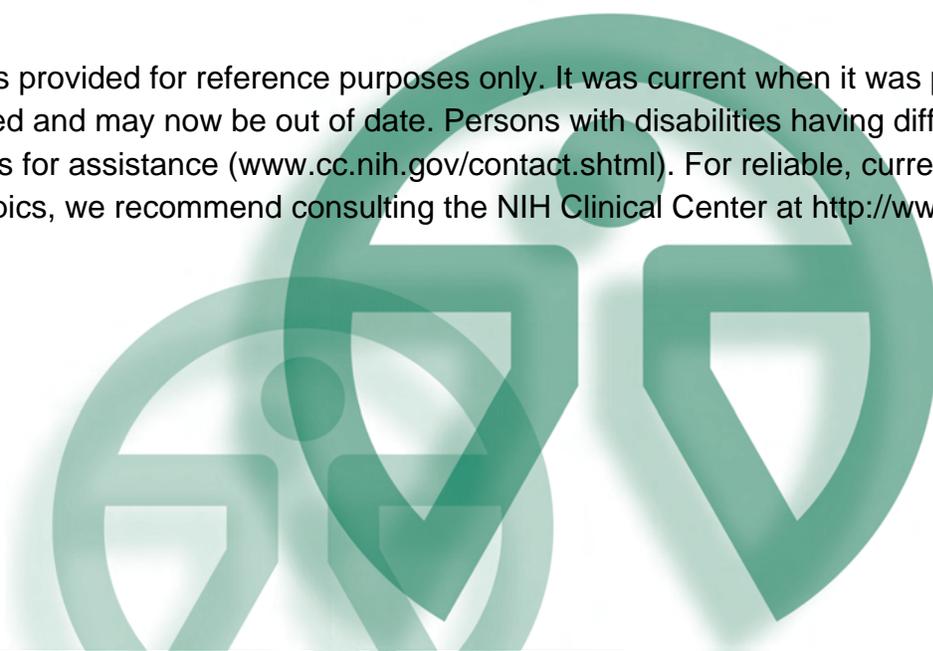


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Strategic Plan

Clinical Center

Environmental Assessment

**National Institutes
of Health**

2009

Clinical Center, National Institutes of Health Strategic Plan – Environmental Assessment

2009



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Executive Summary



The Clinical Center of the National Institutes of Health faces substantial challenges and opportunities in the year 2009 and beyond. During the seven-year period, during which the budget of the National Institutes of Health was doubled, the Clinical Center's budget increased substantially. The CC budget has declined from 17.8 percent of the total IRP budget in 1994 to 12.4 percent in 2008. These tight financial times have necessitated the implementation of a variety of savings, cost sharing and efficiency initiatives and resulted in a large capital equipment gap. As part of Clinical Center strategic planning activities, our organization conducts a thorough environmental assessment to determine Clinical Center strengths, weaknesses, opportunities, and threats. This document represents the seventh iteration of the Clinical Center's strategic plan environmental assessment. The Clinical Center has thirteen years' experience using, evaluating, and modifying its strategic and operating plan. In those thirteen years the factors influencing our environment have continued to change. This document: summarizes the new developments in the Clinical Center's environment since the publication of the last environmental assessment; summarizes the interventions that have been taken to address weaknesses and bolster strengths; identifies changes that have occurred; and provides additional comments within the context of the original environmental assessment.

The Clinical Center has numerous strengths, among them:

- The Clinical Center is the clinical research hospital supporting one of the strongest, most visible scientific programs in the world – the intramural program at the National Institutes of Health;
- The Clinical Center has a critical mass of world-class scientists and clinical investigators working closely together to develop and conduct translational clinical research;

- The support staff and research infrastructure in the Clinical Center are uniquely tailored to support excellence in clinical research;
- The Clinical Center focuses on a unique research portfolio of work that would be difficult, if not impossible, to conduct at other centers;
- The Clinical Center staff are capable of providing, and have consistently provided, the highest quality patient care to clinical research subjects;
- Unlike patient-care-oriented academic centers, the culture of the Clinical Center is science-driven;
- Because of its unique clinical research mission, the Clinical Center has organizational and scientific flexibility that most institutions do not possess; and
- The Clinical Center provides investigators access to expensive and state-of-the-art technologies that are not readily available in many other centers.

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

During the preparation of the first iteration of this document in 1996, self-evaluation also identified several organizational weaknesses at the Clinical Center, among them:

- Existing Clinical Center governance mechanisms were unclear;
- The Clinical Center was subject to bureaucratic inflexibility in personnel, procurement, and fiscal management;
- The Clinical Center's physical plant urgently needed renewal;
- The Clinical Center lacked a strategic plan;

- Clinical Center information systems did not adequately support managerial and financial data and do not integrate clinical, research, managerial and financial data;
- Clinical Center successes were not adequately communicated to the public, to referring physicians, and to the insurance and managed care industries;
- Patient recruitment efforts were increasingly less successful; and
- Some customers viewed the fact that the Clinical Center does not offer complete, integrated medical and surgical services as an institutional weakness.

Progress in Addressing Identified Weaknesses

Over the past thirteen years, many of the weaknesses identified in the initial environmental assessment have been addressed. The Clinical Center governance structure was initially clarified by the establishment of a Board of Governors, which has subsequently had its charter broadened to become the Advisory Board for Clinical Research. During the past seven years the Clinical Center's governance has continued to evolve. A report issued in 2003 by the Institute of Medicine suggested streamlining the governance of the NIH clinical research enterprise. In addition, an advisory panel, the Blue Ribbon Panel on Intramural Clinical Research, convened by the NIH Director in the fall of 2003 once again assessed (and subsequently revised) Clinical Center governance structures. During the tenure of the most recent NIH Director, the NIH administration added additional layers of governance for the Clinical Center and other shared services on the NIH campus. These additional governing bodies added increased customer input, but also increased the complexity of the oversight of the Clinical Center (discussed in more detail below). With respect to the physical plant, we moved into the new Clinical Research Center (CRC) in April of 2005. In addition, we replaced our Medical Information System with a comprehensive, mission-oriented Clinical Research Information System in 2005 and added a new pharmacy information system in 2008. To address the concerns inherent in tighter financial times, the organization has developed strategies to transform our data collection processes in order to provide far more detailed financial data to both Institute and Clinical Center customers and developed some new cost-sharing initiatives with the NIH Institutes to

address the ongoing financial constraints. This year the Clinical Center has launched a new initiative to attempt to communicate more effectively with its referring physicians and patients. These changes and the impact produced by these changes are discussed in detail in this update.

At the urging of the Advisory Board for Clinical Research, the Clinical Center is also seeking ways in which to identify additional revenue streams and to make its resources available to extramural partners. The CC Director has expanded the Bench-to-Bedside award program to include extramural investigators and this new process has been enthusiastically received both by the extramural community as well as by intramural investigators.

Weaknesses Identified Since 1996

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

- Communication practices were inconsistent across the CC and the NIH;
- The Clinical Center did not routinely seek customer input about its services;
- Clinical Center customer service needed improvement;
- The Clinical Center needed to make additional investments to assure workforce diversity;
- The Clinical Center had difficulty reconciling competing Institute demands within a defined budget and had no clear-cut mechanisms for making decisions that benefited the entire organization (as opposed to individual customers/stakeholders);
- The Clinical Center and the institutes have variable infrastructures to support their independent investigators and to support the processes of clinical research, often resulting in uneven processes for scientific and human subjects protections reviews;
- Outpatient surgery and ambulatory care facilities were in need of redesign;
- The very constrained budgets of 2002 through 2009 produced a substantial deficit in capital equipment and required the development of new strategies to gain operational efficiencies,

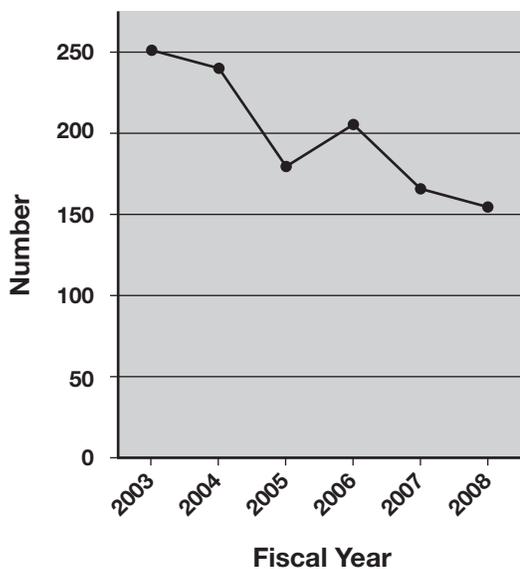
some of which involve cost-sharing with institutes and institute investigators;

- After a peak during the budget doubling years (and immediately prior to opening the new CRC), the inpatient census fell, initially leaving the CC with unused capacity; however, during the past eight months the census has increased in a sustained fashion, significantly outstripping IC plans for the year;
- Institute protocols increasingly require sophisticated and costly molecular genetic tests and sequencing that are not available through CC laboratories.
- Despite the opening of the new CRC, several facilities-related issues present significant barriers to progress, among them: the complexity of the relationship between the CC and the NIH Office of Research Facilities (ORF); the need to resolve facility and environment of care deficiencies identified in a surprise Joint Commission survey; the need to develop strategies to correct deficiencies in ongoing required preventive maintenance and ongoing repair activities in both the Hatfield and the Magnuson buildings; the need to address problems with meeting regulatory requirements for construction and renovation in the hospital; the urgency of addressing an inadequate infrastructure (power, air handling, and chilled water) in the ACRF and adjacent areas that were constructed in the late 1970's. These problems were compounded by the fact that many of the positions in the Office of Research Facilities (ORF) were eliminated (or experienced staff left) as a result of the A-76 process that was designed to assess the practicality of the potential for outsourcing many, if not most, of the ORF positions;
- The changes in the ethics rules that were effected in 2005 concerning stock holdings, consultation for industry, and other compensated outside activities continue to have an adverse impact on recruitment, retention and morale. Whereas the adverse impact is still being felt on the Intramural NIH campus, since similar rules are being applied to academic centers extramurally, the overall impact may be lessened somewhat.
- DHHS facilities are not covered by existing legislation to assure the nondiscoverability of peer review information. Although the VA has legislation that protects peer review information from discovery, the protection does not apply to DHHS healthcare facilities. Legislation providing protection for peer-review has been proposed by the Indian Health Service, but that legislation does not include the Clinical Center or the NIH;
- The new Administration has expressed a clear intention to reform the U.S. healthcare delivery system. Substantial reform of this system will almost certainly have an impact on NIH and the Clinical Center. Until the reform effort develops a clear direction, NIH, the CC, and the academic clinical research community will experience some uncertainty about the impact that this reform will produce;
- The new Administration has expressed a desire to increase the transparency and measurability of the actions of the Federal government and its Agencies. NIH can anticipate increased requirements in this regard over the ensuing several years. One such example of increased transparency is the registering and reporting of clinical trials and their results.
- The CC has substantial underutilized capacity. The CC currently functions at an average inpatient daily occupancy of approximately 70 percent. The outpatient clinics are approximately 50-percent utilized (assuming 12-hour days Monday through Friday and eight hours on Saturdays). The CC's unused physical capacity could foster symbiotic relationships between the intramural and extramural investigators by making available the CC's phenotyping expertise, the GMP facility for making candidate drugs, imaging capabilities including the three cyclotrons for making PET ligands, special blood products, and special laboratory testing, among others. No budget exists to facilitate these interactions. We have no welcoming facilities such as offices and support staff at the CC for visiting investigators.
- There are few extramural and industry partnerships with intramural programs. Since the CC opened in the 1950s intramural investigators have engaged in partnerships with extramural investigators, but the number of intramural-extramural partnerships in clinical research has been relatively few and partnerships with industry have become relatively scarce in recent years. This paucity of partnerships reflects, to some extent, a reluctance of industry to navigate

complex government regulations. More interactions between intramural and extramural investigators would enrich the academic environment in intramural clinical research programs, providing important bridges between early and late phase clinical trials, and likely facilitate recruitment of young investigators to the intramural programs.

- The number of active clinical research protocols is declining. In FY 2008, 1,449 protocols were active and 155 new clinical protocols were initiated at the NIH. This number of new protocols is down 38 percent from 251 in FY 2003 (Figure 1). In addition, a significant concentration of clinical activity occurs in just a few protocols. Only 37 protocols, or 2.6 percent of the total, account for 50 percent of CC patient activity. Of these 37 protocols, 27 (9 clinical trials and 18 natural history studies) account for 29 percent of all clinical activity, while 10 other protocols that screen patients for enrollment into protocols account for an additional 21 percent of patient activity. Another 523 protocols (48 percent) account for 48 percent of the remaining clinical activity

Figure 1. Number of New Clinical Research Protocols



Progress in Addressing Weaknesses Identified between 1996 and 2009

- Through an improved and more detailed annual planning process, the Clinical Center has sought to improve communication practices and

organization planning across the CC and the NIH; this process has continued to evolve over the past three years;

- The Clinical Center has developed several techniques for seeking customer input and routinely uses these data sources for organizational improvement activities; data from ongoing patient surveys are being used to drive redesign of patient care processes that are important to the Clinical Center’s mission and operations;
- The Clinical Center embarked on a major customer service initiative that has produced tangible evidence of improved customer service; this year the Chief Operating Officer and the Director of Radiology and Imaging Sciences are spearheading a follow-up to the initial customer service initiative.
- The Clinical Center undertook a major initiative to assure workforce diversity;
- The Clinical Center continues to work in concert with advisory groups, such as the Advisory Board for Clinical Research, the Institute Scientific Directors, the Intramural Working Group, the Management and Budget Working Group and the Institute Directors, as well as within its own organization, to reconcile competing Institute requests, to address service needs for program expansions and new initiatives, and to maintain stewardship of its resources to be able to meet these expanding needs in a time of modest budget growth. In order to be able to maintain services at equivalent levels during times of budgetary constraints, the CC has shifted the costs of some research support activities to the Institutes and Centers desiring these services
- The CC Director, working with the Clinical Center’s Medical Executive Committee developed two sets of standards: Standards for Clinical Research and Standards for Clinical Care. The Standards for Clinical Research represent the minimum infrastructural standards that all NIH clinical research programs should have in place to assure appropriate investigator support, as well as the safe conduct of clinical research. These Standards were reviewed and revised in 2008. The Standards for Clinical Care represent the minimal standards for clinical care for patients at the NIH Clinical Center;

- The CC is renovating and has already partially opened a redesigned outpatient surgery venue; the remainder of the construction and renovation in this area will be completed in FY 2009;
- To assure efficient operations of our Departments, the CC has developed a process for systematically reviewing the operations of our departments. These operational reviews involve both extramural experts in the field, as well as intramural stakeholders. In addition, CC leadership has launched a Data Transformation Initiative that is designed to provide more precise data about the costs associated with CC services at a more granular level than is possible with the activity-based costing approach
- To address the issue of unused capacity, the CC Director developed a highly successful program for competitive “Bench-to-Bedside” awards to stimulate creative translational work, initially on the NIH campus, and, more recently, including projects involving extramural investigators. In addition, the Director of the Clinical Center has entered into a dialogue with the NIH administration and IC leadership about making more of the Clinical Center’s unique clinical research infrastructure available to extramural scientists.
- The Clinical Center is working with the leadership of the NHGRI and the Clinical Center’s Department of Laboratory Medicine to develop a strategy to meet investigators need for molecular genetic tests. By contracting for these services with a limited number of vendors, we hope to gain volume discounts. In the future we anticipate offering whole genome sequencing capability at the Clinical Center.
- The Director of the Clinical Center established a working group, including the Director, the Clinical Center’s Chief Operating Officer and CC and ORF Deputy Directors, as well as other involved customers and stakeholders in life safety processes in the CC. A new oversight position that reports both to the CC Director and to the Director of ORF was established in 2008. The joint working group meets regularly and is systematically addressing the relevant construction, renovation, maintenance, and engineering and life safety issues to maintain compliance with regulatory standards. Whereas much progress has been made, substantial work remains to be accomplished.

Opportunities and Threats

As part of its environmental assessment, the Clinical Center has also evaluated opportunities and threats that present themselves as a result of changes in its external and internal environments. Most of the factors initially identified as driving change remain present in our environment in the year 2009 and beyond. Among the factors identified from the external and internal environments that are presenting opportunities and/or threats to the Clinical Center’s mission are:

- *The economic recession and the severely declining U.S. and global economies have added a degree of instability to the NIH fiscal outlook. NIH budgets have been substantially constrained during these tight economic times. The Administration’s response to the recession resulted in an economic stimulus plan that included funds for NIH through the American Recovery and Reinvestment Act.*
 - The Clinical Center received \$15M from this Act to help close the capital equipment gap that resulted from the flat budgets for the past seven years.
- The change in political Administration in the U.S. will likely be associated with substantial changes in the Federal science agenda.
 - The new President almost immediately modified the ban on embryonal stem cell research, resulting in the expectation that the Clinical Center’s Department of Transfusion Medicine will need to be able to provide clinical services that support embryonal stem cell research. Other similar changes can be anticipated over the ensuing three years.
- *The dramatic changes in the political climate, including the ongoing wars in Iraq and Afghanistan, the aftermath of the heretofore unthinkable acts of September 11, 2001 and the continued threat of additional acts of terrorism have resulted in unprecedented numbers of returning soldiers who have experienced traumatic brain injuries (TBI) and/or post-traumatic stress disorder (PTSD), have mandated increased attention to emergency preparedness in our institution, have resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries, and have fundamentally altered the day-to-day workplace lives for individuals working on the NIH campus.*

- To address the complex issues relating to hospital and community emergency preparedness in the 21st century, the Clinical Center, the Suburban Hospital Healthcare System, and the National Naval Medical Center formed an emergency preparedness partnership – The Bethesda Hospitals’ Emergency Preparedness Partnership (BHEPP). This Partnership, composed of three diverse organizations that have strikingly complementary resources, has made it possible for the Clinical Center to plan for, and drill about, possible emergency situations in an unprecedented fashion.
 - In 2005, the DHHS Secretary contributed a 250-bed contingency station field hospital to be embedded at the CC for Partnership surge capacity and the Department of Defense provided \$5M in earmarked funding for the Partnership. These resources have been used to procure equipment and supplies, to support drills that are run jointly among the three partners, and to assist with ongoing strategic planning and preparedness assessments. In addition these funds will be used to test novel technologies in emergency situations. To facilitate transportation of patients, equipment and supplies from one facility to another in the time of an emergency, the Partnership also conducted a feasibility study of constructing either bridges or tunnels from NIH to the other partners.
 - In 2008, Congress passed a supplemental bill that, through the Department of Defense, funded a program at the Uniformed University of the Health Sciences (USUHS) to address the major issues associated with TBI and PTSD. The committee language from this bill stipulated that USUHS partner with the Clinical Center to conduct sophisticated imaging studies for this large initiative. Several ICs and Clinical Center Departments – including Radiology and the Rehabilitation Medicine Department – are participating actively in the planning and implementation of this large initiative.
- *The emergence of new infectious diseases, the resurgence of other infections, the increasing risk for pandemic influenza, and the potential for the use of highly pathogenic infectious agents as weapons of bioterrorism presents substantial threats to the public health and is associated with an urgent need to answer relevant scientific questions that may make it possible to mitigate the damage produced by these infectious diseases.*
 - The National Institute of Allergy and Infectious Diseases established a new select agent facility on the NIH campus and another new facility on the campus at Ft. Detrick in Frederick, MD. The Frederick facility includes animal facilities, as well as sophisticated imaging facilities to study animals infected with select agents. The CC Imaging Sciences Program is partnering with NIAID to provide imaging oversight for these studies. In addition, the CC has partnered with NIAID to open a new patient care space in a previously shelled area of the CRC (5 NE). This space provides a home for the Vaccine Research Center clinic in NIAID, but also includes a self-care unit that can be used for vaccine-trial and other low intensity studies. This unit was designed to be able to be contained, in the event that a vaccine study required special containment and also includes a high-containment isolation room that could be used to manage a patient with a select agent infection.
 - *Societal values are changing and these changes are influencing healthcare and clinical research; society relies increasingly on technology and technological advances (including those in the fields of medicine and biomedical research) to provide what has come to be the expected level of health, function, and longevity.*
 - *The population and its health interests and knowledge base are changing rapidly. Patients and clinical research subjects are becoming increasingly sophisticated healthcare consumers; science education in the 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.*
 - *Cost continues to be a primary consideration in healthcare delivery and clinical research. Clinical research is intrinsically expensive; healthcare inflation is high. The net effect is that containing costs in the Clinical Center environment is difficult.*

The current Administration's plan for healthcare reform is likely to have a substantial impact on the healthcare cost structure in the U.S. for the foreseeable future.

- *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.*
- *Clinical Medicine is also experiencing a national shortage of anesthesiologists, nurses, pharmacists, phlebotomists and medical and radiological technical staff.*
- *The pharmacy and biotechnology industries have substantial influence on healthcare costs and processes in American medicine.*
 - Rapidly evolving biotechnology and pharmaceutical product development in the past decade have dramatically altered the practice of medicine in the U.S. Many of these new drugs and devices represent striking breakthroughs in biomedical research and have had a dramatic impact on American medicine. Often these new drugs and devices are approved for single (and often narrow) indications, but may have the potential for substantially broader use. Because of the risks inherent in the process, industry may have limited interest in providing support for scientific studies for broader-scale use of these products. Conducting such studies, while scientifically important, may be extremely costly, as many of these products have been associated with expensive research and development costs. To recoup their investment in research and development, pharmaceutical companies have priced these products accordingly. Over the past two years, the Clinical Center has worked through its governance to develop cost-sharing strategies with the ICs to purchase these marketed agents that are being studied for 'off-label' indications. More recently, The NIH Foundation has been working with leaders in the Pharmaceutical industry to encourage them to donate products or money to

support these ongoing research efforts at the CC. To date, one company, Sanofi-Aventis, has decided to make a donation of their products to support ongoing research and care at the Clinical Center.

- Because of the pivotal roles played by the pharma and biotechnology technology industries in the evolution of American medicine, the opportunities for collaborative research and development between NIH scientists and scientists in these industries are substantial. NIH needs to develop streamlined mechanisms to facilitate these important interactions.

■ *The new Administration, in its fiscal year 2010 budget, has outlined a new management agenda based on six themes:*

- Putting Performance First: Replacing PART with a New Performance Improvement and Analysis Framework
- Ensuring Responsible Spending of Recovery Act Funds
- Transforming the Federal Workforce
- Managing Across Sectors
- Reforming Federal Contracting and Acquisition
- Transparency, Technology, and Participatory Democracy

Performance measures will be evaluated in an ongoing manner and reported in a manner that creates a whole new level of transparency, not only for Federal stakeholders but for the American public. The Obama model takes Bush's emphasis on data collection and public reporting to a new level by focusing on evaluation of trends rather than the prior focus on program scores reported in PART. The emphasis on measurement and evaluation of program trends is intended to compel Agencies to use their measures to improve performance. One might argue that this Administration is attempting to create a more dynamic model of program management and evaluation akin to the classic 'plan-do-check-act' cycle of quality improvement theory. The new Administration has expressed a desire to increase the transparency and availability of this performance

improvement data. In addition to the new emphasis on transparent and proactive performance management, President Obama offers a new approach to managing the federal workforce. In contrast to the downsizing and competitive sourcing model of the prior Administration, the new workforce theme aims to bolster the image of public servants and create new federal jobs.

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

■ *Changes at NIH are also influencing the manner in which the Clinical Center operates; the governance of the Clinical Center has become increasingly complex over the past eight years.*

- The Clinical Center’s governance is complicated. The Advisory Board for Clinical Research evaluates the budget from the dual perspective of outside leaders in healthcare and NIH leaders who understand the clinical research programs. The NIH governance structure consisting of at least five groups reviews the Clinical Center budget from the perspective of a finite envelope of funds available within the NIH central service structure. The two parallel paths of review do not usually reach the same conclusion with regard to funding requirements. The final decision about the budget is made by the NIH Director. In the past few years, due to the multiple reviews and divergent perspectives, the roles of the respective governance groups are called into question. The need for streamlined governance and decision-making with regard to the Clinical Center continues to be a source of discussion and the catalyst for periodic outside reviews.

■ *To address the needs of the Clinical Center’s failing physical plant, a new Clinical Research Center opened in 2005.*

- The organization and administration of patient care in the new facility has been modified from Institute-oriented to program-oriented, necessitating a change in culture and a change in the processes used to provide care.
- The new building has also served as a stimulus for the Institutes to improve and expand their clinical research programs. Several

institutes initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. These program modifications require careful assessment by CC administrators and department managers to assure the provision of seamless clinical research support.

■ *Toward the end of the 1990’s several Institutes developed new initiatives that involve ‘off-site’ activities, and have requested CC support for these activities.*

- These programs range from ‘outreach’ efforts to underserved communities to emergency room-based programs at Suburban Hospital and the Washington Hospital Center to telemedicine projects. This trend toward developing outreach programs designed to offer clinical research opportunities to underserved populations has continued through 2009. NIAID and NIAMS have organized highly successful HIV and rheumatology clinics in the Cardozo community to reach out to the urban Hispanic population in Washington, D.C. In the last three years, both NCI and NHLBI have established presences in this clinic. The Clinical Center has developed strategies to address the many significant regulatory, economic, and logistical issues that arise from these initiatives in order to maintain the highest possible standard of care for the services it provides.

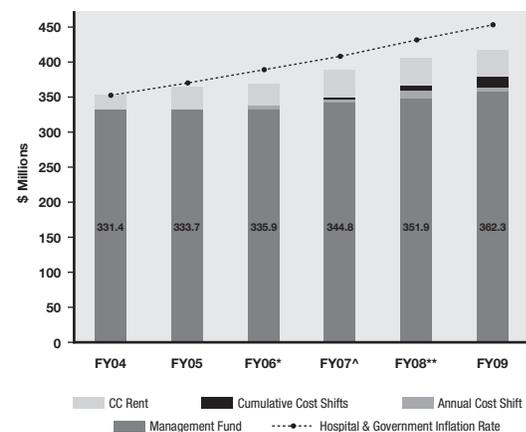
■ *The years 1995-2002 witnessed a doubling of the NIH budget.*

- During the period from 1998 to 2003 in which the NIH budget increased by 106%, the Clinical Center’s budget increased by 38%.
- The NIH intramural budget commitment to clinical research is estimated to be about one third of the total intramural \$3 billion budget, and the CC budget is about one third of this total intramural clinical research investment.
- The Clinical Center is the major hospital utilized by the NIH Institutes to support their intramural clinical research. The Clinical Center’s core budget allocation to support

hospital operations has been relatively flat for five years (Figure 2). Factoring in \$7.1 million of budget-neutral adjustments in FY 2006 and 2007, the core budget for CC operations grew just 7.2 percent from 2004-2009. From FY 2006 to FY 2009 the Clinical Center implemented cost shifts, amounting to a cumulative \$23.2 million, to the Institutes for certain research services. The Institutes' investment to support the CC is more than the core budget to support operations. Institutes pay rent for the hospital space, which has averaged \$33.8 million per year from FY 2004 to 2009 (Figure 2). From FY 2006 to FY 2009 there have been cost shifts to the Institutes for certain research services projected to be \$23.2 million in cumulative value (Figure 2). Thus, evaluating the period from FY 2004 to 2009 the Institutes' total investment in the CC from increased 17.3 percent (an average annual increase of 3.46 percent compared with the average impact of inflation on the CC budget of 4.9 percent annually). During this same period, the budget of the intramural program as a whole increased only 8.2 percent or 1.6 percent annually, not including the accounting correction in 2008 that added the NLM to the intramural budget line.

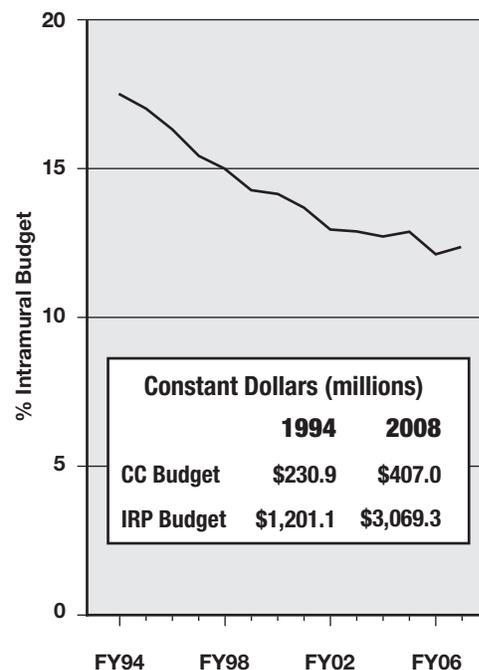
- Over a longer period including the doubling of the NIH budget from 1998 to 2003, the CC budget has grown less rapidly than the rest of the IRP and also has grown less rapidly as a fraction of the intramural program. The CC budget has declined from 17.8 percent of the total IRP budget in 1994 to 12.4 percent in 2008, including the addition of the NLM to the intramural budget line in 2008 (Figure 3). Since FY 1994, after controlling for inflation, the total NIH budget has more than doubled; the intramural research budget has increased 64 percent, while the CC budget has increased by just 15 percent.

Figure 2. Institute Investment in the CC 2004-2009



*FY06 includes budget neutral adjustments for security (\$2.2M) and NIBIB transfer (-\$1.5M)
 ^FY07 includes budget neutral adjustments for CRIS (\$6.4M)
 **FY08 includes additional funding for Capital Replacement

Figure 3. Total Institute Budget Commitments to the CC Budget as a Percentage of the NIH Intramural Budget



*Includes rent and cumulative cost shifts

- The cost shifts have been unpopular with the ICs and have resulted in a rethinking of the manner in which the Clinical Center is funded (i.e., the so-called “school-tax”), with some ICs favoring a return to a ‘fee-for-service’ approach. Unfortunately CC and its census, prior experience with such a “fee-for-service” environment was detrimental because it resulted in decreased use of the CC by the ICs.
- As technology advances, institutes are increasingly requesting more, and more sophisticated (and, therefore, often more expensive), clinical research support. This support includes imaging studies, sophisticated cell processing, and molecular laboratory tests. Such testing is expensive and requires complex (and often expensive) infrastructural support.
- *To address another perceived organizational weakness, the Clinical Center has replaced its medical information system.*
 - The new information system affords the organization the opportunity to develop better departmental, financial, and back-end (i.e., Institute) clinical research support than the previous system. In 2007, we added a new inpatient Pharmacy information system and in 2010 we will add an outpatient Pharmacy system that will include a robotic system for filling prescriptions. In 2008, we added a new Perioperative Information System, and a new Hospital Epidemiology Information System, as well.
- *In the past two years the CC opened a new laboratory, the Laboratory for Informatics Development, and also has launched BTRIS, the Biomedical Translational Research Information System, a powerful new tool for NIH investigators to access research data, develop streamlined mechanisms for protocol reporting and data analysis, and reuse data for hypothesis generation and collaboration. The CC recruited Dr. Jim Cimino from Columbia University to lead both these projects.*
- *The former NIH Director identified a clear need for strategic planning for the Nation’s overall clinical research enterprise and embarked on a path designed to lay out a ‘road map’ for the continued success of clinical research, both in the NIH intramural program, as well as throughout the United States. The CC Director continues to advocate for*
 - strategic planning at the level of the trans-institute NIH intramural clinical research program.*
- *Several years ago, scientists at NIH were the subject of several ethics investigations.*
 - A small number of individuals were found to have been noncompliant with Federal ethics rules. To address these deficiencies and Congressional concerns, NIH developed a new set of guidelines, policies, and review processes. These new policies limit employees’ opportunities for outside activities and also restrict employees’ relationships with industry (effectively barring consultative activities for remuneration and severely limiting opportunities for stock holdings).
- *The gap between salaries NIH is authorized pay and salaries earned by physicians at academic centers has continued to widen, making it difficult to recruit for scarce and/or highly paid specialties and subspecialties.*
 - Coupled with the restrictions on outside activities described above, recruiting and retention have become quite difficult. To counter this trend, NIH developed new salary limits for Title 42, and implemented a modified Title 38 appointment mechanism that includes an improved salary structure. Unfortunately, neither structure was really competitive with salaries at academic centers for the highest salaried scarce medical and surgical specialties. To attempt to address the salary disparities for clinical staff who practice in scarce medical and surgical specialties and subspecialties, the NIH Director and his staff developed a new salary track. Use of this new salary structure has made it possible to be competitive in the recruitment of anesthesiologists, imaging scientists and surgeons.
- *NIH has phased out the extramural General Clinical Research Center awards and program and has replaced this structure with a series of Clinical and Translational Science Awards (CTSAs).*
 - Centers receiving these new awards will, of necessity, be much more integrated than in the previous program and, as a result, will offer unprecedented opportunities for the Clinical Center, as well as for intramural investigators, to partner or participate in their activities. The Clinical Center has already begun a

series of successful interactions and collaborations with the CTSA network. Examples of successful interactions between the Clinical Center and CTSA sites include:

- **Clinical Research Subject Survey** — The Clinical Center developed a clinical research subject survey to assess the satisfaction of participants with clinical research projects and processes. This survey is being adapted and expanded by investigators at the CTSA at Rockefeller University and will be tested broadly across the CTSA network.
- **Informatics** — The Clinical Center, in partnership with intramural institute based investigators, created a new informatics tool called ProtoType, a protocol authoring tool that provides a structure for writing protocols and includes IRB recommended language cassettes and important teaching tools. In addition, ProtoType provides the ability to implement new policy or regulatory requirements rapidly and centrally. ProtoType is designed to be much more than a protocol authoring tool and has the potential to submit protocol information to ClinicalTrials.gov, map protocols for resource projections, send alerts to Principal Investigators for noncompliance with protocol intentions and assist in the preparation of Adverse Event Reports. The Clinical Center looks forward to sharing this new technology with the CTSA network.
- **BTRIS and the Data Repository** — As noted above, the NIH intramural program recently launched the BTRIS project. The Biomedical Translational Research Information System (BTRIS) is a resource available to the NIH intramural community that brings together clinical research data from the Clinical Center and other NIH Institutes and Centers. BTRIS provides clinical investigators with access to identifiable data for the subjects on their own active protocols, while providing all NIH investigators with access to de-identified data across all protocols. BTRIS provides users with advanced search, filtering, and aggregation methods to create data sets to support

ongoing studies and stimulate ideas for new research. BTRIS Version 1.0 contains subject data from CRIS, MIS, NIAID (Crimson) and NIAAA. Future versions of BTRIS will contain additional historical and clinical data back to 1976, images, and subject data from other IC Systems such as NCI.

- **Clinical Research Nursing** — The Nursing Department in the Clinical Center has partnered with nursing leadership at the Rockefeller University as well as nurses from other CTSA programs to define the specialty of clinical research nursing. A new network of Clinical Research nurses is being established that will unify this new career path in nursing, establish training modules for research nurses and identify requirements to be a clinical research nurse.
- **Training** — The NIH Clinical Center, together with IC based investigators, has developed a core curriculum in clinical research with three core courses: an introductory course on the Principles and Practice of Clinical Research, Clinical Pharmacology and Clinical Bioethics (described in more detail below).
- **Bench to bedside awards** — The Clinical Center has coordinated the intramural bench to bedside awards program for 11 years. These awards are designed to promote interaction between basic and clinical scientists. This highly successful program sponsors awards at \$135K per year for two years. Funding for the program is provided by ICs, the Food and Drug Administration (FDA), the NIH Office of Behavioral and Social Sciences Research (OBSSR), the Office of AIDS Research (OAR), the Office of Rare Diseases Research (ORDR), the Office of Research on Women's Health (ORWH), the National Center on Minority Health and Health Disparities (NCMHD), and the National Center for Research Resources (NCRR) and represents a total investment of over \$32M. For the past four years this program has encouraged partnerships between intramural and extramural investigators, including collaborations between

intramural and CTSA scientists. The Clinical Center plans to continue expansion of these awards and to pursue mechanisms for stable program funding.

■ *NIH developed a new Undiagnosed Diseases Program. This program expands and consolidates the NIH intramural program's substantial experience with molecular diagnosis and the management of rare and orphan diseases.*

- This highly successful program has received substantial publicity and has attracted much interest from the media and the public. The Clinical Center played a significant role in creation of the program and continues to provide clinical and infrastructural support for this novel program.

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

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

Introduction



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

The process of self-assessment and improvement is a continuous cycle. In 1995, the Clinical Center was provided with a unique opportunity to conduct a thorough environmental assessment as a result of a mandate from the DHHS Secretary. This review ultimately provided the Clinical Center with an opportunity to review the best practices of 30 facilities throughout the country, with an eye toward adopting as many of these best practices as were relevant to the Clinical Center's environment¹. In the thirteen years that have intervened since this document was initially drafted, the Clinical Center has sought additional input from: 1) its major customers, the NIH Institutes (through our governance structure, through annual planning meetings with each of the institutes, as well as through ongoing dialogue with the Clinical, Scientific, and Institute Directors); 2) a second set of major customers – our clinical research subjects – through ongoing patient perception surveys as well as through regular meetings with the Clinical Center Director's Patient Advisory Group;

3) the extramural academic community (through ongoing reviews by the Clinical Center Board of Scientific Counselors and through the operational reviews of the CC Departments); and through separate meetings convened with outside experts to chart the future courses of the Clinical Center's Bioethics Program, Imaging Sciences Program, Laboratory Medicine Department, the Pain and Palliative Care Service; and Informatics Programs 4) Industry, insurers, and managed care representatives (in meetings designed to address patient recruitment and third party payment issues); 5) Healthcare executives and experienced healthcare administrators (initially through meetings of the Clinical Center's Board of Governors and more recently through the meetings of the Advisory Board for Clinical Research and the operational reviews of the CC departments that they oversee); and 6) intramural and extramural experts in hospital operations, in the conduct of operational reviews of Clinical Center departments. The advice and counsel of these intramural and extramural advisors provide the backbone for the Clinical Center's 2009 environmental assessment. The previous edition of this document was written in 2007. In the intervening years a number of factors in both the internal and external environments have changed substantially, prompting this revision.

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

Clinical Center Strengths



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

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

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

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

The opening of the new clinical research center in 2005 provided an even more effective bridge to the future of clinical research. In the 56 years since the Clinical Center opened its doors to the public, the Clinical Center and its staff have contributed significantly to biomedical science and translational research – moving discoveries in the basic sciences into clinical medicine. In the process of providing the infrastructure and research support for Institute/Center (IC) scientists during this period, the Clinical Center and its staff have developed many unique organizational strengths. Among them are the following:

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

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

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

Perhaps no other center in the world has the collaborative mix of basic scientists and clinical researchers found in the NIH intramural program. This blend of basic and clinical science has provided a critical mass of scientific ferment that has produced striking accomplishments in clinical research over the first 56 years of the Clinical Center's existence. The fact that the basic and clinical scientists work in close proximity produces a cross-fertilization of ideas that is unique in the academic medical community. The quality of the basic and clinical scientists cannot be overemphasized; many of the NIH intramural investigators are recognized as international authorities in their fields.

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

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

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

As noted above, unlike most academic medical centers, studies conducted at the Clinical Center much more frequently evaluate the natural history or pathogenesis of disease states. Clinical trials at the Clinical Center are primarily first in human Phase I and Phase II trials, as compared with most extramural centers, which focus primarily on Phase III and Phase IV studies. The Clinical Center offers a superb venue in which to conduct translational or 'proof of concept'/'proof of principle' studies. Additionally, scientists working at the Clinical Center have assembled cohorts of patients who have rare or

orphan diseases. For patients who have certain of these orphan diseases, the Clinical Center may be the only place where meaningful clinical research studies of their diseases are carried out. The study of rare and orphan diseases has resulted in innumerable contributions to the understanding of basic human physiology, pathology, psychology, genetics, and immunology. The addition of the new Undiagnosed Diseases Program has expanded the Clinical Center's investment in rare and orphan diseases and offers a novel venue for the Clinical Center and the NIH Intramural program to display their expertise.

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

The Clinical Center's staff is committed to the clinical research mission. To provide optimal support for clinical science, the Clinical Center's highly skilled service and support staff have consistently provided excellent care to the subjects of clinical research protocols. The subjects of clinical research studies have a different relationship to the Clinical Center than the relationship patients have with academic medical centers to which they are admitted. The subjects of these studies are partners in the research carried out at the Clinical Center. For this reason, the importance of providing excellence in patient care cannot be overemphasized. The highest quality patient care remains a major objective for Clinical Center staff, an objective that has been reached consistently during its first five decades of existence, and a goal toward which Clinical Center administration and staff continuously strive. Over the past ten years, the Clinical Center has made a substantial investment to find out how our patients view the services provided by Clinical Center staff as well as how they view our clinical research processes. Excellence in patient-care and clinical research support are ever-moving targets. In addition, in the past five years the Clinical Center has made a substantial investment in the safety of the patients participating in clinical research. The electronic Occurrence Reporting System provides useful data about significant occurrences in the hospital, as well as the opportunity to evaluate these events epidemiologically for clusters and trends; Root Cause Analyses and Failure Mode and Effects Analyses provide significant insight into areas in the hospital that are ripe for performance improvement activities; a formal patient safety program evaluates additional opportunities for improvement; and investments in technology – barcoding at the point of care, the outpatient Pharmacy robot, as well as other

information technology systems have contributed substantially to the safety of clinical research subjects at the Clinical Center.

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

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

In the intervening thirteen years since the initial draft of this document was published, many of the Institutes have initiated major external reviews of their intramural clinical programs. A major report issued by the National Academy of Sciences' Institute of Medicine in 2003 addressed issues relating to the overall governance of NIH and underscored the importance of clinical research in the biomedical research enterprise.⁵ In 2003, the Director of NIH convened an advisory panel, The Blue Ribbon Panel on Intramural Clinical Research, to address issues of substance for the Intramural research program. In addition, the then NIH Director embarked on a journey designed to lay out a 'road map' for the continued success of clinical research in the United States. The importance of the former NIH Director's Road Map is that it was designed to define the future path for clinical biomedical research in our country, both in the short and long term.⁶ These and other initiatives suggest that, across the campus, interest in quality clinical research is continuing to increase. In addition, the opening of the new Clinical Research Center, the procurement and implementation of

the new Clinical Research Information System, the increased emphasis on cross-disciplinary molecular projects, the partnerships with extramural scientists in the expanded bench-to-bedside program, and the changing intramural environment have spawned a new level of collaboration and customer-orientation among Clinical Center leadership.

■ **The unique clinical research mission of the Clinical Center allows it organizational and scientific flexibility not enjoyed by other academic institutions.**

Because the primary mission of the Clinical Center is clinical research, the institution does not make commitments, either to its research subjects or to the community, to provide comprehensive health-care services. Since the Clinical Center does not have to commit resources and personnel to an Emergency Room or to general acute care, it can focus its efforts on specific areas of clinical science. For this reason the IC-driven science conducted in the Clinical Center can respond quickly, both to emerging problems for which an immediate change in the national research agenda is needed, as well as to scientific opportunities when they arise. For example, the Clinical Center responded quickly to study: 1) AIDS and HIV infection when the disease first surfaced in society; 2) multiply-drug-resistant tuberculosis when this problem first became apparent; 3) the chemotherapy of ovarian cancer when Taxol became available; 4) the pathogenesis and therapy of the Severe Acute Respiratory Syndrome (SARS); 5) patients with pandemic influenza, including protocols planned to evaluate patients infected with the novel H1N1 (Swine) isolate currently circulating in the population at-large; and 6) the perplexing problem of obesity in the U.S.

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

Since the Clinical Center and the NIH intramural programs are charged with advancing the frontiers of science, the Clinical Center often either develops, or is among the first to acquire, new technologies that facilitate the conduct of clinical research. Scientists working in the NIH Intramural program have access to a new state-of-the-art clinical information system, numerous molecular diagnostic techniques, Positron Emission Tomography (PET) scanners, including PET/CT scanners, three cyclotrons, several magnetic resonance imaging machines

(including 3, 4, and 7 Tesla experimental machines), unique cell-processing facilities, creative functional outcomes measures in our Rehabilitation Medicine Department and a variety of other cutting-edge technologies. In addition, scientists working for, and at, the Clinical Center have the opportunity to forge cooperative research and development agreements (CRADAs) with industry scientists who have developed cutting-edge technologies. In fact, the Clinical

Center often provides a near-ideal venue in which to test such technologies. The Traumatic Brain Injury-Post-Traumatic Stress Disorder collaboration with the National Naval Medical Center will make it possible for the CC to acquire additional imaging technology, including an MR-PET scanner and an extremely high field experimental magnetic imaging device.

Clinical Center Weaknesses



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

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

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

NIH has continued to wrestle with the development of clear, effective governance for the Clinical Center. In 1996, the HHS secretary appointed and convened a new Board of Governors following an outside review of the Clinical Center. The Board of Governors represented a streamlined organizational reporting system for the Clinical Center. However, as a result of the introduction of this new governance system, Institute stakeholders felt somewhat disenfranchised and appealed to the Director of NIH. The Director, NIH appointed an advisory board, initially called the Clinical Center Advisory Council, that permitted the major stakeholders to address Clinical Center issues that are important to the Institutes and to provide advice and counsel to the Director of the Clinical Center. In FY 2000, the then Acting Director of NIH reconstituted this council as the Clinical Center Research Steering Committee (CCRSC). In 2003, the National Academy of Sciences' Institute of Medicine issued a report calling for reorganization of some aspects of the NIH intramural program. The report also underscored the importance of maintaining a robust clinical research infrastructure in the United States. In 2003, the NIH Director convened another advisory panel, The Blue Ribbon Panel on Intramural Clinical Research. This panel was charged with assessing the state of the intramural research program and also evaluated governance structures for the Clinical Center. In response to these recommendations, the

NIH Director made additional modifications of the oversight structure for the CC. The NIH Director subsequently broadened the scope of the Clinical Center Board of Governors and reconstituted it as the Advisory Board for Clinical Research. This committee continues to provide a venue in which the Institutes can contribute to the governance of the Clinical Center, particularly with respect to issues relating to the science agenda. As noted above, as part of the former NIH Director's restructuring related to his Road Map initiative, new oversight committees – the Intramural Working Group, the Facilities Working Group, the Information Technology Working Group, and the Management and Budget Working Group – were convened within the past seven years, contributing additional complexity to Clinical Center oversight.

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

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

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

of Management and Budget, the Office of Personnel Management, the General Services Administration; and all other applicable Federal rules, regulations, and policies, as well as applicable Federal statutes. As a result of this extensive bureaucracy, “The Clinical Center faces a series of very serious barriers to managerial efficiency in areas such as personnel, purchasing, and contracting... 7... The Clinical Center needs a great deal of flexibility to operate productively”⁸. The Report of the DHHS Secretary’s external review committee in 1996 noted that, “whereas the government’s personnel system is structured to provide fair, consistent rules for employees and managers, it undermines the Clinical Center’s efficient operation.”⁹ With respect to fiscal issues, the report states, “As is the case with all government operations, the Clinical Center must spend its entire budget within the fiscal year; no carryover is allowed⁹... The Clinical Center should have a means of retaining reserves from year to year.”¹⁰ The report also notes that the NIH’s existing budget process for the Clinical Center “...makes future Clinical Center funding far more unstable than funding of NIH as a whole.”¹¹ These points were valid in 1996 and remain so in 2009. Many of our advisors have recommended that the Clinical Center’s budget should be a line item – either directly from Congress or in the budget of the Office of the NIH Director.

Since the initial draft of this document was written, the Clinical Center has worked with the Director, NIH and the Directors of the Institutes to try to streamline the Clinical Center’s funding stream. The prior funding mechanism rewarded “non-use” of the Clinical Center. A new funding mechanism was designed, patterned after the concept of a “school-tax.” Because Institute charges were not linked to use in this funding model, it stimulated use of the Clinical Center and provided a far more stable funding stream than the old funding mechanism. This mechanism was put in place in the FY 2000 budget cycle. Appropriations language was written for the FY 1997 budget cycle to allow the Clinical Center to carry over some funds; this language has consistently been approved for subsequent fiscal years. The Clinical Center has also attempted to address the issue of inadequate cost accounting. Initially, the Clinical Center hired a consultant to provide advice about the establishment of an activity-based costing system. The recommendations of the consultant were adopted and the Clinical Center implemented this system. Through its more precise detailing of costs and activities, this activity-based costing system has proved to be of substantial utility to the Clinical

Center’s administration, as well as to its major customers and stakeholders, but unfortunately, this system has not been able to provide the level of detail necessary to provide the Institutes with patient- and protocol-specific cost information. In response to the Institutes’ requests for more precision, the Clinical Center has again turned to consultants, this time from Price-Waterhouse Coopers, who have conducted an in-depth analysis of our current state and have made recommendations concerning the implementation of a data transformation initiative that will yield more precision with respect to the costs associated with goods and services provided to patients participating in clinical research protocols in the Clinical Center and also provide the CC with the ability to benchmark its performance against other academic centers with respect to comparable ‘standard-of-care’ services.

Performance measurement continues as a major organizational focus. The new Administration is focusing on transparency and measurability of government activities. During the past ten years the Clinical Center has collected and continued to refine organization-wide activity data that are used by the Director to assess overall performance. In addition, Clinical Center departments collect data relevant to the performance of their individual departmental operations. The goal of measuring performance is to track departmental and organizational progress toward our strategic goals. Thus, an important aspect of the performance measurement system is making certain that the outcomes and processes being measured are relevant to our key initiatives and strategic goals and that the measurement of these structures, processes, and outcomes allow the Clinical Center to track progress toward these organizational goals. The performance measurement initiative is relevant to both the operations of the Clinical Center as well as to clinical care provided in our facility. By the end of 2009, the Clinical Center Director will have desktop access to an electronic dashboard of clinical and operational performance measures.

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

Eight years ago the Clinical Center's Office of Human Resources Management developed (and had approved by the DHHS Secretary) a program to be able to use a new personnel authority, Title 42, to appoint clinical research support staff. This project – that uses personnel procedures substantially different from traditional governmental personnel systems – has met with measurable success and demonstrates an increase in efficiency of responsiveness and decreased vacancy rates in relevant departments. More recently, the NIH Director and his staff developed a new salary structure for physicians in scarce highly paid specialties and subspecialties. Implementation of this new system has made it possible for the Clinical Center to compensate staff in these specialties and subspecialties and has made it possible for us to recruit individuals in these positions. In fact, we anticipate that by the end of 2009, we will be able to eliminate the need for contract anesthesiologists, resulting in a savings of \$500,000 annually.

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

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

Clinical researchers nationwide have long held the perception that NIH relatively undervalued their work. In 1979, James Wyngaarden, then the Director of NIH, referred to the clinical researcher as an “endangered species”. In response to the concerns of both intramural and extramural scientists concerning the standing of clinical research, the then Director of NIH convened a panel of experts charged

with reviewing the status of clinical research in the United States and making recommendations to the NIH Director on how the Director might ensure effective continuance of clinical research in the U.S. Dr. David Nathan, then president of the Dana Farber Cancer Institute, chaired the committee.

The leadership of the Clinical Center took the panel's recommendations seriously and developed substantive responses to many of them. The Clinical Center's Director has developed an introductory course on the principles and practice of clinical research that has trained more than 7,500 students and has also edited and published a textbook (now in its second edition) that accompanies the course. A Clinical Research Training Program for medical students, including mentoring by some of NIH's most accomplished clinical researchers has been successfully implemented. A collaborative Masters' Degree program (now with several graduates) in clinical research has been developed with Duke University. A required course on clinical research for all principal investigators has been established and is now available on the World Wide Web. A clinical pharmacology course has been developed and implemented (complete with an accompanying textbook) and a Bioethics Course has been developed and implemented. Intramural programs have reviewed and revitalized their clinical research programs. Over the past three years, the Clinical Center has expanded efforts to reach out to the global community in the arena of clinical research training. Clinical Center leadership has been actively engaged in training clinical researchers in South Africa, China, and has been asked to participate in training in Russia. These efforts have resulted in hundreds of clinical researchers being trained and have generated enormous goodwill toward the CC and NIH.

Both NIH and the Clinical Center have engaged in dialogues with the insurance and managed care industry. In late 2001, the NIH Intramural Program invited the Association for the Accreditation of Human Research Protection Programs (AAHRPP) to visit the campus to pilot its new accreditation program process. The NIH Intramural Program is now gearing up to apply for accreditation of its clinical research program through AAHRPP.

■ **The Clinical Center's physical plant urgently needed renewal.**

Because the Clinical Center's physical plant urgently needed renewal, the U.S. Congress provided funding

for the construction of a new facility, the Mark O. Hatfield Clinical Research Center. A 1995/1996 external review noted that, “The Clinical Center’s 48-year-old physical plant is increasingly inadequate for the conduct of clinical research; it requires replacement.”¹² A Congressionally-mandated external review of the NIH intramural program conducted by an advisory committee to the NIH Director’s Advisory Committee also concluded, “In recent years, it has become clear that the infrastructure of the Clinical Center is deteriorating¹³...The External Advisory Committee agrees with the need for renewal of the Clinical Center.”¹⁴

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

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

In 2002, surgeons from several IC’s identified a need for updating and streamlining outpatient/ambulatory surgery processes in the Clinical Center. In a survey of employees conducted in 2002, Clinical Center staff also identified ambulatory surgical care as an area in need of process improvement. In 2003, a white paper on the state of surgery written by the members of the Surgical Advisory Committee in the CC identified the same problem with outpatient/ambulatory procedures. In 2004, the Clinical Center embarked on a major process redesign initiative (discussed below). One of the three major processes selected for redesign was outpatient/ambulatory surgery. The process redesign team presented options for streamlining and improving the ambulatory surgery to the Clinical Center Director. This project required: 1) obtaining customer input about outpatient surgery need, 2) substantial renovation of areas immediately proximate to the operating suite, and redesign of workflow and clinical practices in the Department of Anesthesia and Surgical Services. The project was completed in 2009.

■ **The Clinical Center lacked a strategic plan in 1995; it now has a vibrant strategic and operating plan that is updated annually.**

An external review conducted in 1994 stated, “The Clinical Center lacks a strategic plan describing how it will respond to long-range Institute needs, extramural pressures to reduce costs, and competition to alternatives to intramural research. Without such a plan, decisions that have long-lasting consequences or require long lead-times, will be untimely, if they are made at all.”¹⁵

After obtaining input from major internal (e.g., Clinical Center Department Heads) and external (e.g., IC Directors, IC Scientific, Clinical Directors, and patients) customers, the Clinical Center developed a strategic and annual operating plan. The first plan was presented to, and approved by, the Clinical Center Board of Governors in 1997. The strategic and operating plan continues to be produced each year and is used to provide information and context for the Advisory Board for Clinical Research as well as for the Clinical Center’s myriad other customers and stakeholders. The strategic and annual operating plan is revised annually to make certain it accurately reflects our direction and is responsive to the needs of our customers and stakeholders. The Clinical Center views its strategic and annual operating plan as a dynamic document – projects are continuously being evaluated, revised and improved.

In addition, the Clinical Center drafted its first annual operating plan in 1999 for FY 2000; this process was refined annually, beginning in FY 2000. An FY 2010 plan is being created as this document is being constructed. These documents delineate organizational priorities for the upcoming fiscal year, provide alignment of the short-term organizational priorities with long-term goals, provide a structure to help in decision-making during the fiscal year, and provide a new framework for managerial accountability.

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

The Clinical Center has long been a world leader in the field of “computerizing clinical data;”¹⁵ however, the Clinical Center’s information systems fall short in providing managerial and financial data required by IC and Clinical Center managers. One set of external consultants concluded in 1995 that “...the data provided are retrospective and difficult to use

in operational decisions...The architecture of the computer system is outmoded and cannot effectively integrate data between and among departments.”¹⁶

In the past thirteen years, several projects have been initiated to improve the quality and availability of financial and resource utilization information for better management of Clinical Center operations. In 2007, the Clinical Center recruited its third Chief Financial Officer who now provides overall direction for financial and resource utilization, setting the standards and defining the requirements.

In 2005, the Clinical Center launched a new Clinical Research Information System. Considering the complexity of replacing an information system that was pathbreaking when it was initially implemented in the 1970’s, the activation of the new system proceeded extremely smoothly. In 2006, a new Chief Information Officer was appointed and in 2007 the Clinical Center recruited a Chief for a new laboratory, the Laboratory for Informatics Development who will oversee the design and implementation of BTRIS – a project that will include a large data repository for IC and CC scientists.

In September 2009, the new clinical data center will be opened to house all of the CC Clinical, Research and Administrative systems. The Clinical Data Center was built with N+2 redundancies for air handling, power, network and environmental issues such as fire and flood. The 420 servers within the current data center will be moved to the new data center over the next 6 months and completed March 2010. The new data center will be the cornerstone to provide a robust technical architecture to allow a redundant environment. Currently only the main hospital information system (CRIS) is fully redundant at another site. Over the next 18 months the clinical systems will be configured to be redundant within the new data center and at the CIT Data Center at Building 12. Over the next 5 years we are looking to expand the redundancy to beyond 25 miles to be outside the current grid following NIST standards for redundancy.

In addition, following the development and implementation of an activity-based costing system, the Clinical Center’s Chief Financial Officer and her team, with the assistance of contractors from Price-Waterhouse Coopers have undertaken a major data transformation initiative that is evaluating other approaches to providing even more granular data to our customers and stakeholders. These projects provide the infrastructure for further progress in financial accountability and responsiveness to our

customers’ and stakeholders’ needs for more accurate financial and planning information. Targeted completion for implementation of the data transformation initiative is December 2009.

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

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

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

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

The initiation of the new Undiagnosed Disease Program has resulted in national publicity for the CC and the program and has clearly increased the visibility of the CC.

■ **Through 2009, patient recruitment efforts still are not optimal.**

For a variety of reasons, through 2009, patient accrual remained problematic. Despite significant efforts by the researchers to recruit patients, some excellent and important studies languished for lack of patients.

As noted above, the Office of Communications, Patient Recruitment and Public Liaison has, as its primary mission, the support of patient recruitment

and referral efforts. The primary goal of the service is to increase the enrollment, including women and minorities, to clinical research studies in the Clinical Center. The development of a more uniform, trans-Institute patient travel reimbursement policy may provide additional recruitment incentive.

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

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

The fact that the Clinical Center does not provide full services is perceived by some Clinical Center and IC staff as a disadvantage for several reasons. For some physician research trainees, the fact that the Clinical Center does not offer “full-services”

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

- Partnerships with Johns Hopkins University and the National Rehabilitation Hospital that will facilitate clinical training for fellows and junior staff and will afford senior staff the opportunity to maintain clinical skills;
- A partnership with Johns Hopkins and Suburban Hospital that will facilitate the conduct of studies of acute medical problems (e.g., brain attack, myocardial ischemia) that heretofore have been impossible at the Clinical Center, primarily because of the absence of an Emergency Room; this program opened officially in May 1999; in 2009 the Suburban Hospital Healthcare System (SHHS) was officially integrated into The Johns Hopkins Health System. The implications of having a Johns Hopkins University Health System Hospital across the street from the Clinical Center remain to be determined; nonetheless, the opportunities for collaboration should be increased substantially.
- A partnership with Duke University to facilitate advanced training in clinical research, including the opportunity to receive an advanced degree in Clinical Research;
- A variety of partnerships with local institutions (e.g., Washington Hospital Center, Johns Hopkins, Georgetown, and others) to provide Clinical Center staff with opportunities to maintain clinical competencies.

These extramural affiliations should strengthen training opportunities. Currently, IC staff provide 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 Institute agreement about the “ownership,” or responsibility for, the various consultative services present in the Clinical Center; and 2) to develop a system, based in the Clinical Center’s Medical Information System, to collect information from both consultants and those requesting consultations about the timeliness, appropriateness and the quality of consultations provided by consultative services. The overall goal of the Medical Executive Committee’s subcommittee is to increase the quality of care provided to clinical research subjects at the Clinical Center.

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

- The “Introduction to the Principles and Practice of Clinical Research” course was established in 1995 and provides formal training on how to conduct clinical research effectively. To date, 7,668 students have registered for the course, and 3,039 certificates have been awarded. From 1997-2009, the course has been teleconferenced to 27 domestic and eight international locations. A “live” version of the course was also taught in Beijing, China (November 2008) and Chengdu, China (November 2009). A second edition of the

course textbook was published in April 2007 by Academic Press/Elsevier.

- The “Principles of Clinical Pharmacology” course is designed to meet the needs of clinical and translational researchers and trainees who have an interest in the clinical pharmacologic aspects of contemporary drug development and utilization. The course was established in 1998 and has since had 5,219 students enrolled, attesting to the high level of interest in the subject of clinical pharmacology. The course has also been telecasted to 38 remote sites including 5 international sites. The course faculty prepared a textbook first published in 2001 by Academic Press, with a second edition published in 2007 by Academic Press/Elsevier.
- The “Ethical and Regulatory Aspects of Clinical Research” course is taught annually by the Clinical Center’s Bioethics Department. It was implemented in 1999 and offers formal education and training in the ethical conduct of clinical research. To date, 3,839 students have enrolled. The accompanying textbook, “Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary,” was published by Johns Hopkins University Press.
- The NIH-Duke Training Program in Clinical Research was introduced in 1998 and provides an opportunity for NIH physicians and dentists to receive a Master of Health Sciences in Clinical Research from Duke University School of Medicine. This program, offered via videoconferencing, provides formal courses in research design, research management and statistical analysis. For 2008-2009, six students enrolled into the program; there are 16 students enrolled in the fall 2009 semester. To date 151 students representing a cross-section of NIH Institutes and Centers have enrolled, and 68 have received degrees.
- The Clinical Research Curriculum Certificate program was established in 2004 and is intended for physicians, dentists, and allied health care professionals engaged in or intending to become engaged in clinical or translational investigation (<http://intranet.cc.nih.gov/clinicalresearchtraining/curriculum-cert/index.html>). Individuals who complete the mandatory components of the program are awarded a certificate by the NIH Clinical Center. The required components of the

curriculum include the courses Introduction to the Principles and Practice of Clinical Research, Ethical and Regulatory Aspects of Clinical Research, on-line Clinical Research Training and the computer-based training course for NIH IRB members. An additional institutional review board (IRB) experience completes the curricular requirements for the certificate. As of August 31, 2009, 68 certificates have been issued.

- The Clinical Research Training Program is a public-private partnership supported jointly by the NIH and a grant to the Foundation for NIH from Pfizer, Inc. The CRTP was established in 1997 to train medical and dental students in clinical or translational research after completion of their clinical rotations. Students are assigned a tutor, in their field of interest, who guides them in choosing a mentor for their research project. In fiscal year 2004, NIH Roadmap funds were earmarked to support an expansion of the program allowing for a doubling from 15 to 30 students per year. To date 280 medical and dental students from 79 institutions have participated. Pfizer, Inc has recently announced another three-year grant to the Foundation for NIH to continue support for CRTP from 2010-2013.
- The Clinical Electives Program is administered by Clinical Center's Office of Clinical Research Training and Medical Education and offers visiting medical and dental students from the United States and abroad an opportunity to participate in short term (1-3 months) clinical or clinical research rotations at the NIH Clinical Center. These rotations, of which there are currently 30 in various subspecialties, are designed to provide senior medical or dental students with "hands on" experience working directly with principal investigators who are conducting translational or clinical research. To date, in calendar year 2009, 31 students have participated in the CEP: 15 U.S. medical, 2 osteopathic, and 14 foreign students.
- Graduate Medical Education – The Clinical Center's Office of Clinical Research Training and Medical Education provides administrative oversight to ensure continued accreditation by the Accreditation Council for Graduate Medical Education (ACGME) of the NIH

Clinical Center as an institutional sponsor of residency and fellowship training. In 2008, the NIH Clinical Center was reaccredited by ACGME for a five-year term as a sponsor. In addition, the Clinical Center's Office of Clinical Research Training and Medical Education provides administrative support to the NIH Graduate Medical Education Committee, a trans-NIH committee whose charge is to establish and implement policies and procedures regarding the quality of education and the work environment, to ensure ACGME accreditation of individual specialty or subspecialty graduate medical education programs functioning within the various NIH Institutes and Centers for which the NIH Clinical Center serves as the accredited sponsor. Currently, the NIH Clinical Center serves as the sponsor for 17 graduate medical education training programs: Allergy and Immunology, Anatomic Pathology, Blood Banking/Transfusion Medicine, Critical Care Medicine, Cytopathology, Endocrinology (Adult), Endocrinology (Pediatric), Hematology, Hematopathology, Hospice and Palliative Medicine, Infectious Diseases, Medical Genetics, Medical Biochemical Genetics, Medical Oncology, Psychiatry, Rheumatology and Vascular Neurology. These programs provide specialty/subspecialty clinical and research training to 95 residents and fellows currently under the NIH Clinical Center's ACGME sponsorship.

- Sabbatical Program in Clinical Research Management – The Clinical Research Management Leadership Sabbatical Program is sponsored by the National Institutes of Health Clinical Center in collaboration with other NIH Institutes and Centers and selected sister agencies in the Department of Health and Human Services. This program which will be launched by the end of calendar year 2009 will be available to clinical investigators and others working in domestic and international clinical research settings and will provide an opportunity for these individuals to develop and broaden leadership skills in order to provide an optimal environment for conducting clinical research at their home institutions. The six elective educational modules include: Critical Infrastructure, Support Services, Legal and Regulatory Infrastructure, Communications

and Outreach, Strategic Management, and Funding Opportunities. Participants will be able to tailor an individualized program based on their needs and available time.

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

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

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

to improve quality. Data from the surveys also led to the launch of major improvement initiatives in three areas – coordination of care, informed consent, and ambulatory surgery. These three important organizational processes have been completely renovated through a major process redesign initiative led by the Associate Director for Nursing and Patient Care Services. In 2008, the Clinical Center began conducting continuous surveys of inpatients and outpatients. In addition, we surveyed perceptions of both our patients and our IC customers and stakeholders as part of each of the operational reviews conducted to date (Imaging Sciences, Nursing, Transfusion Medicine, Spiritual Ministry, Laboratory Medicine, Critical Care Medicine, Pharmacy, Social Work, and Rehabilitation Medicine). During 2008 we also surveyed patients about the comparative ‘built environments’ of the old and new hospitals, as well as the perceptions of physicians who refer patients to the CC, and plan, in 2009, to continue to survey inpatients and outpatients and will conduct a specific survey of our pediatric patients and their parents.

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

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

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

In 2009, the Clinical Center has embarked on a follow-up customer service initiative that is spearheaded by the Chief Operating Officer and the new Chief of the Department of Radiology and Imaging Sciences.

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

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

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

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

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

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

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

The CC Director, working with the Clinical Center’s Medical Executive Committee developed a set of Standards for Clinical Research that represent the minimum infrastructural standards that all NIH clinical research programs should have in place to assure appropriate investigator support, as well as the safe conduct of clinical research. Beginning in 2003, the Medical Executive commissioned reviews of each institute’s clinical research programs, based on these standards. The findings from these reviews, which are conducted by NIH peers, were prospectively presented during executive sessions of the Medical Executive Committee meetings. The reviews afforded the individual IC clinical research programs the opportunity: 1) to see how other programs were approaching the new standards; 2) to

identify ‘best-practices’ among the ICs; and 3) to benchmark their own programs against the other programs on the NIH campus. These standards will likely be invaluable when NIH applies for accreditation of its intramural clinical research program to one of the two oversight organizations that currently provide accreditation of clinical research/human subjects protection programs. These Standards were reviewed and revised in 2008 by the Medical Executive Committee.

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

After obtaining significant input from customers and stakeholders the CC designed, and renovated, our outpatient surgery venue. This project, which resulted in much more efficient patient flow and is much more ‘patient-friendly’ was completed in 2009. Additionally, in 2003 stakeholders from several institutes noted that the Clinical Center’s ambulatory care clinic facilities were in need of restructuring and redesign. Clinicians raised questions about the optimal use of clinic space and clinic facilities. In addition, they identified unmet clinical needs (e.g., space to have private discussions with patients about treatment or protocol options, about prognoses). The Clinical Center Director’s Patient Advisory Group has expressed similar concerns. For these reasons, the Clinical Center assembled a team of stakeholders to assess possible restructuring of its outpatient services. The redesign and renovation of these areas is already underway and the round-robin process of redesign and renovation will continue for the next four years. In addition, we identified that the outpatient waiting area in the Pharmacy was inadequate for patient privacy and comfort. A project addressing this deficiency was designed in 2008 and will be implemented in 2009-2010.

■ **The very constrained budgets of 2002 through 2010 required the development of new strategies to gain operational efficiencies.**

To assure efficient operations of our Departments, the CC has developed a process for systematically reviewing the operations of our departments. These operational reviews involve both extramural experts in the field, as well as intramural stakeholders. In addition, to provide ICs with better financial data, we have launched a Data Transformation Initiative that is designed to provide more precise data about the costs associated with CC services. To date, we have conducted operational reviews of the Imaging Sciences Program, Nursing and Patient

Care Services, the Department of Transfusion Medicine, the Spiritual Ministry Department, The Department of Laboratory Medicine, the Critical Care Medicine Department, the Pharmacy Department, the Social Work Department and the Department of Rehabilitation Medicine. These reviews have resulted in a series of suggestions that have generated action plans from the departments that were reviewed that have already produced increased operating efficiencies.

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

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

■ **After a peak during the budget doubling years (and immediately prior to opening the new CRC), the inpatient census has fallen, leaving the CC with underutilized capacity; more recently, in 2009, we have witnessed a resurgence in census.**

Originally established in 1999 by the CC Director to promote collaborations between basic and clinical researchers across institutes and Centers, the highly successful program for competitive “Bench-to-Bedside” awards has served to address the issue of unused capacity and stimulate creative translational work, initially on the NIH campus, and, more recently, including projects involving extramural investigators. In addition, the Director of the Clinical Center has entered a dialogue with the NIH administration and IC leadership about making more of the Clinical Center’s unique clinical research infrastructure available to extramural scientists. Examples of unique infrastructural

resources that may be used to attract extramural investigators includes (but is not limited to: sophisticated functional imaging studies, including MRI, MRA, and PET scanning; intricate cell processing capabilities; molecular diagnostic studies; tailored functional outcome studies, and many others. Making these resources available to extramural investigators (and perhaps even to industry scientists) would likely significantly expand drug and technology development opportunities. Some barriers would have to be overcome to accomplish this, including managing shared resources, the potential for intramural and extramural funds to be used for the same project, and the management of intellectual property. Additional strategies that have been suggested as likely expanding and stimulating capacity within the intramural clinical research program include: 1) increasing the number of tenure-track clinical investigators; 2) centralizing recruitment for clinical investigators to take advantage of trans-institute opportunities; 3) development of clinical research “Manhattan Projects” that involve several ICs; 4) open “diagnostic dilemma” or “fascioma” clinics (e.g., the new Undiagnosed Diseases Program); and 5) encouraging IC tenured and tenure-track investigators to write clinical research protocols. The average daily census has been increased by approximately 8.5% for the past eight months and outpatient visits have also increased by 3.4% when compared with 2008 data. Whereas Clinical Center leadership is extremely encouraged by the expanding census, our 2009 budget did not anticipate costs associated with this expanded census, and if this level of census is maintained for the duration of 2009, the increase in census will provide new challenges for the CC budget.

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

The Clinical Center is working with the leadership of the NHGRI to develop a strategy to meet investigators’ needs for genetic tests. The CC has surveyed investigators twice during the past two years to attempt to learn more about their needs. The basic strategy that has been developed to address this critical need is writing a series of contracts (hopefully including substantial volume discounts). Such an approach would provide a mechanism to meet investigators’ increasing needs in this area, while simultaneously saving resources. A spirited discussion of these needs was held at the Medical Executive Committee meeting to identify potential strategies for funding the necessary contracts. A subcommittee

of the MEC made recommendations and the Clinical Director of NHGRI (who was also at that time the Chair of the MEC) worked with the Department of Laboratory Medicine to establish a list of tests and possible vendors. The Chief of the Laboratory Medicine Department will present a proposal for contracting these tests to the Medical Executive Committee in the summer 2009. Looking into the future, in partnership with NHGRI, the CC is considering to what extent and by what mechanism whole genome sequencing should be provided to clinical investigators using the CC.

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

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

A third facilities-related issue concerns inadequate infrastructure (power, air handling, and chilled water) in the ACRF and adjacent areas that were constructed in the late 1970’s. Several devastating floods have occurred in these areas over the past five years, due to malfunctioning equipment, broken pipes, etc. The Clinical Center’s Operating Rooms, the Department of Transfusion Medicine’s Cell Processing Section, the Department of Laboratory

Medicine, and the Imaging Sciences Program are all housed in this area. Since these are all technologically- and equipment-intensive, and since many of the programs (because of increasing demand for these kinds of studies) are rapidly expanding, addressing the infrastructure shortfall is a major institutional priority. The Director, ORF has made a commitment of additional funds for FY 2009 and beyond to begin addressing these issues as his highest priority.

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

Several years ago, scientists at NIH were subjects of ethics investigations. A small number of individuals were found to have been noncompliant with Federal ethics rules. NIH developed a new set of guidelines, policies, and review processes that severely limit employees' opportunities for outside activities and also severely restrict employees' relationships with industry (effectively barring consultative activities and severely limiting stock holdings). These new restrictive policies have had an adverse impact on recruitment, retention and morale on campus. The Director, NIH is working diligently to improve both the perceptions of NIH held by Congress and other important stakeholders as well as the morale of NIH staff.

- **DHHS facilities are not covered by existing legislation to assure the nondiscoverability of peer review information.**

Although the VA and the Department of Defense have legislation that protects peer review information from discovery, the protection does not apply to DHHS healthcare facilities. Legislation has been proposed by the Indian Health Service, but that legislation does not include the NIH or the Clinical Center. Clinical Center leadership has proposed this issue to the NIH OGC staff as one of the main NIH legislative initiatives for the year. The lack of peer-review protection threatens the integrity of the Occurrence Reporting System, the Root Cause Analysis Program and all other quality activities in the hospital.

- **The new Administration has expressed a clear intention to reform the U.S. healthcare delivery system.**

Substantial reform of the U.S. healthcare delivery system will almost certainly have an impact on NIH and the Clinical Center. Until the reform effort develops a clear direction, NIH and the CC will almost certainly experience uncertainty about the impact that reform will have on the NIH. The Clinical Center leadership will respond proactively to the opportunities and challenges posed by health-care reform.

- **The new Administration has expressed a desire to increase the transparency and measurability of the actions of the Federal government and its Agencies.**

NIH can anticipate increased requirements for transparency of actions and transaction over the ensuing several years. One such example of increased transparency is the registering and reporting of clinical trials and their results required by the passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA). Timely access to information about clinical trials and their results is an important public health issue. Incomplete access to trial information can adversely affect investigators, reviewers and patients. Most authorities believe that the information presented in the scientific literature represents a limited picture of completed clinical trials because negative, neutral or inconclusive trial results are often not reported. Enhanced access to information about current trials and trial results will limit the exposure of study subjects to unnecessary risks. In 1997, Pub. L. No. 105-115 required the NIH to establish a clinical trial registry and required the submission of information about clinical trials testing the effectiveness of drugs for serious or life threatening diseases and conditions, whether federally or privately funded, that are conducted under an Investigational New Drug application (IND). In response to this mandate, the National Library of Medicine (NLM) created ClinicalTrials.gov. The CC encouraged all of its investigators to enroll all of their clinical studies in ClinicalTrials.gov and is working with NIH and NLM leadership to assure that the NIH policies are procedures meeting the spirit of the law, but do not unnecessarily burden investigators. The Intramural program awaits the NIH policy for implementing the FDAAA requirements.

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



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

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

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

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

- Changes in, or influenced by, societal values;
- Changes influenced by cost considerations;
- Process changes in healthcare driven by increasing competition, such as the rise of managed care;
- Changes influenced by shifts in population and population demographics;

- Changes in the practice and delivery of medicine;
- Changes in practice driven by technological advances;
- Changes influenced by governmental initiatives;
- Changes mandated by agency priorities and initiatives.

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

Societal- and Value-Based Factors

The economic recession and the severely declining U.S. and global economies have added a degree of instability to the NIH fiscal outlook. Both the overall NIH and the Clinical Center budgets have been substantially constrained during these tight economic times. The Administration's response to the recession: the economic stimulus plan that included funds for NIH through the American Recovery and Reinvestment Act (ARRA).

- The Clinical Center received approximately \$15M from this Act to help close the capital equipment gap that resulted from the flat budgets of the past several years. Purchases are planned that help address significant backlogs in imaging equipment, information technology, and patient safety equipment, including equipment that supports the ongoing point of care barcoding initiative. Clinical Center leadership is optimistic that additional funds from this initiative may become available in the next fiscal year. Additional funds will help address the capital equipment replacement deficit described above.

The change in political Administrations in the U.S. will likely be associated with substantial changes in the Federal science agenda.

■ Almost immediately following his inauguration, the new President relaxed the restrictions on embryonal stem cell research. Other similar changes can be anticipated over the ensuing three years. The relaxed restrictions on embryonal stem cell research have substantial implications for the Cell Processing Section of the Clinical Center's Department of Transfusion Medicine.

The dramatic changes in the political climate, including the ongoing wars in Iraq and Afghanistan, the aftermath of the heretofore unthinkable acts of September 11, 2001 and the continued threat of additional acts of terrorism have resulted in unprecedented numbers of returning soldiers who have experienced traumatic brain injuries (TBI) and/or post-traumatic stress disorder (PTSD); have mandated increased attention to emergency preparedness in our institution, have required diversion of resources to NIH safety and preparedness activities, have resulted in requests for scientific and intellectual support for the revitalization of the healthcare infrastructure in these war-torn countries, and have fundamentally altered the day-to-day workplace lives for individuals working on the NIH campus.

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

■ The Clinical Center has responded to these new circumstances: by revising and broadening its disaster plan; by preparing and distributing an emergency management flip chart throughout the Clinical Center complex (to make key information readily available to all its staff); by

working with the NIH Continuity of Operation Planning Group, by participating in pandemic influenza planning, and by entering into an emergency preparedness partnership.

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

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

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

■ The Bethesda Hospitals' Emergency Preparedness Partnership has matured substantially over the past five years. The National Library of Medicine has joined the partnership; the Partnership has presented its program and progress at several national forums; through funding provided by the Department of Defense,

the partnership funded several novel research projects focused on improving communication strategies during a disaster response; and the Partnership had a manuscript describing its structure and progress accepted for publication in the *American Medical Association Journal, Disaster Management and Public Health Preparedness*.

- The impact of the dramatic changes on the NIH workforce brought about by the September 11, 2001 disasters and their sequelae cannot be underestimated. Staff continue to be faced, on a day-to-day basis, with substantial uncertainty.
- The Department of Defense funded a large program to address the major issues of TBI and PTSD. The committee language from this bill suggested that the National Naval Medical Center should partner with the Clinical Center to conduct sophisticated imaging studies in this large initiative. The Clinical Center is actively participating the planning and implementation of this large initiative.

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

The past several years have seen the emergence of several new, primarily zoonotic infections, the resurgence of others, and the fear that some exotic infections might be used as agents of bioterrorism. The spread of West Nile Virus from the Middle East to the North American continent, the emergence of hantavirus infections in the U.S. Southwest, the worldwide epidemic of the Severe Acute Respiratory Syndrome (SARS) and the importation of Monkeypox to the U.S. are examples of zoonotic infections associated with new and substantial public health risks for U.S. citizens. The resurgence of tuberculosis and the ever-present threat of pandemic influenza are examples of infectious diseases that can resurface at any time to present significant public health risks. The mail-borne epidemic of anthrax that occurred in 2001 and the sufficient concern in the U.S. Federal Government that the agent of smallpox could be used as an agent of bioterrorism that prompted a nationwide immunization program are examples of the existing bioterrorism threat. Finally, the specter of pandemic

influenza continues to loom over the entire globe as a result of both an unprecedented epidemic of avian influenza as well as a late-season outbreak in the spring of 2009 of novel H1N1 (Swine) influenza that has already been declared pandemic by the World Health Organization. Ongoing aggressive spread of this novel isolate, particularly in the Southern Hemisphere, raises the possibility of severe infection when influenza season returns in the fall of 2009. Emerging infectious diseases, resurgent infections, and biological agents associated with risks as agents of terrorism are all associated with a plethora of unanswered scientific questions. The Clinical Center provides an ideal venue in which to address some of these questions, and over the past three years, the Clinical Center has seen the development of clinical protocols that address some of these issues concerning: West Nile Virus, SARS, multiply-drug-resistant tuberculosis, pandemic influenza, anthrax, and smallpox immunization. With its solid core of basic scientists and nearly ideal translational research environment, the Clinical Center is strategically situated both to be able to respond to these public health emergencies when they arise as well as to be able to answer some of the very perplexing scientific questions. For example, the Clinical Center Department of Laboratory Medicine's Microbiology Service played a pivotal role in interpreting cultures from potentially exposed individuals during the mail-borne anthrax epidemic, processing thousands of cultures. The presence of patients who have these infections present formidable challenges to the NIH workforce and the threat of the emergence of these diseases – either through a natural epidemic or as a result of an act of bioterrorism – is another source of anxiety for both the NIH staff and the surrounding community.

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

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

The fact that the cycle of doubling the NIH budget was completed in 2002 resulted in substantially leaner budget years for NIH over the next few years.

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

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

Americans increasingly value the "Quality of Life".

In the past twenty-five years, society's focus has subtly shifted from "staying alive" to the "quality of life". As Americans have become much more conscious of "quality of life" as an endpoint or outcome, American medicine has, of necessity, been forced to accommodate these changes in values. As American society has turned attention to this issue, Congress has also developed an interest in "quality of life" concepts. This shift in societal focus provides the intramural program and the Clinical Center with the opportunity to include objective and subjective measures of the functional outcomes that contribute directly to the "quality of life" as outcomes of clinical research projects. Particularly in oncologic studies, patients' values and individual, unique measures of "quality of life" may influence their choices of therapy. Clinical Center Departments such as Rehabilitation Medicine, Pharmacy, and Critical Care Medicine have unique opportunities to contribute to Clinical Center studies in this area. Although not traditional 'clinical care,' this unique 'clinical research support' is

an important component of the support provided by certain of the Clinical Center Departments. Ignoring this important trend in its clinical studies could place the Clinical Center at a disadvantage in the eyes of its societal customers. Since the drafting of the initial Clinical Center Environmental Assessment, public interest in "quality of life" issues has not waned; if anything, interest has intensified. Healthcare institutions have developed strategies to begin to measure changes in the "quality of life" that are effected by various therapeutic alternatives. These measurement strategies are a direct outgrowth of the persistent public interest in "quality of life" issues.

Wellness and prevention strategies are increasingly valued.

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

In response to society's interest, NIH has increased its investment in wellness and prevention activities. The external focus on "prevention" and "wellness" has continued to intensify over the past 60 months. Prevention activities are, in general, among the most cost-effective interventional strategies. For these reasons, this trend is likely to continue for the foreseeable future.

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

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

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

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

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

Over the past ten years, the Clinical Center has continued to invest in new technologies, trying to position itself in the forefront of academic institutions in this arena. Clinical Center initiatives in this

area include: the procurement, installation and activation of a new clinical research information system, the creation (in collaboration with private industry) of a new, state-of-the-art cell processing facility, new Positron Emission Tomography/CT imaging technologies, new computer tomography scanners, the purchase of upgraded magnetic resonance imaging capacity, the purchase of new stereotactic neurosurgical equipment, the purchase of a robotic surgical apparatus, additional emphasis on molecular diagnostics in Laboratory Medicine and Transfusion Medicine, the creation of an imaging center, in collaboration with NHLBI, NINDS and Suburban Hospital specifically designed to study acute cardiac and neurological vascular events in the Suburban Hospital Emergency Room, the purchase of an additional magnetic resonance imaging device and renovation of a part of the CC's operating suite to support a new intraoperative imaging program (particularly of use to the NCI Radiation Oncology Program and the NINDS Neurosurgery Program), and the renovation of the Imaging Sciences Radiology suite to support much of this new technology. More recently, in 2009 the Clinical Center partnered with NCI, NHLBI, and NIBIB to create the Center for Interventional Oncology. The Center for Interventional Oncology offers new and expanded opportunities to investigate cancer therapies that use imaging technology to diagnose and treat localized cancers in ways that are precisely targeted and minimally or non-invasive. These new approaches often represent first-in-patient translational applications and leverage the unique and advanced imaging technologies located at the Clinical Center. Technologies in use include cutting-edge magnetic resonance imaging (MRI), positron emission tomography (PET), and computed tomography (CT), combined with the capability to use all three technologies simultaneously to navigate a therapeutic device through the body. The new center's goal is the administration of effective localized or regional cancer treatment by using imaging guidance for the delivery of novel drugs and/or devices. The Clinical Center has also partnered with the NIAID to create an infectious diseases imaging program to support NIAID's new emerging infections program. In addition, the Joint DoD – NIH Traumatic Brain Injury/Post Traumatic Stress Disorder initiative will also contribute to the expansion of the NIH imaging technology base. The initiative will fund an additional CT scanner and a prototype magnetic resonance/positron emission tomography scanner.

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), many investigators have long believed that some segments of the U.S. population have developed a substantial mistrust of the entire clinical research enterprise. A study published by the Clinical Center’s Bioethics Program found very small differences in the willingness of minorities to participate in health research when compared to non-Hispanic whites.¹⁷ These findings suggest that racial and ethnic minorities in the U.S. are as willing as non-Hispanic whites to participate in health research and underscore that efforts to increase minority participation in health research should focus on ensuring access to health research for all groups, rather than changing minority attitudes. Developing programs that reach out to these segments of society to assure access to ongoing studies could enhance the Clinical Center’s reputation and result in a renewed patient-recruitment base. Congress and DHHS view ineffective recruitment of women, minorities, and underserved populations as problematic. Adverse publicity associated with the cloning of farm animals and the proposal to clone humans may present additional problems with certain aspects of the public’s perception of biomedical research.

Clinical Center leadership has attempted to reach out to several minority communities. For example, the Clinical Center’s Office of Communications, 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 Communications, Patient Recruitment and Public Liaison also produced a video to assist in the recruitment of minorities to clinical research studies. In addition, the Clinical Center created a home page on the World Wide Web that includes a description of all active clinical research protocols at the Clinical Center. The Clinical Center also has established a Clinical Bioethics Program, which has positioned the organization to understand the complex issues associated with participation in clinical research, and, as noted above, has provided substantial insight into our understanding of the factors influencing participation in clinical research.

Population- and Clinical Research Subject-Based External Factors

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

Consumerism is a relatively new phenomenon in U.S. healthcare. Because data are freely accessible to the public, 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 Clinical Center delivers high quality healthcare without charge to the participants in its clinical studies, as healthcare customers focus more intensely on cost and quality, the Clinical Center should have an opportunity to recruit study subjects more effectively by appealing to both patients and providers. In addition, as the focus on cost and quality increases, the Clinical Center should have the opportunity to become better recognized as an outstanding clinical research facility.

In the thirteen years since the strategic plan was initially drafted, consumerism in healthcare in the United States has continued to increase. Numerous healthcare organizations have organized themselves along medical “product-lines,” and public advertising of these product-lines (e.g., imaging services, management of coronary artery disease) has increased. Consumers of healthcare in the United States in 2009 are focusing on several issues, among them: 1) ready access to healthcare and to their healthcare providers; 2) clear communication with their providers; 3) provider responsiveness to questions and problems; 4) patient safety; 5) the level of customer service available from their providers, and 6) increased consumer costs associated with these services.

With respect to the safety of patients participating in the clinical research studies at the Clinical Center, the Clinical Center has been proactive in the development of novel approaches to mitigate risk in our environment. We developed an electronic Occurrence Reporting System (ORS) that provides immediate responsiveness about events occurring in our institution and that allows CC staff to evaluate more than 5,000 occurrences annually. These data are used to assess for trends, clusters, and potential sentinel events. We have been able to use these epidemiological data to make improvements in a variety of patient care processes. When sentinel events occur, we routinely conducted detailed root cause analyses of these events, with an eye toward improving our patient care processes to mitigate risks for adverse events. Finally, the CC is interested in using technology to mitigate risk. We conducted two pilot tests of biometrics equipment to assess their potential utility as a patient safety device. In addition in FY 2009-2010 we will implement point-of-care bar-coding technology in patient identification, specimen collection, blood product administration and medication administration.

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 United States is not keeping pace. Studies conducted by the Congressional Office of Technology Assessment, the National Science Foundation, and the American Association for the Advancement of Science in 2001 suggested that science education in the 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.

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

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

The costs associated with the unprecedented rise in the number and size of malpractice suits over the past three decades have contributed significantly to the escalation of healthcare costs in the U.S. Although the Clinical Center has had few such claims, the Clinical Center is, by no means, immune to these actions. This trend presents a challenge to develop effective mechanisms for assuring quality, both in the studies conducted at the Clinical Center, as well as in the care provided to Clinical Center clinical research subjects. In addition, the challenge presented by an increasingly litigious society should galvanize the Clinical Center to seek “customer” input regarding the quality of services provided. The importance of NIH obtaining legal protection to prevent discovery of peer-review activities (discussed in more detail above) cannot be over-emphasized. Having these activities be ‘discoverable’ severely limits their utility.

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

The public has long been interested in alternative and complementary medicine. Whereas medicine and society unquestionably have a great deal to learn from “nontraditional” and “cultural” remedies and treatments, the term “alternative and complementary medicine” has often been used to shroud medical fraud. “Miracle cures” such as Krebiozen and Laetrile often turned out to be far less effective than they were originally touted. The increased societal interest in alternative and complementary medicine proffers the challenge to the intramural program at NIH to develop open lines of communication with its clinical research subjects and the public on these issues. Failing to give credence to the possibility that non-traditional remedies and treatments may have real value runs counter to the science-based culture of NIH. NIH as a truly unbiased, impartial community is ideally situated to address issues such as the safety and efficacy of nontraditional approaches to medical care.

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

Cost-Based External Factors

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

In the past two decades healthcare costs have escalated exponentially, primarily at consumers’ expense. The Federal government, as well as state

and local governments, have become intensely interested in controlling costs. These interests have led to formal scrutiny of the systems and processes in medicine and in healthcare delivery. Cost considerations have had a profound impact on the healthcare industry in the 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 clinical practice across the country; 4) an increasing trend toward the systematization of medicine – evaluation of outcomes, standards of care, clinical guidelines/pathways/care maps; 5) a remarkable shift toward capitation, managed care, and vertically-integrated healthcare systems; 6) a dramatic shift away from subspecialty medicine and an increased emphasis on primary care; 7) more reliance on “non-physician” primary-care and extended-care providers; 8) an aggressive trend toward early discharge and emphasis on outpatient medicine; 9) aggressive competition for healthcare customers; and 10) major centers aggressively streamlining, downsizing, cross-training, and seeking new, more efficient “models of care”. These trends have continued through 2009, but will almost certainly be addressed by the Administration’s healthcare reform efforts.

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

Spiraling costs associated with healthcare and clinical research also led to a downturn in clinical research investigators on the NIH campus. For example, in

1997, the campus had 360 investigators who were principal investigators on clinical research studies and 1,088 active clinical protocols. Today, the campus has witnessed a resurgence of interest in clinical research, fueled both by a former NIH Director who challenged the Institutes to produce cutting-edge translational research as well as by the construction of the new Clinical Research Center. By the end of FY 2003, there were 449 active principal investigators on clinical research projects and 1,239 active clinical research protocols, representing increases of 25% and 14%, respectively when compared with 1997. By the end of FY 2006 there were 547 active principal investigators on clinical research projects and 1372 active clinical research protocols, representing increases of an additional 22% and 11%, respectively when compared with 2003. At the end of FY 2008 there were 478 active principal investigators on clinical research projects and 1449 active clinical research protocols, representing a decrease of 13% and an increase of 6%, respectively when compared to 2006. One concern, however, is that fewer tenured and tenure-track investigators are principal investigators on clinical protocols. In 2001 there were 192 tenured principal investigators who were principal investigators on clinical studies; by 2003, the number had risen to 210. By 2007 this figure had dropped to 156, but in 2008 the number had risen to 202. Similarly, in 2001, 48 tenure-track investigators were principal investigators on clinical protocols. By 2003 this number had risen to 73, and by 2008, this number had fallen to 42 (a reduction of 42%). These data have prompted a major review of career paths for clinical investigators at NIH. As a result of these efforts, in FY 2009 there are 223 tenured principal investigators on clinical studies (an increase of 43%) compared to 2007, and 53 tenure-track investigators on clinical studies.

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

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

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

technology, investment in a good manufacturing practices facility in our Pharmacy Department's Pharmaceutical Development Service, and increased investment in information systems support, among others).

- Evaluation of protocol-based care in a manner analogous to "critical pathways" will likely facilitate the development of a meaningful protocol based cost-accounting system, while simultaneously expediting staffing assignments and organizational planning. The Clinical Center has embarked on an initiative to develop a protocol-writing software package, called ProtoType, which should assist with the increasingly cumbersome process of protocol writing and implementation. This software program will also provide a template for evaluating the clinical quality of the care delivered in the context of the protocol, will provide significant standardization of language in consent documents, should help facilitate human subjects protection review, and should provide a template for assessing the extent to which patients are able to adhere to the protocol as it is written. Standardization of the manner in which protocols are written should also facilitate accreditation of the intramural clinical research program by AAHRPP.
- The shift to a capitated clinical environment in the external community provides both opportunities and threats. Managed care organizations may well be interested in referring patients who would require large financial expenditures for care; conversely, some managed care organizations believe they may be legally barred from referring patients.
- In 1995 and 1996, in response to continued interest from the Office of Management and Budget in having the Clinical Center bill third party payers for some aspects of the care provided at the Clinical Center, Clinical Center leadership developed a four-pronged approach, including: developing a legislative process under which the Clinical Center could be granted the authority to bill third party payers for care delivered to enrollees participating in clinical research; establishing a dialog with managed care representatives concerning their interest in, and willingness to, support clinical research at the Clinical Center; developing an infrastructure to track the costs of participating in clinical research; and prospectively collecting insurance information from Clinical Center patients to

determine the fraction who have insurance coverage and the potential impact of asking clinical research subjects' insurers to cover some of the costs of their care at the Clinical Center. Because the Clinical Center's budget has been effectively flat for the past seven years, modifying the existing mechanisms by which we obtain funding has become a critical success factor to obtaining funds to support the CC.

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

■ The shift toward primary care has resulted in fewer high-quality young physicians in the fellowship pools, and less interest in clinical and basic science among medical school graduates. Many fellowship-training programs are closing. These trends clearly will have an impact on the manner in which the Clinical Center provides care to its clinical research subjects, as well as on the ICs' clinical and basic science training programs. The Clinical Center and the other intramural clinical training programs will have to compete with the major academic institutions for this smaller pool of highly qualified applicants. In addition, the American College of Graduate Medical Education requires broad

clinical exposure in training programs. Obtaining this breadth of clinical exposure is difficult, if not impossible to provide in a program solely based in the Clinical Center. The American College of Graduate Medical Education accreditation standards require that the Clinical Center identify creative solutions and new partners in its training programs.

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

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

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

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

In the time that has elapsed since the initial drafting and subsequent revisions of this document, most of the issues described above related to healthcare costs have persisted, or changed only subtly. The subtle changes that have occurred will likely exert minimal influence on the extent to which cost considerations influence the Clinical Center environment. Despite these somewhat subtle changes, financial considerations continue to be the primary influence on change in healthcare in the United States. The healthcare reform initiative that is currently being planned by the new Administration may have substantial impact on many of the issues discussed above and may substantially alter approaches to cost-recovery and service delivery 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 also keeps sicker patients alive for much longer periods of time. As a result, such patients often remain at-risk for disease- or therapy-related, care-requiring complications for extended periods of time. Such complications are often expensive and labor-intense. Rapid progress does, however, present unique challenges to the management and leadership of the Clinical Center. Rapid progress precipitates abrupt shifts in the research agenda, and often necessitates fast procurement of expensive new equipment, reagents and pharmaceuticals. The Clinical Center is ideally situated to reprogram resources to address new scientific opportunities for translational research. For example, since the previous iteration of this document, the Clinical Center has worked with several IC's to design and implement either innovative new clinical research programs or significant expansions of existing programs.

Effective planning is essential to keep an organization the size of the Clinical Center aligned with the NIH mission, the Clinical Center's mission and vision, and the ICs' rapidly changing research

agendas. Management must remain attuned to the intramural and extramural research cultures, must be able to predict, or at least detect, where progress will occur, and position the organization to capitalize on the progress. When new technologies are identified, the Clinical Center must assess the intramural need, and, where appropriate, adopt the new technologies, and make them available to the intramural scientific community. The management of the Clinical Center has to maintain effective communication with IC leadership to stay aware of progress as it occurs. Further, the Clinical Center departmental leaders must be flexible enough to reprogram resources and embrace progress as it occurs. Only in this way will the Clinical Center be able to supply the quality of clinical research infrastructure necessary to accomplish its mission. In the period following the drafting of the original environmental assessment, the emphasis on molecular medicine, immunogenetics, imaging technologies, and molecular techniques has continued to increase. In addition, the CC has developed a program that is designed to assess the intensity of resource utilization by new protocols prospectively. The Protocol Resource Intensity Assessment (PRIA) project may ultimately help the CC inform ICs of protocols that are potentially resource intensive – prior to their implementation.

The characterization of the human genome has spawned the fields of genomics and proteomics. These fields will likely help shape a substantial fraction of clinical research studies on our campus for the foreseeable future. Information systems technology is advancing almost exponentially and the explosion of this technology is fueling advances in many other biomedical research disciplines. The marked shift toward molecular medicine has engendered numerous additional changes in the complex Clinical Center environment. Molecular techniques have made it possible to identify patients who, either invariably or with a much higher frequency than 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. The creation of the Immunology and Inflammation “Manhattan Project” will facilitate this effort. Scientists are just beginning to unmask the potential of this new technology. The development of molecular techniques has also raised complex questions requiring increased reliance on bioethicists in making decisions regarding genetic

testing, genetic counseling, gene therapy, genetic experiments, and the management of results from genetic tests. Secondly, the move toward molecular medicine has fostered increased investment in the technology needed to conduct these experiments and in personnel expert in managing the extraordinary data sets engendered by this technology. Third, this trend has produced a change in the manner in which we interact with our patients. In the past, extended hospitalizations may have been needed to conduct a study. For some of these experiments, a single phlebotomy may be adequate. Consequently, the Clinical Center has observed a decreased length of stay and less reliance on patient admissions to conduct these studies. Finally, the complexity and specialization inherent in molecular medicine has mandated increasing collaboration among scientific disciplines and has resulted in a clear trend toward more cross-Institute projects.

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

Medicine has begun to focus on costly variation in practice as well as on the benefits of standardization of the processes of care. The past thirteen 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 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 lay public and the healthcare industry – has been made even more acutely aware of the importance of patient safety. The Clinical Center has invested substantial resources in a major Patient Safety initiative that focuses on the occurrence, epidemiology, surveillance for, and prevention of, medical errors. This new program has as its centerpiece a highly successful electronic Occurrence Reporting System (ORS) that has been redesigned based on customer input and is now extensively used by Clinical Center staff. The patient safety initiative involves four major efforts, three of which are focused on determining the real numbers of errors that actually occur in the Clinical Center and attempts to assess to what extent events that occur do get reported

in the Occurrence Reporting System. The fourth aspect of the initiative will implement point-of-care bar-coding to eliminate misidentification and transcribing 'hand-offs,' thereby decreasing opportunities for errors. In addition, the *Joint Commission* has developed mandatory annual patient safety goals for health care institutions wishing to be *Joint Commission* accredited. In our first survey following the implementation of these goals, no deficiencies were identified. The problem identified above that relates to the absence of protection from legal discovery may limit the effectiveness of these strategic programs.

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

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

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

The past decade has seen a worsening of a preexisting problem – a national shortage of crucial patient care and clinical research support personnel. Substantial workforce shortages have developed in Nursing, Pharmacy, Anesthesia, Clinical and

Imaging technical staff, and information technology personnel. In FY 2009, at least in part due to the economic recession, the Clinical Center is actually faring reasonably well in most of these areas (i.e., with less turnover and fewer unfilled positions compared with other institutions in our community). In FY 2009, we continue to experience challenges in recruiting specialty nurses and anesthesiologists and other medical subspecialties for which the current salary structure is not entirely competitive with the private and/or academic sectors. We were successful in recruiting top-flight candidates for the Chief of the Rehabilitation Medicine Department, the Chief of Imaging Sciences and the Chief of the Pharmacy Department.

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

Information systems technology is changing the face of medicine.

The role and importance of information systems management in medicine is changing dramatically. The Clinical Center is well situated to take advantage of the remarkable opportunities presented by the ongoing revolution in information systems management. Teleconferencing and telemedicine are likely to be of great value in the recruitment and management of patients at sites far removed from the Clinical Center. In addition, the striking progress in information systems technology presents unique opportunities to: 1) improve the quality of care provided to Clinical Center research subjects; 2) improve the training of clinicians; 3) create substantial efficiencies in the manner in which clinical research subjects are managed in the institution (e.g., display of histological sections, radiographs, magnetic resonance and computed tomographic scans, etc.) electronically at the patient's bedside or in the investigator's office, as soon as the studies have been interpreted); 4) develop streamlined techniques for protocol writing and monitoring; 5) use the substantial expertise in clinical information systems management that has been developed over the past twenty years to produce an integrated system that meets scientific, clinical, fiscal, and managerial needs;

6) improve patient safety in our complex clinical research environment; 7) perform surveillance for healthcare-associated infections; 8) improve scheduling of admission, procedures and laboratory studies; 9) move toward a paperless, totally electronic medical record. The Clinical Center clearly needs to integrate its patient care information system with a "real-time," effective managerial and fiscal system. In addition, the Clinical Center is faced with the challenge of integrating three different types of data essential for managerial efficiency: 1) clinical patient-care data; 2) financial accounting data; and 3) research laboratory data. The challenges associated with the rapidly accelerating field of medical information systems management are: 1) staying abreast of the technology as it advances; 2) assuring that components of the organization have adequate information systems support to conduct its business efficiently and effectively, while simultaneously assuring that these systems are compatible with each other; and 3) making certain that the organization is consistently investing an appropriate amount of its resources into research, development, and maintenance of information systems technology. The information systems' expertise already present on the NIH campus, combined with the investigational mandate of NIH, provide an ideal milieu for the development of automated, clinically relevant healthcare systems. The procurement and implementation of the new Clinical Research Information System offered the Clinical Center the opportunity to integrate these different kinds of data to improve organizational management and efficiency as well as patient care quality. This past year, following a successful pilot project in 2008, the Medical Executive Committee mandated that physicians and other licensed independent practitioners file progress notes electronically in patients' medical records. The Clinical Center has embarked on the next phase of the development of its Clinical Research Information System by launching the BTRIS project. BTRIS is designed to integrate scientific laboratory and clinical data. Another aim of the project is to create a specimen biorepository that links specimens directly to individual patients and to their genotypes and phenotypes.

In the past eight years, the Clinical Center has increased its investment in information systems technology dramatically. During this time, the Clinical Center has effectively doubled the labor force working in the information systems area. The number of ongoing Clinical Center projects involving information systems improvements is substantial.

The Clinical Center reorganized its informatics operation into two departments and hired a Chief Information Officer to meet organizational needs. The leadership of the Department of Clinical Research Informatics is charged with the oversight of the management of the new Clinical Research Information System. An integrated laboratory system that has an interface to the existing Medical Information System (for our Department of Laboratory Medicine, the Department of Transfusion Medicine, and the NCI Laboratory of Pathology) has been in place for four years, as has the Radiology Information System/Picture Archiving and Communication System (RIS/PACS). The inpatient Pharmacy system and a Peri-Operative Information System (POIS) we implemented in 2007. This past year has seen the introduction of the second phase of the POIS and the implementation of a new electronic Hospital Epidemiology surveillance and outbreak investigation system. An outpatient Pharmacy system will be procured in 2009 and implemented in 2010. This system includes dispensing robotics.

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

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

The American public receives a great deal of its information about medicine, medical progress, and medical and clinical research-related misadventures from the lay press. The press frequently focuses on unique, "newsworthy" numerators, while not necessarily providing relevant denominators for perspective. The press coverage of the late-season epidemic of novel H1N1 (Swine) influenza provides an excellent example of this problem. Such stories may contribute to a general mistrust of medicine and, in the eyes of the American Association of Medical Colleges, have fostered a general decrease in public support for academic medicine. This increasing presence of the press presents a challenge for the Clinical Center. The organization must develop techniques for making certain that the breakthroughs and benefits of the clinical research conducted at the Clinical Center receive appropriate attention in the press.

Medicine has traditionally avoided efforts intended to standardize its practice.

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

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

One effect of the shift toward primary care and away from specialties and subspecialties is that fewer high-quality young physicians are expressing interest in subspecialty training and in careers in basic or translational research. Thus, clinical programs find fewer qualified individuals in fellowship pools. Some training programs have closed; others have downsized significantly; others have moved to a purely clinical focus. Because of the continually decreasing candidate pool, attracting the best and the brightest at the postdoctoral fellow level from within the 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 \$200,000, new graduates often simply cannot afford to take three to seven additional years' training before they begin to repay their debts. This challenge provides the Clinical Center and the NIH intramural program with the opportunity to address some of the financial concerns of new graduates as an incentive to coming to the intramural program. NIH has attempted to address this problem through the creation of three separate loan repayment programs (AIDS, General, and Clinical Research). These programs have become valuable recruitment and retention tools. In addition, within the past two years, NIH has begun to offer payment for licensure for healthcare providers practicing in the Clinical Center, and this past year initiated a recruitment and retention program that allows educational loan repayment up to \$10,000 annually (and to a maximum of \$60,000) for employees or their children.

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

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

academic program that would allow young anesthesiologists scientific opportunities unavailable at other academic institutions because of clinical service demands, (thereby taking advantage of the Clinical Center's unique environment for clinical research). Initial progress in recruitment was "slow but steady," but this past year, the NIH Director initiated a new clinical track salary system for individuals in the scarce and highly paid specialties and subspecialties. We anticipate that the entire anesthesia contract will be assimilated by the end of the fiscal year. The Chief of the Department of Anesthesia and Surgical Services continues to have success recruiting young anesthesia personnel who have interest in science. Contract expenditures dropped substantially in FY 2008 and will be eliminated for the 2010 budget year.

Government-Based External Factors

With each transition of Administration, federal leaders are handed a new Management Agenda which cascades from the Office of the President through the Departments to the individual Agencies. Agency leaders and managers are expected to understand the tenets of the Management Agenda and create implementation plans reflecting the unique mission of their programs while aligning with the broader goals. The Obama Administration, in its fiscal year 2010 budget, offers a management agenda with six overarching themes:

- Putting Performance First: Replacing PART with a New Performance Improvement and Analysis Framework
- Ensuring Responsible Spending of Recovery Act Funds
- Transforming the Federal Workforce
- Managing Across Sectors
- Reforming Federal Contracting and Acquisition
- Transparency, Technology, and Participatory Democracy*

■ Putting Performance First: Replacing PART with a New Performance Improvement and Analysis Framework

Building on the efforts of GPRA, the 2007 Executive Order (EO) on Improving Government Program Performance and PART, the Obama Administration will fundamentally reconfigure

the assessment process for program performance by switching from grading programs as 'successful' or 'unsuccessful' to requiring agency leaders to set priority goals, demonstrate progress and explain trends. As the first step in the process, the Office of Management and Budget (OMB) will ask each major agency to identify a limited set of high priority goals, supported by meaningful measures and quantitative targets that will serve as the basis for the President's meetings with cabinet officers to review their progress. This reformed performance improvement and analysis framework will also emphasize program evaluation. Working with agency leaders and the Performance Improvement Council established under the EO, the Administration will develop options for:

- Establishing a comprehensive measurement system
- Reforming assessment and measurement processes with an emphasis on reporting and explaining trends
- Streamlining reporting requirements under GPRA and PART
- Improving the communication of results to Congress, the public and other stakeholders
- Launching a comprehensive research program to study the effectiveness of strategies to ensure optimum results

■ Ensuring Responsible Spending of Recovery Act Funds

The Administration has moved swiftly to implement processes necessary to oversee American Recovery & Reinvestment Act spending. OMB guidance calls for agencies to go beyond typical standard operating procedures, recognizing the unusual nature of Recovery funds. Recovery Act planning and implementation requirements are intended to ensure:

- Funds are awarded and distributed quickly and fairly
- Recipients and uses of funds are transparent
- Funds are used for authorized purposes
- Projects funded under ARRA avoid unnecessary delays and overruns
- Program goals are achieved

■ Transforming the Federal Workforce

Government performance depends heavily on the quality of its workforce. With a large portion of the workforce projected to retire during the coming decade this presents a number of challenges including the loss of top talent, expertise and institutional knowledge. The retirement wave also presents an opportunity to transform the Government's workforce capacity to address 21st Century challenges using 21st Century systems and processes while reestablishing the prestige of public service.

Current hiring processes are lengthy and fraught with burdensome requirements and outdated systems. Strategic workforce plans are needed in addition to clear job announcements, timely notification to applicants, and metrics regarding the average length of the hiring process and the effectiveness of hiring efforts. Training and rotational opportunities are needed to aide in establishing a healthy leadership pipeline, specifically in identifying possible successors for mission critical positions. Finally, agencies need to improve methods for evaluating employee performance and implementing mechanisms for rewarding success and smart risk-taking.

■ Managing Across Sectors

Effective governance involves managing public sector resources, acquiring new resources from the private and nonprofit sectors and collaborating across the government. In the new agenda the focus will be on determining and then implementing government services to provide the best value for taxpayers.

■ Reforming Federal Contracting and Acquisition

Since 2001 spending on Federal contracts has more than doubled and there has been a significant increase in the dollars awarded without full and open competition and the dollars obligated through cost-reimbursement contracts. The government must strive for an open and competitive process that provides agencies the flexibility to tailor contracts to carry their mission and achieve the policy goals of the Government. In addition, agencies must ensure that the risks associated with noncompetitive contracts are minimized. Moreover, the Government must have the capacity to carry out robust and thorough management and oversight of its contracts in order to meet goals, avoid overages, and curb

wasteful spending. Outsourcing for these services raises concerns and agencies and departments must operate under clear rules prescribing when outsourcing is and is not appropriate. In 2009 the President issued a memorandum on Government contracting that instructs the Director of OMB to work with other officials to issue new guidance on:

- Reviewing contracts
- Maximizing use of competitive processes
- Appropriate use of all contract types
- Assessing the capacity and ability of the Federal acquisition workforce
- Clarifying when outsourcing is and is not appropriate

■ Transparency, Technology, and Participatory Democracy

The Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Agencies and departments should harness new technologies to publish information online about operations and decisions in ways that are accessible while soliciting public feedback identifying the information of greatest use to the public. The Administrative will continue to be innovative in providing better levels of transparency and devising new tools to let citizens have their voices heard. It is critical that the Government manage its information technology program effectively and securely while addressing complications such as privacy concerns that arise with new technologies.

Regulatory requirements are becoming more stringent and more burdensome.

Requirements of organizations that regulate the conduct of patient care and clinical research in the Clinical Center have increased substantially over the past two decades, in many instances without clearly adding value. Some oversight and regulatory activities arise from within NIH (e.g., Office of Protection from Research Risks, Office of Human Subjects Research, Recombinant DNA Advisory Committee, and the Office of Scientific Integrity, and others); others arise from IC programs (e.g., Cancer Treatment Evaluation Program, NCI); others are Departmental- or Agency-based in origin (e.g., Inspector General, Food and Drug Administration);

others arise from other Departments within the government (e.g., Nuclear Regulatory Commission, Occupational Safety and Health Administration), and still others arise out of a continuing need for external evaluation and accreditation of clinical activities (e.g., Joint Commission, College of American Pathologists [CAP], American Association of Blood Banks [AABB]) and oversight/accreditation of clinical research activities (the Association for the Accreditation of Human Research Protection Programs [AAHRPP] and the National Committee on Quality Assurance [NCQA]). The Clinical Center faces the challenge of meeting the increasing requirements of a burgeoning list of regulators with decreasing staff, decreasing resources, and, despite the construction of a new clinical research hospital, aspects of the Clinical Center's physical plant still are in dire need of revitalization (e.g., the ACRF and the accompanying 1979 construction). Simultaneously, the Clinical Center has the opportunity to consolidate certain of these activities (e.g., the AABB or CAP surveys now substitute for both certification by the Center for Medicare and Medicaid Services for the Clinical Laboratory Improvement Act of 1988 [CLIA] and Joint Commission surveys), and the requirements of some others provide justification for the creation of the new Clinical Research Center. The increasingly burdensome nature of regulatory requirements was identified as a major obstacle to the successful conduct of clinical research in a survey of NIH principal investigators in FY 2003. In order to attempt to address some of the bureaucratic barriers to establishing new clinical research protocols, the Clinical Center, working with several IC scientists is developing a software program, called ProtoType, that is designed to assist with the increasingly cumbersome process of protocol authoring. In addition, the Deputy Director of the National Institute of Allergy and Infectious Diseases has launched a campus wide initiative attempting to streamline the bureaucracy inherent in the clinical research process.

In light of the increasing activity in the area of molecular medicine and the virtual explosion of new laboratory tests that can be used for diagnosis and prognosis in medicine, the Clinical Center, and, in fact, the entire NIH has come under increasing pressure to have its laboratories comply with CLIA. The Clinical Center Director was given the task of ensuring that all Intramural laboratories performing laboratory tests linked to patient identifiers that may be used for patient care meet CLIA standards. At the request of the Clinical Center Director, the Chief of the Clinical Center's Department of Laboratory

Medicine established a highly successful program to facilitate NIH laboratories' compliance with the CLIA regulations. To date, the Department of Laboratory Medicine has worked with 72 laboratories throughout the NIH and has assisted in the CLIA certification of 58 of them. Currently, 38 laboratories on campus maintain CLIA certification.

Whereas the Clinical Center has been determined to be a 'non-covered entity' for the new Health Information Portability and Accountability Act (HIPAA), the overall impact of HIPAA compliance by NIH collaborators on the Intramural clinical research program remains to be determined. As we continue to increase our reliance on electronic information sharing – for example, with referring physicians and patients, and as we consider the possibility of cost recovery for some types of services – the Clinical Center may be forced to revisit the necessity for HIPAA compliance.

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

Agency- (NIH-) Based External Factors

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

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

- NIH and Institute administrators have made a major investment in scientific quality. Several

Institutes have conducted detailed external reviews of their intramural programs in the past sixty months. In addition, an external panel convened by the NIH Director (i.e., the Marks/Cassel Committee) issued a detailed report in 1994 that provided clear recommendations to revitalize the intramural program.

- NIH has developed and implemented new, more rigorous tenure-track and tenuring policies.
- The rigor of scientific reviews has been intensified across all Institutes and Centers conducting clinical research.
- The rigor of the prospective scientific review of new clinical protocols has also been intensified.
- Both the prior and immediately preceding NIH Directors, have made major efforts to elevate the status of clinical research on the NIH campus. The net effect from these leadership efforts has been that several institutes have initiated new programs and/or recruited new clinical investigators to buttress their clinical research activities. The Clinical Center has developed a proactive strategy for managing new programs and significant program expansions that includes creation of a project team comprised of IC and Clinical Center stakeholders; scheduled meetings with this implementation team, creation of a project implementation plan, and ongoing follow-up with IC leadership and staff to assure smooth handoff and implementation. One suggestion that these activities are beginning to demonstrate successful rejuvenation of the clinical research program is the fact that the CC census has demonstrated a sustained 4-6 percent increase over the past eight months.
- Successful conduct of clinical research is essential to biomedical progress. Nonetheless, the processes of clinical research are complex, labor-intensive and expensive. For these reasons the prior NIH Director developed a 'road map' for the continued success of clinical research, both in the NIH intramural program, as well as throughout the United States. The NIH Director's Road Map has helped plot the path for clinical biomedical research in the United States and has helped define the precise roles that the NIH Intramural clinical research program and the NIH Clinical Center will need to play in clinical sciences in the decade to come. The road map also helps define the relationship of both the NIH Intramural clinical research program and the NIH Clinical Center to clinical research programs in the extramural clinical research environment.
- As technology advances, institutes are increasingly requesting more, and more sophisticated, clinical research support. During institute planning meetings for the past ten years, an increasing number of requests for clinical research support activities (as opposed to standard care support) have been received. The NIH Intramural Research Program needs to develop a process for deciding (in concert with its collegium of customers) which of the requests to implement, as well as how to present the increased costs associated with these projects to both internal and external customers. Such services (which are often both efficiently and effectively centralized) add substantially to the expense of running the Clinical Center. One example of such a service is the Clinical Center Department of Transfusion Medicine's cell processing facility, which provides protocol-specific cellular therapy support for many specific IC protocols.
- The costs associated with conduct of biomedical research are escalating faster than inflation, necessitating that Institutes carefully evaluate costs and quality of proposed intramural projects with more rigor than has been done in the past and that the Clinical Center develop strategies for prospectively determining the likely costs associated with new scientific projects (the PRIA project described above is one such attempt).
- A variety of factors have conspired to produce an unprecedented level of trans-Institute collaboration and sharing of resources, among them:
 - Increased emphasis on clinical research and on research quality on the NIH campus;
 - Increasing costs of clinical research, and especially the costs associated with the capital equipment required to conduct certain types of studies;
 - Increased reliance on molecular methods, genomics, proteomics, and specific expertise, not necessarily associated with an IC or a discipline, to conduct complex studies;
 - Increased emphasis by Clinical Center and NIH leadership on planning;

- Emphasis on the part of Clinical Center leadership on the inclusion of major customers, partners and stakeholders in the planning process;
 - Joint Clinical Center/IC appointments in Imaging Sciences, Bioethics and Clinical Pharmacology;
 - The construction of the new Clinical Research Center, which is not organized with dedicated “Institute-space,” has fostered collaboration among the “partners” who share ‘program’ space and resources in the new building.
 - The former NIH Director’s Road Map initiatives that required trans-institute collaboration.
 - The implementation of trans-institute “Manhattan”– style translational projects.
- The Clinical Center now has eight years’ experience using the ‘school tax’ funding stream. This approach to Clinical Center funding was established to bolster institutes’ clinical research programs and likely has contributed to expanded use of the Clinical Center. Institutes pay a “school tax” based directly on the size of the Institute’s intramural appropriation to support the Clinical Center (without regard to the extent to which the Institute uses the facility). The disincentive to use the Clinical Center (in the previous funding scheme) has been replaced with an incentive to use it. This approach also solves the problem identified by the previous DHHS Secretary’s evaluation team of the interdependence of Institutes’ budgets under the prior funding structure. As noted above, faced with a flat budget for several years, the Clinical Center shifted some costs for certain research-related services to the ICs, resulting in a resurfacing of concerns about the appropriateness of the school-tax approach. As this document is being written, several possible modifications to the Clinical Center’s funding stream are under consideration by IC and NIH leadership.
- The Clinical Center’s governance is complicated and arduous. The Advisory Board for Clinical Research evaluates the budget from the dual perspective of outside leaders in healthcare and NIH leaders who understand the clinical research programs. The NIH governance structure consisting of at least five groups reviews the Clinical Center budget from the perspective of a finite envelope of funds available within the NIH central service structure. The two parallel paths of review do not usually reach the same conclusion with regard to funding requirements and the final decision is made by the NIH Director. Frequently, due to the multiple reviews and divergent perspectives, the roles of the respective governance groups are called into question. The need for streamlined governance and decision-making with regard to the Clinical Center continues to be a source of discussion and the catalyst for periodic outside reviews.
- The allocation of FTE’s within the NIH is complicated. The total NIH allocation is adjusted in the annual budget process and, as a result, individual IC allocations are adjusted. Over time, the Clinical Center’s ceiling has been reduced from 1984 in 2002; to 1883 for 2007; to 1781 in 2009; however, each IC will be allowed a FTE target of 102% (to account for vacancies), raising the functional CC ceiling to 1817. At a time when clinical research programs are expanding and being reinvigorated, and at a time when the Clinical Center budget has been essentially flat, at best, these budget FTE constraints present an additional challenge to CC leadership and will require creativity and stewardship of resources to meet these expanding service needs.

The NIH budget receives intense scrutiny by Congress and the President

Thirty years ago the costs of clinical research were not a primary concern of the ICs conducting research in the Clinical Center. In the late 1980s and early 1990s, however, the increases in the costs of clinical research in the Clinical Center began to rise significantly faster than the overall intramural budget. Almost simultaneously, the ICs became aware of the substantial differences in the costs of clinical versus bench research. Some ICs began to divest themselves of their clinical research portfolios in order to cut costs. Financial stewardship and increased financial accountability are primary goals for the Clinical Center. New planning mechanisms, new information systems, and new reports of utilization have been developed to provide more and more accurate information to the Institutes.

For the years 1995 to 2002, both the Congress and the President publicly stated a goal of doubling the NIH budget. Thus, NIH (and the Clinical Center) received substantial budget increases during that period. The process of doubling the NIH budget was completed in 2002. Subsequent years’ funding

increases to the present were modest, by comparison and the Clinical Center's budget has held basically flat by NIH since then. Given that certain hospital costs (e.g., pharmaceutical inflation, personnel costs, inflation of costs associated with the purchase of hospital soft-goods) will continue to escalate at a rate that far exceeds intramural budget growth, Clinical Center leadership and managers need to manage expenditures conservatively for the foreseeable future and either develop additional revenue streams or a new funding mechanism that takes these inflationary factors into consideration.

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

- Third party recovery for aspects of care provided at the Clinical Center;
- Developing partnerships with industry (including cost recovery) to use Clinical Center excess capacity;
- Developing partnerships with extramural investigators (including cost recovery) to use Clinical Center excess capacity;
- Working with the Foundation for NIH to try to develop philanthropic support for new initiatives;
- Funding the Clinical Center independently as either a line item in the president's budget or, perhaps, as a line in the NIH Director's budget – ideally indexed to inflation (as is done with the Indian Health Service Hospitals' budgets).

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

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

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

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

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

- The opportunity to seek the expert advice concerning hospital operations and management from nationally-recognized authorities in hospital and research management;

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

The expanded role for the Advisory Board for Clinical Research initially mandated that this board include ongoing assessment of, and encouragement of the

further development of integration of the clinical research programs across the campus. The Board was to provide the NIH Director and the Clinical Center Director with advice about the creation of a meaningful interface between the NIH Intramural Research Program and the network of Clinical and Translational Science Award grantees. Whereas the role of the ABCR is vital to the functioning of the Clinical Center within the rubric of academic health centers, its role must be coordinated effectively with the NIH governance structure whose focus is equitable allocation of central service resources within the context of the NIH campus.

Bibliography



1. Gallin JI, Smits HL. Managing the interface between medical schools, hospitals, and clinical research. *JAMA* 1997;277(8):651-4.
2. Report of the External Advisory Committee of the Director's Advisory Committee, a report of the National Institutes of Health Intramural Research Program, November 17, 1994, U.S. Department of Health and Human Services, p 32.
3. Report of the External Advisory Committee, p 33.
4. Gallin JI, Varmus H. Revitalization of the Warren G. Magnuson Clinical Center at the National Institutes of Health. *Acad Med* 1998;73(5):460-6.
5. Institute of Medicine of the National Academy of Sciences. Enhancing the vitality of the National Institutes of Health: Organizational change to meet new challenges. Report Issued July 29, 2003. Available at: <http://www.iom.edu/CMS/3740/4866/14300.aspx>.
6. NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research. Report Issued January 2004. Available at: <http://www.genome.gov/Pages/About/NACHGR/2004NACHGRAgenda/Tab%20H%20-%20BlueRibbonPanel.pdf>.
7. Opportunity: Revitalizing the NIH Clinical Center for tomorrow's challenges: a report from the DHHS REGO II Options Team, January 1996; p 1-2.
8. DHHS REGO II Options Team report, p 4-1.
9. DHHS REGO II Options Team report, p 3-4.
10. DHHS REGO II Options Team report, Executive Summary, p v.
11. DHHS REGO II Options Team report, p 3-4.
12. DHHS REGO II Options Team report, p 4-6.
13. Report of the External Advisory Committee, p 30.
14. Report of the External Advisory Committee, p 33.
15. DHHS REGO II Options Team report, p 5-2.
16. Wendler D, Kington R, Madans J, et al. Are racial and ethnic minorities less willing to participate in health research? *PLoS Med* 2006;3:e19.



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