Report of the National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB) Task Force on Strategies for Efficient Use of Research Dollars

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Executive Summary

Faced with a limited budget and resulting low paylines, the National Institute of Biomedical Imaging and Biotechnology (NIBIB) formed the Advisory Council Task Force on Strategies for Efficient Use of Research Dollars in May 2014. The Task Force was charged with 1) assessing the needs of the biomedical imaging and bioengineering research community in the context of the technology-oriented mission of the NIBIB and 2) developing strategies to most efficiently address these needs with the limited resources available. This report summarizes the strategies and recommendations arising from Task Force deliberations over the past year.

Strategies and Recommendations:

- 1) Establish target goals for increasing funding success rates and marshal the financial resources needed to reach these targets. Strategies are proposed both for reallocation of existing resources and for introducing new resources via strategic partnerships.
- 2) Optimize and enhance NIBIB impact by increasing the number of investigators and diversity of NIBIB awards. Develop new metrics for evaluating and communicating success and impact.
- 3) Develop new concepts for supporting investigators, targeted to crucial stages in their careers.
- 4) Assess whether the current award structure has created sufficient opportunities for funding underrepresented investigators (e.g. underrepresented minorities, women, junior investigators) and new applicants.
- 5) Improve community perception and morale. Foster a spirit of inclusiveness and desire to contribute to the NIBIB mission.
- 6) Advocate on behalf of the NIH by communicating the broad importance of biomedical research to society.

Background

At the May 2014 NIBIB Advisory Council meeting, members were asked for their input regarding ways to maximize the impact of Institute resources on biomedical research in a time of limited-to-no budget growth. The suggestions and comments made at this meeting fell broadly into two theme areas including funding approaches and enhancing return on investment:

Research Funding Approaches

- Awards geared to support of people as opposed to projects. These might be modeled on the K awards, but for those who are not necessarily at the start or early stages of their careers.
- Rather than focusing on funding people, award mechanisms similar to the program projects grant (P01) can provide needed funding to multiple investigators with a single award.
- We could structure some fraction of awards as smaller awards similar to NSF to fund more people.
- A program could be modeled on the Howard Hughes Medical Institute. In addition, investigators could be required to perform service such as study section review as a condition of award.
- Issues of support and access to resources are fundamentally different at soft money versus hard money institutions and may require different approaches.

 Proposals with a longer budget period (e.g., 7-10 years/R35) that would balance vetted research ideas with the opportunity to pursue exploratory, high-risk projects. This may provide a more stable funding platform for mid to senior investigators

Enhancing Return on Investment

- Partnerships between industry and academia should be encouraged. We need additional/different avenues to develop and support these partnerships.
- We need to improve the return on investment in technology development including the SBIR/STTR program.

The discussion highlighted some key areas for further thought and development. However, it also became clear during the discussion that a more intensive effort would be required to give these issues the consideration that they need to develop truly successful strategies.

To achieve this goal, it was suggested that a term-limited task force be appointed to address this problem. To that end, the Task Force on Strategies for Efficient Use of Research Dollars was created and charged with:

- Reviewing the needs, opportunities and current resources available to advance the mission of the NIBIB
- Developing a set of recommendations as to how the NIBIB might most effectively use its limited resources
- Initiating a broader discussion on the challenges associated with funding biomedical imaging and bioengineering research aligned with the technology-oriented mission of NIBIB

The Task Force held discussions for a full year between May 2014 and May 2015 and met with NIBIB Program Directors in January 2015. The preliminary findings and recommendations of the Task Force were presented during the public portion of the January 23, 2015 Advisory Council meeting. This final report, presented at the May 18, 2015 NIBIB Advisory Council, summarizes the deliberations of the task force and puts forth recommendations for consideration.

The Problem

The NIH philosophy has always been to "fund the best science." Peer review is the main mechanism employed to meet this goal. The process of selecting and supporting outstanding ideas is generally considered to be robust and efficient when paylines are in the ~20+ percentile range.

Because of flat or decreasing NIH budgets, the current paylines are ~9%. This low payline means there are many outstanding projects that have not achieved funding. New and established investigators alike are facing highly competitive grant cycles, and must submit more grants to increase the chances of funding. This situation places the entire funding system under stress and in crisis. These levels have been in place for several years and are anticipated to persist unless significant changes are made.

Awareness of the low paylines can potentially introduce bias into the peer-review process and clearly contributes to frustration in the NIH community. Furthermore, recent data, presented at the January 2015 NIBIB Advisory Council Meeting, suggests that peer review may not always predict scientific impact or outcome. This topic is not well understood and is currently undergoing scholarly evaluation and discussion.

Low paylines can also lead to situations where promising, potentially impactful ideas, technologies and people are not funded. Over time this conundrum has many negative effects, including erosion of the number of investigators in the NIBIB/NIH community and significant deterioration of morale. With intense competition for limited resources, this can also create an environment where important fields or sub-fields can disappear or become marginalized very quickly as new "hot" areas emerge to compete for insufficient dollars. This further challenges our mission to balance conservation and growth of established disciplines with the need to stimulate new, high-risk, high-impact ideas and fields.

Strategies and Recommendations

Increase funding success rates along with the number and diversity of NIBIB-funded investigators:

Because NIBIB federal funding is not increasing, existing encumbered resources must be freed through reallocation, redistribution and/or restructuring of existing budget resources. In addition, the possibility of establishing strategic partnerships to leverage resources should be explored.

A) Re-allocate existing resources

It is estimated that the addition of ~\$3M/year to the RPG pool is required to increase the payline by one percentile point. With the current NIBIB payline at 9th percentile, ~\$9M/year is required to move the payline to the 12th percentile. To achieve the goal of moving the payline to 15%, an additional \$3M/year would be required to continue to improve the payline by one percentile point for each of the next 3 years.

A similar analysis of the impact of ~\$9M/year should be performed with respect to the "success rate" metric. "Success rate", rather than payline, is reported by some NIH Institutes. In 2014 paylines across NIH ranged from 8.7% (NCCAM) to 26.7% (NEI), with a mean of 17.8%. At 13%, NIBIB ranks well below the mean. A desirable target is ~20-25%. As we fund additional applications in the Expanded Opportunity Zone (EOZ) up to the 20th percentile, NIBIB should consider reducing or eliminating the emphasis on a single payline statistic and report a range of payline data in terms of success rates.

Overall, NIBIB should focus on setting realistic timelines and targets for establishing a sliding payline to meet a 20-25% success rate. These goals can be accomplished by creating and implementing new policies and procedures such as:

- In the submission phase, encourage limited budgets, reduced terms, and focused aims, e.g. "small R01s" that are not necessarily focused by technical topic, but are focused in terms of the need to demonstrate cost-effectiveness. This approach could potentially create a new award type of award aligned with NIBIB scientific goals.
- In the pre-award phase, give Program Directors enhanced flexibility by allowing NIBIB to
 identify promising, high scoring, but out-of-payline applications and include them in the
 portfolio at a negotiated reduced cost (NSF style). This action would help increase the
 number of investigators and diversity of NIBIB awards and help maintain a balanced
 portfolio and NIBIB engagement in important areas. This approach is now underway
 with the new EOZ process, and its effectiveness should be evaluated with time.
- In the award phase, increase type 1 and possibly type 2 administrative reductions to be in alignment with other Institutes, e.g. ~15-20%. Certain mechanisms would be exempt from this or would not experience full reductions, e.g. "cost-effective" R01s.

In addition to these changes in resource allocation, consideration should be given to eliminating the R21 program. In 2014, NIBIB received 67% more R21 than R01 (699 vs 418) applications. This may be due, in part, to the fact that other Institutes have gradually eliminated the R21 mechanism, resulting in applications being shifted to NIBIB. Statistical support for this scenario is based on the fact that R21 applications to the NIBIB more than doubled between 2008 and 2014 (339 and 699, respectively), while R01 applications were essentially unchanged (433 and 418, respectively). Potential benefits to eliminating the R21 would be the generation of substantial resources that could be used to enhance overall NIBIB success rate. However, elimination of the R21 should not occur without a carefully considered and well-crafted substitute, such as a new, "small R01" mechanism.

B) Introduce new resources into NIBIB via strategic partnerships

Create a full-time position to pursue the development of strategic partnerships with non-profits (e.g. Gates, HHMI, Pew, Burroughs Wellcome, Beckman Foundation, etc.), global partners, other government agencies, and other NIH Institutes that are aligned with or complement the NIBIB mission. This process should involve careful review of the NIBIB portfolio to determine optimal areas for synergy with other Institutes, Agencies, and Foundations.

NIBIB should engage organizations such as CMS and FDA to better utilize the talent of NIBIB investigators to solve urgent national needs in reducing health care costs, increasing value, improving patient outcome, and enhancing patient satisfaction. Many of the concepts, technologies, and data analysis methods critical to the expected national transformation in health care are supported by NIBIB grants. NIBIB should leverage its longtime support of new device and informatics technologies with the rapidly expanding activities in personalized, precision health care led by companies such as Apple, Google, Microscoft, etc. This could lead to new mechanisms for funding that involve corporate contributions to NIBIB-initiated public-private partnerships. These activities would support ideas to accelerate the NIBIB mission and vision for cost-saving and outcome-enhancing technologies.

Create new mechanisms to address the needs of each career stage:

With downward financial pressures on universities and government, challenges are increasingly arising at all career phases: junior, mid-, and senior. New funding approaches are needed to address these needs. The creation of new award mechanisms can be accomplished by introducing new types of awards and modifying existing awards.

The creation of a "cost-effective" and/or "small R01" and the opportunity for Program Directors to identify and negotiate for a more cost-effective, program-balancing award from out-of-payline applications are some elements of this strategy. A "small R01" would have a budget cap and reduced term, e.g. 3 years. A "cost-effective" R01 might be required to demonstrate significant resource leveraging and/or efficiency so that NIBIB funds support more investigators and/or a broader scope of activities than what would otherwise be possible with a limited budget.

In addition to new R01s, NIBIB should create new award mechanisms that are directed toward supporting individuals at different stages in their career. This mechanism could have a range of structures that integrate concepts spanning from something that resembles the current K-series, to the R35 idea that is under development across NIH. The R35 award could be targeted to a senior investigator population with a strong history of accomplishment, and a new K-series could be considered that would not be restricted to career stage.

A key component of individual investigator awards might be expectations for service to the NIBIB community, focused on participation in review panels, outreach, workshops, etc. While NIH does not require mandatory service, creating expectations through peer participation could be effective. There would also be constraints on the number and type of other awards that can

be held concurrently, where the greatest restriction would be placed on the R35. This is expected to have a positive impact on senior investigators who would be relieved of the administrative burden of having to write multiple small grants with high frequency. In addition to reducing stress, removing senior investigators from the constant pool of "grant churning" would enhance productivity by allowing them to focus more on their research, mentor junior investigators, and actively contribute to improving the quality and consistency of peer review through study section service. These activities could become an expectation for continued funding. Unlike R35s at NCI that are perceived to be a "capstone" for the most elite investigators, NIBIB could aim to create a more accessible mechanism that offers realistic and appealing options for a broader range of investigators.

The small K awards, by contrast, could require transitioning out of this series through submission of R-series grants within a specified interval. Further restrictions could be placed on the number of consecutive awards without R-funding to encourage introducing new investigators and contributors to the NIBIB community. This type of structure would also improve community perception and morale and foster a spirit of inclusiveness and desire to contribute to the NIBIB mission.

Individual investigator awards should be considered as prestigious with special career development opportunities built into the award. Since most of the funds for career development awards go directly to university salary and benefits, NIBIB should consider limiting indirect costs and having them as "named" awards with possible donor recognition. K-awardees may also be eligible to apply for small supplements or extensions for initiating new activities.

Assess the diversity of the NIBIB portfolio and opportunities for funding underrepresented investigators:

To evaluate the diversity of the portfolio, NIBIB has been engaged in detailed analysis of data and performance. This evaluation is an ongoing process, and preliminary observations are encouraging:

From 2008 through 2014 the number of R01 applications have not changed significantly (433 vs 418); the number of R21 (339 vs 699) applications have consistently increased over time.

The number of applicants submitting more than one application is increasing at a slightly greater rate for R21 applications than for R01 applications. Both are ~9-10% of total applications. E.g. R01 in 2014 had 418 total; 380, 35, and 3 for 1, 2, and 3+ applications. R21 had 699 in total with 633, 56, and 10 for 1, 2, and 3+ applications.

Less than half of the applicants are "new investigators" (~40%), but ~70% of new applicants score in the top 10th percentile. Thus, it seems that NIBIB is an institute where new PIs are successfully funded.

Both new and existing applicants have, on average, improved upon their ability to score in the top 10%. Approximately 20% of new applicants and ~7% of existing applicants scored in the top 10th percentile in 2014.

With the percentage of R21s growing so fast, the fraction of R21s awarded is relatively low (10.9%) compared to R01 (16.2%) in 2014.

These data suggest that new investigators are relatively successful at NIBIB, but further analysis is required to determine the diversity of the investigator pool.

Improve community morale and foster a desire to contribute to the NIBIB mission:

The task force believes that it is important to consider forming NIBIB-based review panels to conserve the concepts and intent of newly developed mechanisms. These panels could also be

employed for R21 grants to stimulate true high-risk applications, potentially restoring the original intent of this program, which has clearly changed over the years. To ensure a sufficient pool of qualified reviewers, NIBIB investigators receiving K and R35 awards could join these panels to fulfill their service obligation.

The task force believes that outlook and morale will improve with rising paylines, enhanced service to NIBIB from recipients of K and R35 awards (and others), and by a transparent approach to sharing the task force recommendations to address these challenges. It is anticipated that the NIBIB community will recognize the importance of shared sacrifice in difficult times and will respond positively.

Communicate the broad importance of biomedical research to society:

Advocate on behalf of the entire NIH mission by pointing out the unique impact and role of NIBIB in the creation of intellectual property, jobs, and commercialization through its mission of supporting methods, technologies and design-driven research. NIBIB has been one of the key institutes to foster this culture that is essential for economic growth.

NIBIB should develop and implement a strategic communication and outreach plan to disseminate these messages through stories of success, and other avenues.

Discussion

The Advisory Council Task Force on Strategies for Efficient Use of Research Dollars addressed issues and concerns focused on how to fund a growing population of investigators, enhance diversity of the NIBIB funded scientists, and provide mechanisms for both early stage and struggling investigators to be successful. At the core of these topics is the difficult task of assessing whether current and future policies are effective and ultimately lead to better science. New methods and metrics for assessing scientific quality, impact, and outcomes for grant awardees should be developed to better understand how NIBIB programs and policies affect both society and the scientific community.

Many ideas and programs have been proposed that could provide some measure of stability and relief for investigators. Common questions for discussion that are at the core of these recommendations are:

- How does NIBIB balance supporting people /projects /and centers?
- What is an appropriate level and duration of support for P41s, R01s, and R21s?
- Should NIBIB eliminate R21s and substitute this award with new mechanisms that could help significantly increase our overall success rate?
- Should NIBIB create entirely new categories of awards for senior "pioneers", mid-career investigators, and junior investigators?

The task force recognizes that the proposed actions would have consequences that must be carefully considered. For example, committing funds to a select group of investigators for a longer period to encourage fewer grants and greater focus may have the drawback of reducing turnover (i.e. "new" money) to use each year. This could have an unintended negative effect on the NIBIB payline because a greater percentage of the budget would be tied up in out-year funding. Key issues related to funding individuals include:

• If NIBIB sets aside resources to target funding people rather than projects, who should they be? Should they be early career? Mid-career? Senior Investigators? Should all three career levels have new opportunities or should support be prioritized?

 Would a people-centric funding mechanism benefit investigators at both soft-money and hard-money institutions?

NIH is moving forward with the Outstanding Investigator Award (R35), as a means of funding people rather than projects. Each IC may take a slightly different approach with this award mechanism. NCI and NIGMS have already released R35 FOAs (NCI: http://grants.nih.gov/grants/guide/pa-files/PAR-14-267.html; NIGMS: http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-16-002.html). NIBIB may wish to use these as a starting point for discussions on people-centric awards. For senior investigators, there is considerable interest in a mechanism that would provide longer-term support, e.g. 7 years, to enhance focus and encourage greater service to the NIBIB funded community.

With the development of new programs there should be renewed effort to identify activities that are aligned with the NIBIB mission and worthy of its support. New programs also create a new dilemma, i.e. whether "targeted" FOAs, which are not typically percentile ranked, should be included as part of the payline calculation. Since these awards could further reduce reported funding levels, their introduction should be balanced by a discussion of whether raising the payline is indeed our highest priority and at what cost. Since there is evidence that peer-review, and hence payline, may not always predict scientific impact, additional discussion should involve whether "success rate" and other metrics can be developed to demonstrate that we are fulfilling our mission and funding the best science. Persistent questions related to NIBIB mission include:

- How can we best meet the need for translation of technological advances into practice?
- Are industry partnerships an effective vehicle and how might we best support and encourage these?

The doubling of R21 applications between 2008 and 2014 is considered to be a problem that raises questions about its continued viability and impact on success rate. Positive features to the R21 include its short duration and high turnover rate that brings new investigators into NIBIB without significant out-year commitments. Interestingly, the R21 may have effectively become a 3-year grant with many investigators seeking 1 year and longer no-cost extensions (more research is needed to understand these trends). In addition, academic promotion committees typically place much greater weight on R01 vs R21 awards. As a result, substituting the R21 with "small" and "cost-effective" R01s that have similar features to the R21 such as a budget cap and limited but slightly longer term, e.g. 3 years, should be considered. In general, substituting the R21 with budgetarily similar awards, including enhanced individual investigator mechanisms, should lead to increases in success rate and morale while providing new options and choices.

Ultimately, any changes to NIBIB programs will have consequences, some of which may be unintended. Currently the NIBIB success rate for competing R01 renewals is 23.5%, the 4th lowest in NIH, vs. 53% for NHGRI. This raises an important question about the potentially demoralizing effect of not having established grant programs renewed vs. the drive to have new applications funded. If we start new programs and fund new awards, this may lead to further unintended "squeezing out" of existing awardees.

With so many obvious challenges and urgent needs, the Task Force recommends rapid implementation of a limited number of recommendations most strongly supported by both the council and program staff. Currently, our highest priority recommendations include:

- Setting a goal to increase success rate to ~20-25% and implementing a "sliding scale" payline.
- Creating new resources via restructuring of grants in the post-award phase.
- Selecting promising out of payline awards for reduced and/or negotiated funding.
- Providing new opportunities for funding through new mechanisms: small/cost effective R01s and targeted individual investigator awards such as R35 and K-series at all career levels.

To thoughtfully address these issues and effectively respond to ongoing budget challenges at NIH, Universities, and, more broadly, the Federal Government, we recommend continued internal discussion of these topics. This would best occur through the formation of ongoing advisory council committees that would help develop policy, assess impact, and engage other NIH institutes in pursuing coordinated solutions to these complex problems.