National Institutes of Health Clinical Center

"There's no other hospital like it!"

2007 Operating Plan

Message from the Clinical Center Director

This Clinical Center operating plan highlights important priorities that we will pursue in 2007, to support Institute clinical research programs and to maintain provision of a quality environment for the care of our patients. We continue to be challenged by a flat budget while facing escalating costs, healthcare inflation, and "lots of new ideas." It is imperative that we carry out our mission with a keen eye toward conservation of resources. This year our efforts in support of clinical research will focus on opening two new patient care units, one dedicated to obesity and the other to vaccine development. In addition to providing support for the ongoing studies, we expect to see growth in the areas of sickle cell anemia, pulmonary hypertension, and medical oncology.

The Clinical Center's special combination of clinical resources (e.g., imaging, cell processing, specially trained clinical research nurses), research support services (e.g., biostatisticians, pharmaceutical development, ligand development), training programs in clinical research, and informatics tools (e.g., clinical research information system, ProtoType) offers a robust environment for clinical and translational science. Additionally, the concentration of clinician-investigators at the Clinical Center provides a multi-disciplinary professional community for collaboration. The Clinical Center will pursue a new strategy to foster intramural/extramural collaborations as it participates actively in the Clinical and Translational Science Awards (CTSA) network, an NIH initiative to energize clinical and translational science within the medical community. Finally, evaluation of the bench-to-bedside program expansion with extramural researchers will be completed this year while support of clinical research training programs to develop future clinical researchers remains a priority.

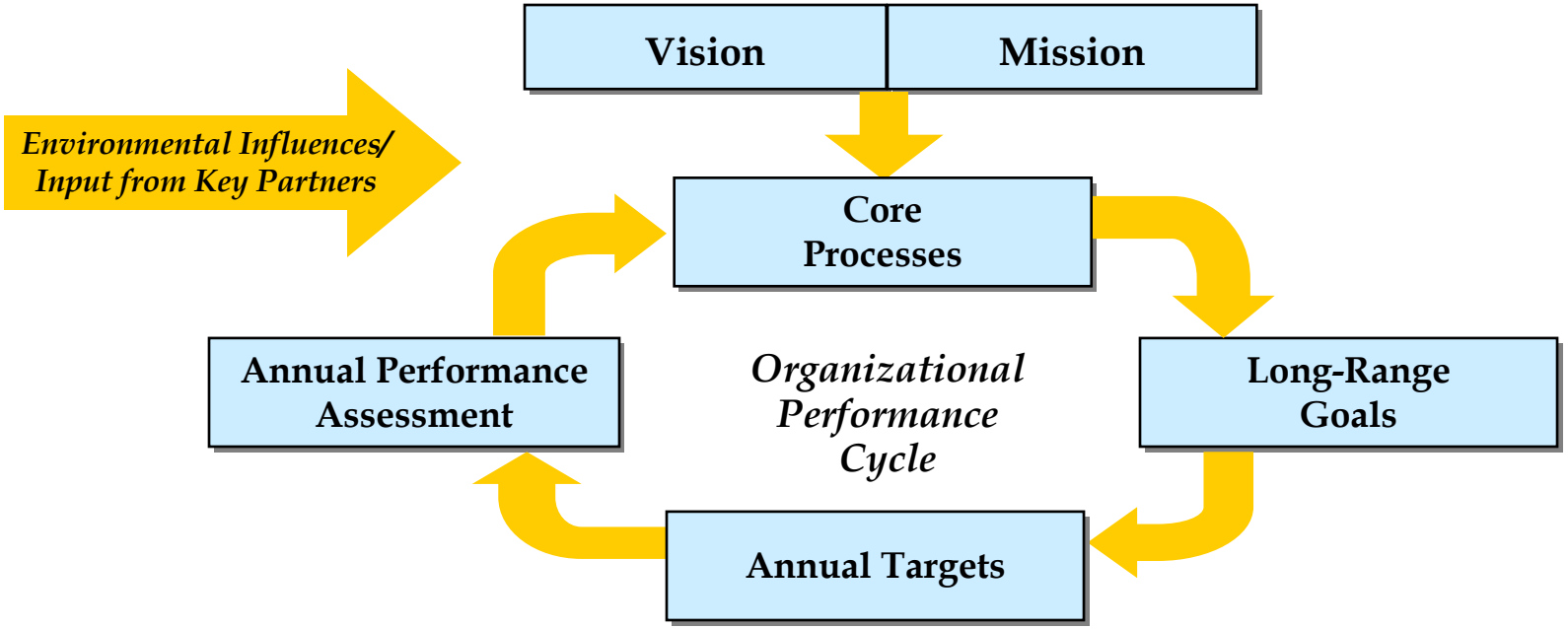
The Clinical Center operating plan impacts our employees by directly communicating what actions and resources we must mobilize to achieve our goals. The commitment and competency of our workforce is fundamental to the Clinical Center's success. I am committed to providing Clinical Center and NIH employees with timely communications as I believe it not only builds trust but also contributes to achieving the best results.

We are all important members of the NIH community. The value of medical research here at the Clinical Center is upheld through our simultaneous support of clinical investigation and the patient experience. However, our competencies today may not be adequate to support tomorrow's science. Our collective efforts must be aimed at developing our staff so we have the skills needed to redirect resources for future programs. The Clinical Center is very fortunate to have a workforce committed to this important mission. Together I believe we can successfully meet the challenges that we face in the coming year and plan for tomorrow's challenges.

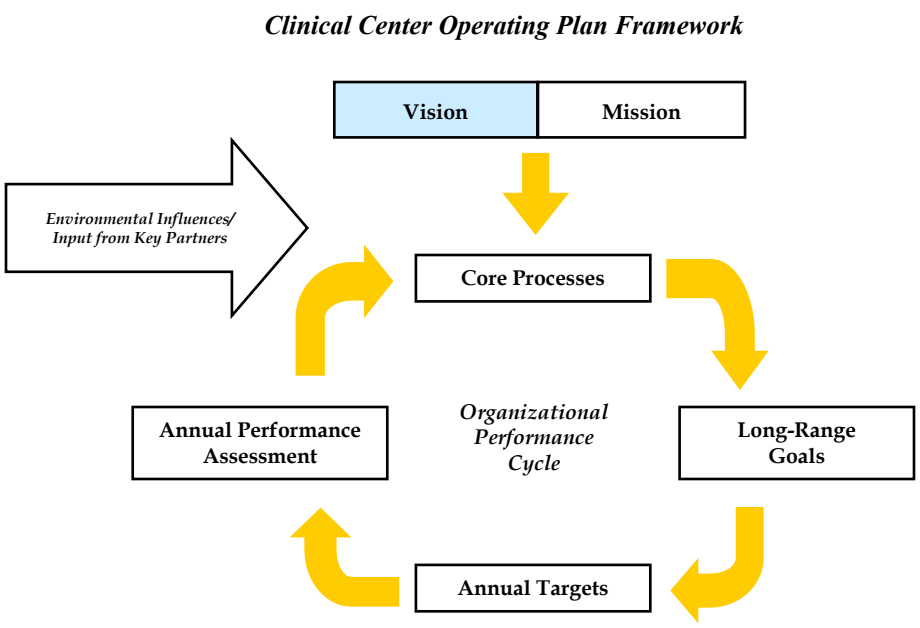
I look forward to working with each of you to achieve the Clinical Center's goals for 2007.

John I. Gallin, M.D.
Director, Clinical Center

Clinical Center Operating Plan Framework



Vision Statement

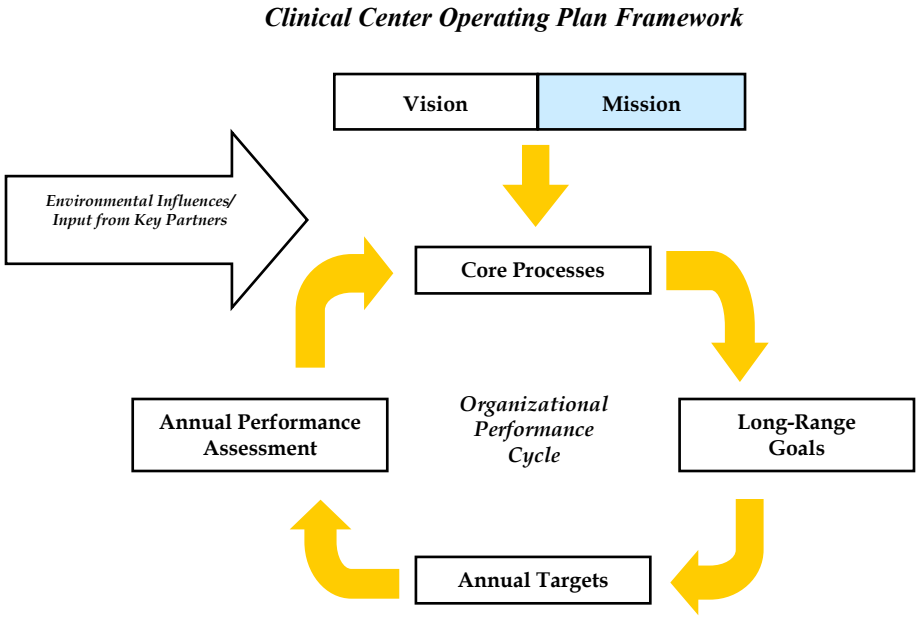


A vision statement:

- ***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 clinical research response to the nation's emerging public health needs.

Mission Statement



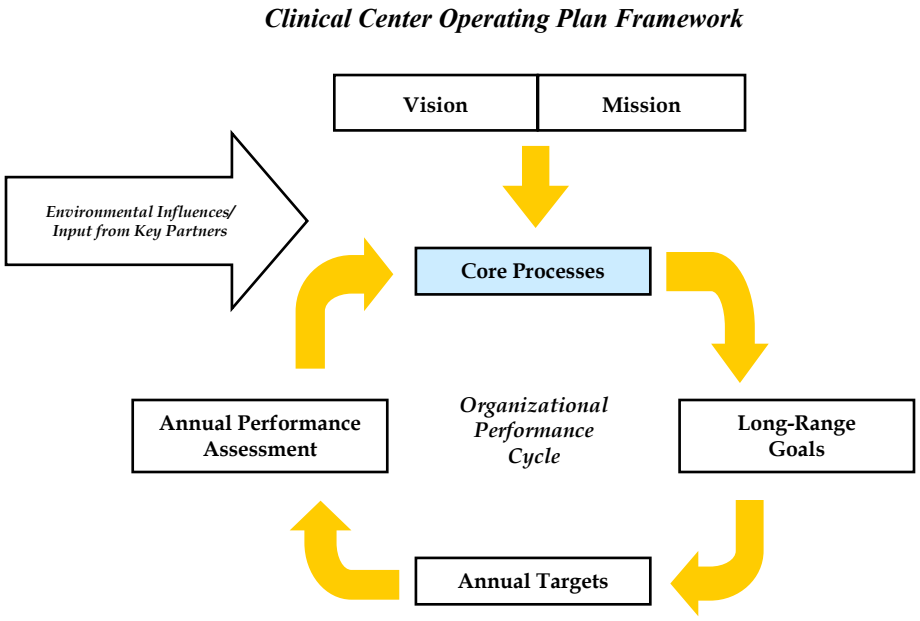
A mission statement answers the question: "What is our fundamental purpose?"

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



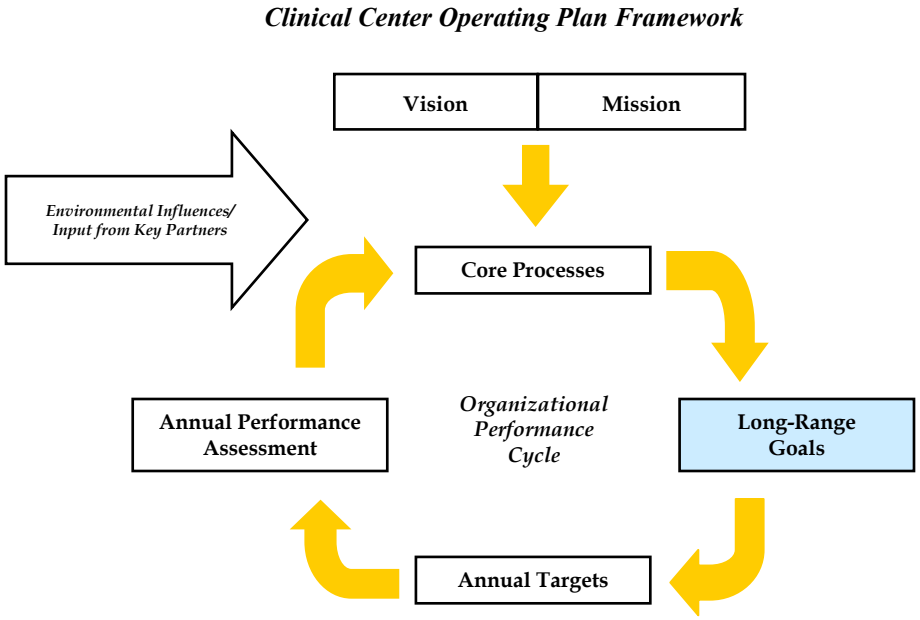
Core processes are the major activities that support the mission.

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.

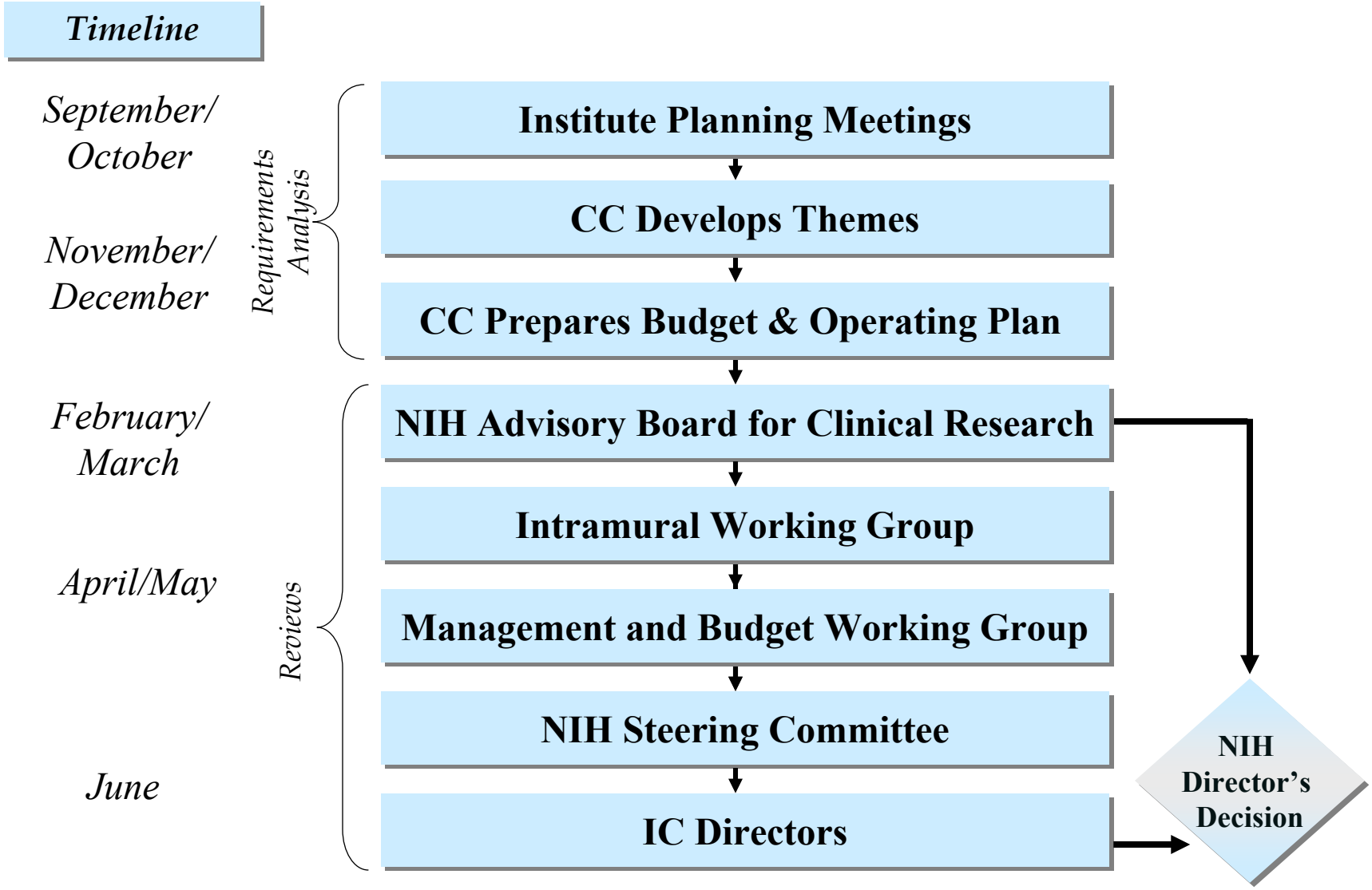
Clinical Center Long-Range Goals



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.*
- *Ensure quality and safety of patient care.*
- *Conserve resources, contain costs, and improve employee satisfaction, performance, and productivity.*

Clinical Center Planning and Budget Review Process



2007 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.*	*Ensure quality and safety of patient care.*	*Conserve resources, contain costs, and improve employee satisfaction, performance, and productivity.*
2007 Annual Targets	1. Support new/expanding Institute programs: - Open Metabolic Unit - Activate Vaccine Research Unit 2. Implement new patient travel policy 3. Develop strategy to enhance the following lab services for clinical diagnostic purposes: - Tissue Typing - Genetic Testing - DNA sequencing 4. Complete business case for next phase of Clinical Research Information System (CRIS) 5. Support NIH Office of Human Subjects Research (OHSR) in applying for AAHRPP accreditation (Association for the Accreditation of Human Research Protection Programs, Inc. ®) 6. Design a plan to provide support for regulatory aspects of protocol development 7. Foster intramural/extramural collaborations: - Participate in Clinical and Translational Science Awards (CTSA) network - Evaluate bench-to-bedside extramural expansion - Launch new curriculum in clinical research management	1. Renovate clinics and ambulatory surgery 2. Improve patient care aspects of CRIS: - Design pharmacy information system - Implement automated clinical documentation for physicians 3. Improve patient wait times. 4. Develop a dashboard and training in clinical performance measurement	1. Improve resource data capture and reporting to: - Institutionalize benchmarking - Ensure accurate attribution of patients and protocols - Provide Institutes with more detailed reports of use 2. Foster leadership and workforce development by providing the following: - Executive coaching for 6-10 employees - Training in effective performance management - Employee exit interviews 3. Develop placement opportunities for people with disabilities, including disabled war veterans.

Financial Assessment of Annual Targets – Clinical Research Support

1	*Support new/expanding Institute programs:* • *Open Metabolic Unit* • *Activate Vaccine Research Unit*	*Both of these initiatives have earmarked operational funds from the sponsoring Institutes.*
2	*Implement new patient travel policy*	*The new travel policy is a NIH-mandated initiative. Any increases in overhead incurred as a result of administering this new policy will be requested by the CC as part of its FY 2008 operating budget.*
3	*Develop strategy to enhance the following lab services for clinical diagnostic purposes:* • *Tissue typing* • *Genetic testing* • *DNA sequencing*	*This initiative has no impact on the FY 2007 budget as the project entails development of a strategy for providing services which will generate a budgetary estimate for consideration in future years.*
4	*Complete business case for next phase of Clinical Research Information System (CRIS)*	*The CRIS project is funded outside of the Clinical Center operating budget through NIH enterprise funds. CC and IC staff time is required but no incremental budget impact is expected.*
5	*Support NIH Office of Human Subjects Research (OHSR) in applying for AAHRPP accreditation (Association for the Accreditation of Human Research Protection Programs, Inc. ®)*	*The financial impact of this initiative is staff time plus an application cost of $70,000.*
6	*Design a plan to provide support for regulatory aspects of protocol development*	*This initiative has no impact on the FY 2007 budget as the project entails development of a strategy for providing services which will generate a budgetary estimate for consideration in future years.*
7	*Foster intramural/extramural collaborations:* • *Participate in CTSA network* • *Evaluate bench-to-bedside extramural expansion* • *Launch new curriculum in clinical research management*	• *Participation in the CTSA network requires only staff time at this point.* • *The CC has received NIH set-aside funds to evaluate the bench-to-bedside project.* • *For the new curriculum, the CC will request funds external to its operating budget through collaboration with other NIH components; only expense is level of effort from CC staff.*

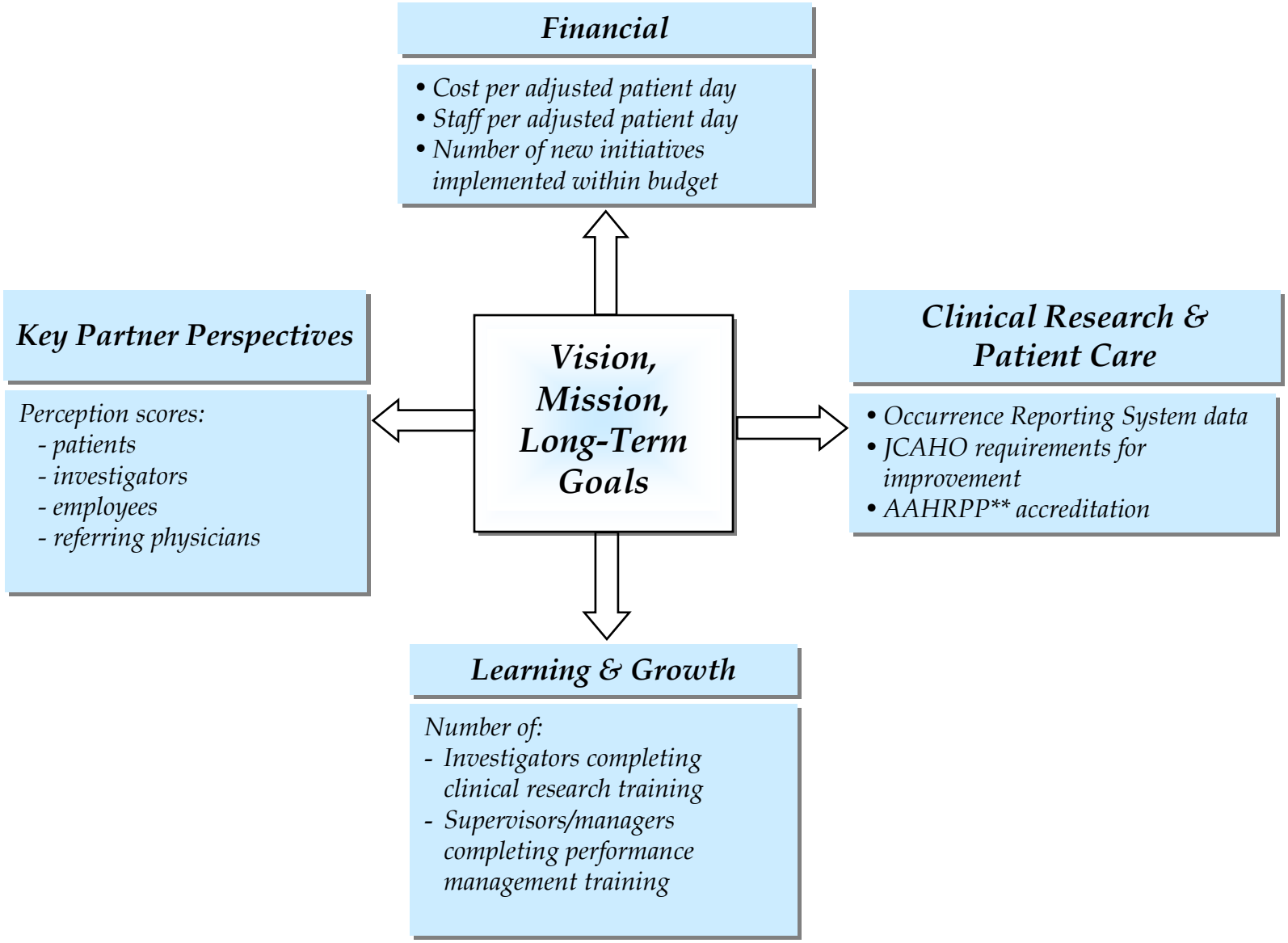
Financial Assessment of Annual Targets - Patient Care

1	*Renovate clinics and ambulatory surgery*	*The funding for these renovation projects requires NIH Building and Facilities (B&F) funds. These funds have been transferred from prior year operating budgets to NIH for this purpose.*
2	*Improve patient care aspects of CRIS:* • *Design pharmacy information system* • *Implement automated clinical documentation for physicians*	*The CRIS project is funded outside of the Clinical Center operating budget through NIH enterprise funds. CC and IC staff time is required but there will be no incremental budget impact.*
3	*Improve patient wait times.*	*The planning for improvements as well as implementation of selected strategies will occur in FY 2007 with no anticipated budgetary impact.*
4	*Develop a dashboard and training in clinical performance measurement*	*Training cost with Maryland Hospital Association is $10,000.*

Financial Assessment of Annual Targets – Operational Management

1	*Improve resource data capture and reporting to:* • *Institutionalize benchmarking* • *Ensure accurate attribution of patients and protocols* • *Provide Institutes with more detailed reports of resource use*	*This initiative was funded with FY 2006 funds. Any additional funds needed will be covered by reprogramming in FY 2007 and/or out-year budget requests.*
2	*Foster leadership and workforce development by providing the following:* • *Executive coaching for 6-10 employees* • *Training in effective performance management* • *Employee exit interviews*	*This initiative is included in the CC base budget in the Office of Workforce Planning and Development.*
3	*Develop placement opportunities for people with disabilities, including disabled war veterans.*	*This initiative will require staff time but no incremental cost to CC budget.*

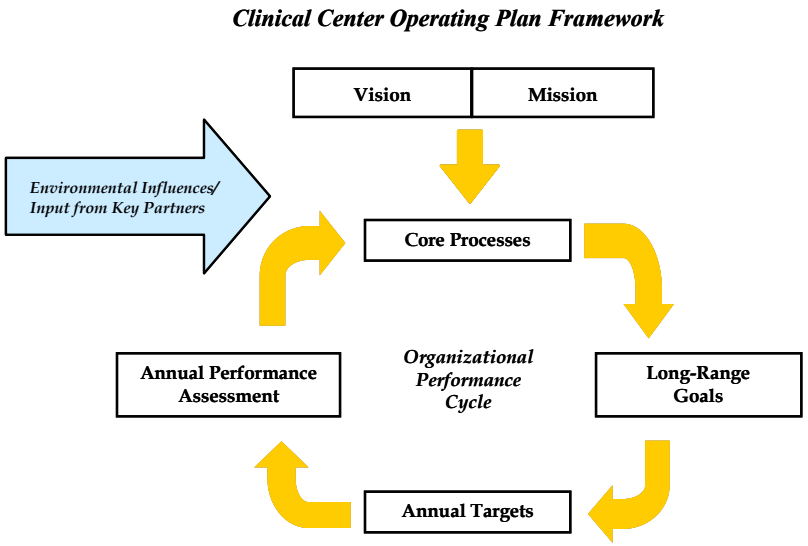
*Measurement Methodology – A Balanced Scorecard Approach**



* *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.®*

Environmental Influences and Key Partners



Environmental influences are drivers/barriers considered in strategy development. Key partners are customers/stakeholders whose input and requirements inform our strategic direction.

Environmental Influences/ Input from Key Partners:

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

Environmental Influences & Key Partners

Government Initiatives

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

DHHS/NIH Drivers

- *"One HHS" – 8 Strategic Goals*
- *NIH Roadmap*
- *Budgetary Constraints*

Health Care Industry

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

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*

Customers/Stakeholders

Internal

- *Patients*
- *Institutes*
- *Clinical Center Employees*

External

- *Extramural Clinical Investigators*
- *Referring Physicians*
- *Advocacy Groups*
- *The Public*

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 GPRA, PMA, 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. Two studies (Food Services and Patient Care Unit Clerks) involving 120 Clinical Center FTEs were completed in 2006 and both studies resulted in the function remaining in-house under a Most Efficient Organization (MEO). A study of the Clinical Center administrative support services function began in 2006 and will affect approximately 80 Clinical Center FTEs; this study will be completed in 2007. No new studies are planned for 2007.

Performance Management Appraisal System (PMAP)

Performance management is the systematic process whereby management involves its employees, as individuals and group members, in improving organizational effectiveness in accomplishing the organizational mission and goals. HHS has adopted a new four-tiered performance management appraisal system (PMAP) to replace the current pass/fail system. The HHS PMAP is being implemented now as the federal workforce is moving toward performance programs that make clear performance distinctions, e.g., multi-level rating programs, and that link performance to awards. Over the past year, all Clinical Center employees have been put on new performance plans and all performance will now be rated under the new system (i.e., exceptional, fully successful, minimally successful, unacceptable).

DHHS/NIH Drivers

"One HHS" – 8 Strategic Goals for 2007

The mission of HHS is to enhance the health and well-being of Americans by fostering and sustaining advances in the sciences underlying medicine, public health and social services. As an agency in HHS, the NIH is dedicated to the conduct and support of medical research. As a part of this agency matrix, all planning and performance goals for the Clinical Center cascade from the HHS strategic plan. The table below reflects alignment of CC Long-Range Goals with HHS Strategic Goals.

	NIH Clinical Center Long-Range Goals		
HHS 2007 Strategic Goals	*Provide timely support for implementation of new Institute clinical research programs and strengthen the infrastructure for delivery of and training in clinical research.*	*Ensure quality and safety of patient care.*	*Conserve resources, contain costs, and improve employee performance and productivity.*
1) Reduce the major threats to the health and well-being of Americans.			
2) Enhance the ability of the Nation's healthcare system to effectively respond to terrorism and other public health challenges.		☑	
3) Increase the percentage of the Nation's children and adults who have access to health care services, and expand consumer choices.	☑		
4) Enhance the capacity and productivity of the Nation's health science research enterprise.	☑	☑	☑
5) Improve the quality of healthcare services.	☑	☑	☑
6) Improve the economic and social well-being of individuals, families, and communities, especially those most in need.			
7) Improve the stability and healthy development of our Nation's children and youth.			
8) Achieve excellence in management practices.	☑	☑	☑

DHHS/NIH Drivers

NIH Roadmap

The NIH Roadmap was introduced in 2003 under the leadership of NIH Director Elias A. Zerhouni, M.D. This Roadmap provides a framework of the priorities that 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. 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, and the Advisory Board for Clinical Research (ABCR) was the result.

Budgetary Constraints

The Congressionally appropriated NIH annual budget (approximately $28B) has remained relatively constant since Fiscal Year (FY) 2004. Consequently, NIH Central Services, including the Clinical Center, have been required to remain constant as well. FY2007 is the 4th year of virtually flat budgets which presents a significant leadership and managerial challenge. The Clinical Center has worked aggressively to become more cost effective in order to support patient census and Institute research program requirements while meeting mandated cost-of-living inflationary pressures associated with required investment in capital equipment and health care expenses including pharmaceuticals and medical supplies.

To date, the Clinical Center has been successful in maintaining service levels through targeted decreases in workforce and other cost-saving measures. However, with a continued flat budget in FY07, and anticipated flat budget for FY2008, the Clinical Center is engaging with the leadership of the NIH and the intramural community to determine prioritization of services and how to improve productivity. It is unlikely that the Clinical Center will be successful in continuing to operate with a flat budget without the reduction or elimination of services in FY2008. The Clinical Center's cost-containment focus for FY2007, however, will be on areas identified through benchmarking efforts in FY2006. Action items from Operational Reviews and additional management efforts are geared to minimize service reductions or eliminations. The Clinical Center remains strongly committed to maintaining a vigorous clinical research infrastructure even within the confines of extremely limited resources.

Health Care Industry

Patient Safety and Clinical Quality

The safe and effective care of patients who 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 to demystify some common misconceptions.

Information 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.

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. A major effort this year has been the reinvigoration of the process of operational reviews which assess the quality and efficiency of CC departments on a three-year cycle.

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 momentum of the PAG continues to increase; at least 20 patients and/or family members attend 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 January 2006, the JCAHO began conducting unannounced accreditation surveys. In September 2006 the Clinical Center received full accreditation under this new survey process.

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

Throughout 2006, a group of clinical fellows representing all Institutes met quarterly with Dr. Gallin. Established in 2004, this committee provides a communications venue for clinical fellows to present issues and initiatives involving the Clinical Center. In 2006, the Clinical Fellows Committee (ClinFelCom) achieved important successes. A ClinFelCom website was established to share group activities and to provide access to resources for grant writing programs available to clinical fellows at NIH. In addition, the group met with NIH leadership to express fellows' concerns regarding access to childcare. As a result, a survey was initiated to gather data and continue dialogue to enhance childcare services. This group assumed leadership in identifying needs for improvement related to pagers for clinical staff. Data were collected and key NIH leaders have engaged in processes to identify resolution to beeper-related issues. The group also focused on educating fellows regarding the importance of using the CC occurrence reporting system for beeper problems and other issues. The ClinFelCom continues to dialogue with NIH leaders to pursue implementation of the Associate Clinical Investigator position, which is in support of efforts spearheaded by the NIH Advisory Board for Clinical Research. Other issues specific to clinical fellows being reviewed by the group include relocation costs, food services, and licensure costs.

Customers/Stakeholders - Internal

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 ICs whose clinical programs are on the Bethesda campus. In FY06, there were a total of 1,372 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 FY06, there were 6,096 admissions, a decrease of 8 percent from FY05; inpatient days decreased 11 percent from the previous year, and the length of stay decreased 6 percent. There was a 9 percent decrease in outpatient visits. In FY06, 1,926 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, is part of the PRPL and provides a pool of healthy volunteers available for all principal investigators. In FY06, the CRVP program registered 4,993 new volunteers.

Clinical Center Employees

The Clinical Center workforce is comprised of approximately 1825 federal employees and approximately 310 contract staff. There are 103 employees (6%) who are officers in the Commissioned Corps of the U.S. Public Health Service. Approximately 82 percent of the Clinical Center workforce is 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 professional occupations with the largest growth have been nursing, medicine, and allied health. The Clinical Center workforce has decreased by 6.2 percent (124 employees) over the past 4 years due to increasing efforts at cost containment in the area of personnel expense. Employee turnover rose slightly during the past year, going from 10% to 12%.The average age of Clinical Center employees is 45.5 years which reflects the health care marketplace in general.

Customers/Stakeholders - External

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, 19 awards were given to intramural-extramural investigators for their work in rare diseases, AIDS, minority health disparities, and women's health; awardees collaborated with 15 extramural partners at 12 different institutions. 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.

Developing the Operating Plan – Institute Input

"What Are the Institutes Telling Us?"

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives

- *Metabolism*
- *Vaccine Development*
- *Medical Oncology*
- *Pulmonary Hypertension and Sickle Cell Anemia*

Clinical Research Support Requirements

- *Tissue Typing*
- *Gene Sequencing*
- *Selected Staffing Needs*
  - *Social Worker for Sickle Cell*
  - *Sleep Technician*
  - *Physician for Metabolic Studies*
- *External Partnerships*

Developing the Operating Plan – Institute Input

"What Are the Institutes Telling Us?"

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Infrastructure/Management Issues

- *Policy for Pediatric Admissions*
- *Data Management/Tracking Issues*
- *Clinical Research Center (CRC) Room Numbering*
- *Data Mining from CRIS*

Workforce Issues

- *Career Development/Training Programs for Post-Fellowship*
- *Recruitment/Retention*

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives

Introduction

The Clinical Center's "themes" document summarizes input provided by Institute scientific and clinical leaders to the Clinical Center's Director and senior staff in a series of annual planning meetings, held in 2006 between October 17th and November 29th. This document collapses information gleaned from these meetings into a series of themes and key areas of growth and change in the intramural clinical research program as described by the Institutes. This information is provided to CC department heads and informs them as they are preparing their annual budget requests. Ultimately, the information derived from these planning meetings guides the Clinical Center in developing its operating plan and in allocating its resources effectively. The goal of these meetings is to align Clinical Center resources to Institute priorities in order to provide optimal support for both clinical research and patient care. Since new Institute initiatives are generally implemented over multiple years, many of the themes (areas of growth or change) documented in this report represent affirmation of last year's Institute requests, with updated information provided. With continued budget constraints projected for FY2007 and FY2008, NIH will need to develop a process for prioritization of new initiatives in the context of ongoing clinical programs.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives -- continued

Metabolism

In 2004, in response to the public health threat posed by obesity in the U.S. population, several Institutes and Centers (ICs) 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 public health crisis. Renovations to existing CRC space to support these research initiatives are almost complete. The 10-bed inpatient care unit on 5SW-N will be ready for occupancy in January 2008 and a diagnostic treatment area on 7SW-S is currently under construction and will include three metabolic chambers. The chambers will be available for use in mid 2007, after commissioning of the unique and sensitive chambers is complete. The metabolic chambers were developed to provide precise metabolic measurements, and, although they were installed as part of the metabolic initiative, they also can support multi-system co-morbidity research for many illnesses. For example, NCI and NIAID have expressed interest in scientifically evaluating the muscle wasting effects of diseases such as cancer and HIV/AIDS, and NIMH is interested in studying the metabolic complexities and weight gain associated with the administration of anti-psychotic medications. Other ICs (e.g., NIAAA, NICHD, NHLBI and NINDS) expressed interest in the metabolic chambers and commented that they would explore their use to foster new avenues for scientific inquiry.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives -- continued

Vaccine Development

Construction of the CRC Vaccine Evaluation Clinic and Special Studies Unit on 5NE has already begun, and completion of work is anticipated to occur in late 2007. As of December, 2006, occupancy of the unit is planned for January 2008. As primary users of the new facility, NIAID investigators will evaluate the safety, immunogenicity, efficacy, and toxicity associated with candidate vaccines, including vaccines for some class A agents of bioterrorism. A key component of the new unit is its division into a vaccine clinic and a self-care unit that also can be used as a containment facility if live-virus vectors are being used in the candidate vaccines. A sophisticated isolation room was added to the original design to augment the containment capabilities of the unit and, specifically, to provide a venue for managing staff who sustain occupational exposures to highly infectious agents, including staff working on the NIH campus and those working at NIH facilities at Fort Detrick. Although the unit's purpose is predominantly focused on vaccine research, other Institutes (e.g. NICHD) have expressed an interest in using the self-care unit for patients who are ready for discharge from an inpatient unit but not ready to be sent home.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives -- continued

Medical Oncology

The NCI reported that new chiefs have been recruited for the Medical Oncology and Radiation Oncology teams. The new Medical Oncology Chief is Dr. Guiseppe Giaccone, who is currently the Head of the Department of Medical Oncology at the Free University Medical Center in Amsterdam, The Netherlands. He is a highly experienced and accomplished academic oncologist. His primary interest is in lung cancer and the NCI envisions that he will be conducting several studies evaluating treatment and management of patients who have lung cancer. These studies will likely be resource-intense. The new Chief of the Radiation Oncology Branch is Dr. Kevin Camphausen, a well-respected NIH candidate. Dr. Camphausen, Dr. Waldmann (representing the Metabolism Branch) and other NCI scientists expressed concern about the Clinical Center's ability to recruit a Nuclear Medicine physician who has expertise in radiolabeling antibodies and other proteins to replace Dr. Carrasquillo. Dr. Helman commented that NCI was considering the creation of an Imaging Center. This initiative and how it might impact the CC Imaging Science Departments was not discussed in detail.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Resource-Intense Clinical Research Initiatives -- continued

Pulmonary Hypertension and Sickle Cell Anemia

Sickle cell anemia is a common, genetically determined hemoglobinopathy and hemolytic anemia that has been shown to be associated with a substantially increased risk for pulmonary hypertension as a life-threatening complication. Current NLHBI/CC research focuses on the vascular complications of sickle cell disease, especially in the area of endothelial dysfunction and pulmonary hypertension, especially as they relate to nitric oxide biology. New protocols will result in a significant expansion of clinical activity for these NHLBI/CC investigators. Patients being studied often become acutely ill and require frequent use of the intensive care unit, extensive use of pharmacy, and transfusion medicine resources.

Clinical Research Support Requirements

Tissue Typing

Because of the closure of the tissue-typing laboratory at the Walter Reed Army Medical Center (where this work has been traditionally done), the NIDDK solid organ transplant program needs to find a new locus for the required organ transplantation tissue typing studies to support their ongoing transplantation activities. The Department of Transfusion Medicine could provide this service; however, moving this service to DTM would require a substantial investment in space, equipment, supplies, as well as required training and certification. The CC will try to identify other facilities where these studies could be done by contract.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Clinical Research Support Requirements -- continued

Gene Sequencing

Over the past five years, the Clinical Center has seen an almost exponential demand for genetic testing and gene sequencing. In the past year, through the "Payment for Outside Medical Services" mechanism, the CC paid more than $500,000 for these tests. In this set of planning meetings, several ICs (e.g., NICHD, NCI, NIAID, among others) identified a high likelihood that they would have increasing needs for these and similar genetic tests over the next five years. Dr. Gallin has expressed an interest in being able to provide these services through a more centralized mechanism. Representatives from NHGRI suggested that we might be able to partner with NHGRI sequencing scientists (at their central sequencing facility in Rockville) to try to identify better mechanisms and strategies for providing these tests to NIH clinical investigators.

Selected Staffing Needs

Several ICs are requesting assistance to support protocol specific staffing needs. NHLBI's sickle cell anemia protocols admit a patient population historically requiring extensive use of CC resources, especially from the Pharmacy Department. Many of the expensive discharge medications could normally be the patient's responsibility (i.e., most of these 'maintenance drugs' would be billable to an insurance company). However, this patient population is substantially underinsured; consequently, the CC has been paying these expenses. Currently a part-time social worker is dedicated to assisting this patient population with obtaining insurance benefits, helping to defray costs incurred by the CC. With the anticipated increased patient recruitment for the pulmonary hypertension and sickle cell protocol, the IC is requesting a full time social worker to handle the workload. In addition, NIDDK is requesting staffing to conduct sleep studies for its new narcolepsy protocols, as the IC does not have access to a sleep technician. NIDDK also raised a question about staffing for the metabolic chamber. Although the current plan is for these chambers to become a multi-IC resource, the responsibility for direct oversight and the day-to-day care of other IC patients using the metabolic chamber has not yet been defined.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Clinical Research Support Requirements -- continued

External Partnerships

Inpatient and outpatient visits to the CC are below 2006 projections, with the hospital's average daily census substantially below the previous five years' norm. ICs have commented that patient recruitment for certain protocols has been a challenge; consequently, patient admissions are below expectations. To counter this situation, ICs are developing extramural partnerships that the ICs hope will provide links to specific patient groups. For example, NHLBI is establishing an outreach program with community hospitals to recruit patients who have coronary heart disease and may benefit from interventional cardiology to support the collaborative program with Suburban Hospital. NHLBI also has partnered with Children's and INOVA hospitals to recruit children with sickle cell anemia and pulmonary hypertension. NIAMS continues its involvement with the Cardozo Clinic. Although patient recruitment to Clinical Center-based protocols from the clinic has so far been somewhat disappointing, NIAMS is hopeful this will change in the future. In hopes of increasing recruitment to several natural history transplant studies, NIDDK has partnered with Washington Hospital Center to enroll post-transplant patients into outpatient NIDDK protocols at the CC. To explore collaborative clinical research opportunities, NIMH is conducting workshops with intramural and extramural scientists to generate ideas and relationships.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Infrastructure/Management Issues

Policy for Pediatric Admissions

Several ICs discussed plans for studying young children, including some studies that plan to involve newborns. During the past year, the Clinical Center had to borrow equipment from the National Naval Medical Center to support protocols in young children. In several planning meetings, IC investigators expressed a desire to study very young children. Historically, the CC has had a policy that prohibited studying children less than two years of age; however, this policy (formerly a Medical Executive Committee policy) is no longer active. Currently the CC has no policy addressing minimum age for protocol participation. CC Nursing Department leadership noted that they believe that we are fully capable of providing comprehensive care for neonates and other very young children. Dr. Gallin identified a need to clarify the policy and to define permissible ages for study participation.

Data Management/Tracking Issues

ICs are evaluating how financial and personnel resources are allocated within the current financial environment. The ability to track relevant and accurate protocol activity and resource utilization data is critical to the management of scarce resources. Correct protocol attribution remains a problem for several institutes. One CRIS-related issue with respect to attribution was identified in the NCI planning meeting. Dr. McKeeby commented that he believed that the identified issue could be addressed with CRIS modifications. The leadership of several ICs expressed interest in more accurate tracking of how IC resources are expended in the provision of consultative care to patients from other ICs (e.g., consult services, PFTs, hearing and eye exams). IC leaders believe that tracking data of this type would assist the ICs in evaluating whether these supporting services are creating stress (i.e., resource drain) on their institutes' clinical and clinical research programs. Other institutes commented that their patient accrual data may be significantly underestimated by current tracking mechanisms; IC participation on collaborative protocols is often attributed completely to one IC, rather than to both participating institutes when shared resources are used to support the patient.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Infrastructure/Management Issues -- continued

CRC Room Numbering

One and a half years after moving into the new hospital, patients, visitors and employees continue to find the CRC room numbering system confusing. The five digit assignment coding (e.g., 6-3551) simply does not provide information that easily identifies where individual rooms lie within the geography of the building. Adding additional signage and several strategically located hospitality booths has not prevented the daily occurrence of individuals becoming lost and unable to find their destinations. Any effort to change the room numbering system must address the financial impact (i.e., approximately ½ - 1 ½ million dollars) to effect mandatory modifications to critical safety systems (e.g., fire alarm, security) that are currently tied to the numbering schema. A small subgroup has been formed to assess strategies to improve staff's, patients' and visitors' abilities to navigate around the CRC. Suggested interventions include: adding directories at key intersections with common destinations (e.g., conference rooms, offices), updating existing floor maps with room numbering information, and/or investigating the ability to add a prefix to all room number signs that includes a geographic indicator such as NE or SW.

Data Mining from CRIS

Much of the clinical information stored in the Clinical Research Information System (CRIS) in patients' medical records (e.g., vital signs, laboratory results, side effect documentation) are precisely the same data that investigators require for their studies. Currently, investigators must review data from CRIS and then manually re-enter the desired information into their research databases. The ability to mine existing data in CRIS and automatically download to the ICs databases is a system enhancement desired by virtually everyone at NIH who is interested in clinical research. Mining data directly from CRIS not only will save labor hours but will eliminate errors resulting from the manual re-entry of data. As a part of the ongoing CRIS project, the CC is currently developing the "Data Mart" capability for ICs to access the totality of information available in CRIS.

Themes from the Fall 2006 Clinical Center/Institute Planning Meetings

Workforce Issues

Career Development/Training Programs for Post-Fellowship

Several Institutes, among them NIAID, NCI and NIMH, are developing programs to promote the career development of their fellows. Given existing obstacles to recruitment and retention, these strategies are forward-thinking and could serve as a benchmark for other ICs.

Recruitment/Retention

Outside activity restrictions, uncompetitive salaries for clinicians, and the recent governmental changes to ethics rules have all had an impact on recruitment and retention. The Clinical Center has collected and organized data from Institutes on difficult to recruit/retain positions and provided this information to NIH leadership to assist in efforts to effect higher clinician salaries.

Developing the Operating Plan – Patient Input

"What Are the Patients Telling Us?"

In its 9th year, the Patient Advisory Group continued to serve as a major source of input into patient-related Clinical Center improvements. Through regular meetings with the Director of the Clinical Center, the group provided valuable input on hospital operations. These conversations have led to enhancements in outpatient services.

The Patient Advisory Group provided advice and feedback on topics including the following:

- *Relocation of the patient library*
- *Emergency preparedness*
- *Clinic wait times*
- *Room service menus*
- *Increased use of technology such as expansion of the patient portal, enhanced bedside-computer access, and modifications to the popular business center for patients*
- *Implementation of the therapeutic labyrinth, geared to provide patients with a safe, meditative space*

Additionally, several group members have represented the patient's perspective in at least two other Clinical Center venues. One member of the Patient Advisory Group represents the patients' perspectives at each meeting of the NIH Advisory Board for Clinical Research. Patients also share their voices in Clinical Center coursework that focuses on the patient's vital role as a participant in clinical research: (1) The Introduction to the Principles and Practice of Clinical Research and (2) The Ethical and Regulatory Aspects of Clinical Research .

Developing the Operating Plan – Employee Input

"What Are the Employees Telling Us?"

The employee survey completed in 2004 influenced an effort to enhance leadership development at the Clinical Center. Employees sent a clear message that leadership behaviors shape workforce morale and productivity. In response, the Clinical Center launched a six month executive coaching pilot in 2006. Staff evaluated this program favorably, and, as a result, it will continue in 2007.

In July 2006, all Clinical Center employees signed onto a new 4-tiered Performance Management Appraisal Program. Federal agencies have been mandated to develop "pay for performance" personnel retention programs. To effectively align with this new HHS initiative, over 280 CC managers and supervisors attended a four-day course on the new performance plan process. The class focused on federal performance and conduct responsibilities. Feedback from the participating managers assisted in customizing how this initiative will be implemented in the Clinical Center.

Additionally, the Clinical Center offered small group discussions to all front line staff to ensure understanding of the new performance management process. Staff feedback from these discussions emphasized the importance of recognition by supervisors, and that the recognition should distinguish excellent performance. Employees reported that although they value monetary rewards, they also highly value timely compliments from supervisors, as such feedback enhances morale and helps contribute to effective teamwork. Additionally, knowing that managers are holding poor performers accountable was frequently stated as critical to providing a sense of positive work morale. In 2007, Clinical Center management will request further feedback from employees and managers to assess the initial impact of the new performance system on the Institute's workforce.

In addition to listening to current personnel, the Clinical Center also is learning from the newest members of the workforce. In 2006, the Clinical Center provided orientation to hundreds of new employees. New employees repeatedly identified the special patient care/clinical research mission as the primary reason people seek employment at the Clinical Center. The diversity of these new employees enriches the workforce. For example, a clinical pharmacologist and former researcher from Tulane was recruited following Hurricane Katrina and is adding his competencies to the clinical research training program; a new leader in the field of Rehabilitation Medicine, NIH's top choice for this position, was recruited from Seattle to oversee this important program; an anesthesiologist back from a tour in Iraq is joining the department of anesthesiology and surgical services; a multilingual interpreter from California has joined the social work department; and, the newest member of the radiology department, is both a linguist and radiologist who will be adding her combined expertise to the field of brain imaging. We are fortunate to have such talented and experienced people become part of the Clinical Center team.