

**Enhancing the Vitality of the
National Institutes of Health:
Organizational Change to Meet
New Challenges**

**Committee on the Organizational
Structure of the
National Institutes of Health**

National Institutes of Health

- **Annual NIH budget ~\$27B**
 - 16% ↑ in FY2003 completed 5 yr. plan to double NIH budget
 - ~ 80% of federal funding of biomedical research and development
- **27 Institutes and Centers**
 - more than 40 unit heads report to Director
 - budget for OD \$189M in '93 to \$259M in '03

Principle Mission

To serve as a mechanism for efficiently and effectively deploying federal resources across a wide array of institutions and individuals in the Nation's scientific community to advance the scientific frontier and ensure research training of special relevance to human health needs.

FY 2001 Appropriations DHHS

Congressional Concerns:

- **the world we live in is changing rapidly**
- **danger of NIH becoming entrenched in the very things that has made it successful**
- **concern for many years over continued growth of institutes, centers and programs as mandated by congress**
- **science of today relies more and more on multi-institutional, multidisciplinary research**

FY 2001 Appropriations DHHS

A persistent issue over the years has concerned continued growth in the number of Institutes, Centers and Programs mandated by congress in response to public demands.

FY 2001 Appropriations DHHS

Congress wants to know:

“Whether NIH’s organizational structure is right for the times?”

The charge was not necessarily to change but to re-examine.

Statement of Task

In response to a Congressional request, the goal of this study was to determine the optimal NIH organizational structure given the context of 21st century biomedical research.

The following specific questions were to be addressed:

Statement of Task

- 1. Are there general principles by which NIH should be organized?**
- 2. Does the current structure reflect these principles, or should NIH be restructured?**
- 3. If restructuring is recommended, what should the new structure be?**
- 4. How will the proposed new structure improve NIH's ability to conduct biomedical research and training, and accommodate organizational growth in the future.**
- 5. How would the proposed new structure overcome current weaknesses, and what new problems might it introduce?**

Recommendation 1

Centralization of Management Functions

Any efforts to consolidate or centralize management functions at NIH, either within NIH or the DHHS level, should be considered only after careful study of circumstances unique to NIH and its successes in carrying out its research and training mission. A structured and studied approach should be used to assure that centralization will not undermine NIH's ability to identify, fund, and manage the best research and training proposals and programs in support of improving health.

Recommendation #2

Public Process for Proposed Changes in the Number of NIH Institute or Centers

Either on receiving a congressional request or at the discretion of the NIH director in responding to considerable, thoughtful, and sustained interest in changing the number of institutes or centers, the director should initiate a public process to evaluate scientific needs, opportunities, and consequences of the proposed change and the level of public support for it. For a proposed addition, the likelihood of available resources to support it should also be assessed and the burden of proof should reside clearly with those seeking to add an organizational element.

Recommendation #3

Strengthen Clinical Research

NIH should pursue a new organizational strategy to better integrate leadership, funding, and management of its clinical research enterprise. The strategy should build on but not replace existing organizational units and activities in the individual IC's intramural and extramural research programs. It should also include partnerships with the nonprofit and private sectors. Specifically, the Committee recommends that several intramural and extramural programs be combined in a new entity to subsume and replace the National Center for Research Resources, to be called the National Center for Clinical Research and Research Resources (NCCRRR). In addition, a deputy director for clinical research should be appointed in the Office of the Director to serve as deputy director and head of the new entity.

Recommendation #4

Enhance and Increase Trans-NIH Strategic Planning and Funding

- A.** The Director of NIH should be formally charged by Congress to lead a trans-NIH planning process to identify major crosscutting issues and their associated research and training opportunities and to generate a small number of major multi-year, but time limited, research programs. The process should be conducted periodically - perhaps every 2 years - and should involve substantial input from the scientific community and the public.
- B.** The Director of NIH should present the scientific rationale for trans-NIH budgeting to the relevant committees of Congress, including a proposed target for investment in trans-NIH initiatives across all institutes. For example, an average target of 5% of overall NIH funding in the first year, growing to 10% or more over 4-5 years, may be appropriate.

Recommendation #4

Enhance and Increase Trans-NIH Strategic Planning and Funding (cont'd)

- C.** The appropriate committee should annually review budget justifications and testimony from the NIH director and from individual IC directors about the participation of each unit in the planned trans-NIH initiatives and the portion of their budgets so directed. Congress should include budget targets in the appropriations report language. The committee recommends beginning with 5% of the overall NIH budget.
- D.** To ensure that each IC uses the target proportion of its budget for trans-NIH initiatives of its choosing, that proportion of the annual appropriation to each unit should be treated as “in escrow” until the NIH director affirms that the unit has committed to its expenditure for the identified trans-NIH initiatives.

Recommendation #4

Enhance and Increase Trans-NIH Strategic Planning and Funding (cont'd)

- E.** The President should include in the budget request, and Congress should include in the NIH appropriation for OD, funds to support an appropriate number of additional full-time staff to conduct the trans-NIH planning process and “jump-start” the initiatives that emerge from this process.

Recommendation #5

Strengthen the Office of the NIH Director

The Office of the Director should be given a more adequate budget to support its management roles or greater discretionary authority to reprogram funding from the earmarked components of its budget when necessary to meet unanticipated needs. In particular, if the director is given the responsibility and authority to conduct NIH-wide planning for trans-NIH initiatives, the director's budget will need to be amplified to take the costs of such planning into account.

Recommendation #6

Establish a Process for Creating New OD Offices and Programs

The public process recommended in Chapter 4 (Recommendation 2) for evaluating a proposal to create a new institute or center or to consolidate or dissolve an institute or center should also be used for a proposal to create, consolidate, or dissolve an office in OD. The process should be used to evaluate the scientific needs, opportunities, and consequences of the proposed change, the likelihood of resources being available to fund it, and public support for the change.

Recommendation #7

A discrete program, **the Director's Special Projects Program**, should be established in OD to fund the initiation of high-risk, exceptionally innovative research projects offering high potential payoff. The program should have its own leader, who reports to the director of NIH, and a staff of short-term (2-4 years) program managers to manage identified projects with advice on program content from extramural panels. The program should be structured to permit rapid review and initiation of promising projects; if peer review is deemed appropriate, the program should use peer review panels created specifically for it and charged with selecting high risk, high potential return projects. Congress should be prepared to provide new funding in the amount of \$100 million, growing to as much as \$1 billion per year for this endeavor, and commit to support it for at least 8-10 years so that a sufficient number of projects can reach fruition. A program review should be conducted during the fifth year to provide mid-course guidance.

Recommendation #8

Promote Innovation and Risk-taking in Intramural Research

The intramural research program should consist of research and training programs that complement and are distinguished from those in the extramural community and the private sector. The intramural program's special status obligates it to take risks and be innovative. Regular in-depth review of each component of the intramural program should occur to ensure continuing excellence. Allocation of resources to the intramural program should be closely tied to accomplishments and opportunities. Inter-institute and intramural-extramural collaborations should be supported and enhanced.

Recommendation #9

Standardize Data and Information Management Systems

For purposes of meeting its responsibilities for effective management, accountability, and transparency, NIH must enhance its capacity for the timely collection, thoughtful analysis, and accurate reporting of the nature and status of its research and training programs and public health advances. Data should be collected consistently across institutes and centers and submitted to a centralized information management system.

Recommendation #10

Set Terms and Conditions for IC Director Appointments and Improve IC Director Review Process

- A.** All IC directors should be appointed for 5-year terms. The possibility of a second and final term of 5 years should be based on the recommendation of the director of NIH, which should include consideration of the findings of an external review of job performance. The authority to hire and fire IC directors should be transferred from the Secretary of Health and Human Services to the NIH director.

- B.** The Director of NIH should establish a process of annual review for the performance of every IC director in terms of his or her effectiveness in fulfilling scientific and administrative responsibilities. The results of such reviews should be communicated, as appropriate, to the Advisory Committee to the Director and/or the Council of Public Representatives.

Recommendation #11

Set Terms and Conditions for the NIH Director appointment

The NIH Director, appointed by the President, should serve for a term of 6 years unless removed sooner by the President. The possibility of a second and final term of 6 years should be based on a positive external review of performance and the recommendation of the Secretary of Health and Human Services.

Recommendation #12

Reconsider the Status of the National Cancer Institute

Congress should reassess the provisions of the National Cancer Act of 1971, particularly as they affect the authority of the NIH director to hire senior management and plan and coordinate the NIH budget and its programs in their entirety.

Recommendation #13

Retain Integrity in Appointments to Advisory Councils & Reform Advisory Council Activity and Membership Criteria

- A. Appointments to advisory councils should be based solely on person's scientific or clinical expertise or his or her commitment to and involvement in issues of relevance to the mission of the institute or center.**

Recommendation #13

Retain Integrity in Appointments to Advisory Councils and Reform Advisory Council Activity and Membership Criteria (cont'd)

- B.** The advisory council system should be thoroughly reformed across NIH to ensure that these bodies are consistently and sufficiently independent and are routinely involved in priority-setting and planning discussions. Councils should be effectively engaged in discussions with IC leadership to enhance accountability, facilitate translation of goals and activities to the scientific community and the public, and provide feedback to the IC director. To achieve sufficient independence and avoid conflicts of interest, a substantial proportion of a council's scientific membership should consist of persons whose primary source of research support is derived from a different institute or center or from outside NIH.

Recommendation #14

Increase Funding for Research Management and Support

Congress should increase the appropriation for RMS to reflect more accurately the essential administrative costs required to effectively operate a world-class \$27 billion/year research organization. Moreover, when additional congressional mandates are imposed on NIH through the appropriations process, they should include funds to cover necessary administrative costs.

Summary

A few thoughts in summary

- **NIH has been productive and immensely successful in part because it is a federation of highly specialized and somewhat independent units.**
- **While a matrix or decentralized structure always presents difficult management and programmatic challenges, the committee concluded that “widespread consolidation or restructuring would not necessarily be best way to resolve those challenges”.**

Summary

A few thoughts in summary cont'd

- The committee did see opportunities for organizational, rather than structural, change – **“administrative modifications”** which could improve the strength, responsiveness, vitality and accountability of NIH.
--measures aimed at transcending a decentralized structure in order to optimize trans-NIH decision making.