

NIA Small Business SEED Fund:

Accelerating Alzheimer's and Aging Research



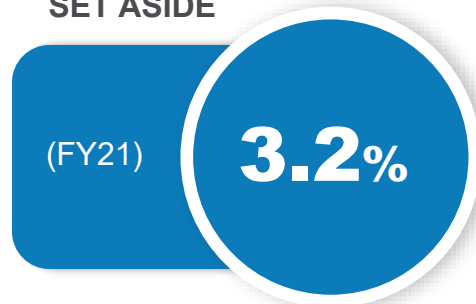
National Institute
on Aging

July 2022

About SBIR and STTR

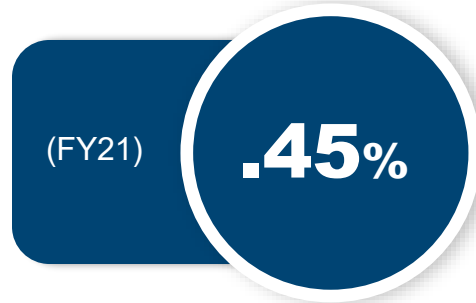
Congressionally Mandated Programs

SET ASIDE



Small Business Innovation Research (SBIR) Program

Set-aside program for small businesses to engage in federal R&D — with potential for commercialization

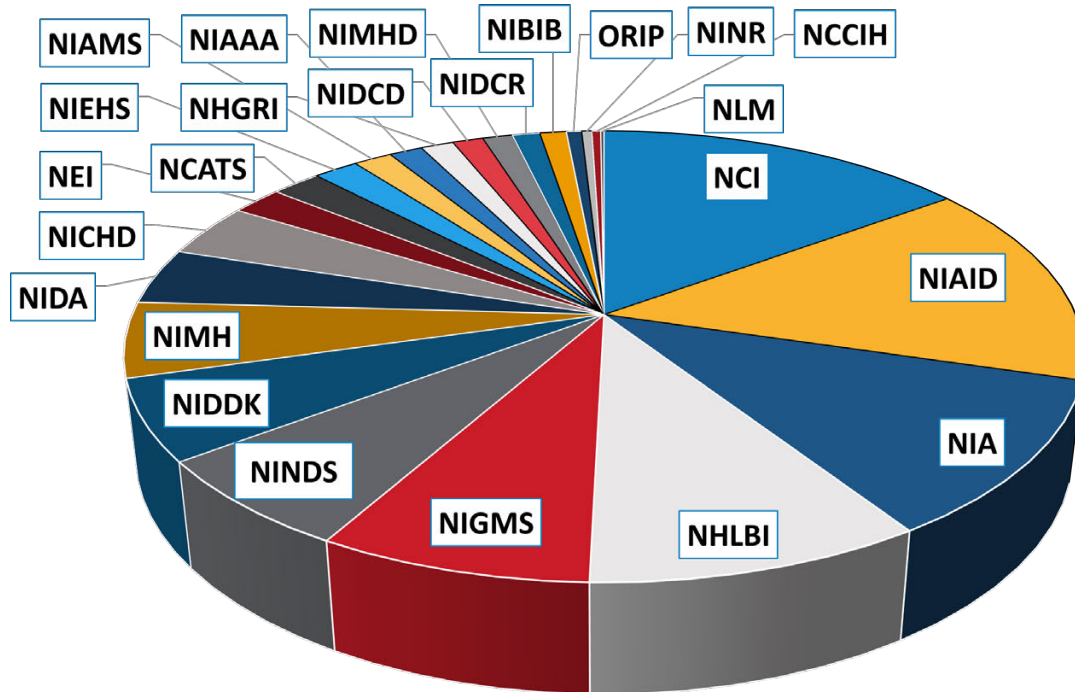


Small Business Technology Transfer (STTR) Program

Set-aside program to facilitate cooperative R&D between small businesses and U.S. research institutions — with potential for commercialization



NIH SBIR/STTR Budget Allocation FY22



**FY22 NIH SBIR/STTR
Budget > \$1.3 billion**

3.2% SBIR, \$1.1 billion
0.45% STTR, \$158 million

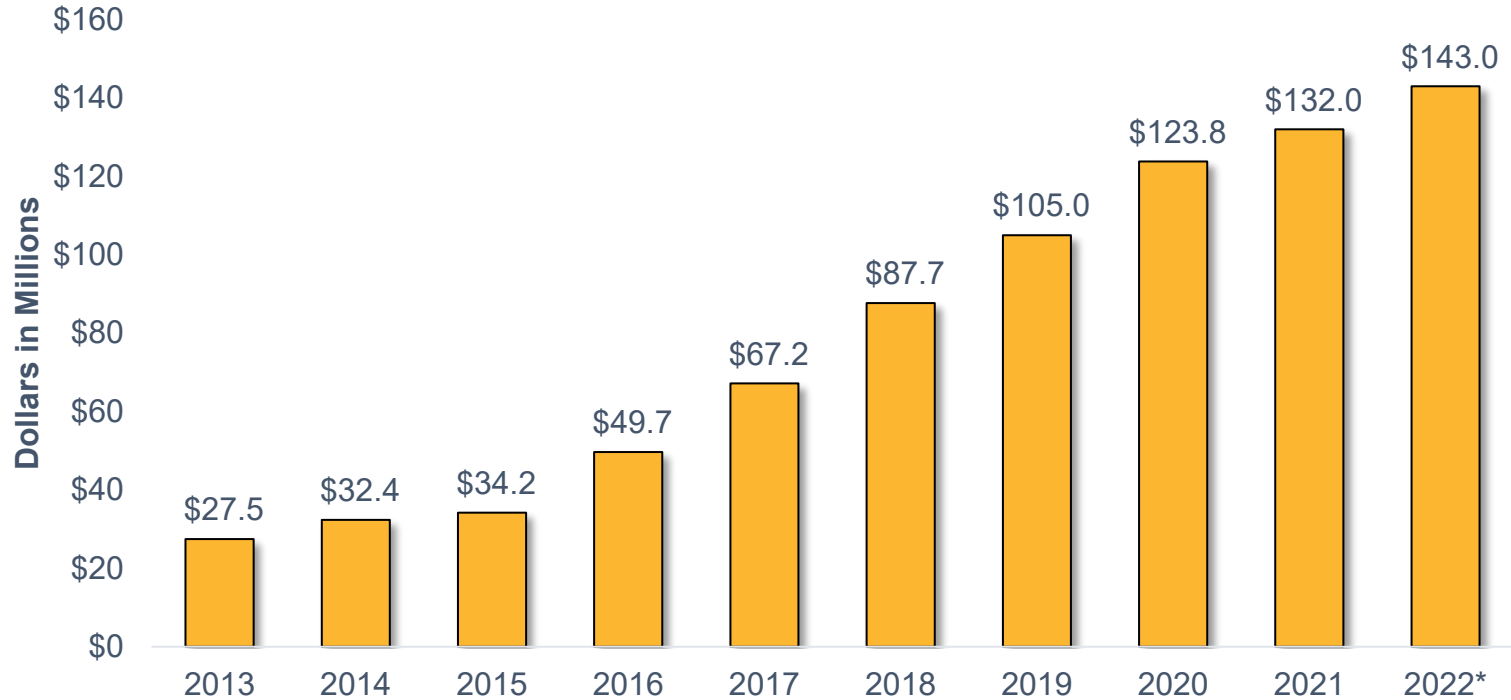
**FY22 NIA SBIR/STTR
Budget > ~ \$143 million***

Represents **significant growth**
from the **FY15 NIA SBIR/STTR**
budget of **~\$34 million**

*estimate



NIA SBIR/STTR Obligation



*estimates



Why Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
 - ❖ **Not a loan**
 - ❖ **No repayment required**
 - ❖ **No impact on stock or shares (non-dilutive)**
- Small business retains intellectual property rights
- Provides recognition, verification, and visibility
- Helps attract additional funding or support (e.g., venture capital, strategic partner)

?



Eligibility

- ✓ Applicant must be a small business
- ✓ 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 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

**AWARDS
ALWAYS MADE
TO THE SMALL
BUSINESS**



Critical Differences

AWARD IS
STILL MADE
TO THE
SMALL
BUSINESS!



SBIR	STTR
<p>Permits research institution partners (e.g., universities)</p>	<p>Requires research institution partners (e.g., universities)</p>
<p>Small business may outsource ~33% of Phase I activities and 50% of Phase II activities</p>	<p>The for-profit small business should conduct a minimum of 40% of the work, and a non-profit U.S. research institution should conduct a minimum of 30% of the work</p>
<p>Eligibility: Project Director/Principal Investigator's primary employment (> 50%) must be with the small business for the duration of the project</p>	<p>Eligibility: An agreement providing necessary intellectual property (IP) rights to the small business is required to carry out follow-on R&D and commercialization</p> <p>Principal Investigator primary employment not stipulated (at least 10% effort to project)</p>



SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	<ul style="list-style-type: none"> • Typically 1 year in length • Awards up to \$300,000, or up to \$500,000 for AD/ADRD • Establish technical merit, feasibility, and potential for commercialization
Phase II	Development & Full R&D	<ul style="list-style-type: none"> • Typically 2 years in length • Awards up to \$2 million, or up to \$2.5 million for AD/ADRD • Continues Phase I R&D efforts • Requires a commercialization plan
Fast Track		<ul style="list-style-type: none"> • One combined application for Phases I and II
Direct-to-Phase II (SBIR only)		<ul style="list-style-type: none"> • Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		<ul style="list-style-type: none"> • Funding for late-stage R&D and technical assistance for commercialization
Phase IIB	Competing Renewal	<ul style="list-style-type: none"> • Up to 3 years • Awards up to \$3 million



Budget Specifics

TOTAL COSTS

- ❖ SBIR/STTR budgets are defined by **total costs**, and subcontracting is limited. Know the rules and the criteria.
- ❖ Check the budget allowance in each funding opportunity.

- ❖ **Can request a 7% fee:**
 - Company profit
 - Part 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 the small business.
 - 3) It is a fee per basis (no indirect costs by fee for service providers).



NIH Funding Mechanisms

Investigator-Initiated Grants

1.

Omnibus Solicitation

3 receipt dates:
January 5 • April 5
September 5

Other Funding Opportunities

2.

Targeted Solicitations

Focused priority
areas with variable
receipt dates

Contracts

3.

Targeted Solicitations

Specified deliverable with
1 receipt date per year



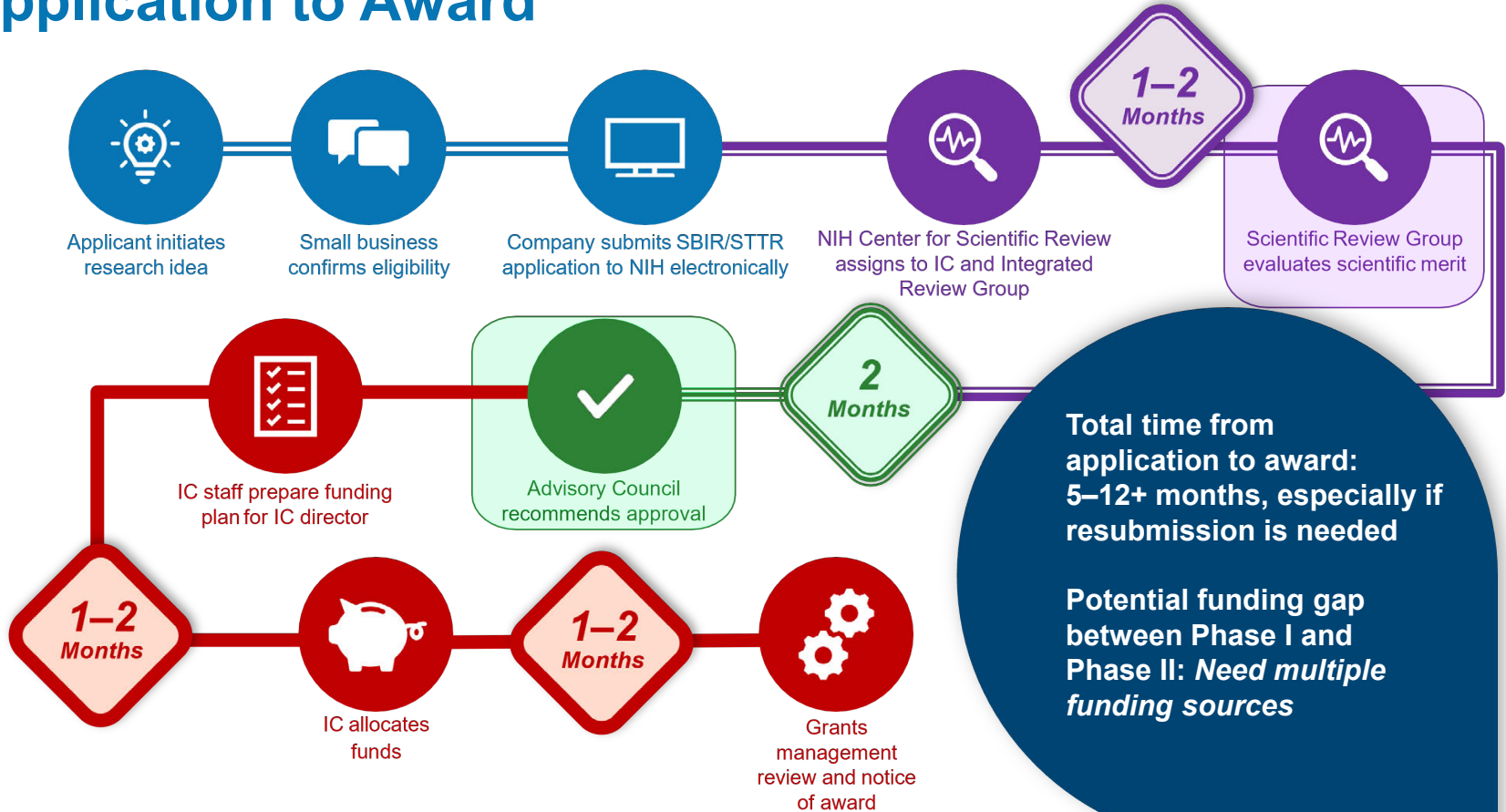
Application Cycles



Standard Due Dates	Review Meetings	Advisory Council Review	Earliest Project Start Date
SEPTEMBER 5	NOVEMBER	JANUARY	APRIL
APRIL 5	JUNE	AUGUST	SEPTEMBER
JANUARY 5	MARCH	MAY	JULY



Application to Award



NIA Small Business Programs: Core Activities



Central Coordination

Administer all SBIR/STTR awards at NIA



Guidance

Help applicants prepare for application/resubmission, and discuss funding options



Outreach

Attend conference/workshops and visit regional 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

Stakeholder Engagement for Cross-Leverage: ADDF SBIR Bridge Funding and Longevity Innovation Summits



NIA Research Divisions

NIA provides SBIR/STTR support through four research divisions:

- **Division of Aging Biology**: Provides a basis in basic biology for preventive 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 levels.
- **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 highest priorities.



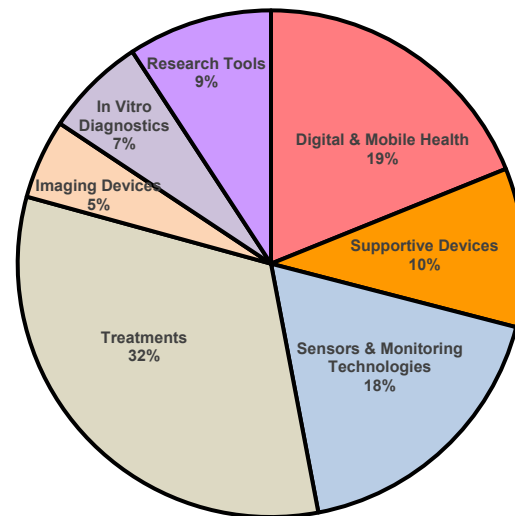
We Strategically Fund Innovations for:

- Alzheimer's disease (AD), AD-related dementias (ADRD), and age-related change in brain function
- Aging in place
- Age-related diseases and conditions
- Research tools

Additional Areas of Interest

- Companion diagnostics and other forms of personalized medicine
- Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand and predict health outcomes
- Novel cell and gene therapies, as well as other novel therapeutic approaches to AD/ADRD
- Biomarkers and diagnostic tools for the early detection of disease
- Prevention and therapeutics that directly target mechanisms related to aging biology
- Assistive technology, devices, and mobile applications for older adults and caregivers
- Tools, technologies, and analytic methods to address health disparities among older adults

Portfolio Classifications (AD & Non AD)

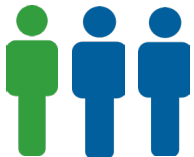


Alzheimer's Disease and Related Dementias

1 in 3

seniors dies with Alzheimer's or other Dementia

Alzheimer's kills more people than breast cancer and prostate cancer **COMBINED**



In 2018, Alzheimer's and other dementias will cost the nation

\$277 BILLION

By 2050, these costs could rise as high as

\$1.1 TRILLION



5.7 MILLION

Americans are living with Alzheimer's

By 2050, this number is projected to rise to nearly

14 MILLION



Alzheimer's is the

6th leading cause of death in the United States

16.1 MILLION

Americans provide unpaid care for people with Alzheimer's or other dementias

These caregivers provide an estimated

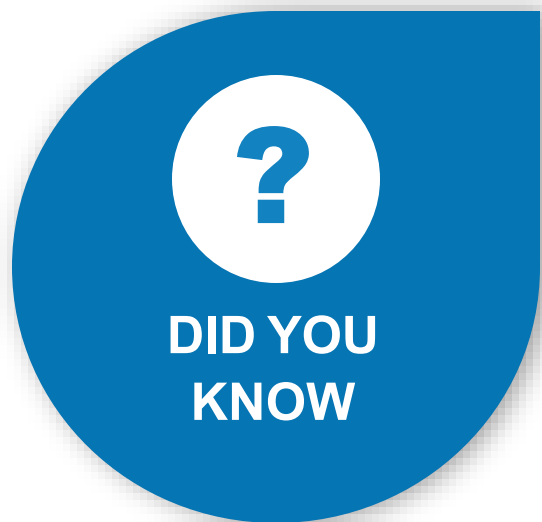
18.4 BILLION HOURS

of care valued at over

\$232 BILLION



Alzheimer's Disease and Related Dementias



- 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 needed to meet the first goal of the National Plan to Address Alzheimer's Disease — to effectively treat and prevent the disease by 2025
- ***NIA funding for small business opportunities has increased 300% during the past 4 years***



NIA Funding Opportunities

	Omnibus FOAs	AD/ADRD-Focused FOAs
SBIR	<p>PA-22-176 (clinical trial not allowed) PA-22-177 (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p>PAS-22-196 (Advancing Research on AD/ADRD)</p> <p><i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>
STTR	<p>PA-22-178 (clinical trial not allowed) PA-22-179 (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p>PAS-22-197 (Advancing Research on AD/ADRD)</p> <p><i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>



NIA Funding Opportunities (Continued)

Commercial Readiness Pilot (CRP) Program	Budget Limits
PAR-20-128 (CRP Technical Assistance; clinical trial not allowed)	\$300,000
PAR-20-129 (CRP Technical Assistance and Late Stage Development; clinical trial not allowed)	\$1.75 million/year for 2 years (\$3.3 million total)
PAR-20-130 (CRP Technical Assistance and Late Stage Development; clinical trial required)	\$1.75 million/year for 2 years (\$3.3 million total)
Supplements & NIA Participating Initiatives	Budget Limits
PA-21-345 (Administrative Supplements to Promote Diversity in Research and Development Small Business; clinical trial not allowed)	\$250,000 in direct costs
NOT-NS-017 (SBIR Technology Transfer; clinical trial not allowed)	Phase I \$300,000; Phase II \$2 million

More funding opportunities: www.nia.nih.gov/research/sbir/nia-small-business-funding-opportunities



NIA Entrepreneurial Development Funding Opportunities

	FOAs	Due Dates	Budget Limits
SBIR	RFA-AG-23-029 (REDI Entrepreneurial Small Business Transition Award; clinical trial optional)	Letter of Intent: January 17, 2023 Application: February 17, 2023	Phase I \$400,000; Fast-Track \$2 million
STTR	RFA-AG-23-030 (REDI Entrepreneurial Small Business Transition Award; clinical trial optional)	Letter of Intent: January 17, 2023 Application: February 17, 2023	Phase I \$400,000; Fast-Track \$2 million
R25	PAR-22-226 (REDI Entrepreneurship Enhancement Award; clinical trial not allowed)	Letter of Intent: 30 days before due date Applications: November 15, 2022; October 18, 2023; October 17, 2024	\$250,000/year in direct costs
K01	PAR-22-227 (REDI Mentored Entrepreneurial Career Development Award; clinical trial not allowed)	Letter of Intent: N/A Applications: November 15, 2022; October 18, 2023; October 17, 2024	\$90,000/year in salary; \$50,000/year in other program-related expenses

Research and Entrepreneurial Development Immersion (REDI)

Empowering spin-offs is critical to biomedical innovation, the economy, and the NIA mission. REDI provides bio-entrepreneurship training to further enrich and diversify NIA training programs. REDI-supported trainees acquire additional non-academic skills for success, such as science communications; intellectual property; regulatory affairs; science policy; consulting; drug discovery, approval, and production; and the business of science, science education, and health care. **Participants from diverse backgrounds are particularly encouraged to apply.**

Visit: <https://www.nia.nih.gov/research/sbir/nia-research-and-entrepreneurial-development-immersion-redi>



NIA Research Topics: FY2023 SBIR Contracts Solicitation

SBIR [PHS-2023-1](#) (FY2023 Contracts Solicitation)

Application Due Date: November 4, 2022, 5 p.m. ET

SBIR PHS-2023-1	FOAs	Phase Eligibility	
		Fast Track	Direct to Phase II
Topic 007	<p>High Throughput CHIP (clonal hematopoiesis of indeterminate potential) Assay as a Powerful Tool to Study CHIP Related Age Associated Diseases</p> <p><i>Budget (total costs, per award): Phase I: \$300,000 for 12 months; Phase II: \$2 million for 2 years</i></p>	✓	✓
Topic 008	<p>Improving Microphysiological Systems for AD/ADRD Therapy Development</p> <p><i>Budget (total costs, per award): Phase I: \$500,000 for 12 months; Phase II: \$2.5 million for 2 years</i></p>	✓	✓
Topic 009	<p>AI/ML Tool for Visualizing Behavioral and Social Science Research</p> <p><i>Budget (total costs, per award): Phase I: \$500,000 for 12 months; Phase II: \$2.5 million for 2 years</i></p>	✓	✓

Visit: <https://www.nia.nih.gov/research/sbir/nia-small-business-research-contract-topics>



Technical and Business Assistance (TABA) Budget Allowance

- **Purpose:** Help small businesses make better technical decisions, solve technical problems, minimize technical risks, and develop and commercialize new products and processes
- **Eligibility:** All SBIR/STTR awardees
- **Examples:**
 - ❖ Technology expertise
 - ❖ Product sales expertise
 - ❖ Intellectual property protections expertise
 - ❖ Market research and validation
 - ❖ Development of regulatory plans
 - ❖ Development of manufacturing plans
 - ❖ Technical and business literature
- **Contact:** [Saroj Regmi, Ph.D.](#)

Request within the Application:

- F. Other Direct Costs, lines 8–10
- Label as “Technical Assistance”

Budget Allowance:

- Phase I up to \$6,500 per year
- Phase II cap of \$50,000



Already have a Phase II? Consider the Commercialization Readiness Pilot (CRP) Program

- Can be simultaneous or follow-on to Phase II and Phase IIB (both SBIR and STTR).
- SB1 mechanism enables an absence of subcontracting restriction. The subcontracting plan must still be justified in the application.
- Special review criteria include a focus on “innovation” of the product.
- Provides funding for activities that are not typically supported by research grants.



Scope of the **Small** CRP

- [PAR-20-128](#): “SBIR/STTR CRP Technical Assistance”
- Total costs limit: \$300,000
- Supports technical assistance, such as:
 - ❖ Development of a regulatory strategy
 - ❖ Development of an IP strategy
 - ❖ Design and planning for a clinical trial, including document assembly
 - ❖ Manufacturing assistance
 - ❖ Market research and activities



Scope of the **Large** CRP

- [PAR-20-129](#) and [PAR-20-130](#): “SBIR/STTR CRP Technical Assistance and Late Stage Development”
- Total costs limit: \$3,360,358 (3x Phase II guideline)
- Supports technical assistance and later-stage R&D not typically supported by Phase II/IIB, such as:
 - ❖ Technical assistance (as listed on previous slide)
 - ❖ Independent replication/confirmation of key studies
 - ❖ Activities to comply and address FDA regulations (including GLP and GMP efforts)
 - ❖ Design optimization, verification, and validation
 - ❖ Process optimization, synthesis, and scale-up
 - ❖ Assay validation and chemistry, manufacturing, and control activities
 - ❖ Clinical studies and trials



Women-Owned & Disadvantaged Small Businesses

- **Goal:** Encourage participation in innovation and entrepreneurship by socially and economically disadvantaged small businesses and women-owned small businesses
- **Women-owned business:** Must be at least of 51% owned and controlled by one or more women and primarily managed by one or more women (who must be U.S. citizens)
- **Socially and economically disadvantaged business:** Must be a minimum of 51% owned and controlled by one or more people who are socially and economically disadvantaged (who must be U.S. citizens)
- Businesses can self-certify during the application process; certification information is encouraged, but not required



Diversity Supplement Program

- **Administrative Supplements to Promote Diversity in Research and Development Small Businesses** — SBIR/STTR Cooperative Agreements ([PA-21-345](#))
- **Eligibility:** All SBIR/STTR awardees
- **Goal:** Improve the diversity of the research workforce by recruiting and supporting students, post-doctorates, and eligible investigators from groups that have been shown to be underrepresented in health-related research or in the SBIR/STTR programs
- **Funding:** Up to \$100,000
- **Applications:** Include identification of the candidate as well as a strong career development plan
- **Deadline:** Applications accepted on a rolling basis
- **Contact:** [Armineh Ghazarian, M.S.F.](#)



ADDF Phase I Bridge Support

Alzheimer's Drug Discovery Foundation (ADDF) funding opportunity for NIA awardees:

- **Eligibility:** U.S.-based companies previously awarded NIA SBIR/STTR Phase I awards or applicants with scored but unfunded applications & Phase II awardees
- **Purpose:** NIA SBIR/STTR awardees can receive interim funding from ADDF to:
 - ❖ Serve as bridge funding as NIA funding decisions are finalized
 - ❖ Enable investigators to continue to generate additional data in support of SBIR/STTR Phase II awards or other NIH grants
- **Contact:** [Zane Martin, Ph.D.](#)
- **Apply:** <https://bit.ly/3c9nqMz>



Resources to Help Research Entrepreneurs

Everyone

Webinars & Events. Watch [archived presentations](#) including a mock peer review session on our website and sign up for future events.

Applicants

Sample Applications. Review other [successful applications](#) on our website to see what information other applicants included and how they presented it.

Applicant Assistance Program. A [10-week coaching program](#) to help prepare your Phase I application. Offered once each standard funding period. Open to first-time and never-funded applicants.

Phase I Awardees

Diversity Supplement. [Funds to recruit and support](#) students, postdocs, and eligible investigators from underrepresented groups that enhance the diversity of the research and entrepreneurial workforce.

Innovator Support. Support from the [NIA Entrepreneurs-in-Residence](#) including business consults, pitch coaching, and company showcase opportunities.

Additional Resources and Support for Grantees. Companies that receive SBIR/STTR awards are [eligible to apply](#) for additional funding, technical assistance, and training programs such as the I-Corps™ at NIH program, C3i Medical Device Entrepreneurial Training Program, and training programs designed for diverse applicants.



NIH Applicant Assistance Program

- Free application preparation **assistance** for 10 weeks
- Participating ICs: NIA, NCI, NHLBI, NINDS, NCCIH, NCATS, NIEHS and NINR

Goal:
Provide a mentor for applicants with great technology but little NIH experience and limited NIH experience in their network.

PROVIDED	NOT PROVIDED
Phase I preparation support and review	Grant writer
Specific Aims page review and advice	Development of research plan
Submission process coaching	Register small business for you Apply to NIH for you



NIH Applicant Assistance Program: Eligibility and Process

- Simple eligibility criteria:
 - ❖ **Never received a small business grant award from NIH**
 - OR**
 - ❖ **Received an award prior to 2010**
- Interested in applicants who are currently underrepresented in the biosciences (not a requirement)
 - ❖ Women-owned small businesses
 - ❖ Minority-owned small businesses
 - ❖ Small businesses operating in an underrepresented (IDeA) state
- **Contact:** [Joy Toliver, M.P.H.](#)

AAP application portal:

<http://bit.ly/2020AAP>

- Answer a series of structured questions
- Upload supporting documents (e.g., abstract)
- Submit



Commercializing Innovation (C3i) Program

- 24-week entrepreneurial training course designed to support medical device innovators in commercializing their products
- **Eligibility:** All SBIR and STTR awardees
- **Goal:** Provide specialized business frameworks and essential tools for successful transition of biomedical technologies from the lab (concept) to the market (clinic)
- **Deadline:** Applications due annually on July 1
- **Contact:** [Saroj Regmi, Ph.D.](#)



I-Corps™ at NIH

- 8 week-intensive entrepreneurship immersion course
- **Eligibility:** Phase I SBIR/STTR awardees
- **Goal:** Offers real-world, hands-on training and customer discovery in life sciences and biotechnology
- **Benefits:**
 - ❖ Provides up to \$55,000 to cover direct program costs
 - ❖ Training from biotech sector experts
 - ❖ Expanding your professional network
 - ❖ Building the confidence and skills to create a comprehensive business model
 - ❖ Gaining years of entrepreneurial skills in only weeks
- **Contact:** [Saroj Regmi, Ph.D.](#)



Entrepreneur-in-Residence (EIR) Support for Awardees



Diane Ignar, P.h.D., R.Ph., provides valuable guidance and entrepreneurial coaching to NIA-funded companies by sharing the knowledge and experience gained during her tenure at GlaxoSmithKline. She has worked in new technology development, preclinical drug discovery, clinical development, and business development. She has held senior leadership roles in life-science startups and has assisted numerous startups at Duke University and University of North Carolina with business strategy, R&D planning and seed funding. Diane holds four patents and has published 40 papers.



John P. Reinhart, C.P.A., M.B.A., provides valuable guidance and entrepreneurial coaching to NIA-funded companies. John has extensive experience in longevity economy innovations and is a co-founder and board member of the Thrive Center in Louisville, Kentucky, a not-for-profit innovation center that brings together consumers, entrepreneurs, researchers, investors, providers, and distributors to explore solutions that enhance both the quality of life and care for a global aging population. He has held executive roles at several health care companies, including a multistate long-term care provider and an electronic health records software venture that was acquired by a NASDAQ company.

Request EIR Support: NIAsmallbusiness@mail.nih.gov



Entrepreneur Workshop Series

Dates: 2021–2022 | [All recordings now available](#)

Goal: Support startups along the journey to commercializing novel scientific products and technologies through a series of entrepreneurship workshops for small business awardees and applicants

Format: Topical presentation by one of NIA's Entrepreneurs-in-Residence, followed by breakout discussions with subject-matter experts

Hosts:

- NIA Small Business Programs
- National Heart, Lung, and Blood Institute's Small Business Program



Investor Showcase and Partnering Opportunities

Bio INVESTOR FORUM

AdvaMed

ACA ANGEL CAPITAL ASSOCIATION

AdvaMed

Bio INVESTOR FORUM

AdvaMed

ACA ANGEL CAPITAL ASSOCIATION

AdvaMed

ACA ANGEL CAPITAL ASSOCIATION

RESI REDEFINING EARLY STAGE INVESTMENTS

Bio INVESTOR FORUM

LIFESCIENCES™ SUMMIT

ACA ANGEL CAPITAL ASSOCIATION

SBIR Awardee Opportunities to Attend Investor Events & Receive Pitch Coaching

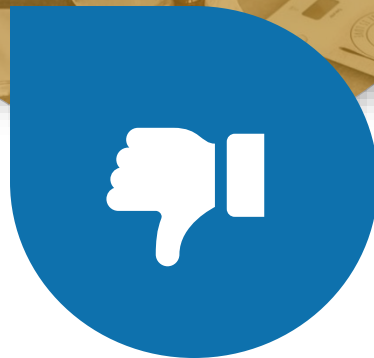


Tips for a Successful Application



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” of lost 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.
- **Contact the NIA Small Business Programs team at least 1 month before the due date to discuss your specific aims and receive feedback.**
- Review similar, currently funded NIH projects to identify competitors and/or collaborators using [NIH RePORTER](#).



NIH RePORTER

- Database of NIH-supported research
- In general, updated weekly with most up-to-date project information



Advanced Projects Search

Researcher and Organization

Fiscal Year ? Current FY is 2022

Principal Investigator (PI) ?

Organization ? Enter at least 3 characters to search

City ?

State ?

Country ?

Congressional District ? Please select a state first

Department Type ?

Organization Type ?

Matchmaker

Find potential Program Officials, ICs, and review panels for your research.

Publications Search

Find publications associated with extramural or intramural funded projects using PubMed IDs (PMID) or PubMed Central IDs (PMC ID).



Sample Applications: A Great Resource

Funded Company	Submission Type	Program and Phase	Application Links
Amprion	Original (Funded)	STTR, Phase II	Full Application Summary Statement
CareBand	Original	SBIR, Phase I	Full Application Summary Statement
CareBand	Resubmission (Funded)	SBIR, Phase I	Full Application Summary Statement
care.coach Corporation	Original	SBIR, Fast-Track	Full Application Summary Statement
care.coach Corporation	Resubmission (Funded)	SBIR, Fast-Track	Full Application Summary Statement
CorticoMetrics	Original	STTR, Fast-Track	Full Application Summary Statement
CorticoMetrics	Resubmission (Funded)	STTR, Fast-Track	Full Application Summary Statement
Crossroads Consulting	Original (Funded)	SBIR, Phase II	Full Application Summary Statement
StarWise	Original (Funded)	STTR, Phase I	Full Application Summary Statement



SF 424 Application Guide

Annotated Form Set for NIH Small Business (SBIR/STTR) Grant Applications

FORMS-F Series – Application due dates on/after May 25, 2020



Table of Contents

Forms	Page #
SF424 (R&R)	2
PHS 398 Cover Page Supplement	4
R&R Other Project Information	6
Project/Performance Site Location(s)	7
R&R Senior/Key Person Profile (Expanded)	8
R&R Budget	9
R&R Subaward Budget Attachment(s) Form	13
PHS 398 Research Plan	14
SBIR/STTR Information	15
PHS Human Subject and Clinical Trial Form	17
Study Record	18
Inclusion Enrollment Report	19
PHS Assignment Request Form	24

Use "Ctrl F"
keyword search
on this document.
That's what I do!

Obtain Software
Applicants must have the free Adobe Reader software to view and submit an application. Learn which versions are compatible.

Write Application
Read tips for developing a strong application that helps reviewers evaluate its science and merit.

Develop Your Budget
Learn about the kinds of costs you may include in your budget submission, the difference between modular and detailed budgets, and more about how to develop your budget.

Format Attachments
Follow these requirements for preparing the documents you attach to your application. Requirements include criteria for the PDF file, fonts, margins, headers and footers, page size, citations, formatting pages, etc.

Rules for Text Fields
Learn the rules for form text fields -- allowable characters, cutting and pasting, character limits, and formatting.

Page Limits
Follow the page limits specified in this table for your specific grant program, unless otherwise specified in the FCR.

Tables
Find instructions, blank data tables, and samples to use with institutional research training applications.

Reference Letters
Some types of programs, such as fellowships and some career development awards, require the submission of reference letters by the referee. Learn about selecting a referee and find instructions for submission.

Biosketches
Biosketches are required in both competing applications and progress reports. Find instructions, blank format pages, and sample biosketches.

Submit
Learn how to submit your application, and about your responsibility for tracking your application and viewing the application image in the eRA Commons before the application deadline. If we can't view your application in eRA Commons, we can't review it.

Use NIH ASSIST for application submission, and review the annotated application forms:
bit.ly/3oukfFI



Specify Institute and Study Section

- Who is going to review your application?
 - ❖ A 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: <https://public.csr.nih.gov/StudySections>
 - ❖ Review the list of study section members.
 - ❖ Request study sections in the optional PHS Assignment Request Form (previously in the cover letter).

Suggest
an IC
assignment

IC scientific
areas of
expertise needed
to review your
application

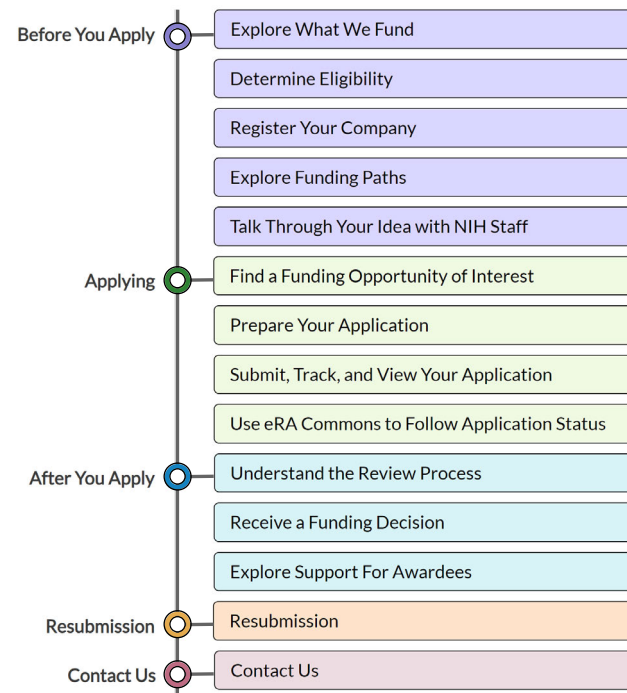
The image shows a screenshot of the PHS Assignment Request Form. The form is titled "PHS Assignment Request Form" and includes a "View Burden Statement" link. It contains sections for "Funding Opportunity Number" and "Funding Opportunity Title", both with input fields. Below these are sections for "Awarding Component Assignment Request (optional)" and "Study Section Assignment Request (optional)". Each of these sections includes a table with three columns (1, 2, 3) and two rows: "Assign to [Component/Study Section]" and "Do Not Assign to [Component/Study Section]". There are also instructions and links for each section. At the bottom, there is a section for "Identify Scientific areas of expertise needed to review your application (optional)" with a table with five columns (1-5) and two rows: "Expertise" and "Only 40 characters allowed".

Suggest
the study
section

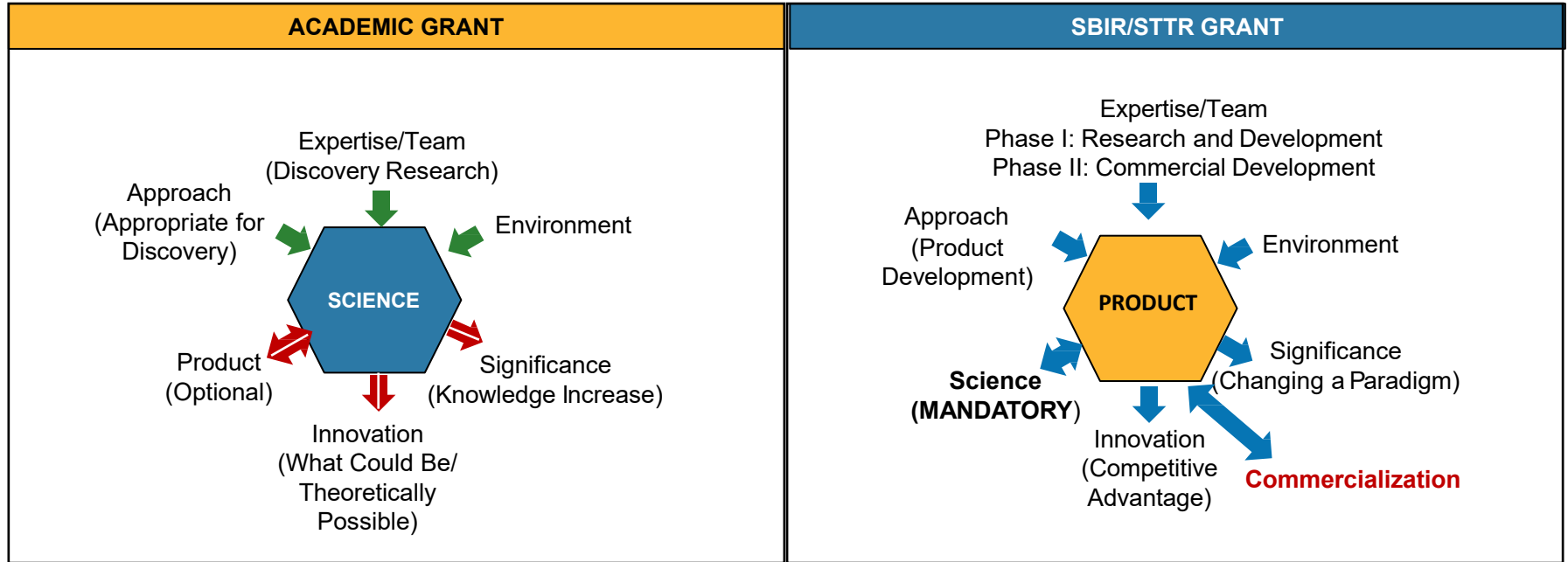


Tip 1: Start Early

- **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.
 - ❖ Follow the SF 424 application guide.
 - ❖ Process and electronic submission information:
<https://seed.nih.gov/small-business-funding/how-to-apply>



Remember: Focus on Product



Review Criteria

SIGNIFICANCE

Does the product address an important problem and have commercial potential? Is there a market for the proposed product?

APPROACH

Are design and methods well developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

INNOVATION

How novel are the technology/product and the approaches proposed to test feasibility? What is the competitive advantage?

INVESTIGATOR

Are the investigators, collaborators, and consultants appropriately trained and capable of completing all project tasks?

ENVIRONMENT

Does the scientific environment contribute to the probability of success? Facilities? Independence?

COMMERCIALIZATION

Is the company's business strategy one that has a high potential for success?



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/STTR grantees, academic collaborators with grant writing experience, professional grant writers*
- **Carefully consider the study design.**
 - ❖ Identify strategies to mitigate risk.
 - ❖ Present alternative approaches if problems are encountered.

*Contact NIA Small Business Programs staff for the most up-to-date information on agency priorities, current NIH policies, etc.



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 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 1/2 to 2/3:

The Elevator Pitch—Why Is It Meritorious?

1. The technology prototype or therapeutic to be developed;
2. The technical innovation the development would represent, the unmet need it addresses, and technical challenges to overcome;
3. The value proposition and competition, and how the technology builds on current scientific premise and/or preliminary data;
4. The proposed specific research aims, including key models, assays, metrics, and quantitative performance milestones; and
5. The relevance of the research and development to NIA's mission.



Last 1/3 to 1/2:

The Specific Aims for the Proposed Project

- Key models, assays, and metrics
- Quantitative performance milestones

Provide your draft Specific Aims page to NIA Small Business Programs staff for feedback.



Draft a Clear Application: Research Strategy

- Address all the review criteria clearly.
- Provide background information.
- Provide a detailed technical plan to achieve the Specific Aims.
- Propose a project scope within the budget and time constraints.
- Preliminary data are not required (in Phase I) but are often needed to be competitive.
- Describe potential pitfalls and alternative angles of attack.
- Approach section should be prioritized real estate; the reviewers tend to focus on that criterion.



Phase I: 6 pages

Phase II: 12 pages



Draft a Clear Application: Other Components

- Letters of support
 - ❖ **Necessary from consultants and collaborators**
 - ❖ **Powerful from clinicians, end-users, investors not on application**
- Phase II commercialization plan (12 pages)
- Biosketches for all senior and key personnel (< 5 pages)
- Budgets for each project period and for each subcontract
- Detailed descriptions of facilities and equipment
- Human subjects research section (if applicable)
- Vertebrate animals section (if applicable)



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;** identify them and suggest strategies to overcome them.
- **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?



Tip 6: Review These Policies

BEFORE YOU SUBMIT:

- **Check whether your application is considered a clinical trial.**
 - ❖ To ensure that your application is not withdrawn, please confirm whether your application is considered a clinical trial according to NIH guidelines: <https://grants.nih.gov/ct-decision/index.htm>
- **Do not include hyperlinks in your application.**
 - ❖ Please make sure that your application is compliant with NIH policy on hyperlinks: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html>
 - ❖ More on this topic: <https://nexus.od.nih.gov/all/2019/05/13/the-dos-donts-of-hyperlinks-in-grant-applications/>



After You Apply

NIH uses a two-level review process:

1. **Peer review:** Applications are assigned to study sections where they are evaluated for scientific and technical merit.
2. **Council review:** The funding Institute/Center's Advisory Council considers the study section's results and determines the relevance of the applications to the IC's priorities and public health needs. The council makes funding recommendations to the IC director.

The Just-in-Time process follows for successful applications:

If you receive a favorable review outcome, you may be asked to submit additional information using the [Just-in-Time \(JIT\) process in eRA Commons](#). For more information about what is expected during the JIT process, [view this tutorial](#).



If You Weren't Funded on the First Try

Rejection is painful, but feedback provides a roadmap for next steps.

- **Carefully review the Summary Statement (written critiques).**
 - ❖ Discuss the Summary Statement with your NIH Program Officer.
 - ❖ Use reviewer comments to improve your application.
- **Revise and resubmit the application.**
 - ❖ Introduction Page: Respond to reviewer critiques.
 - ❖ Be constructive, NOT defensive.
 - ❖ Award rate for resubmissions was **15.8%** compared to **8.3%** for non-resubmissions in FY20
- **Learn more about SBIR/STTR grants.**
 - ❖ Talk to successful applicants.
 - ❖ Understand the review process and dynamics: <http://csr.nih.gov>



Application Resources


- Small Business Resources:
 - ❖ [Sample SBIR Grant Applications from NIA](#)
 - ❖ [Annotated Form Set for NIH SBIR Grant Applications](#)
 - ❖ [SBIR/STTR Application Process](#)
 - ❖ [Small Business Programs, National Institute on Aging](#)
- Database of NIH-Supported Research: [NIH RePORTER](#)
 - ❖ Find Similar Projects and Program Staff: [NIH Matchmaker](#)
- NIA-Supported Animal Model Resources:
 - ❖ [Alzheimer's Disease Preclinical Efficacy Database](#) (models, agents, and markers)
 - ❖ [MODEL-AD Consortium](#) focused on developing next-generation animal models for Alzheimer's
 - ❖ [Aged Rodent Colonies](#) Handbook




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