



Finding the Balance

Report of the
National Institute of Mental Health
Intramural Research Program (IRP)
Planning Committee



Steven Hyman, M.D.
Chairman
National Advisory Mental Health Council
National Institute of Mental Health
Bethesda, Maryland 20892

January 29, 1997

Dear Dr. Hyman:

The Intramural Research Program Planning Committee (IRPPC) is pleased to transmit its report to the National Advisory Mental Health Council of the National Institute of Mental Health (NIMH).

The Fiscal Year 1994 House Appropriations Committee Report mandated that the Director of the National Institutes of Health (NIH) review the role, size, and cost of the overall NIH Intramural Research Program. In turn, the External Advisory Committee of the NIH Director's Advisory Committee recommended that each of the individual IRPs at NIH undergo separate review. At the behest of the National Advisory Mental Health Council, Dr. Rex Cowdry, former Acting Director of the NIMH, formed the IRPPC with the charge of reviewing the rationale for continued investment in the NIMH IRP and evaluating its strengths and weaknesses.

After extensive deliberations between March and December of 1996, our Committee determined that continued investment in the NIMH IRP is strongly justified, provided the research is of the highest quality. The NIMH IRP is a unique national resource in mental health research, with a history of illustrious contributions. It has the capacity to lead the Nation by virtue of its concentration of expertise, special facilities, and far-reaching ability to conduct basic, clinical, and translational research. Nevertheless, the nature of science and the environment in which it is conducted are changing radically. The organizational structures that proved effective in the past do not equip the IRP to meet the opportunities and challenges of the future. In response, our Committee focused on broad structural, organizational, and leadership changes that lay the foundation for scientific renewal. Our report contains 77 recommendations designed to stimulate renewal by providing underlying goals and management tools for how renewal may be accomplished.

We are grateful for the opportunity to develop this report.

Respectfully,

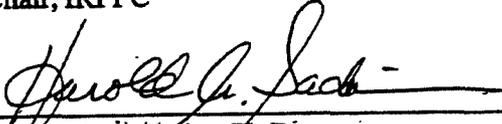
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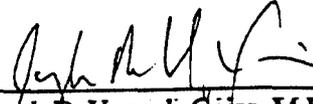
Herbert Pardes, M.D.
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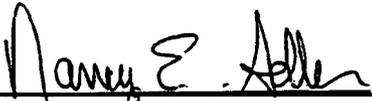
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Co-Chair, IRPPC



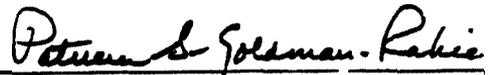
Harold A. Sackeim, Ph.D.
Executive Secret&



Joseph DeVeough-Geiss, M.D.



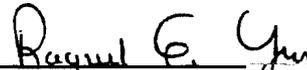
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Patricia Goldman-Rakic, Ph.D.



Norman Anderson, Ph.D.



Raquel E. Gur, M.D., Ph.D.



Floyd Bloom, M.D.



Lily Jah, Ph.D.



Benjamin Stephenson Burney, M.D.



Kenneth S. Kendler, M.D.



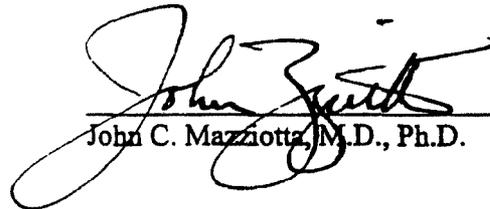
Robert E. Burke, M.D.



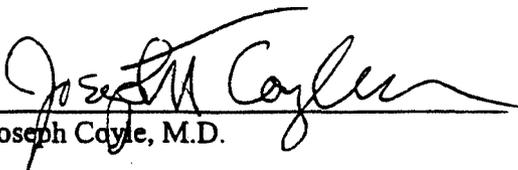
David Kupfer, M.D.



William T. Carpenter, M.D.



John C. Mazziotta, M.D., Ph.D.



Joseph Cayle, M.D.

The Intramural Research Program Planning Committee

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Associate Director for Behavioral and Social Sciences Research, National Institutes of Health.

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Director, Maryland Psychiatric Research Center and Professor of Psychiatry and Pharmacology, University of Maryland School of Medicine.

JOSEPH COYLE, M.D.
Chairman, Consolidated Department of Psychiatry, Harvard Medical School.

JOSEPH DEVEAUGH-GEISS, M.D.
Director, International CNS Clinical Research, Glaxo Wellcome, Research Triangle Park, North Carolina, Clinical Professor of Psychiatry, University of North Carolina at Chapel Hill and Associate Consulting Professor of Psychiatry, Duke University Medical Center.

PATRICIA GOLDMAN-RAKIC, Ph.D.
Professor of Neuroscience, Department of Neurobiology, Yale University School of Medicine.

RAQUEL E. GUR, M.D., Ph.D.
Professor of Psychiatry and Neurology, and Director of Neuropsychiatry, Department of Psychiatry, University of Pennsylvania.

LILY JAN, Ph.D.
Professor of Physiology and Biochemistry, University of California at San Francisco and Howard Hughes Medical Institute Investigator.

KENNETH S. KENDLER, M.D.
Rachel Brown Banks Distinguished Professor of Psychiatry, Virginia Institute of Psychiatric and Behavioral Genetics, Departments of Psychiatry and Human Genetics, Medical College of Virginia/Virginia Commonwealth University.

DAVID KUPFER, M.D.
Thomas Detre Professor and Chairman, Department of Psychiatry, University of Pittsburgh and Director, Mental Health Clinical Research Center for Affective Disorders and Professor, Neuroscience, Western Psychiatric Institute and Clinic.

JOHN C. MAZZIOTTA, M.D., Ph.D.
Professor, Department of Neurology and Director, Brain Mapping Division, Reed Neurology Research Center, UCLA School of Medicine.

Science Writer: MIRIAM DAVIS, Ph.D.
Science and Health Policy Consultant, Silver Spring, Maryland, and Adjunct Assistant Professor, George Washington University School of Public Health.

NIMH Staff Liaisons: NANCY OSTROWSKI, Ph.D. and RICHARD NAKAMURA, Ph.D., Office of Science Policy and Program Planning.

Finding the Balance

Report of the
NIMH Intramural Research Program Planning Committee

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Executive Summary

The Intramural Research Program (IRP) of the National Institute of Mental Health (NIMH) has a history of scientific accomplishments that have advanced our understanding of the causes and treatments of mental disorders. Faced with an explosion in knowledge, rapid changes in technology, and increasing complexity of research questions, the infrastructure and organization that have served the IRP so well in the past are no longer sufficient to guarantee high quality science. Scientific excellence must be the hallmark of the IRP as well as other federally supported research programs. To promote excellence, the IRP must be able to integrate emerging new disciplines with established fields, make use of increasingly sophisticated technologies, create organizational flexibility, provide superb training, and ensure rigor in scientific review. This report represents a proactive effort by the NIMH Intramural Research Program Planning Committee to revitalize the IRP, thus ensuring that the program is poised to make the scientific breakthroughs crucial to easing the burden of mental disorders.

At the behest of the National Advisory Mental Health Council, the former Acting Director of the NIMH formed the Intramural Research Program Planning Committee. Its charge was to review the IRP through an evaluation of the rationale for its continuance and an evaluation of its strengths and weaknesses. Establishing this external Committee was part of a National Institutes of Health (NIH)-wide effort led by the NIH Director, Dr. Harold Varmus, to respond to a Congressional mandate to appraise the size, quality, and cost of the entire NIH intramural program.¹ This Committee's review of the NIMH IRP is the second in a series of independent reviews of each intramural program of the NIH.

The NIMH Intramural Research Program Planning Committee (hereinafter referred to as the Committee) deliberated over a 10-month period and obtained extensive input. The Committee solicited confidential letters from almost 1,000 IRP scientists and staff. It met with the NIH leadership, virtually all of the IRP's past and present leadership, and with members of the intramural and extramural communities, professional societies, and advocacy organizations.

The Committee found strong justification for the continued existence of the IRP, as long as the research is of the highest quality. Mental disorders exact an immense toll on affected individuals, families, and society. The great public urgency, combined with the IRP's capacity for leadership, expertise, special concentration of resources, and ability to take risks in research, present a powerful rationale for its existence. There also are unprecedented research opportunities because of breathtaking progress in science.

After affirming a strong justification for the NIMH IRP, the Committee saw as its principal task to offer recommendations to revitalize the IRP. Successful revitalization depends heavily on the appointment of a permanent Scientific Director committed to unequivocally high standards of scientific excellence, peer review, and the redistribution of resources to outstanding projects, core facilities, recruitment, and retention of its best scientists. The Committee strove to redefine the roles of the IRP leadership and to improve the quality of the post-doctoral training program. The Committee recommended a new mission statement, a long-term planning process, and structural and organizational changes.

¹ U.S. Congress, House of Representatives, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 1994.

Foremost, a renewed IRP is a program committed to uniformly excellent research, training, and international scientific leadership in mental health. A renewed IRP is a program that attracts and retains the highest caliber scientists and post-doctoral fellows. It is a program that conducts innovative basic, clinical, and translational research. It fosters collaborations and mission-oriented research to counteract the unmistakable societal burden of mental disorders. It takes maximal advantage of the special resources of the NIH campus. These are the attributes of a program that warrants continued investment.

The Committee does not foresee a need to increase IRP funding as a percentage of the total NIMH budget. The NIMH IRP budget stood at \$96.7 million in FY 1996, accounting for 14.6 percent of the NIMH budget, a percentage somewhat higher than that of most other NIH IRPs. The committee's recommendations for revitalizing the IRP can be accomplished by organizational restructuring and by resource redistribution via reductions to some programs and investment in new initiatives, staff, and core facilities. The Committee envisions an IRP with relatively small-sized laboratories in which a cadre of scientists pursue a set of projects that are linked or integrated thematically. It also envisions rich collaborations spanning sections, laboratories, and institutional walls, especially because the complexity of research on brain and behavior demands multidisciplinary approaches.

Findings

The following sections present a chapter-by-chapter summary of major findings. Yet one overarching theme permeates all chapters of this report: renewal of the IRP requires the successful balancing of many desirable, yet sometimes competing, sets of priorities. In the course of making decisions, balancing is required by the IRP leadership—the SD, Laboratory/Branch Chiefs, and independent investigators—in their roles as leaders, researchers, mentors, and administrators. The title of this report, “*Finding the Balance*,” was chosen by the Committee to highlight the significance of this theme.

One prominent set of priorities to balance is the need for scientific autonomy of independent investigators versus the need for thematic integration of the many projects in a laboratory or section. The Committee takes the position that the SD and Laboratory/Branch Chiefs must strive for balance without dictating what types of research should be undertaken by independent investigators. Another set of priorities relates to the pursuit of clinical, basic, and translational research, and their relative emphasis. Since each type of research is essential to the scientific vitality of the IRP, the key to finding the right balance lies in emphasizing the area in which the greatest progress in mental health can be achieved, while ensuring an adequate flow of discoveries from the laboratory to the clinic and vice versa.

Another set of priorities to balance is the quality of the science conducted versus its immediate relevance to the mission of the IRP. Balancing is unnecessary when the two are completely compatible. But when they conflict, the Committee urges vigilance about never compromising the quality of science in the pursuit of mission-oriented research. The Committee uses the phrase “mission-oriented research” throughout this report to refer broadly to all types of research—basic, clinical, and translational—that advance the understanding of brain and behavior. The new mission statement recommended by the Committee in Chapter 1 speaks to the importance of each area. While “mission-oriented research” is sometimes used by others to connote applied research, that is not the intention of this Committee.

Leadership

Stable scientific leadership is crucial to revitalizing IRP science. The IRP has had neither a permanent Scientific Director since 1993 nor a permanent NIMH Institute Director from 1994-1996. While the Committee recognizes and supports the changes already instituted by the Acting Scientific Directors, an

urgent task facing the recently appointed Institute Director is the recruitment of a Scientific Director (SD) who can enhance IRP science, improve morale, and flexibly steer the program.

The incoming SD must articulate a vision for the future and launch a planning process to highlight areas of scientific opportunity in pursuit of the mission of the IRP. The SD should seek advice from a newly recommended *ad hoc* planning group that receives input from the intramural and extramural communities. Scientific areas of special attractiveness should be those that take maximal advantage of the IRP's special resources, settings, and expertise. The plan then must serve as a basis for organizational restructuring.

The incoming SD should continue the Acting SD's practice of allocating resources to independent investigators on the basis of recommendations by the Board of Scientific Counselors (BSC), an external peer review body. To shape new scientific directions, the SD needs a discretionary fund for flexible use. With heightened authority and greater control over resources, the SD must be held to the highest standards of accountability.

Laboratory/Branch Chiefs hold critical leadership positions within the IRP. Laboratory/Branch Chiefs should define the goals of the laboratory, foster collaborations and mentoring, and advise the SD on resource allocations. Their most difficult challenge is to balance the need for autonomy of independent investigators with the need for thematic integration and mission-oriented research. In the past, some Laboratory/Branch Chiefs became excessively powerful, without appropriate oversight. This problem has been addressed, in part, at the NIH-wide level by a new tenure-track policy that promotes autonomy for young investigators, and, at the NIMH IRP, by the direct allocation of resources to independent investigators. While this new model of resource allocation enhances the autonomy of independent investigators, the Committee concluded that it may restrict the capability of Laboratory/Branch Chiefs to forge programmatic integration. The Committee determined that discretionary resources also are needed for the Laboratory/Branch Chiefs to offer incentives for collaboration and mission-oriented research. It concluded that, independent of their scientific reviews, the leadership displayed by Laboratory/Branch Chiefs must be rigorously evaluated by the BSC.

Quality of Science

The pursuit of scientific excellence is paramount. The overall quality of IRP science has declined in relation to its historic position at the pinnacle of mental health research. There are areas of brilliance, but there is also research of lesser quality, according to members of the Board of Scientific Counselors and intramural and extramural scientists. To reassume a leadership position, the IRP must perform research of indisputably high quality. At NIH, periodic peer review through the Board of Scientific Counselors, and compliance with its recommendations, is a time-tested means of ensuring scientific quality. The BSC's advice to the SD should serve as justification and guidance for the allocation of resources, space, and staff to outstanding scientific projects.

The Committee endorsed recent NIH-wide policies to heighten the rigor, independence, and uniformity of BSC reviews. It also endorsed the NIMH BSC's policy of conducting stewardship reviews of Laboratory/Branch Chiefs. Stewardship reviews are designed to evaluate leadership, mentoring, and administration. The Committee recommended four criteria for the leadership portion of the stewardship review: (1) quality of science; (2) scientific vision; (3) relevance of projects to the mission of the IRP; and (4) utilization of the special resources of the IRP. It is noteworthy that one of the proposed criteria for evaluating leadership concerns the relevance of projects to the mission of the IRP, for this represents a significant deviation from current BSC practice and NIH policy. The Committee envisions this criterion as applying to the collective output of the laboratory, not to individual projects, with the expectation that the SD and Laboratory/Branch Chiefs should encourage such research. The Committee also found that scientists being reviewed need a clearer understanding of the review criteria. When a review is perceived to be flawed, there must be a set of procedures for the appropriate Laboratory/Branch Chief to appeal in a timely manner.

Recruitment, Retention, and Retirement

Recruitment and retention of talented scientists are essential to the scientific vitality of a research organization. However, in the past five years the NIMH IRP has recruited from outside of NIH only one of its four newly tenured scientists.

To overcome the NIH-wide problem in recruitment, the NIH recently has implemented new legislative authorities for increasing salaries—the Senior Biomedical Research Service (a new personnel system) and Title 38 (a means of supplementing physician pay). These authorities offer greater pay and flexibility and should thereby aid in recruitment. Because of limitations in the available number and nature of these positions, their establishment may not be sufficient to retain the highest caliber scientists. While there are several existing mechanisms of enhancing retention, new authorities may be needed.

Recruitment and retention initiatives only may proceed if resources are redistributed from elsewhere within the IRP. Resource reduction, personnel reassignment, and voluntary retirement are among the available mechanisms to reclaim resources. However, these and other mechanisms rarely have been used in the past. The culture of the IRP, which was molded in an era of growth, must be adjusted to an era of fiscal constraint.

Training and Mentoring

The purpose of the NIH intramural training programs is to produce exemplary independent researchers. Yet the quality of training is highly uneven. The training program of the NIMH IRP, as well as that of the NIH IRP as a whole, must compete more aggressively for exceptional applicants. Steps should be taken to address the fact that post-doctoral fellows have difficulty competing for positions when they leave NIH due to a lack of sufficient grantsmanship and teaching experience. Protracted post-doctoral fellowships can be detrimental to the career of the individual. New initiatives taken by the NIH and by the NIMH IRP have been beneficial, but more remains to be done to enhance post-doctoral training.

The focus of the post-doctoral fellowship should be on training, rather than on fulfilling the technical support needs of the laboratory. Mentors need to invest more in fellows' training and career advancement. With greater emphasis on training, both mentor and trainee are likely to have less time for laboratory work. Therefore, it is imperative for the IRP to formally assess its need for more technical support or non-tenure track scientific positions. Finally, the NIMH IRP training program must be evaluated broadly regarding its quality, size, and the balance between clinical and basic fellowship positions.

Clinical Research

Clinical research faces many obstacles, such as escalating costs, the advent of managed care, and inherent difficulties in its execution, among others. The NIMH IRP represents one of the last bastions of clinical research on a number of psychiatric disorders. With its history of stellar achievement, clinical research at the NIMH IRP justifies continued investment, especially because clinical research elsewhere is under siege.

The IRP's clinical research program needs to be sustained and revitalized, without overly encumbering the IRP from pursuing other research leads. While the Committee recognizes the value of the NIH Clinical Center as a national resource and its need for stable funding, the charges for its use, which in FY 1996 constituted about 22% of the NIMH IRP budget, are of concern. There is growing consensus, not confined to the mental health community, that the charges to the NIMH IRP are excessive. An equitable means of assigning and appealing charges must be developed. As the third largest financial contributor to the Clinical Center budget, the IRP must have additional outside representation on the Board of Governors of the Clinical Center, which will approve a new cost-accounting plan and adjudicate disputes. Finally, the IRP's clinical research program at the William A. White Neuroscience Center at St. Elizabeths Hospital should be incorporated into the Bethesda campus, thereby offering unrestricted access to special facilities,

collaborations, and patients. This consolidation should be contingent upon the space and cost considerations expressed in the recommendations.

Major Recommendations

The Committee made a series of 77 recommendations, many of the most significant of which are summarized below. New NIH-wide policies set in motion by the NIH Director are expected to accelerate the renewal of the NIMH IRP, e.g., the new tenure-track policy, revised policies for the BSC and its reviews, and new recruitment and training initiatives. The Committee's recommendations are designed to build on the changes that are taking place with the aim of fostering renewal.

The Committee recognizes that its recommendations represent new and, in some cases, significant departures from previous modes of operation at the IRP. No advisory group expects its recommendations to be infallible, either in conception or implementation. Therefore, the Committee suggests that the impact of its recommendations be monitored and that appropriate course adjustments be made, as needed.

Mission

- ▶ The Committee recommends that the Mission of the NIMH Intramural Research Program should be:

The IRP conducts basic, clinical, and translational research to advance understanding of the causes, treatments, and prevention of mental disorders through the study of normal and abnormal brain function and behavior. The IRP supports outstanding research that, in part, complements extramural research activities and utilizes the special resources of the National Institutes of Health. The IRP provides an environment conducive to the training and development of clinical and basic scientists. The IRP fosters standards of excellence in the provision of clinical care to research subjects and in the translation of research into effective treatments. The IRP serves as a national resource in response to requests made by the Administration, members of Congress, and citizens' groups for information regarding mental illness.

Leadership

- ▶ One of the highest priorities for the NIMH Director is to recruit an outstanding Scientific Director (SD) who has a history of scientific achievement in a field relevant to the NIMH, who has superb leadership, mentoring, and administrative skills, and who is committed to scientific excellence.
- ▶ Scientific excellence, as judged by the BSC, should be the foremost determinant of resource, space, and staff allocations by the SD to each independent investigator.
- ▶ The SD should articulate a vision for revitalizing the IRP and should seek advice about scientific directions from a newly created *ad hoc* planning group that has broad-based input from the intramural, extramural, and the mental health communities. A long-term plan that includes the identification of areas of scientific opportunity should be formulated by this advisory group.
- ▶ The SD should restructure the organization of the IRP to fulfill the vision and long-term plan.
- ▶ The IRP leadership should reassess the distribution of resources. The distribution of resources should be based on the quality of science and the matching of resources to programmatic needs.

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- ▶ The SD should have a discretionary fund for flexible use to shape scientific directions of the IRP.
 - ▶ Laboratory/Branch Chiefs should develop programs of scientific excellence by encouraging and coordinating, rather than by directing, individuals and groups of researchers. The SD should allocate a portion of the discretionary fund to Laboratory/Branch Chiefs to enable them to encourage thematic integration within their group and to respond to new opportunities, among other goals.

Quality of Science

- ▶ The Committee endorses the BSC policy of performing stewardship reviews of Laboratory/Branch Chiefs that evaluate their leadership, mentoring, and administration. The stewardship evaluation of the SD and Laboratory/Branch Chiefs should include four distinct criteria pertaining to the scientific *leadership* portion of the review: (1) quality of science; (2) scientific vision; (3) relevance of projects to the mission of the IRP; and (4) utilization of the special resources of the IRP. These reviews should help determine whether to continue Laboratory/Branch Chiefs in their current positions.
- ▶ The NIMH leadership should define new policies for changing or rotating Laboratory/Branch Chiefs and policies for closure of Laboratories/Branches.
- ▶ Each independent investigator should develop an independent research program. It is desirable for his or her research portfolio to include research projects that are consistent with the overall theme of the Laboratory or Branch.
- ▶ The placement of basic scientists in clinical laboratories should be rare. The placement is warranted only if it fulfills a programmatic need and if the basic scientist receives adequate mentoring and independence. Such placements should be reviewed carefully.
- ▶ In advance of reviews, the BSC should inform all IRP scientists about the requirements for written submissions, verbal presentations, and review criteria, including the definition of scientific excellence and the relative emphasis on retrospective versus prospective evaluation.
- ▶ The outcome of the BSC review should be transmitted orally to the SD immediately after the review. The SD should transmit, in an accurate and timely manner, the outcome of the review to Laboratory or Branch Chiefs, who should inform tenured and tenure-track scientists. The written BSC report should be issued within but no later than two months of a BSC meeting, in accordance with NIH policy.
- ▶ The NIMH leadership should develop procedures for Laboratory/Branch Chiefs to rapidly appeal to the SD a review of themselves or an independent investigator within their group. It is anticipated that re-reviews will be rare.
- ▶ When scientists seek significant external funding for research conducted in the IRP, the SD or delegate should approve the nature and extent of support before it is accepted. The SD and the BSC should ensure that the externally funded research is subject to review through the regular BSC review process.

Training and Mentoring

- ▶ The IRP leadership should enhance its training program and encourage greater attention to mentoring. Mentoring performed by independent investigators should be evaluated by the BSC. After improvements in the program are made, the quality and the size of training program should be evaluated, as should the balance between the number of basic and clinical post-doctoral fellows.
- ▶ To address manpower problems while avoiding exploitation of post-doctoral fellows, the NIH and the NIMH IRP leadership should reassess the need to hire more non-tenure track and technical support staff. Additional manpower enables mentors and trainees to devote more time to training.
- ▶ The IRP leadership should recruit outstanding post-doctoral fellows and provide training and mentoring that prepares fellows to take extramural positions after 3-5 years.

Recruitment, Retention, and Retirement

- ▶ The IRP leadership should recruit outstanding scientists at all levels. The leadership should take maximal advantage of new and existing personnel mechanisms and the expertise of NIH personnel specialists to offer highly competitive salaries, recruitment bonuses, and research resources (e.g., space, personnel, and equipment).
- ▶ To reclaim resources, the IRP leadership should become knowledgeable about the graceful exit pathways that exist and should work with the scientist to select the appropriate option.

Clinical Research

- ▶ The capacity to engage in interdisciplinary and innovative inpatient clinical research should be a special focus of the NIMH IRP, particularly since clinical research is threatened in the extramural community. Revitalization of clinical research efforts is critical.
- ▶ The Clinical Center charges to the NIMH IRP should be reduced to reflect its patients' lower utilization of services. There is a need for strict cost-accounting and a fee-for-service billing structure.
- ▶ The new Clinical Center Board of Governors should have a non-Government member with a mental health background plus a member from NIMH, which is the third largest contributor to the Clinical Center budget.
- ▶ There are significant advantages to incorporating the clinical neuroscience program from the William A. White building at St. Elizabeths Hospital into the NIMH IRP's program at the Bethesda campus. The NIMH leadership should develop a plan, as if they were freshly recruiting researchers, in order to preserve the strongest elements of this program. Consolidation should be contingent upon the availability of appropriate resources and contiguous space on the NIH campus. Consolidation also should be contingent upon assurances that there will be no additional present and long-term costs to the IRP for its utilization of the NIH Clinical Center due to the incorporation of this clinical research program.
- ▶ The Director, NIMH, should establish a committee to provide long-term external oversight of the revitalization of NIMH's clinical research program.

Introduction

In an era of fiscal austerity and intense competition for resources, all federally supported programs require review, no matter how distinguished their history. Several years ago, Congress mandated an appraisal of the size, quality, and cost of the entire Intramural Research Program (IRP) at the National Institutes of Health (NIH). This Congressional directive prompted the formation of an NIH Director's External Advisory Committee. In its 1994 report, the External Advisory Committee affirmed the need for a diverse NIH intramural research program, yet recommended that each of the individual IRPs that make up NIH's intramural program undergo a separate evaluation.

The NIH Director, Dr. Harold Varmus, has sought to carry out this recommendation. At Dr. Varmus' initiation, the National Cancer Institute was the first Institute to have its IRP assessed by an external advisory committee.² The IRP of the National Institute of Mental Health—the focus of this evaluation—is the second. Evaluations are in the planning stages for the IRPs of the National Institute of Neurological Disorders and Stroke, the National Heart, Lung and Blood Institute, and others.

This evaluation of the NIMH IRP was initiated by the former Acting Institute Director, Dr. Rex Cowdry, at the behest of the National Advisory Mental Health Council. Dr. Cowdry formed the Intramural Research Program Planning Committee (IRPPC)³ to review the rationale for its continued support and to assess its strengths and weaknesses. The timing could not have been more propitious: key leadership positions at the helm of NIMH were either vacant or recently filled. After several years of acting leadership, the Institute now has a permanent Director, Dr. Steven Hyman of Harvard University, who was appointed in April, 1996. Foremost on the agenda for the new NIMH Director is the recruitment of a new Scientific Director to lead the IRP and create an environment devoted to scientific and educational achievement. After the departure of the previous Scientific Director in 1993, the IRP has seen a succession of three different Acting Scientific Directors.⁴ The appointment of a permanent Director and the recruitment of a Scientific Director provide an ideal opportunity for renewal.

Charge to Committee

The formal Charge to the Committee, which is highlighted below, was prepared by the then Acting Director of NIMH, Dr. Rex Cowdry, who presented it to the Committee at the first meeting (March 11-12, 1996). Dr. Steven Hyman, the new Director of NIMH, fully supports the Charge and the efforts of this Committee.

² The National Cancer Institute was reviewed in 1995 by the Ad Hoc Working Group of the National Cancer Advisory Board. Before Dr. Varmus assumed the directorship of NIH, the National Institute of Dental Research voluntarily launched an external review of its IRP in 1993.

³ Hereinafter referred to as the Committee

⁴ Darrell Kirch, M.D., Michael Brownstein, M.D., and Susan Swedo, M.D.

Charge to the Committee

The Intramural Research Program (IRP) Planning Committee is charged with evaluating and, as necessary, redefining the role of the Intramural Research Program in fulfilling the mission of the National Institute of Mental Health. The Committee will review the rationale for the existence of the IRP and determine its optimal role in the national research enterprise. The Committee will assess the strengths and weaknesses of the program, identify areas of basic and clinical science that the IRP can and/or should vigorously pursue, and identify new fields and technologies that represent significant opportunities for advancing NIMH science. The Committee will identify current and future obstacles that deter the IRP from effectively carrying out its research mission and will explore potential solutions. The Committee will issue a final report, including recommendations on actions the IRP can implement during the next five years to strengthen and advance NIMH's science into the next decade.

In carrying out its Charge, the Committee decided to focus on broad structural and organizational issues that would promote scientific excellence and strengthen the IRP for the future. The Committee did not wish to duplicate the retrospective scientific review function of the Board of Scientific Counselors, the formal group of external experts with responsibility to evaluate specific research projects conducted by NIMH. The Committee saw as its primary roles to review the justification for investment in a NIMH IRP and to suggest to the new NIMH Director broad methods of restructuring that will strengthen and advance the science. This task proved to be sufficiently complex that the Committee chose not to identify new fields of scientific opportunity and, instead, left that to a newly proposed long-term planning group.

Process of the IRPPC

The Committee met 6 times over a 10-month period between March and December of 1996. Its first step was to seek comments from all IRP scientists and staff. Letters were sent from the IRPPC Chairman, Dr. Herbert Pardes, to 996 paid and volunteer staff, eliciting their comments about the strengths and weaknesses of the IRP and its unique role in fulfilling the mission of NIMH. Responses were submitted by 114 IRP staff, and they were held in the strictest confidence by the Committee. Neither the NIMH Director nor any other Institute personnel had access to these letters or saw comments attributable to an individual. The Committee directed the preparation of a thematic summary of the letters, which was shared with the NIMH leadership. The chapters of this report draw on anonymous quotations from the letters to illustrate themes that resonated with the Committee.

The Committee reviewed extensive information on budget, personnel, administrative practices, training, recruitment, and many other IRP and NIH-wide policy issues (see Appendices A-C). The Committee had discussions with the NIH Director, NIH Deputy Director, Deputy Director for Intramural Research, and Director of the Clinical Center. The Committee interviewed virtually all of the past and present leadership of NIMH and its IRP, including Dr. Seymour Kety, the first intramural Scientific Director who assumed

leadership in the 1950s. The Committee heard from numerous current and former IRP personnel, including Laboratory and Branch Chiefs, independent investigators⁵, post-doctoral fellows, and administrators. The Committee also heard from a specially convened panel of Chairs from several NIH Institutes' Boards of Scientific Counselors. The Committee visited the Poolesville Animal Center.⁶ The Committee Chairman met personally with IRP staff at an "All Hands Meeting" to acquaint them with the intent and purposes of the Committee. He also made himself available to meet with individual IRP staff members. Finally, the Committee sought input from 32 professional societies and patient advocacy organizations (See Appendix B), some of which were invited to make presentations to the Committee.

Introduction to IRP

History and Contributions

On July 3, 1946, President Harry Truman signed the National Mental Health Act (P.L. 79-487). The Act authorized the National Institute of Mental Health, *with an intramural research program*, and provided for the creation of a National Advisory Mental Health Council to advise the Institute and to recommend grants. Because no appropriation accompanied the authorizing legislation, Robert Felix, M.D., then Director of the Public Health Service's Division of Mental Hygiene and, subsequently, the first NIMH Director, obtained a foundation grant to convene the first meeting of the Mental Health Advisory Council in August of 1946. Congress appropriated funds to the mental health program in FY 1948, thus permitting award of the first mental health extramural research grants. The Division of Mental Hygiene continued to be responsible for the mental health program until the formal establishment in 1949 of the NIMH, including the Intramural Research Program, as one of the National Institutes of Health.

In 1951, Dr. Seymour Kety, renowned for his pioneering studies of cerebral blood flow and metabolism, was appointed to serve as the first Scientific Director of the combined intramural research programs of the NIMH and what was then the National Institute of Neurological Diseases and Blindness. Prior to the existence of NIMH, there was little in the way of a broad-based research tradition in American psychiatry, comparable to that in other areas of medicine. Dr. Kety embarked energetically on the task of outlining, developing, and staffing a mental health research program that would consist, at the first cut, of a Division of Basic Science and a Division of Clinical Science. Under Dr. Kety's leadership, the IRP became a magnet for the prominent researchers of the era. Given Dr. Kety's own interests, neurochemistry emerged as an early area of emphasis. Dr. Roscoe Brady headed a Section on Lipid Chemistry; Dr. Alex Rich headed a Section on Physical Chemistry; and Dr. Kety himself ran a Section on Cerebral Metabolism, all situated in the Laboratory of Neurochemistry, which Dr. Kety directed. Another early component of the program was the Laboratory of Cellular Pharmacology, which was headed by Dr. Giulio Cantoni and counted Dr. Seymour Kaufman among its early distinguished scientists. In 1953, Dr. Kety recruited Dr. Louis Sokoloff to the Section on Cerebral Metabolism. He set off on a research odyssey through fields ranging from neurochemistry to enzyme kinetics to circulatory physiology. This work culminated nearly two decades later in the development of the 2-deoxy-D-glucose method for measuring cerebral glucose metabolism, an accomplishment that moved *in vivo* brain imaging from the realm of theory to feasibility. Dr. Sokoloff's work revolutionized the field of brain imaging, which still flourishes at NIMH.

Another early recruit to the program was Julius Axelrod, who, wooed from the Intramural Research Program of the National Heart Institute to the Laboratory of Neurophysiology, led by Ed Evarts, went on to win the Nobel Prize in Medicine/Physiology in 1970 for his demonstration of the mechanisms through which the

⁵In this report, the term "independent investigator" denotes both a tenured scientist and a tenure-track scientist.

⁶ The Poolesville Animal Center is a unique facility with valuable resources. The most effective use of this facility needs to be addressed by the incoming SD.

brain regulates the actions of neurotransmitters. More generally, the groundbreaking contributions of the early IRP ushered in the medical model for research on mental disorders, serving to draw the field into the mainstream of biomedicine.

Notable scientific contributions in more recent times can be captured by citation analyses and professional recognition. The periodical *Science Watch* found the NIMH IRP to rank among the top neuroscience institutions nationwide in two separate studies of the number of citations per publication. NIMH IRP scientists and former trainees account for about 40 percent of the past presidents of the distinguished professional society, the Society for Neuroscience. Over 20 NIMH IRP scientists and former trainees are elected members of the National Academy of Sciences.

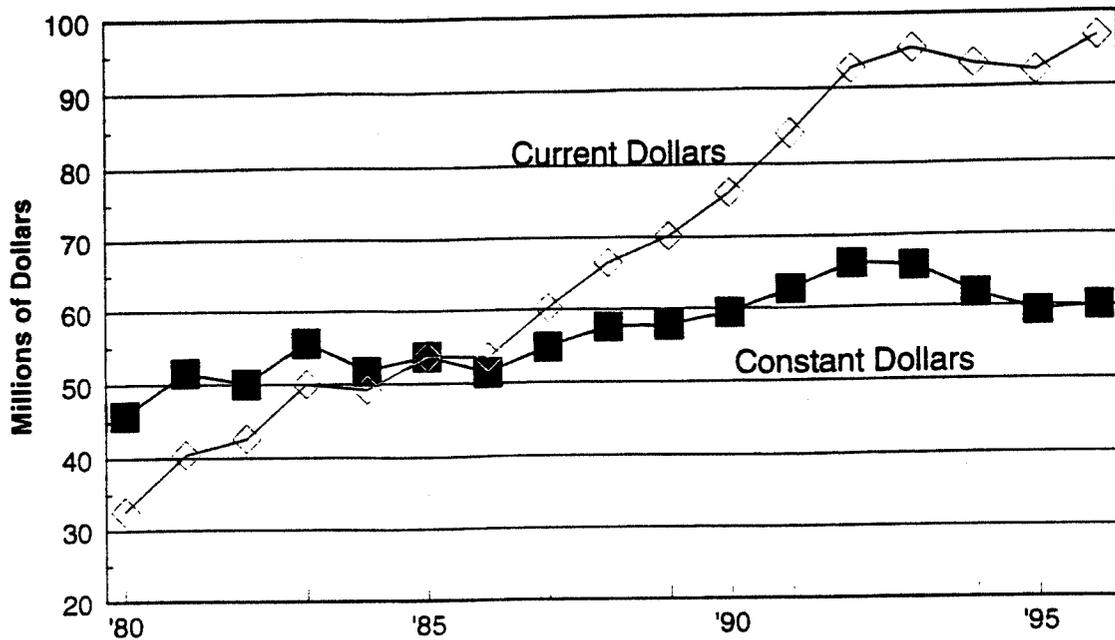
The IRP has been the birthplace of a number of major disciplines within the fields of mental health and neuroscience. The IRP not only achieved international acclaim for spawning new fields but also for spawning great researchers who eventually left to begin research programs at major universities. The IRP is credited with the training of the first generation of researchers and clinicians who transported their knowledge and skills to the extramural scientific community at our Nation's most highly regarded academic centers.

Budget and Personnel

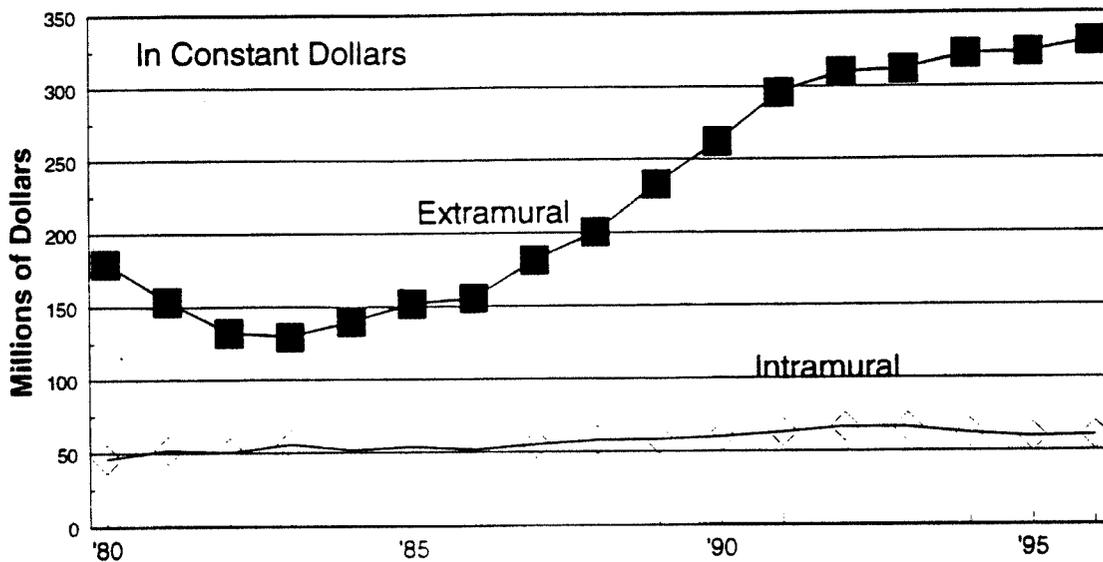
The IRP commanded a budget of \$96.7 million in Fiscal Year 1996. Its 740 paid staff work in 26 Laboratories located in four separate buildings on the NIH campus and in other locations, including the Poolesville Animal Center and the William A. White Building at St. Elizabeths Hospital.

FY 1996 Budget	\$96.7 Million
Budget As % of Total NIMH Budget	14.6 %
Personnel	740 (includes 570 FTEs)
Tenured Scientists	65
Organization	26 Laboratories/Branches 45 Sections

Despite the growth in budget from \$54 million in 1985 to the present, inflation has consumed much of the additional spending power. In constant dollars (which account for inflation) IRP spending has risen \$6 million (or 11 percent) over the past decade (Figure 1-1a). By contrast, the NIMH Extramural Research Program rose \$171 million (in constant dollars), or 112 percent (Figure 1-1b). As a result, the size of the IRP relative to the entire NIMH budget has decreased over this time (Figure 1-2). In 1983, the IRP represented 26% of the total NIMH budget, while in FY 1996 the IRP budget accounted for 14.6%, a higher percentage than the NIH average of 11.3% across all NIH Institutes. The IRP's estimated FY 1997 budget of \$98 million is projected at 14.0% of the NIMH budget. Relative to the number of tenured scientists, the FY 1997 budget represents a substantial level of support.



NIMH Intramural Research Program Budget



NIMH Intramural vs. Extramural Research Program Budget

Figure 1-1a. NIMH Intramural Research Program Budget, Fiscal Years 1980-1996, In Current Dollars and Constant Dollars. Constant Dollars Represent Inflation Adjusted Dollars, with 1985 As the Base Year. *Source: NIMH Budget Office.*

b. NIMH Intramural versus Extramural Research Program Budget, Fiscal Years 1980-1996, In Constant Dollars Only, with 1985 as the Base Year. *Source: NIMH Budget Office.*

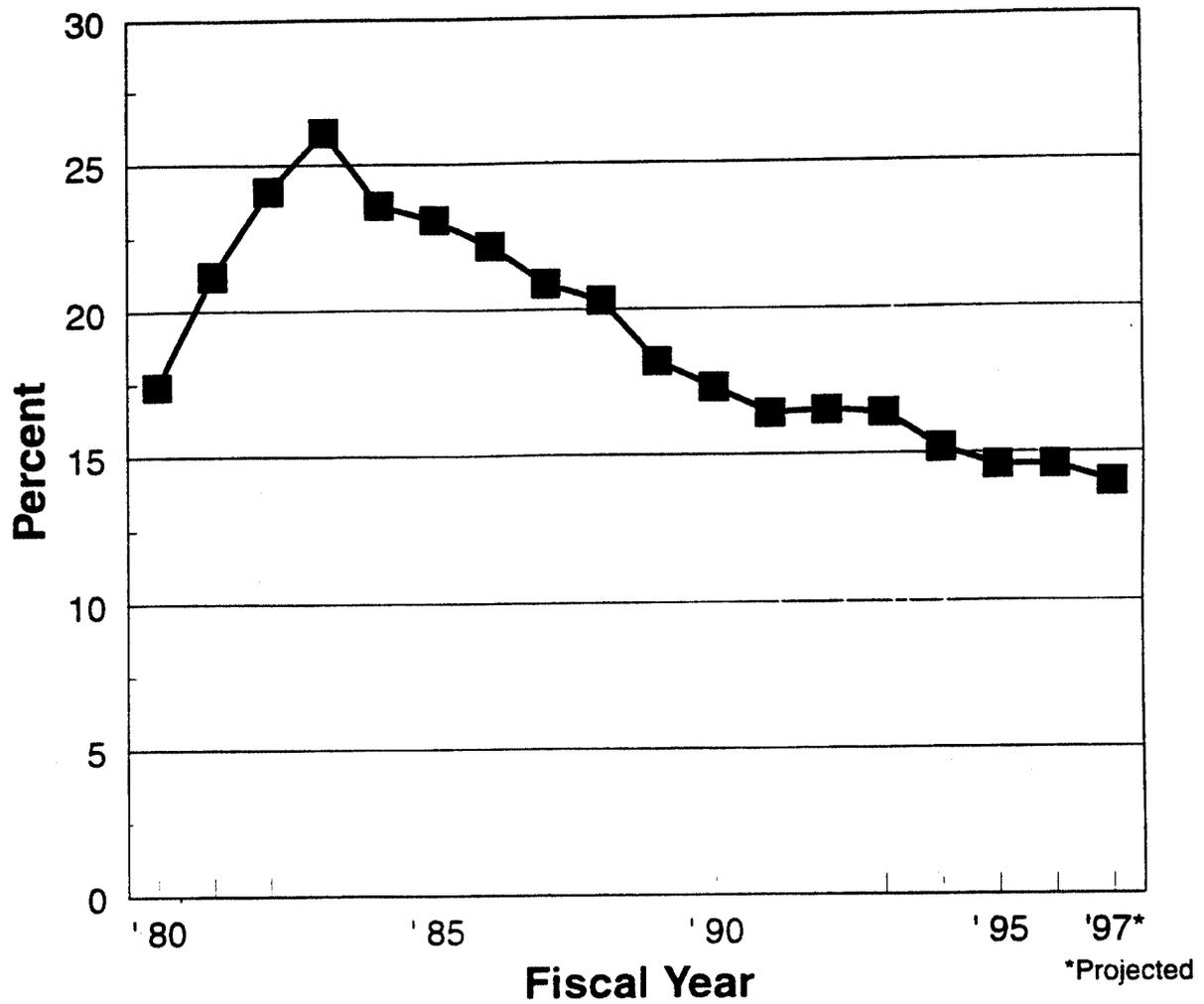


Figure 1-2. IRP Budget As a Percent of the Total NIMH Budget, Fiscal years 1980-1997 *Source: NIMH Budget Office.*

The 740 staff include 570 FTEs⁷ and 170 non-FTE employees. FTEs are permanent employees, such as tenured, tenure-track, and non-tenured scientists, advanced post-doctoral fellows, technicians, administrators, clerical staff, and others engaged in research support. The IRP's 65 tenured scientists account for 9% of the total staff. The number of permanent staff has declined from over 600 in FY 1992 to 570 in FY 1996. Non-FTEs, or temporary employees, are mostly pre-doctoral, post-doctoral, and visiting fellows.

Current Challenges

The NIMH IRP faces a constellation of challenges, some confronting science in general, some unique to the field of mental health, and others arising from within its institutional borders. The nature of scientific research and the environment in which it is conducted are changing radically. Biomedical and behavioral science is being transformed by a virtual explosion in knowledge, ushering in new domains and new tools of investigation. Paradoxically, scientific strategies are becoming increasingly reductionistic and specialized, at a time when questions, particularly in the mental health field, require integration of concepts from many different disciplines. In addition, many types of research and research technologies have become more sophisticated and costly. As a result, an aging research infrastructure needs to be modernized.

The greatest challenge facing the field of mental health is the complexity of brain and behavior. Understanding the structure and function of the brain requires knowledge ranging from the details of interactions among molecules and individual cells to the highest levels of cognition, memory, emotion, and language. All of these levels are relevant to the problem of mental disorders. Only after decades of study has research yielded new tools and approaches to unravel the structure and function of an organ widely considered to be the most inaccessible and complex. Moreover, there are very few useful biological indices for diagnosing mental disorders and monitoring treatment outcomes. For instance, there is no simple blood test, like that used in diabetes, for tracking and diagnosing any mental disorder. Consequently, researchers are deeply reliant on careful assessment of behavior, although there is new hope for biological tests that will complement behavioral assessment. Mental disorders also have complex behavioral manifestations and sometimes overlapping symptomatology. Major advances are likely to depend upon the novel integration of insights that arise from many scientific specialties.

The NIMH IRP confronts a host of more specific organizational challenges. The IRP needs a stable, predictable leader who can articulate a vision for the future. The new leader also needs to ensure a resilient and flexible organizational structure, one in which collaborations can flourish within and across sections, branches, laboratories, and institutional walls. The IRP needs an enhanced commitment to training and mentoring, core facilities, recruitment, and retention of excellent scientists. Resources need to be redirected from elsewhere within the IRP to address these challenges.

Aside from these issues, the foremost challenge for the IRP is to revitalize its science. The IRP is no longer in the exceptional position it once occupied. The quality of its science is uneven: there are elements of excellence, but there also are elements of less than stellar research, according to members of the Board of Scientific Counselors and the judgment of many intramural and extramural scientists. The need for revitalization occurs at a time of increasing pressures on funding, as Congress wrestles with the Federal budget deficit and endeavors to reduce the overall size of the Federal Government. Congress expects greater accountability and greater return on its research investment. In this climate, continued investment in the NIMH IRP at its present level is justified only if the research becomes uniformly excellent.

Rationale for an IRP

Amidst these challenges, both within and beyond the IRP, the Committee deliberated about whether there is

⁷Full-Time Equivalents

continued rationale for the existence of a NIMH IRP. *The Committee concluded that there is a strong rationale for an IRP devoted to mental health and mental disorders, provided the research is of the highest quality.* Mental disorders constitute an extraordinary public health problem and often destroy families, stigmatize affected individuals, and consume enormous societal resources. Their total annual economic cost in the U.S. is estimated at \$147.8 billion.⁸ As a result of international demographic shifts, including aging of some populations, the World Health Organization estimates that by the year 2020, major depression will climb from the *fourth* to the *second* greatest global burden.⁹ The IRP's ability to set the pace of research, its expertise in many mental disorders—including schizophrenia and affective disorders, its concentration of resources, and its special research setting are essential to combating the unmistakable and growing toll of mental disorders. These features, which are described below in greater detail, offer a cogent rationale for the existence of a NIMH IRP.

Researchers at the IRP have the freedom to pursue long-term, high-risk research. The IRP not only affords a stable source of support but also requires projects to be peer-reviewed principally on a retrospective, rather than a prospective, basis. The advantage of retrospective review is that it gives researchers the liberty to stray from the safe and popular, encouraging boldness and innovation. IRP researchers repeatedly assert that much of their most rewarding research would never have been funded in the more conservative climate of the extramural research program. They point to Dr. Louis Sokoloff's seminal work at the IRP on brain imaging that bore fruit only after an almost 20-year odyssey. The wisdom of decades of U.S. biomedical research policy is its support for complementary modes of peer-review—retrospective and prospective—to permit a multiplicity of scientific avenues for probing the most difficult questions in human health.

Numerous other features of the IRP justify investment. The IRP resides within a complex at the NIH that houses a critical mass of researchers exploring a wide spectrum of basic and clinical research opportunities. Few other institutions worldwide offer under one roof the concentration of resources and the possibility of translating basic discoveries into clinical realities. At the NIMH IRP, researchers in gene expression and neuroanatomy work side-by-side with clinical researchers to probe basic problems of brain dysfunction in mental illnesses. The possibility of multi-disciplinary collaboration and access to state-of-the-art scientific and clinical facilities are alluring inducements to the best minds in the field.

The advent of managed care in the extramural community underscores the rationale for IRP *clinical* research. Enrollment in managed care organizations has mushroomed from virtual obscurity in the 1980s to over 70% of working Americans in 1995.¹⁰ Even though managed care has had the beneficial effect of lowering health care expenditures and making health care more affordable, the impact on clinical research in the extramural community has been chilling (see Chapter 6). Many managed care providers appear not to be interested in sustaining a commitment to clinical research. Medical schools are increasingly less able to subsidize clinical research from revenues generated by fee-for-service health insurance plans. A dynamic and vital IRP is a critical bulwark against the nationwide erosion of investment in clinical research.

⁸ Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support (1995). Department of Health and Human Services, National Institutes of Health, Office of the Director. The figure presented here pertains to direct and indirect costs, with 1990 as the reference year.

⁹ Murray, C. and Lopez, A. 1996. Evidence-Based Health Policy--Lessons from the Global Burden of Disease Study. *Science* 274: 740-743.

¹⁰Foster Higgins National Survey of Employer Sponsored Health Plans, 1995. In this survey of both large and small employers, managed care was defined by coverage in either HMOs, PPOs, or Point of Service plans. The survey component of employers with more than 500 employees found managed care to cover 73% of workers; whereas, that of employers with less than 500 employees found managed care to cover 71% of workers.

Finally, a vigorous IRP has the resources and resilience to respond to national health crises. Researchers can swiftly alter the path of their research to meet national imperatives. The IRP's close proximity to congressional and executive branch decision-makers helps to ensure a critical role for the IRP in responding and providing information to policy-makers.

In summary, there is strong rationale for the IRP by virtue of its leadership, size, resources, ability to take risks, and other special features, as long as the research is of the highest quality. There also are unprecedented research opportunities because of breathtaking progress in science, the talent of the IRP's researchers, and strong public support. There is also increasing concern about the future of clinical research in the extramural community. The Committee concluded that the goal of the IRP is to help lead the Nation in conducting research of outstanding quality to advance understanding of the causes, treatment, and prevention of mental illnesses, as well as the biological and psychosocial factors that determine human behavior and its development.

New Mission Statement

With strong rationale for the continued existence of the IRP, the Committee believes that the IRP needs an explicit mission statement. The IRP's official "Functional Statement," presented below, attests to its essential activities, but does not contain key features of a mission statement:

The IRP's Functional Statement

The [NIMH's] Division of Intramural Research Programs (1) Plans and administers a comprehensive, long-term intramural research program dealing with the causes, diagnosis, treatment, and prevention of mental disorders, as well as the biological and psychosocial factors that determine human behavior and development, (2) operates and physically maintains an independent, clinical care facility in the William A. White Building for the study of the mental illnesses; and (3) provides a focus for national attention in the area of mental health research.¹¹

A mission statement is needed to provide strategic direction for the future by speaking to the special roles that the IRP can fulfill. A mission statement also is needed to underscore the importance of high quality science, training, and patient care and to clarify the full scope of the IRP's research and educational activities across disciplines related to mental illness. Finally, it is needed to galvanize IRP staff and signify to them the need to set priorities and to take advantage of their special resources.

Among the special roles for the IRP is the ability to conduct translational research, which is research that translates, or converts, the findings of basic research into new clinical treatments, diagnostic procedures, or preventive regimens. Translational research is bi-directional insofar as it also includes translating clinical findings back to the laboratory for study of more basic questions or development of animal models. With its exceptional concentration of basic and clinical researchers working within the same institution, the IRP can play a major role in forging new ground in translational research. Another special role is the ability to capitalize upon the extraordinary concentration of resources at the NIH IRP as a whole. By carving out these special roles, the NIMH IRP can serve to complement NIMH's extramural research program. The IRP should place high priority on research that is not easily accomplished elsewhere. With these roles in mind, the Committee recommended a mission statement (below) which is repeated at the conclusion of this Chapter.

¹¹ NIH Manual 1125, October 1, 1994, Issuing Office: OMA

Proposed New Mission Statement

The IRP conducts basic, clinical, and translational research to advance understanding of the causes, treatments, and prevention of mental disorders through the study of normal and abnormal brain function and behavior. The IRP supports outstanding research that, in part, complements extramural research activities and utilizes the unique resources of the National Institutes of Health. The IRP provides an environment conducive to the training and development of clinical and basic scientists. The IRP fosters standards of excellence in the provision of clinical care to research subjects and in the translation of research into effective treatments. The IRP serves as a national resource in response to requests made by the Administration, members of Congress, and citizens' groups for information regarding mental illness.

Recent Policy Changes

Under the leadership of Director Harold Varmus, M.D., the NIH is engaged in unprecedented changes. These changes are designed to respond to a rapidly evolving biomedical research environment and to the 1994 Report of the NIH Director's External Advisory Committee. Among the changes are a new NIH-wide tenure policy, new policies for scientific reviews by the Board of Scientific Counselors, and new recruitment and training initiatives, all of which are likely to have profound implications for the NIMH IRP. Equally important are changes in the operation of the Clinical Center. A new Clinical Center is slated for construction on the NIH campus over the next few years to replace the current outmoded and inefficient structure.

Apart from these changes, which affect all NIH intramural programs, the Acting Scientific Director of NIMH has instituted important reforms in the NIMH IRP, including:

- The recommendations of the Board of Scientific Counselors are being relayed to the IRP in a more timely manner and are being used to determine resource allocations by the Acting Scientific Director;
- The Acting Scientific Director has begun to allocate resources directly to each tenured and tenure-track scientist rather than to Laboratory/Branch Chiefs. In the past, Laboratory/Branch Chiefs received resources for their entire laboratory, from which they made the distributions to independent investigators;
- A new NIMH IRP Training Director has been hired as a result of recommendations made by an internal Fellowship Education and Training Committee; and
- An internal group of senior advisors has been assembled to advise the Acting Scientific Director.

These policy changes are discussed in greater detail in the appropriate chapters of this report, along with the Committee's recommendations for a revitalized IRP.

Recommendations

- 1.1 **The Committee recommends that the goal of the NIMH Intramural Research Program should be to help lead the Nation in conducting research of outstanding quality to advance understanding of the causes, treatment, and prevention of mental illnesses as well as the biological and psychosocial factors that determine human behavior and its development.**
- 1.2 **The Committee recommends that the Mission of the NIMH Intramural Research Program should be:**

The IRP conducts basic, clinical, and translational research to advance understanding of the causes, treatments, and prevention of mental disorders through the study of normal and

abnormal brain function and behavior. The IRP supports outstanding research that, in part, complements extramural research activities and utilizes the special resources of the National Institutes of Health. The IRP provides an environment conducive to the training and development of clinical and basic scientists. The IRP fosters standards of excellence in the provision of clinical care to research subjects and in the translation of research into effective treatments. The IRP serves as a national resource in response to requests made by the Administration, members of Congress, and citizens' groups for information regarding mental illness.

Leadership

Introduction

Stable and effective leadership is critical to the renewal of the NIMH IRP. For the past three years, the IRP has been without a permanent Scientific Director. Three Acting Scientific Directors strove to provide leadership during this period of transition. Despite their efforts, the temporary nature of an 'Acting' position limited their ability to respond to a changing biomedical environment. As the IRP confronts the challenges described in Chapter 1, many staff are dispirited and uncertain about the future. A scientific organization cannot thrive without a leader who can flexibly steer the program by providing scientific vision, redirecting resources, recruiting new talent, and unifying diverse elements.

This chapter discusses the roles of the Scientific Director, the Laboratory/Branch¹² Chief, and the independent investigator. It explains how each of these pivotal positions requires redefinition to meet the challenges ahead. One theme that resonates throughout the chapter is that the SD and the Laboratory/Branch Chief must balance the programmatic needs of the IRP with the need for independence of investigators. The chapter also provides some principles for restructuring the IRP, while leaving more detailed organizational decisions to the discretion of the Institute Director and the next Scientific Director. The intention of the Committee is not to micromanage but specifically to recommend examples of the directions to be taken.

Role of Institute Director

One of the highest priorities for the Institute Director (ID) is to recruit an outstanding Scientific Director. Once this is accomplished, the ID's role is to promote the SD's efforts to renew the IRP. For instance, the ID can facilitate the implementation of the SD's plans for recruitment, restructuring, new incentive programs, and the distribution of resources. The ID also plays an important role in securing support from the NIH leadership for the full scope of the SD's organizational changes.

Many issues, like recruitment and training, fundamentally affect the IRP, yet cannot be resolved by the IRP leadership because they are governed by NIH-wide policies. In these cases, the ID plays a vital role in working with the NIH leadership to establish new policies. Finally, the ID needs to help protect sequestered resources in the form of FTEs, space, and money. Sequestered resources are resources that are deliberately set aside, or garnered, for such purposes as recruitment, retention, core facility purchases, and discretionary use. The flexibility of the SD to restructure the IRP and distribute resources is vastly weakened without the protection of sequestered resources.

Letter from IRP staff: "The poor morale is a product of several years of administrative 'drift' followed by uncertainty regarding future leadership and direction, rather than inadequacy in recent leadership ..."

¹² There is little practical distinction between a Laboratory and a Branch. The terms came into usage years ago to distinguish "bench-oriented" Laboratories from "patient-oriented" Branches under the assumption that patients were more comfortable being seen in a "Branch" rather than a "Laboratory." As patient attitudes changed, and new laboratories and branches were formed, the distinction has lost most of its former meaning.

Role of Scientific Director

The Scientific Director (SD) occupies the most pivotal position in the IRP. Past and present NIH policies have endowed this position with broad authority to shape the scientific direction of the program, to allocate resources, to participate in important decisions about recruitment, retention, and other personnel matters, and to manage the day-to-day administrative responsibilities of the program (Table 2-1).

Leadership is fundamental to the role of the SD. In light of the challenges presented in Chapter 1, the SD needs to be an agent of change to steer the IRP to higher quality science. This can only be accomplished through a clearly articulated vision. The SD also must possess creativity and foresight, an exemplary grasp of broad scientific concepts, an ability to recognize promising leads, a reputation for enduring scientific contributions, and a commitment to supporting the highest standards of research. Leadership, however, is more than the embodiment of scientific excellence. Leadership demands skill at communication, administration, and mentoring. It also demands skill at building a cohesive organization, imbued with a sense of excitement, enthusiasm, and devotion to its public health mission. Finally, leadership requires the ability to mobilize scientists into new ways of approaching problems that extend beyond the areas of expertise of even the most gifted.

One of the most difficult challenges facing the leader of a scientific organization is to balance several sets of priorities that sometimes compete with one another. The first set of priorities is the need for scientific autonomy of independent investigators versus the need for programmatic integration to meet public health imperatives. A leader must deftly handle this tension without dictating the types of research projects conducted. Experience has shown that

scientists are most productive when given the independence and freedom to pursue their own research programs. When serendipity propels high quality research into directions unrelated to the mission of the IRP, however, the research should be pursued within the IRP in the short run, yet not over the long-term. Likewise, an effective leader needs to balance the allocation of funds between individual investigators versus multi-disciplinary projects. Because of its concentration of researchers, resources, and other features, the IRP affords the possibility of conducting mission-oriented research through the conduct of larger scale, multi-disciplinary projects that simply may be impossible to conduct elsewhere. A related set of priorities to balance is the quality of the science conducted versus its immediate relevance to the mission of the IRP. In many cases, these are completely compatible, yet mission-oriented research should never be conducted at the expense of scientific quality. A final set of priorities to balance is the relative emphasis on clinical, basic, and translational research. A balance must be struck to ensure an adequate flow of discoveries from the laboratory to the clinic and vice versa, as well as to seize the greatest opportunity for progress in mental health. To weigh these sometimes conflicting sets of priorities, the SD needs to have a vision, the skills described earlier, and flexible management tools. These tools include the ability to allocate resources, to recruit new scientists, to retain and reward superb scientists, and to reorganize the IRP.

Letter from IRP staff: "The SD must be simultaneously a facilitator and a director. Her or his self interests must be identified with the success of the Program as a whole ... The SD must ... be willing to make tough decisions, to establish priorities and the direction of the Program ... Resistance can be effectively managed ... if the leader creates a context of fairness ..."

Vision and Planning Process

To renew the IRP, the foremost role for the new SD is to articulate a bold, yet realistic, scientific vision of the future. A vision of the future should focus selectively on scientific areas in which the IRP can excel and can

Table 2-1. Roles of NIMH Leadership

Scientific Director	Laboratory/Branch Chief
Current Roles	
<ul style="list-style-type: none"> ■ Leader, Scientist, Mentor, Administrator ■ Allocates resources to tenured scientists¹ ■ Encourages integration of research themes across IRP ■ Recommends tenure-track scientists to DDIR² ■ Approves appointments of Laboratory/Branch Chiefs³ ■ Approves non-tenure track scientific appointments 	<ul style="list-style-type: none"> ■ Leader, Scientist, Mentor, Administrator ■ Recommends to SD resource levels for tenured scientists in Laboratory/Branch¹ ■ Encourages integration of research themes within Laboratory/Branch ■ Recommends tenure-track scientists to SD ■ Recruits and recommends to SD non-tenure track scientific appointments ■ Approves appointments of technicians and other support staff
Additional Roles Recommended by the Committee	
<ul style="list-style-type: none"> ■ Establishes vision and planning process ■ Restructures IRP and ensures new structure is evaluated ■ Allocates discretionary resources ■ Encourages collaborations more strongly ■ Seeks advice from Laboratory/Branch Chiefs about future directions 	<ul style="list-style-type: none"> ■ Advises SD on planning and other policy issues ■ Allocates discretionary resources ■ Encourages collaborations more strongly ■ Reviews all scientists and fellows approximately two years prior to BSC review

¹Based on BSC Reviews

²Deputy Director for Intramural Research

³Except for SES Positions

have the greatest impact. While there are many pressing scientific needs, the IRP must exploit areas where the opportunities are the most ripe. In addition, fiscal constraints preclude investing in all areas of mental health research. The IRP portfolio should include projects that take advantage of the special resources of the IRP, including access to special patient populations, inpatient research beds, and state-of-the-art technologies and the ability to pursue innovative, long-term research. In developing a vision for renewal, the new SD must carefully weigh areas of historic achievement and emerging scientific opportunities and needs against resource limitations.

The formulation of a vision by the SD should be informed by input from Laboratory/Branch Chiefs, IRP scientists, extramural scientists, and the diverse mental health community. The new SD is expected to reach out to the IRP's constituencies in an inclusive and open manner. The SD's vision should serve as the basis for the development of a long-range plan by a newly recommended *ad hoc* planning group. The plan should identify a broad range of scientific directions. Its contents should be influenced by the scientific directions proposed by professional and patient associations (Appendix B) in their letters to this Committee and in the future. The plan should contain goals and timelines, yet be flexible enough to shift direction as new scientific opportunities emerge. The recommendations at the end of this chapter identify the specific steps needed to produce a long-range plan with the assistance of an *ad hoc* planning group that is advisory to the SD.

While no leader can be expected to satisfy the disparate needs and demands of all groups, the SD must be fair, responsive, and able to articulate the reasons for a chosen path. Leadership requires making decisions and then forging ahead with surety and determination.

Resource Allocation

The SD is responsible for making resource allocations according to a vision and a program plan. The SD also allocates resources directly to individual tenured and tenure-track scientists by drawing upon the recommendations of the Board of Scientific Counselors (see Chapter 3) and Laboratory/Branch Chiefs. In the past, the SD has traditionally allocated resources to Laboratory/Branch Chiefs who, in turn, distributed resources to independent investigators under their supervision. Recent Acting Scientific Directors instituted new procedures amidst complaints that some Laboratory/Branch Chiefs inappropriately steered resources to their favored projects at the expense of independent investigators, who were deprived of the opportunity to fully develop their own research programs. To restore autonomy, each tenured or tenure-track scientist is now given direct control over his or her own resources,¹³ a policy endorsed by this Committee. With the decentralization of resources, however, comes a new obligation: the SD needs to be even more vigilant about fostering cooperation, collaboration, and thematic integration, while simultaneously protecting the autonomy of individual investigators.

Letters from IRP staff: *"Absent strong leadership, the allocation of resources has not been tied to review-based merit, but rather based on the accumulation of large power bases." "... collaboration between branches and labs is less than optimal ... most of it has to do with the historical ethos of the IRP where competitiveness was paramount and collaboration neither encouraged nor perhaps even desired."*

Flexible Funding

The SD needs novel management tools to rekindle enthusiasm for collaboration and to forge thematic linkages. Existing tools are insufficient. Recognizing the importance of resources as positive incentives to action, this Committee proposes the establishment of a discretionary fund for flexible use by the SD. Setting

¹³ These resources include personnel, space, equipment, supplies, services, and travel.

aside a percentage of IRP funds gives the SD a vehicle to encourage basic-clinical collaborations, translational research, and/or new scientific initiatives. It also could provide a mechanism by which fellows can acquire experience in competing for prospective funds. The NCI is planning to launch a pilot intramural prospectively-based grants program in one of its divisions as a result of a recommendation by the external panel which evaluated the IRP of the National Cancer Institute.¹⁴

A discretionary fund is a means of giving flexibility to the SD to foster programmatic goals and support strong science. The fund could be structured to award support for prospective projects after some type of peer-reviewed process. Since the majority of IRP funds would continue to be allocated via the traditional review process, the creation of a prospective process does not jeopardize a recognized strength of the IRP in attracting and retaining high caliber scientists. The fund also should be used to allocate positions and space as well as research dollars.

Accountability of the Scientific Director

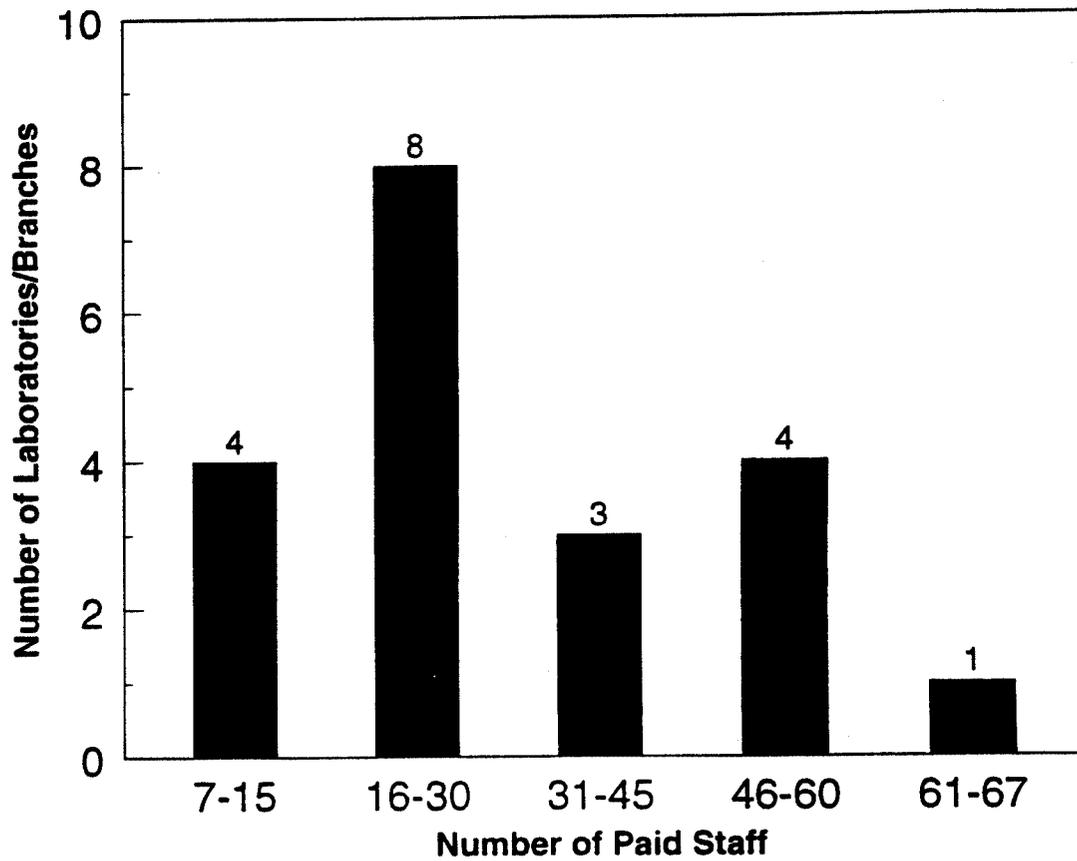
The SD has wide-ranging responsibilities in terms of leadership, resource allocation, mentoring, and administrative oversight. The Committee recommends conferring upon the SD even more responsibility through its recommendations for a planning process and for the creation of a discretionary pool of resources for distribution by the SD. With this degree of authority, it is imperative that the performance of the SD be independently and objectively evaluated. NIH policy now requires stewardship reviews of the SD by an Ad Hoc Committee of the ICD's Advisory Council or Board every 4-6 years. Stewardship reviews, which are distinct from reviews of the SD's scientific projects, evaluate the SD's leadership, administration, and the quality of training and mentoring within the IRP, among other elements. This Committee strongly supports this policy change and offers in Chapter 3 several criteria for stewardship reviews. The leadership should be held to strict standards of accountability.

Role of Laboratory/Branch Chiefs

Laboratory/Branch Chiefs hold important positions of leadership. They serve as scientific beacons by defining the goals of the laboratory and by bringing together talented scientists to conduct first-rate research. They nurture and facilitate the career development of younger scientists and thereby serve as role models to inculcate a laboratory-wide commitment to mentoring. They encourage collaborations and interdisciplinary approaches. After evaluating the performance of independent investigators, BSC reviews, and the programmatic needs of their units, Laboratory/Branch Chiefs advise the SD on scientists' resource allocations, recruitment, tenure, retention, and promotion. Their recommendations carry weight because of their judgment and close interactions with those in their laboratory. The Laboratory/Branch Chiefs also advise the SD on setting priorities and shaping the research directions of the program. A summary of these roles is presented in Table 2-1.

The Laboratory/Branch Chief, like the SD, must strive for thematic integration in the IRP but without compromising the creativity and independence of investigators. This represents one of the most difficult challenges facing the Laboratory/Branch Chief: he or she must strike a balance between the need for investigator autonomy and the need for programmatic direction and integration. In the past, the balance was often shifted in favor of the scientific interests of the Laboratory/Branch Chief, prompting the Acting SD of the NIMH IRP to set a new policy of allocating resources directly to independent investigators instead of to Laboratory/Branch Chiefs. The new policy envisions a cadre of tenured independent investigators producing excellent science by working independently and by collaborating voluntarily with other scientists.

¹⁴There is one existing prospectively-funded grants program within the entire NIH IRP. It is the AIDS Targeted Anti-Viral Program, established in 1990. Administered by NIDDK, it offers start-up funding for investigators new to AIDS research. With approximately \$6 million annually, it funds small grants and large equipment purchases.



Note: The number of Laboratories/Branches does not include service branches and the Office of the Director.

Figure 2-1. Size Distribution of Laboratories/Branches
Source: NIMH Intramural Budget Office, July, 1996.

The past dominance of some Laboratory/Branch Chiefs has been a NIH-wide problem. Over the course of many years, some Laboratory/Branch Chiefs across NIH's intramural program became disproportionately powerful without appropriate oversight. Their dominance was an outgrowth of permissive policies and a failure of leadership, as documented in two previous reports.¹⁵ The NIH's new tenure-track policy is part of a systematic attempt to remedy the dominance of some Laboratory/Branch Chiefs, as well as other NIH-wide problems: it requires national searches for tenure-track positions; it downplays the role of the individual Institute in tenure decisions, which now are made on an NIH-wide basis by the Deputy Director for Intramural Research (see Chapter 4); and it ensures independent research resources for tenure-track positions.

Letters from IRP staff: *"The past independence of the branches has often allowed each branch to operate seemingly as a separate kingdom, almost autocratically." "Unduly large Branches/Laboratories undermine the sound nature of the Branch/Lab structure for research. Branches should remain a functional organization in which the Chief is involved in day to day research."*

The NIMH IRP's new policy of resource allocation directly to independent investigators—coupled with the new NIH-wide tenure track policy—have circumscribed the authority of the Laboratory/Branch Chiefs. The question remains whether the Laboratory/Branch Chiefs retain sufficient tools to shape a cohesive program. The new model assumes that collaborations occur by virtue of leadership and the voluntary efforts of scientists. While it is too early to evaluate whether this model works as intended, the Committee believes that discretionary resources also are needed for the Laboratory/Branch Chiefs to forge programmatic linkages. Laboratory/Branch Chiefs should have access to a portion of the SD's proposed discretionary fund, as a means of stimulating collaboration and integration. These funds are supplementary to those needed for Laboratory/Branch Chiefs' own research and administrative responsibilities. Should these discretionary resources prove to be insufficient, the IRP leadership should explore additional tools for Laboratory/Branch Chiefs to encourage collaboration and focus on programmatic needs.

A related issue is whether Laboratory/Branch Chiefs should have the authority and flexibility to hire non-tenure track scientists and technical support staff. Laboratory/Branch Chiefs may come to rely increasingly on these positions to forge thematic integration because of the growing independence of tenured and tenure-track investigators and post-doctoral fellows. As discussed further in Chapter 5, post-doctoral fellows must be freed of support roles, and a greater emphasis placed on their training so that they may develop as independent scientists. Limiting their time commitment to the laboratory creates more work for others. Because Federal personnel ceilings have restricted Laboratory/Branch Chiefs' ability to hire scientific support staff, new legislation may be necessary. This represents a NIH-wide problem.

Laboratory/Branch Chiefs must be held to stringent standards of accountability by the SD and by the Board of Scientific Counselors. While each Institute's Board of Scientific Counselors is not formally required by NIH policy to evaluate the performance of Laboratory/Branch Chiefs on the basis of stewardship, administration, and mentoring of younger scientists, some Boards of Scientific Counselors, including that serving the NIMH IRP, elect to conduct stewardship reviews. The Committee not only supports this practice, but also proposes in Chapter 3 new criteria governing stewardship reviews. Stewardship reviews should include explicit recommendations about resource allocation, staff, and retention of the position as Laboratory/Branch Chief.

¹⁵The Report of the External Advisory Committee of the Director's Advisory Committee (1994) and A Review of the Intramural Program of the National Cancer Institute by the *Ad hoc* Working Group of the National Cancer Advisory Board (1995).

Role of Independent Investigators

The most important role for each independent investigator is to develop a highly productive, independent research program. The research should be of outstanding quality, driven by focused questions and state-of-the-art methods. It is desirable that the underlying questions should creatively address over the long-term key topics of interest to the laboratory and to the IRP as a whole. The scientist should engage in flexible long-term planning to prioritize studies and seize scientific opportunities. Collaborations with other scientists within NIH and the broader extramural community provide a critical means of enhancing productivity, leveraging resources, gaining access to patients and/or technology, and expanding the scope and depth of research. Finally, the scientist should be committed to the quality mentoring of younger scientists (see Chapter 5).

Beyond these traditional responsibilities, the role of the independent investigator is undergoing metamorphosis. The direct receipt of a resource allocation from the SD empowers each independent investigator to shape his or her own projects. Yet it also imposes new responsibilities. Foremost among these is the responsibility to initiate collaborations. The independent investigator also needs to be an active contributor to the research goals of the Laboratory/Branch, to the IRP's governance, and to its long-term planning. The independent investigator also has a responsibility to be part of the NIH-wide community. Independent investigators cannot benefit from policy initiatives of the NIH leadership and the recommendations of this Committee unless they embrace these new and evolving responsibilities.

Organizational Culture

The SD needs to foster an institutional climate committed to academic values of collegiality, openness of communication, sound scholarship, and research integrity. Collaboration, sharing, cooperation, and mutual respect must prevail. In times of resource constraints, it is even more critical for the SD to redouble efforts at improving the institutional culture, because competition for resources is bound to be a driving factor. The positive features of competition—the quest for excellence in research on normal and abnormal brain function and behavior—need to be promoted.

Organizational Structure

The IRP's current organizational structure—consisting of 26 Laboratories/Branches and 45 sections—has not undergone systematic examination with respect to programmatic content. The structure has evolved largely as a function of the individual interests of Laboratory/Branch Chiefs, without regard to broad programmatic and thematic needs or design. The incoming SD needs to restructure the IRP in accordance with a long-range plan for the future (discussed earlier). One underlying principle in designing a new structure is to ensure that it lends itself to collaborations within and across sections, laboratories, and institutional borders.

As part of restructuring, consideration needs to be given to the size of existing Laboratories/Branches. Figure 2-1 shows the distribution of existing Laboratories/Branches according to the number of paid staff.¹⁶ Laboratories/Branches most commonly have 16-30 staff but range in size from 7 to 67 staff.¹⁷ Five Laboratories/Branches have more than 45 staff. While there is no ideal number of staff for each laboratory, it is clear that some laboratories have grown disproportionately large. Relatively small-sized laboratories are generally more desirable in order to provide programmatic focus and to ensure that younger scientists receive

¹⁶Service branches and the Office of the Director are not included.

¹⁷ As of July 1996. The largest laboratory subsequently has been reduced in size.

sufficient guidance. Larger size laboratories can only be justified on the grounds of a proven track record of scientific accomplishment and pressing programmatic need.

Another organizational issue is whether to place developing basic scientists in clinical laboratories. The well-intended practice by clinical laboratories of recruiting young basic researchers to conduct translational research has led, in a number of cases, to the basic scientist becoming scientifically isolated and deprived of adequate mentoring and career development. Without adequate mentoring and day-to-day interactions with other basic scientists, the quality of their science may be jeopardized.

Conclusions

The appointment of a new Scientific Director is the first priority for revitalizing the IRP. Consistent and effective leadership, accompanied by vision and long-range planning, are essential to reshape the program. The Scientific Director needs innovative tools to steer the IRP, including a pool of discretionary resources. Bestowing more responsibilities on the Scientific Director demands even stricter accountability of this position. Laboratory/Branch Chiefs need a redefined role to give them sufficient authority to encourage collaborations and to shape the scientific direction of their programs. Independent investigators need to develop their own research programs, assume a greater role in initiating collaborations, and contribute to the thematic research focus of their Laboratory/Branch. Finally, the IRP needs organizational restructuring consistent with a new long-term plan.

The recommendations presented below are designed to foster world-class research at the NIMH IRP. They call for the recruitment of an outstanding SD, and they delineate the roles of the Institute Director, SD, Laboratory/Branch Chiefs, and independent investigators. The realization of a world-class program also requires recruitment and retention of outstanding senior and junior scientists who are given suitable salary lines and space, a topic covered in Chapter 4. *To accomplish the recommendations contained in this report, the Committee does not foresee a need to increase IRP funding as a percentage of the total Institute budget.*

Recommendations

Role of the Institute Director

- 2.1 **The Institute Director (ID), NIMH, should recruit an outstanding Scientific Director (SD) and actively support the SD's programmatic efforts. Through coordinated planning efforts with the Deputy Director of Intramural Research (DDIR), NIH, and the Director, NIH, the ID should facilitate recruitment, organizational restructuring, the use of incentive programs, and the allocation of IRP resources based on scientific merit and programmatic need. The ID should obtain broad-based support from the NIH leadership for (1) the programmatic changes necessary for the SD to implement a long-range IRP plan and (2) the protection of sequestered resources at the NIMH IRP to be used for recruitment and revitalization.**
- 2.2 **The Committee expects that, with creative and skillful management, the resources currently available in the IRP should be sufficient to revitalize the scientific program.**

Role of the Scientific Director, NIMH

- 2.3** One of the highest priorities of the ID is to recruit an outstanding Scientific Director (SD). The SD should have a history of scientific achievement in a field relevant to the mission of the NIMH. The SD should demonstrate strong leadership, mentoring, and administrative skills. The SD should make a long-term commitment to the IRP. The SD should possess the skills necessary to foster interactions among basic and clinical researchers, Laboratory/Branch Chiefs, NIMH and NIH leadership, and the mental health community.
- 2.4** The SD should shape the scientific and administrative directions of the IRP. The SD should articulate a vision for revitalizing the program and present this vision to a newly formed *ad hoc* planning group appointed by, and advisory to, the SD. With membership and input from the intramural and extramural communities, the SD and the planning group should produce a long-range plan that sets goals and timelines. The plan should include the identification of areas of scientific opportunity and strategies for implementation. Once this plan is accepted by the SD and endorsed by the ID, the SD should be given the support and authority to implement the plan. A written planning report should be produced every five years and be reviewed by the BSC, ID, and DDIR, NIH.
- 2.5** The SD should restructure the organization of the IRP to fulfill the vision articulated in the long-range plan.
- 2.6** The Committee endorses the recent IRP practice of giving each independent investigator greater autonomy through direct resource allocation. However, with less control over resource allocation by Laboratory/Branch Chiefs, the SD should take the initiative to foster thematic integration of a large number of independent investigators.
- 2.7** The SD should set aside a percentage of the IRP discretionary budget for flexible use to shape the program. For example, portions of these funds could be used to: stimulate translational research; facilitate collaborations between basic and clinical scientists; establish an impartial peer-review process for allocating discretionary funds on a prospective, competitive basis; recruit independent investigators; establish core research facilities; create new programs or Laboratories/Branches; enhance existing programs; support sabbaticals; help with the transition of less productive scientists into more productive roles or into positions outside of the IRP; fund training and retraining; establish a competitive prospective funding process to support independent research by fellows; pay for travel; and for other incentives that promote scientific excellence.
- 2.8** The conduct of the highest quality research depends on the SD's ability to (1) recruit new talent, (2) retain and nurture existing scientific expertise, (3) distribute resources based on BSC reviews and the long-range plan, and (4) redeploy less productive independent investigators. The SD has a range of personnel mechanisms available to retain excellent scientists and to reassign less productive tenured investigators from leadership positions. The SD should use, or, when necessary, create mechanisms that best use the diverse talents of individuals within the IRP.
- 2.9** Top quality science requires a collaborative, supportive environment. The SD must foster open communication with IRP personnel and develop fair and impartial decision making processes. The IRP leadership should develop and distribute a document containing a written description of IRP policies and procedures for decision making.

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- 2.10 The SD's leadership, mentoring, and administration should be evaluated every 4-6 years by an *ad hoc* committee of the National Advisory Mental Health Council, in accordance with recently instituted NIH-wide policy for stewardship reviews. This evaluation is independent of the review of the SD's own research projects (see Recommendation 2.12). Explicit criteria for evaluating stewardship are presented in Recommendation 3.4.
 - 2.11 The NIMH leadership should define policies for changing or rotating Laboratory or Branch Chiefs who do not perform adequately. They should also define procedures and conditions under which Laboratories and Branches are closed based on negative review by the BSC.
 - 2.12 The SD's own research projects, either within NIMH or another Institute, should be reviewed by the Board of Scientific Counselors of the respective Institute, in accordance with NIH-wide policy. Transmittal of the results of the review to the SD should be by the Institute Director (ID), NIMH. Actions taken on the basis of the review should be initiated by the ID in consultation with the Deputy Director for Intramural Programs, NIH.

Role of Laboratory and Branch Chiefs

- 2.13 The IRP's most important goal is scientific excellence in addressing the pressing problems of mental illness. Outstanding science requires fostering creativity and autonomy of independent investigators as well as programmatic linkages within and between laboratories. The Committee strongly favors research units of relatively small size but recognizes the need for occasional, larger-sized laboratories. Laboratory size should be dictated by scientific goals, accomplishments, and programmatic need and not by history. Laboratory size should be evaluated periodically as an integral part of the BSC review of Laboratory and Branch Chiefs. Laboratories and Branches should demonstrate evidence of thematic consistency.
- 2.14 Laboratory and Branch Chiefs are charged with developing and maintaining a program of scientific excellence. They should encourage and coordinate, rather than direct, the efforts of independent researchers, both individually and in small groups. They should provide incentives for innovative research and productivity and support thematic integration. A portion of the discretionary funds of the SD should be allocated to Laboratory and Branch Chiefs to allow them to improve their program, respond to new opportunities, recruit personnel, support infrastructure and encourage collaborations.
- 2.15 Laboratory and Branch Chiefs should play an advisory role to the SD and DDIR in tenure-track recruitment efforts and in planning long-range programs and IRP policies. Laboratory and Branch Chiefs should function in an advisory capacity to the SD with regard to allocation of resources to tenured and tenure-track investigators within their respective programs.
- 2.16 Laboratory and Branch Chiefs should be given more flexibility to hire non-tenure track scientists and technical support personnel.
- 2.17 To strengthen IRP science, each Laboratory and Branch Chief should provide feedback on the performance of all investigators, including independent investigators, fellows, and tenure-track investigators, on a staggered basis, approximately two years prior to review by the BSC.
- 2.18 Laboratory and Branch Chiefs should undergo review by the BSC to evaluate both (1) the quality of science and (2) leadership, mentoring and administrative skills. Recommendations by the BSC should address resource allocations and position/title. The continued appointment

of Laboratory and Branch Chiefs should be based on these reviews, as judged by the SD.

- 2.19 A critical role of the Laboratory and Branch Chief is to stimulate collaboration among basic and clinical scientists. While the Committee recognizes that there are advantages and disadvantages to placing basic scientists in clinical laboratories, such recruitments should be rare. Collaborative research among basic and clinical scientists does not necessarily require the administrative placement of basic scientists in clinical laboratories. Such occasional placements should be stringently reviewed by the SD and BSC and justified by the training record of the mentor and by scientific and programmatic needs. Major consideration should be given to scientific excellence, programmatic linkages, the independence of the basic scientist, and the need for appropriate mentoring.

Role of Independent Investigators

- 2.20 Each independent investigator should develop his or her own research program of scientific excellence. It is desirable that each scientist's research portfolio include research projects that are consistent with the overall theme of the Laboratory or Branch.
- 2.21 Independent investigators should mentor young scientists by sharing scientific expertise and resources and should initiate collaborations with scientists from NIMH, NIH, and the extramural science community.
- 2.22 Independent investigators should display the highest standards of scholarship and should demand equally high standards of trainees. Mentors should emphasize the IRP's primary goal to be the generation of the highest quality science. There should be a reduced emphasis on publication rates and an increased emphasis on innovative science and relevance to the IRP mission.
- 2.23 The success of the SD in fostering excellent science, collegiality, and a collaborative spirit depends heavily upon participation by IRP staff. Independent investigators should direct their energies toward formulating, suggesting, and participating in mechanisms of change; supporting improvements initiated by the SD; providing constructive criticisms when appropriate; and ensuring testing or implementation of new policies and ideas.
- 2.24 Each independent investigator is responsible for the quality of his or her research. It is desirable for independent investigators to seek formal and informal evaluation of research proposals before they are initiated and when critical decision points arise, in addition to the BSC reviews. The SD may consider establishing mechanisms whereby some research plans are prospectively critiqued and revised, collaborative opportunities explored, and resource utilization optimized. This may be particularly valuable for clinical research protocols and for integrating clinical and basic science endeavors.
- 2.25 Each independent investigator is responsible for the optimal use of research resources. To help ease research cost burdens, scientists should share equipment, space, support staff, and other resources, when reasonable.
- 2.26 Independent investigators should formulate prospective research plans that can be justified and/or modified on a continuing basis. These research plans should be the basis for negotiating research projects for incoming post-doctoral fellows (see Chapter 5) and for presentation to the BSC (see Chapter 3).

2.27 Independent investigators should be responsible for shaping their own career development plans and discussing these with their immediate supervisors. This includes proposing strategies for continuing scientific education, updating techniques, planning sabbaticals and developing other proposals for continued career development. The IRP leadership should encourage and support career development, when feasible.

Quality of Science

From its inception 47 years ago, the NIMH IRP established a reputation for scientific excellence. As home to Nobel and Lasker prize winners, the IRP set the pace of research and pioneered new disciplines within the mental health field. The IRP also served as the center of training for a generation of researchers and clinicians, who proceeded to launch research programs at our Nation's distinguished universities.

Over the past decade or so, however, there has been an erosion in the overall quality of IRP science. There remain elements of brilliance, but there is also research of lesser quality, according to members of the Board of Scientific Counselors (BSC) and senior scientists within and outside the IRP. The erosion of IRP science has been accompanied by the emergence of a vigorous extramural research program, with many similar research capabilities. What was once a unique leader, dominating multiple fields, has lost its exceptional position.

To assume once again a position of preeminence, the IRP must achieve the highest standards of quality. These standards include national and international acclaim, high-quality publications, outstanding placement and achievement by former trainees, and recognized impact on the mental health field. The scientific review process conducted by the Board of Scientific Counselors provides an important means of ensuring high standards of quality. For this reason, the function of the BSC occupies most of the later sections of this Chapter.

Science at the IRP must be directed toward capitalizing upon emerging scientific opportunities. The opportunities include rapidly changing technology, an explosion of new research insights, and new molecular, cellular, and system level tools. As researchers seize these opportunities, they must be able to integrate emerging new disciplines with established fields. Today's research environment is markedly different from that four or five decades ago at the origin of the IRP. The nature of science is different, and the needs for review and evaluation are considerably greater. Faced with increasingly complex scientific questions and technologies, one individual is less and less able to expertly design, conduct, and judge all aspects of a research project. Collaborations reign: molecular and neurobiologists work side by side with social and behavioral scientists to understand the functions of genes and the role of the environment. Neuroimaging research, for instance, calls for collaborative input from the psychiatrist, radiologist, radiopharmacist, neuropharmacologist, cognitive psychologist, clinicians with imaging expertise, and data analysts. The individual scientist remains the source of scientific knowledge and advances, but the collaborative environment in which the scientist operates nurtures and intensifies the creative process. Among the greatest challenges is to create mechanisms to facilitate collaborative science in the context of individual resource allocations.

Letters from IRP staff: *"The issue of utmost concern to me is to ... restore the NIMH-IRP program to the outstanding program it once was from the good program it is today." "The IRP continues to lose ground to other institutions who are taking the initiative in brain research." "This panel has the opportunity to protect the IRP as a national asset to assure world class research survives the economic storms that are radically reshaping our health care delivery system." "The IRP is a treasure and should be the centerpiece of psychiatric research in this country."*

Other NIH-wide challenges arise from many quarters: difficulties in recruitment and retention (see Chapter 4), the decline in the quality of the training (see Chapter 5), the increasing costs and complexity of clinical research (see Chapter 6), growing financial debt for young clinical researchers, the new premium on research's cost-effectiveness, and the increasingly pejorative connotation of government service. The NIMH IRP leadership needs to respond to the host of opportunities, challenges, and changing circumstances by marshaling the IRP's distinctive resources, critical mass of researchers, capability to conduct long-term, high-risk research, access to inpatient research beds, and opportunities for interdisciplinary collaboration. Revitalization of the IRP means taking maximal advantage of these special resources, while being held to rigorous standards of research review and accountability.

Since the quality of science is intimately related to the quality of training, the IRP training experience must be exemplary: it should equip post-doctoral fellows with the ability to launch new research programs, initiate exploration of innovative ideas, and make enduring contributions to the mental health field. Because over half of the NIH research conducted intramurally is done by post-doctoral fellows and because the NIMH IRP trains a significant percentage of all NIMH-supported postdoctoral fellows,¹⁸ it is imperative that post-doctoral fellows are trained to conduct science of outstanding quality.

In short, renewal of the IRP is essential to attain the highest standards of scientific rigor and to launch the next generation of scientists and major breakthroughs. The IRP can occupy a distinctive position in the Nation's research portfolio by fostering outstanding science and by taking advantage of its special resources and emerging scientific opportunities. The Committee views as one of its greatest challenges to make recommendations to ensure that the highest quality of science is conducted by the IRP, within the context of a perpetually changing and increasingly complex biomedical research environment.

Letters from IRP staff: *"The NIMH IRP has trained many excellent scientists over the past thirty years. These individuals now direct their own outstanding laboratories at universities ... The strengths of the IRP, including the ability to move quickly on new breakthroughs ... balances the strengths of the extramural system, which emphasizes more conservative ... focus on established topics. Each approach depends on the existence of the other."*

The remainder of this chapter is devoted to the role of the BSC in evaluating the quality of IRP science, and it expands on new NIH-wide policies to enhance this process. In the spirit of renewal, the chapter builds on these new policies specifically by articulating new review criteria for scientific leadership. Finally, the chapter discusses other issues related to the BSC review. The positions expressed in this chapter were developed after receiving valuable guidance from a special panel of BSC Chairs from six NIH Institutes.

The Board of Scientific Counselors

Since 1956, NIH has reviewed its intramural programs by independent peer review through the BSC. The role of each Institutes's BSC is to evaluate the quality of science performed by each independent investigator and to make recommendations to the Scientific Director (SD). Composed mostly of extramural scientists, the BSC serves in an advisory capacity to the SD. Evaluations by the BSC are designed to help the SD promote and support the highest quality science and to shift resources from unproductive scientists to those performing research of the highest caliber.

¹⁸The Report of the External Advisory Committee of the Director's Advisory Committee (1994)

The BSC reviews each independent investigator in a Laboratory or Branch at least every four years. The BSC also evaluates tenure-track scientists, a review that is factored into the tenure decision made by the Deputy Director for Intramural Research (DDIR) (see Chapter 4). *The overall purpose of the BSC review is to assess the quality of scientists' research, with a primary emphasis on past accomplishments and productivity, and, to some extent, on future research plans.*

After its evaluation in 1994 of the BSCs serving all NIH IRPs, the External Advisory Committee (EAC) serving the NIH Director reported that BSC reviews lacked rigor, independence, and uniformity. The NIH Director responded by publishing a NIH-authored implementation plan in the same volume as the EAC report. The implementation plan described revisions in NIH's formal policies governing BSC reviews. The revised policies stipulated new procedures for the rigor, independence, and uniformity of BSCs, and follow-up requirements for the SDs.¹⁹ Some of the key policy changes were: (1) New members to the BSC should be appointed in a way that encourages independence from the SD; (2) BSCs should make explicit recommendations about resource allocations for each independent investigator; (3) Separate stewardship reviews of the SD should be conducted every 4-6 years on the basis of leadership, mentoring, and administration; and (4) The SD should keep the BSC abreast of actions taken or planned as a result of each review. These reforms climaxed in a sea change in thinking about the importance of the BSCs in ensuring that NIH intramural research is of the highest caliber and that resource allocations are tied to performance.

Letter from IRP staff: "... more oversight should be given regarding the quality of the science. The conundrum is to provide this oversight without squelching the flexibility and creativity inherent in the program."

The former Acting Director of NIMH sought to implement many of the new NIH policies, resulting in a more prominent role of the BSC reviews in the SD's decisions about resource allocation. While the Committee strongly supports the SD's actions, it posits that even more is necessary, as described in ensuing sections of this Chapter.

Review of Independent Investigators

The BSC evaluates independent investigators on the basis of scientific excellence, as measured by past accomplishments and, to a lesser extent, future research plans. Scientific excellence should be defined as science that is outstanding on an international scale. Excellence must permeate all elements of research: hypothesis development, experimental design, conduct, interpretation, and impact of results. Projects must be well-crafted, rather than diffuse. Risk-taking and creativity are vital ingredients.²⁰

Past accomplishments serve as the foremost criterion of scientific excellence. Longstanding NIH policy has emphasized past accomplishments—or retrospective review—in intramural, as distinct from extramural, review of science. Yet NIH policy also requires some consideration, albeit to a lesser degree, of the quality of future plans. Accordingly, the BSC serving the NIMH IRP has taken the initiative of spelling out the relative weight it places on retrospective versus prospective evaluation of each scientist: it generally apportions 60% of the review to retrospective accomplishments and 40% to prospective plans. The Committee supports this policy because the quality of planning is an integral component of the quality of science (see Chapter 2).

¹⁹NIH Manual Chapter 3005—"Review and Evaluation of Intramural Programs." (also contained in the External Advisory Committee Report.)

²⁰ See the NIMH BSC document, Review Criteria and Guidelines

Individual research projects are improved by in-depth consideration of the context in which each project is conducted. Detailed research plans improve research design and interpretability and assist in projecting needs for collaborators, resources, space, and trainees.

Stewardship Review

A stewardship review evaluates scientific leadership, mentoring, and administration. Such review is necessary because responsibility for sizable public resources carries a greater level of accountability. New NIH-wide policy requires stewardship reviews of the SD, but it does not expressly require stewardship reviews of the Laboratory/Branch Chief. Since Laboratory/Branch Chiefs also are responsible for a large public investment, the BSC serving the NIMH IRP takes the initiative to perform stewardship reviews of each Laboratory/Branch Chief. *The Committee supports stewardship reviews of Laboratory/Branch Chiefs by the BSC (as opposed to a distinct review body).*

With respect to stewardship reviews of the SD, several reports²¹ were critical of how they were conducted by BSCs across the NIH as a whole. These reports found that when BSC members were essentially hand-picked by each SD, the BSCs were too closely allied to the SDs to conduct objective appraisals of their performance. The NIH responded by altering the appointment process for BSC members and by requiring that the stewardship evaluation be separately carried out every 4-6 years by “an *ad hoc* committee, composed of at least four members ... and report to the ICD’s Advisory Council or Board, which will, based on the report of the *ad hoc* committee, make recommendations to the ICD Director.”²² *The Committee supports stewardship reviews of the SD by an ad hoc committee.* The stewardship review is distinct from review of the SD’s science, which is carried out by the BSC of the Institute in which the SD has a laboratory. (The Committee supports the recent practice of several Institute Directors establishing laboratories in another Institute to eliminate potential conflicts of interest with respect to resources.)

New Review Criteria for Scientific Leadership

The Committee proposes to establish explicit review criteria for the *scientific leadership* portion of the stewardship review of both the SD and the Laboratory/Branch Chief.²³ Four distinct criteria should be used to evaluate their scientific leadership over the research conducted within their supervision: (1) quality of science; (2) scientific vision; (3) relevance of projects to the Laboratory/Branch and to the mission of the IRP; and (4) utilization of the special resources of the IRP. These criteria are in keeping with the new mission statement recommended by the Committee (see Chapter 1). The remainder of the stewardship review is devoted to an evaluation of mentoring and administrative leadership. Each of these criteria is discussed below.

Quality of Science. The SD and the Laboratory/Branch Chief should be judged on the quality of science carried out within their supervision. For the SD, this refers to the scientific output of the IRP as a whole, and, for the Laboratory/Branch Chief, this refers to the output of their group. The body of research—as judged by past accomplishments—should be outstanding on an international scale. This is the

²¹A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? Institute of Medicine, National Academy Press, Washington D.C., 1988, and Report of the External Advisory Committee of the Director’s Advisory Committee, 1994.

²²NIH Manual Chapter 3005 -- “Review and Evaluation of Intramural Programs.” (also contained in the Report of the External Advisory Committee of the Director’s Advisory Committee).

²³While the Committee does not recommend that these criteria formally apply to reviews of independent investigators, they should be given some consideration

same high standard of research excellence used to evaluate independent investigators. Recent BSC reviews of independent investigators should be relied upon to help judge the overall quality of science.

Scientific Vision. The SD should be evaluated on the quality of his or her scientific vision. The formulation of a scientific vision was discussed in Chapter 2. It represents a crucial first step in generating a long-range plan that identifies scientific directions for the IRP. After the development of the plan, the SD should be judged on his or her effectiveness at carrying it out, as well as on flexibility in altering directions as new scientific opportunities emerge. The Laboratory/Branch Chief should be evaluated on his or her contribution to, and later fulfillment of, the long-range plan.

Relevance of Projects. Scientific leadership should be judged, in part, on the relevance of a body of research to the themes of the Laboratory or Branch and to the mission of the IRP. Determining relevance can be sometimes elusive but is aided in two ways: (1) the mission of the IRP is now clearly defined (Chapter 1) and (2) the long-range planning process (see Chapter 2) can be used to identify research themes of the Laboratory/Branch. The IRP needs to conduct ground-breaking research around specific research topics relating to mental disorders. *While not every project conducted within a laboratory is expected to meet the criterion of relevance, the collective output should be judged against this criterion.* Congress increasingly has come to require evidence of success at meeting statutory objectives related to understanding mental health and mental disorders. The IRP must be accountable to both Congress and to its constituencies, whose expectations for success at applied research also have risen. This is not the only review in which research relevance plays a role. The tenure decision, according to new NIH policy, is based in part on the relevance of the candidate's research to the laboratory (see Chapter 4).

Utilization of the Special Resources of the IRP. Research in the IRP also should take advantage of the IRP's special resources, including technologies, expertise, and availability of research subjects offered on the NIH campus (see Chapter 1). The campus is a national resource. The IRP should be a place where high risk, innovation, and collaborations are the hallmark. It should be a place where research complements the efforts of the extramural research program by addressing challenging questions that require either sustained, long-term effort, multidisciplinary expertise, unique patient populations, rapid development of hypotheses, technique development or refinement, high risk/ high benefit research, and a focus on national health problems, among other areas. The SD and the Laboratory/Branch Chief therefore should be judged on how well the program utilizes these special resources. *While not every project conducted within a laboratory is expected to meet this criterion, the collective output should be judged against this criterion.* Through the long-range planning process (see Chapter 2), the IRP leadership needs to identify and emphasize the types of projects that meet this criterion.

Mentoring. The SD and the Laboratory/Branch Chief should be evaluated on the quality of mentoring performed by independent investigators within their supervision. Mentoring has a profound effect on the future of the mental health field, given the size of the IRP's post-doctoral training program (see Chapter 5). The role of a mentor is to produce scientists who have the knowledge, skills, and experience to conduct independent research of the highest caliber.

Administration. The SD and the Laboratory/Branch Chief should be evaluated on the quality of their administrative leadership. This refers to a constellation of efficient practices in personnel, and in budget and space allocation. It refers to the organizational configuration of the IRP, the sharing of resources, and the ease of setting up collaborations within and outside of the IRP. It also refers to the quality of professional relationships between Laboratory/Branch Chiefs, the SD, the Institute Director, and the NIH leadership

(where appropriate). Finally, administrative leadership refers to establishing a climate of cooperation, collegiality, and openness of communication and decision-making.

Instructions to Reviewers and Scientists

BSC members need to receive explicit instructions about the criteria used to evaluate IRP scientists. The relative weight of each criterion should be clearly specified to BSC members and *ad hoc* members. Similarly, the scientists under review should receive detailed explanations about the review criteria. Some scientists, for example, are not aware of the relative emphasis on prospective versus retrospective review in BSC evaluations of the quality of their science. There are numerous other examples of flawed expectations by both BSC members and the scientists under review. In many instances, IRP scientists have not been adequately prepared for the stringency of the review, and their presentations often do not display sufficient attention to detail. Scientists often have not sought constructive criticism on prospective research plans. BSC report summaries for scientists often do not have sufficient guidance about resource allocation, strengths and weaknesses, and suggested directions. The depth and breadth of the focus have been miscommunicated or misunderstood. Younger scientists, in particular, often have received little guidance from their Section and/or Laboratory/Branch Chiefs in preparation for review.

In advance of a BSC review, it is critical that strict guidelines be prepared and communicated to IRP scientists. Scientists need to understand fully the criteria on which their science is judged. These criteria should cover questions such as: "Is this scientist a world leader in his field? Is the science groundbreaking, as well as excellent? Does the research need to be done? Does the research use the special resources of the IRP? Does the science fulfill, in part, the mission of the Institute? Is there an appropriate balance between 'solid' program efforts and higher-risk scientific initiatives or technique development?" Equally important, incentives need to be built into the review system to encourage innovative research, long-term commitments to projects, and greater risk taking. This may be accomplished to a limited extent by decreasing the emphasis on the number of publications, by encouraging competition for resources for more creative, collaborative, and higher-risk projects, or by otherwise increasing the value of participation in potentially high-impact research.

The BSC also should be aware of the IRP's short- and long-range goals developed by the SD's planning committee (Chapter 2). These plans may bear on the BSC's decisions with regard to facilitating mission-directed research, nurturing high quality science, and recommending resource allocations depending on risk/benefit assessments, disease-oriented research, or research questions that are critical to the mental health community. In this manner, the BSC should play a role in the implementation of the long-range plan.

Compliance with BSC Recommendations

Compliance with BSC recommendations is a responsibility that rests with the SD, who must exercise judgment in carrying them out. The SD's discretion is essential, for there inevitably may be problems with specific reviews. They include occasional conflicts between the research agendas of the SD and the BSC, as well as conflicts that arise naturally between experts who hold divergent views. Another area that merits consideration is the potential for future conflicts resulting from BSC review of the science conducted by Institute Directors who have laboratories in other Institutes. There should be external oversight of the stringency of such reviews and limitations on the growth of laboratories that fall between the administrative hierarchies of two Institutes.

When the SD takes action on BSC recommendations, scientific programs succeed or are supplanted by other programs; scientists may or may not be recommended for consideration for tenure; and scientists are reappointed or removed from scientific and leadership positions. In short, future scientific directions of the IRP are determined by the judgments of the BSC.

Composition and Independence

The NIMH BSC has 12 members who are extramural authorities in the mental health field. Each member serves a 5-year term. The Chairman of the BSC is appointed by the NIMH Director after consultation with the out-going chairman, the SD, and the DDIR. Present at each review are at least two members of the BSC and several (usually 8-18) *ad hoc* members—selected by the two BSC members—with expertise in the area under consideration. The *ad hoc* reviewers are screened by the Executive Secretary of the BSC (who currently reports to the SD) to ensure there are no conflicts of interest with scientists being reviewed (i.e., due to co-authorship, collaboration, mentorship, etc.). The dates and agendas for review are set 18-24 months in advance by the BSC and the Executive Secretary.

One pivotal issue that affects the quality of the BSC reviews concerns appointment of new members to the BSC. Earlier reports²⁴ criticized NIH's former policy of having the SD select new members who were then approved by the DDIR. In practice, this policy gave the SD a free hand to appoint new members, resulting in too much control by the SD and too little objectivity by the BSC. To ensure sufficient distance between the BSC and the SD, the NIH leadership issued a new policy requiring approval of new members by the NIH Director, after a careful process initiated by the BSC Chairman. The BSC Chairman solicits nominations, which are submitted to the Institute Director, who then forwards the names to the NIH Director for approval (Figure 3-1). This new procedure should be monitored carefully to ensure it achieves the desired outcome of an arms-length relationship between the SD and the BSC.

In some Institutes, the SD serves as the Executive Secretary for the BSC. Under this authority, the SD/Executive Secretary may be cast in multiple roles: structuring the review, selecting or screening ad-hoc committee members, articulating issues and charging the BSC with addressing specific questions, possibly participating in the review, editing the final report of the BSC, transmitting the outcome of the review to the Laboratory and Branch Chiefs, and, subsequently, evaluating and/or implementing the recommendations of the BSC. This model may not confer sufficient objectivity to the review process to allow the BSC to function optimally. Separation of the BSC review process from the program is desirable because it leaves the SD in the position of evaluating objectively BSC recommendations and deciding whether and how to implement them.

The BSC needs to have a continuous dialogue with the SD regarding all aspects of the program but without the SD's participation in actual reviews. Procedures have been established by other Institutes to guide the interaction between the SD and the BSC. They include the BSC meeting with the SD the night before the meeting to discuss special review issues; having the BSC Chair select all external ad-hoc reviewers; permitting the SD to recommend the exclusion of potential reviewers; and requesting both the SD and ID attend, but do not participate, in reviews.

The NIMH BSC review process conforms to NIH policy. However, the current Executive Secretary of the BSC operates out of the Office of the SD and administratively reports to the SD. The Executive Secretary should be administratively located outside of the SD's direct authority.

Timeliness and Follow-Up to BSC Reviews

Prompt and accurate feedback about the outcome of the BSC review is critical to a successful review process. Consistent with current NIH policy, oral feedback should be delivered to the SD at the end of the review meeting. The SD should then transmit feedback to Laboratory/Branch Chiefs, who, in turn, should inform

²⁴A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? Institute of Medicine, National Academy Press, Washington D.C., 1988; and Report of the External Advisory Committee of the Director's Advisory Committee, 1994.

tenured and tenure-track scientists. It should be recognized, however, that oral recommendations made by *ad hoc* reviewers are subject to revision by the permanent membership of the BSC, who must consider both the *ad hoc* reviewers' comments, short- and long-range programmatic goals, and resource distribution. Rapid transmittal of the BSC's report is crucial in enabling scientists to incorporate BSC comments into their research and to plan for recommended shifts in resources, staff or space. Once the report is final, the SD's response to the BSC recommendations should be prompt. The SD should implement changes recommended by the BSC or justify alternative courses of action at the next BSC meeting.

Some past NIMH BSC practices were impediments to the review process. Final reviews were often not written or forwarded for months, sometimes over a year, after BSC review. Consequently, opportunities were missed for BSC suggestions to have a significant impact on the research. Some BSC reviews were difficult to interpret and lacked clarity, explicit recommendations, and evaluative judgments regarding specific research projects and the quality of science. New NIH-wide policies now urge BSCs to make explicit evaluations and recommendations regarding resource allocation, space, promotion and tenure, and other critical issues and to submit a final report within two months of the meeting.

It is incumbent on the SD to ensure rapid transmittal of BSC reviews and to respond to the BSC's recommendations. The SD needs to decide whether and how to implement the BSC's recommendations. At times in the past, implementation of recommendations became so lax, according to previous reports,²⁵ that NIH responded by requiring SDs to report back to the BSC at its next meeting about actions being planned or already taken and about areas of agreement and disagreement. A written report from the SD to the BSC is now due within 6 months of the receipt of the BSC's report, according to the new NIH-wide policy for follow-up. It is also incumbent upon the BSC to conform to NIH-wide policies.

The panel of BSC Chairs convened by this Committee underscored that communications about the review should be prompt. Some panelists noted that results could be transmitted as early as the same day, with the bulk of the written report completed before the meeting is over. Delays due to editing, re-review by BSC members, and bureaucratic hold-ups have a deleterious impact on staff morale, foster distrust of the leadership, postpone critical decisions, and deprive scientists of potentially valuable information. Final reports should be in the hands of the SD and Institute Director within a few weeks of the review and 2 months after the meeting at the latest. The panel of BSC Chairs endorsed swift and directed actions with regard to resource allocations, promotion actions, appointments and re-appointments to positions. The SD must send the message that there are both negative and positive consequences to review.

Appeals Process

Procedures have been initiated at NIMH to ensure that BSC reviews are rigorous and independent, but are they infallible? The simple answer is no. There is always a possibility that a review is flawed. The most common flaws stem from reviewers' lack of expertise in a particular area, bias, and/or miscommunication between the scientist and the BSC. The result may be a review that is inappropriately negative or

Letters from IRP staff: "... the intramural scientist has very little recourse. While they may get the SD to agree (verbally) the review was inappropriate and/or inaccurate ... the report is final ... This is fatal to the scientist's career at the NIH and certainly can influence job prospects elsewhere." "A system of re-review should be built into the Scientific Counselors' process."

²⁵A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? Institute of Medicine, National Academy Press, Washington D.C., 1988; and Report of the External Advisory Committee of the Director's Advisory Committee, 1994.

inappropriately positive.

There needs to be a set of procedures for a scientist or Laboratory or Branch Chief to appeal the recommendations of the BSC in the event of an adverse review. This was also the conclusion of the blue ribbon panel review of the NCI.²⁶ The key is to permit appeals in a timely manner, so as not to delay the issuance of the BSC final report. The current NIMH BSC considers letters of appeal in the next cycle of reviews (3 years later), not in the review cycle that is being called into question. The NIMH leadership should develop procedures for Laboratory/Branch Chiefs to appeal to the SD a review of themselves or of an independent investigator within their group before the issuance of the final report. However, re-reviews should be the exception rather than the rule.

Independently Funded Research

When IRP scientists receive significant outside sources of research support, such support—for equipment, personnel, space, and other resources—needs, at a minimum, to be approved by the SD (before funds are accepted), and the supported projects need to be evaluated through the regular BSC review process. The receipt of unreviewed support, from foundations, philanthropies, and industry, might easily be construed as a means to circumvent the BSC review process. Circumventing peer review undermines the reputation of the IRP, morale, and, ultimately, undermines recruitment and retention. Outside sources of support almost always carry hidden or indirect costs to the IRP, thereby diminishing the availability of resources to others. On the other hand, independent support is encouraged, especially in an era of constrained resources. Independent funding may be a means of supporting risky and unorthodox research but that in retrospect proves to be visionary. The history of science is replete with such instances.

Negative Reviews

To encourage maximal productivity and scientific excellence, procedures need to be in place to help the SD take action on a negative review forwarded by the BSC. The SD and BSC should clearly indicate the areas of deficiencies and propose remedial actions. Such actions may include recommending sabbatical training, narrowing the focus of the Laboratory or Branch, using special incentives to encourage excellence, reducing staff, trainees, resources and/or space, and proposing a plan for reevaluation within 2 years that specifies the criteria for successful assessment.

When the BSC finds deficiencies serious enough to warrant severe reductions or closure of a laboratory, the SD and BSC should clearly define the areas of deficiencies and propose remedial or alternative actions. Such actions may include those listed above; however, re-evaluation should occur within 1 year of the issuance of the BSC report. A rapid appeals process, involving both internal and external reviewers, should be established and completed no later than 6 months after the issuance of the original BSC review. Decisions to enforce laboratory closure should be accompanied by a detailed phase-out plan to be completed not less than 1 year from the date of re-review. New positions may be created to optimize use of the skills of the scientists, and the NIMH should encourage retraining and support relocation.

Conclusions

The performance of high-quality science is the source of the IRP's most significant strength. While the history of the IRP is full of examples of exceptional achievement, more recently there has been an erosion in the overall quality of science. For the IRP to return to a position of preeminence, IRP scientists must conduct science of the highest quality and must undergo rigorous review by the Board of Scientific Counselors. The

²⁶A Review of the Intramural Program of the National Cancer Institute by the Ad Hoc Working Group of the National Cancer Advisory Board, June 26, 1995.

BSC also must hold the SD and Laboratory/Branch Chiefs to explicit criteria in stewardship reviews. For that purpose, the Committee is providing a new set of criteria for reviewing scientific leadership. Understanding of review criteria is essential, as is action taken to carry out the BSC's recommendations.

Recommendations

- 3.1 The IRP leadership should promote a steadfast commitment to the pursuit of scientific excellence. Scientific excellence, as judged by the Board of Scientific Counselors (BSC), should be the foremost determinant of resource allocations by the SD to each tenured and tenure-track scientist.
- 3.2 The Committee endorses the NIMH BSC policy of performing stewardship reviews of Laboratory/Branch Chiefs' leadership, mentoring, and administration separate from reviews of the quality of their science. The Committee also endorses the NIH policy of requiring a separate stewardship review (apart from a scientific review) of the SD every 4 to 6 years by an *ad hoc* committee of the National Advisory Mental Health Council.
- 3.3 The stewardship evaluation of the SD and Laboratory/Branch Chiefs should include four distinct criteria pertaining to scientific leadership: (1) quality of science; (2) scientific vision; (3) relevance of projects to the Laboratory/Branch and to the mission of the IRP; and (4) utilization of the special resources of the IRP. The stewardship evaluation also evaluates mentoring and administration.
- 3.4 In advance of reviews, the BSC should inform all IRP scientists about the requirements for written submissions, verbal presentations, and review criteria, including the definition of scientific excellence and the relative emphasis on retrospective versus prospective evaluation.
- 3.5 The SD should be free to evaluate objectively the BSC's recommendations and to decide on appropriate courses of action. This can only occur if there is a separation between the review process and program under review. The SD and, to the extent possible, the NIMH Director, should attend the BSC meetings. However, they should refrain from participating in the review, expressing judgments about the quality of science, and commenting on the quality of an individual scientist's research.
- 3.6 The SD should not play a significant role in the appointment of BSC members or *ad hoc* reviewers. The SD should clarify issues for the BSC to address, provide supplementary information to the BSC as needed, and transmit the results of the review to Laboratory and Branch Chiefs.
- 3.7 To encourage separation of the program and the BSC review, the BSC Executive Secretary should not be under the direct authority of the SD.
- 3.8 When the BSC evaluates Laboratory and Branch Chief's scientific work and stewardship (leadership, mentoring, and administrative performance), it should issue two distinct sets of recommendations: one set on changes in resource allocations based on the review of the science, and a second set on reappointment, promotion, or demotion depending on the results of the stewardship review.

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- 3.9 BSC reviews should be clear, frank, and direct specific comments to each scientist under review. The review should address both the quality of science and the allocation of resources. Separate from the quality of science, specific recommendations should be made about increasing, decreasing, or not changing resources, space, staff, and other allocations.**
- 3.10 Attendance at BSC reviews may be a useful educational tool to inculcate standards of scientific excellence among younger scientists. However, the BSC should retain the authority to request that either individual presentations or entire reviews be conducted in the absence of other IRP staff and colleagues. A private format may facilitate more open discussions between the BSC and the scientist.**
- 3.11 The outcome of the BSC review should be transmitted orally to the SD immediately after the review. Also it is recommended that the SD transmit, in an accurate and timely manner, the outcome of the review to Laboratory/Branch Chiefs, who inform tenured and tenure-track scientists.**
- 3.12 The written BSC report should be issued within weeks but no later than 2 months of a BSC meeting, in accordance with NIH policy. This policy requires that the report be transmitted in its entirety to all BSC members, the SD, and the NIMH Director. The SD then is required to transmit appropriate sections to the Laboratory/Branch Chief.**
- 3.13 The NIMH leadership should develop procedures for Laboratory or Branch Chiefs to rapidly appeal to the SD their BSC review or a component of the review pertaining to scientists in their group before the issuance of the BSC's final report. Once an appeals process is formulated, the SD should decide whether an appeal is justified and whether another review should be conducted. It is anticipated that re-reviews will be rare.**
- 3.14 The SD should respond swiftly to the recommendations contained in the final report of the BSC. The SD's actions, or plans, to implement BSC recommendations should be conveyed in writing to the BSC, ID, DDIR, and NIH Director within 6 months of the receipt of the BSC report, all in accordance with NIH policy.**
- 3.15 The NIMH leadership should develop a set of procedures or guidelines to be implemented when the BSC issues negative reviews. These guidelines should include procedures to facilitate the closure and/or downsizing of laboratories that are found to have severe deficiencies.**
- 3.16 When scientists seek significant external funding for research conducted in the IRP, the SD or delegate should approve the nature and extent of support before it is accepted. The SD and the BSC should ensure that the externally funded research is subject to review through the regular BSC review process.**
- 3.17 The Committee is concerned about the lack of clear authorship policies. The IRP leadership should ensure the development of authorship policies in a manner that meets current standards within the scientific community. In general, authorship should be accorded only to those who provide key intellectual and scientific contributions.**
- 3.18 Independent investigators should recognize that the BSC's judgment of scientific excellence is determined by the quality, not the number, of publications.**

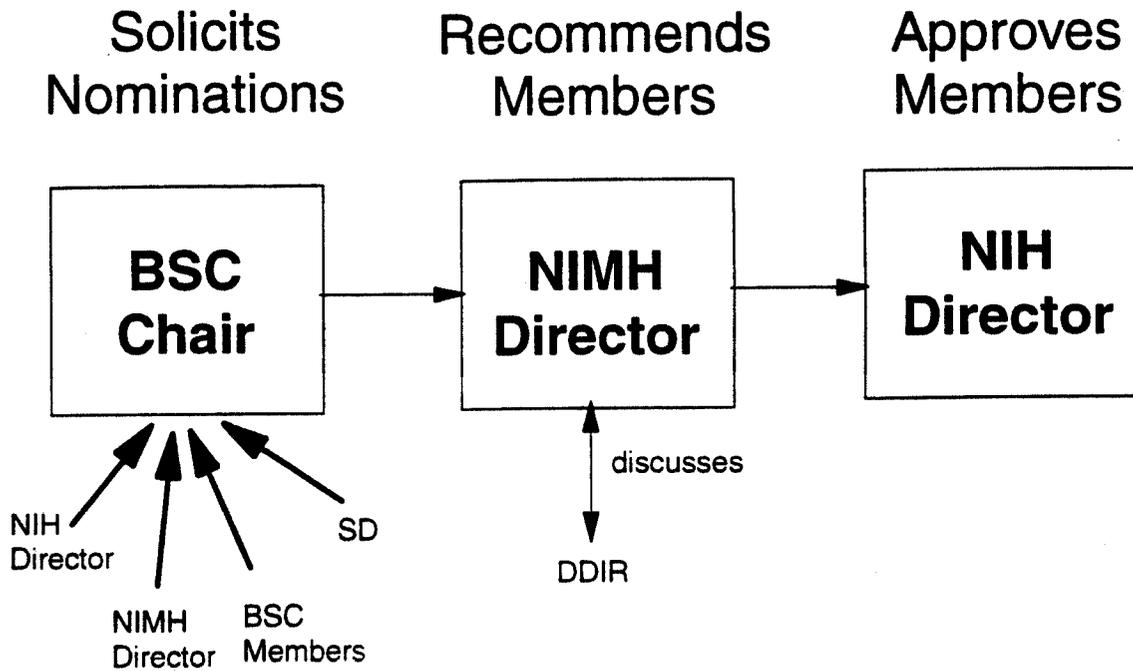


Figure 3-1. Appointment Process for New Members of Board of Scientific Counselors (BSC) *Source: NIH Manual 3005--Review and Evaluation of Intramural Research Programs, Revised, 1994.*

Recruitment, Retention, and Retirement

Introduction

Successful research organizations retain vitality by balancing the sometimes conflicting demands of recruiting talented scientists, retaining outstanding scientists, and the changing of the guard. In recent years, NIH as a whole has been beset by perceptions that its attractiveness has receded and that some of its scientists have been supported too long while performing science of insufficiently high quality. NIH has experienced difficulty in recruiting outside scientists at all levels, despite its many advantages for conducting research. Some of its own most ambitious and talented mid-career and senior scientists have left or have considered leaving. And some of its senior scientists who are considering retirement—or careers beyond research—feel stymied by rigid government rules.

The NIH leadership has acted to remedy some of the problems concerning recruitment, retention, and retirement. New tenure-track policies have been established to offer tenure-track scientists more competitive salaries, benefits, and a firm commitment of independent laboratory resources. New personnel and salary systems have been authorized to enhance compensation for both outside physician recruits and some scientists already on staff. Finally, there is increasing recognition of the need to offer options for reassignment or retirement of independent investigators.

Recruitment

Since the inception of the IRP, there has been a strong bias favoring home-grown scientists in lieu of outside recruitment.²⁷ Many scientists who began their careers with the IRP as post-doctoral trainees hoped to stay until retirement, as was true for other NIH Institutes. Many extended their fellowships beyond reasonable post-doctoral training years. A few (< 1 percent) eventually received tenure. Section Chiefs were promoted through the ranks from the pool of tenured investigators. Laboratory and Branch Chiefs were selected from the pool of Section Chiefs. In short, outside recruitments were few and far between.²⁸ In the past five years, the NIMH IRP recruited from outside of the NIH only one of its four newly tenured scientists. The lack of outside recruitment was, in part, a reflection of the comfort and familiarity with the training of its post-doctoral fellows, as well as of the difficulty of attracting scientists from the outside (see later paragraphs). Yet, for any research organization, failure to recruit new talent tends to produce insularity and deters fruitful interchange with the broader scientific community.

To remedy the lack of outside recruitment, it is necessary to garner positions, space and accompanying resources to enable the new SD to attract first-class scientists to the IRP. This will infuse the program with

²⁷Over time, some post-docs who were promoted to tenure began to work under the direction of their Laboratory/Branch Chiefs, instead of pursuing their own research programs. This practice contributed to the growth of fiefdoms, which are discussed in Chapter 2.

²⁸NIMH routinely brings researchers from the extramural community to its laboratories through time-limited appointments, but these appointments are considered temporary personnel (e.g., Special Experts, IPAs).

fresh perspectives and skills.

Recruitment to tenure-track positions is now governed by a new NIH-wide policy. NIH created this policy in 1994 in an effort to stimulate outside recruitment, establish uniform review criteria, promote scientific autonomy, and ensure NIH-wide review of all candidates. The policy provides a clear set of procedures to steer the 6-year tenure-track process, including the requirement for a national search and mid-course review.²⁹ The final decision to tenure a scientist is made by NIH's Deputy Director for Intramural Research (DDIR), after receiving recommendations from the Institute's Board of Scientific Counselors, its Promotion and Tenure Review Committee, Scientific Director and Institute Director, and, finally from a new NIH-wide Central Tenure Review Committee. Formerly, the decision to tenure was made within an Institute with the approval of the NIH Board of Scientific Directors. According to the new policy, tenure candidates are evaluated on the scientific merit of their research, the contribution of their work to their laboratory or section, scientific independence, productivity, leadership, potential for sustained intellectual growth, and other contributions to the NIH IRP.

What attracts outside recruits to the IRP? Of paramount importance is the ability to conduct full-time research, freed from the constraints of teaching and grant writing. Researchers also are drawn to NIH's seemingly unlimited research opportunities, state-of-the-art facilities, stable salaries and budgets, retrospective review, and opportunities for collaboration. These considerable advantages are tempered by some of NIH's disadvantages: an onerous bureaucracy, cumbersome procurement procedures, rigid personnel rules for hiring and firing, restriction on travel and outside activities, and a lack of portable retirement benefits for those under the Civil Service Retirement System or the Commissioned Corps retirement system.

Tenure-track candidates gain the benefits of a guaranteed salary, a defined research budget, space, and personnel for a maximum of 6 years before the tenure decision is made. These are key to launching an independent research portfolio. By contrast, less than half of tenured academicians receive a full salary from their institution.³⁰ Mid-career recruits to the IRP also can enjoy the benefits listed above, yet in rare cases, need not go through the tenure-track process. A direct hire to tenure can occur under the new NIH policies, as long as the NIH Central Tenure Committee recommends the individual and the DDIR approves.

The competitiveness of NIH IRP salaries has long been a source of frustration in recruitment, but the situation appears to be improving. Two new systems recently have been inaugurated: the Senior Biomedical Research Service and Title 38. These systems provide for salaries of up to \$148,000 and \$200,000, respectively. Along with three existing personnel systems, these two systems are available to external recruits and internal scientists, depending upon their qualifications and the number of available slots. For simplicity, the salary ranges and other features of all five systems are presented in Table 4-1. One feature especially noteworthy in the context of recruitment is that most systems allow *recruitment bonuses of up to 25 percent of base pay*.

The Senior Biomedical Research Service (SBRS) was authorized in legislation passed in 1992, but bureaucratic disagreements between NIH and the Office of Management and Budget prevented its implementation until 1995. There is a statutory limit of 500 SBRS positions available to the Department of Health and Human Services (the parent agency of NIH), of which NIH receives the lion's share of 350. SBRS positions are highly coveted because of high salaries, flexibility in promotions, and portable retirement

²⁹For a complete explanation of the new tenure-track policy, see the Appendix to the Report of the External Advisory Committee of the NIH Director's Advisory Committee, 1994.

³⁰Report of the External Advisory Committee of the NIH Director's Advisory Committee, 1994.

benefits. This last provision allows outside recruitments, mostly from academia, to accrue government retirement benefits into their previous TIAA-CREF or other retirement system.³¹ The first 30 SBRS positions recently were awarded to highly deserving internal NIH IRP scientists after a competitive process. Two scientists from the NIMH IRP were among the first 30 recipients. Another 30 SBRS positions are being garnered for outside recruitment to all NIH Institutes.

Title 38 is a means of granting supplemental pay to physicians. "Title 38" refers to the title of the U.S. Code pertaining to the Department of Veterans Affairs (VA), which was given this statutory authority to help attract physicians. NIH sought, and recently received, approval to apply this authority to physicians at the Clinical Center who spend the bulk of their time with patients in a NIH protocol. Title 38 is not available to Ph.D.s nor to physicians engaged in other types of research. *Currently, seven NIMH scientists are receiving supplemental pay under Title 38.* Title 38 is not an entire personnel system; rather it is a special pay scale overlaid upon Civil Service base pay and rules. Seven or eight factors dictate the amount of what is termed "Physician Special Pay" under Title 38. The largest determinant is the area of specialization, with radiologists and anesthesiologists receiving the highest pay increases and psychiatrists receiving among the lowest. The variation reflects the VA's historical difficulty with recruiting different types of specialists.

The addition of SBRS and Title 38 to the complement of NIH personnel and pay systems enhances the attractiveness of working at the NIMH IRP. An examination of Table 4-1 reveals that independent investigators have the potential to command high salaries, although Ph.D. salaries lag behind those of M.D.s by about \$20,000-\$30,000. The discrepancy between Ph.D. and M.D. salaries also holds true for positions at academic medical centers.³² In summary, recruitment to positions at NIH is improving by virtue of new personnel systems, which offer higher salaries and greater flexibility.

Retention of Tenured Scientists

Retaining productive mid-career and senior scientists within NIH is as important as recruiting new scientists from outside NIH. A healthy mix of talent from both outside and inside is needed for scientific excellence. The NIH has been losing some of its brightest stars to academia and industry. By seeking new pay authorities and by other initiatives, the NIH leadership is to be credited with attempting to reverse this trend. Unfortunately, scientists—particularly Ph.D.s—who receive salary and benefits under the conventional personnel systems are still encumbered by rigid rules governing base pay, promotions, and retirement.

First-rate, highly productive scientists can be encouraged to remain at the IRP through promotions and/or conversion to more lucrative pay and personnel systems, such as Title 38 and SBRS. However, the limited number of SBRS positions or the strict eligibility criteria for Title 38 limit their applicability, especially to Ph.D. scientists. It is incumbent on the Scientific Director and other managers to take advantage of other avenues to retain excellence.

There are several ways to augment salaries under existing Civil Service rules, but they do not enjoy widespread use. Retention bonuses of up to 25 percent of base salary are available to positions under the Civil Service (General Schedule), Senior Executive Service (SES), and Title 38.³³ *Yet only one tenured scientist at NIMH is currently receiving a retention bonus.* Retention allowances can be awarded for up to

³¹The details of how this is to be accomplished have yet to be determined, according to Stephen Benowitz, Director Of Human Resources, NIH.

³²Faculty Salary Survey, January, 1996, Association of American Medical Colleges

³³Retention bonuses are not authorized under SBRS.

Table 4-1. Personnel Systems for Tenured Scientists at NIH
Source: Stephen Benowitz, Director of Human Resources, NIH

Features	Civil Service General Schedule Grades 13-15	Title 38	SBRS	SES	Commissioned Corps
Salary Range:Ph.D.	\$52,900 -- \$95,500	Not Applicable To Ph.D.s	\$73,935 -- \$148,400	\$103,897 -- \$122,700	\$60,000 -- \$120,000 ¹
Salary Range:M.D.	No Physician Bonus (but some incentives)	\$54,600 -- \$200,000	\$75,935 -- \$148,400	\$103,897 -- \$144,800	\$90,000 -- \$150,000 ¹
Ease Of Promotion	Rigid Rules	Some Flexibility	Complete Flexibility	Some Flexibility	Rigid Rules
Promotions Approved by	DDIR ²	DDIR ²	NIH Director ²	NIH Director ²	Surgeon General
Recruitment and Retention Bonuses	Up To 25% of Base Salary	Up to 25% of Base Salary	Not Applicable	Up to 25% of Base Salary	Not Applicable
Special Conditions	None	Supplemental pay scale for Civil Service clinicians and epidemiologist s running clinical trials	Limited number of SBRS positions	Limited number. SES is being phased out of IRP	Free Health Benefits and Excellent Retirement Benefits after 20 years
Retirement System	CSRS or FERS ³	CSRS or FERS	CSRS or FERS	CSRS or FERS	Commission Corps Retirement System
Length of Appointment	No Limit	No Limit	Renewable 4 Year Terms	Recertifica- tion Every 3 Years	Up to 30 Years
Total NIH Allotment	Subject to FTE Ceiling	Subject to FTE Ceiling	300 -- 350 ⁴	200	Subject to FTE Ceiling
Authority to Reassign or Dismiss	Manager Within Institute	Manager Within Institute	NIH Director ³	NIH Director ³	Manager and Office of Surgeon General

¹Includes Housing Allowance And Cost of Living Allowance

²Requires concurrence of Scientific Director and Laboratory/Branch Chief

³Civil Service Retirement System (CSRS) or Federal Employee Retirement System (FERS)

⁴ Figures pertain to the next 3-4 years, but only 30-60 awarded thus far

3 years to match an attractive outside job offer. However, in most instances the scientist must provide evidence of a *bona fide* job offer. The problem is that academic institutions are hesitant to offer a position if they believe their efforts are used instead to justify a retention bonus. More recently, retention allowances can be given to a scientist whom the Scientific Director believes is being actively recruited, even though an offer is not in hand. It may be necessary to address retention more directly and without resorting to subterfuge, no matter how well-intended.

NIH managers also have at their disposal various cash awards, bonuses, and other mechanisms to increase compensation. Scientists are permitted to supplement their salaries by accepting honoraria for outside speaking engagements when they are on approved leave and the subject matter does not relate directly to their current government-supported research. These conditions, although still very restrictive, amount to a relaxation of an earlier ban, which precluded the receipt of honoraria under any circumstances. Staff also are permitted, with approval, to receive supplemental income from outside consulting and private practice.

Pathways for Senior Scientists

The history of science is replete with inspiring examples of Herculean stamina and decades of stellar productivity well beyond the age at which many retire. For example, the doyens of NIMH—Drs. Julius Axelrod, Seymour Kety, and David Shakow—continued to labor in the laboratory long after retirement. Nonetheless, the fact remains that few scientists stay at the pinnacle of productivity throughout their careers.

Exit pathways were rarely mentioned at NIH, especially during an era of explosive growth. Times have changed, resources are more limited, and NIH as a whole is confronted with a growing population of senior scientists for whom there is no mandatory Federal retirement age. The culture of NIH has not yet come to terms with how to pave the way for the departure of respected mid-career or senior scientists no longer producing research of the highest caliber. Some senior scientists would like to step down but feel hampered by the strictures surrounding the receipt of retirement benefits. Civil Service retirement benefits generally are available after 30 years of service, and early retirement comes with a lower annuity. Others may have the all too familiar human frailty of being unable to face their own decline.

Letters from IRP staff: *“There appears no good, ‘clean’ mechanism to ensure transition of aging, respected, productive scientists from positions of power to ... positions that promote continued productivity.” “... some scientists are being supported long after their productive years, and ... new scientists are difficult to recruit.”*

NIH does offer alternative pathways to scientists, but they have not been capitalized upon. These alternative pathways are an important means of reclaiming resources for recruitment, retention of more productive scientists, and improving the overall morale of the organization. The options for departure include retirement, IPAs, reassignment, and resource reduction, each of which is described below.

Voluntary retirement from NIH can be the most desirable from the perspective of management and the scientist. Retirement may be accompanied by generous annuities, depending on the personnel systems, length of service, and grade level, among other factors. The Commissioned Corps, which is more available and attractive to M.D.s than to Ph.D.s, is considered to have the most generous personnel system because, like the military, it is based on a 20-year length of service and a non-contributory retirement system.³⁴ Civil Service

³⁴ This means that the government, rather than the employee, completely pays toward retirement benefits.

retirees obtain benefits from the traditional Civil Service Retirement System³⁵ or the newer system called FERS (the Federal Employee Retirement System)—which is a portable retirement account that supplements Social Security benefits.

When the most distinguished scientists retire, they are eligible for status as “Scientist Emeritus.” This is an honorary position approved by the NIH-wide Board of Scientific Directors. It carries no salary or research budget, but it does confer such benefits as office and/or laboratory space, library privileges, and a parking sticker. Several NIMH scientists hold the distinction of “Scientist Emeritus,” including Drs. Julius Axelrod, Seymour Kety, Giulio L. Cantoni, Paul McLean, and Marian Yarrow.

An IPA is a 4-year visiting research position, the title of which stems from the authorizing legislation, the Intergovernmental Personnel Act. Most NIH managers are familiar with IPAs because they are used routinely to enable researchers from universities and non-profit organizations to join a NIH laboratory on a temporary basis. What managers may not be aware of is that IPAs can be used in reverse: to send NIH scientists to universities and non-profit organizations. NIMH has not used IPAs for this purpose.

Under an IPA, NIH pays a negotiable portion of salary and benefits, ranging up to 100 percent. The years spent away still accrue toward retirement. Laboratory resources, in the form of equipment or personnel, do not usually accompany the IPA recipient. The IPA can be used for NIH scientists to explore alternative careers, such as teaching, public education, health care delivery, health policy, and/or administration. It also can be used as a sabbatical to renew or broaden scientific skills. Finally, an IPA can be structured to take place during the 4 years preceding planned retirement, thus offering earlier departure from the NIH. The outside organization receiving the IPA obtains the benefits of the individual’s expertise at a negotiable cost in salary and benefits. In short, the IPA represents an underutilized mechanism to the benefit of NIH, the outside organization, and the scientist. It offers departure with dignity and opens alternative career pathways for mid-career scientists and those nearing retirement. It deserves greater use in appropriate personnel situations.

Another option is reassignment, the transferring of an employee to another position within NIMH. It is an ideal option for the scientist who is interested in pursuing other positions, such as grant administration. It also is ideal for the Institute if the individual’s skills are needed elsewhere. If the scientist does not want to be reassigned, however, the manager still has full discretion to make the reassignment within the Institute,³⁶ with little appeal opportunity. NIH managers understandably have not been comfortable with exerting their reassignment authority. However, this approach may be reasonable for scientists whose research receives negative review.

The final option is to reduce an independent investigator’s resources, including the closing of a laboratory. Confronted with unfavorable BSC review and failures to rectify the deficiencies, the SD can take action to curtail an investigator’s laboratory budget, space, and/or personnel. The SD has the authority to make these resource reductions or, if necessary, to eliminate them entirely, leaving the investigator only with salary and office space (as opposed to laboratory space, staff, and research budget). The SD’s discretionary authority must be exerted with care. There are instances in which the BSC review can be flawed, particularly when risky projects do not generate results in the expected timeframe. Specific procedures for handling resource reductions are outlined in Chapter 3.

³⁵ This system was discontinued for new recruits in 1984 with the inauguration of FERS, although CSRS still remains in effect for those hired earlier.

³⁶ Commissioned Corps personnel, on the other hand, can be reassigned to any Government office.

Conclusions

The Committee supports actions to garner through attrition a number of positions for outside recruitment. The availability of new payment and personnel systems—Title 38 and SBRs, respectively—markedly aid recruitment. These new systems also can be used to retain the best scientists at NIMH; however, because of limitations in the number of slots or in eligibility, they may not be sufficient for retention. There are other vehicles, including retention bonuses, that could be used more frequently to support excellence. Reassignment or retirement of scientists whose research is not of the highest quality is one means of directing resources to retention and recruitment, as long as such actions are handled in an equitable and dignified way. There are a variety of exit pathways, but they rarely have been used. The culture of NIH, which has been accustomed to growth, needs to reckon with an era of limited resources.

Recommendations

- 4.1 The IRP leadership should recruit outstanding scientists at all levels. The leadership should take maximal advantage of new and existing personnel mechanisms and the expertise of NIH personnel specialists to offer highly competitive salaries, recruitment bonuses, and research resources (e.g., space, personnel, and equipment).
- 4.2 The IRP leadership should retain its best scientists through existing personnel mechanisms, such as retention allowances and cash awards. The judgment of the SD that the investigator is being actively recruited by another organization should be sufficient to award a retention bonus. Should existing mechanisms prove insufficient, especially for Ph.D. scientists, the IRP leadership should seek to authorize new mechanisms.
- 4.3 To reclaim resources, the IRP leadership should become knowledgeable about the graceful exit pathways that exist and should work with the scientist to select the appropriate option.

Training and Mentoring

The NIH intramural program serves as a training institution for thousands of basic and clinical researchers. Numerous NIH alumni now contribute to academic and industry research programs world-wide. In addition to training U.S. citizens, a significant portion of trainees are foreign nationals.³⁷ The NIMH IRP alone trains approximately 200 post-doctoral fellows at a given time, about 45 percent of whom are non-citizens. As an international resource for research training, NIH must ensure that its tradition as fertile ground for post-doctoral training continues into the next century.

Recently, NIH intramural training programs have experienced strain: they have been compelled to compete more aggressively for excellent post-doctoral applicants; they have seen fewer NIH alumni placed in traditional academic and clinical research positions; and there are concerns about inconsistent quality of training and the difficulty of fellows in competing for jobs when leaving the NIH. NIH has responded by the creation of an Office of Science Education, among other steps. For its part, the NIMH IRP established two internal committees to address fellows' concerns. One is a Fellows Committee made up of post-doctoral fellows. The other is a Fellowship Education and Training Committee made up of both fellows and independent investigators. Among the recommendations of these two committees are required performance reviews of fellows and mentors, the creation of a Director for Training, an Office of Education and an Advisory Board, a research curriculum for clinical fellows, and grantsmanship training. Our Committee endorses these recommendations and applauds the steps taken to implement them, including the recent appointment of a Director for Training. The Committee believes that ongoing changes can contribute to improving training in the IRP. However, their impact needs to be evaluated, and additional concerns need to be addressed.

A successful post-doctoral experience is invaluable for refining skills, scientific concepts, and future research directions. Fellows come to the NIMH IRP from a wide range of backgrounds and with considerable differences in career expectations. Formal, didactic training may be useful depending on the needs of each fellow and must be balanced with the invaluable experience of conducting top-quality research. Clearly, no single program can be suited to the research training needs of all. Training goals and strategies should be customized for each fellow to provide an enriching research experience, including exposure to NIH's special resources and environment. Early in the fellowship experience, each mentor and fellow should mutually agree upon short- and long-term goals and strategies to achieve them.

The Committee identified six interrelated concerns: (1) The focus of the fellowship needs to be on training, rather than technical support; (2) A formal manpower assessment needs to be conducted regarding whether more technical and scientific support positions, distinct from training positions, are needed to enable fellows and mentors to concentrate more on training; (3) Senior fellows need to be in a better position to compete for academic positions by acquiring experience in teaching and grantsmanship; (4) Fellowships need to be made more attractive in order to attract the highest-caliber candidates; (5) The NIH Clinical Center, which offers an ideal clinical training environment, needs to be exploited to revitalize clinical research training in mental health; and (6) The fellowship program as a whole needs to be evaluated in terms of quality, size, and the distribution of basic and clinical fellows. Each of these topics is discussed on the following pages.

³⁷From 1985-1995, foreign nationals accounted for 41.0% of IRP trainees across all NIH Institutes.

Post-Doctoral Training Positions

NIMH trains two categories of post-doctoral fellows: training fellows and service fellows. Each of these categories is subdivided into specific positions that carry discrete salary ranges depending on the prior level of post-doctoral experience (Table 5-1). As training fellows progress and are promoted to service fellows,³⁸ they assume increasing responsibility and independent stature. In the beginning, many assume routine research support activities associated with ongoing projects in their Laboratory or Section. With more experience, they initiate and execute independent research projects under the guidance of their mentors. Some senior fellows eventually oversee research conducted by less-experienced fellows. However, some post-doctoral fellows perform an inordinate amount of technical support, which may deprive them of the opportunity for a rich and rewarding post-doctoral training experience.

Because of Federal Civil Service policies, the hiring of technical support staff is permanent and is counted toward an FTE ceiling. Greater reliance on post-doctoral fellows, which are temporary positions, for technical support roles can reduce or avoid the need for a permanent hire. The amount of technical support actually performed by fellows depends to a great extent on their immediate supervisors or mentors and the availability of qualified technical support staff. A balance needs to be found between fellows' research support and training roles to ensure that a laboratory's research proceeds without the exploitation of fellows, who require training and experience in independent research (see below). Mentoring and training must be high priorities for the IRP and cannot be diluted efforts.

Staffing Needs For Technical and Scientific Support

In renewing excellence in mentoring, senior scientists need to assume a greater time commitment to training. Outstanding mentoring is a time- and energy-intensive commitment that inevitably reduces their time for research. Yet the Committee believes that the investment in training yields invaluable long-term dividends for the trainee, the mentor, and the field. At the same time, the decreased length of fellowship terms and the increased demand for didactic and other training experiences will decrease the amount of time fellows can devote to their laboratory. Engaging in competition for small grants and in the conduct of independent research will further curtail fellows' contribution to the laboratory. Improving the training program while meeting the needs of the laboratory may require investment in hiring more technical and support staff. However, FTE ceilings and Civil Service requirements for permanent hiring of technical support staff limit the IRP's personnel flexibility. A formal assessment of the need for increasing numbers of technicians, permanent professional support and technical staff, and non-permanent, term positions should be conducted by the SD in concert with Laboratory/Branch Chiefs and independent investigators. This is a NIH-wide issue.

Letters From IRP Staff: *"Young scientists are being employed as pawns in the game of obtaining recognition, resources, and influence instead of being mentored." "I feel there is much room for improving training. The problems stem from the Institute's lack of commitment to training: I don't think training is a focus at the Institute."*

Outward Mobility and Internal Career Advancement

In the past, approximately 70 percent of tenured NIH scientists were selected from within the ranks of post-

³⁸ Most training fellows are promoted to service fellows unless there is an overall limit on FTEs. Service, unlike training, fellows technically occupy an FTE slot.

Table 5-1. Types of IRP Post-Doctoral Fellows and Published Salary Ranges, 1996 *Source: NIMH IRP Personnel Office, September, 1996*

Type of Fellow	Number at NIMH IRP (N=188)	Yrs. of Post-Doctoral Experience	Published NIH IRP-wide Starting Salary Ranges (Revised Jan., 1996)
Training Fellow			
IRTA ¹ Fellow	64	<5	\$25-38,000
Visiting Fellow*	50	<5	\$25-38,000
Service Fellow			
Staff Fellow	9	<3	\$28-51,000 M.D. \$28-49,000 Ph.D.
Senior Staff Fellow	31	3-7	\$39-77,000 M.D. \$34-65,000 Ph.D.
Visiting Fellows			
Visiting Associate*	25	3-6	\$29-55,000
Visiting Scientist*	9	> 6	\$42-91,000

¹ Named after the authorizing legislation, the Intramural Research Training Act

*Non-Citizen

doctoral fellows.³⁹ Recent NIH policy, however, expects its post-doctoral fellows to remain no longer than 5 years,⁴⁰ at which point the fellow is encouraged to seek employment in academia or other research environments. It is increasingly difficult to find a suitable research position because of fewer academic positions, increasing costs of research, expectations on the part of hiring institutions regarding grantsmanship, and the lack of teaching experience. While there is no formal documentation of this problem, many believe that, relative to earlier years, a lower percentage of former NIH fellows are employed in traditional academic careers. Post-doctoral fellows need to be more competitive when they leave their fellowships. The IRP needs to provide fellows with the tools and training experiences they need for successful careers.

NIMH should provide clear time-tables and contingencies for consideration for tenure-track and tenured positions for those within the IRP who will eventually compete for such positions. Few IRP post-doctoral fellows will be offered a tenure-track position. The Committee believes that this decision should be made within the first 5 years of a post-doctoral fellowship and that tenure decisions should not be delayed beyond 11 years after joining the IRP. This issue transcends NIMH IRP and requires resolution by the NIH.

Attracting High-Quality Post-Doctoral Fellows

At one time, there was no better place than the NIH IRP for research training. Recent years have seen numerous extramural research institutions flourish that now compete with NIH for the best fellows. Fellows' salaries are considered competitive in relation to those offered in academic settings.⁴¹ Yet Federal restrictions on the upper bounds of post-doctoral salaries, limited potential for career advancement, increased financial debt on the part of clinical fellows, high cost of living in the Washington-metropolitan area and decreasing trust in government institutions, among other factors, may contribute to the dwindling numbers of highly qualified post-doctoral applicants. Academic research facilities and pharmaceutical companies have now developed centers of excellence that attract some of the best and the brightest. NIMH should increase the attractiveness of its training program. The Committee commends the IRP on the projected inauguration of new, competitive fellowships to supplement existing ones, but more may be necessary. Authorities under the Clinical Center's Reinvention Laboratory status should be investigated to help attract clinical fellows (see below and Chapter 6). Special inducements should be explored for clinical and basic fellows.

Clinical Research Fellows

NIH's Clinical Center occupies a revered place in the Nation's research program. It is an ideal setting for the transformation of basic research findings into treatments for patients. Nationwide, fiscal pressures on clinical fellows, the advent of managed care, decreasing numbers of patient referrals, and increasingly technical and costly protocols have put clinical research in a precarious position (see Chapter 6). The NIH Clinical Center should remain a protected national resource in which clinical research can thrive, particularly as extramural research hospitals struggle to survive. The Clinical Center offers a significant opportunity for clinical researchers to obtain research and clinical training side-by-side with leaders in the mental health field. The Committee urges the IRP to capitalize on the unique opportunities available at the Clinical Center to revitalize its investment in young clinical research scientists

³⁹Report of the External Advisory Committee of the NIH Director's Advisory Committee, 1994.

⁴⁰The new NIH-wide policy on the terms of post-doctoral fellows (Jan., 1995) permits fellows to remain past 5 years only with the annual permission of the SD and notification of the DDIR. A post-doctoral appointment beyond 8 years requires the approval of the DDIR.

⁴¹Report of the External Advisory Committee of the NIH Director's Advisory Committee, 1994.

The IRP has difficulty attracting excellent M.D.s in biological and psychosocial clinical research and has difficulty supplementing salaries during the training years to remain competitive with non-governmental research centers. Also of concern are problems with the inconsistency in training standards, the lack of formal and informal didactic, clinical skills, and research skills training, and the variable burden of clinical care. In many instances, the system has not provided young clinicians with optimal opportunities for career growth, skills development, management training, and independence. Renewed emphasis must be placed on nurturing clinical research expertise.

Need for Evaluation of the Training Program

After the NIMH IRP training program is suitably restructured, emerging program needs and quality should be reevaluated. Specifically, the size of the training program may require adjustment if new government service positions or support staff positions are created; the number of clinical research fellows might be increased if the program attracts a large number of well-qualified applicants, etc. Formal and critical evaluation of the size, balance between the number of basic and clinical fellows, and the success of the training program should be conducted, and thoughtful consideration given to adjusting the program to meet the needs of the field. This evaluative function may be appropriate for the long-range planning committee that is appointed by the SD, as long as there is input from fellows.

Ensuring a well-balanced post-doctoral experience is a challenge that requires commitment at several levels. Programmatic and research goals must be balanced with the professional and personal needs of the fellows who contribute to research productivity. In the long view, a rich and successful post-doctoral experience may achieve greater scientific impact than the research findings accomplished during the training period. In that sense, the long-range needs of mental health research depend critically on the short-term needs of the field's most valuable resources for the future—today's fellows.

Conclusions

The IRP leadership must redouble its commitment to the training of post-doctoral fellows. The fellowship program must be enhanced to attract the most gifted applicants and to launch fellows' careers. It must emphasize training rather than technical support. Steps taken by the NIH and by the NIMH IRP are commendable, but more must be done at both levels. Senior scientists who significantly expand their investment in training deserve to be rewarded with more fellows and/or deserve relief in the form of greater flexibility in hiring technical and scientific support staff. Clinical research training needs to be fortified, especially by taking full advantage of the resources of the NIH Clinical Center. Finally, a comprehensive evaluation of the training program must be undertaken.

Recommendations

- 5.1 **The issues surrounding training transcend the NIMH IRP and affect NIH as an institution. The NIH leadership should encourage a culture that emphasizes the importance of mentorship and training. Specifically, the NIH leadership should: emphasize training, rather than technical support, in the post-doctoral fellowship; increase salaries for advanced post-doctoral fellows, particularly clinical fellows; establish training programs that attract the highest quality post-doctoral candidates; and reassess needs to hire trained professional staff to ensure research progress in an era where post-doctoral trainees can no longer be pressed into service roles.**
- 5.2 **The goal of the training program is to produce exemplary researchers. Fellows should emerge with a practical foundation for conducting independent research, including their own programmatic research theme and preliminary data, and with a reasonable expectation of**

success in obtaining grant funding.

- 5.3 The Committee charges the SD with responsibility for ensuring the quality of the fellowship training program.**
- 5.4 The training program needs leadership and appropriate resources. The full-time training director should be aided by staff and/ or by a board consisting of staff and fellows. Needs include but are not limited to:**
- a. developing an orientation program for new fellows**
 - b. advising mentors on all aspects of training, including recruitment**
 - c. providing career counseling**
 - d. developing a clinical fellowship core curriculum**
 - e. tracking the performance reviews of fellows and mentors**
 - f. developing policies on research practices that concern fellows, such as authorship policies, collaborative arrangements, career tracks, measures of independence, external funding for research, portability of research projects that can move with them to post-NIH positions, etc.**
 - g. developing a course on responsible conduct in science**
 - h. maintaining a database of educational opportunities available for fellows**
 - i. tracking the careers of fellows after they leave the IRP**
 - j. mediating mentor-fellow conflicts**
 - k. increasing the quality of the fellowship applicant pool**
 - l. ensuring reasonable sick leave and parental leave policies**
 - m. reviewing research plans developed by fellows and mentors**
 - n. advising the SD on all aspects of training**
- 5.5 Fellows should be provided with the opportunity to gain experience in grantsmanship. Didactic training should be provided in grant writing and in the extramural NIH funding system.**
- 5.6 The Committee endorses the recent creation of NIMH IRP Fellowship Awards that are both competitively awarded and highly desirable to attract and retain top quality fellows. Such awards may include increased salary, travel funds, and a modest independent research budget.**
- 5.7 Career development of a fellow extends beyond the laboratory bench. Fellows should be encouraged to interact to a greater extent with each other, with local universities and institutions, and with more senior scientists. Fellows should not feel as though punitive actions may result from their taking advantage of educational experiences outside of the laboratory.**
- 5.8 The mentor should assume greater responsibility for each fellow. The mentor is responsible for contributing to the development of a plan for a successful training experience, communicating expectations and time-lines, and providing appropriate feedback to the fellow. Early in the process, the mentor and fellow should develop a prospective research plan. In addition, mentors should be encouraged to support career development, provide career counseling, and guide the fellow in obtaining a position after leaving NIH.**
- 5.9 The mentor should ensure that each fellow understands his or her role in the branch or laboratory and the overall IRP. Agreement should be reached on a yearly basis about the extent of technical support requirements, research, and training. The fellows should be**

required to frame long-range career plans and systematically work toward a NIH exit path. Issues that should be addressed include options for career development, career paths, the likelihood of senior staff fellow and tenure-track candidacy, duration of appointment, source of support for the appointment, and critical post-doctoral term decision points. The mentor should meet with the fellow at least twice a year to discuss these issues.

- 5.10 The Committee is concerned about the duration of fellowships because longer terms leave fellows ill-prepared to compete for positions in the extramural community. The fellowship experience should last, on average, 3-5 years. This recommendation should be addressed in tandem with obtaining additional manpower for technical support (see recommendation 5.13)
- 5.11 The Training Director and the SD should ensure that evaluation of the mentoring of each fellow is performed on an annual basis. Exit interviews of fellows should be performed and, within a year after leaving the IRP, a written evaluation of the mentor should be requested of each fellow. Evaluation of mentorship and laboratory management should be a part of the Board of Scientific Counselors review of each independent investigator and the written report should directly address these issues. Matching fellows with mentors should depend heavily on prior mentorship success.
- 5.12 Rewards should be established for mentors who demonstrate a serious commitment to effective mentoring and laboratory management strategies and to furthering the careers of their trainees. The greatest reward is the continued allotment of fellowship positions.
- 5.13 Improving the training program while meeting the needs of the laboratory may require investment in hiring more technical and support staff. However, current Federal employment restrictions may limit the IRP's personnel flexibility. The IRP leadership should reassess the need to hire more non-tenure-track scientists and technicians to release fellows from technical support roles. New legislative authorities may be required.
- 5.14 The IRP leadership should evaluate the fellowship program as a whole in terms of quality, size, and the distribution of basic and clinical fellows. Current and past fellows should participate in the evaluation.
- 5.15 Few IRP post-doctoral fellows will be offered a tenure-track position. NIMH should provide clear time-tables and contingencies for consideration for tenure-track and tenured positions for those within the IRP. The Committee believes that this decision should be made within the first 5 years of a post-doctoral fellowship and that tenure decisions should not be delayed beyond 11 years after joining the IRP. This issue transcends NIMH IRP and requires resolution by the NIH.

Clinical Research

The NIMH IRP has a rich concentration of clinical research in the mental health field and represents one of the last few centers with a rich capacity for clinical research on some psychiatric disorders. For well over a decade, clinical research as a whole has been under siege. Escalating costs, inherent difficulties in conducting human research, and a host of other factors have threatened its viability. Nevertheless, the past achievements of the NIMH IRP in this area have gained world-wide recognition, and the future is full of promise. The IRP possesses invaluable clinical resources, which include rare inpatient psychiatry beds that permit long-term, drug-free stays, neuroimaging facilities, and 24-hour access to physicians and research expertise. In light of its distinctive resources and the increasing difficulties in conducting clinical research in the extramural community, clinical research at the NIMH IRP warrants a sustained and enduring commitment.

This chapter first discusses the nature of clinical research and the challenges it faces. It describes how these challenges are even more formidable in studies of mental disorders. It then discusses the NIH Clinical Center and recent recommendations by an advisory committee for its revitalization. It proceeds to a discussion of the dilemmas surrounding Clinical Center charges for NIMH IRP research. Finally, the chapter discusses the NIMH IRP's clinical research program at St. Elizabeths Hospital.

Clinical research, broadly defined, consists of investigations aimed at uncovering the mechanisms and management of disease.⁴² This definition includes studies of human subjects, as well as studies of animal models of disease. While clinical research is about translating laboratory or bench studies into clinically relevant techniques and hypotheses, it also is about bringing hypotheses from human studies back to the laboratory bench to refine animal models and to study questions that cannot be addressed in humans. This two-way interaction is a cardinal feature of clinical research. However, for the purpose of this chapter, clinical research strictly refers to research on human subjects. The NIMH IRP conducts human subjects research at the NIH Clinical Center and at the Neuroscience Center in the William A. White Building on the grounds of St. Elizabeths Hospital in Washington, DC.

Pressures on Clinical Research

Many historical forces have conspired to threaten the viability of clinical research. This is true despite its importance and the accelerated pace of basic science discoveries ripe for clinical evaluation. Two overriding problems are the rising costs and the inherent difficulty of carrying out carefully controlled studies. Clinical research is more demanding than other types of research because of the sophistication required to perform diagnoses, assess change, and control variables and because of needs to protect, recruit, and monitor human subjects, all the while providing excellent clinical care. It is no wonder that the number of extramurally NIH-funded inpatient research beds at universities and medical centers nationwide has declined from over 1,000 in the 1960s to about 470 today.⁴³ The NIH Clinical Center itself has witnessed a gradual decline in the number

⁴²Ahrens, Edward (1992) *The Crisis in Clinical Research*. New York: Oxford University Press.

⁴³The National Center for Research Resources, NIH, funds extramural clinical research through its grants program, the General Clinical Research Centers. In FY95, 75 centers were funded nationwide at a total cost of \$137 million.

of intramural inpatient beds from 504 in FY75 to 359 in FY95.⁴⁴ The new Clinical Center is projected to have a total of 250 inpatient beds.

Beyond the surge in costs and the difficult nature of clinical research are a host of other factors that reduce its attractiveness.⁴⁵ Physicians at academic medical centers have less time to perform research because of competing demands from caregiving, teaching, and the need to generate income for their departments. Moreover, young physicians are often so saddled with debt from their medical training that they are turning increasingly away from research and toward more lucrative careers in patient care. Finally, institutional support for clinical research has waned because of an emphasis on generating revenues from patient care to counteract the decline in Federal and state contributions. This lack of institutional support is compounded under managed care. The reasons for managed care's lack of commitment to clinical research are varied and have not been well studied, but the overwhelming perception of many clinical researchers is that managed care's emphasis on reducing medical costs has blinded administrators to the value of clinical research and its potential role in future cost reductions.

Even though the pharmaceutical industry has increased its expenditures on health research and development, it is less supportive of hypothesis-driven research than NIH, focusing instead on more applied studies. Industry support to academic medical researchers also may be accompanied by restrictions on publishing. Industry's share of health research and development spending has been increasing steadily over the past decade, all the while the Federal share is declining. The Federal share decreased from 50 percent to 37 percent over the 10-year period 1984-1994.⁴⁶ This overall trend has impeded the pursuit of clinical research on questions of a more fundamental nature.

The threats to continued investment in clinical research may be particularly acute in the field of mental health. Clinical trials with psychiatric patients often require long medication washout periods to minimize the effects of prior treatment, the use of placebo control to establish the efficacy of novel interventions, and highly trained staff to yield reliable and valid clinical assessment. Each of these factors increasingly limits the capacity to conduct some forms of clinical research in the extramural mental health community, particularly inpatient research. Mental disorders reflect disruption of higher order brain function, involving the most complex and integrated aspects of human biology and behavior. Studies of the etiology and pathophysiology of mental illness span the domains of molecular biology and genetics, neurophysiology and pharmacology, psychology, and epidemiology. Few settings can marshal a group of investigators with the relevant expertise in clinical science, neuroscience, sociology, and behavioral science. Nonetheless, despite these worrisome threats to the viability of clinical research in mental health, the opportunities for advancing understanding are outstanding. This is vividly illustrated by the recent development of new interventions that for the first time treat mental disorders by targeting specific neurochemical systems and by the profound improvements in our capacity to examine abnormal brain function at the molecular, biochemical, functional and structural levels. A vibrant clinical research program at the NIMH IRP is of paramount importance.

The NIH Clinical Center

The Warren Grant Magnuson Clinical Center on the NIH campus is the centerpiece of clinical research in the U.S. It operated with a budget of \$223.7 million in FY96. It is an extraordinary facility with almost 1,000 protocols, 1,900 full-time staff, 359 inpatient beds, and proximity to laboratory research to encourage

⁴⁴Opportunity: Revitalizing the NIH Clinical Center For Tomorrow's Challenges, January 1996. A report prepared for Health Secretary Donna Shalala by a committee chaired by Doctor Helen L. Smits.

⁴⁵Ahrens, Edward (1992) *The Crisis in Clinical Research*. New York: Oxford University Press.

⁴⁶NIH Data Book 1994, NIH Publication No. 95-1261.

collaboration. The Clinical Center accounts for about 50 percent of research inpatient days and 27 percent of outpatient visits of NIH-supported research throughout the country.⁴⁷ Despite its apparent plentitude, the Clinical Center is affected not only by many of the same ominous trends discussed above but also by its own problems. It has experienced a declining patient census, partly as a result of rising costs; fewer patient referrals from outside of NIH, especially due to the growth in managed care; a deteriorating and outmoded physical plant built in 1953; inefficiencies due to a lack of flexibility in procurement, personnel and budgeting (as a result of rigid government regulations); a complex and unwieldy governing structure; and a confusing and frustrating budget process through a tap—or direct withdrawal of funds—on each participating NIH Institute based on complex and changing allocation formulas (see later section on Clinical Center costs.)

Confronted by these problems, the Department of Health and Human Services—the parent agency of NIH—put forth a proposal to the Vice President in FY94 to privatize the Clinical Center. Due to the controversy this proposal engendered, the question of privatization was posed to a special independent panel.

The Smits Report

DHHS Secretary Donna Shalala convened a panel chaired by Dr. Helen Smits, a former administrator of the Health Care Financing Administration, to consider alternatives to privatization of the Clinical Center. The findings and recommendations contained in a 1996 report (hereinafter referred to as the Smits Report) were based on interviews with the NIH leadership and site visits to the Clinical Center and to other clinical research and medical institutions in the U.S. The Smits Report catalogued the problems (listed in the previous section) and issued recommendations to remedy them. The vast majority of the recommendations have been adopted by the NIH Director and are at various stages of implementation.

The Smits Report expressly recommended that the Clinical Center should not be privatized. Instead, it proposed a battery of changes in governance, budgeting, and management. It also agreed with an earlier report⁴⁸ on the need for construction of a new facility, a recommendation that is moving forward. The design phase is underway, and \$90 million in initial construction funds was recently appropriated by Congress in the FY97 Omnibus Budget Reconciliation Act.

Among other major recommendations of the Smits Report was a call for a more simplified governing structure for the Clinical Center, with participation from outside and inside NIH. A Board of Governors, consisting of 15 members, 9 of whom are from outside NIH, would approve an annual budget, develop strategic plans, and oversee operations. The report also recommended that the Clinical Center have its own clearly defined, stable annual budget; guaranteed access by each participating Institute to a baseline level of activity; the ability to carry over savings from one fiscal year to the next; access by extramural scientists to perform protocols; and a cost-accounting system “designed to provide support for tying costs to

Letters from IRP staff: *“The availability of inpatient beds, and feasibility of national recruiting over a several year period, permits the study of rare, severely ill populations. A current example of this is the present project on Childhood Onset Schizophrenia. Over a five year project ... we have been able to identify and study in depth this extremely rare but highly informative group ... I believe that the six beds our Branch has access to may be the only full-funded research beds in child psychiatry remaining in the country.”*

⁴⁷Opportunity: Revitalizing the NIH Clinical Center For Tomorrow's Challenges, January 1996. A report prepared for Health Secretary Donna Shalala by a committee chaired by Doctor Helen L. Smits.

⁴⁸Report of the External Advisory Committee of the Director's Advisory Committee, 1994.

performance.” This last recommendation is especially important to NIMH, as one of the largest institutional contributors, because it calls for the development of an incentive system in which “efficiency is recognized and rewarded.”⁴⁹ One of the most flagrant problems at the Clinical Center is an incentive system that fails to reward efficiency and lower utilization. The incentive structure is described in an ensuing section.

NIMH IRP at the Clinical Center

The NIMH IRP is the third largest institutional contributor to the budget of the Clinical Center, behind the National Cancer Institute and the National Heart, Lung and Blood Institute. In FY96, the NIMH IRP contributed \$21.4 million, or 9.6 percent of the total Clinical Center budget of \$223.7 million (Figure 6-1). This contribution represented about 22 percent of the entire NIMH IRP budget (Figure 6-2). The IRP’s financial commitment to clinical research at the Clinical Center amounts to a significant portion of its budget.

The IRP is allocated 45 beds at the Clinical Center, yet occupancy generally runs between 55—80 percent. The greatest fraction of its Clinical Center costs is for inpatient days and nursing. Protocols for affective disorders, adult schizophrenia, and child psychiatry require the greatest lengths of stay. The IRP is one of the few places nationwide where such protocols can be undertaken.

Clinical Center Costs

While access to the Clinical Center has exceptional value to the NIMH IRP, the high charges are of considerable concern. The past decade has been characterized by shifting formulas for assigning costs. The NIMH IRP’s steps to control its costs have led to little or no savings due to shifts in the methods of assessing charges. The IRP has little or no recourse in challenging Clinical Center charges, even though it is the third largest payor. The net effect has been a climate of distrust and, from the perspective of the NIMH IRP, excessively high costs. The Committee is deeply concerned that high fixed costs will encumber the new Scientific Director and that renewal of the IRP cannot proceed if excess resources already are committed.

The Clinical Center’s annual budget comes from a tap, or a required payment of funds, on each participating Institute. Each Institute is required to pay this annual tap as part of their contribution to the Management Fund, the central NIH fund from which the Clinical Center receives its budget. The Management Fund also pays for computer services, veterinary services, central library, and other common services needed by all NIH Institutes. An Institute that does not use the Clinical Center only pays into the Management Fund for the other services.

Each NIH Institute using the Clinical Center has limited control over how much it is required to pay the Management Fund. Its only formal input into the budget process has been in the Spring of the preceding fiscal year. At this time, each participating Institute submits a plan to the Clinical Center Director projecting how much it intends to use the facility in the coming year. The plan forecasts how many “workload units” are needed, e.g., how many inpatient days, outpatient visits, hours of anesthesia and surgical services, nuclear medicine units, and the like. Then the Clinical Center management assigns per unit costs, and later applies a complex formula to calculate a total Institute charge (based, in part, on the Institute’s historical usage and the total number of workload units presented in the plan). The total is then submitted directly to a

Letter From IRP Staff: *“The ever changing rules related to bed costs within the Clinical Center have hampered any movement towards revision of bed utilization and have held the IRP hostage to costs and needs of more powerful programs within the Clinical Center. Help is needed.”*

⁴⁹Opportunity: Revitalizing the NIH Clinical Center For Tomorrow’s Challenges, January 1996. A report prepared for Health Secretary Donna Shalala by a committee chaired by Doctor Helen L. Smits.

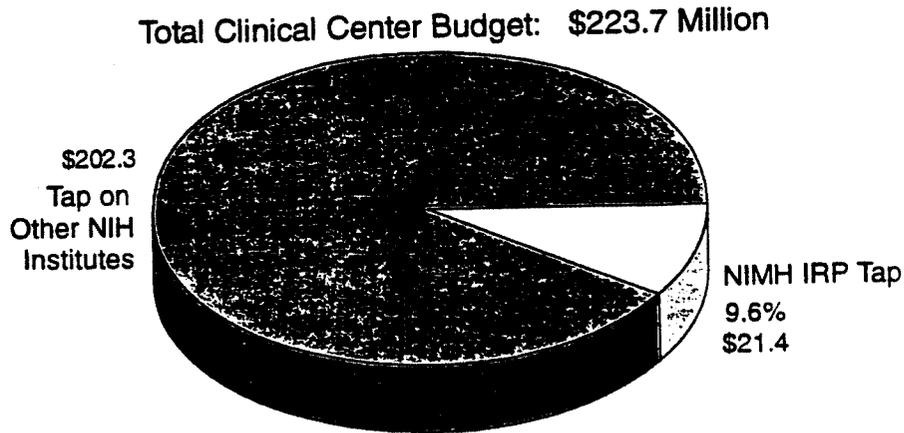


Figure 6-1. NIMH IRP Clinical Center Tap in Relation to Clinical Center Budget, FY 1996, in Millions of Dollars

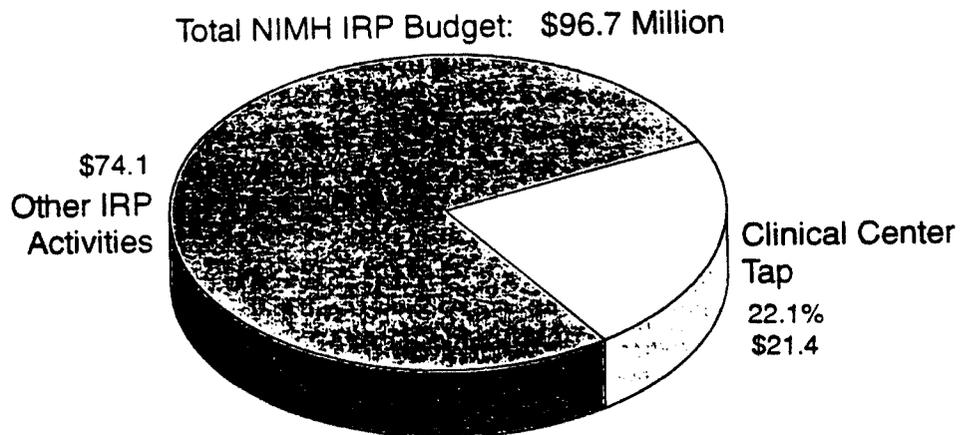


Figure 6-2. NIMH IRP Clinical Center Tap in Relation to NIMH IRP Budget, FY 1996, in Millions of Dollars. A Tap is a Required Payment of Funds *Source: NIMH IRP Budget Office.*

central NIH budget office, which, in turn, taps the Institute for its contribution. The tap translates into a flat fee paid in advance: it does not fluctuate based on the type or volume of services. If the Institute uses less or more than what it has planned, it still pays the same amount that year. There are few incentives for efficiency.

One overarching problem with this system is that Institutes have no control over how costs are assigned or how service usage is tracked and charged. There is no Clinical Center cost accounting system in place, but one is expected to be operative in FY98. There also has been no formal appeals process to arbitrate disputes arising when an Institute believes its fair share differs from what the Clinical Center charges it. The Board of Governors recommended by the Smits Report convened for the first time in the Fall of 1996. This group is designed to adjudicate disputes and serve as a forum for appeals. While the NIMH Acting Scientific Director has been appointed to one of the 15 positions on the Board of Governors, the mental health community needs additional representation. The academic mental health community needs representation to provide expertise about the special needs of research patients with mental disorders.

On the other hand, the Committee also recognizes that the Clinical Center needs a predictable and reasonable budget with which to operate a large, complex facility. It also needs funds for a small research program⁵⁰ of its own, enabling it to attract and retain high caliber Clinical Center staff. Since the Clinical Center does not have a direct congressional appropriation, it needs to charge the Institutes that use it. With limited flexibility to reduce its operational costs because of rigid government rules, the Clinical Center has almost intractably high overhead, which for all practical purposes is a fixed cost. Thus, when one Institute withdraws, the others are required to make up the difference by paying more. The Committee is sympathetic to the dilemma faced by Clinical Center administrators who need budget stability in the face of high overhead. But the Committee also recognizes that the Institute contributors need some control over their costs. A solution should be found to address both points of view.

Since 1985, five different cost allocation formulas have been imposed on participating Institutes. While these formulas are complex and defy simple explanation, they have varied according to the degree of fixed versus variable costs. Fixed costs have been defined, at different times, according to either the number of inpatient beds, space, or an access fee (like a membership fee). Fixed costs have ranged from 0—80 percent of an Institute's charge. Variable costs⁵¹ have been defined, at different times, according to either inpatient days, outpatient visits, or combinations of services. Variable costs also have ranged greatly, generally from 20—80 percent of an Institute's charge. The 1985-1992 formula, for example, rested completely on the variable cost of the number of inpatient days an Institute was allocated. The converse has operated since 1995, when the formula was based on 80 percent fixed costs and 20 percent variable costs.

Between 1985-1992, when inpatient days dictated overall charges, the NIMH IRP maintained a fairly stable inpatient census. Because other participating Institutes lowered their inpatient utilization during this period, the charges to NIMH increased dramatically (Figure 6-3). With the introduction of a new formula in 1993, which assigned 30% to fixed costs based on space and 70 percent to variable costs, NIMH responded by relinquishing a ward.⁵² Then, in 1995, with the introduction of another formula, NIMH sought to lower its costs by reducing its nursing staff by 20 percent. However, by the time the staff reductions were enacted, no

⁵⁰The research program consumes about 3 percent (\$6.7 million) of the Clinical Center's \$223 million budget, according to Clinical Director Dr. John Gallin.

⁵¹ Variable costs have also been divided into prospective and retrospective costs. The prospective component is for services that can be planned for in advance, and retrospective costs are based on utilization from the prior year.

⁵²Did not occur until 1996.

savings accrued. For NIMH, there has been little relationship, if any, between charges and changes in utilization (Figure 6-3).

In recognition of the deleterious effects of changing formulas on planning and utilization, the Smits Report advocated the creation of a cost accounting system. Such a system is intended to link costs to performance and to reward efficiency. By FY98, a cost-accounting system is expected to be in place. It is crucial for this system to be equitable, understandable, and based on utilization.

There is growing consensus, not confined to the mental health community, that the charges to the NIMH IRP are excessive. While the NIMH IRP's charge is \$21.7 million in FY97 it has estimated that an appropriate charge would be in the range of \$16-\$18 million. Rapid resolution of this dispute should be achieved prior to the adoption of an accurate cost-accounting system. The IRP calculates that its current cost per inpatient day, depending on services, ranges from \$1,800-\$2,000. By comparison, an informal survey of nine comparable psychiatric research facilities found the average daily cost to be \$850 (range: \$550-\$1,350). The charges by the Clinical Center do not take into account the lesser intensity of NIMH IRP patient needs, such as their decreased use of surgery, intensive care, and other high unit cost services. Nor do the charges take into account that many inpatients are actually "on pass," meaning they are off the premises. Since many patients require lower cost services, the NIMH IRP believes its charges should be correspondingly lowered.

The NIMH IRP also anticipates a reduction in overall charges resulting from more flexible procurement and staffing policies gained as a result of new authorities to operate the Clinical Center as a "Reinvention Laboratory."⁵³ The Smits Report recommended, and NIH pursued, these authorities, including the ability to apply savings from one fiscal year to the next.⁵⁴ Some predict that reinvention authorities, when fully implemented, may reduce Clinical Center costs by up to 15 percent. The refunds should be returned to each participating Institute.

Finally, it should be noted that the NIMH IRP has taken steps to create more efficient administration of protocols. The NIMH Clinical Director has created a centralized patient admission system to ensure optimal management of resources, while still remaining responsive to the needs of individual investigators. Previously NIMH Branch Chiefs were assigned their own particular ward for which they were responsible. The centralized system has been successful thus far at increasing the number of patient admissions, while decreasing the average length of stay. This new system has the capability to accommodate unscheduled and emergency admissions and optimize bed utilization.

Patient Care

The provision of clinical care to patients is an intrinsic part of research. The highest standards of patient care must prevail. The importance of high-quality patient care is included in the new mission statement recommended by the Committee (Chapter 1). Clinical researchers, nurses, and other clinical staff require experience and training to attend to the special needs of patients during and after their participation as research subjects. Similarly, the clinical infrastructure must be conducive to patient care. The building of a new Clinical Center on the NIH campus presents an ideal opportunity to design a facility that meets the

⁵³A Reinvention Laboratory is a Federal demonstration site which combines reduced regulation, enhanced local autonomy, and improved federal personnel and procurement practices. Some reinvention authorities can be acquired without legislation, while others require legislative changes.

⁵⁴ This is termed "no-year" funding in government parlance.

Patient Volume vs Charges

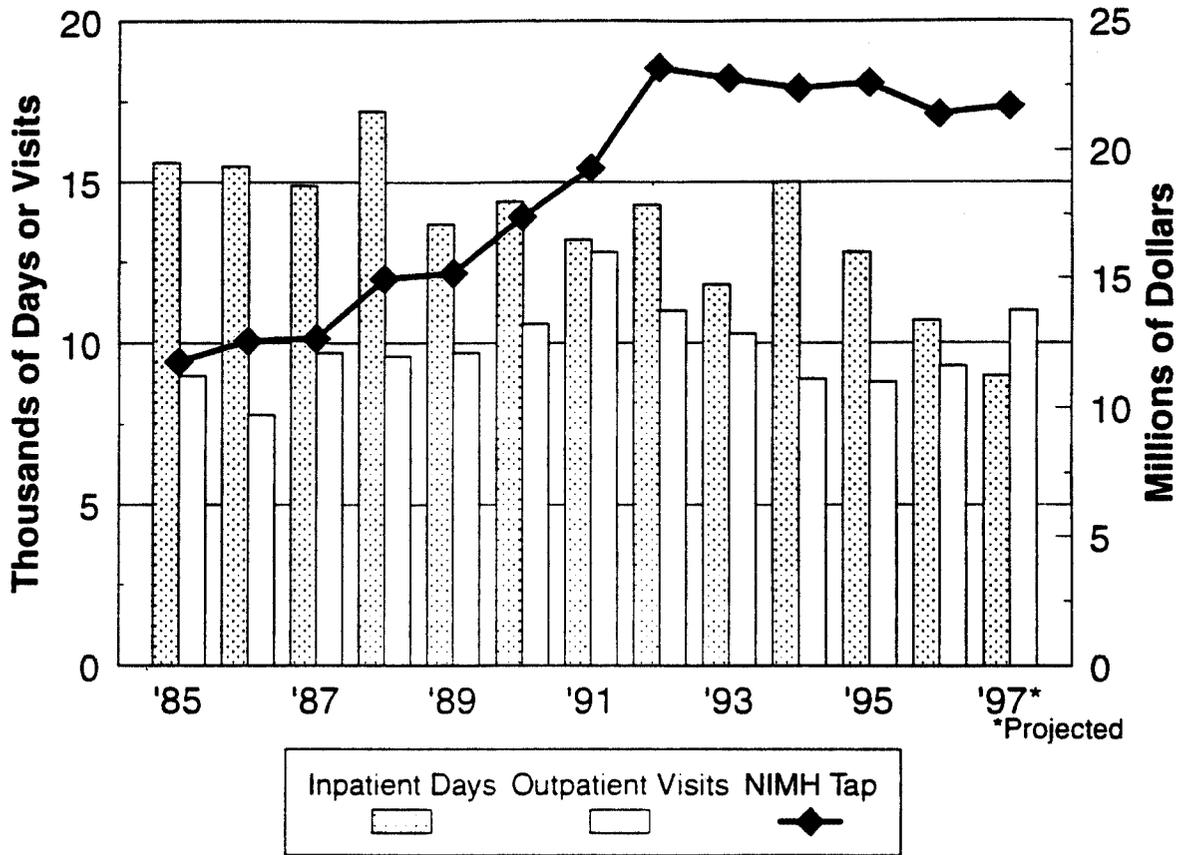


Figure 6-3. NIMH Patient Volume in Relation to Clinical Center Charges in the Form of an NIMH Tap. A Tap is a Required Payment of Funds. *Source: NIMH IRP Budget Office.*

special needs of patients with mental disorders, particularly in the size and layout of specific inpatient wards.⁵⁵

NIMH Neuroscience Center at St. Elizabeths Hospital

Since the 1950s, the NIMH IRP has maintained a world-class research program on schizophrenia at the William A. White Neuroscience Center at St. Elizabeths Hospital in the District of Columbia. The hospital was built in 1852 as the first Federal facility for the care and treatment of the mentally ill. Federal agencies administered the hospital until 1984, when Congress transferred authority for mental health services to the District of Columbia, whose residents accounted for the majority of patients. Nevertheless, NIMH, the last Federal agency to administer the hospital, retained the William A. White Neuroscience Center, where it houses IRP clinical research programs.

NIMH IRP Program at St. Elizabeths	
FY 1996 Budget	\$5.5 Million
Budget As % of Total IRP Budget	5.7 %
Inpatient Research Beds	24
Bed Occupancy	75 %
Square Footage	400,000 square feet*
*laboratory space, wards, storage space, and some unusable space	

Close proximity of clinical researchers to severely ill patients was one of the hallmarks of the facility. St. Elizabeths was the site of pioneering research in the 1950s on the effectiveness of antipsychotic medications. Since that time the program has consistently amassed a record of impressive research accomplishments. Its "brain-bank" collection of over 1,200 post-mortem brains is an invaluable asset to IRP research and to neuropathologists throughout the world. Researchers at St. Elizabeths have consistently been at the forefront of advancing understanding of the causes and treatments of schizophrenia. There is a camaraderie and enthusiasm among the research staff inspired by effective leadership and an unusual setting. The program at St. Elizabeths has ample space, in stark contrast to the Clinical Center. Its bed costs per day are approximately one-fourth those charged by the Clinical Center.

Circumstances, however, are changing. As a result of years of scientific progress, researchers at St. Elizabeths have come to depend increasingly on access to the imaging facilities (PET, MRI) and collaborative opportunities found at the Bethesda campus. This is partly because the research momentum at St. Elizabeths is shifting in the direction of molecular biology and neuroimaging. Independent investigators and fellows are

⁵⁵ Inpatient wards need single rooms for childhood schizophrenics and other acute patients, seclusion rooms, day rooms, swing rooms, low acuity rooms, observation rooms, and a residential/treatment facility.

disadvantaged by the distance separating them from the Bethesda campus and the rich opportunities for scientific collaboration and training.

Beyond scientific advantages, patient access is ironically enhanced at the Clinical Center. The patients at St. Elizabeths Hospital are now generally an aging population of severely ill individuals with schizophrenia, many of whom have been institutionalized since the 1950s and 1960s. This population is not representative of the deinstitutionalized adult schizophrenic population in the U.S. For this reason, only 15 percent of patients studied by St. Elizabeths researchers come from the hospital itself. Patients from outside the area, who constitute most of the research subjects, prefer to be seen at the Bethesda campus. Another change is the building of a new NIH Clinical Center. A new facility offers St. Elizabeths researchers the prospect of participating early on in the architectural design phases to meet the emerging scientific needs of the program. Finally, if fiscal pressures on the District of Columbia eventually lead to the closure of St. Elizabeths, the NIMH IRP would be compelled to close the William A. White Neuroscience Center.

Because of these changing circumstances, the Committee believes that the clinical research program at St. Elizabeths should be incorporated into the NIH Bethesda campus in a manner that preserves the best elements of this remarkable program. Inpatients at St. Elizabeths Hospital can be accommodated by the NIH Clinical Center, where the IRP has excess bed capacity. Unused beds already are being paid for through the Institute's tap.

Conclusions

The clinical research program of the NIMH IRP warrants strong support. The program needs to be sustained and revitalized, without overly restricting the flexibility of the NIMH IRP to pursue new research leads. While the Committee recognizes the value of the Clinical Center as a national resource and its need for stable funding, there is growing consensus, not confined to the mental health community, that the charges to the NIMH IRP are excessive. An equitable means of assigning costs should be developed even prior to the implementation of a cost-accounting system recommended by the Smits Report and slated for FY98. This system must take into account the fact that patients with mental disorders consume less costly services than do other types of patients. Given the special needs of mental health clinical research and given the NIMH's role as the third largest institutional contributor to the Clinical Center, NIMH must have additional representation on the new Board of Governors through a representative from outside the government. This should be someone who is not subject to internal political constraints and can serve as an advocate for NIMH's clinical research needs. Finally, the IRP's program at the William A. White Neuroscience Center at St. Elizabeths Hospital needs to be incorporated into the Bethesda campus because of its special facilities, collaborative opportunities, and access to patients. A move to the Bethesda campus should be accomplished without incurring additional short- or long-term costs beyond those already paid for patient care by the IRP to the Clinical Center. Relocation to the Bethesda campus should preserve the best elements of this program. It should also generate cost savings that can be applied to scientific renewal.

Recommendations

- 6.1 Revitalization of clinical research efforts is critical. The capacity to engage in interdisciplinary and innovative inpatient clinical research should be a special focus of the NIMH IRP, particularly since clinical research is threatened in the extramural community.**
- 6.2 The IRP leadership should ensure the highest standards of patient care in all clinical protocols.**
- 6.3 The Clinical Center charges to the NIMH IRP should be reduced to reflect its patients' lower utilization of services. There is a need for strict cost-accounting and a fee-for-service billing**

structure.

- 6.4 The new Clinical Center Board of Governors should have a non-Government member with a mental health background plus a member from NIMH, the third largest contributor to the Clinical Center budget.
- 6.5 The new Board of Governors should ensure that an equitable system of charges is in place. The charges to NIMH should reflect NIMH's lower utilization of resources. The system also should contain incentives for increased efficiency, in accordance with a recommendation of the Smits Report.
- 6.6 Funds paid in excess of services used should be returned in full to the NIMH IRP. A portion of savings realized from the installation of new Clinical Center management efficiencies also should be returned to the NIMH IRP.
- 6.7 An appeals process should be created to permit Institutes to remedy discrepancies between the amount charged and the services used.
- 6.8 The Committee endorses the recent policy of the NIMH Clinical Director to centralize NIMH's clinical admissions.
- 6.9 The IRP leadership should perform an assessment of needs for improved clinical care infrastructure.
- 6.10 The IRP leadership should provide advice to the Director of the Clinical Center about the design of the new Clinical Center to ensure that the facility meets the special needs of mental health patients and provides for efficiencies in patient care and management.
- 6.11 There are significant advantages to incorporating the clinical neuroscience program from the William A. White building at St. Elizabeths Hospital into the NIMH IRP's program at the Bethesda campus. Scientific demands, ease of patient access and care, a new clinical center on the horizon, and centralized technological capabilities provide a compelling rationale for consolidating all of NIMH's clinical research programs at one site. The NIMH leadership should develop a plan, as if they were freshly recruiting researchers, in order to preserve the strongest elements of this program. Consolidation should be contingent upon the availability of appropriate resources and contiguous space on the NIH campus. Consolidation also should be contingent upon assurances that there will be no additional present and long-term costs to the IRP for its utilization of the NIH Clinical Center due to the incorporation of this clinical research program.
- 6.12 The Director of NIMH should establish a committee that may include former members of the IRPPC to provide long-term external oversight of the revitalization of NIMH's clinical research program. This committee should address plans for the new Clinical Center, NIMH's utilization of Clinical Center facilities, appropriateness of the Clinical Center's charges to NIMH, and the plan and costs for incorporating the neuroscience program at the William A. White Building at St. Elizabeths Hospital into the Bethesda campus, among other issues. In the event that the average patient day costs at the Clinical Center cannot be decreased in the short- and long-term (and, therefore, the St. Elizabeths' Neuroscience program cannot be assimilated into the Bethesda campus without incurring an increase in total Clinical Center charges to NIMH), the Committee should explore alternative arrangements that would permit NIMH's clinical research to proceed with more justifiable costs to the Institute.

Appendices

A. Meeting Dates

March 11-12, 1996

April 26-27, 1996

June 13-14, 1996

September 11-12, 1996

November 14-15, 1996

December 18-19, 1996

B. Associations Invited to Send Comments About the NIMH IRP

1. American Academy of Child and Adolescent Psychiatry
2. American Association of Chairmen of Departments of Psychiatry
3. American Association for Marriage and Family Therapy
4. American Association of Suicidology
5. American College of Neuropsychopharmacology
6. American Hospital Association
7. American Medical Association
8. American Nurses' Association
9. American Psychiatric Association
10. American Psychiatric Nurses' Association
11. American Psychological Association
12. American Psychological Society
13. American Psychopathological Association
14. American Sociological Association
15. Anxiety Disorders Association of America
16. Association of American Medical Colleges
17. Association for Health Services Research
18. Black Psychiatrists of America
19. Institute of Medicine
20. Mental Health Policy Resource Center
21. National Academy of Sciences
22. National Alliance for the Mentally Ill
23. National Alliance for Research on Schizophrenia and Depression
24. National Association of Social Workers
25. National Association of State Mental Health Program Directors
26. National Depressive and Manic Depressive Association
27. National Foundation for Depressive Illness
28. National Mental Health Association
29. Obsessive Compulsive Foundation
30. Society for Education and Research in Psychiatric / Mental Health Nursing
31. Society for Neuroscience
32. Society for Research in Child Development

C. Presentations to the IRPPC

NIH

Harold Varmus, M.D.
Director, NIH

Ruth Kirschstein, Ph.D.
Deputy Director, NIH

Michael Gottesman, M.D.
Deputy Director for Intramural Research, NIH

Stephen Benowitz
Director, Personnel, NIH

John Gallin, M.D.
Director, Clinical Center, NIH

Michael Goldrich
Deputy Director, Clinical Center, NIH

Zach W. Hall, Ph.D.
Director, NINDS

Richard Klausner, M.D.
Director, National Cancer Institute

Alan Leshner, Ph.D.
Director, National Institute of Drug Abuse

Stuart Yuspa, Ph.D.
National Cancer Institute

NIMH

Steven Hyman, M.D.
Director, NIMH

Rex Cowdry, M.D.
Deputy Director, NIMH
and former Acting Director, NIMH

Susan Swedo, M.D.
Acting Scientific Director, IRP

Sanford Markey, Ph.D.
Former Acting Deputy Director
Laboratory of Clinical Science, IRP and
Member, Fellowship Education and Training Committee

David Rubinow, M.D.
Clinical Director, Biological Psychiatry Branch, IRP and
Member, Fellowship Education and Training Committee

Caleb Adler, M.D.
Experimental Therapeutics Branch
NIH Fellows Committee, IRP

Karen Berman, M.D.
Tenure-Track Investigator, Clinical Brain Disorders Branch, IRP and
Member, Fellowship Education and Training Committee

Alan Breier, M.D.
Chief, Section on Clinical Studies, Experimental Therapeutics Branch, IRP and
Chair, Fellowship Education and Training Committee

Michael Brownstein, M.D.
Chief, Section on Genetics and Former Chief, Laboratory of Cell Biology, IRP

Donald Button, Ph.D.
Staff Fellow, IRP

Janet Clark, Ph.D.
Chair, NIMH Fellows Committee, IRP

Jackie Crawley, Ph.D.
Chief, Section on Behavioral Neuropharmacology
Experimental Therapeutics Branch, IRP

Robert Desimone, Ph.D.
Chief, Section on Behavioral Neurophysiology,
Laboratory of Neuropsychology, IRP and
Member, Fellowship Education and Training Committee

Roger Erickson, Ph.D.
Senior Staff Fellow
Laboratory of Neuropsychology, IRP

Frederick Goodwin, M.D.
former Director, NIMH
former Scientific Director, IRP

Charles R. Gerfen, Ph.D.
Acting Chief, Laboratory of Neurophysiology, IRP

Krystyna Isaacs, Ph.D.
NIH Fellows Committee Representative, IRP
IRTA Fellow, Laboratory of Clinical Science

Barry Kaplan, Ph.D.
Associate Director for Training, IRP

Seymour Kety, M.D.
Scientist Emeritus, IRP

Tim Kimbrell, M.D.
Staff Fellow
Biological Psychiatry Branch, IRP

Anil Malhotra, M.D.
Senior Staff Fellow
Experimental Therapeutics Branch, IRP

Mortimer Mishkin, Ph.D.
Chief, Laboratory of Neuropsychology, IRP

Susan Molchan, M.D.
former Senior Clinical Investigator, IRP, currently with FDA

Howard Nash, M.D., Ph.D.
Chief, Section on Molecular Genetics, Laboratory of Molecular Biology, IRP and
Member, Fellowship Education and Training Committee

David Pickar, M.D.
Chief, Experimental Therapeutics Branch, IRP

Robert Post, M.D.
Chief, Biological Psychiatry Branch, IRP

Judith Rapoport, M.D.
Chief, Child Psychiatry Branch

Catherine Roca, M.D.
Senior Staff Fellow, Biological Psychiatry Branch and
Member, Fellowship Education and Training Committee

Brenda Sandler
Financial Manager, IRP

Leslie Ungerleider, Ph.D.
Chief, Section on Neurocircuitry, Laboratory of Neuropsychology, IRP

Theresa Vera, Ph.D.
PRAT Fellow
Laboratory of Cell Biology, IRP

Daniel Weinberger, M.D.
Chief, Clinical Brain Disorders Branch,
Neuroscience Center at St. Elizabeths, IRP

Joseph Whitaker
Supervisory Personnel Management Specialist, IRP

Christine Wichems, Ph.D.
IRTA Fellow
Laboratory of Clinical Science, IRP

Lois Winsky, Ph.D.
Senior Staff Fellow
Laboratory of Clinical Science, IRP

Extramural Community

Marilyn Alberts, Ph.D.
Massachusetts General Hospital

Francine M. Benes, M.D., Ph.D.
Mailman Research Center--McLean Hospital

Steven Childers, Ph.D.
Bowman Gray School of Medicine

Laurie Flynn
National Alliance for the Mentally Ill

Shervert Frazier, M.D.
McLean Hospital

Sandra Honey
National Mental Health Association

Tom Insel, M.D.
Director, Yerkes Regional Primate Center

Darrell Kirch, M.D.
Medical College of Georgia

Susan Leeman, Ph.D.
Department of Pharmacology, Boston University

Connie Lieber
National Alliance for Research on Schizophrenia and Depression

Lee Limbird, M.D.
Vanderbilt University Medical Center

Robert Moore, M.D., Ph.D.
University of Pittsburgh

Francis Narin, Ph.D.
President, CHI Research, Inc.

Steven Paul, M.D.
Lilly Pharmaceutical Co.

William Potter, M.D.
Lilly Pharmaceutical Co.

Tom Rickey
National Depressive and Manic Depression Association

Jerilyn Ross
Anxiety Disorders Association of America

Joshua R. Sanes, Ph.D.
Washington University Medical Center

Morton N. Swartz, M.D.
Massachusetts General Hospital

