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SCIENTIFIC MANAGEMENT REVIEW BOARD

REPORT ON OPTIMIZING THE NIH SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS

March, 2013

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NATIONAL INSTITUTES OF HEALTH
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CONTENTS

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 October 2011, the SMRB was charged by NIH Director Francis Collins with recommending strategies for how NIH can optimize its utilization of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs in ways that advance the NIH mission. In addressing this charge, the SMRB was asked to consider how NIH can support the SBIR/STTR programs in ways that encourage biomedical innovation from small businesses that align with NIH priorities, fund quality proposals yielding the greatest potential for successful commercialization, and leverage existing NIH resources and expertise to enable the success of its grantees. In response to the charge, the SMRB assembled the SBIR/STTR Working Group to conduct extensive consultations, evaluate the programs, and report their findings and recommendations to the full SMRB.

Over the course of its deliberations and consultations with experts and stakeholders in the SBIR/STTR programs and commercialization of biomedical products, the SBIR/STTR Working Group identified three primary areas in which the programs should be improved. First, the programs should be streamlined to reduce delays in the application, review, and award processes. Second, the programs should place greater emphasis on the selection and support of projects with a high likelihood of commercial success. Third, NIH should increase communication and collaborative efforts across the Institutes and Centers (ICs) in order to share lessons learned and leverage existing resources and expertise. The SBIR/STTR Working Group proposed a number of approaches that could be used to achieve these three goals, and these proposals are described in the following report.

I. INTRODUCTION

The National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) reaffirmed certain organizational authorities of Agency officials to: (1) establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH, including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize divisions, centers, or other administrative units within an NIH national research institute or national center, including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The Reform Act also established the Scientific Management Review Board (hereinafter, SMRB or Board) to advise the NIH Director and other appropriate Agency officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

This report distills the deliberations and findings of the SMRB and provides recommendations to NIH regarding how the Agency can optimize its use of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs in support of its mission.

A. Impetus for and Charge to the SBIR/STTR Working Group

The NIH SBIR/STTR programs are one mechanism through which NIH Institutes and Centers (ICs) fund research and development (R&D) projects that address public health needs, primarily by encouraging small businesses to propose innovative research ideas that have the potential for commercialization. Several stakeholders noted that the NIH SBIR/STTR programs differ from programs at some other Federal agencies in that the NIH programs are not focused on developing products and technologies for use by NIH itself. For this reason, identifying which projects have commercial potential and also align with the NIH mission can be challenging and complex. Working Group members and consultants also identified the expense and time typically required to bring biomedical products to the market as another hurdle impeding the success of NIH SBIR/STTR projects.

Despite these challenges, several extensive reviews of the SBIR/STTR programs at NIH have yielded generally favorable results. Most agree that the programs are valuable tools, and Congressional support remains high. In fact, the SBIR/STTR Reauthorization (PL 112-81), which was signed into law on December 31, 2011, requires an increasing percentage of participating agencies' extramural budgets to be set aside for the SBIR/STTR programs. Given the increasing allocation of funds to these programs, on October 26, 2011, Dr. Collins charged the SMRB with recommending strategies for how NIH can optimize the SBIR/STTR programs and use them to advance NIH mission. In response to the charge from Dr. Collins, the SMRB established the SBIR/STTR Working Group to undertake an intensive deliberative process and provide recommendations to the Board for a vote in the Spring of 2013.

B. SBIR/STTR Working Group Process

i. Deliverables. The SBIR/STTR Working Group agreed to recommend to the full Board strategies for how NIH can optimize its SBIR/STTR programs to best advance the NIH mission. In addressing its charge, the Working Group would consider how NIH could support the SBIR/STTR programs in ways that foster biomedical innovation within small businesses that

aligns with the priorities of the NIH ICs; fund quality proposals yielding the greatest potential for successful commercialization; and leverage existing resources and expertise to enable the success of its SBIR/STTR grantees.

ii. Process for Considering Change. At the SMRB's April 2009 inaugural meeting, Board members articulated the need to develop a framework for considering organizational change within the Agency, as it is important to consider carefully the long-term effects of reorganization and assess whether the potential benefits outweigh the potential negative consequences. The resulting framework, outlined in the *SMRB Report* on *Deliberating Organizational Change and Effectiveness* (DOCE),[1] was employed by the SBIR/STTR Working Group in contemplating strategies for optimizing the SBIR/STTR programs at NIH.

As outlined in its DOCE report, the SMRB agreed that any rationale for considering organizational change at NIH must be to enhance the Agency's ability to fulfill its mission—the pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Additionally, the DOCE report established five principles that should underpin any recommendations for organizational change at NIH: 1) strengthen the ability of NIH to carry out its mission; 2) provide an environment for collaboration, coordination, and interaction; 3) bring together synergies; 4) enhance public understanding, confidence, and support; and 5) increase operational efficiency. The report also states that any consideration of organizational change at NIH should follow a systematic and publicly accountable process comprised of three primary steps: assessment of the need for change, evaluation of the options for change, and implementation and evaluation of the change. In the DOCE report, the SMRB identified transparency, communication, and accountability as three attributes that should undergird the deliberative process. These principles, processes, and attributes guided the activities of the SBIR/STTR Working Group and the Board to address the SBIR/STTR charge.

iii. Activities. The SBIR/STTR Working Group held eight meetings, and members conducted six interviews with NIH Institute and Center Directors to understand better how the SBIR/STTR programs are administered across ICs varying in size and mission. The Working Group hosted two public forums in conjunction with full SMRB meetings. The first public forum, held on July 11, 2012, consisted of a series of briefings from SBIR/STTR program managers in order to provide a greater understanding of how agencies across the government have sought to optimize their SBIR/STTR programs. Stakeholders presenting at this meeting included leaders from NIH, the Defense Advanced Research Projects Agency (DARPA), the Department of Energy (DOE), the National Science Foundation, and the Small Business Administration. The second public forum was held on October 3, 2012, and allowed the SMRB to solicit input from representatives of the small business community, investors in biomedical research, and other organizations focused on increasing commercialization (see Appendix A for a list of speakers and dates).

The SBIR/STTR Working Group also provided continual updates to and solicited input from the entire SMRB during its public deliberations held on May 29, 2012, July 11, 2012, October 3, 2012, and January 14, 2013.

[1] To view the SMRB's DOCE report, see http://smrb.od.nih.gov/documents/announcements/DOCE_112010.pdf.

II. OVERVIEW OF NIH'S SBIR/STTR PROGRAMS

A. Federal SBIR/STTR Programs

The SBIR/STTR programs were established with the passage of the Small Business Innovation Development Act of 1982 (P.L. 97-219) and the Small Business Technology Transfer Act of 1992 (Public Law 102-564, Title II), respectively. Under these Acts, agencies with R&D budgets of over $100 million are required to set aside funds (currently 2.7 percent) for an SBIR program, and those with R&D budgets of over $1 billion are required to set aside funds (currently 0.35 percent) for an STTR program. Both programs provide small businesses with the opportunity to receive federal funding for R&D projects that advance the mission of the funding agency. Awards can be made for Phase I and Phase II projects but not for later-stage commercialization activities. The primary difference between the SBIR and STTR programs is that STTR grantees are required to partner with a nonprofit research institution, whereas SBIR grantees may have such partners but are not required to do so. There are 11 Federal agencies with SBIR programs and five with STTR programs. The U.S. Small Business Administration serves as the coordinating agency for the SBIR/STTR programs, overseeing their implementation and progress, and provides reports to Congress on their performance. Further details about the role, structure, and legislative history of the SBIR/STTR programs are available at the Small Business Administration Web site.[2]

The Small Business Administration Web site states that the mission of the two programs "is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy." Congressionally-mandated goals for both programs are to stimulate technological innovation and increase private sector commercialization of innovations derived from Federal R&D. SBIR program goals also include meeting Federal R&D needs and promoting and supporting participation in innovation and entrepreneurship by socially and economically disadvantaged persons. The STTR program has the additional goal of fostering technology transfer through R&D collaborations between small businesses and research institutions.

B. NIH SBIR/STTR Programs

As an R&D-focused agency with a budget of nearly $31 billion in Fiscal Year (FY) 2012, NIH is required to set aside funds for and administer its SBIR/STTR programs. NIH funds one of the largest SBIR/STTR programs in the Federal government, second only to the Department of Defense. In addition to the congressionally-mandated goals for the SBIR/STTR programs described in the previous section, NIH aims to use these programs to further its own mission, which 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 the burdens of illness and disability.

[2] For more information about the SBIR and STTR programs, see http://sbir.gov/about/about-sbir.

Rather than fund and manage the program centrally, NIH ICs fund SBIR/STTR programs according to their share of the overall NIH budget. Staff in the NIH Office of Extramural Research are responsible for supporting the IC SBIR/STTR programs, and the office also serves as liaison to the Small Business Administration, which in turn provides Congress with performance reports on the programs. Office of Extramural Research personnel notify IC staff of program changes and also host town halls to share information with IC staff and encourage them to share lessons learned.

Twenty-four of NIH's 27 ICs have funding authority and therefore have their own SBIR/STTR programs. The ICs that support SBIR/STTR programs fund those applications that are relevant to their respective missions and employ a number of strategies to inform potential applicants about their funding priorities. ICs retain a significant degree of flexibility in how they operate and manage their SBIR/STTR programs. Some have centralized the management of the program, while other ICs distribute management of the SBIR/STTR portfolio among extramural research program staff with expertise in a range of scientific areas. A few ICs have staff with expertise in R&D and commercialization to help administer their programs. ICs also differ in the use of grants versus contracts, general application solicitations versus targeted requests for applications, and the frequency of in-house reviews of applications versus peer review panels in the NIH Center for Scientific Review.

C. Congressional Reauthorization

On December 31, 2011, the SBIR/STTR programs were reauthorized through FY 2017 when the 2012 National Defense Authorization Act (PL 112-81) was signed into law. One important change to the SBIR/STTR programs included in this reauthorization was the gradual increase in the percentage of funds set aside (shown in Table 1). Between FY 2011 and FY 2017, participating agencies are required to increase the funds set aside to 3.2 percent for SBIR programs and to 0.45 percent for STTR programs.

Table 1. Increase in set-aside funds for SBIR/STTR programs FY 2011–2017.

	FY 2011	***FY 2012***	***FY 2013***	***FY 2014***	***FY 2015***	***FY 2016***	***FY 2017***
SBIR	2.5%	2.6%	2.7%	2.8%	2.9%	3.0%	3.2%
	0.30%	0.35%	0.35%	0.40%	0.40%	0.45%	0.45%
Combined	**2.80%**	**2.95%**	**3.05%**	**3.20%**	**3.30%**	**3.45%**	**3.65%**

Other changes introduced under the reauthorization include temporary (three years) authority to use up to 3 percent of the SBIR set-aside for administration, outreach, management of program, and compliance with the statute. The Small Business Administration developed new rules based on the reauthorization that resulted in changes to the guidelines for funding. The guidelines now allow larger awards for Phase I and Phase II in the STTR program (see Table 2). The new rules also place hard limits on the size of awards, although some waivers are still possible (see Table 3). More information about the current rules for program eligibility and other program details can be found at the Small Business Administration Web site.[3]

[3] For more information about the SBIR and STTR programs, see http://sbir.gov/about/about-sbir.

Table 2. Guidelines for Size of Awards

Program	Phase I	Phase II	Prior to Reauthorization
SBIR	$150,000	$1,000,000	$150,000/$1,000,000
STTR	$150,000	$1,000,000	$100,000/$750,000

Table 3. Hard Limits* on Award Size to 50% Over Guidelines

Program	Phase I	Phase II	Prior to Reauthorization
SBIR	$225,000	$1,500,000	Flexible
STTR	$225,000	$1,500,000	Flexible

*Waiver possible for specific topics from the Small Business Administration.

III. FINDINGS OF THE SBIR/STTR WORKING GROUP

Over the course of its deliberations, the SBIR/STTR Working Group reviewed existing reports on the programs and heard from a broad range of stakeholders and experts, including representatives from the research and venture capital communities.

A. Previous Reports

The Working Group agreed with previous studies, including the National Research Council's report *An Assessment of the Small Business Innovation Research Program*,[4] which concluded that the NIH SBIR/STTR programs are meeting their statutory objectives. Some reports raised the prospect of collecting additional data from SBIR/STTR programs and award recipients in order to better assess the management of the programs and the degree to which awardees achieve commercialization. Working Group members learned that the Small Business Administration and NIH are working to improve data collection and analysis, although there are restrictions on surveying awardees after the award period has ended. Overall, based on previous reports and their own findings, Working Group members considered the SBIR/STTR programs to be a tremendous asset to the NIH and noted that the programs are held in strong regard and expectations for their success are high.

B. NIH and IC SBIR/STTR Program Staff Briefings

Working Group members received input from many individuals involved in the SBIR/STTR programs throughout NIH. Members received numerous briefings from the NIH Office of Extramural Research about the NIH SBIR/STTR programs, their history, and the effect of changes brought about by new rules from the Small Business Administration as a result of the recent reauthorization. Of these changes, Working Group members considered the new restrictions on receiving waivers for award total to be most concerning.

In addition to the experiences and insights of IC Directors who served on the Working Group, members received significant input from SBIR/STTR program staff from many ICs. Several

[4] To view the National Research Council report, see http://books.nap.edu/catalog.php?record_id=11964.

served on panels at SMRB meetings, and many more participated in interviews with SBIR/STTR Working Group members. Several common themes arose from these interactions, including the importance of allowing ICs to retain flexibility in how they operate and manage their SBIR/STTR programs; the difficulty of speeding up the application, review, and funding process; and objections to the new restrictions on receiving waivers for award totals.

C. Small Business and Investor Perspectives

Small business owners who have applied to the NIH SBIR/STTR programs were present at SMRB meetings, both as panelists and public commenters. Other private sector participants familiar with the SBIR/STTR programs were also represented, including potential investors in biomedical research projects. Recurrent themes included the challenge of waiting for many months while NIH's application, review, and funding processes take place. Participants emphasized that this presents a significant hardship for those small businesses that are struggling to survive. Difficulty finding qualified reviewers with commercialization expertise and without conflicts of interest was another issue raised.

D. Working Group Findings

While the Working Group considered the SBIR/STTR program to be successful in general, the changes to the program mandated under the SBIR/STTR reauthorization offer the Agency an opportunity to reassess and institute practices to optimize its SBIR/STTR programs. In light of budgetary difficulties expected in coming years, the increasing portion of NIH's budget that will be allocated to the SBIR/STTR programs makes it especially important that the programs leverage their resources in a highly effective manner. Some of the recommendations may have budgetary implications that make implementation challenging during this period of strained resources, but the Working Group encourages NIH to consider carefully the potential benefits of each recommendation on the performance and efficiency of the SBIR/STTR programs.

Based upon their deliberations, as well as consultations with and recommendations from a broad spectrum of stakeholders, members of the SBIR/STTR Working Group unanimously agreed that NIH should take steps to improve its SBIR/STTR programs by speeding up the process, emphasizing commercialization, and strengthening trans-NIH communication and collaborative efforts.

IV. SBIR/STTR WORKING GROUP RECOMMENDATIONS

In order to reach findings and make recommendations for how to improve the SBIR/STTR programs, the SBIR/STTR Working Group sought input from a range of individuals with SBIR/STTR expertise and experience from NIH, other agencies, the small business community, and private sector investors in biomedical projects. Using the insights and input provided by these consultants, Working Group members developed a series of recommendations for how to reduce delays, emphasize commercialization, and strengthen trans-NIH communication and collaboration efforts. These recommendations are summarized in Table 4 and described below.

Table 4. Summary of Findings and Recommendations.

OVERARCHING RECOMMENDATIONS:

- **Decrease delays between application submission and fund disbursal,**
- **Improve the process for selecting and supporting commercially viable projects, and**
- **Strengthen trans NIH communication of best practices and pooling of resources and expertise.**

	CHALLENGE	RECOMMENDATION
DECREASE DELAYS	Applicants are often unclear about submission process which can result in insufficient proposals requiring further work and/or resubmission	Revise funding opportunity announcements to strengthen language encouraging greater communication with IC program staff to increase the likelihood of developing successful proposals
		Create a centralized portal for accessing program resources and non-NIH SBIR/STTR resources
		Increase the visibility and availability of pre-award assistance programs
	Dual levels of peer review introduce long delays between application submission and notice of funding	Establish formal pilot initiatives that experiment with expediting both the peer review and Council review processes
IMPROVE COMMERCIALIZATION	Many investigators are unfamiliar with what it takes to move a promising idea into the market	Explore opportunities for establishing a cadre of advisors to expand knowledge and increase entrepreneurial capabilities
	Peer review panels vary in degree of commercialization knowledge	Require a specific portion of panel to be knowledgeable about the process of commercializing ideas to complement scientific expertise
		Experiment with strategies for increasing the pool of reviewers to diversify reviewer expertise
	Review criteria do not place sufficient emphasis on commercialization	Develop specialized review criteria that appropriately weigh both scientific merit and commercial feasibility
		Explicitly instruct reviewers to evaluate applications based on solid experimental data and broader commercialization impact
	Current metrics for tracking and evaluating the success of implemented strategies (and the program in general) are insufficient	Consider broadening the types of metrics collected (entry into Phase I clinical trials, recruitment of additional investment, INDs)
		Require applicants to disclose all previous SBIR/STTR awards and their outcomes in grant applications
		Withhold Phase II funds until Phase I final reports are submitted
		Pursue efforts to conduct greater post-award reporting (i.e., seek approval from OMB to survey awardees after award award period has ended)
		Fund outcome evaluation using some of the temporary administrative funds allowed under the program's reauthorization
STRENGTHEN TRANS-NIH COLLABORATION	Communication and coordination across ICs and with OER could be strengthened to address numerous challenges such as: • generating sufficient awareness of the program • recruiting successful applications from woman- and minority-owned firms	Establish a formal venue for select IC representatives to share strategies that have been both successful and unsuccessful (meets at least twice each year)
		Establish a "year in review" update to serve as an informal mechanism for ICs to submit their top 3–4 priority efforts
		Provide a centralized resource for assisting in SBIR/STTR program management and training

A. Reduce Delays

Small businesses are faced with urgent timelines that not only determine whether they will succeed but whether they will survive. More should be done to ensure that the NIH SBIR/STTR application, review, and funding cycle aligns with the time demands placed upon small businesses. NIH should take steps to:

i. Assist Applicants with the Proposal Process. Applicants are often unclear about the process for submitting NIH proposals (especially those unfamiliar with the grants process), which sometimes results in unsuccessful proposals that require revision and resubmission, which leads to significant delays. NIH should revise SBIR/STTR funding opportunity announcements to strengthen language encouraging potential applicants to communicate with IC program staff in order to increase the likelihood of developing a successful proposal. A centralized portal should be created to provide small business applicants convenient access to program resources and non-NIH SBIR/STTR resources such as those maintained by state agencies and professional organizations. NIH should also consider increasing the visibility and availability of pre-award assistance programs to improve the quality of applications (e.g., workshops, websites, technical assistance from IC staff).

ii. Expedite Review Process. While there are significant benefits to NIH's dual level peer review process, it often introduces long delays between application submission and notice of funding. NIH should establish formal pilot initiatives that experiment with expediting both the peer review and Council review processes. Such initiatives could include exploring email reviews and electronic Council.

B. Emphasize Commercialization

The ultimate goal of the SBIR/STTR program is to support R&D projects related to NIH's mission that have potential for commercialization, and greater efforts should be made to facilitate this outcome. NIH should explore options for increasing the likelihood of commercialization at each stage of the SBIR/STTR lifecycle. To accomplish this, NIH should:

i. Cultivate Relationships with Mentors. Many investigators, particularly those in academic settings, are unfamiliar with what it takes to move a promising idea into the market. In addition to the assistance provided by NIH program staff, NIH should explore opportunities for establishing a cadre of advisors from the scientific, business, and investment communities to expand knowledge and increase entrepreneurial capabilities of SBIR/STTR awardees. This service could also be expanded to pre-award opportunities in order to enhance proposal quality and further reduce delays.

ii. Diversify Reviewer Expertise. Peer review panels are strong in scientific expertise but vary in degree of commercialization knowledge. Moreover, current panel composition requirements specify at least one industry reviewer, but that person is not required to be knowledgeable in commercialization activities. NIH should require a specific portion of review panels to be experts in commercializing biomedical products and services to complement those with scientific expertise. NIH should also experiment with strategies for increasing the pool of reviewers, such as by strengthening the terms of intellectual property confidentiality to which reviewers agree in

order to assure both applicants and reviewers of the integrity of the NIH review process. NIH's commitment to intellectual property confidentiality should be stated clearly in Requests for Applications.

iii. Tailor Review Criteria. Review criteria do not place sufficient emphasis on commercialization. Scientific merit remains a key element of SBIR/STTR projects, but the research-to-market goals of the program make it necessary to consider review criteria that are different from those for other NIH reviews. NIH should therefore recalibrate the balance of review criteria to emphasize the likelihood of achieving commercialization. This requires the development of specialized review criteria for use in evaluating SBIR/STTR grants that appropriately weigh both scientific merit and commercial feasibility. To increase the value of commercialization potential in review, reviewers should be explicitly instructed to evaluate applications based on solid experimental data and broader commercial impact.

iv. Evaluate Program Outcomes. Current metrics for tracking and evaluating the success of implemented strategies and the program in general are insufficient. NIH should consider broadening the types of metrics collected from SBIR/STTR grantees to include entry into Phase I clinical trials, recruitment of additional investment, and investigational new drug applications (INDs) to the Food and Drug Administration. Applicants should be required to disclose all previous SBIR/STTR awards and their outcomes in grant applications. This would help to identify those who have received multiple SBIR/STTR awards but have not achieved commercialization. To ensure compliance with reporting requirements, NIH should consider withholding Phase II funds until final reports for Phase I projects are submitted. NIH should also pursue efforts to conduct greater post-award reporting such as seeking approval from the Office of Management and Budget to survey awardees after the end of the award period. Finally, some of the temporarily authorized 3 percent of SBIR funds for administrative oversight and process costs should be used to fund outcome evaluations (prior to reauthorization, no funds could be used for management).

C. Increase Trans-NIH Communication and Collaboration

The NIH ICs vary considerably in how they manage programmatic efforts, implement new strategies, and track overall success of the SBIR/STTR programs. More could be done to leverage lessons learned across the ICs, both in terms of successes and failures, and to leverage existing expertise and resources. To maximize trans-NIH communication and collaboration, NIH should:

i. Encourage Communication and Sharing. Several challenges facing the SBIR/STTR program could be addressed through enhanced communication and coordination across ICs and with staff responsible for monitoring and supporting NIH's SBIR/STTR programs in the NIH Office of Extramural Research. Examples of challenges include difficulty generating sufficient awareness of the SBIR/STTR program among innovators in both the academic and small business communities, as well as the need to recruit successful applications from woman- and minority-owned firms (a Congressionally-mandated goal of the program). NIH should establish a formal venue for IC representatives to share strategies that have been both successful and unsuccessful; IC program staff and OER should meet in this venue at least twice each year. A "year in review" update could also be provided to serve as an informal mechanism for ICs to submit their top 3–4

priority efforts over the year. This update could also serve as an update of the success of previous year's top priorities.

ii. Leverage Resources. In addition to sharing lessons learned, individual IC SBIR/STTR programs might benefit from leveraging existing resources, such as by pooling resources to provide better administrative support service. This is especially true for ICs that have difficulty allocating sufficient personnel, expertise, and resources to run the SBIR/STTR programs in an optimal fashion. NIH should consider providing a centralized resource for assisting with staff training and grant and contract management or at least consider enabling ICs to pool expertise and resources.

D. Additional Opportunities and Challenges

Under the SBIR/STTR reauthorization (PL 112-81), NIH is allowed to use 3 percent of the SBIR set-aside for administration, outreach, management of program, and compliance with statute. This provides NIH with an opportunity to fund pilot initiatives that promote commercialization, including making SBIR/STTR proposals more attractive for further investment, potentially through public-private partnerships.

Another element of the reauthorization imposes a potential limitation that may require a response from NIH, namely new limitations on NIH's flexibility to provide large awards beyond the SBIR/STTR cap. This change could be detrimental to the success of biomedical research projects funded under the NIH SBIR/STTR programs. The programs are more likely to generate successful products if the level of funding more closely matches research costs; it is better to provide adequate funding for a smaller number of projects than to provide insufficient funding for many projects. NIH should develop a strategy for articulating the reasons SBIR/STTR funding limits should be waived by the Small Business Administration (e.g., expense of biomedical research).

V. SMRB CONCLUSIONS AND RECOMMENDATIONS

—Pending—

APPENDIX A
Speakers and Dates

MAY 7, 2012

- Thomas Insel, M.D., Director, National Institute of Mental Health, National Institutes of Health
- Margaret Grabb, Ph.D., Chief, SBIR/STTR Programs, National Institute of Mental Health, National Institutes of Health
- Greg Farber, Ph.D., Director, Office of Technology Development and Coordination, National Institute of Mental Health, National Institutes of Health

MAY 9, 2012

- James Battey, Jr., M.D., Ph.D., Director, National Institute on Deafness and Other Communication Disorders, National Institutes of Health
- Roger Miller, Ph.D., Program Director, Neural Prosthesis Development, National Institute on Deafness and Other Communication Disorders, National Institutes of Health

MAY 24, 2012

- Linda Birnbaum, Ph.D., D.A.B.T., A.T.S., Director, National Institute of Environmental Health Sciences, National Institutes of Health
- Heather Henry, Ph.D., Program Administrator and Health Science Administrator, Superfund Research Program, National Institute of Environmental Health Sciences, National Institutes of Health
- Theodore Outwater, Public Health Educator and Program Administrator, Worker Education and Training Program, National Institute of Environmental Health Sciences, National Institutes of Health
- Daniel Shaughnessy, Ph.D., Health Science Administrator, Susceptibility and Population Health Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health

MAY 30, 2012

- Susan Shurin, M.D., Acting Director, National Heart, Lung, and Blood Institute, National Institutes of Health
- Jodi Black, Ph.D., Deputy Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health
- Stephen Mockrin, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health

JUNE 12, 2012

- Alan Guttmacher, M.D., Director, National Institute of Child Health and Human Development, National Institutes of Health
- Louis Quatrano, Ph.D., Director, Behavioral Sciences and Rehabilitation Technologies Program, National Center for Medical Rehabilitation Research, National Institute of Child Health and Human Development, National Institutes of Health

JUNE 21, 2012

- Story Landis, M.D., Director, National Institute for Neurological Diseases and Stroke, National Institutes of Health
- Rajesh Ranganathan, Ph.D., Director, Office of Translational Research, National Institute for Neurological Diseases and Stroke, National Institutes of Health
- Stephanie Fertig, M.B.A., Research Project Manager, National Institute for Neurological Diseases and Stroke, National Institutes of Health
- Christina Vert, M.S., Health Program Specialist, Office of Translational Research, National Institute of Neurological Disorders and Stroke, National Institutes of Health

JULY 11, 2012

- Jodi B. Black, Ph.D., M.M.Sc., Deputy Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health
- Sean Greene, Associate Administrator for Investment and Special Advisor for Innovation, U.S. Small Business Administration
- Elena Koustova, PhD., M.B.A., SBIR/STTR Coordinator, National Institute on Drug Abuse, National Institutes of Health
- Michael Mutty, Director, Contracting Division Defense Advanced Research Projects Agency
- Manny Oliver, Ph.D., Director, SBIR/STTR Programs Office, Department of Energy
- Matthew E. Portnoy, Ph.D., Manager, NIH SBIR/STTR Programs
- Sally J. Rockey, Ph.D., Deputy Director for Extramural Research, National Institutes of Health
- Grace J. Wang, Ph.D., Director, Industrial Innovation and Partnerships Division, Directorate for Engineering, National Science Foundation
- Michael Weingarten, Director, SBIR Development Center, National Cancer Institute, National Institutes of Health
- Jerome Wujek, Ph.D., Research Resources Officer, National Eye Institute, National Institutes of Health

OCTOBER 3, 2012

- Kristina Burow, M.B.A., Managing Director, ARCH Venture Partners
- Gururaj "Desh" Deshpande, Ph.D., Co-founder, Deshpande Center for Technological Innovation
- Alex de Winter, Ph.D., Partner, Mohr Davidow Ventures
- Debra Ellies, Ph.D., Founder, OsteoGeneX
- John A. Gardner, Ph.D., Founder and President, ViewPlus Technologies, Inc.
- Kevin V. Grimes, M.D., M.B.A., Co-director, SPARK Translational Research Program at Stanford University
- Paul Gross, Chairman of the Board, Hydrocephalus Association
- Rex Jakobovits, Ph.D., President, Experiad, LLC
- Lisa M. Kurek, M.S., Managing Partner, BBC Entrepreneurial Training and Consulting, LLC
- Allan W. May, Founder and Chairman, Life Science Angels, Inc.
- Steve Meginniss, Founder and Chief Technical Officer, MagicWheels, Inc.
- Rosibel Ochoa, Ph.D., Executive Director, William J. von Liebig Center for Entrepreneurism and Technology Advancement, University of San Diego
- Anthony Ratcliffe, Ph.D., President and CEO, Synthasome, Inc.
- Armen Shanafelt, Ph.D., Venture Partner, Lilly Ventures
- Robert N. Schmidt, Founder and Chairman, Orbital Research, Inc., and President, Cleveland Medical Devices, Inc.
- Andrew J. Schwab, Managing Partner, 5AM Ventures