National Institutes of Health Clinical Center
2004 Strategic Operating Plan

Warren Grant Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center
"There's no other hospital like it!"

Message from the Clinical Center Director

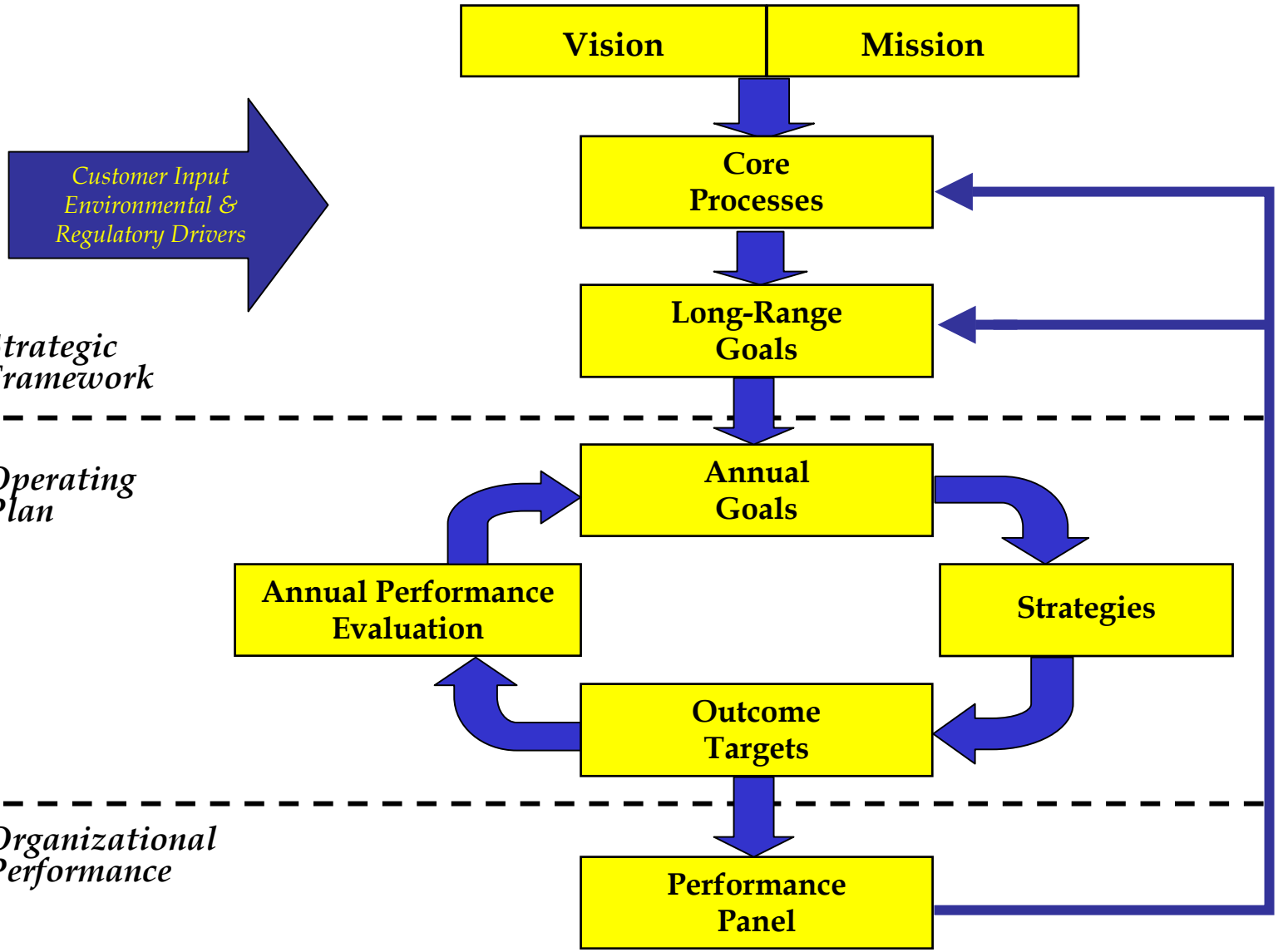
2003 was a year of unprecedented change and exploration of innovative strategies that will reshape the NIH clinical research enterprise. The development of a reinvigorated infrastructure for clinical research directly impacts the mission and vision of the Clinical Center (CC). The NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research has made final recommendations regarding the intramural clinical research program's evaluation of clinical science, partnerships, training, and governance. As we move forward in response to these new challenges, it is my hope that the activities outlined in the Clinical Center's 2004 Strategic Operating Plan will provide effective steps in supporting the NIH Intramural Clinical Research Program.

In 2003 the emergence of SARS challenged us to make sure that our infrastructure remains flexible for responding rapidly to public health crises. The Administration's emphasis on shrinking the federal workforce through competitive outsourcing (OMB A-76) challenged us to re-examine how to maintain and renew our human resources to ensure the highest quality and productivity of staff and the highest return on the public's investment in clinical research. Our success in addressing these and other challenges reinforces my confidence that we have the talent and commitment necessary to reach our goals for 2004.

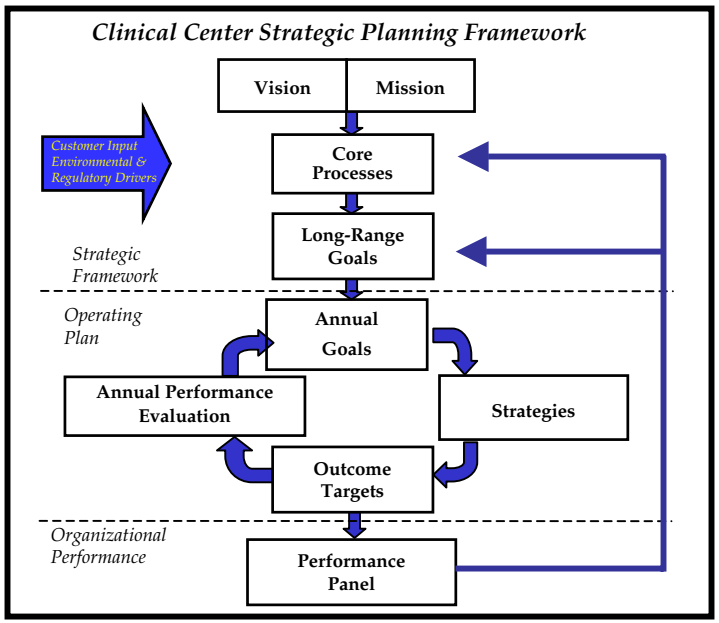
This will be an historic year. Moving into the new Clinical Research Center (CRC), implementing the Clinical Research Information System (CRIS), and opening the Edmond J. Safra Family Lodge are key endeavors that will affect every employee in the Clinical Center. Change is never easy, but these initiatives amplify our capacity for supporting clinical research. These changes will also affect our patients, volunteers, and visitors. Sustaining a "patient-centered" focus will take every employee's compassion and commitment. Our unwavering attention to the patient's experience will ensure a smooth transition. A few months ago a patient made a statement about her care at the Clinical Center that should serve as our standard in partnering with our patients and each other: "You all were able to take a stressful situation and go the extra mile to be positive and helpful. It made all the difference."

John I. Gallin, MD

Clinical Center
Strategic Planning Framework



Clinical Center Customers/Stakeholders



Customers/ Stakeholders

Customers/Stakeholders are internal or external groups of individuals who can directly affect us or who are affected by us.

Analyzing customer/stakeholder expectations will allow us to answer the questions:

- *To whom are we accountable?*
- *Do we understand the requirements for our different customers?*
- *Who has an interest in what we do or in a particular issue and its outcome?*
- *Who can influence us?*
- *Are there any "non-obvious" customers/stakeholders who can limit our options or change our plans?*

Clinical Center Customers/Stakeholders:

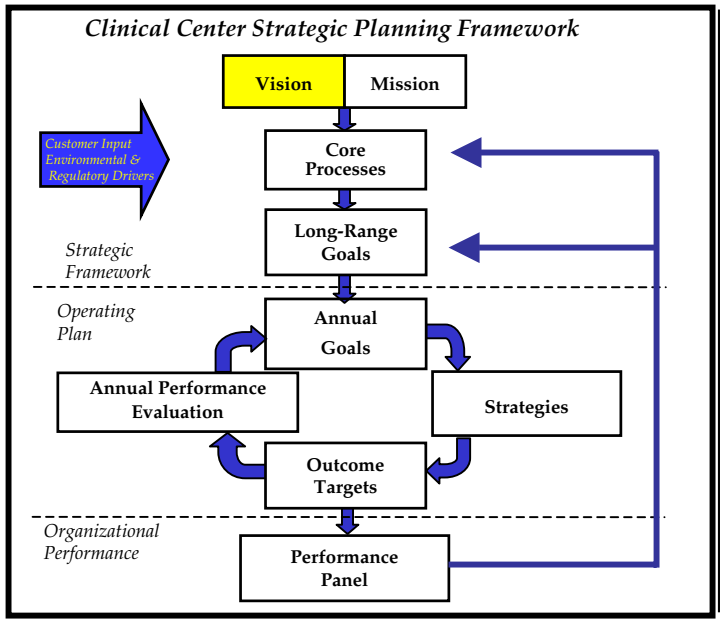
Primary Customers

- *Institutes*
- *Patients*

Other Key Customers/Stakeholders

- *Employees*
- *Referring Physicians*
- *NIH Administration*
- *Extramural Investigators and Collaborators*
- *DHHS*
- *Congress*
- *the Public*

Clinical Center Vision Statement

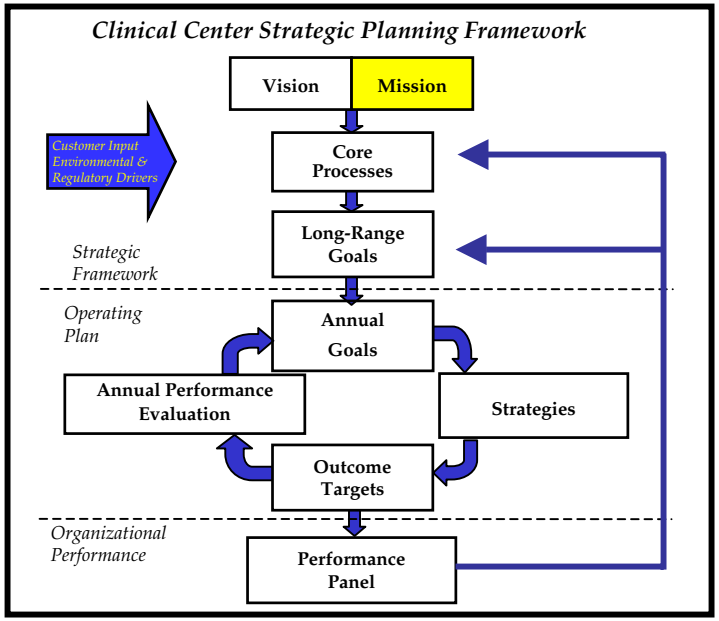


A Vision Statement:

- *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 inpatient and outpatient clinical research. We will continue our rich history for improving the practice of medicine by developing national standards and tools to advance clinical research. We will use our valuable resources to support distinctive and innovative research on common and rare diseases, uphold the safest, most ethical practices of clinical research, respond rapidly to public health crises, and train the next generation of clinical researchers.

Clinical Center Mission Statement



A Mission Statement:

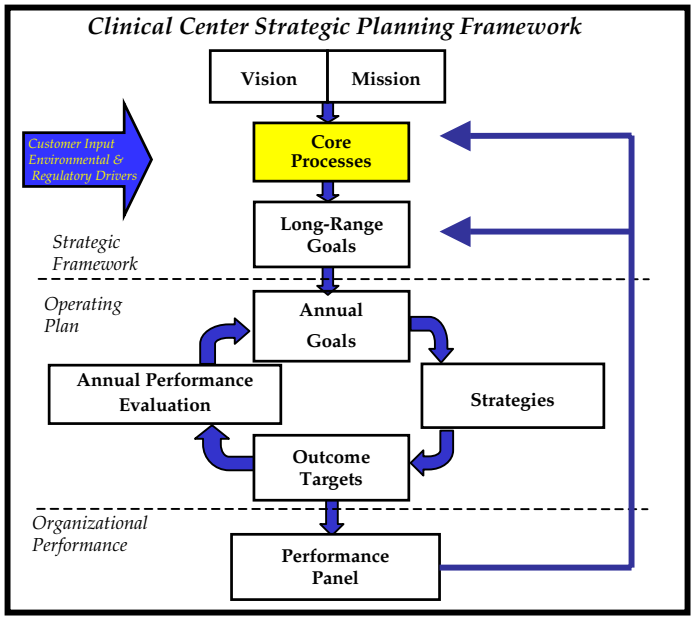
- *answers the question: "What is our fundamental purpose?"*
- *emphasizes the values that are cherished by the organization.*

As the nation's clinical research hospital, the NIH Clinical Center provides an outstanding environment for:

- *inpatient and outpatient clinical care;*
- *clinical research, in particular the application of basic science to clinical medicine; and,*
- *clinical research training.*

The CC achieves this mission through a culture of creativity, intellect, diversity, and the highest ethical standards.

Clinical Center Core Processes



Core Processes:

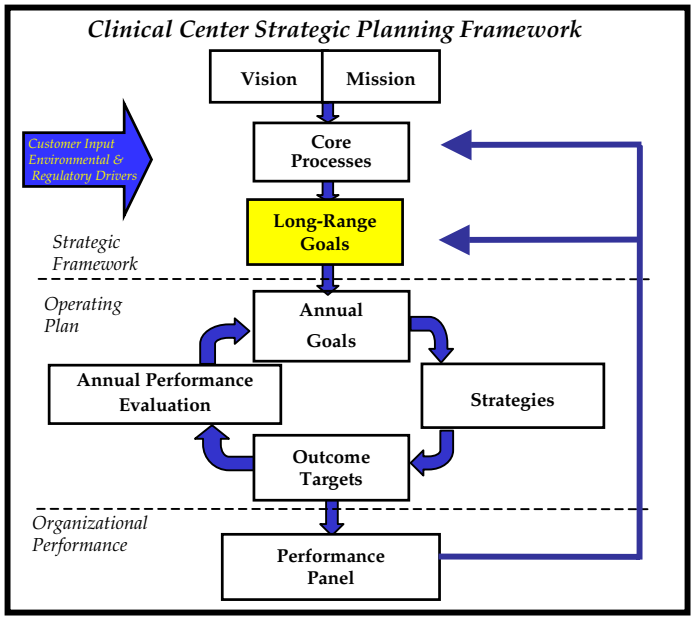
- *are linked activities that generate our primary products and services for Clinical Center customers.*

Clinical Research Support:
Provision of staff, services, and environment that support clinical research

Patient Care:
Provision of the highest quality patient care to participants in clinical research studies

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

Clinical Center Long-Range Goals



Long-Range Goals:

- *define the strategic direction of the organization by bridging the vision, mission, and core processes with action plans and defined outcomes.*

- *Support of distinctive, innovative research in multiple disciplines.*
- *Development and application of innovative technologies.*
- *Training of the next generation of clinical researchers.*

Developing the CC Operating Plan - Institute Input

Institute Planning Process

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

The overall purpose of the planning process is to:

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

CC Research Steering Committee

The Clinical Center Research Steering Committee (CCRSC) consists of representatives from the largest user Institutes in terms of clinical activity as permanent members and rotating members from the remaining Institutes. The CCRSC meets monthly with the CC Director to provide "user" feedback and advice relating to management policy, resource issues, and strategic planning for clinical research at the Clinical Center.

Medical Executive Committee

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

Developing the CC Operating Plan - Institute Input

"What Are Institutes Telling Us?"

Themes from the FY 2004/2005 Clinical Center-Institute Planning Meetings:

Institutes report a need for additional Clinical Center support in the following areas over the next two fiscal years (see following pages for additional details):

- ***Transitioning to the new Clinical Research Center – Integrating Growth***
- ***Improving Outpatient Services***
  - *Outpatient Surgery*
  - *Clinic Redesign*
- ***Offsite Clinical Activity***
- ***Clinical Consult Services***

Transitioning to the New Clinical Research Center – Integrating Growth

At the time of this year's planning meetings, the projected opening of the new Mark O. Hatfield Clinical Research Center (CRC) was one year away. The Clinical Center, in collaboration with the Institutes, the NIH Office of Research Facilities, the general contractor, and an activation consultant, is leading a robust process to activate the new facility. The process includes planning for the patient move (to occur over a weekend in early December 2004), implementing new "partners" teams to provide oversight for multi-Institute patient care units, orienting staff to the new facility, training staff in use of new equipment and systems, developing communication materials for staff and orientation packages for patients, and implementing a new "concept of operations" for all aspects of patient care and support services.

On opening day, the CRC will house 242 inpatient beds (including 22 beds in the intensive care units) and 83 day-hospital stations. Over the past several years, the CC has downsized the number of operational beds to 269 to control costs and to "right size" the inpatient capacity for a smooth transition to the CRC. Currently, the CC is projecting an inpatient average daily census of 153, which translates to an occupancy rate of 63%. However, several new programs have emerged and patient activity is on the rise, giving indication that this occupancy rate will also rise. The Clinical Center actively manages peak census days that will result in occupancy rates in the CRC on peak activity days as high as 78 – 80%. With its state-of-the-art design and spacious facilities, the new CRC provides an optimal venue for both clinical and laboratory work, but at the same time, presents several new management challenges described below.

Since the design of the new CRC in the late 1990's, several clinical research programs have expanded, been initiated, or are currently in the startup phase. Although the hospital was designed with a flexible infrastructure that allows facility modifications to be carried out on interstitial floors with only minimal disruption to the occupied facility, integrating new clinical research programs is complicated and challenging. Although the CC's goal is to maximize use of the new facility and pockets of capacity do exist on selected patient care units, new or expanding clinical research programs rarely present themselves as requiring scattered beds or day stations. Rather, new programs require "blocks" of space with patient beds and adjacent support space for meeting the needs of the clinical research process and specialized space needs for specific patient populations (e.g., patient testing, serial sampling, cooking and recreation facilities for behavioral populations). Second, in the absence of a formal prioritization process for implementing new programs, the CC works with all Institutes equally to accommodate their programmatic needs. Finally, the CRC is operating under a moratorium on renovation change orders by the Department of Health and Human Services. This prohibition, which was put in place in order to bring the construction process to closure, hinders the timely implementation of the clinical research programs being presented by the Institutes in the planning meetings.

Transitioning to the New Clinical Research Center – Integrating Growth

New and Expanding Programs

One notable theme for an area of growth across several Institutes is in the area of behavioral health. Several ICs noted a need for expanded behavioral health activity.

In order to address the burgeoning problem of obesity in the US population, several ICs are proposing a trans-institute collaboration to develop an improved understanding of the pathophysiology of obesity. In addition, this program would attempt to provide additional insight into the prevention and treatment of obesity. The current plan is to address the problem at several levels (i.e., from the molecular level to the bedside). The goal of the new program would be to generate new knowledge regarding the pathophysiology, prevention and treatment of obesity and its multisystem co-morbidities, especially type 2 diabetes mellitus and its complications. The consortium believes these goals could be accomplished by creating a magnet facility in the new CRC that includes state-of-the-art laboratory, clinical investigative, and imaging capabilities that could support NIH-wide intramural scientists interested in obesity research and by using this facility to foster multidisciplinary approaches to obesity research, including metabolism, endocrinology, nutrition, gastroenterology, hematology, genetics and behavioral sciences. The program would require a substantial block of 'behavioral health' type clinical space in the new CRC as well as renovation of existing clinical space to meet its needs.

In addition to the Obesity initiative, several other ICs are planning to expand behavioral health initiatives. The largest of these program expansions is occurring in NIMH, especially in the Mood and Anxiety Disorders Program. NIAAA and NHGRI are also planning modest behavioral health program expansions.

Two additional IC programs have requested clinical space for substantial program expansions. NIAID has initiated the clinical aspect of its Vaccine Research Center with a small outpatient facility on the 12th floor of the existing CC. They have asked for substantial flexible space to accommodate a significant expansion of the program to allow for a self-care unit in the CRC to facilitate containment studies for volunteers receiving live virus vaccines until viral shedding ends. This reconfigured space should also be designed and configured to permit its use as a step-down unit for all Institutes when not serving as an isolation unit.

The NCI Radiation Oncology Program has requested to be allowed to continue to operate the B3 Radiation Oncology Suite as a Research and Development Center for its program. If implemented, this program expansion: 1) presents some logistical issues (due to the distance of the Building 10, B3 facility from the new CRC) and 2) will require additional staff, since clinical Radiation Oncology Programs will be present at two locations in the facility (i.e., in the new CRC basement and in the existing B3 facility). Clinical Center staff are already working with the leadership of the NCI Radiation Oncology Program to delineate the details of CC support for the expanded program.

Improving Outpatient Services

The outpatient census has been steadily increasing and projections indicate continued growth in outpatient activity both with current and new protocols. Outpatient visits grew by 7.4% in FY 2003 and visits for the first quarter of FY 2004 are 14.2% higher than last year at this time.

Several Institutes commented on the need for improved utilization of the clinics, and with growing demand in outpatient studies, had concerns about access to outpatient space. The Clinical Center will focus on improving outpatient services with special attention to ***clinic redesign*** (access to clinic space for Institute programs and improvements in the environment of care for patients) and ***outpatient surgery***.

Clinic Redesign

Based on the current use of the clinic space and scheduling practices, the clinic does not have enough exam rooms to meet the increasing demand for clinic space. However, when the new CRC opens in December 2004, some of the current occupants of the Ambulatory Care Research Facility (ACRF) will relocate to the CRC. The vacated space in the ACRF provides the CC an opportunity to analyze the current scheduling practices, space utilization and configuration, as well as patient flow in the clinics. In concert with the reorganization/reallocation of clinic space, the CC and Institutes have a unique opportunity to evaluate the manner in which care is provided to patients in the outpatient venue.

Results from recent patient and employee surveys, feedback from the Clinical Center Patient Advisory Group, and discussions with several clinical investigators who provide care for patients in the outpatient areas indicate that the physical environment of the clinics as well as current care patterns and processes do not support a patient-centered approach to care. For example, areas in need of improvements in the physical environment include: a dedicated entrance and exit; waiting areas; hallways; exam rooms; consultation rooms; physician areas; conference rooms; dictation areas; radiology services; and proper eating facilities.

Outpatient Surgery

The current Clinical Center surgical suite is the product of the 1983 consolidation of two surgical areas – cancer and neurosurgery – into the Ambulatory Care Research Facility (ACRF). Twenty years ago, patients were admitted one to two days before their scheduled surgical procedure. This allowed ample time for completing surgical and anesthesia work-ups. Anesthetized patients were monitored in the Post Anesthesia Care Unit (PACU) following their surgery. A routine recovery period was one to two hours due to the long acting anesthetics, sedatives and muscle relaxants used.

Improving Outpatient Services (continued)

Outpatient Surgery (continued)

The PACU and Anesthesia Section established a program for minor outpatient surgery (surgical procedures requiring surgeon-administered local anesthetics without sedation) in 1984. A year later, monitored anesthesia care was added.

Currently, pre-operative and post-operative activities occur in the same PACU area. Pre-operative assessment and education are provided by surgery and anesthesia teams, but no truly standardized process exists which all Institutes follow. The PACU staff performs both Phase I care that includes post-operative assessment and acute monitoring of inpatients and outpatients, and Phase II care that encompasses the progression of patient activity to "street fitness," including educating the patient and family about post-discharge activities for outpatients.

The PACU and outpatient clinic staffs have developed numerous workaround processes to meet both the pre-operative and post-operative needs of patients in the limited space available.

With advances in surgical techniques and anesthesia agents, and increased physician and patient demand, outpatient surgery volume has continued to increase at the CC. During FY 2002, the Department of Anesthesia and Surgical Services (DASS) performed 440 surgeries on outpatients and administered anesthesia to 152 outpatients for diagnostic procedures in the Imaging Sciences, Cardiology or Radiation Therapy departments. Since 1988, there has been a 303% increase in outpatient surgical procedures and a 74% increase in inpatient surgical volume, yet staff are caring for this increased number of patients in the same space designed in 1983. In addition to this historical rate of increase, an anecdotal survey of surgeons earlier this year projected approximately a 57% increase in outpatient surgeries if the processes and facilities were improved. The six-bed PACU is no longer adequate for providing the expanding and diverse care required for both inpatients and outpatients, and it compromises patient privacy and confidentiality. Quicker turnaround times and shorter surgeries also contribute to the need for more recovery rooms per operating room. All of these data underscore the need for renovation of the physical space and the processes of care for outpatient surgery at the CC.

Off-Site Clinical Activity

Beginning in the 1990's, several Institutes developed new initiatives that involved 'off-site' activities. These programs have a variety of goals, among them: increasing access for minority and underserved patients to participate in clinical research protocols, providing clinical researchers access to patients who have 'acute diseases' seen in emergency departments, program expansions, increasing recruitment for specific clinical research protocols, and increasing access for investigators and trainees to patients who have 'bread-and-butter' diseases. Several Institutes have requested CC support for these activities. For example, NIAID and NIAMS have organized highly successful HIV and rheumatology clinics in the Cardozo community to reach out to the urban population in Washington, D.C. Several other Institutes have expressed interest in joining NIAID and NIAMS in this clinic enterprise, including NHLBI, NIMH, NCI, NINDS and NIAAA. NCI has organized a smoking cessation clinic in Rockville, and several other programs are considering establishing additional off-site programs to supplement their existing clinical research portfolios and to increase diversity in existing programs. NIAMS is considering opening a second clinic in the Anacostia area of D.C. The Clinical Center has already developed some strategies to address the many significant regulatory, economic, and logistical issues that arise from these initiatives in order to maintain the highest possible standard of care for the services it provides. Nonetheless, as additional off-site programs are initiated, the CC must develop more effective strategies for capturing the activity at these sites and for determining the extent of resources required for CC support of these varied activities.

In FY 2004 and FY 2005 the Clinical Center will develop a data reporting mechanism to accurately capture off-site patient activity and to translate that activity to Clinical Center resource utilization.

Clinical Consult Services

Consultative services continue to be a focus for improvement activities in the Clinical Center. Several ICs identified the need for continued improvement in access to, response by, and quality of clinical consultative services. In addition, the Medical Executive Committee has been addressing this complex topic over the past three years. A new electronic consult-evaluation process has been developed by a subcommittee of the Medical Executive Committee and should be implemented in FY 2004. Several ICs identified deficiencies in consultative services that will need to be addressed in the coming year. Services for which improvements will be sought in the coming year include: gastroenterology, orthopedics, gynecology, plastic surgery, vascular surgery, and a variety of pediatric subspecialty services. Improvement of these programs will require the concerted effort of CC leadership, the Medical Executive Committee, the Surgical Administrative Committee, and the ICs that have traditionally been involved in the provision of these services.

Developing the CC Operating Plan - Patient Input

Patient Advisory Group

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

Suggestions from this year's meetings included: feedback on the newly developed patient information packet, follow-up discussions to the patient survey, plans for the Clinical Center 50th anniversary celebration, input on the customer service and diversity outreach initiatives, campus security issues involving a dedicated patient entrance on campus, and future plans for outpatient clinic redesign. Patients remain engaged in identifying improved processes for patient travel. Two meetings included thorough discussions on proposed patient-related services in the Mark O. Hatfield Clinical Research Center. Excellent suggestions were received from group members on amenities in the new building, preferred signage, and computerized bedside educational resources for patients. Many PAG members participated in the Clinical Center 50th anniversary celebration held in July 2003.

Developing the CC Operating Plan - Patient Input

Patient Perception Survey

The Clinical Center conducted its second patient perception survey in 2002, in collaboration with the National Research Corporation/Picker Institute. Responding to the survey were 1,379 patients – a 62% response rate. Over 90% of Clinical Center patients perceived the quality of the care they received at the Clinical Center as very good or excellent. When compared to the national benchmarks, the Clinical Center excelled in the areas of respect for patient preferences, involvement of family and friends, and emotional support. The following key processes were targeted for study and redesign in response to the results of the survey: interdisciplinary care management, outpatient/ambulatory surgery, and informed consent management.

Developing the CC Operating Plan – Employee Input

Employee Survey

The Clinical Center employee survey (total sample n=1,024) found that 9 out of 10 employees were satisfied or very satisfied with their jobs. There was no significant difference between employee and management responses in most areas related to job satisfaction. The largest predictor of job satisfaction among care providers was the organization of their department to effectively meet customer/patient needs.

Over 80% of all employees indicated they were usually or always treated with respect by their supervisors and co-workers. They similarly have trust and confidence in their co-workers. Supervisors who communicate a value for employee contributions was the largest predictor of overall job satisfaction at the CC. Almost two-thirds of respondents said their supervisor usually valued their contribution. However, the following key areas will be studied further in response to the survey: fair recognition, respect for diversity, and opportunities for employees to offer input into decisions.

Customer Service Part 2: Creating A Culture of Inclusion

The Clinical Center customer service initiative was launched in 2001. Over an 18 month time frame, 2,500 employees participated in customer service training. Since the training, many departments have implemented quality improvement projects that have enhanced patient care and satisfaction. To sustain this value, the CC will launch a diversity management initiative to optimize our workforce talent and skills. A systematic assessment of current diversity activities was completed in late 2003. Feedback from the employee and patient surveys has been reviewed. In early 2004, executive feedback on obstacles and issues faced by the Clinical Center related to diversity will begin. The combined feedback of all employee groups will be used to develop new strategies and to amplify our culture of inclusion.

Developing the CC Operating Plan – Alignment

Alignment with DHHS and NIH Goals

The goals and objectives contained within the **Clinical Center's** plan were developed to support and align with Department of Health and Human Services (DHHS) and National Institutes of Health (NIH) goals and objectives:

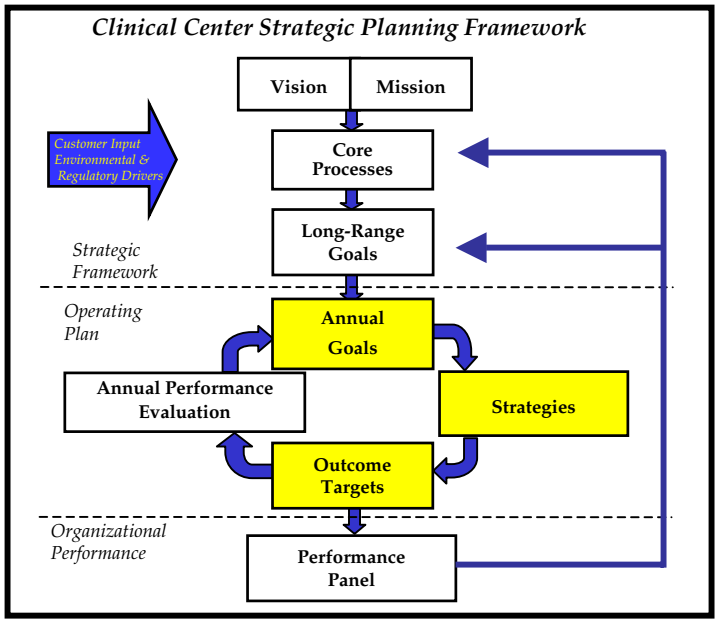
DHHS Goals for 2003-2008:

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

NIH Mission & Objectives for FY 2004:
The NIH mission is to uncover new knowledge that will lead to better health for everyone.

Objective 1 Increase understanding of normal and abnormal biological functions and behavior.
Objective 2 Improve the prevention, diagnosis, and treatment of diseases and disabilities.
Objective 3 Promote development of a talent base of well qualified, highly trained and diverse investigators capable of yielding the scientific discoveries of the future.
Objective 4 Secure facilities for research that are modern, efficient, and safe.

Clinical Center 2004 Annual Goals

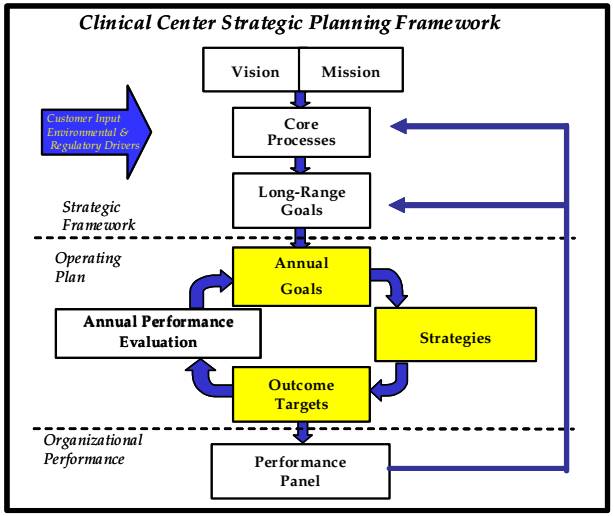


2004 Annual Goals

- *specify the Clinical Center's strategic priorities over the next year to support the achievement of the long-range goals.*

Goals

- *Activate the Mark O. Hatfield Clinical Research Center.*
- *Implement the Clinical Research Information System.*
- *Establish a new curriculum for clinical research training.*
- *Strengthen the infrastructure for clinical research support.*
- *Improve outpatient services.*
- *Implement a Clinical Center-wide cost-containment program.*



2004 Annual Goals

Strategies

Outcome Targets

Annual Goal:
Activate the Mark O. Hatfield Clinical Research Center.

Leader: *Maureen Gormley*
Chief Operating Officer

Strategies:
1) Continue active oversight of the construction/activation interface.
2) Maintain involvement in planning for the A-sector science court.
3) Manage the activation budget.
4) Provide oversight of all activation activities.
5) Expand Hospitality Services to the new NIH entrance for patients and visitors.
6) Implement the eLearning education and website for patients.

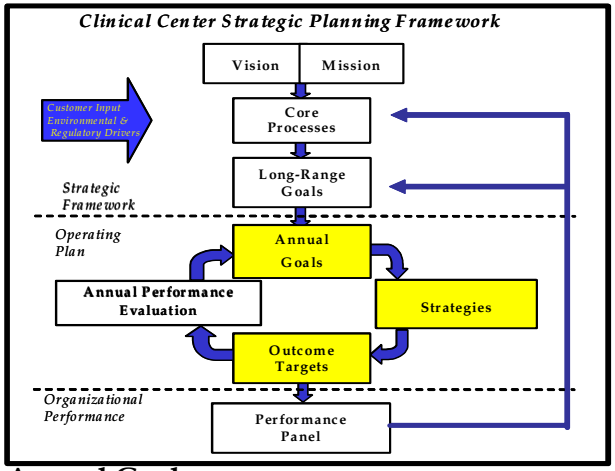
Outcome Targets:
1) Open the hospital in early December 2004.
2) A-sector fully open and operational by hospital opening date.
3) Activation budget comes in on target.
4) Hospital opens in fully operational status (on time with all activation activities complete).
5) All patient volunteers and their families will have easy access to current information and education in the CRC through computer-based programming.

Annual Goal:
Implement the Clinical Research Information System.

Leader: *Steve Rosenfeld, MD*
Chief, Department of Clinical Research Informatics

Strategies:
1) Implement the core medical information system.
2) Implement the nutrition service suite of the nutrition system.
3) Select a surgery system and award a contract.
4) Continue the implementation of the assisted protocol authoring tool ProtoType (under the direction of Robert Nussenblatt, MD) and make available to other research facilities.
5) Develop requirements for the clinical data warehouse.
6) Develop requirements for an admissions and scheduling system.
7) Move and activate CRIS in the CRC.

Outcome Targets:
1) The new core medical information system will be available to all users for results retrieval, placement of orders, and for ancillary clinical documentation.
2) The nutrition system will provide integrated functionality for foodservice and clinical nutrition services.
3) ProtoType will be utilized by NIH investigators to author protocols and by NIH IRBs to track protocol approvals and changes.



2004 Annual Goals

Strategies

Outcome Targets

Annual Goal:

Establish a new curriculum for clinical research training.

Leader: *Fred Ognibene, MD*
Chief, Office of Clinical Research Training and Medical Education

Strategies:

1) Develop draft for new curriculum in clinical research.
2) Obtain approval for curriculum from the Medical Executive Committee.
3) Request a proposal for development of curriculum tracking tool.
4) Develop and implement a communications plan, which will involve the creation of a curriculum website and brochure with the assistance of the Clinical Center Office of Communications.
5) Announce the curriculum to the NIH community.

Outcome Targets:

1) Establish a curriculum website.
2) Develop and disseminate a curriculum brochure.
3) Implement the curriculum tracking tool.
4) Establish baseline number of individuals fulfilling the components and receiving certificates annually for future assessment of program growth and performance.

Annual Goal:

Strengthen the infrastructure for clinical research support.

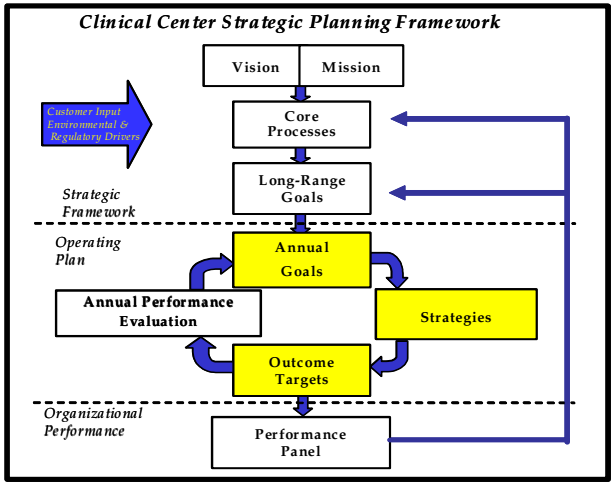
Leader: *David Henderson, MD*
Deputy Director for Clinical Care

Strategies:

1) Implement trans-Institute high priority programs.
    a) Obesity initiative
    b) Behavioral health initiatives
2) Assure access to critical clinical consultative services.
    a) Plastic surgery
    b) Vascular surgery
    c) Pediatric sub-specialties
3) Continue implementation of patient safety program/clinical research project.
    a) Provide results of initial patient safety culture survey to staff.
    b) Complete end of shift surveys of nursing staff.
    c) Implement biometric patient identification pilot study.

Outcome Targets:

1) Develop a plan to provide physical space for the obesity and behavioral health initiatives.
2) Identify Clinical Center operational needs for the obesity and behavioral health initiatives.
3) Develop resource estimates for the obesity and behavioral health initiatives.
4) Contract arrangements for the provision of plastic surgery and vascular surgery consultative services will be in place by June 2004.
5) Identify biometric patient identification device for use in clinical care processes.



2004 Annual Goals

Strategies

Outcome Targets

Annual Goal:
Improve outpatient services.

Leader: *Clare Hastings, PhD, RN, FAAN*
Chief, Nursing and Patient Care Services

Strategies:

1) Redesign Outpatient Surgery.
2) Assess outpatient clinic space and patient flow activity to identify improvements for optimizing patient access and for providing more staff resources.
3) Develop new process for capturing and reporting offsite Institute clinical research activity.

Outcome Targets:

1) Improved services for surgical outpatients and Principal Investigators.
2) Improved utilization of outpatient clinic space and increased patient satisfaction with access to clinic resources.
3) Improved accuracy and reporting of data collection of total Institute clinical research activity.

Annual Goal:
Implement a Clinical Center-wide cost-containment program.

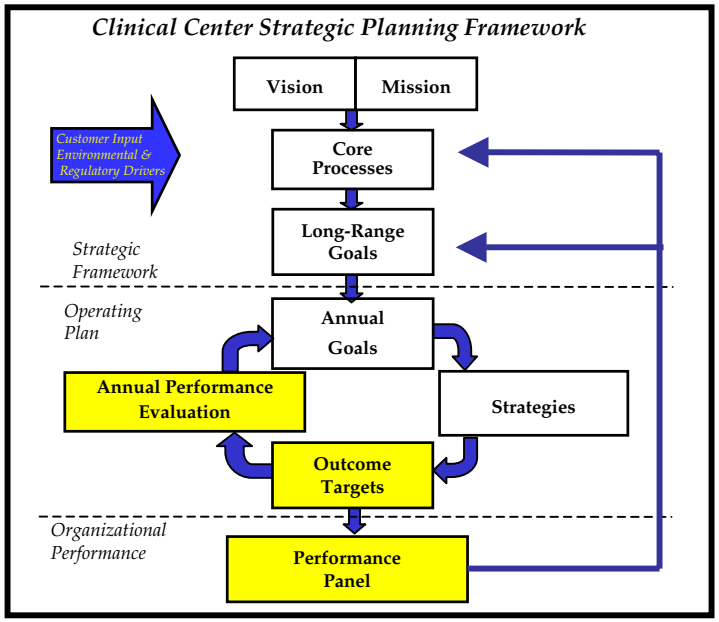
Leader: *Lisa Lacasse*
Chief Financial Officer

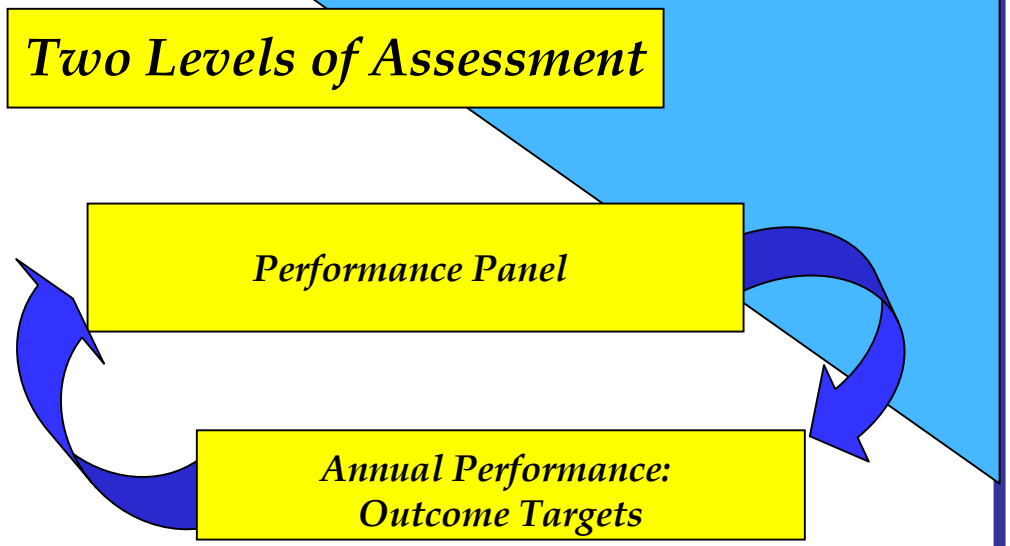
Strategies:

1) Appoint a Task Force of CC senior leadership to identify organizational approaches to reduce operating expenses in the areas of:
   a) Contracts
   b) Supplies
   c) Operating expenses directly related to capital.

Outcome Targets:

1) Reduce the Clinical Center's annual operating expenses by $10M.

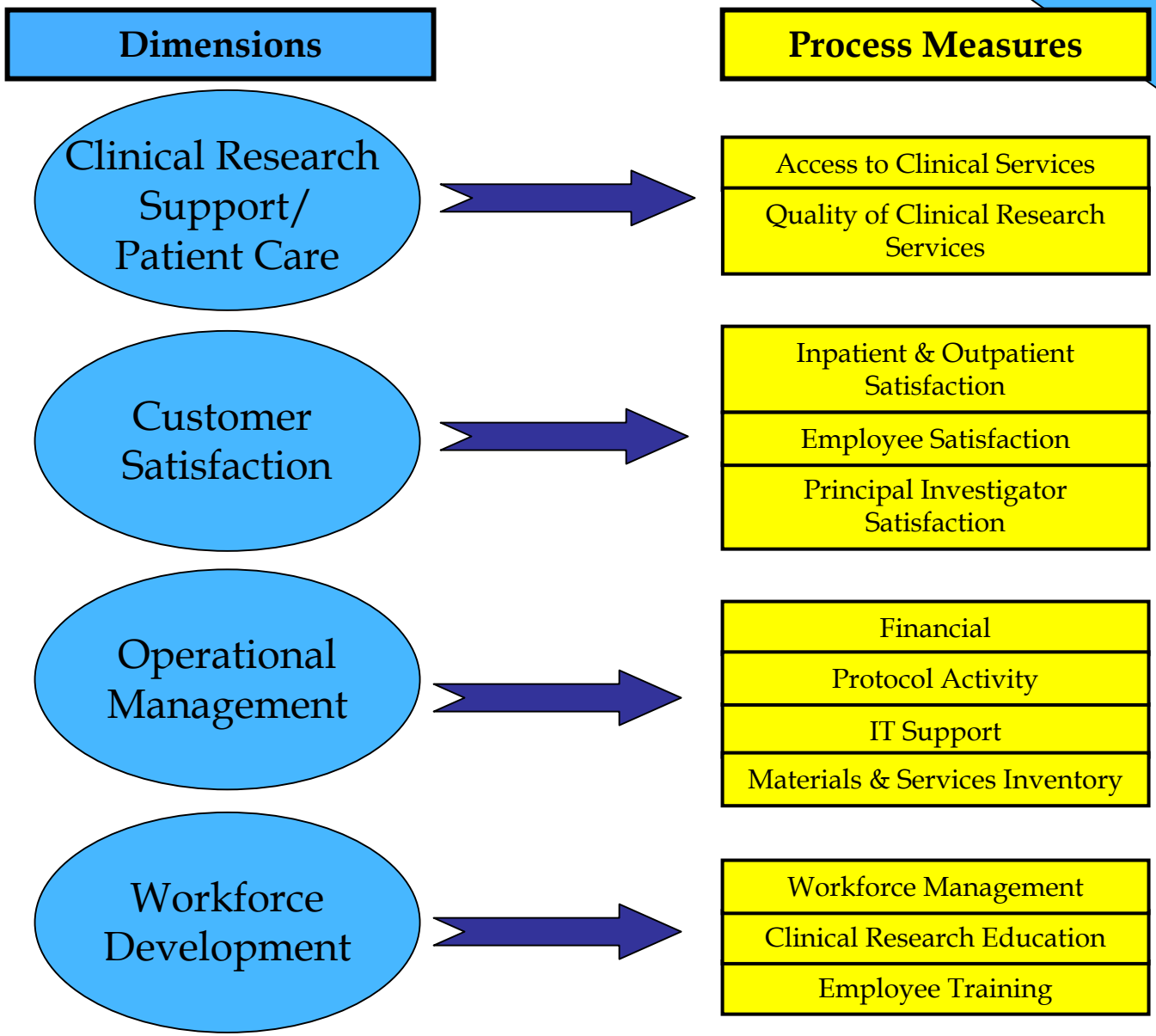




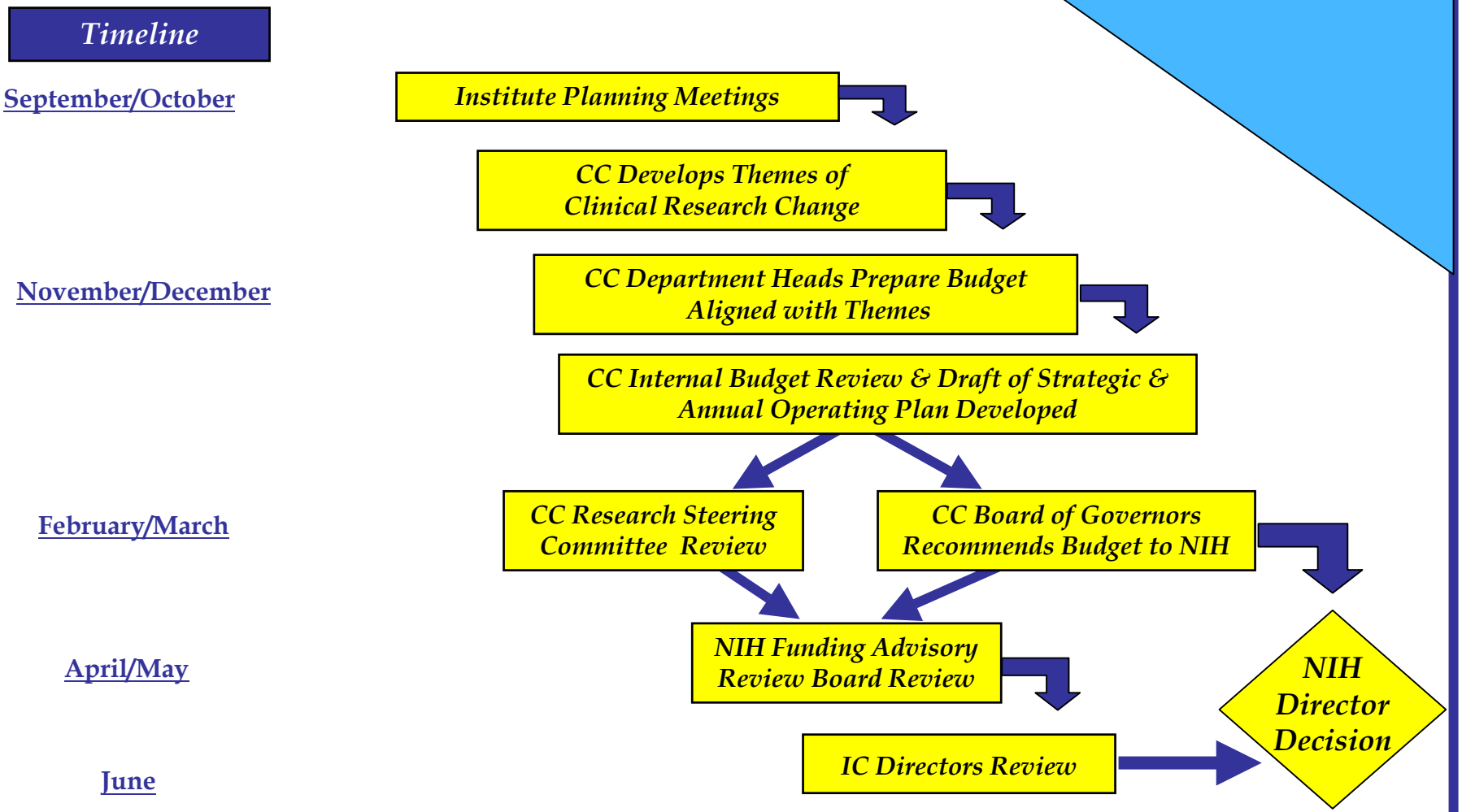
The Clinical Center's Performance Panel is a set of measures used to assess and communicate overall organizational performance. This panel will facilitate data-driven continuous improvement. Measures are identified to assess key components of the three CC core processes: clinical research, patient care, and operations. These measures also help to assess if, and how, new strategies impact core process outcomes and long-term goals. This effort is in alignment with the Office of Management and Budget mandate that federal agencies provide increasing evidence of effective organizational performance.

The measures within the performance panel are quantitative and qualitative. Targets (measurable goals) are set to allow for normal variation. If the measures indicate that outcomes are outside of established acceptable levels, the data are reviewed to understand if there is a potential problem or a best practice developing. This year the Clinical Center is designing a software program to collect and present data from a centralized repository. This repository will provide faster feedback for executive leadership to review with opportunity to proactively respond.

Clinical Center Performance Panel



CC Planning and Budget Development Process*



** This current process is subject to change with the new NIH governance structure implementation.*

Key Drivers to Development of CC Budget

Resource Deployment

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

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

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

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

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