NIH SCIENTIFIC MANAGEMENT REVIEW BOARD

SBIR/STTR WORKING GROUP

Findings and Preliminary Recommendations

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Charge to the SMRB

Recommend strategies for how NIH can optimize its utilization of the SBIR/STTR programs in keeping with the NIH mission.

Charge Considerations

How can NIH support the SBIR/STTR programs in ways that:

- Foster 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 NIH resources and expertise to enable the success of grantees.

Working Group Roster

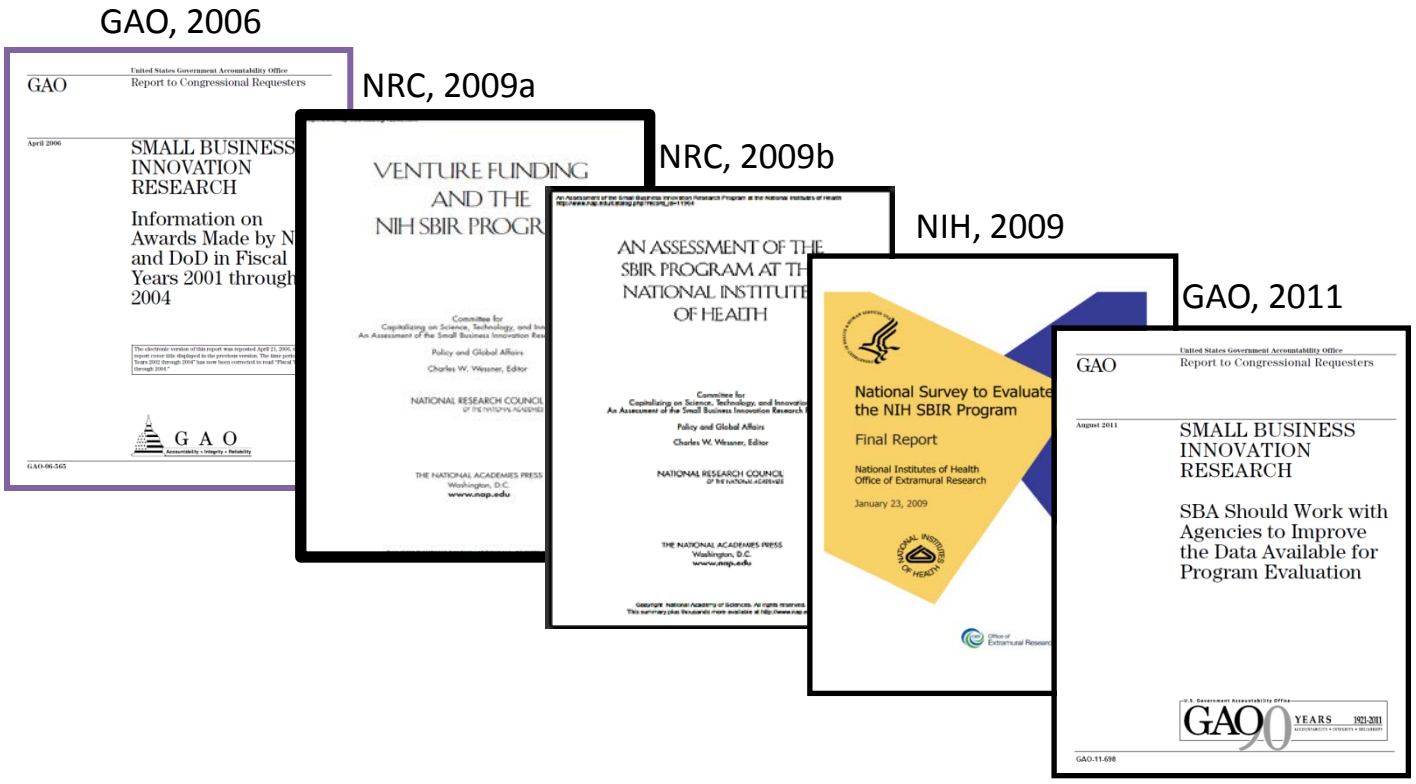
Non-Federal	Federal
Solomon Snyder, MD *(Chair)*	Josephine Briggs, MD
William Brody, MD, PhD	Richard Hodes, MD
Gail Cassell, PhD	Roderic Pettigrew, PhD, MD
Hon. Daniel Goldin	Susan Shurin, MD *(ad hoc)*
Arthur Rubenstein, MBBCh	Harold Varmus, MD/Michael Weingarten *(ad hoc)*
Norman Augustine *(ad hoc)*	

Working Group Process

- Employed framework and process for considering change, as outlined by the Deliberating Organizational Change and Effectiveness (DOCE) Working Group:

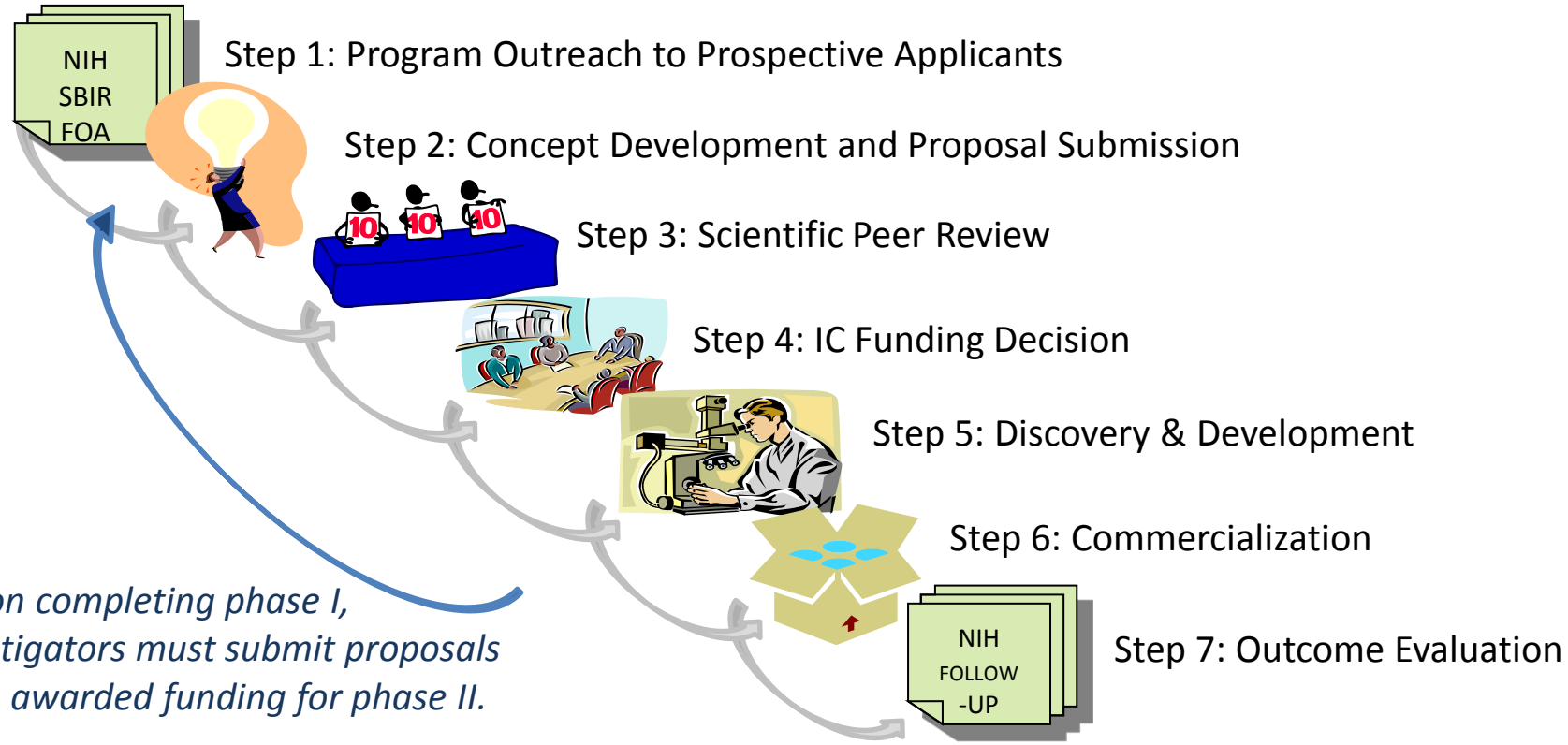
Working Group Process *(cont.)*

- Reviewed previous literature evaluating the SBIR/STTR program



Working Group Process *(cont.)*

- Examined strengths and weaknesses across each stage of the SBIR/STTR lifecycle



Working Group Process *(cont.)*

- Consulted with NIH IC leadership and SBIR/STTR program officers
- Held two stakeholder forums directed towards:
  - SBIR/STTR officials across government agencies
  - Representatives of the small business community
  - Investors in biomedical innovations
  - Leaders of organizations focused on improving commercialization outcomes

General Findings: From Good to Great

- NIH SBIR/STTR programs are meeting their statutory objectives and are considered to be an asset. The expectations for the program are high.
- The program could be improved to:
  - Leverage efficiently the public's investment in supporting innovation within small businesses.
  - Advance the scientific mission of the Institutes.

Overarching Recommendations

- The NIH SBIR/STTR programs could be improved by focusing efforts in the following areas:
  1. Decreasing time delays between application submission and fund disbursal,
  2. Improving the process for selecting and supporting commercially-viable projects, and
  3. Strengthening trans-NIH efforts to communicate best practices and pool/leverage resources and expertise.

Recommendation #1: Reduce Time Delays

Overview of Findings

- 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 SBIR/STTR review/funding cycle aligns with the time demands placed upon small businesses.

SBIR/STTR

Recommendation #1.A.

Assist Applicants with Proposal Process

CHALLENGE

- Applicants are often unclear about the process for submitting proposals (especially those unfamiliar with the grants process) which sometimes results in insufficient proposals that require further work and the need for resubmissions; ultimately leading to significant time delays.

PRELIMINARY DRAFT RECOMMENDATIONS

- Revise guidance documents to strengthen language encouraging potential applicants to communicate with IC program staff early and often to increase the likelihood of developing a successful proposal.
- Create a centralized portal for accessing program resources and non-NIH SBIR/STTR resources (e.g. state agencies, professional organizations, etc.).
- Increase the availability of pre-award technical assistance programs.

Recommendation #1.B.

Expedite Review Process

CHALLENGE

- 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.

PRELIMINARY DRAFT RECOMMENDATIONS

- Establish formal pilot initiatives that experiment with expediting both the peer review and Council review processes. Example initiatives could include exploring email reviews and electronic Councils.

Recommendation #2: Emphasize Commercialization *Overview of Findings*

- The ultimate goal of the SBIR/STTR program is to support research and development with the potential for commercialization to optimize the impact of NIH research. 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.

Recommendation #2.A.

Cultivate Relationships with Mentors

CHALLENGE

- Many investigators are unfamiliar with what it takes to move a promising idea into the market.

PRELIMINARY DRAFT RECOMMENDATIONS

- Explore opportunities for establishing a cadre of advisors (representing the scientific, business, and investment communities) to expand knowledge and increase entrepreneurial capabilities (could also be expanded to pre-award opportunities to enhance proposal quality and reduce time delays as addressed in Recommendation #1).

Recommendation #2.B.

Diversify Reviewer Expertise

CHALLENGE

- 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 do not require that person to be knowledgeable in the commercialization component.

PRELIMINARY DRAFT RECOMMENDATIONS

- Require a specific portion of review panels to be experts in commercializing ideas to complement those with the scientific expertise.
- Experiment with strategies for increasing the pool of reviewers (e.g. assuring IP confidentiality in Requests for Applications).

Recommendation #2.C.

Tailor Review Criteria

CHALLENGE

- Review criteria do not place sufficient emphasis on commercialization.

PRELIMINARY DRAFT RECOMMENDATIONS

- Develop specialized review criteria for use in evaluating SBIR/STTR grants that appropriately assess scientific merit and commercial feasibility.
- Increase the value of commercialization potential in review by explicitly instructing reviewers to evaluate applications based on solid experimental data and broader commercial impact.

Recommendation #2.E.

Evaluate Program Outcomes

CHALLENGE

- Current metrics for tracking and evaluating the success of implemented strategies (and the program in general) are insufficient.

PRELIMINARY DRAFT RECOMMENDATIONS

- 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 final reports for Phase I projects are submitted.
- Pursue efforts to conduct greater post-award reporting such as seeking approval from the Office of Management and Budget to survey awardees for years after their awards have terminated.
- Fund outcome evaluation using some of the temporarily authorized 3 percent of SBIR funds for administrative oversight and process costs (three year pilot program under reauthorization; previously no funds could be used for management).

Recommendation #3: Increase Trans-NIH Collaboration *Overview of Findings*

- The NIH ICs vary considerably in how they manage programmatic efforts, implement new strategies, and track overall success.
- Much could be done to leverage lessons learned across the ICs, both in terms of successes and failures.

Recommendation #3.A.

Encourage Communication and Sharing

CHALLENGE

- Several challenges facing the SBIR/STTR program could be addressed through enhanced communication and coordination across ICs and with OER. Examples of challenges include:
  - Generating sufficient awareness of the SBIR/STTR program among innovators in both the academic and small business communities.
  - Recruiting successful applications from woman- and minority-owned firms (a Congressionally-mandated goal of the program).

PRELIMINARY DRAFT RECOMMENDATIONS

- Establish a formal venue for select IC representatives to share strategies that have been both successful and unsuccessful (meets at least 2x year).
- Establish a "year in review" update to serve as an informal mechanisms 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.
- Provide a centralized resource for assisting in SBIR/STTR program management and training.

FINDINGS & RECOMMENDATIONS

Additional Challenges & Opportunities

- 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.
- Funds could be used to pilot initiatives that promote commercialization, including:
  - Making SBIR/STTR proposals more attractive for further investment, potentially through public-private partnerships
  - Developing a more formal Phase III funding process to include initiation of clinical trials
- A potential limitation is that the Reauthorization removes some of NIH's flexibility to provide large awards beyond the SBIR/STTR cap. 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). The program is more likely to generate successful products if the level of funding more closely matches research costs; it is better to provide adequate funding than to provide insufficient funding to many recipients.