National Institutes of Health
Clinical Center

Warren G. Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center

"There's no other hospital like it!"

2009 Strategic and Annual Operating Plan

Message from the Clinical Center Director

In 2009, the country will move into a new era as our 44th President takes office. Just as the past eight years have brought about many changes, this Administration will unfold its unique plans transitioning our Nation to a new set of priorities. Though the specific impact of these yet unknown changes is not clear, it is certain that the National Institutes of Health will need to refocus its attention and be ready to react nimbly with responsive plans.

The Clinical Center, a cornerstone of support for the NIH intramural clinical research program, also must be attentive to these external changes. However, our organization must keep a disciplined focus on Institute research priorities to understand what resources will best support investigators and provide the most comfortable, safe, and healing environment for our patients. Thoughtful assessment of the needs of our Institute colleagues and their patients will guide the development and implementation of this strategic and annual operating plan.

The "strategic" part of this plan includes a mission and a vision, defining the role the Clinical Center serves within the NIH and the leadership role it plays in the national clinical research community. Recently, these roles have come into question since multiple consecutive years of flat budgets have strained our ability to achieve an optimal level of clinical research support activity - our valuable beds are not full. A focused review of the Clinical Center is planned for this year by a new Congressionally mandated Scientific Management Review Board. This Board will ask some fundamental questions about the NIH's organizational structure and balance and will provide recommendations for enhancing the agency's mission through greater agency flexibility and responsiveness.

The "operational" part of this plan provides a set of annual

targets based on discussions with key Institute stakeholders and patients. These initiatives are considered achievable within our current budget and offer direct support to important research requirements as well as improvements to the way our hospital cares for patients and manages resources.

Our challenges are great but we will continue to meet them. The members of our Clinical Center workforce understand and are dedicated to our important mission. It is this collective contribution of talent and commitment that underlies our success, and will allow us to adapt and to evolve in new directions.

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

Vision Statement
As America's research hospital, we will lead the global effort in training today's investigators and discovering tomorrow's cures.

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.

Mission Statement
To provide a versatile clinical research environment enabling the NIH mission to improve human health by:

• investigating the pathogenesis and natural history of disease;
• developing state-of-the-art diagnostic, preventive and therapeutic interventions;
• training the next generation of clinical researchers; and
• ensuring that clinical research is safe, efficient, and ethical.

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

Core Processes

Clinical Research and Education
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.

Core processes are the major activities that support the mission.

Clinical Center Strategic Goals

• Continually improve the clinical research and training environment.
• Develop and promote best practices for safe and effective care of patients participating in clinical research.
• Deploy resources strategically and efficiently to optimize clinical research programs.

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

1. Pilot strategies to develop measurable improvements in employee recruitment.
2. Implement “Excellence in Customer Service” initiative.
3. Complete the Data Transformation Initiative and establish routine reporting.
4. Initiate “greening” project.

Annual Targets

Each of the 13 annual targets identified below is assigned to a member of the Clinical Center executive team who provides leadership and oversight to the 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 and Education
- Patient Care
- Operational Management

Strategic Goals

- Continually improve the clinical research and training environment.
- Develop and promote best practices for safe and effective care of patients participating in clinical research.
- Deploy resources strategically and efficiently to optimize clinical research programs.

2009 Annual Targets

1. Implement a mechanism for the provision of genetic testing and gene sequencing.
2. Expand bench-to- bedside and clinical research training programs through partnerships with Clinical and Translational Science Award (CTSA)institutions.
3. Establish subspecialty of clinical research nursing in partnership with clinical research nursing consortium.
4. Implement next phase of ProtoType and BTRIS, tools for IT support.

1. Implement next phase of "point of care" barcoding.
2. Implement web-based dashboard for clinical performance measurement.
3. Implement new processes to improve communication with referring physicians.
4. Pilot electronic access for patients to their medical records.
5. Establish metrics for patient intensity measurement for resource allocation in a clinical research setting.

Identifying the Annual Targets

Key Challenges – Confronting the Brutal Facts

In his 2001 management bestseller, Good to Great, Jim Collins points out that effective planning begins with an "honest and diligent effort to determine the truth of the situation…". The two most compelling brutal facts facing the Clinical Center are underutilized capacity and no revenue stream. Simultaneous to these challenges is an ongoing imperative for the Clinical Center to continuously improve the environment it provides to support clinical research and provide patient care.

Underutilized Capacity

The Clinical Center is underutilized as a result of multiple consecutive years of flat budgets straining NIH's ability to generate an optimal level of clinical research. Also contributing to this stagnant activity level is the fact that there are fewer new protocols. A smaller number of Institute tenure track investigators are writing clinical protocols, perhaps a derivative of budgetary constraints, but also due to reported bureaucratic barriers to starting up new studies in an efficient manner. Cutting the number of available beds or reducing the size of the clinical research program are risky propositions because a critical mass of patients is needed to maintain clinical competencies as well as to provide enough volume to make patient throughput worth the investment (i.e., economies of scale).

No Revenue Stream (Other than Intramural Funding)

The Clinical Center is subject to the strains of annual healthcare inflation but does not have a traditional revenue stream to offset costs. It is funded at the beginning of each fiscal year by an allocation from NIH. Thus, unlike other hospitals, admitting more patients to the Clinical Center results in added cost but not added revenue. The Clinical Center can only impact resource availability through cost containment efforts. Although the possibility of third party collection has been analyzed in depth on multiple occasions, the decision to initiate third party collection has been deferred due to the

expense of the billing infrastructure outweighing the possible revenues collected. In addition, NIH intramural leaders felt that the risk of compromising the clinical research mission by charging patient volunteers for standard of care services and burdening principal investigators with additional paperwork in an environment already laden with bureaucratic and regulatory compliance activities was not worth the financial gain.

Maintaining A Vibrant Infrastructure For Clinical Research

In spite of these key challenges, maintaining a vibrant infrastructure for clinical research is a necessary imperative for the Clinical Center. Because addressing the first two key challenges requires the interdependent efforts of Institutes and NIH leadership, this plan primarily identifies ways to improve the environment for patient care and clinical research support, issues which are in the purview of the Clinical Center's mission to solve.

In order to provide context for how the annual targets (i.e., initiatives) in this plan are identified, it is important to understand the distinctive role of the Clinical Center within the NIH intramural clinical research program. A discussion follows.

The Clinical Center and the NIH Intramural Clinical Research Program

At the heart of the NIH campus, the Clinical Center is an integral component of the NIH intramural clinical research program. The portfolio of services it provides - direct patient care, patient support services, training, informatics, environmental support services, and administration - is comparable to academic medical centers. However, with a mission dedicated entirely to clinical research, the Clinical Center is unique in important ways. First, the staff (doctors, nurses, technicians, patient support staff, etc.) are part of the Clinical Center while almost all the investigators work for the Institutes. Second, all patients admitted to the Clinical Center come to participate in research. The Clinical Center does not have an emergency room and does not provide 'standard of care' services beyond what is needed to care for patients on protocols. Finally, the Clinical Center does not have a traditional revenue flow. As a federally funded research hospital, patients are not charged – they are viewed as partners in science. Patient admissions to the Clinical Center are influenced by how much activity Institute investigators generate and availability of NIH funds (which flow through the Institutes to the Clinical Center) to support this activity.

The distinguishing characteristics of the Clinical Center and its place within the NIH intramural clinical research program impact the way that the organization approaches planning. While hospitals typically use planning to proactively identify service lines to meet local marketplace needs, enhance patient volume, and generate revenue, the Clinical Center develops its plan to be responsive to its unique mission - providing the strongest possible environment for conducting clinical research, while also working with NIH intramural leaders to influence broader organizational challenges.

Thus, the initiatives identified in this plan can be categorized in two concentric circles:

- Clinical Center Challenges: Initiatives to improve the patient care, clinical research support, or managerial infrastructure which can be completed within purview of CC mission.
- Intramural Challenges: Issues which impact the success of but are not 'owned' by the CC; some issues can be influenced by the CC through the identification of initiatives in this plan.

Financial Assessment of Annual Targets

Clinical Research and Education

Annual Target

1. Implement a mechanism for the provision of genetic testing and gene sequencing.
2. Expand bench-to-bedside and clinical research training programs through partnerships with Clinical and Translational Science Award (CTSA) institutions.
3. Establish subspecialty of clinical research nursing in partnership with clinical research nursing consortium.
4. Implement next phase of ProtoType and the Biomedical Translational Research Information System (BTRIS), tools for IT support.

Financial Impact for FY 2009

Budget neutral. New contract will bundle services to achieve savings.

Bench-to-Bedside resources to be obtained through identification of new funding partners. Current portfolio funded at $4.5M of non-CC funds. Clinical research training courses funded at $300K in Fiscal Year (FY) 2009. Clinical Research Training Program (CRTP) funds of $1.6M, from Roadmap and a private partner, will expire in FY 2010. New partner(s) and a sustained funding source are needed for CRTP.

Nursing department and affiliated consortium partners support through contribution of time.

No additional resources needed for ProtoType in FY 2009; BTRIS funding provided in FY 2009 budget via $3.3M in Service & Supply funds received from IT Working Group.

Patient Care

Annual Target

1. Implement next phase of "point of care" barcoding.
2. Implement web-based dashboard for clinical performance measurement.
3. Implement new processes to improve communication with referring physicians.
4. Pilot electronic access for patients to their medical records.
5. Establish metrics for patient intensity measurement for resource allocation in a clinical research setting.

Financial Impact for FY 2009
CC budget in FY 2008 included $2.2M to fund this project; it began in 4Q FY 2008.
No new CC resources.
CC budget for FY 2009 includes $450K to fund this project.
CC budget for FY 2009 includes $250K to fund this project.
CC budget in FY 2008 included $220K to fund this project; it began in 4Q FY 2008, and maintenance costs for FY 2009 are included in the launch cost.

Operational Management

Annual Target
1. Pilot strategies to develop measurable improvements in employee recruitment.
2. Implement "Excellence in Customer Service" initiative.
3. Complete the Data Transformation Initiative and establish routine reporting.
4. Initiate "greening" project.

Financial Impact for FY 2009
$100K for contract support in FY 2009 budget.
Achieved through reorganization with potential cost savings greater than $125K.
CC budget includes $900K in FY 2009 to support this initiative.
No new CC resources.

Clinical Center Planning/Budget Review Process

September/October
November/December
Programmatic Requirements
Institute Planning Meetings
CC Develops Themes
CC Prepares Budget & Operating Plan

February/March
April – June
Reviews
NIH Advisory Board for Clinical Research
NIH Steering Committee
IC Directors
Management and Budget Working Group
Intramural Working Group
NIH Director

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

*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.

2009 Presidential Transition

The Clinical Center, in developing the priorities for its strategic and annual operating plan, seeks input not only from Institute investigators and the patients they admit, but also has looked beyond its immediate environment to understand the broader goals of the federal government. The highest level goals which have influenced managerial objectives have come from three federal initiatives described below.

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.

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 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.

While goals may change in the future, given the election, the Clinical Center stands ready to quickly and flexibly respond.

Health Care Industry Trends

<u>Patient Safety and Clinical Quality</u>

The safe and effective care of patients who come to the Clinical Center as participants 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 identify, understand and mitigate 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, Failure Mode and Effects Analysis, and Root Cause Analyses, and proactively identify risks associated with

clinical care and clinical research. Once identified, strategies to reduce or lessen 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 7 to 10 percent per year. In an era of flat budgets, these costs must be alleviated by diligent efforts to offset this growth. The Clinical Center continues collaborating with Institutes as they negotiate with pharmaceutical manufacturers to reduce Clinical Center costs for marketed drugs that are being studied for non-approved indications. Through these negotiations, the Clinical Center anticipates potential net savings of up to $4M. The Clinical Center also is evaluating potential savings from no longer dispensing non-protocol related drugs to outpatients (i.e., drugs supporting patient care independent from, but necessary to support, the clinical research process) when the patient has health care insurance that will cover the expense. Inflation of medical supplies, although at a slower rate of approximately 4 to 6 percent annually, also requires cost containment efforts.

Clinical Research Awareness

Successful clinical research depends on a diverse cadre of volunteers to participate in the investigations as patients and as healthy volunteers. The public's perception of the safety, risks, and benefits of clinical research affects NIH's ability to recruit volunteers into protocols. The Clinical Center must base outreach efforts on a clear understanding of these public perceptions. Public awareness of the issues surrounding clinical research will benefit the clinical research enterprise and recruitment efforts on behalf of the Clinical Center.

*Kohn, L., Corrigan, J., Donaldson, M., Institute of Medicine Committee on Quality of Health Care in
America: "To Err is Human: Building a Safer Health System." The National Academy Press, 2000.

** Committee on Quality of Health Care in America, Institute of Medicine: "Crossing the Quality
Chasm: A New Health System for the 21st Century." The National Academy Press, 2001.

Health Care Industry Trends

Information Technology Development

Healthcare information technology continues to advance at a rapid pace by offering ever improving technologies to support clinical research and patient care. The Clinical Center is committed to investing in these improvements and system enhancements to support cutting edge-research and the highest quality of patient care.

Specifically, the Clinical Center is investigating new methodologies to share and communicate critical information including the use of patient portals, secure messaging between physicians, and mobile technologies. In addition, the health care industry has developed several new system enhancements to reduce medical errors and improve patient safety. The Clinical Center is exploring and/or implementing such technologies, which include radio frequency identification (RFID) technology in bar-coding applications for laboratory and medication administration processes, medication distribution systems, and new systems to address medication reconciliation.

The Clinical Center also is working to develop the Biomedical Translational Research Information System (BTRIS), which will bring Clinical Research Information System (CRIS) and Institute/Center data together in a single repository. The repository will support NIH researchers by allowing the efficient use and reuse of data collected in clinical trials. Specifically, in Fiscal Year (FY) 2009 the Clinical Center will focus on developing BTRIS to include laboratory and other ancillary system data, data generated in the Clinical Research Information System (CRIS) (e.g., nursing documentation and pharmacy data), archived Clinical Center data from the Medical Information System (MIS), and data from NIAID's Clinical Research Information System (CRIMSON). In FY 2010, the Clinical Center will expand BTRIS to include additional data from the Clinical Center and from other Institute/Center systems.

Nursing Shortage

For the last several years the United States has been in the midst of a nursing shortage that was expected to increase over the next decade. Due to recent economic developments, this trend may change. However, the DC metro area and the state of Maryland continue to experience a high nursing vacancy rate. Contributors to this shortage include the number of baby boomers reaching retirement age, a shortage in nursing school faculty to support the number of qualified applicants for nursing programs and the growing need for health care. In addition, the national average nurse turnover rate in hospitals of 8.4%, and average voluntary turnover for first year nurses of 27.1% are further exacerbating the situation. Maryland’s nursing vacancy rate of 10% continues to remain higher than the national average and it is projected that Maryland will have a shortfall of 10,000 nurses in less than a decade.

Biomedical Science Trends

Molecular Medicine

Represents the logical extension of scientific inquiry into human physiology and pathophysiology. Increasingly NIH IRP scientists are using molecular techniques that employ a variety of physical, chemical, biological and medical techniques: 1) to describe molecular structures and molecular mechanisms; 2) to identify molecular and genetic errors associated with disease states; and 3) to develop tailored molecular interventions to correct them. Beginning with the development of the radioimmunoassay and encompassing the tools of genomics, proteomics, microbiomics

and pharmacogenomics, a variety of new techniques have been developed over the past four decades that effectively have created the discipline of molecular medicine.

Genomics

The study of the genetic material of organisms including determining the complete DNA sequence of organisms, as well as the creation of gene maps and the study of interactions that occur among genes. Techniques have been developed over the past two decades to make the field of genomics possible, including techniques for DNA sequencing, gene- and genome-mapping, data storage, and analysis of the huge data sets produced by these studies. NIH scientists played a significant role in the sequencing of the entire human genome.

Proteomics

The large-scale study of proteins and their structure and function. The proteome is the entire complement of proteins, including the modifications made to a particular set of proteins, produced by an organism. These modifications occur in response to stress, physiological changes, and other stimuli and contribute to the physiological metabolic pathways within cells. These proteins and modified proteins can be detected and measured in maps using mass spectroscopy and other sensitive techniques. NIH scientists are using proteomics to evaluate host-parasite interaction, normal and abnormal physiology, the body's response to infection, sepsis, malignancy and in a variety of other settings. Evaluating how proteins are modified in these settings provides insight into molecular physiology and sheds light on possible interventions.

Microbiomics

The study of the complete set of genetic material (i.e., all the genomic material) from all of the microorganisms in a specific environment (e.g., the gut or the skin). This burgeoning field uses molecular tools to evaluate the microbial diversity in specific environments and determine how changes in the microbiota in these environments contribute to health and disease. Many NIH scientists are aggressively using these molecular techniques to assess the impact of the microbiota of specific human environments (e.g., oral cavity, colon, skin, etc.) on health and in specific disease states.

Pharmacogenomics

The evaluation of the impact of genetic variation on patients' responses to the administration of pharmacologic agents by attempting to correlate gene expression or single nucleotide polymorphisms with either efficacy or toxicity of the agent. The pharmacogenomic approach provides the practitioner with an opportunity to select the most appropriate agent for a specific patient based on the patient's genotype, thereby minimizing adverse drug effects. NIH investigators are using these approaches to tailor cancer chemotherapy strategies for individual patients.

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 the creation of 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 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 from FY 2004 to FY 2008 was 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 increases and pressures associated with health care expenses, including pharmaceuticals and medical supplies.

To date, the Clinical Center has been successful in maintaining service levels through careful management of workforce resources 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. While the Clinical Center budget for FY 2009 will be increased by 2.9% to $362.3 million, this is still less than inflationary pressures for the bulk of its cost structure. It is unlikely that the Clinical Center will be successful in meeting a flat budget requirement in FY 2010 without the reduction or elimination of services. The Clinical Center's cost containment focus for FY 2009 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.

Advisory & Review Groups

NIH Advisory Board for Clinical Research

The NIH Advisory Board for Clinical Research (ABCR) is charged with providing 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.

NIH Steering Committee

The NIH Steering Committee was established in 2003 by NIH Director Elias A. Zerhouni, M.D., to provide a consistent strategic direction and streamline the decision making processes at NIH. Specifically, the Committee oversees all corporate functions, resources, and policies other than the setting of corporate scientific direction and priorities, in addition to bringing issues of the highest significance to all IC Directors. Membership consists of ten directors derived from and representing the 27 NIH Institutes and Centers who serve on a rotating basis, and the Committee is chaired by the NIH Director.

Intramural Working Group

The Intramural Working Group (IWG) is charged with the oversight of activities of the NIH Intramural Research Programs (IRP), which includes the conduct of laboratory-based and clinical research (in the Clinical Center and elsewhere) and research training. The IWG reviews issues and recommends policies of trans-NIH importance that require decisions by corporate NIH, including the IC Directors and the NIH Director, but is not involved in the day-to-day operations of the intramural program.

Management and Budget Working Group

The Management and Budget Working Group (MBWG) was established by the NIH Director as an advisory group to the NIH Steering Committee, to facilitate decision making on corporate management and resource issues including human resources. The Working Group provides recommendations to the NIH Steering Committee on funding levels for the Clinical Center and other NIH components that do not have separate appropriations.

Intramural Clinical Research Steering Committee

The NIH Intramural Clinical Research Steering Committee (ICRSC) was established by the NIH Deputy Director for Intramural Research as a forum for trans-NIH governance and policy development in the area of human subjects research. It is expected that the ICRSC will interact as needed with the Intramural Working Group, Board of Scientific Directors, the Medical Executive Committee, the Human Subjects Research Advisory Committee, and the Advisory Board for Clinical Research, to develop and implement plans to improve the environment for clinical research at the NIH, and to coordinate efforts and ensure clear communications about goals, progress, and future directions.

Medical Executive Committee

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.

Board of Scientific Counselors

The Board of Scientific Counselors (BSC) 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. This is accomplished through periodic visits to the laboratories to assess the research of, and evaluate the performance of, independent investigators. 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 Clinical Center has a small portfolio of independent research conducted by the clinical departments which provides the essential clinical support services to Institute clinical researchers.

Scientific Management Review Board

The Scientific Management Review Board (SMRB) was authorized by the NIH Reform Act of 2006 and signed into law by the President in January 2007. This act was the first omnibus reauthorization of NIH in 14 years. A major element of the Reform Act of 2006 was the new authority it gave to the NIH Director to improve program coordination, assemble and analyze accurate data, implement strategic plans based on institute- and center-determined priorities, ensure proper allocation of resources, and further maximize investigator-initiated research in high impact and emerging research areas. NIH Director Elias A. Zerhouni, M.D., nominated individuals to serve as members of the SMRB and the Board was announced in September 2008. The SMRB will examine the NIH's organizational structure and balance and will provide recommendations for enhancing the agency's mission through greater agency flexibility and responsiveness.

Joint Commission

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, the Joint Commission 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. The Clinical Center received full accreditation in 2006 and is preparing actively for its 2009 unannounced survey.

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

Customers/Stakeholders - Institutes

"What are the Institutes Telling Us?"
The NIH is composed of 27 Institutes and Centers (ICs) whose research activities include basic research that explores the fundamental workings of biological systems and behavior, studies that examine disease and treatments in clinical settings, prevention, and population-based analyses of health 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 FY 2008, there were 1,449 active protocols implemented with Clinical Center resources and support; this is a growth of 210 protocols, or 17% over the past five years.

Institute Planning Meetings
A set of "themes", garnered from ongoing discussions with the Institute Directors, Scientific Directors, and Clinical Directors and compiled after the Fall Institute/Clinical Center planning meetings, summarizes information gleaned into a list of key areas of growth and change in the intramural clinical research program. The themes are provided to CC department heads and informs them as they are preparing their annual budget requests. Ultimately, the information derived from interactions with the Institutes guides the Clinical Center in developing its operating plan and in allocating its resources effectively. Understanding what the Institutes are telling us and disseminating this information to Clinical Center department heads allows the Clinical Center to align its resources to Institute priorities in order to provide optimal support for both clinical research and patient care. Since new Institute initiatives are generally implemented over multiple years, many of the themes (areas of growth or change) documented in this report represent affirmation of Institute requests from prior years with updates provided. With continued budget constraints projected for FY 2009 and beyond (as discussed elsewhere in this document), Institutes and their investigators will need to collaborate with the Clinical Center to refine the timing of resource requests and prioritize new initiatives in the context of ongoing clinical programs.

Themes from 2008 Fall Planning Meetings

Head and Neck Cancer (NCI, NIDCD)
Several institutes expressed interest in developing a new initiative in Head and Neck Cancer (NCI, NIDCD, and NIDCR). NCI leadership believes such a research initiative

could be synergistic, and will offer scientific opportunities that could 'piggy back' on this patient population (e.g., lung cancer, HPV, other viruses, etc.). NCI will be working with NIDCR and NIDCD. They have recruited an international expert who will support the initiative. In discussion with the interested ICs, however, we believe that the success of the initiative will depend on the involved ICs' ability to recruit one or two rising investigators. NCI is spearheading this recruitment and has identified an investigator who could be hired to lead the initiative. Recruitment of this investigator faces 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 new investigators. Furthermore, NCI acknowledges that these studies will be resource intensive (e.g., requiring reconstructive plastic surgery, voice therapy, and a variety of other Clinical Center resources) and that the involved ICs need to delineate clearly all of the ancillary needs associated with this program. Clinical Center resources required to support such an initiative would likely include extensive use of critical care, imaging services, rehabilitation medicine, pain and palliative care, and nutrition services. Traditionally surgery has been the focus of most prior science in this field; however, treatment is now evolving toward more involvement of radiation therapy, chemotherapy and immunotherapy. Patient recruitment may offer an additional challenge, as patients may not want to travel to NIH for intensive five days/week treatment, and may prefer non-experimental radiation-based treatment closer to home.

Molecular Genetic Testing, Gene Sequencing, and Cytogenetics

Over the past several years the Clinical Center has witnessed an exponential demand for genetic testing, cytogenetic studies 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 year's set of planning meetings, several ICs (e.g., NICHD, NCI, and 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 already is working to develop strategies that will provide these services at the lowest possible cost, and the highest possible quality via a centralized mechanism. The CC conducted two surveys of customers' needs and worked with the Clinical Director of NHGRI to develop options for presentation 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 when the 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 have a substantial impact on clinical studies. One Institute representative 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 BRCA testing cost, even at 50% reduction, is prohibitive. CC leadership understands that cost-prohibitive genetic testing would be a major point of discussion with the shift to 85% co-pay and will work with IC scientists and vendors to

try to develop a better solution. In addition, the CC has identified genetic testing as a potentially important area for intramural/extramural partnerships. The CC also will work with the NCI to make certain that the cytogenetics test portfolio is broad enough to meet institute needs and that these tests are available to investigators from all ICs.

Undiagnosed Diseases Program

The "Undiagnosed Diseases Program" is a clear spin-off of the movement toward molecular medicine. Using the unique combination of scientific and medical expertise and resources that already are present at the NIH Clinical Center, the Undiagnosed Diseases Program pursues two goals: (1) to provide answers for patients with mysterious conditions that have eluded diagnosis, and (2) to advance medical knowledge about rare and common diseases. A major product of this initiative will be the generation of new clinical protocols relating to the new disease entities that almost certainly will be identified in this process. The Program has been organized by the Clinical Director of the National Human Genome Research Institute (NHGRI), in collaboration with the NIH Office of Rare Diseases (ORD) and the NIH Clinical Center. The program is a trans-NIH initiative that focuses on the most puzzling medical cases referred to the CC by physicians throughout the nation. Many medical specialties from other NIH research Institutes and Centers already have agreed to participate in the Program and will contribute the expertise needed to address the types of problems presented to the staff of the Program. Types of expertise needed to support the initiative include (but are not limited to) endocrinology, immunology, infectious diseases, oncology, dermatology, dentistry, cardiology, and genetics. These specialties and subspecialties already are represented among the cohort of senior attending physician-scientists who meet monthly to discuss candidate cases that have been referred for evaluation in the program. The program already has received 1000 calls to date, reviewed 300 records, and accepted 20 cases. The Clinical Center will continue to provide clinical research support to the program, and in the future will work together to identify resource and staffing needs to ensure its continued growth and success.

Traumatic Brain Injury and Post Traumatic Stress Disorder

During 2008 Congress provided substantial supplementary funding to the Uniformed Services University of the Health Sciences (USUHS) to study Traumatic Brain Injury (TBI) and Post Traumatic Stress Disorder (PTSD) in soldiers returning from the wars in Iraq and Afghanistan who have these syndromes. The Committee language specifically commented that these funds would be used in part to support sophisticated imaging studies to be conducted at the NIH Clinical Center. In collaboration with the Department of Defense, several Institutes and programs including 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 that could contribute substantially to this initiative. 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.

ProtoType

The Institutional Review Board (IRB) process has been identified as a major barrier to clinical research. The Clinical Center's Director and its Office of Protocol Services have invested substantial effort in developing a facilitated electronic standardized solution for part of this problem (i.e., ProtoType). ProtoType is a web-based clinical protocol-writing tool that provides investigators with a standard protocol structure, allowing them to put ideas for new protocols into the proper format to satisfy regulations and facilitate reviews. Use of ProtoType will bring about a more streamlined process for creating protocols, especially for new investigators who are just learning the process. The Neurosciences IRB has already adopted ProtoType as a required format for protocol submission and review. The Clinical Center's goal is for all ICs to implement ProtoType. The CC believes that this approach will help streamline the protocol writing process across the NIH intramural campus and reduce the barriers to clinical research.

Imaging

Demand for imaging as a major component of clinical research support continues to escalate 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 all ICs 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 also have 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 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.

Salaries for Physicians in Scarce Medical and Surgical Specialties

Recruitment activities for physicians in some highly-paid, scarce medical and surgical specialties and subspecialties are often hampered by the inability of NIH ICs to be able to offer salaries that are even remotely competitive. Examples of these specialties and subspecialties include: anesthesiology, interventional and non-interventional radiology, general surgery, thoracic surgery, neurosurgery, orthopedic surgery, radiation oncology, and critical care. NCI is interested in reinvigorating its breast cancer program but is concerned that recruitment also will be a challenge because of their inability to match outside academic salaries. The salary problem is compounded by existing ethics restrictions on outside activities. Virtually all of the most-highly sought-after recruits have 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 also would be viewed as an ethics conflict if the individual were hired as an investigator at NIH. This past year the Clinical Center worked with the NIH Office of the Director to increase the salary ranges for interventional radiologists and anesthesiologists. In addition the CC has submitted a proposal for setting salaries (based on American Association of Medical Colleges' benchmarks) for surgeons. During FY 2009, the Clinical Center will continue to advocate actively for increased salaries for practitioners in the highly-paid scarce specialties and subspecialties for which recruitment continues to be problematic.

Clinical Research Participation of Tenured and Tenure-Track Investigators

NIH intramural leaders have discussed the diminishing numbers of tenure and tenure-track investigators who are writing and conducting clinical research protocols. IC leadership expressed concern that the traditional pathways for investigators to write and conduct these studies are associated with formidable barriers to success. ICs are developing new pathways to address this issue. To shed additional light on the issue, the Clinical Center intends to collect and analyze trend data on the tenure and tenure-track populations and the participation of these investigators in clinical and translational research.

"What are the Patients Telling Us?"

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 FY 2008, there were 6,105 inpatient admissions (an increase of 5% from FY 2007) and more than 90,000 outpatient visits (a decrease of 0.7% from FY 2007). On average, there are 148.6 patients (the same as FY 2007) in the hospital per night, and their length of stay averages 8.5 days (a 1.5% decrease from FY 2007). In FY 2008, 1,420 new research volunteers were enrolled through the Clinical Center's Office of Communications, Patient Recruitment, and Public Liaison Office (OCPRPL) and the Clinical Research Volunteer Program (CRVP). The CRVP is part of the OCPRPL and provides a pool of healthy volunteers available for all principal investigators. In FY 2008, the CRVP program registered 1,713

new volunteers and processed 17,588 payment transactions.

Surveys

As partners in the clinical research process, our patients are well positioned to provide the Clinical Center with valuable information about the quality of care and services provided to them as research participants. The Clinical Center relies on a variety of techniques to elicit our patients' perceptions of their experiences here at the CC.

As part of the Clinical Center's departmental operational review process, patients were queried about their specific impressions and experiences regarding the Pharmacy Department, the Rehabilitation Medicine Department, and the Department of Critical Care Medicine. Information from these surveys was used to inform the reviews of these departments.

In an effort to assess the influence that the physical environment has on the patients' experience, the Clinical Center in 2008 completed a survey of our patients' perceptions of the environment in which we provide care and conduct research. This project was designed to compare patients' impressions of the Warren Grant Magnuson Center environment with their perceptions of the new Mark O. Hatfield Clinical Research Center. Themes assessed included: connection to staff and caregivers; cultivation of a sense of well-being; convenience and accessibility; confidentiality and privacy; inclusion of the family; consideration of impairments; and, closeness to nature and the outside world.

Patients also are surveyed continuously upon discharge through a collaboration with National Research Corporation (NRC+Picker). Patients receive a survey within a month of discharge assessing perceptions of their CC experience using the following dimensions of care: Emotional Support; Respect for Patient Preferences; Physical Comfort; Information, Education and Communication; Coordination of Care; Involvement of Family and Friends; Continuity and Transition; and Access to Care.

In addition to surveys, several processes exist to provide real-time information about how patients view their experience at the Clinical Center.

Patient Representative

The Patient Representative serves as a critical link between the patient and the hospital. The Patient Representative makes every effort to assure that patients are informed of their rights and responsibilities and that they understand what the Clinical Center is, what it can offer, and how it operates. The Patient Representative team, who visit each inpatient upon admission, proactively seeks to identify critical patient care and clinical research issues that Clinical Center patients are facing or may face as a result of volunteering to participate in the research process. In 2008 common issues faced by patients included: problems with travel; difficulties in dealing with the voucher office; lack of necessary information; problems with routine procedures; and misunderstandings between patients and staff.

Patient Portal

Patients now have the capacity to provide online feedback to the Clinical Center leadership about their experience. Every patient's bedside computer has a "Patient Comment Portal" available for use by patients to alert CC leadership to patient problems, including clinical quality of care and service issues. In 2008 feedback included positive and negative comments on issues including: patient care; nutrition; housekeeping; and transportation.

Patient Advisory Group

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 meetings throughout the year. These individuals represent patients who live locally, as well as those who travel long distances to participate in NIH clinical research studies. Meetings are open to all patients and family members, and the discussions from these meetings help identify issues of concern and recommendations that improve efforts to provide the highest quality research and patient care services. One member of the PAG represents the patients' viewpoint 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 including: (1) The Introduction to the Principles and Practice of Clinical Research and (2) The Ethical and Regulatory Aspects of Clinical Research. In 2008, the PAG provided advice and feedback on topics including the following: patient confidentiality; clinic wait times; spiritual ministry within the Clinical Center; construction projects; and increasing awareness of the Clinical Center nationally.

Customers/Stakeholders – Employees

"What are the Employees Telling Us?"

Clinical Center employee turnover is currently 13% in comparison to the average turnover for Maryland hospitals which is 16.7%. Having worked through several years of flat budgets, CC employees are challenged with continuing to function optimally in the face of diminishing resources. Managers are being asked regularly to review key activities, and identify those that are no longer mission critical to ensure optimal resource allocation on priorities. As a result, in many cases, employees who have departed the CC or retired have not been replaced, leaving their colleagues to fill in the gaps by assuming additional responsibilities. Where positions are being backfilled, managers comment that the recruitment process is slow and cumbersome, not always yielding the best possible candidates even after exhaustive searches. Despite these challenges, in the current economic climate, the stability of a position in the federal government is desirable.

New employees continue to express their excitement over coming to work at the

Clinical Center. Their initial impressions confirm that the reputation of the Clinical Center as a workplace with committed employees is real and deserved. From the moment they walk into the hospital, new employees report staff offering them assistance and acting in a positive and caring manner toward them although they are absolute strangers. Friends and family of new employees are often a great recruiting source. Another common announcement heard in orientation is from returning employees who state, "I went out to the 'real world' to gain outside experience and a different perspective and realized how great this hospital is and that I wanted to be here!"

The launch of a new course for supervisors, entitled "Supervisory Essentials" has provided a platform for emerging leaders to share their common struggles in developing their new role. Some of their responses follow: "The opportunity to get to know other colleagues and hear that I am not alone; that leadership development takes time and focus has been a confirming reality check." "The mission of the Clinical Center is too important for me not to develop my leadership skills as much as I can!" "The ability to learn how to reframe the organization from different perspectives will enable me to be a better strategic problem solver."

As part of the Clinical Center's succession plan, an executive coaching program was created two years ago. In this process, managers selected for this special experience are viewed as rising "stars" in the organization who need to continue to strengthen their leadership skills. The results of this program are still being assessed; however, CC employees have been volunteering feedback about the positive changes they have observed in their individual managers who have been coached. Comments such as, "My manager asks for my opinion about problems and ideas much more than she used to." "I don't know what that coach did but my manager just seems more at ease, less stressed and easier to approach regarding problems." "My manager was always a good listener but he does it even better since he had a coach."

Customers/Stakeholders – Clinical Fellows
"What are the Clinical Fellows Telling Us?"

Clinical Fellows Committee
Throughout 2008 a group of clinical fellows representing all Institutes met quarterly with Clinical Center Director John I. Gallin, M.D. 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 staff. As in prior years, ClinFelCom achieved important successes in 2008, many based on feedback received from the 2007 Clinical Fellows Survey. ClinFelCom advocated for a streamlined approval process for moonlighting activities, which became a reality in 2008; residents and fellows are now able to apply for approval of moonlighting activities through an online application administered by the NIH Ethics Advisory Council. Several information technology issues were identified and were addressed by a subcommittee working with Clinical Center informatics staff. For example, this group collaborated in the development of a comprehensive new computerized sign-out tool

which is in the beta-testing phase. ClinFelCom also has been involved in the Clinical Center's efforts to explore instant feedback mechanisms for clinical fellows who use the CRIS electronic medical record system. In response to an Accreditation Council for Graduate Medical Education (ACGME) review and the results of the 2007 Clinical Fellows Committee survey, ClinFelCom provided input to the Clinical Center regarding the purchase of a hot-food items vending machine. This addresses an ACGME citation about the lack of available hot food items during nights and weekends when the cafeterias are closed. Throughout 2008, ClinFelCom continued to address several professional needs of interest to clinical fellows including improved resources for childcare and maternity/paternity leave, ethics restrictions on clinical fellows' acceptance of travel awards and competitive scholarships to scientific conferences. Furthermore, ClinFelCom members continue to serve as representatives on key Clinical Center committees, including the CC Quality and Infection Control Committees, Graduate Medical Education Committee, and Department of Clinical Research Informatics Fellow Advisory Board.

Interface with Extramural Partners
Customers/Stakeholders – Extramural Partners

Extramural Clinical Investigators

In support of the NIH initiative to invigorate clinical research, the CC focused recent efforts on the expansion of programmatic opportunities to include extramural investigators. The 15th offering of "Introduction to the Principles and Practice of Clinical Research" (IPPCR) course occurred this year. Almost 1,000 students enrolled with greater than 50% participating at remote locations, both nationally and internationally. In addition, an intramural NIH team traveled to China to teach the first 'live' IPPCR course to distinguished students in China. In early November, the 6th annual Clinical Investigator Student Trainee forum (CIST) was held for a record 321 participants. This academic forum is supported with public and private funds from the Howard Hughes Medical Institute, the Doris Duke Charitable Foundation, the Sarnoff Endowment for Cardiovascular Sciences, the Fogarty International Center/Ellison Foundation, and the National Institutes of Health. The purpose of this forum is to emphasize the critical importance of translational and clinical research, and to encourage the training of the next generation of clinician-scientists to conduct that research. In addition to clinical research training efforts, the NIH Bench-to-Bedside program expanded this year for its 11th cycle which included new donors and expanded categories of funding. This year's portfolio of projects represents a robust sampling of intramural institute investigators partnering with extramural clinical researchers at academic medical centers, both U.S. and abroad. Since the program's inception, more than 400 investigators have collaborated on 135 funded projects.

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. In 2008 the Clinical Center conducted an extensive assessment of referring physicians' perceptions of the timeliness and utility of communication with NIH physician investigators. Several areas for improvement were identified and the Clinical Center, working with the Medical Executive Committee, has launched an organizational effort to develop strategies to enhance communication and interactions with referring physicians.

Advocacy Groups

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

Measurement Methodology – A Balanced Scorecard Approach*

Operational Management

• Cost Per Adjusted Patient Day
• CC Department Costs..Cost Per Activity..Supplies

•Unpaid Invoices
•Space Utilization
•Square Feet/FTE

Workforce Management

•Staffing
..Turnover Rate
..Vacancy Rate
..FTE Usage Rate
..Reasons for Staff Turnover
..Workforce Demographics
..Employee Satisfaction
•Training
..Clinical Research Trainees
..Management Trainees
..Summer Students
..ACGME (# and year)**
•Diversity
..# of Underrepresented Minorities Hired
..# and Success of Diversity Initiatives

Customer Perspectives
• Patient Wait Times
• Patient Perception Surveys
• Referring MD Surveys
• Operational Review Stakeholder Perception Surveys

Clinical Research Support
•Clinical Activity
..% Hospital Occupancy
..Adjusted Patient Days
•Protocol/PI Activity
..Active Protocols (by type)
..New/Terminated Protocols
..PIs per Institute
•Clinical Quality
..Occurrences by Quarter
..Patient Falls
..Medication Errors

* Developed in accordance with the Kaplan and Norton Balanced Scorecard Method. www.balancedscorecard.org/basics/bsc1.html
** The Accreditation Council for Graduate Medical Education