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Strategic Plan

Environmental Assessment

Warren Grant Magnuson Clinical Center

National Institutes of Health

2004

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Executive Summary

The Warren G. Magnuson Clinical Center of the National Institutes of Health faces substantial challenges and opportunities in 2003 and beyond. Following a 7-year period, during which the budget of the National Institutes of Health was doubled, the NIH faces substantially smaller budget increases. 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 fifth iteration of the Clinical Center's strategic plan environmental assessment. The Clinical Center has 8 years' experience using, evaluating, and modifying its strategic plan. In those 8 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; reviews 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 supports 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 version of this document, remain evident after 8 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 did 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
- The fact that the Clinical Center did not offer complete, integrated medical and surgical services was viewed as an institutional weakness by some customers.

Progress in Addressing Identified Weaknesses

Over the past 8 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; however, to make certain that the Clinical Center's major stakeholders have an opportunity to contribute to the governance, the NIH Director subsequently created additional advisory panels. Over the past 5 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, a new advisory panel, the Blue Ribbon Panel on Intramural Clinical Research, convened by the NIH Director in the fall of 2003, will once again assess the efficacy of current Clinical Center governance structures. Many of the bureaucratic impediments inherent in some official government processes were removed by the Secretary, Department of Health and Human Services. A new Clinical Research Center (CRC) has been funded and constructed and will be ready for occupancy in 2004. Clinical Center staff are busily preparing for the transition from the old to the new building. In addition, the process of replacing the existing Medical Information System with a comprehensive, mission-oriented Clinical Research Information System is proceeding rapidly and should be in place by the time of the move into the new CRC. The organization provides improved and far more detailed financial data to both Institute and Clinical Center customers. These changes and the impact produced by these changes are discussed in detail in this update.

Weaknesses Identified Since 1996

In the 5 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 ensure 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 different infrastructures to support their independent investigators and to support the processes of clinical research;
- Outpatient surgery and ambulatory care models are in need of redesign.

Progress in Addressing Weaknesses Identified between 1996 and 2003

- 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 improvements;
- The Clinical Center has launched a major initiative to ensure workforce diversity;
- The Clinical Center continues to work with advisory groups, such as the Clinical Center Research Steering Committee, 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 a set of Standards for Clinical Research that represent the minimum infrastructure that all NIH clinical research programs should have in place to ensure appropriate investigator support, as well as the safe conduct of clinical research.

Opportunities and Threats

As part of its environmental assessment, the Clinical Center has also evaluated opportunities and threats that have resulted from changes in its external and internal environments. Most of the factors initially identified as influencing change in healthcare delivery and clinical research are still in our environment in the year 2003 and beyond. Among these factors are:

- 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; required diversion of resources to NIH safety and preparedness activities; resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries; and fundamentally altered the day-to-day workplace lives of individuals working on the NIH campus.

- 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 present substantial threats to the public health and are associated with an urgent need to answer scientific questions that may make it possible to mitigate the damage produced by these infectious diseases.

- The declining U.S. and global economies 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 medicine and biomedical research) to provide what has come to be a higher 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 U.S. 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.

- Changes in governmental regulatory requirements and governmental oversight are driving change in medical practice and clinical research. 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 is under construction and is scheduled to open in 2004.

– The organization and administration of patient care in the new facility will be different from current processes. The new building and the change in clinical and administrative governance in patient care presents the CC with a unique opportunity to re-evaluate the processes that we use to provide care and affords us the opportunity to redesign some of these processes to improve patient care quality and/or to improve efficiency.

– The new building is also a stimulus for the Institutes to improve and expand their clinical research programs. Several Institutes have initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. These substantial program modifications and expansions require careful assessment by CC administrators and department managers to ensure 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 offering clinical research opportunities to underserved populations has continued through 2003. 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, DC. NCI has organized a smoking cessation clinic in Rockville, MD, and several other programs are considering additional off-site programs to supplement their existing clinical research portfolios and to increase diversity in existing programs. 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.

– As technology advances, Institutes are requesting more and more sophisticated (and therefore, often expensive) clinical research support.

– To address another perceived organizational weakness, the Clinical Center is renovating its Medical Information System, again requiring careful assessment of the processes of care, with the intent of moving toward electronic patient records. The contract for the backbone of the new system was let in 2003, and the current plan is to implement the initial phase of the new system with the move into the new CRC. The new information system will give the organization an opportunity to develop better departmental, financial, and back-end (i.e., Institute) clinical research support.

– The past several years have seen a doubling of the NIH budget. This doubling was completed in 2003. NIH is preparing for leaner budgets in the future (the so-called "soft landing"). The fact that certain hospital costs will likely continue to escalate at a rate that far exceeds intramural budget growth demands cost-consciousness, cost-effectiveness, efficiency, and creativity from Clinical Center managers.

– 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 and throughout the United States. The Director's road map should define the future path for clinical biomedical research in both the short and long runs. This initiative will help define the Clinical Center's future role and its relationship to clinical research programs in the extramural clinical research environment.

Thus, over the past 8 years, several factors have produced 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 posed by these changes in the context of the identified strengths and weaknesses inher-

Introduction

The Clinical Center finds itself poised for dramatic 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. The Clinical Center must identify its internal strengths and capabilities and 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 given 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 the relevant practices to the Clinical Center's environment.[1] In the 8 years since this document was initially drafted, the Clinical Center has sought additional input from the following: 1) its major customers, the NIH Institutes (through the Clinical Center Research Steering Committee, the Funding Advisory Review Board, 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 surveys and 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 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 2003 environmental assessment. The previous edition of this document was written in 2001. 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 in healthcare, clinical research in general, and clinical research at the Clinical Center.

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 of 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.

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 7 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 at 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 collaborate in research studies and have made numerous substantive scientific contributions. Alignment with the research mission is a highly visible goal at all levels of the organization.

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

As noted above, unlike most academic medical centers, studies conducted at the Clinical Center 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 the highest quality of 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 with the Clinical Center than the relationship patients have with academic medical centers to which they are admitted. Clinical Center subjects are partners in the research carried here. For this reason, the importance of providing excellence in patient care cannot be overemphasized. The highest quality of patient care remains a major objective for Clinical Center staff, an objective that has been reached consistently during its first 5 decades of existence, and a goal toward which Clinical Center administration and staff continuously strive. Over the past 3 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 patient care 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. 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 allows it 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 8 years since the initial draft of this document was published, many of the Institutes have initiated external reviews of their intramural clinical programs. The National Academy of Sciences' Institute of Medicine recently issued a major report addressing topics relating to the overall governance of NIH and underscoring the importance of clinical research in the biomedical research enterprise. 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 started to lay out a road map for the continued success of clinical research in the United States. The Director's road map should help define the future path for clinical biomedical research in our country, in both the short and long terms. These and other initiatives suggest that, across the campus, interest in high-quality clinical research continues to increase. In addition, the planning 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, 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 and to scientific opportunities when they arise. For example, the Clinical Center responded quickly to study the following: 1) AIDS and HIV infection when the disease first surfaced in society; 2) multiple-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; and 5) protocols to study the pathogenesis and therapy of Severe Acute Respiratory Syndrome (SARS).

- **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 numerous molecular 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, 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 and self-assessment, the Clinical Center initially identified several issues that might be considered programmatic or systemic weaknesses.

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

Historically, governance of the Clinical Center was unclear, with multiple committees providing oversight. The net effect was 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 convened a new Board of Governors, which developed and approved a streamlined organizational reporting system for the Clinical Center. This new system made Institute stakeholders feel somewhat disenfranchised and they appealed to the Director of NIH. The NIH Director appointed an advisory board, initially called the Clinical Center Advisory Council, which 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. This council was reconstituted by the Acting Director of NIH in FY 2000 as the Clinical Center Research Steering Committee (CCRSC). The CCRSC continues to provide a venue for Institutes to contribute to the governance of the Clinical Center, particularly on issues relating to the science agenda. An additional advisory group, the Funding Advisory Review Board (FARB), was constituted to recommend funding levels for centralized services on the campus (including the Clinical Center). 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.

Over the past 6 years, the Clinical Center Director has sought advice from other important stakeholders, including Clinical Center 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. The governance structure for the Clinical Center remains complex and will be reviewed in detail by the Director's Blue Ribbon Panel on Intramural Clinical Research. NIH leadership will reassess the roles of each of the various advisory groups in the governance of the Clinical Center through this review.

- **The Clinical Center is subject to bureaucratic inflexibility in personnel, procurement, and fiscal management, especially in the existing budget process, which is confusing and frustrating.**

As part of the National Institutes of Health, the Clinical Center reports to the agency, to the Public Health Service (PHS), and to the Department of Health and Human Services (DHHS). 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, 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…[5] …The Clinical Center needs a great deal of flexibility to operate productively."[6] The 1996 report of the DHHS Secretary's external review committee 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."[7] 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[8] . . . The Clinical Center should have a means of retaining reserves from year to year."[9] 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."[10] These points were valid in 1996 and remain so in 2003.

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 for new clinical research initiatives of the Institutes. To address the issue of inadequate cost accounting, the Clinical Center hired a consultant to provide advice about the establishment of an activity-based costing system. The recommendations of the consultant have been 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 very useful to the Clinical Center's administration, as well as to its major customers and stakeholders.

Performance measurement continues to be a major organizational focus. During the past 6 years the Clinical Center has collected and continued to refine organizationwide 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 operations. 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 allows the Clinical Center to track progress toward these organizational goals. The performance measurement initiative is relevant to both the operations of the Clinical Center and 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 DHHS Secretary. Use of these delegations has helped to address some of the problems relating to inflexibility in personnel and procurement systems.

During the past 5 years, the Clinical Center's Office of Human Resources Management has developed (and had approved by the DHHS Secretary) a pilot program to use a new personnel authority, Title 42, to appoint clinical research support staff. This project—which 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.

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

Clinical researchers nationwide have long held the perception that NIH 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 about the standing of clinical research, the then-Director of NIH convened a panel of experts to review the status of clinical research in the United States and make 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 Director has developed an introductory course on the principles and practice of clinical research, which has been used to train more than 2,900 students. The director has also edited and

published a textbook 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. Collaborative master's degree programs in clinical research have been developed with Duke University and the University of Pittsburgh. 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 (complete with a newly published textbook) and a bioethics course have 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.

- **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."[11] 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[12] . . . The External Advisory Committee agrees with the need for renewal of the Clinical Center."[13]

For these reasons, NIH, the Department of Health and Human Services, and Congress approved the concept of building a new Clinical Research Center. An architect was selected, a private developer was hired, and construction will be completed in 2004. To increase customer input, teams of "Partners" (i.e., Institute staff, Clinical Center staff, and patients who will share space and resources in the new building) were convened to assist in the design process. The Clinical Center and its IC partners are aggressively planning for the transition from Building 10 into the new CRC. Activation of the new CRC is scheduled for fall/winter of 2004.

- **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 to update and streamline outpatient/ambulatory surgery processes in the Clinical Center. A survey of Clinical Center staff conducted in 2002 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 members of the CC's Surgical Advisory Committee identified the same problem with outpatient/ambulatory procedures. In 2003, 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 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 2004.

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 facilities. In addition, they identified unmet clinical needs (e.g., space to have private discussions with patients about treatment, protocol options, or prognoses). The Clinical Center Director's Patient Advisory Group has expressed similar concerns. For these reasons, the Clinical Center is currently assembling a team of stakeholders to assess possible restructuring of its outpatient services and plans to work with involved investigators and staff to address these important issues in the coming year.

- **The Clinical Center lacked a strategic plan in 1995.**

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. One external review 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."[14]

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. This strategic plan has been in place and functioning well as a template for progress over the past 96 months. 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 in FY 2001, FY 2002, and FY 2003. An FY 2004 plan is currently being implemented. 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 8 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 June 1999 a new Chief Information Officer was appointed.

Within the next 12 months the Clinical Center will launch a new Clinical Research Information System. During the past year, the contract for the Clinical Research Information System "backbone" was let and implementation of the new system is underway. In addition, during the past 8 years, the CC Budget Office has implemented and refined an activity-based costing system that provides markedly improved resource utilization data to IC customers. These projects provide the infrastructure for further progress in financial accountability and responsiveness to our customers' and stakeholders' needs. In 2001, the Clinical Center also completed and launched a third project, a Web-based Clinical Center "Service Formulary" that details all of the services provided by the Clinical Center and the Institutes.

- **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."[17]

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. The Clinical Center Board of Governors endorsed the patient recruitment project as part of the long-range goals 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 the end of the 1990s, patient recruitment efforts were viewed as increasingly less successful.**

For a variety of reasons, patient accrual decreased through the end of the 1990s. Despite significant efforts by researchers to recruit patients, some excellent and important studies languished for lack of patients.

As noted above, the primary mission of the Office of Patient Recruitment and Public Liaison is to support patient recruitment and referral efforts. The main goal of the service is to increase the enrollment, including women and minorities, in clinical research studies at the Clinical Center. Performance data from this new service suggest a brisk response to these efforts. Concomitant with these efforts and those of the ICs to rebuild and bolster their intramural clinical research programs, with the exception of the decrease in 2002 related to the events of September 11, 2001, Clinical Center patient activity has been increasing for the past several years. For example, in FY 2003, NIH investigators enrolled 10,262 new patients in Clinical Center protocols, 23 percent of whom were referred to their studies by the Office of Patient Recruitment and Public Liaison.

- **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 stroke difficult, if not impossible. Not offering these services necessitates 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 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 the following:

- 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 studies of acute medical problems (e.g., stroke, myocardial ischemia) that 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 and the University of Pittsburgh 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, and Georgetown University) 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 who maintain clinical research interests in those fields. No formal system of accountability or responsibility exists for the consulting 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 consulting services. The first steps in addressing the issue were the following: 1) to obtain Institute agreement about the "ownership," or responsibility for, the various consulting services 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 quality of consultations provided. 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 electronic aspect of this project encountered many obstacles but was finally launched in 2003.

The Clinical Center has also made a substantial commitment to increase the quality and availability of clinical research training over the past 4 years, as described above. The NIH Director established a Clinical Research Training Program for medical students (analogous to the Howard Hughes's Institute-funded training program in the basic sciences). Students have the opportunity to take courses while being mentored by and working on clinical projects with successful intramural clinical researchers.

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 a multidisciplinary Pain and Palliative Care team, and a General Internal Medicine Service (which has now grown to include three physicians and two nurse practitioners), as well as a General Pediatrics Service (which has recently added a second pediatrician) to provide general pediatrics consultative support.

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

Because it is 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 conduct surveys of its customers and other partners. The CC partnered with the Harvard-based Picker Institute for its initial patient survey. Results from the survey identified areas that needed attention in the organization and 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. 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.

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 positive effect on community relations since its inception 3 years ago.

- **Customer service has not been 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. The Clinical Center embarked on a major customer service initiative. An external contractor was hired to assist with training staff throughout the organization—focusing particularly on 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 the most recent patient survey suggest 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 5 years both NIH and the Clinical Center have 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 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).**

While the Clinical Center, as a service organization, needs to be responsive to the program needs of its IC customers, it should not be involved in setting the clinical research agenda. The Clinical Center Research Steering Committee (CCRSC)—which includes some Institute Directors, the NIH Deputy Director for Intramural Research, and some Institute Scientific and Clinical Directors—is charged with providing the Clinical Center Director with advice about intramural clinical research priority setting.

- **The Clinical Center and the institutes have different 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 infrastructure that all NIH clinical research programs should have in place to ensure appropriate investigator support, as well as the safe conduct of clinical research. Beginning in 2003, the Medical Executive Committee 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 these opportunities: 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.

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 changes 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 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, required diversion of resources to NIH safety and preparedness activities, resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries, and 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. Additional acts of terror, including bioterrorism, seem 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, security staff swab the vehicle for explosives before permitting its entry into the underground garage. The Clinical Center has responded to these new circumstances in several ways: 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 staff); and by developing close working relationships with neighboring Montgomery County hospitals, including the leadership of the National Naval Medical Center and the leadership of Suburban Hospital, as well as with the Montgomery County Collaborative Task Force (for emergency preparedness), to develop cooperative community preparedness plans. The impact of these changes on the NIH workforce cannot be underestimated. Staff are faced daily with increasing levels of uncertainty and respond almost invariably with unprecedented anxiety.

In 2002, the DHHS Secretary asked the NIH Director to assist with the revitalization of the healthcare infrastructure in Afghanistan. The Clinical Center Director and his immediate staff have led this effort for NIH and have continued to support this effort, which began with the restructuring of a maternal and child health hospital in Kabul, the Rabia Balkhi Hospital. Clinical Center staff continue to review progress with the team at the site in Kabul and to provide advice and support for this initiative.

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 present substantial threats to the public health. These factors also are associated with the urgent need to be prepared to address and answer 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 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. Finally, the mailborne epidemic of anthrax that occurred in 2001 and the concern in the U.S. Federal Government that smallpox could be used as an agent of bioterrorism, which prompted a nationwide immunization program, are examples of the existing bioterrorism threat.

Emerging infectious diseases, resurgent infections, and biological agents connected to the risk of terrorism are all associated with a plethora of unanswered scientific questions. The Clinical Center provides an ideal venue in which to address some of these questions, and over the past 3 years, the Clinical Center has seen the development of clinical protocols that address some of the issues concerning West Nile virus, SARS, multiple-drug-resistant tuberculosis, 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 respond to these public health emergencies when they arise and to answer some of the very perplexing scientific questions associated with them. For example, the Clinical Center Department of Laboratory Medicine Microbiology Service played a pivotal role in interpreting cultures from potentially exposed individuals during the mailborne anthrax epidemic, processing thousands of cultures. The presence of patients who have these infections presents formidable challenges to the NIH workforce, and the threat of the emergence of these diseases—either through a natural epidemic or an act of bioterrorism—is another source of anxiety for both the NIH staff and the surrounding community.

The declining U.S. and global economies have added a degree of instability to the NIH environment.

The U.S. and international (and, particularly, the Far Eastern) economies have been struggling during the past 4 years. The economic downturn has resulted in restructuring of Federal, State, and local government 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 be impacted. The fact that the cycle of doubling the NIH budget was completed in 2003 also suggests the potential for leaner budget years in the near future.

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. Increased social awareness has led to a better understanding 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 offers NIH and the Clinical Center 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 25 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, come to accommodate these changes in values. 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 unique measures of the 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 "clinical research support" is an important component of the support provided by certain 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, if anything, 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 3 decades, 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 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 60 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.

The United States is also experiencing an epidemic of obesity. Under the prevention and wellness umbrella, the DHHS leadership has launched a major initiative to combat obesity in the United States. Several NIH Institutes are currently collaborating in the development of an NIH initiative that will be designed to complement DHHS efforts.

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 40 years, the tools of medicine have changed more than in the past 500 years. NIH contributes to this rapidly advancing field and as a result, often has unique opportunities to use these emerging technologies to investigate the frontiers of medicine. Since the Clinical Center is ideally positioned to adapt swiftly to the development of new technologies, it enjoys 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 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 has 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 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 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 10 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 creation (in collaboration with private industry) of a new, state-of-the-art cell processing facility; new positron emission tomography/CT imaging technologies; the purchase of upgraded magnetic resonance imaging capacity; the purchase of new stereotactic neurosurgical equipment; 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; renovation of a part of the CC's 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 Tuskegee study, the Willowbrook studies), some segments of the U.S. population have developed a profound 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 the 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 that 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, which represents black physicians. The Office of Patient Recruitment and Public Liaison 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 established a Clinical 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 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, insurance companies have increased copayment rates, and patients are now paying an increasing fraction of healthcare costs out of their pockets. For these reasons 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, this customer focus should give the Clinical Center 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 8 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 2003 are focusing on several issues, among them: 1) ready access to healthcare and to their healthcare providers; 2) provider responsiveness to questions and problems; 3) patient safety; and 4) the level of customer service available from their providers.

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

While 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 of international standardized tests from 15 developed nations, U.S. students placed last in biology, third from last in chemistry, and fifth from last in physics. Further, the talent pool entering science occupations is diminishing. For example, the percentage of National Merit Scholarship finalists entering careers in science, the health sciences, and engineering has 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. 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 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 not otherwise 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 3 decades have contributed significantly to the escalation of healthcare costs in the United States. Although the Clinical Center has had few such

claims, the number of claims is increasing, and 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 and 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 and complementary" medicine is assuming an increasingly visible role 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 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 nontraditional 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 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 in 2001 the Clinical Center established a Pain and Palliative Care Service that regularly uses a variety of complementary and alternative medicine strategies.

Cost-Based External Factors

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

In the past 2 decades, healthcare costs have escalated exponentially, primarily at consumers' expense. The Federal Government, as well as State and local governments, has become intensely interested in controlling costs. This interest has 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) 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 "nonphysician" 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 2003.

Cost considerations have led to a rethinking of such pivotal issues as the basic processes and models of care delivery; the increasing reliance on nonphysician 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 our need 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 5 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 the number of 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, and by the construction of a 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 percent and 25 percent, respectively, compared with 1997. In addition, several Institutes are currently recruiting for tenure-track clinical investigators as well as for staff clinicians, and these activities should also increase the number of principal investigators who have active clinical research projects and the number of active projects.

These dramatic trends provide both 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 institutionwide focus for the Clinical Center. Despite this emphasis on efficiency, the Clinical Center has 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).

- 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, that 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.

- 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 the following: 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 number 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 the Health Care Financing Administration (HCFA) (now the Centers for Medicare and Medicaid Services [CMS]) to discuss the potential for recovering 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 gave Clinical Center leadership a great deal of insight into the current status of the insurance/managed care industry. The Clinical Center also conducted a 6-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 how 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.

- The trend toward the use of nonphysician providers affords the Clinical Center an opportunity to evaluate the existing model of patient care and to consider the expanded, creative use of nonphysician care providers in intramural clinical research. In addition, the creative use of such personnel may help solve 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 less 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 for patients among healthcare delivery organizations has become even more of a driving force in the healthcare environment in the past 30 months. The aggressive competition for patients and clinical research subjects provides both opportunities and challenges to the Clinical Center. The competition will likely make recruiting patients for clinical studies more difficult. Competition has already had a profound impact on the academic medical community. Institutions that used to operate profitably and had 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 prestige. The Clinical Center's new extramural alliances (discussed above) should strengthen its own and its partners' competitive positions.

- The explosion in technology discussed above provides the Clinical Center with a unique opportunity 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. 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 much longer. As a result, such patients often remain at risk for disease- or therapy-related, care-requiring complications for extended periods. Such complications are often expensive and labor-intensive. Rapid progress in keeping patients alive presents

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., NIDDK, NIMH, NIAMS) to design and implement 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 and 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.

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 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 counseling, gene therapy, genetic experiments, and the management of results from genetic tests.

Second, 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 how we interact with our patients. In the past, a study might have required extended hospitalizations. Now, 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 variations in practice as well as on the benefits of standardization of the processes of care. The past 6 years have seen an increased focus on the industrial model of performance measurement and outcomes assessment in healthcare. The focus on performance measurement has emphasized the importance of organizations and components of organizations having 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, and prevention of medical errors. This 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 numbers of errors that actually occur in the Clinical Center and attempts to assess to what extent such events are reported in the ORS. 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 "handoffs," thereby decreasing opportunities for errors. In addition, the JCAHO has developed mandatory annual patient safety goals for healthcare institutions wishing to be JCAHO-accredited.

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 Committee published a set of Standards for Clinical Research and a process has been put in place to ensure each institute's compliance with the standards. In addition, in late 2001, NIH volunteered to have its clinical research program evaluated as a pilot for the AAHRPP, which has developed an accreditation process for clinical research programs.

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 need.

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

The past 3 years have seen a worsening of an existing problem—a national shortage of crucial patient care and clinical research support personnel. Substantial workforce shortages have developed among Nursing, Pharmacy, Anesthesia, Clinical, and Imaging technical staff, and information technology personnel. In FY 2004, with the exception of our Anesthesiology program, the Clinical Center is faring reasonably well in most of these areas (i.e., with less turnover and fewer unfilled positions compared with other institutions in our community). The anesthesia shortage (discussed in more detail below) is particularly acute.

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 this field. 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 do the following: 1) improve the quality of care provided to Clinical Center research subjects; 2) improve the training of clinicians; 3) create substantial efficiencies in how 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; and 5) use the substantial expertise in clinical information systems management that has been developed over the past 20 years to produce an integrated system that meets scientific, clinical, fiscal, and managerial needs.

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 as follows: 1) staying abreast of the technology as it advances; 2) ensuring that components of the organization have adequate information systems support to conduct business efficiently and effectively, while simultaneously assuring that these systems are compatible with each other; and 3) making certain that the organization is consistently investing an appropriate amount of its resources in the 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 will offer an opportunity for the Clinical Center to integrate these different kinds of data to improve organizational management and efficiency as well as the quality of patient care.

In the past 3 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 has hired a Chief Information Officer and has reorganized the Information Systems staff into two departments—the Department of Network Applications and the Department of Clinical Research Informatics—to meet organizational needs. The leadership of the Department of Clinical Research Informatics is charged with the oversight of the design, procurement, and implementation of the new Clinical Research Information System. This process is inherently collaborative, with Clinical Center and Institute customers taking lead roles in advising the Chief of the Department of Clinical Research Informatics. To date, the many customers have agreed on a plan for replacing the existing Medical Information System with a new Clinical Research Information System backbone and have agreed to a long-term business plan created with substantive customer input. An integrated laboratory system that has an interface to the existing Medical Information System was brought online during the past 2 years, substantially improving information management in Laboratory Medicine, Transfusion Medicine, and Anatomic Pathology (NCI). The first generation of a World Wide Web-based picture-archiving computer system in the Imaging Science Program was launched in 2002, and a refined and expanded second generation of this system should be in place by the time of the move into the new Clinical Research Center. In addition, a former IC Scientific Director has joined our staff part-time to supervise the ProtoType project described above.

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

The U.S. 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. The increasing influence 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 physicians 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 more interest in 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 primary care, interest in subspecialty and clinical research careers is decreasing.

One effect of the shift toward primary care 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 3 to 7 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.

A traditional strength of the intramural program has been that NIH's reputation has led to international collaborations and attracted 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 situation has resulted in fluctuations in academic salaries, particularly for some historically highly paid specialties, such as radiology, surgery (and its subspecialties), and anesthesiology. The fluctuations in anesthesiology salaries initially resulted in a surplus of qualified anesthesia personnel. In response to the surplus, the anesthesiology community 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 NIH Director 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 would be 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 for 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). The report suggested that this approach would likely result in an increased ability to recruit mission-oriented staff in anesthesia and lessen the impact of the salary differential between the Federal and private sectors. The new Chief will attempt to recruit new staff this year.

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, 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 DHHS Secretary 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; this 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 governmentwide 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 beginning in FY 2003. The linkage of performance/outcomes with budget will be 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 has proposed to make the government more citizen-centered (i.e., ensuring as little distance as 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. In support of this goal, since mid-2002 DHHS has implemented a freeze for hiring senior-level administrative staff.

- *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 exempt from these goals, and the CC will be required to participate in these streamlining activities. Over the past 18 months the senior leadership of NIH and the ICs has developed strategic approaches to these streamlining activities.

- *Improved Financial Performance:* The primary goal of this initiative is to reduce erroneous payments.

- *Expanded Electronic Government:* The President wants 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). Two actions aim 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 manner, while ensuring both security and privacy. NIH is currently in the midst of a major initiative that is designed to centralize many IT 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 2 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, among others); others arise from IC programs (e.g., Cancer Treatment Evaluation Program, NCI); others are department- or agency-based (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., JCAHO, College of American Pathologists [CAP], American Association of Blood Banks [AABB]) and oversight/accreditation of clinical research activities (the 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 Centers 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. 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, which is designed to assist with the increasingly cumbersome process of protocol writing and implementation. This software program is intended to streamline and standardize the process of protocol writing. The program is currently being beta-tested at the Clinical Center and scientists working at the Rockefeller University have also expressed interest in testing it.

In light of the increasing activity in molecular medicine and the virtual explosion of new laboratory tests that can be used for diagnosis and prognosis, 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 program has assisted in the CLIA certification of 43 laboratories on the NIH campus. It determined that an additional ten laboratories did not require CLIA certification.

While the Clinical Center has been determined to be a "noncovered 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 comply with 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.

Agency (NIH)-Based External Factors

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

Several factors 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 60 months. In addition, an external panel convened by the NIH Director (the Marks/Cassel Committee) issued a detailed report in 1994 that provided clear recommendations to revitalize the intramural program.[18]

- 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 Directors 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 include 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 hand-off and implementation.

- Successful conduct of clinical research is essential to biomedical progress. However, the processes of clinical research are complex, labor-intensive and expensive. For these reasons, the NIH Director has developed a road map for the continued success of clinical research, both in the NIH intramural program and throughout the United States. The NIH Director's road map will help 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 will also help 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 5 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. As a specific example, the Cell Processing Section of the Department of Transfusion Medicine has developed the expertise to isolate islet cells from cadaver pancreata to support the scientific effort of a subset of NIDDK investigators' protocols.

- The costs associated with conduct of biomedical research are escalating faster than inflation, necessitating that Institutes evaluate costs and quality of proposed intramural projects more rigorously than in the past and that the Clinical Center develop strategies for prospectively determining the likely costs associated with new scientific projects.

- 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 will not be organized with dedicated "Institute space," has fostered collaboration among the partners who will share space and resources in the new building. The new building and the change in clinical and administrative governance in patient care presents the CC with a unique opportunity to re-evaluate the processes that we use to provide care and to redesign some of these processes to improve patient care quality and/or to improve efficiency.

- The Clinical Center now has 3 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. An Institute pays 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.

- The Board of Governors' 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 and 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 1,975 in 2002 to 1,945 for 2003. The proposed ceiling for 2004 is 1,913. At a time when clinical research programs are expanding and being reinvigorated, and at a time when Clinical Center budget growth will be modest at best, these FTE constraints present a 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 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.

Over the past 7 years, both 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 2003. The current administration has stated publicly that subsequent years' funding will be modest by comparison. Given that certain hospital costs (e.g., pharmaceutical

inflation, inflation of costs 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 Clinical Center Board of Governors, whose extramural members have substantial expertise in healthcare operations and financing.[19] 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 Board of Governors have given Clinical Center leadership the opportunity to manage the operations of the organization more efficiently than ever before.

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 has tried over the past several years 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 must improve the accessibility of the Clinical Center and its resources to basic scientists.

As noted above, collaboration among Institutes becomes increasingly important as the new Clinical Research Center is being planned. Institutes will not "own" clinical space in the new building, but will share space in clinical programs. Since the design of the new building will not be Institute-based, but rather based on clinical disciplines or programs of care, Institutes will be required to share space and resources. 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 in 1996 gave the Clinical Center the unique opportunity to be governed through a 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 expert advice about hospital operations and management from nationally recognized authorities in those fields;
- 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 prior system (e.g., delegations of authorities, generic clearance for surveys, etc.).

The Clinical Center's governance is complex. The Director's Blue Ribbon Panel on Intramural Clinical Research will review the intramural research program in late 2003 and early 2004 and assess the efficacy of the current approach to governance. The Panel will make further recommendations to the Director concerning appropriate modification in governance as a result of this review.

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