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National Institutes of Health Clinical Center 2008 Environmental Assessment

A companion document to the Clinical Center Strategic and Annual Operating Plan

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health

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Executive Summary

The Clinical Center of the National Institutes of Health continues to face substantial challenges and opportunities. During the seven-year period, during which the budget of the National Institutes of Health was doubled, the Clinical Center's budget increased substantially. For the last five years, however, the Clinical Center's budget has been essentially flat, necessitating the implementation of a variety of savings, cost-sharing and efficiency initiatives. As a part of Clinical Center strategic planning activities, our organization conducts a thorough environmental assessment to determine Clinical Center strengths, weaknesses, opportunities, and threats. This document represents the sixth iteration of the Clinical Center's strategic plan environmental assessment. The Clinical Center has eleven years' experience using, evaluating and modifying its strategic plan. In those eleven years the factors influencing our environment have continued to change. This document: summarizes the new developments in the Clinical Center's environment since the publication of the last environmental assessment; the interventions that have been taken to address weaknesses and bolster strengths; identifies changes that have occurred; and provides additional comments within the context of the original environmental assessment.

The Clinical Center has numerous strengths, among them:

- The Clinical Center is the clinical research hospital supporting one of the strongest, most visible scientific programs in the world – the intramural program at the National Institutes of Health;
- The Clinical Center has a critical mass of world-class scientists and clinical investigators working closely together to develop and conduct translational clinical research;
- The support staff and research infrastructure in the Clinical Center are uniquely tailored to support excellence in clinical research;
- The Clinical Center focuses on a unique research portfolio of work that would be difficult, if not impossible, to conduct at other centers;
- The Clinical Center staff are capable of providing, and have consistently provided, the highest quality patient care to clinical research subjects;
- Unlike patient-care-oriented academic centers, the culture of the Clinical Center is science-driven;
- Because of its unique clinical research mission, the Clinical Center has organizational and scientific flexibility that most institutions do not possess; and
- The Clinical Center provides investigators access to expensive and state-of-the-art technologies that are not readily available in many other centers.

These strengths, which were identified in the initial rendition of this document, remain evident after eleven years' experience with the strategic plan.

During the preparation of the first iteration of this document, self-evaluation also identified several organizational weaknesses at the Clinical Center, among them:

- Existing Clinical Center governance mechanisms were unclear;
- The Clinical Center was subject to bureaucratic inflexibility in personnel, procurement, and fiscal management;
- The Clinical Center's physical plant urgently needed renewal;
- The Clinical Center lacked a strategic plan;
- Clinical Center information systems did not adequately support managerial and financial data and do not integrate clinical, research, managerial and financial data;

- Clinical Center successes were not adequately communicated to the public, to referring physicians, and to the insurance and managed care industries;
- Patient recruitment efforts were increasingly less successful; and
- Some customers viewed the fact that the Clinical Center does not offer complete, integrated medical and surgical services as an institutional weakness.

Progress in Addressing Identified Weaknesses

Over the past eleven years, many of the weaknesses identified in the initial environmental assessment have been addressed. The Clinical Center governance structure was clarified by the establishment of a Board of Governors, which has subsequently had its charter broadened to become the Advisory Board for Clinical Research. Over the past five years the Clinical Center's governance has continued to evolve. A report issued in 2003 by the Institute of Medicine suggested streamlining the governance of the NIH clinical research enterprise. In addition, an advisory panel, the Blue Ribbon Panel on Intramural Clinical Research, convened by the NIH Director in the fall of 2003 once again assessed (and subsequently revised) Clinical Center governance structures. We moved into the new Clinical Research Center (CRC) in April of 2005. In addition, we replaced our Medical Information System with a comprehensive, mission-oriented Clinical Research Information System, also in 2005. To address the concerns inherent in tighter financial times, the organization has developed strategies to provide far more detailed financial data to both Institute and Clinical Center customers and developed some new cost-sharing initiatives with the NIH Institutes to address the ongoing financial constraints. These changes and the impact produced by these changes are discussed in detail in this update.

Weaknesses Identified Since 1996

In the eleven years since the initial draft of this document was prepared, several additional potential weaknesses were identified, and addressed, among them:

- Communication practices were inconsistent across the CC and the NIH;
- The Clinical Center did not routinely seek customer input about its services;
- Clinical Center customer service needed improvement;
- The Clinical Center needed to make additional investments to assure workforce diversity.
- The Clinical Center had difficulty reconciling competing Institute demands within a defined budget and had no clear cut mechanisms for making decisions that benefited the entire organization (as opposed to individual customers/stakeholders).
- The Clinical Center and the institutes have variable infrastructures to support their independent investigators and to support the processes of clinical research.
- Outpatient surgery and ambulatory care facilities are in need of redesign.
- The very constrained budgets of 2002 through 2008 required the development of new strategies to gain operational efficiencies.
- After a peak during the budget doubling years (and immediately prior to opening the new CRC), the inpatient census has fallen, leaving the CC with unused capacity.
- Institute protocols increasingly require sophisticated and costly genetic tests that are not available through CC laboratories.
- Despite the opening of the new CRC, several facilities-related issues present significant barriers to progress, among them: the need to address Joint Commission requirements for the atrium of the new CRC, deficiencies in ongoing required preventive maintenance and ongoing repair activities in both the Hatfield and the Magnuson buildings, problems with meeting regulatory requirements for construction and renovation in the hospital, and an inadequate infrastructure (power, air handling and chilled water) in the ACRF and adjacent areas that were constructed in the late 1970s. These problems are compounded by the fact that many of the positions in the Office of Research Facilities (ORF) are currently being studied in the A-76 process for potential outsourcing. As a result they have had many of their staff leave and are unable to replace them until the study is complete.
- Changes in the ethics rules concerning stock holdings, consultation for industry, and other

compensated outside activities have had an adverse impact on recruitment, retention and morale.

Progress in Addressing Weaknesses Identified between 1996 and 2007

- Through an improved and more detailed annual planning process, the Clinical Center has sought to improve communication practices and organization planning across the CC and the NIH;
- The Clinical Center has developed several techniques for seeking customer input and routinely uses these data sources for organizational improvement activities; data from the combined patient and employee surveys are being used to drive redesign of three processes that are important to the Clinical Center's mission and operations;
- The Clinical Center embarked on a major customer service initiative that has produced tangible evidence of improved customer service;
- The Clinical Center has initiated a major initiative to assure workforce diversity;
- The Clinical Center continues to work in concert with advisory groups, such as the Advisory Board for Clinical Research, the Institute Scientific Directors, and the Institute Directors, as well as within its own organization to reconcile competing Institute requests, to address service needs for program expansions and new initiatives, and to maintain stewardship of its resources to be able to meet these expanding needs in a time of modest budget growth;
- The CC Director, working with the Clinical Center's Medical Executive Committee developed two sets of standards: Standards for Clinical Research and Standards for Clinical Care. The Standards for Clinical Research represent the minimum infrastructural standards that all NIH clinical research programs should have in place to assure appropriate investigator support, as well as the safe conduct of clinical research. The Standards for Clinical Care represent the minimal standards for clinical care for patients at the NIH Clinical Center.
- The CC has designed, and is in the process of renovating, our outpatient surgery venue. This project should be completed in 2008.
- To assure efficient operations of our Departments, the CC has developed a process for systematically reviewing the operations of our departments. These operational reviews involve both extramural experts in the field, as well as intramural stakeholders. In addition, to provide ICs with better financial data, we have launched a Data Transformation Initiative that is designed to provide more precise data about the costs associated with CC services. The CC has also implemented a system of 'co-payments' for ICs desiring services to support their individual research programs.
- To address the issue of unused capacity, the CC Director developed a highly successful program for competitive "Bench-to-Bedside" awards to stimulate creative translational work on the NIH campus. This initiative has been expanded to make it available to extramural investigators who wish to partner with intramural scientists in a translational research project. In addition, the Director of the Clinical Center has entered a dialogue with the NIH administration and IC leadership about making more of the Clinical Center's unique clinical research infrastructure available to extramural scientists.
- The Clinical Center is working with the leadership of the NHGRI to develop a strategy to meet investigators need for genetic tests. By writing a series of contracts that will include volume discounts, we hope to be able both to meet these expanding needs as well as save resources.
- The Director of the Clinical Center established a working group, including the Director and Deputy Directors of the CC and ORF, as well as other involved customers and stakeholders in life safety processes in the CC. A new position was established by ORF. This group meets regularly and is systematically addressing the relevant construction, renovation, maintenance, engineering and life-safety issues to maintain compliance with regulatory standards. NIH funded a modification and the CRC atrium to insure patient and staff safety and that modification is now complete.

Opportunities and Threats

As part of its environmental assessment, the Clinical Center has also evaluated opportunities and threats that present themselves as a result of changes in its

external and internal environments. Most of the factors initially identified as driving change remain present in our environment in the year 2007 and beyond. Among the factors initially identified from the external and internal environments that are influencing change in healthcare delivery and clinical research are:

- The dramatic changes in the political climate, including the ongoing wars in Iraq and Afghanistan, the aftermath of the heretofore unthinkable acts of September 11, 2001 and the continued threat of additional acts of terrorism have mandated increased attention to emergency preparedness in our institution, have required diversion of resources to NIH safety and preparedness activities, have resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries, and have fundamentally altered the day-to-day workplace lives for individuals working on the NIH campus.
  - To address the complex issues relating to hospital and community emergency preparedness in the 21st century, the Clinical Center, the Suburban Hospital Healthcare System, and the National Naval Medical Center formed an emergency preparedness partnership – the Bethesda Hospital Emergency Preparedness Partnership (BHEPP). This partnership, composed of three diverse organizations that have strikingly complementary resources, has made it possible for the Clinical Center to plan for possible emergency situations in an unprecedented fashion.
  - The DHHS Secretary contributed a 250-bed contingency station field hospital to be embedded at the CC for partnership surge capacity and the Department of Defense provided $5M in earmarked funding for the Partnership. These resources have been used to procure equipment and supplies, to support drills that are run jointly among the three partners, and to assist with ongoing strategic planning and preparedness assessments. In addition, these funds will be used to test novel technologies in emergency situations. In addition, the partnership conducted a feasibility study of constructing either bridges or tunnels from NIH to the other partners.
- The emergence of new infectious diseases, the resurgence of other infections, and the potential for the use of highly pathogenic infectious agents as weapons of bioterrorism presents substantial threats to the public health and is associated with an urgent need to answer relevant scientific questions that may make it possible to mitigate the damage produced by these infectious diseases.
- The declining U.S. and global economies also have added a degree of instability to the NIH fiscal outlook.
- Societal values are changing and these changes are influencing healthcare and clinical research; society relies increasingly on technology and technological advances (including those in the fields of medicine and biomedical research) to provide what has come to be the expected level of health, function and longevity.
- The population and its health interests and knowledge base are changing rapidly. Patients and clinical research subjects are becoming increasingly sophisticated healthcare consumers; science education in the United States is not keeping pace with the rest of the world and the U.S. population is becoming less "science-literate"; societal demographics are changing; society has become increasingly litigious; and interest in "alternative and complementary" medicine is increasing.
- Cost continues to be a primary consideration in healthcare delivery and clinical research. Clinical research is intrinsically expensive; healthcare inflation is high. The net effect is that containing costs in the Clinical Center environment is difficult.
- Medicine, the practice of medicine and the conduct of clinical research are changing rapidly. Science is becoming increasingly collaborative, and progress in biomedical research produces natural change in the research agenda. All healthcare institutions are being asked to measure performance and to demonstrate performance improvement. Patient safety and human subjects protection have become increasingly important. We are also experiencing a national shortage of anesthesiologists, nurses, pharmacists, phlebotomists and medical and radiological technical staff.

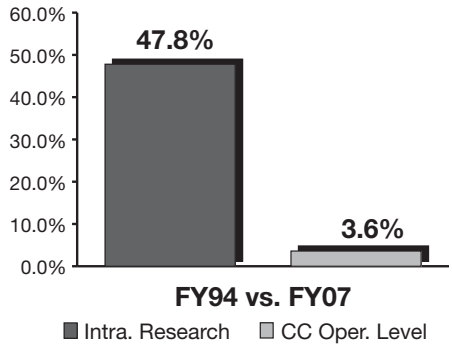
- The pharmacy and biotechnology industries have substantial influence on healthcare costs and processes in American medicine.
  - Rapidly evolving biotechnology and pharmaceutical product development in the past decade have dramatically altered the practice of medicine in the United States. Many of these new drugs and devices represent striking breakthroughs in biomedical research and have had a dramatic impact on American medicine. Often these new drugs and devices are approved for single (and often narrow) indications, but may have the potential for substantially broader use. Because of the risks inherent in the process, industry may have limited interest in providing support for scientific studies for broader-scale use of these products. Conducting such studies, while scientifically important, may be extremely costly, as many of these products have been associated with expensive research and development costs. To recoup these investments these products have been priced accordingly.
  - Because of the pivotal roles played by the pharma and biotechnology technology industries in the evolution of American medicine, the opportunities for collaborative research and development between NIH scientists and scientists in these industries are substantial. NIH needs to develop streamlined mechanisms to facilitate these important interactions.
- Changes in governmental regulatory requirements and governmental oversight are driving change in medical practice and clinical research. The impact of increased regulatory requirements on NIH, on the hospital and its operation, and on the clinical research process cannot be overemphasized. The President reiterated an interest in downsizing and outsourcing and has also issued five major goals for reforming governmental management practices, including goals relating to:
  - Budget and Performance Integration
  - Strategic Management of Human Capital, including Administrative Restructuring and Streamlining
  - Competitive Sourcing (A-76)
  - Improving Financial Performance
  - Expanding Electronic Government.

Each of these goals is discussed in more detail in the text.

- Changes at NIH are also influencing the manner in which the Clinical Center operates.
  - To address the needs of the Clinical Center's failing physical plant, a new Clinical Research Center opened in 2005.
  - The organization and administration of patient care in the new facility has been modified from Institute oriented to program oriented, necessitating a change in culture and a change in the processes used to provide care.
  - The new building has also served as a stimulus for the Institutes to improve and expand their clinical research programs. Several institutes initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. These program modifications require careful assessment by CC administrators and department managers to assure the provision of seamless clinical research support.
  - Toward the end of the 1990s, several Institutes developed new initiatives that involve 'off-site' activities, and have requested CC support for these activities. These programs range from 'outreach' efforts to underserved communities to telemedicine projects. This trend toward developing outreach programs designed to offer clinical research opportunities to underserved populations has continued through 2007. NIAID and NIAMS have organized highly successful HIV and rheumatology clinics in the Cardozo community to reach out to the urban Hispanic population in Washington, D.C. In the last three years, both NCI and NHLBI have established presences in this clinic. The Clinical Center has developed 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.
  - The years 1995-2002 witnessed a doubling of the NIH budget. During the time that the NIH budget increased by 105 percent, the

Clinical Center's budget increased by 37.8 percent. Examining these data using constant (FY 1994) dollars, the IC's intramural budget increased by 48 percent from FY 1994 to 2007, whereas the Clinical Center's budget increased 3.6 percent (see figure, below).

Percent Change in Intramural Research and CC FYs 1994–2007
(In Constant Dollars)



Since 2002, the Clinical Center's budget has remained essentially flat. The fact that certain hospital costs continued to escalate (pharmaceutical products, personnel costs, medical soft goods, etc.), demanded cost-consciousness, cost-effectiveness, efficiency and creativity from Clinical Center managers. In an attempt to maintain a constant, high-quality level of services provided and to attempt to meet the needs of new initiatives, the Clinical Center has shifted some of the costs associated with research services from its budget to those of the institutes. These cost shifts have been unpopular with the ICs and have resulted in a rethinking of the manner in which the Clinical Center is funded (i.e., the so-called "school tax").

- As technology advances, institutes are increasingly requesting more, and more sophisticated (and, therefore, often expensive), clinical research support.

- To address another perceived organizational weakness, the Clinical Center has replaced its medical information system. The new information system affords the organization the opportunity to develop better departmental, financial, and back-end (i.e., Institute) clinical research support than the previous system.

- The NIH Director has identified a clear need for strategic planning for the Nation's overall clinical research enterprise and has embarked on a path designed to lay out a 'road map' for the continued success of clinical research, both in the NIH intramural program, as well as throughout the United States. The importance of the Director's Road Map is that it should define the future path for clinical biomedical research, both in the short and long runs. A crucial aspect of this initiative for the Clinical Center is that the initiative will help define the Clinical Center's future role and its relationship to clinical research programs in the extramural clinical research environment.

- As part of the restructuring for the Road Map, the NIH Director restructured the oversight of central services on the NIH campus. The major new advisory bodies for the Director that have an oversight function for the CC are the Intramural Working Group, and its subgroups, the Facilities Working Group and the Financial Working Group. Both the Institute Directors and the Scientific Directors continue to provide input to the NIH Director about central services, as well. In addition, the NIH Director broadened the scope of the CC's Board of Governors to make this group advisory to the NIH Director about clinical research in general, including clinical research in the CC. The NIH Director renamed this group, "The Advisory Board for Clinical Research." These changes in oversight have resulted in additional scrutiny of the CC and its operations.

- During the past three years, scientists at NIH have been the subject of several ethics investigations. A small number of individuals were found to have been noncompliant with Federal ethics rules. To address these deficiencies and Congressional concerns, NIH developed a new set of guidelines, policies, and review processes. New policies have eliminated employees' ability to consult for remuneration with commercial entities and dictate more stringent rules on financial holdings for senior employees. Employees may still establish official duty collaborations with industry and have been encouraged to do so.

- The gap between salaries NIH is authorized pay and salaries earned by physicians at academic centers has continued to widen, making it difficult to recruit for scarce and/or highly paid specialties and subspecialties. Coupled

with the restrictions on outside activities described above, recruiting and retention have become quite difficult. To counter this trend, NIH has developed new salary limits for Title 42, and is beginning to implement a modified Title 38 appointment mechanism that includes a salary structure that is much more competitive with academic centers.

- NIH is phasing out the extramural General Clinical Research Center awards and program and is replacing this structure with a series of Clinical and Translational Science Awards (CTSAs). Centers receiving these new awards will, of necessity, be much more integrated than in the previous program and, as a result, will offer unprecedented opportunities for the Clinical Center, as well as for intramural investigators, to partner or participate in their activities. The Clinical Center has already begun a series of successful interactions and collaborations with the CTSA network. Examples of successful interactions between the Clinical Center and CTSA sites include:

  – *Clinical Research Subject Survey.* The Clinical Center developed a clinical research subject survey to assess the satisfaction of participants with clinical research projects and processes. This survey is being adapted by investigators at the CTSA at Rockefeller University and will be tested broadly across the CTSA network.

  – *Informatics.* The Clinical Center, in partnership with intramural institute based investigators, created a new informatics tool called ProtoType, a protocol authoring tool that provides a structure for writing protocols and includes IRB recommended language cassettes and important teaching tools. In addition, ProtoType provides ability to rapidly implement centrally new policy or regulatory requirements. ProtoType is designed to be much more than a protocol authoring tool and has the potential to submit protocol information to clinicaltrials.gov, map protocols for resource projections, and send alerts to Principal Investigators for noncompliance of protocol intentions and assisted preparation of Adverse Event Reports. The Clinical Center shared ProtoType with the Rockefeller University investigators early in its development and Rockefeller University investigators provided valuable feedback to its development. The Clinical Center looks forward to sharing this new technology with the CTSA network.

  – *Data Repository.* The NIH intramural program recently launched the second phase of the Clinical Research Information System (CRIS) completed a few years ago. The initiative, called CRIS II, is being led by the Clinical Center in partnership with the NIH intramural programs. The major goal of CRIS II is to build a data repository to coordinate hospital-based information with bench information generated by the institutes. We are planning to construct the new intramural data repository in partnership with the CTSA network.

  – *Clinical Research Nursing.* The Nursing Department in the Clinical Center has partnered with nursing leadership at the Rockefeller University as well as nurses from other CTSA programs to define the specialty of clinical research nursing. A new network of Clinical Research nurses is being established that will unify this new career path in nursing, establish training modules for research nurses and identify requirements to be a clinical research nurse.

  – *Training.* The NIH Clinical Center, together with IC-based investigators, has developed a core curriculum in clinical research with three core courses: an introductory course on the Principles and Practice of Clinical Research, Clinical Pharmacology and Clinical Bioethics (described in more detail below).

  – *Bench-to-bedside awards.* The Clinical Center has sponsored intramural bench to bedside awards for the past nine years designed to promote interaction between basic and clinical scientists. This highly successful program has sponsored 119 awards at $100K/year for two years at a total investment of over $20M. For the past two years the awards have included partnerships between intramural and extramural investigators where intramural scientists invite extramural partners, including partnerships with intramural and CTSA scientists. The future plan is to expand these awards and allow extramural investigators to identify intramural partners.

- Partially due to the limited funding for all of NIH, the census of the Clinical Center has dropped over the past few years. The Clinical Center Director, working with IC and NIH leadership has developed innovative strategies for forming partnerships with extramural investigators. For example, the highly successful intramural program for novel 'bench-to-bedside' awards has been expanded to include extramural investigators who are interested in partnering with intramural scientists in the conduct of a project. Although additional strategies may require legislation for implementation, the Clinical Center continues to pursue these in order to maximize the use of its unique resources.

Thus, over the past eleven years, several factors, taken together, have resulted in a substantial change in the culture of the NIH intramural community. These factors and the resulting change in the internal environment are enumerated in this document.

This report assesses these opportunities and threats in detail in the context of the identified strengths and weaknesses inherent in the Clinical Center.

Introduction

The Clinical Center finds itself poised for more change in an increasingly complex healthcare environment. A clear understanding of this complicated environment, including a detailed assessment of the organization's strengths, weaknesses, opportunities, and factors from the internal and external environments that pose a threat to the organization is essential for the Clinical Center to succeed in the next decade and beyond. To be successful, the Clinical Center must be able to identify its internal strengths and capabilities and be able to position itself to meet the challenges posed by the dramatic changes in healthcare and in the healthcare industry in the United States.

The process of self-assessment and improvement is a continuous cycle. In 1995, the Clinical Center was provided with a unique opportunity to conduct a thorough environmental assessment as a result of a mandate from the DHHS Secretary. This review ultimately provided the Clinical Center with an opportunity to review the best practices of 30 facilities throughout the country, with an eye toward adopting as many of these best practices as were relevant to the Clinical Center's environment[1]. In the eleven years that have intervened since this document was initially drafted, the Clinical Center has sought additional input from: 1) its major customers, the NIH Institutes (through our governance structure, through annual planning meetings with each of the institutes, as well as through ongoing dialogue with the Clinical, Scientific and Institute Directors); 2) a second set of major customers – our clinical research subjects – through ongoing patient perception surveys as well as through regular meetings with the Clinical Center Director's Patient Advisory Group; 3) the extramural academic community (through ongoing reviews by the Clinical Center Board of Scientific Counselors and through the Operational reviews of the CC Departments); and through separate meetings convened with outside experts to chart the future courses of the Clinical Center's Bioethics Program, Imaging Sciences Program, Laboratory Medicine Department, and the Pain and Palliative Care Service; 4) Industry, insurers, and managed care representatives (in meetings designed to address patient recruitment and third party payment issues); 5) Healthcare executives and experienced healthcare administrators (through meetings of the Clinical Center's Board of Governors); and 6) Intramural and extramural experts in hospital operations, in the conduct of operational reviews of Clinical Center departments. The advice and counsel of these intramural and extramural advisors provide the backbone for the Clinical Center's 2007 environmental assessment. The previous edition of this document was written in 2004. In the intervening years, a number of factors in both the internal and external environments have changed substantially, prompting this revision.

The Clinical Center's environmental assessment is divided into three segments: 1) Clinical Center strengths; 2) organizational weaknesses; and 3) external trends and factors influencing change: a) in healthcare, b) in clinical research in general, and c) in clinical research at the Clinical Center, including an emphasis on opportunities that present themselves to the Clinical Center in the context of these other findings.

Clinical Center Strengths

The Clinical Center serves as focal point for clinical research in, and is an integral component of, the NIH biomedical research community. As a national resource, the Clinical Center provides the patient care, services and environment needed to initiate and support the highest quality conduct of, and training in, clinical research. The Clinical Center provides a unique venue and opportunity in which to conduct studies that bridge the gap between basic science and clinical application at the patient's bedside. In 1994, a panel of extramural advisors convened at the request of the Director of NIH to assess the status of the intramural research program noted that the Clinical Center has been, ". . . a unique and invaluable resource for the direct clinical application of new knowledge derived from basic research". In the conclusion of their report, these external advisors noted,

"Upon analysis of the programs of the Clinical Center facility, the External Advisory Committee is strongly of the opinion that the Clinical Center is essential to the intramural research program. The committee recognizes that a crucial asset of the Clinical Center complex is the flexibility it offers to respond to new opportunities and needs by rapid redirection of resources, such as with research on human immunodeficiency virus, breast cancer, and prostate cancer. Because the Clinical Center is not obligated to provide all types of clinical services, it can more readily redirect resources to new, innovative areas of research. In addition, the existence of a high caliber staff, on-site, with expertise in clinical research, allows for the rapid implementation of new initiatives.[2]

The Committee also recognizes that the Clinical Center, with its appropriate facilities and support staff, allows scientists to conduct long-term clinical studies of individual patients and large families that would be difficult, if not impossible, to do in the extramural community because of the lack of sufficient and long-term funding. It also provides an excellent setting for the training of clinical investigators."[3]

In the late 1990s, the NIH leadership invested heavily in the revitalization of the Clinical Center.[4] This revitalization has helped position the Clinical Center to meet the expanding clinical research agendas of the institutes for the foreseeable future.

The opening of the new Clinical Research Center in 2005 provides and even more effective bridge to the future of clinical research. In the 50 years since the Clinical Center opened its doors to the public, the Clinical Center and its staff have contributed significantly to biomedical science and translational research—moving discoveries in the basic sciences into clinical medicine. In the process of providing the infrastructure and research support for Institute/Center (IC) scientists during this period, the Clinical Center and its staff have developed many unique organizational strengths. Among them are the following:

- **The Clinical Center is the clinical research hospital supporting the intramural program of the National Institutes of Health.**

The National Institutes of Health is among the most respected scientific organizations in the world. The NIH intramural program has received consistent intellectual and scientific support from the academic scientific community as well as steady economic support from the government of the United States. As the clinical research arm of the intramural component of the NIH, the Clinical Center is not subject to the extremes of funding crises prevalent in the extramural community. For this reason, some types of studies (particularly those relating to natural history and disease pathogenesis, as well as studies of orphan diseases) can be conducted almost nowhere else but, and nowhere as well as, at the Clinical Center. At a time in which funding for the NIH is increasing at a substantially lower rate then during the past seven years, the Clinical Center must exhibit careful stewardship of its resources.

- **The Clinical Center has a critical mass of world-class scientists and clinical investigators working closely together.**

Perhaps no other center in the world has the collaborative mix of basic scientists and clinical researchers found in the NIH intramural program. This blend of basic and clinical science has provided a critical mass of scientific ferment that has produced striking accomplishments in clinical research over the first 50 years of the Clinical Center's existence. The fact that the basic and clinical scientists work in close proximity produces a cross-fertilization of ideas that is unique in the academic medical community. The quality of the basic and clinical scientists cannot be overemphasized; many of the NIH intramural investigators are recognized as international authorities in their fields.

- **The support staff and research infrastructure in the Clinical Center is uniquely tailored to support excellence in clinical research.**

Unlike most academic medical centers, Clinical Center support staff and service personnel have been recruited to support a clinical research, rather than a purely patient care, mission. The service and support staff at the Clinical Center provide unrivaled support for clinical research. Many of the services provided by Clinical Center Departments would likely not be found in most academic institutions and have been developed entirely to support the clinical research enterprise. The Clinical Center staff also provide state-of-the-art clinical diagnostic support services. Support staff and service personnel often function as collaborators in research studies and have made numerous substantive scientific contributions. At all levels of the organization, alignment with the research mission is a highly visible goal.

- **The Clinical Center focuses on a specialized research portfolio.**

As noted above, unlike most academic medical centers, studies conducted at the Clinical Center much more frequently evaluate the natural history or pathogenesis of disease states. Clinical trials at the Clinical Center are primarily Phase I and Phase II trials, as compared with most extramural centers, which focus primarily on Phase III and Phase IV studies. The Clinical Center offers a superb venue in which to conduct translational or 'proof of concept'/'proof of principle' studies. Additionally, scientists working at the Clinical Center have assembled cohorts of patients who have rare or orphan diseases. For patients who have certain of these orphan diseases, the Clinical Center may be the only place where meaningful clinical research studies of their diseases are carried out. The study of rare and orphan diseases has resulted in innumerable contributions to the understanding of basic human physiology, pathology, psychology, genetics and immunology.

- **The Clinical Center provides quality patient care to its clinical research subjects.**

The Clinical Center's staff is committed to the clinical research mission. To provide optimal support for clinical science, the Clinical Center's highly skilled service and support staff have consistently provided excellent care to the subjects of clinical research protocols. The subjects of clinical research studies have a different relationship to the Clinical Center than the relationship patients have with academic medical centers to which they are admitted. The subjects of these studies are partners in the research carried out at the Clinical Center. For this reason, the importance of providing excellence in patient care cannot be overemphasized. The highest quality patient care remains a major objective for Clinical Center staff, an objective that has been reached consistently during its first five decades of existence, and a goal toward which Clinical Center administration and staff continuously strive. Over the past ten years, the Clinical Center has made a substantial investment to find out how our patients view the services provided by Clinical Center staff as well as how they view our clinical research processes. Excellence in patientcare and clinical research support are ever-moving targets.

- **The culture of the Clinical Center is science-driven.**

The principles of performance improvement are based on the principles of epidemiology. The culture and mission of the Clinical Center are grounded entirely in science. Clinical Center scientists and managers are familiar with the epidemiologic orientation of performance improvement. Scientists and staff are accustomed to using epidemiologic principles to analyze data and to make decisions. For this reason, Clinical Center staff are well positioned to collect and analyze managerial data and to integrate the results of data analysis into decisions affecting the manner in which the work of the organization is conducted. The entire organization has been

trained in the epidemiologic principles of performance improvement and both managers and line employees use these principles. The science-based culture of the Clinical Center positions the Clinical Center extremely well to use these principles scientifically to: 1) collect data for performance measurement; 2) analyze the data to address identified problems; 3) propose interventions based on solid, scientifically obtained data; and 4) assess the usefulness of these interventions.

In the intervening eleven years since the initial draft of this document was published, many of the Institutes have initiated major external reviews of their intramural clinical programs. A major report has recently been issued by the National Academy of Sciences' Institute of Medicine addressing issues relating to the overall governance of NIH and underscoring the importance of clinical research in the biomedical research enterprise.[5] In 2003, the Director of NIH convened an advisory panel, the Blue Ribbon Panel on Intramural Clinical Research, to address issues of substance for the Intramural research program. In addition, the NIH Director has embarked on a journey designed to lay out a 'road map' for the continued success of clinical research in the United States. The importance of the Director's Road Map is that it should help define the future path for clinical biomedical research in our country, both in the short and long term.[6] These and other initiatives suggest that, across the campus, interest in quality clinical research is continuing to increase. In addition, the opening of the new Clinical Research Center, the procurement and implementation of the new Clinical Research Information System, the increased emphasis on cross-disciplinary molecular projects, the partnerships with extramural scientists in the expanded bench-to-bedside program, and the changing intramural environment have spawned a new level of collaboration and customer orientation among Clinical Center leadership.

- **The unique clinical research mission of the Clinical Center allows it organizational and scientific flexibility that most institutions do not have.**

Because the primary mission of the Clinical Center is clinical research, the institution does not make commitments, either to its research subjects or to the community, to provide comprehensive health-care services. Since the Clinical Center does not have to commit resources and personnel to an Emergency Room or to general acute care, it can focus its efforts on specific areas of clinical science. For this reason the IC-driven science conducted in the Clinical Center can respond quickly, both to emerging problems for which an immediate change in the national research agenda is needed, as well as to scientific opportunities when they arise. For example, the Clinical Center responded quickly to study: 1) AIDS and HIV infection when the disease first surfaced in society; 2) multiply-drug-resistant tuberculosis when this problem first became apparent; 3) the chemotherapy of ovarian cancer when Taxol became available; 4) an innovative solid organ transplantation program; 5) protocols to study the pathogenesis and therapy of the Severe Acute Respiratory Syndrome (SARS); 6) protocols to study patients with pandemic influenza; and 7) protocols designed to study the perplexing problem of obesity in the United States.

- **The Clinical Center provides access to expensive state-of-the-art technologies that are not readily available in many other centers.**

Since the Clinical Center and the NIH intramural programs are charged with advancing the frontiers of science, the Clinical Center often either develops, or is among the first to acquire, new technologies that facilitate the conduct of clinical research. Scientists working in the NIH Intramural program have access to a new state-of-the-art clinical information system, numerous molecular diagnostic techniques, Positron Emission Tomography (PET) scanners, three cyclotrons, several magnetic resonance imaging machines (including 3, 4, and 7 Tesla experimental machines), unique cell-processing facilities, creative functional outcomes measures in our Rehabilitation Medicine Department, and a variety of other cutting-edge technologies. In addition, scientists working for, and at, the Clinical Center have the opportunity to forge cooperative research and development agreements (CRADAs) with industry scientists who have developed cutting-edge technologies. In fact, the Clinical Center often provides a near-ideal venue in which to test such technologies.

Clinical Center Weaknesses

As a result of both evaluations by external advisors as well as self-assessment, the Clinical Center initially identified several issues that might be considered programmatic or systemic weaknesses.

- **Existing Clinical Center governance mechanisms are complex.**

Historically, governance of the Clinical Center was unclear, with multiple committees providing oversight. The old structure lacked clarity in how decisions were made. The net effect of the indistinct lines of authority is that the Clinical Center lacked the means to manage its business efficiently.

NIH has continued to wrestle with the development of clear, effective governance for the Clinical Center. In 1996, the Clinical Center appointed and convened a new Board of Governors. The Board of Governors developed and approved a streamlined organizational reporting system for the Clinical Center. As a result of the introduction of this new governance system, Institute stakeholders felt somewhat disenfranchised and appealed to the Director of NIH. The Director, NIH appointed an advisory board, initially called the Clinical Center Advisory Council, that permitted the major stakeholders to address Clinical Center issues that are important to the Institutes and to provide advice and counsel to the Director of the Clinical Center. In FY 2000, the Acting Director of NIH reconstituted this council as the Clinical Center Research Steering Committee (CCRSC). In 2003, the National Academy of Sciences' Institute of Medicine issued a report calling for reorganization of some aspects of the NIH intramural program. The report also underscored the importance of maintaining a robust clinical research infrastructure in the United States. In 2003, the NIH Director convened another advisory panel, the Blue Ribbon Panel on Intramural Clinical Research. This panel is charged with assessing the state of the intramural research program and will also evaluate governance structures for the Clinical Center. In response to these recommendations, the NIH Director made additional modifications of the oversight structure for the CC. The NIH Director subsequently broadened the scope of the Clinical Center Advisory Committee and reconstituted it as the Advisory Board for Clinical Research. This committee continues to provide a venue in which the Institutes can contribute to the governance of the Clinical Center, particularly with respect to issues relating to the science agenda. As noted above, as part of the NIH Director's restructuring related to his Road Map initiative, new oversight committees – the Intramural Working Group, the Facilities Working Group, and the Financial Working Group – were convened within the past three years.

Over the past eleven years, the Clinical Center Director has sought advice from other important stakeholders, including Clinical Center clinical research subjects and clinical research principal investigators. The Clinical Center Director maintains a Patient Advisory Group that has provided and continues to provide advice to the Director from the unique perspective of clinical research subject-participants. Thus, because of the multiplicity and complexity of its myriad stakeholders, the governance structure for the Clinical Center remains complex.

- **Historically, the Clinical Center was subject to bureaucratic inflexibility in personnel, procurement, and fiscal management; acquisition in 2001 of new Title 42 personnel authorities and other delegations of authority have provided some relief.**

As a center in the National Institutes of Health, the Clinical Center reports to the agency, to the Public Health Service, and to the Department of Health and Human Services. Its activities are subject to agency rules, regulations and policies; PHS rules, regulations and policies; DHHS rules, regulations and policies; rules, regulations and policies of the Office of Management and Budget, the Office of

Personnel Management, and the General Services Administration; and all other applicable Federal rules, regulations and policies, as well as applicable Federal statutes. As a result of this extensive bureaucracy, "The Clinical Center faces a series of very serious barriers to managerial efficiency in areas such as personnel, purchasing, and contracting…[7] …The Clinical Center needs a great deal of flexibility to operate productively."[8] The Report of the DHHS Secretary's external review committee in 1996 noted that, "whereas the government's personnel system is structured to provide fair, consistent rules for employees and managers, it undermines the Clinical Center's efficient operation."[9] With respect to fiscal issues, the report states, "As is the case with all government operations, the Clinical Center must spend its entire budget within the fiscal year; no carryover is allowed[9]. . . The Clinical Center should have a means of retaining reserves from year to year."[10] The report also notes that the NIH's existing budget process for the Clinical Center "...makes future Clinical Center funding far more unstable than funding of NIH as a whole."[11] These points were valid in 1996 and remain so in 2007.

Since the initial draft of this document was written, the Clinical Center has worked with the Director, NIH and the Directors of the Institutes to try to streamline the Clinical Center's funding stream. The prior funding mechanism rewarded "non-use" of the Clinical Center. A new funding mechanism has been designed, patterned after the concept of a "school tax." Because Institute charges are not linked to use in this new funding model, it has stimulated use of the Clinical Center and will provide far more stable funding than the old funding mechanism. This new mechanism was put in place in the FY 2000 budget cycle. Appropriations language was written for the FY 1997 budget cycle to allow the Clinical Center to carry over some funds; this language has again been approved for the present fiscal year. These carryover funds provide an important source of revenue support for new clinical research initiatives of the Institutes. The Clinical Center has also attempted to address the issue of inadequate cost accounting. Initially, the Clinical Center hired a consultant to provide advice about the establishment of an activity-based costing system. The recommendations of the consultant were adopted and the Clinical Center has implemented this system. Through its more precise detailing of costs and activities, this activity-based costing system has proved to be of substantial utility to the Clinical Center's administration, as well as to its major customers and stakeholders. In response to the Institutes' requests for more precision, the Clinical Center has again turned to consultants, this time from Price-Waterhouse Coopers, who have conducted an in-depth analysis of our current state and have made recommendations concerning the implementation of financial systems and a data transformation initiative that will yield more precision with respect to the costs associated with goods and services provided to patients participating in clinical research protocols in the Clinical Center.

Performance measurement continues as a major organizational focus. During the past ten years the Clinical Center has collected and continued to refine organization-wide activity data that are used by the Director to assess overall performance. In addition, Clinical Center departments collect data relevant to the performance of their individual departmental operations. The goal of measuring performance is to track departmental and organizational progress toward our strategic goals. Thus, an important aspect of the performance measurement system is making certain that the outcomes and processes being measured are relevant to our key initiatives and strategic goals and that the measurement of these structures, processes and outcomes allow the Clinical Center to track progress toward these organizational goals. The performance measurement initiative is relevant to both the operations of the Clinical Center as well as to clinical care provided in our facility.

In the years since the initial draft of this document was written, NIH has also received several delegations of authority from the Secretary, Department of Health and Human Services (e.g., Title 42 f personnel authority; Title 42 g personnel authority, and Title 38 personnel authority modifications). Use of these delegations has helped to address some of the problems relating to inflexibility in personnel and procurement systems.

Eight years ago the Clinical Center's Office of Human Resources Management developed (and had approved by the DHHS Secretary) a program to be able to use a new personnel authority, Title 42, to appoint clinical research support staff. This project – that uses personnel procedures substantially different from traditional governmental personnel systems – has met with measurable success and demonstrates an increase in efficiency of responsiveness and decreased vacancy rates in relevant departments.

In the past three years, the Clinical Center has developed a 'managing performance' initiative. The goal of this initiative is to encourage Department Heads and Supervisors to get the most from their employees, to make certain that Clinical Center employees work to their potentials and to make certain that our Departments have the right people on the job. The Clinical Center hired an attorney who has extensive governmental personnel experience to oversee the project and to provide support to the Department Heads. This initiative has had a significant salutary impact on the overall quality of the Clinical Center's workforce, has provided us with the opportunity to retrain some staff for positions for which they are more qualified, as well as the opportunity to separate staff who are not productive and consistently under-perform. During a time of severe financial constraint this initiative has provided the organization with flexibility far beyond what has traditionally been available.

- **Many intramural and extramural scientists believe that clinical research is not valued as highly as is basic science.**

Clinical researchers nationwide have long held the perception that NIH relatively undervalued their work. In 1979, James Wyngaarden, then the Director of NIH, referred to the clinical researcher as an "endangered species". In response to the concerns of both intramural and extramural scientists concerning the standing of clinical research, the then Director of NIH convened a panel of experts charged with reviewing the status of clinical research in the United States and making recommendations to the NIH Director on how he might ensure effective continuance of clinical research in the United States. Dr. David Nathan, president of the Dana Farber Cancer Institute, chaired the committee.

The leadership of the Clinical Center took the panel's recommendations seriously and developed substantive responses to many of them. The Clinical Center's Director has developed an introductory course on the principles and practice of clinical research that has trained more than 2,900 students and has also edited and published a textbook (now in its second edition) that accompanies the course. A Clinical Research Training Program for medical students, including mentoring by some of NIH's most accomplished clinical researchers has been successfully implemented. A collaborative Masters' Degree program (now with several graduates) in clinical research has been developed with Duke University. A required course on clinical research for all principal investigators has been established and is now available on the World Wide Web. A clinical pharmacology course has been developed and implemented (complete with an accompanying textbook) and a Bioethics Course has been developed and implemented. Intramural programs have reviewed and revitalized their clinical research programs. Both NIH and the Clinical Center have engaged in dialogues with the insurance and managed care industry. In late 2001, the NIH Intramural Program invited the Association for the Accreditation of Human Research Protection Programs (AAHRPP) to visit the campus to pilot its new accreditation program process. The NIH Intramural Program is now gearing up to apply for accreditation of its clinical research program through AAHRPP.

- **Because the Clinical Center's physical plant urgently needed renewal, the U.S. Congress provided funding for the construction of a new facility, the Mark O. Hatfield Clinical Research Center.**

A 1995/1996 external review noted that, "The Clinical Center's 48-year-old physical plant is increasingly inadequate for the conduct of clinical research; it requires replacement."[12] A Congressionally mandated external review of the NIH intramural program conducted by an advisory committee to the NIH Director's Advisory Committee also concluded, "In recent years, it has become clear that the infrastructure of the Clinical Center is deteriorating [13] ...The External Advisory Committee agrees with the need for renewal of the Clinical Center."[14]

For these reasons, NIH, the Department of Health and Human Services, and the Congress approved the concept of building a new Clinical Research Center, an architect was selected, a private developer hired, and construction completed in 2004. Patients were moved into the new hospital in April of 2005. To increase customer input in the governance of the new hospital, teams of "Partners" (i.e., institute staff and Clinical Center staff who share space and resources in the new building) were convened. The transition from the Magnuson building into the new CRC occurred seamlessly.

- **Clinical researchers identified a need for restructuring the processes involved in outpatient surgery and outpatient care.**

In 2002, surgeons from several ICs identified a need for updating and streamlining outpatient/ambulatory surgery processes in the Clinical Center.

In a survey of employees conducted in 2002, Clinical Center staff also identified ambulatory surgical care as an area in need of process improvement. In 2003, a white paper on the state of surgery written by the members of the Surgical Advisory Committee in the CC identified the same problem with outpatient/ambulatory procedures. In 2004, the Clinical Center embarked on a major process redesign initiative (discussed below). One of the three major processes selected for redesign was outpatient/ambulatory surgery. The process redesign team has already presented options for streamlining and improving the ambulatory surgery to the Clinical Center Director. This project, which will require substantial renovation of areas immediately proximate to the operating suite, is scheduled for FY 2008.

- **Although the Clinical Center lacked a strategic plan in 1995; it now has a vibrant plan that is updated annually.**

Although a strategic plan was drafted in 1990, this plan was never implemented. The plan was never used for conjoint planning with the ICs, nor was it used to facilitate decision-making. An external review conducted in 1994 stated, "The Clinical Center lacks a strategic plan describing how it will respond to long-range Institute needs, extramural pressures to reduce costs, and competition to alternatives to intramural research. Without such a plan, decisions that have long-lasting consequences or require long lead-times, will be untimely, if they are made at all."[13]

After obtaining input from major internal (e.g., Clinical Center Department Heads) and external (e.g., IC Directors, IC Scientific and Clinical Directors) customers, the Clinical Center developed a strategic plan. The plan was presented to, and approved by, the Clinical Center Board of Governors. The strategic and operating plan is used to provide information and context for the Advisory Board for Clinical Research as well as for the Clinical Center's myriad other customers and stakeholders. This strategic plan has been in place and functioning well as a template for progress over the past eleven years. The strategic plan is revised annually to make certain it accurately reflects our direction and is responsive to the needs of our customers and stakeholders. The Clinical Center views its strategic plan as a dynamic document – projects are continuously being evaluated, revised and improved.

In addition, the Clinical Center drafted its first annual operating plan in 1999 for FY 2000; this process was refined annually, beginning in FY 2000. An FY 2008 plan is being created as this document is being constructed. These documents delineate organizational priorities for the upcoming fiscal year, provide alignment of the short-term organizational priorities with long-term goals, provide a structure to help in decision-making during the fiscal year, and provide a new framework for managerial accountability.

- **Clinical Center Information Systems do not adequately support managerial and financial data.**

The Clinical Center has long been a world leader in the field of "computerizing clinical data;"[15] however, the Clinical Center's information systems fall short in providing managerial and financial data required by IC and Clinical Center managers. One set of external consultants concluded in 1995 that "...the data provided are retrospective and difficult to use in operational decisions... The architecture of the computer system is outmoded and cannot effectively integrate data between and among departments."[16]

In the past eleven years, several projects have been initiated to improve the quality and availability of financial and resource utilization information for better management of Clinical Center operations. In 2003, the Clinical Center recruited its second Chief Financial Officer who now provides overall direction for financial and resource utilization, setting the standards and defining the requirements.

In 2005 the Clinical Center launched a new Clinical Research Information System. Considering the complexity of replacing an information system that was pathbreaking when it was initially implemented in the 1970s, the activation of the new system proceeded extremely smoothly. In 2006, a new Chief Information Officer was appointed and the Clinical Center is currently recruiting a new Chief for a new laboratory, the Laboratory of Informatics Development who will oversee the design and implementation of CRIS II – a project that will include a large data repository for IC and CC scientists. In addition, as noted above, the CC Budget office implemented and refined an activity-based costing system that provided markedly improved resource utilization data to IC customers. In addition, the Chief Financial officer and her team, with the assistance of contractors from

Price-Waterhouse Coopers have undertaken a major data transformation initiative that is evaluating other approaches to providing even more granular data to our customers and stakeholders. These projects provide the infrastructure for further progress in financial accountability and responsiveness to our customers' and stakeholders' needs for more accurate financial and planning information.

- **Clinical Center successes are not adequately communicated to the public, to referring physicians, and to the insurance and managed care industries.**

In 1996, the DHHS Secretary's Options Team report concluded that, "The outstanding work of the Clinical Center is not being communicated to those outside NIH in an effective manner. The public, insurers, and referring physicians must be informed about the ways that the Clinical Center promotes the highest standards for conducting research and training researchers."[15]

To address problems previously identified by focus groups and by external consultants, the Clinical Center has developed a marketing strategy, which includes letting a substantial contract to develop a public relations/marketing initiative and the creation of the Office of Patient Recruitment and Public Liaison, which in 2007 merged with Communications to form the new Office of Communications, Patient Recruitment and Public Liaison. The Clinical Center Board of Governors endorsed the patient recruitment project as part of the long-range goals included in the strategic plan. The three major communications goals of this new Office are:

- To increase the visibility of the Clinical Center as a national center for clinical research
- To increase recognition of the Clinical Center as a national center for the training of clinical investigators;
- To educate the public about clinical research.

- **Through 2007, patient recruitment efforts still are not optimal.**

For a variety of reasons, through 2007, patient accrual remained problematic. Despite significant efforts by the researchers to recruit patients, some excellent and, in some instances, important studies languished for lack of patients.

As noted above, the Office of Patient Recruitment and Public Liaison has, as its primary mission, the support of patient recruitment and referral efforts. The primary goal of the service is to increase the enrollment, including women and minorities, to clinical research studies in the Clinical Center. The development of a more uniform, trans-Institute patient travel reimbursement policy may provide additional recruitment incentive.

As a result of the events of 9/11/2001, DHHS mandated that the NIH campus be maintained under an increased level of security, mandating that the campus be completely encircled by a fence with security personnel supervising entry onto the campus at each gated entrance. The screening process is detailed, involving visual inspection of vehicles and personal searches of individuals coming onto campus. Patients and visitors have found these increased security measures to be intrusive and oppressive and have complained often about the inconvenience, delay, and intrusiveness of the security screening. Many staff believe that implementing these DHHS-mandated procedures has had an adverse impact of patient recruitment. In an attempt to address patient and visitor concerns, the Clinical Center's Director advocated for, and was ultimately successful in obtaining, a dedicated gate entrances for patients and their families. This gate, which is manned by security personnel, as well as staff from the Clinical Center's Hospitality Service, has streamlined the process for campus entry for patients and their visitors. Some programs (e.g., the NIAID Vaccine Research Center normal volunteer program) believe that even this new streamlined process is a barrier to recruiting normal volunteers. For certain programs (e.g., the NIMH Autism program, the NIAID Vaccine Research Center, and the National Institute on Alcohol Abuse and Alcoholism, off-campus screening sites are being considered. The Clinical Center is supporting these programs through staff consultation about: facilities preparation and management, centralized scheduling, information technology, medical records, specimen handling and processing.

- **Although not offering "full services" was perceived as an organizational strength because it permits organizational efficiency and flexibility, not offering complete, integrated medical and surgical services is viewed as an institutional weakness by some customers.**

The fact that the Clinical Center does not provide full services is perceived by some Clinical Center and IC staff as a disadvantage for several reasons. For some physician research trainees, the fact that the Clinical Center does not offer "full-services" limits the desirability of the Clinical Center as a training site. In addition, some institutes perceive that this 'less-than-full-service' status limits their research opportunities. For example, not having an emergency room makes studies of myocardial infarction and/or brain attack difficult, if not impossible. Not offering these services necessitates developing procedures to acquire some types of support from local academic or community physicians. Response times for outside consultants are occasionally less than optimal. Additionally, their investment in, and commitment to, the Clinical Center patient population is almost invariably less than that of the NIH investigators. Because the Clinical Center does not see a full spectrum of illness, maintaining clinical competencies and training staff is difficult and often requires relationships with extramural institutions. To address these issues, the ICs and the Clinical Center have forged alliances with extramural institutions. Some examples of these alliances include:

- Partnerships with Johns Hopkins University and the National Rehabilitation Hospital that will facilitate clinical training for fellows and junior staff and will afford senior staff the opportunity to maintain clinical skills;
- A partnership with Johns Hopkins and Suburban Hospital that will facilitate the conduct of studies of acute medical problems (e.g., brain attack, myocardial ischemia) that heretofore have been impossible at the Clinical Center, primarily because of the absence of an Emergency Room; this program opened officially in May 1999;
- A partnership with Duke University to facilitate advanced training in clinical research, including the opportunity to receive an advanced degree in Clinical Research;
- A variety of partnerships with local institutions (e.g., Washington Hospital Center, Johns Hopkins, Georgetown, and others) to provide Clinical Center staff with opportunities to maintain clinical competencies.

These extramural affiliations should strengthen training opportunities. Currently, the overwhelming majority of consulting services are provided by IC staff; traditionally, these consulting services have been managed by ICs maintaining clinical research interests in those fields. No formal system of accountability or responsibility exists for the consultation services. For this reason, not all ICs have emphasized the importance of responsiveness in clinical consultation, nor do their clinical services put forth the effort to maintain their clinical expertise. In mid-1997, the Medical Executive Committee formed a subcommittee to address the perceived problems with consultative services. The first steps in addressing the issue were: 1) to obtain Institute agreement about the "ownership," or responsibility for, the various consultative services present in the Clinical Center; and 2) to develop a system, based in the Clinical Center's Medical Information System, to collect information from both consultants and those requesting consultations about the timeliness, appropriateness and the quality of consultations provided by consultative services. The overall goal of the Medical Executive Committee's subcommittee is to increase the quality of care provided to clinical research subjects at the Clinical Center.

The Clinical Center has also made a substantial commitment to increase the quality and availability of clinical research training over the past four years, as described above. The CC established its Office of Clinical Research Training and Medical Education in May 2003. This office is responsible for the development, administration and evaluation of clinical research training and medical education initiatives that contribute to the professional growth and development of NIH clinician-scientists and other health care professionals. In the fall of 2007, the office expanded to include a number of trans-NIH educational initiatives that were moved from the NIH Office of Intramural Training and Education. The current inventory of courses and programs includes:

- "Introduction to the Principles and Practice of Clinical Research" – was established in 1995, provides formal training on how to conduct clinical research effectively. To date, 6,330 students have registered for the course, and 2,349 certificates have been awarded. From 1997-2007, the course was teleconferenced to 22 domestic and five international locations. A second edition of the course textbook was published in April 2007 by Academic Press/Elsevier.

– "Principles of Clinical Pharmacology" course – is designed to meet the needs of researchers who have an interest in the clinical pharmacologic aspects of contemporary drug development and utilization. The course was established in 1998. Since then, 3,912 students have enrolled. A second edition of the course textbook was published in September 2006 by Academic Press/Elsevier.

– "Ethical and Regulatory Aspects of Clinical Research" – this course is taught annually by the Clinical Center's Bioethics Department. It was implemented in 1999 and offers formal education and training in the ethical conduct of clinical research. To date, 2,865 students have enrolled. The accompanying textbook, *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, was published by Johns Hopkins University Press.

– The NIH-Duke Training Program in Clinical Research was introduced - 1998 and provides an opportunity for NIH physicians and dentists to receive a Master of Health Sciences in Clinical Research from Duke University School of Medicine. This program, offered via videoconferencing, provides formal courses in research design, research management and statistical analysis. For 2007-2008, six students enrolled into the program. To date, 132 students representing a cross-section of NIH Institutes and Cente-rs have been admitted and 54 have received degrees.

– The Clinical Research Curriculum Certificate program was established in 2004 and is intended for physicians, dentists, and allied health care professionals fully engaged in or intending to become engaged in clinical or translational investigation (see *http://intranet.cc.nih.gov/clinicalresearchtraining/curriculumcert.shtml*). Individuals who complete the mandatory components of the program are awarded a certificate by the NIH Clinical Center. As of September 4, 2007, 50 certificates have been issued.

– The Clinical Research Training Program (CRTP) is a public-private partnership supported jointly by the NIH and a grant to the Foundation for NIH from Pfizer Inc. The CRTP was established in 1997 to train medical and dental students in clinical or translational research after completion of their clinical rotations. Students are assigned a tutor, in their field of interest, who guides them in choosing a mentor for their research project. In fiscal year 2004, NIH Roadmap funds were earmarked to support an expansion of the program allowing for a doubling from 15 to 30 students per year.

In an effort to improve the clinical services provided to clinical research subjects, the Clinical Center has launched several new clinical initiatives in the past decade, including the establishment of a multidisciplinary Pain and Palliative Care team, a General Internal Medicine Service (that has now grown to include two physicians and two Nurse Practitioners), as well as a General Pediatrics Service (that includes two physicians and a nurse practitioner) to provide general pediatrics consultative support.

The Clinical Center has not routinely sought customer input about its services.

As a service organization, customer input is crucial to the smooth functioning of the hospital. In 1997, the CC sought and received a generic clearance from the Office of Management and Budget to be allowed to conduct surveys of its customers and other partners. We have recently submitted our fourth request for a generic clearance to conduct such surveys. The CC initially partnered with the Harvard-based Picker Institute for its initial patient survey. Results from the survey identified areas that needed attention in the organization, but also established new quality benchmarks for the Picker group in terms of overall perceptions of quality. Picker was sold to the National Research Corporation (NRC) in 2001; however, the Picker 'perception' surveys have become the centerpiece of the NRC portfolio, so the Clinical Center has been able to maintain continuity in its customer perception program. In 2002, we conducted simultaneous employee and patient surveys centered on the Picker dimensions of care. The survey demonstrated improvement in the area of customer service following the customer service training initiative and also identified some areas ripe for improvement, including coordination of care, the ambulatory surgery program and process and the informed consent process. The results from these conjoint surveys have been used to identify areas needing organizational improvement.

One minor example of the outcomes of these surveys is the development of a patient smoking area for patients coming to the CC. The need for this area was identified, at least in part through these surveys, and is now functional. These data led to the launch of major improvement initiatives in three areas – coordination of care, informed consent and ambulatory surgery. These three important organizational processes have been completely renovated through a major process redesign initiative led by the Associate Director for Nursing. In 2007, the Clinical Center began conducting continuous surveys of inpatients and outpatients. In addition, we surveyed perceptions of both our patients and our IC customers and stakeholders as part of each of the operational reviews conducted to date (Imaging Sciences, Nursing, Transfusion Medicine, Spiritual Ministry and Laboratory Medicine). Assuming that our generic clearance request from OMB is again approved, in 2007-2008 we will also survey patients about the comparative 'built environments' of the old and new hospitals, physicians who refer patients to the CC, and pediatric patients and their parents.

The CC Director established a Patient Advisory Group in 1998. This group is composed of current and former patients and provides the Director with the patients' perspectives about service quality in our hospital. This group has also helped identify issues that have become the focus of performance improvement activities (see customer service initiative, below). In part to improve our interface with the public, and to improve our outreach to minority and underserved communities, the CC established the Patient Recruitment and Public Liaison Center. This new center has had a substantial salutary effect on community relations since its inception six years ago.

- **Historically (pre-1994), customer service was not an identified institutional priority.**

The Clinical Center Director's Patient Advisory Group identified a need for organizational improvement in the area of basic courtesy and customer service. In response to this identified need, the Clinical Center embarked on a major customer service initiative. An external contractor was hired to assist with the training of staff throughout the organization – focusing particularly those at major customer/stakeholder interfaces. This program was received with a great deal of enthusiasm by Clinical Center staff. As noted above, results from patient surveys suggests that this initiative has had a beneficial effect from our patients' perspectives.

- **The Clinical Center has substantial opportunities to increase its attention to workforce diversity and healthcare disparities.**

Over the past five years, both NIH and the Clinical Center have also become increasingly aware of an organizational need to honor cultural diversity and to develop policies of inclusiveness for our workforce and in our everyday practices. The prior NIH Acting Director identified health disparities as a major NIH priority. The Clinical Center has successfully competed for funds from the NIH Center for Minority Health to facilitate recruitment of minorities into clinical studies. In addition, the Clinical Center is embarking on a major diversity awareness program and has redoubled its efforts to recruit minority staff. As part of this effort the CC has established a summer student training program that focuses on the recruitment of minority students. The challenge of recruiting talented women and minorities to the Clinical Center cannot be overemphasized. The NIH salary structure often lags behind competing academic centers, and is rarely competitive with industry. Talented women and minority candidates are consistently highly recruited. NIH has established the Office of Minority Health and a trans-NIH Working Group on Women in Biomedical Careers with an eye toward increasing our recruitment efficacy in this highly competitive field. One problem identified by the NIH Working Group on Women in Biomedical Careers relates to the challenge of retention – i.e., keeping talented women and minorities in the field of clinical research when salaries are not competitive and when other personal and family related issues place demands on the investigator's time. Ideally, such individuals can be nurtured into positions of leadership, despite these obstacles.

- **The Clinical Center had difficulty reconciling competing Institute demands within a defined budget and has no clear cut mechanisms for making decisions that benefit the entire organization (as opposed to individual customers).**

Whereas the Clinical Center, as a service organization, needs to be responsive to the program needs of its IC customers, the Clinical Center should not be involved in setting the clinical research agenda. Each IC sets its own scientific agenda.

The NIH Director convened a mini-retreat in 2007 to address institutional issues relating to the identification of NIH institutional priorities for clinical research. As one result of the retreat, the NIH Director charged the entire organization with identifying crosscutting projects (i.e., analogous to the "Manhattan Project") that will involve multiple Institutes. In addition, the Advisory Board for Clinical Research provides the Clinical Center Director with advice about intramural clinical research priority setting. Other recommendations from this retreat include:

- Increasing the number of tenure-track clinical investigators; such an increase could be facilitated by centralized recruitment strategies and pooling of IC resources with a goal of first getting the best recruits, and then allowing them to later align themselves with ICs.
- Re-opening fascinating, difficult clinical challenge or "fascinoma" clinics that had been used in the past to evaluate patients who are diagnostic conundrums and present broad, clinical challenges.
- Making the CRC available to extramural research and industry provides expanding opportunities in areas of drug and technology development and access to a larger cohort of patients (discussed below).

The Clinical Center and the Institutes have variable infrastructures to support their independent investigators and to support the processes of clinical research.

The CC Director, working with the Clinical Center's Medical Executive Committee, developed a set of Standards for Clinical Research that represent the minimum infrastructural standards that all NIH clinical research programs should have in place to assure appropriate investigator support, as well as the safe conduct of clinical research. Beginning in 2003, the Medical Executive commissioned reviews of each institute's clinical research programs, based on these standards. The findings from these reviews, which are conducted by NIH peers, are being prospectively presented during executive sessions of the Medical Executive Committee meetings. The reviews afforded the individual IC clinical research programs the opportunity: 1) to see how other programs were approaching the new standards; 2) to identify 'best-practices' among the ICs; and 3) to benchmark their own programs against the other programs on the NIH campus. These reviews will likely be invaluable when NIH applies for accreditation of its intramural clinical research program to one of the two oversight organizations that currently provide accreditation of clinical research/human subjects protection programs.

Another feature of the variable research support infrastructure across institutes is the variety and sophistication of information systems to support protocol data management, patient recruitment and accrual statistics and IRB management. This disparity was noted during the development of the clinical research data repository business case and continues to be driver in the requirements for the planned system.

Outpatient surgery and ambulatory care facilities are in need of redesign.

With significant input from customers and stakeholders the CC has designed, and is in the process of renovating, our outpatient surgery venue. This project, which should result in a much more efficient patient flow and is much more 'patient-friendly' should be completed in 2008. Additionally, in 2003 stakeholders from several institutes noted that the Clinical Center's ambulatory care clinic facilities were in need of restructuring and redesign. Clinicians raised questions about the optimal use of clinic space and clinic facilities. In addition, they identified unmet clinical needs (e.g., space to have private discussions with patients about treatment or protocol options, about prognoses). The Clinical Center Director's Patient Advisory Group has expressed similar concerns. For these reasons, the Clinical Center assembled a team of stakeholders to assess possible restructuring of its outpatient services. The redesign and renovation of these areas is already underway and the round-robin process of redesign and renovation will continue for the next four years.

The very constrained budgets of 2002 through 2008 required the development of new strategies to gain operational efficiencies.

To assure efficient operations of our Departments, the CC has developed a process for systematically reviewing the operations of our departments. These operational reviews involve both extramural experts in the field, as well as intramural stakeholders. In addition, to provide ICs with better financial data, we have launched a Data Transformation

Initiative that is designed to provide more precise data about the costs associated with CC services. To date, we have conducted operational reviews of the Imaging Sciences Program, Nursing and Patient Care Services, the Department of Transfusion Medicine, and the Spiritual Ministry Department. The Department of Laboratory Medicine will be reviewed in September 2007. These reviews have resulted in a series of suggestions that have generated action plans from the departments that were reviewed that have already produced increased operating efficiencies.

In addition, the CC has developed strategies to share some costs with Institutes for services that are primarily performed to support IC program research (e.g., research PET scanning, certain Transfusion Medicine Department products designated for research use, licensed pharmaceutical products being evaluated for 'off-label' indications). Whereas this strategy should help the CC manage financially during these very constrained times, senior leadership has concern that continued implementation of such cost-sharing strategies has the potential to suppress new ideas and perhaps negatively affect the organization.

Finally, the Clinical Center's Advisory Board for Clinical Research has provided oversight for a series of operational reviews of Clinical Center Departments and has made numerous suggestions to improve operating efficiency. This Board is comprised of internal customers and extramural experts in healthcare and hospital operations. Their advice has been extremely valuable in streamlining Clinical Center operations.

- **After a peak during the budget doubling years (and immediately prior to opening the new CRC), the inpatient census has fallen, leaving the CC with unused capacity.**

To address the issue of unused capacity, the CC Director developed a highly successful program for competitive "Bench-to-Bedside" awards to stimulate creative translational work on the NIH campus. This initiative has been expanded to make it available to extramural investigators who wish to partner with intramural scientists in a translational research project. In addition, the Director of the Clinical Center has entered a dialogue with the NIH administration and IC leadership about making more of the Clinical Center's unique clinical research infrastructure available to extramural scientists. Examples of unique infrastructural resources that may be used to attract extramural investigators includes (but is not limited to: sophisticated functional imaging studies, including MRI, MRA and PET scanning; intricate cell processing capabilities; molecular diagnostic studies; tailored functional outcome studies, and many others. Making these resources available to extramural investigators (and perhaps even to industry scientists) would likely significantly expand drug and technology development opportunities. Some barriers would have to be overcome to accomplish this, including managing shared resources, the potential for intramural and extramural funds to be used for the same project, and the management of intellectual property. Additional strategies that have been suggested as likely expanding and stimulating capacity within the intramural clinical research program include: 1) increasing the number of tenure-track clinical investigators; 2) centralizing recruitment for clinical investigators to take advantage of trans-institute opportunities; 3) develop clinical research "Manhattan Projects" that involve several ICs; 4) open "diagnostic dilemma" or "fascinoma" clinics; and 5) encouraging IC-tenured and tenure-track investigators to write clinical research protocols.

- **Institute protocols increasingly require sophisticated and costly genetic tests that are not available through CC laboratories.**

The Clinical Center is working with the leadership of the NHGRI to develop a strategy to meet investigators' needs for genetic tests. The CC has surveyed investigators twice during the past year to attempt to learn more about their needs. The basic strategy that has been developed to address this critical need is writing a series of contracts (hopefully including substantial volume discounts). Such an approach would provide a mechanism to meet investigators' increasing needs in this area, while simultaneously saving resources A spirited discussion of these needs was held at the Medical Executive Committee meeting to identify potential strategies for funding the necessary contracts. As a first pass, the MEC suggested that the CC be responsible for paying for all genetic testing that have FDA-approved indications for diagnosis.

- **Despite the opening of the new CRC, several facilities-related issues present significant barriers to progress.**

As a result of an unannounced Joint Commission visit, several deficiencies in ongoing required pre-

ventive maintenance and ongoing repair activities in both the Hatfield and the Magnuson buildings, as were problems addressing life-safety regulatory requirements for construction and renovation in the hospital (e.g., the construction/renovation permitting process, the development of, and training staff in interim life-safety measures, among others). These problems are compounded by the fact that many of the positions in the Office of Research Facilities (ORF) are currently being studied in the A-76 process for potential outsourcing. As a result they have had many of their staff leave and are unable to replace them until the study is complete. The Director of the Clinical Center established a working group, including the Director and Deputy Directors of the CC and ORF, as well as other involved customers and stakeholders in life-safety processes in the CC. A new position was established by ORF that reports directly to both the CC Director and the Director, ORF. This group meets regularly and is systematically addressing the relevant construction, renovation, maintenance, engineering and life-safety issues to maintain compliance with regulatory standards.

A third facilities-related issue concerns inadequate infrastructure (power, air handling and chilled water) in the ACRF and adjacent areas that were constructed in the late 1970s. Several devastating floods have occurred in these areas over the past five years, due to malfunctioning equipment, broken pipes, etc. The Clinical Center's Operating Rooms, the Department of Transfusion Medicine's Cell Processing Section, the Department of Laboratory Medicine, and our Imaging Sciences Program are all housed in this area. Since these are all technologically and equipment-intense, and since many of the programs (because of increasing demand for these kinds of studies) are rapidly expanding, addressing the infrastructure shortfall is a major institutional priority. The Director, ORF has made a commitment of additional funds for FY 2008 to begin addressing these issues as his highest priority.

- **Changes in the ethics rules concerning stock holdings, consultation for industry, and other compensated-outside activities have had an adverse impact on recruitment, retention and morale.**

During the past three years, scientists at NIH have been subjects of several ethics investigations. A small number of individuals were found to have been noncompliant with Federal ethics rules. NIH developed a new set of guidelines, policies, and review processes. New policies have eliminated employees' ability to consult for remuneration with commercial entities and dictate more stringent rules on financial holdings for senior employees. These new restrictive policies have had an adverse impact on recruitment, retention and morale on campus. The Director, NIH is working diligently to improve both the perceptions of NIH held by Congress and other important stakeholders as well as the morale of NIH staff.

Factors in the External and Internal Environments Influencing Change in Healthcare Delivery and Clinical Research

Assessing the external and internal environments will afford the Clinical Center the opportunity to address several important questions, the answers to which will help shape the Clinical Center's vision for the future. Among these important questions are the following:

- What external forces or trends are influencing the Clinical Center environment?
- How are these forces or trends currently influencing the Clinical Center, and how will they likely influence the manner in which the Clinical Center operates in the future?
- How is the Clinical Center positioned to manage these trends?

These external and internal influences and trends will undoubtedly present the Clinical Center with both opportunities and challenges. Thus, the analysis of these factors will include both "Clinical Center opportunities" and "Clinical Center challenges for the future." Certain of these external factors simultaneously present opportunities and threats.

Clinical Center staff have visited many centers across the country that are viewed as "best-in-class". In discussions with the leaders of these organizations, many factors driving change in the healthcare and clinical research environments were identified. These factors can be divided into "challenges and opportunities" and can be loosely grouped into several general categories.

- Changes in, or influenced by, societal values;
- Changes influenced by cost considerations;
- Process changes in healthcare driven by increasing competition, such as the rise of managed care;
- Changes influenced by shifts in population and population demographics;
- Changes in the practice and delivery of medicine;
- Changes in practice driven by technological advances;
- Changes influenced by governmental initiatives;
- Changes mandated by agency priorities and initiatives.

As a result of the dramatic changes taking place in science, medicine, and the healthcare industry, the Clinical Center faces the following opportunities, challenges, and potential threats.

Societal- and Value-Based Factors

The dramatic changes in the political climate, including the wars in Iraq and Afghanistan, the aftermath of the heretofore unthinkable acts of September 11, 2001 and the continued threat of additional acts of terrorism have mandated increased attention to emergency preparedness in our institution, have required diversion of resources to NIH safety and preparedness activities, have resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries, and have fundamentally altered the day-to-day workplace lives for individuals working on the NIH campus.

Terrorist acts directed against the United States have increased steadily over the past years. The potential for additional acts of terror, including bioterrorism, seems likely, if not inevitable. The events of September 11, 2001 had a profound and lasting impact on the United States. These events forced a rethinking of how we, as Americans, conduct virtually every aspect of our lives. The need to focus resources on national defense and public safety also have mandated substantial changes in our internal environment. The perimeter of the NIH campus is now fenced and campus entry points are staffed with security screeners. If one wishes to park in a below-building garage, the security staff swab the vehicle for explosives before permitting its entry into the underground garage.

The Clinical Center has responded to these new circumstances: by revising and broadening its disaster plan; by preparing and distributing an emergency management flip chart throughout the Clinical Center complex (to make key information readily available to all its staff); by working with the NIH Continuity of Operation Planning Group, by participating in pandemic influenza planning, and by entering into an emergency preparedness partnership.

To address the complex issues relating to hospital and community emergency preparedness in the 21st century the Clinical Center, the Suburban Hospital Healthcare System, and the National Naval Medical Center formed an emergency preparedness partnership – the Bethesda Hospital Emergency Preparedness Partnership. This partnership, composed of three diverse organizations that have strikingly complementary resources, has made it possible for the Clinical Center to plan for possible emergency situations in an unprecedented fashion.

The DHHS Secretary contributed a 250-bed contingency station field hospital to be embedded at the CC for partnership surge capacity and the Department of Defense provided $5M in earmarked funding for the Partnership. These resources have been used to procure equipment and supplies, to support drills that are run jointly among the three partners, and to assist with ongoing strategic planning and preparedness assessments. These funds also will be used to test novel technologies in emergency situations. In addition, the partnership conducted a feasibility study of constructing either bridges or tunnels from NIH to the other partners. The Bethesda Hospital Emergency Preparedness Partnership has run several, highly successful complex drills that involve the staff from all three facilities.

The Bethesda Hospital Emergency Preparedness Partnership has also developed close working relationships with other Montgomery County hospitals, and the Montgomery County Collaborative Task Force (for emergency preparedness) as well as with the Capitol Area Emergency Preparedness Planning team. This, the Clinical Center and the NIH in general are much better prepared to deal with emergency situations than at any time in the past.

The impact of the dramatic changes on the NIH workforce brought about by the September 11, 2001 disasters and their sequelae cannot be underestimated. Staff continue to be faced, on a day-to-day basis, with substantial uncertainty.

The emergence of new infectious diseases, the resurgence of other infections, and the potential for the use of highly pathogenic infectious agents as weapons of bioterrorism presents substantial threats to the public health and are associated with the urgent need to be prepared to address and answer relevant scientific questions that may make it possible to mitigate the damage produced by these infectious diseases.

The past several years have seen the emergence of several new, primarily zoonotic infections, the resurgence of others, and the fear that some exotic infections might be used as agents of bioterrorism. The spread of West Nile Virus from the Middle East to the North American continent, the emergence of hantavirus infections in the U.S. Southwest, the worldwide epidemic of the Severe Acute Respiratory Syndrome (SARS), and the importation of Monkeypox to the United States are examples of zoonotic infections associated with new and substantial public health risks for U.S. citizens. The resurgence of tuberculosis and the ever-present threat of pandemic influenza are examples of infectious diseases that can resurface at any time to present significant public health risks. The mail-borne epidemic of anthrax that occurred in 2001 and the sufficient concern in the U.S. Federal Government that the agent of smallpox could be used as an agent of bioterrorism that prompted a nationwide immunization program are examples of the existing bioterrorism threat. Finally, the specter of pandemic influenza continues to loom over the entire globe as a result of an almost unprecedented epidemic of avian influenza and the real possibility that the avian virus might make the jump to become an aggressive, transmissible human pathogen. Emerging infectious diseases, resurgent infections, and biological agents associated with risks as agents of terrorism are all associated with a plethora of unanswered scientific question. The Clinical Center provides an ideal venue in which to address some of these questions, and over the past three years, the Clinical Center has seen the development of clinical protocols that address some of these issues concerning: West Nile Virus, SARS, multiply-drug-resistant tuberculosis, pandemic influenza, anthrax and smallpox immunization.

With its solid core of basic scientists and nearly ideal translational research environment, the Clinical Center is strategically situated both to be able to respond to these public health emergencies when they arise as well as to be able answer some of the very perplexing scientific questions. For example, the Clinical Center Department of Laboratory medicine Microbiology Service played a pivotal role in interpreting cultures from potentially exposed individuals during the mail-borne anthrax epidemic, processing thousands of cultures. The presence of patients who have these infections present formidable challenges to the NIH workforce and the threat of the emergence of these diseases – either through a natural epidemic or as a result of an act of bioterrorism – is another source of anxiety for both the NIH staff and the surrounding community.

Declining funds for biomedical research also has added a degree of instability to the NIH environment.

The U.S and international economies have been struggling during the past seven years. The economic downturn has resulted in restructuring of Federal, State and local governmental budgets. Corporations have cut back research and development efforts and many small biotech companies have gone bankrupt. With increasing financial support required to maintain the war effort in Afghanistan and Iraq, the additional requirement of substantial funds intended to assist with the revitalization of those countries, and the substantial investment in homeland security, the budgets for Federal Agencies will likely continue to be impacted significantly. The fact that the cycle of doubling the NIH budget was completed in 2002 resulted in substantially leaner budget years for NIH over the next few years.

U.S. society has steadily increased its perceptions of social responsibility.

Society has become more attuned to social responsibility for healthcare delivery since the 1960s. Interest in, and expenditures for, medical care for the elderly and the socially disadvantaged has increased dramatically during the past 30 years. The costs associated with providing care to elderly and indigent patients have begun to stress the healthcare delivery system. The increased social awareness has led to an increased appreciation of the role of alcohol and substance abuse in society, has shed light on the unique health problems associated with aging, and has clearly contributed to the founding of the National Institute on Aging, the National Institute on Alcohol and Alcohol Abuse, and the National Institute on Drug Abuse. This trend toward increasing social responsibility provides NIH and the Clinical Center with an opportunity to create and conduct landmark studies in these important areas. Conversely, because of increasing social responsibility, some in U.S. society would prefer to divert research dollars to support current costs of medical care. Such an approach is particularly understandable in the short-term, but may be more costly in the long run.

Americans increasingly value the "Quality of Life."

In the past twenty-five years, society's focus has subtly shifted from "staying alive" to the "quality of life." As Americans have become much more conscious of "quality of life" as an endpoint or outcome, American medicine has, of necessity, been forced to accommodate these changes in values. As American society has turned attention to this issue, Congress has also developed an interest in "quality of life" concepts. This shift in societal focus provides the intramural program and the Clinical Center with the opportunity to include objective and subjective measures of the functional outcomes that contribute directly to the "quality of life" as outcomes of clinical research projects. Particularly in oncologic studies, patients' values and individual, unique measures of "quality of life" may influence their choices of therapy. Clinical Center Departments such as Rehabilitation Medicine, Pharmacy, and Critical Care Medicine have unique opportunities to contribute to Clinical Center studies in this area. Although not traditional 'clinical care,' this unique 'clinical research support' is an important component of the support provided by certain of the Clinical Center Departments. Ignoring this important trend in its clinical studies could place the Clinical Center at a disadvantage in the eyes of its societal customers. Since the drafting of the initial Clinical Center Environmental Assessment, public interest in "quality of life" issues has not waned; if anything, interest has intensified. Healthcare institutions have developed strategies to begin to measure changes in the "quality of life" that are effected by various therapeutic alternatives. These measurement strategies are a direct outgrowth of the persistent public interest in "quality of life" issues.

Wellness and prevention strategies are increasingly valued.

In the past three decades, the U.S. society has increasingly focused attention on nutrition, diet, exercise, and avoidance/cessation of smoking and alcohol consumption. This focus on health and wellness again provides the NIH intramural program with clear opportunities to study basic mechanisms of health and the pathogenesis of disease states relating to this societal focus.

In response to society's interest, NIH has increased its investment in wellness and prevention activities. The external focus on "prevention" and "wellness" has continued to intensify over the past sixty months. Prevention activities are, in general, among the most cost-effective interventional strategies. For these reasons, this trend is likely to continue for the foreseeable future.

One area where the focus on "quality of life" issues has not impacted American society is the remarkable, continuing problem of obesity in our society. Under the prevention and 'wellness' umbrella, DHHS leadership launched a major initiative to combat obesity in the United States. Several NIH Institutes are currently collaborating in a trans-institute NIH initiative that is designed to complement DHHS efforts. NIH responded by creating a new unit in the CRC dedicated to metabolic studies and the installation of two metabolic chambers to measure caloric intake and output with precision. This new unit was opened in 2007 and the metabolic chambers are in the process of being fully commissioned as this document is being written. These chambers provide another unique tool for investigators interested in perplexing problems related to metabolism – whether related to obesity or the wasting syndromes associated with oncologic chemotherapy and/or HIV infection.

Technology in medicine is advancing almost exponentially; technologic advances are highly publicized; thus, these advances become "desired".

Medical technology blossomed in the 1990s. In the past forty years the tools of medicine have changed more than in the past five hundred years. NIH contributes to this rapidly advancing field, and, as a result, often has unique opportunities to use these technologies as they are being introduced into society to investigate the frontiers of medicine. Since the Clinical Center is ideally positioned to adapt swiftly to the development of new technologies, such rapidly advancing technologies provide the Clinical Center with unique opportunities to enhance its national and international reputation as a creative, innovative institution. Such new technologies often have direct impact on cost. Occasionally the required capital expenditures for new equipment are quite large and some technologically advanced procedures are labor intensive. These changes tend to increase the costs of care. In other instances, introduction of new technologies have been associated with less invasive procedures and decreased length of hospital stays (e.g., laparoscopic cholecystectomy), thereby decreasing the net costs of care, despite the outlay for the necessary capital equipment.

The delineation of the human genome has resulted in a proliferation of studies in the field of genomics and proteomics that will likely quickly move science to more sophisticated, gene-based studies and, likely to a younger patient population. The focus on genomics and proteomics will also likely (at least ultimately) favor prevention studies.

A general trend in the Clinical Center over the past several years is toward increased intensity/acuity of services per patient visit (i.e., more and more sophisticated imaging studies, more molecular tests per patient visit, more sophisticated cellular therapies, increasing numbers of serial studies, etc.) Many such studies are outside the bounds of what would traditionally be characterized as 'standard care' but easily fit under the rubric of 'clinical research support'.

Over the past ten years, the Clinical Center has continued to invest in new technologies, trying to position itself in the forefront of academic institutions in this arena. Clinical Center initiatives in this area include: the procurement, installation and activation of a new clinical research information system, the creation (in collaboration with private industry) of a new, state-of-the-art cell processing facility, new Positron Emission Tomography/CT imaging technologies, new computer tomography scanners, the purchase of upgraded magnetic resonance imaging capacity, the purchase of new stereotactic neurosurgical equipment, the purchase of a robotic surgical apparatus, additional emphasis on molecular diagnostics in Laboratory Medicine and Transfusion Medicine, the creation of an imaging center, in collaboration with NHLBI, NINDS and Suburban Hospital specifically designed to study acute cardiac and neurological vascular events in the Suburban Hospital Emergency Room, the

purchase of an additional magnetic resonance imaging device and renovation of a part of the CCs operating suite to support a new intraoperative imaging program (particularly of use to the NCI Radiation Oncology Program and the NINDS Neurosurgery Program), and the renovation of the Imaging Sciences Radiology suite to support much of this new technology.

Some sectors of the U.S. population have become highly suspicious of "clinical research".

As a result of adverse publicity arising from certain infamous clinical studies (e.g., the Tuskeegee study, the Willowbrook studies), some segments of the U.S. population have developed a substantial mistrust of the entire clinical research enterprise. Developing programs that reach out to these segments of society with sensitivity could enhance the Clinical Center's reputation and result in a renewed patient-recruitment base. Congress and DHHS view ineffective recruitment of women, minorities, and underserved populations as problematic. Recent adverse publicity associated with the cloning of farm animals and the proposal to clone humans may present additional problems with certain aspects of the public's perception of biomedical research.

Clinical Center leadership has attempted to reach out to several minority communities who have not been traditionally invested in the clinical research process. For example, the Clinical Center's Office of Patient Recruitment and Public Liaison has interacted with the local Hispanic community, and the Director of the Clinical Center made a presentation to the Annual Meeting of the National Medical Association. The Office of Patient Recruitment and Public Liaison also produced a video to assist in the recruitment of minorities to clinical research studies. In addition, the Clinical Center created a home page on the World Wide Web that includes a description of all active clinical research protocols at the Clinical Center. The Clinical Center also has established a Bioethics Department, which has positioned the organization to address the complex issues associated with cultural biases toward participation in clinical research.

Population- and Clinical Research Subject-Based External Factors

Patients and clinical research subjects are becoming increasingly sophisticated healthcare consumers.

Consumerism is a relatively new phenomenon in U.S. healthcare. Because of the free availability of data, individuals have access to much more information about medicine and healthcare. As a result of the increasing publicity associated with iatrogenic and nosocomial medical misadventures, and as a result of the increasing media coverage of progress and problems in healthcare, the special standing of physicians in the community – the mystique of the white coat – has essentially disappeared. As healthcare costs have escalated, to try to maintain profit margins, insurance companies have increased copayment rates, and patients are now paying an increasing fraction of healthcare costs out of their pockets. For this reason the healthcare customer has become much more interested in cost and quality comparisons when procuring healthcare services. Since the Clinical Center delivers high quality healthcare without charge to the participants in its clinical studies, as healthcare customers focus more intensely on cost and quality, the Clinical Center should have an opportunity to recruit study subjects more effectively by appealing to both patients and providers. In addition, as the focus on cost and quality increases, the Clinical Center should have the opportunity to become better recognized as an outstanding clinical research facility.

In the eleven years since the strategic plan was initially drafted, consumerism in healthcare in the United States has continued to increase. Numerous healthcare organizations have organized themselves along medical "product lines," and public advertising of these product lines (e.g., imaging services, management of coronary artery disease) has increased. Consumers of healthcare in the United States in 2007 are focusing on several issues, among them: 1) ready access to healthcare and to their healthcare providers; 2) clear communication with their providers; 3) provider responsiveness to questions and problems; 4) patient safety; and 5) the level of customer service available from their providers.

With respect to the safety of patients participating in the clinical research studies at the Clinical Center, the Clinical Center has been proactive in the development of novel approaches to mitigate risk in our environment. We developed an electronic Occurrence Reporting System (ORS) that provides immediate responsiveness about events occurring in our institution and that allows CC

staff to evaluate more than 5,000 occurrences annually. These data are used to assess for trends, clusters, and potential sentinel events. We have been able to use these epidemiological data to make process improvements in a variety of patient care processes. When sentinel events occur, we routinely conducted detailed root cause analyses of these events, with an eye toward improving our patient care processes to mitigate risks for adverse events. Finally, the CC is interested in using technology to mitigate risk. We have run two pilot tests of biometrics equipment to assess their potential utility as a patient safety device. In addition, in FY 2008 we will submit an exhaustive Request for Proposals (RFP) for the broad-scale implementation of bar-coding technology in several clinical and patient-care processes.

Scientific literacy is decreasing in the United States; science education in the United States is not keeping pace with Europe and Asia.

At the same time that consumerism in healthcare is burgeoning, the quality and efficacy of science education in the United States is not keeping pace. Studies conducted by the Congressional Office of Technology Assessment, the National Science Foundation, and the American Association for the Advancement of Science in 2001 suggested that science education in the United States is lagging substantially behind that of Europe and the Far East. Comparing the results from 15 developed nations of international standardized tests, United States students placed last in biology, third from the last in chemistry, and fifth from last in physics. Further, the talent pool entering science occupations is also diminishing. For example, the percentage of National Merit Scholarship finalists entering careers in science, the health sciences, and engineering have been steadily decreasing. If the net impact of faltering science education in the United States is that science per se is valued less in U.S. society, the likelihood that biomedical science discoveries and science-based health interventions – the forte of the National Institutes of Health – will be undervalued or misunderstood is increasing.

Societal demographics are changing.

Data from the U.S. Office of Vital Statistics demonstrate that life expectancy is lengthening; therefore, the U.S. population is becoming older. Older patients require more healthcare and develop different medical problems. When coupled with the value shifts noted above, these demographic changes subtly modify the national research agenda. This modified agenda provides NIH scientists with scientific opportunities. In addition, the demographics of large metropolitan population centers are also changing. The percentage of minorities and underserved individuals in the populations of major U.S. cities continues to increase. As these populations continue to expand, the Clinical Center is faced with the challenge of developing effective communication strategies with these segments of society. Since healthcare delivery to these populations is currently suboptimal, the development of effective communication strategies might serve both the interests of these communities and the Clinical Center by offering access to a quality of healthcare otherwise not available, while simultaneously providing a source for patient recruitment.

Society has become increasingly litigious; malpractice claims have increased dramatically; malpractice insurance rates have escalated almost exponentially.

The costs associated with the unprecedented rise in the number and size of malpractice suits over the past three decades have contributed significantly to the escalation of healthcare costs in the United States. Although the Clinical Center has had few such claims, the Clinical Center is, by no means, immune to these actions. This trend presents a challenge to develop effective mechanisms for assuring quality, both in the studies conducted at the Clinical Center, as well as in the care provided to Clinical Center clinical research subjects. In addition, the challenge presented by an increasingly litigious society should galvanize the Clinical Center to seek "customer" input regarding the quality of services provided.

"Alternative, complementary and integrative" medicine are assuming increasingly visible roles in U.S. medicine.

The public has long been interested in alternative and complementary medicine. Whereas medicine and society unquestionably have a great deal to learn from "nontraditional" and "cultural" remedies and treatments, the term "alternative and complementary medicine" has often been used to shroud medical fraud. "Miracle cures" such as Krebiozen and Laetrile often turned out to be far less effective than they were originally touted. The increased societal interest in alternative and complementary medicine proffers the challenge to the intramural program at

NIH to develop open lines of communication with its clinical research subjects and the public on these issues. Failing to give credence to the possibility that non-traditional remedies and treatments may have real value runs counter to the science-based culture of NIH. NIH as a truly unbiased, impartial community is ideally situated to address issues such as the safety and efficacy of nontraditional approaches to medical care.

In the late 1990s, NIH has increased its emphasis on the evaluation of alternative and complementary medicine. A Center for Alternative and Complementary Medicine was created at NIH in 1998. Funding for studies of these approaches was increased. Major clinical trials of alternative and complementary therapies funded by NIH are in progress. The emphasis on alternative and complementary medicine is also apparent in the Clinical Center, where for the past several years an external consultant skilled in acupuncture has been providing treatment to patients with chronic pain. In addition, senior Staff Clinicians from the Clinical Center Department of Rehabilitation Medicine have been trained to perform acupuncture and, the Clinical Center established a Pain and Palliative Care Service in 2001 that regularly uses a variety of complementary and alternative medicine strategies NIH is poised to study the efficacy of the complementary and alternative therapies reiki and "pet therapy" in Clinical Center clinical studies.

Cost-Based External Factors

Cost continues as a major driving force in the U.S. healthcare industry.

In the past two decades, healthcare costs have escalated exponentially, primarily at consumers' expense. The Federal government, as well as state and local governments, have become intensely interested in controlling costs. These interests have led to formal scrutiny of the systems and processes in medicine and in healthcare delivery. Cost considerations have had a profound impact on the healthcare industry in the United States, leading to: 1) increased reliance on the use of business management theory (e.g., CQI, reengineering, etc.) to attempt to generate efficiencies in the healthcare industry; 2) a careful assessment of the substantial variation in patterns of care of individual diseases or conditions; 3) a call for standardization of clinical practice across the country; 4) an increasing trend toward the systematization of medicine – evaluation of outcomes, standards of care, clinical guidelines/pathways/care maps; 5) a remarkable shift toward capitation, managed care, and vertically-integrated healthcare systems; 6) a dramatic shift away from subspecialty medicine and an increased emphasis on primary care; 7) more reliance on "non-physician" primary-care and extended-care providers; 8) an aggressive trend toward early discharge and emphasis on outpatient medicine; 9) aggressive competition for healthcare customers; and 10) major centers aggressively streamlining, downsizing, cross-training, and seeking new, more efficient "models of care". These trends have continued through 2007.

Cost considerations have led to a rethinking of such pivotal issues as the basic processes and models of care delivery; the increasing reliance on "non-physician" primary care providers; an increasing penetration of managed care into the healthcare marketplace; a dramatic increase in competition for patients, and a shift to outpatient, day-hospital and primary care medicine, among many others. Whereas the costs of care and payment for care are primary drivers for the healthcare industry, the regulatory environment and the human subjects protection rules are the primary drivers in the NIH/Clinical Center environment. The Clinical Center finds common ground with the healthcare industry in the need for us to maintain fiscal accountability to our customers and stakeholders. Several of the newer strategies and approaches have also become highly visible in the Clinical Center over the past five years, including increased use of physician extenders and a continued shift toward outpatient and day hospital studies.

Spiraling costs associated with healthcare and clinical research also led to a downturn in clinical research investigators on the NIH campus. For example, in 1997 the campus had 360 investigators who were principal investigators on clinical research studies and 1,088 active clinical protocols. Today, the campus has witnessed a resurgence of interest in clinical research, fueled both by the NIH Director who has challenged the Institutes to produce cutting-edge translational research as well as by the construction of the new clinical research center. By the end of FY 2003, there were 449 active principal investigators on clinical research projects and 1,239 active clinical research protocols, representing increases of 14 and 25 percent, respectively, when compared with 1997. By the end of FY 2006, there

were 547 active principal investigators on clinical research projects and 1,372 active clinical research protocols, representing increases of an additional 22 and 11 percent, respectively, when compared with 2003. One concern, however, is that fewer tenured and tenure-track investigators are principal investigators on clinical protocols. In 2001, there were 192 tenured principal investigators on clinical studies; by 2007 this figure had dropped to 156 (a decrease of 19 percent). Similarly in 2001, 48 tenure-track investigators were principal investigators on clinical protocols and by 2006, this number had fallen to 18 (a reduction by nearly 63 percent). These data have prompted a major review of career paths for clinical investigators at NIH.

The following external trends will also provide numerous opportunities and threats to the Clinical Center and to the NIH intramural program.

- Adoption of new business management principles will likely foster organizational efficiencies.

  Organizational efficiencies remain an institution-wide focus for the Clinical Center. Despite this emphasis on efficiency, the Clinical Center has, nonetheless, been able to support substantial growth in some areas (e.g., the development of the stem-cell/cell processing facility, creation of a new Clinical Bioethics Department, substantial investment in state-of-the-art imaging technology, and increased investment in information systems support, among others).

- Evaluation of protocol-based care in a manner analogous to "critical pathways" will likely facilitate the development of a meaningful protocol-based cost-accounting system, while simultaneously expediting staffing assignments and organizational planning. The Clinical Center has embarked on an initiative to develop a protocol-writing software package, called ProtoType, which should assist with the increasingly cumbersome process of protocol writing and implementation. This software program will also provide a template for evaluating the clinical quality of the care delivered in the context of the protocol, will provide significant standardization of language in consent documents, should help facilitate human subjects protection review, and should provide a template for assessing the extent to which patients are able to adhere to the protocol as it is written. Standardization of the manner in which protocols are written should also facilitate accreditation of the intramural clinical research program by AAHRPP.

- The shift to a capitated clinical environment in the external community provides both opportunities and threats. Managed care organizations may well be interested in referring patients who would require large financial expenditures for care; conversely, some managed care organizations believe they may be legally barred from referring patients.

- In 1995 and 1996, in response to continued interest from the Office of Management and Budget in having the Clinical Center bill third party payers for some aspects of the care provided at the Clinical Center, Clinical Center leadership developed a four-pronged approach, including: developing a legislative process under which the Clinical Center could be granted the authority to bill third party payers for care delivered to enrollees participating in clinical research; establishing a dialog with managed care representatives concerning their interest in, and willingness to, support clinical research at the Clinical Center; developing an infrastructure to track the costs of participating in clinical research; and prospectively collecting insurance information from Clinical Center patients to determine the fraction who have insurance coverage and the potential impact of asking clinical research subjects' insurers to cover some of the costs of their care at the Clinical Center.

- In 1996, Congress provided language in the NIH Authorization that permitted the Clinical Center to collect from third party payers. In February and March, 1997, the Clinical Center held meetings with representatives from insurance companies, managed care organizations large, self-insured corporations and from the Health Care Financing Administration (HCFA) (now the Center for Medicare and Medicaid Services [CMS]) to discuss the potential for recovery of some of the costs of clinical research and to address the possibility of broadening the Clinical Center's referral base to encompass patients from health maintenance organizations and large insurer networks. The meeting provided Clinical Center leadership a great deal of insight into the current status of the insurance/managed care industry. The

Clinical Center also conducted a six-month study of the insurance status of patients participating in clinical research studies at the Clinical Center. The Clinical Center's Board of Governors reviewed all of the information collected in this process, and, after careful consideration of the information recommended against the Clinical Center pursuing third party payment for clinical research performed at the Clinical Center.

- The shift toward primary care has resulted in fewer high-quality young physicians in the fellowship pools, and less interest in clinical and basic science among medical school graduates. Many fellowship-training programs are closing. These trends clearly will have an impact on the manner in which the Clinical Center provides care to its clinical research subjects, as well as on the ICs' clinical and basic science training programs. The Clinical Center and the other intramural clinical training programs will have to compete with the major academic institutions for this smaller pool of highly qualified applicants. In addition, the American College of Graduate Medical Education requires broad clinical exposure in training programs, which is difficult, if not impossible to provide in a program solely based in the Clinical Center. The American College of Graduate Medical Education accreditation standards require that the Clinical Center identify creative solutions and new partners in its training programs.

- The trend toward the use of "non-physician" providers affords the Clinical Center an opportunity to evaluate the model of patient care currently in use and to consider the expanded, creative use of "non-physician" care providers in intramural clinical research. In addition, the creative use of such personnel has already helped address the problem generated by the ever-diminishing fellowship pools.

- The trend toward outpatient and day-hospital medicine, which is paralleled in the Clinical Center's operating statistics, provides an opportunity for Clinical Center scientists to develop creative, less expensive and labor-intensive protocols that can be conducted in our day hospitals and outpatient clinics. A substantial number of even labor-intensive studies can be conducted in the 'day-hospital' environment These trends should be useful to Clinical Center and IC management in terms of reducing the costs of clinical research.

- Competition among healthcare delivery organizations for patients has become even more of a driving force in the healthcare environment in the past thirty months. The aggressive competition for patients and clinical research subjects provides both opportunities and challenges to the Clinical Center. The intense competition for patients will likely make recruiting patients for clinical studies more difficult. Competition has already had a profound impact on the academic medical community. Institutions which used to operate profitably and which used to have substantial excess revenues that could be used to help fund clinical research projects have had to scramble to remain solvent. High quality institutions continue to seek partnerships with the Clinical Center to facilitate their research and training agendas, to increase their visibility in certain markets, and as a marker of the prestige of the institution. The Clinical Center's new extramural alliances (discussed above) should strengthen its and its partners' competitive positions.

- The explosion in technology discussed above provides the Clinical Center with a unique opportunity to use these cutting-edge technologies to develop less expensive types of care. The Clinical Center is uniquely situated to address the challenge of developing medical technologies that reduce the costs of medical care.

In the time that has elapsed since the initial drafting and subsequent revisions of this document, most of the issues described above related to healthcare costs have persisted, or changed only subtly. The subtle changes that have occurred will likely exert minimal influence on the extent to which cost considerations influence the Clinical Center environment. Despite these somewhat subtle changes, financial considerations continue to be the primary influence on change in healthcare in the United States.

Medical-Practice-Based External Factors

Medicine, the practice of medicine and the conduct of clinical research are changing rapidly; progress in biomedical research produces natural change in the research agenda.

Medical progress also keeps sicker patients alive for much longer periods of time. As a result, such

patients often remain at-risk for disease- or therapy-related, care-requiring complications for extended periods of time. Such complications are often expensive and labor-intense. Rapid progress does, however, present unique challenges to the management and leadership of the Clinical Center. Rapid progress precipitates abrupt shifts in the research agenda, and often necessitates fast procurement of expensive new equipment, reagents and pharmaceuticals. The Clinical Center is ideally situated to reprogram resources to address new scientific opportunities for translational research. For example, since the previous iteration of this document, the Clinical Center has worked with several ICs (e.g., NIAID, NINDS, NIDDK, NIMH, NIAMS) to design and implement either innovative new clinical research programs or significant expansions of existing programs.

Effective planning is essential to keep an organization the size of the Clinical Center aligned with the NIH mission, the Clinical Center's mission and vision, and the ICs' rapidly changing research agendas. Management must remain attuned to the intramural and extramural research cultures, must be able to predict, or at least detect, where progress will occur, and position the organization to capitalize on the progress. When new technologies are identified, the Clinical Center must assess the intramural need, and, where appropriate, adopt the new technologies, and make them available to the intramural scientific community. The management of the Clinical Center has to maintain effective communication with IC leadership to stay aware of progress as it occurs. Further, the Clinical Center departmental leaders must be flexible enough to reprogram resources and embrace progress as it occurs. Only in this way will the Clinical Center be able to supply the quality of clinical research infrastructure necessary to accomplish its mission. In the period following the drafting of the original environmental assessment, the emphasis on molecular medicine, immunogenetics, and molecular techniques has continued to increase. In addition, the CC is piloting a project with four Institutes to attempt to assess the intensity of resource utilization by new protocols prospectively. The Protocol Resource Intensity Assessment (PRIA) project may ultimately help the CC inform ICs of protocols that are potentially resource intensive – prior to their implementation. The pilot for this project (which involves substantial collaboration from the IC partners) should be completed in 2008.

The characterization of the human genome has spawned the fields of genomics and proteomics. These fields will likely help shape a substantial fraction of clinical research studies on our campus for the foreseeable future. Information systems technology is advancing almost exponentially and the explosion of this technology is fueling advances in many other biomedical research disciplines. The marked shift toward molecular medicine has engendered numerous additional changes in the complex Clinical Center environment. Molecular techniques have made it possible to identify patients who, either invariably or with a much higher frequency that the general population, will develop debilitating diseases. Remarkable opportunities for evaluating host responses to illness have recently become available through the use of computerized assessment of gene expression by microchip gene arrays. Scientists are just beginning to unmask the potential of this new technology. The development of molecular techniques has also raised complex questions requiring increased reliance on bioethicists in making decisions regarding genetic testing, genetic counseling, gene therapy, genetic experiments, and the management of results from genetic tests. Secondly, the move toward molecular medicine has fostered increased investment in the technology needed to conduct these experiments and in personnel expert in managing the extraordinary data sets engendered by this technology. Third, this trend has produced a change in the manner in which we interact with our patients. In the past, extended hospitalizations may have been needed to conduct a study. For some of these experiments, a single phlebotomy may be adequate. Consequently, the Clinical Center has observed a substantially decreased length of stay and less reliance on patient admissions to conduct these studies. Finally, the complexity and specialization inherent in molecular medicine has mandated increasing collaboration among scientific disciplines and has resulted in a clear trend toward more cross-Institute projects.

All healthcare institutions are being asked to measure performance and to demonstrate performance improvement.

Medicine has begun to focus on costly variation in practice as well as on the benefits of standardization of the processes of care. The past nine years have seen an increased focus on he industrial model of 'performance measurement' and outcomes assessment in healthcare. The focus on performance

measurement has emphasized the importance for organizations and for components of organizations to have clearly measurable outcomes and processes. In addition, regulatory agencies, such as the JCAHO require that healthcare institutions demonstrate performance improvement activities.

Patient safety and human subjects protection in clinical research have become increasingly important.

As a result of the Institute of Medicine's report, "To Err Is Human," the nation – both the lay public and the healthcare industry – has been made even more acutely aware of the importance of patient safety. The Clinical Center has invested substantial resources in a major Patient Safety initiative that focuses on the occurrence, epidemiology, surveillance for, and prevention of, medical errors. This new program has as its centerpiece a highly successful Occurrence Reporting System (ORS) that has been redesigned based on customer input and is now extensively used by Clinical Center staff. The patient safety initiative involves four major efforts, three of which are focused on determining the real numbers of errors that actually occur in the Clinical Center and attempts to assess to what extent events that occur do get reported in the Occurrence Reporting System. The fourth aspect of the initiative is designed to assess the utility of linking biometric identification techniques with two dimensional bar-coding to eliminate person-to-person and transcribing 'hand-offs,' thereby decreasing opportunities for errors. In addition, the JCAHO has developed mandatory annual patient safety goals for health care institutions wishing to be JCAHO accredited. In our first survey following the implementation of these goals, no deficiencies were identified.

Similarly, misadventures and mistakes in clinical research have given rise to increased scrutiny of the research environment and have resulted in increased regulatory requirements for a prescribed infrastructure to be in place to facilitate the conduct of research. NIH has been at the vanguard of this issue; in FY 2001 the Medical Executive published a set of Standards for Clinical Research and a process has been put in place to assure each institute's compliance with the standards. In addition, in late 2001, the NIH volunteered to have its clinical research program evaluated as a pilot for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) that has developed an accreditation process for clinical research programs. The NIH intramural program plans on formally applying for AAHRPP accreditation in 2008.

Another way in which the institution has responded to concerns about human subjects' protection is to develop programs to train investigators in the principles and practice of, as well as the ethics of, clinical research. Our organization was among the first in the nation to require completion of a basic course in clinical research principles in order to be an approved investigator on a protocol. All NIH investigators also are required to take training in the ethical conduct of clinical research. In addition, several other clinical research training courses and programs (described in more detail above) address this identified need.

The healthcare industry is also experiencing a national shortage of nurses, pharmacists, anesthesiologists, and medical and radiological technical staff.

The past decade has seen a worsening of a preexisting problem – a national shortage of crucial patient care and clinical research support personnel. Substantial workforce shortages have developed in Nursing, Pharmacy, Anesthesia, Clinical and Imaging technical staff, and information technology personnel. In FY 2007, the Clinical Center is actually faring reasonably well in most of these areas (i.e., with less turnover and fewer unfilled positions compared with other institutions in our community). In FY 2007, we continue to experience challenges in recruiting specialty nurses and anesthesiologists and other medical subspecialties for which the current salary structure is not entirely competitive with the private and/or academic sectors. We were successful in recruiting our first-choice candidate for the Chief of our Rehabilitation Medicine Department and major recruitments are ongoing for Chiefs of Imaging Sciences and the Pharmacy Department.

All personnel shortages present potential threats to CC operations, should they become more severe, and should the CC be unable to use its unique and attractive work environment to overcome market pressures. Therefore, the CC is assuming a proactive stance, including using alternative personnel authorities to speed the hiring process, making use of all available mechanisms to create and maintain competitive salary and reward structures, and aggressively marketing CC job opportunities.

Information systems technology is changing the face of medicine.

The role and importance of information systems management in medicine is changing dramatically. The Clinical Center is well-situated to take advantage of the remarkable opportunities presented by the ongoing revolution in information systems management. Teleconferencing and telemedicine are likely to be of great value in the recruitment and management of patients at sites far removed from the Clinical Center. In addition, the striking progress in information systems technology presents unique opportunities to: 1) improve the quality of care provided to Clinical Center research subjects; 2) improve the training of clinicians; 3) create substantial efficiencies in the manner in which clinical research subjects are managed in the institution (e.g., display of histological sections, radiographs, magnetic resonance and computed tomographic scans, etc.) electronically at the patient's beside or in the investigator's office, as soon as the studies have been interpreted); 4) develop streamlined techniques for protocol writing and monitoring; 5) use the substantial expertise in clinical information systems management that has been developed over the past twenty years to produce an integrated system that meets scientific, clinical, fiscal, and managerial needs; and 6) move toward a paperless, totally electronic medical record. The Clinical Center clearly needs to integrate its patient care information system with a "real-time," effective managerial and fiscal system. In addition, the Clinical Center is faced with the challenge of integrating three different types of data essential for managerial efficiency: 1) clinical patient-care data; 2) financial accounting data; and 3) research laboratory data. The challenges associated with the rapidly accelerating field of medical information systems management are: 1) staying abreast of the technology as it advances; 2) assuring that components of the organization have adequate information systems support to conduct its business efficiently and effectively, while simultaneously assuring that these systems are comßpatible with each other; and 3) making certain that the organization is consistently investing an appropriate amount of its resources into research, development, and maintenance of information systems technology. The information systems expertise already present on the NIH campus, combined with the investigational mandate of NIH, provide an ideal milieu for the development of automated, clinically relevant healthcare systems. The procurement and implementation of the new Clinical Research Information System offered the Clinical Center the opportunity to integrate these different kinds of data to improve organizational management and efficiency as well as patient care quality. This past year, a pilot project incorporating electronic documentation by physicians and other licensed independent practitioners was launched successfully. We anticipate that this project will be fully implemented across all licensed independent practitioners in the CC by the end of FY 2008. The Clinical Center has now embarked on the next phase of the development of its Clinical Research Information System by launching the CRIS II project. CRIS II is designed to integrate scientific laboratory and clinical data. Another aim of the project is to link to a specimen biorepository that manages data on the NIH collection of human samples.

In the past six years, the Clinical Center has increased its investment in information systems technology dramatically. During this time, the Clinical Center has effectively doubled the labor force working in the information systems area. The number of ongoing Clinical Center projects involving information systems improvements is substantial. In addition, plans for the new Clinical Research Center include state-of-the-art information systems management – for data management in both clinical research and clinical care.

The Clinical Center reorganized its informatics operation two departments and hired a Chief Information Officer to meet organizational needs. The leadership of the Department of Clinical Research Informatics is charged with the oversight of the management of the new Clinical Research Information System. An integrated laboratory system that has an interface to the existing Medical Information System (for our Department of Laboratory Medicine, the Department of Transfusion Medicine, and the NCI Laboratory of Pathology was also brought on-line, as were a Radiology Information System/Picture Archiving and Communication System (RIS/PACS), and a Peri-Operative Information System (POIS). An improved Pharmacy information management system is currently being designed and will be implemented within the next year.

An increasing fraction of CC patients find Clinical Center clinical research programs via the Internet. The National Library of Medicine has developed a website (*http://www.clinicaltrials.gov*) that provides regularly updated information about federally and privately supported clinical research. This unique website provides information about each trial's purpose, who may participate, locations where the study is being conducted, and phone numbers where an interested individual may get additional details. The information provided on *ClinicalTrials.gov* should be used in conjunction with advice from health care professionals. The role of the Internet in informing patients about their diseases and treatments is increasing almost exponentially. Individual patients and support groups write daily 'blogs' that characterize their diseases, associated complications, and both traditional and novel therapies. In addition to information available through the National Library of Medicine website, *www.ClinicalTrials.gov*, the Clinical Center and NIH Institute websites also provide detailed information about the intramural clinical research program and the clinical studies that are available for participation.

The public learns about medicine, medical progress, and medical misadventures from the lay press.

The American public receives a great deal of its information about medicine, medical progress, and medical and clinical research-related misadventures from the lay press. The press frequently focuses on unique, "newsworthy" numerators, while not necessarily providing relevant denominators for perspective. Such stories may contribute to a general mistrust of medicine and, in the eyes of the American Association of Medical Colleges, have fostered a general decrease in public support for academic medicine. This increasing presence of the press presents a challenge for the Clinical Center. The organization must develop techniques for making certain that the breakthroughs and benefits of the clinical research conducted at the Clinical Center receive appropriate attention in the press.

Medicine has traditionally avoided efforts intended to standardize its practice.

The fact that medicine has attempted to maintain itself as an "art" rather than a science has led to wide variation in the ways in which physicians provide care for patients who have similar illnesses or similar disease presentations. Pioneering studies evaluating medical systems and processes have documented substantial variation in care delivered to patients with similar syndromes and similar severity. These studies and the burgeoning interest in "process improvement" have resulted in an increasing focus on the systems and processes of medicine. This focus has also produced a heightened level of interest in the design and conduct of behavioral, clinical effectiveness, and cost effectiveness studies. Driven by cost concerns, the "outcomes" of various care strategies have become increasingly important. Most "outcomes" analyses are based on scientifically sound epidemiologic principles. For this reason, the Clinical Center is strategically positioned to assess a variety of outcomes (e.g., physiologic, symptomatic, functional, perceptual, economic and societal) in its ongoing natural history and disease pathogenesis studies, as well as in clinical trials. Including assessment of these kinds of outcomes will help make the basic and translational science products of the Clinical Center's work relevant to medicine today.

As medicine moves toward both primary care and toward specialties and subspecialties associated with large salaries, interest in careers in clinical research is decreasing.

One effect of the shift toward primary care and toward the high-paying specialties and subspecialties is that fewer high-quality young physicians are expressing interest in subspecialty training and in careers in basic or translational research. Thus, clinical programs find fewer qualified individuals in fellowship pools. Some training programs have closed; others have downsized significantly; others have moved to a purely clinical focus. Because of the continually decreasing candidate pool, attracting the best and the brightest at the postdoctoral fellow level from within the United States has become increasingly difficult for the intramural program. This problem is undoubtedly complex, involving heavy medical school debt burden, a move toward primary clinical care, and the incentive that academic centers have for keeping their best. With the costs of a medical education now easily exceeding $150,000, new graduates often simply cannot afford to take three to seven additional years' training before they begin to repay their debts. This challenge provides the Clinical Center and the NIH intramural program with the opportunity to address some of the financial concerns of new graduates as an incentive to coming to the intramural

program. NIH has attempted to address this problem through the creation of three separate loan repayment programs (AIDS, General and Clinical Research). These programs have become valuable recruitment and retention tools. In addition, within the past year, NIH has developed the potential to pay for licensure for healthcare providers practicing in the Clinical Center. We anticipate that this new procedure will be implemented in FY 2008.

A traditional strength of the intramural program has been that the international reputation of the NIH leads to international collaborations and attracts motivated and gifted postdoctoral fellows from the international scientific community. These fellows work in NIH programs, supporting the NIH mission. Their work at NIH, in turn, facilitates the development of their careers when they return to their respective countries.

The shift toward primary care has also resulted in an overabundance of physicians in some specialties and subspecialties and a shortage in others. This relative surplus has resulted in fluctuations in academic salaries, particularly for some historically highly paid specialties, such as radiology (particularly interventional radiology), surgery (and surgical subspecialties), and anesthesiology. The fluctuations in anesthesiology salaries initially resulted in a surplus of qualified anesthesia personnel. In response to the surplus, the academic anesthesiology leadership downsized anesthesia training programs, resulting in a significant decrease in supply of new staff. Over time, this decreased supply has precipitated a crisis in the supply of qualified anesthesiologists. As noted above, many academic institutions, including the Clinical Center, have encountered significant difficulties in being able to pay competitive academic salaries and to hire personnel to provide first-rate anesthesia services. Historically, the Clinical Center's Department of Anesthesia and Surgical Services was entirely service-based. By the end of 2002, the Clinical Center was beginning to have difficulty recruiting first-rate staff to its anesthesia program. Particularly because the program had been service-based, the discrepancies in salary between our program and those of service-based anesthesiologists in the metropolitan Washington community were substantial. The Director, NIH recommended that the CC retain an external consultant to advise the Clinical Center's Director about approaches to the shortage of qualified anesthesia staff. The consultant's report, which was delivered to the Clinical Center Director in early 2003, recommended offering salaries competitive with at least the 50th percentile of salaries from the survey of anesthesia salaries conducted by the American Association of Medical Colleges. The report also recommended the establishment of a Department of Anesthesia and Surgical Services in the Clinical Center that was similar in scope and mission to other existing successful CC clinical departments, including the creation of a modest academic research program. In response to the consultant's report, in FY 2003, the CC conducted a successful search for a new Chief of the restructured department and committed additional resources – including FTE, space and funding – to support the revitalized department. The Clinical Center's approach was entirely consonant with the external consultant's recommendations. The consultant's report argued that offering a more academic program that would allow young anesthesiologists scientific opportunities unavailable at other academic institutions because of clinical service demands, (thereby taking advantage of the Clinical Center's unique environment for clinical research). Although the progress has been "slow but steady," the Chief of the Department of Anesthesia and Surgical Services continues to have success recruiting young anesthesia personnel who have interest in science. Contract expenditures will drop substantially in FY 2008. NIH has responded by approving salaries that are competitive with those reported by the AAMC.

Government-Based External Factors

The Federal Government has reiterated an interest in downsizing and outsourcing. In 2001, the President issued five major goals for reforming management in government.

Each year, primarily as a consequence of the penetration of managed care in the healthcare marketplace, in order to compete, academic centers have fewer dollars available for clinical research. Similarly, Federal agencies are responding to five goals of the current administration. "Outsourcing," administrative consolidation, and privatization are frequent considerations. Privatization represents one mechanism that can be used to make government smaller, more efficient, and more responsive to customers' needs. Public/private partnerships have become increasingly common.

During the 1990s, the Secretary, DHHS granted numerous delegations of authority for personnel, procurement, and logistics that have been frequently requested by the NIH community. Perhaps paramount among these delegations of authority were personnel/appointment mechanisms (e.g., Title 38, Title 42) that permitted the Clinical Center to pay highly competitive salaries to most physicians, nurses and allied health professionals that previously would have been impossible under standard Title 5, General Schedule pay authorities. The combination of fluctuating salaries for some medical specialties because of market pressure (discussed above) plus the remarkable flexibility of these new personnel authorities made it possible for the Clinical Center to assimilate contracts that were previously necessary to provide adequate medical coverage for Clinical Center patients. The Clinical Center has continued to seek additional organizational efficiencies.

As noted above, the Bush Administration has reiterated an interest in government-wide management reforms and has established five major management reform goals:

- *Budget and Performance Integration.* The OMB vision is to provide a greater focus on organizational performance, by formally integrating performance/outcomes with budget decisions. The ultimate intent is to have agencies produce performance-based budgets. The linkage of performance/outcomes with budget was phased in, with OMB initially working with agencies to identify outcomes for a few programs, and to determine how effectiveness can be improved.

- *Strategic Management of Human Capital.* The President proposed to make the government more citizen-centered (i.e., ensuring as little distance as is possible between the citizens and decision-makers). Two approaches will be used to address this goal: 'flattening'/streamlining (i.e., administrative restructuring) the federal hierarchy, (i.e., reducing the number of layers), and using workforce planning to help agencies redistribute higher-level positions to front-line, service delivery positions that interact with citizens.

- *Competitive Sourcing.* The President has proposed to increase competition for activities performed by the government as listed on agency FAIR Act inventories, beginning with a requirement in FY 2003 that agencies complete public-private or direct conversion competitions involving 10 percent of the FTE listed on their Federal Activities Inventory Reform Act inventories. NIH is not immune from these goals and the CC will be required to participate in these streamlining activities. Over the past eighteen months the senior leadership of NIH and the ICs have developed some strategic approaches to these streamlining activities (examples follow).

  – *Improving Financial Performance.* The primary goal of this initiative is to reduce erroneous payments.

  – *Expanding Electronic Government:* The President proposed a coordinated approach to E-government that crosses agency boundaries. Specifically, the administration wants to: 1) prioritize and manage e-government projects effectively by improving IT capital planning; 2) create a citizen-centered web presence and build e-government infrastructures that include e-procurement and e-grants; and 3) develop an E-government approach that is performance/outcomes oriented and contributes to the administrative restructuring initiative (and that includes specific goals). To accomplish this goal: 1) agencies will be required to identify IT investments that can be redirected, restructured or consolidated; and 2) agencies should maximize the use of electronic means to deliver services and benefits in a citizen-centric matter, while assuring both security and privacy. NIH is currently in the midst of a major initiative that is designed to centralize many information technology functions on the campus.

Regulatory requirements are becoming more stringent and more burdensome.

Requirements of organizations that regulate the conduct of patient care and clinical research in the Clinical Center have increased substantially over the past two decades, in many instances without clearly adding value. Some oversight and regulatory activities arise from within NIH (e.g., Office of Protection from Research Risks, Office of Human

Subjects Research, Recombinant DNA Advisory Committee, Office of Scientific Integrity, DHHS ethics regulations and reviews for clinical investigators' personal financial holdings, among others); others arise from IC programs (e.g., Cancer Treatment Evaluation Program, NCI); others are Departmental- or Agency-based in origin (e.g., Inspector General, Food and Drug Administration); others arise from other Departments within the government (e.g., Nuclear Regulatory Commission, Occupational Safety and Health Administration), and still others arise out of a continuing need for external evaluation and accreditation of clinical activities (e.g., Joint Commission on Accreditation of Healthcare Organizations [JCAHO], College of American Pathologists [CAP], American Association of Blood Banks [AABB]), and oversight/accreditation of clinical research activities (the Association for the Accreditation of Human Research Protection Programs [AAHRPP] and the National Committee on Quality Assurance [NCQA]). The Clinical Center faces the challenge of meeting the increasing requirements of a burgeoning list of regulators with decreasing staff, decreasing resources, and a physical plant that is in dire need of revitalization. Simultaneously, the Clinical Center has the opportunity to consolidate certain of these activities (e.g., the AABB or CAP surveys now substitute for both certification by the Center for Medicare and Medicaid Services for the Clinical Laboratory Improvement Act of 1988 [CLIA] and JCAHO surveys), and the requirements of some others provide justification for the creation of the new Clinical Research Center. The increasingly burdensome nature of regulatory requirements was identified as a major obstacle to the successful conduct of clinical research in a survey of NIH Principal Investigators in FY 2003. In order to attempt to address some of the bureaucratic barriers to establishing new clinical research protocols, the Clinical Center, working with several IC scientists, is developing a software program, called ProtoType, that is designed to assist with the increasingly cumbersome process of protocol authoring. In addition, the Deputy Director of the National Institute of Allergy and Infectious Diseases has launched a campus-wide initiative to attempt to streamline the bureaucracy inherent in the clinical research process.

In light of the increasing activity in the area of molecular medicine and the virtual explosion of new laboratory tests that can be used for diagnosis and prognosis in medicine, the Clinical Center, and, in fact, the entire NIH has come under increasing pressure to have its laboratories comply with CLIA. The Clinical Center Director was given the task of ensuring that all Intramural laboratories performing laboratory tests linked to patient identifiers that may be used for patient care meet CLIA standards. At the request of the Clinical Center Director, the Chief of the Clinical Center's Department of Laboratory Medicine established a highly successful program to facilitate NIH laboratories' compliance with the CLIA regulations. To date, the Department of Laboratory Medicine has worked with 72 laboratories throughout the NIH and has assisted in the CLIA certification of 58 of them. Currently, 38 laboratories on campus maintain CLIA certification.

Whereas the Clinical Center has been determined to be a 'non-covered entity' for the new Health Information Portability and Accountability Act (HIPAA), the overall impact of HIPAA compliance by NIH collaborators on the Intramural clinical research program remains to be determined. Although the existing Clinical Center Medical Information System cannot be reengineered to be compliant with the tenets of the HIPAA legislation, the Clinical Center's Director has stated publicly that the new Clinical Research Information System will address the spirit of the HIPAA legislation.

In addition to the regulatory requirements for the Agency, for clinical care, and for hospital management, NIH also faces increasing regulatory requirements for the conduct of clinical research. Regulatory requirements for human subjects protection, for radiation safety, for genetic therapy, for drugs and devices, for recombinant DNA, and for a variety of other issues have increased dramatically over the past several years, resulting in an increasing time from the development of a novel hypothesis to the implementation of a clinical research protocol. The Clinical Center is working diligently to try to streamline these processes as much as is possible. The CC Director has developed an electronic protocol-authoring tool (ProtoType) that should facilitate electronic submission and management of new protocols. In addition, the Deputy Director for Clinical Research of NIAID has assembled a campus-wide team of stakeholders who are working systematically to address as many of these regulatory impediments as possible.

Agency- (NIH-) Based External Factors

As a result of a constellation of factors, the culture of the NIH Intramural program is changing.

Several factors, taken together, have produced, and are continuing to produce, a substantial change in the environment and culture of the NIH Intramural program. Among these factors are the following:

- NIH and Institute administrators have made a major investment in scientific quality. Several Institutes have conducted detailed external reviews of their intramural programs in the past sixty months. In addition, an external panel convened by the NIH Director (i.e., the Marks/Cassel Committee) issued a detailed report in 1994 that provided clear recommendations to revitalize the intramural program.[16]

- NIH has developed and implemented new, more rigorous tenure-track and tenuring policies.

- The rigor of scientific reviews has been intensified.

- Both the current and immediately preceding NIH Director, have made major efforts to elevate the status of clinical research on the NIH campus. The net effect from these leadership efforts has been that several institutes have initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. The Clinical Center has developed a proactive strategy for managing new programs and significant program expansions that includes creation of a project team comprised of IC and Clinical Center stakeholders; scheduled meetings with this implementation team, creation of a project implementation plan, and ongoing follow-up with IC leadership and staff to assure smooth handoff and implementation.

- Successful conduct of clinical research is essential to biomedical progress. Nonetheless, the processes of clinical research are complex, labor-intensive and expensive. For these reasons, the NIH Director developed a 'road map' for the continued success of clinical research, both in the NIH intramural program, as well as throughout the United States. The NIH Director's Road Map has helped plot the path for clinical biomedical research in the United States and will help define the precise roles that the NIH Intramural clinical research program and the NIH Clinical Center will play in clinical sciences in the decade to come. The road map also helps define the relationship of both the NIH Intramural clinical research program and the NIH Clinical Center to clinical research programs in the extramural clinical research environment.

- As technology advances, institutes are increasingly requesting more and more sophisticated clinical research support. During institute planning meetings for the past eight years, an increasing number of requests for clinical research support activities (as opposed to standard care support) have been received. The NIH Intramural Research Program needs to develop a process for deciding (in concert with its collegium of customers) which of the requests to implement, as well as how to present the increased costs associated with these projects to both internal and external customers. Such services (which are often both efficiently and effectively centralized) add substantially to the expense of running the Clinical Center. One example of such a service is the Clinical Center's cell processing facility, which provides protocol-specific cellular therapy support for many specific IC protocols.

- The costs associated with conduct of biomedical research are escalating faster than inflation, necessitating that Institutes carefully evaluate costs and quality of proposed intramural projects with more rigor than has been done in the past and that the Clinical Center develop strategies for prospectively determining the likely costs associated with new scientific projects (the PRIA project described above is one such attempt).

- A variety of factors have conspired to produce an unprecedented level of trans-Institute collaboration and sharing of resources, among them:

  – Increased emphasis on clinical research and on research quality on the NIH campus;

  – Increasing costs of clinical research;

  – Increased reliance on molecular methods, genomics, proteomics, and specific expertise, not necessarily associated with an IC or a discipline, to conduct complex studies;

– Increased emphasis by Clinical Center and NIH leadership on planning;

– Emphasis on the part of Clinical Center leadership on the inclusion of major customers, partners and stakeholders in the planning process;

– Joint Clinical Center/IC appointments in Imaging Sciences, Bioethics and Clinical Pharmacology;

– The construction of the new Clinical Research Center, which is not organized with dedicated "Institute-space," has fostered collaboration among the "partners" who share 'program' space and resources in the new building.

– The NIH Director's Road Map initiatives that require trans-institute collaboration.

– The new recommendation to initiate trans-institute "Manhattan" -style translational projects.

- The Clinical Center now has six years' experience using the 'school tax' funding stream. This approach to Clinical Center funding was established to bolster institutes' clinical research programs and likely has contributed to expanded use of the Clinical Center. Institute pay a "school tax" based directly on the size of the Institute's intramural appropriation to support the Clinical Center (without regard to the extent to which the Institute uses the facility). The disincentive to use the Clinical Center (in the previous funding scheme) has been replaced with an incentive to use it. This approach also solves the problem identified by the previous DHHS Secretary's evaluation team of the interdependence of Institutes' budgets under the prior funding structure. As noted above, faced with a flat budget for five years, the Clinical Center shifted some costs for certain research-related services to the ICs, resulting in a resurfacing of concerns about the appropriateness of the school-tax approach. As this document is being written, several possible modifications to the Clinical Center's funding stream are under consideration by IC and NIH leadership.

- The Advisory Board for Clinical Research oversight of Clinical Center operations lessens the extent to which the Clinical Center must try to respond to the competing priorities of its Institute customers. This increased independence should permit the Clinical Center to become more efficient and to foster collaboration among the Institutes conducting research in the Clinical Center.

- Consonant with both the DHHS initiative to restructure and streamline administrative services as well as the President's outsourcing initiative, the NIH leadership has imposed FTE ceiling reductions for all ICs. The Clinical Center's ceiling has been reduced from an operational ceiling of 1975 in 2002 to 1857 for 2007. The proposed ceiling for 2008 is 1837; however, each IC will be allowed an FTE target of 102 percent (to account for vacancies), raising the functional CC ceiling to 1883. Thus, even though the functional ceiling has been raised, the CC budget will not be increased to accommodate additional personnel to fill these slots. At a time when clinical research programs are expanding and being reinvigorated, and at a time when the Clinical Center budget has been essentially flat, at best, these budget FTE constraints present an additional formidable challenge to CC leadership and will require creativity and stewardship of resources to meet these expanding service needs.

The NIH budget receives intense scrutiny by Congress and the President.

Twenty-five years ago the costs of clinical research were not a primary concern of the ICs conducting research in the Clinical Center. In the late 1980s and early 1990s, however, the increases in the costs of clinical research in the Clinical Center began to rise significantly faster than the overall intramural budget. Almost simultaneously, the ICs became aware of the substantial differences in the costs of clinical versus bench research. Some ICs began to divest themselves of their clinical research portfolios in order to cut costs. When the current Clinical Center Director was appointed, he made financial stewardship and increased financial accountability a primary goal for the organization. New planning mechanisms, new information systems, and new reports of utilization were developed to provide more and more accurate information to the Institutes.

For the years 1995 to 2002, both the Congress and the President publicly stated a goal of doubling the NIH budget. Thus, NIH (and the Clinical Center) have received substantial budget increases for the past several years. The process of doubling the NIH budget was completed in 2002. Subsequent years' funding was modest, by comparison and the Clinical Center's budget was held flat by NIH for that period. Given that certain hospital costs (e.g., pharmaceutical inflation, personnel costs, inflation of costs associated with the purchase of hospital soft-goods) will continue to escalate at a rate that far exceeds intramural budget growth, Clinical Center leadership and managers need to manage our expenditures conservatively for the foreseeable future.

The Clinical Center has taken several approaches to increasing its organizational efficiency, including the assimilation of expensive contracts, the institution of operational reviews for Clinical Center departments, and increasing reliance on the Advisory Board for Clinical Research, whose extramural members have substantial expertise in healthcare operations and financing twenty. The Board, which includes numerous healthcare executives from prestigious extramural academic centers, provides advice to the Director of the Clinical Center concerning Clinical Center operations. The modified governance structure and the Advisory Board for Clinical Research have provided Clinical Center leadership with the opportunity to manage the operations of the organization more efficiently than ever before. Nonetheless, the very tight financial times brought about by having essentially flat budgets for the past five years have prompted NIH and IC leadership to revisit the school tax and the Clinical Center's funding stream. Other possible approaches to increasing revenue include:

- Third party recovery for aspects of care provided at the Clinical Center;
- Developing partnerships with industry (including cost recovery) to use Clinical Center excess capacity;
- Developing partnerships with extramural investigators (including cost recovery) to use Clinical Center excess capacity.

Institute research agendas compete directly with each other; for NIH to improve overall corporate efficiency, collaboration among ICs is essential.

Occasionally, IC research agendas compete directly with each other. Although NIH efforts have been expended over the past several years to attempt to facilitate trans-IC collaboration, because of the highly competitive nature of some areas of investigation, collaboration has sometimes been difficult to achieve. Because ICs compete for Clinical Center resources, while independently valuing widely disparate services, the Clinical Center is faced with the challenge of meeting these varied requirements while fostering collaboration and cooperation among IC scientists in a cost-competitive environment. In addition, the Clinical Center is faced with the challenge of integrating basic science and basic scientists into the clinical research agenda of the NIH intramural program. Because many basic scientists are unaware of the clinical opportunities and venues in which to apply basic science findings, the Clinical Center is faced with the challenge of improving the accessibility of the Clinical Center and its resources to basic scientists.

As noted above, collaboration among Institutes has become increasingly important with the opening of the new Clinical Research Center. Institutes share space related to their clinical programs in the new CRC. Since the design of the new building is not "institute-based," but rather based on clinical disciplines or programs of care. Institutes share space and resources in the new facility. The nature of modern molecular medicine calls for more cross-Institute collaboration.

NIH has endorsed a change in governance for the Clinical Center.

The creation of the Clinical Center's Board of Governors (now the Advisory Board for Clinical Research) in 1996 provided the Clinical Center with the unique opportunity to be supervised through a governance structure that can prepare the organization to compete effectively in the clinical research arena for the foreseeable future. The new governance structure has permitted the following unique opportunities for Clinical Center management:

- The opportunity to seek the expert advice concerning hospital operations and management from nationally recognized authorities in hospital and research management;
- The opportunity to manage the clinical research process more efficiently than under the prior system;
- The opportunity to facilitate change far more efficiently than under the prior system;
- The opportunity to seek and develop organizational flexibilities not possible under the existing system (e.g., delegations of authorities, generic clearance for surveys, etc.).

The expanded role for the Advisory Board for Clinical Research mandates that this board include ongoing assessment of, and encouraging the further development of integration of the clinical research programs across the campus. The Board is also providing the NIH Director and the Clinical Center Director with advice about the creation of a meaningful interface between the NIH Intramural Research Program and the network of Clinical and Translational Science Award grantees.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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NIH Clinical Center

For administrative use
January 2008