Funding mechanisms and program management at the National Heart, Lung, and Blood Institute: confronting new challenges and exploring new opportunities

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Over the past 8 years, the National Institutes of Health (NIH) budget appropriation has lost purchasing power, with erosion of the benefits of the doubling of the budget less than a decade ago. For the first time in 40 years, the NIH appropriation in fiscal year 2011 was 1% less than in the previous year. The National Heart, Lung, and Blood Institute (NHLBI) has been closely managing its funds to protect its core functions: support and conduct of research, and training of biomedical research scientists. Rigorous evaluations of funding mechanisms, management of clinical studies, set-aside programs and funding guidelines are designed to help the Institute, in consultation with its advisory council, to minimize the long-term impact of extreme resource limitations on the advance and conduct of science. This report describes some recent actions taken by the NHLBI to maximize support for investigator-initiated research, maintain a balanced portfolio, and provide as much support as possible for established and early-stage investigators. (Blood. 2011;118(20):5380-5382)

Introduction

The National Heart, Lung, and Blood Institute (NHLBI) has a long tradition of prudent fiscal management. The NHLBI has always been careful in making long-term commitments to maximize our flexibility to support new scientific opportunities and minimize the extent to which we would find ourselves to be overextended when the lean years set in. It is now safe to say that the lean years are here. Although we have no way of knowing whether the lean years will extend to or even beyond the Biblical standard of 7, there is little doubt that we are in for quite a few more. Already, the purchasing power of the NHLBI appropriation has eroded to the point that it is now equivalent to what it was a full decade ago. Our appropriation was reduced in current dollars by 1% in fiscal year (FY) 2011. The most optimistic projections for the National Institutes of Health (NIH) appropriation in FY 2012 (start date: October 1, 2011), are that it will remain at the FY 2011 level, or below the FY 2010 level.

Although a budget of ~ $3 billion may still meet the standard long ago established by Senator Everett Dirksen as “real money,” with a real loss in purchasing power serving a rich, broad, and hungry scientific portfolio requiring nurture and maintenance, we are obligated to continue to look rigorously at everything we are doing. We must ensure that we are providing the American taxpayers the greatest possible return on their investment in biomedical research.

Funding mechanisms

The NHLBI allocates the overwhelming majority (~ 90%) of the total NHLBI’s appropriation for the support of extramural research. Thus, we regularly review and assess the relative contributions of the various funding mechanisms we use. As has been a long-standing practice of the NHLBI, before considering any alteration in our use of existing funding mechanisms, we assemble and evaluate available relevant data and seek the advice of the National Heart, Lung, and Blood Advisory Council (NHLBAC). We recently followed that model in deciding to modify our use of one funding mechanism (the Exploratory/Development Grant, R21) and to discontinue our use of another (the Method to Extend Research in Time or [MERIT] award, R37).

Exploratory/development grant (R21) mechanism

The R21 is a 2-year award that, as indicated by its name, is intended to provide support for exploratory research projects. R21 applications are expected to have substantially less preliminary data than would ordinarily be required in a regular Research Project Grant (R01) application. The lower (or absent) threshold for preliminary data may be attractive both to established investigators who are interested in pursuing substantial alterations in their research directions and to young investigators who think that an R21 presents an opportunity to assemble the data that they will need to support an R01 application. For established investigators, the R21 may just be the impetus they need to embark on an exploration of a new high-risk, but potentially high-return, research direction. For early-stage investigators, it may just be an attractive opportunity but provide insufficient time to obtain the results needed to support an R01.

According to our most recent data, early-stage investigators are just as successful as established investigators in obtaining R01s but are less successful than established investigators in obtaining R21s. Moreover, the majority of early-stage investigators who apply for and receive R01s do so without having previously had an R21. In other words, R21s are not easier to obtain for early-stage investigators; and most importantly, having an R21 is not an essential first step toward obtaining an R01. We therefore think that early-stage investigators who have already accumulated sufficient data should not apply for an R21 but rather seek to establish themselves as independent investigators by applying for an R01. Those early-stage investigators without sufficient data for an R01 would be far better off applying for the NIH Pathway to Independence Award (K99/R00) if they are eligible to do so. The K99/R00 fosters and enables the transition from the career development status of the K99...
award component to the independent investigator status of the R00 component by providing an initial phase of 1-2 years of mentored support followed by up to 3 years of independent support on securing an independent-tenure track or equivalent research position.

As we discontinue our participation in the parent NIH R21 program announcement, we expect to issue targeted funding opportunity announcements to invite applications in new, exciting areas where investigators may not have much data. These opportunities will be available to investigators with a track record in research who do not require mentors. This will enable us to direct funds to areas of scientific opportunity and maximize the return on investment.

**MERIT award (R37) program**

The MERIT award (R37) program was created by the NIH in 1986 “to provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner.” Recipients of the award could not apply but were to be nominated by the funding NIH institute from its competing R01 awards and then endorsed by the national advisory council. The benefit of being designated as a MERIT awardee was that the recipients would be afforded a simplified renewal for a second 5-year period without reapplication so long as they met certain criteria of continued productivity. Given the high standard that the NHLBI has historically insisted on for nominating and approving an R37 award, it is not surprising that most of the awardees did indeed maintain their productivity. In some sense, it was a self-fulfilling prophecy: those who were identified as highly productive and thus selected for a MERIT award continued to be productive.

However, that also means that, with or without the MERIT, most of those selected for the R37 would have continued to be funded even if they had to submit a regular competing renewal R01 application. In other words, the only likely effect of discontinuing the MERIT award is that those who might have received the award in the future will not have the opportunity to obtain one simplified renewal. Both the NHLBI and the NHLBAC adjudged that slight disadvantage to be insufficient in the current funding environment to justify exempting any applicants from full competition through peer review. That fundamental principle of fairness is why the NHLBI, with the support of the NHLBAC, has announced that it will no longer make any awards using the R37 mechanism. The NHLBI will continue to honor its existing commitments to those who have received the R37; existing MERIT awards will be supported and extended as long as the investigators meet the established criteria.

**Clinical studies management**

The success of the NHLBI in supporting critical clinical studies that have established the standard of care for the prevention and treatment of numerous heart, lung, and blood diseases has been well documented. Yet given the current funding environment, we think that we must examine rigorously even our most successful programs to identify potential opportunities for savings. Over the past 5 years, we have been doing just that for all of the clinical studies we support. We have tightened the requirements for efficient management of studies to ensure that they are conducted as efficiently as possible. Our major focus has been on accrual and study conduct in clinical trials that enroll 150 subjects or more, observational studies that enroll 1000 subjects or more, and our clinical research networks. Regular monitoring of accrual and assessment of study feasibility is essential for the ethical conduct of human subjects research and the proper stewardship of public funds. We have hired clinical trial specialists with real-world experience in the conduct of clinical trials in each of our extramural program divisions to help manage the trials and the grants and contracts that support them. We have also provided clear guidance for establishing recruitment benchmarks (http://www.nhlbi.nih.gov/funding/policies/accrual_guidelines.htm) and heightened our oversight of patient recruitment so that we can now quickly identify those studies with lagging accrual and discontinue those that have demonstrated a clear inability of enrolling the numbers of participants needed to answer their primary scientific questions. We have engaged the principal investigators in our clinical centers and data coordinating centers as full partners in examining our clinical studies, and it is their support that has ensured the success of our efforts to provide more effective oversight and management.

**Small business innovative research and small business technology transfer programs**

Each year, the NHLBI’s legislatively mandated expenditures for Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) compose 2.5% and 0.3%, respectively, of our extramural budget. Because of their relatively short standard award length, our combined investment in the 2 programs actually represents a considerably greater percentage (7%-9%) of our new commitments (competing award dollars) each year. As envisioned by the establishing legislation, the programs are intended to support domestic small business concerns in the conduct of research and development that has the potential for commercialization.

In the past, the NHLBI relied almost exclusively on the general NIH-wide solicitations for SBIR and STTR grant applications. Although those solicitations always included illustrative examples of areas of NHLBI interest, they were not in any way directed to strategic NHLBI needs. The recommendations of an internal NIHBI effort to reconsider our use of the SBIR/STTR were presented to, and strongly endorsed by, the NHLBAC in May 2010. Their primary emphasis was on redirecting the NHLBI’s SBIR/STTR investment through targeted solicitations for SBIR/STTR grant applications and contract proposals to address the translation of basic science discoveries into new and better diagnostics and treatments. That would be an important objective at any time in the life of the program, but it is an especially compelling one in light of our current fiscal reality.

**Funding guidelines**

The changes in NIH peer review instituted in 2007 have limited applicants to a single resubmission if an application is not funded the first time it undergoes review, as opposed to 2 resubmissions. Projects that do not achieve a fundable priority score after 2 reviews are no longer eligible for consideration unless redesigned so extensively that they qualify as new applications. To expedite funding of grants that scored well with their initial review (A0), which were statistically likely to be funded after resubmission, the NHLBI rebalanced its paylines to ensure that original applications succeed at a rate equivalent to that of resubmissions. This has required a graduated payline, with different criteria for first and
resubmissions for the past 2 years. Using this approach, we have awarded more than half of our grants promptly after the first review, without additional paperwork and discussion required by resubmissions. In FY 2008 and FY 2009, we were able to fund a total of 5 more grants than would have been funded without this rebalancing. As the funding patterns change with the elimination of the A2, we anticipate a single payline for A0 and A1 applications.

Early-stage investigators\(^4\) are now scored as a group separate from established investigators to level the field. With the funding advantage given to early-stage investigators at the NHLBI, funding rates are equivalent for early-stage investigators and established investigators.\(^5\)

The Enhanced Review Criteria\(^6\) explicitly emphasize critical considerations, such as innovation, and assign scores for each. The new shortened application format will demand even more rigorous attention to preparation of cogent, persuasive grant applications. The message to applicants should be clear: Scientific quality, logical thinking, clear writing, attention to detail, and critical review are more important than ever. Applicants, with the proactive support of scientific and administrative leaders at the institutions that depend on NIH grant funding, need to plan ahead, get constructive feedback and mentoring early and often, and ensure that every application submitted is the very best it can be.

In conclusion, the dramatic reductions in the burdens of heart, lung, and blood diseases that occurred in the United States and throughout the world over the past half-century have been realized because of the evidence base derived from basic and clinical biomedical research. The unprecedented breadth of scientific opportunities available to us in the second decade of the 21st century offers the promise for even greater reductions. Our collective responsibility is to work together to use our available resources most effectively to pursue those opportunities to advance science and improve the public health. We at the NHLBI, working in partnership with the scientific community, are responsible for allocating those resources as wisely as possible, and the recipients of those resources are obligated to use them as wisely as possible. As the physicist Ernest Rutherford is reported to have said, “We haven’t got the money, so we’ve got to think!”\(^7\)

Acknowledgments

The author thanks Dr Carl Roth, Acting Deputy Director of NHLBI and Director of the NHLBI Office of Science and Technology, who provided essential assistance in the writing and revisions of this manuscript, and Dr Stephen Mockrin, Director of the Division of Extramural Research Activities, who provided valuable advice and editing.

Authorship

Contribution: S.B.S. wrote the manuscript.

Conflict-of-interest disclosure: The author declares no competing financial interests.

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References

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