



Task Force on NIH's Intramural Research Program

ABSTRACT

The National Institutes of Health (NIH) operates the most extensive health research program in the world. A key component—spending about 10 percent of available funds—is the research effort on the NIH campus, the Intramural Research Program (IRP), which includes its Clinical Center. This program has a distinguished history of discovery, including serving as home to five Nobel Prize winners. However, it currently lacks a clearly defined mission within the overall NIH effort. In addition, concerns have been raised by Congress and NIH leadership—and exacerbated by current fiscal constraints—about whether today the IRP fully exploits its unique situation given the abundance of excellent biomedical research institutions elsewhere in the United States. Given the fiscal restraints of the present era, getting the greatest value from this program seems mandatory. The FasterCures Task Force was convened to recommend to the incoming Administration a framework within which to refresh the IRP, giving it a distinct mission and identity. This mission is three-fold: to focus on translational research and training, especially work that utilizes the unique capabilities of the NIH Clinical Center; to be prepared to respond to new opportunities and challenges; and to focus on complex, long-term, innovative basic research goals that would be difficult to pursue in the extramural environment.

I. About *FasterCures* and This Document

FasterCures is dedicated to saving lives by saving time. Formed under the auspices of the Milken Institute in 2003, its mission is to identify and implement global solutions that can accelerate the process of discovery and clinical development of new therapies for the treatment of deadly and debilitating diseases. *FasterCures* does not fund research or try to reform the delivery of healthcare. Many others are working hard in those areas already. Rather, it seeks ways to amplify the productivity of the considerable resources and expansive infrastructure dedicated to finding new medical solutions. The organization aims to catalyze systematic change by:

- evaluating current systems of disease prevention, research, development, and treatment;
- identifying barriers to efficiency, effectiveness, and expediency in those systems;
- creating achievable action plans to improve those systems; and
- applying seasoned leadership to implementation of those action plans in concert with organizations seeking new medical solutions

In 2007, *FasterCures* organized a Task Force under the leadership of its Board member David Baltimore to examine how to strengthen the mission and impact of the NIH Intramural Research Program. Given the likelihood of constrained budgets and limited opportunities for expansion of NIH's research programs in the near future, it is especially critical that NIH make the best and most efficient use of the IRP, one of its most valuable resources.

The advent of a new Administration and Congress provides the opportunity for the new Executive, working with Congress, to initiate a transformation in the scope, mission, and culture of the IRP, one that can be accomplished even in a period of fiscal constraints. The *FasterCures* Task Force has developed this transition plan for the next Administration to accomplish needed change in the NIH IRP, including but not limited to:

- focusing its mission;
- creating programs of cutting-edge, high-risk research that cannot easily be done elsewhere because of the need for substantial resources, or stable and longer term funding;
- providing intellectual and physical resources that are uniquely appropriate for a given public health need;
- ensuring the ability to mobilize resources in response to emerging challenges or opportunities;
- providing unique and outstanding training opportunities in translational and clinical science;
- offering novel mechanisms for public/private partnerships in the development of new diagnostics and therapeutics;
- making the Clinical Center more productive and more integrated into the IRP's newly defined mission;
- setting national standards for the conduct of translational and clinical research; and
- serving as the nation's preeminent site for translational research.

The *FasterCures* Task Force focused on both strategic and policy issues that restrict NIH's ability to use the IRP as a way to fast-track and promote rapid advances in basic, translational, and clinical research, including, but not limited to:

- current conflict of interest rules;
- the governance and strategic planning processes in the IRP;
- administrative and legislative obstacles to rapid change;
- cultural and historical obstacles to change;
- limitations of the NIH Director's authority;
- and other issues, as identified by the committee.

II. Background

The NIH IRP and the Extramural Research Program comprise the two components of NIH's research enterprise. Since the IRP's inception as a public health laboratory in the early 1900s, the program has grown in size and breadth, now supporting 6,000 scientists and trainees in all disciplines at its own laboratories, most of which are on the NIH campus in Bethesda, Maryland. The IRP currently has an annual budget of \$2.9 billion, roughly 10 percent of the total NIH budget.

Organizationally, the individual laboratories and sections answer to the 19 separate institutes and centers of NIH that conduct applied and basic biomedical research in particular disease or subject areas through their intramural programs. Thus, the IRP has a federated structure with each of the 19 programs operating under a different mandate based on its institutional home and mission. Each institute or center differs with respect to goals, scope, absolute size, and allocation of funding between extramural and intramural research.

The IRP has contributed substantially to NIH's mission, especially with regard to its basic research effort, its training programs and the presence of its unique research hospital, the Mark O. Hatfield Clinical Research Center (or the Clinical Center, the world's largest clinical research unit). There are several examples of highly innovative and unique scientific programs within the IRP and the program has produced five Nobel Prize winners. It has accomplished focused, integrated, interdisciplinary approaches to biomedical problems that are the envy of the world. In addition, the advantage of long-term, stable, and substantial funding has allowed the IRP to initiate and sustain large-scale longitudinal projects, or address the complexities of difficult, high-yield therapeutic and prophylactic targets.

Despite the significant contributions the IRP has made to advancing public health, concerns have been raised by Congress and NIH leadership—and exacerbated by current fiscal constraints—about whether it continues to meet its full potential to address emerging national needs and opportunities in biomedical research. As biomedical research has changed, and the nation's research infrastructure has evolved over the past 50 years, some people question what makes the IRP distinguishable from its extramural counterparts and

whether its mission should be realigned or refocused on issues of significant public health importance.

Over the past 15 years, several external and internal groups have reviewed the operations and mission of the IRP.¹ In general, these reviews were spurred by concerns about: the quality of the program; its continued necessity given the large expansion of the extramural program over time; its ability to recruit and retain top scientists; its system of scientific review and granting of tenure; and its ability to justify its uniqueness, flexibility, and responsiveness to public health needs. Several groups have concluded that there is unevenness in quality, quality control, and productivity across the program.

Some of the responses to these reviews have resulted in dramatic and large-scale changes, for example, in the hiring practices and reviews of IRP scientists, interactions with industry, and construction of the new Clinical Center. However, other responses yielded incremental changes around the margins. Still, there remains a sense that this enormous national resource is not being exploited to its fullest extent to serve the research needs of the public and private biomedical research enterprise and the public health.

III. The *FasterCures* Task Force Vision Statement for the NIH IRP

The NIH IRP is a unique national resource given its sizable budget, long-term and stable funding, large cadre of scientists and technicians, expansive infrastructure, and close proximity to the NIH leadership. Much excellent research has come from the IRP since its creation in the 1950s. The success of the IRP has generated deep understanding of normal biological processes and the pathological processes underlying disease states.

Some of this knowledge has been translated into diagnoses and therapies for disease; examples are recent advances in diagnosing lymphoma and the development of antiretroviral agents for HIV. However, the IRP has not consistently established a mission distinctly separate from that of the extramural biomedical community. The opportunity to translate more of the discoveries of modern science into practical use suggests that modifying the mission of the IRP could give it a unique focus more appropriate and responsive to today's research environment. The IRP should not be a mirror image of the extramural community, but rather should take on distinctive and strategic research programs that respond to pressing needs in the research community. Its special status offers the opportunity for a research program that is at once highly stable but nimble enough to be responsive to change, and immune from the limitations faced by the extramural community (e.g., short-term funding and competing demands, such as teaching and clinical services).

¹ NIH. Report of the External Advisory Committee of the Director's Advisory Committee (1994); NIH/NCI. Report of the National Cancer Advisory Board Ad Hoc Working Group on the Intramural Research Program (1995); IOM. Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health (1998); NAS. Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges (2003); NIH. NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research (2004); NIH. Report of the National Institutes of Health Blue Ribbon Panel on Conflict of Interest Policies (2004).

Importantly, the IRP should become more outcomes-focused, meaning it should strategically seek solutions to clinical problems through benchwork, animal models, and human studies. Its focus on basic questions should be seen as supportive of solving pressing health problems, and the IRP should be measured by its success in contributing to improved health.

Such a transformation will require congressional and administrative action and leadership. The NIH Director must be supportive of reform and granted the authority to implement change in the IRP. The NIH Director and Deputy Director for Intramural Research should lead a priority-setting and review strategy that is more strategic and consistent across institutes, one that facilitates collaboration among the various institutes and centers and focuses more on quality control and accountability. Institute and center directors should be assessed on their ability to implement these strategies and carry out the IRP mission.

IV. Sources of Input for This Plan

The Task Force reviewed prior reports issued on the NIH IRP and subsequent NIH responses and implementation plans. It also retained the expertise of Foley Hoag, LLP in exploring regulatory and statutory authorities and limitations affecting the IRP. Most importantly, a series of interviews were conducted with individuals familiar with the IRP—either as current or former employees in leadership positions—and with leaders in the extramural community and private sector (see Acknowledgments). In each of these interviews the Task Force explored the following questions:

- Is the current structure of the IRP preventing NIH from tackling grand challenges?
- Do the current ethics rules allow IRP scientists to conduct focused, applied, problem-oriented research?
- Should the IRP continue to offer and/or expand its training programs?
- Are there patterns or trends suggesting certain strengths of the IRP that should be expanded or emphasized?
- Are there activities that are done especially well because of the unique budgetary policies or resources in the IRP?
- Are NIH intellectual property policies affecting intramural scientists reasonable? Do they encourage or stifle innovation?
- Are the clinical research activities appropriate and distinctive?
- Is NIH making best use of its clinical research infrastructure?
- How might the IRP more routinely and effectively team with the extramural community in the areas of translational and clinical research?
- Does the Director's authority have to be expanded to allow for more far-reaching and strategic changes?
- Should there be a more centralized clinical research strategy?
- What areas of research should the IRP be focused on?

The Task Force found a broad spectrum of perspectives on the quality and importance of the IRP, ranging from a belief that the program effectively conducts high quality research that has qualitatively improved over the last decade to individuals questioning its continued existence. However, most interviewees believe the program is a valuable component of NIH's research program that must be supported and sustained, but with some key areas needing improvement or change.

Interviewees agreed that the IRP must be less risk-averse, a characteristic that permeates much of the extramural community because of the way that investigator-initiated grants are reviewed. IRP scientists operate under a different review process that emphasizes evaluation of past progress rather than future plans. Most interviewees agreed that because of its stable and long-term funding, permanence of government employees, and huge infrastructure, the IRP should be on the cutting edge of research that is not likely to be conducted in the extramural community, or that is too high-risk for private investment. Most agreed that there are opportunities to optimize the program, both scientifically and in terms of public health, and that there are costs to not doing so.

Based on these various inputs, the Task Force offers the following recommendations for change.

V. Recommendations for Change

The Task Force identified several crucial areas where shifts in policies, programs, or leadership priorities would exploit the unique aspects and resources of the IRP in a time of fiscal constraint. It is important to recognize, however, that the Task Force interviews and research revealed quite a range of variation in the quality and innovative aspects of intramural programs across the institutes and centers. Thus, some of the recommended changes—regarding mission, better use of resources, more stringent quality review, and the need for more high-risk, innovative research—are targeted more to some programs than others. However, several issues identified by the Task Force affect all IRP programs, because they are central to trans-NIH policies. These include use of the Clinical Center, ethics rules, budget strategies, training, and development of core resources.

A. NIH should articulate an overarching mission for the IRP and strategies for meeting goals over the next five years.

It is clear that the IRP is not monolithic; rather, it is the sum of its parts, which vary significantly in terms of focus, mission, quality, and size. The Task Force found examples of outcomes-driven (mission-oriented) strategic research across the IRP, but they are not evenly or well distributed. To better serve the public health, the IRP needs a central and well articulated mission, to be achieved in diverse ways.

Because of its distinctive budgetary status within the NIH—which provides its scientists with long-term stable funding—and because of the availability of the Clinical Center, the IRP should adopt a clear mission, focused specifically on advancing translational and clinical research in the interest of public health. This

mission would not eliminate basic research from the IRP toolset, but it should require that basic research programs be either 1) related to translational and clinical goals, or 2) high-risk and well suited to the review and funding mechanisms of the IRP versus the ERP.

Basic research is the earliest stage of research, carried out for the advancement of knowledge, without necessarily any regard to its application to practical problems.
Translational research is the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment and prevention of human disease—the critical bridge between basic research and clinical research. It includes intermediate steps such as identification of biomarkers, target and pathway validation, and development of and testing in animal models.
Clinical research is research involving human subjects aimed toward approved treatments for patients. It may include patient-oriented research, epidemiologic and behavioral studies, or outcomes research and health services research.

Several interviewees expressed frustration that the IRP has stopped being a model for how to do research in areas where extensive basic research has been done and the field is ready to move forward. These “translational” studies often do not compete well in the traditional investigator-initiated (R01) climate of ERP funding, where the principal approach is an individual investigator conducting leading-edge work. The ERP funding environment and the reward structure of universities often limit the development of interdisciplinary cooperative research programs, which are so essential to translational research, providing a great opportunity for the IRP.

The IRP’s mission should be the basis on which funding and resource allocations are made across and among institutes and centers (ICs). Each IC can and will meet this mission in its own way, but there has to be a vigorous commitment to supporting programs that have the direct goal of improved health. The mission has to be embraced by the next NIH Director, institute and center directors, and fully supported by the Secretary of Health and Human Services.

Action Items:

- The incoming NIH Director should rapidly undertake a planning exercise to create the new mission statement for the IRP. The planning process should include leadership from NIH, the extramural research community, industry, and patient advocates.
- Following the completion of the mission statement, the Scientific Directors of the relevant institute and centers, in collaboration with the Boards of Scientific Counselors, should develop a five-year organizational and strategic plan for aligning their respective intramural programs with the mission. ICs with smaller intramural programs might decide to more narrowly focus their programs. A concerted effort should be made to identify ways in which institutes and centers could pool or share resources to better achieve the new mission. (The consolidation of neuroscience efforts across the IRP in the Porter Neuroscience Research Center is an example.)
- One way to change the current culture is through the review process and criteria for allocating funds in the IRP. NIH leadership must provide increased guidance

to institutes and centers and their Scientific Directors and Boards of Scientific Counselors to improve the quality of their programmatic and individual reviews in ways that support and reinforce the mission. Review criteria must be altered to more aggressively encourage risk-taking and innovation in translational and clinical research. Programs not pursuing translational or clinical research (including use of the Clinical Center) should be asked to justify their strategy (e.g., scientific opportunities lie elsewhere).

B. The Clinical Center must be fully utilized and the IRP's clinical research program should be expanded.

The Mark O. Hatfield Clinical Research Center was opened in 2005, its size and configuration based on recommendations of a 1994 External Advisory Committee of the Director's Advisory Committee. The facility houses inpatient units, day hospitals, and research laboratories and connects to the original Warren Grant Magnuson Clinical Center. The 870,000-square-foot Hatfield building has 234 inpatient beds and 82 day-hospital stations. This arrangement can be easily adapted to allow more inpatient beds and fewer day-hospital stations, or vice versa, because the facility's design is highly flexible.

The Clinical Center is the largest dedicated research hospital in the country and its existence in the IRP represents one of NIH's most unique resources. It provides some of the nation's best imaging equipment, phenotyping expertise, and access to a wide range of clinical research specialists. As a world-class facility, it has the potential to excel in research efforts focused on rare and orphan diseases and on pre-clinical and methods research essential to building tools, platforms, and protocols for the entire clinical research enterprise.

Yet the Clinical Center is an underutilized resource. With only 1,400-1,500 active protocols per year, it rarely reaches 60 percent occupancy, and its potential as a national resource for the public health is not being met. There are several factors contributing to this problem:

- Salary constraints, ethics policies, and lack of emphasis on clinical research in some institute intramural programs combine to diminish the overall clinical research capacity in the IRP.
- The way the Clinical Center is funded may create disincentives for its use.
- Collaboration with the ERP and industry to more fully use the Clinical Center is inhibited by the broader policy issues affecting the IRP raised in the recommendation below (i.e., commingling of funds and ethics rules).

With regard to salary constraints, clinical research is the most expensive type of research to conduct because of, among other expenses, the cost of personnel. Clinical investigators, by virtue of their medical training and ability to provide patient services, are able to draw higher salaries in the extramural community and industry than in the IRP. The inability of NIH to pay competitive salaries to intramural clinical investigators creates an obstacle for some institute intramural programs.

The mechanisms used to fund the Clinical Center deserve reconsideration. In 2000, a new Clinical Center funding formula known as the "school tax" assessment, initially suggested by the Clinical Center Board of Governors, was instituted. This change was intended to provide a more predictable annual assessment for institutes, and to promote increased institute utilization of the Clinical Center. This model no longer linked the amount that an institute is assessed for the Clinical Center to its utilization of Clinical Center services. Instead, institutes' funding assessments for the Clinical Center are based on their proportional share of the NIH intramural budget. While various minor corrections to the formula have been made over time, institutes are contributing to the funding of the Clinical Center regardless of their utilization.

In general, the "school tax" was intended to cover all patient care activities and the costs for all protocols. However, since the NIH budget has flattened, the Clinical Center budget has not kept abreast with inflation (the budget increased 4 percent from 2003-2008, lower than the rate of inflation and much lower than the rate of increase in healthcare costs). As a result, to keep the programs of the Clinical Center open, it has had to shift costs for non-patient activities (i.e., research services) to the institutes. These "cost shifts" are in essence "user fees" and have forced prioritization of some institutes' clinical research activities, resulting in reduced use of the Clinical Center.

Finally, more efforts are needed to open up the Clinical Center facilities to industry and the extramural research community. In addition, there needs to be more active collaboration between the Clinical Center and the Food and Drug Administration (FDA) to address urgent questions pertinent to emerging diagnostics, devices, therapies, and vaccines. Because of the high cost of clinical research facilities and equipment, it makes no sense to have every extramural clinical research facility similarly equipped or focused on building the same core tools. In 1997, the NIH Director's Panel on Clinical Research reported to the Advisory Committee to the NIH Director that "The NIH should continue to improve the quality of clinical research and strengthen research management in the Warren Grant Magnuson Clinical Center (CC) and extend the availability of its resources and expertise, as well as those of the Institutes and Centers (ICs), to extramural investigators."

Some efforts have been made to increase use. In 1999, the Clinical Center established the Bench-to-Bedside Awards to integrate the work of basic and clinical scientists on the NIH campus. The program expanded in 2006 to encourage partnerships between intramural and extramural programs. In 2009, the program will expand again so that extramural principal investigators with an existing NIH grant can initiate proposals by seeking an intramural partner at NIH to be the project leader and point of contact. This type of mechanism might be adapted to encourage greater use of the Clinical Center by extramural investigators collaborating with Clinical Center scientific personnel.

Action Items:

- The NIH Director should charge the newly constituted Scientific Management Review Board with the task of reviewing options for funding the Clinical Center to enhance greater utilization and removing any current disincentives for use (e.g., the school tax, user fees). Such options might include:
 - fully funding the Clinical Center through a line item that is adjusted annually for inflation;
 - providing funds for the Clinical Center to offset inflationary costs in a given fiscal year;
 - offsetting inflationary or budgetary obstacles through competitive use of the facility, open to the extramural and private research communities.
- Create streamlined mechanisms by which extramural researchers and industry can more fully use the Clinical Center for projects in collaboration with the IRP. This might include giving the Clinical Center and/or institutes the flexibility and authority to negotiate broader collaborative agreements or public-private partnerships, taking into consideration ethics rules and intellectual property rights.
- Explore the possibility of the Clinical Center controlling a pool of funds to make use of the facility feasible for investigators who otherwise could not afford it, for example through a program similar to the Bench-to-Bedside Awards.
- NIH should seek the necessary statutory or regulatory remedies needed to compensate clinical investigators at a competitive level.

C. The IRP should be encouraged to systematically and proactively mobilize resources to rapidly and effectively respond to emerging scientific challenges and opportunities.

Interviewees told the Task Force that the nation is lacking sufficient capacity to quickly and/or forcefully respond to emerging biomedical research needs and challenges (e.g., biothreats, vaccine development, rapid diagnosis, breakthrough discoveries). Because of the way the extramural community is funded, it can take as long as 18 months from the time that a need or scientific opportunity is identified until research begins in the laboratory or clinic.

As part of its focus on translational and clinical research, the IRP should strengthen its capacity to serve on an as-needed basis as a rapid response/consulting service for the biomedical research community. This function would serve to collect preliminary data on a high-risk concept, conduct proof-of-principle studies, or perform research in support of more rapidly meeting regulatory requirements (e.g., FDA). Such capacity would create a resource for critical translational studies that 1) would take too long to be funded and executed through the ERP; 2) would be of critical importance to clinical research but are too “generic” or upstream for any one company to pursue; or 3) because of uncertainty might require a long-term commitment of time and resources. This would accelerate the process of generating early or fundamental data

that could then be shared with the ERP and industry for more extensive studies or development.

To achieve this goal, it is critical that the IRP be able to consult and partner with the ERP and industry, as needed, for such purposes. In fact, it is hard to imagine a scenario in which such collaborations would not be essential, as expertise should be drawn from all available sectors on an as-needed basis to tackle the issue. In addition, the IRP must find ways to contend with its limited ability to increase or diversify its scientific capacity because of the constraints imposed by current and longstanding personnel policies.

Building such capacity would require a major directive from the NIH Director, with material and policy support from the Secretary of HHS and Congress. Such efforts potentially could be supported through the Common Fund, the Director's discretionary funds, novel use of the Foundation for the NIH, supplemental appropriations, reprogramming of funds, or more strategic use of contracting and short-term appointments to build scientific capacity. Current mechanisms—such as Public-Private Partnerships, Cooperative Agreements, Cooperative Research and Development Agreements (CRADAs) and Material Transfer Agreements (MTAs)—might serve as mechanisms for meeting these goals, but their limitations must be explored. In particular, more aggressive programs are needed to bring extramural and industry researchers to the NIH campus for short, intensive periods of time.

Two major barriers would have to be removed for such a capacity to function. The first concerns the alleged prohibition against commingling of IRP and ERP funds and resources. The second concerns revision of the current individual conflict of interest rules to allow such collaboration and the development of an NIH institutional conflict of interest policy. The ability to fully exploit the resources of the IRP requires that these issues be addressed.

With regard to the first barrier, the Task Force is unaware of specific controlling legal authority in statute or regulations that prohibits commingling of intramural and extramural funds. Instead, as a general matter, the separation or combination of such funds are controlled by general principles of appropriations law, and by specific enactments relating to agency discretion in reallocating appropriated funds. The bottom line is that NIH may legally reallocate, reprogram, or use funds in a different way than specified in its annual appropriations, but only through specific mechanisms and subject to the oversight requirement that the Director explain himself or herself to Congress.

With regard to the second barrier, current NIH ethics policy governing individual conflicts of interest has had a sometimes stifling effect on recruitment and retention of clinical investigators. In the view of many interviewees, it has prevented important collaborations in translational and clinical research. While there is a genuine need for clear ethics guidelines, the current policy inhibits the IRP's ability to serve national needs and should be revised if its rapid response capacity, among other of our

recommendations, is to succeed. In addition, NIH must develop a policy regarding *institutional* conflicts of interest that allows legitimate and ethical interactions to occur between the IRP and extramural and industrial partners.

Action Items:

- Within the first year of his or her term, the new NIH Director, in collaboration with NIH leadership and the HHS Secretary should identify existing capacities to achieve this goal. Strategies that require statutory or regulatory changes should be targeted for action. In particular, NIH should clarify and/or reverse the arbitrary and misinterpreted prohibition on commingling of IRP and ERP resources.
- NIH must explore ethical options for working with private industry sponsors and investigators on a more flexible basis than through CRADAs and Cooperative Agreements, or modify the current mechanisms to allow such collaborations on a timelier basis.
- NIH should revisit the current individual conflict of interest policy to assess whether it is interfering with recruitment, retention, or innovation in translational and clinical research.
- NIH should develop a policy on institutional conflicts of interest to expand productive collaborations while ensuring accountability.

D. The IRP should be the premier national program for translational and clinical research training.

The IRP has a long history of providing training opportunities for postdoctoral fellows and physician scientists. In the 1960s, it was the premier training site in clinical science, in part because opportunities in the extramural program were minimal. However, today's IRP programs for clinical investigators are relatively small compared to training programs for laboratory work. Most interviewees agreed that there is a need for the IRP to again become the centerpiece of translational and clinical research training, the requirements of which have changed dramatically in the past 40 years. There are new and emerging critical needs in clinical research with regard to developing better platforms, clinical trial methodology, and methods research. In addition, more clinical research training is needed in rare and neglected diseases, which sometimes require different approaches and methods than routine randomized controlled clinical studies. Within the training programs, there should be increased opportunities to expose medical students to the excitement and need for clinical research, to encourage them to pursue careers in clinical research.

Action Items:

- Expand and enhance the clinical scientists training program, creating opportunities for extramural scientists to spend time on the NIH campus pursuing training and research opportunities.
- Create training programs in clinical research management, including partnering with FDA.
- Expand programs for providing clinical science trainees with research funds that

can be taken to an extramural institution upon completion of training.

E. The IRP should play a central role in developing and sustaining large-scale, long-term projects.

Some of the best examples of the IRP's excellence can be found in projects and programs requiring a long-term investment in and support of a research concept from the basic to developmental level, or significant infrastructure support of personnel and capital equipment. Examples include the Vaccine Research Center, the National Center for Biotechnology Information, the numerous imaging programs, phenotyping capacity in the Clinical Center, bioinformatics initiatives, and large-scale data intensive projects, such as Genomewide Association Studies (GWAS) and biobanking. These resources serve both the IRP and the extramural program.

Action Items:

- IRP leadership should take a more proactive role in identifying such projects and working with the NIH Director and each other to pool resources and focus hiring practices on needed expertise.
- NIH should establish ways to maximize use of the IRP core facilities by academic and industry researchers modeled after the programs at the National Laboratories of the Department of Energy.

VI. Conclusion

In the coming years, the American public and policymakers will be focused on reforming our healthcare system, and rightly so. But at the same time we must nurture our health *cure* system. Only if we translate promising scientific research into new therapies and acquire a better understanding of how to prevent and treat disease will we have any hope of reducing healthcare costs, productivity losses, and human suffering.

To advance human health at a time of constrained federal budgets, we must increase the effectiveness of our investment in biomedical research and maximize the impact of the almost \$3 billion investment we make every year in the NIH IRP, a valuable national resource. It must have a clearly articulated and transparent mission, strategies in place to fully use its clinical and training resources, the capacity to respond to emerging short-term opportunities and threats, as well as the ability to support and sustain large-scale and long-term projects.

The IRP has long served as an important element of the U.S. biomedical research effort. Today, the external academic community provides the driving force of basic discovery, freeing the IRP to serve other roles. In this way the IRP can regain its centrality within the research community and be seen again as a leading-edge institution for biomedical progress.

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Anna Barker

Deputy Director
Director for Advanced
Technologies and Strategic
Partnerships
National Cancer Institute

Edward Benz

President
Dana-Farber Cancer Institute

David Botstein

Anthony B. Evnin Professor
of Genomics
Director, Lewis-Sigler
Institute for Integrative
Genomics
Princeton University

Thomas Cech

President
Howard Hughes Medical
Institute

Stephen Chanock

Investigator
Pediatric Oncology Branch
National Cancer Institute

Francis Collins

Former Director
National Institute for Human
Genome Research

David Cox

Senior Vice President and
Chief Scientific Officer
Biotherapeutics and
Innovation Center
Pfizer Inc.

James Doroshow

Director, Division of Cancer
Treatment and Diagnosis
National Cancer Institute

Anthony Fauci

Director
National Institute of Allergy
and Infectious Disease

Joseph Fraumeni

Director, Division of Cancer
Epidemiology and Genetics
National Cancer Institute

John Gallin

Director
NIH Clinical Center

Michael Gottesman

Deputy Director for Intramural
Research
National Institutes of Health

Lee Helman

Scientific Director for Clinical
Research
National Cancer Institute

Barry Hoffer

Scientific Director
National Institute on Drug
Abuse

Richard Klausner

Managing Partner, The Column
Group
Former Director, National
Cancer Institute

Alan Koretsky

Scientific Director
National Institute of
Neurological Disorders and
Stroke

Douglas Lowy

Chief, Laboratory of Cellular
Oncology
National Cancer Institute

John Niederhuber

Director
National Cancer Institute

John Porter

Partner, Hogan & Hartson
Former Member of Congress

Mark Schiffman

Investigator, Division of Cancer
Epidemiology and Prevention
National Cancer Institute

Harold Shapiro

President Emeritus
Professor of Economics and Public
Affairs
Princeton University

Louis Staudt

Investigator, Metabolism Branch
National Cancer Institute

Margaret A. Tucker

Director, Human Genetics
Program
National Cancer Institute

Robert Wiltout

Scientific Director for Basic
Research
National Cancer Institute

Harold Varmus

President, Memorial Sloan-
Kettering Cancer Center
Former Director, National
Institutes of Health

Elias Zerhouni

Former Director, National
Institutes of Health

***FasterCures* Task Force Members**

David Baltimore, *Chair*

Robert A. Millikan Professor of Biology
California Institute of Technology

Karen Antman

Provost
Boston University Medical Campus

Gail Cassell

Vice President of Scientific Affairs
Eli Lilly and Company

Alan Leshner

Chief Executive Officer
American Association for the Advancement of Science

Carl Schramm

President
Ewing Marion Kauffman Foundation

Myrl Weinberg

President
National Health Council