SCIENTIFIC MANAGEMENT REVIEW BOARD
REPORT ON THE NIH CLINICAL CENTER

DECEMBER, 2010

NATIONAL INSTITUTES OF HEALTH
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EXECUTIVE SUMMARY

The Scientific Management Review Board (SMRB) was established under the National Institutes of Health (NIH) Reform Act of 2006 to advise the NIH Director and other appropriate officials on the use of certain organizational authorities reaffirmed under the same act. At the inaugural SMRB meeting on April 27-28, 2009, Board members unanimously agreed to convene the NIH Intramural Research Program (IRP) Working Group to examine the overall intramural research program at NIH. In light of the urgent fiscal crisis facing the NIH Clinical Center, the Board decided to focus the Working Group's initial deliberations and recommendations on the fiscal sustainability and utilization of the Clinical Center. Recommendations regarding the optimal organization of the overall NIH intramural research program will be addressed in subsequent analyses and a separate report.

The Clinical Center's mounting fiscal constraints, including its inability to keep pace with inflation, served as the original impetus for the Working Group's deliberations. However, in-depth analyses uncovered additional obstacles to developing and sustaining an optimal environment for clinical research at the agency. These challenges may be grouped into three themes: (1) vision and role; (2) governance; and (3) budget. Given the intersection of these three themes, the Working Group determined that each thematic challenge should be addressed individually as well as in relation to each other.

After determining that organizational change is needed, the Working Group considered a variety of reorganization options to address the identified challenges. Ultimately, the Working Group recommended that the NIH Clinical Center have an expanded vision and role; a streamlined governance structure; and a stable, adequate budget for fiscal viability and sustainability. Consequently, funding options were analyzed in terms of their ability to position the Clinical Center as a national resource, prioritize clinical research at NIH, streamline governance, and enhance programmatic planning. Based on the analyses, the Working Group recommended that the Clinical Center's budget be funded by a line item in the Office of the Director appropriation.

At its meeting on December 7, 2010, the SMRB considered the final recommendations of the IRP Working Group and concurred with the Working Group's findings. Presented with the options identified by the IRP Working Group, a majority of the Board (14 favored; 0 opposed) voted to recommend to the NIH Director that the NIH Clinical Center have an expanded vision and role with resources optimally managed to enable both internal and external investigator use; a simplified governance structure capable of developing and overseeing a clear, coherent budgetary and programmatic plan for clinical research (see Figure 3); and a budget linked to a strong planning process, that remains stable in source and equitable in distribution and is effective in attracting and supporting a high quality workforce, and assure efficient use. Toward this end, the SMRB recommended that the Clinical Center be funded by a line item in the Office of the Director appropriation.

I. Introduction

The National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) reaffirmed certain organizational authorities of agency officials to: (1) establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH, including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The Reform Act also established the Scientific Management Review Board (hereinafter, SMRB or Board) to advise the NIH Director and other appropriate agency officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

This report distills the deliberations of the NIH Intramural Research Program (IRP) Working Group, a subcommittee of the SMRB, regarding the fiscal sustainability and utilization of the NIH Clinical Center, a component of the intramural research program at NIH. The report culminates in recommendations regarding a new vision and role for the NIH Clinical Center and modifications to the Clinical Center's current governance structure and funding mechanism. Additional dimensions of the intramural research program at NIH will be analyzed and discussed in a separate report.

A. Impetus for and Charge to the IRP Working Group

Although the IRP Working Group was convened to examine the overall intramural research program at NIH, the urgent fiscal crisis facing the NIH Clinical Center prompted the Board to focus the Working Group's efforts on issuing recommendations regarding the fiscal sustainability and utilization of the Clinical Center. Upon completion of this task, the group will return to providing an analysis of and recommendations regarding the optimal organization of the overall NIH intramural research program.

B. IRP Working Group Process

In addressing its charge, the IRP Working Group was mindful of recent scientific opportunities, public health needs, and new research technologies. Additionally, careful considerations were given to the following:

- Current functions, scope, organization, and roles of the Intramural Research Program and the Clinical Center;
- Criteria for contemplating changes in organization and management (informed by the report of the SMRB entitled *Deliberating Organizational Change and Effectiveness*);
- Alternative business models;
- Strategies for implementing changes in organization and management; and
- Metrics and methodologies for evaluating the impact of changes in organization and management.

The Working Group met eight times by teleconference, twice in person, and hosted two public forums (October 30, 2009, and May 19, 2010) to solicit input from experts and stakeholders. Participants in these meetings included NIH intramural researchers, NIH extramural grantees, scientific organizations, experts in the administration of research organizations, representatives for Clinical Center patients, patient advocacy and consumer organizations, and representatives of pharmaceutical and biotechnology industries. Briefings were provided on the following topics regarding the NIH Clinical Center (see Appendix A for a list of individual speakers and dates):

- Current fiscal challenges, with perspectives from NIH institute directors and key NIH staff;
- Mission, function, capabilities, and vision for the future, with perspectives from distinguished NIH investigators and advisers;
- Business models for hospital management, with perspectives from research hospital administrators;
- Introduction to collaborations between the extramural and intramural communities regarding current and potential uses, with perspectives from key NIH staff;
- Exploration of the practicality, feasibility, and desirability of expanding use, with perspectives from distinguished clinical investigators; and
- Potential opportunities and collaborations, with perspectives from potential users of the NIH Clinical Center.

On February 22, 2010, the Chair of the IRP Working Group briefed the NIH Director, the Chair of the SMRB, and the Chair of the Substance Use, Abuse, and Addiction Working Group on the status of the Working Group's deliberations. On March 10, 2010, the IRP Working Group Chair consulted with the NIH Advisory Board for Clinical Research (ABCR), which advises on the operations, budget, and strategic operating plans of the Clinical Center. Finally, the IRP Working Group provided continual updates to and solicited input from the entire SMRB during its public deliberations held on November 13, 2009, March 10, 2010, and May 18-19, 2010. The full Board voted on recommendations regarding this issue on December 7, 2010.

II. THE NIH CLINICAL CENTER: ORGANIZATION, BUDGET, AND CURRENT ISSUES

A. Overview

The NIH Clinical Center, the largest hospital in the world dedicated exclusively to clinical research, is comprised of two major facilities: The Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Clinical Research Center. The Warren Grant Magnuson Clinical Center, opened in 1953, is a 14-story building housing 15 outpatient clinics, operating rooms, the Department of Laboratory Medicine, the Department of Transfusion Medicine, and most of the Radiology and Imaging Department. The Mark O. Hatfield Clinical Research Center, added to the original facility in 2004, houses 234 inpatient beds and 82 day-hospital stations. Each year, staff within the Clinical Center

examine 10,000 new patients, admit 6,000 inpatients, and conduct 95,000 outpatient visits. Additionally, in 2010 the combined facility:

- Posts an average hospital stay of 9.5 days;
- Houses 1,200 credentialed physicians, dentists, and Ph.D. researchers, along with 620 nurses and 450 allied health-care professionals, such as pharmacists, dietitians, medical technologists, imaging technologists, therapists, medical records and medical supply staff;
- Houses more than 1,600 laboratories that conduct basic and clinical research; and
- Has an average occupancy rate of approximately 70 percent.

The Clinical Center supports the broad, diverse research missions of NIH institutes and centers. With 1,450 active protocols at the time this report was published, the Clinical Center serves as a home for investigative initiatives into the pathogenesis and natural history of human disease; the development of state-of-the-art diagnostic, preventive, and therapeutic interventions; clinical investigator education and training; and programs for the safe, efficient, and ethical conduct of clinical research. Because the Clinical Center is a research facility, only patients meeting the specific requirements of an approved research protocol are admitted, but unlike other hospitals, patients are not assessed fees for treatment and care if provided.

Also housed within the Clinical Center are exceptional scientific and technological resources that facilitate the conduct of translational and clinical research. These resources include a high throughput small molecule and RNA interference screening center, imaging and phenotyping facilities, preclinical testing programs, Good Manufacturing Practices (GMP) facilities in the pharmacy and for Positron Emission Tomography (PET) ligands, and an animal research program. These facilities and programs expertly equip Clinical Center investigators to investigate disease across a translational continuum.

Based upon numerous briefings and a thorough review of Clinical Center activities and data, the Working Group concluded that the Clinical Center has an impressive array of strengths:

- Investigators are encouraged to devote full attention to clinical research and scientific discovery;
- Flexible research environment permits nimble responses to emergent scientific opportunities and public health needs;
- Funding structure allows for care at no cost to the patient;
- Investigators have immediate access to cutting-edge technologies;
- Specialized research capabilities support high-risk trials for life threatening diseases;
- High-risk/high reward research is permitted and supported;
- A critical mass of highly skilled individuals are housed within a central network;
- Unique expertise and resources advance facilitate first-in-human studies and rare disease research;
- Patient populations can be consistently studied across time, facilitating the collection of longitudinal data;

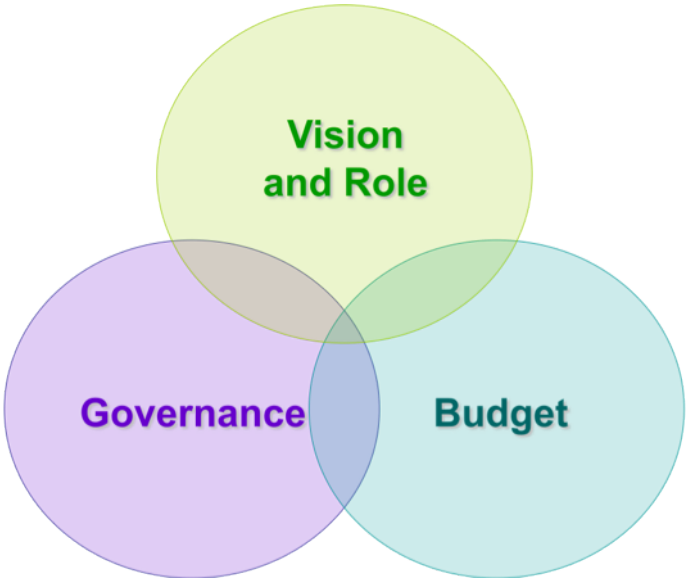
- Unique interdisciplinary environment fosters distinct training opportunities to study human biology and pathology; and
- It provides a visible window to NIH for the public and policy makers.

B. Challenges

Despite its numerous strengths and achievements, the Clinical Center faces formidable challenges to its future vitality. Current funding for the NIH Clinical Center faces mounting constraints due to the inability to keep pace with inflation. Simply increasing the "school tax"—the fee assessed to each institute or center's intramural research program to support the Clinical Center (discussed in detail in the budget section)—is not a viable solution for ensuring fiscal sustainability, as the hospital annual inflationary costs exceed the overall growth of the intramural research program budget. Therefore, increasing the funds for the Clinical Center would occur only at the expense of other research conducted within the intramural research program, including important basic research initiatives. An additional complication is the inclusion of the budget for the core operations of the Clinical Center as a component of the agency's Central Services, which forces the Center to compete with other NIH-wide services such as electricity, heat, building maintenance, and snow removal in the appropriations process.

Although the Clinical Center's funding challenges served as the original impetus for the Working Group's deliberations, in-depth analyses uncovered additional obstacles to developing and sustaining an optimal environment for clinical research at the agency. These challenges include the lack of a clear trans-NIH vision for clinical research, difficulties in translating basic research into clinical practice, obstacles to recruiting and retaining clinical investigators, and restrictive intellectual property and conflict of interest regulations. Moreover, the conduct of research in the Clinical Center is hindered by, for example, barriers to extramural use of the facilities and increasing costs that strain flat intramural budgets. Collectively, these challenges may be grouped into three themes: (1) vision and role; (2) governance; and (3) budget. Given the theoretical as well as practical intersection of these three themes, the Working Group determined that each thematic challenge should be addressed specifically as well as in relation to the other two thematic challenges (see Figure 1).

Figure 1. The interrelated challenges facing the Clinical Center.



i. Vision and Role

The Clinical Center has boasted a long, distinguished history of significant research accomplishments. It also has served as a home for many of our Nation's leading clinical investigators and academic leaders and is considered by many to be the premier institution for training the next generation of clinical researchers. Nonetheless, the traditional perception is that the Clinical Center is a resource intended only for NIH and its intramural program. Given the unique resources, expertise, and patient populations housed within this Center, some have argued that allowing qualified external investigators to conduct research at the Clinical Center could yield tremendous benefits to the clinical research enterprise overall.[1] Potential resources of interest may include access to the Center's unique patient populations, services, specialized and expensive equipment clinical research training, Bench-to-Bedside program, and the facility itself, which is an unparalleled research environment.

Expanding the Clinical Center's role in the clinical research enterprise is especially relevant in the current environment, as there is increasing pressure to manage resources—both intramural and extramural—with optimal efficiency and effectiveness. Of note, the current mission and budgetary policies have resulted in this facility being underutilized (e.g., beds, laboratory and diagnostics services), creating an unused capacity and opportunity for external researchers to access these facilities and resources. Rather than yielding benefits just to those within the intramural program, the Clinical Center should be viewed as the valuable national resource that it is —a research hospital capable of providing unique resource capacity for the conduct of translational and clinical research. Examples of how this facility could be used by the extramural community include its PET and imaging facilities, its phenotyping and diagnostic services, and GMP facility for making candidate drugs. Furthermore, expanding the network for collaborations could potentially enrich both the intramural and extramural research. A more fully deployed Clinical Center also would ensure the continued recruitment of distinguished investigators and pipeline of the next generation of clinical scientists.

The Working Group acknowledged that any effort to actualize an expanded vision and role for the Clinical Center requires that the agency address several existing barriers:

- The perceived lack of commitment to funding and prioritizing clinical research at the NIH Clinical Center;
- Existing policies and regulations restricting the optimal leveraging of resources (e.g., intramural/extramural collaborations, intellectual property, conflict of interest); and
- Issues pertaining to the recruitment, retention, and mentorship of clinical investigators.

Regarding the first barrier, the Working Group found that, in order to demonstrate a clear commitment to clinical research at the agency and establish the Clinical Center as a valued national resource, it is critical that it be supported by a stable funding source and

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[1] National Research Council. (2003). *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*. Washington, D.C.: National Academies Press; FasterCures: Center for Accelerating Medical Innovation. (2009). *Task Force on NIH'S Intramural Research Program.* Available at: http://www.fastercures.org/index.cfm/Resources/Publications.

have the benefit of an efficient, effective governance structure. Potential options for these changes are analyzed and evaluated in the governance and budget sections of this report. With respect to the second barrier, the Working Group explored real and perceived restrictions pertaining to use of the Clinical Center by external investigators. The Working Group worked closely with key NIH staff with extensive knowledge of the statutory, regulatory, and policy considerations and limitations. Some of these relate to use of government facilities by non-federal personnel, co-mingling of intramural and extramural research funds, ability to collect money from outside sources, and management and administrative issues (e.g., governing laws and policies, conflict of interest policies, intellectual property requirements, liability coverage). In addition, NIH clinical directors reported on the current usage of the Clinical Center by outside investigators to better understand the nature of activities conducted under the current policy framework. The Working Group acknowledged that many of these details would require further investigation. As for the third set of barriers—problems in the recruitment, retention, and mentorship of investigators—an expanded vision for the Clinical Center, with diverse opportunities for exchange and interaction with investigators around the world, could produce an enhanced collaborative environment for conducting translational and clinical research and for training new investigators.

The Working Group also queried the external community regarding the practicality, feasibility, and desirability of expanding access to the NIH Clinical Center (see Appendix A for participant list). Speakers emphasized that the Clinical Center is critical to the NIH as a whole, because it is the most visible NIH presence to Congress, the media, and the public. Several speakers stated that resources afforded to the Clinical Center should be available to both intramural and extramural investigators. When asked to provide examples of how they could foresee using the Clinical Center and its resources, speakers cited clinical research training opportunities, collaborative approaches to the study of rare diseases, the possibilities for clinical research with a co-located laboratory component (particularly first-in-human studies), and the GMP facilities.

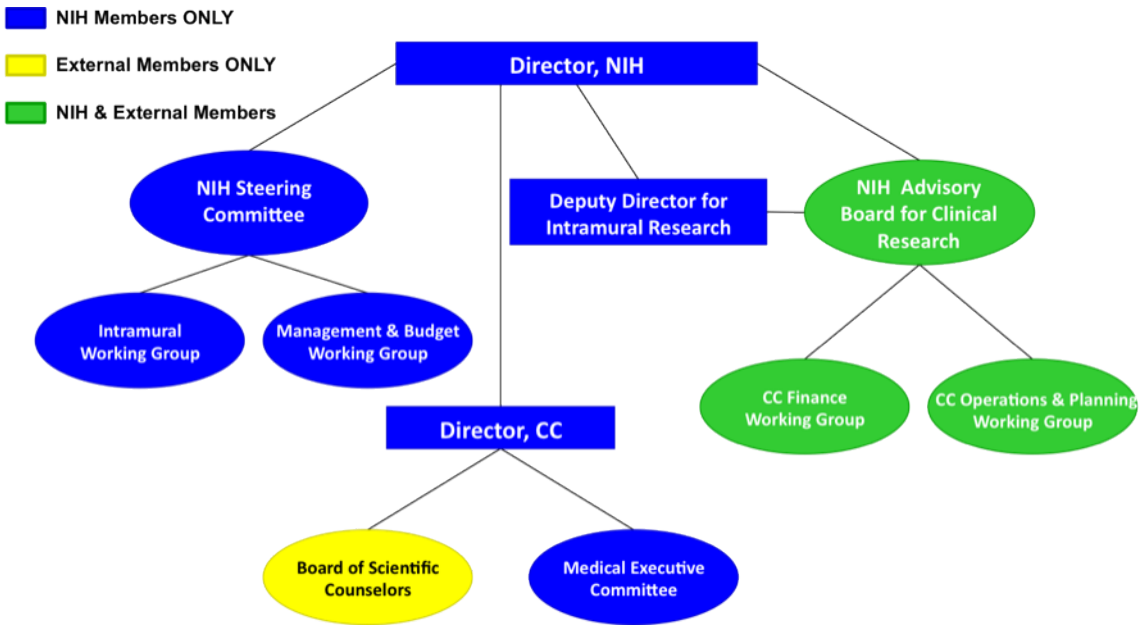
Of note, panelists cautioned the agency about requiring extramural investigators to pair with intramural investigators or establishing an overly burdensome logistical "start-up" process in order to reap the benefits of this facility; such requirements or bureaucratic hurdles could deter external investigators from using this facility. Instead, the Clinical Center should employ a rigorous peer review system to assess the value and priority of a given research project. Several panelists suggested that the Clinical Center could be positioned as a hub in a major clinical and translational research network, such as the Clinical and Translational Science Awards (CTSAs).

ii. Governance

Oversight of clinical research at the NIH is a complex process, engaging individuals and groups from both intramural and external communities (see Figure 2). Clinical research priorities are set at the institute and center level, with each specific institute or center formulating its own plan in accordance with its research mission. Any given institute's plan for clinical research must then run a gauntlet of approvals in the agency's hierarchy, with review and approval by the institute's clinical director, who establishes the direction

for intramural clinical research; the institute's scientific director, who establishes the scope of clinical research within the context of the institute's broader intramural research agenda (i.e., basic and clinical research); and the institute's director, who establishes the overall vision for clinical and basic research within the broader institute portfolio involving both the intramural and extramural communities. This institute-specific planning is then considered in the context of the NIH Director's goals and vision for the agency, taking into account trans-agency initiatives and research gaps.

Figure 2. Current oversight structure of the NIH Clinical Center.



In the past three years, NIH has established an ad hoc group of institute and center directors to identify and solve problems in clinical research and has more recently established a steering committee, chaired by the Deputy Director for Intramural Clinical Research, Dr. Daniel Kastner. According to Dr. Kastner in his testimony on September 22, 2009, these groups and other trans-NIH planning committees have made recommendations resulting in trans-NIH initiatives and a new strategy to reduce bureaucratic barriers to the conduct of clinical research at NIH. Also critical to this planning process is the NIH Advisory Board for Clinical Research (ABCR). The ABCR provides advice and guidance to integrate the vision, planning, and operations of the intramural clinical research programs of the NIH, including clinical research conducted at the Clinical Center, and oversees this facility's operations budget and strategic operating plans. Both the ABCR and the steering committee have attempted to address the issue of trans-NIH clinical research planning; however, there is broad-based concern at NIH that this type of planning may undermine the role for each institute and center in setting priorities for its own scientific programs.

In summary, the current governance system has become increasingly complex and redundant over time, and expert input from the NIH ABCR is sometimes marginalized (see Figure 2). The absence of an overall strategic vision for clinical research at NIH, the

development of multiple, institute- and center-based plans, and a complex, unwieldy governance structure are symptomatic of a less than effective approach to realizing the potential of this crucial activity within the agency's mission. There can be no doubt that excellent clinical research is well underway at the Clinical Center, but a more strategic, integrated approach would undoubtedly advance the work of the institutes and centers and the agency as a whole.

iii. Budget

The budget for the NIH Clinical Center is developed annually by assessing a fee to the intramural research program of each institute and center. Twenty-three of the 27 institutes and centers have an intramural research program. This "school tax" is calculated as a percentage of the size of the institute or center's intramural research program, regardless of its actual usage of the Clinical Center. This model was originally intended to provide a simple, predictable method for budget construction and has helped, in some cases, to spur increased usage of the Clinical Center. Prior to the implementation of this mechanism, alternative funding methods were used, including fee-for-service (charging based upon usage) and dissociating fixed and variable costs. These models were ultimately rejected because they were too complex, they did not produce stability (e.g., institutes and centers could not plan their intramural budgets due to fluctuations in Clinical Center taps), or they created disincentives to the use of the Clinical Center by the institutes and centers (e.g., fee-for-service models led to dwindling clinical research activity).

When the school tax funding mechanism was implemented in 2000, it was designed to be "budget neutral" such that the contributing institutes and centers would incur no additional costs to their budgets. As the costs for clinical research have risen, however, so have the operating costs of the Clinical Center. This problem has been exacerbated recently by the relatively flat budget for the agency over several consecutive years. As a result, over the last five years, the budget for the Clinical Center has grown faster than the overall budget for the intramural research program—a development that has, in turn, strained the program's own funding. These fiscal difficulties have been compounded by the location of the Clinical Center budget line in Central Services, which forces the Center to compete with other NIH central services in the budget allocation process. Because of funding limits, only limited funds are available for redistribution to the Center while maintaining core operations of the agency.

To accommodate rising costs, the Clinical Center has been forced to shift the costs of several crucial research services to the institutes and centers, in total or in part, on a fee-for-service basis. Dr. John Gallin, Clinical Center Director, reported to the Working Group on October 30, 2009, that cost shifting of selected research support services between 2004 and 2010 is projected to recover up to $24 million and has included such services as:

- Housekeeping for laboratories
- Research nurses
- Research PET
- Research blood products

- The NIH Family Lodge
- Genetic testing and cytogenetics
- Non-protocol related take-home drugs (shift to patients)
- Patient recruitment
- Outside medical services
- Off-label drugs that are subject of study

Although these cost shifts have provided some relief to the Clinical Center budget, they have resulted in several unintended consequences. For example, paying for rising clinical fees out of their relatively small, flat budgets has discouraged some smaller institutes and centers from using the Clinical Center.

Dr. Gallin also cited several additional tactical cost savings approaches deployed throughout 2004-2009, resulting in savings of approximately $60 million. These approaches include capital equipment deferrals, staff reductions/workforce planning, departmental savings, operational efficiencies, and reducing the Clinical Center research budget. In spite of these actions, funding for the Clinical Center remains insufficient.

Although the current school tax has provided a relatively stable, fair mechanism for funding the Clinical Center for nearly 10 years, it is incapable of keeping pace with inflation and ensuring stability in the face of restricted budgets. Moreover, the lack of stable funding has led some to question whether clinical research is a distinct priority at NIH and to express concerns regarding the future viability of the Clinical Center. For example, in an April 2008 letter to the NIH Director, NIH ABCR Chair Dr. Edward Benz called for an external review, commenting that "the Clinical Center is not viable without a fundamental change in the amount and mechanism of funding." Additionally, because of budget limitations, some of the smaller institutes and centers that have paid their respective portions of the school tax no longer have enough funds for the actual conduct of clinical research. While others have invested additional funds for clinical research, some are finding that the cost shifts associated with certain types of research, (e.g., PET, blood bank) threaten the operation of critical clinical research programs.

Finally, of relevance to the previous discussion of governance challenges is the fact that the process for developing the Clinical Center budget is not linked to its governance structure. A streamlined governance structure should facilitate a budgeting process that supports standard hospital inflationary costs and provides incentives for institutes and centers to invest their discretionary funds in clinical research while encouraging efficient use of the Center's resources.

III. THE FUTURE OF THE NIH CLINICAL CENTER: OPTIONS AND RECOMMENDATIONS

As previously noted, early in its deliberations the Working Group concluded that the Clinical Center's fiscal challenges should not be addressed in isolation from broader considerations of vision and governance. To address these concerns, the Working Group developed recommendations that articulate an expanded vision and role for the Clinical Center, describe the requisite governance structure for realizing this vision, and clarify and evaluate the options for ensuring the Clinical Center's fiscal sustainability.

A. Expanded Vision and Role

Recommendation: The role of the NIH Clinical Center should be to serve as a state-of-the-art national resource, with resources optimally managed to enable both internal and external investigator use.

Although the Clinical Center traditionally has been perceived as a resource for NIH and its intramural investigators, the Working Group members agree that this perception can and should be broadened. Opening the doors of the Clinical Center to external investigators could create new intellectual partnerships and ultimately foster recruitment of early-stage investigators to NIH. Currently, there is available physical capacity to support extramural access to the Clinical Center, although current funding to support such an initiative does not exist (see Appendix B for discussion). Extramural investigators could be invited, through appropriate review mechanisms, to take advantage of the Clinical Center's resources and expertise. These resources include, but are not limited to, (1) unique patient populations (e.g., rare and orphan diseases, undiagnosed diseases program, traumatic brain injury); (2) laboratory services (e.g., phenotyping, genotyping); (3) candidate drug development; (4) repositories (e.g., research blood products, stem cell, tissue); (5) imaging (e.g., PET, computer assisted smart needles for biopsy and drug delivery); (6) clinical trials infrastructure (e.g., first in human studies); (7) databases (e.g., ProtoType, Biomedical Translational Information System); and (8) clinical research training programs, fellowships, and exchange programs. In addition, the successful Bench-to-Bedside Program, which creates partnerships between intramural and extramural investigators, would benefit from a stable funding model with increased resources.

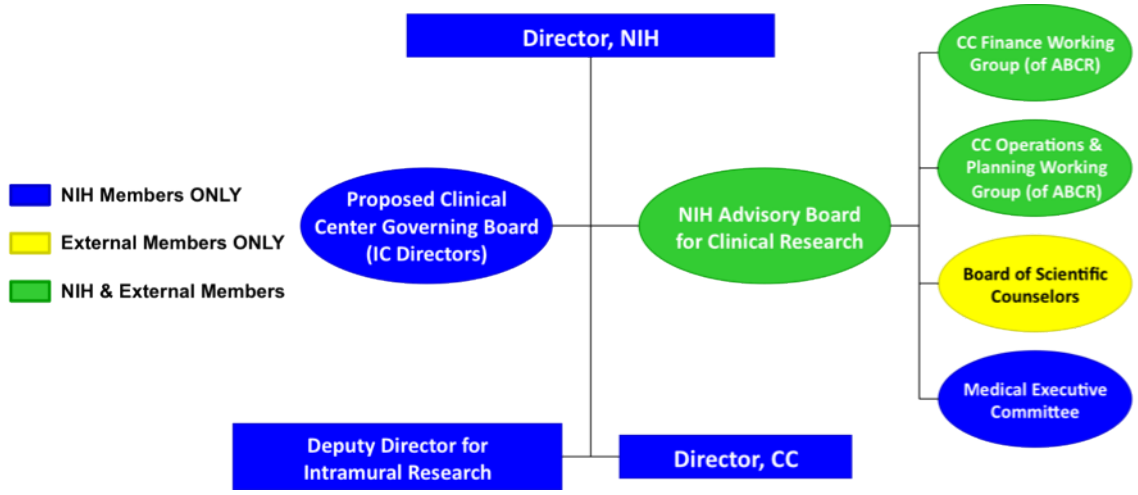
The Working Group recognizes that realizing this expanded vision will require modifications to the existing administrative and operational procedures, as well as in regulations and policy. Thus, this new vision for the Clinical Center will require additional considerations regarding a range of issues: some have to do with feasibility (e.g., availability of resources, capacity analysis); others concern administrative matters (e.g., conflict of interest, intellectual property, protocol approval); and still others concern reimbursement (e.g., recovery of costs, allocation of extramural funds). The Working Group believes that over time, many of these issues can be resolved through policy change, clarification of existing laws and regulations, a revised budget process (as described below), a new governance approach, or, if necessary, legislative action. For this goal to be realized, the mechanism whereby extramural investigators can use the Clinical Center must be clear, efficient, and as straight forward as possible.

B. Streamlined Governance

Recommendation: The NIH Clinical Center's governance should have a simplified structure, capable of developing and overseeing a clear, coherent budgetary and programmatic plan for clinical research.

The Working Group recommends that the current governance structure be modified to facilitate the development and implementation of an overall strategic vision for clinical research within the agency's total portfolio of intramural and extramural research, and specifically with regard to the conduct of research at the Clinical Center. After consideration of several variants (see Appendix C), the Working Group agreed upon a governance structure that facilitates knowledgeable input from both external and internal advisers. The recommended governance structure would eliminate oversight by the NIH Steering Committee, establish a new governing board comprised of institute and center directors, and strengthen the role of the ABCR (see Figure 3).

Figure 3. Recommended oversight structure for the NIH Clinical Center.



It is certain that the clinical research priorities of the individual institutes and centers, in addition to those of the agency as a whole, will inevitably vary in terms of scope, potential impact, requisite funding, etc. Nonetheless, it is critical that a process for analyzing, weighing, and ultimately determining these priorities be established, along with determining accountabilities that are both effective and transparent. Therefore, the Working Group emphasizes the need for a streamlined governance structure focused on clinical research, drawing on both intramural and external representation. This structure should be based on interest and expertise, but not on ownership; that is, the group must function more as "trustees" responsible for the effective governance of the assets of the organization. The ABCR is well constituted to take a major responsibility for this role.

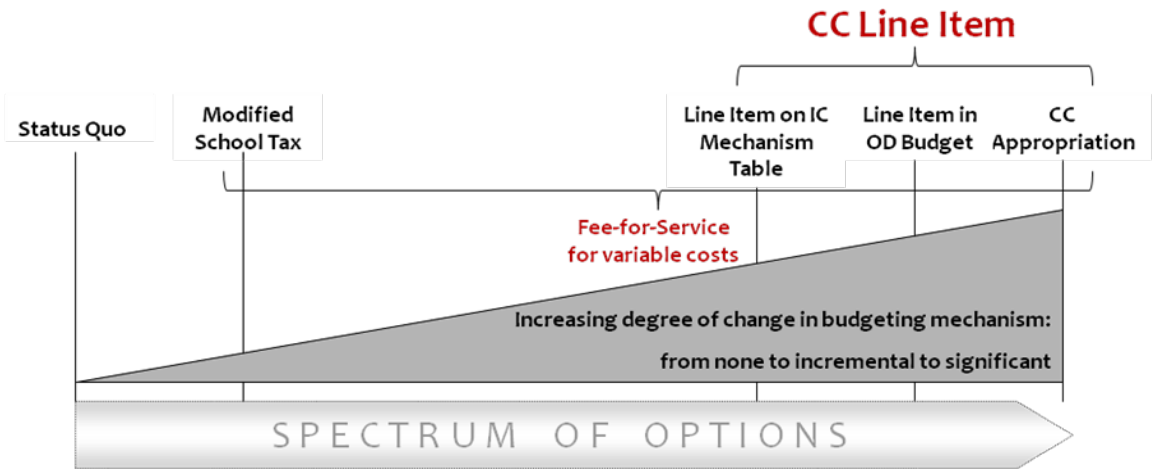
C. Stable, Adequate Budget for Fiscal Viability and Sustainability

Recommendation: The NIH Clinical Center budget should be linked to a strong planning process, remain stable (in source) and equitable (in distribution), be

effective in attracting and supporting a high quality workforce, and assure efficient use.

In its analyses and deliberations, the Working Group considered a spectrum of funding models and assessed each model's potential for establishing and maintaining a stable budget. Ultimately, the Working Group conducted an in-depth analysis of the following five options: the status quo of the current school tax, a modified school tax, a line item in institute and center mechanism table, a line item in the Office of the Director appropriation, and a direct Congressional appropriation. These options can be conceptualized along a spectrum, increasing in degree of change of budgeting mechanism (see Figure 4).

Figure 4. Potential funding models: A spectrum of options.



In addition to their ability to ensure the fiscal sustainability of the Clinical Center, these options were analyzed in terms of their ability to position the Clinical Center as a national resource, prioritize clinical research at NIH, streamline governance, and enhance programmatic planning. These models, along with their strengths and weaknesses, are described in detail in Appendix D.

Based on the analyses outlined above, the Working Group recommended that the Clinical Center be funded by a line item in the Office of the Director appropriation. The Working Group is confident that this model will maximize flexibility, while concurrently offering stability and minimizing hierarchical reporting structures. Moreover, this mechanism will achieve several key aims: one is to balance the priorities of the individual institutes and centers and those of the agency as a whole; another is to permit the articulation and realization of a trans-agency vision for clinical research; and a third aim is to provide a stable budget to sustain the vitality of the Clinical Center and of the agency's clinical research mission.

As mentioned in the analyses of options in Appendix D, this model would support an expanded vision for the Clinical Center. It could provide greater visibility for the Clinical

Center, facilitate awareness of its availability to the external community, and signal that clinical research is a high priority for the agency. It should be noted that this budget mechanism would require a one-time transfer of funds from the intramural program. Funds only come out of the total NIH budget when the annual increase in the NIH budget is less than that year's inflationary increase of running the Clinical Center (see Table 1).

IV. SMRB CONCLUSIONS AND RECOMMENDATIONS

At its meeting on December 7, 2010, the SMRB received, discussed, and debated the final report of the IRP Working Group. Presented with the options identified by the IRP Working Group, a majority of the Board (14 favored; 0 opposed) voted to recommend to the NIH Director that the NIH Clinical Center have an expanded vision and role with resources optimally managed to enable both internal and external investigator use; a simplified governance structure, as depicted in Figure 3, capable of developing and overseeing a clear, coherent budgetary and programmatic plan for clinical research; and a budget linked to a strong planning process, that remains stable (in source) and equitable (in distribution) and is effective in attracting and supporting a high quality workforce, and assure efficient use. Toward this end, the SMRB recommended that the Clinical Center be funded by a line item in the Office of the Director appropriation.

By expanding the Clinical Center's vision and role, streamlining its governance structure, and providing a sustainable budget, the agency can occupy a unique position of leadership and responsibility for identifying, developing, and implementing more effective strategies for achieving the ultimate aims of biomedical and clinical research. By accepting and acting upon the recommendations set forth in this report, the SMRB believes that NIH can take several crucial steps in advancing the cause of clinical research, both within and beyond the agency. Although much more will be required to realize the full potential of clinical research—by NIH, by academic institutions, and by industry—these crucial steps will place the agency's own contributions to this goal on a sounder, more sustainable footing.

Table 1. Hypothetical model for meeting escalating cost of the NIH Clinical Center.

FY	Budget (MILLIONS)	ABCR Recommended Increase for Following Year	NIH Oversight Group Recommended Increase	Increase in Overall NIH Budget	$ Required from Total NIH Budget (MILLIONS)	Total NIH Budget (BILLIONS)	Cumulative Total Needed from Total NIH Budget (MILLIONS)	% of Total NIH Budget in Current Year Not Coming from IRP	Cumulative % of Total NIH Budget for CC Not Coming from IRP
2010	$362.0	5%	3%	3%	$7.24	$31.26	$7.24	0.023%	0.023%
2011	$380.1	3%	1%	1%	$7.60	$31.57	$14.84	0.024%	0.047%
2012	$391.5	4%	3%	3%	$3.92	$32.55	$18.76	0.012%	0.058%
2013	$403.2	3%	3%	3%	$0.00	$33.53	$18.76	0.000	0.056%
2014	$415.3	4%	2%	2%	$8.31	$34.20	$27.07	0.024%	0.079%

APPENDIX A

Speakers and Dates

APRIL 27-28, 2009

- Colleen Barros, Deputy Director, Office of Management, NIH
- Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH Debra Lappin, Senior Vice President, B&D Consulting
- Michael M. Gottesman, M.D., Deputy Director, Office of Intramural Research, NIH
- John I. Gallin, M.D., Director, Clinical Center, NIH
- Marc Smolonsky, Director, Office of Legislative Policy and Analysis, NIH
- Lawrence A. Tabak, D.D.S. Ph.D., Director, National Institute of Dental and Craniofacial Research and Acting Deputy Director, NIH
- Harold Varmus, M.D., President, Memorial Sloan-Kettering Cancer Center
- Elias Zerhouni, M.D., Senior Fellow-Global Health, Bill & Melinda Gates Foundation and Senior Adviser, Johns Hopkins Medicine

SEPTEMBER 14, 2009

- Michael M. Gottesman, M.D., Deputy Director, NIH Office of Intramural Research
- John I. Gallin, M.D., Director, NIH Clinical Center
- Stephen Katz, M.D., Ph.D., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
- Elizabeth G. Nabel, M.D., Director, National Heart, Lung, and Blood Institute

SEPTEMBER 22, 2009

- Ronald G. Evens, M.D., Chair, NIH Advisory Board for Clinical Research and Senior Executive Officer, BJC HealthCare
- Daniel Kastner, M.D., Ph.D., Clinical Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
- Cliff Lane, M.D., Clinical Director, National Institute of Allergy and Infectious Diseases
- Steven Rosenberg, M.D., Ph.D., Chief of Surgery, National Cancer Institute

OCTOBER 30, 2009

- Colleen Barros, Deputy Director for Management and Chief Financial Officer, NIH
- John Bartrum, Associate Director, NIH Office of Budget
- Edward J. Benz, Jr., M.D., President and Chief Executive Officer, Dana Farber Cancer Institute; and Susan Smith Professor of Medicine, Professor of Pediatrics, and Professor of Pathology, Harvard Medical School

- John J. Finan, F.A.C.H.E., President and Chief Executive Officer, Franciscan Missionaries of Our Lady
- John I. Gallin, M.D., Director, NIH Clinical Center
- Michael M. Gottesman, M.D., Deputy Director, NIH Office of Intramural Research
- R. Edward Howell, Vice President and Chief Executive Officer, University of Virginia Medical Center
- Barbara M. McGarey, J.D., Office of the General Counsel, U.S. Department of Health and Human Services

NOVEMBER 12, 2009

- Michael Gottesman, M.D., Deputy Director, NIH Office of Intramural Research

MARCH 10, 2010

- Hal G. Rainey, Ph.D., M.A., Alumni Foundation Distinguished Professor and Ph.D. Director, Department of Public Administration and Policy, University of Georgia

APRIL 20, 2010

- Francis Collins, M.D., Ph.D., NIH Director
- Francis Patrick White, NIH Associate Director for Legislative Policy and Analysis

MAY 19, 2010

- Robert M. Califf, M.D. Donald R. Fortin, M.D., Professor of Cardiology; Director, Duke Translational Medicine Institute; Vice Chancellor for Clinical Research, Duke University School of Medicine
- Arthur S. Levine, M.D. Senior Vice Chancellor for Health Sciences, and Dean, School of Medicine, University of Pittsburgh
- Allen M. Spiegel, M.D. The Marilyn and Stanley D. Katz Dean, Albert Einstein College of Medicine, Yeshiva University
- William F. Crowley, Jr., M.D. Founder and former Chair, Clinical Research Forum and Clinical Research Foundation
- Mark T. Gladwin, M.D. Division Chief of Pulmonary, Allergy and Critical Care Medicine; Director, Vascular Medicine Institute, University of Pittsburgh Medical Center
- Steven K. Libutti, M.D. Director, Montefiore-Einstein Center for Cancer Care
- Samuel C. Silverstein, M.D. John C. Dalton Professor and Chair, Department of Physiology and Cellular Biophysics; Professor of Medicine, College of Physicians and Surgeons, Columbia University; Member of the Board of Directors, Damon Runyon Cancer Research Foundation

APPENDIX B

Extramural Access Funding Sources

The additional funding needed to establish the Clinical Center as a national resource for clinical research could be provided in the form of new monies to the NIH or from an appropriation.

Unused CC capacity can be made available to the external community (extramural researchers, foundations, industry, etc.) through a variety of applicable mechanisms:

- NIH grantees could prospectively plan access to the Clinical Center when writing grants;
- Extramural grantees could pay for Clinical Center services without prospective planning if provided for by Congressional language formulated in the line item;
- Funding for extramural grantees to use the Clinical Center could come from a special fund in the Office of the NIH Director that supplements cooperative agreements and encourages intramural-extramural partnerships; or
- For non-NIH grantees, private funds could be transferred to the Clinical Center under Title 3, section 327A of the Public Health Service Act.

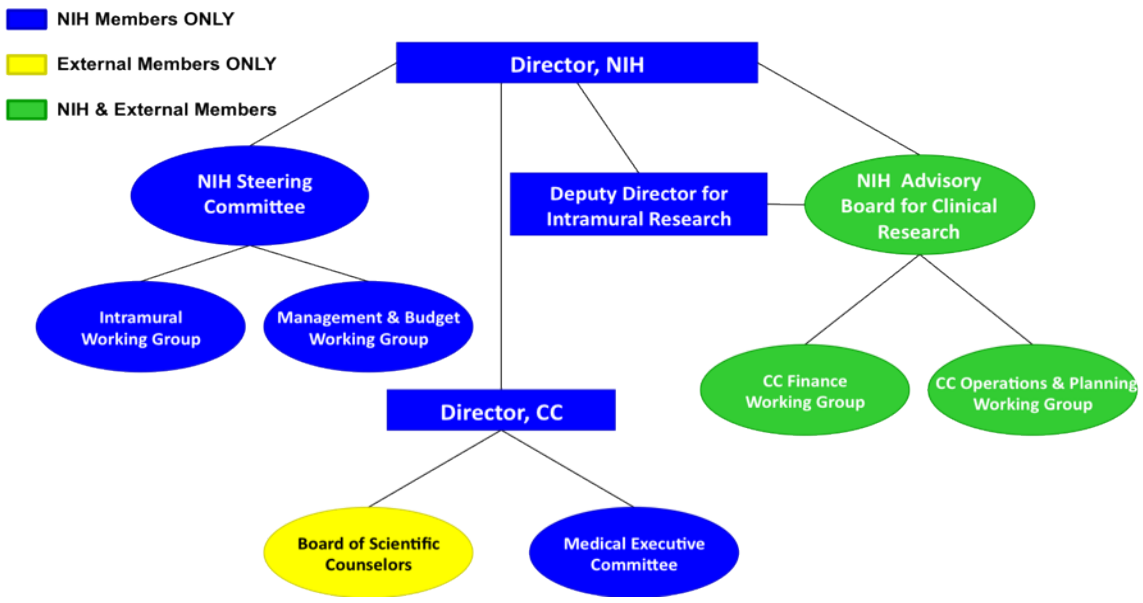
Other sources of outside funds should continue to be evaluated for opportunities to provide additional revenue streams to the Clinical Center. For example:

- Third party collection for diagnostics, recognizing the core strength of the Clinical Center as a diagnostic facility, could be made available nationally on a reimbursable basis (e.g., pathology, undiagnosed diseases program, microbiology). A careful economic analysis would be required to determine if a compelling return on investment could be achieved. Most likely, this would only be supportable if Congressional language were to allow the Clinical Center to bill CMS;
- Outside funds and other authorities should be evaluated to provide additional revenue streams to the Clinical Center;
- Funding for extramural grantees to use the Clinical Center could come from a special fund in the Office of the NIH Director that supplements cooperative agreements and encourages intramural-extramural partnerships. For non-NIH grantees, private funds could be transferred to the Clinical Center under a reimbursable authority (Title 3, section 327A).
- Non-NIH money to support Clinical Center activities (foundations, philanthropy, and industry) could go to the Clinical Center via the Foundation for the NIH.

APPENDIX C

Potential Governance Options

A.



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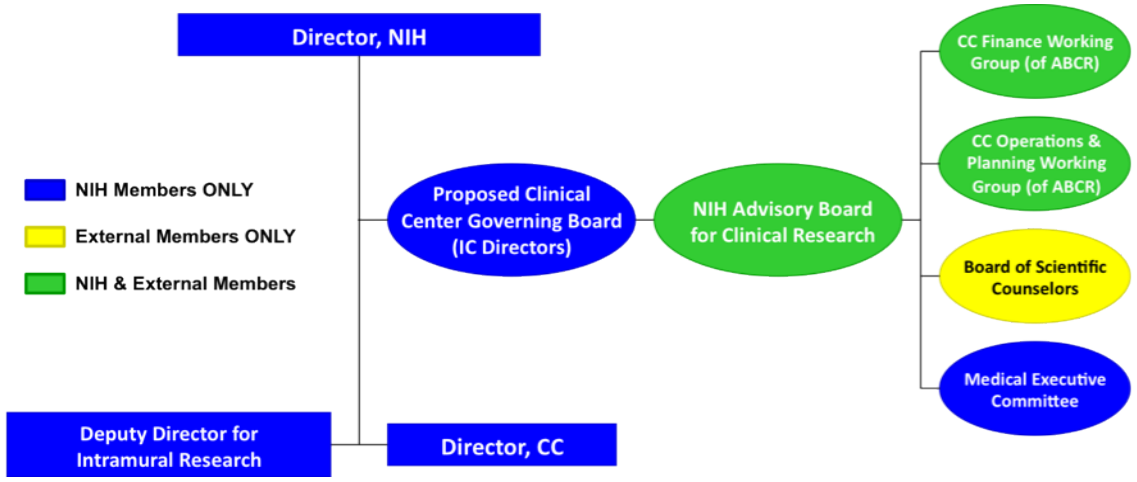
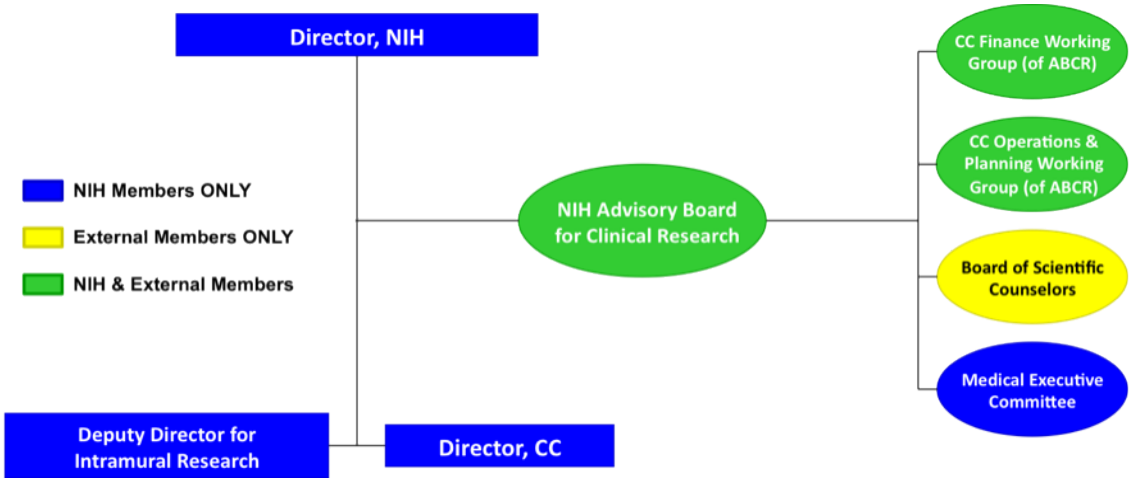
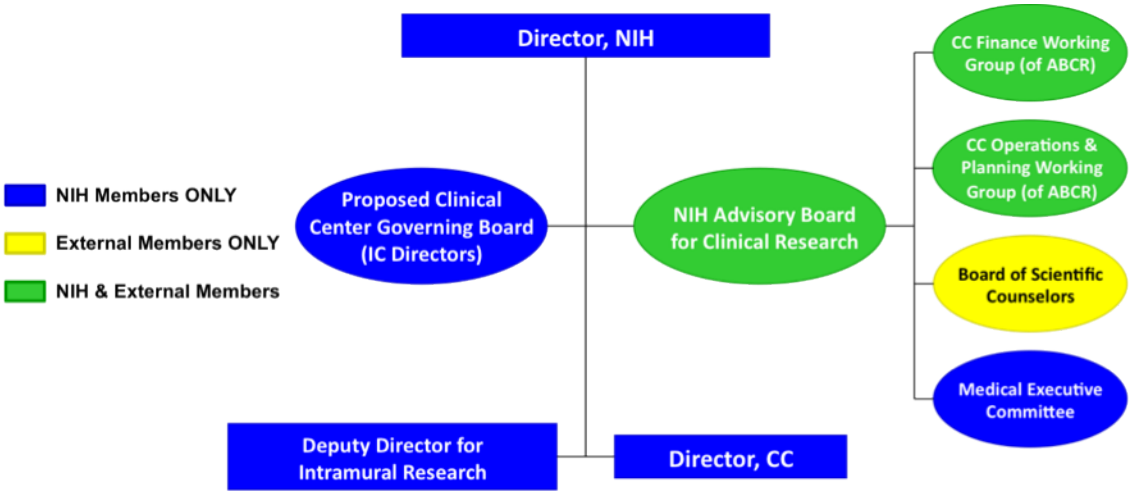


C.


Director, NIH
NIH Members ONLY
External Members ONLY
NIH & External Members
NIH Advisory Board for Clinical Research
CC Finance Working Group (of ABCR)
CC Operations & Planning Working Group (of ABCR)
Board of Scientific Counselors
Medical Executive Committee
Deputy Director for Intramural Research
Director, CC

D.


Director, NIH
NIH Members ONLY
External Members ONLY
NIH & External Members
Proposed Clinical Center Governing Board (IC Directors)
NIH Advisory Board for Clinical Research
CC Finance Working Group (of ABCR)
CC Operations & Planning Working Group (of ABCR)
Board of Scientific Counselors
Medical Executive Committee
Deputy Director for Intramural Research
Director, CC

APPENDIX D

Detailed Analysis of Funding Options

School Tax (status quo)

Description: In this model, funding for the Clinical Center (as described in detail previously in this report) is supported by each institute and center's intramural research program budget and NIH internally reallocates appropriated funds to the Clinical Center via Central Services.

Strengths and Weaknesses: Extramural funds are prohibited from being transferred into the Clinical Center management fund, limiting external use and subsequent visibility. There is no direct relationship established between usage of the Center and assessment of fees to the institutes and centers. Subsequently, this model should maximize utilization and incentivize the conduct of clinical research. However, this model might be perceived to be unfair by some institutes and centers, as there is no relationship between the funds provided and the benefits received. An additional strength of this model is that the locus of decision-making remains within the agency and does not require additional oversight by HHS, the Office of Management and Budget, or Congress. The complex governance structure within the agency, however, requires input from numerous parties and conflates NIH-driven program oversight and budget review. Furthermore, this model provides no incentive for the efficient use of the Clinical Center or a strategic focus on clinical research, as the planning process is derived at the institute and center level. For the reasons mentioned previously, this model is not recommended for ensuring the fiscal sustainability of the Clinical Center.

Modified School Tax Model

Description: This model is similar to the original school tax model; however, in this model, the fixed and variable costs are dissociated. The fixed costs continue to be assessed via the school tax mechanism, while variable costs are assessed based on an institute or center's total usage of the Clinical Center (similar to a fee-for-service). NIH internally reallocates appropriated funds to the Clinical Center via Central Services.

Strengths and Weaknesses: While this model establishes a clearer relationship between usage and benefits received and incentivizes efficiency, variants of this option in the past have reduced usage of the Clinical Center, potentially jeopardizing the priority of clinical research within the agency. Additionally, it only moderately lessens the financial burden on the intramural research program, as it cannot account for the difference in inflationary costs. At this point in time, it is unclear as to whether variable cost assessments can be made precisely.

A Clinical Center Line Item in the Mechanism Table of Each Institute and Center

Description: In this model, NIH proposes to Congress its intent to provide a specified amount to the Clinical Center for fixed costs from the total amount appropriated to the institutes and centers. Thus, funding for fixed costs is derived from the entire NIH budget. Each institute carries its portion of the fixed cost payment in this new, visible line item in its mechanism table. The total amount appropriated initially is subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably from the intramural research program (through a one-time adjustment). Once funds are appropriated, they are transferred from the institutes and centers to the Clinical Center via Central Services.

Variable costs can be introduced and budgeted within each institute and center's intramural research program line in its mechanism table. Unlike fixed costs, this amount is not visible in HHS, OMB, and Congressional submissions. Variable cost assessments for each institute and center are introduced based upon total usage and are developed initially when fixed costs are calculated, but can be refined prior to the beginning of the fiscal year. Once budget levels are appropriated, funds are transferred to the Clinical Center via Central Services.

Strengths and Weaknesses: This model could provide a greater visibility for the Clinical Center, facilitate awareness of availability to the external community, and signal that clinical research is a high priority for the agency. However, as discussed, variable cost assessment fails to incentive use, and it is unclear whether variable cost assessments according to use can be made precisely at this time. This mechanism would also result in shifting budget formulation and review to the NIH-wide budget formulation process, effectively simplifying governance. Conversely, simplifying governance within the agency effectively results in the fixed costs being submitted to Congress, which establishes a funding limitation that requires Congressional notification for any reprogramming. The most substantial difference with the line item options is that the Clinical Center budget would be funded from a larger pool of resources and would provide greater flexibility to adjust funding for variable costs. While this mechanism cannot compensate for the rising costs of clinical research, these costs will be less burdensome on the intramural programs.

A Clinical Center Line Item in an NIH Office of the Director (OD) Appropriation

Description: In this model, NIH proposes to Congress its intent to provide a specified amount of funding to the Clinical Center as a line item within the OD appropriation. The amount is requested as part of the appropriations process and is derived from the entire NIH budget. The total budget is developed by the NIH Director with input from the governing board and is initially subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably the intramural research program (through a one-time adjustment).

Congress, in taking action on the budget proposal, ultimately sets the funding level. Once funds are appropriated, they are allocated directly to the Clinical Center (i.e., there is no transfer through Central Services). During a fiscal year, should there be need for

additional funds in excess of the amount appropriated, a reprogramming request may be submitted to Congress; however, the source of funds must be derived from OD funds and cannot be transferred from the institutes and centers. Variable cost assessments to each institute or center can be introduced based on total usage and would be budgeted in each institute and center's intramural research program line, upon congressional approval. Regarding the designated evaluation criteria:

Strengths and Weaknesses: This model yields similar strengths and weakness as line item options. However, additional strengths for this model include the ability to facilitate a NIH-wide strategic focus for and trans-NIH initiatives in clinical research. Care must be taken in assuaging concerns that the Clinical Center is organizationally situated within the Office of the Director.

Direct Congressional Appropriation

Description: Similar to the item in the OD appropriation, in this model, NIH proposes to Congress funding levels that are then directly appropriated to the Clinical Center (similar to appropriation process for all other institutes and centers), enacting the funding level into law. The amount is requested as part of the appropriations process and is derived from the entire NIH budget. The total budget is developed by the NIH Director with input from the governing board and is initially be subtracted from other appropriate mechanisms where these costs are currently budgeted, presumably the intramural research program (through a one-time adjustment).

Congress, in taking action on the budget proposal, ultimately sets the funding level. Once funds are appropriated, they are allocated directly to the Clinical Center (i.e., there is no transfer through Central Services). During a fiscal year, should there be a need for funds in excess of the amount appropriated, a budget transfer request may be submitted, which requires statutory budget transfer authority. Variable cost assessments to each institute or center can be introduced in this model based on total usage and could be budgeted in each institute and center's intramural research program line, upon congressional approval. Depending on the language that Congress uses for the appropriation, adding more funds for variable cost assessments might be an improper augmentation/supplementation. Regarding the designated evaluation criteria:

Strengths and Weaknesses: Again, this model yields similar benefits to the other line item options. Additional strengths for this model include maximal stability in funding for the Clinical Center. However, additional weaknesses to this model include the perception that the Clinical Center is competition for the other institutes and centers and potentially accentuates a perceived split between basic and clinical research Furthermore, the Clinical Center budget submitted to Congress enacts funding into law, which would requires careful language in the statute to avoid potential challenges and limitations to reprogramming.