatment of mental illness.

Target (4) To assess partnership involvement, NDEP is providing feedback forms to members of the Partnership Network to assess their usage of the NDEP messages and materials. More broadly, all of the NIH Institutes are continuing to establish and maintain a variety of relationships to further efforts to disseminate research findings.

Goal d) Increase awareness of clinical research and support participation in clinical trials.

To enable and support NIH-funded research, a steady, diverse, and substantial pool of patient and normal volunteers is needed. The quality of clinical research and its ability to improve the public's health care depend on the nation's physicians having the opportunity to refer patients to current studies and on patients having the information they need to learn about and participate in clinical trials.

FY 2001 Targets:

(1) Continue to develop materials and methods to educate the public about the importance of clinical research and to interest individuals and their families in participating in clinical studies (supported by NIMH).

(2) Increase the number and diversity of individuals who contact the NIH Clinical Center by 20% over FY 2000 figures.

(3) Initiate a communication and outreach program to reach physicians, community groups, and the general public that will result in a 15% increase in initial contacts to the Patient Recruitment and Public Liaison Office (PRPL) over FY 2000 figures.

(4) Improve NCI efforts to increase participation and retain minorities, under-served populations, and the elderly in clinical trials.

(5) Develop Web-based clinical trials tools that will improve the development, conduct, and ease of participation in NCI-sponsored clinical trials.

(6) Strengthen relationships with and outreach to target audiences through more than 60 constituency groups nationwide to help deliver the latest scientific information about drug abuse and addiction prevention and treatment, and to provide feedback on emerging grassroots issues.

Performance Assessment – Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets:

(1) Build and maintain networks of communication and support for clinical research between NIMH and consumer and advocacy

organizations and professional groups nationally, regionally, and locally.

(2) Develop methods and materials to improve communication with minorities and ethnic groups and to encourage them to participate in (NIMH-sponsored) clinical research, thus meeting a critical public health need.

(3) Develop simplified and easy-to-understand informed consent forms to help patients better understand a study's treatments and tests and their possible benefits and risks before deciding whether or not to participate.

(4) Increase visitors to NCI's *cancerTrials* Web Site and the amount of information about cancer trials to patients, health professionals, the public and the media in all areas including prevention, detection, diagnosis, and treatment.

Performance Assessment--Basis and Data: Outreach efforts will be tracked, documented, and assessed. Communication methods and materials will be evaluated to determine reach to target audiences and acceptance of the messages.

Validation/Verification: Written documentation confirming project implementation and impact findings will be provided.

FY 1999 Performance Assessment

FY 1999 Target: **Initiate a broad-based communications and public outreach program to reach physicians, and eventually, community groups and the general public.**

FY 1999 Achievement Summary:

- Target met. The outreach program was initiated in the 3rd quarter of FY 1999.

Sources of FY 1999 Assessment Data: Numerical targets were not established for FY 1999. Baseline data collected during this fiscal year served to establish FY 2000 targets.

Discussion of Performance: The outreach efforts assist the Institutes to accrue patients to clinical research studies by increasing awareness, prompting inquiries about research, and linking eligible patients to specific studies. These activities included establishing a Community Outreach Leadership Group of 13 leaders of major ethnic minority organizations; development of a videotape, physician brochure, physician database, and protocol information sheets; contacting 60 minority organizations and health care organizations to distribute materials and present presentations;

establishing contacts with 23 senior citizen organizations and attending 2 senior health fairs to distribute information; conducting mailings to physicians and links with physician Web sites; and placing 106 ads and study announcements in newspapers, newsletters, and magazines. Initial outreach efforts in FY 1999 were fully under way for "protocol clusters"--protocols categorized by disease (e.g., HIV) and target audience (e.g., senior citizens). The initiation of outreach and recruitment initiatives resulted in an increase of 174 calls per month to the call center during the last two quarters of the FY. FY 1999 program data revealed that recruiting for specific protocols resulted in increased enrollment to those protocols.

Next Steps: Recruitment for specific protocols proved to be resource-intensive and, as expected, did not affect overall recruitment across Institutes. As a result, continued assistance will be offered for specific protocols, and the same time, physician and community outreach will be broadened to a number of different disease groups and target audiences.

Goal e) Establish a Clinical Trials Database, as required by the FDA Modernization Act.

Currently, there is no consolidated source of information on clinical trials for drugs for serious or life threatening diseases and conditions. Many of today's most effective interventions are the direct result of knowledge gained through clinical trials -- studies that evaluate the safety and effectiveness of new drugs and other interventions. Facilitating access to information on clinical trials is an important national goal. At the present time, the NIH Home Page provides consolidated access to eight clinical trials databases: the NCI's Physician's Data Query; the AIDS Clinical Trials information System, Rare Disease Clinical Trials Database; Clinical Center Studies, the NEI Clinical Trials database, the NHLBI Clinical Trials database, the NIA Alzheimer's Disease Clinical Trials database, and the NIAID Clinical Trials database. A central or common database does not exist. The database required by the FDA Modernization Act will include all federally and privately funded clinical trials for drugs for serious or life threatening diseases and conditions submitted under Investigational New Drug (IND) applications.

Establishing toll-free telephone access to the Clinical Trials Database will be complex and expensive. Due to the uncertainties regarding the demands that could be placed upon the system (that is, the number of calls), the many possible designs for the system, and the varying levels of service that might be provided, a competitive contract will be awarded to study options for design and level of service.

FY 2001 Targets: **(1) Implement an outreach program to promote the database as a resource for patients, physicians, researchers, community health groups and others.**

(2) Implement, at least on a pilot basis, toll-free telephone access to information in the Clinical Trials Database.

Basis and Data: *Basis and Data:* The principal measures of achievement for each of these targets are implementing the projects and subsequently tracking, documenting and assessing the effects of outreach and informational activities.

Validation and Verification: Documentation of achievement of these targets will be available in publicly accessible reports.

FY 2000 Targets: **(1) Expand the Clinical Trials Database to include trials from other federal agencies and the private sector.**

(2) Develop options for implementation of toll-free telephone access to information in the Clinical Trials Database.

Basis and Data: Documented establishment of a clinical trials database to which other federal agencies and the private sector will submit information. Documentation of contract award and of progress in developing options for the toll-free number.

Validation and Verification: Documentation of the achievement of these targets will be available in publicly accessible reports.

Assessment of FY 1999 Performance

FY 1999 Target: Develop and implement the Clinical Trials Database.

FY 1999 Achievement Summary:

- This project has met its FY 1999 target.
- Based on the legislative requirements and discussions with NIH collaborating Institutes and Centers (ICs) and other groups, data elements were developed for the Clinical Trials Database. A prototype Internet-based database was designed, and an on-line data entry system was developed for use by NIH ICs. Data from the eight existing clinical trials databases together with data from all other ICs that support clinical trials were incorporated into the prototype system. In addition, focused testing was conducted.

Sources of FY 1999 Assessment Data: The performance data for this target are valid and verifiable. A paper describing the clinical trials database appeared in late summer 1999: McCray ,AT., *A National Resource for Information on Clinical Trials*. National Forum Vol. 79, No. 3, 1999, 19-21.

Discussion of Performance: Based on the legislative requirements of Section 113 of the FDA Modernization Act of 1997 and discussions with NIH collaborating ICs and other groups, data elements were developed for the clinical trials database. National Library of Medicine staff designed and implemented a prototype clinical trials database and developed processes for electronic transfer of clinical trials data from NIH ICs. NLM also developed an on-line data entry system for use by groups at NIH. In September 1999, focused testing of the database began.

Next Steps: The first version of the clinical trials database will be available to the public in early FY 2000. This initial version of the system will contain primarily NIH sponsored trials. The second version to be made available later in FY 2000 will begin to include trials from other federal agencies and the private sector.

Goal f) Improve the National Library of Medicine's customer service and information services for individuals seeking medical information.

The National Library of Medicine (NLM) collects, organizes, and makes available biomedical science information to investigators, educators, practitioners, and the public, and carries out programs designed to strengthen medical library services in the United States. Its electronic databases, including MEDLINE, are used extensively throughout the world.

The NLM's 1997 introduction of free searching of its MEDLINE database of journal references via the Web has proved very popular. The other parts of NLM's "medical literature" collection (books, audiovisuals, serial titles) have just become accessible via the Web. These three catalog databases were primarily used by librarians who are trained searchers. Opening a combined catalog database to the public via easy Web access should greatly increase their usage.

The pilot program called the NLM Public Library Initiative offered small cash grants, training of public librarians by nearby medical librarians, and assistance with outreach to public libraries to improve their health information services for consumers. The results of the 9-month pilot program, which began in October1999 and involved 39 public library systems in 10 states, have encouraged the NLM to offer support for consumer health information programs in other parts of the Nation. This plan received endorsement of the Library's Board of Regents in May 1999 when it expanded NLM's target audiences and affirmed that the Library has an important role in consumer health information. NLNM will award some 40 "outreach" contracts in January 2000 to medical libraries to support their working with public libraries and other community organizations to improve the public's access to reliable health information.

FY 2001 Target: Expand the NLM's consumer health information program to ensure that a medical library in every state and major metropolitan area is working with public libraries and community organizations to improve the public's access to health information.

Basis and Data: Successful achievement will be marked by the milestone identified in the target above.

Validation and Verification: Documentation of the achievement of this target will be available in publicly accessible reports.

FY 2000 Targets: (1) Ensure that no less than 85 percent of respondents to a customer feedback instrument rate NLM services at least satisfactory.

(2) Increase the usage of NLM's existing catalog-based databases for books, serials, and audiovisuals by 15 percent.

(3) Increase the number of "health topics" in the Web-based MEDLINE *plus* to 300.

Basis and Data: Information collected from a customer feedback instrument installed in FY1999 will serve as baseline data for the tracking and enhancement of customer service interactions, including the frequency of use of a toll-free telephone number and service response times. Under NLM's legacy (non-Web) system there were 1.32 million searches of the catalog-based databases for books, serials, and audiovisuals in FY1997. The new LOCATORplus Web Site, introduced in Spring 1999, provides easy access to NLM's catalog databases for the first time. As of Fall 1999, the site averages about 35,000 hits monthly.

Validation and Verification: Documentation of the achievement of this target will be available in publicly accessible reports.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Provide a single toll-free telephone number to reach customer service staff.**

(2) Implement a system to track customer service interactions, measure response times, and record customer feedback on NLM products and services.

FY 1999 Achievement Summary:

- Target (1) was met. The toll free number was instituted. The current rate of callers on the toll-free number is more than 30,000 per year.

- Target (2) was met. The NLM has installed a sophisticated software program (CustomerQ software of Quintus Inc.) and has successfully implemented a program that tracks inquiries, measures response times, and records customer feedback on NLM services.

Sources of FY 1999 Assessment Data:
Target (1) The toll free number is 1-888-346-3656 (1-888-FINDNLM).

Target (2) The above data are actual and verifiable using the Quintus software.

Discussion of Performance:
Target (1) The toll-free number is staffed by reference librarians who are experienced in providing information for health professionals (24 percent of calls) and who now also can provide access to

authoritative health information for the general public (76 percent of calls). This has become especially important as the NLM's consumer health activities result in a toll-free number becoming more widely known.

Target (2) As the worlds' largest medical library and the hub of a national network of medical libraries, the NLM seeks to provide health information services for professionals and consumers. Reference assistance is available for patrons on-site, via the toll-free telephone number and, increasingly, via e-mail. The tracking software, which initially tracked only e-mail inquiries, was adapted in July 1999 to handle inquiries via the toll-free number. The current workload rate is 40,000 e-mail reference inquiries per year.

Next Steps:
Target (1) The toll free number will continue to be supported to ease access to the NLM.

Target (2) It is expected that these rates will rise as the NLM's toll-free number and e-mail address become more widely known. Data received so far have been helpful in allocating and scheduling staff resources to handle efficiently customer requests. As more information is received and processed through the software about the nature and frequency of various categories of inquiries, reference librarians will be able to more quickly and accurately respond to requesters, both health professional and the public.

2.1.2.3 Technology Transfer

The broad purpose of NIH's technology transfer activities is to promote the efficient transfer of new technology forthcoming from NIH research to the private sector, to facilitate and enhance the development of new drugs, other products, and methods of treatment that benefit human health. Beyond the promise to advance public health, technology transfer contributes to the global competitiveness of the nation's businesses and ultimately to the U.S.'s economic prosperity.

At present, NIH has one of the most active technology transfer programs in government. Through these activities, NIH has forged partnerships with industry and other external research organizations that have enhanced and augmented the capacity of NIH to conduct laboratory and clinical research.

To achieve the potential, NIH must continue to build the organizational structure necessary to facilitate technology transfer for NIH-supported investigators and to develop effective, well-articulated technology transfer policies and guidelines. This will involve:

- Working with the Department of Health and Human Services, the Congress, and our research partners to establish and implement rational technology transfer policies.

- Establishing timely and effective procedures and guidelines that facilitate patenting, licensing, and cooperative research projects within intramural NIH;

- Encourage and provide incentives for NIH intramural scientists to participate in technology transfer through patenting.

The performance goals that follow address each of these areas.

Performance Goals Summary Table – Technology Transfer

Performance Goals	FY Targets	Actual Performance	Details
a) Increase the number of scientists who have received training in technology transfer.	***FY 2001 Target*** Train existing and new staff on Web-based technology transfer training modules and through attendance at the annual technology transfer seminar. Seek to have 25% of scientists complete the training module. ***FY 2000 Targets*** (1) Implement training module. (2) Contact 20% of NIH scientific staff. ***FY 1999 Target*** Contractor development of a Web-based training module.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target not met.**	Page 97
b) Enhance outreach to commercial entities.	***FY 2001 Targets*** (1) Increase the number of Employee Invention Reports (EIRs) by 5% over the level in FY2000. (2) Increase the number of Licensing agreements in FY2001 by 3% over the level in FY 2000. (3) Promote private sector participation and investment in applications of research discoveries by increasing the number of executed CRADAs by 3 % over the level in FY 2000. ***FY 2000 Targets*** (1) Increase in the number of EIRs by 5% or more over the FY 1999 level. (2) Increase the number of License Agreements executed in FY 2000 by 3% over the FY 1999 level. (3) Increase the number of executed CRADAs by 3% over the level in FY 1999. ***FY 1999 Targets*** (1) Increase the number of EIRs by 5% or more over the FY 1998 level of 287. (2) Increase the number of license agreements executed in FY 1999 by 3% over the 215 executed in FY 1998.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) not met.** **FY 1999 target (2) not met.**	Page 99

Performance Goals	FY Targets	Actual Performance	Details
	(3) Increase the number of executed CRADAs by 3% over the 43 executed in FY 1998.	**FY 1999 target (3) exceeded.**	
c) Maintain oversight and protection of the public investment in NIH research through increased monitoring of licensee activities.	***FY 2001 Targets*** (1) NIH review audits of sales. (2) When indicators show that sales and royalty information may be incorrect, NIH will conduct reviews of up to 3 licensees during the year.	FY 2001: To be reported in January 2002.	Page 102
d) Patent portfolio review and management to maximize return for public health.	***FY 2000 Target*** No more than 30% of unlicensed patents from before FY 1995 being retained by the agency. ***FY 1999 Target*** No more than 50% of unlicensed patents from before FY 1995 being retained by the agency.	FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 103

Performance Goal Details - Technology Transfer

Goal a) Increase the number of scientists who have received training in technology transfer.

It is important that NIH's scientific and technology transfer staff have up-to-date information on legal requirements, policies, and procedures regarding technology transfer activities and responsibilities as a federal employee. The broad purpose of this goal is to provide information and training to the scientific community at NIH on technology transfer procedures. As of FY 1999, there are approximately 4,000 research investigators who would be targeted for training. This would be a continuing activity, based on training efforts developed in FY 1999 and commenced in FY 2000.

FY 2001 Target: **Train existing and new staff on Web-based technology transfer training modules and through attendance at the annual technology transfer seminar. Seek to have 25% of scientists complete the training module.**

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) Implement the training module.**

(2) Contact 20% of NIH scientific staff.

Performance Assessment -- Basis and Data: Several measures provide a comprehensive account of progress in achieving this goal's targets -- attendance of NIH scientists at the Annual Technology Transfer Retreat and related seminars, distribution of policies and information materials, and the number of scientists who access and complete the new on-line, Web-based training module.

Performance Assessment -- Validation and Verification: Attendance sheets will be reviewed and information will be taken from the new online Web-based training program that is to capture information on persons who have completed the module.

Assessment of FY 1999 Performance

FY 1999 Target: Contractor development of a Web-based training module.

FY 1999 Achievement Summary:

- Target not met. Work is to be completed in January 2000.
- Scripting of several modules was delayed. This created a delay in providing the narrative to the computer programmers for development of the on-line program.

Sources of FY 1999 Assessment Data: The final product is Web-based training program that will be the basis for all training in FY 2000 and beyond.

Discussion of Performance: With the completion of the Web-based training module, the effort under this goal will be directed to system testing and training of NIH scientists as outlined in the targets for FY 2000 and beyond

Next Steps: Testing will be conducted in January 2000.

Goal b) Enhance outreach to commercial entities.

This goal involves activities along a number of lines: enhance NIH marketing with commercial entities; improve electronic and other marketing techniques to simplify access to NIH technologies for licensing purposes; improve the search engine for use in reviewing NIH technologies available for licensing; and work with NIH ICs and the private sector to promote its participation and investment in research.

Several measures are important in gauging the overall success of these efforts. Employee Invention Reports (EIRs)---In the technology transfer field, a general "rule of thumb" has evolved over time which estimates the level of invention reporting that can reasonably be anticipated from research activity. NIH's goal is to eventually reach the "rule of thumb" ratio of one EIR per $2 million of intramural research funding. Without technologies constantly being developed and in the pipeline, a technology transfer program cannot survive. Licensing Agreements---To increase productivity and the movement of technologies from the laboratory into the marketplace, NIH proposes to increase activity associated with marketing and licensing of available technologies, with a goal of increasing the number of licensing agreements by 3% over the corresponding figure for the previous fiscal year. Cooperative Research and Development Agreements (CRADAs)---The agency uses the CRADA mechanism to enable commercial entities to work with federal laboratory personnel in collaborative activities to enhance possible development of new technologies that would be difficult to develop in isolation. This goal is to continue at 3% per annum growth rate for the foreseeable future.

Increased activity in each of these areas is difficult to develop and is subject to numerous external influences that could prevent the attainment of the goals. These include the shifting of research interests of possible partners, the continuing desirability of working as a partner with the federal government and adhering to government requirements, internal staffing levels and resources, economic conditions affecting private industry, among others (see the further discussion below under FY 1999 assessment).

FY 2001 Targets:

(1) Increase the number of Employee Invention Reports (EIRs) by 5% over the level in FY 2000.

(2) Increase the number of Licensing Agreements in FY 2001 by 3% over the level in FY 2000.

(3) Promote private sector participation and investment in applications of research discoveries by increasing the number of executed CRADAs by 3 % over the level in FY 2000.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 1999 below.

FY 2000 Targets: **(1) Increase the number of EIRs by 5% or more over the FY 1999 level.**

(2) Increase the number of License Agreements executed in FY 2000 by 3% over the FY 1999 level.

(3) Increase the number of executed CRADAs by 3% over the level in FY 1999.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 1999 below.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Increase the number of EIRs by 5% or more over the FY 1998 level of 287.**

(2) Increase the number of License Agreements executed in FY 1999 by 3% over the 215 executed in FY 1998.

(3) Increase the number of executed CRADAs by 3% over the 43 executed in FY 1998.

FY 1999 Achievement Summary:

- Target (1) was not met. The increase amounted to 2.5% rather than the 5% targeted.

- Target (2) was not met. These number licenses decreased in FY 1999 by 5%, to 204.

- Target (3) was exceeded. The increase in CRADAs in FY 1999 was 10%, more than triple the targeted amount.

Sources of FY 1999 Assessment Data: All data was taken from the NIH Invention Tracking System, which is the operational system containing official information on each reported activity.

Discussion of Performance: The number of EIRs was at an increased level over the previous year but fell short of the goal that was set forth. The Licensing goal fell short of the target, but was still a significant level of activity when benchmarked against other federal agencies and educational institutions. The CRADA goal was exceeded this year and continues the increase in

activity achieved over the past two years. The exact nature of the shortfall from the goals is not known. There is a point in any organization when the level of new intellectual property development becomes a stable level. It will take a review of data over the next 3-5 years to better analyze whether or not this has occurred. Additionally, there is the view that due to the number of vacant licensing positions that existed this past year, it was difficult to process more licenses. This view will need to be evaluated over the next few years.

Additionally, there are a number of factors beyond NIH's control that may have affected performance in achieving these goals. Licensing Agreements. One factor is NIH's ability to increase outreach activity through national and international research, trade, and technology transfer meetings and conferences. Another factor is the number of invention reports submitted by scientific staff. A third factor is economic and other conditions such as the reinstatement of the Reasonable Pricing Clause may not be favorable to long term investment by commercial entities in government technologies. CRADAs. External influences on goal achievement: economic and other conditions, such as reinstatement of the Reasonable Pricing Clause, may not be favorable to commercial entities entering into partnerships with federal laboratories. These reasons will need to be analyzed over the next few years to see if they were and are relevant factors.

Next Steps: IC Technology Development Coordinators will be reminded of the projected goals for this activity and the need to increase efforts to identify new technologies. This combined with the new training effort should assist in bringing the level of reporting to where it was last year.

Licensing activity is below the previous year due primarily to the large number of vacancies in licensing positions that occurred this year. When recruitment is completed for these 7 positions, we expect that the level of licensing should increase over that of the last year.

CRADA activity appears to be progressing well and NIH will continue to pursue such partnerships as are deemed appropriate.

Goal c) Maintain oversight and protection of the public investment in NIH research through increased monitoring of licensee activities.

While the transfer of technology is an important concern, it is equally of concern to ensure that the technologies licensed to commercial entities are being carried out properly and the amount of royalties being paid to the government is correct. In support of this concern, the NIH has instituted monitoring activities that require licensees to have special financial audits conducted of their sales activity and the results conveyed directly to the NIH by their auditors whenever sales involving the licensed technology are in excess of $2 million per year. This provides an independent verification of information reported to NIH in royalty reports. In addition, reviews will be conducted when staff, after the review of various indicators, find that there are inconsistencies in the information being reported to the NIH and information found in other official company documents. (Note: This is a new goal in FY 2001.)

FY 2001 Targets: **(1) NIH review audits of sales.**

(2) When indicators show that sales and royalty information may be incorrect, NIH will conduct reviews of up to 3 licensees during the year.

Basis and Data: Audit reports are submitted as required.

Validation and Verification: Copies of audit reports will be on file as will copies of any reviews conducted.

Goal d) Patent portfolio review and management to maximize return for public health.

The agency needs to monitor its portfolio of patented technology to ensure that time and resources are not being spent on technologies which are outdated because of new inventions or new avenues of research have rendered the technology to be of little commercial value. The agency will undertake reviews with intramural laboratory staff to delete these types of technologies from our patent portfolio and retain an inventory of technologies that have utility and can be actively marketed. A sound management target which is based on professional technology transfer staff judgements, is that the inventory will include no more than 30% of the pre FY1995 unlicensed patents as of the onset of this initiative. (Note: Target beyond FY 2000 is not currently planned, as this goal is expected to be completed in FY 2000.)

FY 2000 Target: No more than 30% of unlicensed patents from before FY 1995 being retained by the agency.

Basis and Data: The percentage of pre-FY 1995 patents remaining in the current portfolio unlicensed provides a direct measure of the progress on this goal. An assessment of the FY1999 and FY 2000 patent license portfolio will be conducted to determine this figure. Data for this portfolio review will be generated from NIH's new Technology Transfer Information Management System. (TTIMS).

Validation/Verification: The data system is an integrated information system that is used in day to day operations of the office. Data is drawn from the day to day activities and reported in specially designed reports. Data integrity is important for all aspects of operations and continual checks are made on the veracity of the data.

Assessment of FY 1999 Performance

FY 1999 Target: No more than 50% of unlicensed patents from before FY 1995 being retained by the agency.

FY 1999 Achievement Summary:

- Target met.

Sources of FY 1999 Assessment Data: Data from the Information Tracking System confirms that this goal was achieved this past fiscal year. The data system is the official operating system and

contains information on all patents retained by the agency. If patents are no longer maintained, that information will be reflected in the official status in the system.

Discussion of Performance: This goal was achieved through the analysis of patent files and determining whether or not there was value in retaining the active patent rights to the technologies. NIH has numerous early stage technologies that are far ahead of what industry can sometimes absorb immediately. It takes time for industry to catch up with the research findings and utilize NIH products. Therefore, it is reasonable for a biomedical technology transfer operation to have a significant number of technologies that are still active 5 to 10 years after they were patented.

Next Steps: We will continue to pursue the goal to reduce the number of cases to 30% or less than were in existence at the onset of the initiative. Systems and techniques developed with this project will be used on an ongoing basis in the future to reduce unnecessary inventory of patented technologies.

2.1.2.4 Priority Setting

Given the importance of medical research in fighting disease and improving the nation's health, the enormous range of possible subjects of research, and the thousands of talented investigators who seek funding, the National Institutes of Health (NIH) must make choices about where and how it spends its money.

The process of choosing is called setting prioritiesBa complex application of principles and mechanisms that guide the NIH in the continuous activity of managing its budget. Making choices is complex and often difficult: the NIH mission and its history demonstrate that no one thing B no single disease, no single investigator, no single Institute, no single method of funding research B comes first or claims permanent priority over others. Managing the NIH's budget requires many decisions.

There are 23 research Institutes and Centers (ICs) within the NIH. By law each must be funded and each is committed to certain domains of medical science (e.g., cancer, heart disease, aging, mental health). Their existence sets rough limits on both the current budget and future budgets. The appropriations process, from the President's request through final passage of the bill by the Congress, obligates each IC to determine how to allocate its own funds among many different activities of science B including investigator-initiated grants, the intramural research program, and research training, among others. These decisions are tailored to the IC=s research objectives. Each IC also decides which specific research grant applications to fund among those proposed by researchers working at universities or other research centers and whether to emphasize certain research topics within its domain. The net effect of these decisions determines how much of the entire NIH budget is devoted to work in certain scientific disciplines (e.g., neurosciences, microbiology, genetics) or on certain diseases.

Public and congressional inquiries about how the NIH spends its money often focus on the amounts given to certain ICs or devoted to research on a specific disease. Research on any disease is not confined to one Institute, and no Institute is dedicated to a single disease. An Institute's budget is an inadequate measure of support for research on specific diseases. Research into many diseases is often carried on in several Institutes simultaneously, e.g., several Institutes are supporting research on Alzheimer's disease.

It is also extremely difficult to assign the large investments in basic research to any one disease. For example, the number of grants specifically devoted to heart attacks is smaller than the number of grants awarded for research on cardiac muscle biology and lipid metabolism, which have obvious and promising implications for understanding, preventing, and treating heart attacks.

From long experience, we know that research aimed at one target often hits another, e.g., a gene causing breast cancer in mice plays a role in the development of brain tissue. It is impossible to attribute research and discoveries like this to one disease. There is, consequently, no Aright@ amount of money, percentage of the budget, or number of projects for any disease.

Congress, the public, health advocacy groups, and researchers have had a long-standing interest in priority setting at the NIH. Discussions about priority setting reflect the special interests and needs of the many and various individuals and constituent groups who are interested in, and affected by, medical research. Continued interest in the policies and processes used by the NIH to determine funding allocations for medical research led to a requirement in the FY 1999 House Appropriations Report for the Secretary of Health and Human Services to contract with the Institute of Medicine (IOM) to conduct a study to examine how NIH decides what to fund, what mechanisms exist for public input into the process, and the role of Congress in directing the allocation of funding among areas of research. The IOM=s report, released in July 1998, made recommendations in four categorical areas in which NIH is continuing or initiating activities: (i) soliciting public comments on research goals, (ii) establishing criteria for allocating research funds, (iii) strategic planning, and (iv) responding to Congressional mandates and requests for information.

Various criteria influence the allocation of resources on a continuous basis. These criteria were supported by the IOM in their study of priority setting at the NIH.

$ responding to public health needs, as judged by the incidence, severity, and cost of specific disorders. Calculating these needs is difficult, and there is not always a clear correlation between expense and results.

$ applying stringent review for scientific quality on all research proposals in order to return the maximum possible on the public's investment in medical research.

$ recognizing that many significant advances occur when new findings, often unforeseen, expand experimental possibilities and open new pathways for the imagination. Not all problems are equally approachable, no matter their importance to public health. Pursuit of a rare disease may often have unexpected benefits for more common problems. By the same token, increased spending on a disease is wasteful when there are neither promising pathways to follow nor an adequate number of qualified investigators to fund.

$ maintaining a large and diverse portfolio of . Because we cannot predict discoveries or anticipate the opportunities fresh discoveries will produce, the NIH must support research along a broad B in fact, expanding B frontier.

$ supporting the human capital and material assets of science. To this end, the NIH's budget supports research training, acquisition of equipment and instruments, some limited construction projects, and grantee institutions' costs of enabling the research programs.

The NIH builds its budget by evaluating current opportunities and public health needs while maintaining strong support for investigator-initiated research.

Performance Goals Summary Table – Priority Setting

Performance Goals	FY Targets	Actual Performance	Details
a) Completion of the review of the structure of selected clinical trials programs, implementation of the recommendations from selected program reviews, and completion of transfer and integration of selected program initiatives into different organizations to provide more effective support of scientific research.	***FY 1999 Targets*** (1) Progress in implementing the recommendations of the NIMH Intramural Research Program Planning Committee. (2) Completion of a review of three options for the administrative structure of the current adult NIAID AIDS clinical trials programs. (3) Integration of the Women's Health Initiative into the NHLBI.	**FY 1999 target (1) met** **FY 1999 target (2) met** **FY 1999 target (3) met**	Page 109
b) Progress in responding to the Institute of Medicine Report recommendations for improving public input and priority setting at the NIH.	***FY 2001 Targets*** (1) Implementation of activities to enhance public input into NIH activities. (2) Progress in implementing appropriate recommendations of the Institute of Medicine regarding the NIH priority setting process. ***FY 2000 Targets*** (1) Implementation of activities to enhance public input into NIH activities. (2) Progress in implementing appropriate recommendations of the Institute of Medicine regarding the NIH priority setting process. (3) Development of draft strategic plans by each of the research Institutes and Centers. ***FY 1999 Targets*** (1) Implementation of activities to enhance public input into NIH activities. (2) Progress in implementing appropriate recommendations of the Institute of Medicine regarding the NIH priority setting process.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met** **FY 1999 target (2) met**	Page 113
c) Ensure that NIH-supported research reflects the changing	***Annual Targets*** Sponsorship of Institute and Center workshops and panels that assess the	FY 2001: To be reported in January 2002.	Page 117

Performance Goals	FY Targets	Actual Performance	Details
nature of scientific opportunities and public health needs.	scientific progress and identify emerging public health needs and scientific opportunities. Incorporate the findings and recommendations from these workshops and panels into updated plans, priorities, and proposal submission requests for Institute and Center research programs.	FY 2000: To be reported in January 2001. **FY 1999 target met.**	

Performance Goal Details - Priority Setting

Goal a)	**Completion of the review of the structure of selected clinical trials programs, implementation of the recommendations from selected program reviews, and completion of transfer and integration of selected program initiatives into different organizations to provide more effective support of scientific research.**

The NIH Institutes and Centers (ICs) review, on a periodic basis, the structure, organizational location, and other aspects of their intramural and extramural research programs. This is accomplished via reviews carried out by their respective Boards of Scientific Counselors, ad hoc external review committees, and National Advisory Councils/Boards. These groups make recommendations for improvements which are considered by IC and/or Office of the Director (OD) leadership and, when appropriate, plans are developed to implement and effect such changes. (Note: Targets beyond FY 1999 are not planned as this goal is expected to be completed in FY 1999.)

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Progress in implementing the recommendations of the NIMH Intramural Research Program Planning Committee.**

(2) Completion of a review of three options for the administrative structure of the current adult NIAID AIDS clinical trials programs.

(3) Integration of the Women=s Health Initiative (WHI) into the NHLBI.

FY 1999 Achievement Summary:

- Target (1) was met.

  Following the mandate of a House Appropriations Committee Report, the NIMH Intramural Research Program Planning Committee (IRPPC) was formed to review the strengths and weaknesses of the NIMH IRP. In January 1997, the committee forwarded to the National Advisory Mental Health Council a detailed series of recommendations for changes and

refinements in nearly all aspects of the functioning of the IRP (*Finding the Balance: Report of the National Institute of Mental Health Research Program Planning Committee*). All of these recommendations have now been addressed. Some highlights of the actions taken are described below, organized according to the major categories of recommendations by the IRPPC.

Recommendation	Action
Adopt a Mission Statement.	The IRP proposes to accept, with minor rewording, the mission statement proposed by the IRPPC. The new mission statement is: AThe IRP conducts basic, clinical, and translational research to advance understanding of the causes, treatments, and prevention of mental disorders through the study of normal and abnormal brain function and behavior. The IRP supports outstanding research that uses the special resources of the NIH and complements extramural research. The IRP provides an environment conducive to the training and development of clinical and basic scientists. The IRP fosters standards of excellence in the clinical care and ethical treatment of research participants. The IRP serves as a national resource in response to requests made by the Administration, members of Congress, and the public for information regarding mental illness.@
Establish Permanent Leadership	A permanent Scientific Director has been appointed. As recommended in the IRPPC report, new scientific directions for the IRP have been sought from the intramural and extramural neuroscience and mental health communities. The NIMH Board of Scientific Counselors (BSC) established two workgroups: one focused on future directions in clinical research and the other on future directions specifically in the field of genetics.
Improve the Quality of Science	To ensure the independence of investigators, resources are now assigned individually to all tenured and tenure-track investigators, rather than only to laboratory chiefs. Resource levels are set after taking into account the recommendations of the BSC, which reviews each investigator every 4 years. The BSC reports have resulted in closure or downsizing of laboratories for unproductive lines of research and in enhanced support for promising new research directions, based on outstanding scientific merit and programmatic needs.
Strengthen Training and Mentoring.	The appointment of an Associate Director for Training and the establishment of a formal training and evaluation program for fellows address many of the recommendations of the IRPPC. Mentoring of training fellows is now a key criterion for the BSC evaluation of investigators.
Pursue the Recruitment, Retention, and Retirement of Scientists.	The IRP is utilizing new hiring and salary mechanisms provided by the Senior Biomedical Research Service, Title 42, and Title 38 authorities to recruit and retain outstanding basic and clinical researchers. Active recruitments are underway for heads of a new Mood Disorders and Anxiety Branch, Human Genetics Laboratory, and Animal Genetics Laboratory, and three new junior faculty have been hired. Additional recruitments at senior and junior levels will be made as space for clinical and basic research becomes available. To help reclaim resources for recruitment, the IRP has adopted graceful exit and support policies for investigators who leave the IRP for university appointments
Revitalize Clinical Research.	To ensure that human subjects participate only in clinical research of the greatest value, all existing NIMH clinical protocols were reviewed for scientific merit by a panel of the BSC. All new protocols are reviewed for scientific merit by both extramural and intramural investigators before they can be initiated. These scientific reviews are in addition to the thorough review for human subject protections carried out by the IRP Institutional Review Board. In addition, the long-term future of the NIMH research programs at St. Elizabeth=s Hospital has been secured by relocating

Recommendation	Action
	them to the Bethesda campus. The infrastructure for clinical research has been enhanced by the establishment of a new clinical research and recruitment core and ethics training program, under the NIMH IRP Clinical Director, by the acquisition of new high-field imaging instruments and magnetoencephalography (MEG) machines, and by the establishment of a new brain imaging core facility under a newly recruited MRI physicist. The clinical program also will benefit from the planned recruitment efforts described above.

- Target (2) was met.

  NIH sponsored HIV/AIDS clinical trials were first funded by NIAID in 1986 through AIDS Treatment and Evaluation Units (ATEU). This effort was subsequently expanded into the AIDS Clinical Trials Group (ACTG). In 1989, NIAID established the Terry Beirn Community Program for Clinical Research on AIDS (CPCRA), which also supports therapeutic clinical trials.

  In March 1998, the OAR convened Task Force on Integration of the Adult HIV/AIDS Clinical Trials Networks evaluated existing programs and made recommendations to help design a better-integrated, adult clinical trial system. The Task Force considered a number of different structural options including maintenance of the status quo, creation of a single adult clinical trials network out of the Adult ACTG and CPCRA, and complete restructuring. The Task Force concluded that it would be inappropriate to dictate a specific structure, especially one that would be implemented more than 2 years hence. Instead, the Task Force recommended that the overriding principle should be to create the strongest possible clinical trials group(s) around the particular expertise and scientific focus of the investigators involved. The Task Force also specified six essential capabilities for an integrated clinical trials structure, including the capability to:

  - conduct a range of trials from small proof-of-concept studies (Phase I) to large randomized clinical-outcome (Phase III) trials
  - enroll diverse populations
  - enroll patients form diverse research sites (academic and community practice venues)
  - conduct state-of-the art analysis and disseminate findings rapidly
  - respond flexibly to scientific opportunities
  - perform cross-protocol or cross-study analyses.

  NIAID incorporated this advice in the Request For Applications for the Adult Therapeutic Clinical Trials Program for AIDS (RFA 98-013). The goal of RFA 98-013 is to establish multiple clinical trial groups that, as a whole, are capable of addressing the broad therapeutics research agenda detailed in Project 2000, which delineates the Institutes' scientific goals and priorities in HIV/AIDS therapeutics. The awardees will have the capacity to conduct all phases of clinical trials and address high-priority research questions. The scope of activity will range from pathogenesis studies requiring extensive laboratory support to large, long-term studies that evaluate clinical management strategies. Each

application will be an integrated package consisting of (1) a Coordinating and Research Operations Center, (2) a Statistical and Data Management Center, and (3) Clinical Sites. Each of the Research Groups may address either a broad or a focused agenda, but must be capable of maintaining a minimum annual subject census of 2000 participants and must have a detailed plan for interacting with other NIH-sponsored AIDS clinical research groups. Each Group can propose a structure that best supports the Group's scientific agenda. Proposals pursuant to RFA 98-013 were considered by the National Allergy and Infectious Disease Council in September 1999. NIAID expects to make the first awards in January 2000.

- Target (3) was met.

  The WHI program has been fully integrated into the NHLBI. Administratively, the program reports to the Director, NHLBI. The Special Ad Hoc Group on the WHI, an independent advisory group which was formerly a subcommittee of the Advisory Committee for Research on Women's Health, is now a Working Group of the National Heart, Lung, and Blood Advisory Council. The cross-NIH nature of the program has been maintained and expanded. The Director, NHLBI, and the Director, Office of Research on Women=s Health (ORWH), NIH, serve as Co-Chairs of the study. The community prevention study is conducted through an interagency agreement with the Centers for Disease Control and Prevention; 2000 is its final year.

Sources of FY 1999 Assessment Data:

Target (1): NIMH report. Hyman, SE and Desimone, R. Status of NIMH Intramural Research Program Renewal. NIMH Director's Report to the National Advisory Mental Health Council, February, 2000. (An interim report was presented to NAMHC in Feb 1999.)

Target (2): Report on the Task Force on Integration of Adult HIV/AIDS Clinical Trial Networks

Target (3): NHLBI fact book available on the NHLBI Website.

Discussion of Performance: Meeting this target in FY 1999 is part of NIH=s success in completing this goal.

Next Steps: Additional targets beyond FY 1999 are not planned because the Committee=s recommendations have been fully implemented and because the WHI has been fully integrated into the NHLBI.

Goal b) **Progress in responding to the Institute of Medicine Report recommendations for improving public input and priority setting at the NIH.**

The NIH seeks and receives input from review panels, workshops, and other outside sources regarding NIH activities, including priority setting. Emerging public health problems and the need to rapidly respond to new research opportunities require that the NIH continually review and implement appropriate recommendations from relevant constituencies. NIH recognizes the value of enhanced public input and has taken specific actions to strengthen its efforts in this regard.

FY 1999 Target: **(1) Implementation of activities to enhance public input into NIH activities.**

(2) Progress in implementing appropriate recommendations of the Institute of Medicine regarding the NIH priority setting process.

FY 1999 Achievement Summary:

- Target (1) was met.

  The IOM recommended: ANIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each Institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The Director=s Office of Public Liaison should review and evaluate these mechanisms and identify best practices.@

  Offices of Public Liaison (OPL) have been established in the Office of the Director (OD) and in each IC. The OD and ICs have each designated an individual to serve as its Public Liaison Officer <http://www.nih.gov/welcome/publicliaison/Ic-plo1.htm>. Within the OD, the Office of Communications is being expanded and has been renamed the Office of Communications and Public Liaison. The possible functions of all of the OPLs were discussed with 23 public representatives who met with the NIH Director on September 23, 1998. Core functions of the OPLs discussed at this meeting include: conducting outreach to constituency groups and serving as a contact point for the public and a place where Congress can refer its constituents. Several additional activities for the OPLs were suggested: educating the public about research; carrying out activities recommended by the new Director=s Council of Public Representatives (COPR); and identifying public concerns and bringing them to the attention of the COPR.

The IOM also recommended: "The Director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH Director, to facilitate interactions between NIH and the general public." A Director's Council of Public Representatives (COPR) has been established. This Council is staffed by the OD Office of Communications and Public Liaison. The NIH Director appointed 20 members of the COPR from over 250 applicants. The NIH Director also invited the remaining candidates to join as COPR Associates. The membership of the COPR represents a broad array of backgrounds, experiences, and vocations. The COPR Associates will provide a pool of candidates from which to replace current members at the end of their terms and will be a source for ad hoc members and consultants for specific tasks and questions that arise. The COPR has held two open meetings on April 21 and October 21, 1999 that have been well publicized, including videocast coverage of the proceedings. COPR members have been engaged in a variety of subcommittees, workshops, and meetings that address a wide range of cross-cutting biomedical research issues. For example, five COPR members participated in the NIH FY 2001 Budget Retreat in June 1999. Institute and Center Directors presented areas of research opportunity and special need and described cutting edge science and new programs that want to start or expand. In addition, several COPR associates participated in the National Institute of General Medical Sciences Human Diversity Workshop in July 1999, providing valuable community perspectives. Another COPR member served on a liaison committee with the National Academy of Sciences to discuss priority setting in the social and behavioral sciences.

The IOM also recommended that, "The public membership of NIH policy and program advisory groups should be selected to represent a broad range of public constituencies." The IC Directors are reviewing the membership of their policy and program advisory groups and are including representatives of public constituencies on these groups, as appropriate.

- Target (2) was met.

The IOM made a total of 12 recommendations in its July 1998 report, "Scientific Opportunities and Public Needs - Improving Priority Setting and Public Input at the National Institutes of Health," including the three recommendations discussed above. NIH's activities related to the remaining nine recommendations are provided below.

Recommendation	Action
1) The Committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.	No action by NIH is necessary at this time.
2) NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.	Through the development of Institute and Center strategic plans, including public involvement in that process, NIH is clarifying and assessing its priority setting processes.
3) In setting priorities, NIH should strengthen	One of the criteria that the NIH considers in developing

Recommendation	Action
its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.	and allocating the NIH budget has received considerable attention and was singled out by the IOM for special attentionBthe use of data on burden and costs of diseases. Because of conceptual problems and data deficiencies, the NIH must carefully consider how it could further incorporate burden of illness measures into the priority setting process. NIH sponsored a small group meeting on June 28 to identify data sources, review models for the use of burden/cost of disease data for priority setting, and explore how these data might be used to show how research has led to improvements in health. Follow-up actions will be to form an intragency working group of DHHS agencies on summary measures of health and burden of illness and to encourage the Institutes and Centers to pursue development of disease models.
4) NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.	The NIH is continuing to assess its methods for developing reports about spending by disease. It is extremely difficult to separate research that is Adirect@ and that which is Arelated@ to a disease. Because some 50 percent of the NIH research budget is spent on efforts to understand the fundamental processes of cells and organisms that cannot be directly associated directly with a specific disease C so-called Abasic research@ C much of the NIH budget is difficult to categorize by specific disease areas. In addition, because of the nature of reporting, a specific project may be categorized under several areas, e.g., a project focused on liver cancer in women would be reported under liver disease, cancer, and women=s health. Data on funding by disease that are reported in total for NIH are not perfect, but do provide a good indicator of funding trends from one year to another. Consequently, for the interim, NIH proposes to continue its current practice of reporting.
5) In exercising the overall authority to oversee and coordinate the priority setting process, the NIH Director should receive from the Directors of all of the Institutes and Centers multi-year strategic plans, including budget scenarios, in a standard format on an annual basis.	The NIH Director has requested that each IC develop a 2-5 year strategic planBwith input from a wide range of NIH constituents, including patient and other health advocates, scientists, health care providers, Congress, the Administration, NIH staff, and other representatives of the public by December 31, 1999.
6) The Director of NIH should increase the involvement of the Advisory Committee to the Director (ACD) in the priority setting process. The diversity of the Committee=s membership should be increased, particularly with respect to its public members.	The NIH Director has involved the ACD in the priority setting process in a variety of ways including their participation in: discussions of future research directions and infrastructure issues; annual reviews of research goals with the leadership of the NIH; assessment of NIH=s research program under the Government Performance and Results Act; and discussions of the public policy implications of potentially sensitive areas of research, e.g., stem cell research and gene therapy. The ACD membership has been expanded by three, and these positions have been filled by public members.

Recommendation	Action
7), 8) and 9)	Addressed above under Target 1.
10) The U.S. Congress should use its authority to mandate specific research programs, establish levels of funding for them, and implement new organizational entities only when other approaches have proven inadequate. NIH should provide Congress with analyses of how NIH is responding to requests for such major changes and whether these requests can be addressed within existing mechanisms.	No action by NIH is needed at this time.
11) The Director of NIH should periodically review and report on the organizational structure of NIH, in light of changes in science and the health needs of the public	As appropriate, the NIH will provide Congress with full analyses of how the agency proposes to respond to Congressional mandates for specific research programs and levels of funding for them, or for establishment of new organizational entities.
12) Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority setting process, including stronger analytical, planning, and public interface capacities.	Not applicable to the NIH.

Sources of FY 1999 Assessment Data:

Target (1) A news and information Website has been established for COPR associates and can be accessed at: http://www.nih.gov/welcome/publicliaison/get-involved/copr/coprnews.html.

Target (2) "Report to the House Committee on Appropriations on NIH Priority Setting Activities," February, 1999.

Discussion of Performance: The NIH continues to engage in a variety of activities related to the broad issue of setting research priorities, and some of these have been expanded or modified in response to the IOM report.

Next Steps: The NIH Office of the Director and each of the ICs will continue to proactively engage in priority setting activities, including enhancing our efforts to increase public participation in all facets of the agency=s programs.

Goal c) **Ensure that NIH-supported research reflects the changing nature of scientific opportunities and public health needs.**

Establishing and continuously updating research priorities is essential to ensure scientific progress, meet national needs, and efficiently use available resources. Setting priorities is a complex process involving consideration of many factors including determining which areas of science are ripe for pursuit and how research can best be harnessed to meet public health needs. The considerations that influence the planning and spending of budgets are many and opinions about them are solicited from the extramural scientific community, patient advocacy groups, health care providers, Congress, the Administration, and NIH staff. These opinions are gathered through various means, as appropriate to the decision-making process and include review groups, composed of accomplished investigators established to evaluate grant applications for scientific merit; meetings of national advisory councils, with representatives from the public, medical, and scientific communities, to review a broad range of its policies; external advisory groups to assess NIH-wide activities and to recommend programmatic directions based on changes in the science and public health needs; and input from representatives of patient and other health advocacy organizations, DHHS, OMB, other Federal agencies, and the Congress on a variety of issues of common concern.

Annual Target: **Sponsorship of Institute and Center workshops and panels that assess the scientific progress and opportunities and identify emerging public health needs. Incorporation of findings and recommendations from these workshops and panels into updated proposal submission requests for Institute and Center research programs.**

Basis and Data: Identification of the scientific/public health areas for which workshops were held and the recommendations made, and changes in existing or implementation of new research program initiatives. This will include evidence such as: (1) workshops, panels, and other meetings held to solicit public input into NIH activities and (2) issuance of Requests for Applications (RFA), Program Announcements (PA), and Requests for Applications (RFAs) that encourage research in areas of identified need.

Validation/Verification: Listings of workshops and other meetings convened by the Institutes and Centers will be provided. Agendas and reports or summaries of these meetings will be available for verification of the specific recommendations made. Likewise, lists of program announcements (PA) and requests for applications (RFA) issued by the Institutes and Centers will be provided. The actual PAs and RFAs will be available for verification of their existence and validation that their content is consistent with recommendations from workshops or other forums.

Assessment of FY 1999 Performance

FY 1999 Target: **Sponsorship of Institute and Center workshops and panels that assess the scientific progress and opportunities and identify emerging public health needs. Incorporation of findings and recommendations from these workshops and panels into updated proposal submission requests for Institute and Center research programs.**

- FY 1999 target was met.

  Following are illustrative examples of the types of Institute and Center workshops and panels that assess scientific progress and opportunities and identify emerging public health needs. This information is organized by GPRA research program performance goals.

  Related to research goal (a) Add to the body of knowledge about normal and abnormal biological functions and behavior

Name of Workshop, Panel, or Other Meeting and Date Held
Prostate Cancer Progress Review Group Implementation Meeting – January 27, 1999
Breast Cancer Progress Review Group Implementation Meeting – January 28, 1999
Cancer Survivorship: Research Challenges and Opportunities for the New Millennium – March 8-9, 1999
DES Research Update 1999: Current Knowledge, Future Directions – July 19-20, 1999
NCI Director's Working Group Meetings: Signatures of Cancer Cells – June 13-14, 1999; Cancer Genetics – December 15-16, 1998 and February 18, 1999
Third National AIDS Malignancy Conference -- May 26-27, 1999
Head and Neck Cancer Workshop – February 21-23, 1999
Special Populations Working Group – May 26, 1999
Alveolar Epithelial Transport Workshop: Basic Science to Clinical Medicine – September 1-2,1999
Fibrin Turnover in Lung Inflammation and Cancer – September 27-28, 1999
Pulmonary Immunobiology and Inflammation – August 26-27, 1999
Role of the Polymorphonuclear Leukocyte in Sickle Cell Disease – May 28, 1999
Sleep and Host Defense Mechanisms – August 24-26, 1999
Sleep Needs, Patterns, and Difficulties of Adolescents – September 22, 1999
Parenting and the Child's World – August 1999
Family Process and Child Well-Being in Low Income Families – September 17-16, 1999
Add Health Workshop on Research in Progress – July 7-8, 1999
Male Contraception: Views for the 21st Century -- September 9-10, 1999
Town Meeting held in conjunction with an NIEHS workshop on "Decreasing the Gap: Developing a Research Agenda on Socioeconomic Status, Environmental Exposures and Health Disparities" – May 26,1999
Practical Issues in the Use of Probabilistic Risk Assessment – February 28-March 2, 1999
Environmental Medicine Research and Training: Defining the Field -- March 11, 1999

Name of Workshop, Panel, or Other Meeting and Date Held
Biomarkers: Taking Stock, An EPA/NIEHS In-House Workshop on Applying Biomarker Research – August 30-31, 1999
Town Meeting on "Preventing Environmental Disease: Barriers and Solutions" – January 19-20, 1999
The Role of the Environment in Parkinson's Disease -- July 22, 1999
Advances in Uterine Leiomyoma Research – October 7-8, 1999
Genomic Imprinting and Environmental Disease Susceptibility – October 8-10, 1998
Gene Environment Interactions in Common Clinical Conditions – March 10, 1999
Genetic and Environmental Effects on Health: New Methods for Epidemiologic Design and Analysis – June 10-12, 1999 [f]
New Evidence Connecting Cardiovascular Disease and Osteoporosis – September 14-15, 1999
NIH Symposium on the Biology of Stress -- February 4, 1999
NIGMS Structural Genomics Targets Workshop – February 11-12, 1999
Annual MARC/MBRS Biomedical Research Symposium – June 22, 1999
Workshop on Population-Based Samples for the NIGMS Human Genetic Cell Repository – July 20, 1999
Metabolic Research in the New Millennium – September 13-14, 1999
Structural Genomics Targets Workshop – February 11-12, 1999
Co-factors in Gene expression, December 15-16, 1998
Series of workshops to develop a consensus on scientific priorities for a trans-NIH comprehensive research plan. Scientific and special areas of interest included: natural history and epidemiology; etiology and pathogenesis; therapeutics; vaccines; behavioral and social science; and research related to racial and ethnic minorities – March 1999 [b,c,d,e,g,]
Focus Group to Review the Centers for AIDS Research Program. Co-sponsored by other NIH ICs – May 1999 [c,e]
Working Group to "Review the NIH Perinatla, Pediatric, and Adolescent HIV Research Priorities" – June 1999 [c,e]
Model Genetic Organisms for the Study of the Nervous System and Behavior – October 1999 [f]
Interactions Between Drugs of Abuse and Pharmacotherapeutic Agents Used in the Treatment of AIDS and Drug Addiction – September 9-10, 1999 [c,e]
Workshop on Phytoestrogen and Healthy Aging: Gaps in Knowledge – June 2-4, 1999
Conference on "Women and Alcohol Problems: Developing a Health Services Agenda" – November 5-6, 1998
Workshop on "Cross Collaborations in Alcohol Use Disorders: New Avenues for Research," cosponsored by the Japanese Ministry of Health – November 10-12, 1998
Symposium on "Perspectives on Fetal Alcohol Syndrome (FAS) Research of the National Institute on Alcohol Abuse and Alcoholism," – December 3-4, 1998.
"Genetic Factors of Alcoholism –USA-Chile-Canada Workshop," cosponsored in conjunction with the International Center for Alcohol Policies, Comision Nacional de Investigacion Cientifica y Tecnologica – January 4-6, 1999.
Workshop on "Monkey Models in Alcohol Research: Behavioral, Neuroendocrine, and PET Imaging Correlates" – January 29, 1999.
Symposium on "Alcohol Problems and Women's Lives: Evaluating the Context in Which Alcohol Problems Occur and are Treated" – June 26, 1999.
Mini Symposium on "Alcohol for Diabetics: Beneficial or Detrimental?" June 27, 1999.
Emerging Issues in Microbial Infections and Cardiovascular Diseases Workshop – October 29-30, 1998 [c,d,e]
Toward a Molecular Understanding of Craniofacial Morphogenesis – November 22-24, 1998 [b,c,d]
Head and Neck Cancer Workshop – February 21-23, 1999 [c,d,e]
Genetics of Human Dentition – September 13, 1999
Workshop on Trigeminal Neuralgia – September 14, 1999

Name of Workshop, Panel, or Other Meeting and Date Held
International Conference on Batten Disease (sponsored in conjunction with the Batten Disease Support and Research Association) – July 1999
Batten Disease Workshop: New Directions in Research for the Neuronal Ceroid Lipofuscinoses (cosponsored with NIH Office of Rare Diseases and the Children's brain Disease Foundation) – April 1999 [e]
International Sturge-Weber Syndrome Symposium (in conjunction with the Sturge-Weber Foundation and ORD, NIAMS, and NICHD) – June 1999
Progressive Supranuclear Palsy (PSP) International Meeting (in conjunction with ORD, and the PSP Society) – March 1999
Workshop on Neural Stem Cells: Promoting Repair and Plasticity of the Nervous System – July 1999
International Friedreich's Ataxia Conference (cosponsored with ORD and the Friedreich's Ataxia Research Alliance) – June 1999
Neurobiology in Ataxia-Telangiectasia (A-T); in conjunction with the A-T Children's Project – November 1999
Spinal Muscular Atrophy (SMA) Workshop (supported by the SMA advocacy group, Andrew's Buddies; held at the Neuroscience Center with NINDS sponsorship) – May 1999
Strategic Planning Task Force Meeting -- July 26-27, 1999
Micronutrients and Infectious Diseases: Cellular and Molecular Immunomodulatory Mechanisms – September 16-17, 1999

Related to research goal (b) Develop new or improved instruments and technologies for use in research and medicine

Name of Workshop, Panel, or Other Meeting and Date Held
EEG Based Computer Interface – June 16-20, 1999
Making the Connection: Coordinating Neuroimaging and Functional Paradigms for Understanding Pediatric Neurodevelopment – September 29-October 1, 1999
Computer-Based Internet and Virtual Training Methods in Safety and Health – April 26-27, 1999 [c]
NIGMS/NCRR Workshop on High-Resolution Electron Microscopy – July 23, 1999
Workshop on the Development of Interactive Databases – November 11-12, 1999
Imaging the Beta Cell – April 19-20, 1999
The Value of Linked Data in Aging Research – May 19, 1999
Workshop on "QTL Mapping Alcohol-Related Behavioral Traits" – August 20-21, 1998
Symposium on "Applications of Gene Knockout Techniques to Alcohol Research" – November 7, 1998
Special Conference on "State-of-the-art Methodologies in Health Services Research" – April 19-20, 1999
Workshop on "Screening for Chemically-Induced Mutant Mice with Altered Behavior Patterns" – May 13, 1999
Workshop on "Use of Oligonuleotide Arrays to Analyze the Neurobiology of Drug Abuse" – May 20, 1999
Symposium on "Multiplex Hybridization Arrays and Alcohol Research" – July 1, 1999.
Workshop on "Qualitative Methods in Health Research: Opportunities and Considerations in Application and Review" – September 30-October 1, 1999
Fluoride Research Workshop – February 1, 1999 [c]
Workshop on Development of New Technologies for Saliva and Other Oral Fluid-Based Diagnostics – September 12-14, 1999 [d]
International Collaborative Research on Fluoride: Research Needs Workshop – May 10-12, 1999 [c]

Inter-Institute (the Pediatric Neuroimaging Network with NIMH and NICHD) Invitational Conference on Coordinating Neuroimaging and Functional Paradigms for Understanding Pediatric Neurodevelopment – September 1999 [d]

Related to research goal (c) Develop new or improved approaches for preventing or delaying the onset of progression of disease and disability

Name of Workshop, Panel, or Other Meeting and Date Held
Workshop for Cancer Prevention and Control Among Latinos – April 23, 1999
Workshop on Strategies for New Clinical Trials for Prostate Cancer Chemoprevention – August 8-9, 1999
Chemoprevention Implementation Group – March 3-4, 1999
Dietary Supplements of Potential Benefit to Patients with Sickle Cell Disease – May 24-25, 1999
Unintended Pregnancy in the U.S. – March 11-12, 1999
Women's Health in Sports and Exercise – June 11-13, 1999
Stepping Away from OA: Prevention of Onset, Progression, and Disability – July 23-24, 1999
Epidem. Of Chronic Renal Insuff., September 27-28, 1999
Hepatitis C and Related Viruses – June 6-9, 1999
"Improving HIV Care and Prevention into the 21st Century: Integrated Care for the Multiply Diagnosed." In collaboration with VA, DHHS, HUD, ONAP, ONDCP – June 1999 [d,e]
"Primary HIV Prevention: Designing Effective Programs for People Living with HIV." In collaboration with the AIDS Research Institute, UCSF and the National Association of People with AIDS – June 1999
NIDA Town Meeting: Understanding Drug Abuse and Addiction: Myths vs. Reality – November 10, 1999 (Seattle, WA) and May 1999 (Atlanta, GA) [e]
Drugs in the Workplace – May 3-4, 1999
Developing an Agenda for Drug Prevention Services Research – March 17, 1999
Communications Research and the Anti-Drug Media Campaign – April 26-27, 1999
Antioxidants: Strategies for Interventions in Aging and Age-related Diseases – July 14-16, 1999 [e]
Behavioral Change Consortium (Disease prevention through behavioral change) – September 16-17, 1999
Caloric Restriction: Clinical Implications Advisory Panel – March 8-10, 1999
Panel on "Assessment and Screening for Alcohol and Other Drug Use" – November 16, 1998
Symposium on "Alcohol and Sleep" – May 2, 1999
Workshop on "Future Directions for Research on Alcohol and Sleep" – May 3-4, 1999
Symposium on "Adolescence and Alcohol: Implications For College Drinking" – June 3, 1999
Panel 1 of the National Advisory Council on Alcohol Abuse and Alcoholism Subcommittee on College Drinking, entitled "Context and Consequences" – June 10-11, 1999
Panel 2 of the National Advisory Council on Alcohol Abuse and Alcoholism Subcommittee on College Drinking, entitled "Treatment and Prevention" – June 17-18, 1999
Prevention of Craniofacial Anomalies – September 22-23, 1999
Planning Meeting for Oral Health in Africa (WHO/AFRO, WHO/HQ) – March 30-April 1, 1999 [d,e]
Early Childhood Caries Workshop – spring 1999
Emerging Infections: Control through Behavioral Interventions – June 3-4, 1999
Group A Streptococcus (GAS) Consultation to the NIAID and Extramural GAS Program Review and Discussion and Evaluation of GAS Vaccines – December 14-15, 1998

Related to research goal (d) Develop new or improved methods for diagnosing disease and disability

Name of Workshop, Panel, or Other Meeting and Date Held
Meeting of the Clinical Advisory Subcommittee of the National Advisory General Medical Sciences Council – April 12, 1999 [e]
Endoscopic Research Priorities – December 12-13, 1998 [e]
Workshop on Comorbidity Assessment of Older Cancer Patients – July 29-30, 1999
Imaging and Biological Markers of Diagnosis and Progression of Alzheimer's Disease – September 27-28, 1999
Symposium on "Can We Identify and Treat Alcohol Problems in the ER?" – August 22, 1999

Related to research goal (e) Develop new or improved methods for treating disease and disability

Name of Workshop, Panel, or Other Meeting and Date Held
Lung Cancer State of the Science: Molecular Targets for Therapy in Lung Cancer – September 14-15, 1999
Development of New Therapies for Rare Blood – July 14, 1999
Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes – September 27-28, 1999
Critical Research Issues in Myelodysplastic Syndromes – April 30, 1999
Postpartum Hemorrhage and Placenta Accreta – February 11-12, 1999
Neuropsychiatric Manifestations of Systemic Lupus – May 24-25, 1999
New Research Strategies in Osteogenesis Imperfecta – September 27, 1999
NIGMS Pharmacogenetics Populations Advisory Group Meeting – May 27, 1999
Non-Alcoholic Steatohepatitis – December 10-11, 1998 [c]
Complementary and Alternative Medicine in Chronic Liver Disease – August 22-24, 1999
Workshop on "Detection of Potential Toxicities Following Perinatal Exposure to Antiretrovirals" – January 1999
HIV/AIDS in Drug Abuse Treatment Settings: Expanding Research and Practice – March 25-26, 1999
Research on Linkages Between Drug Treatment and Other Systems of Care – June 26, 1999
The Economics of Public Health: Financing Drug Abuse Treatment Services – July 9, 1999
"NIAAA/State of Hawaii Research Forum: Alcohol Research and Applications to Treatment" – March 3, 1999.
Workshop on "Preclinical Medications Development" – November 16-17, 1998.
"Research-to-Practice Forum" – October 26, 1998.
Workshop on "Alcohol and Immunology/AIDS" – March 30-31, 1999.
Workshop on "The Essentiality Of Dietary Reference Intakes (DRIs) For Omega-6 and Omega-3 Fatty Acids," co-sponsored with the NIH Office of Dietary Supplements; the Center for Genetics, Nutrition and Health; the International Society for the Study of Fatty Acids and Lipids; and the NICHD -- April 7-9, 1999.
Symposium on "Neuropeptides and Alcohol Intake" – April 28, 1999.
Symposium on "Brief Interventions and Early Recognition and Treatment of Hazardous and Heavy Drinking" – April 30, 1999.
Workshop on "Future Directions for Research on Alcohol and Sleep" – May 3-4, 1999

Name of Workshop, Panel, or Other Meeting and Date Held
Symposium on "Medications Development for Alcoholism: From Laboratory to Patient" – May 1, 1999
Symposium on "Preclinical and Clinical Interaction Studies of Acamprosate and Naltrexone" – June 30, 1999
Symposium on "Alcoholism Treatment and Health Care Costs" – June 30, 1999
Workshop on "Neuroscience, Clinical Practice and Services Research" – November 4-6, 1999
Deep Brain Stimulation for Parkinson's Disease Working Group – March 1999
Workshop on "Transplantation in HIV+ Patients" – September 1999

Related to research goal (f) Develop critical genomic resources, including the DNA sequences of the human genome and the genomes of important model organisms and disease-causing microorganisms

Name of Workshop, Panel, or Other Meeting and Date Held
Non-Mammalian Models Workshop – February 16-17, 1999
The Role of Behavior Genetics Research in NIDA's Vulnerability to Drug Addiction Initiative – May 1999
Program for Testing Biological Intervention for Healthy Aging – September 14-16, 1999 [c]
Functional Genomics Workshop – September 14-15, 1999
Meetings of the 5 largest NHGRI-funded genome sequencing centers – December 1998, February 1999, May 1999, July 1999
5th International Strategy Meeting on Human Genome Sequencing – September 1999
The Microarray Meeting: Technology, Application and Analysis – September 1999
ELSI Research, Planning and Evaluation Group (ERPEG) Meeting – March 1999
Blue Ribbon Panel on Microbial Genome Sequencing -- May 12-13, 1999
Workshop on Human Immune Response Genes -- September 27, 1999

Related to research goal (g) Work towards the President=s goal of developing an AIDS vaccine by 2007

Name of Workshop, Panel, or Other Meeting and Date Held
Vaccine Research Center Strategic Planning Retreat – April 16-17, 1999
AIDS Vaccine Research Center Workshop on "New Concepts in HIV Vaccine Developments" – May 3-5, 1999

The following represent examples of Requests for Applications (RFAs), Program Announcements (PAs), Requests for Proposals (RFPs), or other follow-up actions that were issued/occurred in FY 1999 that resulted from workshops, panels, and other meetings that were

held in previous years. These solicitations are organized by GPRA research program performance goal.

Related to research goal (a)-- Add to the body of knowledge about normal and abnormal biological functions and behavior

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
Research grant proposals that reference the Breast or Prostate Progress Review Group reports will receive special consideration in the exception funding process.	Breast Cancer PRG Implementation Meeting, 1/28/99; Prostate Cancer PRG Implementation Meeting, 1/27/99
Mouse Models of Human Cancer Consortium (RFA CA-98-013)	Preclinical Models Working Group (first convened 12/96; regular meetings thereafter)
PAs for non-mammalian models	Preclinical Models Working Group (first convened 12/96; regular meetings thereafter)
RFA: Airway Remodeling and Repair in Asthma – 1999-2003	(1) Airway Biology and Disease Program Special Emphasis Panel – June 1997 (2) NHLBI Workshop: Airway Remodeling and Repair – September 14-15, 1998
RFP: Follow-up of an Adult Cohort with a Known Infant Feeding History	Meeting on the Significance of Phytoestrogens in Human Formula, May 15, 1997
RFP: Russia / U.S. Maternal and Child Health Statistics	8th Meeting of Gore-Chernomyrdin Health Committee, February 1997
RFA: English Literacy in Spanish-Speaking Populations	The Development of English Language Literacy Skills in Spanish-Speaking Children, October 1998
PA: Co-Activators and Co-Repressors in Gene Expression	Trans-NIH Workshop: Co-Activators and Co-Repressors in Gene Expression, December 15-16, 1998
RFA: Basic Science Research on Female Pelvic Floor Disorders [d]	Pelvic Floor Disorders Workshop, September 28-29, 1998
PA: Rett Syndrome: Genetics, Pathophysiology [d]	NICHD Workshop on Rett Syndrome, June 16-17, 1997
RFA: Superfund Hazardous Substance Research Program	Superfund Basic Research Program Research Needs Evaluation Workshop – October 15, 1998
RFA: Health Disparities: Linking Biological and Behavioral Mechanisms with Social and Physical Environments	Decreasing the Gap: Developing a Research Agenda on Socioeconomic Status, Environmental Exposures and Health Disparities – January 20-22, 1999 (Oakland); May 26, 1999 (Baltimore); July 7-9, 1999 (Chicago)
RFA: Environment/Infection/Gene Interactions in Autoimmune Disease	Linking Environmental Agents to Autoimmune Disease – September 1-3, 1998
RFA: The Role of the Environment in Parkinson's Disease	The Role of the Environment in Parkinson's Disease – July 22, 1999
PA: Bone and the Hematopoietic and Immune Systems – issued April 13, 1999	Bone and the Hematopoietic and Immune Systems – August 1997
PA: Biobehavioral Pain Research - issued November 27, 1998	Biobehavioral Pain Research - January 1994
PA: Bioengineering Research Partnerships – issued October 29, 1998	Bioengineering Symposium – February 1998
RFA: Core Centers for Musculoskeletal Disorders - issued August 2, 1999	Meetings that led to Centers Working Group II Report -- published 1997

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Rheumatic Diseases Core Centers - issued August 2, 1999	Meetings that led to Centers Working GroupII Report -- published 1997
PA: Structural Biology of Membrane Protein (reannouncement)	Structural Biology of Respiratory Enzymes – August 16-17, 1993
PA: Integrative and Collaborative Approaches to Research	National Advisory General Medical Sciences Council Subcommittee Meetings – April 1998
PA: Protein Structure Initiative (Structural Genomics)	NIGMS Protein Structure Initiative Meeting – April 24, 1998
PA: Protein Structure Initiative (Structural Genomics) - SBIR/STTR	NIGMS Protein Structure Initiative Meeting – April 24, 1998
PA: Evolutionary Mechanisms in Infectious Diseases	Working Group on Infectious Diseases – October 1998
RFA: Large-Scale Collaborative Project Awards	National Advisory General Medical Sciences Council Subcommittee Meetings – April 1998
RFA: Pilot Projects for the Protein Structure Initiative (Structural Genomics)	NIGMS Protein Structure Initiative Meeting – April 24, 1998
PAR: Bioengineering Research Grants. Release date: October 29, 1998	Bioengineering Symposium -- February 27-28, 1998
PAS: Bioengineering Research Partnerships. Release date: October 29, 1998	Bioengineering Symposium – February 27-28, 1998
PA: Protein Structure Initiative (Structural Genomics). Release date: June 22, 1999	Structural Genomics Targets Workshop – February 11-12, 1999 Structural Genomics Project Planning Meeting – November 24, 1998 Protein Structure Initiative Meeting – April 24, 1998
PA: Protein Structure initiative (Structural Genomics)--SBIR/STTR. Release date: June 22, 1999	Structural Genomics Targets Workshop – February 11-12, 1999 Structural Genomics Project Planning Meeting – November 24, 1998 Protein Structure Initiative Meeting – April 24, 1998
RR: Centers of Clinical Research Excellence at RCMI Eligible Institutions with Medical Schools. Release date: January 20, 1999	NCRR Strategic Plan
RR: Guidelines for Additional Time and support for Clinical Associate Physician (CAP) Awards. Release date: August 10, 1999	NCRR Strategic Plan
FRAM Study, a broad-based prevalence study to determine the prevalence of body composition changes and metabolic disturbances in HIV-infected individuals – funded September 1999 [e]	Panel meeting on "The Metabolic Complications and Body Composition Changes in HIV-infected Individuals" – November 1998
RFA: Genetics of Drug Addiction Vulnerability RFA: NIDA Center for Genetic Studies	1) Prospects for the Molecular Genetics of Drug Abuse – October 27, 1999 2) Genetic Vulnerability to Drug Abuse – September 1998
RFA: Protein Structure and Function in Aging and Late-life Disease – June 1999 [b]	Peptide and Protein Integrity: Special Features in Aging – August 1997
PA: The Aging Senses: Relationships Among Multiple Sensory Systems – June 1999	Changes in Multimodal Sensory Systems with Aging – September 1996
RFA: Exploratory Projects for Longitudinal Genetic Epidemiologic Studies on Aging – May 1999 [f]	Genetic Epidemiology of Aging and Survival Outcomes – April 1998

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
PA: Aging and Old Age as Risk Factors for Multiple Primary Tumors – December 1998 [d]	Multiple Primary Tumors Workshop – June 1996
RFA: Neurobiological Mechanisms of Adolescent Alcohol Abuse – issued November 25, 1998	Incorporated recommendations made by the NIAAA National Advisory Council Subcommittee meeting entitled "Neuroscience and Behavioral Research Portfolio Review" – May 11-13, 1998
RFA: Innovative Research on Human Mucosal Immunity	Ad Hoc Panel on NIDR AIDS Research – 1997
PA: Mechanisms of AIDS Pathogenesis: Collaborative Teams	Ad Hoc Panel on NIDR AIDS Research – 1997
PA: Low Birthweight in Minority Populations [e,d]	Workshop on Oral Diseases and Adverse Pregnancy Outcomes – 1997
PA: Evolutionary Mechanism in Infectious Diseases	Infectious Diseases Planning Workshop – 1997
PA: Research on Microbial Biofilms	Infectious Diseases Planning Workshop – 1997
PA: Innate Immunity	Infectious Diseases Planning Workshop – 1997
RFA: International Collaborative Oral Health Research Planning Grant [b,c,d,e,f]	Multiple NIDCR workshops have emphasized the need for international collaboration
Vision Research - A National Plan: 1999-2003 [b,c,d,e,f]	Retinal Diseases Panel – June 1997
Vision Research - A National Plan: 1999-2003 [b,c,d,e,f]	Corneal Diseases Panel – May 1997
Vision Research - A National Plan: 1999-2003 [b,c,d,e,f]	Lens and Cataract Panel – April 1997
Vision Research - A National Plan: 1999-2003 [b,c,d,e,f]	Glaucoma Panel – April 1997
Vision Research - A National Plan: 1999-2003 [b,c,d,e,f]	Strabismus, Amblyopia, and Visual Processing Panel – April 1997
RFP: Pediatric Study Centers for an MRI Study of Normal Brain Development, issued August 1998 and first Centers funded in late fiscal year 1999. The three ICs have also formed the "Pediatric Neuroimaging Network" to develop outreach and maintain communications with the neuroimaging community and to conduct conferences, workshops, etc. [c,d]	NINDS/NIMH/NICHD-sponsored workshop: Tools for Pediatric Neuroimaging; resulted in several recommendations to the NIH, with the top priority involving the need for a normative study of brain structural development – September 1997
RFA: The Role of the Environment in Parkinson's Disease in September 1999	NIEHS-convened Forum on the Role of the Environment in Parkinson's Disease – July 1999

Related to research goal (b) -- Develop new or improved instruments and technologies for use in research and medicine

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Creutzfeldt-Jakob Disease (CJD) Assay Methods Development – 1999 to 2003	Special Emphasis Panel on CJD and Blood Transfusion – September 24-25, 1997
RFA: Mouse Sperm Cryopreservation	Priority Setting for Mouse Genomics and genetic Resources – March 1998; Panel on Mouse Sperm Cryopreservation – June 1998
RR: Database Management of NIH-Supported Chimpanzees – Release date: May 25, 1999	NIH Chimpanzee Management Program – September 1998 and NAS Report on Chimpanzees
PAR: NCRR Shared Instrumentation Grant – Release date: December 22, 1998	NCRR Strategic Plan
PA: Technologies to Improve the Utility of Animal Models – Release date: January 22, 1999	NCRR Strategic Plan
PAR: Developing and Improving Institutional Animal Resources – Release date: February 19, 1999	NCRR Strategic Plan
Biotechnology (Administrative Supplements to be issued)	Biotechnology Centers – September 23, 1999
RFA: "Technologies for Gene Expression Analysis in the Nervous System" – December 11, 1998	Incorporated recommendations made by participants in meetings of the trans-NIH working committee of the Brain Mapping Anatomy Project – 1998
RFA: "Phenotyping the Mouse Nervous System and Behavior" – January 22, 1999	Incorporated recommendations made by participants at the workshop on "Priority Setting for Mouse Genomics and Genetics Resources" – March 19-21, 1998
RFA: "Mouse Mutagenesis and Phenotyping: Nervous System and Behavior" – March 31, 1999	Incorporated recommendations made by participants at the workshop on "Priority Setting for Mouse Genomics and Genetics Resources" – March 19-21, 1998
PA: "Mouse Brain Atlas for Functional Genomics" – February 3, 1999	Incorporated recommendations made by participants in meetings of the trans-NIH working committee of the Brain Molecular Anatomy Project – 1998
A goal of this workshop is production by mid to late 2000 of written guidelines for inclusion of qualitative research methods in NIH proposals. The document is targeted for both applicants and reviewers to increase the number of submissions of competitive qualitative research proposals.	Workshop on "Qualitative Methods in Health Research: Opportunities and Considerations in Application and Review" – September 30-October 1, 1999
PA: SBIR/STTR & Control of Microbial Biofilms	Infectious Diseases Planning Workshop – 1997
PAS: Bioengineering Research Partnerships (from NIH BECON)	Bioengineering: Building the Future of Biology and Medicine - BECON – 1998
PAS: Bioengineering Research Grants (from NIH BECON)	Bioengineering: Building the Future of Biology and Medicine - BECON – 1998
Vision Research - A National Plan: 1999-2003 [c,e]	Visual Impairment and Its Rehabilitation Panel – April 1997

Related to research goal (c) -- Develop new or improved approaches for preventing or delaying the onset of progression of disease and disability

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Pediatric Asthma Clinical Research Network – 1999 to 2004	Airway Biology and Disease Program Special Emphasis Panel – June 1997
RFA: Decreasing Weight Gain in African-American Preadolescent Girls – 1999 to 2007	NIH Special Emphasis Panel on Intervention Studies in Children and Adolescents to Prevent Cardiovascular Disease – September 1997
PA: Biobehavioral Pain Research	Biobehavioral Pain Research: A multi-institute assessment of cross-cutting issues and research needs – January 1994
PA: Occupational Safety and Health Research – issued August 18, 1999	Meetings that led to development of the National Occupational Research Agenda – 1996
Racial and Ethnic Disparities in the Etiology of Type 2 Diabetes in the U.S. – September 14, 1999 [a]	Several meetings with the Assistant Secretary on Racial Disparities – 1998-1999
NIH Training and Career Development Workshop on HIV Prevention Research for and by Racial and Ethnic Minorities – August 1999	Series of workshops to develop a consensus on scientific priorities for a trans-NIH comprehensive HIV/AIDS research plan. Special areas of interest include research related to racial and ethnic minorities – March 1999
Official 1999 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with HIV. Published in MMWR, the Annals of Internal Medicine, and Clinical Infectious Diseases. Distributed nationwide to physicians for the treatment of HIV-infected individuals.	U.S. Public Health Service/Infectious Disease Society of America meting on "Guidelines for Prevention of AIDS-related Opportunistic Infections" – March 1999
PA: Drug Abuse Prevention Intervention Research – October 5, 1999	1) Health services research symposium steering committee – December 9, 1997 2) Organization and management of drug abuse prevention and treatment services – March 5, 1998 3) Effectiveness and outcomes of drug abuse prevention and treatment – March 19, 1998 4) The economics of drug abuse prevention and treatment services – April 7, 1998 5) Promoting drug abuse prevention & treatment services – April 28, 1998 6) Forging the link: Health services research on drug abuse prevention & treatment, at the association for health services research annual meeting – June 1998 7) Drug Abuse Prevention Through Family Interventions – June 1996 8) Perspectives on Rural Substance Abuse – May 21-23, 1996

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
The Next Generation of Prevention Research – December 1999	1) Health services research symposium steering committee – December 9, 1997 2) Organization and management of drug abuse prevention and treatment services – March 5, 1998 3) Effectiveness and outcomes of drug abuse prevention and treatment – March 19, 1998 4) The economics of drug abuse prevention and treatment services – April 7, 1998 5) Promoting drug abuse prevention & treatment services – April 28, 1998 6) Forging the link: Health services research on drug abuse prevention & treatment, at the association for health services research annual meeting – June 1998 7) International Classification of Prevention Trials – December, 1998 (Co-sponsored NIMH, SPR, CSAP)
RFA: Prevention Services Replicating a School-Based Program – January 1999	Effectiveness and outcomes of drug abuse prevention and treatment – March 19, 1998
PA: Diversity in Medication Use and Outcomes in Aging Populations – May 1999	Pharmacokinetics and drug interactions in the elderly and special issues in elderly African-American populations – April 1997
RFA: *In Vivo* Medication Development for Alcohol-Related Conditions – issued January 27, 1999	Incorporated recommendations made by participants at a workshop on "Preclinical Medications Development" – November 16-17, 1998
PA: Effectiveness of Strategies for Preventing DUI Recidivism – issued March 18, 1999, in conjunction with the National Highway Traffic Safety Administration (NHTSA)	Incorporated recommendations made by participants at a workshop on "Sentencing Options for DUI Offenders" – May 17-18, 1996, which also led to preparation of a collaborative work entitled "*Sentencing and Dispositions of Youth DUI and Other Alcohol Offenses: A Guide for Judges and Prosecutors,"* published by NHTSA in September 1999.
RFA: Prevention of Alcohol-Related Problems Among College Students – issued November 25, 1998	Incorporated recommendations from a variety of meetings and workshops, including the initial meeting of the NIAAA National Advisory Council Subcommittee on College Drinking -- September, 1998; and meetings hosted by the Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Administration (SAMHSA) and the U.S. Department of Education – 1998
A memorandum of understanding (MOU) was developed between NIAAA and NIAID for the development and integration of specialized alcohol abuse intervention modules within HIVNET Protocol 015, entitled "A Randomized Clinical Trial of the Efficacy of a Behavioral Intervention to Prevent Acquisition of HIV among Men Who Have Sex with Men," also known as "Project EXPLORE."	Integrated Behavioral and Biomedical AIDS Working Group – May 1-2, 1997

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
PA: Research on Child Neglect, in March 1999 (with OBSSR, NIAAA, NICHD, NIDCR, NIDA, NIMH, and ACYF; Dept. of Justice; Dept. of Education and PA: Career Development Awards: Child Abuse and Neglect Research, in August 1999 (with NIMH, NICHD, NIDA, NIAAA, NICHD)	NIH Child Abuse and Neglect Working Group 1998 report on future research, and the research priority areas identified in the 1993 National Academy of Sciences report, "Understanding Child Abuse and Neglect." NIH Child Abuse and Neglect Technical Assistance Workshop conducted by NINDS, NIMH, and NICHD in February 1999 for prospective career development awardees.
RFA: HIV Prevention Trials Network	HIVNET Program Review – June 1996
RFP: Accelerated Candidate Malaria Vaccine Development	Blue Ribbon Panel on Malaria Vaccine Development – June 1997

Related to research goal (d) -- Develop new or improved methods for diagnosing disease and disability.

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFAs: In vivo Cellular and Molecular Imaging Centers	Imaging Working Group – July 17-18, 1997, first meeting
Early Detection Research Network [c]	Prevention Program Review; 10 meetings between April 1996 and March 1997
Small Animals Imaging Network	Imaging Working Group – July 17-18, 1997, first meeting
Imaging Pnacreatic Beta-Cell Mass, Function, or Inflammation – December 21, 1999-January 21, 2000 [a,e]	Workshop on Imaging the Pancreatic Beta Cell – April 19-20, 1999

Related to research goal (e) -- Develop new or improved methods for treating disease and disability

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFP: Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) – 1999 to 2003	Pulmonary Artery Catheterization and Clinical Outcomes (PACCO) NHLBI and FDA Workshop – August 1997
Broad Agency Agreement: Retinoid Treatment in Emphysema: Feasibility Studies -- 1999 to 2002	NHLBI Workshop: Clinical Trial Feasibility: All-Trans-Retinoic Acid for the Treatment of Emphysema -- September 16, 1998
RFA: Strategies to Augment Alveolization -- 1999 to 2003	Special Emphasis Panel on Strategies to Augment Alveolization -- September 29, 1997
PA: Mechanisms Underlying Individual Variations in Drug Responses	Understanding Individual Variations in Drug Responses: From Phenotype to Genotype – June 9-10, 1998

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Pharmacogenetic Research Network and Database	Understanding Individual Variations in drug Responses: From Phenotype to Genotype – June 9-10, 1998
New Strategies for the Treatment of Type 1 Diabetes – September 30, 1999-April 14, 2000 (and all other current diabetes initiatives)	Diabetes Mellitus: Challenges and Opportunities (led to other RFAs as well) – September 1997
Hepatitis C – September 9, 1999 [a]	Sixth International Symposium on Hepatitis C and Related Viruses – June 6-9, 1999
Complementary Medicine and Chronic Liver Disease – September 1999	Alternative and Complementary Medicine and Chronic Liver Disease – August 22-24, 1999
Basic Research on the Metabolism of Iron Chelation [a]	Iron: From Current Biochemistry to New Chelator Development Strategies – September 21-22, 1998
PA: Pilot Studies on Gene Therapy Vectors for Metabolic Diseases – October 18, 1996	AAV Vectors: Gene Transfer into Quiescent Cells – June 6, 1995
RFA: Protease Inhibitor Related Atherosclerosis in HIV Infection	Panel meeting on "The Metabolic Complications and Body Composition Changes in HIV-infected Individuals" – November 1998
RFA: Bringing Research to Practice	1) Health services research symposium steering committee – December 9, 1997 2) Organization and management of drug abuse prevention and treatment services – March 5, 1998 3) Effectiveness and outcomes of drug abuse prevention and treatment – March 19, 1998 4) The economics of drug abuse prevention and treatment services – April 7, 1998 5) Promoting drug abuse prevention & treatment services – April 28, 1998 6) Forging the link: Health services research on drug abuse prevention & treatment, at the Association for Health Services Research annual meeting – June 1998 7) Integrating treatment and health services research – July 11, 1998
RFA: Research on Drug Courts	1) Barriers to Criminal Justice Research – January 22-23, 1997 2) Several meetings co-sponsored by the National Drug Court Institute – 1998-99 3) Health services research symposium steering committee – December 9, 1997 4) Organization and management of drug abuse prevention and treatment services – March 5, 1998 5) Effectiveness and outcomes of drug abuse prevention and treatment – March 19, 1998 6) Forging the link: Health services research on drug abuse prevention & treatment, at the association for health services research annual meeting – June 1998
RFA: Research on Care at the End of Life, in January 1999	NIH workshop, Symptoms in Terminal Illness (a related FY 1998 PA, Management on Symptoms at the End of Life, is subsumed in this RFA) – September 1997

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Consortium on Deep Brain Stimulation (DBS) for the Treatment of Parkinson's Disease (PD) and Other Neurological Disorders, in September 1999	NINDS Working Group on DBS for PD – March 1999
RFP: Collaborative Tolerance Research Network (CTRN)	The Expert Panel on Immune Tolerance – February 1998
RFP: Statistical & Clinical Coordinating Center for CTRN	The Expert Panel on Immune Tolerance – February 1998
AI: Non-Human Primate Transplant Tolerance Cooperative Study Group	The Expert Panel on Immune Tolerance – February 1998
RFP: Network on Antimicrobial Resistance in Staphylococcus Aureus	Consultation on the Emergence of Drug Resistance in *Staphylococcus aureus* – September 1997
RFA: Hepatitis C Cooperative Research Units and Centers	–NIH Consensus Development Conference on Management of Hepatitis C – March 1997 –Expert Panel on NIAID's Research-Based Framework for Progress on Hepatitis C – May 1997

Related to research goal (f) -- Develop critical genomic resources, including the DNA sequences of the human genome and the genomes of important model organisms and disease-causing microorganisms

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
Mouse Cancer Genome Anatomy Project	Preclinical Models Working Group – first convened December 1996;regular meetings thereafter
RR: Mutant Mouse Regional Resource Centers -- Release date: January 22, 1999	Priority Setting for Mouse Genomics & Genetics Resources – June 11, 1998
RR: National Stem Cell Resource – Release date: December 23, 1998	International Workshop Comparative Gamete & Embryo Cryopreservation -- March 19-20, 1998
PAR: Midcareer Investigator Award in Mouse Pathobiology Research – Release date: February 19, 1999	Priority Setting for Mouse Genomics & Genetics Resources -- June 11, 1998
PA: Novel Approaches to Enhance Stem Cell Research – Release date: April 13, 1999	International Workshop Comparative Gamete & Embryo Cryopreservation – March 19-20, 1998
PAR: Development of Non-Mammalian Models and Related Biological Materials for Research – Release date: June 17, 1999	Non-Mammalian Models Workshop – February 16-17, 1999
Collins *et al.*, "New Goals for the U.S. Human Genome Project: 1998-2003" Science 282:682-689, October 1998.	--Five Year planning meetings: May 1997, September 1997, January 1998, May 1998 (2) --ELSI goals resulted from ELSI Research, Planning and Evaluation Group (ERPEG) Meetings: September 1997, December 1997, February 1998, April 1998, May 1998, September 1998
RFA: Studies of the Ethical, Legal and Social Implications of Research into Human Genetic Variation – April 1999	ELSI Research, Planning and Evaluation Group (ERPEG) Meetings – September 1997, December 1997, February 1998, April 1998, May 1998, September 1998, March 1999

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: Network for Large-Scale Sequencing of the Mouse Genome – December 1998	--Priority Setting Meeting for Mouse Genomics and Genetics Resources – March 1998 --Priority Setting Meeting for Mouse Genomics and Genetics Resources, First Follow-up Meeting – October 1998
--Formation of the Trans-NIH Coordinating Committee for Non-Mammalian Models (CCNMM) --PA: Development of Nonmammalian Models And Related Biological Materials For Research	Non-Mammalian Models Workshop – February 1999
--Formation of Mammalian Gene Collection Project (co-directed by NHGRI and NCI) --RFA: Technologies for Generation of Full-length Mammalian cDNA – March 1999	NHGRI Five Year Planning Meetings: --Functional Analysis of Genomic Sequences – December 1997 --Airlie House Meeting – May 1998
PA: Advanced Development of Genomic Technologies	Workshop convened by NHGRI at Cold Spring Harbor Laboratory – May 1998
PA: Genome Scholar Development and Faculty Transition Award – November 1998	NHGRI Advisory Council meetings
List of Prioritized Organisms for Sequencing and New Support Mechanism for Large-Scale Genome Sequencing	Blue Ribbon Panel on Microbial Genome Sequencing – May 1999

Related to research goal (g) --Work towards the President=s goal of developing an AIDS vaccine by 2007

Title or RFA/PA/RFP or Brief Description of Follow-up Action and Date/Timeframe	Name of Workshop/Other Meeting and Date Held
RFA: HIV Vaccine Trials Network	AVEG/HIVNET Summit Meeting – January 1998

Sources of FY 1999 Assessment Data: RFAs and PAs are published in the NIH Guide for Grants and Contracts and RFCs are published in the Commerce Business Daily.

Discussion of Performance: As stated previously, the factors that influence the planning and spending of the NIH budget are complex, and input from a broad range of individuals and organizations is sought to inform the decisionmaking process. The workshops and subsequent follow-up actions summarized above are representative of NIH=s successful efforts in this regard.

Next Steps: The NIH will continue to convene workshops and panels that identify public health needs and assess scientific progress and opportunities across the spectrum of medical research programs that we support and conduct, and we will take appropriate actions to implement the recommendations from these meetings.

2.1.2.5 Grants Administration and Peer Review

Approximately eighty-five percent of NIH's budget goes to support research in universities, medical centers, and other institutions around the country. As such, NIH considers it very important to maintain effective and efficient grants administration and a high quality of peer review, such that the highest quality of research is selected for support.

To ensure that the most meritorious research projects are considered for funding, NIH employs a peer review process in which prominent scientists from around the country evaluate each request for support and, through this, provide advice to NIH staff in the selection process. Furthermore, afterwards of funding, it is important to ensure that the research is carried out appropriately and monitored.

The most important requirements of the peer review process are that the process is fair, remains current with the science it is reviewing, and is organizationally well designed to accommodate the many applications for research support and training that NIH receives. It is also essential that NIH provide support to investigators in a timely fashion, so that the important effort of providing for the health of the nation can proceed efficiently.

Finally, the expenditure of the nation's financial resources for the conduct of research also demands appropriate oversight. And towards this end, efficient and effective administration, improved customer service, and enhanced communication and reporting processes are essential.

Maintaining the effectiveness of the numerous processes and systems involved and responding to the evolving needs of science entail continuing effort. The areas below are of current attention in this regard, and form the basis for the performance goals discussed in the subsequent pages of this section:

- Improve the support for research by reviewing current mechanisms and implementing appropriate changes
- Improve the responsiveness and efficiency of NIH's research administration systems to the grantee community
- Strengthen NIH's capacities for the conduct of electronic research administration
- Strengthen grantee institution compliance with grant requirements
- Ensure that grant applications submitted to NIH receive fair and appropriate review.

Performance Goals Summary Table – Grants Administration and Peer Review

Performance Goals	FY Targets	Actual Performance	Details
a) Address the needs of new investigators.	***FY 1999 Target*** Following discontinuation of the FIRST program, take the necessary action to ensure that the needs of new investigators are being met.	**FY 1999 target met.**	Page 137
b) Accommodate the unique needs of bioengineering researchers.	***FY 1999 Target*** Redesign the R24 program to accommodate the unique needs of bioengineering researchers.	**FY 1999 target met.**	Page 139
c) Strengthen grantee institution understanding of compliance requirements to ensure proper stewardship of public funding for research.	***FY 1999 Target*** Establish a program of continuing education for grantees that provides benchmarks, best practices, professional guidance, etc. to the community.	**FY 1999 target met.**	Page 140
d) Enhance oversight of the NIH peer review process.	***FY 2001 Targets*** (1) Increase the number of IRG external advisory groups from 6 to 9. (2) Begin implementation of recommendations from the Boundaries Panel. ***FY 2000 Target*** Enhance study section operations by doubling the number of IRG external advisory groups from 3 to 6. ***FY 1999 Target*** Conduct various assessments of the functions and organization of NIH study sections.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 142
e) Improve and enhance Electronic Research Administration (ERA) and communication with the extramural community.	***FY 2001 Target*** Capability for full electronic grant administration. ***FY 2000 Target*** Full deployment of key ERA business process modules. ***FY 1999 Target*** Design and test new systems.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target exceeded.**	Page 144
f) Implement electronic research progress	***FY 2001 Target*** Expand electronic progress reporting to	FY 2001: To be reported in January 2002.	Page 147

Performance Goals	FY Targets	Actual Performance	Details
reporting by the extramural community.	NIH's top 150 awardee institutions. ***FY 2000 Targets*** (1) Implement electronic progress reporting with all 65 newly "on-line" institutions participating in the FDP. (2) Begin pilot testing of progress reporting for multi-project mechanisms. ***FY 1999 Target*** Streamline post-award reporting, while continuing to ensure appropriate oversight and enhancement of recipient compliance with reporting and accountability requirements.	FY 2000: To be reported in January 2001. **FY 1999 target met.**	
g) Improve customer service to grantees.	***FY 2001 Target*** Further facilitate expediting the processing of the most meritorious grant applications by reducing the receipt-to-award cycle from 9-10 months to 6-7 months. ***FY 2000 Target*** Expedite the processing of the most meritorious grant applications by extending to all NIH Institutes the use of expedited *en bloc* Council review procedures. ***FY 1999 Target*** Identify approaches to expedite the processing and award of grant applications.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 149
h) Improve grantee reporting of inventions developed with federal funds.	***FY 2000 Target*** Fully establish the Edison electronic invention reporting system for use by all grantee institutions, and expand its use to other government agencies. ***FY 1999 Target*** Enhance recipient compliance with reporting and accountability requirements.	FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 151

Performance Goal Details - Grants Administration and Peer Review

Goal a) Address the needs of new investigators.

Over time, we often find that the original intent of established programs can cease to meet grantees' needs. A recent case in point is the First Independent Research Support in Transition (FIRST) award. An evaluation of the FIRST award program indicated that its utility in establishing a strong cohort of new investigators was not supported by the available evidence, such as success rates of grantees in securing subsequent research support. Consequently, the program was discontinued, and new investigators are now encouraged to apply for regular research grant support, which is able to provide a significant increase in award amounts. NIH has pledged to ensure by constant monitoring that the number of new investigators receiving support will not diminish from year to year.

Assessment of FY 1999 Performance

FY 1999 Targets: Following discontinuation of the FIRST program, take the necessary action to ensure that the needs of new investigators are being met.

FY 1999 Achievement Summary:

- This target has been met.
- Major accomplishment this fiscal year contributing to this has been:

  -- The face page of the grant application form (PHS 398) has been modified to include a check box to enable new investigators to self-identify themselves. In this way, reviewers are able to apply appropriate considerations in reviewing these applications, and Institute staff can take new-investigator status into consideration when making awards.

Sources of FY 1999 Assessment Data: The new face page of PHS 398 has been made available to the applicant community. Data on numbers of applications and success rates are maintained in the central NIH IMPAC database, so that subsequent determination of success rates of new investigators can be monitored with reasonable and objective data.

Discussion of Performance: Initially with the elimination of the R29 program, new investigators were asked to identify themselves as such on grant applications, and ICs were asked to take this information into consideration in making awards. Now, the PHS 398 has been modified to permit applicants to check a box to identify themselves as new investigators. Effectiveness of these measures will be determined by the numbers of new investigators funded and success rates.

Data on success rates and numbers of new investigators funded in FY 1999 are incomplete at this time and will be reported as soon as they are available.

Next Steps: Additional targets beyond FY 1999 are not planned, although periodic monitoring of the IMPAC database will be done to ensure continued maintenance of success rates.

Goal b) Accommodate the unique needs of bioengineering researchers.

As science advances and diversifies, experimentation from diverse disciplines begins to have an impact on biomedical and behavioral research, altering what grantees need to accomplish their research. In its continual monitoring of those needs, for example, the NIH has determined the need to modify the use of its research grant mechanisms to accommodate newly emerging bioengineering research.

Assessment of FY 1999 Performance

FY 1999 Target: Redesign the R24 program to accommodate the unique needs of bioengineering researchers.

FY 1999 Achievement Summary:

- The target was met.
- Major accomplishments this fiscal year contributing to this have been:

  -- In addition to a program announcement soliciting applications for R01 Bioengineering Research Grants, a program announcement was published, employing a modified R24 mechanism to establish a new cadre of Bioengineering Research Partnerships. In response to this announcement, 120 applications were received; of those, 65 have already been reviewed and 13 were funded in FY 1999.

Sources of FY 1999 Assessment Data: All numbers are verifiable in the IMPAC data base.

Discussion of Performance: The response of the community to the announcement for applications for Bioengineering Research Partnerships was impressive. Furthermore, reviewers indicated that they had no difficulties in applying appropriate criteria in evaluating these applications. The reviewers' assessments of the applications clearly indicate that the measures taken and guidance provided to the applicant community have met the needs of bioengineering researchers to enable submission of high-quality applications.

Next Steps: The remaining 55 applications will undergo review in FY 2000, and it is possible that others among the 65 that were reviewed in FY 1999 but not funded will receive support in FY 2000. The success of this first announcement has led the NIH to reannounce the program in FY 2000. For this solicitation, the concept of the Bioengineering Research Partnership is considered sufficiently mainstreamed for both applicants and reviewers that the announcement will use the standard R01 (regular research grant) mechanism.

Goal c) **Strengthen grantee institution understanding of compliance requirements to ensure proper stewardship of public funding for research.**

With the receipt of public support, institutions and investigators accept the responsibility to conduct research ethically and honestly, and to provide proper stewardship of federal funds. Given this responsibility, an effective strategy to enhance compliance is to work in partnership with grantees and national professional organizations to develop standards of self-assessment for compliance in all areas of grants administration such that institutions will be able to evaluate the effectiveness of their oversight procedures and management controls. NIH proposes to expand outreach efforts by establishing a program of continuing education for grantees that provides benchmarks, best practices, and professional guidance to the grantee community. Such a program is intended to enhance the ability of institutions to assess their systems and promote effective research compliance and stewardship of NIH research funds.

Assessment of FY 1999 Performance

FY 1999 Target: **Establish a program of continuing education for grantees that provides benchmarks, best practices, professional guidance, etc. to the community.**

FY 1999 Achievement Summary:

- The target was met.
- Major accomplishments this fiscal year contributing to this have been:

  -- In FY 1999, NIH staff gave 22 presentations on compliance issues as part of extramural outreach efforts to grantee organizations and national professional organizations, almost double the number of similar presentations given in FY 1998.

  -- In FY 1999, NIH reinvigorated the NIH Regional Seminar program, increasing their frequency from one per year since 1995 to two per year, and placing a renewed emphasis on compliance issues.

  -- In FY 1999, NIH gave two institution-specific joint training sessions focusing on areas of deficiency in extramural research administration, one with Thomas Jefferson University and the other with the University of Minnesota. These were the first such training sessions given by the NIH.

-- In addition to these outreach efforts, the NIH Grants Policy Statement, which outlines the policies and procedures to be followed by all NIH grantees, was updated in FY 1999 with an increased focus on compliance.

-- Finally, the Office of Extramural Research (OER) has continued to increase the information it provides on its Web sites in order to increase public accessibility to current policies and procedures. The OER grants page provides information to approximately 35,000 users per month and has become a primary vehicle for dissemination of timely and critical information to the public.

Sources of FY 1999 Assessment Data: Although no hard data exist on rates of compliance, experience indicates that the majority of cases involving non-compliance are due to a lack of knowledge and systems deficiencies rather than an intentional disregard of the rules. Thus, NIH anticipates that increasing activity aimed at heightening the community's awareness of its compliance responsibilities will have a positive effect. Data on the number of presentations have been formally reported to the Deputy Director for Extramural Research (DDER) and are objectively verifiable. Numbers of Web site hits are centrally maintained and objectively verifiable.

Discussion of Performance: The success of these efforts toward attainment of the goal is evidenced by full attendance at compliance workshops, the enthusiastic response and positive feedback received from the grantee community, and the increasing number of invitations to give similar presentations at other institutions. These compliance-related presentations and reviews have also resulted in the development of tools to assess the effectiveness of organizational management systems that can help institutions strengthen deficient systems before problems involving federal funds develop. In addition, the revised policy statement is more explicit about roles, responsibilities and lines of communication among the various individuals involved in the grant relationship; it indicates that acceptance of an NIH grant creates a legal relationship with legally binding rights and obligations; and it makes clear that the NIH will not hesitate to enforce a grantee's obligations and to penalize noncompliance.

Next Steps: Targets beyond the FY 1999 expansion efforts have not been planned. However, the NIH anticipates utilizing the information gained from each of the compliance-related activities as the basis for development of a proactive compliance program model. Such a model would be used by the NIH to enhance grantee awareness of the responsibilities involved in the stewardship of federal funds.

Goal d) Enhance oversight of the NIH peer review process.

Applications for support from the NIH are reviewed initially for scientific and technical merit by peer review groups comprised of scientists from the extramural research community. Initial Review Groups (IRGs) are clusters of peer review groups that review applications within a particular area of science. There are currently twenty IRGs within the NIH Center for Scientific Review (CSR).

An IRG external advisory group of extramural scientists monitors and assesses whether the IRG's review groups (study sections) have the necessary scope and depth of expertise to review applications within their area of science. This process is one means of ensuring that the peer review process keeps pace with current advances in research and that the peer reviewer expertise is appropriate for the needs of modern science. Increasing the number of IRG external advisory groups is part of an effort to enhance study section operations.

In addition, a broader look at the entire organization and structure of the CSR peer review system has been undertaken by a "Boundaries Panel" comprised of highly recognized experts in the biomedical and behavioral sciences.

FY 2001 Target: **(1) Increase the number of IRG external advisory groups from 6 to 9.**

(2) Begin implementation of recommendations from the Boundaries Panel.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: **Enhance study section operations by doubling the number of IRG external advisory groups from 3 to 6.**

Basis and Data: The number of IRG external advisory groups in operation will be one measure of achievement of this target. Other evidence will include completed modifications to CSR study section organization resulting from recommendations of the Boundaries Panel.

Validation and Verification: CSR provides periodic updates on the number of external advisory groups established and in operation. Modifications to study section organization are broadly disseminated (e.g., via the Web) -- as proposed, for public comment, and when changes are instituted.

Assessment of FY 1999 Performance

FY 1999 Target: Conduct various assessments of the functions and organization of NIH study sections.

FY 1999 Achievement Summary:

- The FY 1999 target was met.
- Major accomplishments this fiscal year contributing to this have been:

  -- The draft Report of the Boundaries Panel has been completed and has been disseminated to the community for comment.

  -- The integration of neurosciences and AIDS review in CSR was completed and study sections have been established and are now operative.

  -- The integration of behavioral and social science review in CSR was completed by the end of FY 1999.

Sources of FY 1999 Assessment Data: The draft Boundaries Panel report detailing the conduct of an assessment of overall study section organization was made available to the community on the CSR Web page. Internal assessments of neurosciences, AIDS, and behavioral and social sciences led to integration of their peer reviews into CSR and dissemination of new review structure to the community via the Web.

Discussion of Performance: The completion of integration efforts and the draft report of the Boundaries Panel mark the completion of the first phase of a comprehensive review of the entire CSR study section organization.

Next Steps: The Boundaries Panel will consider comments from the community to its draft report in early FY 2000. The Phase 1 report will be finalized, and Phase 2 will begin, i.e., the establishment of study sections within the reorganized IRGs. The establishment and operation of the IRG external advisory groups is currently ahead of schedule. It is now anticipated that at least 7, not 6, will be active by the end of FY 2000.

Goal e) **Improve and enhance Electronic Research Administration (ERA) and communication with the extramural community.**

Enabling extramural research institutions to use ERA technologies will greatly facilitate preparation of grant applications by research investigators, processing of applications by NIH staff, and management of awards by grantee organizations and NIH staff. NIH has begun development of the NIH ERA Commons, a Web-based client/server environment where the NIH and grantee community will conduct their research administration business electronically. Once the system is fully deployed and operational, the NIH will be able to maintain timely, secure electronic communication with extramural grantee business partners and will have the ability for full electronic research administration from application submission through closeout.

The following modules of the NIH Commons are planned and are in various stages of development/deployment:

Status: The Status interface allows institutional officials and principal investigators, with appropriate security, to access information on the status of pending applications and awards electronically. The module also allows principal investigators to view summary statements with complete confidentiality as soon as the summary statement is completed.

E-SNAP and CNAP: The e-SNAP and CNAP modules allow principal investigators and corresponding administrative officials from grantee organizations to submit and approve all information pertaining to the non-competing continuation in a fully electronic form, without duplication of Form PHS 2590 or submission of any hard copies of the application package. The modules also allow principal investigators to update their abstracts as the science warrants. E-SNAP accommodates awards eligible for the simplified non-competing award process, whereas CNAP handles the complex awards.

X-Train: The X-Train Training Appointment System allows information on trainee appointments that have traditionally been collected on Form 2271 to be submitted electronically. It allows grant administrative officials to record and obtain information about their trainees. X-Train replaces a less efficient Internet-based trainee appointment system that NIH has used since 1996 to collect over 2,000 training appointment forms.

Admin: The Admin module supports the establishment, monitoring, and updating of institutional and professional profiles to relieve administrative officials, principal investigators, and key grant personnel from having to re-key information. The system standardizes the information collected on applicant institutions and individuals, thereby minimizing the redundancy of information collected with every grant application.

Fellowships: The fellowship module will enable electronic submission of the Public Health Service individual National Research Service Award (NRSA) Form PHS 416-1.

CGAP: The CGAP module will accommodate the competing grant award process. Information traditionally submitted on the application for a Public Health Service Grant Form PHS 398 will be submitted through this module.

The Federal Demonstration Partnership (FDP) will be used for piloting new ERA systems. The FDP is a cooperative effort among federal research agencies and 65 research universities and non-profit research centers. The FDP was established to increase research productivity by streamlining the administrative process and reducing the administrative burden on principal investigators, at the same time maintaining responsible and effective stewardship of federal research funds. Thus, these institutions were a natural choice as the first extramural partners to be brought on-line with the NIH's ERA system.

FY 2001 Target: **Capability for full electronic grant administration.**

Performance Assessment – Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: **Full deployment of key ERA business process modules.**

Basis and Data: Achievement of this target will be measured by the number of institutions registered.

Validation and Verification: Publicly available ERA status reports indicate the number of registered FDP Institutions.

Assessment of FY 1999 Performance:

FY 1999 Target: Design and test new systems.

FY 1999 Achievement Summary:

- The FY 1999 target was exceeded.
- Major accomplishments this fiscal year contributing to this have been:

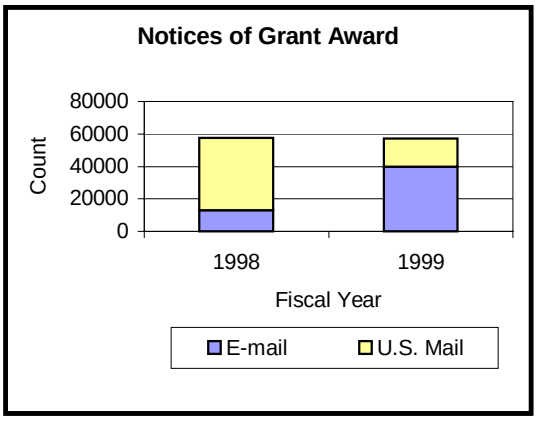
-- In FY 1999, 1,554 users from 74 organizations within the Federal Demonstration Partnership registered to use the NIH Commons. Logins to the Commons average 36 a day.

-- E-SNAP began receiving the first electronic applications in a limited pilot in May 1999. As of the end of FY 1999, NIH received 22 e-SNAPs and the pilot had expanded to involve 10 institutions. Updated abstracts collected through the e-SNAP submissions have been

made available to the public on-line through CRISP, thereby providing the public with the most up-to-date information on scientific projects funded by NIH.

-- X-TRAIN is currently in a limited pilot involving fifteen schools. The CNAP, CGAP and Fellowship modules are in the detailed design phase of their development.

-- The Electronic Notice of Grant Award (NGA) system was pilot tested in FY 1998 and fully deployed at the beginning of FY 1999. As can be seen from the following graph, in the first year of implementation the grantee community has embraced the technology and almost 70% of all notifications of awards are now made electronically. Electronic notifications of grant award (NGA) are generated by IMPAC II, NIH's internal extramural research information management system that works in conjunction with the NIH Commons to accommodate a fully electronic grant life cycle. This service has been made available to all NIH grant and cooperative agreement recipients having the capability to receive NGAs electronically.



-- NIH has also taken a leadership position with the development of the Federal Commons. By assuming this role NIH is assuring that internal progress in the area of ERA will utilize technologies that will be the standards across the government. Standard data dictionaries have been developed in this interagency effort that will allow for easy sharing of information between agencies and departments.

Sources of FY 1999 Assessment Data: Data on the use of the NIH ERA Commons and Edison have been generated through computerized tracking systems that are objective and verifiable. ERA status reports are regularly submitted to the DDER and are made available to the public on the OER Web Site at http://grants.nih.gov/grants/era/era.htm.

Discussion of Performance: In FY 1999 electronic research administration and communications with the extramural community have been significantly enhanced. Users can now update institutional and/or personal profiles through the Admin module, as well as check on the status of their applications and view their summary statements through the Status module. Achievement in the area of electronic research administration has surpassed our expectations in FY 1999 toward reaching the overall goal. Consequently, future year targets have been revised.

Next Steps: In FY 2000, NIH intends to expand deployment of the Status and X-Train modules in particular. ERA continues to be an area of high priority for NIH. NIH components will continue to devote considerable effort and resources towards the goal of achieving a fully electronic grant life cycle.

Goal f) Implement electronic research progress reporting by the extramural community.

Electronic progress reporting will be an immediate focus for the electronic research administration capability provided to our extramural partners. Initially, electronic progress reporting will only be available for the simpler, single-project grant mechanisms. But ultimately it will be expanded to more complex multidisciplinary projects conducted by several collaborating investigators.

FY 2001 Target: Expand electronic progress reporting to NIH's top 150 awardee institutions.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: (1) Implement electronic progress reporting with all 65 newly "on-line" institutions participating in the FDP.

(2) Begin pilot testing of progress reporting for multi-project mechanisms.

Basis and Data: Principal measures marking achievement of the target will be the number of FDP institutions implementing electronic reporting and the number of multi-project mechanisms introduced to the system. Information available in NIH's IMPAC database will provide the means to monitor progress on these targets.

Validation and Verification: Periodically available reinvention reports will document progress and indicate the number of institutions participating in pilots.

Assessment of FY 1999 Performance

FY 1999 Target: Streamline post-award reporting, while continuing to ensure appropriate oversight and enhancement of recipient compliance with reporting and accountability requirements.

FY 1999 Achievement Summary:

- The FY 1999 target was met.

- Major accomplishments this fiscal year contributing to this have been:

  -- E-SNAP is the new system that allows for the electronic submission of progress reports. E-SNAP began receiving the first electronic applications in a limited pilot in May 1999. As of the end of FY 1999, NIH received 22 e-SNAPs and the pilot had expanded to involve 10 institutions. Updated abstracts collected along with the progress reports through electronic submissions have been made available to the public on line through CRISP, thereby providing the public with the most up-to-date information on scientific projects funded by the NIH.

Sources of FY 1999 Assessment Data: Data on e-SNAP have been generated through computerized tracking systems that are objective and verifiable. ERA status reports are regularly submitted to the DDER and are made available to the public on the OER Web Site at http://grants.nih.gov/grants/era/era.htm.

Discussion of Performance: The NIH is well on its way toward full implementation of electronic progress reporting by the extramural research community through its focus on development of its ERA systems. Now that progress reporting is accommodated within the e-SNAP module of the NIH ERA Commons and advancements on the Commons are addressed in Goal e), it is artificial to separate the goal of electronic progress reporting from the overall ERA effort. In the future, this and Goals e) will be combined.

Next Steps: In FY 2000, the NIH intends to expand deployment of e-SNAP to allow increasing numbers of grantees access to the electronic progress reporting system.

Goal g) Improve customer service to grantees.

Shortening the time between submitting a research proposal and receiving the research funds means that the highest quality research will begin sooner or that an already productive research program will continue uninterrupted. Even in instances where funding cannot begin earlier (e.g., funding a competing continuation application must await the end of the previous non-competing segment), earlier *notification* of pending awards provides enhanced stability of the research enterprise.

FY 2001 Target: Further facilitate expediting the processing of the most meritorious grant applications by reducing the receipt-to-award cycle from 9-10 months to 6-7 months.

Basis and Data: Progress on this target will be measured by the number of such applications that receive award or notice of award within 6-7 months of receipt. (For the purpose of this goal, the "most meritorious" applications are generally defined as those with technical merit ratings in the top 15% across NIH.)

Validation and Verification: This information is available in NIH's IMPAC database.

FY 2000 Target: Expedite the processing of the most meritorious grant applications by extending to all NIH Institutes the use of expedited *en bloc* Council review procedures.

Basis and Data: Currently, about half of the NIH Institutes employ expedited *en bloc* Council review procedures. These procedures permit earlier award and/or notice of award. Internal NIH policy has recently been disseminated that this option is available to and encouraged for all NIH Institutes. Progress on this goal will be gauged by the extent to which all NIH Institutes have begun using these procedures.

Validation and Verification: Progress on this target will be documented in the ICs' periodic reporting to the Deputy Director for Extramural Research.

Assessment of FY 1999 Performance

FY 1999 Target: Identify approaches to expedite the processing and award of grant applications.

FY 1999 Achievement Summary:

- The FY 1999 target was met.

- Major accomplishments this fiscal year contributing to this have been:

  -- A major impact in expediting the awards process has been the establishment of procedures, including electronic enhancements, to expedite Council concurrence with peer review determination – a procedure called expedited *en bloc* concurrence. In essence, Council concurrence for certain applications can be obtained prior to the Council meeting, permitting more timely awards.

Sources of FY 1999 Assessment Data: The procedures developed for *en bloc* concurrence have been disseminated across the NIH Institutes through a Policy Announcement (PA-99-01) issued by the DDER. Data on the development and implementation of expedited *en bloc* Council concurrence across the NIH Institutes have been presented to the DDER, and through the forum of the DDER's Extramural Program Management Committee, the experiences of the ICs are continually shared.

Discussion of Performance: Other streamlining efforts are currently focusing on the rapid turn-around of feedback to the reviewer and in return, back to the NIH for more rapid consideration of proposed project modifications and subsequent funding. These approaches have the NIH well on its way to achieving its FY 2000 and FY 2001 Targets. Currently, nearly half of the NIH Institutes have adopted expedited *en bloc* Council concurrence. A synopsis of these approaches was presented in the August 30, 1999 issue of *The Scientist*: "Taking the Sting out of Applying for NIH Grants."

Next Steps: Extension of these expedited procedures to other Institutes is expected over the next fiscal year. In addition, further applications of electronic enhancements will continue, with the hope of additional time- and/or cost-savings in other areas of the receipt-to-award process.

Goal h) Improve grantee reporting of inventions developed with federal funds.

The Bayh-Dole Act was enacted in 1980 to ensure the transfer of technology from federally funded extramural research laboratories to the commercial/public sector. The Act stipulates that all grantees must report on inventions, patents, and licenses that have resulted from federally funded research. To support this requirement, the NIH has developed an electronic research administration system, "Edison," which is designed to receive, store, sort, and provide reports on invention, patent, licensing and invention utilization. Edison is the first secure interactive Web site developed as part of the NIH electronic research administration system. Use of Edison significantly reduces the 15 cycles of paper correspondence typically involved in patent and invention reporting to 3, dramatically shortening reporting time and effort, as well as making more information available in a usable format for grants administrators.

FY 2000 Target: Fully establish the Edison electronic invention reporting system for use by all grantee institutions, and expand its use to other government agencies.

Basis and Data: Demonstrated use of Edison by all grantee institutions registered to do electronic commerce with NIH by the end of FY 2000. Additional federal research agencies will be encouraged to adopt the Edison system for their reporting requirements so that the federal government can implement a common interface for the research community. The number of grantee institutions registered will be monitored through NIH's IMPAC database.

Validation and Verification: Memoranda of Understanding with participating agencies will verify their use of the system.

Assessment of FY 1999 Performance

FY 1999 Target: Enhance recipient compliance with reporting and accountability requirements.

FY 1999 Achievement Summary:

- The FY 1999 target was met.
- Major accomplishments this fiscal year contributing to this achievement have been :

-- One hundred and eighty-nine institutions are now using Edison. This number represents a 40% increase since FY1998.

-- In FY 1999, an additional 2 federal agencies have signed Memoranda of Understanding indicating that they will be now use Edison to meet their patent and invention reporting requirements.

Sources of FY 1999 Assessment Data: Data on Edison have been generated through computerized tracking systems that are objective and verifiable. This information is included in the ERA status reports that are regularly submitted to the DDER and made available to the public on the OER Web Site http://grants.nih.gov/grants/era/era.htm.

Discussion of Performance: The increasing numbers of users of the Edison system can be attributed, in part, to NIH's outreach efforts. NIH has increasingly encouraged the community to participate in using the system through presentations and demonstrations at NIH regional seminars and at national and regional professional meetings of researchers and research administrators.

Recruitment efforts of other federal agencies have been very successful. A total of 10 agencies have decided to use Edison for patent and invention reporting. Memoranda of Understanding document each agency's use of Edison. Use of the system by multiple agencies will facilitate the establishment of a common interface between the federal government and the research community.

Great strides have been made in FY 1999 towards achievement of the goal of improving grantee reporting of inventions developed with federal funds. These efforts will continue into FY 2000 and beyond, although no specific targets are planned beyond FY 2000 since the goal will be completed at that time.

Next Steps: Outreach efforts encouraging use of the Edison system will continue through presentations at the NIH regional seminars and at national and regional professional meetings of researchers and research administrators. Relevant federal agencies that do not yet use the Edison system will be encouraged to do so. New and existing ERA systems will be designed to enhance compliance with invention reporting requirements by directing users to the Edison system.

2.1.2.6 Management and Administration

NIH would be unable to maintain its world-class stature in research without strong management and administrative support to the research community. These support services are provided through the efforts of NIH's Office of Management. The Office's roles include: (1) advising the NIH Director and staff on all phases of NIH-wide administration and management activities; (2) providing leadership and direction to all aspects of management; (3) overseeing the management of functions in the area of budget and financial management, personnel management, management policy, management assessment, program integrity, contract procurement and logistics management, engineering services, safety, space and facilities management, support services and security operations.

The major concerns currently in the management and administration realm are:

- Continuous improvement of all management processes including the implementation of best practices, improved compliance with the Prompt Payment Act, and ensuring generally that NIH resources are properly managed and safeguarded

- Ensuring that NIH makes its information technology investments in ways that support the overall NIH Mission

- Improving efficiency and effectiveness for all procurement and contracting activities

- Ensuring the soundness of the NIH property management system and property regulations/policies

- Making certain that the human resource services are providing personnel-related services, including user friendly systems, in accordance with NIH policies and guidelines

The performance goals for this area, discussed below, encompass a number of initiatives and ongoing activities to improve NIH's processes and capabilities in each of these domains of need.

Performance Goals Summary Table – Management and Administration

Performance Goals	FY Targets	Actual Performance	Details
a) Implement the recommendations of the Arthur Andersen, Inc. study of administrative practices and costs at NIH.	***FY 2001 Target*** Finish meeting the milestones and targets that go beyond the FY 2000 goals. ***FY 2000 Target*** Complete the implementation of all recommendations as decided upon by the NIH Director and the IC Directors. ***FY 1999 Targets*** (1) Complete NIH Director and IC Directors review and decision-making for all recommendations. (2) Implement recommendations related to the Chief Information Officer and the Chief Financial Officer.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met.** **FY 1999 target (2) met.**	Page 158
b) Implement the Director's overall strategy to improve information technology (IT) management at NIH.	***FY 2001 Target*** Continue implementation of the Director's overall strategy to improve information technology (IT) at NIH by developing a strategic IT vision and a formal IT investment process. ***FY 2000 Targets*** Complete implementation of the technical recommendations. ***FY 1999 Targets*** (1) Ensure Year 2000 (Y2K) compliance for all NIH mission critical systems. (2) Complete NIH IT organizational, investment, and vision activities.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met.** **FY 1999 target (2) met.**	Page 161
c) Improve compliance with the Prompt Pay Act.	***FY 2001 Target*** Continue to reduce interest penalties and increase discounts by paying 93% of invoices on time. ***FY 2000 Target*** Reduce interest penalties and increase discounts by paying 93 % of invoices on time.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 165

Performance Goals	FY Targets	Actual Performance	Details
	FY 1999 Target Reduce interest payments and increase discounts by paying 93% of invoices on time.	**FY 1999 target met.**	
d) Improve the efficiency of the small acquisition process by continuing to expand the Purchase Card Program.	***FY 2001 Target*** (1) 2,500 card holders. (2) 4,200 people trained to use cards. (3) $200 million in orders. ***FY 2000 Targets*** (1) 2,000 card holders. (2) 3,600 people trained to use cards. (3) $160 million in orders. ***FY 1999 Targets*** (1) 1,600 card holders. (2) 3,000 people trained to use cards. (3) $110 million in orders.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) not met.** **FY 1999 target (2) not met.** **FY 1999 target (3) exceeded.**	Page 168
e) Improve customer satisfaction with the quality of products and services.	***FY 2001 Target*** A 90% overall average rating of approval for procurement offices as measured by the ABS. ***FY 2000 Target*** An 85% overall average rating of approval for procurement offices as measured by the ABS.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 171
f) Expand the use of Performance Based Contracting.	***FY 2001 Target*** Allocate $21.2 million of the available NIH contracting dollars to Performance Based Contracting (PBC) eligible contracts. ***FY 2000 Target*** Allocate $19.8 million of the available NIH contracting dollars to PBC eligible contracts.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 173
g) Ensure the soundness of the NIH property management system.	***FY 2001 Target*** Complete the FY 2001 milestones in the personal property management improvement plan and achieve a loss rate	FY 2001: To be reported in January 2002.	Page 174

Performance Goals	FY Targets	Actual Performance	Details
	of less than 6% of the property in the inventory. ***FY 2000 Target*** Complete the FY 2000 milestones in the personal property improvement plan and achieve a loss rate of no more than 8% of the total property in the inventory. ***FY 1999 Targets*** 1) Complete the activities listed above to resolve the property inventory discrepancies, including the completion of the property inventory, resolution of inventory discrepancies and reviews by the Board of Survey to determine the reason for discrepancy and proper disposition of the property. (2) Complete the NIH Director and IC Directors review and decision-making and the time lines for implementing the system improvement processes.	FY 2000: To be reported in January 2001. **FY 1999 target (1) partially met.** **FY 1999 target (2) met.**	
h) Ensure that NIH equipment loan agreements are properly executed, that equipment is not shipped until agreements are signed, and that NIH equipment is properly accounted.	***FY 1999 Target*** Complete the revision and implementation of the relevant property regulations.	**FY 1999 target met.**	Page 177
i) Simplify data entry and update into property systems.	***FY 2001 Target*** Complete the pilot project for the commercial software applications and report results to the ICs. ***FY 2000 Target*** Implement the pilot project(s) in one or more of the ICs.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 178
j) Ensure that proper procedures are followed with regard to equipment provided to contractors in the intramural research program.	***FY 1999 Target*** Complete implementation of the review system.	**FY 1999 target met.**	Page 179
k) Identify and pilot new approaches to providing human resource services	***FY 2001 Target*** Complete the development and begin the pilot implementation of decision support	FY 2001: To be reported in January 2002.	Page 181

Performance Goals	FY Targets	Actual Performance	Details
which increase manager satisfaction with personnel system flexibility and ease of use.	systems for recruitment, selection, and employee performance: CareerHere and the Career Recruitment Information Management System (CRIMS). ***FY 2000 Target*** A 10% increase in manager satisfaction with personnel system flexibility and ease of use as reflected in the 1999 survey outcome against the 1997 baseline. ***FY 1999 Target*** Complete the delegations of authority and related training.	FY 2000: To be reported in January 2001. **FY 1999 target met.**	
l) Reduce key time and attendance error rate indices by implementing the Integrated Time and Attendance System (ITAS).	***FY 2001 Target*** Reduce the FY 2000 levels of the error rate indices by 20%. ***FY 2000 Target*** Reduce the benchmark levels of the error rate indices by 20%. ***FY 1999 Target*** Complete implementation of the ITAS system.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 184
m) Perform a review to ensure that Intergovernmental Personnel Act (IPA) Agreements are properly executed before assignments begin.	***FY 1999 Target*** Complete review of a sample.	**FY 1999 target exceeded.**	Page 186
n) Ensure that overpayments do not occur in NIH fellowship programs and that bankruptcy statutes are complied with in collecting past over-payments.	***FY 2001 Target*** Achieve a 50% reduction in the number of over-payments. ***FY 2000 Target*** Complete implementation of the Fellowship Payment System (FPS). ***FY 1999 Target*** Complete implementation of corrective measures and begin implementation of the FPS.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 187

Performance Goal Details - Management and Administration

Goal a) Implement the recommendations of the Arthur Andersen, Inc. study of administrative practices and costs at NIH.

This initiative is intended to enhance the efficiency and effectiveness of the agency's business operations. After a seven-month review, Arthur Andersen, Inc. made 80 recommendations regarding administrative costs and practices at NIH. These recommendations included: establishing a Center for Information Technology, hiring a Chief Information Officer, decentralizing acquisitions, elevating the Chief Financial Officer position to the Deputy Director of Management level, and undertaking a major technology transfer education and orientation program.

The NIH Director and the IC Directors decided that 79 of the 80 recommendations were appropriate for NIH implementation.

FY 2001 Target: Finish meeting the milestones and targets that go beyond the FY 2000 goals.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Complete the implementation of all recommendations as decided upon by the NIH Director and the IC Directors.

Basis and Data: An Implementation Oversight Committee (IOC) and the Deputy Director of Management (DDM) are monitoring the review and implementation of the recommendations with an emphasis on the action required to deal with priority issues. The IOC and DDM will document recommendation review and implementation. Recommendations identified for implementation will have implementation plans developed that will focus on desired outcomes/outputs to be completed in specific time frames.

Validation/Verification: A tracking system has been developed to ensure implementation is continuing on pace. In addition to tracking the general progress toward the implementation of recommendations, where possible specific quantifiable data will be developed for each recommendation to provide supporting documentation that the recommendation has been implemented. This supporting documentation will validate the completion of recommendations such as, a redesigned process by a certain date,

development of an automated system to replace a manual process, or transition of a certain percentage of an activity from centralized to decentralized.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Complete NIH Director and IC Directors review and decision-making for all recommendations.**

(2) Implement recommendations related to the Chief Information Officer and the Chief Financial Officer.

FY 1999 Achievement Summary:

- Target (1) met. The NIH Director and the IC Directors reviewed the recommendations decided that 79 of the 80 recommendations were appropriate for NIH implementation.

- Target (2) met. Arthur Anderson recommended that the Chief Financial Officer position be elevated to the Deputy Director of Management level. This recommendation was accepted and implemented. Arthur Anderson recommended that the NIH hire a Chief Information Officer. This recommendation was also accepted and implemented.

Sources of FY 1999 Assessment Data: An Implementation Oversight Committee (IOC) has reviewed the recommendations and commissioned the creation of a tracking system to be overseen by the Deputy Director of Management (DDM).

Discussion of Performance: Deciding which of the 80 Arthur Andersen Inc. goals were appropriate was the obvious first step toward improving the administrative management of NIH. Once the recommendations were accepted, actual implementation could begin. The IOC and DDM have monitored the review and implementation of the recommendations with an emphasis on the action required to deal with priority issues. The IOC & DDM will document recommendation review and implementation.

The Arthur Andersen initiative is intended to enhance the efficiency and effectiveness of the NIH's business operations. One of the initiative's findings was that then current staffing patterns were hindering efficiency and effectiveness. Specifically, the organization needed a Chief Information Officer. Also, NIH's position of Chief Financial Officer was seen as too low in the organization when benchmarked against private industry and other government agencies. The two positions now make NIH a more rational and effective organization.

Next Steps: Recommendations identified for implementation by the IOC & DDM will have implementation plans developed that will focus on desired outcomes/outputs to be completed in specific time frames, none of which currently are expected to go beyond FY 2001. Priority issues have been identified and will be acted on as appropriate. An electronic tracking system is being developed to aid in tracking the NIH-wide implementation of the recommendations.

A committee has been formed for further study of the one recommendation made by Arthur Anderson that has been deferred at this time.

Other recommendations identified for implementation by the IOC will have implementation plans developed that will focus on desired outcomes/outputs to be completed in specific time frames. Priority issues have been identified and will be acted on as appropriate. An electronic tracking system is being developed to aid in tracking the NIH-wide implementation of the recommendations.

Goal b) Implement the Director's overall strategy to improve information technology (IT) management at NIH.

The optimal support of research requires information technology (IT) policies and services that are efficient and effective -- for scientific and administrative systems, as well as for internal and external business. To this end, a number of specific strategies are being pursued by the agency, including: ensuring that all NIH mission critical systems are Year 2000 (Y2K) compliant as of December 31, 1999; completing implementation of NIH's revised IT organizational structure to provide improved management of and support for the agency's IT investments; developing a strategic, corporate "IT vision" for NIH; and continuing implementation of technical recommendations set forth by the NIH Information Technology Central Committee (ITCC).

FY 2001 Target: Continue implementation of the Director's overall strategy to improve information technology (IT) at NIH by developing a strategic IT vision and a formal IT investment process.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Complete implementation of the technical recommendations.

Basis and Data: NIH's IT Board of Governors will monitor strategy implementation. This will be done by ongoing oversight of the projects to ensure they are on track and achieving the desired goals.

Validation/Verification: Documents related to the strategic goals and vision and Investment Review Reports will be forwarded to and reviewed by the NIH IT Board of Governors.

Assessment of FY 1999 Performance

FY 1999 Targets: (1) Ensure Year 2000 (Y2K) compliance for all NIH mission critical systems.

(2) Complete NIH IT organizational, investment, and vision activities.

FY 1999 Achievement Summary:

- Target (1) met. All 14 of NIH mission critical systems have been determined to be Y2K compliant.

- Target (2) met. NIH has revised its IT organizational structure under a Chief Information Officer (CIO). The NIH CIO has led the establishment of a new NIH IT investment management process and the development NIH's IT strategic vision.

Sources of FY 1999 Assessment Data:
Target (1) Y2K Compliance: NIH obtained an outside contractor to conduct an independent verification and validation (IV&V) review to verify compliance. Final reports on the IV&V reviews of the 14 NIH mission critical systems were completed and all mission critical systems were verified as Y2K compliant in July 1999. The final IV&V reports were submitted to DHHS.

Target (2) NIH IT Organization: The NIH Director approved establishment of the Center for Information Technology (CIT) in February 1998. The new organizational structure was published in the *Federal Register* on February 20, 1998. CIT's revised internal structure was published in the *Federal Register* on March 31, 1999. As part of this new IT organizational structure, the NIH Director also formed NIH's IT Board of Governors (BoG) and the NIH CIO established the NIH IT Management Committee (ITMC). During 1999, the NIH CIO presented NIH's IT vision and goals, and final investment review process the NIH BoG and NIH ITMC. Information on these activities is located on the NIH CIO activities Web page at http://cio.cit.nih.gov/

Discussion of Performance:
Target (1) Y2K Compliance: This target was an important part of the NIH's overall strategy to improve IT management by taking necessary corrective actions to ensure that NIH mission critical systems will remain operational.

The IV&V process documents all Y2K compliance test results and ensures that any problems are corrected. Under the IV&V review process, an outside contractor:

-- Performed an analysis of the documentation to validate that the remediation and tests already conducted by NIH on the mission critical systems were correct and have been completed;

-- Conducted independent tests to identify areas of risk; and

-- Reviewed system contingency plans and recommended changes.

Achievement and verification of this target was necessary for producing objective evidence of Y2K readiness for the NIH community and the public.

Target (2) NIH IT Organization: The appointment of a new NIH CIO and establishment of CIT addressed the ITCC's recommendations to the NIH Director for improving the management of NIH's IT resources. CIT was established to provide, coordinate and manage IT and advance computational science and biomedical knowledge. CIT is a result of merging the former NIH IT components - the Division of Computer Research and Technology, NIH's Office of Information

Resources Management, and the Telecommunication Branch from NIH's Office of Research Services.

To further improve the management of NIH's IT resources, the IT BoG and NIH IT ITMC were established to advise the NIH Director and CIO on critical IT areas.

-- The NIH IT BoG is composed of Office of the Director and Institute and Center senior level representatives from the NIH administrative, scientific, clinical, and extramural communities. As part of its role as an advisory group to the NIH CIO on IT issues, the IT BoG has provided oversight on the organizational changes in the management of IT at NIH and the development of the corporate NIH IT vision.

-- The NIH ITMC is composed of the senior IT officials from each IC. The committee advises the NIH CIO on IT management and planning and serves as a communication vehicle between the IC and the CIO on IT issues.

The organizational changes in the management of IT at NIH are designed to facilitate smooth transitions to new technology; a well-managed, secure infrastructure; and integrated systems that support the variety of NIH business processes. The organizational changes also meet requirements established in the Clinger-Cohen Act (formerly the Information Technology Management and Reform Act, or ITMRA). These requirements include aligning IT initiatives with missions and goals, implementing a sound and integrated IT architecture, developing IT investment planning and control processes, and measuring the contribution of IT investments to mission results.

The CIO has worked closely with the IT BoG and ITMC to develop a strategic corporate IT vision for NIH, which includes a strengthening of business area ownership of IT systems through the NIH IT Investment Review Process. The IT Investment Review Process was created to select, manage, and evaluate the results of NIH's IT investments.

Next Steps:
Target (1) Y2K Compliance: To continue to ensure the Y2K readiness of the mission critical systems, NIH has established a policy and general framework for evaluating and making changes to the mission critical systems between July 1999 and January 2000. Under this policy, all changes to the 14 NIH mission critical systems made prior to September 1999 were reassessed by an IV&V review to ensure the system is still Y2K compliant.

After October 1, 1999, NIH imposed a moratorium on implementing any changes to mission critical systems. Under the policy, requests for the system changes needed to be approved by the NIH CIO before implementation and the system was reevaluated with an IV&V review to verify continued Y2K compliance. Emergency fixes were handled according to the procedures outlined under the system's contingency plan.

Target (2) NIH IT Organization: During the next year, NIH will continue to refine its corporate IT vision. As part of this process, NIH will enhance efforts to identify current information needs that reflect the changing requirements of the NIH community. NIH will then further revise its IT

Strategic Plan to reflect these changing requirements and describe how IT supports the goals identified in the NIH GPRA plan.

Goal c) Improve compliance with the Prompt Pay Act.

By paying its bills on time, NIH improves relations with the vendor community and saves for research dollars that would otherwise cover late payment interest penalties. In FY 1998, 79% of invoices were paid on time, and in FY 1999 through April, about 92% of invoices were paid on time. Based on technology and process improvements, NIH expects to reduce interest penalties and increase discounts for timely payments in FY 1999 and FY 2000.

Because NIH is so decentralized, it is much more difficult for NIH to achieve the 100% level mandated by the Act than it is for most other federal agencies. This goal and its targets are designed to improve NIH as much as possible in this area.

FY 2001 Target: Continue to reduce interest penalties and increase discounts by paying 93% of invoices on time.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Reduce interest penalties and increase discounts by paying 93 % of invoices on time.

Basis and Data: Monitoring data on the timing of invoice payments will provide the principal basis for assessment. NIH's Office of Financial Management (OFM) routinely prepares this information.

Validation/Verification: OFM uses a reporting format that is in compliance with the Prompt Payment Act and has been reviewed and accepted by the Office of the Inspector General (OIG) as a part of the Chief Financial Officer (CFO) audit process. This information can be reported for various time periods and is routinely reconciled to ensure accuracy with accounting records.

Assessment of FY 1999 Performance

FY 1999 Target: Reduce interest payments and increase discounts by paying 93% of invoices on time.

FY 1999 Achievement Summary:

- Target was met. In FY 1999, 94% of invoices were paid on time, exceeding the target of 93%. Interest payments were also reduced. Even though the number of invoices and ontime payment, are trending favorably, the number of discounts taken has actually decreased. The number of discounts taken depends on a number of factors independent of Prompt Payment, and therefore, this measure is not used to gauge the success or failure of this target.

- The decrease in the number of on-time payments for FY 1998 was a direct result of a staff shortage and the lack of timely receiving. In FY 1999 the staffing level was increased, as was the number of on-time payments. As a result, during FY 1999, the amount of interest penalties *decreased* by $274K.

Total Invoices, On-Time Payments, and Discounts Taken			
	FY 1997	**FY 1998**	**FY 1999**
Total Invoices	400,369	386,266	417,327
On-time Payments	361,325	303,823	390,230
Percent Paid on time	90%	79%	94%
Discounts Taken	2,197	2,281	1,738

Sources of FY 1999 Assessment Data: The NIH uses an automated invoice tracking /payment system as part of the Administrative Data Base (ADB) to schedule the release of payments. The ADB is programmed to automatically schedule payments based on the later of the date a proper invoice is received in the designated billing office or the date that the goods/services were entered as received in the accounting system. The ADB is also programmed to automatically calculate and apply interest when due. The system is programmed to release payments in accordance with prompt payment guidelines. This system collects statistics on prompt payments, late payments and interest paid on a daily basis.

Discussion of Performance: OFM used various strategies to exceed the target of 93%. A few of the more concentrated efforts to increase the number of on-time payments was to enhance the Purchase Card Program; to upgrade the personal computers, database servers and other hardware used to support the bill payment processes, and to conduct educational seminars. Devoting time and attention to these efforts contributed significantly to goal achievement. For example, automating the purchase card reconciliation process proved to be less labor intensive for staff members and made them more willing to use a purchase card, a mechanism with a 100% on-time record. NIH finance staff, procurement staff, receiving officials and vendors have participated in training sessions to improve the efforts to meet this goal.

This goal and its targets are designed to improve NIH as much as possible in this area. Nevertheless, NIH is a highly decentralized operation handling in excess of 45,000 invoices a month, a volume of work that challenges the efforts to meet this goal. There is also a management concern that the cost of meeting this goal can not exceed the savings realized.

Next Steps: Work is currently underway to develop the requirements for the new NIH Business System. Many of the features of the new system will have a dramatic impact on the manner in

which invoices are paid. For example, reminders will be sent to the originator of a purchase order when an invoice has been submitted and remains unapproved for payment. Also, vendors will have greater access to the purchase orders, contracts etc, thus allowing them to bill in accordance with the agreement. This alone should decrease the number of invoices paid late. An intensive training seminar is scheduled for the procurement and administrative staff at an NIH Institute in November. The seminar will stress the importance of receiving, as well as provide an overview of the entire payment process. Finally, an increased number of staff will be dedicated to the bill payment process. This will allow staff to be more responsive to NIH's customers and become more proactive in dealing with problem vendors.

Goal d) Improve the efficiency of the small acquisition process by continuing to expand the Purchase Card Program.

Expanded use of purchase cards by both scientific and administrative staff will reduce costs associated with procurement activities, expedite the acquisition of needed goods and services, and facilitate timely payment of bills. Improvements in the reconciliation process are planned to deal with the key complaint of cardholders.

At the end of April FY1999, NIH had 1,350 card holders, 2,800 people trained to use purchase cards, and $65.5 million in purchase card orders.

The Purchase Card Program is projected to continue to expand although at a slower rate. Training classes now average 50-60 persons per session, a fall-off from the 70-80 per session at the program's initiation.

FY 2001 Target: **(1) 2,500 card holders.**

(2) 4,200 people trained to use cards.

(3) $200 million in orders.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) 2,000 card holders.**

(2) 3,600 people trained to use cards.

(3) $160 million in orders.

Basis and Data: Performance will be assessed by the Office of Administration (OA) based on Automated Database reports on purchase card transactions.

Validation/Verification: NIH's Automated Data Base (ADB) is a mainframe computer database that integrates acquisition, financial, and inventory information. For acquisition, it is an automated system that tracks orders from requisition through close-out. The bank's purchase card transactions are downloaded into the ADB daily. These transactions represent all NIH purchase card activity for the day, and when compiled, represent NIH's payment for the 30-day billing cycle. Since information is downloaded directly from the bank, there is full confidence that the number and value of transactions

is accurate. In addition, the OA keeps records on the number of card holders and individuals trained as a part of its authorization process.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) 1,600 card holders**

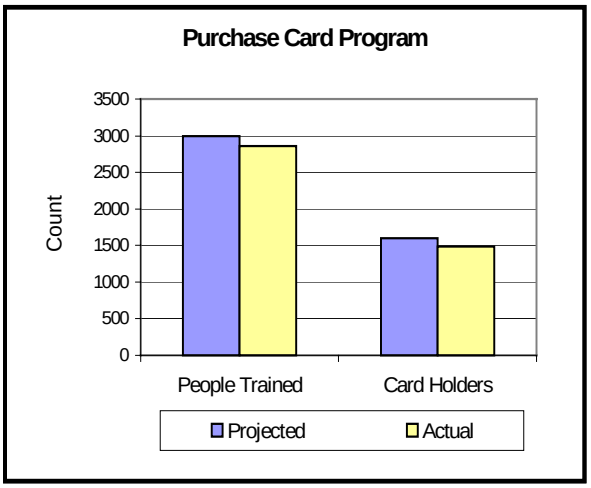
(2) 3,000 people trained to use cards

(3) $110 million in orders

***FY 1999 Achievement Summary**:*

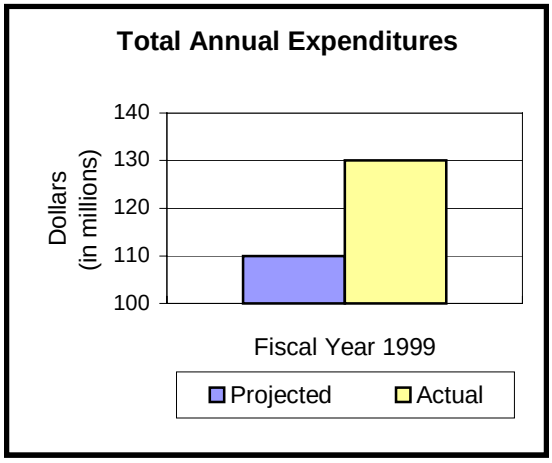
- Target (1) was not met. There were 1,485 cardholders -- short of the 1,600 target.
- Target (2) was not met. In FY 1999, 2,860 people were trained to use purchase cards – just below the 3,000 target.
- Target (3) was exceeded. The $130,000,000 volume of orders exceeded the $110,000,000 target.

Sources of FY 1999 Assessment Data: Performance was assessed by the Office of Administration (OA) based on ADB reports on purchase card transactions. The ADB is a mainframe database that integrates acquisition, financial and inventory information. For acquisition, it is an automated system that tracks orders from requisition through close-out. The Bank's purchase card transactions are downloaded into the ADB daily. These transactions represent all NIH purchase card activity for the day, and when compiled, represent NIH's payment for the 30-day billing cycle. Since information is downloaded directly from the Bank, there is full confidence that the number and value of transactions is accurate. In addition, OA keeps records on the number of card holders and individuals trained as a part of its authorization process.



Discussion of Performance: As can be seen, two of the stated targets, number of people trained to use the card and the total number of cardholders, did not reach the projected volumes that were established for FY 1999. A significant factor that influenced these under achieved goals had to do with the central and decentralized acquisition structure that exists at NIH. Each IC has, to some degree, delegated procurement responsibility within its own organization.

This function represents approximately 350 ordering officials (purchasing agents) that are located throughout the ICs. These employees provide acquisition support for laboratories, administrative offices, and divisions. Of the 350 agents, nearly 80% are trained purchase cardholders and use the card extensively. With these agents in place, many ICs elect not to authorize purchase cards for use by individual lab chiefs or administrative officers. The last target, total annual expenditures for FY 99 was surpassed by over 20 million dollars. So, although the number of cardholders has leveled off, use of the purchase card has greatly increased showing clearly that NIH is meeting its goal of expanding the use of purchase cards.



Next Steps: The Purchase Card Program at NIH has exceeded many expectations since its inception in 1995. The level of training has been enhanced to include videos, text material, electronic presentations of the ADB, and guest speakers representing the Javits, Wagner, O'Day National Industries for the Blind acquisition requirements. Permanent training classes are scheduled once each month and numerous training sessions are provided for off-campus sites such as the National Institute of Environmental Health Science in North Carolina, the National Institute on Aging in Baltimore and the Cancer Research Development Center in Frederick, MD. In addition, there are monthly brown bag meetings for general discussions on the program. The program also introduced outreach activities at central locations at NIH to introduce the purchase card and provide guidance on the formal training sessions. Though number of users has begun to level off as use of the purchase card becomes routine at NIH, the amount of use, as seen through the dollar amount of the purchases on the card, is expected to continue to rise.

Goal e) Improve customer satisfaction with the quality of products and services.

The NIH is participating in the Office of the Secretary's Acquisition Performance Measurement and Improvement Initiatives to develop common intra-agency acquisition performance goals. The system uses a common and balanced set of procurement performance measures developed by DHHS and other federal agencies and is endorsed by the Office of Management and Budget and the President's Management Council.

The Acquisition Balanced Scorecard is a means of assessing customer satisfaction with the acquisition functions provided to 18 Institutes and Centers. The use of the ABS as a model to link performance of critical business processes with organizational goals is widely accepted in government and industry.

FY 2001 Target: A 90% overall average rating of approval for procurement offices as measured by the ABS.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: An 85% overall average rating of approval for procurement offices as measured by the ABS.

Basis and Data: The Office of Administration (OA) will use the Acquisition Balanced Scorecard (ABS) to measure performance toward this goal. An ABS survey provides NIH's Office of Contracts Management (OCM) with an overall rating on such factors as quality, timeliness, knowledge, and the overall value of products and services provided. This feedback is useful in identifying key areas for improvement and for planning initiatives to achieve desired customer service goals. When this instrument was used in FY 1998 to survey the customers of three ICs, the average score was 4.1 out of 5.0. Since the original instrument was developed for use within DHHS, the rating scale has been changed from a 5 point scale to a percentage of positive responses. When the ratings for those offices surveyed in FY 1998 were converted to the new system, 93 percent rated the procurement offices as doing an overall good job. At the end of FY 1999, 6 offices had been surveyed and the results indicated that NIH has an overall average rating of 89 percent. By the end of FY 2000, NIH will have rated at least 9 of the largest awarding offices.

Validation/Verification: OCM has a contract with the Logistics Management Institute (LMI) to assist in the implementation of the ABS survey. Using the Internet, LMI

surveys the individual contracting offices. Reports are provided to each office. OCM reports on the NIH as a whole.

Goal f) Expand the use of Performance Based Contracting.

Performance Based Contracting (PBC) allows vendors to be innovative in responding to NIH requirements for specific products and services. In addition, it provides useful indicators of overall contractor performance. As new contract requirements or contract renewals arise, they will be reviewed to determine if use of PBC is appropriate. (Note: This is a new goal in FY 2000.)

FY 2001 Target: Allocate $21.2 million of the available NIH contracting dollars to PBC-eligible contracts.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Allocate $19.8 million of the available NIH contracting dollars to PBC-eligible contracts.

Basis and Data: The Office of Administration (OA) will use the Automated Data Base (ADB) reports and the Information for Management, Planning, Analysis, and Coordination (IMPAC) system to identify contract dollars awarded. The target amounts are based on monies planned for obligation under active performance-based contracts and estimates of amounts expected to be obligated under the newly awarded performance-based contracts.

Validation/Verification: Both the ADB and the IMPAC data bases are used by NIH management for basic management reporting and tracking purposes. Each of the data bases have numerous edits to ensure that the data entered are correct, and the IC OAs are required to reconcile information generated by their systems with their own records to ensure the accuracy of the data on a routine basis.

Goal g) Ensure the soundness of the NIH property management system.

The management of personal property is a major component of the overall management and administrative duties of any organization. This function is easily visible and understandable to the public. Correspondingly, successes and failures are often viewed as an easily available indicator of the administrative health of an organization. At NIH, the critical element in this process is the system of records of accountable property that are maintained by the ICs within the Property Management Information System (PMIS). The accuracy of these records is confirmed by the conduct of physical inventories. The goal of the physical inventory is to assess whether NIH assets are in the recorded locations and to confirm that all accountable property is appropriately recorded in the management system. All of these measures are ultimately designed to assure that property assets are available for use in support of the various NIH missions and that they are used in an efficient and effective manner.

FY 2001 Target: Complete the FY 2001 milestones in the personal property management improvement plan and achieve a loss rate of less than 6% of the property in the inventory.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Complete the FY 2000 milestones in the personal property improvement plan and achieve a loss rate of no more than 8% of the total property in the inventory.

Basis and Data: The Office of Administration (OA) will measure progress on the implementation of the personal property management improvement plan. Loss rates will be determined from data in the Property Management Information System (PMIS) and from other information such as property loss reports and other discrepancies found in the system that is assembled by the Property Management Division (PMD) inventory support contractor.

Validation/Verification: The Property Management Improvement Plan includes specific goals and objectives that involve specific outcomes/outputs to ensure the tracking and successful implementation of goals. The PMIS database includes several edits and reconciliations to ensure that the data are as correct and accurate as possible. A personal property physical inventory has been completed in each of the past two years to determine if property is being properly recorded and managed. This inventory is used to update the information in the database to ensure accuracy and the proper management of NIH property.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Complete the activities listed above to resolve the property inventory discrepancies, including the completion of the property inventory, resolution of inventory discrepancies and reviews by the Board of Survey to determine the reason for discrepancy and proper disposition of the property.**

(2) Complete the NIH Director and IC Directors review and decision-making and the time-lines for implementing the system improvement processes.

FY 1999 Achievement Summary:

- Target (1) was partially met. NIH completed 100% of the 1999 physical inventory and produced management reports on discrepancies. NIH resolved all capital property inventory discrepancies and resolved a significant part of the non-capital property inventory discrepancies related to the 1998 property inventory. Boards of Survey continue to operate and are expected to remain so.

- Target (2) was met. During the 1998 and 1999 calendar years, Office of Administration (OA) representatives met with IC management personnel, individually and collectively, to announce and to discuss changes to management practices and procedures. The proposed changes included, but were not limited to the delegation of certain property management functions; the conduct of physical inventories; and the institution of Property Survey Boards. The entire process is part of an overall, long term Personal Property Management Improvement Plan, which NIH intends to implement over the next few years. These improvements received general approval, including "buy-in" by the ICs.

Sources of FY 1999 Assessment Data:
Target (1) PMIS data were used to determine the progress achieved in improving the management of NIH property. OA provides ongoing tracking and management of the various improvements needed in the NIH property management process. Weekly reports are provided to IC management on their progress towards inventory reconciliation. Discrepancy reports are provided to each of the IC Property Management Representatives weekly.

Target (2) The target was accomplished through meetings and discussions. There are no measurable data elements for this target.

Discussion of Performance: Preliminary figures show significant reductions in loss rates at the end of the 1999 inventory when compared to the 1998 inventory. Reduced loss rates reflect improvements in practices and policies. This is significant, particularly when related to capital losses. This level of reduced loss rates for capital items meets the DHHS GPRA goals for the period as well.

The improvements to property management practices and procedures during FY 1998 and FY 1999 resulted in a downgrade of a prior material weakness related to property management accounting practices in the annual Chief Financial Officer (CFO) audit of NIH's financial statement, to a reportable condition. We expect that continued progress in this area will ultimately result in the removal of all conditions.

Next Steps: Physical inventory and related property management activities will continue for the foreseeable future. Many of these activities are required by regulation. Others are used as a measure of the state of management controls. Processes, such as the Property Survey activity are being integrated into the normal administrative environment

The processes presented to NIH management are being institutionalized as administrative practices at NIH. Further improvements are expected in systems and processes as business systems are updated over the next several years and more authority and responsibility are provided to the ICs.

Goal h) **Ensure that NIH equipment loan agreements are properly executed, that equipment is not shipped until agreements are signed, and that NIH equipment is properly accounted.**

To deal with delinquent property loans recorded in the Property Management Information System (PMIS), property regulations have been revised to require that loaned equipment be inventoried at the time it is shipped and that the receiving organization provide documented reconciliation with property records. (Note: Targets beyond FY 1999 are not currently planned, as this goal is expected to be completed in FY 1999.)

Assessment of FY 1999 Performance

FY 1999 Target: **Complete the revision and implementation of the relevant property regulations.**

FY 1999 Achievement Summary:

- The target was met.
- The relevant property regulations have been revised. They are now being put in final form and submitted for publication. The regulation has already been communicated verbally to all of the ICs through the Personal Property Management Committee and the process is already in place and being executed.

Sources of FY 1999 Assessment Data: The target was to revise the regulations and put them into effect. While we are still in the publication process, the regulations themselves have been in effect and are currently being used to process loans through the Property Management Division.

Discussion of Performance: ICs are moving to keep their loan documentation current and to properly document any property being placed on loan. As stated earlier, property on expired loan which has not been returned is considered missing for inventory purposes and must be resolved prior to reconciliation of that office's accounts. The Office of Administration (OA) has completed the revision and has implemented these regulations. Additional management controls have been established to assure that property loans are properly executed and kept current. For example, physical inventories of property include any property from loans that have expired. This requires that the loans either be kept up to date, that the property is disposed of, or that the property be returned to avoid an inventory discrepancy.

Next Steps: This activity is being institutionalized through the implementation of this regulatory change. Publication of the new regulations is anticipated in the near future.

Goal i) Simplify data entry and update into property systems.

Many ICs have expressed a desire for a simplified and up-to-date property tracking system. The current Property Management Information System (PMIS) is scheduled to be replaced as part of the new enterprise business system. Until that time, it is felt that a reasonably small expenditure for an off-the-shelf front end for the PMIS will result in significant increases in accuracy and will help to reduce the work effort required to maintain property records. (Note: This is a new goal in FY 2000.)

FY 2001 Target: Complete the pilot project for the commercial software applications and report results to the ICs.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Implement the pilot project(s) in one or more of the ICs.

Basis and Data: Documented milestone achievement pertaining to the installation, operation, testing, and appropriate reporting to the ICs of one or more commercial, off-the-shelf, property systems in the NIH environment.

Validation/Verification: The Office of Administration (OA) will provide ongoing monitoring/tracking of the implementation of the objectives to simplify data entry into the property system by ICs. Further, specific criteria will be developed to make appropriate decisions for potentially fully implementing a new data entry process. The criteria could include the time required to enter a record, the time to update/reconcile and monitor property, and the accuracy of data.

Goal j) Ensure that proper procedures are followed with regard to equipment provided to contractors in the intramural research program.

NIH Property Administrators will review contractor's property management systems on a rotating basis to ensure that equipment is properly used, recorded, maintained, and disposed of when no longer needed. In addition, agreements have been put in place to include NIH property in the samples inventoried by other agencies using NIH resources. (Note: Targets beyond FY 1999 are not currently planned as this goal is expected to be completed in FY 1999.)

Assessment of FY 1999 Performance

FY 1999 Target: Complete implementation of the review system.

Achievement Summary:

- The target was met. The review system has been implemented.
- Major accomplishments associated with this during the fiscal year are:

  -- An agreement was established with the Office of Naval Research incorporating NIH property into any reviews conducted by their organization as contractors. It is expected that this will result in a periodic review of many of the larger NIH contracts with universities (a large portion of our contracts). Additional agreements are being negotiated with the Defense Contract Management Command for inclusion of NIH property in their assessments of shared contractors.

  --A letter was issued to all NIH contractors requesting their end of fiscal year property inventory balances to determine the contractors with the largest quantities and values of property, indicating those with the greatest risk. Reports are being received.

Sources of FY 1999 Assessment Data: The contractor's end of year fiscal inventory balances are being received and kept in the NIH Office of Financial Management (OFM). Copies of the Office of Naval Research property reviews, which include NIH property at universities and non-profit institutions in the sample, are kept in NIH's Office of Administration, Office of Logistics Management.

Discussion of Performance: The new review system and the end of year fiscal reports should help ensure that proper procedures are followed with regard to equipment provided to contractors in the Intramural Research program. In addition to the achievements discussed above, NIH

received, courtesy of the National Aeronautics and Space Administration, Goddard Space Flight Center, an automated tracking system for annual contractor reports as well as the scheduling of property system analysis. This program was provided at no cost to NIH and will prove significant in the management of this activity, by allowing NIH to more efficiently track contractor reports and schedule property reviews. Since the system is both free and more efficient than those in place currently, NIH will be able to continue to lower its costs while the review system is implemented.

Next Steps: This activity will continue to be conducted for all contracts when government property has been furnished and/or all contracts where contractors are able to purchase property on the account of the government. Each year a portion of the contract base will be reviewed.

Reviews will continue to be performed of contractors' processes and systems for managing property. Contractors will also be asked to develop various reports to determine if they are adequately managing their accountable property. Based on the information acquired, contractors will be asked to make appropriate improvements to their property management process/system that will be tracked/monitored by the Office of Administration.

Goal k) **Identify and pilot new approaches to providing human resource services which increase manager satisfaction with personnel system flexibility and ease of use.**

Following delegation of significant personnel authorities from the DHHS to NIH, the agency has initiated a comprehensive evaluation -- in conjunction with the National Academy of Public Administration (NAPA) -- of the implementation of these authorities. Additional efforts are underway to identify and pilot new approaches to providing human resource services.

FY 2001 Target: **Complete the development and begin pilot implementation of decision support systems for recruitment, selection, and employee performance: CareerHere and the Career Recruitment Information Management System (CRIMS).**

Basis and Data: There are three phases to the implementation of these systems: 1. deployment of CareerHere as an NIH-wide interactive vacancy announcement system; 2. piloting and subsequent NIH-wide deployment of the CRIMS merit promotion and recruitment system; and 3. linkage of the CareerHere and CRIMS systems to integrate vacancy announcement, recruitment, classification and performance management into a seamless process.

Validation/Verification: Phase 1 (deployment of CareerHere as a vacancy announcement system) is now completed. Each of the subsequent phases has a rollout schedule that includes piloting and evaluation. At the end of each stage of the pilots, end users will be asked to provide their assessment of the systems to make appropriate corrections. Six months after the completion of the final phase, technical review of the software will be completed. In addition, managers and HR professionals will be asked to evaluate the utility of the software in streamlining the recruitment process.

FY 2000 Target: **A 10% increase in manager satisfaction with personnel system flexibility and ease of use as reflected in the 1999 survey outcome against the 1997 baseline.**

Basis and Data: NIH's Office of Human Resource Management (OHRM) will analyze the results of the NAPA surveys of NIH managers. In 1997, NAPA surveyed NIH managers to assess the utility and flexibility of the agency's personnel systems. The basic findings of this survey were that less than 20% of managers reported the personnel system was customer focused; less than 20% found the system flexible and easy to use; and only about 30% found the system contributed to organizational goals and objectives. Follow-up surveys are planned for 1999 and 2001.

Validation/Verification: Specific questions will be included in the future NAPA surveys for determining managers' satisfaction with the new system. In addition, specific criteria and information will be developed for assessing if the new system is in fact providing better results, is easy to use, and if it contributes to the organization's goals and objectives.

Assessment of FY 1999 Performance

FY 1999 Target: Complete the delegations of authority and related training.

FY 1999 Achievement Summary:

- The target was met. Delegations have been completed and related training given to managers who will exercise these authorities.

- Major accomplishments during the fiscal year associated with this are:

  -- The NIH has redelegated a number of Title 5 authorities to the ICs as of the end of FY 1999.

  -- NIH's Office of Human Resources Management (OHRM) conducted briefings for senior managers to inform them of the scope and content of the delegations and of their responsibilities to ensure that they are exercised in a proper manner. More intensive briefings and training were available for managers and administrative staff who will be working with the new authorities on an operating basis.

  -- OHRM has designed a series of training modules that were available for use by ICs to train managers who will exercise these delegated authorities. Further, several ICs have developed and implemented their own training procedures.

Sources of FY 1999 Assessment Data: OHRM continues to track to what extent the ICs are further redelegating these authorities down to the lowest level possible. All the delegations are posted to the OHRM Homepage and all scheduled training pertaining to the use of the delegations has been completed.

Discussion of Performance: The goal of completing the delegation of the authorities to the ICs and providing training to management and administrative staff who will be exercising these authorities in the future has been completed. In addition, spot post-audits and management control reviews have revealed little or no problem with compliance with applicable regulations now that these authorities are being exercised at lower levels within NIH and the ICs. Although not a stated goal, it is expected that further redelegation of these authorities down to the lowest level possible within each IC will greatly enhance managerial satisfaction with the personnel system, as unnecessary levels of review and approval are eliminated resulting in increased

efficiency and less delay in taking actions related to these authorities. Accordingly, OHRM will continue to lobby the ICs to further redelegate these authorities within their IC.

Next Steps: With redelegations to the ICs and training completed, NIH will conduct a FY 2000 review to determine the degree of managerial satisfaction with the personnel system.

Goal l) Reduce key time and attendance error rate indices by implementing the Integrated Time and Attendance System (ITAS).

NIH's Integrated Time and Attendance System (ITAS) project is designed to minimize staff burden and maximize the accuracy associated with recording employee work hours and leave data. This will assure accurate accounting of NIH funds for salaries and benefits.

FY 2001 Target: Reduce the FY 2000 levels of the error rate indices by 20%.

Basis and Data: NIH's Office of Human Resource Management (OHRM) will measure and document the improvements achieved in each of several principal error rate indices.

Validation/Verification: OHRM will compare the new data with the benchmarks established in 1998 to determine if the targets are being met. Adjustments to the system/process will be made as needed to ensure the new process is working properly.

FY 2000 Target: Reduce the benchmark levels of the error rate indices by 20%.

Basis and Data: OHRM will measure and document the improvements achieved for each of several principal error rate indices. When benchmarked in calendar year 1998, the levels of these key indices were: 1,700 payroll error corrections processed; 1,500 missing time and attendance reports; 20,000 time and attendance problem reports; and 1,100 timekeeper initiated corrections as reported by NIH's Automated Data Base (ADB).

Validation/Verification: After full implementation, OHRM will compare the new data with the benchmarks established in 1998 to determine if the targets are being met. Adjustments to the system/process will be made as needed to ensure the new process is working properly.

Assessment of FY 1999 Performance

FY 1999 Target: Complete implementation of the ITAS system.

Achievement Summary:

- The FY 1999 target was met.

- By the end of FY 1999, NIH's Office of the Director (OD) and all 25 ICs had implemented and were running the ITAS timekeeping system. All of these ICs now use ITAS as their sole production timekeeping system. The NIH legacy time-keeping system (TAIMS) is no longer supported.

Sources of FY 1999 Assessment Data: The ITAS system is a component of the overall NIH payroll system. An audit of the payroll system will verify completion of ITAS implementation at NIH.

Discussion of Performance: The new system greatly reduces and may possibly eliminate the traditional timekeeper role. By supporting electronic leave request and approval and by implementing exception-based timekeeping, ITAS completely automates the most labor intensive traditional timekeeping tasks. Both paperwork and the number of data entry and payroll errors have been reduced. By design, ITAS relieves users from the need to understand complex timekeeping rules and procedures. Timekeeping rules are embedded in the system's programming logic. The ITAS system can also be configured to support a variety of approaches to timekeeping instead of forcing users to conform to one model.

Next steps: During FY 2000, NIH will measure key payroll error rate indices under ITAS and compare them to those prevailing under the previous system (TAIMS) to determine the degree of improvement brought about by the new system.

Although the client-server technologies involved in ITAS are advanced, they no longer represent the leading edge. An effort to migrate ITAS to Web-based technologies is underway. In the first phase of this effort, a Web interface for the employee time and attendance functions was developed and deployed. Currently, this interface is being extended to include leave approving official functions. Ultimately, all ITAS functions will migrate to the Web environment. Several other federal agencies (such as the Social Security Administration and the Federal Emergency Management Administration) are considering adoption of ITAS to replace their time and attendance reporting systems.

Goal m) Perform a review to ensure that Intergovernmental Personnel Act (IPA) Agreements are properly executed before assignments begin.

An initial review of IPA agreements in 1998 indicated that some had been improperly established during the previous year. To ensure proper execution, a sample of Agreements will be reviewed in FY 1999 to assess compliance with existing policies. (Note: Targets beyond FY 1999 are not currently planned, as this goal is expected to be completed in FY 1999.)

Assessment of FY 1999 Performance

FY 1999 Targets: Complete review of sample.

FY 1999 Achievement Summary:

- The FY 1999 target was exceeded.
- During FY 1999, NIH's Office of Human Resources Management (OHRM) conducted post-audits of all IPA cases and found that the ICs continue to comply with the regulatory requirements and policies.
- As a result of the Management Control Review conducted in FY 1998, OHRM has maintained close oversight of Intergovernmental Personnel Act (IPA) Agreements throughout NIH. IPA cases reviewed during FY1999 have been in compliance with the regulatory requirements set forth by 5 CFR Part 334, as well as with DHHS, OPM, and NIH policies and procedures.

Sources of FY 1999 Assessment Data: Upon the completion of OHRM's initial review of IPAs in 1998, ICs were required to review all IPA Agreements not included in the sample and to certify to OHRM that all cases were correct. Subsequently, all personnel office staff verified that they had in fact reviewed all IPA Agreements and made corrections where appropriate and established procedures to prevent recurrence of these problems. ICs also indicated the intent to train staff on IPA policies and procedures.

Discussion of Performance: The review conducted in 1998 served as an effective tool in identifying the problems ICs were experiencing with the execution of IPA Agreements and bringing those problems to resolution. The review of the follow-up sample was completed in 1999, and the ICs were found to be in compliance with IPA regulations and policies.

Next Steps: The OHRM will continue to conduct post-audits and IPA reviews in an effort to promote ethically and technically sound IPA Agreements.

Goal n) Ensure that overpayments do not occur in NIH fellowship programs and that bankruptcy statutes are complied with in collecting past over-payments.

Because fellowships involve advanced payments, over-payments sometimes occur in situations involving early terminations or transfers of fellows. To deal with these potential problems, the following measures have been taken: development of a system to certify that a fellow is present and in training, delivery of payments in arrears, timely IC notification to the Office of Financial Management (OFM) about early departures.

FY 2001 Target: Achieve a 50% reduction in the number of overpayments

Basis and Data: Once implemented, the Fellowship Payment System (FPS) will reduce over-payments by certifying a fellow is present and in training. This system pays fellows in arrears, as opposed to the current system which pays in advance, making overpayments less likely. Procedures implemented in FY 1999 will provide more timely notification from ICs to OFM about early departures, which should also help to reduce the number of over-payments.

Validation/Verification: Information from NIH's Automated Data Base (ADB) will be used to determine if the number of over-payments have been reduced.

FY 2000 Target: Complete implementation of the Fellowship Payment System.

Basis and Data: An FPS Working Group has been established to provide oversight of the development and implementation of the FPS. An action plan has been developed that provides all the milestones needed to implement this system. This plan is reviewed on a monthly basis by the Working Group to ensure that the system is implemented on a timely basis. The Working Group measures progress by tracking the pilot test and eventual implementation of the new system. In addition, the ADB will be used to determine if the amount of over-payments has been reduced

Validation/Verification: The first phase of this goal will be achieved when all ICs are using the new system. The final verification will occur about six months later when the new system will be tested to see if there has been a substantial reduction/elimination of over-payments.

Assessment of FY 1999 Performance

FY 1999 Targets: Complete implementation of corrective measures and begin implementation of the Fellowship Payment System.

FY 1999 Achievement Summary:

- The FY 1999 target was met. Implementation of corrective measures is complete. Implementation of the Fellowship Payment System (FPS) is progressing as expected.

- Major accomplishments during the fiscal year associated with this are:

  -- New procedures have been implemented to provide the Office of Financial Management (OFM) with more timely notification of fellows' departures.

  -- An FPS Working Group has been established to provide oversight of the development and implementation of the FPS.

  -- Pilot testing of the FPS has begun at five ICs.

Sources of FY 1999 Assessment Data: The FPS Working Group is meeting monthly to discuss the implementation of the FPS. Because many of the same principals are involved, assessment of the new procedures is also taking place during this group's working sessions. The Working Group measures progress by tracking the pilot test and eventual implementation of the new system.

Discussion of Performance: The corrective measures include a new policy by which the Office of Financial Management (OFM) checks with the Office of General Counsel before all bankruptcy cases. Also, there is more timely notification of OFM by the ICs when a fellow leaves NIH. The new procedures are a simple first step toward the goal of reducing overpayments.

Next Steps: When the next phase is implemented by January 2000 close to 80% of NIH fellows will be in the FPS. By the end of FY 2000 all NIH Fellows will be in the FPS. An action plan has been developed that provides all the milestones needed to implement this system. This plan is reviewed on a monthly basis by the FPS Working Group to ensure that the system is implemented in a timely manner.

2.2 Research Training and Career Development Program

2.2.1 Program Description, Context, and Summary of Performance

Program Description and Context. The Research Training and Career Development Program addresses the NIH's major, long-term goal to "promote the development of a suitable talent base of well qualified, highly trained, and diverse investigators capable of yielding the scientific discoveries of the future."

To achieve this long-term outcome, NIH provides training support through National Research Service Award (NRSA) and Career Development Award programs and undertakes outreach activities to encourage interest in scientific careers. These programs are designed to increase our ability to attract and retain the best and brightest minds in biomedical research and to develop a group of well-trained, highly skilled scientists who are ready to meet the nation's needs for health-related research, first as post-doctoral researchers and finally as productive principal investigators. NIH's training and career development programs are also designed to enhance the diversity of the biomedical research labor force.

NIH research training and career development support is tailored to the needs of different career levels. For example, students who are beginning graduate training need to learn the conceptual and theoretical aspects of the science they hope to eventually practice. For individuals at this level, the NIH supports broad, multidisciplinary training grants. This kind of support allows universities to assemble a sufficient number of students to justify the development of an educational curriculum in biomedical, behavioral, or clinical research. Students learn the fundamentals in a structured but competitive atmosphere that accelerates knowledge acquisition. The didactic experiences are normally supplemented with laboratory rotations that help define the frontiers of modern science and the methods used to address current research problems. Lab rotations also teach students that there are often a number of different experimental approaches to a specific problem. NIH research training grants have been such successful vehicles for graduate training that the widely cited report *Reshaping Graduate Education* published in 1995 by the National Academy of Sciences recommended that all federal agencies should emulate this approach.

Once students are ready to select a dissertation project, the content of training needs to change. In this phase, students operate primarily as apprentices, working on some aspect of a faculty member's ongoing research effort. Most biomedical graduate students receive support during this phase of their training as a trainee or as a research assistant to their mentor's funded project. In addition, NIH funds a small number of individual predoctoral fellowships. All of these forms of support have been adapted to emphasize the experience of working on a defined research problem under the close supervision of a faculty mentor.

At the postdoctoral level, the NIH supports an extension and expansion of the apprenticeship approach through individual fellowships and research assistantships. NIH also offers additional training grant opportunities to individuals who are new to research or who want to focus their training on a specific disease area.

To capture individuals with clinical experience and those who have experience in a non-biomedical field such as computer science or physics, the NIH offers career awards. Most of the career awards are individual awards like fellowships, but often include provisions for an initial didactic phase to provide for formal acquisition of the concepts and theoretical understanding the candidate will need as an independent researcher. During the course of these awards, the candidate spends an increasing amount of time in an apprentice mode working on a specific project. By the end of the three to five year period of support, the candidate should be ready to apply for his/her own research grant. Recognizing that applicants for career awards are generally physicians who have completed their clinical specialty or sub-specialty training by the time they apply for these awards, career awards offer higher levels of income and benefits than training grants and fellowships.

It should not be concluded that all training grants, fellowships, and career awards are rigidly used in the manner described above. There are many and flexible approaches geared to the career needs of a particular population. For example, many young medical students and residents receive a period of full-time research training supported by an institutional training grant. Several clinical boards have been encouraged to recognize the importance of a research experience and to permit a period of research training to count toward clinical certification. NIH believes that these opportunities teach young clinicians the value of research and also serve as a tool to recruit physicians into full-time research careers. NIH has also started to offer a limited number of special transitional career awards to postdoctoral researchers that activate when the individual negotiates a suitable faculty level research position.

NIH's Institutes and Centers (ICs) also use the various award mechanisms to recruit individuals from racial and ethnic groups that are currently underrepresented in science. The Minority Access to Research Careers and the Career Opportunities in Research Programs are research training grants administered by the National Institute for General Medical Science (NIGMS) and the National Institute for Mental Health (NIMH), respectively. These grants fund research training experiences for honors undergraduates at universities with a substantial minority enrollment, and they serve as an important method of attracting underrepresented students into careers in health-related research. It should also be pointed out that all NIH research training grants include a minority recruitment requirement. To comply with this requirement, all funded research training grants must have a plan for recruiting individuals from underrepresented groups. In many cases, graduate and postdoctoral training programs with NIH support will form collaborations with minority serving schools to directly recruit students and postdoctorates. Pressure to develop a diverse labor force is therefore exerted at all points along the continuum from college to independence, with the aim of eventually achieving full integration of all underrepresented groups into the research labor force.

The participation rates of women in biomedical and behavioral research differ from that of underrepresented racial and ethnic groups. At both the graduate and postdoctoral levels, women participate at higher rates than their male counterparts in the behavioral sciences and are close to parity with men in biomedical sciences. Women remain underrepresented, however, at the faculty level and, consequently, are underrepresented in the pool of NIH principal investigators. NIH has engaged in a number of different programs to remediate this problem. These include

offering career development awards and supplements to research grants to support the re-entry of individuals who have dropped out of research to care for children and other relatives. The NIH has also issued a Notice of Proposed Rulemaking to permit part-time training opportunities for individuals who have pressing family responsibilities. All of these approaches are designed to help women remain in science or to return to their scientific careers after a family-related hiatus.

GPRA Research Training and Career Development Program			
Budget (000's)	**FY 1999 Actual**	**FY 2000 Estimate**	**FY 2001 Estimate**
	$ 811,120	$ 913,352	$ 954,153
Major Functional Areas	**Training Support** -- Enhance training programs at the predoctoral, postdoctoral, and early career developmental level to ensure a continuing supply of capable individuals in areas of National need.		
	Outreach – Encourage participants to pursue research careers and foster the recruitment and retention of under represented groups into careers as researchers.		

Summary of Performance. NIH established 5 performance goals with 12 corresponding performance targets for the Research Training and Career Development Program for FY 1999. A snapshot of these targets shows the following:

- 75 percent (9 of 12) of all targets were partially met, met or exceeded.
  - 8 percent (1 of 12) targets were exceeded.
  - 50 percent (6 of 12) of all targets were met.
  - 17 percent (2 of 12) targets were partially met (targets with multiple performance elements where some elements were met).

In the pages that follow, specific details are provided for each FY 1999 goal and target of the Research Training and Career Development program.

2.2.2 Goal-by-Goal Presentation of Performance Goals and Results

2.2.2.1 Training Support

The overall goal of NIH training and career development programs is maintaining a highly trained population of scientists that can address the nation's future health-related research needs. To accomplish this important task, the NIH uses a number of different award mechanisms to provide a flexible and varied series of high-quality training opportunities tailored to the career needs of the recipients. Considerable attention is provided to ensure that experiences supported are focused on the acquisition of knowledge and skills necessary to become a productive researcher. Some of these opportunities are listed below:

Institutional National Research Service (NRSA) Research Training Grants (T32) are most often used to encourage institutions to assemble a group of graduate students at a similar point in their education. The assembly of students and stable support provided by the training grant encourages universities to develop a broad and multidisciplinary training programs tailored to the needs of the trainees. Training grants also can be used to support students and postdoctorates learning the theories and practical aspects of research related to a particular disease or organ system. Other training grants are used to support students in programs leading to a dual research degree such as the MD/PhD. A special type of research training grant (T34) is used to support honors undergraduates at minority serving institutions under the Minority Access to Research Careers (MARC) and the Career Opportunities in Research (COR) programs.

Individual NRSA Predoctoral Fellowships (F31) are used to support supervised training at the graduate level. A variant of the predoctoral fellowship provides support for the didactic as well as project focused training experiences for disabled and minority graduate students.

Individual NRSA Postdoctoral Fellowships (F32) are used to support postdoctoral training for doctoral level scientists who need additional research experience in order to successfully compete for independent research funding. Fellows contribute to a defined research project under the supervision of a sponsor or mentor.

Mentored Research Scientist Development Awards (K01) support mentored career development experiences for fully-trained researchers who may have dropped out of research because of family responsibilities or are switching to a new field of research.

Mentored Clinical Scientist Development Awards (K08) are used to provide full-time salary support for individuals who have finished or nearly finished their clinical training and wish to pursue a career in research. Many K08 awardees are physicians who have had very little research experience. The first phase of this award usually consists of a period of largely didactic experience that is followed by closely supervised project-focused learning experience. It is expected that most recipients of K08 awards will be ready to apply for independent research support by the end of the five year award period.

Career Transition Awards (K22) support the transition of a postdoctoral researcher to an independent research position. Usually, the postdoctoral researcher applies without institutional affiliation. The award often provides an extension of the current supervised position followed by a provisional award that is activated when a suitable independent research position is negotiated. Some of the K22 awards exclude the period of postdoctoral experience and only support a period of independent research. Transitional awards are still being offered as a pilot program and NIH Institutes still use these awards in different ways. More information is available on the NIH Website at http://grants.nih.gov/training/careerdevelopmentawards.htm.

Mentored Patient-Oriented Research Career Development Awards (K23) are similar to the K08 awards but focus on research that involves human patients. This award is an important part of the Director's Initiative on Clinical Research that is described later in this section.

Midcareer Investigator Award in Patient-Oriented Research Awards (K24) support up to half-time experiences for established investigators who want to develop their capacity to conduct high quality patient-oriented research as well as train more junior investigators such as those supported by a K23 award.

Clinical Research Curriculum Development Awards (K30) stimulates training in patient-oriented research by offering support to institutions for the construction of a curriculum designed to provide the theoretical and conceptual understanding necessary for high-quality clinical research.

The NIH uses these awards and several others to carry out the goal of maintaining a highly skilled research labor force. Planning the approximate number of awards to be made in each category described above is a complex process that considers program continuity and emerging needs.

Continuity is important because training often takes more than 10 years from the beginning of graduate school until the end of postdoctoral training. To retain the best students and to ensure that their training is of the highest quality, the NIH tries to maintain a consistent level of support for the overall program. Because students and postdoctoral researchers frequently draw on a number of different support options over the course of their training, it is important to make these options as predictable and stable as possible.

The NIH also responds to evidence of emerging needs. For example, a NIH Director's Panel on Clinical Research recommended establishing the *Mentored Patient-Oriented Research Career Development Awards* (K23), *Midcareer Investigator Award in Patient-Oriented Research Awards* (K24), and *Clinical Research Curriculum Development Awards* (K30) awards in FY 1998 to address the identified shortages of patient-oriented researchers. The NIH expects to make at least 80 K23 and K24 awards to new and mid-career clinical researchers in each of the next several years. The NIH has also committed to improving the curriculum available to aspiring clinical researchers by funding at least 20 *Clinical Research Curriculum Development*

Awards (K30) in FY 1999. Similarly, NIGMS has launched a training program in bioinformatics and computational biology in response to emerging needs.

NIH also engages the National Academy of Science (NAS) in the process of planning for future human resource needs. Every four years, as required by the Public Health Act, Section 489, the NIH asks the NAS to analyze trends and make recommendations about the size, quality, and the nature of NIH's training programs. NIH views these studies as very important for identifying special and continuing needs for biomedical and behavioral scientists. The NAS report makes specific recommendations about the number of training positions to be supported in broad disciplinary areas and provides NIH with numerical targets for training programs in future years. The eleventh edition of this series of reports is currently being completed and should be delivered early in calendar year 2000. NIH will review the report when it becomes available and develop a plan to implement recommendations likely to be of benefit to the agency's training and career development programs.

Notably, one of the considerations identified in the National Academy's 1993 version of this report *(Meeting the Nation's Needs for Biomedical and Behavioral Scientists*) concerned tracking and evaluation of the careers of training award recipients. In response to this recommendation, NIH launched a comprehensive evaluation of the predoctoral and postdoctoral training programs and is in the process of developing a Web-based tracking system to facilitate future career outcome studies. This information system will operate under the NIH Commons (see Grants Administration and Peer Review Goal e) for a discussion). The specific features for training programs are still in the development stage, but will be referred to collectively as *X-Train*. This system will make it easier for training program directors to appoint trainees to training grants, and trainees will find it easier to provide career information to NIH.

Career outcome evaluation studies such as that now being conducted by the NIH coupled with the more comprehensive external reviews of the type conducted by the NAS help ensure that the NIH research training and career development programs are of uniformly high quality and are sufficient to meet the nation's needs for biomedical and behavioral researchers.

Overall, maintaining the effectiveness of the training program as well as its impact on the recruitment of bright, young scientists into biomedical research entails a continuing effort. The areas below are of current attention in this regard, and form the basis for the performance goals discussed in the pages included in this section:

- Ensure that training and career support options continue to be attractive recruitment vehicles for young graduate students and postdoctorates.

- Continue to evaluate the size and focus of the NIH training programs by conducting periodic, formal assessments of future needs for biomedical and behavioral researchers.

- Ensure that human resource needs in the area of clinical research are being addressed as recommended by the Director's Initiative on Clinical Research.

- Strengthen the capacity to electronically collect appointment and award information on fellows and trainees as a means of developing improved methods for long-term career tracking.

- Conduct studies on the effectiveness of the NIH training programs.

Performance Goals Summary Table – Training Support

Performance Goals	FY Targets	Actual Performance	Details
a) Maintain adequate application and award rates in key training support areas.	***FY 2001 Target*** Continue to monitor and maintain an application flow consistent with success rates close to the historical levels of 40 percent for fellowships (F32s); 60 percent for research training grants (T32s) and entry-level career awards (K01 and K08). ***FY 2000 Target*** (1) Review and respond to the forthcoming quadrennial assessment of the nation's future need for biomedical and behavioral research scientists prepared by the National Academy of Sciences (NAS). (2) Continue to monitor and maintain an application and award flow consistent with success rates close to the historical levels of 40 percent for fellowships (F32s); 60 percent for research training grants (T32s) and entry-level career awards (K01, K08). ***FY 1999 Target*** Maintain an application flow that is consistent with success rates close to the historical levels of 40 percent for fellowships (F32s), and 60 percent for research training grants (T32s) and entry-level career awards (K01 and K08).	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 198
b) Increase the pool of clinical researchers who can conduct patient-oriented research.	***FY 2001 Target*** Continue to issue at least 80 awards each in the K23 and K24 categories over the course of the fiscal year. ***FY 2000 Target*** Issue at least 80 awards each in the K23 and K24 categories over the course of the fiscal year. ***FY 1999 Targets*** (1) Re-announce the career award components of the Director's Initiative on Clinical Research. (2) Issue at least 80 awards each in the K23 (Mentored Patient-Oriented Research Career Development) and K24 (Mid-career Investigator Award In Patient-Oriented	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met.** **FY 1999 target (2) exceeded.**	Page 203

Performance Goals	FY Targets	Actual Performance	Details
	Research) categories over the course of the fiscal year and at least 20 K30 (curriculum development) awards.		
c) Expand the role of electronic capabilities in the administration of research training and career development activities.	***FY 2001 Target*** (1) At least 50% of all training appointments received electronically. (2) All electronically received appointment information is used to establish trainee appointment records and personal profiles within the IMPAC II system. ***FY 2000 Target*** (1) Increase by 40% over the 1999 number of trainee appointment forms received electronically. (2) Increase by 40% over the 1999 number of trainees, fellows, and career award recipients who maintain electronic records for career tracking purposes in the NIH Person database. (3) Develop a plan for ongoing evaluations of NIH research training programs as well as a plan for periodic, comprehensive career outcome studies.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001.	Page 206
d) Develop processes for monitoring the effectiveness of NIH training programs.	***FY 2001 Target*** Begin utilizing the long-term tracking database. ***FY 2000 Target*** Initiate preliminary work on the long-term tracking database. ***FY 1999 Target*** (1) Complete an evaluation study of NIH pre- and post-doctoral training programs based on existing data. (2) Add training activities functions to the NIH Commons.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) partially met.** **FY 1999 target (2) not met.**	Page 208

Performance Goal Details - Training Support

Goal a) **Maintain adequate application and award rates in key training support areas.**

Application rates and award rates for NIH training and career development programs are rough but important indicators of the continuing attractiveness and continuity of these programs to the applicant community. Application rates provide qualitative information about the attractiveness of individual award options and serve as a rough indicator of whether a particular award is meeting the needs of the applicant pool. For example, if the application rate were to fall precipitously for a particular award, the NIH might attempt to determine if the particular provisions of that award remained competitive with other opportunities or if the population of individuals targeted has changed in some way. To provide an example of how these types of considerations are used, a recent analysis indicated a shortage of clinicians in biomedical research and in particular a shortage of researchers with skills working with human subjects. To address this shortage, the NIH developed the *Mentored Patient-Oriented Career Development Award* (K23). The features of that award were patterned after the *Mentored Clinical Scientist Development Awards* (K08) which had been available to support similar career development experiences for many years. But, because salaries and research expenses provided by the K08 had not been changed for several years and because the environment within the academic medical center has been squeezed economically, institutions could no longer provide as much additional support for the research experiences of their clinical faculty. Accordingly, in creating the K23, the NIH increased salary limits and funds available to support research and development costs and is closely monitoring application rates.

The success rate of applicants in obtaining funding is also an important factor in ensuring an award is attractive to potential applicants. If an applicant perceives that his/her chances of getting an award are small, chances are he/she will opt for other support options. At the same time, success rates are a rough indicator of the quality of award recipients. For individual awards like the *Individual NRSA Postdoctoral Fellowships* (F32), success rates have traditionally been between 35 and 45 percent. This means these applications are carefully scrutinized to make sure the candidates and the proposed training experience are of the highest quality. By maintaining a success rate in this range, applicants have a sense of their likelihood of award. For awards like *Institutional National Research Service (NRSA) Research Training Grants* (T32), there is considerable self-selection because the application includes extensive information about the success of former students and postdoctorates. Because of this self-selection and the fact that applicants are normally well established faculty who understand the NIH review system, a considerably higher success rate (near 60%) is more typical. Even so, it remains important to maintain some stability in the overall success rate so that applicants know what to expect.

For certain programs, such as the Director's Initiative on Clinical Research, NIH established numerical targets for the total number of awards. Accordingly, the NIH set a goal of 80

Mentored Patient-Oriented Research Career Development Awards (K23) and *Midcareer Investigator Award in Patient-Oriented Research Awards* (K24) in each of the next several fiscal years and at least 20 of the *Clinical Research Curriculum Development Awards* (K30) in FY 1999. These targets have been established to convey to the applicant community that these new awards are an important new opportunity for clinicians interested in a career in patient-oriented research.

For most of NIH's award programs, there are no specific numerical goals. For these awards, consistency is very important, so that the pool of potential applicants has some awareness of the number of awards that are likely to be made and the probable success rates. For many of NIH's award programs, the quadrennial NAS report (discussed above) provides approximate recommendations about the overall number of individuals to be supported by the research training programs. There is, however, only rough guidance about how positions should be allocated to specific types of awards or to specific fields of research. Accordingly, NIH does not set numerical goals and permits applications from any area of health-related science under most training and career development awards.

This absence of rigid goals and set-asides for specific research areas offers a number of advantages. It accords the applicant pool considerable flexibility in addressing new and emerging areas of research for which training is needed. By maintaining flexible goals for the more established training programs, the response to changing research opportunities can be more rapid.

FY 2001 Target: **Continue to monitor and maintain an application flow consistent with success rates close to the historical levels of 40 percent for fellowships (F32s); 60 percent for research training grants (T32s) and entry-level career awards (K01 and K08).**

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: **(1) Review and respond to the forthcoming quadrennial assessment of the nation's future need for biomedical and behavioral research scientists prepared by the National Academy of Sciences (NAS).**

(2) Continue to monitor and maintain an application and award flow consistent with success rates close to the historical levels of 40 percent for fellowships (F32s); 60 percent for research training grants (T32s) and entry level career awards (K01, K08).

Basis and Data: (1) The aforementioned NAS report is prepared and published every four years by staff and an external panel (Committee on National Needs for Biomedical and Behavioral Research Personnel) of the National Research Council. This periodic analysis of the current programs and estimate of future trends is developed by the NAS

pursuant to Title I of the National Research Service Act of 1974 (P.L. 93-348 as amended). NIH will formally communicate its assessment of the recommendations and plans for program adjustments to Congress. (Because publication of the National Academy report has been delayed, implementation plans are likely to be prepared in FY 2000, for implementation in FY 2001 and later years.) (2) Performance will be gauged by the number of applications and awards for NRSA training grants (T32), individual NRSA postdoctoral fellowships (F32), and individual career development award applications (K01, K08). NIH will use data from the Information for Management, Planning, Analysis and Coordination database (IMPAC) to enumerate the total number of applications received and the total number of applications awarded during this time period.

Validation and Verification: IMPAC is a comprehensive database at NIH, built and refined over many years, that covers the agency's extramural research activities. Included here are records of research contracts, records of in-process grant applications, and inter- and intra-agency agreements. The data in IMPAC is compared to accounting data maintained by the Office of Financial Management on a daily basis and there is a record of all applications and awards processed by the NIH.

Assessment of FY 1999 Performance

FY 1999 Target: **Maintain an applications flow that is consistent with success rates close to the historical levels of 40 percent for fellowships (F32s), 60 percent for research training grants (T32s) and entry level career awards (K01 and K08).**

FY 1999 Achievement Summary:

- The target has been met.

- A sufficient number of applications were received in FY 1999 to maintain a consistent NIH contribution to the support of training in health-related science. Also, success rates were sufficiently close to historical rates for Individual Fellowships (F32s), Institutional Research Training grants (T32s), Mentored Research Scientist Development Awards (K01), and Mentored Clinical Scientist Development Awards (K08) to indicate that the number of applications was relatively consistent and that high quality applications were available for funding.

Data available from NIH's IMPAC administrative data system are shown in the table below. In FY 1999, the NIH received 1,981 F32 applications, 567 T32 applications, 271 K01 applications, and 478 K08 applications. These numbers are relatively consistent with the number of applications received in FY 1998 and suggest that these awards continue to be popular options for career development support. The success rates for these four award mechanisms are also relatively consistent with historical levels. The more than 40% of F32 applications awarded in FY 1999 is an increase over FY 1998. This kind of variability can be expected from year to

year. Success on training grants are near 60 percent as expected and success rates on the two career development awards K01 and K08 are close to historical levels.

Success Rate and Number of Training Grant Awards and Applications by Grant Type						
	1998			1999		
Grant Type	Applications	Awards	Success	Applications	Awards	Success
F31	508	242	48%	501	253	50%
F32	2,146	844	39%	1,981	863	44%
K01	266	90	34%	271	101	37%
K08	536	311	58%	478	248	52%
K23	1	1	100%	202	85	42%
K24	0	0	N/A	185	81	44%
K30	0	0	N/A	64	35	55%
T32	512	329	64%	567	362	64%
T34	34	18	53%	39	20	51%

Sources of FY 1999 Assessment Data: The data in this table are taken from NIH's administrative data system IMPAC, which is used to monitor all NIH applications and awards. IMPAC is a comprehensive database at NIH, built and refined over many years, that covers the agency's extramural research activities. Included here are records of research contracts, records of in-process grant applications, and inter- and intra-agency agreements. The data in IMPAC is compared to accounting data maintained by the Office of Financial Management on a daily basis and there is an record of all applications and awards processed by the NIH.

Discussion of Performance: Although application rates and success rates are only rough indicators of the popularity and quality of NIH programs, these measures are especially important for managing training and career development programs. Training a researcher typically takes more than 10 years from entrance to graduate school to application for independent research support to accomplish. Because of this extended training period, consistency of NIH support is an important element of the program. Stability in application rates is a rough indicator of consistency; it also indicates that the various features of the award remain attractive to aspiring researchers. A predictable success rate also helps applicants gage the probability for success and therefore helps them select a support option that is best considering their career stage. For example, a postdoctorate that feels that he/she is not in the top half of the peer group might be well advised not to apply for an Individual Postdoctoral Fellowship but to seek support from some other source. A stable success rate also provides an indication that high quality applications are available for award. Nonetheless, while consistency is important, NIH considers any numerical target for a standing program to only be approximate. This conveys to the applicant community that it will accommodate applications in new and emerging areas of science and that not all of NIH's training resources are locked into specifically identifiable initiatives.

Next Steps: The NIH will continue to monitor the application and success rates for its training programs, with due recognition that there will be some variability from year to year.

Goal b) Increase the pool of clinical researchers who can conduct patient-oriented research.

Recommendations for increasing research capacity in the area of patient-oriented research stemmed from an NIH Director's Panel on Clinical Research and an Institute of Medicine (IOM) Committee on Addressing Career Paths for Clinical Research. Both groups identified a need to increase the pool of clinical researchers who can conduct patient-oriented studies, to capitalize on the discoveries based on molecular approaches and translate them to clinical settings. The recommendations included expanding and improving training programs in patient-oriented research for both entry-level and mid-career clinical investigators.

Accordingly, NIH has recently established three new career development mechanisms: (1) the *Mentored Patient-Oriented Research Career Development Awards* (K23) for the support of young investigators; (2) the *Midcareer Investigator Award in Patient-Oriented Research Awards* (K24) for the support of mid-career investigators in research and mentoring; and (3) *Clinical Research Curriculum Development Awards* (K30) for curriculum development in clinical research. All three of these awards appear to be attractive to potential applicants, and NIH expects they will eventually increase the number of productive scientists working in this important area. To convey NIH's commitment to training in this area, the initiative specified that at least 80 K23 and 80 K24 awards would be made in each of the next 5 fiscal years to achieve a steady state of approximately 400 of each type of award. This target was chosen as a compromise between estimated needs for new researchers and the need to increase the capacity to provide this type of training. The K30 was targeted for 20 awards in FY 1999, but does not extend into future years.

FY 2001 Target: Issue at least 80 awards each in the K23 and K24 categories over the course of the fiscal year.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Issue at least 80 awards each in the K23 and K24 categories over the course of the fiscal year.

Basis and Data: Performance will be measured by the number of applications and awards in the K23 and K24 categories. NIH will use the IMPAC database to enumerate the total number of applications received and the total number of applications awarded during this time period.

Validation/Verification: IMPAC is a comprehensive database at NIH, built and refined over many years, that covers the agency's extramural research activities. Included here are records of research contracts, records of in-process grant applications, and inter- and intra-agency agreements. The data in IMPAC is compared to accounting data maintained by the Office of Financial Management on a daily basis and there is an record of all applications and awards processed by the NIH.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Re-announce the career award components of the Director's Initiative on Clinical Research.**

(2) Issue at least 80 awards each in the K23 (Mentored Patient-Oriented Research Career Development) and K24 (Mid-career Investigator Award In Patient-Oriented Research) categories over the course of the fiscal year and at least 20 K30 (curriculum development) awards.

FY 1999 Achievement Summary:

- Target (1) has been met. The K23, K24, and K30 programs, which are part of the Director's Initiative on Clinical Research, were reannounced in October and November of this year.

- Target (2) has been exceeded. In FY 1999, the NIH made 85 K23 awards, 81 K24 awards, and 35 K30 awards.

Sources of FY 1999 Assessment Data:
Target (1) The revised and reissued career award announcements related to this target are available in the NIH Guide for Grants and Contracts as follows:

Mentored Patient-Oriented Research Career Development Award (K23), Published: October 8, 1999 http://grants.nih.gov/grants/guide/pa-files/PA-00-004.html

Midcareer Investigator Award in Patient-Oriented Research (K24), Published: October 8, 1999 http://grants.nih.gov/grants/guide/pa-files/PA-00-005.html

Clinical Research Curriculum Award (K30), Published: November 19, 1999
http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-00-002.html

Target (2) Data for this target have been drawn from IMPAC, the NIH's administrative data system. IMPAC is a comprehensive database at NIH, built and refined over many years, that covers the agency's extramural research activities. Included here are records of research contracts, records of in-process grant applications, and inter- and intra-agency agreements. The data in IMPAC is compared to accounting data maintained by the Office of Financial

Management on a daily basis and there is an record of all applications and awards processed by the NIH.

Discussion of Performance: The revised and reissued career award announcements reiterate the NIH commitment to support training in this area. The announcements also clarify eligibility criteria for these awards that will help expand and define the target population for the K24.

The achievement of this goal means that these awards are beginning to concretely address the concerns of the NIH Director's Panel on Clinical Research. The capacity for clinical training is being increased and a new population of highly training clinical researchers will become available to help move research findings from the laboratory to the clinic.

Next Steps: Enhancing the nation's capacity to conduct clinical research, remains an important goal. Consistent with this goal, the NIH will continue to monitor the number of patient-oriented research career awards in the future as indicated in the FY 2000 and 2001 targets. The need for new announcements will be reassessed on an annual basis.

Goal c) **Expand the role of electronic capabilities in the administration of research training and career development activities.**

Organizations receiving NRSA institutional training grants are required to report on the appointment of trainees supported under the grant. To facilitate this reporting, NIH is developing, as part of its electronic research administration system, a Web-based interface that provides for the electronic submission of trainee appointment and termination information. This electronic system will improve the ease of data entry and processing, in addition to improving the quality of data. The specific features of this system are still in the development stage, but will be referred to collectively as the Electronic Trainee Activities System (X-Train). The X-Train utility will reside on the NIH Commons (see Grants and Administration Goal e).

During FY 2000 and FY 2001, capabilities for electronic receipt of appointment and termination information will be enhanced and integrated with other components of NIH's electronic research administration system. This will facilitate the tracking of research trainees, fellows, and career award recipients. These individuals will be able to provide relevant personal and training information using an interface accessible through a standard Web browser. The information will be entered directly into a database at NIH to establish a personal profile for each individual. In the future, individuals will be able to update his/her personal profile to indicate advancement to new positions, publications, appointment to advisory groups, and receipt of research project support. It will also give individuals immediate access to his/her own records, as required by the Privacy Act.

Each electronic form submitted -- after examination for accuracy -- creates a new electronic record in the IMPAC database. This information will provide the primary basis for performance assessment. All data to be entered in this system are checked against carefully verified data related to the training grant and fellowship awards. In 1997, in a precursor system to X-Train, the NIH received 614 trainee appointment forms electronically. In 1998, more than 1,029 forms were received electronically for a 68 percent increase over the previous year. Beginning in FY 2000, X-Train will completely replace the precursor system and will be initially tested by 15 Federal Demonstration Partnership institutions. It is expected that some aspects of this interface will be in operation by the end of FY 2000 and fully operational by the end of FY 2001. A link to the future X-Train system is currently available on the NIH Commons Web Page at https://www-commons.cit.nih.gov/.

These new capabilities will improve and streamline the processing of training and career award data and greatly expand career tracking capabilities. Access to richer data on training experiences and career outcomes will permit NIH to undertake more comprehensive and informed career outcome evaluations of its training programs. It will also permit matching the performance of former trainees and fellows to specific characteristics of their training programs to enhance the quality of those programs. A more efficient and effective research training

program should enable the NIH to better respond to the constantly changing national needs and priorities for research training. (Note: This was a new goal in FY 2000)

FY 2001 Targets: **(1) At least 50% of all training appointments received electronically.**

(2) All electronically received appointment information is used to establish trainee appointment records and personal profiles within the IMPAC II system.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) Increase by 40% over the 1999 number of trainee appointment forms received electronically.**

(2) Increase by 40% over the 1999 number of trainees, fellows, and career award recipients who maintain electronic records for career tracking purposes in the NIH Person database.

(3) Develop a plan for ongoing evaluations of NIH research training programs as well as a plan for periodic, comprehensive career outcome studies.

Basis and Data: Data on the number of appointment forms received will be based on information from the IMPAC data system. All electronic appointment forms received via X-Train will establish a personal profile that will be used in the future for tracking career outcomes.

Validation and Verification: Each electronic form received is held in a temporary database until the contents are reviewed and approved by the NIH official responsible for the training grant. At that point, the information is loaded in to the Trainee Appointment File, which is a permanent part of the NIH IMPAC management information system. IMPAC is a comprehensive database, built over many years that covers and documents the agency's extramural research activities. Enhancements to the Trainee Appointment File and IMPAC more broadly are expected as part of the process of upgrading this database to a relational system.

Goal d) Develop processes for monitoring the effectiveness of NIH training programs.

NIH recognizes the importance of developing and managing its training programs based on sound knowledge about their ongoing effectiveness. Towards this end, the agency has initiated a comprehensive evaluation of the National Research Service Award (NRSA) programs for predoctoral and postdoctoral research training. This effort examines program effectiveness by determining how many recipients of this training support apply for and receive subsequent NIH fellowship support, apply for and receive subsequent NIH research grant support, publish in peer reviewed journals, and remain in scientific careers. All of these outcomes are related to the overall goal of training and maintaining a population of highly trained individuals capable of carrying out the nation's biomedical and behavioral research mission.

In response to the 1994 NAS Report, *Meeting the Nation's Needs for Biomedical and Behavioral Personnel*, NIH established a staff committee and launched a comprehensive career outcome study which is not completely finished. The original plan incorporated three different analytical components: (i) Complete an assessment of career outcomes based on existing data sources and the characteristics of former NRSA trainees and fellows. The career outcomes of NRSA recipients would then be compared to those of individuals in selected comparison groups. (ii) Conduct a sample survey of former NRSA recipients and comparison group, to identify specific and non-academic outcomes as an assessment of the impact of program elements. (iii) Establish a long-term career tracking mechanism for NRSA-supported individuals, to gather systematic longitudinal data on the relationships between program processes (e.g., duration, type of support) and outcomes. Subsequent to the initiation of these evaluation studies, the NIH Committee on Research Training Assessment (CORTA), determined that the information within the existing National Science Foundation Survey of Doctoral Recipients was sufficiently robust to obviate the need for a separate survey. Accordingly, segment (ii) of the evaluation plan that called for a sample survey was determined not to be needed.

FY 2001 Target: Begin utilizing the long-term tracking database.

Basis and Data: Once the X-Train system is completed, the NIH will begin encouraging all former trainees and fellows to update their personal profile. All such former trainees will be asked to provide information on their publications, awards, and employment. This information will constitute the heart of the long-term tracking database and will permit an assessment of the career advancement and productivity of former recipients of NRSA support.

Validation and Verification: All personal data recorded in the Personal Profiles will be based on information provided and verified by the individual. At the time an individual adds data to his or her personal profile, he or she will be asked to provide assurance that

the information is correct. Information on specific NIH awards in the personal profile will be based on additional NIH records. Information on publications can be verified by links to the NIH MEDLARS system or by exploring the Institute for Scientific Information database.

FY 2000 Target: **Initiate preliminary work on the long-term tracking database.** (Analytical component iii. identified in the introductory discussion to this goal).

Basis and Data: The functionality of the system will be tested and verified. For example, it will be determined that receipt of trainee appointment information reliably establishes a Personal Profile. Individuals will have access to their profile for verification. Subsequent formal interactions, such as submission of a grant application, with the NIH will be reliably recorded in the Personal Profile.

Validation and Verification: It can be independently verified that all formal interactions with the NIH are accurately recorded n the Personal Profile. Furthermore, individual trainees and former trainees will be asked to certify the information in their own files.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Complete an evaluation study of NIH pre- and post-doctoral training programs based on existing data.** (Analytical component i. in the introductory discussion to this goal).

(2) Add training activities functions to the NIH Commons.

FY 1999 Achievement Summary:

- Target (1) has been partially met. A draft report of the NRSA Predoctoral Training Evaluation Study *The Early Career Outcomes of NRSA Predoctoral Trainees and Fellows,* Office of Extramural Research, has been completed and is available. A similar approach will be used for the postdoctoral training evaluation study. Data sets for the postdoctoral study have been compiled but not analyzed.

- Target (2) has not been met. The X-Train software has been available for internal testing for several months, but due to problems with related functions of the Commons, such as the Personal Profile System, X-Train is not yet operational.

Sources of FY 1999 Assessment Data:
Target (1) This study matches data from NIH datasets on trainees and fellows with the NSF Doctorate Record File to create a group of predoctoral NRSA recipients with at least 9 months of support who have earned a Ph.D. Comparison groups of Ph.D.s are constructed from individuals

without NRSA support who graduated at the same time in similar fields either from institutions with NRSA or without NRSA support. The report then describes the time to degree, the success in getting NIH fellowships and research grants, the types of positions attained, as well as the number and impact of any publications. Outcome data are obtained from NIH and NSF data files such as the Trainee Fellow File, the Consolidated Grant Applicant File, the Doctorate Record File, and the Survey of Doctoral Recipients. Information on publications and their impact was obtained from the Institute of Scientific Information. The design of the study was managed by a staff committee called the Committee on Research Training Assessment (CORTA).

Target (2) X-Train will be operationalized on the NIH Commons. Information on the Commons is available at https://www-commons.cit.nih.gov/ . The future link to X-Train currently appears on this Web site and should be activated some time in FY 2000.

Discussion of Performance:
Target (1) This evaluation compares Ph.D. Graduates in biomedical research who have received at least 9 months of predoctoral NRSA support with students who graduated at the same time from universities with NRSA support or from universities without NRSA support. The study clearly shows that students with NRSA support have more successful research careers than their colleagues without NRSA support. To provide an example, NRSA recipients complete their doctorate in a shorter period of time, they are more likely to apply for and receive NIH postdoctoral fellowships, they are more likely to obtain tenure track positions, they are more likely to assume positions at distinguished institutions, they are more likely to apply for and receive NIH and NSF research grants, they publish their research findings more frequently, and those publications are cited more frequently. These findings are statistically significant and the more favorable career outcomes of NRSA recipients are consistent across all variables examined. The findings of this study support previous assessments by the NAS which have shown that research training experiences are of high quality and generally lead to more successful and productive careers than other available methods of support. The NRSA programs clearly contribute to the overall goal of creating a cadre of well-trained researchers capable of carrying out the nation's research mission.

Target (2) Developing a Web-based appointment process is essential to simplify the reporting appointment and award information. The process will be much easier for trainees and their program directors, the data will feed directly into an NIH database after verification, and it will establish a personal profile system that will be essential to future career outcome studies.

Next Steps:
Target (1) These evaluation studies of both predoctoral and postdoctoral NRSA recipients are complex, multifactorial studies and are expected to be completed and published in FY 2000. If it is discovered that NRSA recipients are not performing at least as well as individuals in relevant comparison groups, the operation of these programs will be analyzed and appropriate policy modifications developed.

Target (2) It is now expected that X-Train and the electronic appointment system will be tested and fully operational during FY 2000.

2.2.2.2 Outreach

Outreach efforts are necessary to stimulate applications and to let prospective trainees know about careers in research and the availability of support from NIH. NIH outreach efforts disseminate technical information about the features of awards, how they are reviewed and awarded, and how to obtain information from the NIH.

These functions are carried out in a number of ways, as described below.

NIH maintains an extensive Website which describes training and career development activities within the intramural laboratories and at institutions around the country. NIH announces programs in the *NIH Guide for Grants and Contracts*. NIH provides a comprehensive list of all training and career development opportunities in an easy to use booklet, which is also available on the Website. NIH provides a listing of all funded institutional research training grants on the Website. In addition to these publications and Web listings, NIH provides informational booths at many national conferences on biomedical research. For example, NIH staff manage a booth at almost all conferences sponsored by the Federation of American Societies of Experimental Biology (FASEB). NIH staff distribute printed information at these conferences and provide individualized advice about appropriate programs and the means to access newly published information.

The NIH also relies on the *NIH Research Training Web Site* as an important means of providing information on both intramural and extramural training opportunities. The Web Site is accessible at http://grants.nih.gov/training/. The Web Site includes links to job listings and various types of career resources for scientists. The extramural research training site at http://grants.nih.gov/training/extramural.htm provides an entry point for most research training and career development awards available to extramural institutions. The entire NIH Website receives more than 5 million hits per month and the research training page (cited above) is the 6th most frequently hit page on the site. It therefore constitutes an important and growing part of the NIH outreach effort.

Overall, ensuring a continual supply of young investigators in health related research requires that the applicant community is continuously and accurately apprised of options for training and career development support from the NIH. The two performance areas described below form the basis for the performance goals described in this section:

- Adjust outreach activities as needed to ensure a continuing flow of students and postdoctorates into health-related research careers.

- Continue to monitor the participation of racial and ethic minorities in NIH training programs and adjust outreach efforts as needed to enrich the diversity of the research labor force.

Performance Goals Summary Table – Outreach

Performance Goals	FY Targets	Actual Performance	Details
a) Encourage interest in scientific research careers and widely communicate information on the training and career development options available.	***FY 2001 Target*** Continue to monitor the need for new announcements and other outreach activities based on application rates, the age and accuracy of existing announcements, and informal assessments of confusion within the target applicant pool. ***FY 2000 Target*** Evaluate the effectiveness of the revised announcements, informational materials, and the new training Web Site. ***FY 1999 Target*** (1) Revise and publish announcements related to NIH research training and career development opportunities. (2) Reissue announcements for the F32, K01, K02, K05, K07, K08, K12, K23, and K24 award categories. (3) Reissue the announcement for Minority and Disability Research Supplements. (4) Republish the booklet *Research Training and Career Development Programs Supported by the National Institutes of Health.* (5) Re-announce programs as necessary to stimulate the submission of applications.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) met.** **FY 1999 target (2) partially met.** **FY 1999 target (3) met.** **FY 1999 target (4) not met.** **FY 1999 target (5) met.**	Page 214
b) Increase the interest of women and under-represented minorities in pursuing research careers.	***FY 2001 Target*** Continue to identify areas within the population of NIH supported trainees that are not responding to efforts to increase demographic diversity. Develop remedial plans to address these problems as needed. ***FY 2000 Target*** Plan action as appropriate to address demographic areas where interest is abnormally low or declining. ***FY 1999 Target*** (1) Prepare a report identifying the demographics of the individuals supported by the NRSA mechanisms and career award mechanisms.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) not met.**	Page 219

Performance Goals	FY Targets	Actual Performance	Details
	(2) Issue a Notice of Proposed Rulemaking to permit part-time NRSA support and part-time payback options for individuals with pressing family obligations or disabilities.	**FY 1999 target (2) met**.	

Performance Goal Details - Outreach

Goal a) **Encourage interest in scientific research careers and widely communicate information on the training and career development options available.**

The NIH encourages interest in scientific careers by making information on training and career development opportunities readily available. NIH staff attend scientific meetings to encourage students and postdoctorates to take on a career in biomedical research. Additionally, to advertise the availability of various support options, NIH issues announcements in the *NIH Guide to Grants and Contracts* which is sent to an extensive listserve as a means of ensuring that all interested potential applicants have the information they need to apply for NIH programs. The NIH has developed a extensive Website that replicates and organizes the information published in the *NIH Guide for Grants and Contracts.* The Website contains information on training options in both the intramural and extramural programs at (http://grants.nih.gov/training/). The NIH also publishes a popular booklet called *Research Training and Career Development Programs Supported by the National Institutes of Health*. The contents of this booklet are organized by career level and contains useful tables that helps students locate NIH funded opportunities available at their own universities as well as opportunities that require a separate application to the NIH. The contents of this booklet can be found at http://grants.nih.gov/training/extramural.htm.

FY 2001 Target: **Continue to monitor the need for new announcements and other outreach activities based on application rates, the age and accuracy of existing announcements, and informal assessments of information needs within the target applicant pool.**

Basis and Data: The NIH will continue to monitor the number of new applications across the various types of training support mechanisms. Outdated announcements will continue to be replaced if they are older than three years. The number of downloads from the NIH Website will continue to be monitored. The NIH will also monitor the use of its Website and meet with potential users to discuss the usefulness of the displays.

Validation and Verification: The publication date of announcements in the *NIH Guide for Grants and Contracts* is indicated on all publications so the date of publication can be immediately verified. The booklet *Research Training and Career Development Programs* will be published on the Web and will be updated to reflect the development of new programs as well as changes in the features or contacts for existing programs.

FY2000 Target: Evaluate the effectiveness of the revised announcements, informational materials, and the new training Website.

Basis and Data: The effectiveness of the training Website will be measured by the number of downloads requested. The effectiveness of the dissemination activities will be determined by soliciting input from users and assessing the need for additional information from the NIH Outreach Office.

Validation and Verification: NIH's Center for Information Technology routinely measures the number of downloads from various parts of the Website. This provides a proxy measure on the use of the Website. Monitoring calls to the Outreach Office provides an indication of the quality of the information on the Website.

Assessment of FY 1999 Performance

FY 1999 Targets: (1) Revise and publish announcements related to NIH research training and career development opportunities.

(2) Reissue announcements for the F32, K01, K02, K05, K07, K08, K12, K23, and K24 award categories.

(3) Reissue the announcement for Minority and Disability Research Supplements.

(4) Republish the booklet *Research Training and Career Development Programs Supported by the National Institutes of Health.*

(5) Re-announce programs as necessary to stimulate the submission of applications

F*Y 1999 Achievement Summary:*

- Target (1) was met. Announcements for the K01, K02, K05, K08, K23, K24, and K30 were republished.
- Target (2) was partially met. As noted above, announcements for the K01, K02, K05, K08, K23, K24, and K30 were republished. The F32 and K12 have been drafted and discussed within the NIH and will be published in January, 2000.
- Target (3) has been met. Announcements for the Minority and Disability Supplements were published in May, 1999.

- Target (4) has not been met. A draft of the *NIH Research Training and Career Development Programs Booklet* has been completed and is available on the NIH Website, but it has not yet been republished.

- Target (5) has been met. The standing programs have received a sufficient number of applications so that programs need not be reannounced for this purpose. Application rates for the most common research training and career development programs remain close to historical levels.

Sources of FY 1999 Assessment Data:
Targets (1) and (2). These announcements can be viewed on the NIH Website at the locations shown in the following table:

Activity Code	Career Award	Web Address
K01	Mentored Research Scientist Development Award	http://grants.nih.gov/grants/guide/pa-files/PA-00-019.html
K02	Independent Scientist Award	http://grants.nih.gov/grants/guide/pa-files/PA-00-020.html
K05	Senior Scientist Award	http://grants.nih.gov/grants/guide/pa-files/PA-00-021.html
K08	Mentored Clinical Scientist Development Award	http://grants.nih.gov/grants/guide/pa-files/PA-00-003.html
K23	Mentored Patient-oriented Research Career Development Award	http://grants.nih.gov/grants/guide/pa-files/PA-00-004.html
K24	Midcareer Investigator Award in Patient-Oriented Research	http://grants.nih.gov/grants/guide/pa-files/PA-00-005.html
K30	Clinical Research Curriculum Award	http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-00-002.html

Target (3) These announcements can be viewed on the NIH Website in the following locations:

Research Supplements for Underrepresented Minorities
http://grants.nih.gov/grants/guide/pa-files/PA-99-104.html
Research Supplements for Individuals with Disabilities
http://grants.nih.gov/grants/guide/pa-files/PA-99-105.html

Target (4) The *NIH Research Training and Career Development Booklet* is available in draft form on the NIH Intranet at http://oerwebdev.od.nih.gov/training/careerdev/ and is nearly complete. The completed booklet will be published early in calendar year 2000.

Target (5) As described earlier, application rates are monitored using the administrative database, IMPAC.

Discussion of Performance:
Targets (1) and (2) Updating announcements is an essential part of disseminating current and comprehensive information on research training and career development programs. Current and accurate announcements aid potential applicants in understanding the nature of each award and in selecting an award tailored to their needs. This helps ensure a brisk flow of applications for

NIH support options, which is necessary to ensure a sufficient level of new training to meet future needs.

Target (3) The programs described in these two research supplement announcements are particularly useful and successful in recruiting individuals with disabilities and individuals from underrepresented racial and ethnic groups into research careers. Principal investigators on currently funded research grants can submit an abbreviated application to their program official. Awards made under this program provide additional funds to employ a high school, college, or graduate students as well as scientists at more advanced stages of their careers such as postdocs or faculty members. The application must provide assurance that the individual to be supported is from a racial/ethnic group underrepresented in science or is disabled as defined by the Americans with Disabilities Act. Information on the number of awards made in FY 1998 under this program is described at http://grants.nih.gov/training/minoritysupplements/minoritysupplements.pdf. More than 1,000 individuals each year are selected for support under this program. Because salary limits and other features of these awards change from time to time it is important to ensure that accurate information is available. These awards encourage institutions to consider the diversity of their workforce and help ensure that adequate researchers will be available in the future.

Target (4) The *NIH Research Training and Career Development Booklet* is perhaps the most popular document that NIH distributes at scientific meetings. It is organized by career level and separated into sections for the intramural program and the extramural programs. Each program description includes information about how to find the program announcement and whom to call. The Office of the Director and the individual NIH Institutes and Centers make a concerted effort to ensure that the information included is current and that contact points for individual programs are accurate. Because this document is so important in helping people understand the nature and function of NIH training and career development programs, it is directly related to the goal of maintaining and adequate supply of researchers.

Target (5) NIH routinely replaces announcements more than 3 years old to ensure that the information provided is a sufficient description of current programs. Republishing announcements on a regular schedule also helps avoid confusion about the continuity of particular programs. Students and university administrators frequently call to make sure that applications for those programs are still being accepted. Individuals may also simply assume that these programs are no longer available and may simply not apply.

In general, providing timely and accurate information on programs is essential for maintaining adequate application rates. NIH cannot meet its goal of maintaining a well-trained research labor force unless it can make training awards and support career development, which depend directly on an adequate flow of applications.

Next Steps:
Targets (1) and (2) In FY 2000, the NIH will continue its effort to ensure that the information available to the applicant community is current and easy to access. This is an ongoing responsibility and will be continued indefinitely.

Target (3) The NIH will continue to monitor the utilization of research supplements to support racial and ethnically underrepresented groups as well as disabled scientists using the report published annually at http://grants.nih.gov/training/outcomes.htm .

Target (4) The *NIH Research Training and Career Development Booklet* will be completed when all links have been checked and the document has been suitably Web-linked to related documents. Once the document has been finalized on the Web it will be published in paper form. This process will be completed early in calendar year 2000.

Target (5) As stated earlier, NIH needs to continue to monitor application rates to ensure that the support mechanisms offered remain attractive. If application rates fall, a program needs to be reannounced. In some cases, the features of the award may also need to be changed. But in all cases a new announcement will be issued.

Goal b) Increase the interest of women and under-represented minorities in pursuing research careers.

NIH is committed to training and supporting a research community that reflects the nation's social diversity. Accordingly, NIH supports a number of training programs specifically designed to provide support to minority graduate and postdoctoral students and to recruit them into research at all career levels. NIH also supports programs designed to enhance the retention of women in biomedical research careers. An important aspect of these efforts is a continual monitoring of the demographics of the workforce and the population of individuals in training. This ongoing vigilance permits an assessment of the value of existing initiatives and the identification of emerging problem areas.

FY 2001 Target: Continue to identify areas within the population of NIH supported trainees that are not responding to efforts to increase demographic diversity. Develop remedial plans to address these problems as needed.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Plan action as appropriate to identify and address demographic groups for which interest in training is abnormally low or declining.

Basis and Data: This target will involve identifying areas of need by querying NIH's IMPAC data systems about the racial, gender and ethnic diversity of the NIH-supported training and research labor force, and identifying appropriate intervention strategies. If it appears that the substantial NIH effort to address diversity within the training workforce is having little or no effect on the participation of underrepresented racial or ethnic groups, the NIH will develop plans to adjust outreach and recruitment activities.

Validation and Verification: IMPAC is a comprehensive database at NIH, built and refined over many years, that covers the agency's extramural research activities. Included here are records of research contracts, records of in-process grant applications, and inter- and intra-agency agreements. The data in IMPAC is compared to accounting data maintained by the Office of Financial Management (OFM) on a daily basis and there is an record of all applications and awards processed by the NIH. In spite of multiple safeguards on the quality of this data, there is some indication that the number of individuals reporting unknown racial/ethnic affiliation is increasing (see Table under the FY 1999 target). NIH will be investigating this particular issue to see if the number of

individuals who elect not to provide this information is increasing or if it reflects data capture issues here at the NIH.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Prepare a report identifying the demographics of the individuals supported by the NRSA mechanisms and career award mechanisms.**

(2) Issue a Notice of Proposed Rulemaking to permit part-time NRSA support and part-time payback options for individuals with pressing family obligations or disabilities (which is intended particularly to respond to the needs of young women).

FY 1999 Achievement Summary:

- Target (1) has not been met. Programs have been developed to extract race/ethnicity data on individuals newly appointed to NIH research training grants, but the analysis has not been completed.

- Target (2) has been met. The NPRM for 42 Part 66 was published in the *Federal Register* on June 30.

Sources of FY 1999 Assessment Data Summary:
Target (1) Data on graduate students and postdoctorates newly appointed to NIH research training grants (T32) has been extracted from the Trainee Appointment Files of the IMPAC data system. Data is submitted to the NIH on Statement of Appointment Forms (PHS 2271) which are submitted by all individuals at the time of appointment and reappointment to an NIH training grant. The race ethnicity questions are only completed, however, on initial appointments, which is why the data is presented in this way. An analysis of the race and ethnicity of individuals appointed to research training grants is confounded in a number of ways. One of the options on the race/ethnicity reporting block allows respondents to indicate that they wish to withhold this information. Another source of unknown information relates to the rate at which appointment information is received and entered into the Trainee Appointment File.

Note in the table below that the total number of appointments is considerably lower for FY 1998 than for previous years. This is not reflective of the total number of positions supported or the number of training grants made. It probably reflects the rate at which appointment information is received and entered into the IMPAC data system. The final issue relates to a small number of specific training programs that are restricted to underrepresented students or postdocs or awards that are limited to institutions with a substantial minority enrollment. Because of all these factors the data shown in the following table should be considered preliminary.

Preliminary Information on the Race and Ethnicity of New Predoctoral and Postdoctoral Appointments to Institutional NRSA Research Training Grants (T32)							
Fiscal Year	Underrepresented Groups		Asian and White American		Total Unknown	Total Known	Total Appointments
	Number	Percent	Number	Percent	Number	Number	Number
1995	414	10.9%	3,371	89.1%	613	3,785	4,398
1996	406	10.4%	3,503	89.6%	594	3,909	4,503
1997	363	10.5%	3,099	89.5%	837	3,462	4,299
1998	307	11.4%	2,381	88.6%	1,221	2,688	3,909
Note: "Underrepresented Groups" includes Native Americans, African Americans, Hispanic Americans, and Pacific Islanders. Percentages are of "Total Known."							

Target (2) The NPRM document is available on the GPO Website at http://www.gpo.ucop.edu/cgibin/gpogate?waisdoc=1&doctype=TEXT&docid=::::1105154+21156+/diska/wais/data/1999_register/fr30jn99.dat.wais&server=1999_register/frwais.access.gpo.gov

Discussion of Performance:
Target (1) Every NRSA Institutional Research Training Grant (T32) is required to have a plan to recruit individuals from underrepresented groups. These plans are reviewed in every competing application and for renewal applications, the applicant must furnish information about the success of program's recruitment efforts during the previous award period. Applications without an adequate plan and renewal applications with programs that have not been successful in recruiting minorities are not awarded. This provides a very powerful incentive for all programs to actively consider the diversity of their programs. Because minority groups comprise an increasing share of the nation's population, the involvement of individuals from these groups will be increasingly important in the research labor force. In addition, it is important that the ideas and research priorities of the U.S.'s increasingly diverse population are incorporated into future research efforts.

Target (2) As amended by Congress in 1993, Section 487 of the Public Health Service Act requires the NIH conduct the NRSA program in a "manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities) into fields of biomedical or behavioral research". The issuance of this NPRM and the anticipated issuance of the final rule will allow the NIH to offer part-time appointments to people with family responsibilities and others who have a need for this type of research training. It is anticipated that this feature will aid in the recruitment and retention of women and individuals from disadvantaged backgrounds in research careers.

Next Steps:

Target (1) The preliminary report on the racial/ethnic composition of newly appointed trainees is being refined to check coding and to exclude a small number of minority targeted program and to see if we can resolve the racial/ethnic classification of some of the unknowns. This report will be completed in FY 2000.

Target (2) NIH will publish the final rule sometime in calendar year 2000. NIH has already implemented the provisions described in the NPRM in an informal way. Based on these experiences, Manual Chapter 4810 will be modified to clearly specify under what conditions a trainee or fellow can engage in part-time research training or service payback. It will also describe how benefits and payback obligations will accrue during part-time training.

2.3 Research Facilities Program

2.3.1 Program Description, Context, and Summary of Performance

Program Description and Context. The Research Facilities Program addresses the NIH's major, long-term goal to "secure facilities for research that are modern, efficient and safe." NIH's activities and resources in this Core Program area are directed along two principal lines: *Intramural Modernization and Maintenance* and *Extramural Assistance*.

Intramural Modernization and Maintenance -- The NIH has over 11 million gross square feet of federally-owned facilities, which must keep pace with the demands of rapidly changing technologies and priorities in medical and behavioral research. In addition to the over 70 buildings located on the main NIH campus in Bethesda, Maryland and the National Institute of Environmental Health Science (NIEHS) campus in Research Triangle Park, North Carolina, the NIH maintains several off-campus field stations, including the NIH Animal Center in Poolesville, Maryland; the Frederick Cancer Research and Development Center at Fort Detrick in Frederick, Maryland; the Gerontology Research Center in Baltimore, Maryland; and the Rocky Mountain Laboratory in Hamilton, Montana.

The original construction of these buildings and facilities spans a period of more than 60 years, dating back to the June 1936 legislation which authorized Building 1 on the Bethesda campus. As a result, the NIH is now contending with an aging physical plant, and many buildings, facilities, and utility systems have reached or are nearing the end of their useful life. In addition, the emergence of new technologies, the evolving scope of medical research, and other factors lead to facility obsolescence and the need for modernization and replacement of facilities.

Facilities revitalization goals are established through a process which annually evaluates building and facility program needs. This effort culminates in the NIH Buildings and Space Plan, the Agency Capital Plan, and a Five Year Development Program. Other tools used to plan, program, and budget for capital assets include: facility assessments and surveys, engineering studies, technologically driven initiatives and advancements, changes in regulatory requirements, and the recommendations of the approved NIH Facilities Master Plan.

The Buildings and Facilities program (B&F) is composed of five major areas: Essential Safety and Health Improvements, Repair and Improvements, New Construction, Renovations, and Building Equipment/System Upgrades. The focus of the B&F is to provide facilities which are in compliance with applicable safety, accreditation, and other regulatory requirements; efficient in terms of indoor and outdoor environment and energy consumption; and effective in meeting research needs.

Extramural Assistance -- NIH is authorized under the Public Health Service Act to “make grants to public and non-profit private entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities” for medical and behavioral research and research training. Such grants to extramural research facilities are awarded competitively, with grantee institutions required to obtain matching funds for the specific project awarded.

The NIH collaborates with the National Science Foundation to assess the condition of existing facilities and identify needs for new and refurbished research facilities nationwide. These studies provide the major source of objective data for national research infrastructure policy and planning needs. When particular needs are identified, the NIH offers competitive funding opportunities. This support encompasses "bricks & mortar" modernization and replacement of existing research facilities -- all of which result in new capabilities that can open areas of innovative research activity.

GPRA Research Facilities Program			
Budget (000's)	**FY 1999 Actual**	**FY 2000 Estimate**	**FY 2001 Estimate**
	$ 239,343	$ 250,443	$ 232,697
Major Functional Areas	**Intramural Modernization and Maintenance** – Support the construction, renovation, and maintenance of NIH research facilities located on the Bethesda campus and at off-campus field stations to enable NIH intramural researchers to continue to conduct state-of-the-art medical research.		
	Extramural Assistance -- Assist in the construction and modernization of non-federal facilities at academic institutions and other centers of research excellence to enhance their ability to conduct high-quality research.		

Summary of Performance. NIH established 6 performance goals with 8 corresponding performance targets for the Research Facilities Program for FY 1999. A snapshot of these targets shows the following:

- 88 percent (7 of 8) of all targets were partially met, met or exceeded.
  - 38 percent (3 of 8) of all targets were met.
  - 50 percent (4 of 8) targets were partially met (targets with multiple performance elements where some elements were met).

In the pages that follow, specific details are provided for each FY 1999 goal and target of the Research Facilities program.

2.3.2 Goal-by-Goal Presentation of Performance Goals and Results

2.3.2.1 Intramural Modernization and Maintenance

NIH's Buildings and Facilities (B&F) activities encompass five major areas: (1) Essential Safety and Health Improvements, (2) Repair and Improvements, (3) New Construction, (4) Renovations, and (5) Building Equipment/System Upgrades. These are all directed at providing facilities for intramural research which are in compliance with applicable safety, accreditation, and other regulatory requirements; are efficient in terms of indoor and outdoor environment and energy consumption; and are effective in meeting research needs.

NIH uses a systematic approach to the management of its capital assets. New facilities -- to support emerging technologies or to replace existing facilities which have exceeded their useful life expectancy -- are provided when viable and feasible. Existing facilities are renovated or upgraded on a case by case basis. Goals for facility revitalization are established through a process which annually evaluates building and facility program needs. This effort culminates in the NIH Buildings and Space Plan, the Agency Capital Plan, and a Five Year Development Program. Other tools used to plan, program, and budget for capital assets include: facility assessments and surveys, engineering studies, technologically driven initiatives and advancements, changes to accommodate new regulatory requirements, and the recommendations of the approved NIH Facilities Master Plan.

In addition, to support these initiatives, reliable sources of power, heating, cooling and other utility systems are essential. Accreditation initiatives are also often involved.

Currently, the major challenges NIH faces with respect to its intramural facilities are the age of its building inventory (see earlier discussion), a lack of state-of-the-art space to support advancements in research (which hurts in the recruitment of top research talent and which can hinder the effectiveness and/or use of new technologies), and the continuing resource drain (such as more repairs, higher maintenance costs, and lower fuel efficiency) associated with its building and infrastructure deficiencies.

In response, B&F activities are either ongoing or are soon to be initiated in a number of major areas:

- Enhance the reliability of campus-wide utility distribution systems
- Ensure facilities are in condition to receive appropriate accreditation
- Continue renovation and new construction projects
- Improve efficiency and effectiveness of the NIH Real Property Inventory

The performance goals for this program area, discussed below, encompass a number of initiatives and ongoing activities to improve NIH's processes and capabilities in each of these domains of need.

New construction is currently underway to provide a facility to support research on a vaccine for AIDS to promote collaborative structural, molecular and other biological research in the Louis Stokes Laboratories, and to promote state-of-the-art clinical research in the new Mark O. Hatfield Clinical Research Center.

Performance Goals Summary Table – Intramural Modernization and Maintenance

Performance Goals	FY Targets	Actual Performance	Details
a) Improve maintenance of intramural facilities and the availability and reliability of NIH utility distribution systems to support research requirements.	***FY 2001 Targets*** (1) Continue projects to correct building and utility system deficiencies, repair interior and exterior of buildings, and repair off-campus facilities. (2) Complete construction of campus-wide utility distribution systems, renovation and modernization of existing boilers, and the extension of the power plant to provide the necessary equipment to support the heating and cooling requirements of facilities on the NIH Bethesda campus. ***FY 2000 Targets*** (1) Continue projects to correct utility system deficiencies, repair interior and exterior of buildings, and repair off-campus facilities. (2) Complete construction of 90% of planned utility systems for the west and north sections of the campus; complete utility systems supporting the southeast, south, and southwest sections of the campus. ***FY 1999 Targets*** (1) Complete projects in the following backlog categories: campus utilities, exterior and interior building repairs, roof repairs, and off-campus facility repairs. (2) Complete construction of the Utility Tunnel Extension Project and the relocation of underground utilities to support the Power Plant Extension Project.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target (1) partially met.** **FY 1999 target (2) partially met.**	Page 230
b) Complete the Dale and Betty Bumpers Vaccine Research Center.	***FY 2000 Target*** Complete construction of the Dale and Betty Bumpers Vaccine Research Center. ***FY 1999 Targets*** (1) Provide interim laboratory space for vaccine research. (2) Complete design and begin construction of the new vaccine research center.	FY 2000: To be reported in January 2001. **FY 1999 target (1) met.** **FY 1999 target (2) met.**	Page 234

Performance Goals	FY Targets	Actual Performance	Details
c) Complete the Louis Stokes Laboratories Building.	***FY 2001 Target*** Complete construction. ***FY 2000 Target*** Complete 95% of construction. ***FY 1999 Target*** Complete 65% of construction.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target not met.**	Page 236
d) Complete the new Mark O. Hatfield Clinical Research Center.	***FY 2001 Target*** Complete 50 % of construction. ***FY 2000 Target*** Complete the superstructure and exterior wall system. ***FY 1999 Target*** Complete the design and the first phase of site work.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target partially met.**	Page 238
e) Complete the Warren Grant Magnuson Clinical Center Revitalization Program.	***FY 2001 Targets*** Start design for the interim renovations and for Phase I of the Building 10 Revitalization Program.	FY 2001: To be reported in January 2002.	Page 240
f) Maintain the quality of the NIH Animal Care Program and construct a Central Vivarium.	***FY 2001 Targets*** Award a construction contract for the sitework and foundation for a Central Vivarium facility on the NIH Bethesda campus as design is being completed. ***FY 2000 Target*** Begin design for the Central Vivarium sitework and foundation and the programming effort for the facility. ***FY 1999 Target*** Receive accreditation from the Association of Assessment and Accreditation of Laboratory Animal Care International	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target met.**	Page 241
g) Construct a Neuroscience Center on the NIH Bethesda Campus	***FY 2001 Targets*** (1) Complete design by the spring of 2001. (2) Award a construction contract by the Summer of 2001.	FY 2001: To be reported in January 2002.	Page 243
h) Utilize a systematic process to manage and account for NIH's Real Property Inventory	***FY 2001 Targets*** (1) Provide Foundation Information for Real Property Management (FIRM) online monitoring and reporting capabilities at the	FY 2001: To be reported in January 2002.	Page 244

Performance Goals	FY Targets	Actual Performance	Details
	desk of each stakeholder involved with real property management. (2) Validate the NIH real property inventory and populate the FIRM database with the appropriate facility descriptive information, size, function, initial cost, and replacement cost. (3) Launch a pilot program to implement the FIRM and operate in this mode for one fiscal year.		

Performance Goal Details - Intramural Modernization and Maintenance

Goal a) **Improve the maintenance of intramural facilities and the availability and reliability of NIH utility distribution systems to support research requirements.**

NIH is responsible for ensuring that all repairs and improvements to intramural facilities keep pace with research and patient care demands, rapidly changing technological advancements, and research priorities. Work has been targeted in several areas to systematically reduce the backlog of deferred maintenance for NIH capital assets, which range in age from 20 to 40 years and are nearing or have exceeded their useful life expectancy.

Modernization or replacement of the aging inventory and supporting systems is essential to the success of NIH's research objectives in the 21st century. Accomplishments are subject to the availability of funding.

FY 2001 Targets: **(1) Continue projects to correct building and utility system deficiencies, repair the interior and exterior of buildings, and repair off-campus facilities.**

(2) Complete construction of campus-wide utility distribution systems, renovation and modernization of existing boilers, and extension of the power plant to provide the necessary equipment to support the heating and cooling requirements of facilities on the NIH Bethesda campus.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 1999 below.

FY 2000 Targets: **(1) Continue projects to correct utility system deficiencies, repair the interior and exterior of buildings, and repair off-campus facilities.**

(2) Complete construction of 90% of planned utility systems for the west and north sections of the campus; complete utility systems supporting the southeast, south, and southwest sections of the campus.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track schedules and costs of the various projects to correct deficiencies, improve system operations, provide new facilities, and enhance the level of dependability of building and utility distribution systems on NIH campuses.

Validation/Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Assessment of FY 1999 Performance

FY 1999 Targets: **(1) Complete projects in the following backlog categories: campus utilities, exterior and interior building repairs, roof repairs, and off-campus facility repairs.**

(2) Complete construction of the Utility Tunnel Extension Project and the relocation of underground utilities to support the Power Plant Extension Project.

FY 1999 Achievement Summary:

• Target (1) was partially met. Most, but not all, of the scheduled projects were completed. 100% of the off-campus facility repair and 100% of the roof repair projects, 92% of the exterior and interior repair projects, and 86% of those associated with campus utilities systems were completed based on FY1999 targets. The accompanying chart summarizes the overall accomplishments.

FY 1999 Goals Assessment Summary
Improve the Maintenance of Intramural Facilities

Backlog Areas	Scheduled Projects	Completed Projects	Projects in Progress	Completion Percentage
Campus Utilities	21	18	3	86%
Roof Repairs	4	4	0	100%
Exterior and Interior and Building Repairs	12	11	1	92%
Off Campus Facility Repairs	5	5	0	100%
Total	**42**	**38**	**4**	**91%**

Note: Campus Utility and the Exterior/Interior projects under this goal will be completed in the second quarter of FY 2000.

• Target (2) was partially met. Construction of the Utility Tunnel Project reached the 100% milestone in FY1999 as scheduled. Construction to relocate the underground utilities to support the Power Plant Expansion Project was 98% complete at the end of FY1999.

FY 1999 Goals Assessment Summary
Construction Projects

Project	Construction Milestone	Target Date	Actual Date
Utility Tunnel Expansion	Start	July 1996	July 1996
Power Plant Expansion	Completion	November 1998	Feb 1999

Note: The Power Plant Expansion Project was 98% complete at the end of FY 1999.

Sources of FY 1999 Assessment Data: ORS Management Information Systems, as well as contractor's progress reports, meetings, certified invoices, and site inspections, were used to verify and validate accomplishment of the targeted project goals for FY1999.

Discussion of Performance:
Target (1) The NIH was successful in providing more reliable and less breakdown prone site, building, and infrastructure systems to support research requirements. Ninety one percent (91%) of the FY 1999 targeted goal to reduce the number of projects focused on the aging building inventory and both the interior and exterior systems to support them, was achieved. This is only part of a continual effort to assess, renovate, and replace NIH capital assets which have exceeded, or are nearing their useful life expectancy. Funding and the need to satisfy current and emerging technologies directly impact the reduction of projects under this objective.

Target (2) The objective is to complete construction of the Utility Tunnel Project, and to relocate utilities to support the Power Plant Expansion Project met the expectations of the NIH. The Utility Tunnel Project provided new utility systems to support current and future research needs in the west and east areas of the Bethesda campus. It also incorporated features to enhance maintenance and make servicing the systems as orderly as possible to the scientific community.

The Utility Tunnel Project is part of NIH's campus wide effort to respond to current and emerging scientific needs. This project is consistent with the recommendations of the 1991 and 1995 NIH Master Utility Plans (which identified utility system deficiencies and new system requirements to meet the individual and collaborative research mission of the NIH.)

Next Steps:
Target (1) The campus utility and exterior/interior repair projects not finalized in FY 1999 are currently in construction and will be completed in the 2nd quarter of FY 2000. The NIH strategy is to continue evaluation of its capital assets through condition assessments and specialized studies. Future goals and targets are subject to the results of the final funding provided to support reducing the project backlog.

Target (2) The FY 1999 project relocated utilities to support construction of the FY 2000 Power Plant Expansion Project. This will help provide the necessary power plant equipment to support heating, ventilation and air conditioning needs on the NIH Bethesda Campus. The remaining 2% of the underground utilities project will be completed in FY 2000.

Goal b) Complete the Dale and Betty Bumpers Vaccine Research Center.

The Dale and Betty Bumpers Vaccine Research Center (VRC) is a consolidated facility to support all aspects of vaccine research, including the integration of modern immunological science with detailed understanding of the pathogenesis of HIV infection, the development of immunogens and vectors, and new approaches to vaccination. The VRC will provide approximately 7,859 gross square meters (84,600 gross square feet) of laboratory, animal care, administrative, and educational space for the NIH Intramural Program. (Note: Targets beyond FY 2000 are not currently planned, as this goal is expected to be completed in FY 2000.)

FY 2000 Target: Complete construction of the Dale and Betty Bumpers VRC.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation/Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Assessment of FY 1999 Performance

FY 1999 Targets: (1) Provide interim laboratory space for vaccine research.

(2) Complete design and begin construction of the new vaccine research center.

FY 1999 Achievement Summary:

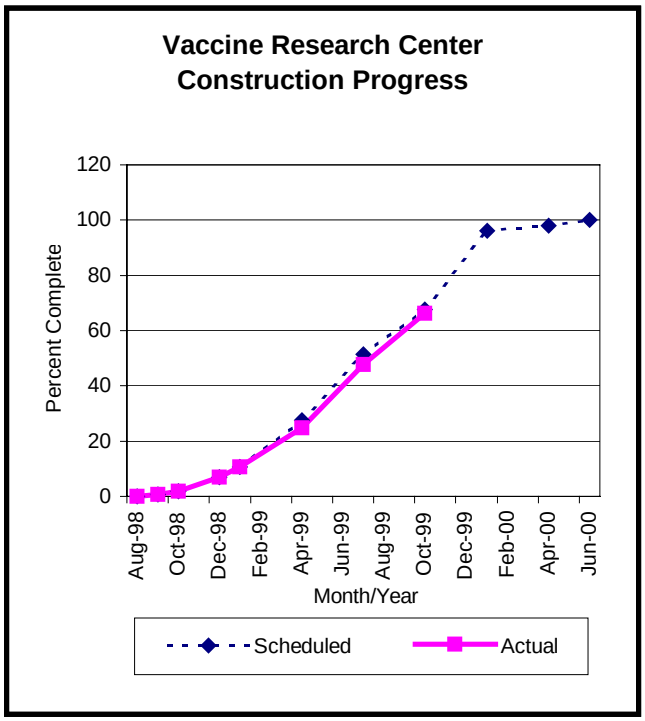
- Target (1) was met. Interim laboratory space has been provided for vaccine research
- Target (2) was met. Design of the VRC was completed and construction started in September 1998.

Sources of FY 1999 Assessment Data:

Target (1) Laboratory space for vaccine research has been made available at the program level. A decision was made to fund this space at the individual program level, allowing each program to take care of its own needs – accordingly space availability was not tracked centrally. An audit at the individual program level would verify what each program did to satisfy its need for space.

Target (2) The Office of Research Services Management Information Systems, as well as the final design documents, contractor's reports, certified invoices, meetings and site inspections, were used to document, monitor, validate and track planned and actual accomplishments of project goals.

Discussion of Performance: Delivery of the Dale and Betty Bumpers Vaccine Research Center in the shortest possible timeframe directly affects NIH's ability to find a vaccine for AIDS. As the accompanying chart indicates, by the end of FY 1999, actual construction had reached 66.2%, compared to the 67.6% planned.



NIH has utilized unique contracting procedures to streamline the acquisition and ultimately, the earliest possible delivery of the Dale and Betty Bumpers Vaccine Research Center. Through the use of a Developer Manager, design time was shortened and construction proceeded as a parallel activity. This will place the NIH in a strategic research position to respond to the President's challenge to develop a vaccine for AIDS by calendar year 2007.

Next Steps:
Target (1) Completion of the VRC will end the need for interim Laboratory space

Target (2) Completion of the VRC is scheduled for FY 2000.

Goal c) Complete the Louis Stokes Laboratories Building.

The Louis Stokes Laboratories (Building 50) will include laboratories, animal facilities, and associated administrative space. Various NIH ICs -- National Institute of Diabetes and Digestive and Kidney Diseases, National Human Genome Research Institute, National Cancer Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Deafness and Other Communication Disorders, and the National Heart Lung and Blood Institute -- will utilize this facility.

FY 2001 Target: Complete construction.

Performance Assessment – Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Complete 95% of the construction.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation/Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

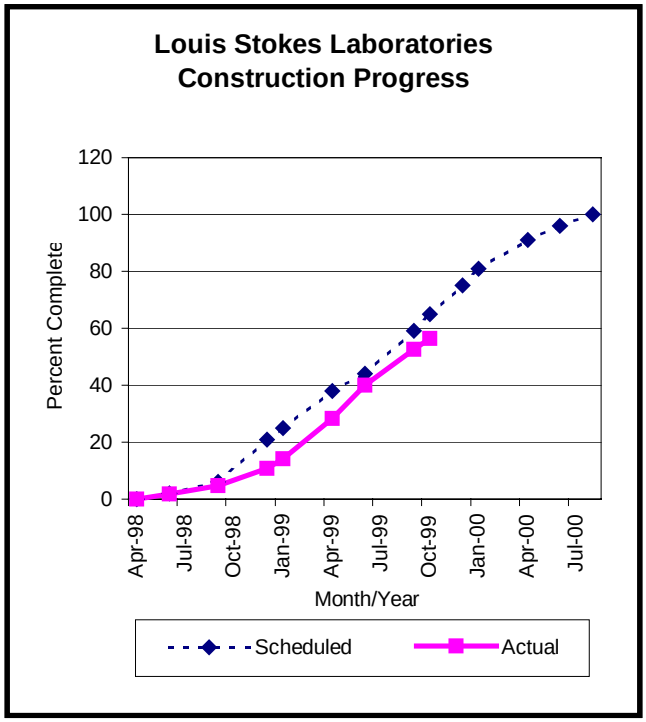
Assessment of FY 1999 Performance

FY 1999 Target: Complete 65% of construction.

Achievement Summary:

- FY 1999 target not met.
- Construction of the Louis Stokes Laboratories (Building 50) was 56.4% complete at the end of FY1999 as compared to the targeted of 65%.

The accompanying chart summarizes the targeted versus actual construction performance levels achieved.



Sources of FY 1999 Assessment Data: ORS Management Information Systems, ISO 9000 procedures, as well as contractor's progress reports, certified invoices approved by the Project Officer, meetings, and site inspections, were used to verify and validate the project's progress.

Discussion of Performance: In FY 1999, there was a 10% deviation from the scheduled construction performance goal. This variation was driven by the need to make space adjustments to support current and projected research requirements. Construction completion is now projected for December 2000 rather than the end of FY 2000. This delay is required to standardize the individual and collaborative research requirements of the various institutes scheduled to occupy the facility.

Next Steps: Completion of the Louis Stokes Laboratories (Building 50) is now projected for December 2000, rather than at the end of FY 2000. We anticipate no long-term impact to the NIH research mission as a result of not meeting the FY1999 short-term construction performance goal. When completed in December 2000, the Louis Stokes Laboratories Building will permit institutes currently occupying inadequate research spaces to relocate to the structure to fulfill their mission of developing cures, new treatment modalities and technologies associated with infectious diseases, immunogenetics, cellular and developmental biology, musculoskeletal and skin diseases, cell biology and other areas.

Goal d) Complete the Mark O. Hatfield Clinical Research Center.

The Clinical Research Center (CRC) will provide 78,965 gross square meters for a 250 bed research hospital, allied clinical facilities, and adjacent laboratories.

FY 2001 Target: Complete 50% of construction

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Complete the superstructure and exterior wall system.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation/Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Assessment of FY 1999 Performance

FY 1999 Target: Complete the design and the first phase of site work.

FY 1999 Achievement Summary:

- FY 1999 target was partially met.
- Design of the Mark O. Hatfield CRC reached the 95% phase in FY1999 reflecting a 5% deviation from the target. Construction for the first phase of the sitework to support the facility was completed on schedule in the 2nd quarter of FY1999 (January 1999).

Sources of FY 1999 Assessment Data: ORS Management Information Systems including the ISO 9000, as well as contractor's project progress reports, certified invoices approved by the

Project Officer, meetings and site inspections, were used to verify and validate the project's progress.

Discussion of Performance: Design reached the 95% phase at the end of FY 1999. The complexity of the facility and the need to respond to newly emerging requirements, delayed completion of this effort. This has provided an opportunity to further enhance the facility to support the collaborative nature of today's and future research.

The NIH was successful in completing the first phase of the sitework for the project. This permits continuation of the building foundation work and erection of the structural support systems, a significant step toward making the facility weather-tight.

Next Steps: The minor delay in the design process will not have a detrimental impact in completing the facility by the end of FY 2002. The duration of the project provides adequate time to make adjustment to construction activities including those on the critical path.

Goal e) Complete the Warren Grant Magnuson Clinical Center Revitalization Program.

The current Warren Grant Magnuson Clinical Center (Building 10) has undergone numerous renovations and expansions in the past. Studies indicate that the major building systems providing critical electrical power, lighting, heating, ventilation, air conditioning, and plumbing services Building 10, vary in age and condition, do not have the capacity to meet the current demands of research, and are at the end of their service life.

Routine maintenance and system repairs cannot keep pace with the vast number of deficiencies and operating inefficiencies in the facility. Construction of the new Mark O. Hatfield Clinical Research Center (CRC) provides a unique opportunity to revitalize Building 10 for adaptive re-use to support NIH's research mission.

This project will reconfigure space in the existing facility to reduce over-crowded conditions, and to satisfy new research initiatives and congressional mandates. Building systems will be replaced to provide adequate capacities, to mitigate potentially unsafe environmental conditions, and to reduce maintenance and operating costs.

Success of the Building 10 Revitalization Program is dependent upon completing the interim construction efforts on various floors of the facility to house administrative and laboratory programs which will remain in Building 10 after the CRC is completed. Without this action, the NIH will not be able to provide safe, efficient and code compliant space to accommodate programs not included in the new CRC, and those which are integral to and support the Building 10 Revitalization Program. Upon completion of the Interim Renovations, Phase I of the Building 10 Revitalization Program can begin. (Note: This is a new goal in FY 2001.)

FY 2001 Target: Start design for the interim renovations and for Phase I of the Building 10 Revitalization Program.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation and Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Goal f) Maintain the quality of the NIH Animal Care Program and construct a Central Vivarium.

Animal Care. For the NIH to fulfill its mission, it is essential that animal care facilities are accredited by the Association of Assessment and Accreditation of Laboratory Animal Care International (AAALAC). It is also crucial that the condition and environment in each facility, is suitable and adaptable to respond to emerging research demands.

Central Vivarium. The existing animal facility complex, Buildings 14/28, houses various animal species to support the research requirements for the Institutes on the Bethesda Campus. The sprawling nature of the complex, the over 40 year age of each structure, the facility conditions, and the limited capabilities of the infrastructure, have driven the need for significant renovations and upgrades.

It is crucial that a modern, compact, state-of-the-art central vivarium be provided to consolidate ongoing programs into efficient, effective, and well-functioning space to respond to current and emerging research needs for animal modeling.

The new Central Vivarium is also necessary to permit the removal of the Building 14/28 Complex to support future development of the southern quadrant of the campus consistent with the recommendations of the approved NIH Facilities Master Plan.

Construction will provide central utilities, site infrastructure animal holding, receiving and quarantine areas, procedure rooms, specialized laboratories, administrative support spaces and the necessary mechanical, electrical and other utility systems to comply with AAALAC accreditation guidelines and other applicable building codes and regulations.

FY 2001 Target: Award a construction contract for the sitework and foundation for a Central Vivarium facility on the NIH Bethesda campus as design is being completed.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Target: Begin design for the Central Vivarium sitework and foundation, and the programming effort for the facility.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation and Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Assessment of FY 1999 Performance

FY 1999 Target: Receive accreditation from the Association of Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Achievement Summary:

- FY 1999 target met.

- AAALAC surveyors conducted a site visit of the NIH during the week of July 26, 1999. NIH received confirmation of Deferred Continued AAALAC accreditation based on the recommendations in this site visit.

Sources of FY 1999 Assessment Data: A letter from AAALAC confirms accreditation. The AAALAC site visit report recommended necessary program enhancements. Each of them is being reviewed and will be used as guidelines for continuous improvements to the NIH Animal Care Program.

Discussion of Performance: The final accreditation decision is not expected until the third quarter of FY 2000, after NIH responds to the program enhancements recommended in the site visit report.
The establishment of dedicated program management and implementation teams will greatly enhance NIH's success in managing the operations of the animal care and use program.

Next Steps: Specialized management teams will remain focused on AAALAC accreditation and compliance programs to provide high quality services to the NIH research and scientific community. The results of the accreditation decision will help shape NIH's continuous goal to remain fully accredited, provide the optimum facility environment, and the right level of resources at the right time to support advancements in biomedical research. The end objective remains to facilitate improvements to the health of all Americans and peoples of the world.

Goal g) Construct a Neuroscience Center on the NIH Bethesda Campus.

NIH is committed to the creation of the National Neuroscience Center at NIH. Currently, the neuroscience program at NIH is dispersed among several ICs. Scientists are segregated in one or more pre-clinical departments, removed from colleagues in clinical departments of neurology, psychiatry, neurosurgery, or anesthesiology. Elimination of these artificial barriers would create an environment where scientists focused on fundamental and clinical research could better collaborate and more quickly translate there findings into effective therapies for neurological and psychiatric disorders. Furthermore, nearly all of the space currently housing NIH neuroscience programs is not suitable for today's research standards. No major renewal in buildings housing neuroscience research has occurred in 30 years except in one structure. The major core facilities available to NIH neuroscientists have not kept pace with technological breakthroughs in genetics and imaging.

Most of the cellular and molecular neuroscience on campus is conducted in Building 36, which is located in the southwest section of the Bethesda campus. Most of the laboratories in the facility are partitioned into small modules which are separated by concrete walls that will not support collaborative research. The facility lacks shared equipment rooms, common areas for laboratory meetings, library facilities, seminar rooms, and space for ongoing scientific discourse. Building 35, a one story structure, adjacent to Building 36, would be demolished and replaced with a 200,000 square foot modern laboratory. After Building 35 is completed, Building 36 would be vacated, renovated, and expanded. (Note: This is a new goal in FY 2001.)

FY 2001 Targets: (1) Complete design by the Spring of 2001

(2) Award a construction contract by the Summer of 2001.

Basis and Data: The Office of Research Services will use its Management Information Systems to document, monitor, and track the schedule and cost of providing this facility.

Validation and Verification: ORS Management Information Systems will be used to capture planned and actual project schedules and budgets. ISO 9000 (an internationally recognized collection of quality system standards which sets requirements for an efficient system of management), as well as contractor's project progress reports, meetings and site inspections are being used to verify and validate accomplishment of project goals. In addition, contractors are required to certify when they submit invoices that the work has been completed and the sign-off by the Project Officer is also a certification that the work has been completed before payment is made.

Goal h) Utilize a systematic process to manage and account for NIH's Real Property Inventory.

The NIH research mission is supported by over 200 facilities in its real property inventory. To respond to a recent Chief Financial Officer's report on how the accounting of its numerous facilities is managed, NIH has embarked upon the use of a uniformly recognized real property management tool, called Foundation Information for Real Property Management (FIRM). This system provides essential accounting and reporting tools to satisfy auditing requirements and the overall mission of the NIH. (Note: This is a new goal in FY 2001.)

FY2001 Targets:

(1) Provide FIRM online monitoring and reporting capabilities at the desk of each stakeholder involved with real property management.

(2) Validate the NIH real property inventory and populate the FIRM database with the appropriate facility descriptive information, size, function, initial cost and replacement cost.

(3) Launch a one year pilot program for FIRM and integrate the lessons-learned into NIH's formalized accounting and reporting procedures for real property management.

Basis and Data: Documented implementation of the pilot program for FIRM. Reports will be generated to validate the accuracy and completeness of database for each NIH facility. Evaluations will be conducted by the cognizant NIH CFO to assure that this tool is used efficiently and effectively for the NIH to conduct its business.

Validation and Verification: After the pilot project has been completed there will be an assessment of the FIRM project against specific criteria to determine if the management tool met the goals established. If the decision is made for full implementation, an implementation plan will be developed and completed. After the new process has been operating for several months, as assessment will be made to determine if the goals are being met NIH-wide. This will provide verification that the system is operating properly.

2.3.2.2 Extramural Assistance

Biomedical research facilities are a critical component of the nation's science and engineering research infrastructure. The availability and condition of biomedical research space directly affects the scope and quality of the biomedical research conducted at the nation's colleges, universities, medical schools, hospitals, and other research organizations.

NIH's extramural research facilities construction programs work to address this important need for more biomedical research facilities. The broad priorities for these programs are:

- Respond to requests from the extramural research community for financial assistance in undertaking research facility modernization and construction.

- Conduct critical reviews to ensure that the construction of such facilities are safe and appropriately designed to enable the conduct of high quality research.

NIH is authorized under the Public Health Service Act, Title IV, Section 481A "Modernization and Construction of Facilities" to "make grants to public and non-profit private entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities" for biomedical and behavioral research and research training.

Under the NIH extramural research facilities construction programs, construction grants for extramural research facilities support the costs of design, renovation, and construction of non-federal basic and clinical research facilities. These grants address the biomedical and behavioral research, research training, or research support needs of an institution or a research area at an institution. Facility construction that may be supported under this program includes construction of new facilities, additions to existing buildings, completion of uninhabitable "shell" space in new or existing buildings, and major alterations and renovations. This "bricks & mortar" modernization and replacement of existing research facilities provides new capabilities that can open areas to innovative research activity.

NIH collaborates with the National Science Foundation in conducting a biennial survey to assess the condition of existing facilities nationwide and to identify needs for new and refurbished research facilities. The survey provides the major source of objective data for national research infrastructure policy and planning needs. The 1998 survey determined that construction/renovation projects totaling $11.4 billion were needed at scientific and engineering research facilities at colleges and universities but were deferred due to lack of funds. In recognition of these findings, NIH offers funding opportunities, on a competitive basis.

The number of extramural research facility construction awards that NIH makes varies from year to year. This is dependent both on the level of funds provided by Congress and on the number of applications received that are deemed scientifically meritorious. For example, in FY 1999, 31 awards for a total of $29.6 million were made and in FY 1998, 22 awards for a total of $20.6 million were made.

Each construction grant application undergoes a two-tiered peer review. First, an NIH scientific and technical peer review group evaluates applications for scientific and technical merit. Next, the National Advisory Council or Board of the Institute or Center conducts a second level of review. Reviewers evaluate applications to determine how the proposed change in the research environment would facilitate the applicant institution's ability to conduct, expand, improve, or maintain biomedical research. It is through this two-tiered peer review process that NIH ensures that awarded construction grants have high scientific and technical merit and meet the changing needs of the research environment.

Applicants must ensure the availability of matching funds for the construction project. Then, when a grant is awarded, NIH must approve the construction designs before construction may begin. The designs are reviewed by engineers at NIH and must meet applicable codes before approval. Review by the engineers, who have expertise in the design of biomedical facilities, also helps to ensure that the facility will be designed in a way that maximally supports biomedical research.

NIH does not have oversight responsibility over a grantee's completion of a construction project. However, if the project is not completed within the designated timeframe, usually five years, the awarded funds revert back to the federal government. In order to encourage project completion and to review whether the construction is following the approved designs, NIH may conduct site visits during construction and/or after project completion.

Performance Goals Summary Table – Extramural Assistance

Performance Goals	FY Targets	Actual Performance	Details
a) Approve construction designs that are in compliance with federal and NIH design regulations and guidelines, and with other relevant local, national, and international codes and standards.	***FY 2001 Target*** (1) Final construction design documents approved for 100% of grants awarded in FY 1998. (2) Final construction design documents approved for 50% of grants awarded in FY 1999. (3) Final construction design documents approved for 25% of grants awarded in FY 2000. ***FY 2000 Target*** (1) Final construction design documents approved for 100% of grants awarded in FY 1997. (2) Final construction design documents approved for 50% of grants awarded in FY 1998. (3) Final construction design documents approved for 25% of grants awarded in FY 1999. ***FY 1999 Target*** 100 % of awarded construction projects meet federal and NIH safety and architectural design regulations and are in compliance with the scope of the application.	FY 2001: To be reported in January 2002. FY 2000: To be reported in January 2001. **FY 1999 target partially met.**	Page 248

Performance Goal Details - Extramural Assistance

Goal a) **Approve construction designs that are in compliance with federal and NIH design regulations and guidelines, and with other relevant local, national, and international codes and standards.**

As discussed earlier, the impact of NIH's extramural research facilities grants programs is directly influenced year-to-year by both the number of applications that NIH receives from the extramural research community and by the funds that the Congress makes available. Accordingly, the most meaningful way to measure the success of this program is to track the number of awards that have had their final construction designs approved.

New and emerging biomedical research cannot be performed without well-designed facilities to develop and use cell cultures, new animal strains, therapeutics, and vaccines. To protect the public, specially designed biocontainment facilities are required to isolate, contain, and investigate infectious and other potentially hazardous agents. Furthermore, research laboratories are sophisticated and complex environments that must be specially designed to meet the demands of experimental study, testing, and analysis, and to meet the requirements for a safe environment for personnel and the public. This double mission means that laboratories must provide levels of safety, space conditioning, and indoor air quality well above that maintained in conventional office buildings. A research laboratory's environmental conditioning system must provide protection and comfort for the occupants of the laboratory building, including those in associated non-research space.

After a construction application is awarded, but before construction may begin, another review is conducted to ensure the facilities are designed in accordance with federal and NIH design regulations and guidelines and with other related local, national, and international codes and standards. Depending on the nature of the project, the construction applicant may be required to submit up to three sets of designs: schematic design, design development, and final construction design. The applicable design documents must be approved before construction may begin.

Generally, the total project period for construction grants may be up to five years. The time between award and the approval of final construction design documents may take several years and is contingent on the grantee submitting satisfactory designs. Since awards are made towards the end of the fiscal year, the earliest approval of the final construction design documents is not possible until the next fiscal year.

Target percentages for the fraction of applications with final construction design approval are listed below that are based on a good management rule-of-thumb for this program.

FY 2001 Targets: **(1) Final construction design documents approved for 100% of grants awarded in FY 1998.**

(2) Final construction design documents approved for 50% of grants awarded in FY 1999.

(3) Final construction design documents approved for 25% of grants awarded in FY 2000.

Performance Assessment -- Basis and Data and Validation/Verification information is the same as for FY 2000 below.

FY 2000 Targets: **(1) Final construction design documents approved for 100% of grants awarded in FY 1997.**

(2) Final construction design documents approved for 50% of grants awarded in FY 1998.

(3) Final construction design documents approved for 25% of grants awarded in FY 1999.

Basis and Data: The engineers who review the construction designs transmit an approval letter to the Institute or Center when the final construction design documents are approved. Issuance of this approval letter for each grant is the primary measure of achievement for this target.

Validation and Verification: The final construction design approval letter for each grant is contained in the official grant files.

Assessment of FY 1999 Performance

FY 1999 Target: **100% of awarded construction projects meet federal and NIH safety and architectural design regulations and are in compliance with the scope of the application.**

FY 1999 Achievement Summary:

- Target partially met. One hundred percent of the grants awarded in FY 1996-1999 received scientific peer review and concurrence. However, only 43.3% received engineering design review and approval. (See table below.)

- However, as discussed more fully below, this target could not have been met within the fiscal year and should not have been set as it was in the FY 1999 Annual Performance Plan.

Accordingly, corrective adjustments have been made in the performance plan for FY 2000 and beyond.

Summary results for the three indicators are listed in the accompanying table.

		Indicators		
Fiscal Year	**# Grants Awarded**	**# with Priority Score**	**# with Council/Board Concurrence**	**# with Design Approval**
1996	22	22	22	20
1997	22	22	22	17
1998	22	22	22	5
1999	31	31	31	0
TOTAL	97	97	97	42
% of Indicator to # Grants Awarded		**100%**	**100%**	**43.3%**

Assignment of a priority score indicates that the grant was reviewed by an NIH scientific peer review group and concurrence from the Council or Board indicates that the second level of the two-tier review was conducted. Both of these indicators ensure that the proposed construction will create needed biomedical research space. Approval of the final construction designs indicates that the designs were reviewed and approved by engineering experts. Together, these three indicators were used to demonstrate that each construction award meets federal and NIH safety and architectural design regulations and are in compliance with the scope of the original application that was submitted.

Sources of FY 1999 Assessment Data: The priority scores and concurrences are contained in the NIH IMPAC System and the design approval letters are contained in the official grant files.

Discussion of Performance: The reason that the goal was not met was because the target did not appropriately take into account the timing/operational realities of the program. Approval of 100% of the construction designs for the grants awarded during FY 1996-1999 was not possible because most of the construction awards are made in September, the end of the fiscal year. This means that most of the grantees who received their awards in FY 1999 did not have sufficient time to develop, submit, and receive approval of their designs before the end of the fiscal year. The grantee often must have three different levels of designs approved before final approval is given. Depending on the complexity of the designs, it may take a grantee more than one year to receive final construction design approval.

To more accurately measure the success of the program, the FY 1999 target should have been structured like the targets for FY 2000 and 2001. If this had been done, the following would have been the FY 1999 targets:

(1) Final construction design documents approved for 100% of grants awarded in FY 1996.
(2) Final construction design documents approved for 50% of grants awarded in FY 1997.

(3) Final construction design documents approved for 25% of grants awarded in FY 1998.

The results for these three targets, had they been used, are summarized in the adjacent table and as follows:

Results Based on Revised Targets			
	Target 1 FY 1996	**Target 2 FY 1997**	**Target 3 FY 1998**
# Grants Awarded	22	22	22
# Designs Approved	20	17	5
% Designs Approved	91%	77%	23%
Targets	**100%**	**50%**	**25%**

Target (2) would have been met and Targets (1) and (3) would have mostly been met. Although two out of three of the targets would not have been met, these targets are a better measure of the program's success and can be used to identify areas in which there is room for improvement.

Next Steps: For FY 2000 and beyond, the goal and targets have been restructured to better reflect the operational realities of the program. Since the data on priority scores and concurrences demonstrates process oriented goals and will always be 100%, these indicators will not be used in the future. The number of grants that have received construction design approval is a much more relevant indicator of the program’s overall achievement.

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Appendix 1

Approach to Performance Assessment

Assessment and Reporting

NIH's Annual Performance Plans include both 1) performance goals that can be assessed through objective/quantitative measures and 2) performance goals that reflect descriptive performance criteria.

Where objective/quantitative measures can be used, performance assessment is a process, principally, of directly comparing data on actual achievement with the stated target levels. The majority of NIH performance goals are of this form.

Where such measures are not available, GPRA also provides an avenue for an agency to define performance goals that rely on criteria which are more nearly descriptive in nature. Although, the law's expectation in this case is that an assessment process will be implemented that is systematic, unbiased, and able to meet a test of independent confirmation.

Objective/Quantitative Performance Goals.

The vast majority of the performance goals in the Plan have objective/quantitative targets. In most cases, data will be provided in the performance report to allow a direct comparison between the performance goal and the actual performance level. Or, in those cases where the goal is to complete an action, data will be provided that demonstrates that the action has been completed. Where a performance goal is not met, a discussion of why the goal was not met will be provided. Additionally, revised plans or schedules for meeting unmet goals will be identified, unless it is determined that it is infeasible to meet the goal.

The specifics on the data sources underlying performance assessment vary by the goal, and the details are discussed goal-by-goal in Part II of this document. Generally, however, the data for assessing objective/quantitative performance goals will come from a variety of sources at NIH.

Data Tracking and Collection Systems - Most performance comparisons for quantitative goals will be based on data from information systems that are designed to track a particular operation.

For example, the table below identifies some of the data systems that are currently used at NIH to track and develop data for performance comparisons.

System	Purpose	Types of Data
IMPAC (Information for Management, Planning, Analysis, and Coordination)	IMPAC is a comprehensive database covering NIH's extramural research activities.	• Records of research contracts • Records of in-process grant applications • Inter- and intra-agency agreements
CRISP (Computer Retrieval of Information on Scientific Projects)	CRISP is a searchable database (maintained by NIH) of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions.	• Abstracts and indexing terms for funded research projects
PRTS (Purchase Request Tracking System)	A comprehensive online data system for NIH managers/administrator to initiate and track purchase requests to vendors.	• Purchase request details • Sources, competition, and P.O. clearance • Delivery status
Edison	Edison supports a "common face" for invention reporting by federal grantees and contractors. (Edison now operates among several federal agencies, but was pioneered at NIH.) Edison provides technology for NIH (and other federal agencies) to manage extramural invention portfolios in compliance with federally mandated invention reporting requirements.	• Invention disclosures • Patents • Licenses • Invention utilization

Completion of Studies/Actions - Where a goal is to complete an action (e.g., respond to a recommendation) categorical (descriptive) indicators will be provided that will confirm the completion or status of the project. Examples of studies and reports that will be useful for GPRA reporting include those developed by and for the use of peer review and advisory councils and other distinguished independent panels and committees, to help chart scientific directions and select the most promising research to support.

Program Evaluation Activities - Objective evaluation is already a well established component of NIH's regular planning and management activities for most of its programs. Such studies are often used to provide basic data on program performance, identify avenues for program improvement, and consider the implications of emerging issues on program operation. NIH also conducts a number of special evaluation studies in conjunction with such agencies as the National Academy of Sciences and the National Science Foundation -- such as large scale, long-term studies of scientific personnel and training needs, research facilities and research instrumentation.

Information from ongoing and planned program evaluation studies will be used where relevant for GPRA assessment. Some evaluations will be initiated particularly for GPRA assessment purposes.

Descriptive Performance Goals for Research Outcomes.

Agency missions directed primarily at advancing basic science face unique challenges in relying on only the objective/quantitative performance goals preferred under GPRA. It is neither feasible nor sufficient to capture the breadth and impact of such research outcomes through entirely numeric goals and measures. Therefore, quantitative assessment cannot adequately portray the effectiveness of the performance of NIH's research program.

The Challenge of Measuring Research Performance - Conventional scientific research metrics (e.g., publications, citations and patents) gauge only some dimensions of research output. These measures provide relevant data, but they are insufficient for generating a full picture of the overall research program. As the President's Office of Science and Technology Policy and the numerous others who have studied the processes of science, technology, and innovation over many years have commented, the linkages between inputs and outputs in science are complex and non-linear. Outcomes are usually very difficult to foresee with any degree of accuracy. The full value of any given research finding is usually only barely visible at the time of discovery, and reaches a state of fruition often only after many years or in combination with other advances. Furthermore, the downstream impact of basic research is usually dependent on substantial further development of new knowledge by private industry, other public sector researchers, or other economic actors.

Intermediate versus Ultimate Outcomes - The ultimate outcomes of medical research are, of course, improved health, longevity, and quality of life for all Americans. Each year the NIH can document a number of major medical "culminations" that are visible as practical health benefits, and are often accompanied by economic benefits.

In the recent past, for example, NIH-supported research culminated in the first successful treatment for acute ischemic stroke, using recombinant tissue plasminogen activator (tPA). It has also contributed to the declining mortality rates for many cancers, including some common ones, and to a reduction in disability rates among the elderly. Additionally, while we do not yet know exactly how the human immunodeficiency virus (HIV) causes AIDS, we have learned enough crucial information about HIV to develop effective therapies for patients with AIDS. The results of efforts by government, academic, and industrial scientists are the drug combinations that can markedly improve and extend the lives of many people infected by HIV.

Nevertheless, the more numerous and immediate outcomes of the Nation's investment in medical research are the incremental findings and accomplishments that increase our knowledge of fundamental life processes. These "intermediate" advances provide building blocks for future medical culminations. For example, a detailed map of portions of the human genome was recently assembled and posted on the Internet. This easily accessible map provides the latest research information about genes and their function in both health and disease in a well organized and easily understandable manner. It provides scientists and medical personnel, as well as students and the public with a window of progress on one of the most extraordinary scientific undertakings of our century—the mapping of the human genome. Although it is only partially complete, the mapping project has already advanced our understanding of the genetic

basis of many diseases by significantly accelerating a number of disease gene hunts. The map was instrumental, for instance, in locating and isolating genes responsible for Alzheimer's disease, inherited colon cancer, a bone growth disorder resulting in short stature, and a congenital digestive disorder.

None of these intermediate accomplishments directly and/or immediately improve human health. They are, however, essential research steps which inspire and enable further work that will lead to improved understanding, diagnosis, treatment, and prevention of human disease -- and are the expected outcomes of NIH's mission.

Assessment of Descriptive Data

Descriptive data provide much of the necessary context for assessment of NIH's Research Program. Narrative descriptions of research accomplishments outline a specific research advance within the context of what was previously known and unknown about the topic; the scientific and/or medical significance of the research area and the accomplishment; the research that will follow from the finding; potential applications of knowledge from the research, if known; and potential economic implications of the advance, if known. This information provides a perspective for where an advance fits in within the continuum of medical research, and its potential contribution to understanding and improving human health.

Independent Review Process. Agencies whose missions include basic and clinical research face unique challenges in developing the objective/quantitative performance goals preferred under GPRA. The NIH has concluded that strictly numeric goals and measures are neither feasible nor sufficient to capture the breadth and impact of NIH's Research Program. The GPRA anticipated such situations and provides an avenue for an agency to define performance goals that rely on criteria which are descriptive in nature. In such situations, the GPRA requires the agency to develop an independent review process for assessing performance related to qualitative goals. For NIH, this applies to five of its seven Research Program outcome goals:

- Add to the body of knowledge about normal and abnormal biological functions.
- Develop new or improved instruments and technologies for use in research and medicine.
- Develop new or improved approaches for preventing or delaying the onset or progression of disease and disability.
- Develop new or improved methods for diagnosing disease and disability.
- Develop new or improved approaches for treating disease and disability.

In compliance with the GPRA, NIH developed an independent assessment process for evaluating the outcomes resulting from its Research Program, comparing these outcomes with the qualitative performance goals for the Research Program, and reporting on the status of NIH achievement of these goals. In the broadest of terms, the assessment involves gauging the extent

to which NIH's stewardship of the medical research enterprise leads to important discoveries, new knowledge, and improved techniques that are applied to the development of new or improved diagnostics, treatments, and preventive measures.

FY 1999 Assessment Materials. The assessment material for review in FY 1999 was prepared by the NIH Institutes and Centers (ICs). Each IC was asked to provide 10-20 science advances, 10-20 science capsules, and 1-2 Stories of Discovery. The ICs were also asked to "code" the scientific narratives as to the primary and secondary GPRA goal that they address. The narratives were sorted among the five qualitative GPRA Research Program goals and the awards/honors were placed in a separate section in the assessment notebook. The assessment material spanned nearly 500 pages and included almost 600 advances, capsules, and stories of discovery.

The assessment material consisted of four types of narratives, that together provide an extensive–but by no means exhaustive–illustration of NIH's research outcomes that address the qualitative Research Program performance goals:

- *Science Advances*. Purpose: to describe a specific scientific discovery published within the past year and supported by NIH funding, to place it in the larger context of what is known and unknown, and to describe the significance of the finding to science, health, and/or the economy. Science advances are one-page narratives that contain a descriptive title, a background section, a description of the advance, a discussion of the significance or implications of the advance, and citations of the scientific publications that support the advance. The actual published articles were not provided as part of the assessment materials, but were available upon request and at the Working Group meeting.

- *Science Capsules.* Purpose: to provide a snapshot of the breadth and scope of NIH Research Program outcomes. There are obvious limitations to the sheer number of detailed, one-page science advances that the Working Group members could be expected to review and assimilate. Science capsules are the "Cliff notes" version of science advances, consisting of a short paragraph that succinctly captures an advance and its significance, as well as citations.

- *Stories of Discovery*. Purpose: to address the major limitation of traditional science advances–the fact that they address a single, incremental finding. Biomedical progress is usually achieved through long-range investments in research; advances usually occur slowly and incrementally, often build upon one another, and sometimes have applications to seemingly unrelated areas of medicine. Stories of discovery are 1-2 page narratives that focus on one topic. Each story traces the major developments in that area over several decades. Important connections between advances in science and improvements in the quality of life, health, and health care, as well as any resulting economic benefits are also highlighted.

- *Research Awards/Honors.* Purpose: to demonstrate outside evaluation and recognition of the value of NIH Research Program outcomes. The award write-ups are brief descriptions of

national and international scientific awards/honors received by NIH scientists and grantees within FY99. The brief narratives identify the researcher(s) and the award, describe the work being honored, and the significance/purpose of the award.

Data Verification and Validation

The vast majority of NIH's performance goals contain quantitative or otherwise objective targets. In most all cases, the basis for performance demonstration will involve data that are uncontroversial, credible, and open to independent public scrutiny. The strengths and weaknesses of particular data sources in preparing the annual performance assessments necessarily vary by the performance goal. These issues are reviewed, as they arise, in the commentary on performance assessment plans that accompanies each performance goal in Part II. Where there is warranted concern about the limitations of a data series for a particular evaluation task, it is identified in the course of this discussion.

NIH has established and maintains many large scale databases to meet its ongoing management needs (such as IMPAC - see earlier above) or with other federal agencies (such as Edison - see earlier above). These databases play a role in the agency's GPRA performance assessment process. In general, these are public databases, created over a number of years, through competitive proposals and subject to outside review of knowledgeable experts, and are maintained through standard data quality protocols. These data are widely regarded, within and outside of NIH, as providing a credible picture of various aspects of the nation's biomedical research enterprise.

Performance assessment for NIH's research outcome goals poses unique challenges in data validation and verification. This matter has been discussed earlier in this section. Virtually all of the outside advisory groups that have looked at this issue over the last several years (e.g., OSTP, National Academy, Office of Naval Research, various other science agencies) have affirmed the centrality of peer review by technical experts in developing findings about the productivity of basic research programs. The process envisioned by NIH to prepare the annual assessments of its research goals - also discussed earlier - relies chiefly on such a peer review process. The review committee will be include individuals outside of NIH with appropriate expertise, to assure both objectivity and sound findings.

Finally, performance assessment for some goals will involve completion of special program evaluation studies. Such work is often conducted at NIH through outside contractors, who can bring particular expertise to bear on the analytical issues at hand. Contracts for such efforts are typically awarded through competitive proposals and subject to technical review, both pre-award and with draft final report in hand.

Appendix 2

Changes and Improvements Over Previous Year

Many key aspects of NIH's FY 2001 Annual Plan/Report parallel the FY 1999 and 2000 Annual Plans -- including organization according to three Core Programs (Research, Research Training & Career Development, and Research Facilities), trans-NIH aggregation of programs, and performance goals that address both program outcomes and the process means (e.g., priority setting, grants administration) through which NIH's programs are implemented.

Nonetheless, a number of changes and improvements have been introduced in the FY 2001 document to benefit from the agency's learning in prior fiscal year Plan, to provide greater focus and supporting information, to respond to the evolving guidance from DHHS, OMB, and others on the most useful content, and, importantly, to provide the Annual Assessment Report for FY 1999 goals and targets.

Changes and Improvements in the Format of the FY 2001 Plan

Presentation of Three Years of Data. The present document contains material covering: final statements of performance goals/targets for FY 2001, revised final goals/targets for FY 2000, and performance assessment information for the final goals/targets in FY 1999 (as listed in the FY 2000 Annual Plan).

DHHS Standardized Format. DHHS has directed that all OPDIVs submit their FY 2001 Annual Plans/Reports in a common format. This action was taken by the Department in response to comments from outside reviewers, such as OMB and GAO, who had a difficult time making cross-comparisons among the OPDIVs' plans due to wide differences in format. The new format involves mandatory section headings, more background and explanatory information, and greater detail on the means and strategies through which program achievement is pursued.

Integration of Annual Plan and Annual Performance Report. All federal agencies subject to GPRA are mandated to submit an annual performance assessment report comparatively soon after the close of the fiscal year. As a part of the standardized format, DHHS has concluded that integration with the Annual Plan is the most efficient way to provide this assessment information and has directed that all OPDIVs submit FY 1999 report and assessment findings along with their "final" Annual Plans for FY 2001.

Improvements in goals and related targets. As part of our annual review of performance goals and targets, it was noted that some goals could be clearer by either combining them with other goals or splitting them into more than one goal. Additionally, to reduce confusion between outcomes and output goals versus goals for outcomes and goals for means, "Outcomes"

performance goals sections with an "Outcomes" label were either renamed, or the goals within the section moved to another appropriate section. In the latter case, the section was then eliminated. These changes were made solely for clarity of presentation. In no instances were FY 1999 targets changed or eliminated.

The following table summarizes the changes/improvements made performance goals for each program.

Summary of Goal/Target Changes and Improvements Over the Prior Year

Table identifies significant changes in the FY 2001 Plan compared to the "final" FY 2000 Plan, published February 1999.

Program/Section	Summary of Changes/Improvements
Research Research	• **FY 2001** – 7 performance goals with active targets. • **FY 2000** – 7 performance goals with active targets. • **FY 1999** – 7 performance goals with active targets. Changes and Improvements in FY 2001 Annual Plan/Report: No changes in the essential thrust of the FY 2000 goals. The section has been re-titled as "Research" – listed previously as "Outcomes." Goal f): The targets in FY 2001 and FY 2000 have been updated to reflect the rapid progress in genome research in FY 1999.
Research Communication of Results	• **FY 2001** – 6 performance goals with active targets. • **FY 2000** – 6 performance goals with active targets. • **FY 1999** – 6 performance goals with active targets. Changes and Improvements in FY 2001 Annual Plan/Report: The main thrusts of this program remain largely as charted in FY 2000 and 1999. However, there has been an extensive reorganization and restatement of the goals and targets stated in the "final" FY 2000 Plan (February 1999) to better reflect program priorities and an outcomes orientation. Even so, all previously published FY 1999 targets are retained as stated. The "final" FY 2000 Plan contained a goal (e) addressing the widespread application of information technologies. In light of the role these technologies play widely across NIH's communications activities, this goal has been deleted in the FY 2001

Program/Section	Summary of Changes/Improvements
	Plan, but all the existing FY 2000 and 1999 targets have been reallocated to the other goals where they most directly fit. Similarly, the "final" FY 2000 Plan contained a goal (b) addressing evaluation issues for various communications programs. In light of the centrality of performance evaluation to all goals in this program, this goal was eliminated in the FY 2001 plan and all the existing FY 2000 and 1999 targets have been reallocated to the other goals as appropriate. Goals a), b), c) – These reflect a splitting of the FY 2000/1999 goal a) into three separate goals according to major user populations. The goals have also been restated to better focus attention on the intented outcome, namely enhanced awareness in the user populations. Goal d) – No changes in thrust, but the FY 2000 targets have been restated in places to clarify the activities involved. Goal f) – No changes in thrust, but the FY 2000 targets have been enlarged and restated, on "revised final" basis, to better reflect the ongoing activities related to this goal.
Research Technology Transfer	• **FY 2001** – 3 performance goals with active targets. • **FY 2000** – 3 performance goals with active targets. • **FY 1999** – 3 performance goals with active targets. <u>Changes and Improvements in FY 2001 Annual Plan/Report</u>: No significant changes in essential thrust of the goals over FY 2000. However, the five goals and associated targets in the FY 2000 Plan have been re-organized into three goals and targets to better present main program management themes. One new goal has been added for FY 2001. Goal a) – Statement of the goal has been simplified. But no change in associated targets. Goal b) – Represents a composite of three separate but substantively similar goals in the FY 2000 Plan. Goal c) – New in FY 2001 Goal d) – Completion expected in FY 2000 and does not have subsequent targets.
Research Priority Setting	• **FY 2001** – 2 performance goals with active targets. • **FY 2000** – 2 performance goals with active targets. • **FY 1999** – 3 performance goals with active targets. <u>Changes and Improvements in FY 2001 Annual Plan/Report</u>:

Program/Section	Summary of Changes/Improvements
	No basic change in thrust, but Goal a) in the FY 2000 Plan has been split into Goals a) and b) in the FY 2001 Plan, to more clearly identify separate activities. Goal b) – An additional target has been added in FY 2000, on a revised final basis, to include an important ongoing activity.
Research Grants Administration and Peer Review	• **FY 2001**- 4 performance goals with active targets. • **FY 2000** - 5 performance goals with active targets. • **FY 1999** - 8 performance goals with active targets. <u>Changes and Improvements in FY 2001 Annual Plan/Report</u>: No changes in essential thrust of goals from previous years. Goals a) and b) – Reflects an explicit separation of two targets that were combined under a single Goal in the FY 2000 Plan. Goals a), b), and c) – Completion expected in FY 1999. Goal c) – Statement of goal has been refined from that in the FY 2000 Plan. Goal g) – FY 2000 target has been modified on "revised final" basis to account for changes in management's approach to achieving process improvements. Goal h) – Completion expected in FY 2000 and does not have subsequent targets.
Research Management and Administration	• **FY 2001** – 11 performance goals with active targets. • **FY 2000** – 11 performance goals with active targets. • **FY 1999** – 11 performance goals with active targets. <u>Changes and Improvements in FY 2001 Annual Plan/Report</u>: No change in essential thrust of the goals from previous years. Goal f) – FY 2000 target has been restated, on "revised final" basis, to facilitate better measurement of target achievement. Goal i) – New goal with targets in both FY 2001 and 2000 (inserted on "revised final" basis). Goal l) – Goal has been restated from what is in FY 2000 Plan to better focus on outcomes measurement. Goal n) – Goal redefined to include continuing effort and management targets beyond FY 1999. Goals h and j) – Completion expected in FY 1999 and do not have subsequent targets.

Program/Section	Summary of Changes/Improvements
Research Training and Career Development Training Support	• **FY 2001** – 4 performance goals with active targets. • **FY 2000** – 3 performance goals with active targets. • **FY 1999** – 4 performance goal with active targets. Changes and Improvements in FY 2001 Annual Plan/Report: The FY 2000 Plan's distinction between "Outcome" and "Means" goals has been eliminated. All training support goals have been combined into the present section. No changes in the essential thrust of the prior year's goals for this program. Goal a) – Statement of the goal has been revised to bring it better in line with what the program actually manages. Goals c) and d) – Some revisions in the FY 2000 targets have been introduced on a "revised final" basis, as a result of review commentary and mid-year progress assessment for FY 1999.
Research Training and Career Development Outreach	• **FY 2001** - 2 performance goals with active targets. • **FY 2000** - 2 performance goals with active targets. • **FY 1999** - 2 performance goals with active targets. Changes and Improvements in FY 2001 Annual Plan/Report: The FY 2000 Plan's distinction between "Outcome" and "Means" goals has been eliminated. All outreach goals have been combined into the present section. No change in essential thrust of the goals from previous years.
Research Facilities Intramural Modernization and Maintenance	• **FY 2001** – 6 performance goals with active targets. • **FY 2000** – 5 performance goals with active targets. • **FY 1999** – 5 performance goals with active targets. Changes and Improvements in FY 2001 Annual Plan/Report: Intramural facilities goals listed as either "outcomes" or "means" in the FY 2000 and FY 1999 Annual Plans have been combined into the present single category. No changes over FY 2000 in the essential thrust of the goals. Goals b), c) – Completion expected in FY 2000 and do not have subsequent targets. Goals e), g), h) – New in FY 2001.

Program/Section	Summary of Changes/Improvements
Research Facilities Extramural Assistance	• **FY 2001** - 1 performance goal with active targets. • **FY 2000** - 1 performance goal with active targets. • **FY 1999** - 1 performance goal with an active target. <u>Changes and Improvements in FY 2001 Annual Plan/Report</u>: Extramural facilities goals listed as either "outcomes" or "means" in the FY 2000 and FY 1999 Annual Plans have been consolidated into the present section. Goal a) – Reflects the integration of what were two separate goals in the FY 2000 Plan. The multiple targets now incorporated for FY 2001 and 2000 provide a better match with ongoing program management parameters. The previously published FY 1999 goal is retained as the FY 1999 target.

Appendix 3

Linkage to the DHHS and OPDIV Strategic Plans

NIH's Core Programs (Research, Research Training and Career Development, Facilities) broadly support goals and objectives articulated in the Department of Health and Human Service's (DHHS) Strategic Plan (1997). Principle linkages occur under Goal Six, *Strengthen the Nation's Health Sciences Research Enterprise and Enhance Its Productivity*, where NIH research is a key element. (See Objectives 6.1, 6.2, 6.6 and 6.7 below.) However, NIH's research, training, and facilities activities also contribute to many other of the Department's more than thirty strategic objectives.

DHHS's *FY 2000 Performance Plan Summary* (1998) identifies NIH research, training, and/or facilities programs as components of HHS strategic objectives in the following areas:

DHHS Objective 1.1:	Reduce Tobacco Use, Especially Among Youth
DHHS Objective 1.2:	Reduce the Number and Impact of Injuries
DHHS Objective 1.3:	Improve the Diet and the Level of Physical Activity of Americans
DHHS Objective 1.4:	Curb Alcohol Use
DHHS Objective 1.5:	Reduce the Illicit Use of Drugs
DHHS Objective 1.6:	Reduce Unsafe Sexual Behaviors
DHHS Objective 2.3:	Improve the Healthy Development and Learning Readiness of Preschool Children
DHHS Objective 2.5:	Increase Opportunities for Seniors to Have an Active and Healthy Aging Experience
DHHS Objective 3.3:	Improve Access to and the Effectiveness of Health Care Services for Persons with Specific Needs
DHHS Objective 5.1:	Improve the Public Health Systems' Capacity to Monitor the Health Status and Identify Threats to the Health of the Nation's Population
DHHS Objective 6.1:	Improve the Understanding of Normal and Abnormal Biological Processes and Behaviors

DHHS Objective 6.2:	Improve the Prevention, Diagnosis, and Treatment of Disease and Disability
DHHS Objective 6.4:	Increase the Understanding of and Response to the Major Issues Related to the Quality, Financing, Cost, and Cost-Effectiveness of Health Care Services
DHHS Objective 6.5:	Accelerate Private Sector Development of New Drugs, Biologic Therapies, and Medical Technology
DHHS Objective 6.6:	Improve the Quality of Medical and Health Science Research by Strengthening the Base of Highly Qualified Scientific Investigators
DHHS Objective 6.7:	Ensure that Research Results are Effectively Communicated to the Public, Practitioners, and the Scientific Community

References

U.S. Department of Health and Human Services, *Strategic Plan*, September 30, 1997.

U.S. Department of Health and Human Services, *FY 2000 Performance Plan Summary*, February 1999.

Appendix 4

Performance Measurement Linkages with Budget, Cost Accounting, Information Technology Planning, Capital Planning, Program Evaluation

Budget

NIH links performance measures to budget and accounting, as appropriate, to meet the requirements of GPRA and other management reporting such as under the Chief Financial Officers (CFO) Act and the Government Management and Reform Act (GMRA).

Under NIH's aggregated approach (see Sec. 1.2), performance goals are grouped according to the three Core Programs: Research, Research Training and Career Development, and Research Facilities. In NIH's current budget and cost accounting system, dollars are not directly associated to each goal (such association is not required under GPRA). However, NIH has developed a "crosswalk" for how each budget mechanism (e.g., Research Project Grant, Research Management and Support, Construction, etc.) links to the core programs. In this way, NIH distributes its total budget authority by GPRA Core Program.

Cost Accounting

NIH develops and reports the cost of its 3 programs on its audited Statement of Net, as required by the CFO Act, the GMRA, and the Office of Management and Budget. These reported costs are derived using an accrual basis of accounting as required by federal accounting standards and the Federal Financial Management Improvement Act. These amounts differ from the reported obligations or budgetary resources included in budget documents that use an obligation basis of accounting.

NIH includes cost measures for performance goals, as appropriate, in its service and supply fund activities. NIH finances these activities using a fee for service cost recovery method. NIH develops cost per unit of good or service and benchmarks these unit costs with other providers of similar or complementary goods and services. Also, NIH strives to increase stakeholder value by reducing the cost per unit of good or service wherever possible.

Information Technology Planning

Rather than being a separate entity, Information Technology (IT) is woven throughout the NIH research program and linked to the goals identified in the NIH Annual Performance Plan. Performance goals that reflect how IT is utilized by the NIH research community are found in all three of the Core Programs of the plan.

In addition, the NIH Annual Performance Plan currently includes a specific goal related to the implementation of the NIH Director's overall strategy to improve IT management at NIH. As part of this process, NIH has revised its IT organizational structure under a Chief Information Office and has put into place an IT Investment Review Process including an IT Board of Governors and an NIH IT Management Committee (ITMC). A strategic corporate IT vision for NIH is being developed, including a strengthening of business area ownership of IT systems. NIH will then revise its IT Strategic Plan to reflect this new corporate IT vision and further describe how IT supports the goals identified in the NIH annual performance plan.

Also, NIH formalized the NIH IT Investment Review process in a collaborative process with the recently established NIH ITMC. Under this process, IT projects will be reviewed and evaluated to determine if they support goals in the NIH annual performance plan. This IT Investment Review process will be described in the revised IT Strategic Plan.

Capital Planning

NIH's planning for capital projects is woven throughout the annual performance plan, notably in the sections addressing "Management and Administration" and "Intramural Modernization and Maintenance." Additional information on capital projects can be found in the detailed budget tables prepared by NIH's Office of Financial Management.

Evaluation

The complexities and challenges of evaluating and assessing fundamental science have become more widely recognized as science agencies have implemented the GPRA. The GPRA stresses the use of evaluation to develop measures for reporting on program results. NIH's major evaluation priority areas fall within the three broad program areas: research, research training and career development, and facilities. NIH conducts evaluations in these areas to assess strategies and goals, develop performance measures and improve operations. NIH reports annually on its GPRA related evaluation activities through the DHHS report, *Research, Demonstration and Evaluation Activities.* Additionally, and as part of GPRA reporting, NIH will refer to specific evaluations and evaluation results as they relate to individual performance plan goals.

Appendix 5

The NIH's Institutes and Centers

Institute/Center	Mission
National Cancer Institute	NCI conducts and supports programs to understand the causes of cancer; prevent, detect, diagnose, treat, and control cancer; and disseminate information to the practitioner, researcher, patient, and public. The Institute's efforts are directed at reducing the burden of cancer morbidity and mortality, and ultimately, at preventing the disease.
National Heart, Lung, and Blood Institute	NHLBI's research program is directed at diseases of the heart, blood vessels, lungs, and blood and at transfusion medicine. Its activities encompass innovative basic, clinical, population-based, and health education research.
National Institute of Dental and Craniofacial Research	NIDCR's research program is directed at understanding, treating, and ultimately preventing the infectious and inherited craniofacial-oral-dental diseases and disorders that compromise millions of human lives.
National Institute of Diabetes and Digestive and Kidney Diseases	NIDDK conducts and supports research, training, health information dissemination, and other programs with respect to diabetes millitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.
National Institute of Neurological Disorders and Stroke	NINDS conducts and supports research and training on the normal and diseases nervous system in order to reduce the burden of neurological diseases. The research program is ultimately directed at improving the prevention, diagnosis, and treatment of the hundreds of disorders affecting the nervous system. Including stroke; epilepsy; demyelinating disorders such as multiple sclerosis; tumors; pain; traumatic injury of the brain and spinal cord; degenerative disorders such as Parkinson's disease; movement disorders; developmental disorders such as autism, the myasthenias and muscular dystrophies; and numerous autoimmune, metabolic, and genetic disorders.
National Institute of Allergy and Infectious Diseases	NIAID conducts and supports research that strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.
National Institute of General Medical Sciences	NIGMS supports basic biomedical research that is not targeted to specific diseases, but increases understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS attempts to ensure the vitality and continued productivity of basic biomedical research, while producing the next generation of scientific breakthroughs and training the next generation of scientists.

Institute/Center	Mission
National Institute of Child Health and Human Development	NICHD conducts and supports research on fertility, pregnancy, growth, development, and medical rehabilitation. The Institute's broad purpose is to ensure that every child is born healthy and wanted, and grows up free from disease and disability.
National Eye Institute	NEI conducts and supports research, training, health information dissemination, and other programs that are directed at blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind.
National Institute of Environmental Health Sciences	NIEHS conducts and supports research on how environmental exposures, genetic susceptibility, and age interact to affect an individual's health. It's overall purpose is to reduce the burden of human illness and dysfunction from environmental causes.
National Institute on Aging	NIA conducts and supports research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities; and the promotion of a better quality of life for all older Americans.
National Institute of Arthritis and Musculoskeletal and Skin Diseases	NIAMS conducts and supports research, training, and information dissemination directed at understanding the normal structure and function of bones, muscles, and skin, as well as the numerous and disparate diseases that affect these tissues.
National Institute on Deafness and Other Communication Disorders	NIDCD conducts and supports basic and clinical research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. These diseases and disorders currently affect some 46 million Americans. Basic and clinical research focused on understanding the normal processes and disorders of human communication are motivated both by intrinsic scientific interest and importance to the health of the nation.
National Institute of Mental Health	NIMH conducts and supports research on the brain and behavior – basic, clinical, epidemiological, and health services research. The Institute's activities are broadly dedicated to understanding, treating, and preventing mental illnesses.
National Institute on Drug Abuse	NIDA conducts and supports research across a broad range of disciples that bear on drug abuse and addiction and disseminates information about its research findings. The Institute's broad purpose is to help reduce drug abuse and to improve the options for addiction prevention and treatment.
National Institute on Alcohol Abuse and Alcoholism	NIAAA conducts research directed at improving the treatment and prevention of alcoholism and alcohol-related problems. The Institute's broad objective is to reduce the enormous health, social, and economic consequences of this disease.
National Institute of Nursing Research	NINR has a broad mandate to sponsor research on the clinical care of individuals and their responses to health problems. Scientists supported by the Institute seek to understand and mitigate the effects of acute and chronic illness and disability, promote healthy behaviors and prevent the onset or worsening of disease, and improve the environment in which healthcare is administered.

Institute/Center	Mission
National Human Genome Research Institute	NHGRI supports the NIH's participation in the Human Genome Project, a worldwide research effort directed at analyzing the structure of human DNA and determining the location of the estimated 100,000 human genes. At the intramural level, NHGRI develops technology for understanding, diagnosing, and treating genetic diseases.
National Center for Research Resources	NCRR advances biomedical research and improves human health through research projects and shared resources that create, develop, and provide a comprehensive range of human, animal, technological, and other resources. There are four main areas of concentration: biomedical technology, clinical research, comparative medicine, and research infrastructure.
National Center for Complementary and Alternative Medicine	NCCAM conducts and supports basic and applied research and training and disseminates information on complementary and alternative medicine to practitioners and the public.
Fogarty International Center	FIC leads the NIH's efforts to advance the health of the American public and citizens of all nations through international cooperation on global health threats.
Warren Grant Magnuson Clinical Center	The Clinical Center is the clinical research facility of the NIH. It provides patient care, services, training and the environment in which NIH clinician-scientists creatively translate emerging knowledge into better understanding, detection treatment and prevention of human diseases.
Center for Scientific Review	CSR carries out initial peer review of the majority of research and research training applications submitted to the NIH. Peer review is the foundation of the NIH grant and award process. The Center also serves as the central receipt point for all Public Health Service applications and makes referrals to scientific review groups for scientific and technical merit review and to funding components for potential award.
National Library of Medicine	NLM is one of three national medical libraries. It collects, organizes, and makes available biomedical science information to investigators, educators, and practitioners. It also carries out programs to strengthen medical library services in the United States. NLM's electronic databases, such as MEDLINE, are used extensively throughout the world.
Center for Information Technology	CIT provides, coordinates, and manages information technology and seeks to advance computational science.