SCIENTIFIC MANAGEMENT REVIEW BOARD REPORT ON STREAMLINING THE NIH GRANT REVIEW, AWARD, AND MANAGEMENT PROCESS

JULY, 2015

NIH National Institutes of Health
Turning Discovery Into Health

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ACKNOWLEDGEMENTS

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EXECUTIVE SUMMARY

The Scientific Management Review Board (SMRB) was established under the National Institutes of Health (NIH) Reform Act of 2006 to advise the NIH Director and other appropriate officials on the use of certain organizational authorities reaffirmed under the same act. In 2014, NIH leadership charged the SMRB with recommending ways to further optimize the process of reviewing, awarding, and managing grants in a way that maximizes the time researchers can devote to research while still maintaining proper oversight. In addressing this charge, the SMRB was asked to consider how NIH could streamline the grant-making process and shorten the time from application to allocation of funds, as well as address the administrative requirements for principal investigators and their institutions.

NIH has been a world leader in the process of scientific review, and NIH's peer review process is a key part of funding the most innovative and meritorious biomedical research. Reviewing and awarding grants efficiently is of growing importance in a time when NIH is facing large volumes of applications from ever-increasing numbers of applicants. The increased volume of applications is straining the peer review system, especially given that a relatively stable fraction of the community serves as reviewers even as the number of applications rises. This strain combines with budgetary uncertainty to delay the process of making funding decisions, resulting in some applicants waiting more than a year between the conclusion of peer review and a funding decision.

As the competition for funding intensifies, investigators are spending greater portions of their time preparing and writing grants, leaving them with less time to conduct research. Even if peer review is favorable and funding is likely, additional administrative hurdles can extend the time to award. Once the funds are in hand, investigators must provide regular progress reports and engage in effort reporting as well. All of these factors drain researchers' time and effort and take researchers away from their scientific pursuits.

In addressing these issues, the SMRB met with experts and stakeholders in NIH's granting process, including grant applicants and awardees, research administrators from institutions across the U.S., NIH Scientific Review Officers, NIH Extramural Research Program staff, the NIH Director and Deputy Director for Extramural Research, and the Director of NIH's Center for Scientific Review. The SMRB also heard from officials at other federal agencies, nongovernmental funding organizations, and foreign biomedical research agencies about different approaches to grant review and award processes.

The SMRB carefully considered potential tradeoffs inherent in the process and only reviewed recommendations that would not compromise the quality of peer review and NIH grant oversight for the sake of speed. The SMRB was also mindful that reducing the burden on one group might increase burden in another area and that speeding up one part of the process could create a bottleneck at a future step. The SMRB paid particularly close attention to any actions that would increase the burden on investigators or that would disadvantage any subpopulation of applicants. Any potential solution that might streamline the grant-making process but could put additional burden on investigators was examined with extra scrutiny.

Ultimately, the SMRB made 10 recommendations that could streamline the process of grant review, award, and management:

- NIH should strive to fast-track awards for high-priority, top-scoring applications.

- NIH Institutes and Centers (ICs) should share best practices for reducing time to award.

- Where practical, ICs should provide partial funding to promising applications early in the fiscal year, with more complete funding to follow when the IC budget for the fiscal year has been determined. NIH should seek ways to apply this two-step process with minimal administrative burden.

- NIH should pilot test an expanded pre-application process in which potential applicants voluntarily submit brief summaries of proposed projects. Those applicants with projects deemed the most promising would be encouraged to submit a full application.

- NIH should deepen its pool of peer reviewers by continually encouraging grantees to participate in the process. In addition, the pool of reviewers should reflect the diversity that NIH strives for within the scientific workforce; NIH should increase the diversity of expertise called upon for peer review and should carefully integrate more early stage investigators in the review process.

- NIH should consider pilot testing an expansion of its continuous submission policy.

- NIH should ensure that review staff have the necessary tools and procedures to maximize efficiency and should consider adding review staff to handle the increased volume of grant applications when a specific need is identified.

- NIH should evaluate its just-in-time procedures to identify mechanisms that might enhance efficiencies, including modifying existing procedures.

- NIH should consult outside efficiency experts to review specifically targeted administrative aspects of the granting process and identify potential efficiencies and improved policies and procedures.

- NIH should consider prize competitions as a mechanism to generate innovative ideas to improve the grant process.

In addition, the SMRB encourages NIH to convey the impact of delayed funding on advancing the nation's medical research priorities, to motivate decision-makers to consider solutions that could lead to an expanded timeline for NIH spending authority.

The SMRB's findings and recommendations are described in detail in this report.

I. INTRODUCTION

A. Overview of NIH's grant-making process

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.[1]

The National Institutes of Health (NIH) is a taxpayer-funded U.S. federal agency responsible for supporting basic, clinical, and translational biomedical research. NIH is made up of 27 Institutes and Centers (ICs), each with its own mission, ranging from combatting cancer to curing vision disorders to addressing health disparities. Most of the research supported by NIH is conducted at universities and other public and private research institutions that are located in every state across the U.S., and NIH must ensure that the research it supports is scientifically meritorious and addresses basic, clinical, and translational research priorities. NIH awards funds primarily through a competitive awards process, in which scientists submit research grant applications that are reviewed by a panel of peers—other scientists who are knowledgeable about the science underlying the proposed research.

NIH grant applications typically undergo two levels of review. Upon receipt, applications are referred to both a scientific review group and to one of 24 research-funding ICs—depending on which IC is aligned most closely with the proposed research area—for consideration. NIH's Center for Scientific Review (CSR) manages the receipt and referral process and arranges the peer review of 73 percent of NIH grant applications; peer review of the remainder of the applications is conducted by scientific review officers (SROs) within each IC.

In the first level of evaluation, peer review panels assign each application a score that is based on scientific merit and other criteria[2]. Upon receiving a list of meritorious applications, ranked by percentile score, the IC Director and staff consider which applications will best advance their research mission and address program priorities. Because each IC has multiple priority research areas but not enough funds to support all meritorious applications, ICs must be strategic in their selection of which applications to fund, so ICs are not required to adhere

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[1] National Institutes of Health (NIH). (2013). *Mission*. Retrieved from http://www.nih.gov/about/mission.htm.

[2] NIH. (2015). *Peer review criteria and considerations*. Retrieved from http://grants.nih.gov/grants/peer_review_process.htm#Criteria.

strictly to the ranking of scores assigned by peer review panels and can opt to fund slightly lower-scoring applications that address another priority research area. For example, ICs' missions typically encompass multiple diseases. An IC might want to support research portfolios in all of these disease areas, even if all research applications looking at one disease received better scores from peer review panels than applications looking at another disease. These strategic discussions occur during the second level of review, in which each IC's scientific advisory council/board makes recommendations regarding their concurrence with the primary review for each application, as well as on the application's public health relevance and alignment with the IC's program priorities.[3]

This two-stage peer review process involves significant time and effort, but it promotes rigor and fairness in the selection of meritorious research that will advance our understanding of diseases, disabilities, other conditions, and human health. In its instructions to reviewers, NIH states that the core values of peer review are expert assessment, transparency, impartiality, fairness, confidentiality, integrity, and efficiency.[4] Peer review is at the heart of the NIH enterprise and academic biomedical research, and it makes the biomedical research ecosystem stronger.[5]

NIH believes that peer review ensures that as much of the most meritorious and rewarding science as possible, given budget constraints, is funded, which is key to maintaining the competitiveness of American biomedical research on the global stage. In an address to the National Academy of Sciences in April 2013, President Obama noted that "to maintain our edge, we've got to protect our rigorous peer review system and ensure that we only fund proposals that promise the biggest bang for taxpayer dollars… That's what's going to maintain our standards of scientific excellence for years to come."[6] In December 2014, the Coalition to Promote Research, an alliance of universities, patient advocacy groups, and professional societies, wrote a letter to Congress in support of NIH

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[3] NIH. (2015). *Second level of review—Advisory Council or Board.* Retrieved from http://grants.nih.gov/grants/peer_review_process.htm#Second.

[4] NIH. (2013). *NIH peer review: grants and cooperative agreements.* Retrieved from http://grants.nih.gov/grants/peerreview22713webv2.pdf.

[5] Barnard, J. (2014, December 14). NIH grant process boosts science through peer review. *Columbus Dispatch.* Retrieved from http://www.dispatch.com/content/stories/science/2014/12/14/1-nih-grant-process-boosts-science-through-peer-review.html.

[6] Obama, B. (2013, April 29). Remarks by the President at the 150th anniversary of the National Academy of Sciences. Retrieved from https://www.whitehouse.gov/the-press-office/2013/04/29/remarks-president-150th-anniversary-national-academy-sciences.

peer review, saying, "We stand united in our support for the NIH, its mission, and its world-renowned peer review process."[7] Although NIH's peer review process remains a key component of U.S. global leadership in biomedical research, recent changes to the funding landscape have brought new challenges.

B. Current landscape and challenges facing NIH's grant-making process

NIH funding doubled between 1998 and 2003, increasing from $13.7 billion to $27.1 billion. However, since 2003, NIH's purchasing power has declined substantially, due to budget cuts and an increased rate of inflation for medical research compared with other sectors.[8] Thus, even a flat NIH budget has resulted in a decline of overall purchasing power. The doubling of the NIH budget was followed by a near doubling of the number of individual applicants, from approximately 19,000 in 1998 to about 32,000 in 2011.[9] The number of grant applications also doubled, from 31,000 in 1998 to more than 62,000 in 2014.[10] These increases in the numbers of applicants and applications coincided with a leveling off of the NIH budget and a net reduction in purchasing power.

What has caused this dramatic increase in the numbers of applicants and applications? Part of the explanation lies in the doubling of the budget: Trainees (including graduate students and postdoctoral fellows) make up a large part of the biomedical workforce,[11] and increased funding for biomedical research has also led to an increase in the number of trainees. At the same time, demographic shifts in the nation's population have also affected the biomedical workforce. Scientists are remaining in the workforce longer and retiring later: In 1998, only 5 percent of NIH direct costs went to principal investigators (PIs) older than 65,

[7]   Coalition to Promote Research (2014, December 2). Letter. Retrieved from https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=15729.

[8]   Moses, H., 3rd, Matheson, D. H. M., Cairns-Smith, S., George, B. P., Palisch, C., & Dorsey, E. R. (2015). The anatomy of medical research: U.S. and international comparisons. *JAMA,* 313: 174–189. PMID: 25585329.

[9]   Rockey, S. (2012, August 9). More applications; many more applicants [blog post]. Retrieved from http://nexus.od.nih.gov/all/2012/08/09/more-applications-many-more-applicants/.

[10]   NIH RePORT. (2015). *Research grants: competing applications and awards.* Retrieved from http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=159&catId=2.

[11]   NIH RePORT. (2012). *ACD Biomedical Workforce Working Group data.* Retrieved from http://report.nih.gov/investigators_and_trainees/acd_bwf/.

but in 2014 this number was almost 12 percent.[12] New investigators are now competing with prior generations of scientists for funding in an ever-expanding pool of applicants.

This trend toward rising numbers of applicants and applications shows no signs of abating. The size of the biomedical research workforce continues to increase as trainees enter an ever-growing workforce with fewer faculty-level opportunities. The job market for life sciences Ph.D.s has suffered as a result. One recent analysis found that while 53 percent[13] of life science graduate students want to become PIs, having their own labs, only 8 percent will become tenure-track faculty.[14, 15]

For those who do become PIs, obtaining research funding is an increasingly challenging prospect. With many more applications and less available funding, NIH success rates (i.e., the percentage of reviewed grant applications that ultimately receive funding) have fallen from an average of 25 percent in 1998 to 15 percent in 2014.[16] The falling success rate leads PIs to spend significantly more time preparing applications for grant funding. From 1997 to 2014, as the number of competing applications rose from 31,000 to 62,000,[17] the number of grants awarded rose only from 10,000 to 12,500 (Figure 1).[18]

A recent article by several members of both NIH and the academic biomedical research community concluded that the funding system is "in perpetual disequilibrium, because it will inevitably generate an ever-increasing supply of scientists vying for a finite set of research resources and employment

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[12] Rockey, S. (2015, March 15). More data on age and the workforce [blog post]. Retrieved from http://nexus.od.nih.gov/all/2015/03/25/age-of-investigator/.

[13] Sauermann, H., & Roach, M. (2012). Science PhD career preferences: levels, changes, and advisor encouragement. *PLoS One, 7*(5), e36307. PMID: 22567149.

[14] Polka, J. (2014, April 11). *Where will a biology Ph.D. take you?* Retrieved from http://ascb.org/where-will-a-biology-phd-take-you/.

[15] Biomedical Research Workforce Working Group, The Advisory Committee to the Director (2012). *Biomedical Research Workforce Working Group report.* Retrieved from http://acd.od.nih.gov/Biomedical_research_wgreport.pdf.

[16] NIH RePORT. (2015). *Peer reviewers, by fiscal year and type of review.* Retrieved from http://report.nih.gov/NIHDatabook/Charts/Default.aspx?sid=0&index=0&catId=23&chartId=285.

[17] NIH RePORT. (2015). *Research and training grants: competing applications by mechanism and selected activity codes.* Retrieved from http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=200&catId=2.

[18] NIH RePORT. (2015). *Research grants: competing applications and awards.* Retrieved from http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=159&catId=2.
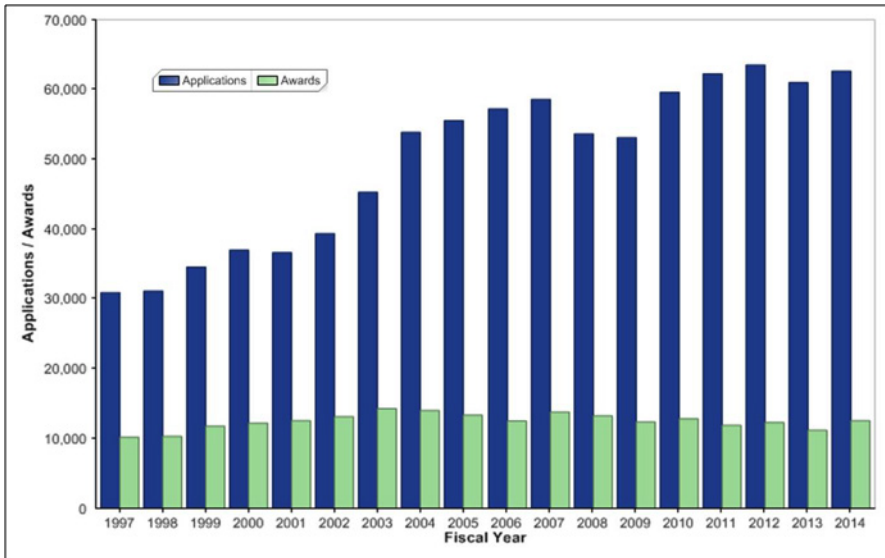
Figure 1. The number of applications submitted (dark blue bars, left) has risen markedly since 1997, while the number of awards (green bars, right) has remained relatively constant.

opportunities."[19] This disequilibrium has led to a vicious cycle, in which the hypercompetitive environment further exacerbates the problem: PIs who do not receive funding continue to submit applications, and the number of investigators continues to increase. The increasing competition for funding also results in a drain on researchers' time. To get research funding, PIs spend more time preparing and submitting grant applications, which cuts into time that the PIs could be spending supervising their labs and applying valuable ideas and insight to their own research. In 2015, when NIH amended its submission policy to allow an unsuccessful resubmission to be submitted as a new application for the next grant cycle, the number of research applications reviewed by CSR increased by more than 12 percent in each of the first two rounds. This change will increase the burden on an already taxed review infrastructure and likely will decrease the success rate for research applications for 2015, despite a budget increase.

Another hurdle PIs face is the time lag between submission of their application and finding out whether their grant application will be funded. The average time from submission to award for an NIH grant is 9 to 10 months, with notable variability. It is difficult for PIs to plan longer-term research projects or make

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[19] Alberts, B., Kirschner, M. W., Tilghman, S., & Varmus, H. (2014). Rescuing U.S. biomedical research from its systemic flaws. *Proceedings of the National Academy of Sciences of the United States of America,* 111, 5773–5777. PMID: 24733703.

purchasing or staffing decisions due to uncertainty about whether they will have the funds to support new acquisitions or payroll adjustments. The time delay for competing renewal applications may mean that research staff need to be laid off because there is insufficient funding for them to continue their work. Even once an award is made, numerous reporting requirements can consume PIs' time and reduce their focus on research.

An additional burden on PIs, as well as NIH staff, is the high demand for review generated by the increase in the number of applications. Even as the number of applications has soared, the number of reviewers has remained relatively stable.[20] The sheer volume of applications has put a strain on the system, leading to an increased workload for reviewers that slows the process of evaluating applications. Reviewers now are often asked to review more applications per cycle than in the past. When surveyed, reviewers indicated that they can review a maximum of eight applications and that they would prefer to review between just four and six applications.[21] However, some are being asked to review 12 or more applications per funding cycle. Staff from NIH's CSR have stated that the system is operating at capacity with the current volume.[22]

C. Charge to SMRB

The NIH Reform Act of 2006 (Public Law 109-482) established the Scientific Management Review Board (SMRB or the Board) to advise the NIH Director and other appropriate agency officials on the use of their organizational authorities.

The majority of NIH funding is distributed through grants to extramural researchers, so it is vital that NIH optimize grant-making in a way that streamlines the process while maintaining accountability and high performance standards. Given the challenges described above, NIH sought advice from the SMRB on ways to improve the grant-making process. The range of backgrounds and perspectives represented on the SMRB provided NIH with the opportunity to seek high-level advice regarding the grant-making process as a whole. Specifically, NIH asked members of the SMRB to recommend ways to further optimize the process of reviewing, awarding, and managing grants to maximize the time researchers can devote to research while

[20] NIH RePORT. (2015). *Peer reviewers, by fiscal year and type of review.* Retrieved from http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=285&catId=23.

[21] Roberts, L., Pearson, K., & Amero, S. (2015, March 9). Results of the peer review capacity evaluation. Presentation to SMRB.

[22] Nakamura, R. (2014, December 15). Presentation to SMRB.

still maintaining proper oversight. In addressing this charge, the SMRB considered how NIH could do the following:

- Streamline the grant-making process and shorten the time from application to allocation of funds; and

- Address the administrative requirements for applicants and their institutions, scientific reviewers, Council members, and NIH staff while maintaining a high-quality review and management process.

SMRB members were asked to take the following steps in their deliberations:

- Assess each aspect of the current NIH grant-making process and determine whether any change is warranted;

- Examine grant-making processes in other U.S. agencies, research funding bodies, and nations, and any available reviews of these systems to assess the strengths and weaknesses of different approaches;

- Seek input from the general public, stakeholders in the biomedical research community, participants in the grant-making process, and individuals with expertise in the review, awarding, and management of biomedical research grants in the U.S. and abroad; and

- Identify possible strategies for improving the NIH grant-making process and articulate the rationale for choosing those strategies.

D. SMRB process

SMRB members who formed the Working Group on NIH's Grant Review, Award, and Management Process examined each step, from writing applications to post-award oversight, and looked for ways to streamline the process. They met with experts and stakeholders in NIH's granting process, including grant applicants and awardees, research administrators from institutions across the U.S., NIH SROs, NIH Extramural Research Program staff, the NIH Director and Deputy Director for Extramural Research, and the Director of NIH's CSR. The group also heard from officials at other federal agencies and nongovernmental funding organizations, as well as foreign biomedical research agencies, about different approaches to grant review and award processes.

A full list of consultants can be found in Appendix A. The Working Group provided updates to and solicited input from the entire SMRB during public deliberations on May 7, 2014; July 7–8, 2014; October 14, 2014; December 15, 2014; and July 6, 2015.

II. PRINCIPLES FOR STREAMLINING NIH'S GRANT-MAKING PROCESS

While the formal charge to the SMRB addressed streamlining the grant-making process, the Board appreciates that NIH's grant review, award, and management process is complex and that any suggested changes likely will have ripple effects. As such, the Board kept a few principles in mind when considering potential recommendations.

One primary principle during deliberations was that proposed changes should not sacrifice the quality of peer review that investigators expect from NIH in the name of faster review.

The SMRB was also mindful of the follow-on effects of any recommendations. Decreasing the burden on one group might increase burden in another area, for example, and speeding up one part of the process could create a bottleneck at a future step. Similarly, the SMRB members gathered information about potential unintended consequences from changing the process. Members of the Board considered potential effects carefully as they developed their recommendations, to create the maximum benefit with the fewest drawbacks.

As all possible consequences were weighed, the SMRB paid particularly close attention to any actions that would increase the burden on investigators. Any potential solution that might streamline the grant-making process but that would require additional investigator burden was given extra scrutiny. Unless a clear benefit that would outweigh the cost was identified, the SMRB did not consider those solutions further.

Finally, the SMRB intentionally avoided recommending changes that would disadvantage any subpopulation of applicants. The SMRB and NIH maintain that a diverse population of applicants and grantees is critical to maintaining a vibrant scientific and intellectual community.

III. SMRB FINDINGS AND CONSIDERATION OF POSSIBLE CHANGES

In accordance with its charge, the SMRB deliberated on potential changes to the grant award process by examining each step of the process. For each step, the Board considered the challenges and opportunities, as well as potential solutions, to streamlining the process. The following sections describe the steps in NIH's grant review, award, and management process and some of the changes the SMRB members considered during their deliberations. Ultimately, not all of these potential changes were recommended for NIH's consideration; those that were are listed in Section IV: Recommendations.

A. Writing and submission

NIH grant applicants typically begin writing their applications several months before the due date, investing significant time in articulating their project plans and goals. Once the application is complete, the applicant's institution or organization submits it; nearly all applications are filed through the federal portal, Grants.gov. On average, each NIH extramural scientist submits 1.4 grant applications per year.[23] In a recent survey of nearly 1,800 NIH grant recipients, respondents estimated that they spent nearly 20 percent of their time preparing grant applications and subsequent progress reports.[24] This estimated time burden, combined with historically low success rates for grant applications, creates a discouraging atmosphere among applicants and grantees, who could be more productive if they spent a greater portion of their time conducting innovative research.

Within this step, the Board considered the following potential strategies to streamline the process:

A1. Improve the function of Grants.gov
Grants.gov serves as the federal portal for submission of nearly all NIH grant applications. Established in 2003, it operates under the governance of the Office of Management and Budget and is managed by the U.S. Department of Health and Human Services (HHS). Within HHS, the management of Grants.gov falls under the purview of the Assistant Secretary for Financial Resources. NIH is one

[23] Rockey, S. (2012, August 9). Many applications; many more applicants [blog post]. Retrieved from http://nexus.od.nih.gov/all/2012/08/09/more-applications-many-more-applicants/.

[24] Roberts, L., Pearson, K., &, Amero, S. (2015, March 9). Results of the peer review capacity evaluation. Presentation to SMRB.

of 26 federal grant-making agencies that use Grants.gov as their grant application portal. Although it works closely with the Grants.gov Program Management Office, NIH has no direct control over the website's functionality.

In their deliberations, the SMRB members noted problems with the Grants.gov application process. Applicants find the system cumbersome and not compatible with software and databases used by most academic and research institutions. The NIH Office of Extramural Research (OER) will continue to play an important role in working within the governance structure to overcome these difficulties to the benefit of NIH applicants. The SMRB noted that OER's development and implementation of the Application Submission System & Interface for Submission Tracking (ASSIST) represented a major improvement in the grant submission process.[25] The Board was supportive of OER's ongoing efforts and did not make specific recommendations other than to endorse these efforts.

A2. Implement a pre-application process

Many of the funding agencies and organizations engaged by the SMRB employ a pre-application process in which potential applicants submit a "pre-application," a brief summary of an application, before submitting the full application. The SMRB looked at various scenarios in which pre-applications are reviewed and applicants with ideas that are deemed most promising are invited to submit full applications. Such processes are intended to reduce the burden on applicants, who might otherwise spend time writing a full application that is not likely to be funded, and on reviewers, who would have fewer full applications to review.

The Board heard descriptions of different approaches toward the review of these pre-applications. Some organizations had program staff conduct the review themselves; others convened separate peer review panels to review pre-applications and full applications; still others convened the same panel of experts twice, first to review the pre-applications and then to review the full applications.

NIH has employed a pre-application mechanism that, thus far, has been limited in scope. The Board considered how a pre-application process could be used for a broader range of applications, noting the concern that voluntary submission of pre-applications and their review might lengthen the overall time from initial contact to award. However, such a process could enhance applicants' success rates and reduce overall time to award if the need for resubmission were obviated.

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[25] Rockey, S. (2015, April 30). More ASSISTance options for submitting your application to NIH [blog post]. Retrieved from http://nexus.od.nih.gov/all/2015/04/30/more-assistance-options-for-submitting-your-application-to-nih/.

The SMRB found that the idea warranted further exploration and recommended that NIH consider piloting this approach on a broader range of applications. After further consultation with CSR, the Board endorsed an approach in which NIH could identify some upcoming Funding Opportunity Announcements (FOAs) and include instructions for the submission of pre-applications, which would be reviewed by the same peer review panel that would review the subsequent applications. Submission of pre-applications would be voluntary, and although the pre-application reviews might discourage applicants from submitting a full application, applicants would not be prevented from doing so. Outcomes (e.g., number of full applications submitted and time to award) would be compared against the results of similar FOAs released at approximately the same time.

> *Recommendation: NIH should pilot test an expanded pre-application process in which potential applicants voluntarily submit brief summaries of proposed projects. Those applicants with projects deemed most promising would be encouraged to submit a full application.*

A3. Fund investigators, not projects

The SMRB heard from NIH and other organizations about initiatives in which promising investigators receive funding based on their overall research program rather than on specific projects. For example, the Board discussed the Howard Hughes Medical Institute's Investigator and Early Career Scientist programs, which support researchers engaging in high-risk, high-reward research and have admirable track records. In addition to financial support, the programs minimize non-research requirements to reduce the administrative burden on researchers.

Several NIH programs are experimenting with this model. The NIH Common Fund supports the Pioneer Awards and New Innovator Awards, two programs for high-risk, high-reward research. Pioneer Awards fund individual scientists of exceptional creativity who propose pioneering, possibly transformative approaches to major challenges in biomedical and behavioral research. New Innovator Awards support creative new investigators at an early career stage. Several NIH ICs are also piloting person-centered grant mechanisms. For example, the National Institute of Environmental Health Sciences initiated the Outstanding New Environmental Scientist (ONES) program to foster the careers of outstanding junior scientists while supporting innovative environmental health research.

NIH is also piloting awarding longer grants to provide more stable support for investigators, to allow them more freedom to innovate and explore new lines of inquiry. The pilots include the National Cancer Institute's Outstanding Investigator Award,[26] which will provide long-term support to investigators who have extraordinary records of cancer research productivity and who propose to conduct exceptional research, and the National Institute of General Medical Science's Maximizing Investigators' Research Award (MIRA). By supporting an investigator's research through a single unified grant rather than through a series of separate individual research project grants, MIRA will allow researchers the freedom to explore new avenues of inquiry that arise during the course of their work.

The Board endorsed NIH's efforts in this area and urged the further development of similar programs.

A4. Encourage grantee institutions to provide more input to researchers preparing grant applications

Many members of the Board, as well as several invited speakers, noted that research institutions have a vested interest in improving the quality of applications submitted, even if doing so results in fewer submissions to NIH. To ensure that the best possible applications are submitted, many institutions have developed programs to help faculty prepare successful grants. For example, Vanderbilt University's Edge for Scholars program[27] has several initiatives to help early career faculty, including giving the school an institutional role in protecting time for grant preparation, spurring productivity, offering guidance in grantsmanship, facilitating community with other early career faculty through social media and other forums, and providing access to an extended network of senior scientists for advice and mentoring relationships. One initiative allows investigators to submit their original or revised grant application for internal review by senior faculty members who have served on NIH review panels. A video of the review and a written critique are provided to the investigator. Similarly, Duke University has programs to help early career scientists with grant preparation by enlisting

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[26] NIH. (2014). *Funding opportunity announcement: Outstanding Investigator Award (R35).* Retrieved from http://grants.nih.gov/grants/guide/pa-files/PAR-14-267.html.

[27] Vanderbilt University. (2015). *Edge for Scholars.* Retrieved from https://my.vanderbilt.edu/edgeforscholars/.

senior faculty with NIH review experience to provide detailed feedback on draft grant applications.[28] [29]

These are just two of many programs at research institutions and professional societies across the country, all intended to help early career scientists succeed in the NIH grant process. The SMRB discussed ways for these programs to become even more widespread, and the Board agreed that sharing best practices would be beneficial to the entire academic biomedical research community. However, the Board determined that this sharing and interaction would be best at the institutional level and that there was not a specific role for NIH in this area.

B. Receipt and referral

NIH's Division of Receipt and Referral within CSR receives approximately 84,000 applications per year, some of which it refers to other agencies. Applications for NIH funding that are compliant with NIH policies are assigned simultaneously to an NIH IC for funding consideration and to a Scientific Review Group (SRG) for peer review. The receipt and referral process takes an average of two weeks, and very few referrals are contested. Due to the speed and efficiency with which CSR accomplishes receipt and referral, the Board did not identify particular ways to streamline this step.

C. Peer review

As previously noted, each application NIH accepts for funding consideration undergoes a two-step review process. The initial step, peer review by an SRG or a Special Emphasis Panel consisting of recognized experts in relevant scientific fields, assesses the overall scientific merit of an application by scoring it based on pre-established criteria. Commonly used criteria include significance, approach, innovation, investigator, and environment, although criteria may vary with different grant mechanisms.[30] The second level of review, performed by the ICs' Advisory Councils, takes other factors (e.g., public health, program priorities) into account. Although peer review is the gold standard for awarding grants for

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[28] Duke University (2015). Path to Independence Program. Retrieved from https://medschool.duke.edu/about-us/faculty-resources/faculty-mentoring/grant-writing-programs/path-independence-program.

[29] Duke University (2015). K Club. Retrieved from http://medschool.duke.edu/faculty/office-faculty-development/k-club.

[30] NIH. (2014). *Review criteria at a glance (for parent announcements)*. Retrieved from https://grants.nih.gov/grants/peer/Review_Criteria_at_a_Glance_MasterOA.pdf.

scientific research, the process is time-consuming, and the growing number of applications puts more burden on reviewers. To try to address these challenges, the SMRB considered the following potential solutions.

C1. Increase the pool of potential reviewers

Given the challenges posed by the growing number of applications, the SMRB deliberated on strategies for increasing the pool of potential reviewers. Data from internal analyses indicate that while many NIH grantees participate actively in the peer review process, a substantial number of established investigators are not engaged in peer review for various reasons. Some investigators may be hesitant to accept invitations to serve as reviewers because they are already serving NIH in other capacities or due to time constraints or other issues; others may not have been asked. The Board discussed several strategies for improving participation of NIH grantees, noting that NIH already encourages investigators to participate in the process. For example, a recent NIH Guide Notice[31] addressed this issue, and the SMRB strongly encourages NIH to repeat such messages on an ongoing basis.

The Board also discussed broadening the range of grantees asked to serve as reviewers. Involving senior, experienced investigators is vital to the quality and integrity of peer review. However, the Board felt that less-established investigators also have a role in the peer review process. Since the biomedical research community is increasingly concerned about the next generation of researchers, including more early career investigators could both alleviate burden on the reviewer pool and help early stage investigators learn more about the process. The participation of additional junior investigators should be balanced carefully with more senior researchers to ensure that a breadth and depth of expertise are represented on review panels.

The Board also noted the importance of including more diversity in the reviewer pool to reflect the growing diversity in the research workforce. In addition to looking at those with Ph.D.s and medical degrees, NIH should consider extending review invitations to people with a wider variety of degrees, such as those in dentistry, nursing, veterinary science, and public health. Doing so would be in keeping with NIH efforts to broaden the definition of the biomedical workforce.[32]

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[31] NIH. (2015). *Reinforcing service to the biomedical research community.* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-035.html.

[32] Biomedical Research Workforce Working Group, The Advisory Committee to the Director (2012). *Biomedical Research Workforce Working Group Report.* Retrieved from http://acd.od.nih.gov/Biomedical_research_wgreport.pdf.

> *Recommendation: NIH should deepen its pool of peer reviewers by continually encouraging grantees to participate in the process. In addition, the pool of reviewers should reflect the diversity that NIH strives for within the scientific workforce; NIH should increase the diversity of expertise called upon for peer review and should carefully integrate more early stage investigators in the review process.*

C2. Streamline and improve peer review meetings

The Board discussed numerous options for streamlining peer review meetings, such as increasing the number of virtual meetings to reduce travel burden on reviewers and cost. The group affirmed the value of in-person meetings but also strongly encouraged NIH to explore virtual meeting options, especially among established review groups where many of the participants have had in-person meetings in the past. The SMRB noted that CSR and many ICs already have undertaken such innovations and endorsed those groups' efforts.

The Board also noted that the experience of participating in a peer review panel had changed over the years. New policies, such as those affecting food and beverage provision, have made participating in panels less hospitable than in the past. Providing modest refreshments facilitates the discussion that forms the core of rigorous peer review and maximizes the efficient use of reviewers' time and energy. The Board urged rule makers to consider modest modifications to some of these policies to enhance reviewer participation and satisfaction.

C3. Modify the review cycle

Both primary peer review and secondary Advisory Council review occur in three cycles per year. The current timing of the third cycle leaves NIH staff with little time to make grant awards for applications reviewed in that cycle. Frequently, a backlog of applications from the two previous cycles has accumulated, creating an end-of-year workload that places a large burden on NIH staff.

The SMRB considered reducing the number of cycles per year from three to two in an attempt to reduce burden for reviewers and NIH staff alike. However, the Board ultimately decided that such a change was unlikely to affect the number of applications received, merely shifting a greater burden into the two remaining cycles.

C4. Implement a continuous submission policy for all grantees

The Board also discussed broadening NIH's existing continuous receipt policy (rather than three deadlines per year), which currently applies to a limited pool of applicants (e.g., members of standing peer review committees and IC Council members). For example, the National Science Foundation (NSF) recently pilot tested a continuous submission policy for one of its programs. Unexpectedly, this led to a substantial reduction in the overall number of applications received. The SMRB considered whether this might be possible for NIH. However, the organizations that the SMRB consulted handle a significantly lower volume of applications than NIH does, and they operate their peer review systems differently. In addition, implementing a rolling submission policy at NIH might increase the time from application to award, as the period between submission and review might be extended. Even so, the SMRB felt that PIs and ICs could benefit from expanding the continuous submission policy. Such an expansion would enable PIs who are applying for multiple grants or mechanisms to spread out their application efforts over time. PIs could also benefit if the pressure of looming grant deadlines were eliminated. Continuous submission could alleviate burdens on research institutions as well by smoothing out administrative workflow needed to prepare applications for submission. The Board noted that because NIH currently extends continuous submission privileges to PIs who serve as reviewers, expanding the policy to all grantees should not cause much disruption to the system.

> *Recommendation: NIH should consider pilot testing an expansion of its continuous submission policy.*

C5. Strategically increase NIH review staff to handle the large volume of applications

The SMRB noted that NIH review staff have maintained a relatively constant timeline for conducting peer review, despite the rapid increase in applications. However, sustaining this steady flow has increased staff workload. With the number of applications unlikely to stop rising in the near future, the burden on staff may not be sustainable. The SMRB considered several strategies for increasing review staff if a specific need were identified, such as allowing NIH intramural staff to rotate through CSR and the other ICs to conduct peer review. However, training review staff is a long-term investment, so temporary rotations may not be the best solution. The SMRB recommends that NIH consider increasing the number of review staff but urges NIH to evaluate the need for additional staff

carefully by first ensuring that current staff have tools and procedures at their disposal to maximize efficiency.

> *Recommendation: NIH should ensure that review staff have the necessary tools and procedures to maximize efficiency and should consider adding review staff to handle the increased volume of grant applications when a specific need is identified.*

D. Award decision

Following peer review, IC Directors must determine which applications to fund. Each IC Director carefully considers the peer review score, taking into account the scores of other applications, the recommendations of program staff and the Advisory Council, the IC's needs and priorities, and, if possible, the IC's budget.

The time needed to make funding decisions varies widely between ICs, funding mechanisms, and fiscal years. One reason for the variation is that it is difficult for IC Directors to make funding decisions without knowing their exact budget for a fiscal year. While top-scoring grants often are funded and low-scoring grants usually are not funded, the funding status of grants with midrange scores remains uncertain in the absence of a congressionally-specified IC budget. In the past decade, the majority of federal budgets have been appropriated during or after the second quarter of the fiscal year. Delays in the appropriations process for the new fiscal year can result in delayed funding decisions, as IC Directors wish to avoid promising funding and then having to revoke it.

The SMRB discussed a number of ideas to accelerate the award decision process. While the SMRB feels that all of the recommendations put forward in this report are important, the three recommendations in this section are most responsive to the charge and thus should have higher priority, so they are listed first in the summary table of recommendations in Section IV.

D1. Fast-track awards for high-priority applications

Most ICs currently fast-track the high-priority, top-scoring applications that they are confident they will fund. However, the share of applications that are fast-tracked varies from one IC to another, and fast-tracking is hindered in the absence of an agreed-upon federal budget, so fast-tracking may be less effective early in

the fiscal year. In addition, when operating under a continuing resolution, ICs can commit only the amount of funds that they had committed at the same time point the previous year. Within these limitations, the SMRB supports fast-tracking awards for the maximum possible number of high-priority, top-scoring applications.

> *Recommendation: NIH should strive to fast-track awards for high-priority, top-scoring applications.*

D2. Share best practices for strategies to reduce time to award

Some practices that allow one IC to make decisions more quickly than another may be transferable between ICs, but differing IC missions and resources limit other strategies' portability. The SMRB recommends that NIH ICs share best practices for reducing the time from submission of an application to award of a grant.

In addition, to both inform potential grantees of their application status as quickly as possible and alleviate the end-of-year workload faced by grants management staff, the SMRB encourages IC Directors to make funding decisions as early in the fiscal year as they can. The Board noted the wide variation between ICs in the amount of time from application to award and determined that efficiencies and best practices should be shared among all levels of NIH leadership and staff.

> *Recommendation: ICs should share best practices for reducing time to award.*

D3. Provide partial funding of some grants while awaiting final NIH budget appropriations

In the absence of a final budget, ICs may be limited in the funds they can award at certain times of the year (e.g., under a continuing resolution, described above). However, it may be possible to start awarding funds more quickly to a larger number of grantees by funding some grants at a partial level initially. The full amount of the award would be paid later in the year when the budget is finalized. This strategy could help PIs avoid the need to lay off and then re-hire staff while they await a funding decision, even if the full amount of the grant is not made available until after the budget is determined.

The Board noted some caveats to this approach. Partial funding may be more viable for certain grant mechanisms; for example, work on research project grants could begin with partial funding, but large clinical trials, epidemiological studies, or training grants might need a full year's funding to launch. Partial funding might increase NIH administrative burden and slow down the process of issuing funds, because the partial and eventual full funding would have to be handled separately by NIH grants management staff, potentially doubling the workload.

Despite these concerns, the SMRB found that instituting a partial funding process early in the fiscal year could be of great benefit to investigators and research institutions and recommended that NIH devise processes to provide partial funding and subsequent full funding with minimal administrative burden.

> *Recommendation: Where practical, ICs should provide partial funding to promising applications early in the fiscal year, with more complete funding to follow when the IC budget for the fiscal year has been determined. NIH should seek ways to apply this two-step process with minimal administrative burden.*

E. Award issuance

Applications that receive funding are reviewed for a variety of other considerations, including verification of compliance with public policy requirements, disclosure of other sources of support, confirmation of animal or human subjects protocol approval, and assessment of the management systems of the applicant and their institution.[33] To forestall the need for investigators to spend time and energy providing administrative information during the initial grant-writing process, and to allow time for institutional approval processes to proceed in parallel with peer review, NIH generally requests this information only for applications with favorable scores. Collectively, these later-stage requests for information are known as "just-in-time" procedures.

Although they are designed to save applicants time during the process of grant writing and submission, just-in-time procedures can slow the issuance of awards. Gathering documentation on human subject approval, animal protocols, or

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[33] NIH. (2015). *Pre-award process—competing applications.* Retrieved from http://grants.nih.gov/grants/managing_awards.htm#pre.

biosafety approval, then delivering and verifying that information, increase the time it takes to issue an award. The SMRB noted that the just-in-time process should be examined further, and the Board urged NIH to consider a more in-depth evaluation of these procedures, potentially with the aid of outside efficiency experts.

ICs may choose to negotiate changes to an applicant's proposed budget before issuing a formal Notice of Award. An IC can propose that an application's timeline, scope, or aims be modified due to programmatic changes, existing support for the same applicant, or peer reviewer concerns. In addition, any budget change of 25 percent or more requires that the proposed project be explicitly altered to fit the new budget. In response to such changes, applicants may modify their proposed research plan, appeal an IC's decision, or withdraw the application.[34] Once a final budget has been agreed upon, a Notice of Award detailing the time and amount of funding for the project is issued to the applicant. However, these budget negotiations can slow award issuance, since the IC and the applicant must agree before a Notice of Award can be issued.

Better software for grants management could streamline budget negotiations, as well as subsequent tracking of awards. NIH staff are currently working to develop such systems to improve this process.

> *Recommendation: NIH should evaluate its just-in-time procedures to identify mechanisms to enhance efficiencies, including modifying existing procedures.*

F. Award management

Individual applicants and institutions conduct and manage their research programs and are responsible for the day-to-day operations of their grant. They are able to make some changes independently, such as no-cost extensions, carrying-over of unobligated funds, and small-scale re-budgeting that does not affect the project's scope. However, some grant actions explicitly require NIH approval: changes in key personnel, the grantee's institution, or carryover funds.

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[34] National Institute of Allergy and Infectious Diseases. (2011). *Research funding: your award may differ from your request*. Retrieved from http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7fundgrant.aspx#b.

In addition, NIH awarding offices monitor grants through review of progress reports, correspondence with the grantee, audit reports, site visits, and review of other information available to NIH.

PIs and institutions are required to submit ongoing reports related to their project: financial reports, reports of subawards to contractors, invention reports, progress reports, and the fulfillment of audit requirements, as well as renewals of human subject or animal approval. Grants management specialists review expenditure reports, keeping track of administrative and fiscal status. Program officers also review progress reports to determine whether continued funding is merited. These reporting requirements allow NIH to ensure that funds are spent productively and to evaluate whether the grantee can complete the project within the allotted budget and timeframe.

Many grantees feel that this reporting is a heavy burden on the process of conducting research. A 2012 survey of more than 12,000 investigators with federally funded grants[35] found that, on average, faculty reported spending 42 percent of the time allocated to their research projects on administration activities related to those projects, rather than actual research activities. Strikingly, this percentage has remained the same since an initial survey of 6,000 participants in 2005. The same report listed proposal preparation and post-award administration as top administrative burdens on researchers and found that junior faculty reported larger burdens than their more senior colleagues. These administrative burdens represent a single source of the accumulation of burden across multiple institutional and federal sources, including Institutional Animal Care and Use Committees (animal study approvals), institutional review boards (human subject approvals), biosafety panels, funding organizations, and other potential science-regulating entities. These requirements are important to protect humans and animals in research and the public's health and safety, as well as ensuring that tax dollars are expended appropriately. Many of these reports and processes are mandated by Congress. However, NIH recognizes the significant workload that these requirements produce and continually strives to streamline the process as

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[35] Not all respondents were NIH grantees; recipients of grants from any federal agency were included in the survey. According to the report, roughly 30 percent of respondents were in the biological and biomedical sciences, 30 percent were researchers in the physical sciences and engineering, 10 to 15 percent were from clinical and medical sciences, and a little more than 10 percent were in the social and behavioral sciences. The remainder included agricultural sciences, education, humanities and arts, and other non-listed fields.
Schneider, S. L., Ness, K. K., Rockwell, S., Shaver, K., & Brutkiewicz, R. (2012). *2012 faculty workload survey: research report*. Retrieved from http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.

much as possible. The SMRB heard from OER about how the office is working to reduce administrative burden, and the Board encourages NIH to continue to pursue these efforts.

F1. Continue ongoing efforts to remove grant management burden

NIH is committed to reducing the burden on grantees. In fall 2012, NIH implemented the federal government–wide Research Performance Progress Report (RPPR) system to standardize and streamline the process of submitting annual progress reports, which program officers and grants management staff use to assess progress and compliance. As part of a larger White House initiative to reform reporting across the federal government, NIH is taking steps to streamline effort reporting, make it easier to charge reasonable costs to direct costs, and provide simple, automatic, no-cost extensions under appropriate conditions.[36] NIH is also simplifying the electronic submission of noncompeting awards through an online portal known as eSNAP (Electronic Streamlined Non-Competing Award Process).

The multi-source nature of administrative burdens makes them particularly difficult to solve with individual, targeted interventions, especially when reporting is mandated by statute. NIH currently approaches the issue of administrative burden as an optimization problem, making changes throughout the process so that various steps are more streamlined, automated, or otherwise user-friendly.

G. Other opportunities to streamline the grant-making process

In the course of its deliberations, the SMRB discussed potential strategies designed to streamline two or more steps of the granting process.

G1. Hire efficiency experts to review the granting process

Officials at other agencies and organizations reported that outside efficiency experts using a variety of approaches, such as Lean Six Sigma principles, had helped them streamline their own granting and decision-making processes. Some NIH practices cannot be changed, due to statutory requirements, but others could be modified to alleviate burden on the extramural community as well as NIH staff. To help NIH identify some of these policies and procedures, the Board discussed the possibility of consulting outside efficiency experts. For example, experts could work with NIH to examine pre-application processes, identifying potential efficiencies by eliminating redundancies in grant application

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[36] Rockey, S. (2014, January 17). New reforms to federal grant policies [blog post]. Retrieved from http://nexus.od.nih.gov/all/2014/01/17/new-reforms-to-federal-grant-policies/.

requirements and forms. Experts could also evaluate the just-in-time process to determine where it could be made less burdensome or altered to speed up award issuance. Another potential area where outside experts may be helpful is in procedures to monitor progress of funded applications. Currently, IC program officials and grant management specialists separately collect information on ongoing awards. Re-examining this information, how it is collected, and potential redundancies could result in new procedures that would reduce burden on grantees and NIH staff.

> *Recommendation: NIH should consult outside efficiency experts to review specifically targeted administrative aspects of the granting process and identify potential efficiencies and improved policies and procedures.*

G2. Consider using prize authority to solicit ideas for streamlining the process

NIH often taps the extramural research community for innovative ideas to tackle a range of challenges. The SMRB considered recommending a prize competition to solicit solutions from the academic, private, and philanthropic sectors to streamline the grant award and/or management process. NIH has the statutory authority to conduct prize competitions, wherein a small monetary award can be offered in a public competition in exchange for a product or idea, allowing NIH to tap a larger community for ideas and offer incentives for valuable contributions. The Board noted that the intricate, complex grant award and management process is difficult to understand externally, which may limit the odds of receiving successful suggestions. However, a prize competition could offer fresh perspectives on the bottlenecks in the system. With crowdsourcing becoming increasingly popular, the SMRB decided that this could be an effective way to solicit new ideas to streamline the grant-making process.

> *Recommendation: NIH should consider prize competitions as a mechanism to generate innovative ideas to improve the grant process.*

G3. Modifying NIH's budget and spending authority

Each year, Congress appropriates funds for federal agencies to use in supporting their respective missions. When conferring this authority to the agencies, Congress specifies criteria for spending the funds, including stipulations that the funds be obligated within a particular timeframe. For NIH, Congress appropriates funds on a yearly basis and instructs that funds must be obligated within a given fiscal year. Unspent funds are returned to the U.S. Treasury. The stipulation to obligate funds by the end of the fiscal year, combined with the frequent uncertainty of the budget for much of the year due to continuing resolutions, creates a significant end-of-year workload for NIH staff and is a major driver of the timeframe in which grants are awarded.

The SMRB discussed the potential of several alternative budget scenarios to speed up the award process, including the potential expansion of NIH's spending authority to two or more years. This would allow award issuance beyond the end of the fiscal year and could result in a standard timeline from application to award that would remain constant throughout the year.

The Board noted that the current appropriations system is not optimal for scientific research, which often requires long-term projects and a mix of advance planning and flexibility to respond to urgent scientific needs and opportunities. NIH planning and decision-making would benefit most from the certainty conferred by multi-year budgets. Ideally, a five-year budget, coinciding with the length of most NIH grants, would allow NIH the stability to engage in long-term planning while maintaining requisite flexibility.

While the SMRB supports modification to NIH's budget and spending authority to be more conducive to the pace and time horizon of scientific research, this decision is in the purview of Congressional appropriators and not within the power of NIH to affect. The SMRB, however, encourages NIH to convey the impact of delayed funding on advancing the nation's medical research priorities to motivate decision-makers to consider solutions to achieve an expanded timeline for NIH spending authority.

IV. RECOMMENDATIONS

The SMRB and the NIH Grant Review, Award, and Management Process Working Group sought input from a range of individuals with expertise and experience from NIH, other U.S. federal agencies, international governmental funding agencies, nonprofit funders of biomedical research, and the grantee community. With insights and input from these advisers, as well as the depth of personal experience among Grant Review, Award, and Management Process Working Group members, the SMRB developed a series of recommendations for streamlining NIH's grant review, award, and management processes. The rationale for these recommendations is discussed above, in Section III: SMRB Findings and Consideration of Possible Changes, and they are summarized and listed below. While the SMRB feels that all of these recommendations are important, the first three recommendations most directly address the charge and should receive higher priority. The remaining recommendations are presented in the order in which they are discussed in the report.

Number	Recommendation	Page
1	NIH should strive to fast-track awards for high-priority, top-scoring applications.	24
2	ICs should share best practices for reducing time to award.	24
3	Where practical, ICs should provide partial funding to promising applications early in the fiscal year, with more complete funding to follow when the IC budget for the fiscal year has been determined. NIH should seek ways to apply this two-step process with minimal administrative burden.	25
4	NIH should pilot test an expanded pre-application process in which potential applicants voluntarily submit brief summaries of proposed projects. Those applicants with projects deemed most promising would be encouraged to submit a full application.	17
5	NIH should deepen its pool of peer reviewers by continually encouraging grantees to participate in the process. In addition, the pool of reviewers should reflect the diversity that NIH strives for within the scientific workforce; NIH should increase the diversity of expertise called upon for peer review and should carefully integrate more early stage investigators in the review process.	21
6	NIH should consider pilot testing an expansion of its continuous submission policy.	22

Number	Recommendation	Page
7	NIH should ensure that review staff have the necessary tools and procedures to maximize efficiency and should consider adding review staff to handle the increased volume of grant applications when a specific need is identified.	23
8	NIH should evaluate its just-in-time procedures to identify mechanisms that might enhance efficiencies, including modifying existing procedures.	26
9	NIH should consult outside efficiency experts to review specifically targeted administrative aspects of the granting process and identify potential efficiencies and improved policies and procedures.	29
10	NIH should consider prize competitions as a mechanism to generate innovative ideas to improve the grant process.	29

V. CONCLUSIONS

The SMRB Working Group on Grant Review, Award, and Management Processes presented the findings and recommendations found in this report during an SMRB meeting on July 6, 2015. SMRB members endorsed the report (12 in favor; 0 opposed). The findings and recommendations presented in this report address potential opportunities for reducing the burden on investigators and NIH staff and decreasing the time to decision or award. The SMRB believes that NIH can improve its grant review, award, and management processes by exploring the recommendations set forth in this report.

NATIONAL INSTITUTES OF HEALTH SCIENTIFIC MANAGEMENT REVIEW BOARD

APPENDIX A: SPEAKERS AND CONSULTANTS

May 7, 2014

- Richard Nakamura, Ph.D., Director of the Center for Scientific Review, NIH

- Sally J. Rockey, Ph.D., Deputy Director for Extramural Research, NIH

July 8, 2014

- Robin A. Barr, D.Phil., Director of the Division of Extramural Activities, National Institute on Aging, NIH

- Alicia Dombroski, Ph.D., Director of the Division of Extramural Activities, National Institute of Dental and Craniofacial Research, NIH

- Lisa Goffman, Ph.D., Professor of Speech, Language, and Hearing Sciences, Purdue University

- Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, National Institute of General Medical Sciences, NIH

- Gary L. Harris, Ph.D., Professor of Electrical and Computer Engineering, Associate Provost for Research, and Dean of the Graduate School, Howard University

- Richard D. Hichwa, Ph.D., Professor in Radiology and Senior Associate Vice President for Research, University of Iowa

- James M. Larner, Ph.D., Professor and Chair of the Department of Radiation Oncology, University of Virginia School of Medicine

- Christy L. Ludlow, Ph.D., Professor of Communication Sciences and Disorders, James Madison University

- Richard Nakamura, Ph.D., Director of the Center for Scientific Review, NIH

- Sally J. Rockey, Ph.D., Deputy Director for Extramural Research, NIH

- Donald Schneider, Ph.D., Senior Advisor, Center for Scientific Review, NIH

- Miron L. Straf, Ph.D., Deputy Director of the Division of Behavioral and Social Sciences and Education, National Academies of Sciences, Engineering, and Medicine

September 12, 2014

- Michael Marletta, Ph.D., Member, Howard Hughes Medical Institute Scientific Review Board

- Carl Rhodes, Ph.D., Senior Scientific Officer, Howard Hughes Medical Institute

September 15, 2014

- Diane de Ryss, Director, Grants & Contracts Services, Finance and Strategy Division, Bill & Melinda Gates Foundation

- Lynne H. Smith, Deputy Director, Investment Workflow, Bill & Melinda Gates Foundation

September 26, 2014

- Linda Blevins, Ph.D., Senior Technical Advisor, Office of Science, Department of Energy

- Michael Santos, Ph.D., Deputy Director, Strategy, Planning & Management and Discovery & Translational Sciences, Bill & Melinda Gates Foundation

October 14, 2014

- Alyson Fox, Ph.D., Head of Grants Management, Wellcome Trust (U.K.)

- Declan Mulkeen, Ph.D., Chief Science Officer, Medical Research Council (U.K.)

- Sonny Ramaswamy, Ph.D., Director, National Institute of Food and Agriculture, U.S. Department of Agriculture

- Joanne S. Tornow, Ph.D., Deputy Assistant Director for Social, Behavioral, and Economic Sciences, National Science Foundation

November 3, 2014

- Candace Major, Ph.D., Program Director, Division of Ocean Sciences, National Science Foundation

- Stephen Meacham, Ph.D., Senior Staff Associate, Office of International and Integrative Activities, National Science Foundation

December 15, 2014

- Elva D. Diaz, Ph.D., Associate Professor, Department of Pharmacology, University of California, Davis

- Ervin R. Fox, M.D., Professor of Clinical Cardiology, University of Mississippi Medical Center

- Raquel Gur, M.D., Ph.D., Professor of Psychiatry, Neurology, and Radiology, University of Pennsylvania Perelman School of Medicine

- Della Hann, Ph.D., Deputy Director, Office of Extramural Research, Office of the Director, NIH

- Walter J. Koroshetz, M.D., Acting Director, National Institute of Neurological Disorders and Stroke, NIH

- David A. Savitz, Ph.D., Vice President for Research, Brown University

March 9, 2015
- Luci Roberts, Ph.D., Director of Planning and Evaluation, Office of Extramural Research, NIH