

**FasterCures**

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## ***FasterCures* Task Force Calls for New Mission and Focus for National Institutes of Health's Intramural Research Program**

The Intramural Research Program (IRP) consumes nearly ten percent of the budget of the National Institutes of Health (NIH). The IRP has a highly regarded history of discovery but today lacks a clearly defined mission within the overall NIH effort. *FasterCures*, a nonprofit center of the Milken Institute, convened a task force headed by David Baltimore to recommend to the incoming Administration a framework within which to refresh the Intramural Research Program, giving it a distinct mission and identity in the service of improving public health. This mission is three-fold: to focus on translational research, especially work that utilizes the unique capabilities of the NIH Clinical Center; to be prepared to respond expeditiously to new scientific opportunities and challenges; and to focus on high-risk, long-term basic research goals that would be difficult to pursue in the extramural research environment.

The Task Force recommends the following:

- **NIH should articulate an overarching mission for the IRP and strategies for meeting goals over the next five years, focused specifically on advancing translational and clinical research in the interest of public health.**
  - The incoming NIH Director should rapidly undertake an inclusive planning exercise to create the new mission statement for the IRP.
  - 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.
  - 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.
- **The Clinical Center must be fully utilized and the IRP's clinical research program should be expanded.**
  - 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 the current disincentives for use.
  - Create streamlined mechanisms by which extramural researchers and industry can more fully use the Clinical Center for projects in collaboration with the IRP.



- 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.
- NIH should seek the necessary statutory or regulatory remedies needed to compensate clinical investigators at a competitive level.
- **The IRP should be encouraged to systematically and proactively mobilize resources to rapidly and effectively respond to emerging scientific challenges and opportunities.**
  - 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. 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 industry on a more impromptu and/or 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.
- **The IRP should be the premier national program for translational and clinical research training.**
  - 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.
- **The IRP should play a central role in developing and sustaining large-scale, long-term projects.**
  - 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.

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 medical research and maximize the impact of the almost \$3 billion investment we make every year in the NIH Intramural Research Program.



## **The *FasterCures* Task Force Vision Statement for the NIH IRP**

The NIH Intramural Research Program (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, it 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 goal 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 same limitations faced by the extramural community (i.e., short-term funding, competing demands, such as teaching and clinical services).

Importantly, the IRP should become more outcomes-focused, meaning it should strategically seek solutions to clinical problems through bench work, animal models, and human studies. Its focus on basic questions should be seen as supportive of solving pressing medical problems and 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; that facilitates collaboration among the various institutes and centers; and that focuses more on quality control and accountability. IC Directors should be assessed on their ability to implement these strategies and carry out the IRP mission.



## ***FasterCures* Task Force on the NIH IRP**

### **Key Opinion Leader Interviews**

The following individuals gave their time, perspectives, and consideration to the issues raised in this report through interviews and focused meetings. They are not responsible for the contents of this report.

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## Members of the *FasterCures* Task Force on the NIH IRP

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