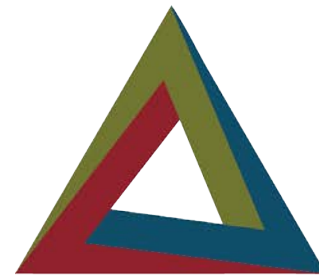


SBIR & STTR Writing a Winning Proposal – Life Sciences

PHASE I APPLICATIONS



APIOix
Innovation Transfer

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 (<https://www.unlv.edu/econdev/sagesouth>) to assist technology-based small businesses (<https://apioix.com/sbir-assistance>)

- 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

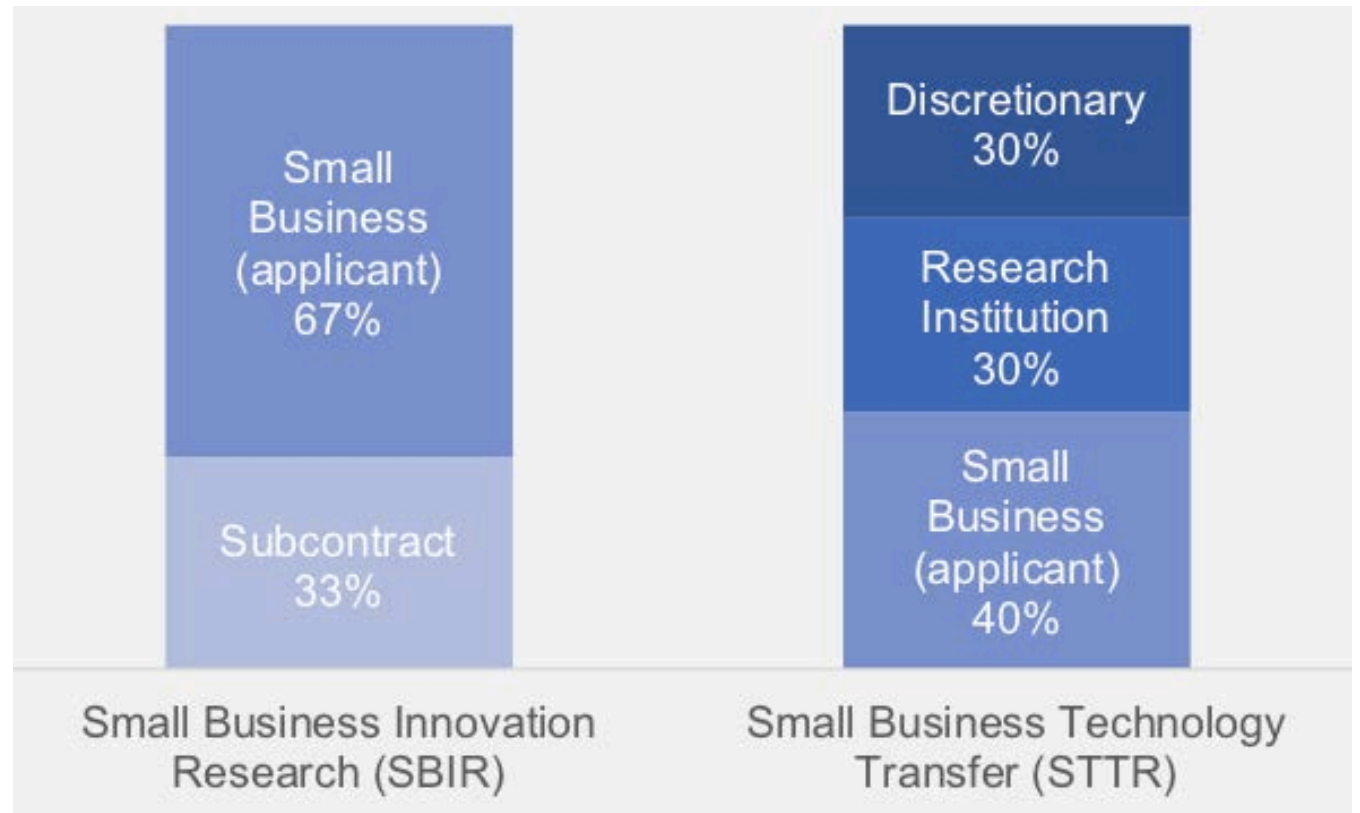
- In the words of program founder Roland Tibbetts: "to provide funding for some of the best early-stage innovation ideas; ideas that, however promising, are still too high risk for private investors, including venture capital firms."



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 REGISTRATIONS AND SUBMISSIONS					
	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

Writing Tips

Writing time



Reviewing time



Discussion time



Reading proposals is hard work

Complex nature of the technology

Jargon, definitions, concepts, unfamiliar words

Therefore, keep the language, structure, flow, simple – make it easy for the reviewers

Writing tips

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

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

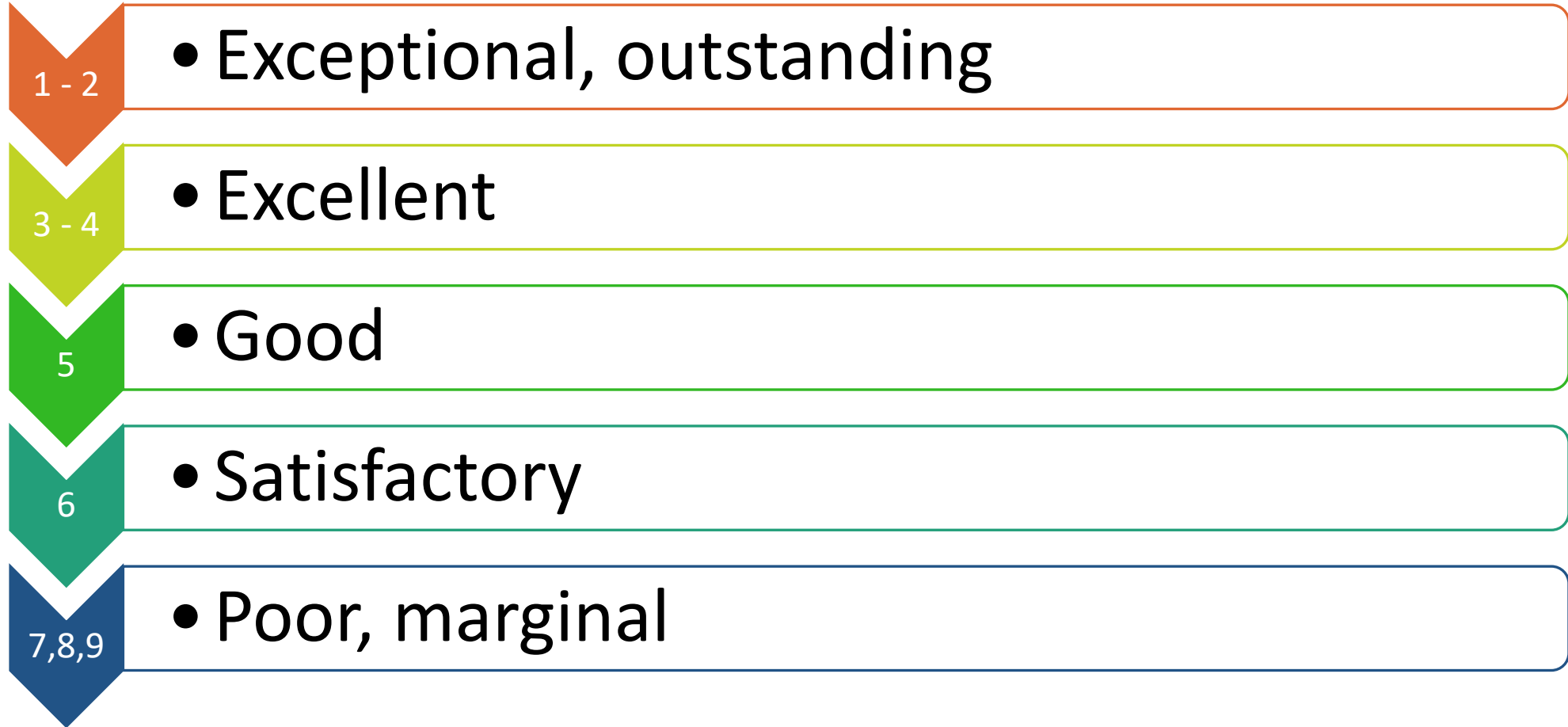
The high efficacy of our lead compound, JD216, in anti-proliferative assays for Tamoxifen resistant, Herceptin-resistant and HER2-overexpressors breast cancer models provides a scientific justification for moving forward as rapidly as possible.

Avoid confusing language

- Double, triple negatives
- “Not only...”

Essential information needs to be included

Reviewers Scale



Components of a Proposal to NIH – Phase I

Abstract/introduction/project summary

Statement of work

- Objectives
- Approach
- Related work
- Significance
- Impact
- Other

6-10 pages

Documents that comprise the proposal

Commercial development plan

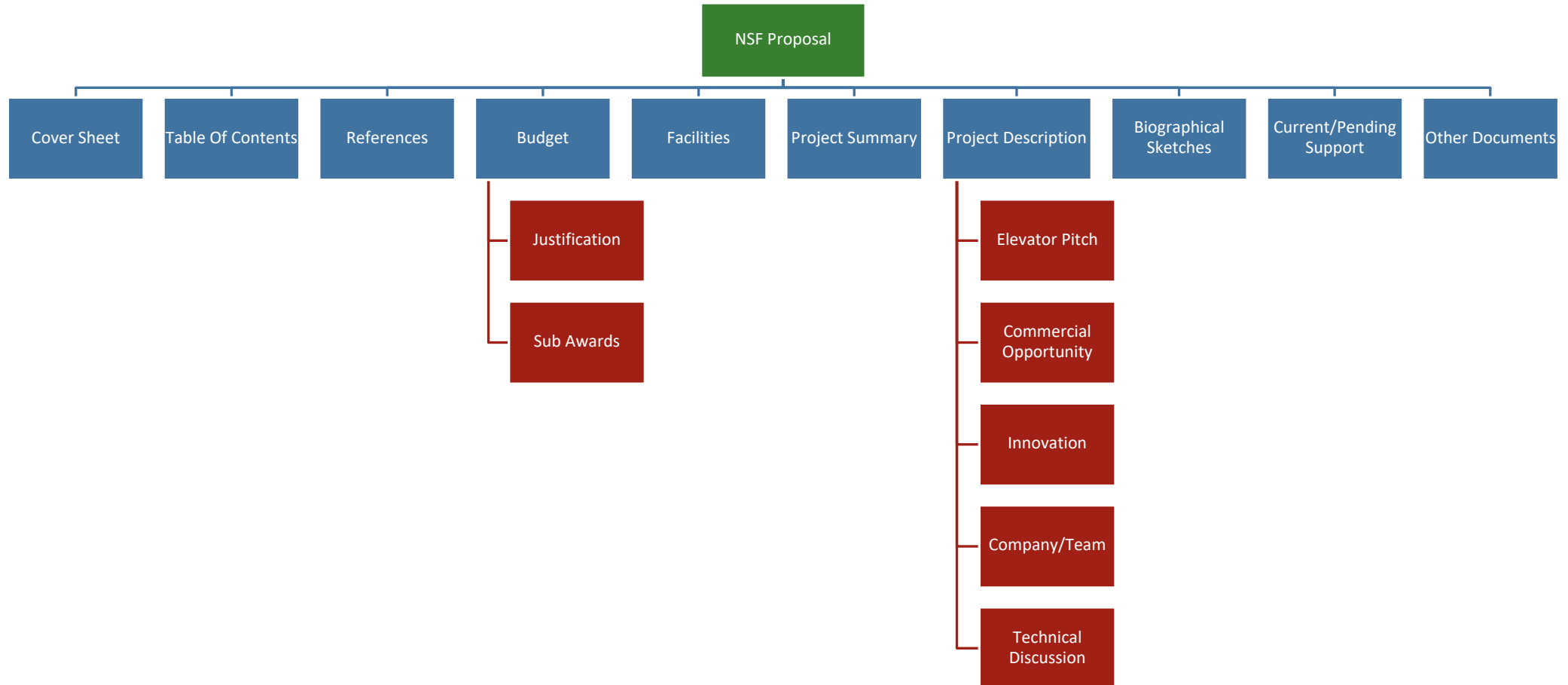
Budget and budget justification

Company and key personnel

- SF424 (R&R) cover page
- Table of contents
- Performance sites
- R&R other project information
- Project summary/abstract
- Project narrative
- Facilities and other resources
- Equipment
- Personnel justification
- R&R key personnel
- Biosketches
- Current and pending support
- R&R Budget period
- Budget justification
- R&R cumulative budget
- Subaward budget(s)
- Total direct costs
- SBIR/STTR Information
- R& Outside the US
- Prior SBIR phase I/II awards
- PHS cover page supplement
- PHS research plan
- Specific aims
- Research strategy
- Multiple PI leadership plan
- References
- Letters of support

~70-80 pages

Components of a Proposal to NSF – Phase I



Components of Proposal – Phase I

Specific aims

Significance

Innovation

Approach & scientific rigor

Animals and human subjects

Environment

Commercialization Plan

Investigators

Letters of support

Specific Aims

Each needs to be specific and actionable

- Measurable outcomes
- Dependent versus independent aims
- Milestones associated with each aim

Clarity is very important

Phase II aims – what are you going to accomplish in phase II if phase I is successful

Significance

Scientific premise

- Underlying evidence and scientific foundation
- Justification for proposed work
- Strengths and weaknesses of prior work

Benefit of your innovation/product

Commercial potential

- Product/service that addresses a need
- Competitive landscape

Innovation

Commercial perspective – not academic

Frame the discussion

- Commercialization of the (innovation/solution) to address a problem being faced by your potential customers
- Phase I vs Phase II
- Taking the innovation to market

Keep in mind, reviewers will also look for:

- Novel concepts, methodologies, instrumentations, interventions
- Refinement, improvement, or approaches

Approach & Scientific Rigor

Overall strategy and methodology – reflect specific aims

Scientific rigor – *application of scientific method that supports unbiased design, analysis, interpretation*

- Alternative strategies and reason for selecting proposed approach
- Benchmarks for success – what constitutes successful outcomes
- Risks and risk mitigation
- Animal and human subjects
 - Protection
 - Risks
 - Inclusion/exclusion criteria, representative populations
- Statistical analysis
- Numbers of animals/subjects
- Data management
- Resource authentication plan (after scoring)
 - Cell lines, specialty chemicals, antibodies, other biological materials

Environment

Environment

- Facilities and equipment
- Access to resources
- Innovation ecosystem
 - Incubators/accelerators
 - Professional services
 - Access to capital – angel networks, venture capital
 - Scientific/technical environment
- Programs
 - NSF I-Corps, Lean Launch Pad, FAST

Commercialization Plan

Phase I – about ½ to 1 page

- Company
 - Vision, mission, objectives
 - Size, projected growth
- Team – beyond the technical expertise
 - Operations, manufacturing, marketing
 - Regulatory
 - Legal
- Market, size, customers, unmet need
- Competitions
- Collaborations or strategic partnerships
- Intellectual property

Phase II – much more detailed

- Company
 - Team
 - Market
 - Customer
 - Product
 - Track record
 - Revenue and Sustainability
 - Financing
 - Competition
 - Barriers and drivers (mini-SWOT)
 - Regulatory pathway
 - Quality control requirements
 - HIPAA
 - Intellectual property
-

Investigators

Biosketches are important

- Use correct form
- Provide reviewers with justification that you have the right team
 - Perform the work
 - Run the company
- Describe the roles and contributions as they relate to the proposed project
- Record of accomplishments as they relate to the proposed project
- Opportunity to highlight relevant expertise and skills

Letters of Support

DO NOT “clone” the letters

Advisors

Potential customers/collaborators

Scientific/business leaders who are not part of the company

Technology transfer offices – where technology is being licensed from a university

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

Budgeting Basics

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

Budgeting Basics

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)

Budgeting Basics

Indirect costs – cost of running the business – also known 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

Budgeting Basics

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 can be used for a variety of services (including, but not limited to):

- Assistance with product sales,
- Intellectual property protections
- 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?

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

Resources

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

- Provide general information and email link to obtain additional information

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

- 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>

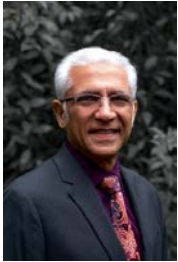
- Access to presentations on SBIR/STTR topics such as budgeting basics, subcontracting, how to write a winning proposal, basics of customer discover, and agency specific requirements.

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

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

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

Thank You



Arundeeep 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. arundeeep@apioix.com



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. ray@apioix.com



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. michael@apioix.com