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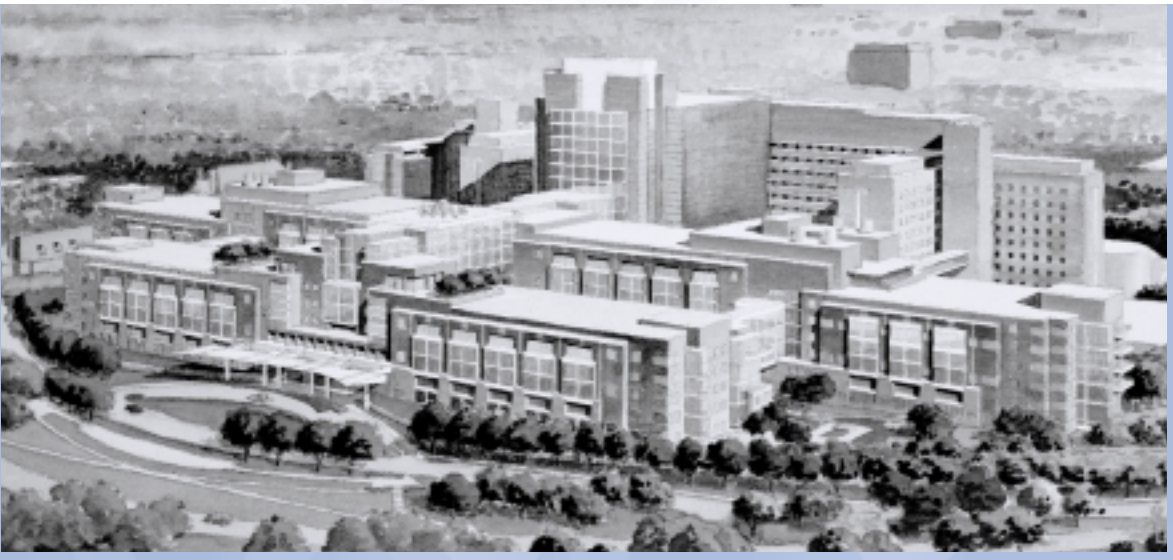

Strategic Plan

Environmental Assessment

Warren Grant Magnuson Clinical Center

National Institutes of Health

2001

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Executive Summary

The Warren Grant Magnuson Clinical Center (CC), National Institutes of Health, United States Department of Health and Human Services (DHHS) faces substantial challenges and opportunities as it moves into the 21st century. In 1996 in response to concerns about the rising costs of conducting clinical research at the CC, the DHHS Secretary commissioned an external review of CC operations. To determine the CC's optimal operating structure, a review group (that came to be known as the "Options Team") visited cutting-edge academic, non-academic, public, private, and federal healthcare institutions throughout the United States. One of the major recommendations resulting from the review effort was for the CC to engage in strategic planning, and, as part of that activity, conduct a thorough environmental assessment to determine CC strengths, weaknesses, opportunities, and threats. This document represents the fourth edition of the CC's Strategic Plan Environmental Assessment. The CC has five years of experience in the use, evaluation, and modification of its strategic plan. In that time factors influencing the CC environment have continued to change. This document summarizes interventions that have been taken to address weaknesses and bolster strengths; identifies changes that have occurred; and provides additional commentary within the context of the original environmental assessment.

The CC has numerous strengths, among them:

1. The CC is the clinical research arm of one of the strongest, most visible scientific programs in the world – the intramural program at the National Institutes of Health;

2. The CC has a critical mass of world class scientists and clinical investigators working closely together to develop and conduct translational clinical research;

3. The CC support staff and research infrastructure are uniquely tailored to support excellence in clinical research;

4. The CC focuses on a unique research portfolio that would be difficult, if not impossible, to conduct at other venues;

5. The CC staff are capable of providing, and have consistently provided, the highest quality patient care to clinical research subjects;

6. Unlike patient-care-oriented academic medical centers, the CC culture is science-driven;

7. Because of its unique clinical research mission, the CC has an organizational and scientific flexibility that most institutions do not possess; and

8. The CC provides investigators access to expensive, state-of-the-art technologies that are not readily available in many other venues.

These strengths, identified in the initial version of this document, remain evident after five years of experience with the strategic plan.

Self-evaluation, during preparation of the first edition of this document, also identified several organizational weaknesses at the CC, among them:

1. Existing CC governance mechanisms were unclear;

2. The CC was subject to bureaucratic inflexibility in personnel, procurement, and fiscal management;

3. The CC's physical plant urgently needed renewal;

4. The CC lacked a strategic plan;

5. CC information systems did not adequately support managerial and financial data and did not integrate clinical, research, managerial and financial data;

6. CC successes were not adequately communicated to the public, to referring physicians, and to the insurance and managed care industries;

7. CC patient recruitment efforts were increasingly less successful; and

8. The fact that the CC does not offer complete, integrated medical and surgical services may be an institutional weakness.

Progress in Addressing Identified Weaknesses

During the past five years, many of the weaknesses identified in the initial environmental assessment have been addressed. The establishment of the Board of Governors clarified the CC governance structure; however, to make certain that the CC's major stakeholders have an opportunity to contribute to the governance, the NIH Director has subsequently created additional advisory panels. In the past two years the CC's governance has continued to evolve. The DHHS Secretary removed many of the bureaucratic impediments inherent in certain official government processes. A new Clinical Research Center is being built. Markedly improved financial information (e.g., activity-based costing data) is now readily available to CC and NIH Institute/Center (IC) staff, and a highly successful Patient Recruitment and Public Liaison Service has been established. These changes and their impact are discussed in detail in this Strategic Plan Environmental Assessment update.

Weaknesses Identified Since 1996

In the interim period since this document's first edition, several additional potential weaknesses have been identified, specifically:

1. Communication practices are inconsistent across the CC and the NIH;

2. The CC has not routinely sought customer input about its services;

3. CC customer service needs improvement;

4. The CC has substantial opportunities to increase its attention to workforce diversity and healthcare disparities; and

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

Opportunities and Threats

The CC has also evaluated opportunities and threats presenting themselves as a result of changes in its internal and external environments. Most of the factors identified as change agents remain present in the CC's current environment. Among the internal and external environmental factors initially identified as influencing change in healthcare delivery and clinical research are:

1. The sociopolitical climate, potential for increased acts of terrorism, and declining economy will add a degree of instability to the NIH environment in the next few years.

2. Societal values are changing and bearing influence on healthcare and clinical research. Society relies increasingly on technology and its advances, including those in medicine and biomedical research, to provide what has become an expected level of health, function, and longevity.

3. The U.S. population and its interests and knowledge base are changing rapidly: patients and clinical research subjects are becoming increasingly sophisticated healthcare consumers; science education in the U.S. 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.

4. Cost continues to be a primary consideration in healthcare delivery and clinical research. Clinical research is intrinsically expensive and healthcare inflation is high. The net effect is that cost containment in the CC environment is difficult.

5. 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. Nationwide a shortage of nurses, pharmacists, and medical and radiological technical staff remains a continuing problem.

6. Changes in governmental regulatory requirements and governmental oversight are driving change in medical practice and clinical research. In FY 2001, the President reiterated an interest in downsizing and outsourcing while issuing five major goals for reforming governmental management practices, including goals relating to:

- Budget and Performance Integration
- Strategic Management of Human Capital
- Competitive Sourcing
- Improving Financial Performance
- Expanding Electronic Government

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

7. Changes at NIH are also influencing the manner in which the CC operates.

- To address the needs of the CC's failing physical plant, a new Clinical Research Center is under construction and projected to open in 2004.
- The organization and administration of patient care in the new facility will be different from existing mechanisms. The new building and the change in clinical and administrative governance in patient care presents the CC with a unique opportunity to reassess the processes used to provide care and affords an opportunity to redesign some of these processes for improvement in patient care quality and/or efficiency.
- The new building has also served as a stimulus for the ICs to improve and expand their clinical research programs. Several ICs have initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. These substantial program modifications and expansions require the careful assessment of CC administrators and department managers.
- Several ICs have developed new initiatives that involve 'off-site' activities, and have requested CC support for these activities. These programs range from underserved communities' outreach efforts to telemedicine projects. The CC must develop strategies to address the many significant regulatory, economic, and logistical issues arising from these initiatives in order to maintain the highest possible care standards for the services it provides.
- As technology advances, the ICs increasingly request more and more sophisticated and, therefore, expensive clinical-research support.
- To address another perceived organizational weakness the CC is renovating its medical information system, again requiring careful assessment of the processes of care, with the intent of moving toward a completely electronic medical record. The new information system will also give the organization an opportunity to develop better departmental, financial, and back-end (i.e., IC) clinical-research support than the existing system.
- The past several years have seen a doubling of the NIH budget. This doubling will be complete in 2003 and NIH is preparing for leaner budgets in subsequent years (the so-called 'soft landing'). The fact that certain hospital costs will likely continue to escalate at a rate far exceeding intramural budget growth demands cost consciousness and creativity from CC managers.

Thus, during the past five years a combination of factors has resulted in a substantial cultural change in the NIH intramural community. These factors and the resulting change in the internal CC environment are enumerated in this document.

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

Introduction

The CC 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, and opportunities, and factors from the internal and external environments that threaten the organization is essential for the CC to prevail in the next decade and beyond. To succeed, the CC must identify its internal strengths and capabilities and position itself to meet the challenges posed by ongoing changes in American healthcare delivery systems and industry.

In 1995, the CC was provided with a unique opportunity to conduct a thorough environmental assessment as a result of a mandate from former DHHS Secretary Donna Shalala that the CC undergo a detailed external review of its operations. Dr. Helen Smits, former Deputy Administrator for the Health Care Financing Administration (HCFA), led the Options Team that conducted this review. This review ultimately provided the CC with an opportunity to study the best practices of 30 facilities throughout the country, with an eye toward adopting many of these best practices at the CC.[1] In the intervening 60 months since this document was first written, the CC has sought additional input from: 1) its major customers, the NIH ICs (through the Clinical Center Research Steering Committee, formerly the Clinical Center Advisory Council), the Clinical Research Revitalization Committee, the Funding Advisory Review Board, and the Clinical, Scientific, and Institute Directors; 2) the extramural academic community (through ongoing reviews by the Clinical Center Board of Scientific Counselors); and through separate meetings convened with outside experts to chart the future courses of the CC's Bioethics Program, Imaging Sciences Program, Laboratory Medicine Department, and the Pain and Palliative Care Service; 3) industry, insurers, and managed care representatives (in two meetings designed to address patient recruitment and third party payment issues); 4) healthcare executives and experienced healthcare administrators (through meetings of the CC's Board of Governors); and 5) intramural and extramural experts in hospital operations, in the conduct of operational reviews of CC departments. The advice and counsel of these intramural and extramural advisors provide the backbone for the CC's current environmental assessment.

The CC's 2001 Strategic Plan Environmental Assessment is divided into three segments: 1) CC strengths; 2) CC organizational weaknesses; and 3) external trends and factors influencing change: a) in healthcare; b) in clinical research, in general; and c) in clinical research at the CC, including an emphasis on opportunities that present themselves to the CC in the context of these other findings.

Clinical Center Strengths

The CC serves as the clinical research arm, and an integral component of, the NIH biomedical research community. As a national resource, the CC provides the patient care, services, and environment needed to initiate and support the highest quality, conduct of, and training in, clinical research. The CC 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 science advisors convened at the request of the NIH Director to assess the status of the intramural research program noted that the CC 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 CC to meet the expanding clinical research agendas of the ICs for the foreseeable future.

In the 48 years since the CC opened its doors to the public, the CC 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 IC scientists during this period, the CC and its staff have developed many unique organizational strengths. Among them are the following:

- **The CC is the clinical research arm of the intramural program of the NIH.**

The NIH is among the most respected scientific organizations in the world. Its intramural program has received consistent intellectual and scientific support from the academic scientific community as well as steady economic support from the U.S. government. As the clinical research arm of the intramural component of the NIH, the CC 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 CC.

- **The CC 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 during the first 48 years of the CC's existence. The fact that the basic

and clinical scientists work in close proximity produces a cross-fertilization of ideas that is unique in the academic medical community. The quality of the basic and clinical scientists cannot be overemphasized; many of the NIH intramural investigators are recognized as international authorities in their fields.

- **The support staff and research infrastructure in the CC are uniquely tailored to support excellence in clinical research.**

Unlike most academic medical centers, CC support staff and service personnel have been recruited to support a clinical research, rather than a purely patient care, mission. The service and support staffs at the CC provide unrivaled support for clinical research. The CC staff also provides state-of-the-art clinical diagnostic support services. Support staff and service personnel often function as collaborators in research studies and have made numerous substantive scientific contributions. At all levels of the organization, completion of the research mission is a highly visible goal.

- **The CC focuses on a unique research portfolio.**

As noted above, unlike most academic medical centers, studies conducted at the CC much more frequently evaluate the natural history or pathogenesis of disease states. Clinical trials at the CC 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 CC offers a superb venue in which to conduct translational or 'proof of concept' studies. Additionally, scientists working at the CC have assembled cohorts of patients who have rare or orphan diseases. For patients who have certain orphan diseases, the CC may be the only place where meaningful clinical research studies of their conditions 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 CC provides the highest quality patient care to its clinical research subjects.**

The CC's staff is committed to the clinical research mission. To provide optimal support for clinical science, the CC's highly skilled service and support staffs have consistently provided excellent care to the subjects of clinical research protocols. The subjects of clinical research studies have a different relationship to the CC than the relationship patients have with a typical academic medical center to which they are admitted. The subjects of these studies are partners in the research carried out at the CC. For this reason, the importance of providing excellence in patient care cannot be overemphasized. Excellence in patient care remains a major objective for the CC staff, an objective that has been reached consistently during its first four decades of existence, and a goal toward which CC administration and staff continuously strive. Excellence in patient care is an ever-moving target.

- **The culture of the CC is science-driven.**

The principles of performance improvement are based on the principles of epidemiology. The culture and mission of the CC are grounded entirely in science. CC scientists and managers are familiar with the epidemiological orientation of performance improvement. Scientists and staff are accustomed to using epidemiological principles to analyze data and to make decisions. For this reason, CC staff are well positioned to collect and analyze managerial data and to integrate the results of data analysis into decisions affecting the manner in which the work of the organization is conducted. The entire organization has been trained in the epidemiological principles of performance improvement and both managers and line employees use these principles. The science-based culture of the CC positions it extremely well to use these principles scientifically to: 1) collect data for performance measurement; 2) analyze the data to address identified problems; 3) propose interventions based on solid, scientifically obtained data; and 4) assess the usefulness of these interventions.

In the intervening 60 months since the first edition of this document many of the ICs have initiated major external reviews of their intramural clinical programs. The Director's Clinical Research Panel has also underscored the importance of quality clinical research. These and other initiatives suggest that, across the campus, interest in quality clinical research is increasing. In addition, the planning of the new Clinical Research Center, the increased emphasis on cross-disciplinary molecular projects, and the changing intramural environment have spawned a new level of collaboration and customer-orientation among CC leadership.

- **Because of its unique clinical research mission, the CC has organizational and scientific flexibility that most institutions do not have.**

Because the primary mission of the CC is clinical research, the institution does not make commitments, either to its research subjects or to the community, to provide comprehensive healthcare services. Because the CC does not have to commit resources and personnel to an Emergency Room or general acute care, it can focus its efforts on specific areas of clinical science. For this reason the IC-driven science conducted in the CC can respond quickly, both to emerging problems for which an immediate change in the national research agenda is needed, as well as to scientific opportunities when they arise. For example, the CC responded quickly to study: 1) AIDS and HIV infection when the disease first surfaced in society; 2) multiple-drug-resistant tuberculosis when the problem first became apparent; 3) chemotherapy for ovarian cancer when Taxol became available; and 4) solid organ transplantation program when innovative transplantation approaches were developed.

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

Since the CC and the NIH intramural programs are charged with advancing the frontiers of science, the CC often either develops, or is among the first to acquire, new technologies that facilitate the conduct of clinical research. Scientists working at the CC have access to numerous molecular techniques, Positron Emission Tomography (PET) scanners, three cyclotrons, several Magnetic Resonance Imaging (MRI) machines (including the 3, 4, and 7 Tesla experimental machines), unique cell-processing facilities, and a variety of other cutting-edge technologies.

Clinical Center Weaknesses

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

- **Existing CC governance mechanisms are unclear.**

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

In the past 60 months, the NIH has continued to wrestle with the development of clear, effective governance for the CC. In 1996, the CC appointed and convened a new Board of Governors. The Board of Governors developed and approved a streamlined organizational reporting system for the CC. As a result of the introduction of this new governance system, IC stakeholders felt somewhat disenfranchised and appealed to the NIH Director. A new advisory board, initially called the Clinical Center Advisory Council, was then appointed by the NIH Director that permitted the major stakeholders to address CC issues that are important to the ICs and to provide advice and counsel to the Director of the Clinical Center. This council has recently been reconstituted by the NIH Acting Director as the Clinical Center Research Steering Committee (CCRSC). The CCRSC continues to provide a venue in which the ICs can contribute to the governance of the CC. An additional advisory group, the Funding Advisory Review Board (FARB), has also been constituted by the NIH Acting Director to recommend to the Acting Director through the IC directors funding levels for centralized services on the campus (including the CC). In the past three years, the CC Director has sought advice from another important stakeholder – CC patients. The CC Director created a Patient Advisory Group that has provided and continues to provide advice to the Director from the perspective of clinical research participants. The governance structure for the CC remains complex, however, the relative roles each of these new (as well as the older, existing) advisory groups play in the governance of the CC are being clarified.

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

As a center in the NIH (agency), the CC reports to the agency, the Public Health Service (PHS), and the Department of Health and Human Services. Its activities are subject to agency rules, regulations, and policies; PHS rules, regulations, and policies; DHHS rules, regulations, and policies; rules, regulations, and policies of the Office of Management and Budget, the Office of Personnel Management, the General Services Administration; and all other applicable Federal rules, regulations, and policies, as well as applicable Federal statutes. According to the DHHS Options Team report, 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] With respect to procurement, the report states, "The Clinical Center's procurement system is time-consuming, labor-intense, costly, and slow to change."[7] With respect to personnel systems, the report states, "The government's personnel system is so complex that managers and employees find it difficult to understand. It is so fragmented that they have difficulty making the system support their needs. Although the government's personnel system is structured to provide fair, consistent rules for employees and managers, it undermines the Clinical Center's efficient operation."[8] With respect to fiscal issues, the report states, "As is the case with all government operations, the Clinical Center must spend its entire budget within the fiscal year; no carryover is allowed

[9]...the Clinical Center should have a means of retaining reserves from year to year."[10] The report also notes that the NIH's existing budget process for the Clinical Center "...makes future Clinical Center funding far more unstable than funding of NIH as a whole." [11] Finally, external reviewers suggested that the Clinical Center did not have an effective cost-accounting system that provided "timely information about performance and cost."[12]

Since the first edition of this document was written, the CC has worked with the NIH Director and the Directors of the ICs in an effort to streamline the CC's funding stream. The old funding mechanism rewarded "non-use" of the CC. A new funding mechanism has been designed, patterned after the concept of a "school-tax." Because IC charges are not linked to use in this new system, it should stimulate use of the CC 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 CC to carry over some funds; this language has again been approved for the present fiscal year. These carryover funds provide an important source of revenue support for new clinical research initiatives of the ICs. The CC has also attempted to address the issue of inadequate cost accounting. The CC hired a consultant to provide advice about the establishment of a cost-accounting system. The recommendations of the consultant have been adopted and the CC is implementing the new system. This new activity-based costing system should be of substantial utility to the CC's major customers and stakeholders.

Performance measurement continued as a major organizational focus in 2001. During the past three years the CC has collected organization-wide activity data that are used by the Director to assess overall performance. In addition, CC departments collect data relevant to the performance of their individual operations. The goal of measuring performance is to track departmental and organizational progress toward our strategic goals. Thus, an important aspect of the performance measurement system is making certain that the outcomes and processes being measured are relevant to our key initiatives and strategic goals and that the measurement of these structures, processes, and outcomes allow us to track progress toward these organizational goals. The performance measurement initiative is relevant to both the operations of the CC as well as to clinical care provided in our facility.

In the years since the initial draft of this document was written, NIH has also received several delegations of authority from the DHHS Secretary. Use of these delegations has already begun to address some of the problems relating to inflexibility in personnel and procurement systems.

During the past two years the CC's Office of Human Resources Management has developed (and had approved by the DHHS Secretary) a pilot program to be able to use a new personnel authority, Title 42, to appoint clinical research support staff. This project – novel in the government – is underway. Initial performance measurement activities related to implementation of the project suggest an increase in efficiency of responsiveness and decreased vacancy rates in relevant departments.

- **Many intramural and extramural authorities believe that clinical research is relatively undervalued.**

Clinical researchers nationwide have long held the perception that NIH relatively undervalued their work. In 1979, then NIH Director James Wyngaarden, referred to the clinical researcher as an "endangered species." In response to the concerns of both intramural and extramural scientists concerning the standing of clinical research, Dr. Harold Varmus, Director, NIH convened a blue-ribbon panel of experts (the Clinical Research Panel) that was charged with reviewing the status of clinical research in the U.S. and making recommendations to the NIH Director on how that office might ensure effective continuance of clinical research in the U.S. Dr. David Nathan, president of the Dana Farber Cancer Institute, chaired the committee. The committee made ten formal recommendations, which can be summarized as follows:

- NIH should monitor and track resources committed to clinical research.
- NIH should ensure fair and effective reviews of clinical research grant applications.
- NIH should initiate programs that enhance the attractiveness of careers in clinical research to medical students.
- NIH should ensure the quality of training for clinical researchers by careful mentoring and by requiring formal training in clinical research.

- NIH should initiate new support mechanisms for young and mid-career clinical investigators.

- NIH should increase the scope of, and funding for, General Clinical Research Centers.

- NIH should continue to improve the quality of clinical research and strengthen clinical research management at the CC and make its resources available to extramural investigators.

- NIH should enter and sustain a dialogue on enhancing clinical research with academic centers, private foundations, pharmaceutical manufacturers, and managed care organizations.

- NIH should expand efforts to educate the public about the importance of clinical research.

The leadership of the NIH and of the CC took these recommendations seriously and developed substantive responses to many of them. An introductory course on the principles and practice of clinical research has trained 2,000 students and an accompanying textbook for the course has been written. A Clinical Research Training Program for medical students, including mentoring by some of NIH's most accomplished clinical researchers has already been successfully implemented. Two collaborative Masters' 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 has been developed and implemented (complete with a newly published textbook) and a Bioethics Course has been developed and implemented. Intramural programs have reviewed and revitalized their clinical programs. Both NIH and the CC have begun dialogues with the insurance and managed care industry. These activities are described in detail elsewhere in this document.

- **The CC's physical plant urgently needs renewal.**

"The Clinical Center's 48-year-old physical plant is increasingly inadequate for the conduct of clinical research; it requires replacement."[13] 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[14]...The External Advisory Committee agrees with the need for renewal of the Clinical Center."[15]

NIH, DHHS, and Congress approved the concept of building a new Clinical Research Center, an architect was selected, a private developer hired, and construction is progressing. Congress has now provided funding for the total construction project. To increase customer input in the design process, teams of partners (i.e., IC staff, CC staff, and patients that will share space and resources in the new building) have been convened to assist in the design process. The CC and its IC partners are aggressively planning for the transition from Building 10 into the new facility.

- **The CC 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."[16]

After obtaining input from major internal (e.g., CC Department Heads) and external (e.g., IC Directors, IC Scientific and Clinical Directors) customers, the CC 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 during the past 60 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 CC views it's strategic plan as a dynamic document – projects are continuously being evaluated, revised and improved.

In addition, within the past year the CC has drafted its first annual operating plan for FY2000; this process was refined in FY2001; and an FY2002 plan is under development. 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.

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

The CC has long been a world leader in the field of "computerizing clinical data;"[17] 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 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."[18]

In the past 60 months, several projects have been initiated to improve the quality and availability of financial and resource utilization information for better management of CC operations. The CC recruited its first 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.

In the past year, the CC has reorganized its Information Systems staff to include two departments – the Department of Network Applications (DNA) and the Department of Clinical Research Informatics (DCRI). A major focus of the DCRI is to design, procure and implement a new Clinical Research Information System (CRIS). During the past year much progress has been made toward this acquisition. Extensive customer input has been received and a general plan for acquisition of the CRIS backbone (replacing the old Medical Information System) has been developed. In addition, during the past five years the CC Budget office has implemented an activity-based costing system that provides markedly improved resource utilization data to IC customers. The CC has also embarked on a major project to track patient care activity in clinical protocols (i.e., 'protocol mapping'). These projects provide the infrastructure for further progress in financial accountability and responsiveness to our customers' and stakeholders' needs for more accurate financial and planning information. The CC has recently completed and launched a third project, the creation of a Web-based CC "Service Formulary" that details all of the services provided by the CC and the ICs.

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

The 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."[19]

To address problems previously identified by focus groups and by external consultants, the CC has developed a marketing plan, 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 CC Board of Governors endorsed the patient recruitment project as part of the long-range goals included in the strategic plan. The three major communications goals of this new Office are:

- To increase the visibility of the CC as a national center for clinical research
- To increase recognition of the CC as a national center for the training of clinical investigators; and
- 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 recruitment decreased, despite significant efforts by the researchers to recruit patients, some excellent and, in some instances, important studies have languished for lack of patients.

As noted above, the Office of Patient Recruitment and Public Liaison has, as it's primary mission, the support of patient recruitment and referral efforts. The primary goal of the service is to increase the enrollment, including women and minorities, to clinical research studies in the CC. 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, for the first time in several years, CC inpatient activity increased.

- **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 can also be viewed as an institutional weakness.**

The fact that the CC does not provide full services is perceived by some CC and IC staff as a disadvantage for several reasons. For some physician research trainees, the fact that the CC does not offer "full-services" limits the desirability of the CC as a training site. Not offering these services necessitates developing procedures to acquire some types of support from local academic or community physicians. Response times for outside consultants are occasionally less than optimal. Additionally, their investment in, and commitment to, the CC patient population is almost invariably less than that of the NIH investigators. Because the CC 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 CC have forged alliances with extramural institutions. Some examples of these alliances include:

- Partnerships with Johns Hopkins University and the National Rehabilitation Hospital that will facilitate clinical training for fellows and junior staff and will afford senior staff the opportunity to maintain clinical skills;

- A partnership with Johns Hopkins and Suburban Hospital that will facilitate the conduct of studies of acute medical problems (e.g., brain attack, myocardial ischemia) that heretofore have been impossible at the CC, 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; and

- A variety of partnerships with local institutions (e.g., Washington Hospital Center, Johns Hopkins, Georgetown, and others) to provide CC an opportunity to maintain clinical competencies.

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

The CC has also made a substantial commitment to increase the quality and availability of clinical research training over the past four years, as described above. The NIH Director also established a "Clinical Research Training Program" for medical students (analogous to the Howard Hughes Medical Institute-funded training program in the basic sciences). This program was established 36 months ago and is now completing a very successful third year. Students have the opportunity to take courses, while under the mentorship and working on clinical projects with, successful intramural clinical researchers.

In response to concerns raised by patients and the clinical staff of the CC about the efficacy of symptom management strategies in the institution, the CC assembled a panel of experts in Pain Management and Palliative Care for a conference at the Stone House on the NIH main campus. This panel provided the organization with additional impetus to create a Pain Management and Palliative Care Service for CC patients. The CC convened a search committee and recruited a Chief of this new service, Dr. Ann Berger. Patients and staff, alike, have received this service enthusiastically. The team has been in place for more than a year. The service uses both traditional and nontraditional approaches to help alleviate pain, other symptoms and suffering in

our patients and has become an integral part of quality care in the CC.

The CC has also recruited an exceptional General Internist and two Nurse Practitioners to provide Internal Medicine consultations for CC patients. This service was initiated in 1998 and has met with enthusiastic approval. Based on ongoing performance measurement data, the service has become busy enough to warrant the recruitment of a second internist. The CC hopes to have this individual in place by January 2002. In addition, the CC recruited a second pediatrician to provide general pediatrics consultative support.

- **Communication practices are inconsistent across the CC and the NIH.**

At its department heads retreat in 2001, CC staff identified inadequate interpersonal communication between CC and IC staff as a major organizational obstacle. Retreat attendees underscored that inadequate communication within the organization (i.e., among departments, between administration and the departments, and between the administration and line staff), as well as communications with major stakeholders (i.e., CC – IC interactions, physician – patient interactions, and physician referring interactions) were in need of significant improvement.

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

As a service organization, customer input is crucial to smooth functioning of the CC. In 1997, the CC initially partnered with the Harvard-based Picker Institute for its initial patient survey. Results from the survey identified areas that needed attention in the organization, but also established new quality benchmarks for the Picker group in terms of overall perceptions of quality. Picker was sold to the National Research Corporation (NRC) in 2001; however, the Picker 'perception' surveys will remain a part of the NRC portfolio, so the CC will be able to maintain continuity in its customer perception program. This coming year an outpatient survey, a pediatrics survey, and an employee survey are planned. In addition, plans are being formulated for a survey of referring physicians. 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 patient's perspective about service quality in at the CC. This group has also helped identify issues that have become the focus of performance improvement activities (see customer service initiative, below). To improve interface with the public, to improve outreach to minority and underserved communities, and to assist in recruitment for clinical trials, the CC also established the Patient Recruitment and Public Liaison Center. This new center has had a substantial salutary effect on both patient recruitment and community relations since its inception three years ago.

- **Customer service has not been an identified institutional priority.**

The CC Director's Patient Advisory Group identified a need for organizational improvement in the area of basic courtesy and customer service. In response to this identified need, the CC has embarked on a major customer service initiative. An external contractor has been hired to train staff throughout the organization – focusing particularly those at major customer/stakeholder interfaces. Anecdotal reports from members of the Patient Advisory Group suggest that the training is already bearing fruit. This training will also be offered to other NIH and contract staff (i.e., outside of the CC) that interacts with CC patients and the public.

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

During the past five years both NIH and the CC have also become increasingly aware of an organizational need to honor cultural diversity and to develop policies of inclusiveness for the CC workforce and everyday practices. The NIH Acting Director has identified health disparities as a major NIH priority. The CC has successfully competed for funds from the NIH Center for Minority Health to facilitate recruitment of minorities into clinical studies. In addition, the CC has embarked 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.

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

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

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

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

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

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

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

Societal & Value-Based Factors

The political climate, the potential for increased acts of terrorism, and the declining economy will add a degree of instability to the NIH environment over the next few years.

Terrorist acts directed against the U.S. have increased steadily over the past years. The potential for additional acts of terror, including bioterrorism, seems likely, if not inevitable. The declining economy and the need to focus resources on national defense and public safety may mandate changes in our internal environment. The CC is working to anticipate some of these problems, by revising and broadening its disaster plan, by preparing for the 'soft landing;' and by working to increase organizational efficiency.

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

Society has become more attuned to social responsibility for healthcare delivery since the 1960s. Interest in, and expenditures for, medical care for the elderly and the socially disadvantaged has increased dramatically during the past 30 years. The

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

Americans increasingly value the "Quality of Life."

In the past 25 years, society's focus has subtly shifted from "staying alive" to the "quality of life." Americans have become much more conscious of "quality of life" as an endpoint or outcome and American medicine has, by necessity, been forced to accommodate these value changes. As American society has turned attention to this issue, Congress has also developed an interest in "quality of life" concepts. This shift in societal focus provides the intramural program and the CC 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 oncology studies, patients' values and individual, unique measures of "quality of life" may influence therapy choices. CC departments such as Rehabilitation Medicine, Pharmacy, Anesthesia and Surgical Services, and Critical Care Medicine have unique opportunities to contribute to CC studies in this area. Although not traditional 'clinical care,' this unique 'clinical research support' is an important component of the support provided by various CC departments. Ignoring this important trend in its clinical studies could place the CC at a disadvantage in the eyes of its societal customers. Since the first edition of this document, public interest in "quality of life" issues has not waned. If anything, interest has intensified. Healthcare institutions have developed strategies to begin to measure changes in the "quality of life" that are effected by various therapeutic alternatives. These measurement strategies are a direct outgrowth of the persistent public interest in "quality of life" issues.

Wellness and prevention strategies are increasingly valued.

In the past three decades, 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 also 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. In a speech at Stanford University Medical School in 1997, the NIH Director underscored the NIH commitment to these activities and enumerated the ways in which NIH has become increasingly invested in wellness and prevention strategies. The external focus on "prevention" and "wellness" has continued to intensify over the past 30 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.

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

Medical technology blossomed in the 1990s. Tools of medicine have changed more during the last 40 years than in all five hundred years past. NIH contributes to this rapidly advancing field, and as a result often has unique opportunities to use these technologies as they are being introduced into society to investigate the frontiers of medicine. Since the CC is ideally positioned to adapt swiftly to the development of new technologies, such rapidly advancing technologies provide the CC with a unique opportunity to enhance its national and international reputation as a creative, innovative institution. Such new technologies often have direct impact on cost. Occasionally the required capital expenditures for new equipment are quite large and some technologically advanced procedures are labor intensive. These changes tend to increase the costs of care. In other instances introduction of new technologies have been associated with less invasive procedures and decreased length of hospital stays (e.g., laparoscopic cholecystectomy), thereby decreasing the net costs of care, despite the outlay for the necessary capital equipment.

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

A general trend in the CC over the past several years is toward increased intensity/acuity of services per patient visit (i.e., more sophisticated imaging studies, more molecular tests per patient visit, 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.

During the past five years, the CC has continued to invest in new technologies, trying to position itself at the forefront of academic institutions in this arena. Several new initiatives in this area are already in progress. These include a public-private collaboration to create a new, state-of-the-art cell processing facility, and the purchase of new infared imaging technology, new stereotactic neurosurgical equipment and an upgrade in magnetic resonance imaging capacity. There is also more emphasis on molecular diagnostics in Laboratory Medicine and Transfusion Medicine and the creation of a new imaging center, in collaboration with NHLBI, NINDS, and Suburban Hospital (Bethesda, MD), specifically designed to study acute cardiac and neurological vascular events in the Suburban Hospital emergency room.

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 substantial mistrust of the entire clinical research enterprise. Developing programs that reach out to these segments of society with sensitivity could enhance the CC's reputation and result in a renewed patient-recruitment base. Congress and DHHS could view ineffective recruitment of women, minorities, and underserved populations with disdain. Recent adverse publicity associated with serious adverse events resulting from clinical research, 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.

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

Population & Clinical Research Subject-Based External Factors

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

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

In the 60 months 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 1999 are focusing on several issues, among them: 1) ready access to healthcare and to their healthcare providers; 2) provider responsiveness to questions and problems; and 3) the level of customer service available from their providers.

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

At the same time that consumerism in healthcare is burgeoning, the quality and efficacy of science education in the U.S. 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 have suggested that science education in the U.S. is lagging substantially behind that of Europe and the Far East. Comparing the results from 15 developed nations of international standardized tests, U.S. students placed last in biology, third from the last in chemistry, and fifth from last in physics. Further, the talent pool entering science occupations is also diminishing. For example, the percentage of National Merit Scholarship finalists entering careers in science, the health sciences, and engineering have been steadily decreasing. If the net impact of faltering science education in the U.S. 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.

Life expectancy is lengthening; therefore the U.S. population is becoming older. Older patients require more healthcare and develop different medical problems. When coupled with the value shifts noted above, these demographic changes subtly modify the national research agenda. This modified agenda provides NIH scientists with scientific opportunities. In addition, the demographics of large metropolitan population centers are also changing. The percentage of minorities and underserved individuals in the populations of major U.S. cities continues to increase. As these populations continue to expand, the CC 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 CC by offering access to a quality of healthcare otherwise not available, while simultaneously providing a source for patient recruitment.

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

The costs associated with the unprecedented rise in the number and size of malpractice suits over the past three decades have contributed significantly to the escalation of healthcare costs in the U.S. Although the CC has had few such claims, the number of claims is increasing, and the CC 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 CC, as well as in the care provided to CC clinical research subjects. In addition, the challenge presented by an increasingly litigious society should galvanize the CC 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 turn out to be far less effective than they are originally touted. The increased societal interest in alternative and complementary medicine proffers the challenge to the intramural program that NIH develop open lines of communication with its clinical research subjects and the public on these issues. Failing to give credence to the possibility that non-traditional remedies and treatments may have real value runs counter to the science-based culture of NIH. NIH as a truly unbiased, impartial community is ideally situated to address issues such as the safety and efficacy of nontraditional approaches to medical care.

In the late 1990s, NIH has increased its emphasis on the evaluation of alternative and complementary medicine. A Center for Alternative and Complementary Medicine has been created at NIH. Funding for studies of these approaches has been 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 CC where for the past several years an external consultant skilled in acupuncture has been providing treatment patients with chronic pain. In addition, a senior Staff Clinician from the CC department of Rehabilitation Medicine has been trained to perform acupuncture. More recently, the CC has established a Pain and Palliative Care Service (described previously in more detail).

Cost-Based External Factors

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

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

Cost considerations have led to a rethinking of such pivotal issues as the basic processes and models of care delivery; the increasing reliance on non-physician primary care providers; an increasing penetration of managed care into the healthcare marketplace; a dramatic increase in competition for patients; and a shift to outpatient 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/CC environment. The CC finds common ground with the healthcare industry in the need to maintain fiscal accountability to customers and stakeholders. Several of the newer strategies and approaches have also become highly visible in the CC in the past five years, including increased use of physician extenders and a continued shift toward outpatient and day hospital studies.

Spiraling costs associated with healthcare and clinical research also led to a downturn in clinical research investigators on the NIH campus. For example, in 1997, the campus had only 386 investigators who were principal investigators on clinical research studies. During the past three years, the campus has witnessed a resurgence of interest in clinical research, fueled both by the NIH Director who has challenged the ICs to produce cutting-edge translational research as well as by the construction of a new Clinical Research Center. By the end of 2001, 417 principal investigators had active clinical research protocols, the highest number since 1995.

These dramatic trends provide numerous opportunities and threats to the CC and to the NIH intramural program.

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

- Evaluation of protocol-based care in a manner analogous to "critical pathways" will likely facilitate the development of a meaningful protocol based cost-accounting system, while simultaneously expediting staffing assignments and organizational planning. Such an approach will also provide a template for evaluating the clinical quality of the care delivered in the protocol as well as the extent to which patients are able to adhere to the protocol as it is written.

- The CC has developed an initiative to map all of the active clinical research protocols. These maps provide a template for the research plan and the requisite services but also serve to delineate the resources needed to support these studies. During the past two years, new software to support the protocol mapping process has been purchased and a contractor has been hired to facilitate the implementation of the software. The Director of the Clinical Center hired a Special Assistant who has extensive administrative experience at the University of Maryland to spearhead the protocol-mapping project.

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

- In 1996 Congress provided language in the NIH Authorization that permitted the CC to collect from third-party payers. In February and March, 1997, the CC held meetings with representatives from insurance companies, managed care organizations large, self-insured corporations and from the Health Care Financing Administration (HCFA) to discuss the potential for recovery of some of the costs of clinical research and to address the possibility of broadening the CC's referral base to encompass patients from health maintenance organizations and large insurer networks. The meeting provided CC leadership a great deal of insight into the current status of the insurance/managed care industry. The CC also conducted a six-month study of the insurance status of patients participating in clinical research studies at the CC. The CC's Board of Governors reviewed all of the information collected in this process, and, after careful consideration of the information recommended against the CC pursuing third-party payment for clinical research performed at the CC.

- The shift toward primary care has resulted in fewer high-quality young physicians in the fellowship pools, and less interest in clinical and basic science among medical school graduates. Many fellowship-training programs are closing. These trends clearly will have an impact on the manner in which the CC provides care to its clinical research subjects, as well as on the ICs' clinical and basic science training programs. The CC 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 non-physician providers affords the CC an opportunity to evaluate the model of patient care currently in use and to consider the creative use of non-physician primary 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 medicine, which is paralleled in the CC's operating statistics, provides an opportunity for CC scientists to develop creative, less expensive and labor-intensive protocols that can be conducted in the out-

patient clinics. This trend should be useful to CC and IC management in terms of reducing the costs of clinical research.

- Competition among healthcare delivery organizations for patients has become even more of a driving force in the healthcare environment in the past 60 months. The aggressive competition for patients and clinical research subjects provides both opportunities and challenges to the CC. The intense competition for patients will likely make recruiting patients for clinical studies more difficult. Competition has already had a profound impact on the academic medical community. Institutions that used to operate profitably and that used to have substantial excess revenues that could be used to help fund clinical research projects have had to scramble to remain solvent. High quality institutions continue to seek partnerships with the CC to facilitate their research and training agendas, to increase their visibility in certain markets, and as a marker of the prestige of the institution. The CC's new extramural alliances (discussed above) should strengthen its and its partners' competitive positions.

- The explosion in technology provides the CC with a unique opportunity to use these cutting-edge technologies to develop less expensive types of care. The CC 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. Two may have receded a bit; though, at the time of this writing, the extent to which they have receded is not clear. The first of these is the nearly exponential increase in capitated, managed care. In some areas the healthcare market may have become saturated with health maintenance organizations and managed care providers. In other areas of the country interest in fee-for-service medicine has been rekindled. Second, the trend toward early discharge has received both public and Congressional scrutiny and may have been reversed, at least for some specific circumstances. The subtle changes that have occurred will likely exert minimal influence on the extent to which cost considerations influence the CC environment. Despite these somewhat subtle changes, cost considerations continue to be the primary influence on change in healthcare in the U.S.

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 keeps sicker patients alive for much longer periods of time. As a result, such patients often remain at risk for care-requiring complications for extended periods of time. Such complications are often expensive and labor intensive. Rapid progress does, however, present unique challenges to the management and leadership of the CC. Rapid progress precipitates abrupt shifts in the research agenda, and often necessitates fast procurement of expensive new equipment, reagents and pharmaceuticals. The CC is ideally situated to reprogram resources to address new scientific opportunities for translational research. For example, since the last edition of this document, the CC has worked with several ICs (e.g., NIDDK, NIMH, NIAMS) to design and implement innovative new clinical research programs.

Effective planning is essential to keep an organization the size of the CC aligned with the NIH mission, the CC's mission and vision, and the ICs' rapidly changing research agendas. Management must remain attuned to the intramural and extramural research cultures, must be able to predict, or at least detect, where progress will occur, and position the organization to capitalize on the progress. When new technologies are identified, the CC 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 CC has to maintain effective communication with IC leadership to stay aware of progress as it occurs. Further, the CC departmental leaders must be flexible enough to reprogram resources and embrace progress as it occurs. Only in this way will the CC be able to supply the quality of clinical research infrastructure necessary to accomplish its mission. In the time period following the drafting of the original environmental assessment, the emphasis on molecular medicine and molecular techniques has continued to increase.

The characterization of the human genome has spawned the fields of genomics and proteomics. These two fields will likely help shape a substantial fraction of the future of clinical research studies on the NIH campus for the foreseeable future. Information systems technology is advancing almost exponentially and the explosion of this technology is fueling advances in many other biomedical research disciplines. The marked shift toward molecular medicine has engendered numerous additional changes in the complex CC 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. Secondly, the move toward molecular medicine has fostered increased investment in the technology needed to conduct these experiments and in personnel expert in managing the extraordinary data sets engendered by this technology. Third, this trend has produced a change in the manner in which we interact with our patients. In the past, extended hospitalizations may have been needed to conduct a study. For some of these experiments, a single phlebotomy may be adequate. Consequently, the CC 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-IC projects.

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

Medicine has begun to focus on costly variation in practice as well as on the benefits of standardization of the processes of care. The past three 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 for organizations and for components of organizations to have clearly measurable outcomes and processes. In addition, regulatory agencies, such as the Joint Commission on the Accreditation of Healthcare Organizations (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. Similarly, misadventures and mistakes in clinical research have given rise to increased scrutiny of the research environment and have resulted in increased regulatory requirements for a prescribed infrastructure to be in place to facilitate the conduct of research. NIH has been at the vanguard of this issue; the Medical Executive Committee published a set of Standards for Clinical Research and a process has been put in place to assure each IC's compliance with the standards. In addition, the NIH has volunteered to have its clinical research program evaluated as a pilot for an organization that plans to develop an accreditation process for clinical research somewhat analogous to JCAHO accreditation for clinical care.

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 clinical research. The CC was among the first organizations in the nation to require completion of a basic course in clinical research principles in order to be an approved investigator on a protocol. In addition several other clinical research-training courses (described previously in more detail) address this identified need.

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

The past three years have seen a worsening of a preexisting problem – a national shortage of crucial patient care and clinical research support personnel. Substantial workforce shortages have developed in nursing, pharmacy, clinical and imaging technical staff, and information technology personnel. In 2001, the CC is actually faring extremely well in these areas (i.e., with less turnover and fewer unfilled positions compared with other institutions in our community).

Nonetheless, all these 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 alternative personnel authorities to speed the hiring process, making use of all available mechanism to create and maintain a competitive salary and reward structure, 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 CC is well situated to take advantage of the remarkable opportunities presented by the ongoing revolution in information systems management. Teleconferencing and telemedicine are likely to be of great value in the recruitment and management of patients at sites far removed from the CC. In addition, the striking progress in information systems technology presents unique opportunities to: 1) improve the quality of care provided to CC research subjects; 2) improve the training of clinicians; 3) create substantial efficiencies in the manner in which clinical research subjects are managed in the institution (e.g., display of histological sections, radiographs, magnetic resonance and computed tomography scans, electronically at the patient's beside or in the investigator's office, as soon as the studies have been interpreted); and 4) 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 clinical, fiscal, and managerial needs. The CC clearly needs to integrate its patient care information system with a real-time, effective managerial and fiscal system. In addition, the CC is faced with the challenge of integrating three different types of data essential for managerial efficiency: 1) clinical patient-care data; 2) cost-accounting data; and 3) research-laboratory data. The challenges associated with the rapidly accelerating field of medical information systems management are: 1) staying abreast of the technology as it advances; 2) assuring that components of the organization have adequate information systems support to conduct its business efficiently and effectively, while simultaneously assuring that these systems are compatible with each other; and 3) making certain that the organization is consistently investing an appropriate amount of its resources into information systems technology. The information systems expertise already present on the NIH campus, combined with the investigational mandate of NIH, provides an ideal milieu for the development of automated, clinically relevant healthcare systems.

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

The Clinical Center has hired a Chief Information Officer and has reorganized the Information Systems staff into two departments – the Department of Network Applications (DNA) and the Department of Clinical Research Informatics (DCRI) – to meet organizational needs. The leadership of DCRI is charged with the oversight of the design, procurement and implementation of the new Clinical Research Information System (CRIS). This process is inherently collaborative, with CC and IC customers taking lead roles in advising the Chief of DCRI. To date, the many customers have agreed on a plan for replacing the existing Medical Information System with a new CRIS 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 also brought online during the past two years, substantially improving the information management in Laboratory Medicine, Transfusion Medicine, and Anatomic Pathology (NCI).

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

The American public receives a great deal of its information about medicine, medical progress, and medical and clinical research-related misadventures from the lay press. The press frequently focuses on unique, "newsworthy" numerators, while not necessarily providing a denominator for perspective. Such stories may contribute to a general mistrust of medicine and, in the eyes of the American Association of Medical Colleges have fostered a general decrease in public support for academic medicine. This increasing

presence of the press presents a challenge for the CC. The organization must develop techniques for making certain that the breakthroughs and benefits of the clinical research conducted at the CC receive appropriate attention in the press.

Medicine has traditionally avoided efforts intended to standardize its practice.

The fact that medicine has attempted to maintain itself as an "art" rather than a science has led to wide variation in the ways in which physicians provide care for patients who have similar illnesses or similar disease presentations. Pioneering studies evaluating medical systems and processes have documented substantial variation in care delivered to patients with similar syndromes and similar severity. These studies and the burgeoning interest in "process improvement" have resulted in an increasing focus on the systems and processes of medicine. This focus has also produced a heightened level of interest in the design and conduct of behavioral, clinical effectiveness, and cost effectiveness studies. Driven by cost concerns, the "outcomes" of various care strategies have become increasingly important. Most "outcomes" analyses are based on scientifically sound epidemiological principles. For this reason, the CC 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 CC's work relevant to medicine today.

The value of assessing the extent to which clinical research practices are standardized has become evident in the CC's clinical research environment. At the NIH level, the standardization of clinical research practices has been a major focus of the Clinical Research Revitalization Committee. As noted above, the CC has embarked on an initiative to "map" all the active clinical research protocols – both to determine the resources needed to support these studies as well as to track the extent to which the studies are proceeding as planned. In addition, Congress has mandated that NIH invest more in the area of "health-services" and/or medical "outcomes" research.

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 U.S. 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 $125,000, new graduates often simply cannot afford to take three to seven additional years' training before they begin to repay their debts. This challenge provides the CC 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 the international reputation of the NIH leads to international collaborations and attracts motivated and gifted postdoctoral fellows from the international scientific community. These fellows work in NIH programs, supporting the NIH mission. Their work at NIH, in turn, facilitates the development of their careers when they return to their respective countries.

The shift toward primary care has also resulted in an overabundance of physicians in some specialties and subspecialties. This relative surplus has resulted in fluctuations in academic salaries, particularly for some historically highly paid specialties such as radiology and anesthesiology.

Government-Based External Factors

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

Each year, primarily as a consequence of the penetration of managed care in the healthcare marketplace, in order to compete, academic centers have fewer dollars available for clinical research. Similarly, Federal agencies are responding to five goals of the new administration. Outsourcing 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 previous administration, 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 are new personnel/appointment mechanisms (e.g., Title 38, Title 42) that permit the CC to pay highly competitive salaries to physicians, nurses, and allied health professionals that previously would have been impossible under standard Title 5, General Schedule pay authorities. The combination of fluctuating salaries for some medical specialties because of market pressure (discussed above) plus the remarkable flexibility of these new personnel authorities has made it possible for the CC to assimilate contracts that were previously necessary to provide adequate medical coverage for CC patients. For example, the CC had previously been unable to pay salaries that were competitive with those at academic medical centers for radiologists and anesthesiologists. These services, therefore, were contracted out. The new pay authorities made it possible for the CC to assimilate the radiology contract (projected annual savings in excess of 1.2 million dollars) and the anesthesiology contract (annual savings of up to 1.2 million dollars). The CC has continued to seek additional organizational efficiencies. During FY2001-2002, the CC assimilated the last eight positions from a longstanding (and formerly quite large) contract supporting the Imaging Sciences Program.

The new administration has reiterated an interest in government wide-management reforms and has established five major management reform goals:

1. **Budget and Performance Integration:** The Office of Management and Budget (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 FY2003. 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.

2. **Strategic Management of Human Capital:** The President has proposed making the government more citizen centered (i.e., ensuring as little distance as is possible between the citizens and decision makers). Two approaches will be used to address this goal: flattening or streamlining 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.

3. **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 FY2003 that agencies complete public-private or direct conversion competitions involving 10 percent of the FTE listed on their Federal Activities Inventory Reform Act inventories over that competed to meet the FY2002 competition goal. NIH will submit implementation plans for achieving this goal and the CC will be required to participate in these streamlining activities.

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

5. **Expanding 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 per-

formance/ outcomes oriented (and includes specific goals). To accomplish this goal:
1) agencies will be required to identify information technology investments that can be redirected or restructured; 2) agencies should maximize the use of electronic means to deliver services and benefits in a citizen-centric matter, while assuring both security and privacy.

Regulatory requirements are becoming more stringent and more burdensome.

Requirements of organizations that regulate the conduct of patient care and clinical research in the CC have increased substantially over the past two decades, in many instances without clearly adding value. Some oversight and regulatory activities arise from within NIH (e.g., Office of Human Subjects Research, Recombinant DNA Advisory Committee, Office of Scientific Integrity); others arise from IC programs (e.g., Cancer Treatment Evaluation Program, NCI); others arise from governmental agencies/departments (e.g., Inspector General, Food and Drug Administration) or organizations (e.g., Nuclear Regulatory Commission, Occupational Safety and Health Administration), and still others arise out of a continuing need for external evaluation and accreditation of clinical activities (e.g., Joint Commission on Accreditation of Healthcare Organizations [JCAHO], College of American Pathologists [CAP], American Association of Blood Banks [AABB]). The CC 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 CC 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 & Medicaid Services for the Clinical Laboratory Improvement Act of 1988 [CLIA] and [JCAHO] surveys), and the requirements of some others provide justification for the renewal of the CC.

In light of the increasing activity in the area of molecular medicine and the virtual explosion of new laboratory tests that can be used for diagnosis and prognosis in medicine, the CC, and, in fact, the entire NIH has come under increasing pressure to have its laboratories comply with CLIA. The CC Director has been given the task of ensuring that all intramural laboratories performing laboratory tests linked to patient identifiers that may be used in patient care meet CLIA standards. To establish the processes, to perform the internal proficiency tests, and to maintain the records necessary to comply with CLIA, will likely be viewed as substantial regulatory burden by NIH investigators.

Agency (NIH)-Based External Factors

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

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

- NIH and IC administrators have made a major investment in scientific quality. Several ICs have conducted detailed external reviews of their intramural programs in the past 60 months. In addition, an external panel convened by the NIH Director (i.e., the Marks/Cassel Committee) issued a detailed report that provided clear recommendations to revitalize the intramural program.[20]

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

- The rigor of scientific reviews has been intensified.

- The NIH Director, and several intramural scientists have made a major effort 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 CC has developed a proactive strategy for managing new programs and significant program expansions that includes biweekly meetings with all IC and CC stakeholders, the creation of an implementation plan, and ongoing follow-up with IC leadership and staff to assure smooth implementation.

- As technology advances, institutes are increasingly requesting more, and more sophisticated, clinical research support. During institute planning meetings for the past two years, an increasing number of requests for clinical research support activities (as opposed to standard care support) have been received. The CC 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 CC. One example of such a service is the CC's Clinical Epidemiology and Biostatistics Service. This service, initially established to meet the needs of CC investigators, has been expanded to meet the needs of some institute investigators. Some institutes that lack adequate biostatistics and study design support have been willing to fund part or all of a full time employee to allow their investigators access to the service.

- The costs associated with conduct of biomedical research are escalating faster than inflation, necessitating that Institutes carefully evaluate costs and quality of proposed intramural projects with more rigor than has been done in the past.

- A variety of factors have conspired to produce an unprecedented level of trans-IC 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 CC and NIH leadership on planning;

  - Emphasis on the part of CC leadership on the inclusion of major customers, partners and stakeholders in the planning process; and

  - Joint CC/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 for the organization to reassess the processes that it uses to provide care and affords the opportunity to redesign some of these processes to improve patient care quality and/or efficiency.

- During the past two years a new funding stream has been established for the CC. This funding mechanism is influencing IC stakeholders to bolster their clinical research programs and has likely contributed to increasing use of the CC. ICs pay a "school tax" based directly on the size of the ICs' intramural appropriation to support the CC (without regard to the extent to which the IC uses the facility); the disincentive to use the CC (in the previous funding scheme) has been replaced with an incentive to use it. This approach also solves the problem identified by the Smits Committee of the interdependence of the ICs' budgets under the prior funding structure.

- The Board of Governors oversight of CC operations lessens the extent to which the CC must try to respond to the competing priorities of its IC customers. This increased independence should permit the CC to become more efficient and to foster collaboration among the ICs conducting research in the CC.

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 CC. In the late 1980s and early 1990s, however, the increases in the costs of clinical research in the CC 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 CC 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 ICs. Even in the year 2001, however, the CC still faces the challenge of overcoming a reputation, developed from 1950 through the 1970s, of not being cost conscious.

In the past several years, both the Congress and the President have publicly stated a goal of doubling the NIH budget. Thus, NIH and the CC have received substantial budget increases for the past several years. The process of doubling the NIH budget will be completed in 2003, and NIH leadership believes that subsequent years may not see such robust increases in funding. Given that certain hospital costs (e.g., pharmaceutical and soft goods inflation) will continue to escalate at a rate that far exceeds intramural budget growth, CC leadership and managers need to plan now for leaner times in the future. The next two years provide the CC with an excellent opportunity to identify organizational efficiencies, develop cost-consciousness and to develop innovative approaches to care and clinical research delivery to allow the CC to remain financially sound within the budget that NIH gives to the organization. The CC has taken several approaches to increasing its organizational efficiency, including the assimilation of expensive contracts, the institution of operational reviews for CC departments, and increasing reliance on the CC Board of Governors who have substantial expertise in healthcare operations.[20] The Board, which includes numerous healthcare executives from prestigious extramural academic centers, provides advice to the CC Director concerning CC operations. The modified governance structure and the Board of Governors have provided CC leadership with the opportunity to manage the operations of the organization more efficiently than ever before.

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

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

As noted above, collaboration among ICs becomes increasingly important as the new Clinical Research Center is being planned. ICs 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 or center based, but rather based on clinical disciplines or programs of care, ICs will be required to share space and resources in the new facility. The nature of modern molecular medicine calls for more cross-IC collaboration. The CC and IC stakeholders worked together to form groups of partners among the ICs that will be sharing space and resources in the new facility**.** These groups of partners have increased the quality of the planning effort substantially.

NIH has endorsed a change in governance for the CC.

The creation of the CC's Board of Governors provided the CC with the unique opportunity to create a governance structure that can prepare the organization to compete effectively in the clinical research arena for the foreseeable future. The new governance structure has permitted the following unique opportunities for CC management:

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

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