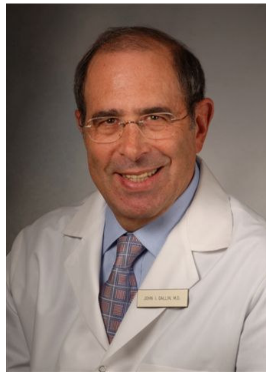
National Institutes of Health Clinical Center

"There's no other hospital like it!"

2006 Operating Plan

Message from the Clinical Center Director



The NIH Clinical Center faces unprecedented opportunities and challenges in 2006. Our compelling mission and ongoing collaboration with Institutes guide the development of this operating plan. Clinical Center efforts in 2006 will focus on supporting exciting new research in the areas of obesity, vaccine research, interventional cardiology, autism, pulmonary hypertension, and reproductive endocrinology. The challenge is to maintain the vibrancy of the intramural clinical research program within a climate of budgetary constraints. This difficult situation mandates that we work more efficiently and effectively than ever before.

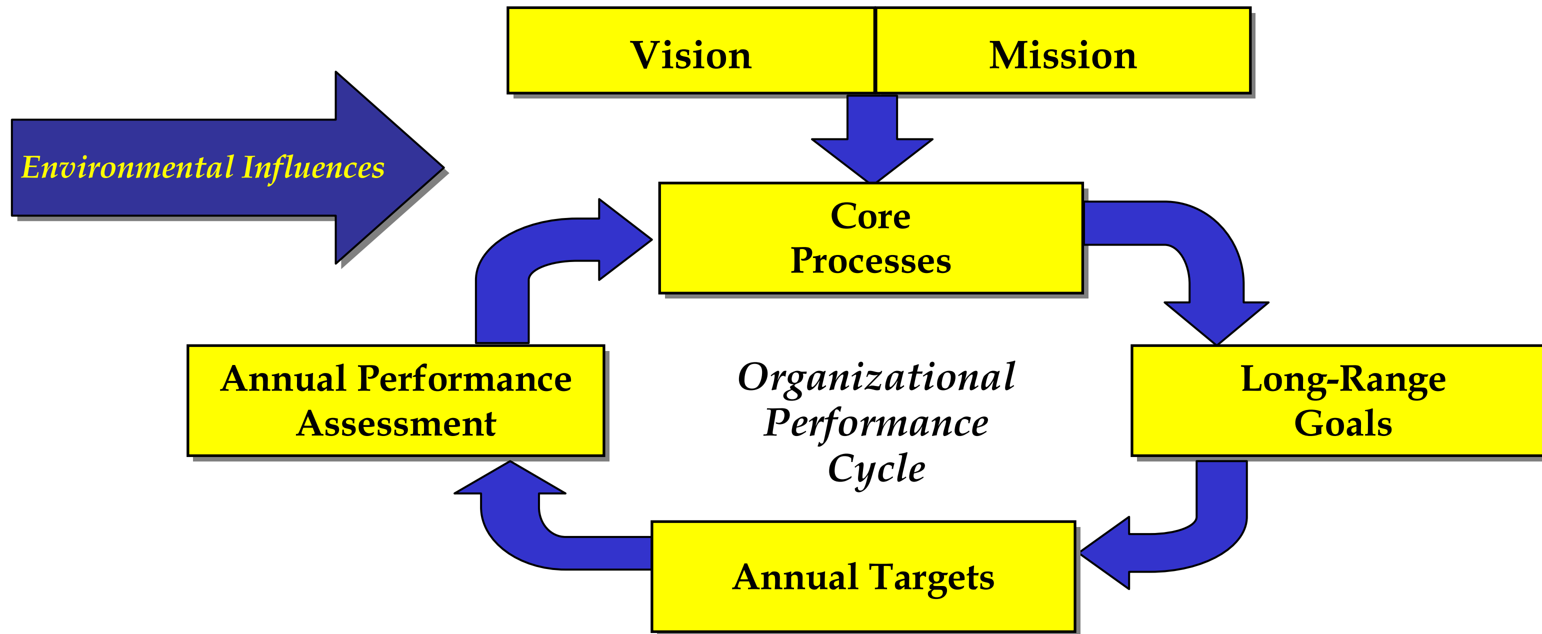
We must strengthen our infrastructure for delivery of clinical research as well as ensure that the quality and safety of patient care remain our first priority. We need to continually seek better ways to conserve resources and reduce costs. I believe we can successfully respond to these opportunities and challenges if we plan together and examine carefully what services are needed and which ones we can curtail. One of our most valuable resources is our employees. I remain committed to developing the potential of Clinical Center employees through effective training and career development. Maximizing employee performance and productivity will be a strong priority this year.

A leader's responsibility is to listen and reassess ideas and plans as often and as honestly as possible without wavering from the original objective. It will take the commitment, creativity, and cooperation of every member of the Clinical Center team as we move forward. Every employee can help create a stronger culture by sharing information in work teams, listening carefully, and exchanging perspectives.

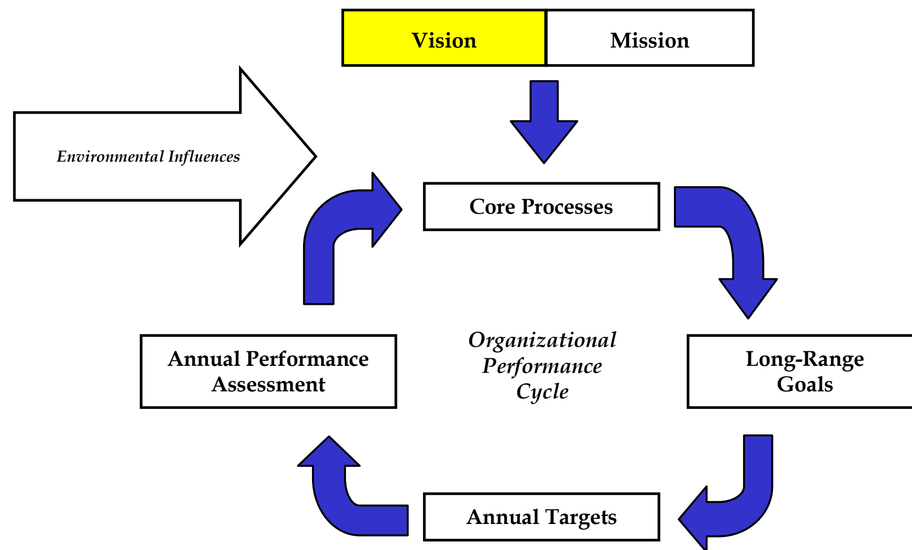
The Clinical Center team is exceptional, and I look forward to working with all of you in making 2006 another outstanding year.

John I. Gallin, MD
Director

Clinical Center Operating Plan Framework



Vision Statement

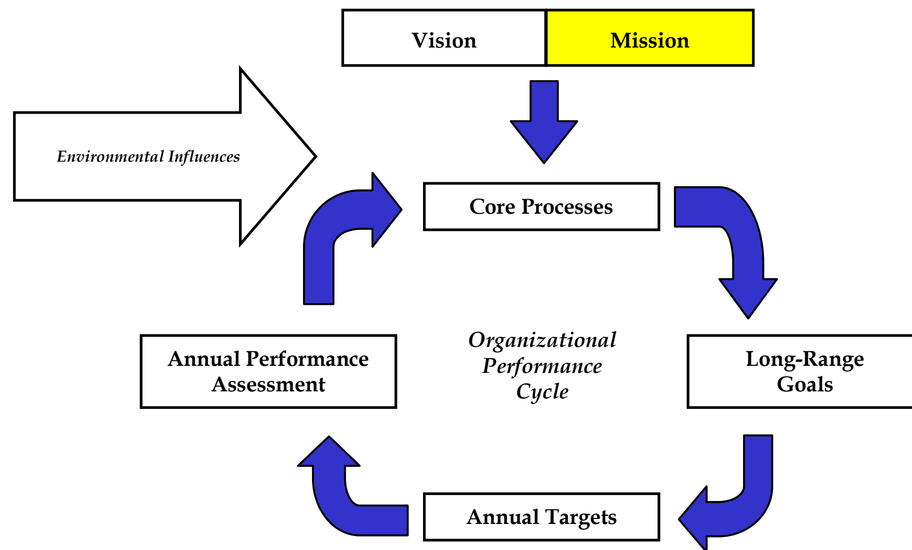


A vision statement:

- *answers the question: "What do we strive to be?"*
- *is the leadership's view and a guiding concept of what the organization wants to do or become.*

The NIH Clinical Center will serve as the nation's premier research hospital for conducting clinical research to improve the health of humankind. It will also serve as a national resource for clinical research by developing diagnostic and therapeutic interventions; enhancing systems to ensure the safe, efficient, and ethical conduct of clinical research; training clinical researchers; and leading the response to the nation's public health needs.

Mission Statement



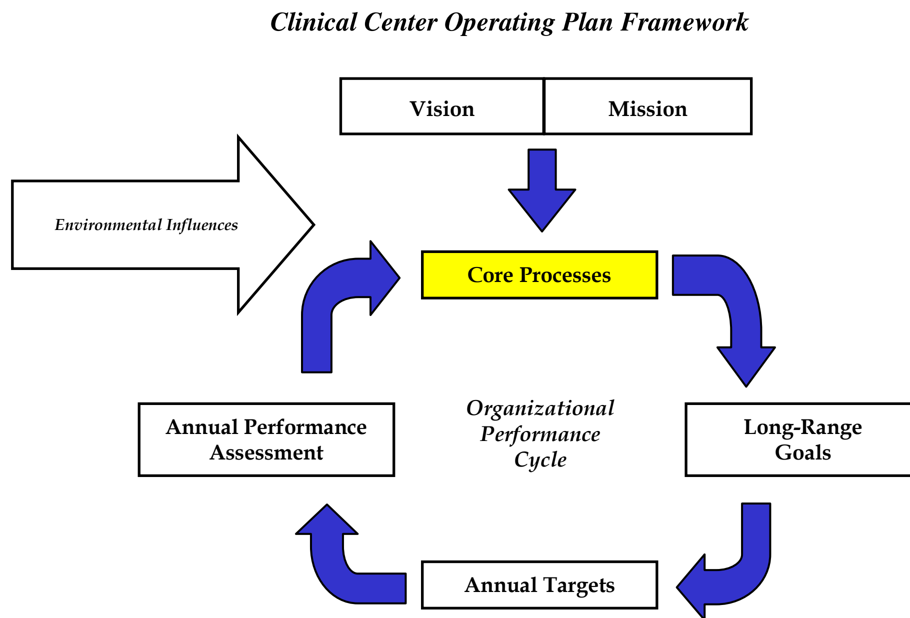
A mission statement answers the question: "What is our fundamental purpose?"

As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates:

- *Development of diagnostic and therapeutic interventions*
- *Training of clinical researchers*
- *Development of processes to ensure the safe, efficient, and ethical conduct of clinical research.*

The Clinical Center achieves this mission through a culture that fosters collaboration, innovation, diversity, and the highest ethical standards.

Core Processes



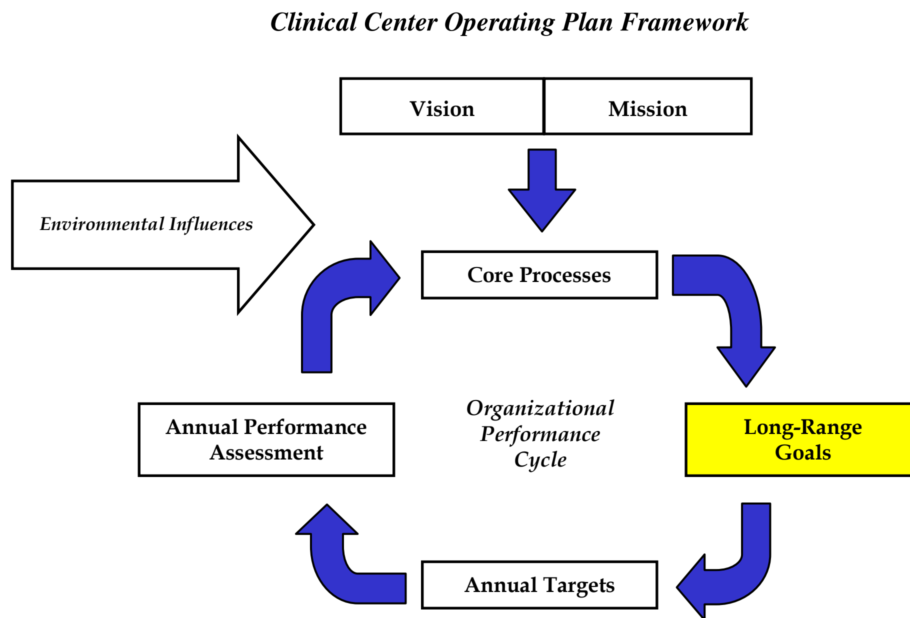
Core processes are the major activities that support the mission.

Clinical Research Support:
Provide staff, services, training, and environment to support clinical research.

Patient Care:
Provide outstanding patient care to participants in clinical research studies.

Operational Management:
Provide resources such as personnel, budget, and capital equipment in the most cost effective and efficient manner.

Clinical Center Long-Range Goals



Long-range goals translate the vision, mission, and core processes into performance-based action plans.

- *Provide timely support for implementation of new Institute clinical research programs and strengthen the infrastructure for delivery of and training in clinical research.*
- *Improve quality and safety of patient care.*
- *Conserve resources, contain costs, and improve employee satisfaction, performance, and productivity.*

Clinical Center Planning and Budget Development Process

Timeline	Process
September/ October	Institute Planning Meetings
	CC Develops Themes
November/ December	CC Prepares Budget
February/ March	NIH Advisory Board for Clinical Research
	Intramural Working Group
April/May	Management & Budget Working Group
	NIH Steering Committee
June	IC Directors

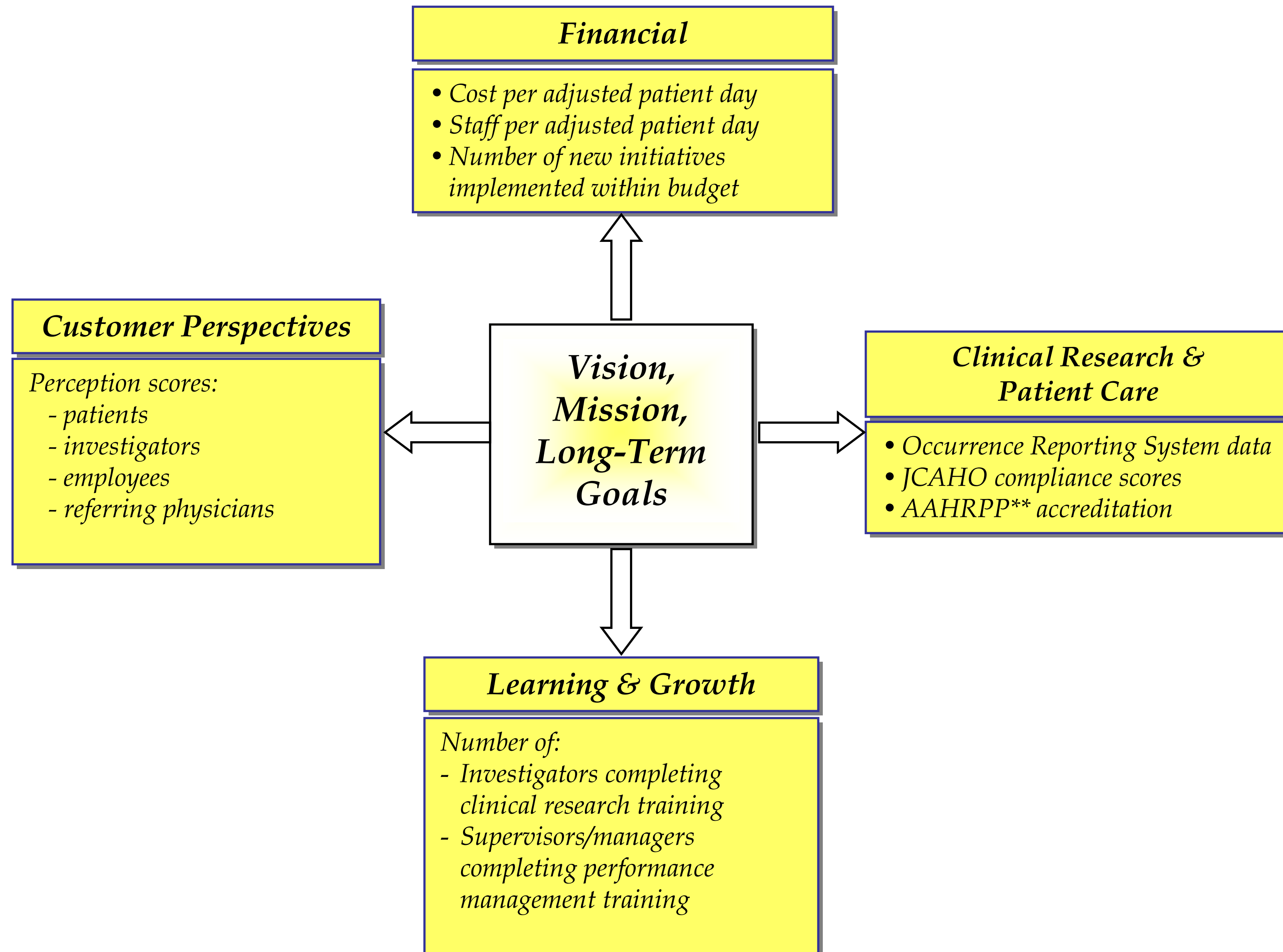
NIH Advisory Board for Clinical Research → NIH Director Decision

IC Directors → NIH Director Decision

2006 Clinical Center Operating Plan – Annual Targets

Core Processes	*Clinical Research Support*	*Patient Care*	*Operational Management*
Long-range Goals	*Provide timely support for implementation of new Institute clinical research programs and strengthen the infrastructure for delivery of and training in clinical research.*	*Improve quality and safety of patient care.*	*Conserve resources, contain costs, and improve employee satisfaction, performance, and productivity.*
2006 Annual Targets	*New Clinical Research Initiatives* 1. Support implementation of the following programs: - Obesity (NIDDK/Multi-Institute) - Vaccine Research (NIAID) - Interventional Cardiology (NHLBI) - Autism (NIMH) - Pulmonary Hypertension (NHLBI) - Reproductive Endocrinology (NICHD) - Intramural/Extramural Collaborative Research *Infrastructure Enhancements* 2. Implement new bench-to-bedside awards program with extramural community. 3. In collaboration with US Surgeon General, implement new clinical research awareness initiative. 4. Expand clinical research training programs locally, nationally, and internationally.	1. Improve provision of the following outpatient services: - clinic facilities & patient access - outpatient surgery suite. 2. Improve clinical documentation through enhancements to CRIS. 3. Conduct survey of referring physicians to identify opportunities for improvements. 4. Implement bar coding to improve patient safety.	1. Develop a collaborative resource management model with Institutes that creates incentives for efficiency while supporting program activity. 2. Enhance Clinical Center leadership development by assuring that all managers & supervisors are trained in federal performance management. 3. Under the guidance of the NIH Advisory Board for Clinical Research, conduct operational reviews (quality and cost assessments) of the following Clinical Center programs: - Imaging Sciences - Nursing.

*Measurement Methodology – A Balanced Scorecard Approach**



* *Developed in accordance with the Kaplan and Norton Balanced Scorecard Method. www.balancedscorecard.org/basics/bsc1.html*

** *The Association for the Accreditation of Human Research Protection Programs, Inc.®*

Financial Impact of Annual Targets

The Clinical Center, in setting its annual targets, chose to focus on initiatives that would be attainable within the constraints of the operational budget. The table below describes the sources of funding that are either set aside or earmarked for each target.

Category	#	Target	Funding
Clinical Research Support	1	**Support implementation of the following programs:** •Obesity (NIDDK/Multi-Institute) •Vaccine research (NIAID) •Interventional Cardiology (NHLBI) •Autism (NIMH) •Pulmonary Hypertension (NHLBI) •Reproductive Endocrinology (NICHD) •Intramural-Extramural Collaborative Research	Supplemental funds for obesity have been provided to the Clinical Center for facility modifications and ongoing operational expenses. Facility modifications for vaccine research unit are being funded outside the Clinical Center operating budget; operational expenses are incremental and expected to impact FY07 budget. Based upon the amount required to support operational expenses for identified new clinical research initiatives, Clinical Center operating funds will either be reprogrammed via a reprioritization with the Institutes, or additional funds will be requested.
Clinical Research Support	2	**Implement new bench-to-bedside awards program with extramural community.**	The Clinical Center Director has secured commitments of $3.1M of additional funding to support the expansion of the bench-to-bedside awards program this fiscal year . No new funds are being expended.
Clinical Research Support	3	**In collaboration with US Surgeon General, implement new clinical research awareness initiative.**	The Clinical Center Director is leading the planning with the Surgeon General on this key initiative and working collaboratively on implementation with the NIH Office of Communications and Public Liaison (OCPL). Funding is being provided by NIH OCPL with supplemental requirements being reprogrammed out of existing Clinical Center Communications budget.
Clinical Research Support	4	**Expand clinical research training programs locally, nationally, and internationally.**	The Clinical Center Office of Clinical Research Training and Medical Education's operational budget supports these training programs. No new funds are being expended.
Patient Care	5	**Improve provision of the following services:** **•Clinic facilities and patient access** **•Outpatient surgery suite.**	The Clinical Center carried over FY05 funds to support outpatient improvements. Planning is under way to augment the layout and patient flow in the clinics. The decision to proceed with outpatient improvements is contingent upon release of the FY06 funding level for the Clinical Center by the NIH. If the CC receives a reduced funding level, these two renovation projects will be deferred.
Patient Care	6	**Improve clinical documentation through enhancements to CRIS.**	Although the Clinical Center is responsible for the planning and implementation of CRIS, the project is funded outside the Clinical Center operating budget through the NIH Enterprise Funding for Information Technology. On-going operational expenses will be transitioned to the Clinical Center's operating budget in FY07.
Patient Care	7	**Conduct survey of referring physicians to identify opportunities for improvements.**	The Clinical Center operating budget includes annual funds for surveying patients, employees, and other stakeholders. The surveys, administered on a rotating basis, will focus this year on perceptions of referring physicians. No new funds are required to support this survey effort. If opportunities for improvement are identified, funds may be needed to implement them.
Patient Care	8	**Implement bar coding to improve patient safety.**	This project will be pursued with either Clinical Center Director's reserve funds or by applying for NIH set-aside funds for evaluation projects.

Financial Impact of Annual Targets - continued

Operational Management	#	Target	Financial Impact
	9	**Develop a collaborative resource management model with ICs that creates incentives for efficiency while supporting program activity.**	This effort is a management activity that will utilize staff from the Clinical Center Office of the Director. No new resources will be required to assemble this improvement team.
	10	**Enhance Clinical Center leadership development by assuring that all managers & supervisors are trained in federal performance management.**	This effort is funded through the budget of the Clinical Center Office of Workforce Leadership Training and Organizational Development. Funds that have in the recent past been used to improve Clinical Center orientation and offer customer service training will be reprogrammed to support this new focus.
	11	**Under the guidance of the NIH Advisory Board for Clinical Research, conduct operational reviews (quality and cost assessments) of two Clinical Center departments.**	This effort is a management activity that will utilize staff from the Clinical Center Office of the Director. No new resources will be required to conduct the operational reviews.

Environmental Influences

Environmental influences identify internal and external drivers that impact our organization and inform our strategic direction.

Clinical Center Operating Plan Framework

Vision | Mission

Environmental Influences

Core Processes

Long-Range Goals

Annual Targets

Annual Performance Assessment

Organizational Performance Cycle

Environmental Influences:

- *Government Initiatives*
- *DHHS/NIH Drivers*
- *Review & Advisory Bodies*
- *Customers*
- *Health Care Industry*

Environmental Influences

DHHS/NIH Drivers

- "One HHS" – 20 Department-Wide Goals
- NIH Roadmap
- Budgetary Constraints

Government Initiatives

- Government Performance & Results Act (GPRA)
- President's Management Agenda (PMA)
- Program Assessment Rating Tooling (PART)
- Competitive Sourcing (A-76)

Review & Advisory Bodies

- NIH Advisory Board for Clinical Research (ABCR)
- Medical Executive Committee (MEC)
- Board of Scientific Counselors (BSC)
- Patient Advisory Group (PAG)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- Clinical Fellows Committee

Health Care Industry

- Patient Safety/Clinical Quality
- Pharmaceutical/Supply Inflation
- Clinical Research Awareness
- Information Technology Development

Customers

Internal
- Institutes
- Patients
- Clinical Center Employees

External
- Extramural Clinical Investigators
- Referring Physicians
- Advocacy Groups

Government Initiatives

Government Performance and Results Act (GPRA)

The Government Performance and Results Act (GPRA), enacted in 1993, requires federal agencies to establish standards for measuring their performance and effectiveness. The law requires federal agencies to develop strategic plans describing their overall goals and objectives; annual performance plans containing quantifiable measures of their progress; and performance reports describing their success in meeting those standards and measures.

President's Management Agenda (PMA)

The President's Management Agenda (PMA), announced in the summer of 2001, is an aggressive strategy for improving the management of the federal government. It focuses on five areas of management weakness across the government where improvements and the most progress can be made. The five key government-wide areas are:

Strategic Management of Human Capital *– having processes in place to ensure that the right person is in the right job at the right time, and is not only performing, but performing well;*

Competitive Sourcing *– regularly examining commercial activities performed by the government to determine whether it is more efficient to obtain such services from federal employees or from the private sector;*

Improved Financial Performance *– accurately accounting for the taxpayer's money and giving managers timely and accurate program cost information to make informed management decisions and control costs;*

Expanded Electronic Government *– ensuring that the federal government's $60 billion annual investment in information technology (IT) significantly improves the government's ability to serve citizens and that IT systems are secure, are delivered on time, and within budget; and,*

Budget and Performance Integration *– ensuring that performance is routinely considered in funding and management decisions and that programs achieve expected results and work toward continual improvement.*

Government Initiatives (continued)

Program Assessment Rating Tool (PART)

The Program Assessment Rating Tool (PART) is the "quality control" assessment tool overseen by the Office of Management and Budget that is used to evaluate the fulfillment of the PMA and implementation of GPRA on a program-specific basis. PART requires performance measures to be outcome-oriented.

The content and principles in The Government Performance and Results Act, The President's Management Agenda, and PART influence how the Clinical Center executes its planning and performance monitoring activities.

Competitive Sourcing (A-76)

The Clinical Center in collaboration with the NIH Institutes and Centers continues to participate in the competitive outsourcing initiative put forth as a primary goal in the President's Management Agenda (PMA). Agencies are expected to determine their "core competencies" and decide whether to build internal capacity or contract for the services from the private sector. This is intended to maximize agency flexibility in getting work done more effectively and efficiently. The outcome of two studies, with potential impact to 120 Clinical Center FTEs, will be known in 2006. A new study planned to begin in 2006 will affect potentially 85 additional FTEs.

DHHS/NIH Drivers

"One HHS" – 20 Department-wide Goals

The Department of Health and Human Services (HHS) has established an overarching direction by putting forth 20 department-wide goals in order to function as a coordinated entity and maximize efficiency. These goals direct all HHS planning and performance management efforts. The mission of HHS is to enhance the health and well-being of Americans by fostering strong and sustained advances in the sciences underlying medicine, public health and social services. As an agency in HHS, the NIH is one of the foremost centers for the conduct and support of medical research. As the Clinical Center is a part of this larger agency matrix, all planning and performance goals are aligned with the HHS strategic plan as depicted in the table below. Specifically, Clinical Center goals cascade from 13 of the 20 HHS objectives.

HHS Objectives (HHS identified 20 objectives for 2006; 13 objectives of which Clinical Center activities align.)	Clinical Center Long Range Goals		
	Provide timely support for implementation of new Institute clinical research programs and strengthen the infrastructure for delivery of and training in clinical research..	**Improve quality and safety of patient care.**	**Conserve resources, contain costs, and improve employee performance and productivity.**
1) Transform the healthcare system	X		
2) Strategically manage human capital	X		X
3) Complete the FY 2006 competitive sourcing			X
4) Advance medical research	X		
5) Improve financial performance			X
6) Expand electronic government	X	X	
7) Protect life, family, and human dignity		X	
8) Improve budget and performance integration			X
9) Improve the human condition around the world	X		
10) Achieve performance accountability			X
11) Promote quality, relevance, & performance of research and development activities	X		
12) Emphasize healthy living and prevention of disease, illness, and disability	X		
13) Eliminate improper payments			X

DHHS/NIH Drivers

NIH Roadmap

The NIH Roadmap was introduced in 2003 under the leadership of NIH Director Elias A. Zerhouni, MD. This Roadmap provides a framework of the priorities NIH as a whole must address in order to optimize its entire research portfolio. It lays out a vision for a more efficient and productive system of medical research. There are three primary areas of focus: new pathways to discovery; research teams of the future; and re-engineering the clinical research enterprise. Next, the NIH Director convened a blue ribbon panel to make recommendations to align the future direction of the intramural clinical research program with the larger clinical research enterprise re-engineering plan. A key recommendation was to create a single governing body to provide oversight for the intramural clinical research program.

Budgetary Constraints

The doubling of the NIH budget from $14B to nearly $28B during fiscal years 1998–2003 resulted in significant additional resources to the Institutes as well as the Clinical Center. However, the NIH has received nominal increases since the doubling of the budget concluded, with a 1.4 percent increase in FY05 and a pending FY06 budget that is virtually flat. The Clinical Center received a 0.3 percent increase and has a pending 0.1 percent increase during the respective time periods. The Clinical Center has worked diligently to become more cost effective in order to sustain the patient census while meeting mandated cost-of-living increases (3.44 percent in 2005) for nearly 60 percent of the budget; continued inflationary pressures associated with health care expenses such as pharmaceuticals and medical supplies; and required investment in capital equipment.

To date, the Clinical Center has been successful in maintaining service levels through targeted decreases in workforce and other cost saving measures. However, with an anticipated flat, or even reduced budget in FY07, the Clinical Center is engaging with the leadership of the NIH, as well as with the intramural community, to determine prioritization of services and how to improve productivity. The Clinical Center is continuing an aggressive cost-containment effort of more than $16M in FY06 to ensure the highest quality support for patients and to maintain a vigorous clinical research infrastructure within the context of extremely limited resources.

Review and Advisory Bodies

NIH Advisory Board for Clinical Research (ABCR)

The NIH Advisory Board for Clinical Research (ABCR) is charged to provide guidance to integrate the vision, planning, and operations of the intramural clinical research programs of the NIH. The Board advises, consults with, and makes recommendations to the NIH Director and other key leaders. The Board is composed of nine extramural scientists and experts in health care administration and eight NIH intramural scientists. The Board guides in the development of trans-NIH strategic planning and advises on the budget and operating plan of the Clinical Center.

Medical Executive Committee (MEC)

The Medical Executive Committee (MEC) advises the Clinical Center Director on clinical aspects of operations and develops policies governing standards of medical care in the Clinical Center. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives.

Clinical Center Board of Scientific Counselors (BSC)

The purpose of this group is to secure unbiased and objective evaluation of the independent research programs of the Clinical Center and the work of individual scientists. Expert scientists from outside the NIH participate as members of this review group. The Board of Scientific Counselors of the Clinical Center was established in October 1990 and advises the NIH Director, NIH Deputy Director for Intramural Research, and the Clinical Center Director on the Clinical Center's intramural clinical research programs through periodic visits to the laboratories to assess the research of, and evaluate the performance of, independent investigators.

Patient Advisory Group (PAG)

The Patient Advisory Group (PAG) was established in 1998 when some of our patients were invited to provide their perspectives on the design of the new Clinical Research Center. The PAG continues to increase momentum; at least 20 patients and/or family members attending quarterly meetings. These individuals represent patients who live locally, as well as those who travel long distances to participate in NIH clinical research studies. The meetings are open to any patients or family members who would like to attend. The discussions from these meetings help identify issues of concern and make recommendations that improve the Clinical Center's efforts to provide the highest quality research and patient care services.

Review and Advisory Bodies (continued)

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The Joint Commission evaluates and accredits nearly 16,000 health care organizations and programs in the United States. An independent, not-for-profit organization, JCAHO is the nation's predominant standards-setting and accrediting body in health care. Since 1951, JCAHO has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations. For example, standards are set for such areas as medical and nursing staff credentialing, fire and emergency responses, patient safety, and continuous improvement of the services provided for patients. In April of 2003, JCAHO communicated its intent to begin conducting all regular accreditation surveys on an unannounced basis beginning in January 2006.

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

The Association for the Accreditation of Human Research Protection Programs, Inc.® (AAHRPP®) is a nonprofit organization that offers accreditation to institutions engaged in research involving human participants. Incorporated in April 2001, AAHRPP seeks to ensure compliance and raise the bar in human research protection by helping institutions reach performance standards that surpass the threshold of state and federal requirements through self-assessment, peer review, and education.

Clinical Fellows Committee

Created in 2004 to serve as a communications venue for clinical fellows, this highly energized new committee meets quarterly with Dr. Gallin. Membership includes clinical fellows representing all Institutes. In 2005, the Clinical Fellows Committee (ClinFelCom) proposed a new Assistant Clinical Investigator position to bridge the postdoctoral experience between fellowship and tenure track. This new Assistant Clinical Investigator position title has been approved by the Medical Executive Committee, the NIH Deputy Director for Intramural Research, and the NIH Scientific Directors. In addition, the Clinical Fellows Committee developed a survey of fellows to assess their experiences and their opinions about the quality of care at the Clinical Center. The committee also pursued a mechanism for fellows to obtain affordable disability insurance.

Internal Customers

Institutes

The NIH is composed of 27 Institutes and Centers (ICs) 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 needs. The Office of the Director, NIH, provides leadership, oversight, and coordination for the enterprise. The Clinical Center supports the intramural clinical research efforts of the IC's whose clinical programs are on the Bethesda campus. In FY05, there were a total of 1,357 active protocols implemented with Clinical Center resources and support; this is a growth of more than 20 percent since FY00.

Patients

Patients come to the NIH from every corner of the United States seeking answers to their scientific and medical questions. They represent both genders and all ages, races, cultures, and socio-economic groups. In FY05, there were 6,619 admissions, a decrease of 4.7 percent from FY04; however, inpatient days decreased only 0.1 percent from the previous year, a result of increased length of stay for the organization by 3.1 percent. There was a 2.8 percent decrease in outpatient visits. In FY05, 2208 new research volunteers were enrolled through the Clinical Center's Patient Recruitment and Public Liaison Office (PRPL) and Clinical Research Volunteer Program (CRVP),. The CVRP formerly the Healthy Volunteer Office, and part of the PRPL, provides a pool of healthy volunteers available for all principal investigators. In FY05, the CRVP program registered 5,913 new volunteers.

Clinical Center Employees

There is strong race and ethnic diversity in our workforce of approximately 1,846 Clinical Center employees. There are 111 employees (6 percent) who are officers in the Commissioned Corps of the U.S. Public Health Service. Approximately 82 percent of the Clinical Center workforce are assigned to clinical and patient care departments and the remaining 18 percent is in administration and operational support departments. Over the past 20 years, the largest professional growth occupations in the Clinical Center have been nurses, allied health professionals, and administrative professionals. The Clinical Center workforce has increased by less than 1 percent over the past 10 years, with a decline of more than 100 employees over the past 2 years due to increasing efforts at cost containment in the area of personnel expense. Employee turnover remains steady and low at 10 percent. The average age of Clinical Center employees has risen to 45.5 years, which reflects the health care marketplace in general.

External Customers

Extramural Clinical Investigators

In support of the NIH Director's initiative to invigorate clinical research, a goal of the NIH Roadmap, the Clinical Center has expanded the intramural bench-to-bedside awards to include extramural partners. In 2006, more than 20 awards will be given to intramural-extramural investigators for their work in rare diseases, AIDS, minority health disparities, and women's health. Funding for these projects has been provided by Institutes and other components of the NIH.

Referring Physicians

Good bi-directional communication with referring physicians is essential to continuity of care and maintaining open and effective patient referral networks. Referring physicians have commented that the NIH should improve the provision of discharge reports to provide timely and proactive patient follow-up. The Clinical Center will work with the Medical Executive Committee to initiate ongoing surveys of referring physicians.

Advocacy Groups

Patient advocacy groups and disease-oriented foundations are important resources for understanding the needs of various patient populations. The Clinical Center will promote interactions with these groups to better understand how to support NIH patients and to conduct meaningful outreach and referral.

Health Care Industry

Patient Safety and Clinical Quality

The safe and effective care of patients that come to the Clinical Center to participate in a clinical research protocol is an essential aspect of the Clinical Center's mission. The landmark Institute of Medicine report, "To Err is Human," called on health care organizations worldwide to take an active and aggressive approach to identifying, understanding and mitigating risk associated with hospitalization. The inherent risks associated with clinical research make this call to action of even greater relevance to the Clinical Center. Clinical Center staff and investigators continually review the patient environment using the Clinical Center Occurrence Reporting System to identify risks associated with clinical care and clinical research. Once identified, strategies to reduce or eliminate risk are devised and implemented.

Pharmaceutical/Supply Inflation

The Clinical Center budget is impacted each year by the rising costs of drugs and medical supplies. One out of every $10 spent in the Clinical Center goes toward drug purchases. Although the Clinical Center belongs to a drug purchasing consortium, drug inflation at approximately 10 percent growth per year must be mitigated by diligent efforts to offset growth. Inflation of medical supplies, although at a slower rate of approximately three percent annually, also requires active cost containment efforts.

Clinical Research Awareness

The ability of the NIH to recruit patients into protocols is affected by the public's perception of the safety, risks, and benefits of clinical research. The Clinical Center must understand these public perceptions and do its part to explain the research process as clearly as possible, to raise public awareness of the benefits of participating in clinical research and demystify some common misconceptions.

Technology Development

The health care industry offers ever improving technologies supporting diagnostics, research, pharmacology, management of patients, and operational information. The Clinical Center is committed to investing in these technologies to maintain our ability to provide cutting-edge research and treatments and to manage the Clinical Center as efficiently and effectively as possible. Operating new technologies also requires an investment in training and constant reexamination of workforce skills to support these technologies.

Developing the Operating Plan – Institute Input

"What Are the Institutes Telling Us?"

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

New Institute Clinical Research Initiatives

- *Obesity (NIDDK/Multi-Institute)*
- *Vaccine Research (NIAID)*
- *Interventional Cardiology (NHLBI)*
- *Autism (NIMH)*
- *Pulmonary Hypertension (NHLBI)*
- *Reproductive Endocrinology (NICHD)*
- *Intramural-Extramural Collaborative Research*

Core Service Requirements

- *Cell Processing*
- *Imaging Sciences*
- *Nursing Support*
- *Phenotyping Center*
- *Outpatient Improvements*

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

New Institute Clinical Research Initiatives

Obesity (NIDDK/Multi-Institute)

In 2004, in response to the burgeoning problem of obesity in the U.S. population, several Institutes and Centers (ICs), with NIDDK as lead, proposed a trans-Institute collaboration to: 1) develop an improved understanding of the genetics and pathophysiology of obesity; 2) provide additional insight into the prevention of obesity; and, 3) develop new strategies for the treatment of this emerging public health crisis. The current plan is to address the problem at several levels (i.e., from the molecular level to the bedside and back). The collaborative initiative will also focus on the multi-system co-morbidities associated with obesity; especially type 2 diabetes mellitus and its complications. The search for a program director is ongoing and may expand to include a joint intramural-extramural appointment. The consortium plans to establish a metabolic program in the new Hatfield Center that includes state-of-the-art laboratory and imaging facilities, as well as clinical investigative and imaging capabilities that will: assist in recruiting outstanding scientists for the program, attract extramural collaborations and support NIH-wide intramural scientists interested in obesity research. The investment of several Institutes in the program should foster a true multidisciplinary approach to this formidable problem. The initial focus of the work will be on the endocrine and metabolic effects of extreme weight loss, as well as on narcolepsy associated with obesity. Plans to renovate existing space in the Hatfield Center are in process, creating a 10-bed inpatient patient care unit and a diagnostic treatment area that will include three metabolic chambers. The possibility of dynamic intramural/extramural collaboration will require additional office space to support collaborating extramural investigators who will, of necessity, be present at the Clinical Center to participate in these studies.

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

New Institute Clinical Research Initiatives - continued

Vaccine Research (NIAID)

The Clinical Research Center Vaccine Evaluation Clinic and Special Clinical Studies Unit is under design with anticipated completion in 2007. NIAID will be evaluating the safety, immunogenicity, efficacy, and toxicity associated with the administration of new candidate vaccines, including potentially some vaccines against certain agents of bioterrorism. A key component of the new unit is its division into a vaccine clinic and a special clinical studies unit that could also be used as a containment facility if live-virus vectors were being used in the candidate vaccines. Several Institutes have also expressed interest in possible use of the clinical studies unit for patients ready for discharge from inpatient status but not ready to be discharged home.

Interventional Cardiology (NHLBI)

NHLBI and Suburban Hospital are entering a collaboration to conduct cardiothoracic surgery clinical trials. Suburban Hospital has received its certificate of need to perform cardiac surgery. Although studies could begin in 2006, the Institute predicts protocol activity will likely begin in early 2007. Patients coming to the Clinical Center from Suburban for post-operative research protocols will likely be acutely ill. These post-operative cardiac surgery patients will require clinical expertise not currently present in the Clinical Center workforce and the effort will necessitate extensive cross-training of Clinical Center staff to prepare for this new patient population. An interventional cardiology study (i.e., balloon dilation of adolescents who have coarctation of the aorta) is currently being discussed that would likely require cardiovascular surgery stand-by. If the Clinical Center is to support even stand-by cardiothoracic surgical cases (the current proposal would be to use the new Suburban 'team' for the procedures), we will need to invest in new equipment, additional employees, and substantial training of staff. Operating room modifications also might be required in the FY07 Clinical Center budget. The cardiac surgery program will also affect activity in the outpatient clinics and needs to be incorporated into the clinic realignment process. All of these programs have substantial resource implications for many Clinical Center departments (Critical Care, Rehabilitation Medicine, Transfusion Medicine, Laboratory Medicine, Social Work, and Imaging Sciences, among others).

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

New Institute Clinical Research Initiatives - continued

Autism (NIMH)

NIMH is initiating a series of clinical studies to address the important issue of autism. Studies are planned to improve the clinical characterization and early diagnosis of autism through a natural history protocol. The Clinical Center has partnered with NIMH to establish an NIMH building located on Cedar Lane to facilitate screening of children for subsequent inclusion in these studies. The majority of the initial studies planned are outpatient protocols. Some of the studies require procedures (e.g., lumbar punctures and MRIs with sedation) that will of necessity have to be conducted in the Clinical Center. In the first year of operation, staff estimate between 300 to 350 outpatient visits and 50 sets of inpatient procedures. When in the clinic or having procedures performed in the Clinical Center, these patients will likely be resource-intense.

Pulmonary Hypertension (NHLBI)

NHLBI, in collaboration with NIDDK and Clinical Center Critical Care Medicine staff, is planning a substantial expansion of their pulmonary hypertension program. This program is an outgrowth of the nitric oxide biology and sickle cell anemia programs that have been ongoing in these three ICs for several years. Over the past few years, the program has studied pulmonary hypertension in patients with sickle cell disease. The program is now being expanded to include patients who have pulmonary hypertension of varied etiologies, including primary pulmonary hypertension. NHLBI is anticipating a substantial increase in inpatient and outpatient visits in this program. Patients who are admitted to these studies will often require invasive procedures and many, if not most, will require ICU admissions.

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

New Institute Clinical Research Initiatives - continued

Reproductive Endocrinology (NICHD)

NICHD has recruited an outstanding senior investigator to establish a new clinical gynecology/reproductive endocrinology program, including a substantial focus on in vivo fertilization research. The program will represent a new area of scientific interest for the NICHD intramural program and for the Clinical Center. Three new protocols will focus on recurrent pregnancy loss, unexplained infertility, and failed fertility treatments. NICHD has not yet defined the resource requirements for the new program, nor have they defined the planned scope of the program. Additional resources will be needed to support the program, but the extent and types of resources required for the new program are not yet known.

Intramural-Extramural Collaborative Research

Several ICs expressed an interest in fostering intramural/extramural collaboration. These activities are viewed as consonant with Dr. Zerhouni's Roadmap for NIH. Developing creative approaches to mechanisms that will foster this type of collaboration will offer several potential benefits to NIH. Among them: the potential for more (i.e., both extramural and intramural) scientific expertise to be involved in creative bench-to-bedside projects. Such creative translational projects will likely have a substantial salutary effect on recruitment of clinical investigators and may allow us to stretch our currently strained clinical research budget in the intramural program.

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

Trans-Institute Service Requirements

Cell Processing

A major theme from the FY05 fall planning meetings continuing into FY06 is the demand for cellular therapy products from the Department of Transfusion Medicine. Demand for cell processing activities, including apheresis, sophisticated cell selection procedures, and expansion procedures continues to escalate. NCI, NHLBI, NIDCR, and NIAID use these services for research protocols involving refractory cancers with ex-vivo-expanded autologous NK cells, craniofacial defects, and immunodeficiencies such as chronic granulomatous disease. NCI's ability to expand several of their research protocols is limited by the cell processing availability.

Imaging Sciences

The past several years have seen a steadily increasing demand on cutting-edge imaging studies in a variety of IC clinical programs. Virtually every IC has new studies that require MRI, MRI spectroscopy, clinical PET, and computed tomography PET scans. Based on this year's planning meetings, we anticipate continued increase in demand (both in quantity and sophistication) for these procedures. In addition, we have added a new MRI machine in the operating suite that supports the use of this imaging modality in a variety of invasive procedures. To meet the increasing demands, additional resources will likely be required in Imaging Sciences.

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

Trans-Institute Service Requirements - continued

Nursing Support

The several new initiatives described previously (in addition to the program expansions) will certainly require additional nursing FTE and in some instances will require nursing skills not currently present in the Clinical Center Nursing Department (e.g., cardiac surgery intensive care). To maintain existing programs at their current levels and to be able to launch the new initiatives (e.g., obesity, reproductive endocrinology, etc.), additional resources will be needed in Nursing to support these programs.

Phenotyping Center

The Clinical Center has an ongoing history of solving clinical diagnostic dilemmas. For the past few years several programs have expressed interest in identifying phenotyping as a major initiative for the Clinical Center. In this regard, NIAID has already begun a phenotyping clinic for patients presenting perplexing diagnostic problems. Additionally, several other ICs have expressed an interest in this concept, including NIDDK, NHGRI, and NICHD. A phenotyping program might dovetail with several other of the new initiatives (e.g., obesity, intramural/extramural collaboration, etc.). The Clinical Center will monitor the progress of the NIAID clinic to assess resource requirements and will continue dialogue with the Medical Executive Committee about other ICs' efforts in the phenotyping arena. This initiative holds the promise of unifying efforts associated with many existing, and several of the new, programs. Additionally, the phenotyping effort should also provide superb opportunities by providing collaborative and translational opportunities for scientists across the campus who are engaged in basic science genomics and proteomics projects.

Themes from the Fall 2005 Clinical Center/Institute Planning Meetings

Trans-Institute Service Requirements - continued

Outpatient Improvements

One year ago, at the 2004 fall planning meetings, the Institutes, and centers indicated major support for operational and structural improvements in the outpatient clinics. In addition, the Institutes gave very high priority to renovating the surgery department, to establish new outpatient surgery space. Although these two initiatives received very high priority in 2004 by the Clinical Center Board of Governors and the NIH intramural working group, they were not funded in the allocated FY05 budget. During the fall 2005 planning meeting, the Institutes renewed their desire to give improvement of outpatient services a very high priority.

Developing the Operating Plan – Patient Input

"What Are the Patients Telling Us?"

In 2005, Patient Advisory Group members provided valuable input into major organizational initiatives including occupancy of the Mark O. Hatfield Clinical Research Center and the Edmond J. Safra Family Lodge. Recommendations regarding signage, privacy needs, computer requirements, handicap accessibility features, and food services enhanced the transition to these new buildings.

Many other operational programs were reviewed by group members and constructive opportunities for improvement were identified. Group members contributed the following:

- *Development of a "built environment" patient survey to assess patient perceptions in the old and new hospitals*
- *Input into the development of clinical research protocol electronic informed-consent documents*
- *Need for electronic access by patients to medical information*
- *Improvements to outpatient services, specifically regarding scheduling and wait times*
- *Review of Pharmacy Department services with suggested enhancements for patient access to services*
- *Endorsement of the newly establishment Bereavement Program managed by the Pain and Palliative Care Service*
- *Suggestions for the Clinical Center pilot program on biometrics*

Developing the Operating Plan – Employee Input

"What Are the Employees Telling Us?"

Feedback obtained from employees and supervisors who participated in this year's customer service training and exit interviews identified the need for greater support from senior leadership, supervisors and managers. This feedback aligns with the 2004 employee survey results indicating that a supervisor's value for employee contributions was the strongest predictor of job satisfaction, and the leadership survey findings that on occasion, diversity was not perceived to be valued.

As a result, the Clinical Center senior leadership held two retreats to examine the changing context of the Clinical Center and the implications on present and future management practices. One outcome from this effort was the identification of the need to strategically leverage all levels of Clinical Center leadership if succession planning is to become stronger and employee commitment and productivity is to excel. Subsequently a performance management program for supervisors and managers was successfully piloted. Full implementation of this program will begin in January of 2006 as part of the Clinical Center leadership development program. A coaching pilot is currently underway to further enhance leadership development and succession planning. Managers were selected based on their current performance excellence and their "potential" for greater leadership.

Finally, in responding to a climate of limited resources and tight budgets, the need to optimize the successful integration of new employees in the Clinical Center is even more critical. Therefore, the new employee orientation program was re-designed in 2005 based on feedback from new employees as well as managers to make it more effective and efficient. Orientation for all new Clinical Center employees now includes training in each of the Clinical Center competencies within the first week of orientation. The revised "new employee" orientation program includes a new diversity appreciation module and customer service training module that offers tips on how to effectively integrate into the unique and complex culture of the Clinical Center.