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Creative Partnerships for Funding Nursing Research

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Abstract

The Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer Research (STTR) program are two federal funding mechanisms that some nurses in academic positions have used to support research and development of innovative nursing products or services. Both the SBIR and STTR mechanisms are excellent sources of funding for nurse researchers who want to capitalize on relationships with small businesses or obtain seed money to fund high risk projects with potential to attract new venture capital. This paper provides an overview of NIH-funded SBIR and STTR programs and summarizes similarities and differences between the programs. The paper also describes unique features of NIH SBIR and STTR funding mechanisms that differentiate them from other R-series funding mechanisms, reviews evaluation criteria for SBIR and STTR projects, and discusses critical partners and resources for proposal development. Finally, the paper describes characteristics of successful partnerships and provides examples of SBIR/STTR-funded projects.

Keywords

research funding; small business; technology innovations; set-aside programs; SBIR; STTR

Congress mandates that federal agencies with extramural research and development budgets over a specified amount must designate a percentage of their extramural budget for small businesses, known as a “set-aside” program. Few nurses, including those in academic positions, are aware of this mandate or of its related funding mechanisms that are available

from numerous federal departments and agencies including the National Institutes of Health (NIH) of the Department of Health and Human Services (HHS). Fewer still have successfully applied for and received support through these funding mechanisms. The Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program are two such set-aside mechanisms that a limited number of nurses in academic positions have used to support research and development of innovative nursing products or services. SBIR and STTR mechanisms assist the small business and research communities by supporting research needed to commercialize innovative technologies, with the ultimate goal of developing health care related products and services that have commercial merit and public health benefit. This paper: 1) provides an overview of the NIH SBIR (R43; R44) and STTR (R41; R42) funding mechanisms, the three-phase structure of these programs, eligibility requirements, and similarities and differences between the programs; 2) describes unique features of SBIR and STTR funding mechanisms that differentiate them from other NIH R-series funding mechanisms (R01, R03, R15, R21); 3) reviews evaluation criteria for NIH SBIR and STTR projects; 4) discusses critical partners, resources for proposal development, and characteristics of successful partnerships; and 5) gives examples of four NIH-funded SBIR/STTR research projects, including challenges the teams faced and how they were resolved.

Overview of NIH SBIR and STTR Funding Mechanisms

The SBIR program was established by the U. S. Congress under the Small Business Innovation Development Act of 1982 (Public Law 97-219) and has been reauthorized twice since then. Federal agencies with extramural research and development budgets over \$100 million are required to administer SBIR programs using an annual set-aside of 2.5%. Currently, eleven federal departments and agencies participate in the SBIR program, including the Center for Disease Control, Department of Defense, and National Institutes of Health. To date, over \$12 billion has been awarded by the SBIR program to various small businesses. The STTR program was established ten years later by the Small Business Technology Transfer Act of 1992 (Public Law 102-564, Title II) and has also been reauthorized twice. Federal agencies with extramural research and development budgets over \$1 billion are required to administer STTR programs using an annual set-aside of 0.30%. Currently, five federal departments and agencies participate in the STTR program. HHS participates in both SBIR and STTR programs; however, the NIH is the only HHS agency that participates in both programs and the only agency that participates in the STTR program. Additionally, the NIH is the largest civilian agency and the second largest participating federal agency overall in these programs (NIH, 2009). Because there is substantial variation in the way SBIR and STTR programs are implemented across federal agencies and departments and because most nurse researchers submit grant applications to NIH, this article focuses on SBIR and STTR mechanisms specific to NIH.

The Small Business Association's Office of Technology administers both the SBIR and STTR programs, which have the common purpose of stimulating innovative research and development of small business concerns (SBCs) that may ultimately lead to increased competition, productivity, and economic growth. The focus is on increasing participation of SBCs in federal research and development and on increasing private sector commercialization of innovations derived from federal research and development. As of 2010, 23 NIH institutes and centers participate in both the SBIR and STTR programs. Both programs use the SF 424 application and electronic submission process with specific aims, research strategy (significance, innovation, approach including preliminary studies for new applications and progress report for renewal or revision applications), and human subjects sections. The major difference between SBIR/STTR and more well-known NIH R-series grants is a focus on business and commercialization plans. Indeed, legislations to reauthorize

the SBIR and STTR programs consistently emphasize this goal by requiring agencies to include as a review criterion the commercial potential of a proposed project.

Three-Phase Structure of SBIR and STTR Programs

Both the SBIR and STTR programs are competitive three-phase funding mechanisms that provide qualified SBCs with opportunities to propose innovative ideas that meet specific research and development needs of the federal government. Phases I and II of the research projects are supported using SBIR/STTR funds, which includes a 7% fee that is intended as a reasonable profit for the SBC that may be used for any purpose, including additional effort under the SBIR/STTR award. In Phase III, the SBC must pursue commercialization with non-SBIR/STTR funds, which can be either federal or non-federal.

Phase I

Similar to an R03 or R21 pilot study (1 page for aims and 6 pages for research strategy), the overall objective of Phase I is to establish “proof of concept” as a prerequisite to further support in Phase II. Specific goals of Phase I are to: 1) establish technical and scientific merit of the research; 2) provide evidence for feasibility; 3) demonstrate potential for commercialization; and 4) determine the quality of performance of the SBC. Federal support for NIH Phase I awards does not typically exceed \$100,000 in total costs (includes 7% fee/profit) and the funding period does not typically exceed six months for SBIR or one year for STTR awards. The goals of Phase I must be met before applications for Phase II are considered for funding.

Phase II

Similar to an R01 or R15 (1 page for aims and 12 pages for research strategy), the major aim of Phase II is to demonstrate efficacy of the innovation that was developed in Phase I. Phase II awards are only made to SBCs that had Phase I awards and Phase II funding is contingent on meeting the feasibility benchmarks that were specified for Phase I. Phase II applications also must provide a solid foundation for pursuing Phase II efficacy research. Submission of a concise commercialization plan (no more than 12 pages) that clearly describes commercial potential for the product or service is critical for Phase II applications. Commercialization plans that are supported by letters of interest or commitment from future funding sources for Phase III are more likely to receive favorable reviews. Federal support for NIH SBIR and STTR Phase II awards does not typically exceed \$750,000 in total costs (includes 7% fee/profit) and the funding period does not typically exceed two years. However, the amount of funding and project time line may be adjusted to meet the goals of the proposed project if there is adequate justification and prior approval from appropriate NIH staff before the application is submitted.

Phase III

The key objective of Phase III is for the SBC to pursue commercialization of the product or service that was developed during Phase I and Phase II awards. However, the work of moving the innovation from laboratory to marketplace must be undertaken without SBIR or STTR funds. Thus, the SBC must identify other federal or non-federal funding sources to be used in the commercialization of products or services such as small business loans, private investors or “angels”, venture capital firms, research contracts, limited partnerships; strategic alliances, and joint ventures.

Eligibility Requirements

Eligibility criteria are defined on both individual and institutional levels. In terms of institutional eligibility, only U.S. SBCs are qualified to submit applications for SBIR or STTR funding. Prior to receiving an award, successful SBC applicants are screened for meeting all of the eligibility criteria summarized in Table 1. More specifically, not only must the SBC be organized for profit, it must be located in the U.S., operate primarily in the U.S., or make a substantial contribution to the U.S. economy by tax payment or use of U.S. products or services. The SBC must be owned and controlled (minimum of 51%) by one or more persons who are U.S. citizens or permanent resident aliens and it must have fewer than 500 employees for the 12 months prior to application submission. Finally, the SBC cannot dominate the market or field in which it is proposing the research. NIH program staff evaluate these criteria prior to award. If it appears that the SBC does not meet the eligibility criteria concerning size, the NIH will request an official size determination by the Small Business Administration.

On the individual level, any person with the necessary skills, knowledge, and resources for carrying out the research activities proposed in the SBIR/STTR application is eligible to serve as the Principal Investigator (PI) or Project Director (PD). As with other NIH funding mechanisms, more than one person may fulfill these roles. If multiple PIs/PDs are designated for the project, they share the authority and responsibility and are jointly accountable for conducting the project and for appropriate reporting to the funding agency. However, as noted below, there are differences between the two funding mechanisms in the *primary employment* and *commitment of effort* for the PI/PD.

Similarities and Differences between SBIR and STTR Programs

There are many similarities between the SBIR and STTR programs. Both use federal set-aside funds as seed money to SBCs to spawn technology growth, and both use a competitive three-phase funding mechanism with similar amounts of money and time allocated to Phases I and II. Both require that the SBC is *always* the applicant. The key differences between the programs lie in the way they are structured, the required level of participation in the research effort, and the primary employment of the Principal Investigator/Project Director (PI/PD) (Table 2).

The SBIR program is structured for a SBC to *independently* engage in federal research and development with potential for commercialization. Although the SBC is permitted to subcontract with a research institution, this association is not required. If the SBC does establish a subcontract, in Phase I, at least 2/3 of the research effort must be performed by the SBC and a maximum of 1/3 of the research effort may be performed by subcontractors. In Phase II, at least 1/2 of the research effort must be performed by the SBC and a maximum of 1/2 of the research effort may be performed by subcontractors. Under the SBIR program (Phase I and Phase II), the PI/PD must have his or her primary employment (> 50%) with the SBC at the time funding is awarded and for the duration of the project, including no-cost extensions. If multiple PIs/PDs have been named, at least one of them must be employed by the SBC and that individual will serve as the primary point of contact. If the contact PI/PD is employed by a university in a clinical or research position (e.g. clinical professor; research associate), then a letter from the Dean (or equivalent official) must be provided to confirm that upon award, the contact PI/PD will become and remain less than half-time at the university for the duration of the SBIR project. This requirement is to ensure that more than one half of the contact PD/PI's time is available to be spent in the employ of the SBC.

The STTR program, in contrast, is structured to facilitate *cooperative* research, development, and technology transfer between a SBC and a U.S. non-profit research institution. That is,

the SBC must partner (via a subcontract) with a non-profit university, a university-affiliated hospital, a federally funded research and development center (FFRDC), or a qualified non-profit research institution. In Phases I and II, at least 40% of the research effort must be performed by the SBC and at least 30% must be performed by the single, partnering research institution. Because the research effort is split between the SBC and the research institution, the STTR program requires a written agreement between the SBC and research institution for allocation of intellectual property rights and rights to carry out follow-on research and development. An example of an STTR Model Agreement is available as a Microsoft Word document at NIH's website (<http://grants.nih.gov/grants/funding/sbir.htm>).

In the STTR program, the primary employment of the PI/PD is not stipulated. The PI/PD may be employed by the SBC or by the partnering university or research institution as long as there is an official relationship between the SBC and the PI/PD. If the PI/PD is from the university or research institution, he or she is not required to receive a salary from the SBC, but the PI/PD must commit a minimum of 10% effort to the STTR project. If the PI/PD is employed at a university, the determination of the official relationship and percent effort will be verified prior to funding. Though not required, a letter of support provided by the Dean (or other university official) to support the PI's/PD's commitment of a minimum 10% effort to the STTR project should be submitted with the grant application.

Is the SBIR or STTR an Appropriate Mechanism for Your Research?

As nurse researchers, we are familiar with the many R-series funding opportunities defined by the NIH including the R03, R15, and R21, which provide funding for small scale projects and developmental, exploratory research, and the R01, which provides funding for larger scale studies, longitudinal research, and clinical trials. However, less well-known is the funding that is available through the SBIR and STTR programs. Although applications for SBIR and STTR awards must come from SBCs, nurse researchers can play a key role in collaborating and partnering with SBCs to develop and test innovative products or services that can advance nursing science and improve health care. So, how do you determine if an SBIR or STTR is an appropriate funding mechanism for your research? In addition to the obvious questions of whether the amount of time and money available are sufficient to accomplish your research aims, you should ask yourself these five questions:

- What product or service will be developed?
- Does this product or service have potential for commercialization?
- Will the work done in Phase I lead to work in Phase II?
- Who owns the product or service?
- Do you have a small business partner?

In the academic world, research and scholarly activities often generate knowledge products and services that have great potential for commercialization. Most nurses don't think about commercialization of knowledge products and services, but commercialization through SBIR and STTR awards is a legitimate and effective way to translate research into practice. To compete successfully for an SBIR or STTR award, you must clearly describe the product or service you plan to develop or test. Then you must articulate the deficiency in the market that the product or service addresses, target customer(s), competitors in the market, and how your product or service improves on what competitors offer. Also, you must clearly describe how work in Phase I will lead to Phase II and the measurable milestone(s) that will indicate success in Phase I and will justify progression to Phase II. Finally, you must delineate who owns the product or service and who will be your small business partner. You may currently be working with someone who qualifies as a SBC (JJM & CJF; DJW). Or you may need to

seek out a SBC that would be a good match for your ideas (EBH & CES). It is even conceivable that a faculty member owns a small business (DJW) and can identify another qualified individual as PI/PD.

Unique Features of SBIR and STTR Funding Mechanisms

An important way in which SBIR and STTR grants differ from other R-series grants is the need for plans to deal with intellectual property and conflict of interest. Additionally, marketing and commercialization of the produce or service are vital for SBIR and STTR grants.

Intellectual Property

A key element for an investigator to decide the appropriateness of the SBIR or STTR mechanisms is the status of the intellectual property ownership for the product or service. As defined by the World Intellectual Property Organization (2010), an agency of the United Nations, the term intellectual property refers broadly to the creations of the human mind. Intellectual property law is typically divided into two branches: industrial property, which protects inventions and copyright, which protects literary and artistic works. The major difference is that an invention is defined as a product or a process that provides a new way of doing something or offers new solutions to technical problems. These new solutions or “ideas” can be protected by a patent if they fulfill certain legal criteria. On the other hand, copyright law protects only the “form of expression” of ideas, not the ideas themselves. Examples of nursing inventions include new devices, methods of treatment, interventions, educational programs, and patient care tools.

In SBIR and STTR projects, new product or service ownership belongs to the entity (person, business, non-profit organization) that first conceives and creates the product or service. Ownership of products or services developed with grant funds belong to the grantee (e.g., business, university) not to the PI/PD of the grant. Many universities, however, have policies for distributing revenue from products or services to the units and people that contributed to development of the product or service. Ownership of the product or service that belongs to a business is consistent with the appropriateness of the SBIR program for further research and development, perhaps with a subcontract to a university for needed expertise. In contrast, ownership residing with a university or other organization can be transferred (sold or licensed with a contractual agreement) to a business, which would be consistent with either the STTR or SBIR programs for further research and development, depending upon which entity provides the PI/PD.

Ownership by a faculty member of products or services never entangled with a university presents several opportunities for the faculty member. First the faculty member can share ownership with the university by negotiating a contractual agreement to collaborate with a small business and apply for support from the STTR program. Second, as an individual the faculty member can license the product or service to a small business and apply for support from the SBIR program. Third, the faculty member can form a small business, hire a PI/PD, and apply for support from the SBIR program. This third opportunity requires the faculty member to become a business owner with a business plan that addresses appropriate capital, facilities, personnel, legal advice, and market analysis. Before one submits a SBIR or STTR application, it is important to know how involved one wants to be in a business and who owns the intellectual property for the product or service.

Conflict of Interest

For the faculty member, academic organization, and small business, the entrepreneurial goals of SBIR and STTR programs produce potential for conflict of interest. The SBIR/

STTR programs' emphasis on commercialization of products and services means there is potential financial gain for all individuals and entities, which means there is potential for scientific integrity to be influenced by financial incentives. Similar to other R-series grants, for all SBIR/STTR Phase II awards, NIH requires academic organizations and businesses to manage the potential conflict. Conflict management plans must follow the organization's policies and must focus on reducing potential for bias to influence the scientific integrity of the research. For example, potential subjects are informed of the potential financial gain before they consent, persons with conflict do not consent subjects and do not conduct primary data management and data analysis, or external reviewers inspect study findings to reduce inappropriate interpretation. The amount of potential financial gain influences the parameters of the conflict management plan. Small business owners who also are faculty members are likely to have substantial restrictions on their involvement in the research process to reduce potential for bias motivated by financial gain. NIH also requires Institutional Review Boards, including private ones that often review commercial research, to address potential for conflict, which means the business entity must also consider ways to demonstrate that financial gain incentive will not bias Phase II SBIR/STTR research, especially data analysis and interpretation. Transparencies are required in the research process to minimize bias influenced by financial motives that are inherent in the SBIR/STTR research funding mechanism.

Marketing and Commercialization

The marketing and commercialization goals of the SBIR/STTR programs are important for both Phase I and Phase II applications. A market analysis must be completed before either application is submitted to show potential for the product or service to be commercially viable. The market analysis cannot be part of the research plan or supported by Phase I or Phase II funds. The Phase I application should include the market analysis and show the potential sales that can be expected if the Phase I feasibility benchmarks are met and the product or service is developed and commercialized after Phase II. A fully developed commercialization plan is required in the Phase II application, including agreements for production, marketing, and distribution with other entities if the SBC does not have such capacity. A strong case for the potential revenue stream based on the market analysis, production and marketing costs, and evidence for the proposed pricing structure also enhances the Phase II application, especially since a goal of the SBIR/STTR programs is to help small businesses add to the nation's economy.

The thought of doing a market analysis or of commercializing their ideas may deter some nurse researchers from pursuing the SBIR or STTR grant mechanisms. Indeed, some nurse researchers may be wary of the term "for profit," because their personal experience too often suggests "for profit" comes at the expense of patient care. Yet the purpose of the SBIR/STTR programs is to fund projects and ideas that ultimately are profitable – because, ideally, the projects that are funded help create, sustain, and grow jobs and even businesses.

The SBC with whom you are working should be knowledgeable about marketing and commercialization in general. But you will have unique knowledge about the marketplace that they do not have. A simple way to think about market analysis and a marketing plan is to use the analogy of fishing. Imagine you want to spend the day catching lots of fish. Without realizing it, you would probably put an informal "marketing plan" together before you began your day. You would begin by asking (and answering) many different questions, all designed to get yourself a basket of fish by the end of the day. For example, where would you fish? You would avoid dry stream beds, lakes, or ponds absent fish. You would avoid fishing in crowded waters where the chance of catching something is more limited. Perhaps you would choose an isolated spot where you could verify that fish were, indeed, present. In business, this is called primary research. You investigate to see if a market exists for the

product or service you wish to sell. This research can be as simple as reading many articles to see if a need exists for your product or service, or it can be more elaborate and comprehensive. For example, you might check with other fishermen, to query where the best biting was on any given day. In business, this is called a “focus group” approach in which you ask potential customers if they would purchase what it is you are trying to sell and under what circumstances. This focus group approach can be done by email, by discussion board, or by paying a market research firm. The idea is to determine whether a need exists, whether your product or service fills that need, whether customers are willing to pay for your product or service, and where those customers are.

Evaluation Criteria for SBIR and STTR Projects

SBIR and STTR applications are reviewed by study sections using the same criteria as for other grants, such as NIH's other R-series funding mechanisms (i.e. R01, R03, R15, R21): significance, investigators, innovation, approach, and environment. However, the focus of the review is on the *product or service* that is being developed or tested as well as on the *science*. For example, the significance of the project is not only focused on whether the study addresses an important problem but also on whether the product or service is marketable, has commercial potential, and whether the technology has a competitive advantage over existing technologies. Significance is also addressed in terms of societal benefit from the product or service and future advancement of scientific knowledge and discovery.

The investigators must be qualified in terms of experience, knowledge, and skills for coordinating and managing the proposed SBIR/STTR project. And the relationship between the PI/PD and the SBC must be appropriate and meet the criteria previously described (see section on eligibility). If a SBC does not have an experienced individual to serve as PI/PD, it will need to hire someone who can serve that role or partner with an experienced investigator from a research institution or university. This need is often how nurses become involved in SBIR/STTR grant applications. In fact, the NIH hosts a website whose sole purpose is to foster collaborative opportunities within the SBIR/STTR programs (<http://grants.nih.gov/grants/funding/corp.htm>). The SBIR/STTR Collaboration Opportunities and Research Partnerships (CORP) website posts information from SBCs in need of a researcher with a specific area of expertise and from researchers with an idea or area of expertise in need of a SBC as a collaborative partner. NIH reviews information submitted regarding expertise needed and expertise provided before the data are added to the list.

To evaluate innovation of the SBIR/STTR project, reviewers look for creative hypotheses that challenge existing models and novel approaches or original methods used in the development or testing of the product or service described in the SBIR/STTR application. Successful SBIR/STTR applications typically frame innovation in terms of whether the product or service represents new technology, a significant improvement over existing technology, or a new application of existing technology.

The approach for accomplishing the aims of the proposed SBIR/STTR project is evaluated in terms of the underlying conceptual framework and its integration with the design, methods, and analysis components of the research. The applicant should identify potential problems or pitfalls and consider alternative strategies and remedies. The research plan should provide a clear description of how technical and commercial feasibility will be established, including the articulation of clear and measureable milestones and evaluation procedures.

Finally, the environment will be evaluated for quality of performance of the SBC and for sufficient access to resources, including equipment and facilities. Both the SBC environment

and the environment of the partnering research institution or university will be assessed and evidence for institutional support and presence of appropriate collaborative agreements will be evaluated. Reviewers will also look for evidence of likelihood of a successful collaboration between the SBC and the partnering research institution or university.

Critical Partners

For nurses employed in academic settings, the success of the research will rest heavily on having an appropriate SBC partner – one who appreciates the science and who can seize business opportunities when they arise. Business and academia have very different cultures (think Mars versus Venus) so it is vital to identify and resolve fundamental differences in priorities, values, and work styles that may interfere with implementation of the research project. You must learn to speak each other's language, to capitalize on the strengths and skills of each partner, and to collaborate on sensitive issues, particularly money. In general, academic settings move at a slower pace, focus on basic and applied research, are risk-averse, and have multiple missions of education, clinical practice, and research. Conversely, businesses generally move at a faster pace, focus on research that solves problems, take calculated risks, and have a single mission to develop new products or services that will turn a profit.

Another critical partner is your university Office of Technology Transfer or Intellectual Property Office, which is responsible for assisting inventors, authors, and other creators of intellectual property in the process of intellectual property (IP) disclosure, protection, marketing and licensing. If you are submitting an STTR application, this office will help you draft the intellectual property agreement between your institution and the SBC. If other investigators in your institution have previously submitted SBIR or STTR applications, the Grants Management Office will have experience to assist you with such unique aspects of the SF 424 application as the SBIR/STTR Information Form, the letter of contractual agreement, and other issues that arise when the SBC is the applicant organization. Finally, you may need to involve other academic or research partners or other industry contacts as consultants in the project.

Resources for Proposal Development

Writing a grant application is always a time-intensive effort and this is true for SBIR/STTR applications. Even for nurses who are experienced grant-writers, this type of research will present some challenges. However, there are many resources available. One of the first things you should do is talk with one or more previous SBIR/STTR recipients within or outside your institution. Ask if you can read their SBIR or STTR applications and perhaps their summary statements. Writing an SBIR or STTR requires a shift in your thinking and in your writing style. Because the NIH review group will include individuals with both business and health care backgrounds, you must sell your product or service as well as your science. Reading other people's applications will help you develop the skills to do this, even if their topic area is completely different than your own. If your academic or research institution provides consulting funds, it is also beneficial to have an external reader who has experience with SBIR/STTR applications critique your proposal before you submit it.

Another excellent resource is the NIH SBIR/STTR website (<http://grants.nih.gov/grants/funding/sbir.htm>). It is filled with information to help SBCs navigate the grant application process – from how to register on the eRA Commons site to numerous downloadable files on writing and submitting the application and a variety of technical assistance programs that provide SBCs with commercialization, marketing, and manufacturing assistance specific to their needs. The NIH website is also an excellent resource for nurse researchers who are familiar with the grant application process but who need to understand the nuances of the

SBIR and STTR programs. To see numerous examples of funded projects, the SBIR and STTR Success Stories website (http://grants1.nih.gov/grants/funding/sbir_successes/sbir_successes.htm) provides a brief description of each project, the technology, product, or service developed, and how it was commercialized.

Finally, consider getting independent consultation to assist with developing your SBIR or STTR application. One of the co-authors (JJM) attended a two-day workshop on NIH SBIR/STTR grants and contracts sponsored by Biotechnology Business Consultants (<http://www.bioconsultants.com>), a company that assists SBCs and non-profit institutions to design and implement grant development programs. This two-day session provided detailed information on the core principles of preparing fundable SBIR/STTR applications including application preparation and submission, the review process, common problems and how to avoid them, preparing a marketing and commercialization plan, and post-award grants management.

Characteristics of Successful Partnerships

Similar to other research teams, SBIR/STTR applications and implementation processes benefit from common goals and expectations, transparency, and respect for strengths of team members. Written specification is critical and should include what all team members are expected to do during the application and implementation process, how they will be rewarded financially during the product development and testing phases, and financial responsibilities and rewards when the product is commercialized. Respect for intellectual property is needed and documented with written agreements. Unless stipulated by contracts, all intellectual property derived from the SBIR/STTR award belongs to the small business, including new intellectual property created during the award. Transparency regarding intellectual property ownership is needed at all times to assure that optimal innovation can occur during the project and be rewarded financially when the product is commercialized or new products are conceived. Agreements that promote gain for all team members enhance successful partnerships among the nursing faculty, academic institution, and small business as they partner to create innovations, knowing that they will all benefit from the commercialization of the product or service.

Examples of Successful SBIR/STTR Funded Research Projects

This section provides a brief description of four SBIR and STTR projects conducted by the authors. Table 3 summarizes key features of funded SBIR and STTR studies.

Example 1: PAINReportIt® (Diana J. Wilkie)

In collaboration with Nursing Consult, LLC, a company based in Seattle Washington, M. Kay M. Judge, EdD, RN (owner) and Diana J. Wilkie, PhD, RN, FAAN (faculty then at the University of Washington, UW and now at the University of Illinois at Chicago, UIC) conducted a Phase I SBIR study (1R43 NR04742) to demonstrate feasibility of an innovative computerized pain assessment tool, PAINReportIt.® This tool was Dr. Wilkie's intellectual property (IP) and she and Dr. Judge created eNURSING llc and both assigned their IP to this company for Phase III marketing and distribution. Successful demonstration of feasibility testing led them to conduct a Phase II study (1R44 NR04742) to test adoption issues and outcomes when PAINReportIt® was used in outpatient oncology clinics in an integrated health care system located in Tacoma, WA. After successful completion of the Phase II study, the PAINReportIt® product was marketed by eNURSING llc and used in Dr. Wilkie's research at the UW (2 R01 studies) and UIC (3 pilot studies, 3 R01s, and an international collaboration study in Taiwan). In August 2008 when conflict management issues at UIC became overwhelming, eNURSING llc transferred ownership of

PAINReportIt® back to Nursing Consult, LLC, the company that is now marketing the product (801-414-0627). Numerous publications report the findings of the PAINReportIt® studies (Huang et al., 2003; Jha et al., In press; Judge, Luedke, & Wilkie, In review; Page, Weaver, Wilkie, & Simuni, 2009; Wilkie, Huang, et al., 2001; Wilkie et al., 2003; Wilkie et al., 2009; Wilkie et al., In press). In 2005, PAINReportIt® received the Information Technology Award for Clinical Nursing Applications from Sigma Theta Tau International Honor Society of Nursing.

The team faced a challenge at the beginning of the Phase II study when the university-affiliated cancer center learned their institution had made a policy to disallow subcontracts for SBIR studies. All of the pre-award arrangements and plans for the adoption and implementation of the product within a clinical cancer setting in Arizona became irrelevant. Building on collaborations in Seattle, the team recruited a new setting in Tacoma, WA and moved the study from Arizona to Tacoma. Study implementation was also affected by the organization's interpretation of HIPAA (Health Insurance Portability and Accountability Act) regulations. Instead of implementing the study in the reception area, the research consent process was required by the organization to be done in a private room. The team completed the study but was not able to determine if the reception and waiting-room plans for implementing the product would be a viable clinical option.

Example 2: Internet-Based Education on End-of-Life Issues for Mental Health Providers (Diana J. Wilkie)

Building on successes of TNEEL (Tool-kit for Nurturing Excellence at End of Life; Wilkie, Judge, Wells, & Berkley, 2001), Dr. Wilkie and eNURSING llc partnered with the American Psychological Association (APA) to develop an Internet-based educational program on end of life for psychologists and other mental health professionals. Prior to submitting the Phase I SBIR application, eNURSING and APA executed a memorandum of understanding that would serve as the basis for subcontract agreements for Phase I and Phase II research activities and a distribution agreement for Phase III when the product would be fully developed and ready to market and distribute. The Phase I research was funded (1R43 MH070226) and completed with a one-module prototype tested for acceptability by the target population. Success in meeting the Phase I benchmarks supported the Phase II application, which was funded (1R44 MH070226). In Phase II, the team produced 10 modules for Internet delivery, 10 text-based modules with the same content as the Internet modules, and completed a randomized controlled trial of the two learning methods (Internet versus text-based learning) with 552 participants. The Phase II study showed similar knowledge gains in both learning conditions but better acceptability outcomes in the Internet condition. The final product, a 10-module Internet-Based Education on End-of-Life Issues for Mental Health Providers, was completed in August 2009 and is now available for continuing education offered by APA (<http://www.apa.org/ce/eol.html>). eNURSING llc will receive quarterly royalty payments from APA based on per module use for five years, when the distribution agreement will be renegotiated. Two manuscripts reporting Phase I and Phase II findings are nearly ready for submission.

The team faced a challenge when they learned the Phase II study would be funded and the PI changed his mind about leading the study. The project director from the Phase I study had just completed her dissertation so the team recruited her to serve as the PI for the Phase II study. This change in plans required her to have a 51% appointment with eNURSING llc as PI and a 49% appointment with the APA as project director. The role combination was challenging but she applied her skills and talents masterfully to complete the study. In the first four months of commercialization, 184 different users have purchased 440 modules from the APA website.

Example 3: Living With Heart Failure (Elizabeth Blanchard Hills and Carol E. Smith)

The research team for SBIR 1R43 AG17007 “Heart Failure: Videotape Education for Older Adults” included Elizabeth Blanchard Hills (PI), an experienced health news reporter, Carol E. Smith, RN, PhD (Co-I), an experienced nurse researcher, and videographers. Their relationship was facilitated when Blanchard, seeking a research partner, was introduced to Smith by the director of the Technology Transfer Office at the University of Kansas. The team created a series of DVDs and printed materials entitled *Living with Heart Failure*, which aimed to improve the self-management skills of patients. Part of the work that was achieved under the auspices of this SBIR subsequently led to a current NIH clinical trial entitled “Rehospitalization Prevention Clinical Trial,” 5R01 HL085397 (Carol E. Smith, PI).

At the start of the project, one of the challenges for the team was language and process. The principal investigator, Blanchard, came from the for-profit world of small business ownership. The nurse investigator, Smith, came from the world of academia and science. In addition, Smith had more experience functioning within the constraints and resources of a large organization. A story the team now remembers fondly caused a bit of consternation initially: When faced with the task of getting IRB approval, Blanchard (whom had not yet heard the phrase “IRB approval”) called the associate chancellor of the University, assuming he could expedite the approval process. He did – by calling Smith and asking her to “get a handle” on her rogue principal investigator! She did, they moved forward, and today they laugh about the incident.

Living with Heart Failure uses visual illustration, simple memory aids, and layman's language to improve learning outcomes of heart failure patients and their family members. The videos focus on “real life” situations and problems, and offer appropriate strategies for dealing with heart failure. For example, scenes show patients how to recognize and report edema, and how to increase medication compliance. The videotapes/DVDs were finalists in the 2007 International Freddy Awards, which recognize outstanding work in the field of video-based patient education. Other finalists included CNN and the Discovery Channel.

The research team used scientific and educational theory standards in creating the videos. Content is based on a combination of evidence-based American College of Cardiology/ American Heart Association National Guidelines, JCHAO Discharge Criteria, as well as additional input from heart failure patients and their family members. Early drafts were tested in focus groups with cardiologists, cardiac nurse practitioners, and discharge planners. Research with 18 heart failure patients and family members revealed they identified with the situations in the videos, and correctly identified self-management guidelines.

Living with Heart Failure was then tested on a small group of recently discharged heart failure patients. Results from the pilot study showed an increased awareness of heart failure self-care management, coupled with a decrease in hospital readmissions. The pilot study was published in *Clinical Nursing Research* (Smith, Koehler, Moore, Blanchard & Ellerbeck, 2005). In previous studies, Smith produced other award-winning video education series that were verified in clinical trials to improve patient outcomes (Smith et al., 2003; Smith, 2007). The target audience for the videos created under the SBIR grant comprises hospital discharge planners, home health agencies, cardiology offices, and health care insurers. The company successfully marketed the series to a large home health care agency in Texas, and continues to seek a strategic alliance with a large pharmaceutical company. It has not yet received a Phase II award.

Example 4: Using Technology to Deliver Evidence-Based Interventions to Caregivers of Persons with Alzheimer's Disease (Judith J. McCann and Carol J. Farran)

Family care for persons with Alzheimer's disease and other dementias is a growing public health concern and caregivers need appropriate, timely, and ongoing training to successfully meet their caregiving responsibilities. The NIH has invested considerable financial resources into testing caregiver interventions. However, few successful interventions are translated into everyday practice and most reach only a small proportion of caregivers. This project used the STTR funding mechanism to translate the content of an evidence-based intervention conducted by members of the research team (Farran et al., 2004; 2007) from a group-based, face-to-face format to a web-based format so that it can reach a much larger and more diverse number of caregivers of persons with Alzheimer's disease and other dementias.

This STTR Phase I project (1R41 AG032159) is a collaboration between Upstairs Solutions, LLC (Joel Ehrlich) located in Skokie, IL and researchers (Judith J. McCann, PhD, RN and Carol J. Farran, DNSc, RN, FAAN) from the College of Nursing, Rush University Medical Center in Chicago, IL. Upstairs Solutions, LLC is a small business dedicated to the design and delivery of high-quality online health care training products, specifically for nurses and other staff working in long-term care settings. Drs. McCann and Farran have extensive experience in observational and intervention research related to family caregiving and Alzheimer's disease. Prior to submitting the STTR application, Dr. McCann had consulted with Upstairs Solutions as a content expert to help them develop several online modules on dementia care in nursing home and assisted living facilities. When Drs. McCann and Farran decided they wanted to develop an online version of the caregiver intervention, they approached Upstairs Solutions about becoming their partner in an STTR Phase I application. The collaboration benefited both partners. Drs. McCann and Farran capitalized on Upstairs Solutions' expertise in development of high-quality healthcare online training and education products and Upstairs Solutions acquired new business opportunities that were consistent with, but outside of, its core market.

The long-term goal of this STTR project is to develop and test web-based technology (eLearning) for family caregivers of persons with Alzheimer's disease and other dementias that will increase their competency to provide care and improve their mental health. We are currently in Phase I, which is designed to develop two prototype modules and to examine feasibility and preliminary effectiveness of the modules. Important questions addressed in Phase I are:

1. Can the content of a face-to-face, group-based intervention be successfully translated to a web-based format?
2. Will family caregivers respond positively to the web-based learning experience?
3. Are web-based caregiver interventions effective?

In Phase II, we will develop the remainder of the intervention modules, develop Spanish language versions of these modules, and conduct a randomized controlled trial with white, black, and Hispanic caregivers to determine effectiveness of these modules to improve caregiver knowledge and skills, decrease caregiver stress, and improve long-term caregiver mental health outcomes. Ultimately, the product that will be developed in Phase II (*Caregiver Take Care!*) will fill a unique niche in the commercial caregiver support market that can reach a diverse population of family caregivers, including working, isolated, minority, and other underserved caregiver populations.

One challenge the team faced on this project was different views about how to allocate funds for the research assistant who would be responsible for: 1) assisting with module

development; 2) recruiting and enrolling caregivers into the study; 3) monitoring completion of online modules and data collection; 4) conducting qualitative telephone interviews after caregivers viewed the modules; and 5) assisting with analysis of qualitative data. Initially, all agreed that the full-time research assistant would work under the direction of Dr. McCann and split her time between the SBC and university locations. When it came time to sign off on the sub-award contract, however, the SBC asked to reconsider this decision. They were in need of a part-time assistant for their business. If they had STTR funds for a half-time research assistant, they could hire a well qualified full-time assistant who could split her time between the SBC and the STTR project. McCann resisted this initially because the decision was not ideal for accomplishing the work of the research project. However, in the interest of maintaining a collegial partnership, McCann agreed to the new arrangement. It created some problems because McCann had to train and supervise two research assistants working in two locations and the team had to decide how to split the workload between the two part-time research assistants. This willingness to compromise paid off because the SBC devoted additional resources to module development and to instituting system processes that streamlined the research project.

Conclusion

SBIR and STTR mechanisms are excellent sources of funding for nurse researchers who want to capitalize on relationships with small businesses or obtain seed money to fund high risk projects with potential to attract new venture capital. These funds are viewed by NIH as an “underutilized pool of money” (J. McCann, personal communication, April 2007) and funding success rates of SBIR and STTR applications are historically higher than other R-series grants. In 2008, the success rate for SBIR/STTR applications was 28.7% overall (25% for Phase I and 46.6% for Phase II applications; NIH, 2008b). In that same year, success rates were 19% for R01s, 22% for R03s, 26.3% for R15s, and 16.5% for R21s; NIH, 2008a).

Nursing faculty members have substantial intellectual property that they may own or own with other people and academic organizations. The products from that intellectual property can be commercialized to benefit society and the owners of the intellectual property. The SBIR and STTR programs offer attractive funds to develop nursing knowledge products that also can be used in our research. And because most small businesses know how to market, partnering with a small business gets these nursing knowledge products into practice more quickly and efficiently. Synergy between business and academic goals can feed scholarly and financial success. Establishing and honoring conflict management plans is essential for transparency in science that minimizes bias yet maximizes financial gain from the scientific enterprise. Nurse scientists are well positioned to balance the competing demands in an ethical environment that also values financial profit.

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Table 1

What is a Small Business According to the SBIR/STTR Program?

-
- Is a for-profit company
  - Located or operated primarily in the U.S.
  - Is at least 51% U.S. owned or controlled
  - Has fewer than 500 employees
  - Not dominant in the field in which it is proposing the research
-

Table 2

Comparison of NIH SBIR and STTR Programs

	SBIR	STTR
Structure	SBC can independently engage in federal research and development	Facilitates cooperative research, development, and technology transfer between a SBC and a U.S. non-profit research institution
Subcontractors	May have subcontractors involved	Must have a non-profit research institution involved as subcontractor
Phase I Level of Effort	At least $\frac{2}{3}$ of the research effort must be performed by the SBC	At least 40% of the research effort must be performed by the SBC
	Maximum of $\frac{1}{3}$ of the research effort may be performed by consultants and/or subcontractors	At least 30% of the research effort must be performed by the non-profit research institution
Phase II Level of Effort	At least $\frac{1}{2}$ of the research effort must be performed by the SBC	At least 40% of the research effort must be performed by the SBC
	Maximum of $\frac{1}{2}$ of the research effort may be performed by consultants and/or subcontractors	At least 30% of the research effort must be performed by the non-profit research institution
Principal Investigator or Project Director	Primary employment (> 50%) must be with the SBC	Primary employment may be with the SBC or the partnering research institution
		PI/PD must commit at least 10% effort to the project
Intellectual Property	Intellectual property belongs to the SBC	Intellectual property agreement required between the SBC and research institution
Project Duration	Phase I: Approximately 6 months Phase II: 2 years	Phase I: Approximately 1 year Phase II: 2 years
Maximum Award Amount	Phase I: \$100,000 (includes 7% fee to SBC) Phase II: \$750,000 (includes 7% fee to SBC)	Phase I: \$100,000 (includes 7% fee to SBC) Phase II: \$750,000 (includes 7% fee to SBC)

Key: SBC = Small business concern

Table 3

Examples of Four SBIR/STTR Projects

Investigators	SBIR/STTR (Awarding Agency)	Phase	Research Focus	Small Business Partner	Goals or Aims	Product or Service Developed
M. Kay M. Judge (PI) Diana J. Wilkie (Co-I)	SBIR (NINR)	Phase I	Pain assessment in patients with cancer	Nursing Consult, LLC Company provides education, consultation, and research related to the management of commonly occurring pain, and wound/ostomy issues	1) Describe PAINReportIt® feasibility 2) Conduct 6 to 8 focus groups on PAINReportIt® receptivity 3) Use data from tasks 1 and 2 to build beta version of PAINReportIt® on CD ROM	PAINReportIt®, an alpha version, interactive software program to help patients describe and document their pain as a multidimensional experience
		Phase II			Assess organizational implementation issues and outcomes, clinician behavior, and patient outcomes that follow adoption of PAINReportIt®	PAINReportIt® available on CD ROM for purchase at 801-414-0627
Karen Brown (PI) Diana J. Wilkie (Co-I) John Anderson (Co-I)	SBIR (NIMH)	Phase I	Web-based end-of-life education program for mental health providers	eNURSING llc Company develops evidence-based electronic and online tools for patient-centered health care, health care provider support and education.	1) Assemble an Advisory Board 2) Develop one module as a functional prototype for the end-of-life (EoL) program 3) Describe feasibility and acceptability of the training program through content analysis of two, 8-person focus groups	Demonstrated feasibility of one module
Martha Mihaly (PI) Diana J. Wilkie (Co-I) John Anderson (Co-I)		Phase II			1) Revise the functional EoL prototype module 2) Develop nine additional modules 3) Develop a 10-module self-study package 4) Compare the two learning conditions (Internet EoL vs. text-based) in 300 psychologists and mental health workers for effectiveness and appeal	10 module program, <i>Internet-Based Education on End-of-Life Issues for Mental Health Providers</i> , developed and tested and now offered for continuing education by the American Psychological Association with royalties paid to eNURSING llc
Elizabeth Blanchard Hills (PI) Carol E. Smith (Co-I)	SBIR (NIA)	Phase I	Self-management in older adults with heart failure	InformMED Company develops branded patient educational materials	1) Produce a series of four instructional videotapes and their associated printed materials for post-hospitalization congestive heart failure patients	Available at http://search.apa.org/continuing education?query=&facet=cformat:End-of-life%20issues%20and%20care <i>Living with Heart Failure</i> , a series of DVDs and printed materials to improve self-management skills of patients with heart failure Available for purchase or license at 913-485-0387

Investigators	SBIR/STTR (Awarding Agency)	Phase	Research Focus	Small Business Partner	Goals or Aims	Product or Service Developed
Judith J. McCann (PI) Carol J. Farran (Co-I) Joel Ehrlich (Co-I)	STTR (NIA)	Phase I	Education and training for family caregivers of persons with Alzheimer's disease and other dementias	Upstairs Solutions, LLC Company develops and markets online educational materials to address the training and compliance needs of long-term care facilities	2) Evaluate response to these instructional materials relating to their content, intervention timing, ease of use, clarity, and perceived motivational impact 3) Recommend improvements in the materials and the protocol for a Phase II study	<i>Caregiver Take Care!</i> , two web-based, interactive, multimedia training modules to help family caregivers manage behavioral symptoms of dementia
1) Develop two prototype online training modules 2) Conduct usability testing and formative evaluation to assess feasibility 3) Conduct summative evaluation research to examine preliminary effectiveness						

Key:

- NINR = National Institute of Nursing Research
- NIMH = National Institute of Mental Health
- NIA = National Institute on Aging
- LLC = Limited Liability Corporation