The NIH/NIA SBIR/STTR Programs

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@NIA_SBIR
Key Points

• Overview of the NIH SBIR & STTR Programs
• 3 Phases of Funding
• Application to Award Process
• Your Advocates - NIA Office of Small Business Research
• NIA Small Business Funding Opportunities and Programs
• Tips on Applying
NIH SBIR/STTR Programs

• The NIH SBIR program funds early stage small businesses that are seeking to commercialize innovative biomedical technologies. This competitive program helps small businesses participate in federal research and development, develop life-saving technologies, and create jobs.

• The NIH STTR program is similar to the NIH SBIR program, but requires that the small business formally collaborate with a research institution in Phase I and Phase II.

• Important take away:
  SBIR/STTR funding has significantly increased:
  Total of > $1.1B at NIH (FY19)
  Total of > $100M at NIA (FY19)
NIH SBIR/STTR Budget Allocations
FY18

<table>
<thead>
<tr>
<th>Grant Type</th>
<th>% of Total</th>
<th>Total Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBIR</td>
<td>3.2%</td>
<td>$1B</td>
</tr>
<tr>
<td>STTR</td>
<td>0.45%</td>
<td>$141M</td>
</tr>
<tr>
<td><strong>Total FY18:</strong></td>
<td><strong>-</strong></td>
<td><strong>$1.145B</strong></td>
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FY19 NIA SBIR/STTR Budget is > $100M
Congressionally Mandated

**SET ASIDE FY19**

**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

3.2%

**SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

.45%
Why Seek SBIR/STTR Funding

• Provides seed funding for innovative technology development
  – Not a Loan
  – No repayment is required
  – Doesn’t impact stock or shares in any way (non-dilutive)

• Intellectual property rights retained by the small business
• Provides recognition, verification, and visibility
• Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner).
Eligibility

• Applicant must be a Small Business Concern (SBC)
• Organized for-profit U.S. business
• 500 or fewer employees, including affiliates
• > 50% U.S.-owned by individuals and independently operated
  OR
• > 50% owned and controlled by another (one) business concern that is > 50% owned and controlled by one or more individuals
  OR (SBIR ONLY)
• > 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Award is always made to small business
## Critical Differences

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permits</strong> research institution partners (e.g., universities)</td>
<td><strong>Requires</strong> research institution partners (e.g., universities)</td>
</tr>
<tr>
<td>Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities</td>
<td>Minimum 40% of the work should be conducted by the small business concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)</td>
</tr>
<tr>
<td><strong>ELIGIBILITY:</strong> The PD/PI’s primary employment (i.e., &gt;50%) MUST be with the SBC for the duration of the project period</td>
<td><strong>ELIGIBILITY:</strong> IP Agreement providing necessary IP rights to the SBC in order to carry out follow-on R&amp;D and commercialization --- PI primary employment not stipulated (min.10% effort to project)</td>
</tr>
</tbody>
</table>

*Award is *still* made to small business!*
Phased Program

**Discovery Phase I**
- Feasibility

**Development Phase II**
- Full R/D

**Phase I → Phase II**
- Fast-Track
- Direct to Phase II

**Competing Renewal Award Phase IIB**
- $3M for up to 3 years
  - Commercialization Readiness Pilot (CRP)
  - Congressionally approved, pending NIH implementation
  - $3M for up to 3 years
  - Only Some ICs Participate

**Commercialization Phase III**
TOTAL COST BUDGETS

- SBIR Budgets are defined by total cost and subcontracting is limited. Know the rules and the criteria.
- Check Budget allowance in each FOA

Can request a 7% Fee
- Company Profit
- Of total budget

Fee for Service: CRO-type activities can count as small business costs providing that:
1. It is a commercially available service
2. All analysis is done by small business
3. Fee per basis (no indirect costs by fee for service providers)
Budget Specifics: Technical Assistance

- 2018 NDAA added additional SBIR budget allowance for technical assistance:
  - Phase I up to $6,500 per year (up from $5K/year)
  - Phase II technical assistance cap to $50K
  - Caveat: if requested, company cannot participate in NIH Technical Assistance Programs (CAP, Niche)

- To provide small business concerns engaged in SBIR or STTR projects with technical and business assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, product sales, IP protections, market research, market validation, development of regulatory plans, manufacturing plans, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in:
  - making better technical decisions concerning such projects;
  - solving technical problems which arise during the conduct of such projects;
  - minimizing technical risks associated with such projects; and
  - developing and commercializing new commercial products and processes resulting from such projects, including intellectual property protections

Request within the APPLICATION
Request in F. Other Direct Costs lines 8-10 on SBC budget
Label as “Technical Assistance
NIH Funding Mechanisms

Omnibus Solicitation:
Investigator initiated
3 receipt dates
(Jan. 5, Apr. 5, Sept. 5)

FOAs: Targeted Solicitations
Focused priority areas
w/variable receipt dates

Contracts: Targeted Solicitation
Once per year
Specified Deliverable
(NIA not currently participating)

https://sbir.nih.gov
Application to Award: Steps

1. Applicant initiates research idea
2. Small Business Concern confirms eligibility
3. Submits SBIR/STTR grant application to NIH electronically
4. NIH Center for Scientific Review assigns to IC and IRG
5. Scientific Review Group evaluates scientific merit
6. Advisory Council recommend Approval
7. IC staff prepare funding plan for IC Director
8. IC allocates funds
## Application Cycles

<table>
<thead>
<tr>
<th>Due Dates</th>
<th>Review Meetings</th>
<th>Advisory Council Round</th>
<th>Earliest Project Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 5</td>
<td>March</td>
<td>May</td>
<td>July</td>
</tr>
<tr>
<td>April 5</td>
<td>June</td>
<td>August</td>
<td>September</td>
</tr>
<tr>
<td>September 5</td>
<td>November</td>
<td>January</td>
<td>April</td>
</tr>
</tbody>
</table>
NIH 2018 SBIR/STTR
% of Applications Funded

- Fast Track: 20.1% SBIR, 20.9% STTR
- Phase I: 18.4% SBIR, 20.9% STTR
- Phase II: 42.2% SBIR, 34.6% STTR
- Phase IIB: 38.1% SBIR, 0.0% STTR
Technical Assistance Programs

**Niche Assessment Program – Foresight Science & Technology**
(Phase I Awardees)

- Helps jump start commercialization efforts
- Determines competitive advantages
- Develops market entry strategy

**Commercialization Accelerator Program – Larta, Inc.**
(Phase II Awardees)

Technical Assistance/Training in:
- Strategic/business planning
- FDA requirements
- Technology evaluation
- Manufacturing issues
- Patent and licensing issues

Helps build strategic alliances
Facilitates investor partnerships
Individualized mentoring/consulting
Entrepreneurship Training and Resources

I-Corps™ at NIH
An intensive Entrepreneurial Immersion course for scientists

12 Participating ICs + CDC

C3I and other programs available at some ICs.

Facilitating Partnerships

Entrepreneurs in Residence
NIA SBIR/STTR Obligations

Dollars in Millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Dollars in Millions</th>
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<tbody>
<tr>
<td>2013</td>
<td>$27.5</td>
</tr>
<tr>
<td>2014</td>
<td>$32.4</td>
</tr>
<tr>
<td>2015</td>
<td>$34.2</td>
</tr>
<tr>
<td>2016</td>
<td>$49.7</td>
</tr>
<tr>
<td>2017</td>
<td>$67.2</td>
</tr>
<tr>
<td>2018*</td>
<td>$87.7</td>
</tr>
<tr>
<td>2019*</td>
<td>$105.0</td>
</tr>
</tbody>
</table>

*estimates
NIA Office of Small Business Research

Core Activities

**CENTRAL COORDINATION**
Administer all the SBIR/STTR awards at the NIA.

**GUIDANCE**
Help applicants prepare for application, resubmission, and discuss funding options.

**OUTREACH**
Attend conferences and workshops & visit regional-based organizations to raise awareness of the program.

**FUNDING**
Seed emerging technology areas by developing targeted funding opportunities and Omnibus interest topics.

**NETWORKING**
Facilitate connections between awardees and potential strategic partners. (NIA programs/external partners).

**ENTREPRENEURSHIP**
Provide entrepreneurship training, as well as webinars on key commercialization-related topics.

4 Programmatic Divisions of the NIA

• **Division of Aging Biology**: The overall goal is to provide a basis in basic biology for preventative and interventional strategies to increase resilience and extend healthy aging.

• **Division of Behavioral and Social Research**: Supports research and research training on the processes of aging at both the individual and societal level.

• **Division of Geriatrics and Clinical Gerontology**: Supports research on health/disease in older people and research on aging over the human lifespan, including its relationships to health outcomes.

• **Division of Neuroscience**: Supports research to further the understanding of neural and behavioral processes associated with the aging brain. Research on dementias of old age — in particular Alzheimer's disease — is one of the division's highest priorities.
### NIH Omnibus Solicitation: Primary FOA

<table>
<thead>
<tr>
<th>Announcement</th>
<th>Title</th>
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<tbody>
<tr>
<td>PA-18-574 (R43/R44)</td>
<td>SBIR Omnibus/Parent - Clinical Trials Not Allowed</td>
</tr>
<tr>
<td></td>
<td><strong>Accepts Direct to Phase II</strong></td>
</tr>
<tr>
<td>PA-18-573 (R43/R44)</td>
<td>SBIR Omnibus/Parent - Clinical Trials Required</td>
</tr>
<tr>
<td></td>
<td><strong>Accepts Direct to Phase II</strong></td>
</tr>
<tr>
<td>PA-18-575 (R41/R42)</td>
<td>STTR Omnibus/Parent - Clinical Trials Not Allowed</td>
</tr>
<tr>
<td>PA-18-576 (R41/R42)</td>
<td>STTR Omnibus/Parent - Clinical Trials Required</td>
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</tbody>
</table>

**Award Budgets can be submitted up to $300K for Phase I and $2M for Phase 2 in the various ADRD waiver topics. Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines.**
Alzheimer’s Disease and Related Dementias

Did you know?
• Alzheimer’s disease is the 6th leading cause of death in the U.S.
• 16.1 million Americans provide unpaid care for people with Alzheimer’s or other dementias. These caregivers provided an estimated 18.4 billion hours of care valued at over $232 billion.
• Deaths from Alzheimer’s increased 123% between 2000 and 2015.
• Early and accurate diagnosis could save up to $7.9 trillion in medical and care costs.
• In 2018, Alzheimer’s and other dementias will cost the nation $277 billion. By 2050, costs could rise as high as $1.1 trillion.
ADRD Opportunity

• Today, more than 5 million Americans are living with Alzheimer’s, the only leading cause of death that cannot be prevented, cured, or even slowed.

• The nation’s leading researchers have said continued significant investments are still needed if we are to meet the first goal of the National Plan to Address Alzheimer's — to effectively treat and prevent Alzheimer’s by 2025.

• Funding for small business opportunities has increased significantly over the past four years resulting in 300% growth in small business funding opportunities at the NIA.
ADRD Funding Areas

- Prevention
- Diagnosis
- Treatment
- Care
- Research and Clinical Tools
- Mobile Technology
- Novel Devices

PAS-18-187 (SBIR)
Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional)
Accepts Direct to Phase 2

PAS-18-188 (STTR)
Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional)

**Award Budgets can be submitted up to $450K for Phase I and $2.5M for Phase 2 in the various ADRD waiver topics. Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines.**
NIA Interest Areas: ADRD

PAR-18-512
Testing Lifespan/Healthspan-Extension Interventions in Models of Alzheimer's Disease (AD/ADRD) (SBIR R43/R44 Clinical Trial Not Allowed)

PAR-18-514
Testing Lifespan/Healthspan-Extension Interventions in Models of Alzheimer’s Disease (AD/ADRD)(STTR R41/R42 Clinical Trial Not Allowed)

Award Budget
- FOA caps: $350K (Phase I), $2.0M (Phase II)
  **Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
NIA Interest Areas: ADRD (2)

PAR-18-329 (SBIR)
Technology to Detect, Monitor and Assess Daily Functions in Individuals with Cognitive Decline, Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD) (SBIR R43/R44 Clinical Trial Not Allowed)

PAR-18-326 (STTR)
Technology to Detect, Monitor and Assess Daily Functions in Individuals with Cognitive Decline, Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD) (R41/R42 Clinical Trial Not Allowed)

Award Budget
- FOA caps: $350K (Phase I), $2.0M (Phase II)
**Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
**Award Budgets can be submitted over the caps in the various ADRD waiver topics. Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
## NIA Interest Areas: ADRD (4)

<table>
<thead>
<tr>
<th>FOA Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAR-18-587</td>
<td>Assistive Technology for Persons with Alzheimer's Disease and Related Dementias and Their Caregivers (R41/R42 - Clinical Trials Optional)</td>
</tr>
<tr>
<td>PAR-18-588</td>
<td>Assistive Technology for Persons with Alzheimer's Disease and Related Dementias and Their Caregivers (R43/R44 - Clinical Trial Optional)</td>
</tr>
<tr>
<td>PAR-18-186</td>
<td>Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R43/R44 Clinical Trial Optional)</td>
</tr>
<tr>
<td>PAR-18-185</td>
<td>Development of Socially-Assistive Robots (SARs) to Engage Persons with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R41/R42 Clinical Trial Optional)</td>
</tr>
</tbody>
</table>

### Award Budget

- Assistive Technology FOA caps: $500K per year, up to 2 years (Phase I), $1.0M per year, up to 2 years (Phase II)
- Robots FOA caps: $350K (Phase I), $2.0M (Phase II)

**Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines.**
NIA Interest Areas: Translational Research

T1 Translational Research on Aging: Small Business Innovation Awards (R43/R44)  PAR-18-183

Strategies for Prevention and Treatment of Age-Related Pathologies

- **Development of stem or progenitor cell based interventions for tissue regeneration and/or wound healing.**
- **Discovery/Development and/or Evaluation of drugs, biologics or natural products to treat frailty, sarcopenia, osteoporosis or cognitive impairment.**
- **Development of new vaccine formulations to improve vaccine responses in older adults.**

Award Budget
- FOA caps: $225K per year, up to 2 years (Phase I), $1.5M per year, up to 3 years (Phase II)

**Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
NIA Interest Areas: Translational Research (2)

T2 Translational Research on Aging: Small Business Innovation Awards (R43/R44) PAR-18-184

- Advance availability of novel devices, products, health care practices and programs to benefit the lives of older adults
- Dissemination of results from clinical studies into everyday clinical practice and health decision making in geriatric medicine
- Development of new techniques for enhancing research productivity in aging research; for example: data mining approaches

Award Budget
- FOA caps: $225K per year, up to 2 years (Phase I), $1.5M per year, up to 3 years (Phase II)

**Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines**
REMINDER: iCare-AD/ADRD Challenge

Improving Care for People with AD/ADRD Using Technology Challenge

• Seeks to spur the development of technology applications to improve dementia care coordination and/or care navigation

• Up to $400,000 in cash prizes may be awarded to teams or individuals that participate in the competition

• Submissions accepted from October 1, 2018 through June 30, 2019

• See https://nia.nih.gov/challenge-prize for full prize details
Tips on Applying
What is NIA Looking For?

• Innovative solution to significant unmet clinical need

• Solution that has significant commercial potential

• Projects should:
  • Leverage the expertise of the company/founder
  • Seek funding to produce feasibility data (Phase 1) or conduct product-focused development activities (Phase 2)

• Proposals are encouraged from:
  • Start-up companies too early for private investment
  • Established SBCs seeking to pursue new projects
When NOT to Apply

• Chasing NIH funding solicitations – “why not?”

• Need cash urgently
  • Time from application to award is 6-9 months
  • Applications usually require a resubmission to get a fundable score resulting in 12+ months from submission of first application

• “Me too” product matching competitor’s capabilities (NEVER)

• Incremental innovation (DEPENDS)

• Basic research still required to demonstrate feasibility

• Attempting to “bridge the gap” when you have lost your R01
Developing the First Draft

• Consider your company’s strengths and how to exploit them.

• Consider your company’s weaknesses and how to address them.

• Identify the **Key Question** to be addressed.

• **Recommend contacting an appropriate NIH Program Director (NIA: OSBR) in advance (at least 1 month before due date) to discuss your specific aims and receive feedback.**

• **Review similar, currently-funded NIH projects to identify competitors and/or collaborators:** [NIH Project RePORTER](https://report.nih.gov/).
NIAID Sample Applications: A Great Resource

https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

<table>
<thead>
<tr>
<th>PI and Grantee Institution</th>
<th>Sample Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jose M. Galarza of Technovax, Inc.</td>
<td>&quot;Broadly protective (universal) virus-like particle (VLP) based influenza vaccine&quot; (SBIR Phase I/R43)</td>
</tr>
<tr>
<td>Mark Poritz* of BioFire Diagnostics, LLC.</td>
<td>&quot;Rapid, automated, detection of viral and bacterial pathogens causing meningitis&quot; (SBIR Phase I / R43)</td>
</tr>
<tr>
<td>Patricia Garrett of Immunetics, Inc.</td>
<td>&quot;Rapid Test for Recent HIV Infection&quot; (SBIR Phase II / R44)</td>
</tr>
<tr>
<td>Michael J. Lochhead of MBio Diagnostics, Inc.</td>
<td>&quot;Point-of-Care HIV Antigen/Antibody Diagnostic Device&quot; (SBIR Phase II / R44)</td>
</tr>
<tr>
<td>Kenneth Coleman of Aretis Corporation</td>
<td>&quot;Antibiotics for Recalcitrant Infection&quot; (SBIR Fast-Track)</td>
</tr>
<tr>
<td>Timothy C. Fong of Cellerant Therapeutics, Inc.</td>
<td>&quot;Novel indication for myeloid progenitor use: Induction of tolerance&quot; (STTR Phase I/R41)</td>
</tr>
<tr>
<td>Raymond Houghton, InBios International, and David AuCoin, University of Nevada School of Medicine</td>
<td>&quot;Antigen Detection assay for the Diagnosis of Melioidosis&quot; (STTR Phase II/R42)</td>
</tr>
</tbody>
</table>
SF 424 Application Guide

“Ctrl F” Keyword Search this document – that’s what I do!

Use NIH Assist for Application Submission and Review the Annotated Application Forms:
Specify Institute and Study Section

• Who is going to review your application?
  – Combination of academic and industry reviewers
    • Primary reviewers read your application, and lead the discussion
    • All members of the Review Panel will score your application

• Identify the most appropriate study section BEFORE you submit your application.
  – See CSR website for study section descriptions
  – See the list of study section members
  – Request study sections in the optional PHS Assignment Request Form (previously in the cover letter)
Specify Institute & Study Section: Application

IC scientific areas of expertise **needed** to review your application

Suggest an IC Assignment

Suggest the study section
**Tip 1: Start Early**

- **Strong proposals take time to develop**
  - Carefully read the funding solicitation and allow time to address all of the key requirements
  - Assemble a strong scientific team
  - Gain access to equipment, facilities and other resources
  - Obtain letters of support from collaborators

- **Complete the necessary administrative registrations**
  - Start at least 2 months before deadline
  - See SF424 application guide (grants.gov, eRA Commons)
  - [http://sbir.nih.gov](http://sbir.nih.gov): see info on *Electronic Submission*
  - **New Applicants Infographic:** [https://sbir.nih.gov/infographic](https://sbir.nih.gov/infographic)
Remember: Focus on Product

**ACADEMIC GRANT**
- Expertise/Team (Discovery Research)
- Approach (Appropriate for discovery)
- Product (optional)
- Innovation (What could be/theoretically possible)
- Environment
- Significance (Knowledge increase)

**SBIR/STTR GRANT**
- Expertise/Team
- Phase I: Research and Development
- Phase II: Commercial Development
- Approach (Product Development)
- Environment
- Science (MANDATORY)
- Innovation (Competitive Advantage)
- Significance (Changing a paradigm)
- Commercialization
Tip 2: Refine your vision

• **Start informal discussions to clarify the product vision**
  • Technical experts, potential customers, investors, commercialization partners, and other stakeholders

• **Seek help from others with experience and insights**
  • Current/prior SBIR grantees
  • Academic collaborators with grant writing experience
  • Professional grant writers*
  • Engage with SBIR program staff for the most up-to-date information on agency priorities, current NIH policies, etc.

• **Carefully consider the study design**
  • Identify strategies to mitigate risk
  • Present alternative approaches if problems are encountered
Tip #3: Build the Right Team

• Select a Principal Investigator (PI) with the right expertise

• For multidisciplinary projects, consider a multi-PI team

• **Consider other partners to fill the gaps**
  • Academic collaborations
  • Consultants and CROs
  • Strategic partners / other large companies
  • “Seasoned” entrepreneurs who understand product development and have experience
Tip #4: Draft a Clear Application

- Specific Aims (1 page): *The Executive Summary and First Impression*

- First ½ to 2/3: The Elevator Pitch – Why is it the most meritorious???
  - Describe the unmet need that you are attempting to address
  - Highlight the technology’s major strengths and competitive advantage
  - Include textual highlights of preliminary data
  - How will it change the ________ paradigm

- Last 1/3 to ½: Describe the aims for the proposed project
  - Include key models, assays, and metrics
  - Include quantitative performance milestones

- Provide your draft Specific Aims page to NIA staff for feedback
Tip #4: Draft a Clear Application (2)

- Research Strategy (Ph1: 6 pages; Ph2: 12 pages)
  - Address all of the review criteria clearly
  - Provide background information
  - Provide detailed technical plan to achieve the Specific Aims
  - Propose a project scope within the budget and time constraints
  - Preliminary data not required (Ph I), but needed to be competitive
  - Describe potential pitfalls and alternative angles of attack
  - The approach section should be prioritized real estate as the reviewers tend to focus on that criterion
Tip #4: Draft a Clear Application (3)

- Other application components
  - Letters of support
    - Necessary from consultants and collaborators
    - Powerful from clinicians, end-users, investors not on grant app
  - Phase II Commercialization Plan (12 pages)
  - Bio-sketches for all senior and key personnel (< 4 pages)
  - Budgets for each project period & for each subcontract
  - Detailed descriptions of facilities and equipment
  - Human subject research section (if applicable)
  - Vertebrate animals section (if applicable)
## SBIR Review Criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Considerations</th>
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</thead>
<tbody>
<tr>
<td><strong>Significance</strong></td>
<td>Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td>Are design and methods well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?</td>
</tr>
<tr>
<td><strong>Innovation</strong></td>
<td>How novel is the technology/product and the approaches proposed to test its feasibility? What is the competitive advantage?</td>
</tr>
<tr>
<td><strong>Investigator</strong></td>
<td>Are the investigators, collaborators and consultants appropriately trained and capable of completing all project tasks?</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td>Does the scientific environment contribute to the probability of success? Facilities? Independence?</td>
</tr>
<tr>
<td><strong>Commercialization</strong></td>
<td>Is the company’s business strategy one that has a high potential for success?</td>
</tr>
</tbody>
</table>
Tip #5: Conduct Your Own Peer Review

BEFORE YOU SUBMIT:

• Read your application as if you were a reviewer
  • What are the weaknesses?
  • Don’t try to hide potential pitfalls; address them upfront, and suggest strategies to overcome potential problems

• Ask your collaborators to critically review the application

• Solicit feedback from independent readers
  • Do they understand the proposal?
  • Are they excited about the idea, the potential impact, and the experimental approach?
What if you are not funded on first try?

• Rejection is painful, BUT...
• Feedback provides a roadmap for next steps
  • Carefully review the Summary Statement (written critiques)
  • Use reviewer comments to improve your application
  • Discuss Summary Statement with your NIH Program Director
• Revise and resubmit the application
  • Introduction Page: Response to reviewer critiques
  • Be constructive, NOT defensive
• Learn more about SBIR/STTR grants
  • Talk to successful applicants
  • Understand review process and dynamics -http://csr.nih.gov
Application Resources

Small Business:

- Sample SBIR Grant Applications
- Annotated Form Set for NIH SBIR Grant Applications
- SBIR/STTR Application Process Infographic
- Office of Small Business Research, National Institute on Aging

Databases of NIH-supported Research [NIH RePORTER](https://reporter.nih.gov/)

NIA-Supported Animal Model Resources Available to Academics and Small Business Interests:

Alzheimer’s Disease Preclinical Efficacy Database (Models, Agents, and markers): [AlzPED](https://alzped.org/)

[MODEL-AD Consortium](https://www.model-ad.org/) focused on developing next gen animal models for AD.
Ways to Stay Informed and Connected


- Visit the [NIH Grants Guide](https://www.nia.nih.gov/grants) to search all active NIA funding opportunities

- Subscribe to our blog to stay up to date with the latest from NIA: [https://www.nia.nih.gov/research/blog](https://www.nia.nih.gov/research/blog)

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