SBIR and STTR Programs:
The Private Sector, Public Sector and University Trifecta

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Abstract

The process of creating and transitioning the storehouse of university research and development to commercial products is by its nature a true partnership of great university innovators, experienced entrepreneurs and adequate funding sources. In the United States, the process of university innovation to commercialization begins deep in university laboratories, where researchers engage in more than $40 billion of cutting edge research and development annually (National Science Foundation, 2006). However, the culture of the university often does not readily endorse quality research with rapid return on investment (ROI) through the traditional commercialization process. In 1982, the Federal government recognized the need to promote university spin-off companies and passed the Small Business Innovation Development Act. In effect, the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs that were spawned from this legislation create a trifecta of resources from the private, academic, and

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government sectors to bring research to the marketplace. This article will enhance the reader's overall understanding of the commercialization process within a university to include a discussion of the advantages of participating in the SBIR/STTR programs, and to underscore the necessity of forming commercialization partnerships to maximize the potential for success of funded SBIRs/STTRs in Phase III.

Keywords: Small Business Innovation Research Program, Small Business Technology Transfer Program, research, private funding, business incubator programs, collaborations, NIH, research and development, social science, technology, grant review process.

Introduction

The landscape of research funding is changing in the 21st century. As it does, it is critical that university researchers collaborate with experienced entrepreneurs and funding sources to stay on the cutting edge of scientific progress. Within the United States, the entire process of university innovation to commercialization begins deep in university laboratories, where faculty, graduate students, and post-doctoral researchers engage in more than $40 billion of cutting edge research and development annually (National Science Foundation, 2006). However, the culture of the university often does not readily endorse quality research with rapid return on investment (ROI) through the traditional commercial process. The scientific community's endorsement of the quality of the research is provided through peer review of publications in leading journals and through attainment of leadership positions in the faculty member's relevant societies. In fact, most university research is years away from market readiness. It is a culture that is designed to be open, long-term, multi-disciplinary, and focused on basic research.

The private sector on the other hand, has different cultural measures and outcomes. Corporate (industry) culture is more secretive and its research is typically shorter-term, lower risk, and focused on applied research for maximizing profits. This creates a cultural challenge for universities and private sector corporations that want to collaborate and transfer technology to the marketplace. General business development strategies are often ineffective in engaging a national audience of technology commercialization partners as the process of fully engaging with universities in research and technology transfer involves a clash of cultures and motivational factors that often stymies successfully transferring technologies to the private sector. Yet, university technology licensing to start-up companies is a growing phenomenon in the US and is funded by multiple sources. Approximately 600 new university spin-off companies are being formed annually. However, many university spin-off companies never recognize their full potential due to the management team's inexperience in fully utilizing university resources such as researchers and infrastructure to create maximum value, manage intellectual property issues and create shareholder wealth (NSF, 2006).

In 1982, the Federal government recognized the need to promote university spin-off companies and passed the Small Business Innovation Development Act. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs were created to "ensure that the nation's small, high-tech,

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innovative businesses are a significant part of the federal government's research and development efforts" by teaming private sector expertise and university cutting edge research with public sector funding (SBIR.gov, 2008, ¦ 1). In effect, the SBIR and STTR programs create a trifecta of resources to bring research to the marketplace. However, relatively few universities or private sector companies fully understand the programs or the process.

This article will enhance the reader's overall understanding of the commercialization process within a university to include a discussion of the advantages of participating in the SBIR/STTR programs, and to underscore the necessity of forming commercialization partnerships to maximize the potential for success of funded SBIRs/STTRs in Phase III.

NIH Small Business Innovation Research Grant, Phase I (R43) and Phase II (R44) and the Small Business Technology Transfer Research Grant Mechanisms Phase I (R41) and Phase II (R44)

The SBIR and STTR programs are distinct funding mechanisms for U.S. small business concerns (SBC) that are solicited within two annual "parent" NIH funding opportunity announcements (FOA), Program Announcements (PA), Requests For Applications (RFA), and Requests for Proposals (RFP), all of which notify the grantee/contract community of continuing, new, or expanded program interests for which grant applications are invited. Investigator-initiated SBIR/STTR projects submitted in response to Parent SBIR/STTR FOAs or to special PAs are reviewed by the NIH Center for Scientific Review, while RFAs and RFPs are generally reviewed by institutes or centers (ICs) within the NIH; those that will award grants under a specific PA or RFA are listed in the specific FOA.

The SBIR program is a Congressionally-mandated set-aside program (2.5% of an agency's extramural research and development [R&D] budget) for domestic small business concerns to engage in research/R&D that has the potential for commercialization. The STTR uses an annual set-aside of 0.30% of extramural agency funds. The Small Business Administration provides administrative oversight of the SBIR and STTR Programs through its Policy Directives.

The SBIR Program includes the following objectives: using small businesses to stimulate technological innovation, strengthening the role of small business in meeting Federal R/R&D needs, increasing private sector commercialization of innovations developed through Federal SBIR R&D, increasing small business participation in Federal R/R&D, and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned business concerns in the SBIR program. The STTR and SBIR programs are similar in that both seek to increase the participation of small businesses in Federal R&D and to increase private sector commercialization of technology developed through Federal R&D. The unique feature of the STTR program is the requirement for the applicant small business concern to collaborate formally with a U.S. research institution in Phase I and Phase II.

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The SBIR/STTR Programs are structured in three phases:

Phase 1: The objective of Phase I is to establish the technical merit and feasibility and potential for commercialization of the proposed R/R&D efforts and to determine the quality of performance of the small business awardee organization prior to providing further Federal support in Phase II. Support under Phase I normally may not exceed $100,000 total costs (direct costs, F&A costs, and negotiated fee) for a period normally not to exceed six months for SBIR and one year for STTR. Applicants to the NIH are advised to propose budgets and timelines that are appropriate for the scope of the scientific project.

Phase II: The objective of Phase II is to continue the R/R&D efforts initiated in Phase I. Funding is based on the results achieved in Phase I and the scientific and technical merit and commercial potential of the project proposed in Phase II. Only Phase I awardees are eligible for a Phase II award. Support for SBIR and STTR Phase II awards normally may not exceed $750,000 total costs (direct costs, F&A costs, and negotiated fee) for a period normally not to exceed two years.

Phase III: The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR/STTR funds the commercialization objectives resulting from the Phase I/II R/R&D activities. In some Federal agencies, Phase III may involve follow-on non-SBIR/STTR funded R&D or production contracts for products, processes or services intended for use by the U.S. Government.

At NIH, deviations from the Phase I/Phase II statutory award amount and project period guidelines are acceptable but must be well justified and should be discussed with appropriate NIH staff prior to submission of the application.

The Phase I award is smaller in scope and more time limited than the full Phase II award. Twenty-three of the 27 NIH ICs offer these mechanisms; specifics such as project period and amount of award may vary. The Phase I awards are often designed to support the early stages of an innovative research concept by encouraging the applicant to use this mechanism to obtain preliminary data for a subsequent Phase II application. This may be ideal for small start-up companies with an academic researcher who often has teaching or agency obligations and needs some release time, yet is not ready for total immersion in a commercial research career.

Projects typically funded in Phase I include: (a) pilot or feasibility studies; (b) secondary analysis of existing data; (c) development of research methodology; and (d) development of new research technology. Phase I can serve as an important developmental step for a small business researcher partnering with an academic researcher, whether they are approaching the research enterprise as a practitioner-member of a research team or as a scholar-member of an agency team.

Reviews of all NIH research grant applications are based on the following criteria: significance, approach, innovation, investigator(s), and environment. In addition, reviewers assess the involvement of human subjects and protections from research risk relating to their participation in the proposed research, and adequacy of plans for care and use of vertebrate animals in research. The reasonableness of

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the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may also be assessed.

Since the SBIR/STTR award is always made to the small business, the small business must have all of the necessary regulatory (i.e., OHRP and OLAW) assurances in place, regardless of where the animal or human subject research takes place. One advantage of the Phase I is that minimal preliminary data are not expected to be described in the application as they are for the traditional R01 mechanisms.

Two options are available to apply for a SBIR or STTR award: by an investigator-initiated proposal or in response to a special announcement. In the first, the researcher designs a project and then identifies an NIH institute with matching goals. The second and typically recommended approach is to identify a PA or RFA that corresponds to the researcher's interest area; this can be accomplished by exploring funding opportunities at the NIH Small Business Funding Opportunities website (http://grants1.nih.gov/grants/funding/sbir.htm). Applicants are encouraged to subscribe to the NIH Guide for Grants and Contracts and to visit the websites of specific NIH Institutes and Centers to learn of emerging interests and areas of high priority.

Eligibility for the SBIR and STTR programs is limited to U.S. SBCs. An SBC is one that, on the date of award for both Phase I and Phase II funding agreements, meets *all* of the criteria described in the current SBIR or STTR parent funding opportunity announcement available from the NIH Small Business Funding Opportunities website. The definition of eligible individuals who may serve as Principal Investigators (PI) is broad and includes any individual with the skills, knowledge, and resources necessary to carry out the proposed research, particularly individuals from underrepresented racial and ethnic groups or disabled persons. For SBIR, the PI must be at least 50% employed by the SBC at the time of award and for the duration of the project. STTR projects do not specify employment criteria, but the PI must have a formal arrangement with the SBC and must devote a minimum of 10% time and effort to the STTR project.

New Opportunities

The SBIR and STTR funding mechanisms open new opportunities for university researchers. As scientists begin to incorporate more technology into their research efforts, they are realizing the advantages of partnering with businesses with similar interests. The University of California, Berkley and the University of Illinois at Urbana-Champaign recently announced a partnership with global energy firm BP "to lead an unprecedented $500 million research effort to develop new sources of energy and reduce the impact of energy consumption on the environment" (Sanders, 2006, ¦ 1). While the partnership ignited a firestorm of debate among academics, the realities of modern research are such that, without such partnerships, it will be nearly impossible for universities to be competitive in today's cutting edge research environment.

Social science is not an exception. Social science researchers are beginning to use more technology to tackle societal problems. One such researcher from the University of Tennessee, Dr. John S. Wodarski, is using computer technology to prevent college drinking. His computer intervention program, based on previous computer technology alcohol assumption assessments, attempts to reduce irresponsible drinking (Wodarski & Long, in press). Another team of researchers from

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the University of Southern Mississippi has developed technology for youth courts and detention centers in five Mississippi counties that improves information management between systems that work with juvenile offenders. The software they created, called SWORD, helps agencies working with juveniles to collaborate and address issues with youthful offenders in a holistic manner while at the same time protecting their private information (Forster & Rehner, 2003). At the University of Alabama, Dr. Michael Parker and his team have also utilized internet technology to create an online assessment for caregivers to older persons. His Parent Care Readiness Program (PCR-Program) consists of a computerized, comprehensive, evidence-based assessment of the full spectrum of parental caregiving tasks, and a tailored intervention program that adult children can implement (Parker, Toseland, Roff, Klemmack et al., in press).

The goal of these social scientists is to create research that solves problems in society. However, the delivery systems and management of those systems are usually not the scientists' primary foci. This is where partnerships with the business sector are crucial. While scientists are busy with research, the market is forging ahead with innovative technologies to meet market demands and creating remarkable organizations capable of delivering products in an efficient manner. The advantage to social science in using business sector technology is that it allows the scientists to couple the very best research with the very best technology and delivery management solutions. The SBIR and STTR funding programs were created by NIH to provide federal funding for such collaborations. The onus for social scientists is to highlight to NIH the significance of each of their projects (or what impact this technology would have on the social problems they address) and make the case that their research is truly innovative.

Preparing to Write an SBIR/STTR Grant

The FOA includes information on how to access the application materials along with instructions for registering at Grants.gov, the central portal for all Federal applications, and for registering on the website of the Electronic Research Administration (eRA; http://era.nih.gov/), NIH's infrastructure for electronically reviewing, monitoring, and administering grant awards. This must be done at least two months in advance of submitting the applications because NIH now requires electronic submissions of SBIR/STTR grants. The NIH website offers a useful tutorial on electronic submission. The SBIR and STTR use the SF 424 Research and Related application forms that are available using a downloadable link contained within each SBIR/STTR FOA. The FOA also provides a link for help in preparing the required budget pages and justification. The SBIR and STTR programs are the only NIH grants that allow SBCs to include a fee or profit in the application.

The research plan required for a Phase I grant application is shorter (15 pages) than the research plans required for Phase II (25 pages) applications, and both contain the following sections: Specific Aims, Background and Significance, Preliminary Studies, Research Design, and Methods. A Commercialization Plan (15 pages) is required in Phase II applications. It is advisable for the first-time applicant to have a mentor or experienced grants consultant to answer questions and review the application. NIH program staff members are also available to provide assistance, and they strongly encourage new investigators to call or email their questions. Primary contacts for the SBIR/STTR program at each IC are listed in the SBIR/STTR Program Topics and Description. The Links and Resources page on the NIH CSR

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site provides a link to an NIH Mock Study Section video that outlines the review and scoring process. Another invaluable resource is the NIH's Computer Retrieval of Information on Scientific Projects (CRISP) database (http://www.crisp.cit.nih.gov), which can be searched to locate current and past awarded grants for SBCs. CRISP also provides information about partnering university, topic area, investigator, or other criterion to learn what has been funded and what unanswered scientific questions remain.

Three ways to obtain a copy of a successful grant are to (a) contact the principal investigator directly, (b) obtain a copy through the Freedom of Information Act by contacting the institute program officer, or (c) call the NIH Freedom of Information Office at 301-496-5633. Contacting the principal investigator may also provide additional information and encouragement for a project. Finally, many college- and university-sponsored program offices regularly conduct workshops on applying for NIH funding. NIH also has a sample application on its website: http://www.niaid.nih.gov/ncn/sbir/app/default.htm

The Grants.gov SBIR/STTR Application Guide SF424 (R&R) on the NIH website, http://grants.nih.gov/grants/funding/424/index.htm, is essential when navigating the application requirements. When preparing to write the proposal, an investigator should remember that reviewers are judging the feasibility of the project being completed within the limited financial resources and time constraints proposed in the Phase I application. Reviewers also carefully consider whether the project has commercial potential that is transferable to real-world practice and/or provides pilot data for a subsequent Phase II, application and whether it is within the researcher's capabilities. Finally and most importantly, reviewers are interested in whether the proposed project fits with the research priorities of the IC.

A recommended step for a new SBC investigator completing a SBIR/STTR application is to establish a solid mentor relationship with a senior investigator in the field of study. According to Hesselbrock (2006), qualities to look for in a mentor include common professional interests, available time to devote to mentoring, and whether the person has the necessary NIH-related research experience. The investigator should also consider whether he or she likes and trusts the person and whether he or she is open to advice from this person. Likewise, being a successful mentee involves creating short-term and long-term goals for professional growth, meeting regularly with the mentor and focusing each meeting by having an agenda, using the mentor's resources wisely, providing appropriate feedback, and avoiding competition with the mentor.

For a new investigator to hear the truth in a positive way from an expert in his or her field is truly a gift. The scientific reputation of the mentor and other collaborators can influence the confidence that a reviewer has in the proposed project. This is especially true with an SBIR/STTR Phase I because it does not require the same consideration of the qualifications, track record, or preliminary data of the principal investigator, who is often a new researcher.

Writing the SBIR/STTR Application

When writing the application, completeness, significance, originality, and clarity matter. State the hypothesis or underlying principles clearly in both the Specific Aims of the Research Plan and in the Abstract:

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1. Highlight the importance and innovation of the project.
2. Be sure the project has a coherent direction.
3. Demonstrate that the objectives are attainable within the stated time frame.
4. Explain what gaps in science and/or commercialization the project would fill. If a similar product/service exists, clearly explain why the proposed product/service is better and why it is innovative.
5. Refer to the literature thoroughly and thoughtfully, but not to excess. Research proposals typically do not fare well when applicants are unaware of relevant published work, products, or services or when the proposed research or study design has already been tried and judged to be inadequate.
6. Where appropriate, include well-designed and clear tables and figures. Use titles that are accurate and informative. Label the axes and include legends. Reviewers will look for discrepancies between what is shown and what is described in the proposal. Be sure to explain the details, or reviewers may see things differently from what applicants intended.
7. Edit and proofread thoroughly for typographical and grammatical mistakes, omitted information, and errors in figures and tables.
8. Have other colleagues review the application. They can point out unclear statements and other problems such as typographical errors, omitted figures, absent biographical sketches, missing letters, and confusing budget justifications.

The Project Summary/abstract is critically important. Based on the Project Summary and the title, the Scientific Review official at NIH determines which Study Section within an Integrated Review Group (IRG) will review the application. The Project Summary should be a clear and concise statement of the objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. It is a snapshot of the significant questions and hypotheses, specific aims and objectives, and important contributions and commercial potential that this project can make. It should be written and rewritten and read by an experienced grants person for feedback before submission. The Specific Aims section is the first part of the 15-page Phase I Research Plan. It is recommended, but not required, that this section be hypothesis-driven. NIH guidelines for reviewers (NIH, 2007) state that a strong application should have sound ideas, address important issues, and generate confidence that the research will make a significant difference.

The Specific Aims section should list measurable objectives intended for completion by the end of Phase I or Phase II. Do not confuse Specific Aims with long-term goals for a product. Specific aims are the objectives of the research project, project milestones, and the accomplishments by which the success of the project is measured. This section should capture the enthusiasm of the reviewers (particularly the primary and secondary), since all reviewers will read it. Choose aims reviewers can easily assess. Choose objectives for the Phase I proposal that can be easily and fairly evaluated at the conclusion of this phase. To avoid being overly ambitious, limit the proposal to three to four specific aims.

Most importantly, Specific Aims should be focused and clearly express the importance and limitations of the project. Organize and define the aims so they can

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be directly related to the research methods. Begin this section by stating the general purpose or objectives of the research, which may be organized in outline form: Specific Aim 1, Milestone; Specific Aim 2, Milestone; etc. If the SBC is submitting more than one application, make sure the specific aims differ.

The Background and Significance section contains the peer reviewed literature, organized to flow logically within the context of a strong literature-based rationale. It develops the ideas presented in the Specific Aims section and identifies gaps in the literature. This is one of the sections likely to be read by all the reviewers, so write this section in nontechnical terms for the broader audience. Tell the reviewers how this work suits the NIH mission to improve health through science. Tie the science to curing, treating, or preventing disease. When reviewing an application, reviewers will judge the likelihood that the research can make an impact on public health. Describe how this research is innovative and how it could produce a significant commercial product or service. Innovative means new technologies, significant improvement of existing technologies, or development of new applications for existing technologies. Specifically identify the commercial opportunities and societal benefits that the project is intended to address. State concisely the importance of the proposed research by relating its specific aims to the longer-term objectives of Phase II.

Keep it brief! Why is the project or specific research question important? Write a compelling argument that supports the research to develop a solution to a real problem that affects real people. Consider including a diagram that illustrates the "big picture" by delineating expected achievements in Phase I (aims and milestones), plans and objectives for Phase II, and what the ultimate commercial endpoint will be in Phase III. Consider the following questions:

1. Does the proposed project have commercial potential to lead to a marketable product or process?
2. Does this project address an important problem?
3. What may be the anticipated commercial and societal benefits of the proposed activity?
4. If the aims of the application are achieved, how will scientific knowledge be advanced?
5. Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?
6. Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?

The applicant would be wise to identify potential reviewers and to include relevant articles the reviewers have published. The final sentence should clearly identify the timeliness, significance and commercial potential of the proposed research project without overstating its importance. The Phase I application guide states that the Preliminary Data section is not required. However, some preliminary data can serve to assure reviewers that the proposal has a high probability of success. Applications with convincing preliminary data are likely to score better than applications containing only good ideas. NIH review guidelines state that if preliminary data are provided, they must be evaluated scientifically. Whether investigator-generated data are presented or not, this section should contain a strong

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justification for the approach by providing literature and supporting data. Interpret preliminary results critically. Give alternative meanings to the data to demonstrate it may be able to meet future challenges.

In the Research Design and Methods section the researcher spells out the study design in detail. Reviewers often find that this section is underdeveloped. When reviewers judge an application the Research Design and Methods section has the most "weight" even though the review criteria are not numerically "weighted." Organize this section in accordance with the specific aims. It's helpful to create a timetable showing how and when the aims will be accomplished, including any overlap of experiments and alternative paths. Use flow charts and decision trees to show paths of experiments and how they progress, including paths that show alternatives -- what will happen if there are negative results. Anticipate reviewers' questions about the feasibility of the proposal, e.g., access to reagents, equipment, or study populations. Describe sources if reagents or equipment are not generally available. If collaborators will provide them, include letters from the sources.

Describe in detail the experimental design and procedures to accomplish the specific aims. While reviewers are experts in the field and familiar with current methodology, do not assume they will know how the proposed research will proceed. The reviewers need to be assured that applicants know what they are doing. It is not sufficient to state "we will grow a variety of viruses in cells using standard in vitro tissue culture techniques." In this example, reviewers would want to know which viruses, cells, and techniques; the rationale for using this particular system; and precisely how the techniques will be used. Include a detailed discussion of the way in which results will be collected, analyzed, and interpreted. Remember, the reviewers must be convinced that the proposed project is a great idea. The applicant must show through a succinct explanation that he or she understands the science and can do the research.

Make sure the experiments are in a logical sequence, flowing from one another with clear starting and finishing points. Show a timeline for experiments, and take care to propose a realistic level of work for the allotted time. Answer these questions: Are the procedures feasible and within the collaborators' expertise and competence? Reviewers must be convinced that the right methods have been proposed, especially if the methods are innovative; state why they were chosen and what will be done to avoid technical problems. Point out any procedures, situations, or materials that may be hazardous to personnel and describe the precautionary measures that will be taken in handling the materials, and the training people involved have had in safe practices. The application must state what special facilities are available to protect the environment and staff.

To fill in expertise, rely on consultants. State how collaborators or consultants will fit into the work. List them as key personnel, and provide biographical sketches. Include a section called "Potential Risks and Alternative Strategies," which discusses potential difficulties and limitations of the proposed procedures and proposes solutions to them. Since reviewers are experienced researchers, they will be aware of possible problems. Discuss alternative approaches if the initial approach proves not to be feasible or if a result is not what was expected. Tell reviewers what will happen if results are negative, how this will also advance the field, and what the next steps may be. Discuss in detail the methods for gathering and interpreting data and making sure the experiment can yield statistically significant results.

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It is very important to also include the milestones and criteria which will determine that feasibility has been demonstrated. Consider whether the following questions have been addressed after completing this section:

1. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project?
2. Is the proposed plan a sound approach for establishing technical and commercial feasibility?
3. Does the applicant acknowledge potential problem areas and consider alternative strategies?
4. Are the milestones and evaluation procedures appropriate?

Give thorough consideration to the need of any human subject or animal involvement in the Phase I feasibility work. Although no specific page limitation applies to these sections of the application, be succinct. If there is no animal or human subject research, indicate "Not applicable" in this section of the research plan. If there is animal or human subject involvement by the SBC or the collaborators, these sections must be completed and all assurances must be in place at the time of award. Failure to address the required elements will result in the application being designated as incomplete and will be grounds for NIH to return the application without peer review.

If the proposal includes working closely with an investigator from another institution, briefly describe any consortium or contractual arrangements, stating the roles of the people or organizations involved. STTR applicants must enter into a Technology Transfer Agreement with their research institution partners, and it is good practice for any external collaborations. Explain the programmatic and fiscal arrangements made between the SBC and the contractor(s). SBCs often lack all of the expertise "in-house" to complete the proposed research. The inclusion of consultants who are credible, known experts in their field can strengthen the research team, add credibility to the application and greatly improve its quality.

Grant Review Process

Grant applications that are submitted in response to the Parent SBIR/STTR FOAs or specific PAs are handled by the NIH Center for Scientific Review (CSR), which receives applications and organizes and coordinates NIH grant review activity. (RFAs are generally reviewed by the ICs.) CSR activities are organized into integrated review groups (IRGs), which are clusters of study sections, also called scientific review groups, responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources. The study section is selected by the IRG staff and is composed of a panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. IRGs, study sections, meeting dates, and rosters of section members (potential reviewers) are listed at the CSR website (http://cms.csr.nih.gov/) and at the eRA website for investigators who are in the eRA system.

In the PHS 398 cover letter component of the SF424R&R application, the investigator may request a specific IC, IRG, and study section and should identify the disciplines involved in the research and the expertise needed to appropriately

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review the application (e.g., someone with expertise in qualitative research methods). Although the PI may not request specific reviewers, the PI may state who should not review the application and why. An NIH glossary (http://grants.nih.gov/grants/glossary.htm) and a tutorial on applying for NIH grants (http://www.nlm.nih.gov/ep/Tutorial.html) are both useful tools.

So, who actually reviews the grant? First, one or more CSR Referral Officers examine the application and determine the most appropriate IRG to assess its scientific and technical merit. The application is then assigned to one of the IRG's study sections. A study section typically includes 20 or more scientists from the community of productive researchers. The application also will be assigned to the IC best suited to fund your application should it have sufficient merit. (More than one IC may be assigned if appropriate.)

Referral Officers follow established guidelines that define the review boundaries of each study section. These boundaries frequently overlap, and more than one study section may have the expertise to review the application. PI's may request in a cover note that the application be assigned to a particular study section or IC. The CSR referral office seriously considers such requests. The combined expertise of the scientists in a study section is intended to span the breadth and diversity of the science it covers. CSR may recruit temporary reviewers or secure mail reviews from outside consultants. As soon as the application is received and assigned to a study section, notices are posted to the PI's online NIH eRA Commons account.

The Scientific Review Officer analyzes the content of the application, checks it for completeness, and decides which reviewers can best evaluate it. All study section members have access to the application through the NIH eRA Commons, but only two or three members review it in detail and provide written reviews. As previously discussed, criteria for review are (a) significance, (b) approach, (c) innovation, (d) investigator or investigators, (e) environment, and (f) other (human subjects, representation, budget). Through a process called streamlining, only the top 50% of grants receive discussion and a numeric rating. About 50% are placed in the bottom half and are unscored (as designated by a double asterisk). Both scored and unscored applications receive summary statements of comments from reviewers, which are invaluable in the resubmission process. NIH applicants are allowed two revised applications. Priority scores for the top 50% range from 100 to 500 with 100 being a perfect score. Generally, 100 to 150 means outstanding (but no guarantee of funding), 150 to 200 is excellent, 200 to 150 is very good, 250 to 300 is good, and 300 to 500 is acceptable.

Depending on several factors (institute, number of applications received, type of award, percentile cutoff depending on the budget), applications scored above a specific score (e.g., 150) may have to be resubmitted. After the study section review committee meets and the summary statement has been prepared, the next level of review is conducted by the IC's Advisory Council or Board, which considers the study section's recommendations and determines the relevance of the proposed research to the priorities of the institute and to public health needs. If approved by the advisory council the application is on its way to the NIH grants management division that implements the funding process.

Concerns most often cited by reviewers include: (a) the applicant had overreached; (b) the project was overly ambitious, which raised feasibility questions (a common problem with Phase I applications); (c) follow-up terms were unclear; and

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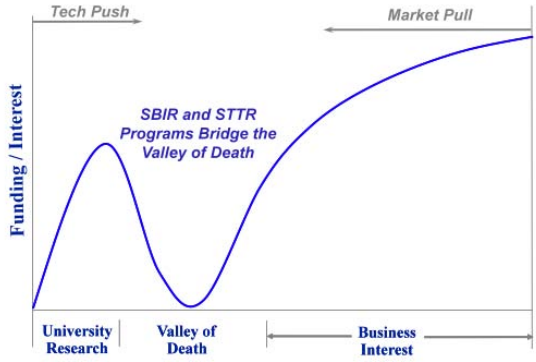
(d) the significance of the research was not clearly demonstrated. Consultation with the IC project officer is strongly encouraged before submitting a revised application. In the revised application the initial reviewers' concerns must be carefully attended to. The important messages are: (a) Follow the instructions in the FOA and ask for help with anything that is not understood, (b) don't expect to be funded after the first application, and (c) don't give up! Research conducted by small business concerns partnering with academia is vitally important to the NIH's objective of bridging the gap between research and community practice to improve public health. The SBIR/STTR award is an important mechanism for small business concerns and research institutions to use in helping realize this objective.

SBC Collaborations with Universities in SBIR and STTR Programs

From a university/SBC collaboration standpoint, SBIR and STTR programs can provide key funding to advance a technology through what has been termed the "Valley of Death" - that point in the life cycle of technology development where the research is transitioning from a basic "academic" research program to an "applied" focused development program (Figure 1). As any technology SBC or entrepreneur and many university faculty have experienced, this transition point can be very difficult as the technology is sometimes too far along for significant further federal funding, but not yet sufficiently developed and risk mitigated to attract significant industry attention for adoption or funding. The SBIR and STTR three-phased programs are ideally designed to provide stage-gate funding for technologies that are candidates to successfully transition to full production. The SBIR and STTR scheme of increased funding with successful demonstration of the technical and commercial merits of early stage technologies provides for scarce resources in this stage of development with risk mitigation as funds are only provided as success is demonstrated.

Figure 1. The Valley of Death.



From an academic standpoint, the SBIR and STTR programs provide an avenue to transition some university technologies/research to the private sector by extending the technology work from pure research into the development regime,

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and therefore create a pipeline of more attractive technologies for SBC collaborative development and ultimate commercialization through an SBIR or STTR project.

A typical faculty member's team might undertake anywhere from hundreds of thousands to millions of dollars in funded research annually, with over 60% of funding coming from federal agencies and the remainder being supplied by private sector companies (5-15%), foundations, state resources, and other organizations. It's important to note that at any given time research teams will typically be working on several synergistic research projects in their field funded by multiple sources.

Over 70% of university research is categorized as basic (research for the sake of knowledge) versus applied development (research for the sake of meeting a specific market need through development of a product or service). As a comparison, typically less than 10% of corporate research is categorized as basic (NSF, 2006). Basic research provides the foundation for fundamental technology breakthroughs for next generation corporate products, establishing a key role for US universities in the overall advancement of technology today and in the future. Often, basic research is years from market readiness, but the SBIR and STTR programs can provide catalytic funding to transition academic research to industrial development.

NIH, academia and business have a stake in many endeavors, such as putting new technology to work, preparing young people for productive careers, exchanging valued goods and services, and advancing knowledge in directions that matter. In fact, a partial listing of collaboration avenues between SBCs and universities shows a broad cross section of mutually beneficial areas to the private, government, and academic sectors:

1. Joint research with government sponsors
2. College, Department, Institute, and Center Advisory Boards
3. Facility usage
4. Proactive student recruitment
5. Student internships and co-ops
6. Faculty sabbaticals
7. Visiting researchers and scientists
8. Distance education / lifelong learning
9. Sponsored research
10. Product / Technology donations
11. Support for student clubs
12. Student scholarships, fellowships, endowments, professorships
13. Participation in short courses, seminars, workshops

These significant opportunities for collaboration have presented industry with motivation to work with academia on SBIR, STTR, and other collaborative R&D programs. Over the last 20 years, the US private sector has increasingly relied on universities to undertake some of the basic research that spawns breakthrough products of the future -- research that entrepreneurs and SBCs are either not equipped to undertake themselves or are not able to fund internally with their focus on near term product development that affects the bottom line. At the same time, US universities have substantially ramped up their programs to commercialize technologies to the greater impact of society. It's important to realize that university/SBC collaboration and technology transfer is a relatively young field, having been

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truly active only since the Bayh-Dole Act of 1980, but it's growing dramatically (albeit with its share of growing pains), as evidenced by the data below. As of 2006, US universities, hospitals, and research institutes produced substantial technology transfer results including (Association of University Technology Managers, 2006):

1. $45B in undertaken sponsored research.
2. 18,874 Invention Disclosures with an average of about $2.5M R&D per invention.
3. 15,908 patent applications and 3,255 US patents issued to US universities in 2006 compared with less than 250 in 1980.
4. 4,963 licenses and options executed with 64% issued to startups & SBCs.
5. 697 products launched (4,350 since 1998) based on university or nonprofit research results introduced in 2006 in the US alone.
6. 553 new companies (1.5 per day). 5,724 companies were spun-out from US universities, hospitals & research institutes since 1980.

More to the point, much of the market success in this field has been catalyzed by research and licensing collaborations with entrepreneurs and SBCs, a trend that is rapidly accelerating. Federal SBIR and STTR programs are focused specifically on funding of these types of truly breakthrough technologies, making universities attractive R&D partners for many SBCs who participate in the SBIR and STTR programs.

Achieving the aforementioned results has taken a dedicated effort by many groups in the university and the private sectors, ranging from faculty and students to university administrators, entrepreneurs, and SBC executives and research leaders. Each stakeholder in the process, whether internal (students, staff, faculty, and administration) or external (SBCs, entrepreneurs, and investors) to the university, plays a key role in making the university effective and proactive at generating and commercializing technology through SBIR/STTR collaborations.

Cultural Challenges to University/SBC Collaborations

Robust university/SBC collaboration and technology commercialization programs include a multitude of engagement mechanisms ranging from Industrial Advisory Boards, which guide university research and educational efforts at various levels, to sponsored and collaborative research such as SBIR/STTR, and technology licensing and commercialization. These programs are most productive when the university and entrepreneurs / industry partners understand each other's cultural differences, key motivators, and other critical factors affecting the collaborative environment. As Putman (1981) observed, cultures can differ in several parameters:

1. *Members:* academics or businessmen
2. *Principles:* For academics, these include to publish or perish, reward brilliance, get famous, and advance knowledge. For businessmen, these include to deliver value to the business, reward consistent achievement, make money, and climb the corporate ladder.
3. *Esthetics:* elegance, simplicity, and beauty versus speed, low cost, and minimal trouble and delay.

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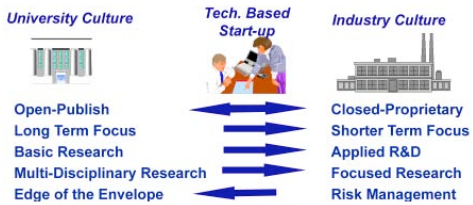
4. *Language:* "intuitively obvious," "left as exercise for the reader," and "as first shown by..." versus "24 by 7," "six sigma," and "measures of success."
5. *Worlds:* One is filled with students, funding sources, publications, academic societies and conferences; the other is filled with projects, delivery dates, contracts, markets, and customers.
6. *Practices:* graduating, getting a grant, achieving tenure, and making a name versus completing a project, climbing the corporate ladder, closing a deal, and building a team.

While the general fields of university/industry collaboration and technology transfer have made significant advances over the last 20 years, universities and the private sector, including SBCs, oftentimes continue to struggle in consistently coming to common ground when working together. Whether in implementing an SBIR or STTR project, working with entrepreneurs to spin-out a university technology-based company, or entering into negotiations with a market leading company to move technology from a university lab to the marketplace through licensing and development, war stories of difficulties and failures abound despite a wealth of proven success in all of these areas. While one can point to various challenges that are highlighted in specific situations, obstacles to successful university / industry collaborations and subsequent technology transfer are usually rooted in misconceptions of each sector's role, responsibilities, motivational drivers, and success criteria. In a word, the cultural differences inherent in the private and public sectors many times materialize as obstacles to a successful collaboration and transfer of a technology to a private sector client such as an SBC. While it's always dangerous to generalize, one can readily see (Figure 2) that the cultural gaps between universities, SBCs, and large industry players can be evidenced in definitive ways that affect collaboration potential such as timeframes (semester vs. weeks), focus (basic vs. applied research), management (decentralized vs. hierarchical, project management driven), and bottom line focus (discovery vs. profit / shareholder value).

Figure 2. Significant Cultural Differences.



These cultural gaps are also evident within universities, where philosophical struggles between and amongst administrators and researchers with regard to the proper balance between basic and applied research are common. These challenges can be further exacerbated in SBIR/STTR projects that encompass relatively short time frames and vary in applied research, which are not the university's norm.

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Additionally, the field of US university/SBC collaboration and technology transfer, while having made great strides since passage of the Bayh-Dole Act in 1980, is still somewhat foreign to many university researchers and views of what is considered technology transfer can vary greatly among the contributors. For example, Figure 3 shows what one could argue are all valid, yet myriad, definitions of industrial collaboration and technology transfer avenues, ranging from contractual mechanisms such as sponsored research agreements and technology licenses to "softer" ways to transfer information and technology from one organization to another - seminars, consultation, publications, and graduation, which without a doubt are the university's broadest means to affect industry with the results of its basic research.

Figure 3. Different Views -- What Constitutes Tech Transfer.

- **Intellectual Property - knowledge "ownership"**
  - Patents
  - Copyrights
  - Know-how
  - Trade Secrets
  - Trademarks
- **Technology Transfer Professional Views**
  - Licensing
  - Sponsored Research Agreements
  - Cooperative R&D Agreements
- **Researcher Views**
  - Consulting
  - Publications
  - Collegial Interchange
  - Seminars
  - Conferences
  - Graduates
- **Company Views**
  - Licensing
  - Consulting

When an SBC engages with a university in an SBIR or STTR project, it's critical that the two parties agree on specific technology transfer and collaboration terminology to avoid having to face that challenge at an inopportune time when the research is already on-going and deadlines are approaching.

Other Primary Challenges to SBC / University Collaboration

While it's instructive to review the cultural foundation for many of the obstacles to universities, SBCs, and entrepreneurs working together, experience in implementing industrial collaboration and technology transfer programs and individual projects from all three of these perspectives has highlighted four primary, concrete areas of collaborative obstacles that must be overcome:

1. Intellectual Property: When potential university/SBC/entrepreneur collaborations such as an SBIR or STTR project are considered, the first and foremost issue in frequency and intensity of argument is intellectual property ownership and rights. One of the key differentiators between research contracts funded by the public sector (federal agencies such as the National Institutes of Health, National Science Foundation, Department of Defense, National Aeronautics and Space Administration, and Department of Homeland Security) and the private sector (SBCs and large companies) involves treatment of intellectual

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property that might result from the research project. Under the Bayh-Dole Act of 1980, a federal funding agency will generally contribute the rights to intellectual property (patents, copyrights, trademarks) from projects that the agency funds to the university. Faculty and graduate students funded by the university have already agreed to assign intellectual property developed under funded projects to the university in their employment agreements. The university is then free to engage in technology marketing and licensing as it sees fit.

In an industrially sponsored project such as SBIR or STTR, each party (university and SBC) may sometimes want full ownership of all intellectual property generated in a collaborative project, and come to loggerheads very quickly, as this is often initially deemed a "deal breaker." However, experience shows, and university technology licensing and industrial collaborative research data support, the premise that universities and the private sector have learned to overcome this obstacle. In spite of the occasional war story of "the university deal that went sour," US universities and SBCs usually come to terms that provide universities with ownership of the intellectual property that their faculty and students develop, while providing sufficient commercialization rights to SBCs. Boilerplate industry-sponsored research agreements in universities usually include a first option to a royalty-bearing license to technology produced in the research project on a good-faith negotiations basis. While this type of uncertain language can often cause heartburn for entrepreneurs or SBCs working with a university, and, more to the point, providing the funds for university research to support a future product, the result is that the university and its researchers are able to benefit from the fruits of their inventiveness, the entrepreneur or company is able to stake an exclusive or semi-exclusive position in commercializing the technology, and the public benefits from research that is commercialized for the common good.

2. Limited private sector resources for external research support: Again generalizing, over the last 10 years, private sector discretionary budgets for external R&D support have been reeled in and focused on fewer areas with nearer term payoff potential and a very strong linkage to the company's bottom line. While the validity of this strategy and the long term effect is beyond the scope of this paper, what is clear is that this has had a significant impact on SBC sponsored and collaborative research with universities. University researchers have had to adjust their expectations of industry sponsorship and the deliverables / timelines that are being expected to meet the industrial researcher needs. No longer can faculty count on multi-year industrial contracts with sometimes vague objectives. The entrepreneurial picture is even more demanding as each decision to allocate scarce resources to research and development is a decision to pull those dollars from other very key parts of the company's lifeline, including marketing, operations, and sales. However, entrepreneurs and SBCs need to clearly understand that only a very small percentage of university technologies is anywhere near ready to go to market. SBC technologies that are developed in SBIR or STTR programs are more often than not advanced along the R&D curve from the university standard basic research. Most technologies that are licensed by universities to the private sector (entrepreneurs, small, or large companies) require months to years of

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development to make them market ready, and entrepreneurs need to account for this in their budgeting. They must also realize that they are now dealing with and relying on follow-on research with an organization (the university) and professionals (the faculty and graduate students) who are influenced by different cultural drivers and timeframes as discussed above.

3. Research guidance/focus to meet company specific needs: As is clearly evident to those who have experienced the university, entrepreneur, and industry cultures, the university's dedication to knowledge for the sake of knowledge and discovery (basic research) rather than the more definitive industrial profit motive of bringing technology to market (applied research) is a wonderful and necessary facet of society, but can also be foreign and frustrating to an entrepreneur or SBC research manager who is being pushed to justify university research investments in terms of potential impact on the bottom line and progress toward the SBIR or STTR project goals. Entrepreneurs and industry researchers aiming to maximize their collaborations with universities must understand and appreciate that discovery is not as predictable as development and the nature of a university's research "workforce" (graduate students, post docs) means that the R&D results that industry is seeking must dovetail with the educational mission of the university. This can be very difficult for industry in the face of volatile industry environments (e.g., mergers, acquisitions, and shrinking profit margins), but is still a university foundational element that can't be ignored. At the same time, a university researcher's up-front understanding of and an SBC's continued communication of the nature, timing, and criticality of a company sponsor's needs can go a long way toward establishing an SBIR or STTR research project that is truly focused on meeting the sponsor's needs and timelines. This is an especially critical element for SBCs that are often living on a razor's edge of timelines and budgets and must get the most from each collaboration or license or risk the future well being of their company.

4. Confidentiality: Universities in the past have suffered under the often false label of "leaking information like a sieve." This is due at least in part to the university's open culture of information exchange and collaboration in the pursuit of knowledge. While the academic and industry sectors have come to relatively common agreement on how confidential information should be transmitted between the organizations and protected, what can be problematic are publication requirements for students and faculty vs. an SBC's desires to withhold company-sensitive information and proprietary research results from competitors and to protect intellectual property. The authors would argue that this potential problem can usually be mitigated with clear, on-going communications throughout the SBIR or STTR project so that confidential or proprietary information can be properly managed in publications without affecting a student's educational progress or unduly delaying a faculty member's publications or endangering patent positions.

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