National Institutes of Health Clinical Center
"There's no other hospital like it!"

2005 Operating Plan

Message from the Clinical Center Director

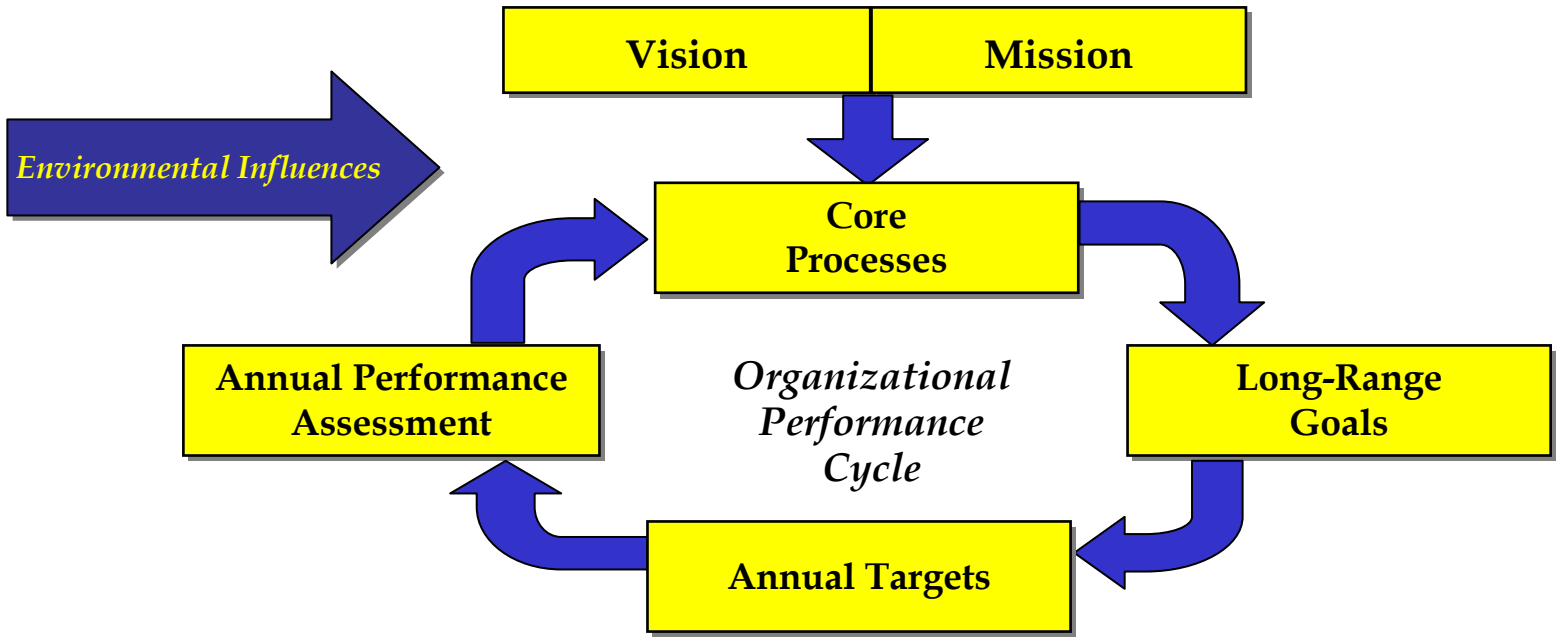
2005 promises to be a historic year for the NIH Clinical Center, with the patient move into the new Mark O. Hatfield Clinical Research Center and the next phase of implementation of the Clinical Research Information System (CRIS). The new hospital increases our capacity to support state-of-the-art clinical research and CRIS extends this capacity with new, reliable electronic services for investigators, patients, and staff. The new Edmond J. Safra Family Lodge will open in spring 2005, providing a comfortable, home-like setting for patient families and guests as their loved ones participate in research protocols at the hospital just steps away.

This plan outlines strategies that CC staff and Institute clinical leaders agree we must implement to sustain the Clinical Center mission effectively. This year's operating plan is particularly important as we are now faced with achieving our goals within the constraints of ever tightening budgets. The need for all of us to proactively identify and increase cost savings, to assess the privatization of some services, and to prioritize ongoing activities is critical.

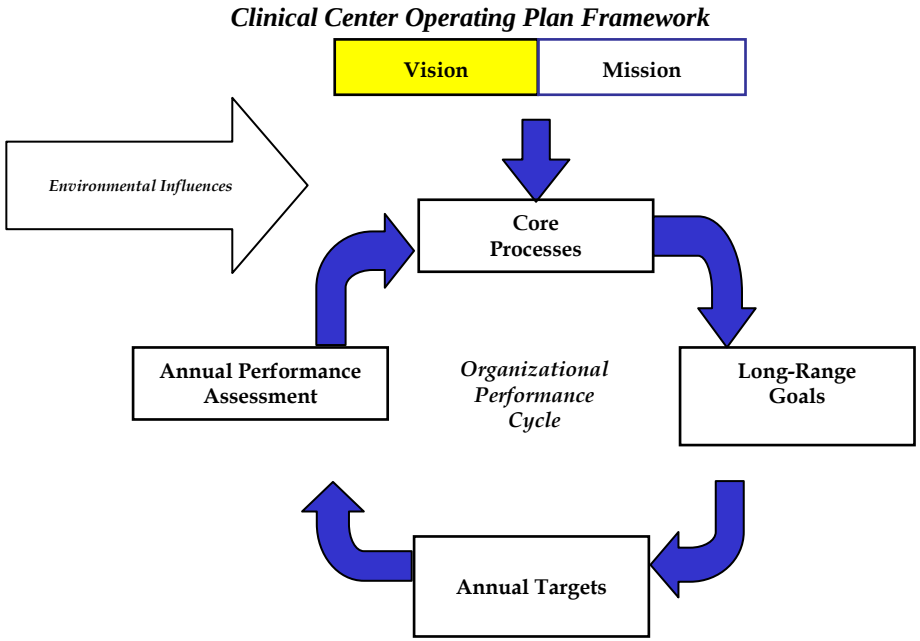
I want to take this opportunity to recognize and thank each Clinical Center employee. Their committed actions, sustained enthusiasm, and consistent efforts to maintain the highest quality of support for our patients and clinical research efforts enabled us to successfully achieve important goals in 2004. I have every confidence that our team's efforts and commitment will make 2005 another successful year.

John I. Gallin, MD
Director

Clinical Center Operating Plan Framework



Vision Statement

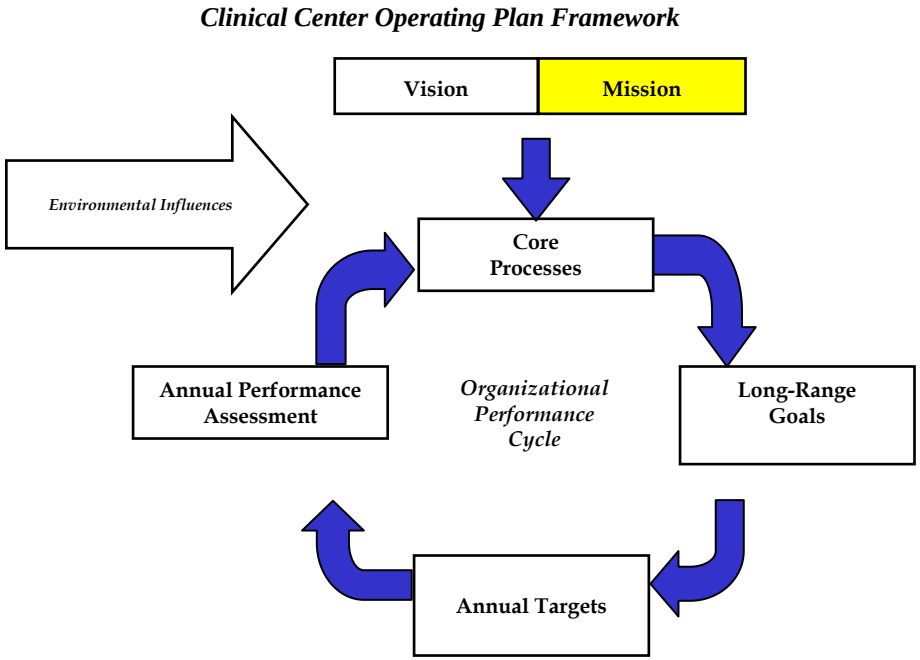


A vision statement:

- ***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 human kind. 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



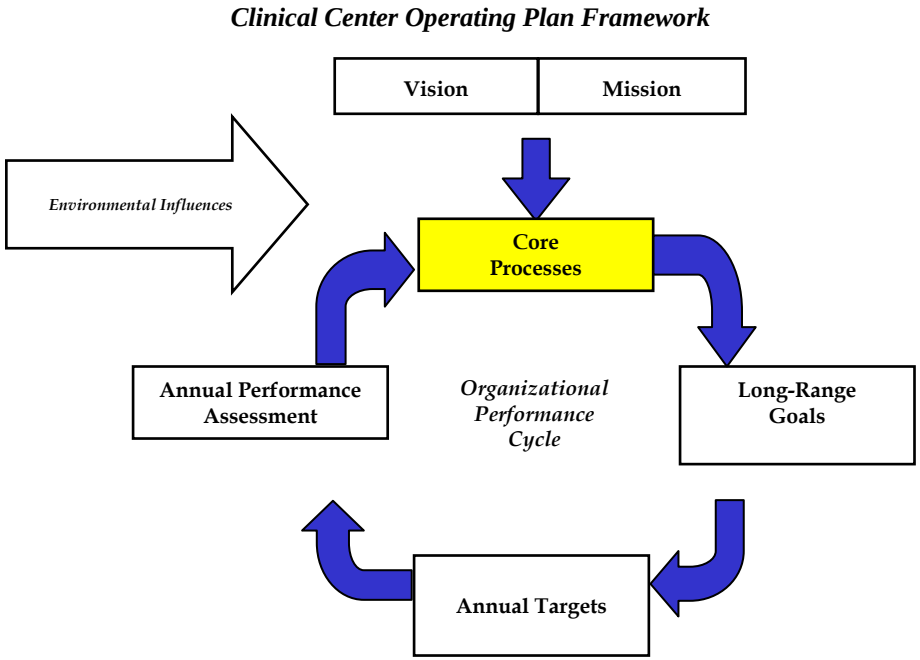
A mission statement answers the question: "What is our fundamental purpose?"

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; and,*
- *development of processes to ensure the safe, efficient, and ethical conduct of clinical research.*

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

Core Processes



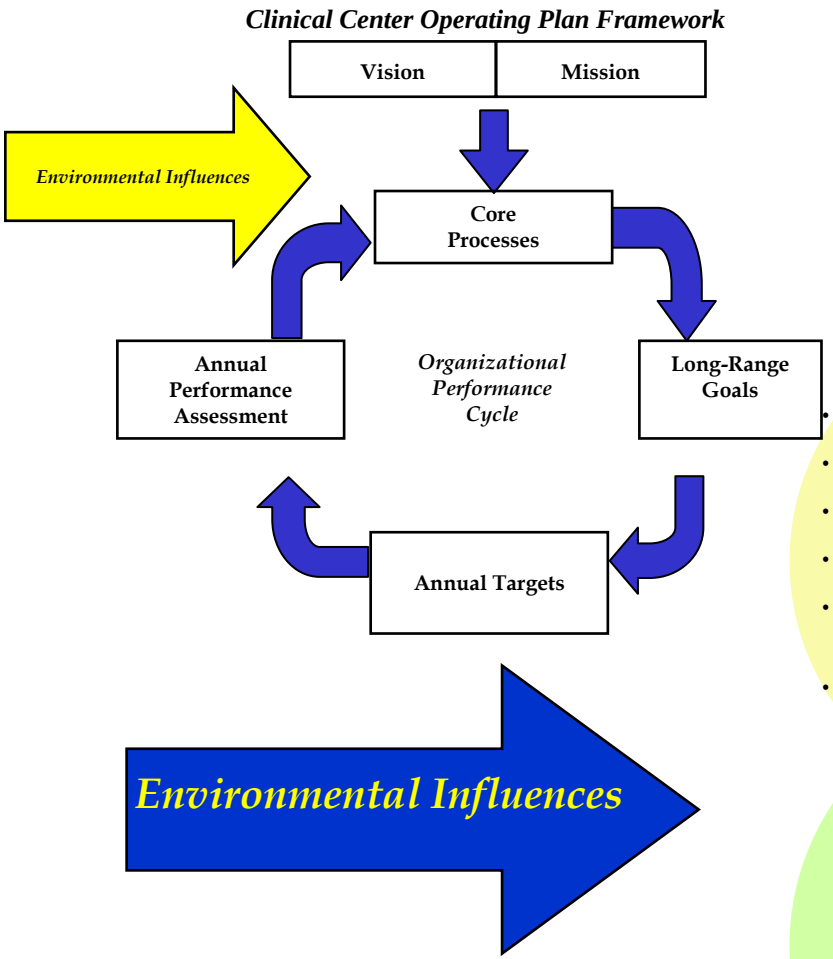
Core processes are the major activities that support the mission.

Clinical Research Support:
Provide staff, services, training, and environment that 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.

Environmental Influences



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

Review & Advisory Bodies

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

Internal Customers

- Institutes
- Patients
- CC Employees

External Customers

- Extramural clinical investigators
- Referring physicians
- Advocacy Groups

NIH Drivers

- Roadmap
- Budgetary Constraints
- Administrative Restructuring & Consolidation (ARAC)

Government & Agency-wide Initiatives

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

Review and Advisory Bodies

Advisory Board for Clinical Research

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 Director, NIH 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 the trans-NIH strategic planning and also advises on the budget and operating plan of the Clinical Center.

Medical Executive Committee (MEC)

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

CC Board of Scientific Counselors (BSC)

The purpose of this group is to secure unbiased and objective evaluation of the independent research programs of the CC 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.

Review and Advisory Bodies (continued)

Patient Advisory Group (PAG)

The Patient Advisory Group (PAG) was established in 1998 when some of patients were invited to provide their perspectives on design of the new Clinical Research Center. The PAG continues to increase momentum with at least twenty 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.

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 announced 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.

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. Currently there are a total of 1,239 active protocols being implemented with CC resources and support.

Patients

Patients come to the NIH from every corner of the United States seeking answers to their scientific and medical questions. They are of all ages, races, cultures, and socio-economic groups. In fiscal year 2004, there were 6,944 admissions, an increase of 2.4 percent; inpatient days were 7.6 percent higher than in the previous year; and there was a 9.8 percent increase in outpatient visits. The CC Normal Volunteer Office has existed since 1955 and provides a pool of normal volunteers available for all institute principal investigators. In FY 2004, over 7,066 volunteers were referred to institute studies.

Clinical Center Employees

With strong race and ethnic diversity comprising our workforce, there are approximately 1,850 Clinical Center employees. One hundred and sixteen employees (15 percent) are officers in the Commissioned Corps of the U.S. Public Health Service. About eighty percent of the CC workforce is assigned to clinical and patient care departments and the remaining twenty percent is in administration and operational support departments. Over the past twenty years, the largest professional growth occupations in the CC have been nurses, allied health professionals and administrative professionals. The CC workforce has declined by eight percent over the past ten years. Employee turnover remains steady and low at ten percent. The average age of CC employees has risen to 45.3 years which is reflective of the healthcare marketplace in general.

External Customers

Extramural Clinical Investigators

In support of the NIH Roadmap for Clinical Research and as a follow up to NIH's issuance of a Request for Applications (RFA) to obtain planning grants for Regional Translational Research Centers (RTRC's), Dr. Gallin and CC senior staff have hosted several meetings with extramural organizations who have an interest in collaborating with the Clinical Center. The question being addressed is how the CC can serve the extramural community and, therefore, become more of a national resource. To date, extramural colleagues have expressed an interest in new tools for informatics (such as ProtoType and a data warehouse for clinical research), training (a place for investigators to complete sabbaticals in clinical research and learn about the administration of a large clinical research facility), and access to special resources (such as a Good Manufacturing Practice facility for making candidate drugs, access to unique patient populations, and special imaging technologies). Some of this sharing of resources or special arrangements can be reciprocal with discussions touching on intramural investigators being able to access large patient populations for referrals, using shared databases for informatics, and sending trainees to extramural sites for rotations.

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 CC will work with the Medical Executive Committee to initiate ongoing surveys of referring physicians.

Advocacy Groups

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

NIH Drivers

NIH Roadmap

The NIH Roadmap was introduced in 2003 under the leadership of Elias A. Zerhouni, M.D., Director, NIH. 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 3 percent increase in fiscal year 2004 and 1.4 percent increase in fiscal year 2005. The Clinical Center received a 1.9 percent increase and a 0.3 percent increase during the same respective time periods. During a time period of significant census growth, mandated cost-of-living increases of 4.1 percent in 2003 and 3.7 percent in 2004 for the vast majority of the Clinical Center's workforce, and continued inflationary pressures associated with health care expenses such as pharmaceuticals and medical supplies, the Clinical Center has worked diligently to become more cost effective within our clinical research environment.

To date, we have been successful in maintaining service levels through targeted decreases in our workforce and other cost saving measures; however, with an anticipated flat budget again in FY06, the intramural community will need to help the CC prioritize services and eliminate those that are no longer affordable. We have launched an aggressive cost containment effort to support patient care and clinical research infrastructure within extremely limited resources.

NIH Drivers (continued)

Administrative Restructuring and Consolidation (ARAC)

Administrative restructuring and consolidation is NIH's strategy to align with the "one HHS" goals by consolidating services across Institutes and Centers (ICs). A Steering Committee was established in early spring 2003, composed of IC Directors, senior executive staff from the NIH Office of the Director, as well as members from the intramural and extramural programs, to advise the Director and Deputy Director on improving NIH operations. Eight working groups have been formed to examine major operational functions.

Government and Agency-wide Initiatives

Government Performance and Results Act (GPRA)

The Government Performance and Results Act (GPRA), enacted in 1993, requires federal agencies to establish standards 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, and 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 and Agency-wide 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 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 (GPRA), The President's Management Agenda (PMA), and PART influence how the Clinical Center executes its planning and performance monitoring activities.

"One HHS"

To align with PMA goals, the Department of Health and Human Services (HHS) has set an overarching direction in order to function as a single entity and coordination of efforts. This strategic vision currently directs all HHS planning and performance efforts. The mission of HHS is to enhance the health and well-being of Americans by fostering strong sustained advances in the sciences underlying medicine, public health and social services. As one of the agencies 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. The HHS Strategic Plan "One HHS" Outcome Goals for 2004-2009 are as follows:

Goal 1	*Reduce the major threats to the health and well-being of Americans.*
Goal 2	*Enhance the ability of the Nation's health care system to effectively respond to bio-terrorism and other public health challenges.*
Goal 3	*Increase the percentage of the Nation's children and adults who have access to regular health care and expand consumer choices.*
Goal 4	*Enhance the capacity and productivity of the Nation's health science research enterprise.*
Goal 5	*Improve the quality of health care services.*
Goal 6	*Improve the economic and social well-being of individuals, families, and communities, especially those most in need.*
Goal 7	*Improve the stability and healthy development of our Nation's children and youth.*
Goal 8	*Achieve excellence in management practices.*

Government and Agency-wide Initiatives (continued)

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. Three studies will be conducted in 2005 that include the Clinical Center with the potential to impact approximated 175 FTE.

Developing the Operating Plan – Institute Input

"What Are the Institutes Telling Us?"

Institute Planning Meetings

Every fall the CC Director completes a series of planning meetings with individual Institutes. Attendees include: Clinical Directors, Scientific Directors, Institute Directors, and Clinical Center senior administrative and clinical staff. Also invited are Institute Branch Chiefs and Clinical Center Department Heads. Following these meetings, the Clinical Center generates a thematic summary of growth areas in the intramural clinical research program. Institute leaders verify plans, review resource projections, and identify any service support issues.

The overall purpose of the planning process is to:

- *obtain Institute plans for use of Clinical Center resources in the upcoming fiscal year and beyond;*
- *review and develop new objectives for the Clinical Center operating plan in alignment with Institute needs; and,*
- *elicit feedback from Institutes on the availability and quality of Clinical Center services.*

Themes from the Fall 2004 CC/Institute Planning Meetings

- *Outpatient services*
- *National phenotyping center*
- *Multi-institute obesity research program*
- *Matched unrelated stem cell transplantation*
- *Vaccine development*
- *Expansion of specialty and subspecialty training programs*
- *Pediatrics*

Themes from the Fall 2004 CC/Institute Planning Meetings

Outpatient Services

At the 2003 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 renovate the surgery department to establish new outpatient surgery space. Although these two initiatives received very high priority in 2004 by the CC Board of Governors and the NIH intramural working group, they were not funded in the allocated 2005 budget. During the fall 2004 planning meeting, the institutes renewed their desire to give improvement of outpatient services a very high priority.

National Phenotyping Center

A major theme that emerged from the fall 2004 planning meetings was to establish program based clinics for phenotyping patients. Almost every institute described a need for expanded clinics to evaluate patients with rare (orphan) diseases or unusual manifestations of common diseases. A few of the many examples of specific institute directions include the NHGRI, in collaboration with the Office of Rare Diseases and multiple institutes, to expand its orphan disease clinic; NIAID's plan to open a clinic to evaluate patients with recurrent and unusual infections; and NIAMS plans to expand the Cardozo clinic to see patients with rheumatologic diseases and patients with periodic illnesses. It was anticipated that many patients seen in phenotype clinics would either be enrolled into existing protocols or be recognized as having a new disease and become the basis for new protocols. Phenotype clinics would serve the extramural clinical research community by establishing new clinical standards for defining different diseases and would provide an important service to referring physicians and patients by assisting in the diagnosis of unsolved complex clinical problems.

Themes from the Fall 2004 CC/Institute Planning Meetings

Multi-Institute Obesity Research Program

In 2004, in response to the burgeoning problem of obesity in the U.S. population, several Institutes and Centers (ICs) proposed a trans-institute collaboration to: 1) develop an improved understanding of the 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 consortium plans to establish a magnet facility in the new CRC that includes a state-of-the-art laboratory, as well as clinical investigative and imaging capabilities that could support NIH-wide intramural scientists interested in obesity research. The investment of several institutes in the program should foster multidisciplinary approaches to obesity research. 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. The program will require a substantial block of 'behavioral health' clinical space in the new CRC. Some renovation of existing clinical space, including installation of a metabolic chamber, will be required to meet program needs.

Matched Unrelated Stem Cell Transplantation

Several institutes expressed an interest in creating a multi-institute collaborative program employing matched, unrelated donor stem cell transplantation. Institutes expressing interest to date include NCI, NIAID, and NHLBI; however other ICs will likely have similar interests. Creation of this program will be resource-intense, but the institutes that will be performing these studies anticipate cutting back on other stem cell transplantation programs, so as not to increase service demands inordinately. Nonetheless, the creation of the matched, unrelated donor program will almost certainly increase demand for critical care medicine services and may increase demand on certain aspects of transfusion medicine services.

Themes from the Fall 2004 CC/Institute Planning Meetings

Vaccine Development

Another general area in which activity is increasing is vaccine development. NIAID is aggressively pursuing a SARS DNA vaccine and a West Nile virus DNA vaccine, in addition to ongoing studies with candidate vaccines for human immunodeficiency virus. Clinical trials of candidate malaria vaccines will also likely begin in 2005. NCI has created a new vaccine branch to develop anti-cancer vaccines and NICHD is expanding its current vaccine effort to prevent anthrax and tuberculosis. The new CRC will house a Vaccine Testing/Self-Care Unit that is currently being designed as a modification to the new facility in space that had previously been "shelled". The current vaccine clinic will remain in the existing CC to provide continuity for this growing program until the new space is ready.

Expansion of Specialty and Subspecialty Training Programs

Clinical training remains a focus of several institutes' clinical programs. In the coming year, several clinical training initiatives were identified in the planning meetings, among them: NINDS is considering the creation of a neurology residency program; NIAAA is planning to develop direct training and education programs for scientists to become certified in mental health/ alcohol clinical investigation, including an emphasis on evidence-based practice; NIDDK is planning new clinical training programs including a reinvigorated gastroenterology fellowship as well as an advanced fellowship in clinical research.

Pediatrics

Pediatric efforts have been increasing at the Clinical Center over the past several years and this trend will likely continue in 2005.

- *NIAID plans to open a new Pediatric Allergy Clinic.*
- *NCI has launched a new pediatric vaccine branch.*
- *NICHD is expanding its current vaccine efforts.*
- *NIMH is considering the development of an autism program.*
- *NHGRI will increase its pediatric pulmonary functions studies.*

These expansions will almost certainly require additional CC clinical staff and space.

Developing the Operating Plan – Patient Input

"What Are the Patients Telling Us?"

In 2004, Patient Advisory Group members engaged in assessing CC therapeutic patient programs as well as making recommendations for the final stages of CRC planning. Feedback on therapeutic programs included:

- *need for improved outpatient services, including reduced clinic waiting time, more comfortable and less crowded waiting areas, and private places for consultations. (This input influenced the creation of a patient care goal to address outpatient services in the 2005 Operating Plan.)*
- *input into the development of a new model for "room service delivery" by the Nutrition Department. (This new system has been implemented with favorable feedback from patients.)*
- *a high regard for the value and continued provision of services by the Pain & Palliative Care Service. (The CC continues to support the Pain & Palliative Care Service.)*
- *support for the therapeutic value of the Caring Canines Program.(The CC continues to provide Caring Canines Program for patients.)*
- *suggestions for further expanded outreach initiatives to enhance patient recruitment to minority populations such as the Cardozo Clinic (Further discussions with Institutes on outreach services were integrated into the 2004 Planning Meetings).*
- *input into the planned services at the Edmond J. Safra Family Lodge. (Lodge scheduled to open in Spring 2005. Much of the input of the Patient Advisory Group influenced the design of the facility and service requirements for patients' families.)*

Patient feedback on the provision and planning of selected Clinical Center services that have been implemented during CRC activation include:

- *improved amenities (e.g., coffee shop, gift shop);*
- *install electronic kiosks to provide way-finding and patient information;*
- *increase the number of hospitability stations throughout the building; and,*
- *provision of a business center for patients and families.*

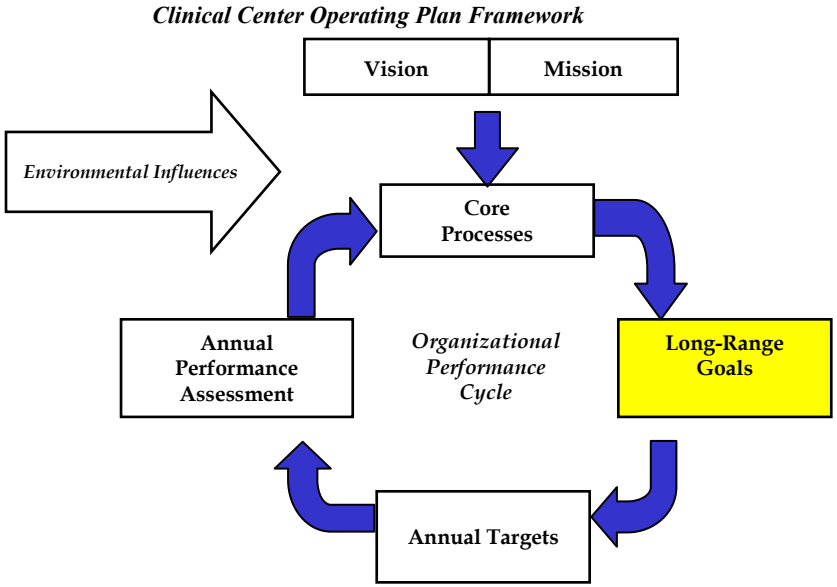
Developing the Operating Plan – Employee Input

"What Are the Employees Telling Us?"

Results from an employee survey completed in 2004 indicated that a supervisor's value for employee contributions was the strongest predictor of job satisfaction and that on occasion, diversity was not valued. As a result, the Clinical Center initiated a diversity management program to respond to survey findings.

Interviews related to diversity were conducted with the Clinical Center senior staff and reviewed by the executive leadership. The general thematic perception based on these interviews was the need to improve management and leadership skills. Subsequently, the Clinical Center launched the planning and implementation of a leadership development program to include the integration of leadership succession planning, development of employee competencies, and diversity management. A training session to improve management skills will be the focus of a two-day department heads retreat in April 2005.

Clinical Center Long-Range Goals



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

- *Facilitate implementation of innovative Institute clinical research programs.*
- *Develop new tools for conducting and managing clinical research.*
- *Serve as a national resource for training and supporting clinical research teams.*
- *Improve quality and safety of patient care.*
- *Conserve resources, reduce costs, and improve employee performance and productivity.*

2005 Clinical Center Operational Planning Matrix

Long-term

	Clinical Research Support			Patient Care	Operational Management
Core Processes					
Long-range Goals	Facilitate implementation of innovative Institute clinical research programs.	Develop new tools for conducting and managing clinical research.	Serve as a national resource for training and supporting clinical research teams.	Improve quality and safety of patient care.	Conserve resources, reduce costs, and maximize employee performance and productivity.
Executive Leadership	David Henderson, M.D. Maureen Gormley, R.N., MPH Clare Hastings, R.N., PhD Lisa Lacasse, MBA	Stephen Rosenfeld, M.D.	Frederick Ognibene, M.D.	David Henderson, M.D. Clare Hastings, R.N., PhD	Lisa Lacasse, MBA. Maureen Gormley, R.N., MPH
Measurement Methodology For Long-range Goals	• Institute perception of CC responsiveness to new program requirements.	• Stakeholder perceptions. • External collaborations. • % completion of new tools deployed. • Frequency of use of new tools (internal/external).	• Number and demographics of participants by program, course and location and number of clinical research curriculum certificates awarded at the CC. • Utilization of resources (web hits, DVD distribution, etc.) • Publication of text book and articles describing training initiatives.	• Perception scores (patient, staff, investigator, referring MD). • JCAHO accreditation scores. • Occurrence Reporting System Data.	• Cost per clinical research patient day adjusted for research intensity. • FTEs per clinical research patient day. • Staff perception surveys. • Vacancy/turnover rate. • Diversity profile. • Number of staff on performance plan.

Annual

2005 Annual Targets	1. Support implementation of multi-Institute obesity and NIAID vaccine research programs. 2. Activate the Clinical Research Center and adapt patient care and administrative processes to new hospital.	1. Disseminate ProtoType, an automated tool to assist investigators in writing protocols. 2. Implement CRIS Phase II, including the data warehouse. 3. Implement research intensity measurement system.	1. Develop a sabbatical program in clinical research management.	1. Improve provision of outpatient services. 2. Test the utility of a patient biometric identification system. 3. Implement patient bedside information system.	1. Complete feasibility study on third party reimbursement. 2. Launch leadership and diversity development program. 3. Prioritize and implement cost saving strategies. 4. Identify benchmarks for resource requirements in clinical research.

CC Planning and Budget Development Process

Timeline

Key Drivers to Development of CC Budget

Resource Deployment

Many of the drivers described in this plan impact budget requirements for the Clinical Center. The CC budget development process is organized in the context of three major categories: Commitment Base, Clinical Research Program Changes, and Hospital Infrastructure Requirements. This breakdown complies with the 'commitment base' format requested by the NIH Funding Advisory Review Board and creates a framework within which CC department heads can align requests.

During annual planning meetings with Institutes, areas of emphasis for clinical research within the intramural program are identified. The Clinical Center synthesizes the input and develops a thematic summary of areas of change and growth due to new or expanding programs. This information is provided to CC department heads who translate Institute research directions into resource requirements and related departmental budget needs.

Each year as the Clinical Center budget is developed, department heads consider ongoing costs in each of several categories of needs known in the federal sector as 'object classes.' For example, these categories include salaries and benefits, equipment, travel, supplies, training, and contracts. Although many of these ongoing costs (e.g., salaries and benefits, cost-of-living increases) are non-discretionary, the Clinical Center's executive management team evaluates each department's submission at the 'line item' level – taking a zero-based approach to budget development. This practice allows for evaluation of costs to identify opportunities for efficiencies and to facilitate realignment of resources to assure funding for new and expanding clinical research needs and critical management initiatives.

Hospital infrastructure requires changes that are organizational-wide, as well as department-specific. Whereas clinical research program changes are in direct response to new areas of emphasis identified by the Institutes, this category of resources includes changes implemented for the good of the entire organization. For example, these changes might be regulatory-driven (e.g., adverse-event reporting system); patient care-related (e.g., new patient safety program); or program-driven (e.g., purchase of updated software).

Often the CC identifies internal efficiencies and is able to fund these improvements within existing resources. This internal planning allows the CC to shift resources to support aspects of clinical research program changes without increasing the overall budget.