

**Needs Assessment of the NIAID
Small Business Innovation Research (SBIR) and
Small Business Technology Transfer Research (STTR)
Programs
FINAL REPORT**

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Executive Summary

Purpose of Needs Assessment

The purpose of this evaluation was to improve management of policies and procedures for the NIAID Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs. The goals of this needs assessment were to:

- Define SBIR/STTR mission statement document
- Understand SBIR/STTR management processes, identify specific areas that could be improved, and make improvement recommendations
- Propose program improvement pilot studies.

Primary Improvements

Improvement outcomes of this evaluation were:

- Gained transparency in understanding SBIR/STTR processes and key decisions across all divisions, including budget and grants management
- Designed trans-NIAID collaborative program improvements
- Identified and began piloting program improvement modifications.

NIAID SBIR/STTR Program Mission Statement

The mission of the NIAID domestic small business program is to judiciously fund research and development of products or services that prevent, diagnose, and treat allergic, immunologic, and infectious diseases.

SBIR/STTR Process Improvement Recommendations

- Establish a trans-NIAID group to meet quarterly/semi-annually to provide a forum to continue assessing and improving the NIAID SBIR/STTR program.
Rationale: The evaluation highlighted the importance of transparency, communication and trans-NIAID collaboration to establish a healthy SBIR/STTR program.
- Periodically assess: 1) ratio between Phase I and Phase II applications and awards, 2) paylines for Phase I and Phase II SBIRs and STTRs, and 3) SBIR/STTR funding caps and periods of performance to make adjustments in a timely manner to maintain a healthy portfolio.
Rationale: The SBIR/STTR portfolio and pipeline is susceptible to fluctuations. More fluid management can facilitate maintaining a healthy pipeline, such as actively encouraging more applications in years when excess funds are anticipated, and funding caps when funds are tight, for better stewardship of SBIR/STTR funds.
- Develop an SOP with steps and criteria for making decisions on end of year and above payline awards such as: 1) differential paylines for Phase I and Phase II, 2) using rank in addition to percentile, and 3) balancing across programmatic priorities.
Rationale: Outlining steps and criteria will increase transparency in decision-making, balance the portfolio and improve short- and long-term planning.
- Review initiatives and NIAID grant portfolios to identify scientific areas that could have projects suitable for the SBIR/STTR program and explore PAR and RFA, as appropriate.
Rationale: Investigators can be encouraged to consider SBIR/STTR announcements to increase numbers of SBIR/STTR applicants, and can overall improve quality of applications.

- Develop an SBIR/STTR training for NIAID Project Officers who administer SBIR/STTR grants within their portfolio and organize a special interest group for the SBIR/STTR program.
Rationale: Most Program Officers have few SBIR/STTR grants in their portfolio; training will increase their knowledge about the program and build SBIR/STTR management expertise.
- Develop training course for NIAID staff that provides information on types of contracts and grants, differences between contracts and grants, and similar topics/issues to assist staff in making decisions on appropriate funding mechanisms to achieve various program objectives.
Rationale: Build management expertise and improve knowledge of contracts and grants as alternative funding mechanisms for different mission needs.

SBIR Pilot Study Recommendations and Methods for Evaluation

- Solicit fast-track contract topics for SBIR product development; extend funding and period of performance levels¹
Rationale: The goals are to attract a set of small businesses more likely to respond to contract opportunities; expand NIAID SBIR constituency; and encourage Divisions to prioritize R&D needs to be more mission specific.
Evaluation: Assess if: (1) goals of using SBIR contract mechanism were achieved, and (2) benefits are greater than contract management and administration costs.
- Provide NIH CSR percentile rank, along with score, for all reviewed applications to Division SBIR/STTR Coordinators.²
Rationale: The goal is to provide information to improve decision-making for select pay awards.
Evaluation: Assess if a percentile rank improves decision-making and quality of awards.
- Request NIH CSR to review and score all applications up to 60 percent of submissions level.³
Rationale: The goal is to increase number of scored applications from CSR to provide more applications to choose from for funding.
Evaluation: Assess if more scored applications improves numbers of eligible applications and quality of awards.
- Develop a parallel PAR SBIR/STTR for a RFA. Still an outstanding issue whether SBIR/STTR Program permits use of funds for PAR?
Rationale: Goal is to stimulate SBIR/STTR applications in priority areas and to direct review process to the Institute to increase quantity of SBIR/STTR applications in specific areas.
Evaluation: Assess if (1) goals of using PAR mechanism were achieved, and (2) if benefits achieved are greater than added management and administration costs.

Members of trans-NIAID Evaluation Team

TEAM MEMBER	AFFILIATION	TEAM MEMBER	AFFILIATION
Daniela Livnat (Project Officer)	DAIDS	Charles Grewe	DEA (Contracts)
Gregory Milman	DEA (SBIR)	Michael Wright	DEA (Grants)
Nancy Jones	SPEB	Brad Schwartz	BFMB
David Kosub	SPEB	Cindy Fuchs	OTD
Barbara Mulach	DMID	Paul Young (Senior Evaluator)	NOVA Research Company
Susan Daniels	DMID		
Bert Maidment	DAIT	Lisbeth Jarama (Senior Evaluator)	NOVA Research Company

1 Implemented in Small Business Innovation Research (SBIR) Program Contract Solicitation (PHS 2009-1)

2 To be implemented in next SBIR/STTR grant applications review cycle

3 Agreed to by CRS, and to be implemented in next SBIR/STTR grant applications review cycle.

Introduction and Background

The NIAID Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs are funded by set asides of NIH extramural budget, 2.5% and 0.3% respectively. Congress established the SBIR program in 1982 and reauthorized it through FY2008, and established the STTR program in 1992 and reauthorized it through FY2009. Both programs are in the process of reauthorization by Congress. Both programs are for small business concerns to engage in research targeted to product development, either independently (SBIR) or in collaboration with a university or other non-profit research institution partner (STTR), which have potential for commercialization. In FY2006, NIH invested approximately \$640M in the SBIR/STTR programs and NIAID invested approximately \$100M.

The NIAID sets aside 2.5% of its extramural research budget to support this research and product development for small business programs, such as products or services that improve public health in areas relevant to the Institute. The NIAID FY2006 SBIR and STTR budgets were approximately \$88.5M (183 projects) and \$11.3M (30 projects), respectively. In addition, these 113 projects were managed by 71 Program Officers across NIAID Divisions (144 Phase I and 69 Phase II).

Purpose and Goal of the NIAID SBIR/STTR Needs Assessment

The purpose of this evaluation was to examine whether NIAID SBIR/STTR policies, procedures, and/or operational activities and structures can be optimized to improve program management in research and development of products or services that are relevant to the Institute's mission. The needs assessment goal was to identify specific areas of the NIAID SBIR/STTR program management that could be improved to better aid in overall selection of grant applications that will be more likely to move a product or service along the commercialization pathway in areas that promote NIAID's mission.

Needs Assessment Performance Methodology

The NIAID SBIR/STTR needs assessment methodology was structured to assess stakeholder needs, develop program goals, and determine how SBIR/STTR programs might be modified and redesigned to achieve stated goals. The following steps were accomplished through Evaluation Team meetings, presentations to understand processes and procedures, within NIAID and other NIH offices—NCI and CSR—and individual and group interviews with NIAID program stakeholders.

Step 1: Information gathering—Each Division, the central NIAID DEA small business office, Budget Office, Grants Management, and Contracts Management explained their process (how their component of the SBIR/STTR program currently functions). In the case of the Contracts Management office, the general contract application, review, and award process was described, since NIAID does not currently sponsor the SBIR contract mechanism. The presentations focused on informing on decision points (e.g., how are SBIR announcements generated) and how these processes facilitate accomplishing the Division's programs mission/goals (and if not, why not?), what works and what doesn't work, bottlenecks and/or barriers, and "process limiting steps"). A DEA Small Business Office developed flowchart provided an excellent starting point for describing an overview of processes.

In 2006-07, the National Cancer Institute was requested by the NIH Director to evaluate the SBIR Program and to make recommendations to increase effectiveness of the SBIR program for the NIH. The NIAID SBIR Evaluation Team deemed it important to collect information regarding this process, reasons for and purpose of recommendations, and NCI pilot improvement studies being or scheduled to be conducted. Thus, there was an information gathering session with the Program Director of that effort, Dr. Michael Weingarten, on the NCI Evaluation Branch's SBIR study, with a

focus on how their process worked and why they've made their change recommendations. **Appendix B** provides a copy of the NCI's presentation.

During NIAID Evaluation Team meeting discussions, it became clear that the SBIR/STTR grant review process at the NIH CSR was an important step in the success of the program. Therefore, a special meeting of the Evaluation Team was scheduled to hear from CSR representatives.

Step 2: NIAID SBIR/STTR process diagrams—NOVA received and modified Dr. Milman's process flow/decision map flowchart to extend decision points and process flows, based on process component descriptions from Evaluation Team representatives in Step 1 (**Appendix A**).

Step 3: Brainstorming and categorizing—Once program goals were agreed upon and discrete processes were documented, the Team brainstormed possible alternative options for each defined process without consideration for feasibility or practicality. The objective of this process was to identify all ideas that might be considered and operated in an unrestricted environment, regardless of their practicality. At the end of the meeting, the options list contained the following items:

- | | |
|---|---|
| <p>➤ Program management</p> <ul style="list-style-type: none"> ▪ Central versus distributed management (IC/Division/Program) ▪ NIAID review (with contracts) ▪ Dedicated SBIR/STTR personnel ▪ Marketing/outreach (travel, network with scientific community) ▪ External advisory committee ▪ Portfolio management ▪ Reduced turnaround (contracts) ▪ Performance management (benchmarks, milestones) (contracts) ▪ Emphasis on development/product (contracts) | <p>➤ Funding mechanisms</p> <ul style="list-style-type: none"> ▪ Mission-specific (versus straight percentage) ▪ More contracts ▪ Assess commercialization potential ▪ Different paylines for Phase I and Phase II (to balance portfolio) ▪ Select Pay (tied to payline) ▪ Competitive renewal for Phase I ▪ Past awardee performance |
|---|---|

Step 4: Narrowing project management alternatives—The Evaluation Team discussed each process and focused ideas on feasible and practical alternatives to the current process, and prioritized these alternatives for possible future pilot studies. This prioritization process required examining issues such as: what changes would enable the program to better meet its goals, what might be implemented as a pilot in the short-term versus long-term (e.g., would require NIAID or NIH policy changes). Three high-priority options in program management and two in portfolio management were selected for development of a stakeholder survey to gather additional input on practicality and acceptability from other NIAID intramural program management staff.

- | | |
|--|--|
| <p style="text-align: center;">Program Management</p> <ul style="list-style-type: none"> ➤ Centralized management through a formal SBIR/STTR Program Office, with dedicated portfolio managers, versus distributed management by Division ➤ Develop/implement a SBIR contract mechanism ➤ Institute-wide versus Division-based process for funding decisions | <p style="text-align: center;">Portfolio Management</p> <ul style="list-style-type: none"> ➤ Increase Select Pay awards ➤ Increase awards that address high-priority areas and help balance the portfolio |
|--|--|

Step 5: Defining evaluation questions and associated stakeholders—Based on the prioritized SBIR/STTR project management improvement opportunities, NOVA in collaboration with the NIAID Evaluation Team members defined this study’s evaluation questions. The Evaluation Team reviewed the questions and identified primary stakeholders (implementers and those impacted by possible resulting pilot projects). This process included identifying what information is needed to support decisions on alternatives, who has expertise to answer questions, and what metrics would be used to evaluate results.

Step 6: Conduct appropriate interviews/meetings with identified stakeholders to address and/or answer the evaluation questions—Based on Step 5, NOVA staff, in collaboration with SPEB staff conducted in-depth guided group interviews (and individual interviews with identified persons who could not attend the group interviews) to understand and document issues, opportunities, and strengths and weaknesses of identified improvement opportunities. A copy of the interview guide is provided in **Appendix C**.

Step 7: Review findings from interviews—Information collected was presented to the Evaluation Team to review findings and inform interpretations as well as design recommendations for process changes and pilot studies. The Findings Report is provided in **Appendix D**.

Step 8: Prepare recommendations of project management process alternatives and identify potential pilot projects—The Evaluation Team identified possible recommendations to improve NIAID SBIR/STTR program management that will be presented to the NIAID Executive Committee. This Evaluation Team also designed possible pilot studies of project management alternatives that might be implemented at NIAID and ways to assess the pilots. NOVA compiled and documented recommendations and possible pilot studies into this Needs Assessment Final Report.

Developing the NIAID SBIR/STTR Mission

A key component of the needs assessment was to ensure that recommendations would be appropriate within the context of the mission for NIAID SBIR/STTR program. Therefore, establishing a NIAID SBIR/STTR mission statement was an activity of several Team meetings. Once the Team had agreed to a final working mission statement, a meeting was held on February 28, 2008, with Dr. McGowan, and the mission statement was finalized.

NIAID SBIR/STTR Mission Statement

The mission of the NIAID domestic small business program is to judiciously fund research and development of products or services that prevent, diagnose, and treat allergic, immunologic, and infectious diseases.

Primary Outcome

The Evaluation Team perceived the primary and most important outcome of this study was that it brought interested NIAID staff together to form an involved senior management group to consider what kinds of improvements to the SBIR/STTR program might be possible, and increased Team understanding of NIAID SBIR/STTR processes and procedures. The NIAID Evaluation Team represented all NIAID stakeholders involved in the process, thereby ensuring better understanding, process transparency across functions in the institute, and collaboration in current and future program improvements and pilot studies. The Evaluation Team recommended that this trans-NIAID group continue to meet quarterly to provide a forum to continue assessing and improving the NIAID SBIR/STTR program.

Identifying Opportunities for SBIR/STTR Process Improvements

In January 2008, the NIAID SBIR/STTR Evaluation Team members brainstormed to develop a comprehensive list of process improvement opportunities. The Team did not consider feasibility or practicality of the ideas in an attempt to get all ideas discussed.

Proposed SBIR/STTR improvement opportunities were identified in primary 2 areas: (1) changes in organizational and portfolio management and (2) development of an SBIR contract award mechanism. The Team then focused on prioritizing options based on whether they were practical and feasible and/or likely to result in improvements in the SBIR/STTR management process. The discussion of process improvement options from the Minutes of the February meeting are provided in **Appendix E**.

Organization and portfolio management changes considered included activities such as:

- Consolidating SBIR/STTR administration and portfolio management in a DEA-OD central office with full-time, dedicated SBIR/STTR Program Officers.
- Changing balance between payline awards and select pay awards.
- Increasing or removing Phase I and Phase II funding caps.

Contract award mechanism considered potential strengths and weaknesses of using SBIR contracts to better achieve NIAID SBIR goals and expand NIAID SBIR/STTR constituencies. It is perceived that SBIR contracts may attract a set of small businesses that are more likely to respond to contract opportunities.

Key Findings from CSR Process Presentation

In April 2008, the Evaluation Team participated in a discussion with three invited Scientific Review Administrators (SRAs) from the NIH CSR regarding their process in review and scoring of SBIR and STTR grant applications. Key findings included:

- Difficult for CSR to get reviewers from industry.
- SRAs look for potential end-users for the proposed product to serve as reviewers.
- SRAs are told they must triage 50% of applications; complex rules govern what applications actually get discussed and scored by the entire review group.
- 65% of Phase I applications have potential for FDA approval, and almost 100% of Phase II.
- Major determination factor by reviewers in scoring is if a similar product already exists or the proposed product does not improve healthcare process.
- Phase I and II applications in area of discovery are reviewed along with Phase I and II applications that are farther along development pathway; therefore, concern that first group may look more innovative than second group, and may therefore score higher.
- Actual scores of triaged applications are available from CSR for a short period of time after Review Group meeting, and can be requested.
- Percentile scores of all applications reviewed by a study section may be a better indicator of scientific quality than raw scores when comparing scores across all study sections.
- CSR panels encourage NIH institute programs to issue Program Announcements (PAs) for specific topics directed to SBIR/STTR potential applicants.
- CSR panels encourage NIH institute programs to provide guidance to applicants in grantsmanship and responding to Summary Statements.

Key Findings from Stakeholder Interviews

Based on identified improvement options, a list of potential evaluation questions for NIAID SBIR/STTR Program Officers and others with a vested interest in the SBIR/STTR programs (i.e., stakeholders) was developed and subsequently reviewed and refined by the Evaluation Team. These preliminary evaluation questions were used to conduct individual interviews with four NIAID Program Officers and their comments and responses were recorded. This information was subsequently presented to the Evaluation Team for further refinement of the survey questionnaire. These Preliminary Findings are provided in **Appendix F**.

NOVA subsequently conducted stakeholder group interviews. Participants in these interviews represented all divisions participating in SBIR/STTR awards—DMID, DAIT, DAIDS, and representatives from the Budget Office, Contracts Management Office and Grants Management Office. A summary of key general findings is presented below. A more in-depth listing of findings that were presented to the Evaluation Team for review and decisions is provided in **Appendix D**.

- Current administration and management structure with a DEA-level small business office, individual Division-level SBIR/STTR liaisons, and science-based Program Officers with mixed grant portfolios functions effectively.
- Mixed opinions concerning NIAID providing assistive advice on business management issues—market research, business/marketing planning, obtaining investors—some perceiving this as an Institute gap that should be addressed and others perceiving that these issues should be addressed by small businesses retaining expert consultants, keeping NIAID focused on advising on good science.
- No benefits to having separate Phase I or Phase II funding pools or establishing minimum/maximum award numbers. Mixed opinions regarding changing balance between payline awards and select pay awards--some indicating current process satisfactory, others indicated paylines be established to ensure quality science with excess funds used to provide select pay awards at Division-level discretion.
- Most interviewees were not familiar with contract funding mechanisms. Perceived no benefit to Phase I contracts due to short timeframe (6 months) and low funding caps. Also contracts require too much management/administration relative to grants.
- SBIR/STTR Phase I and Phase II funding caps should be substantially increased or removed to allow application product development science to dictate funding levels.

SBIR/STTR Process Improvement Recommendations

The following are specific process improvement recommendations vetted through the Evaluation Team for implementation consideration.

- Develop and issue RFI to solicit information on SBIR/STTR needs and improvement opportunities from extramural research communities (academic and commercial), and/or consider another Needs Assessment Evaluation Study to gather information on needs and improvement opportunities of extramural research communities (this would require OMB clearance for survey(s) and focus groups).

[**Note:** it was decided at a subsequent meeting that this is an NIH-level issue and will be referred to the NIH SBIR/STTR Office by NIAID for consideration and possible future action; therefore, it was deleted from the final set of recommendations.]

- Explore the possibility and implementation details for conducting multiple SBIR contract solicitation cycles, other than just the one in August. If possible, consider a one year Pilot Study of priority contract topics.

[**Note:** it was decided at a subsequent meeting that this is not a practical recommendation given the extensive time and effort to prepare a NIAID-only contract solicitation process; therefore, it was deleted from the final set of recommendations.]

- Identify BAAs, RFAs and PAs that might be applicable to small businesses.
 - a. What specific language needs to be included to allow eventual funding with SBIR or STTR funds?
 - b. For U01 and U19 solicitations, "NIAID has the option to issue any awards deemed eligible under the requirements of the SBIR program as U43 or U44 activity in lieu of a U01 or U19."

[**Note:** it was decided at a subsequent meeting that this recommendation needs additional exploratory research and discussion to determine feasibility.]

- Explore feasibility and legal requirements to use SBIRs/STTRs to conduct Cooperative Agreement grants—either in conjunction with other Cooperative Agreement grants (unrestricted) or as stand-alone Cooperative Agreement.

[**Note:** it was decided at a subsequent meeting that this recommendation needs additional exploratory research and discussion to determine feasibility.]

- SBIR Caps –
 - a. Periodically assess SBIR/STTR funding caps and periods of performance (especially Phase I) to ensure in line with Institute mission and objectives, and to make SBIRs more attractive and expend more SBIR funds without sacrificing scientific quality.
 - b. Or, remove funding caps (if legally permissible) as long as Divisions ensure sufficient quantity and quality of Phase II applications to meeting mandated funding requirements. If we don't fund enough Phase I applications, NIAID will not have enough Phase II applications to meet mandated funding requirements.
- Consider different paylines for Phase I and Phase II SBIRs and STTRs.

Rationale: To increase numbers of SBIR/STTR applicants and applications by providing more opportunity and to use greater percentage of SBIR funds.

- Develop and implement training programs (that blend DAIT and DAIDS/DMID processes) or interest groups for POs on the SBIR/STTR mechanisms.
 - a. Encourage identification of SBIR/STTR topics/applications (product development opportunities) within Program Officer's broader grant portfolios
 - b. Conduct regular reviews of portfolios for opportunities with NIAID and Division SBIR managers

Rationale: To increase numbers of SBIR/STTR applicants and quality applications.

- Develop and implement a staff training program that encompasses using and managing grants and contracts, and includes training on SBIRs/STTRs, or a separate certification course only on SBIR/STTR grants and contracts. (The training course should be a thorough discussion, with tutorials on types of grants (R-series, Cooperative Agreements, etc.), types of contracts, differences between contracts and grants in terms of Program Announcements,

Requests for Applications, Contract Statement of Work, differences in review and award processes, differences in monitoring and reporting requirements, etc.).

Rationale: To build expertise and improve knowledge in managing SBIRs/STTRs, and to build expertise and improve knowledge of contracts and grants in general as alternative funding mechanisms for different NIAID mission needs.

SBIR Pilot Study Recommendations and Methods for Evaluation

The following are specific pilot project recommendations vetted through the Evaluation Team for implementation consideration.

- Pilot Study: Solicit fast-track contract topics for priority product development; consider using expanded funding levels of Phase I = \$300,000 for 1-year and Phase II = \$2,200,000 for 3-years; total fast track = \$2.5M for 4 to 5 years. Evaluate results to include: number of applications, quality of applications (scores), effort in putting together evaluation panels, number of awards, and award outcomes (e.g., did award result in delivery of identified product at acceptable level of development? progress to Phase II award?)

Rationale: To determine whether SBIR contract mechanism results are worth additional management and administration effort; to attract a set of small businesses that are more likely to respond to contract opportunities; to expand NIAID SBIR constituency; to encourage Divisions to prioritize R&D needs to be more mission specific.

- Pilot Study: Provide NIH CSR percentile rankings along with raw scores for all reviewed applications to Division SBIR/STTR Coordinators. After one year of review cycles, analyze Phase I awards and accomplishments (e.g., accomplishments and progression to Phase II award) between scores and percentiles to better understand if percentile awards, particularly for select pay awards, improves the SBIR/STTR award decision-making process.

Rationale: Percentile rankings provides additional opportunity to get best science funded by improving decision-making for select pay awards outside payline.

- Pilot Study: Request NIH CSR to review and score all applications up to 60 percent of submissions level. After one year of review cycles, analyze number of awards at 60 percent review level versus number of awards at current review percent level (which is about 45% for SBIRs).

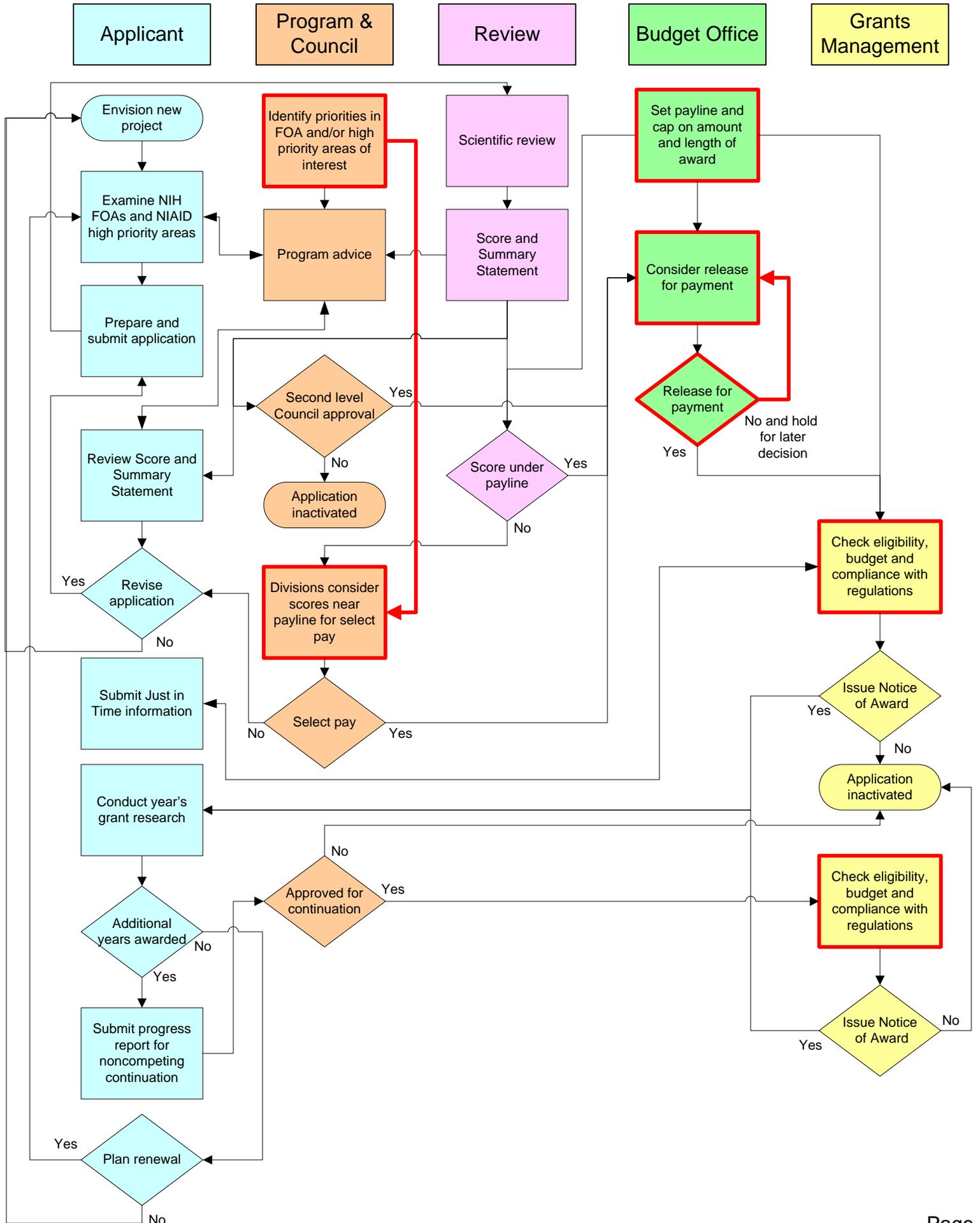
Rationale: Increase number of scored applications from CSR to provide more funding choices.

- Explore, and if possible, pilot using SBIR/STTR funding for a parallel SBIR/STTR PAR for a selected priority RFA.

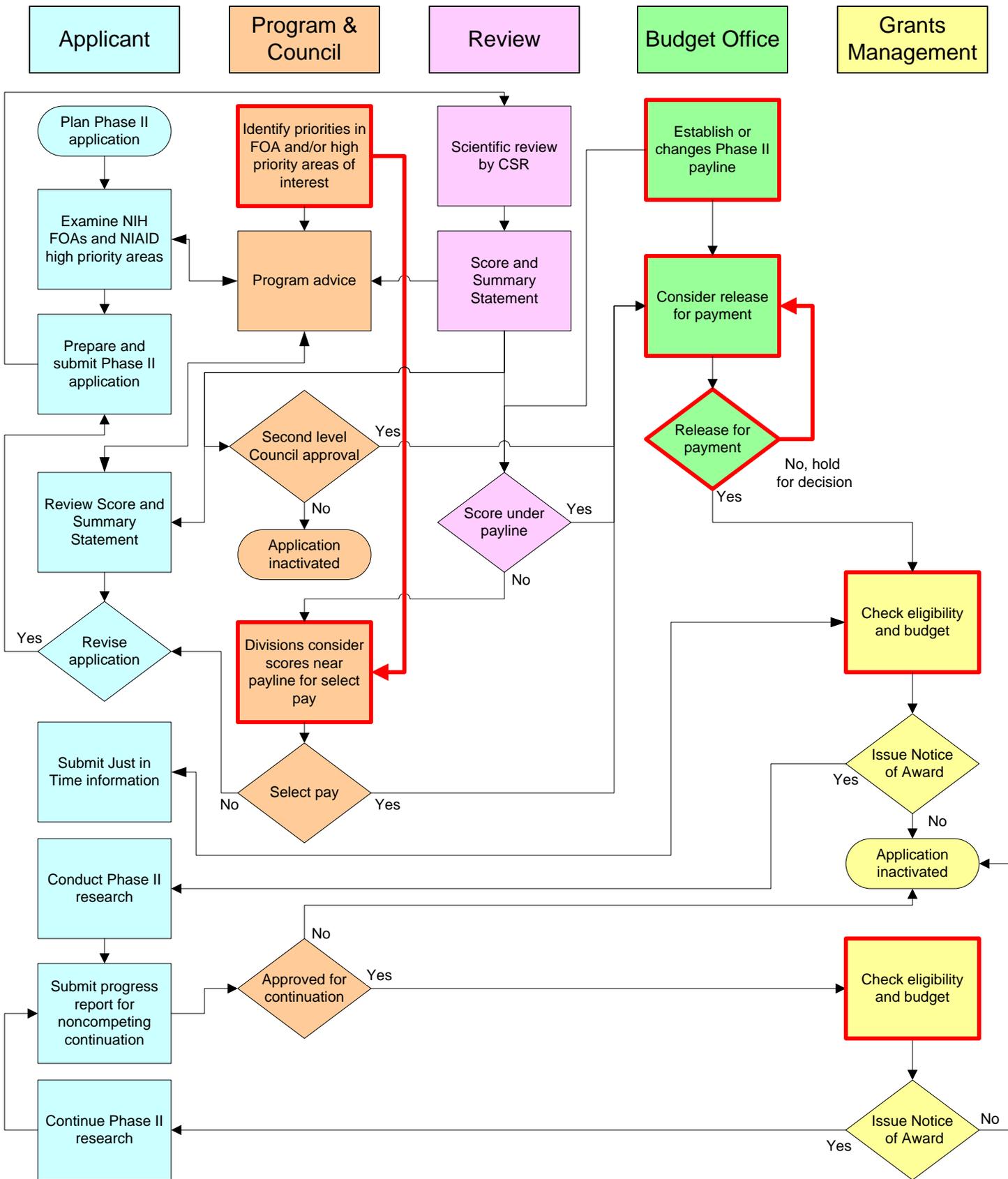
Rationale: Directs review process to the Institute and increases quantity of SBIR/STTR applications and future awards.

Appendix A
SBIR/STTR Award Process
Flowcharts

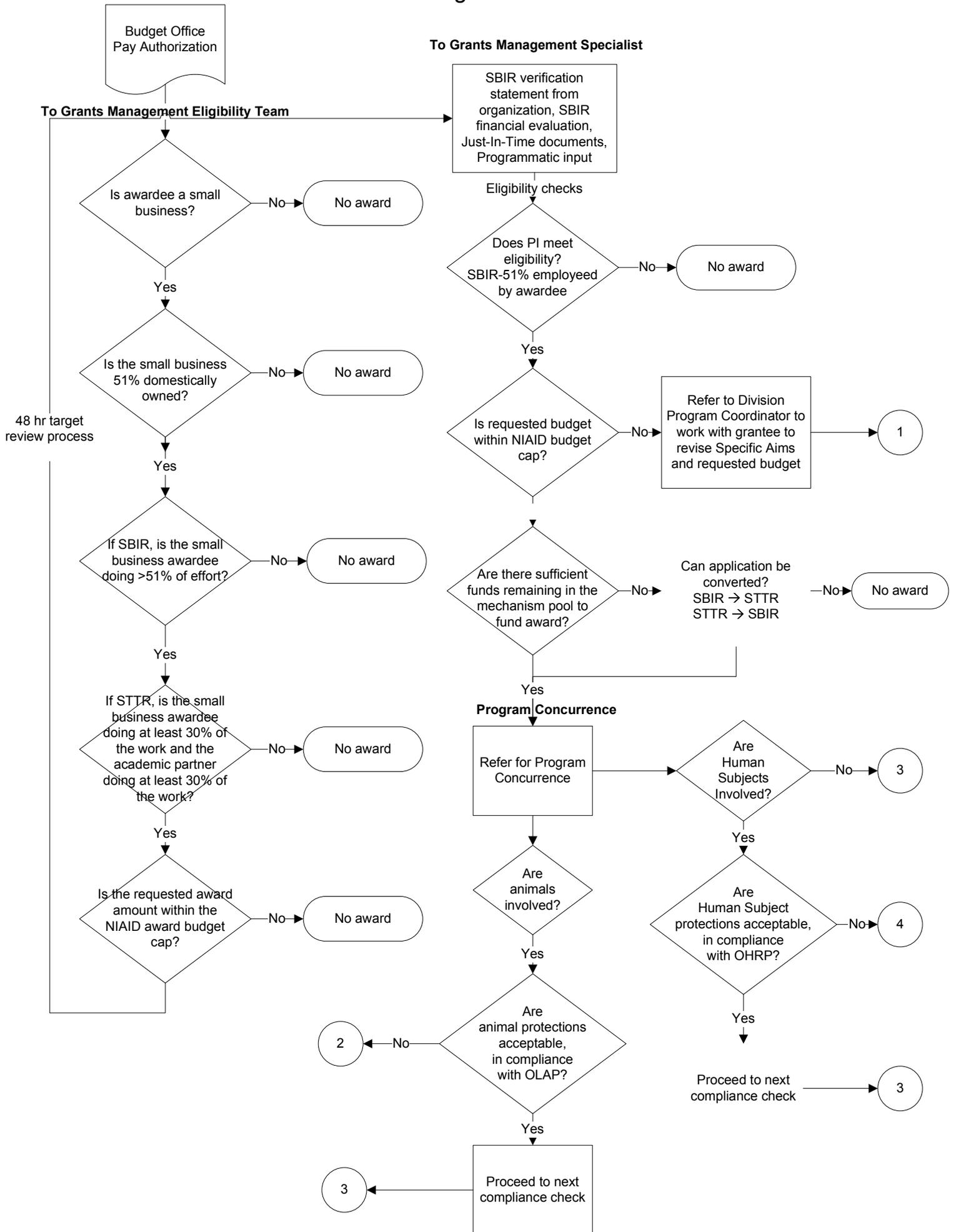
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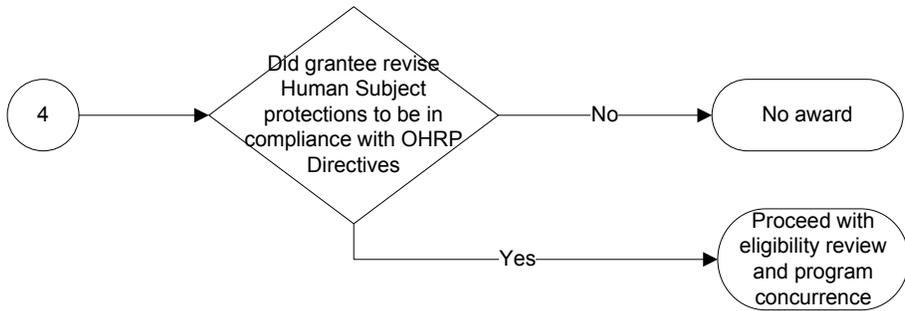
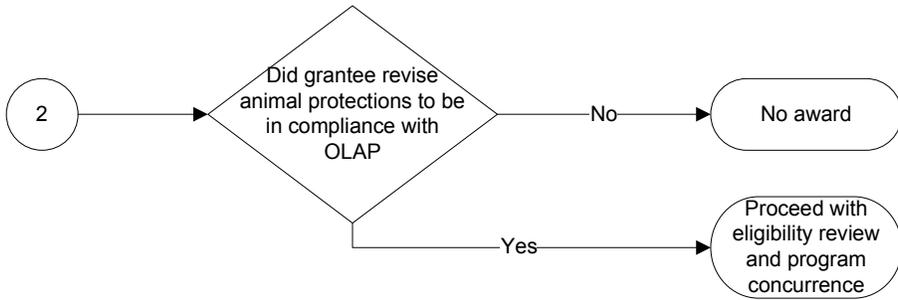
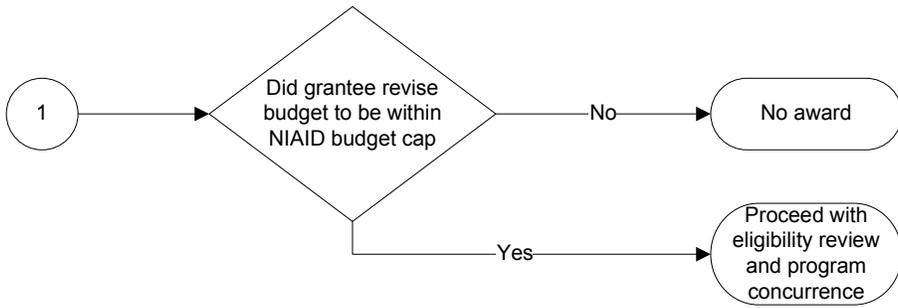


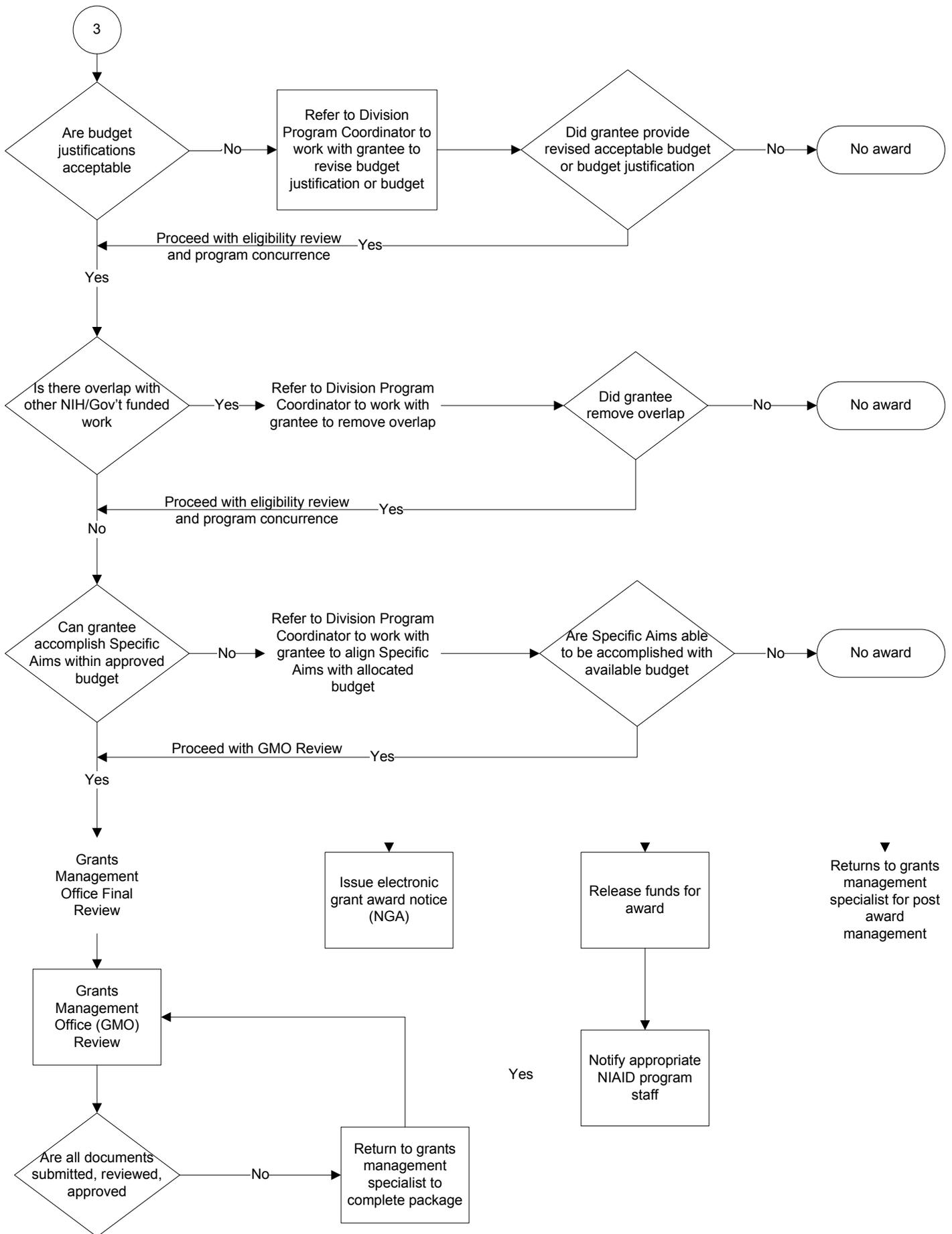
Phase II



Grants Management Process

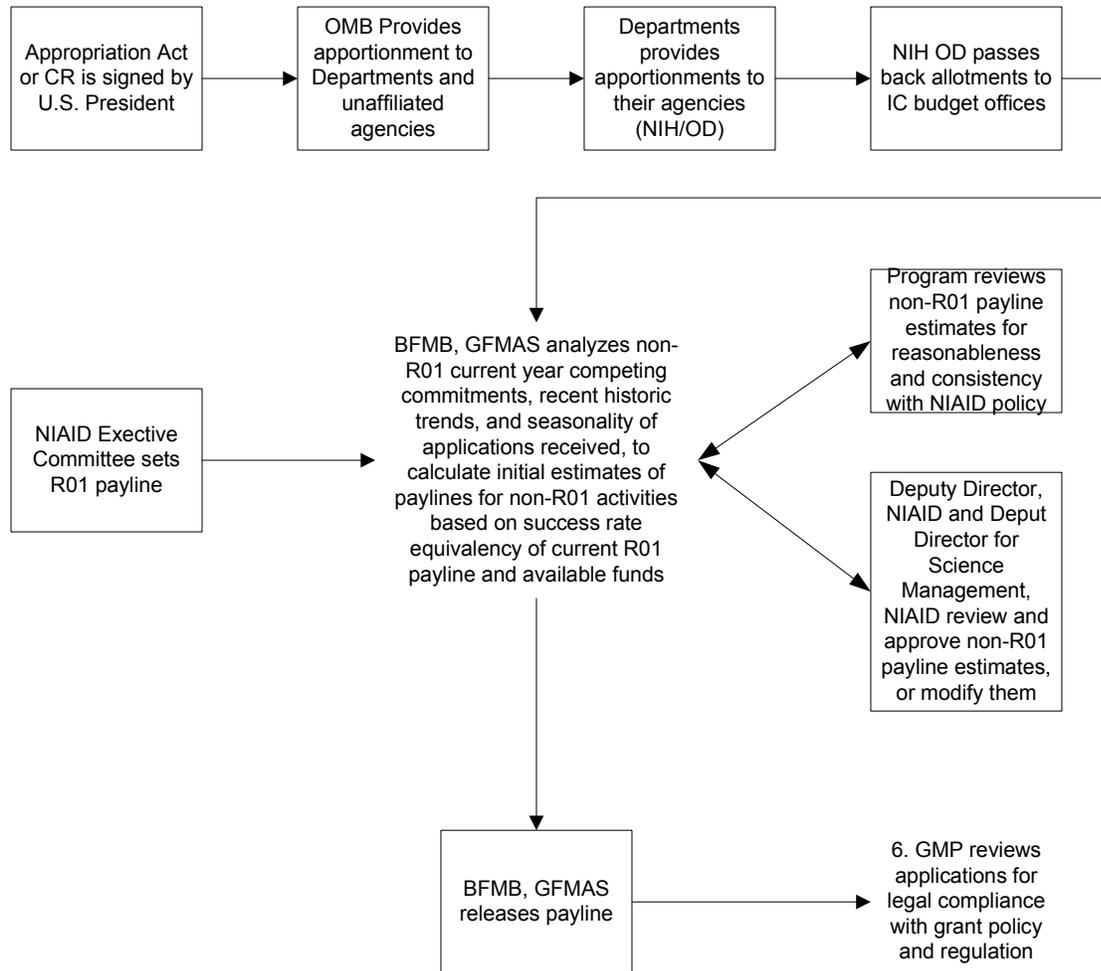






Budget Office Process

The Budget Execution Process for Payline Funding Actions



Appendix B
NCI SBIR & STTR Recommendations
Presentation to NIAID Evaluation Team



Enhancing the NIH SBIR/STTR Efforts

Presentation to NIAID

Michael Weingarten

Director, NCI SBIR Development Center

January 15, 2008



Charge from the NIH Director

October 2006 – Request from Dr. Zerhouni to Dr. Niederhuber for NCI to lead an effort to examine the near \$650 million NIH SBIR Program with a target of enhancing the program's outcomes

NCI's Response

- December 2006 – Dr. Niederhuber presented four overarching recommendations to Dr. Zerhouni**
- Presentations followed to the NIH Steering Committee and IC Directors**
- Dr. Zerhouni asked that all recommendations be implemented on a pilot basis at NCI with interested ICs to work with NCI**
- Since February 2007, NCI has been working to implement the recommendations**

Four Recommendations

Specific Recommendations Being Implemented

- 1. Focus Solicitations on Commercially Viable Technologies**
- 2. Establish SBIR Development Centers**
- 3. Co-invest With the Private Sector to Bridge SBIR Projects Toward Commercialization**
- 4. Assemble External SBIR Advisory Committee**
 - **NIH-level**
 - **NCI-level**

#1: Focus Solicitations on Commercially Viable Technologies

Today, most SBIR awards are funded through an investigator-initiated approach heavily focused on grants

Proposal: Improve success in commercialization by focusing on more directed research.

- Priorities should balance **mission need** and the potential for **commercialization**
- **Catalyze targeted technology development** and draw **private sector investment** in areas such as drug development and assays that measure treatment response
- **Increase contracts** (currently represent 4% of the set-aside) to 20-25% over the next 1-2 years — and between 25-50% over the next 3-5 years

#1 (cont'd): Focus Solicitations on Commercially Viable Technologies

- **IC's would:**

- Determine and target specific high-risk, high-impact technology priority areas

- Set aside a significant portion of SBIR funds to support those areas

- **NIH Benefits:**

- IC can closely manage the awardee's progress toward specific milestones and the development of a product

- NIH's "Other Transactions" authority provides greater flexibility in administration and management of projects

- Allows greater participation by Intramural Research programs (within Ethics guidelines)

NCI SBIR Contract Topics

(FY 2008)

- **Development of Anti-Cancer Agents**
- **Development of Molecular Pharmacodynamic Assays for Targeted Therapies**
- **Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer**
- **Multifunctional Therapeutics Based on Nanotechnology**
- **Antibody Array for Cancer Detection**
- **Biosensors for Early Cancer Detection and Risk Assessment**
- **Novel and Improved Methods to Measure Cancer Epigenetic Biomarkers**
- **High-Throughput Assays for Isolation and Characterization of Cancer Stem Cells**
- **Assay Systems for Drug Efficacy Using Cancer Stem Cells**
- **Integrating Patient-Reported Outcomes in Hospice and Palliative Care Practices**
- **Portable e-Technology Diet and Physical Activity Tools for Consumers**
- **Patient-Centered Coordinated Cancer Care System**
- **System to Analyze and Support Biomarker Research and Development Strategies**
- **Biopsy Instruments and Devices that Preserve Molecular Profiles in Tumors**
- **Advances in Protein Expression of Post-Translationally Modified Cancer Related Proteins**
- **Development of Clinical Quantitative Multiplex High-Throughput Mass Spectrometric Immunoassay for Detecting Low Abundance Cancer Related Proteins/Peptides in Bodily Fluids**

NCI Grant Topics

- Technologies and Software to Support Integrative Cancer Biology Research, [PAS-07-242](#)
- Technology Development for the Detection and Evaluation of Chemical and Biological Carcinogens, [PAS-07-240](#)
- Technology for the Detection and Characterization of Low Abundance Proteins, Peptides, or micro RNAs, [PAS-07-241](#)

#2: Establish IC SBIR Development Centers

Today, SBIR program management is generally dispersed within the IC's, with few full-time managers

- For example, at NCI, awards are managed by 40 people who each spend about 10-15% of their time on SBIR
- Few IC SBIR program managers have significant industry or commercialization experience

Proposal: Pool talent to optimally manage the program by creating IC SBIR Development Centers.

- These would be **dedicated SBIR management teams**
- Recruit existing staff to work on the program full time
- **Recruit new program managers with technology commercialization experience in the life sciences industry**
- Build IC coalitions with common technology needs

#2 (cont'd): Establish IC SBIR Development Centers

- **ICs are the customers**
- Each participating IC determines its priorities and directs the use of its resources with the development center
- **Centers will offer a menu of reimbursable services**, following the Technology Transfer Service Center model
 - Assess commercial potential of IC technology priorities
 - Write solicitation topics/post-solicitation activities
 - Market program to attract the best companies
 - Evaluate commercialization potential of proposals
 - Provide awardee management & support
 - More active monitoring of awards
 - Facilitate awardee commercialization

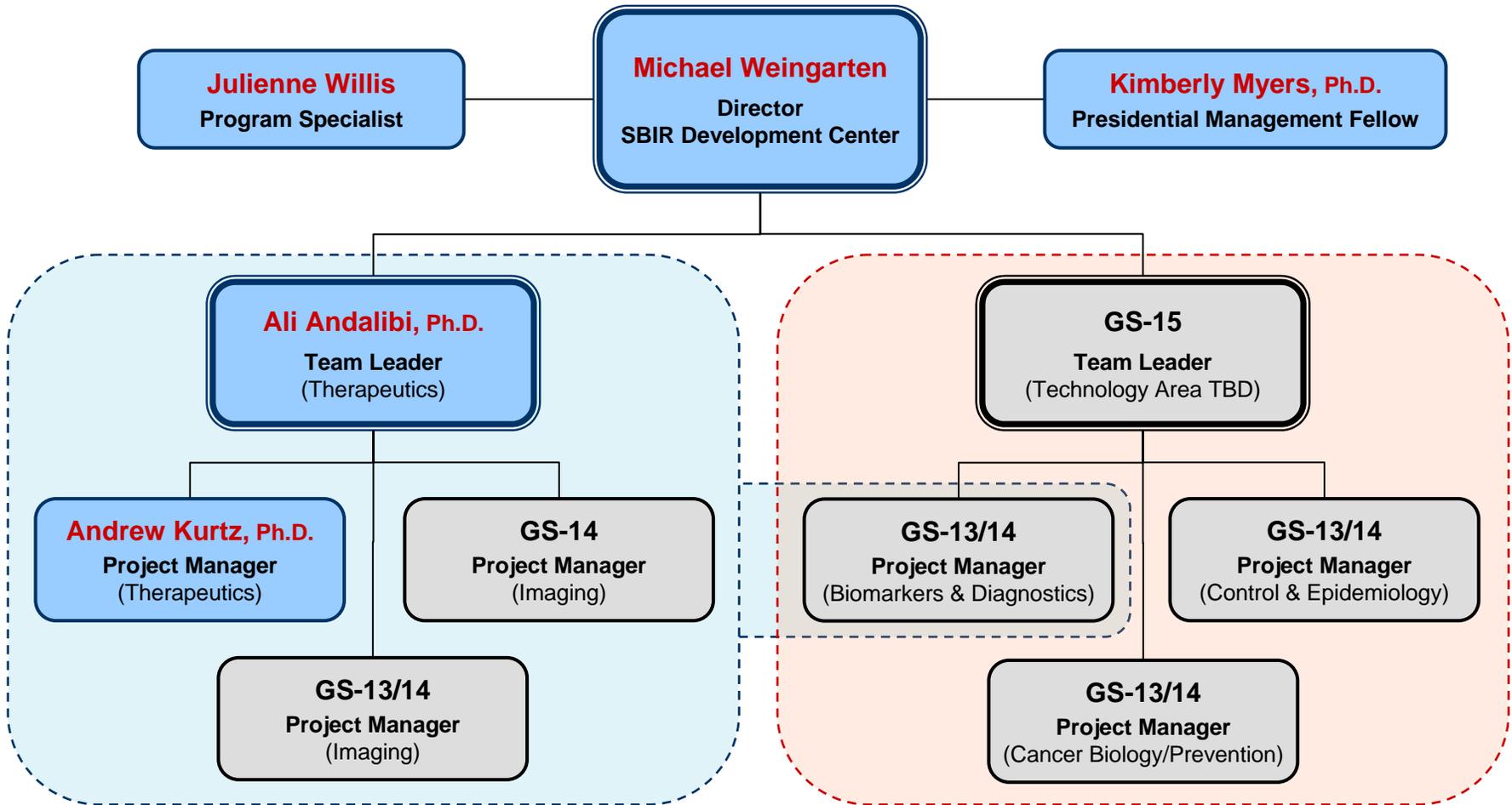
#2 (cont'd): Establish IC SBIR Development Centers

- **Benefits:**

- **Efficiencies of scale** in program management
- **Smaller ICs will be able to tap into commercialization expertise for better results**
- **ICs have a better opportunity to collaborate** on joint solicitations to accelerate critical technologies
- **Program managers will have expertise and networks to mentor emerging SBIR companies** in commercialization strategy and process

- **NCI is putting together the first SBIR Development Center in FY 08**

NCI SBIR Development Center Organization Chart



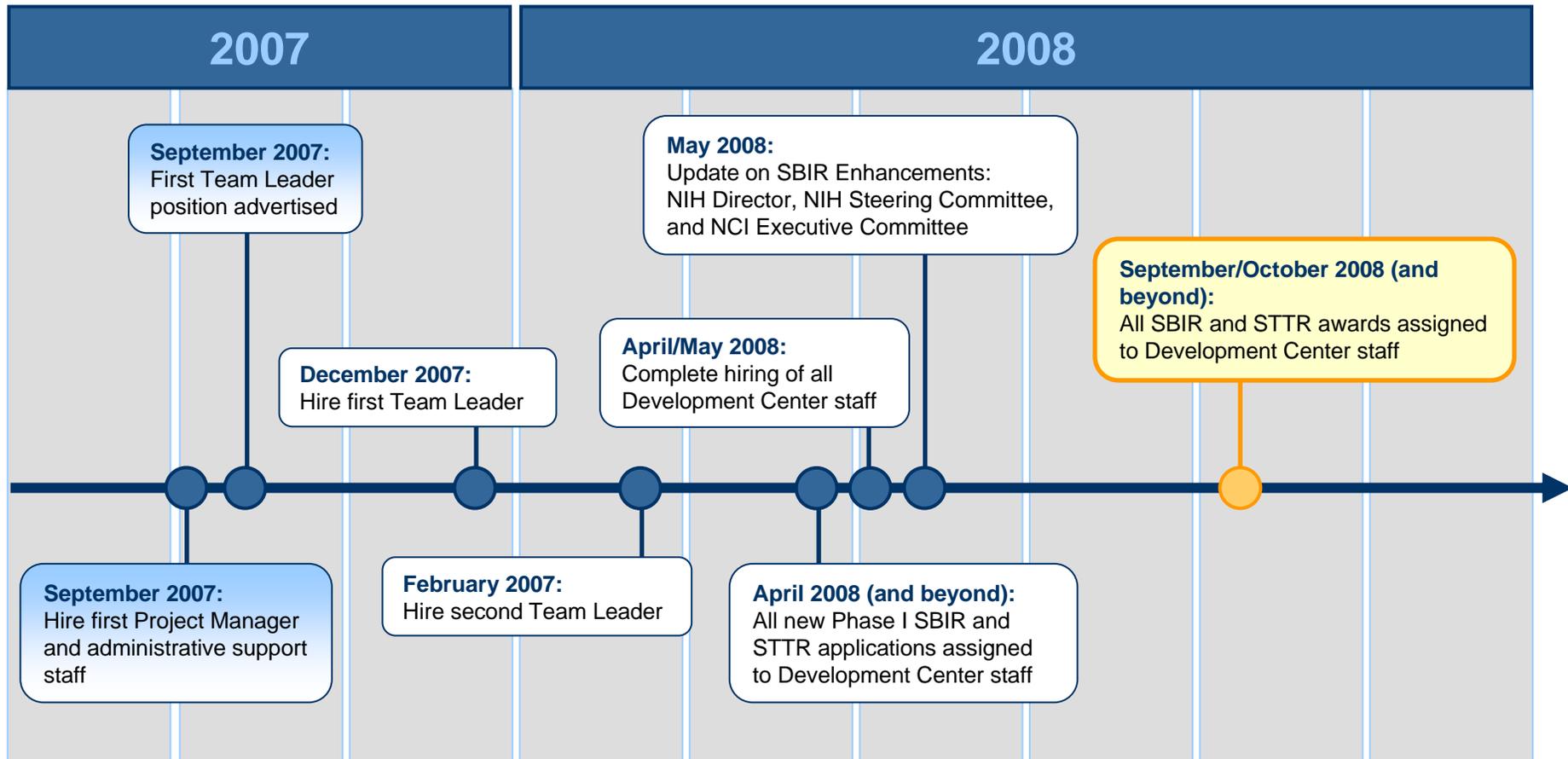
- **Goal is to hire Team Leaders with complementary expertise**
- **Significant cross-talk between teams, particularly in the area of biomarkers**

Development Center Workload (NCI portfolio)

NCI Focus Area	Specific Topics	Estimated Awards
Cancer Treatment & Diagnosis	Therapeutics development (excluding radiation therapy)	75-80
	Radiation therapy	25-30
	Biomarker development, diagnostics, and pharmacodynamic assays	40-45
	Imaging technologies and image-guided interventions	60-65
Cancer Biology	All topics	35-40
Cancer Prevention	All topics	35-40
Cancer Control and Population Sciences & Cancer Epidemiology and Genetics	All topics	30-40
Total		300-340

} 200-220
total

SBIR Development Center Transition Timeline



#3: Bridge SBIR Projects Toward Commercialization

Today, many awardees complete the SBIR Phase II award without advancing the technology far enough to attract private investment

- Significant resources are required for getting through the FDA approval process
- This funding gap is known as the **“Valley of Death”**
- To address this funding gap, some ICs offer “SBIR Phase II Competing Renewal” awards
 - **Funding is not milestone based**
 - **No commitment required from the private sector to invest in these projects**

#3 (cont'd): Bridge SBIR Projects Toward Commercialization

Proposal: Create an “SBIR Bridge Fund” award demonstration project.

- Accelerate projects to commercialization by:
 - Filling the funding gaps that currently exist
 - **Sharing in the investment risk and incentivizing private investors to fund earlier stage projects**
- Requires the SBIR company to either raise matching funds from the investment community or strategic partners
 - Opportunity to leverage millions in external resources
 - Leverage private investor’s due diligence process
- **Modeled after NSF’s “Phase IIB Option” program**
 - In FY 06, NSF invested \$18M in this program and raised \$58M in matching funds from the investment community

Example: How the SBIR Bridge Award would apply in the area of Drug Development



The “**Valley of Death**” is the problem

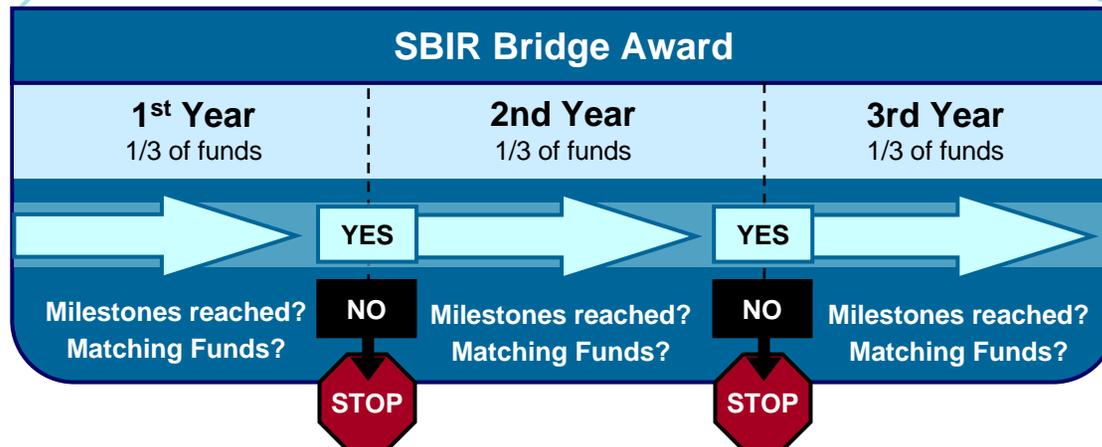
Example: How the SBIR Bridge Award would apply in the area of Drug Development



SBIR Bridge Award addresses the problem by bridging the “**Valley of Death**”

SBIR Bridge Award allows NIH to share investment risk by incentivizing private investors to evaluate projects and commit funds much earlier

Example: How the SBIR Bridge Award would apply in the area of Drug Development



#3 (cont'd): Bridge SBIR Projects Toward Commercialization

- **NCI is developing an RFA with a focus on cancer therapeutics and cancer imaging.**
- **We plan to make 5-10 awards in FY 2009 and a total of 20-30 awards over a 5 year period.**
- **We expect NCI total costs per award to be up to \$1M per year over a 3 year period.**
- **With matching funds included, each award would be up to \$6M.**

What about life science investors?

Some of the potential players we've talked to...

University Venture Capital



Director, New Ventures, Office of Technology Development



Associate Director, Center for Innovative Ventures



Traditional Venture Capital



Partner



General Partner



georgia venture partners

Managing Director

Corporate Venture Capital



Vice President, New Ventures



Managing Director, Novartis Option Fund

Strategic Partners



Vice President, Executive Director
Biogen Idec Innovation Incubator (bi3)

SRI International

Senior Director, Business Development
Biosciences Division

State-Sponsored Technology Funds

LIFE SCIENCES GREENHOUSE of Central Pennsylvania

President and CEO

Angel Networks

&

Foundations

We are still working to engage these communities, which are expected to be key participants

Examples of Successes from the NSF SBIR Program

- **Picarro lasers for flow cytometry and other uses were sold to Spectra Physics for \$8.5 million plus royalties.**
- **CFD Research Corp. out-licensed its technology for software modeling of respiratory drug delivery for \$7.7 million plus royalties.**
- **Dharmacon siRNA production methods & techniques were sold to Fisher Scientific for \$80 million and at the time of sale had “\$10’s of millions in sales a year.”**
 - **Joint NCI/NSF success**

#4: Assemble External SBIR Advisory Committee

Proposal: Establish a small body to advise the NIH leadership on SBIR future directions and strategic approaches.

- Could be a subcommittee of the NIH Director's Advisory Committee
- Communities that could provide valuable input include:
 - Angel investors
 - Venture capital investors
 - State small business organizations
- Committee members can assist in identifying potential investors for SBIR projects

#4: Assemble External SBIR Advisory Committee

- **Primary functions of the NCI group will be to:**
 - **To provide advice on new initiatives such as the Bridge Award.**
 - **To identify new ways that the Development Center can facilitate success for our companies after awards have been made**
 - **To assist us in identifying key metrics and evaluating NCI's overall SBIR program**

Short-term Success Metrics

Summary of NCI SBIR Contract Topics (2006 versus 2007)

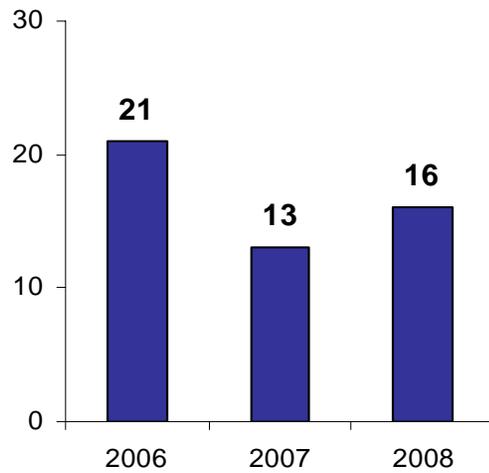
- **We focused on fewer topics (those with greatest commercial potential)**
13 (2007) compared to 21 (2006)
- **We received more contract proposals overall**
72 (2007) compared to 63 (2006)
- **The average number of proposals received per topic nearly doubled**
 $\underline{5.5} = 72/13$ (2007) compared to $\underline{3.0} = 63/21$ (2006)
- **We received more proposals overall¹ that rated “technically acceptable”**
49 (2007) compared to 44 (2006)
- **The average score² of “technically acceptable” proposals improved 5.0%**
731 (2007) compared to 681 (2006)

¹ The percentage of proposals that rated “technically acceptable” was very similar in both years: 68% = 49/72 (2007) compared to 70% = 44/63 (2006).

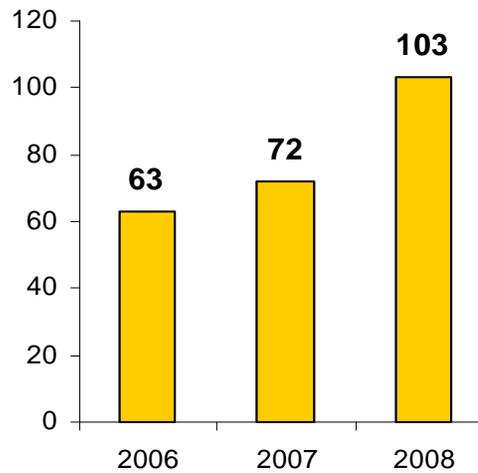
² Proposals are scored on a scale from zero, worst possible, to 1000, best possible.

NCI SBIR Contract Topics Recent Trends

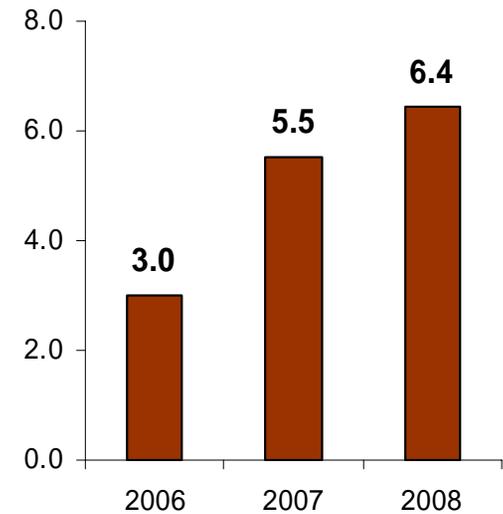
Contract Topics



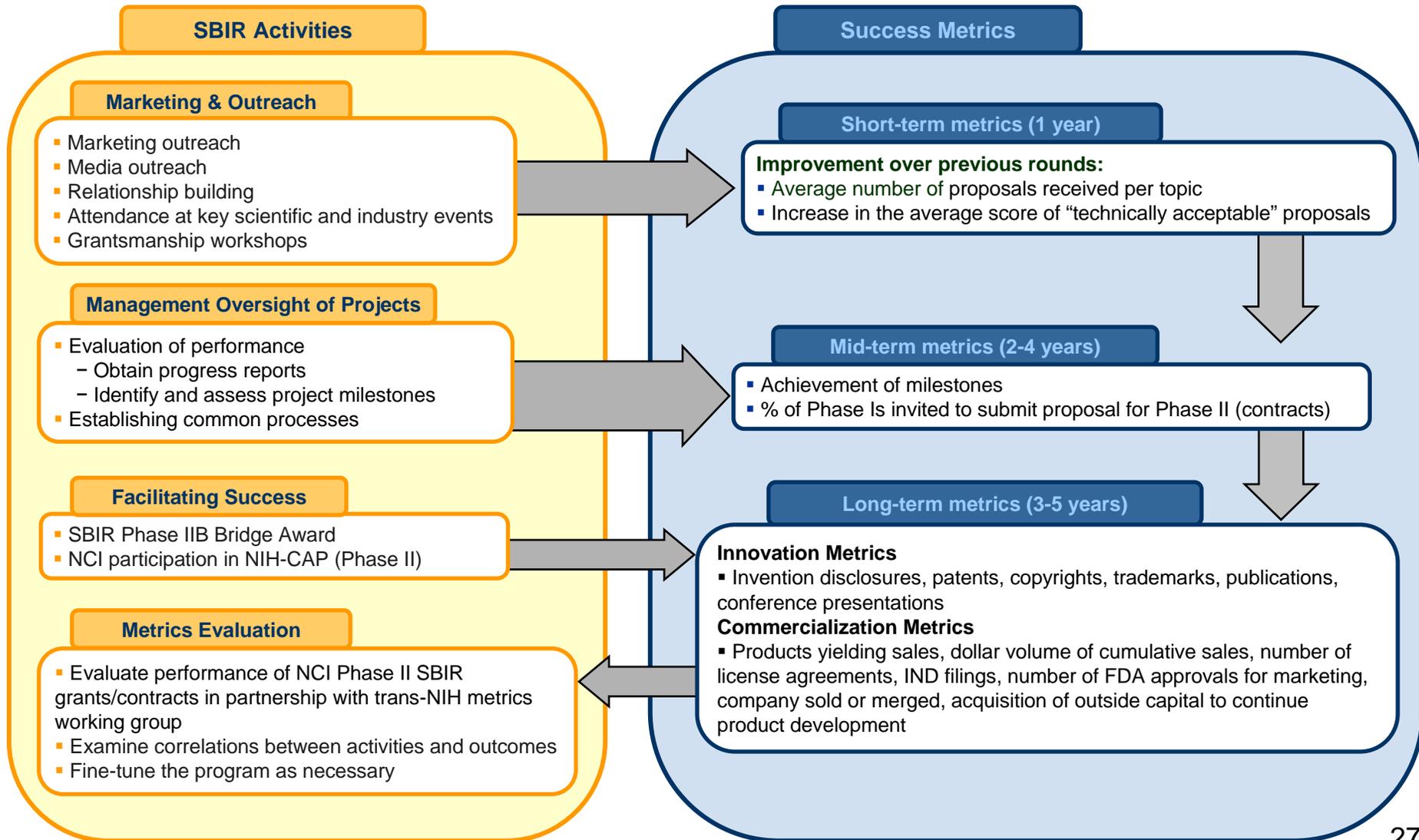
Proposals Received (Total)



Proposals Per Topic (Avg)



Draft Success Metrics





Enhancing the NIH SBIR/STTR Efforts

Michael Weingarten

Director, NCI SBIR Development Center



Appendix C
SBIR/STTR Process Improvements
Group Interview Guide

SBIR/STTR Process Improvement Opportunities

NIAID is evaluating possible new ways to improve organizational management of the NIAID SBIR/STTR program, along with alternative methods to make funding decisions. You have been identified as a NIAID program officer with experience in managing SBIR/STTR grants or a NIAID staff member with experience managing other types of applied research and/or product development grants, and therefore, can provide valuable insight about the NIAID SBIR/STTR process and ideas for improving it.

This form is for your review, as you will be contacted in the near future to participate in one of several group interviews of 8 to 10 stakeholders from across NIAID. The group interviews will be conducted by NIAID's SBIR/STTR Needs Assessment contractor, NOVA Research Company.

The list of questions below is meant as a discussion guide to give you an opportunity to think about these topics prior to the group interview. You do not need to respond to these questions in written form, if you can participate in one of the group interview sessions. However, your input to this process is important, therefore, if you are unable to attend one of the groups, we still would appreciate hearing your concerns, issues, and ideas. Please feel free to answer any or all of these questions in writing and send them to NOVA Research at: PAYoung@NOVAREsearch.com, with a Subject Line: Responses to SBIR Process Improvement Opportunities.

The proposed SBIR/STTR improvement opportunities are divided into 2 areas: (1) organization and portfolio management and (2) contract award mechanism.

SBIR/STTR Organization and Portfolio Management

1. How are SBIRs/STTRs administered and portfolios managed in your Division?
2. What do you consider are **strengths** and **weaknesses** of your Division's current administration and portfolio management structures? For example, having a single point-of-contact for monitoring and advising on SBIR/STTR program changes, training, fielding applicant questions.
3. How many SBIR/STTR grants do you manage? Do you have other applied research/product development grants or contracts that you manage?
4. What do you consider would be the advantages and disadvantages in having a central NIAID office for SBIR/STTR administration? For SBIR/STTR portfolio management (e.g., progress monitoring)?
5. What do you think would be the advantages and disadvantages of having a full-time SBIR/STTR program officer whose primary responsibility is only an SBIR/STTR portfolio?
- 5a. When you talk with potential SBIR/STTR applicants and/or awardees, what are the areas in which you are uncomfortable providing advice. For example, product commercialization, obtaining 3rd party investors, etc. Please be prepared to discuss.
6. How should NIAID distribute SBIR award funds? Some factors you may want to consider include:
 - Balance between payline awards and select pay awards
 - Strengths and weaknesses of creating separate funding pools for Phase I and Phase II SBIRs
 - Minimum/maximum number of awards for Phase I and Phase II awards
 - Phase I and Phase II funding caps on awards.

SBIR/STTR Contract Award Mechanism--

1. How familiar are you with the SBIR contract mechanisms used at other ICs?
2. Which of your Division research or product development goals would be a better fit for SBIR contracts compared to SBIR/STTR grants?
3. In your opinion, should NIAID offer a contract mechanism for SBIRs? Why?/Why Not?
4. What are potential **strengths** and **weaknesses** of NIAID using a contract mechanism for SBIR awards?
5. Do you have time, interest, and capability to manage SBIR contract awards?
6. Please comment on strengths/weaknesses or pros/cons of SBIR grants versus SBIR contracts. Some factors that you may want to consider include:
 - Developing SBIR contract Statement of Work
 - SBIR application to award time (Phase I and Phase II)
 - Opportunity to emphasize product development and commercialization to market
 - Incorporating performance benchmarks and milestone into monitoring process
 - Incorporating past performance review as a component of award decision process.

THANK YOU FOR THINKING ABOUT YOUR RESPONSES TO THE ABOVE SBIR/STTR
PROCESS IMPROVEMENT OPPORTUNITIES. YOU WILL BE CONTACTED SOON
REGARDING PARTICIPATING IN A GROUP INTERVIEW TO DISCUSS THESE ISSUES.

Appendix D
SBIR/STTR Process Improvements
Group Interview Findings

SBIR/STTR Process Improvement Opportunities Group Interview Comments and Recommendations

Topic Area: SBIR/STTR Organization and Portfolio Management

1. How are SBIRs/STTRs administered and portfolios managed in your Division?

DMID: Individuals in branches/scientists are SBIR/STTR Project Officers, based on the scientific content of the application. Project Officers handle full range of grant types in their scientific area. There is a Division-level person in OD that oversees the whole process and handles questions that individual POs can't handle, usually related to SBIR/STTR processes. Indications that SBIRs are a low priority for some POs but not for others. Questions/issues that cannot be handled at the Division level are forwarded to Greg Milman for response. One issue that surfaced is that some POs would like to participate in applicant/grantee calls with Greg, so they can continue to learn how to answer similar questions in the future, as well as to know what their grantee was told, so they know answers provided, as they continue to work with their grantee.

DAIDS: Individuals in branches/scientists are SBIR/STTR Project Officers, based on the scientific content of the application. Project Officers handle full range of grant types in their scientific area. There is a Division-level person in OD that oversees the whole process and handles questions that individual POs can't handle, usually related to SBIR/STTR processes. Questions/issues that cannot be handled at the Division level are forwarded to Greg Milman for response.

DAIT: One individual in OD handles all SBIRs/STTRs—both administrative (tracking, reporting, etc.) and individual grant portfolio management activities (e.g., interaction with grantees, review of progress reports/final reports). This individual has secondary assistants who are primarily science-based, who sometimes take a secondary role (i.e., addressing issues of science, reviewing/approving progress/final reports, participates in recommending applications for select pay in their science area). Again, questions that can't be answered at Division level are forwarded to Greg Milman for response.

2. What do you consider are strengths and weaknesses of your Division's current administration and portfolio management structures? For example, having a single point-of-contact for monitoring and advising on SBIR/STTR program changes, training, fielding applicant questions.

Strengths: better management at Division where POs have in-depth current knowledge of science of the application, grantees have access to scientists familiar with what they (grantee) is trying to do, can provide advice re: science of application as well as science of processes after award; also, can better inform grantees of what's going on in science area—since managing a broad range of research grant types, can refer R-type grantees (who are small businesses) to SBIR when see product development opportunities, can connect small businesses with academics and others doing similar science for advancing product development capabilities.

Critical need for both the Division-level central person who is first line for many questions and issues on process and procedures, as well as Institute-level with Greg Milman, who is really interested in SBIRs/STTRs, can stay on top of changes in legislation/procedures, can address questions of Company eligibility, and similar business/procedures questions.

Weaknesses: get variability in interest of what SBIR grantees are doing—some very interested, some see as burden because take more time than traditional R-type grantees. Because often handling only a few grantees, don't have opportunity to develop knowledge of SBIR/STTR process nuances, and can't be much help in areas such as business plan, market research, acquiring 3rd-party support, etc. These issues are elevated to Division and most frequently onto Greg Milman. PO can only support science side, not the SBIR business side.

Unevenness of information provided to applicants, particularly concerning business aspects.

Another weakness of broad management distribution is that many POs have too few SBIRs to warrant attending SBIR/STTR grant reviews. Since SBIR panels are ad hoc reviewers, seems that often reviewers don't understand the purpose of SBIRs as product development (e.g., state that SBIR should show preliminary clinical data), and therefore, SBIR applications don't get good review scores. Needs a strong

Concern in DAIT, that while process works very well and LP does tremendous job with SBIRs, that if he retires, what will happen to the process, since may not be able to replace him with someone with equal passion/intensity regarding SBIRs/STTRs, and capacity to handle all Division SBIRs and knowledge of Division staff to go to for science questions/assistance.

3. *How many SBIR/STTR grants do you manage? Do you have other applied research/product development grants or contracts that you manage?*

Variety, from none to over 200, depending on individual. Those with few SBIRs usually also manage all grant types within their scientific area/expertise. Some manage both contracts and regular R-type grants. Some manage primarily cooperative agreements—usually oriented towards clinical trials.

Some POs have Cooperative Agreement grants for product development, which are not limited to small businesses. Cooperative Agreements are a strong funding mechanism for product development. Would like to have the capability to fund small businesses in cooperative agreements with SBIR/STTR funds.

4. *What do you consider would be the advantages and disadvantages in having a central NIAID office for SBIR/STTR administration? For SBIR/STTR portfolio management (e.g., progress monitoring)?*

Advantages include:

Many expressed that current structure of Institute-level individual (e.g., Greg Milman) is critical to the process, as he provides a full-time person to keep current with changes in legislation, procedures, respond to various reports on SBIR/STTR program activities (e.g., science distribution, etc.), respond to nuances in program with applicants and grantees (e.g., am I eligible, where can I go to get help with my marketing plan). Also critical to have Division-level coordinator, to handle some science and most non-science issues with applicants and grantees, to provide Division-level reporting on program activities/accomplishments, to attend institute and NIH-level SBIR/STTR meetings/conferences, and to be aware of what is going on in Division across many types of grants.

Central office would better know how to deal/support the novice applicant in the range of topics that a small business must address administratively and operationally in preparing an application and conducting a grant.

Consistency of SBIR administration and management across all SBIR awards. Would not have the time and cost associated with training everyone in Acquisitions about SBIRs.

Disadvantages include:

Ability of a central office to recognize product development opportunities in the full range of a scientific area and be able to recommend to a grantee (e.g., R01 grantee) a product development opportunity within their research and advise them how to find complementary small business partner.

In a central office, lack of ability to maintain the in-depth science understanding of current developments across the broad range of science performed by NIAID.

In a central office, lack of ability to know the budget dollars available across a scientific area in different types of grant mechanism in order to advise a scientific applicant which type of grant program to apply for (e.g., R43 versus R34 versus R03, etc.)

A central office would still need to have individuals assigned to specific science areas to advise applicants (much like current Division coordinators), and would have to know the scientists in each science area to refer the applicant for scientific issues, therefore, not benefit to further centralization.

Taking SBIRs management out of Divisions/away from science-based POs would reduce their thinking about SBIR/STTR opportunities arising in other types of grants, but on the flip side, at least in DAIT, the central Division coordinator provides information to other POs as to what's being done in SBIR/STTR science/product development in their science areas.

Several in both groups indicated they see no real significant benefits to more centralization, that the current structure works exceeding well in meeting PO needs.

5. *What do you think would be the advantages and disadvantages of having a full-time SBIR/STTR program officer whose primary responsibility is only an SBIR/STTR portfolio?*

Advantages include:

Someone to go to for policies, procedures, eligibility criteria, other nuances of SBIR/STTR program and to do reporting to DHHS, Congress, etc. on SBIR/STTR activity.

Great ideas, but would have to be sure that number of topics and number of grants or contracts awarded could be managed by the one full-time program officer.

Disadvantages include:

POs with mixed grant-type portfolios have an increased ability to recognize product development opportunities within their range of grants and therefore, be able to recommend SBIR product development opportunities to their grantees along with partnership opportunities.

POs with mixed grant-type portfolios are better able to retain across programs science expertise for technical input to applicants/grantees.

POs with multiple type grants are much more aware of full range of funding opportunities to suggest to applicants and can make "appropriate marriages in poster aisles".

Reporting on the science being conducted across all types of grants would be very difficult for a central office or a designated science person within a division, if they had to get SBIR/STTR science information from a person in a central office.

POs in divisions can get more mileage from product development science by being able to interact early with academic community during basic research activities to identify product development opportunities and help guide researchers in that direction, or to assist researchers in making appropriate connections if their institution is not interested in product commercialization/fostering SBIR/STTR product development opportunities.

POs indicated they would like more SBIR/STTR process information/knowledge from Greg regarding answers to their grantees questions, so they know how to better continue to advise their grantees.

5a. When you talk with potential SBIR/STTR applicants and/or awardees, what are the areas in which you are uncomfortable providing advice. For example, product commercialization, obtaining 3rd party investors, etc. Please be prepared to discuss.

Institute should have resident expertise to help Phase II applicants with marketing plan portion of Phase II applications, since many scientists don't know how to do this piece.

Most POs do not have expertise in product commercialization, but this is needed by most small business grantees and the Institute should find a way to provide this assistance.

Some universities have very active business development groups to help with Phase II applications, particularly business planning/market research, while other universities discourage this, at which point if product development is to move forward, NIAID PO or someone within NIAID needs to provide assistance in directing/assisting in finding complementary for-profit partners.

A gap at NIAID is being able to provide assistive advice on business planning, obtaining 3rd party investors; need a central SBIR/STTR business person, like current NIAID Technology Transfer group.

Refer applicants/grantees who have business related questions to Greg Milman and/or to NIH Small Business Representative (Joanne) and to new NIH Commercialization Assistance Program to SBIR Phase II Awardees.

NIH is involved in science, not business, so if applicants/grantees have business related questions, they should find expert consultants in these areas—which are easy to find—since that is the consultants business, and NIH should not take on this responsibility.

6. How should NIAID distribute SBIR award funds? Some factors you may want to consider include:

- **Balance between payline awards and select pay awards.**

Continue with current process of awarding by payline score.

Question whether scores above 200 should be funded because quality declines.

Should provide a small Select Pay pool for exceptional grants that get a low score either because reviewers don't understand purpose of SBIR program or has very good science but not a good grant writer.

- *Strengths and weaknesses of creating separate funding pools for Phase I and Phase II SBIRs.*

No benefit to separate funding pools.

With separate pools, may have to fund some really poor quality applications/science in order to spend all the funds, if don't get adequate number of applications.

Phase I and II funds should come from the same pool, as they are very closely related.

- *Minimum/maximum number of awards for Phase I and Phase II awards.*

It would help in contract administration on both the acquisition and program sides if there were a minimum and maximum number of awards, as there would be more ability to balance workloads.

Not getting sufficient numbers of quality applications now, so don't try to set numbers for awards, results in funding bad science.

Context of merit quality is a function of available funds—as funding goes up, merit quality goes down.

- *Phase I and Phase II funding caps on awards.*

Should eliminate funding caps on NIAID SBIRs/STTRs—application budget should reflect the work described to be done. Too often know from the start of award that grantee will not be able to accomplish what they described, because of insufficient funds—if worth doing, worth paying to do.

Remove funding caps for NIAID awards—NIAID product development efforts are expensive in most instances (e.g., renting space/equipment in an approved biocontainment facility) and applicants need to be able to ask for funds appropriate to what suggesting to do—funding caps hinder applications and quality of applications in NIAID mission areas.

Funding caps serve a negative purpose in accomplishing NIAID product development mission areas and are probably a reason for decline in both quantity and quality of SBIR applications.

Topic Area: SBIR/STTR Contract Award Mechanism--

1. How familiar are you with the SBIR contract mechanisms used at other ICs?

Varied, some very familiar, some not at all familiar with contract mechanism in general or SBIR contract mechanism, in particular.

Comments relative to SBIR contract mechanism included:

No benefit of Phase I SBIR contracts because of low dollar amounts (\$100K) and short timeframe for NIAID-type product development feasibility/practicality testing.

If do have SBIR contracts, would want to have multiple solicitation periods, not just the one in August, to give applicants more opportunities to apply.

Do whatever is most efficient to spend SBIR/STTR dollars for effective product development with good science; don't limit opportunities to just grants.

Already have all types of product development contracts to encourage full service product development. Sometimes suggest to contractors to expand an effort or to conduct side product development research through SBIR grant, that could also be an SBIR contract if the mechanism were available.

Other related comments not specific to this question:

Would like possibility to do a "mixed" solicitation", that is to issue an unrestricted RFQ, and if qualified respondent is a small business, make award as an SBIR contract.

Would like possibility to do a "mixed" Cooperative Agreement solicitation, that is to issue an unrestricted PA/RFA, and if qualified respondent is a small business, make award as an SBIR grant or contract.

Many nonprofits are doing product development, but not interested in setting up a for-profit entity just for an SBIR, so lose one from of product development funding opportunity.

2. Which of your Division research or product development goals would be a better fit for SBIR contracts compared to SBIR/STTR grants?

Already have lots of unrestricted product development contracts—up to 5-year efforts. Would like to have possibility to convert a small business contract to a SBIR contract, without going through a separate SBIR solicitation process; therefore, don't need a separate SBIR contract mechanism.

Might use SBIR contract mechanism, if could accommodate cooperative agreement product development contracts or grants.

Nothing special to get from SBIR contract that not already getting through SBIR grants—so no contracts.

No contracts—contracts cost so much more to administer than grants, would have to add FTEs to manage.

Contracts have a 5 to 1 administrative burden relative to grants, so don't need contracts to get to same point as can achieve with grants.

3. *In your opinion, should NIAID offer a contract mechanism for SBIRs? Why?/Why Not?*

Positive comments include:

Already have product development contract mechanism, but might be worthwhile to pilot to see what quantity and quality of proposals are received for a very few specific contract ideas, since have extra SBIR dollars to spend.

Would need a pilot to determine numbers of likely awards for future funding allocations.

Suggest a trial topic in the next SBIR contract solicitation.

Why Not comments include:

No, because contracts have too high management/administration time requirements.

If could use contracts for specific solicited cooperative agreements (e.g., development of product for specific disease indication), might be OK as another type of funding mechanism.

Contracts would allow more control over deliverables, but timeframe doesn't allow time for many deliverables—i.e., Phase I on time for one deliverable.

Have sufficient diversity already through grants and product development contracts to meet current product development opportunities.

4. *What are potential strengths and weaknesses of NIAID using a contract mechanism for SBIR awards?*

Strengths:

Would be a useful mechanism if could use to fund Cooperative Agreements for small businesses in product development arena.

Weaknesses:

Take too much time to administer and manage.

Inability to transfer funds between contract and grant mechanism without high level approvals, therefore, could end up with more monies unspent if don't get either enough or enough good contract proposals.

5. *Do you have time, interest, and capability to manage SBIR contract awards?*

Too much work in contract process/management.

Generally, no.

6. *Please comment on strengths/weaknesses or pros/cons of SBIR grants versus SBIR contracts.*

Some factors that you may want to consider include:

- ***Developing SBIR contract Statement of Work***

A lot more work.

- ***SBIR application to award time (Phase I and Phase II)***

No comments.

SBIR/STTR Process Improvement Opportunities: Group Interview
Comments/Recommendations

- *Opportunity to emphasize product development and commercialization to market.*

No comments.

- *Incorporating performance benchmarks and milestone into monitoring process.*

No comments.

- *Incorporating past performance review as a component of award decision process.*

No comments.

SBIR/STTR Other Comments/Recommendations from Group Interviews

1. **Recommendation:** Allow SBIRs/STTRs to be used for conducting clinical trials for product development in a Cooperative Agreement type mechanism—both Phase I and Phase II development. This mechanism would also provide more opportunities (as is currently available through Cooperative Agreement grants) to provide scientific/technical assistance to keep grantees on course with their product development activities.
2. **Recommendation:** Allow R43s/R44s to roll into R34 for furthering clinical trials.
3. **Recommendation:** Allow R43s/R44s to be converted to U awards.
4. **Recommendation:** Pilot using percentile ranking for SBIR grants because ad hoc study sections vary and this would eliminate some ambiguity of scores between study sections. After a couple of cycles, analyze awards and accomplishments between scores and percentiles to better understand if improves process.
5. **Recommendation:** Provide capability for contract or grant Cooperative Agreements for clinical trials.
6. **Recommendation:** Provide a capability to issue an RFA that has a Note that small businesses are encouraged to apply and if qualified, will be funded as an SBIR award. Can not provide any insight as to how this would work in real terms.
7. **Comment:** Lots of small businesses are conducting product development under other types of grants—e.g., Cooperative Agreements, product development contracts, product clinical trials, etc.—and these should somehow be paid for with SBIR funds, to allow more funding for non-small businesses.
8. **Comment:** Use of electronic application review process for SBIR does not work for SBIRs—do not get much chat from reviewers in this review mode, so primary scores stand. This occurs even after reviewers are provided encouragement, reminders to chat, and have participated in multiple review cycles. Very different in face-to-face reviews, even with same reviewers where there is a lot of talk about applications—perhaps reviewers don't want their ideas/thoughts/comments in writing.
9. **Comment:** Can have hands-on interaction with SBIR grantees to more closely monitor progress—just needs to be established by PO, but Phase I is only on 6-month effort, although most grantees ask for a 6-month No Cost Extension.
10. **Comment:** Advanced Technology grants are for 2 years, not SBIR, but another mechanism that can be used for product development and have more hands-on interaction with grantees.

Appendix E
Discussion Minutes
of
SBIR/STTR Process Improvement Options

EVALUATION TEAM MEETING

Contract for Needs Assessment of NIAID SBIR and STTR Programs

Tuesday, February 5, 2008 ♦ 2:30–4:00 p.m.

DRAFT: Meeting Minutes

Management Options for the NIAID SBIR/STTR Program

- ♦ A list of management options was developed during a brainstorming session at the January meeting. The list was divided into two subsets of options: program management options and funding mechanism options. (An appendix at the end of this document contains a transcript of the lists as they were displayed on a whiteboard during the meeting.)
- ♦ Today's discussion focused on adding any options that may have been missed in the previous discussion and on prioritizing options based on whether they are practical/feasible and/or likely to result in improvements in the SBIR process.

Possible Additions to the Lists of Management Options

- ♦ The team should consider adding competitive renewal of Phase I SBIRs to the funding mechanisms list. This could assist Phase I recipients who are almost ready to move on to Phase II.
- ♦ In evaluating a Phase I applicant's likelihood of success, the past performance of the individual or organizational applicant should be considered (e.g., number of Phase I SBIRs that resulted in award of Phase II SBIRs).
- ♦ Review of SBIR applications should emphasize the applicant's approach to product development in addition to descriptions of research methodology.

Discussion of Program Management Options

- ♦ Centralized management can take place at the IC, Division, or program level.
- ♦ Internal NIAID review of SBIRs is feasible for contracts but not for grants. ICs can work with the NIH Center for Scientific Review (CSR) to arrange for special review by panels whose members are familiar with the relevant mechanisms and topics.
- ♦ Increased involvement of NIAID program staff in providing technical assistance to awardees and applicants may be feasible only under a centralized form of management. Input is needed from the research and development community to determine whether expanded technical assistance is needed.
- ♦ The "dedicated personnel" list item is a subtopic under the "central versus distributed management" issue.
- ♦ It is probably not realistic to expect new resources to support marketing and outreach activities targeting small businesses.
- ♦ The option of establishing an external advisory committee is another subtopic under the central versus distributed management topic.
- ♦ Portfolio management is related to the mission-specific versus straight percentage management option.
- ♦ Reducing turnaround time is only relevant to contracts—NIAID has no control over the timeline for CSR review of grant applications. Thus, this item is closely related to the option to increase emphasis on the contract mechanism.

- ◆ Performance management and emphasizing product development are also closely related to the option to increase emphasis on the contract mechanism.

Discussion of Funding Mechanisms Options

- ◆ Mission-specific funding decisions and funding based on scoring of applications are not mutually exclusive options. Select Pay is a mission-specific process, but most funding decisions are based on scores.
- ◆ Establishing a NIAID SBIR contracts program would make it possible to address several of the issues listed under program management options and presents an opportunity to improve portfolio management.
- ◆ Assessing commercialization potential is relevant to both grants and contracts.
- ◆ The proposal to establish separate paylines for Phase I and Phase II is intended to help balance the portfolio between the two mechanisms.
- ◆ Using Select Pay to maximize resources available to support mission-specific priorities is another portfolio management tool. It should be remembered that adding contracts to the portfolio would reduce resources available for Select Pay.
- ◆ The “leverage” list item refers to the possibility of encouraging or even requiring companies to supplement funding provided by NIAID with outside resources. Leveraging of funds could be required of Phase II and bridge funding applicants above the payline who are supported through Select Pay.
- ◆ Competitive renewals for Phase I SBIRs are probably unnecessary because grantees who need additional time for Phase I work have access to supplements and no-cost extensions. However, the process for providing supplements is difficult. The possibility of creating set-aside funds for SBIR Phase I supplements may be an appropriate topic for further discussion as an additional portfolio management issue.

Conclusions

- ◆ Portfolio management, centralized management, and establishment of a contracts program for SBIRs emerged as important concerns during this discussion. It may be possible to combine some of the listed options to address these central themes.

Appendix: Transcribed Whiteboard

- ◆ Program management
 - Central versus distributed management (IC/Division/Program)
 - NIAID review (can be done with contracts)
 - Dedicated personnel (tied to central versus distributed management))
 - Marketing/outreach (travel, network with scientific community)
 - External advisory committee
 - Portfolio management
 - Reduced turnaround (contracts)
 - Performance management (benchmarks, milestones) (contracts)
 - Emphasis on development/product (contracts)
- ◆ Funding mechanisms

- Mission-specific (versus straight percentage)
- More contracts
- Assess commercialization potential
- Different paylines for Phase I and Phase II (to balance portfolio)
- Select Pay (tied to payline)
- Competitive renewal for Phase I
- Past awardee performance

Appendix F
Preliminary Survey Questionnaire
and
Preliminary Interview Findings
from
First Set of Individual Interviews

SBIR/STTR Process Improvement Opportunities Survey

Several months ago, NIAID created an SBIR/STTR Needs Assessment Team to identify gaps and opportunities to improve program and portfolio management of the SBIR/STTR programs to bring the programs more into alignment with NIAID mission objectives. In light of this activity, there are several process opportunities that our NIAID Team is requesting input from you, as NIAID staff, to better ascertain practicality of these opportunities for possible pilot project improvements. In order to collect this information, we are requesting that you complete this survey and return it to NAME, ADDRESS on or before DATE. Please share your thoughts, concerns, suggestions, or other comments in the spaces provided. This survey should only take about 20 minutes for you to complete.

The survey is divided into three primary opportunity areas:

(1) Centralize SBIR/STTR organization and portfolio management; (2) Institute a SBIR/STTR contract mechanism; and (3) Increase SBIR/STTR NIAID priority and portfolio balance grant awards.

Centralize SBIR/STTR Organization and Portfolio Management.

Q1: Should NIAID establish a central organizational office at the OD-level to award and manage SBIRs/STTRs? Yes No.

Comments:

Q2: Should NIAID have full-time SBIR/STTR portfolio program officials, whose primary responsibility is their SBIR/STTR portfolio? Yes No.

Comments:

Q3: Should full-time SBIR/STTR portfolio managers be assigned to an OD-level central SBIR/STTR office? Yes No.

Comments:

Q4: Should there be an external SBIR/STTR Advisory Committee of researchers, product managers, investment managers, corporate managers to:

(1) Mentor awardees in product development/commercialization Yes No.

Comments:

(2) Provide input to NIAID program officials on commercialization potential of SBIR/STTR applications? Yes No.

Comments:

(3) Assist NIAID with program-priority concept outreach? Yes No.

Comments:

(4) Advise on past performance/performance potential during review and award process Yes No.

Comments:

Institute a SBIR/STTR Contract Mechanism

Q1: Should NIAID implement an SBIR/STTR contract award mechanism? Yes No.

Comments:

Q2: Does NIAID have or can it provide resources and expertise to perform contract application reviews? Yes No.

Comments:

Q3: Would your response to Q1 above change if SBIR/STTR contract would—

(1) Reduce time from application to award? Yes No.

Comments:

(2) Emphasize product development and commercialization to market versus science research and new knowledge? Yes No.

Comments:

(3) Enable incorporating performance benchmarks and milestone? Yes No.

Comments:

(4) Enable incorporating past performance review as a component of award decision process? Yes No.

Comments:

(5) All of the above? Yes No.

Comments:

Increase SBIR/STTR NIAID priority and portfolio balance grant awards

Q1: Should NIAID increase the number of SBIR/STTR Select Pay awards in order to more optimally fund program-priority applications? Yes No.

Comments:

Q2: Should NIAID create separate SBIR/STTR funding pools for Phase I and Phase II SBIR/STTR applications to ensure better portfolio balance over time? Yes No.

Comments:

Would you be willing to participate in an individual interview Yes No. or a group interview Yes No on these three SBIR/STTR process improvement opportunities in the next several weeks?

Comments:

SBIR/STTR Process Improvement Opportunities Survey

Preliminary Findings

General Comments:

- Generally, the survey is clear, but can definitely use some significant revisions. First paragraph is too long with too much jargon—should be brief—what about, what action requested, what plan to do with results.
- Opportunity area (3) needs clarity, recommendation: “Improve SBIR/STTR Portfolio Balance”.
- A one or two sentence explanation after each opportunity area, explaining a little about the thinking of the Evaluation Team would be useful.
- After question revisions, send out questionnaires with request to participate in a group interview, with representation in each group across divisions, for best results. Thus, participants have opportunity to think about responses ahead of time, but really get to discuss their responses in an open forum with cross-fertilization of ideas and practicality.

Opportunity Area 1: Centralize SBIR/STTR Organization and Portfolio Management

- **Q1 general comments:** Needs some clarifying—what are you proposing to centralize—administration (already done this), Institute-wide SBIRs/STTRs? Program Officers funding resources? Need to know what proposing to centralize before being able to answer.
 - **Q1 content comments (4-No)**
 - Keep grants in the divisions and branches with the resident scientific expertise, so that work is integrated with scientific expertise.
 - NIAID mission objectives/science portfolios are too diverse, therefore it would not be practical for just a few centralized staff to manage entire NIAID portfolio.
 - Retain central OD-level coordination to keep up with legislation, program changes, and responses to program general queries.
 - Perhaps need two questions—one addressing central administration and one addressing central grants technical management.
 - In DAIT, SBIRs are already centrally administered and works well.
 - Breadth of scientific areas is too broad to centralize scientific management, can't centralize too much more.
 - Have a mixed science portfolio of R01s, R21s, SBIR/STTRs, etc. is a good thing, because research program officials have a broader reference frame for the science.
 - Would be helpful for central office that could provide more program education about SBIRs, particularly to new program officials about SBIR/STTR product development responsibilities.
 - Some NIAID science areas are relatively small and a central office might focus on the major mission areas—e.g., HIV/AIDS, to the detriment of smaller programs.
- **Q2 general comments: None**
 - **Q2 content comments (3-No, 1-Yes)**
 - SBIR/STTR application process is an opaque process, so critical to understand and therefore, full-time program officials would have the time to really understand the process and be better able to help fledging applicants.

- Need synergy by program officials across different funding mechanisms— SBIRs/R01, R21, R34 grants/contracts/clinical trials.
- Some divisions already have a full-time SBIR/STTR program official, but not enough SBIRs/STTRs to have full-time work, so must have other responsibilities.
- **Q3 general comments:** Need to change portfolio managers to program officials, so clear to whom you are referring. This questions is probably not necessary, given questions 1 and 2, particularly if Q1 is reframed into two questions—administration vs technical management.
 - **Q3 content comments (4-No)**
 - Like having SBIR program official close-by for quick reference on process questions.
 - Get more immediate and focused attention to management and science issues.
 - Need to retain with scientific expertise and overall same science portfolio.
 - Program is in the best position to transfer technology to other types of funding mechanisms or assist with identifying either internal or external resources to discuss commercialization issues/opportunities.
 - Some program officials would leave for other positions because SBIR/STTR science quality is not high, therefore doesn't retain intellectual science interest.
 - **Q4 general comments:** Is this practical? How would such a group of external advisors dealt with intellectual property issues in either applications or performance? Awardees definitely need mentoring, the questions is how best to accomplish this.
 - **Q4 (1) Mentor awardees: content comments (1-No, 3-Not sure)**
 - Applicants who get a fundable score usually understand the grant mechanism, so if in a commercial company, they should know what they should do, and will usually seek their own assistance.
 - Would be nice to have as a resource, but most of the issues are not in mentoring, rather grantees (most of whom are at academic institutions) have greater challenges at the institutional level in creating their small business—some institutions very receptive, but majority not, and some even discourage creating small businesses to pursue product development (SBIR/STTRs)
 - To be able to reach out to organizations with expertise in critical areas using an AC expertise could have some value.
 - **Q4 (2) Provide commercialization potential input to NIAID program officials: content comments (2-No, 2-Yes)**
 - NIAID already has a Technology Transfer office and could take on this responsibility, don't need another committee.
 - At present time with only grants, this would not be useful.
 - Program officials already give investigators information to pursue helpful additional training/opportunities.
 - Lots of value to outside objective input, as program officials are focused on NIAID mission and may miss opportunities that other would see (external persons).
 - External advisors would be look at commercialization potential more objectively— market/market share.
 - Would probable get good input in this area from external resources who would have a broader commercial perspective.

- **Q4 (3) Provide program-priority concept outreach: content comments (2-No, 1-Yes, 1 Maybe)**
 - **General: Needs rewording and a brief explanation—not clear what concept is being asked about.**
 - Would be a great assistance in some science/product development areas.
 - Would be great if gave program officials more flexibility in determining program priority areas.
 - Unclear that an AC would have better entre to science groups.
 - Not sure how such a concept would work, therefore how to respond.
 - With internet today, can put information on the Web and point companies to it and Division points of contact could readily handle outreach activities.
- **Q4 (4) Advise on past performance/performance potential content comments: (2-No, 2-Yes)**
 - **General: Needs some rewording—example, after performance potential—add “of applicant, after scientific review and scoring”.**
 - This is constrained by application received, and today at least, as overwhelming majority comes from organizations with no track record, so not a useful opportunity.
 - SBIR applicants should understand that past performance is an important evaluation review criteria and therefore, the application should speak for itself and past performance should be included for reviewers.
 - Could be very helpful in specific scientific areas where expert depth of knowledge would be useful, particularly for performance potential.

Opportunity Area 2: Institute a SBIR/STTR Contract Mechanism

- **Q1 general comments:** Generally straight-forward, understandable of what opportunity is about. However, one interviewee stated that more explanatory text was needed to better frame the issue of why considering a contract mechanism, what does the contract mechanism allow that is not available through the grant mechanism, particularly of persons will be asked these questions who are not familiar with contracts.
- **Q1 content comments (2-No, 2-Yes)**
 - NIAID’s mission is generally to purchase research, interest is in encouraging small businesses to develop a basic research capability, and contracting is too targeted a mechanism, does not allow sufficient research development flexibility.
 - Generally, NIAID does not restrict contracts to small business—everyone should have an opportunity to propose to develop a high-priority product that NIAID needs. Since NIAID generally wants investigator-initiated science projects, contracts are not a good mechanism for this for only small businesses.
 - Contracts would be a great opportunity as provides more product development control, more executive decision flexibility, and more opportunity to have direct interaction with organization during process.
 - Currently interact with grantees a lot in product development grants—work collaboratively with multiple grantees because of product development complexity—more like a Cooperative Agreement, so not sure what contracts offers in addition.
 - How to write the RFP could be the biggest issue/barrier to effective SBIR contracts, since there are lots of priorities to encourage.

- **Q2 content comments: (2-No, 2-Maybe)**
 - **General: This question is probably not necessary as a general question, as it is really answered by the Contracts Management Group, not individual program officials.**
 - NIAID already contracts out for grant reviewers for special science areas, therefore, not a problem to do the same for contracts.
 - Contracts reviews are already done through external expert review panels.
- **Q3 general comments: General:** This question definitely needs rewording/reworking, because it doesn't apply if the Answer to Q1 is Yes (it assumes Q1 is a No response). Need to divorce Q3 from Q1 and make the set of questions each a stand-alone question. Example: "Is reduction in time from application to award an important factor for SBIR contracts?" or "I would like a contract because it . . ."
- Need an additional question in this area: *Is the product development via contract mechanism an effective funding mechanism? If not, how could it be made more effective?***
- **Q3 (1) Reduce time to award, content comments: (2 No, 2 Yes)**
 - For AIDS-related grants, these are already expedited, so would probably not make much difference, not important issue.
 - Always a good thing to reduce time from application to award, but already have hyper-accelerated reviews, so probably wouldn't make a difference.
 - Advantages and disadvantages—with contracts, only a one-time submission, so if don't get funded, have to wait a year to see if concept included again; in grants get three opportunities to resubmit.
 - Depends on what types and quality of applications are being submitted.
- **Q3 (2) Emphasize product development/commercialization, content comments: (4-Yes)**
 - Already look at SBIR opportunities this way, pickup high-quality SBIR grants (and other types of grants) and transition them to contracts after proof-of concept.
 - SBIR viewed as a way-station/alternative pathway.
 - Basic research grants stimulate the research/basic discoveries, then move grantee to SBIRs (contracts would be another nice mechanism to accomplish this).
 - Easier to spin-off a small business to accomplish commercialization through the SBIR mechanism.
- **Q3 (3) Enable incorporating performance benchmarks and milestones, content comments: (4-Yes)**
 - Highly advantageous.
- **Q3 (4) Enable incorporating past performance review. Content comments: (1-No, 2-Yes, 1-No response)**
 - What would a past performance review provide, since a lot of organizations don't have any past performance record.
 - Academic investigators who have incorporated into small business are just starting up, and therefore can't be evaluation on organizational past performance, rather get evaluated on "did they do good, productive science in their academic institution?"
 - OK, but should not hurt that have no past performance experience.
 - Good feature to consider—do they want to go to a commercial product, or get picked-up by a larger company.

Opportunity Area 3: Increase SBIR/STTR NIAID priority and portfolio balance for grant awards

- **Category General Comments:** This category needed brief explanation to all of the interviewees. All wanted to know what the Evaluation Team had in mind, what was some of the Team's discussion regarding this opportunity. Reword this section to clarify, example "Improve SBIR/STTR NIAID Portfolio Balance".
 - **Q1 Content comments: (1-No, 2-Yes, 1-No response)**
 - **General:** One person asked about Select Pay, as they had never done a Select Pay and were not sure how the mechanism worked.
 - Another asked how NIAID would go about increasing funds for Select Pay, and I explained that one mechanism would be to lower the SBIR/STTR payline score. This raised the question of how this would be handled across the Divisions—i.e., we may need to provide more explanation on this, or just indicate that details are not worked out, at the moment just looking to get an understanding of whether this is an opportunity, and if so implementation concept would be the next step.
 - NIAID currently does not provide enough flexibility to program officials as may be optimal in making more and better Select Pay decisions.
 - Current problem is not funding less applications, rather not enough high-quality project applications being received to make best use of available funding.
 - SBIR pool is already too high, thus bringing down the scientific rigor of projects, need to focus on getting more high-quality applications.
 - Good opportunity, as would provide more flexibility of operations to take into account factors in decision-making that study sections don't know, thus, would be very helpful.
 - **Q2 Content comments: (1-No, 3 No response)**
 - Because of low numbers of quality applications, probably not necessary.
 - Have not seen this as an issue in several years of Phase I/Phase II applications.
 - Lots of SBIR money, so not necessary.
 - Would need more detail on how this mechanism would work, what would happen to any excess Phase I or Phase II pool funds?
 - R21/R33 funding should be available to fund any successful Phase I if there was not sufficient Phase II SBIR/STTR funding available, therefore, not necessary.

Appendix G

Listing of Acronyms

Listing of Acronyms Used In Report

CSR	Center for Scientific Review
DEA	Division of Extramural Activities
PA	Program Announcement
PAR	Program Announcement Request
R&D	Research and Development
RFA	Request for Application
SBIR	Small Business Innovation Research
SOP	Standard Operating Procedure
SRA	Scientific Review Administrator
STTR	Small Business Technology Transfer