National Institutes of Health Clinical Center

"There's no other hospital like it!"

2008 Strategic and Annual Operating Plan

Message from the Clinical Center Director

The Clinical Center's 2008 strategic and annual operating plan provides a framework for focusing priorities over the next 12 months as we carry out our important work in support of clinical research, patient care, and effective management. Many factors contribute to helping define the specific steps we need to take as an organization, including the research and program plans of our Institute partners and feedback from the bodies that review, govern, and advise the Clinical Center.

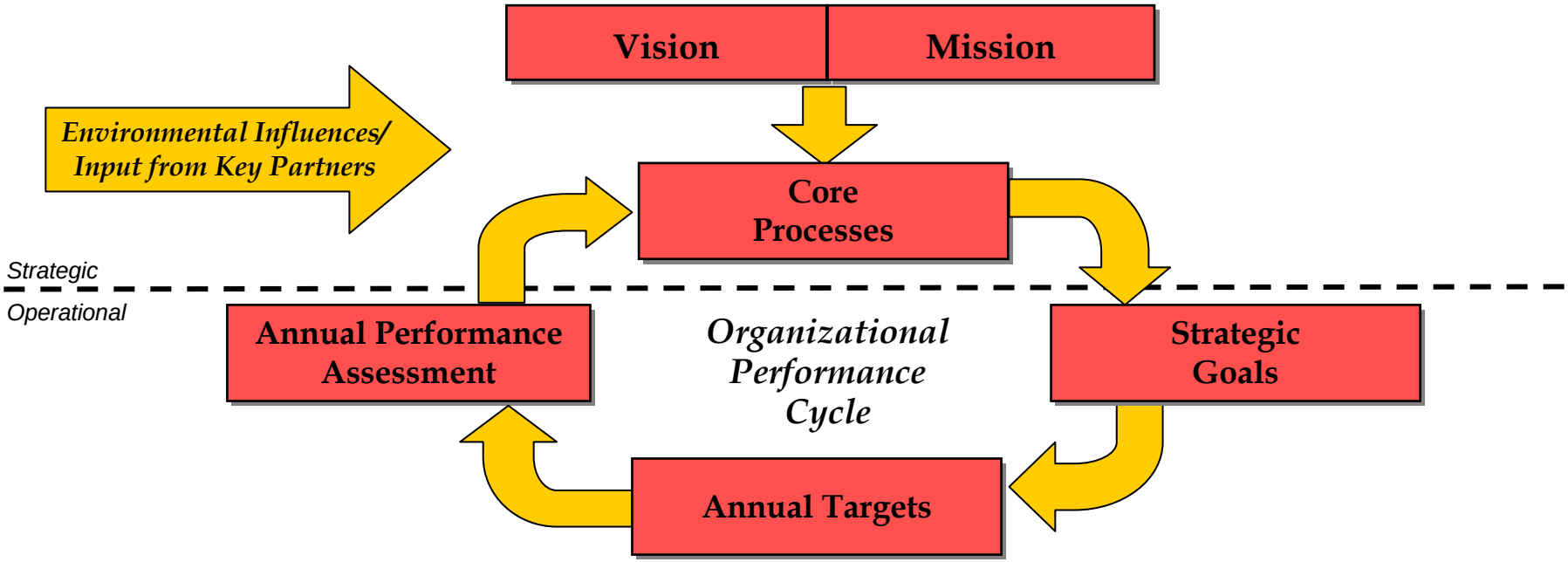
Because of the unique nature of the Clinical Center's mission, many of our goals again this year address projects that will benefit clinical research efforts at NIH and beyond. We will play key roles in developing trans-NIH research initiatives and in defining clinical research roles. We will lead efforts that will enhance patient safety and facility improvements. We will strengthen our ability to attract and keep an outstanding and diverse workforce. We will further programs that support our capability to do more with fewer resources.

Successfully meeting the 2008 goals set forth in this plan depends on all of us working together, supporting each other, and performing to the highest standards. I invite you to review the 2008 Operating Plan to better understand our specific goals and the extensive coordination and input that drive their development.

The Clinical Center has an exceptionally dedicated and talented workforce. Your contributions are central to all Clinical Center successes, and I value your tremendous commitment.

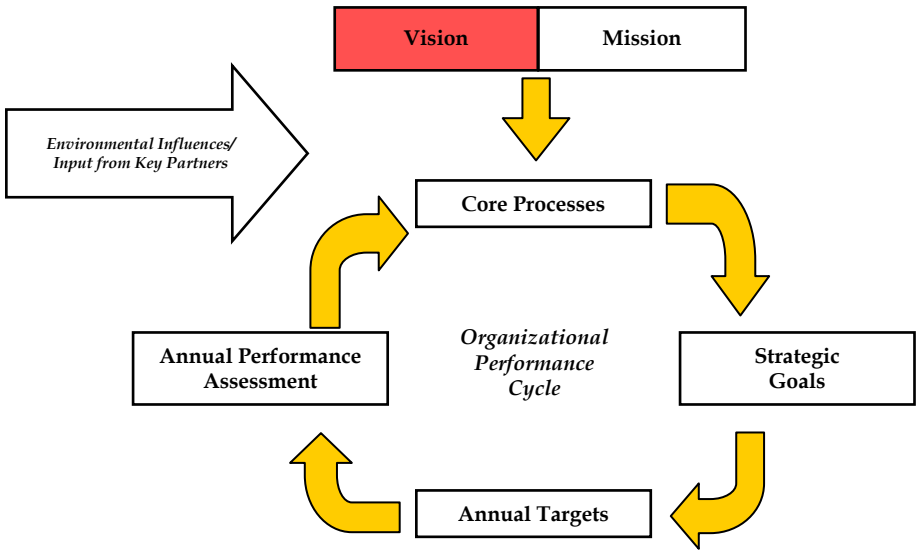
John I. Gallin, M.D.
Director, NIH Clinical Center

Clinical Center Strategic and Annual Operating Plan Framework



Vision Statement

Clinical Center Strategic and Annual Operating Plan Framework

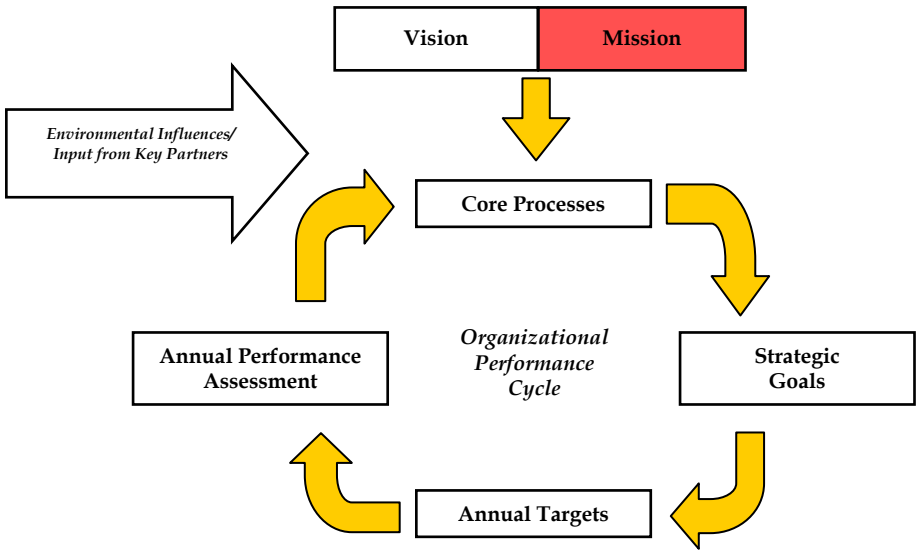


A vision statement: answers the question: "What do we strive to be?" and is a shared view that defines what the organization wants to do or become.

The NIH Clinical Center will serve as the nation's premier research hospital for conducting clinical research to improve the health of humankind. The Clinical Center also will serve as a national resource for clinical research by fostering dynamic interactions with outside partners; 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

Clinical Center Strategic and Annual Operating Plan Framework



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

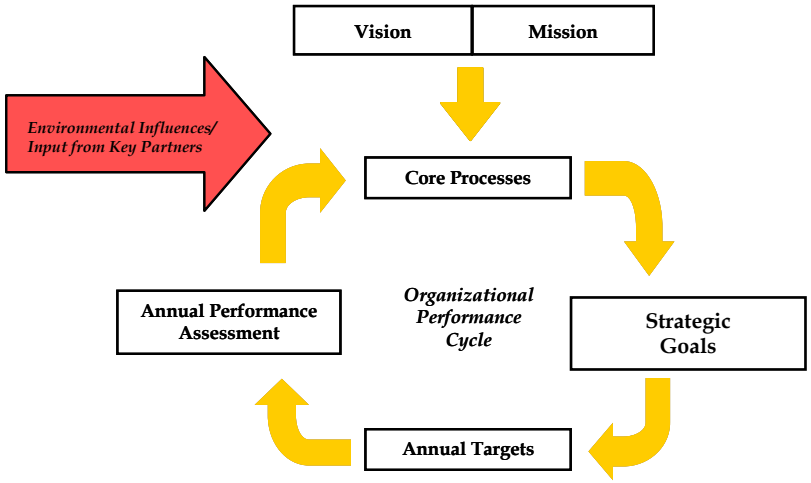
As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates:

- *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.

Environmental Influences and Key Partners*

Clinical Center Strategic and Annual Operating Plan Framework



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/Stakeholders*

*For full text version of environmental influences, see *National Institutes of Health Clinical Center, 2008 Environmental Assessment, a companion document to the Clinical Center Strategic and Annual Operating Plan*.

*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

- *NIH GPRA 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*

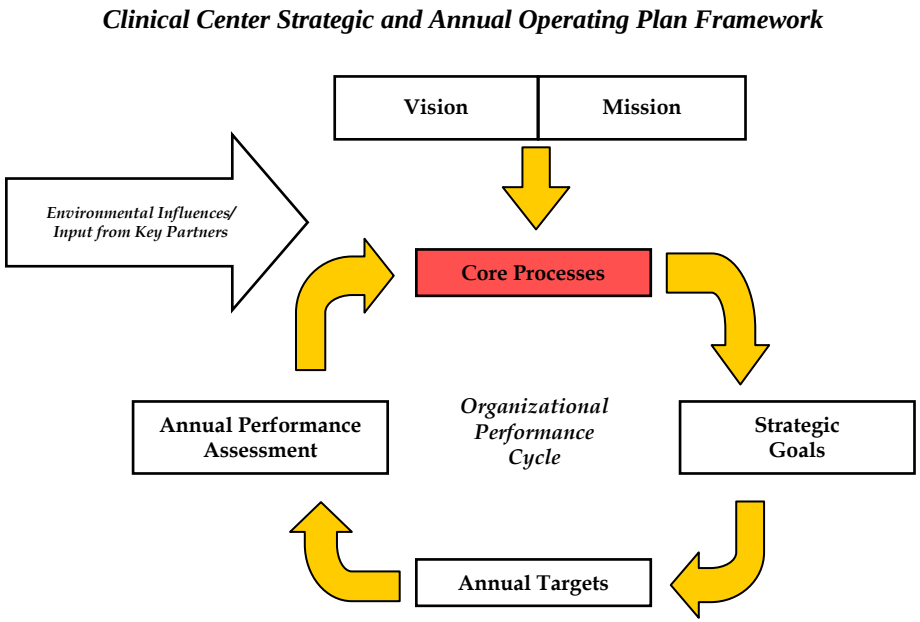
Customers/Stakeholders

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

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

**See Appendix: 2008 Environmental Influences/Key Partners Input*

Core Processes



Core processes are the major activities that support the mission.

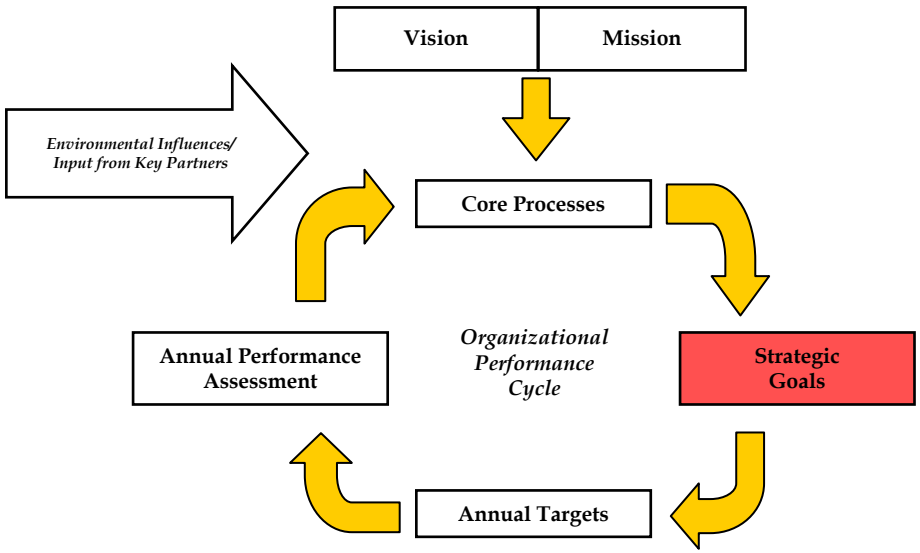
Clinical Research Support:
Provide staff, services, training, and the environment to support clinical research.

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 Strategic Goals

Clinical Center Strategic and Annual Operating Plan Framework

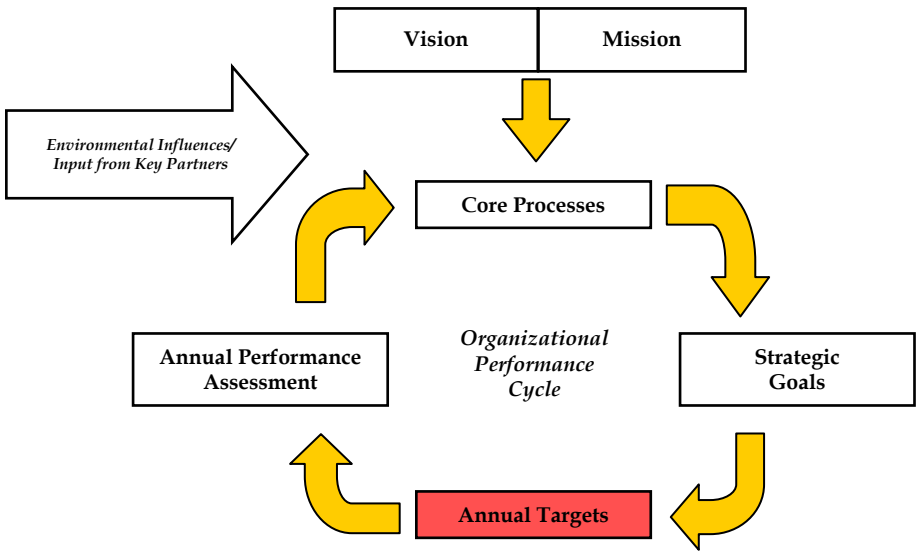


Strategic goals translate the vision, mission, and core processes into performance-based action plans.

- *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 Annual Targets

Clinical Center Strategic and Annual Operating Plan Framework



Annual targets are priority initiatives that the organization will focus on over the next year (or more). These targets are chosen based on information gleaned from the environmental assessment and/or input from key customers and stakeholders.

See next page for 2008 Clinical Center Annual Targets

2008 Clinical Center Operating Plan – Annual Targets

Each of the 11 annual targets identified below is assigned to a member of the Clinical Center executive team who provides leadership and oversight to development of a project plan for each target. Each project plan includes a definition of the scope of the initiative, a statement of what outcomes will be achieved, and a timeline with milestones identified. All projects are monitored on a quarterly basis by presentations to the Clinical Center Executive Committee and other key stakeholders. An end-of-year evaluation is developed which summarizes progress toward goals adapting the "green, yellow, red light" reporting approach in use by the federal Office of Management and Budget.

Core Processes	Clinical Research Support	Patient Care	Operational Management
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 satisfaction, performance, and productivity.*
2008 Annual Targets	1. Facilitate implementation of the following NIH clinical research initiatives: - Special Clinical Studies Unit (for vaccine development); - Rare diseases clinic; - Trans-NIH program in Immunology, Autoimmunity, Inflammation, and Imaging; and, - Intramural/extramural partnerships. 2. Establish trans-NIH translational imaging sciences program. 3. Initiate new Clinical Research Data Repository (CRIS II). 4. Provide tools to support the development of the subspecialty of clinical research nursing nationally.	1. Implement first bar-coding project for patient safety. 2. Implement ongoing patient perception surveys and complete referring physician survey. 3. Implement a new organizational structure for the management of the hospital's 'environment of care.'	1. Launch phase II of Data Transformation Initiative to achieve industry standard data for reporting and analyzing six CC departments. 2. Achieve the following workforce development goals: a. implement new approaches aimed at effective succession planning, enrichment of diversity, and retention of high performing staff; and, b. design and implement a competency-based training program for supervisors.

Financial Assessment of Annual Targets – Clinical Research Support

Annual Target	*Financial Impact for FY 2008*
1. Facilitate implementation of the following NIH clinical research initiatives: - Special Clinical Studies Unit (for vaccine development); - Rare diseases clinic; - Trans-NIH program in Immunology, Autoimmunity, Inflammation, and Imaging; and, - Intramural/extramural partnerships.	No new resources required for FY2008. - Special Clinical Studies Unit, no impact on FY08 budget - Rare diseases clinic: costs covered by NIH Office of Rare Diseases. - Trans-NIH program: CC will provide support as program evolves. - CC leaders participate in CTSA network and support bench-bedside program.
2. Establish trans-NIH translational imaging sciences program.	Organizational changes facilitated by CC have been budgeted at $1M for FY 2008.
3. Initiate new Clinical Research Data Repository (CRIS II).	No impact on CC budget as funding comes from NIH IT enterprise budget.
4. Support the development of the subspecialty of clinical research nursing nationally and provide tools to support.	Participation by existing staff; no new resources.

Financial Assessment of Annual Targets - Patient Care

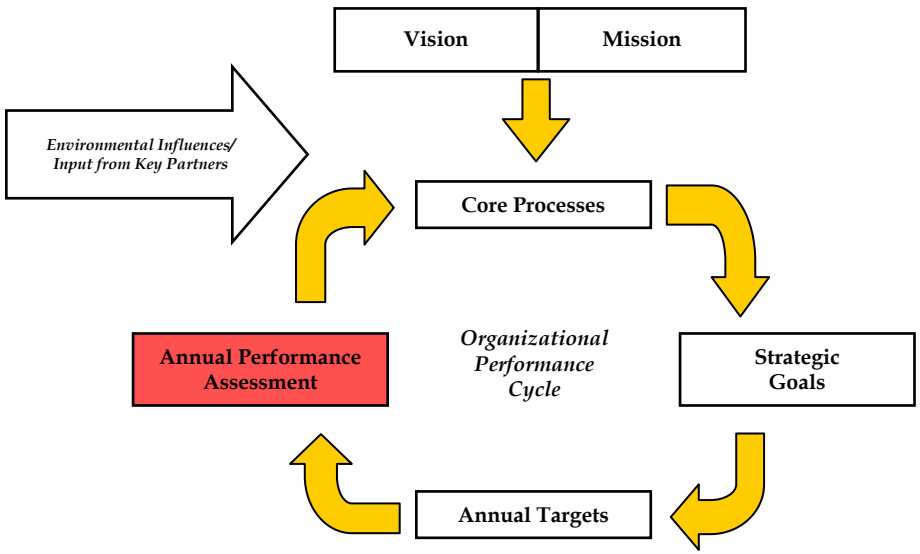
Annual Target	*Financial Impact for FY 2008*
1. Implement first bar-coding project for patient safety.	CC budget includes $1M in FY08 to support this initiative.
2. Implement ongoing patient perception surveys and complete referring physician survey.	CC budget includes $100K in FY08 to support this initiative.
3. Implement a new organizational structure for the management of the hospital's 'environment of care.'	Requires no new CC resources.

Financial Assessment of Annual Targets – Operational Management

Annual Target	*Financial Impact for FY 2008*
1. Launch phase II of Data Transformation Initiative to achieve industry standard data for reporting and analyzing six CC departments.	FY08 budget includes $1.7M to support this initiative.
2. Achieve the following workforce development goals: a. implement new approaches aimed at effective succession planning, enrichment of diversity, and retention of high performing staff; and, b. design and implement a competency-based training program for supervisors.	No new resources in FY08; funded within existing resources of CC Office of Organizational Development.

Clinical Center Annual Performance Assessment

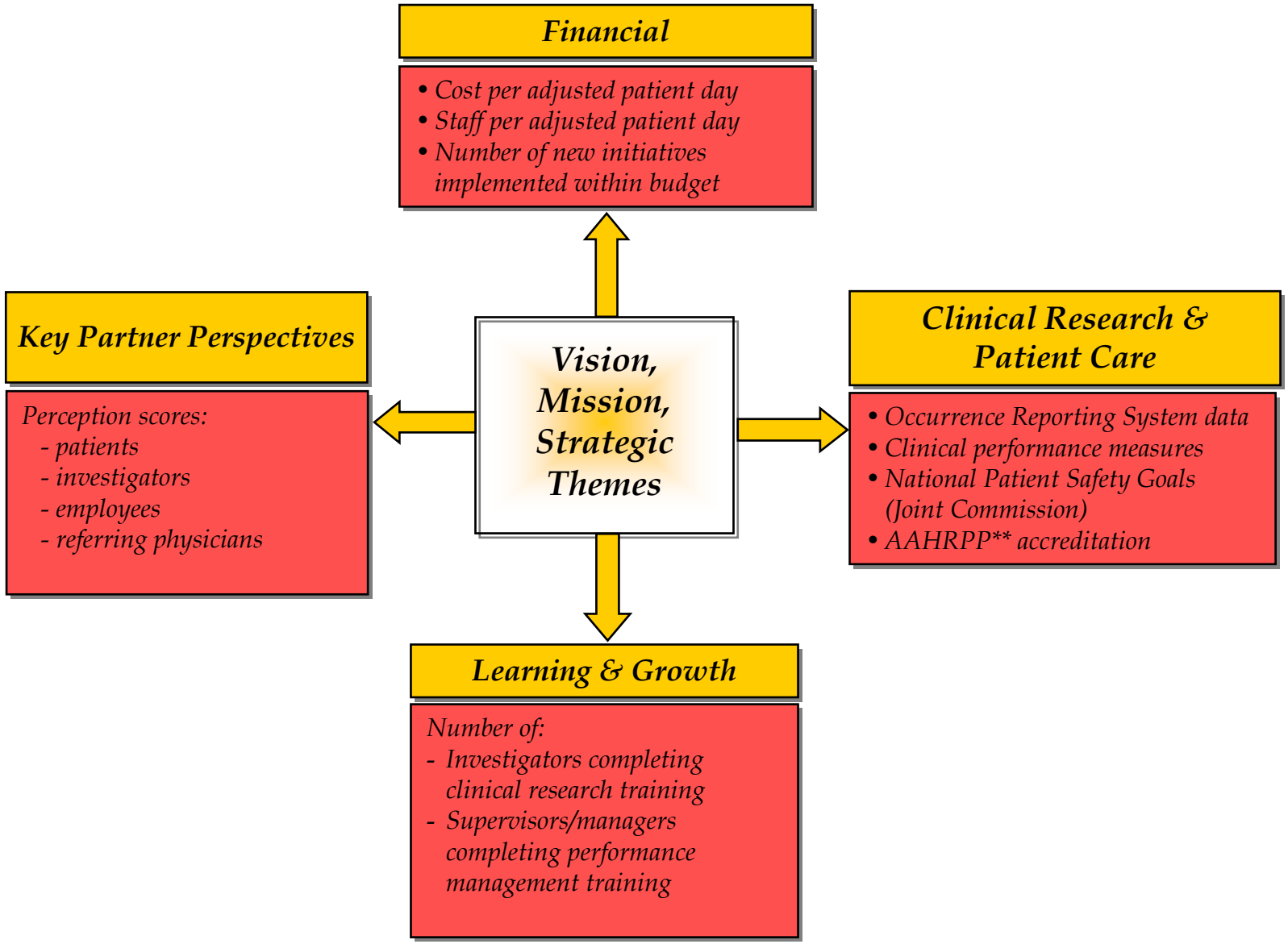
Clinical Center Strategic and Annual Operating Plan Framework



The annual performance assessment is an evaluation process that checks the progress of each annual target against its planned milestones. On a quarterly basis, the executive leader of each annual target presents a progress report to the Clinical Center executive committee and other key stakeholders. Overall progress of annual targets in supporting strategic goals, core processes, mission, and vision is assessed using a balanced scorecard approach.

See next page for Clinical Center Measurement Methodology – A Balanced Scorecard Approach

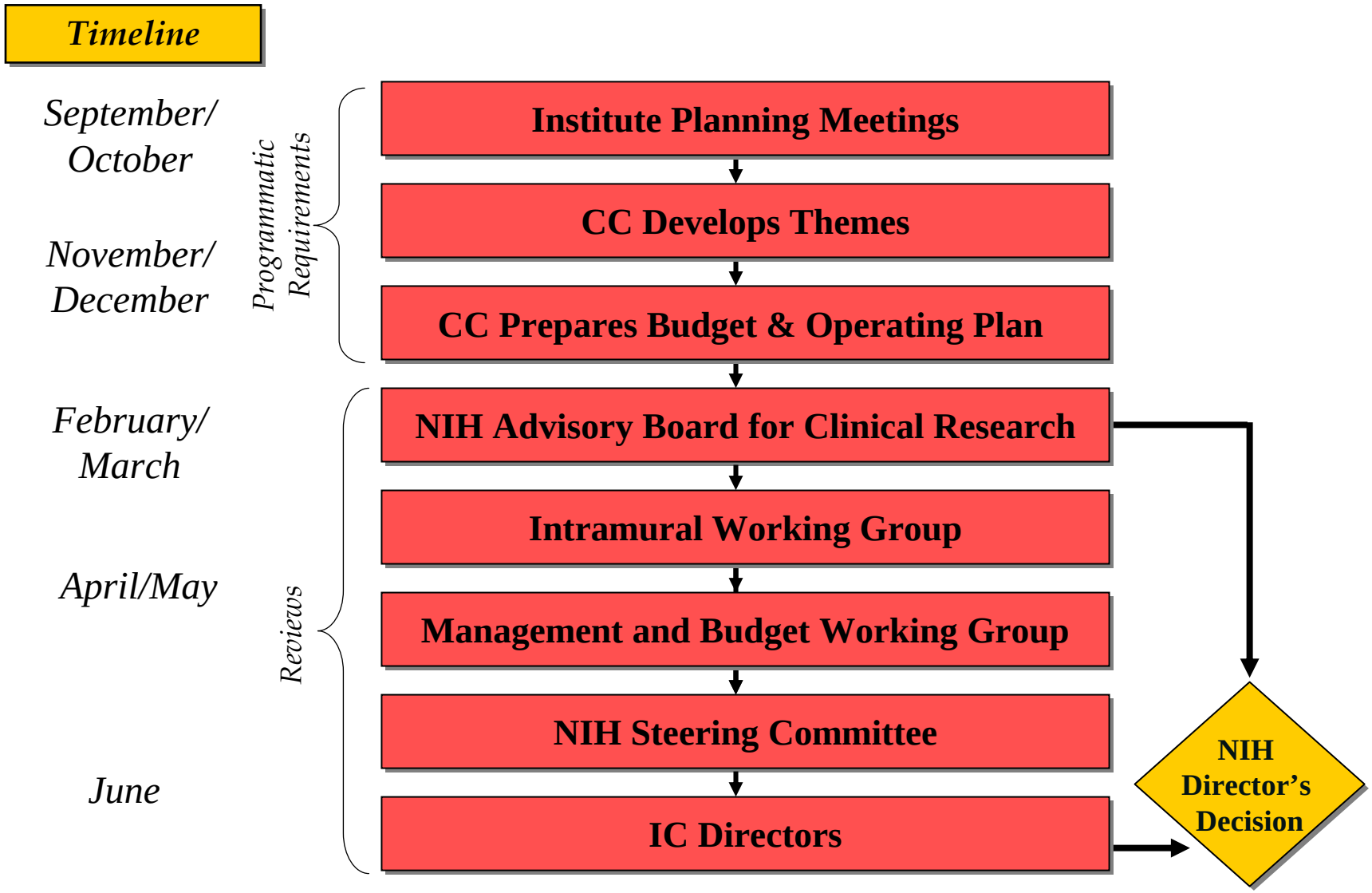
*Measurement Methodology – A Balanced Scorecard Approach**



* *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.®*

Clinical Center Planning and Budget Review Process



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. A study of the Clinical Center administrative support services function affecting approximately 80 Clinical Center FTEs was completed in 2007. This function will remain in-house under a Most Efficient Organization (MEO). A new study involving the patient care coordinator function (approximately 25 FTEs) will be undertaken in 2008.

Performance Management Appraisal System (PMAP)

Performance management is the systematic process whereby management involves its employees, as individuals and group members, to improve organizational effectiveness by 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 link performance to awards and that make clear performance distinctions, e.g., multi-level rating programs. Over the past year, all Clinical Center employees have been put on new performance plans and all performance now will be rated under the new system (i.e., exceptional, fully successful, minimally successful, unacceptable).

"One HHS": Linkage Of Clinical Center Goals To NIH GPRA Goals

As an agency in DHHS, the NIH is dedicated to the conduct and support of medical research. All planning and performance goals for the NIH cascade from the HHS strategic goals. In turn, the Clinical Center strategic themes for 2008 align to support the NIH GRPA Goals. The table below reflects this linkage.

Clinical Center Strategic Goals			
NIH GPRA Performance Goals	***Clinical Research Support*** *Provide timely support for implementation of new Institute clinical research programs and strengthen the infrastructure for delivery of and training in clinical research.*	***Patient Care*** *Ensure quality and safety of patient care.*	***Operational Management*** *Conserve resources, contain costs, and improve employee satisfaction, performance, and productivity.*
Scientific Research Outcomes	☑	☑	
Communication and Transfer of Results	☑		
Capacity Building and Research Resources	☑		☑
Strategic Management of Human Capital	☑		☑
Program Oversight and Improvement		☑	☑

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 $28.7B) has remained relatively constant since Fiscal Year (FY) 2004, increasing a total of 4% during this period. Consequently, NIH Central Services, including the Clinical Center, have been required to remain relatively constant as well. In FY 2008, the Clinical Center received a 2% budget increase to support much needed capital replacement items. Even with the FY 2008 increase, the total Clinical Center budget growth since FY 2004 is 4%, mirroring NIH as a whole. 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 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. The Clinical Center is engaging with the leadership of the NIH and the intramural community to identify strategies to offset the shortage of intramural funding. Without additional funds, the Clinical Center will require additional support to prioritize services and improve productivity. It is unlikely that the Clinical Center will be successful in meeting a flat budget requirement in FY 2009 without the reduction or elimination of services. The Clinical Center's cost-containment focus for FY 2008, will be on implementing strategies and controls in dispensing pharmaceuticals for off label and/or non-protocol use. 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," and their follow-up report, "Crossing the Quality Chasm: A New Health System for the 21st Century,"called on health care organizations worldwide to take an active and aggressive approach to identifying, understanding and mitigating risk associated with the processes of medical care. 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 (including the replacement of older, less expensive drugs with newer, expensive agents) increases by 10 to 15 percent per year. In a era of flat budgets, these costs must be mitigated by diligent efforts to offset this growth. This year the Clinical Center has embarked on a new initiative to recover the costs for marketed drugs that are being studied for non-approved indications from the Institutes conducting the studies. It is anticipated that this will result in a net savings to the Clinical Center of more than $4M. Inflation of medical supplies, although at a slower rate of approximately three to five percent annually, also requires active cost containment efforts.

Health Care Industry

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. The past five years have seen a remarkable trend toward molecular medicine. The unraveling of the human genome, the development of molecular diagnostics, and the the development of the fields of genomics and proteomics are leading medicine into dramatically new territory. Investment in these new technologies also requires an investment in capital equipment and ongoing maintenance contracts, in addition to 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. In summer 2007, the Clinical Center was surveyed (unexpectedly) for its 'environment of care' management and is working closely with NIH Office of Research Facilities to implement a new organizational structure to address deficiencies.

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 2007 a group of clinical fellows representing all Institutes met quarterly with Dr. Gallin. Established in 2004, the Clinical Fellows Committee (ClinFelCom) provides a communications venue for clinical fellows to present issues and initiatives involving the Clinical Center to Dr. Gallin and other CC staff. As in prior years, ClinFelCom achieved important successes in 2007. Several information technology issues involving clinical fellows were identified and became an area of focus for a subcommittee working with Clinical Center informatics leaders. For example, this group identified the need to replace the pagers used by Clinical Center patient care providers. With input into the selection and prioritization of distribution of new pagers, ClinFelCom has followed closely the implementation plan for the new pager system. Additionally, the subcommittee pursued strategies to minimize the number of passwords needed by clinicians for patient care services. Issues related to maintaining confidentiality of computer passwords were also emphasized. ClinFelCom members requested reimbursement for renewal of medical licenses, and by the end of the year, NIH received authority to reimburse Clinical Center patient care providers for medical licensing fees. The ClinFelCom continued to dialogue with NIH leaders regarding implementation of the Associate Clinical Investigator position which would serve as a potential career pathway post clinical fellowship. A policy to implement this new position with associated salaries and resources was also approved recently. Throughout 2007, ClinFelCom continued to address several professional needs of interest to clinical fellows including improved resources for childcare and maternity/paternity leave as well as streamlined approval for moonlighting activities. The year concluded with a satisfaction survey of clinical fellows, and data with appropriate follow-up will be reviewed in the upcoming year.

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 (Deputy Director for Intramural Research) 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 FY07, there were a total of 1,390 active protocols implemented with Clinical Center resources and support; this is a growth of ~11% over the past five years.

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 FY07, there were 5,825 admissions, a decrease of 4.4% from FY06; inpatient days decreased 0.7%from the previous year, and the length of stay increased 3.7%. There was a 4.5% decrease in outpatient visits. In FY07, 1770 new research volunteers were enrolled through the Clinical Center's Office of Communications, Patient Recruitment, and Public Liaison Office (OCPRPL) and Clinical Research Volunteer Program (CRVP). The CVRP is part of the OCPRPL and provides a pool of healthy volunteers available for all principal investigators. In FY07, the CRVP program registered 1802 new volunteers.

Clinical Center Employees

The Clinical Center workforce is comprised of approximately 1770 federal employees and approximately 324 contract staff. There are 95 employees (5%) who are officers in the Commissioned Corps of the U.S. Public Health Service. Approximately 80 percent of the Clinical Center workforce is assigned to clinical and patient care departments and the remaining 20 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 8 percent (156 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 12% to 13%.The average age of Clinical Center employees is 46 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 2007, 19 awards were given to intramural-extramural investigators for their work in rare diseases, AIDS, minority health disparities, and women's health. Since the program expanded last year to include extramural partners, a total of 27 bench-to-bedside awards have included investigators at 21 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 is working with the Medical Executive Committee to initiate ongoing surveys of referring physicians in 2008 and will develop improvements based on survey feedback.

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?"

Introduction

The Clinical Centers Director, senior staff, and department heads meet with Institute scientific and clinical leaders in a series of planning meetings each Fall to discuss areas of growth and change in the intramural clinical research program as described by the Institutes. This information helps the Clinical Center understand resource requirements and ultimately guides the Clinical Center develop its operating plan and allocate 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 section represent affirmation of last year's Institute requests, with updated information provided. With continued budget constraints projected for 2008 and 2009, NIH will need to develop a process for prioritization of new initiatives in the context of ongoing clinical programs.

Themes from the Fall 2007 Clinical Center/Institute Planning Meetings

The following list of themes are described more fully in the pages that follow.

Proposed Trans-IC Collaborative Projects

- *Head and Neck Cancer (NCI, NIDCD)*
- *Traumatic Brain Injury and Post-Traumatic Stress Disorder (NIMH, NINDS, CC)*

Clinical Research Support Requirements

- *Imaging*
- *Support for the NCI Anatomic Pathology Services*
- *Cytogenetics, Genetic Testing, and Gene Sequencing*

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- *Increased Cost Sharing*
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- *Recruiting Talented Investigators Remains a Formidable Challenge*

Fall 2007 – Clinical Center/Institute Planning Meeting Themes

Proposed Trans-IC Collaborative Projects

Head and Neck Cancer (NCI, NIDCD)

NCI and NIDCD are interested in head and neck cancer protocols and believe such a research initiative could be synergistic, capturing other IC's interest by offering scientific opportunities that could 'piggy back' on this patient population (e.g., lung cancer, HPV, other viruses, etc.). Establishing a head and neck cancer initiative, however, requires the recruitment of one or two rising superstars. NCI is spearheading this recruitment but is faced with several challenges, the most significant of which include the current inability to offer competitive salaries and the inability to offer laboratory, clinical and office space for the new investigators. Research for this type of cancer has historically focused on surgery as the primary treatment modality, but treatment is now evolving toward more involvement of radiation therapy, chemotherapy and immunotherapy. Clinical Center resources required to support such an initiative would likely include extensive use of critical care, rehabilitation medicine, pain and palliative care, quality of life and nutrition services. Patient recruitment may offer an additional challenge, as patients may not want to travel to NIH for five days/week treatment, preferring non-experimental radiation-based treatment closer to home.

Traumatic Brain Injury and Post-Traumatic Stress Disorder (NIMH, NINDS, CC)

In collaboration with the Department of Defense, several Institutes and Centers (ICs) have expressed interest in studying both post-traumatic stress disorder as well as traumatic brain injury in veterans returning from war. Because of the ongoing wars in both Iraq and Afghanistan, we have an unfortunate, but unique opportunity to study this growing national health problem. The NIMH, NINDS and the Clinical Center Rehabilitation Medicine Department have expressed interest in conducting collaborative studies designed to assess factors predicting favorable and/or unfavorable outcomes for patients experiencing traumatic brain injury. In addition, the Clinical Center and several other Institutes/Centers have unique resources to evaluate the efficacy of interventions in both post-traumatic stress disorder and traumatic brain injury patients. The Clinical Center, NIMH and NINDS have extensive experience conducting complex clinical trials related to neurological and psychiatric diseases and have access to cutting-edge technologies, including state-of the-art imaging equipment, genomics, and proteomics. Finally, the Clinical Center's Department of Rehabilitation Medicine has a 30-year history of supporting neurological and psychiatric research and has developed many of the functional assessment measures used today. Studies are being designed to assess the impact of traumatic brain injury on functional, cognitive and mental health in veterans returning from battle with these complex problems.

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Clinical Research Support Requirements

Imaging

Demand for imaging as a major component of clinical research support continues to escalate. Demand is increasing both in terms of the numbers of studies required as well as the complexity of the studies requested. During this year's planning meetings, virtually every IC noted that their plans included increasing emphasis on computed tomography (CT), positron emission tomography/CT, and magnetic resonance imaging. Both the demand for, and the complexity of, interventional studies have also increased. Several ICs expressed concern about the CC's ability to meet increasing demand for imaging support of their clinical and translational studies. The CC is recruiting for a new chief of Imaging Sciences and a consensus is building that both the structure and vision of the CC imaging program needs to change in order for the NIH intramural imaging programs to thrive. The CC and our IC partners are working to construct a new vision that includes both the creation of an incentive system that encourages radiologists to deliver outstanding care while pursuing careers in translational research, as well as a system under which the intramural programs of the ICs make resource investments to support CC imaging scientists. This exciting new program will involve restructuring of the CC imaging group to include several "Centers of Excellence," as well as modifications in: 1) the compensation scheme for imaging scientists, 2) the coordination of human imaging on campus, 3) the character and oversight of training programs in imaging and imaging sciences research, and 4) the relationships with other IC programs for the conduct of research by CC imagers.

Support for the NCI Anatomic Pathology Services

The leadership of NCI Anatomic Pathology Program has been vacant for some time now, and, whereas hiring a new chief is a top priority for the Institute, recruiting for this position has been quite difficult. The recruitment has been significantly hindered by both the inability to offer a competitive salary, as well as by the small amount of space allocated to this program. Potential candidates have not been interested in coming to such an outdated and cramped facility. This issue was reinforced when the Accreditation Council for Graduate Medical Education (ACGME) recently cited the Anatomic Pathology fellowship program for not meeting programmatic standards with respect to space. To prevent the lab's residency accreditation from being revoked, NCI was required to issue a decision letter to the ACGME outlining a corrective action plan. NIH is reviewing several options to resolve this situation that include accelerating renovation and use of the Magnusson building (i.e., old Building 10).

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Clinical Research Support Requirements

Cytogenetics, Genetic Testing, and Gene Sequencing

Over the past several years, the Clinical Center has seen an exponential demand for genetic testing and gene sequencing. In the past year, Institutes have been paying for 50% of the costs associated with these tests and the CC has paid the remaining 50% through the "Payment for Outside Medical Services" mechanism. 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. CC leadership would like to be able to provide these services through a more centralized mechanism. We conducted two surveys of customers' needs and worked with the Clinical Director of NHGRI to develop options to present to the Medical Executive Committee (MEC). The MEC established a subcommittee to examine the options. Several other potential solutions are being explored, including the possibility of partnering with NHGRI sequencing scientists (at their central sequencing facility in Rockville) to try to identify better mechanisms and strategies for providing less expensive testing for instances in which Clinical Laboratory Improvement Act-approved testing is not required. During this year's planning meetings, IC scientists noted that the financial burden of these tests is beginning to impact on clinical studies. One Institute commented that they now ask the patient's home physician to have the tests done and then send the results to NIH. As a result, this IC is contemplating closing a protocol because the BRAC-A testing cost, even at 50% reduction, is currently prohibitive. CC leadership understands that cost-prohibitive genetic testing would be a major point of discussion with the shift to 85% co-pay and identified genetic testing as a potentially important area for intramural/extramural partnerships.

Fall 2007 – Clinical Center/Institute Planning Meeting Themes

Infrastructure/Management Issues

Increased Institute Cost Sharing

The NIH Management and Budget Working Group (MBWG) has recommended increased cost sharing by the institutes for both research PET services and non-clinical care research blood products. This cost sharing would increase the institute responsibility for expenses from 30% to 85%. The working group also recommended that the NIH develop a policy that would no longer have the Clinical Center provide non-protocol outpatient drugs to patients. The CC Clinical Research Informatics team and the Pharmacy Department leadership are working on strategies that will facilitate implementation of the MBWG recommendations. Implementation of a policy to no longer provide outpatients with non-protocol drugs will need a significant amount of discussion as it is a complex issue. Whereas the MBWG recommendation could provide up to an additional 2% of funding for the Clinical Center, every institute voiced concern on the impact of the recommendations on their respective budgets. Numerous leaders expressed concern that the short term strategy to provide additional funding to the CC may have long-term consequences, especially if the net result is lower usage of the targeted services because the institute can no longer afford to pay for them.

Lack of Space for Growing Research Programs

The lack of space for growing research programs is an overarching issue for every institute and encompasses laboratory, storage and administrative space requirements. For example, current investigators struggle to find sufficient space to store specialized equipment and, by default, must store such equipment in their offices. The lack of administrative space for staff that provide essential clinical and scientific support is also hindering recruitment and is another example of the criticality of the issue. To address this significant problem, Scientific Directors are reviewing space assignments.

Recruiting Talented Investigators Remains a Formidable Challenge

In addition to the inability to provide sufficient laboratory and administrative space, Institutes often are unable to offer competitive salaries to potential recruits, especially in certain specialties, such as thoracic, neurological and orthopedic surgery, radiation oncology, and imaging. NCI is interested in reinvigorating its breast cancer program but is concerned that recruitment will be a challenge because of their inability to match outside academic salaries. Ethics restrictions are also a substantial barrier for recruiting investigators. Many such recruits participate in numerous outside activities (many of which would likely be precluded by NIH ethics rules); and many potential recruits have spouses who work with biotechnology or pharmaceutical companies that present ethics conflicts, if the individual were employed at NIH.

Developing the Operating Plan – Patient Input

"What Are the Patients Telling Us?"

In its 10th 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 and Clinical Center staff, the group provided valuable input on hospital operations. These conversations have led to enhancements in many services.

In 2007, the Patient Advisory Group provided advice and feedback on topics including the following:

- *Conflict of interest and protocols*
- *Patient confidentiality*
- *Clinic wait times*
- *Cleanliness standards in hospitals*
- *New metabolic unit*
- *Patient library*
- *Facility enhancements for individuals with disabilities*
- *New technologies for patients including a patient feedback system available on bedside computers*

Additionally, several group members have continued to represent 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?"

For the Clinical Center to effectively and efficiently manage its mission, a sufficient and qualified workforce must be sustained. Ensuring that such a workforce will be there in the future requires strategic workforce planning and management. A high number of federal workers will be retirement eligible in the next five years. While most federal employees do not immediately retire upon reaching eligibility, the numbers are expected to be higher in comparison to the past decade. Retirees represent some of the most experienced and knowledgeable staff. This Clinical Center must know the skills and numbers of employees needed to effectively replace them. Adding complexity is the reality of a workforce in flux. The demographics are changing and there is an emerging multigenerational workforce driving new and different employee expectations. Additionally, the job market more competitive than in the past and flat budgets continue, making the recruitment and retention of the best staff a critical strategic concern for Clinical Center leadership.

One strategy to address recruitment and retention concern was launched in July of 2007. The Clinical Center initiated a six month exit interview pilot to better understand workforce turnover. Fifty-five employees and thirty managers participated. This represents 48% of the turnover during that period. The pilot involved asking employees to complete a written survey and to participate in a face-to-face exit interview. Managers were interviewed to elicit their perceptions of the employee's leaving as positive or negative turnover. Positive turnover is defined as an employee who is not meeting performance standards successfully or would not be hired again by the manager. Negative turnover is defined as employees the manager wanted to retain but was unsuccessful. Twelve employees (10%) retired during the pilot. Over 50% of other employees leaving chose jobs that provided higher salaries, promotions and /or better work schedules. The impact of employees leaving and the ability to recruit for their positions was assessed by the managers. This data aligned with the current CC workforce profile regarding "hard to fill" positions. Thematically, over 90 percent of those leaving the CC felt dedicated to and a part of the mission.

Regarding employee retention, the Clinical Center is completing the second year of the federal government's "pay for performance" personnel retention system. This year succession planning received added focus by extending the executive coaching program to select a few highly talented mid-level managers interested in further development of their leadership skills. Considering talent management, some senior managers chose to do 360° leadership assessments of their entire management and clinical leadership teams to develop better focused performance plans for leadership development. Another retention strategy implemented was a "brown bag" management lecture series open to all employees interested in leadership development and knowledge of federal rules and regulations regarding employee performance. The brown bag series was held once a month and led by experts in leadership and federal regulations. Employee evaluations reflected high attendance (average of 45 employees per session) and high satisfaction with the program.