



DEC 10 2002

Harold T. Shapiro, Ph.D.  
Chairman, Committee on the Organizational Structure of the NIH  
Woodrow Wilson School of Public and International Affairs  
Princeton University  
355 Wallace Hall  
Princeton, NJ 08544

Dear Dr. Shapiro:

At the request of the National Institutes of Health (NIH) Council of Public Representatives (COPR), I am forwarding the enclosed report as prepared by the Council. The independent conclusions and recommendations in this report regarding the organizational structure and management of the NIH cover a range of topics specifically from the public perspective.

As you may be aware, the COPR is a forum for discussing issues affecting the broad development of agency policy, programs, and research goals and for advising the NIH Director on these matters. It also advises and assists the NIH Director to enhance public participation in NIH activities, to increase public understanding of the NIH, and to bring important matters of public interest forward for discussion in public settings. The COPR membership comprises a variety of backgrounds, cultures, and geographic origins; its twenty-one members all share a vital interest in the work of the NIH.

I trust you and the committee will find this report helpful in your deliberations.

Sincerely,

Elias A. Zerhouni, MD  
Director

CC:  
Fran Sharples, Ph.D.

Enclosure

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**REPORT TO THE DIRECTOR  
OF THE NATIONAL INSTITUTES OF HEALTH  
ON THE ORGANIZATIONAL STRUCTURE AND MANAGEMENT  
OF THE NIH  
FROM THE COUNCIL OF PUBLIC REPRESENTATIVES**

**December 2, 2002**

**Members of the Director's Council of Public Representatives:**

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## INTRODUCTION

The Council of Public Representatives (COPR) was created as the public voice of the American people, in the broadest and least encumbered sense, to the Director of the National Institutes of Health (NIH). This report, stimulated in part by a study underway by the Institute of Medicine (IOM), is a piece of the ongoing dialogue on how the NIH can best manage biomedical research on behalf of all Americans.

The American public supports NIH research with its wallets and by putting their very bodies on the line to make clinical trials possible. They will continue to do so only if they trust that research and the people who conduct it. Maintaining and enhancing that essential trust requires constant, diligent work on the part of the NIH that is based upon five key principles:

1. Empowering patients and the public as full partners in the research process
2. Promoting transparency of operations and information
3. Treating the whole patient, not simply the disease
4. Strengthening the link of bench to bedside
5. Enhancing communications as integral to all of these functions

In this report we use these five principles to analyze aspects of the structure and function of the NIH that may be considered by the IOM committee. We believe they are integral to guiding any reorganization. We also offer recommendations for the NIH Director to consider in conjunction with the IOM committee report. An appendix contains additional thoughts and recommendations that are important for the Director to consider.

## KEY POINTS:

- **Any reorganization of the NIH should be less concerned with the organizational chart of that body than with its functionality.** Most observers believe that the present structure, while complex and at times vexing to navigate, has produced remarkable success in advancing biomedical research and has contributed greatly to improving health in the United States and the world.
- **Structural changes potentially could diminish the link between the bench and the bedside.** The experience gained in treating patients can lead to insights that can be pursued in the lab, and vice versa. We are wary of changes that might diminish these ties.
- **Biomedical research will fulfill its promises only through combining the high tech of cutting-edge science with the high touch of human interactions.** The process begins with the collaborative establishment of research priorities and continues through decisions on individual health and care.

- **The focus should be on creating mechanisms that better respond to the breadth of interests of those with a stake in biomedical research and that offer greater flexibility in recognizing and supporting innovative ideas**, many of which may challenge or even threaten the status quo. The pressure for new Institutes and Centers arises when people feel that their concerns are not being addressed. Simply restructuring the organizational chart of the NIH will do little by itself to reduce those pressures.
- **Leadership, openness, flexibility, and money are all important qualities in ensuring success at the NIH, but most important of these is leadership.** Continuity of leadership is essential. At the very least, the Administration and the NIH should act to ensure that senior positions at the NIH are filled promptly.

In sum, the goal in changing the existing framework of the NIH should be to create mechanisms that embrace and are responsive to all constituencies, including the American public, as partners in the research process; that facilitate collaborative interactions between those partners; and that are more open to change and new ideas.

## **PROLIFERATION OF INSTITUTES AND CENTERS**

The proliferation of Institutes and Centers has occurred primarily through two mechanisms: one arising from a perceived need on the part of the NIH, as with the National Human Genome Research Institute, and the other as a consequence of the NIH being seen as insufficiently responsive to specific constituencies, as was the case with the National Center for Complementary and Alternative Medicine. This also holds true for the formation and establishment of the Council of Public Representatives (COPR).

The greater administrative burden of those added structures can be a legitimate cost of including valid constituent interests that may arise from time to time. However, we remain generally skeptical of the need to create additional Institutes and Centers. Although a consolidation or clustering of some existing structures has a certain logic, one must also consider the internal and political costs associated with such activity and choose priorities wisely. What might initially seem logical or rational on paper often does not remain so when one examines the details.

Organizational rationality should not be an end in itself. Rather, the purpose of any reorganization should be to significantly improve functionality and/or reduce administrative costs. Because the nature of research and “known truths” is constantly changing, so too the framework within which to conduct that research must be flexible and evolving.

Furthermore, not only is disease complex, so too are patients. Even a “simple” disease often can initiate a cascade of increased risks for other afflictions. The comorbid patient is the rule, not the exception. The public realizes the limitations of treating disease and

demands that the focus of treatment be on the whole patient, not his or her parts. Research must reflect that demand.

There is value in having overlapping and redundant responsibilities, particularly in a process such as research, where both goals and the paths to those goals often are not yet fully known. It is one way of reducing the risks of orthodoxy, where a single approach and set of gatekeepers can preclude support for differing approaches. It also can induce some degree of competition, which often is a good thing.

Creation of the Office of AIDS Research is a useful case study in how to manage structural change. Former NIH Director Harold Varmus has written of it as "a compromise to avoid an especially contentious fusion of AIDS programs into a full-fledged Institute." It was, in his eyes, at least a partial success in reining in the further proliferation of Institutes.

An important factor in that outcome was the decision by AIDS activists, historically one of the most potent advocacy communities and then at the peak of its influence, *not* to seek such an Institute. Much of the reason why is that the NIH, particularly through the leadership of Anthony Fauci, made extraordinary and groundbreaking efforts to include the affected community as partners in shaping the research agenda. Community leaders had a stake in the process, bought into the outcome, and felt no need to carve out a special Institute.

#### *Recommendations:*

- The NIH should do a better job of educating both the general and targeted publics to underlying principles of biomedical research, such as, genomics, cell signaling, and other broad areas that underlay all biological functioning. It should better demonstrate how trans-NIH research affects specific areas of disease and contributes to better outcomes for the whole patient. This may relieve some of the pressure to create additional institutes and centers.
- The NIH should do a better job of integrating all constituencies as partners in all aspects of research, to increase the "buy in" into that process and the priorities that it sets. It should better identify and make explicit existing expenditures in disease areas as part of demonstrating its commitment to individual disease areas and to the concept of transparency.
- The U.S. Congress should enact legislation mandating the process through which Institutes and Centers will be created, so that it guarantees ample opportunity for public comment on such structural changes such as:
  - A process for the creation of new Institutes and Centers must be identified.
  - The public must be involved in determining how that process is constructed.
  - The process itself must encompass public participation.
  - The Congress should mandate that this process be used in the creation of new Institutes and Centers.

## OFFICE OF THE DIRECTOR

Biomedical research today is moving in the direction of a multidisciplinary approach to discovery, in part because of increasingly sophisticated research tools and computational power are giving us the ability to handle the complexity of large data sets and to integrate them in ways that are orders of magnitude greater than they were even a decade ago. This central fact of contemporary biomedical research supports the idea of a greater role for the Office of the Director at the NIH. That office, unlike every other one at the NIH, uniquely has the broad responsibility of advancing health—not a specific disease, or approach, or organ, but the overall health and well-being of the American public. It should be given the resources necessary to fulfill that mandate.

We do not mean to suggest a centralized or directed approach to research; that would be antithetical to the principles at the core of the NIH since its founding. Rather, we seek to equip the Director with the tools necessary to facilitate and integrate research on a trans-NIH basis, so that he may truly be first among equals.

The budget of the Office of the Director has not kept pace with growth in the overall NIH budget, even while it has taken on added responsibilities. Over the last decade, the total NIH budget has increased by 125%, whereas the Director's budget has increased only by 88%. It has shrunk from 0.4% to 0.3% of the total budget.

### *Recommendation:*

- The Office of the Director needs additional funds in order to perform existing functions properly. As that Office takes on new tasks, sufficient funding should be added to properly implement those new tasks.

**Research Leadership:** One option in strengthening the hand of the Director is to give that Office more money that can be awarded on a discretionary basis to shifting priorities and emerging opportunities across all of the NIH. We encourage that to some extent, though we wish to avoid creation of a parallel administrative bureaucracy (and pressures for funding) that might arise from placing extraordinarily large sums in the Office.

We believe another mechanism offers equal or greater opportunity to promote better-integrated research and enhance the authority of the Director. It would encourage Institutes and Centers to pursue research that the Director has identified as NIH priorities. It would not give the Director an absolute veto over trans-Institute research, which still could be conducted with other funds, but it would help to direct a portion of their funding toward centrally defined priorities.

***Recommendation:***

- Mandate that each Institute and Center spend a minimum “floor” amount of its research budget on trans-Institute programs approved by the Director.

We believe the commitment to such trans-Institute programs should be significant. Some have suggested that the floor be 20% of the total budget, but we are not prepared at this point to offer any guidance on budgetary targets.

**Administrative Consolidation:** The larger Institutes generally have a critical mass to efficiently carry out most administrative functions. It is clear that many of the smaller Institutes and Centers do not have those scales of operations. Certain functions could more rationally be carried out on a centralized basis. We recognize that NIH has already carried out many of these efforts and we support them.

**Data Systems and Nomenclature:** The promise of enhanced health based on knowledge of the human genome ultimately will require huge data sets for maximum understanding of those complex interactions. That will not be achieved through single studies but through the integration of data from vast numbers of studies.

Failure to implement standardization, and even delay in doing so, carries a price that is measured in deferred development of therapy, increased risk in clinical trials, and patient deaths. The recent development of harmonized mechanisms of reporting serious adverse events in gene transfer trials, which the NIH and the Food and Drug Administration are implementing, is a useful model for broader application.

***Recommendation:***

- The NIH must establish single, unitary standards for data collection and integration that apply to all NIH-sponsored research activity. The actual performance of many of these tasks need not be centralized, and in many instances may benefit from being decentralized. Voluntary compliance is always preferable; however, it may become necessary to arm the Office of the Director with both the tools and the power to expedite this process in a timely manner.

**Communications:** The NIH devotes tremendous resources to and effectively communicates with researchers through the peer review process and the conduct of scientific meetings. It is much less effective in communicating with other partners in the research process, most notably the general public, in part because it devotes few resources to those tasks.

There are exceptions to this. For example, the National Library of Medicine has made a concerted effort to create resources that are accessible to the general public. As a result, its web site has become one of the most credible and most visited health sites in the world.



Reorganization must improve the nature, quality, and mechanisms of communication with the American public so that the public and patients can become truly informed, active, and equal partners in fulfilling the NIH mission of improving health.

Unfortunately, the NIH has seldom proactively and effectively reached out to the broad American public through the medium of television. It is the single most important vehicle in contemporary America for reaching both a broad audience and underserved minority populations. Even the largest Institutes would be hard pressed to exploit this media potential on their own in a cost effective manner. The smaller Institutes and Centers cannot even dream of utilizing television.

***Recommendation:***

- The NIH should greatly expand its communications activities with the general public and with other targeted partners in biomedical research, principally through increased use of television and associated technologies. Most of this increased activity should be on a centralized basis within the Office of the Director and should emphasize technical communications skills and external contact. We also recognize the continued importance of having information officers within Institutes and Centers, where they are close to the actual work of those bodies and can develop an understanding of that research, as well as the facility to translate those research findings into language that all can comprehend.

**Clinical Trials:** Public concern is that some Institutes and Centers have insufficient capacity to carry out the large-scale clinical trials in areas of their responsibility that are necessary to improve the nation's health. This is particularly true when it comes to data safety monitoring and other functions of patient protection.

***Recommendation:***

- The Office of the Director should establish centralized core management and safety support for clinical trials for use by those Institutes and Centers that do not have sufficient scale to adequately support such activities on their own.

**Education and Training:** The NIH has invested heavily in education and training in research. Perhaps best known are post-doctoral fellowships. But the span of activity is much broader; it includes promoting state-of-the-art standards of care for medical practitioners through the Office of Medical Application of Research, stimulating public school students to consider a career in biomedical research, and recent educational initiatives to strengthen patient protections in clinical trials. One element that is missing is investment in the education and training of the public to better serve their role as a partner in the research process.

***Recommendation:***

- A program should be created within the Office of the Director to further the education and training of the public to better fulfill its partnership role in the research process. We see this as a broad mandate embracing public members from the level of the local institutional review board through COPR. The NIH should undertake this activity in collaboration with other government agencies, associations, foundations, and other groups external to the NIH.

**FUTURE STEPS**

COPR recognizes that the structure and management of NIH is a continuing matter that will be revisited periodically. We anticipate making further comments after reviewing the forthcoming IOM report and we will continue to evaluate all NIH operations in light of the five principles articulated in this document.

## APPENDIX

### NIH STAFFING LEVELS

The NIH budget has increased from \$4 billion to \$27 billion over the last 20 years. The absolute numbers of grants has increased by 40%; the value of the average grant has increased three-fold, to \$375,000; and the complexity of research has increased enormously. However, staffing levels (full-time employees) at the NIH have increased by only about 20%.

This state of affairs raises the very real possibility that the NIH is understaffed to best administer its program responsibilities. Peer review can act as one kind of check on poor allocation of resources, but program review also is necessary. That cannot occur if program officers are stretched too thin and have neither the time nor the resources for adequate site visits and interactions with grantees.

Of equal or greater importance to good stewardship of the expenditure of public resources is the role that NIH program officers can play in facilitating interaction between grant recipients. They can be catalysts, stimulating a "cross-pollination" of ideas and collaborations in what otherwise might be more isolated nodes of research activity. Crossing the boundaries of disciplines and of geography is increasingly important. This facilitator role of NIH program administrators often is not given the recognition and support that it merits.

An internal examination by the NIH, while useful, will always carry the perception of being self-serving. Staffing levels need to be examined by a body that is perceived by all to be objective.

#### *Recommendation:*

- The adequacy of NIH staffing levels should be examined by an independent organization. If the IOM committee feels that this issue falls outside of its current mandate, then we urge that another outside body be charged with addressing this issue.

### RESEARCH = GROWTH

We recognize that health is an important and vibrant part of the nation's economy—about 14% of gross domestic product by most estimates. Medical centers have long been engines of local and regional economic growth. So it is no surprise that biotechnology is seen as not only the cutting edge of the next generation of improvements in human health, but also as important for the economic life of the communities that house or hope to house such operations.

This has created political pressures to direct NIH funding for Centers of Excellence and other large-scale investments in biomedical research to locations other than what standards of "the best science" might indicate. We are not so naive as to think that these pressures can be eliminated entirely, nor in many ways should they be. However, we believe that these opportunities should be leveraged to the greatest extent possible to build partnerships and attract additional resources to biomedical research.

*Recommendation:*

- Mechanisms should be created, either through NIH regulations or, if necessary, by an act of Congress, to require that projects above a certain size require a matching commitment of local resources. We can envision those commitments entailing a combination of efforts by state and local governments, businesses, and the nonprofit sector, but we do not pretend to recommend the details of such arrangements. We believe these mechanisms can be important ones in fostering broader partnerships in biomedical research.