SBIR & STTR Writing a Winning Proposal – Physical Sciences



PHASE I APPLICATIONS



About SBIR/STTR Assistance

The Nevada Governor's Office of Economic Development provides assistance to companies in the preparation and submission of SBIR/STTR proposals

The goal is to increase the number of proposals submitted and grants awarded under the SBIR/STTR program to Nevada technology-based small businesses

APIO Innovation Transfer (APIOiX) works in partnership with UNLV's SAGE program (<u>https://www.unlv.edu/econdev/sagesouth</u>) to assist technology-based small businesses (<u>https://apioix.com/sbir-assistance</u>)

- Assessment of the business concept
- Guidance for registration of the company
- Review and input on project pitches and proposals
- Assistance in submitting the proposals



About APIOiX

Programs, Services, and Solutions to Accelerate Innovation Ecosystems

APIOiX accelerates innovation through business development, training, and technical assistance to innovators and inventors at universities, small businesses, and government entities across the globe.





Eligibility for SBIR/STTR Funding

"America's Seed Fund" Technology based Diverse portfolio Commercial application Non-dilutive funding

STTR requires partnership with a research institute The Nation's largest source of early stage/high risk funding for start-ups and small business

 In the words of program founder Roland Tibbetts: "to provide funding for some of the best early-stage innovation ideas; ideas that, however promising, are still too high risk for private investors, including venture capital firms."





Small Business Technology Transfer Program (STTR)

An STTR project requires the small business, to be teamed with a non-profit research institution

- The applicant is always the small business
- However, the PI for the project can be from the research institution
- The small business and the research institutions must be US based
- The narrative should clearly state what work is done where
- Each entity will need their budgets and budget justifications entered separately





Preparing your Company

Incorporate (LLC is most common followed by "C" Corp.)					
Apply for and obtain EIN					
Register in SAM.gov and obtain UEI (Unique Entity ID) -					
https://www.sbir.gov/sites/default/files/Company_Registration_Guide.pdf					
ADDITIONAL REQUIRED R	EGISTRATION	IS AND SUBN	AISSIONS		
	NASA	HHS	NSF	DOE	DOD/DARPA
Electronic Handbook (EHB)					
eRA Commons					
GRANTS.gov					
NSF Fastlane					
Portfolio Analysis and Management System (PAMS)					
FEDCONNECT.gov					
Funding Accountability and Transparency ANCT					
Subaward Reporting System					
DOD Submission Website					



Preparing your Company – Common Errors

Find the right FOA / study section

Find the right instructions

- The FOA and associated guide need to be followed
- Forms may vary from one FOA to another
- Follow font and margin requirements
- Biosketch format needs to be followed

Upload the right documents to the right place

Ensure that all required documents are included



Preparing your Company – General Tips

SBIR/STTR awards are not academic grants

Eligible to receive award

Product definition – unfulfilled need/customer/market

Right team to develop the product

Resources and time to write the proposal

• Be prepared for writing (150 to 450 hours of work) – Success rate is about 15%

Fits the business objectives

Fit with a specific funding opportunity announcement (FOA)

- Understand the goals of the program/solicitation and the review criteria
- Talk to agency program managers

Phase I or Phase II or Fast Track







Reviewing time

Discussion time

Reading proposals is hard work

Complex nature of the technology

Jargon, definitions, concepts, unfamiliar words

<u>Therefore, keep the language, structure, flow, simple</u> – make it easy for the reviewers



Writing tips

Writing style – APA style guide (<u>https://apastyle.apa.org</u>)

American (English) grammar

Short sentences

Avoid jargon

Define terms

Consistent use of terms, abbreviations, and phrases

Judicious use of underlining/bold

DO NOT change fonts



Writing Tips

Negative versus positive statements

Avoid Long sentences

"Moreover, our most dramatic findings (extremely high efficacy of the novel pro-drug JD216 in anti-proliferative assays, the demonstrated capacity of PARTHEX compounds to be anti-proliferative in drug-resistant and difficult-to-treat models (Tamoxifen resistant, Herceptin-resistant and HER2-overexpressors)) and their ability to sensitize these resistant cells to established chemotherapeutics provide a scientific justification for moving forward as rapidly as possible."

Vs

The high efficacy of our lead compound, JD216, in anti-proliferative assays for Tamoxifen resistant, Herceptin-resistant and HER2-overexpressors breast cancer models provides a scientific justification for moving forward as rapidly as possible.

Avoid confusing language

- Double, triple negatives
- "Not only..."

Essential information needs to be included



DOE Program Areas





Components of a Proposal – DOE Phase I

90-day process

DOE merit review criteria – initial administrative review

Meets the stated Funding Opportunity Announcement (FOA) requirement – consistency with mission,

policies, and other strategic and budget priorities

- Identifies a topic and subtopic from the FOA
- Contains sufficient information for a meaningful technical review

Research versus development

Does not duplicate previous or current DOE-funded work



Components of a Proposal – DOE Phase I

DOE merit review criteria – technical merit review (each section is equally weighted)

- Strength of the Scientific/Technical Approach
- Innovativeness of the idea and the approach
- Significance of the scientific or technical challenge
- Thoroughness of the presentation
- Ability to competently carry out the project
- Qualifications of the PI, other key staff, subcontractors and consultants,
- Level of adequacy of equipment and facilities
- Soundness and level of adequacy of the work plan
- Proposed research effort is justified by DOE investment \$\$

Impact

- Significance of the technical and/or economic benefits of the proposed work, if successful
- Likelihood that the proposed work could lead to a marketable product or process
- Likelihood that the project could attract further development funding
- Appropriateness of the data management plan for the proposed work



DOE Reviewers

Organization	Percentage of all reviewers
Business and industry	12
DOE national laboratories	46
Government	10
Universities	32



DOE Review Process

The process varies

- Individual reviews followed by a panel discussion
- Individual remote review with a panel or without panel discussion

Reviewers have three weeks to provide a response

• Up to one-third of the reviewers don't make this deadline

DOE funding track record (2018 data)

Letters of intent received	2,665			
Phase I proposals submitted	1,548			
Phase I proposals awarded	395			
Recommended for funding	193			
Award rate = 26%				



DOE Review Process

Award process is orchestrated by Technical Topic Managers (TTMs)

- Awards are categorized by score 1-3 (3 being highest)
- Proposals are further ranked by TTMs and portfolio managers
- Decision making varies by office depending on missions and communities served
 - Commercialization time frames
 - Targeted commercial application versus broader market opportunities

"If someone says we're developing the technology for medical imaging, we'll reject it because it has to meet our needs"

"What we want to see is a commercial product. What I tell everybody who calls me and contacts us is you need to define who your customer is because it is not me. Don't tell me 'here is something that would solve your problem.' I do not have a problem.... Some of the technologies can take a decade or longer to commercialize"



DOD Phase I Proposal

Volume 1: Proposal Cover Sheet

Volume 2: Technical Volume

Volume 3: Cost Volume

Volume 4: Company Commercialization Report

Volume 5: Supporting Documents

Always refer to the Broad Agency Announcement (BAA) for specifics and directions



Broad Agency Announcement Schedule

On this page, you can view active BAAs (pre-released or open for proposal submission) and upcoming BAAs, as well as access archived BAAs. DoD Components may release BAAs outside of the pre-scheduled Joint DoD BAA cycles. These will appear as Component BAAs, with a pre-release, open and close date, or as Annual BAAs, with topics released throughout the year with varying open and close dates. Please refer to each topic under the Annual BAAs for more information.

CTIVE BAAS						^
Joint DoD/Component BAAs	Program	Year	Pre-Release	Open Date	Close Date	BAA and Topic Details
Air Force SBIR X23.4	SBIR	2023	Oct 21, 2022	Oct 25, 2022	Nov 22, 2022	BAA Instructions 2 Topics
Annual BAAs	Program	Year	The Annual BA	As are open throu	ghout the year.	BAA and Topic Details
DoD SBIR 2022.4	SBIR	2022				BAA Instructions 0 Topics
DoD STTR 2022.D	STTR	2022				BAA Instructions 0 Topics



Page and font requirements specified

- 1. Identification and Significance of the Problem or Opportunity.
- 2. Technical Objectives.
- 3. Statement of Work (include Subcontractors and/or Research Institutions).
- 4. Related Work.
- 5. Relationship with Future Research or Research and Development.
- 6. Commercialization Strategy.
- 7. Key Personnel.
- 8. Foreign Citizens.
- 9. Facilities/Equipment.
- 10. Subcontractors/Consultants.
 - SBIR.
 - STTR.
- **11**. Prior, Current or Pending Support of Similar Proposals or Awards.
- **12**. Technical Data Rights.
- 13. Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software



DOD – Phase I (Vol 1)

Proposal Cover Sheet

- https://www.dodsbirsttr.mil/submissions/, prepare the Proposal Cover Sheet
- No proprietary information to be included



1. Identification and Significance of the Problem or Opportunity.

Specific technical problem being addressed and importance

2. Technical Objectives.

List specific aims of the project and questions being addressed by each specific aim

3. Statement of Work (include Subcontractors and/or Research Institutions).

Detailed description of the approach, methods, specific tasks, where work will be done and by whom, and potential results

4. Related Work.

Describe related activities conducted by key personnel, consultants, and sub awardees.

5. Relationship with Research or Research & Development

Significance of success in Phase I as it lays the foundation for Phase II, and what will needed to successfully complete Phase II



6. Commercialization Strategy.

One page description of the strategy for commercialization. This can include DOD and other Federal Agencies as potential customers and should include potential private sector customers. Must include market need and potential market size.

7. Key Personnel.

Describe the experience, awards, and publications of all key personnel

8. Foreign Citizens.

Identify all non-US nationals or those with dual citizenships, including country of origin, type of work visa, and role in the project working for the company or sub contractor or as consultants

9. Facilities/Equipment.

List facilities to be used and all significant instrumentation and budget justification for purchases if being made



10. Subcontractors/Consultants.

Outline the efforts and roles of any subcontractor and consultants. Ensure that the work being performed by subcontractors meets the requirements under SBIR and STTR guidelines

11. Prior, Current or Pending Support of Similar Proposals or Awards.

Provide details of any other grants or pending proposals for work that is similar to the work described in the proposal

12. Technical Data Rights.

Acknowledge the government's right to royalty-free license to use such technical data only for government purposes

13. Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software

Outline any restrictions to the government's rights to Technical Data.



DOD – Phase I Proposal

Volume 3: Cost Volume

• Must use the on-line cost volume form on the Defense SBIR/STTR Innovation Portal (DSIP)

Volume 4: Company Commercialization Report

• Report of funding outcomes from prior SBIR & STTR awards (if any). Must update at least every five years.

Volume 5: Supporting Documents

- REQUIRED documents: Contractor Certification Regarding Provision of Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment and Foreign Ownership or Control Disclosure
- Optional documents: Letters of support, additional cost information, others



DOD Evaluation Criteria

The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.

The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.

The potential for commercial (Government or private sector) application and the benefits expected to accrue from this commercialization.



Components of a Proposal to NSF – Phase I





Components of a Proposal to NSF – Phase I

Cover Sheet and Certification

Project Summary – 1 page maximum – no proprietary information

Project Description – 10 pages minimum, 15 pages maximum

- Elevator pitch: 1 page or less
- The commercial opportunity: 2 -4 pages
- The technical solution: 1-3 pages
- The company/team: 1-3 pages
- Intellectual merit, technical discussion, and R&D plan: 5 (min)-6 pages
- Broader impacts: 1 page

References Cited

Biographical sketches

Budget, subaward budget

Budget justification



Elevator pitch (1 page or less)

- The Customer who, why, what unmet need
- The Value Proposition why would they buy it, benefits to the customer, difference from competition, societal value
- The Innovation description, novelty, differentiate from currently available solutions



Commercial opportunity (2-4 pages)

- Total market, addressable market
- Market drivers, barriers, economics
- Market opportunity validated, customers, business model, competitive landscape (now and projected)
- Commercial risks
- Commercialization approach revenue potential, underlying assumptions
- Resources what is needed, plans to acquire



Technical solution (1-3 pages)

- Description of solution and the technology stage of development
- Key technical challenges and risks what risks are you mitigating in Phase I
- Intellectual property background, foreground, plan to protect
- NSF lineage* roots in non-SBIR/STTR NSF funding
- I-Corps lineage* Participation in an I-Corps cohort



The company/team (1-3 pages)

- Founders & key personnel level of effort, backgrounds and experience relevant to undertake the project
- Vision, mission, and objectives
- Business fit
- Revenue history (if applicable) includes funding from all sources
- Consultants & subawards role, qualifications, expertise



- Intellectual Merit, technical Discussion and R&D Plan (5 (min)-6 pages)
 - Detailed description of innovation why, benefits, additional background
 - Key objectives phase I aims that address technical & commercial feasibility
 - Milestones key technical goals
 - R&D plan timeline, objectives, experiments, computations, etc. need to reflect key objectives



Broader impact (1 page)

- Societal and economic benefit (American Innovation and Competitiveness Act (P.L. 114-329, Section 102))
 - Increasing the economic competitiveness of the United States.
 - Advancing of the health and welfare of the American public.
 - Supporting the national defense of the United States.
 - Enhancing partnerships between academia and industry in the United States.
 - Developing an American STEM workforce that is globally competitive through improved pre-kindergarten through grade 12 STEM education and teacher development, and improved undergraduate STEM education and instruction.
 - Improving public scientific literacy and engagement with science and technology in the United States.
 - Expanding participation of women and individuals from underrepresented groups in STEM.



References Cited

Biographical sketches

Budget, subaward budget

Budget justification



Create a Schedule – Week 1

Review the solicitation topics and down select

Download funding opportunity announcement and agency checklist

Generate questions

Understand the structure of a responsive proposal

- Sections
- Organization
- Page limits, font and margin requirements

Establish the deadline – two to three days before solicitation deadline

Initiate registrations - SAM, grants.gov, Fastlane...



Create a Schedule – Week 2

Speak with program managers/topic authors if allowed

- Agencies are sometimes limited in the FOA
- Whether your innovation is generally consistent with what the agency is seeking

Create your team - filling out registrations, collecting bios, and editing

Establish who will serve as internal reviewers on the draft proposal

Establish dates to complete sections of the proposal



Create a Schedule – Week 3, 4

Ensure registrations are complete or in process

Decide SBIR vs STTR

Define roles and prepare letters of commitment

- University
- Subcontractors

Start drafting the proposal



Create a Schedule – Week 5, 6, 7

Continue drafting proposal

Start developing budget

- SBIR versus STTR review the budget guidelines and directions
- Work backwards
- Direct and indirect costs, fee
- Understand allowable versus non-allowable costs

Budget narrative/justification

• Numbers have to match those in the budget

Review checklist

- Ensure registrations are complete/in process
- Biosketches, letters of commitment, letters of support



Create a Schedule – Week 8,9,10

Review and finalize sections of proposal

Prepare documents for uploading

Make sure documents are uploaded to the right sections

Run automated check of proposal

NIH allows you to amend sections

After you submit and before the deadline



STTR vs. SBIR

• SBIR: 67% at the company 33% at consultant / subcontract

• STTR: 40% small business, 30% academic/research institute, 30% at either

Consultants are an external expense (not included in the small business portion of the budget)

Direct vs indirect expenses

Indirect rate

Profit



Direct costs

- Key personnel project hours
- Equipment,
- Travel
- Partner efforts (ex. consultants or subcontractors)

Fringe benefits – benefits provided to employees (may be direct or indirect costs depending on agency)



Indirect costs – cost of running the business – also know as F&A

- Rental/lease expense
- Phone, internet, electricity etc.
- Insurance
- Employee benefits

Indirect cost rate

- Overhead, general and administrative costs, and fringe costs
- Usually a maximum of 40% (NSF allows up to 50%)
- Need documentation



Profit – also referred to as "Fee"

• 7% to 11% depending on agency – 7% is the most common

- Request all of it
- Entitled to it under the program
- Does not require explanation in the budget justification
- It is the most flexible money you will get use it for anything
 - Filing for IP protection, equipment purchase, consultants, unforeseen expenses
- If max budget is \$250,000 7% is \$17,500
 - Budget the project for \$232,500



Budget Basics

Phase I amount:	\$250,000
Fee / profit (7%):	\$17,500
Remaining Budget:	\$232,500
Indirect Rate (40%):	\$232,500/1.4
Direct Budget:	\$166,071
Indirect Budget:	\$66,429



NSF/NIH Budget Guidelines

Senior personnel, other personnel, Fringe benefits

Equipment

Travel (foreign travel not allowed in Phase I)

Materials & supplies

Consultant services (letter of collaboration, \$1,000 per day, Bio sketch)

Computer services

Subawards

Other services

- Up to \$10,000 for CPA services / purchase of cost accounting system
- Up to \$10,000 for NSF "Beat-the-Odds Boot Camp"

Indirect costs

Fee

TABA

NSF only pays for personnel that are performing technical work on the project



What is TABA?

Technical and Business Assistance (TABA) or Discretionary Technical Assistance (DTA)

TABA cab used for a variety of services (including, but not limited to):

- o Assistance with product sales,
- Intellectual property protections
- $\ensuremath{\circ}$ Market research and market validation
- Development of regulatory plans and manufacturing plans.

Agency	Phase I	Phase II
Department of Defense (DOD)	\$6,500	\$50,000
National Institutes of Health (NIH)	\$6,500	\$50,000
Department of Energy (DOE)	\$6,500	\$50,000
National Aeronautics and Space Administration (NASA)	\$6,500	\$50,000
National Science Foundation	N/A	\$50,000
U.S. Department of Agriculture (USDA)	\$6,500	\$50,000
Department of Homeland Security (DHS)	\$6,500	\$50,000
National Institute of Standards and Technology (NIST)	\$6,500	\$50,000
Department of Transportation (DOT)	\$5,000	\$50,000
Department of Education (ED)	\$6,500	\$50,000
Environmental Protection Agency (EPA)	\$6,500	\$10,000



Budget Narrative

IN PHASE I: Justification on direct and indirect cost development

- Key / other personnel
 - Roles, tasks being performed, month effort, present time, salary requirements, fringe benefits
- Equipment
 - What is it and how is going to be used
 - Equipment \$5,000 and over needs to be broken out
- Materials and supplies
 - What materials are going to be needed to complete the project
- Sub awards
- Rent
- Other



Basic Questions

What is the difference between direct, indirect, and G&A costs?

Direct	Indirect	G&A	
Labor	Supervision	Office support salaries	
Materials	Supplies	Stationary	
Travel	Maintenance	Telephone/Internet	
Testing	Depreciation	Postage	
Equipment	Utilities	Bank charges	
Consultants	Rent	Legal expenses	

What are appropriate wages or consultant fees?

<u>https://www.bls.gov/bls/blswage.htm</u>



Resources

APIOiX Small Business and Technical Assistance: <u>https://apioix.com/sbir-assistance</u>

• Provide general information and email link to obtain additional information

SBIR / STTR Tools & Resources: <u>https://apioix.com/tools-resources</u>

 Links to finding grant solicitations, examples of successful proposals (Phase I, Phase II, Fast Track), NSF Project Pitch rubric, budget templates for NIH and NSF Phase I proposals, budget justification templates for NSF and NIH

APIOiX Learning Center: https://apioix.com/learning-center

 Access to presentations on SBIR/STTR topics such as budgeting basics, subcontracting, how to write a winning proposal, basics of customer discover, and agency specific requirements.

SBIR presentations and slides: <u>https://www.sbir.gov/tutorials/accounting-finance/</u>

Salary validation: https://www.bls.gov/oes/current/oes_nat.htm#11-0000

NIH annotated SF424: <u>https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_SmallBus_forms-e.pdf</u>



Thank You



Arundeep S. Pradhan, MS Pharm Ad., RTTP has been engaged in technology transfer for over 30 years; was at the forefront of creating the biotech burst in Salt Lake City; helped develop the first biotech roadmap for Colorado; and, helped create the first biotech incubator and the first translational research development center in Portland, Oregon. Mr. Pradhan served on the AUTM Board, was the AUTM President in 2009, and AUTM Foundation President and Board Chair in 2011. He was the interim CEO of a research tools startup and currently serves as the president of Apio Innovation Transfer (APIOiX) and as the CEO and the vice-president for business development of Practical Biotechnology, an oncology therapeutics startup. Mr. Pradhan managed technology transfer offices at the University of Utah, Colorado State University Research Foundation, and Oregon Health and Science University. He continues to work with clients across the globe. <u>arundeep@apioix.com</u>



Ray Wheatley, MS CLP(E) is former Director for Technology Commercialization in the Office for Technology Development at the University of Texas Southwestern Medical Center, retiring in 2015 with 31 years of service. Mr. Wheatley and his staff evaluated over 2,500 new invention disclosures which led to more than 650 issued US patents and hundreds of foreign patents. These efforts resulted in more than 900 negotiated option agreements, license agreements and intellectual property management agreements generating more than \$178 million in license revenues. In addition, over 30 start-up companies were created. He has worked with US and foreign companies, including major pharmaceutical companies, venture capital firms and leading medical device manufacturers. He has been an invited speaker at many national and international meetings and has spoken on a variety of topics, most notably on negotiation skills and advanced licensing topics. <u>ray@apioix.com</u>



Michael Batalia, PhD is a serial entrepreneur and an expert in academic technology commercialization. He is also a member of the Mission II Team for the Perlan Project, an effort to fly engineless aircraft to the edge of space. He has over 16 years of experience in academic technology transfer, intellectual property management, and licensing at Wake Forest University as executive director of commercialization and North Carolina State University as associate director then director of technology transfer. Dr. Batalia is active regionally and internationally in support of technology transfer and biotechnology. He has served on the Boards of the Association of University Technology Managers, the North Carolina Biotechnology Center, the Biotechnology Advisory Committee of Piedmont Triad, and the North Carolina Center of Innovation for Nanobiotechnology. He is a co-founder of Wide Eyed Technologies and the CSO for Arctic, Inc. <u>michael@apioix.com</u>

