NIA Small Business SEED Fund:

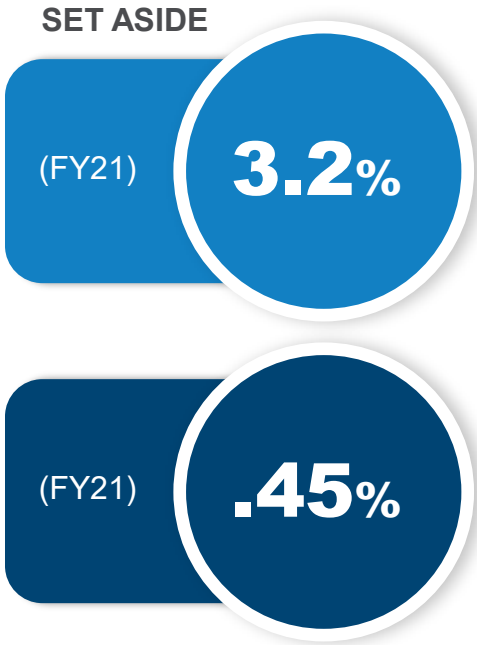
Accelerating Alzheimer's and Aging Research

National Institute on Aging

JLABS December 2022

About SBIR and STTR

Congressionally Mandated Programs



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 Programs

SBIR

The program ***funds early-stage small businesses seeking to commercialize innovative life science technologies and services.*** This competitive program helps small businesses participate in federal R&D, develop life-saving technologies, and create jobs.

STTR

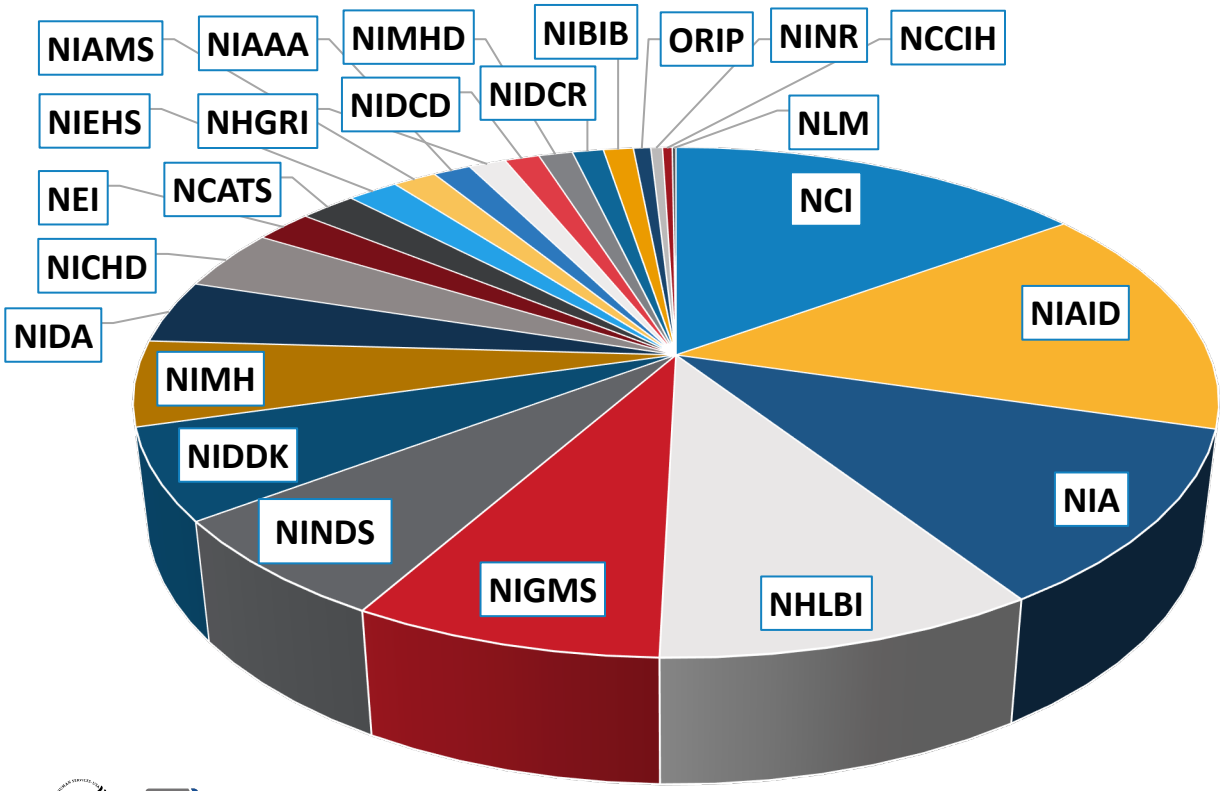
The program is similar to the SBIR program but ***requires that the small business formally collaborate with a research institution.***

SBIR/STTR funding has significantly increased:

NIH: Total of > $1.3 billion* (FY22)

NIA: Total of > $143 million* (FY22)

NIH SBIR/STTR Budget Allocation FY22



FY22 NIH SBIR/STTR Budget > $1.3 billion

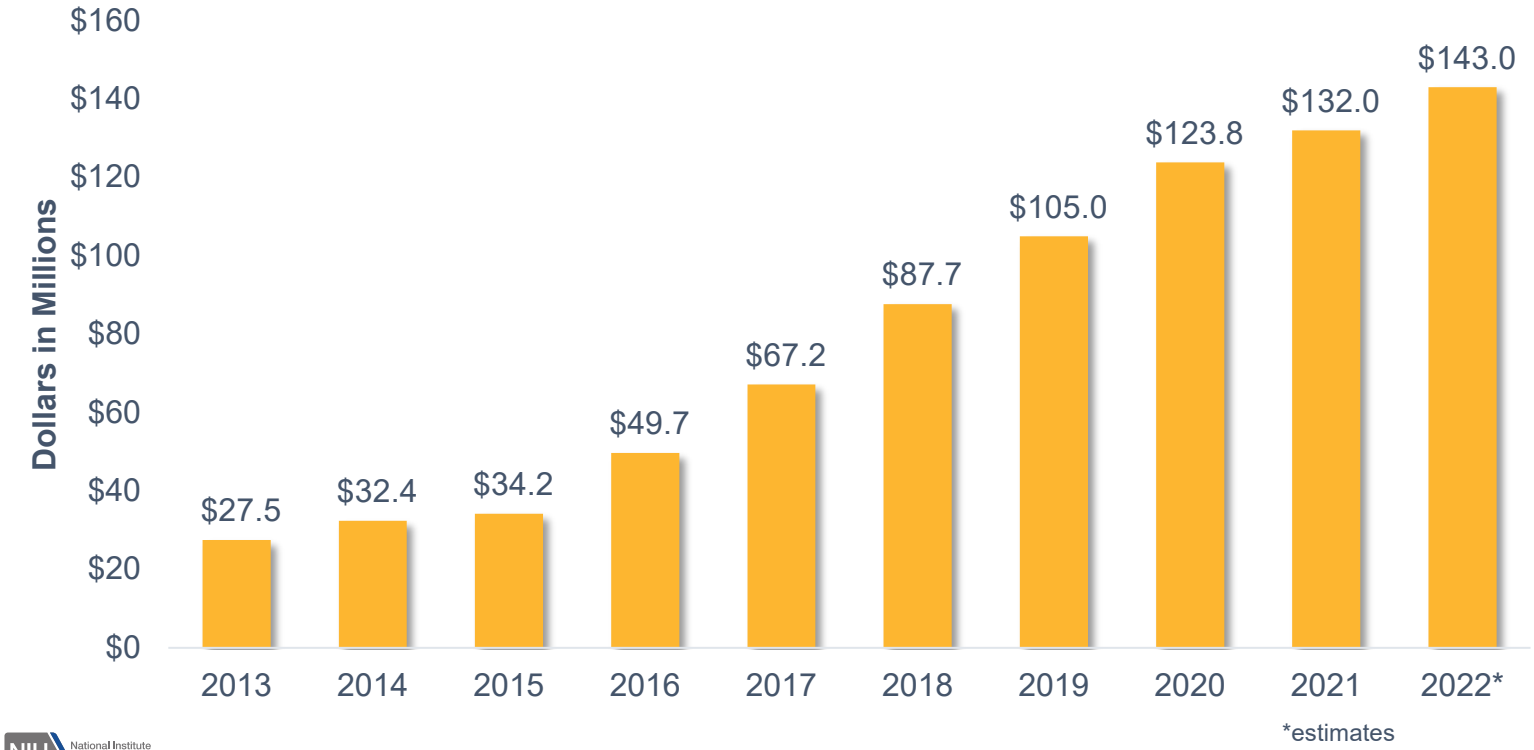
3.2% SBIR, $1.1 billion
0.45% STTR, $158 million

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



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

Critical Differences

AWARD IS STILL MADE TO THE SMALL BUSINESS!

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

SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	• 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	• 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		• One combined application for Phases I and II
Direct-to-Phase II (SBIR only)		• Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		• Funding for late-stage R&D and technical assistance for commercialization
Phase IIB	Competing Renewal	• 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.

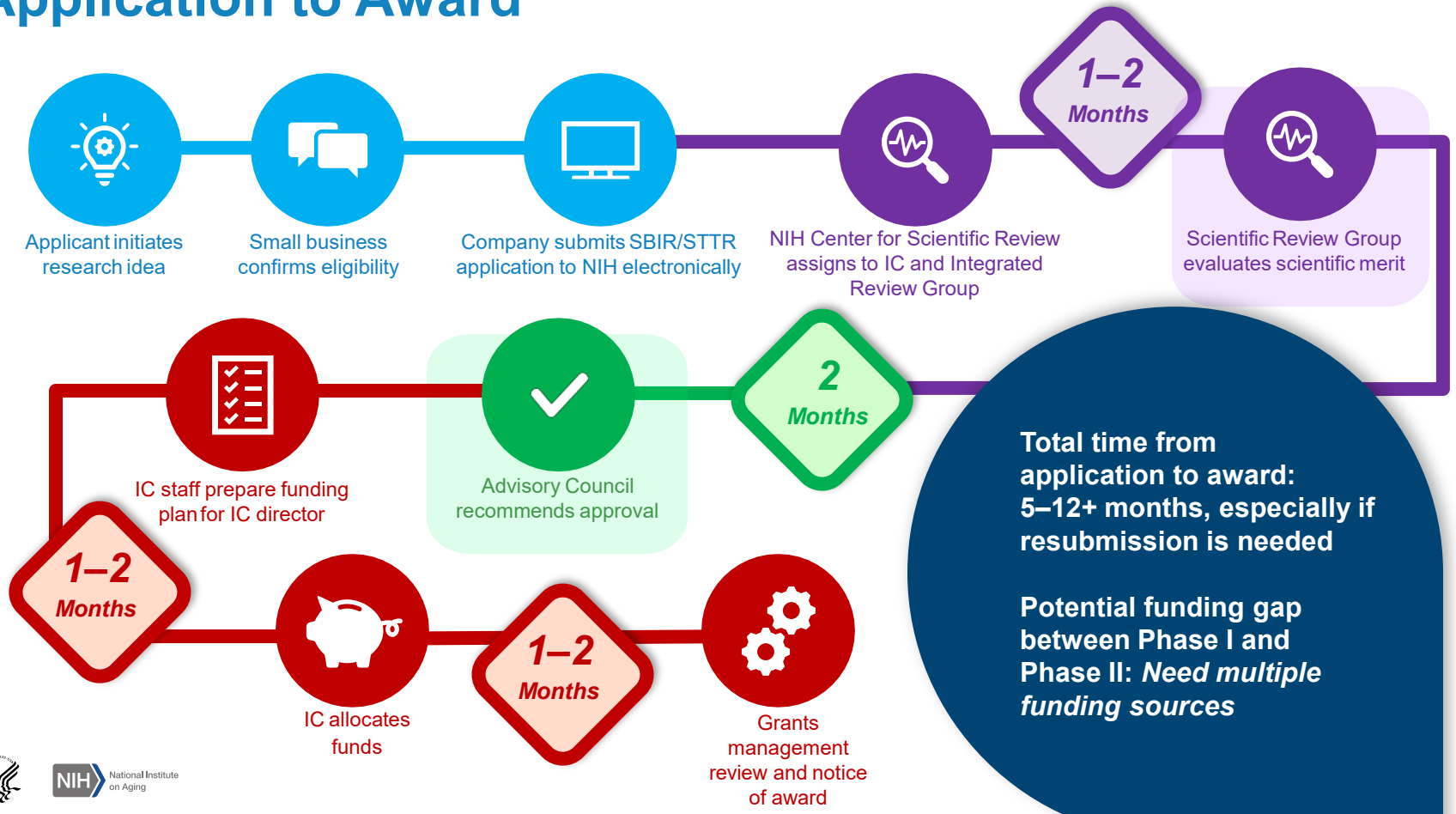
Targeted Solicitations

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



NIH National Institute on Aging

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

Meet the Office of Strategic Extramural Programs

Todd Haim,
Director

Shoshana Y. Kahana,
Deputy Director

M-D Kerns,
HSA

Armineh Ghazarian,
Analyst

John Reinhart,
EIR

Joshua Hooks,
AAAS Science
Policy Fellow

Joy Toliver,
Analyst

Diane Ignar,
EIR

Entrepreneurial and/or Small Business Focus

Maria Carranza,
Training Officer,
HSA

Jamie Lahvic,
HSA

Training and Career Development Focus

Chelsea Dinneny,
Analyst

Administrative Coordination

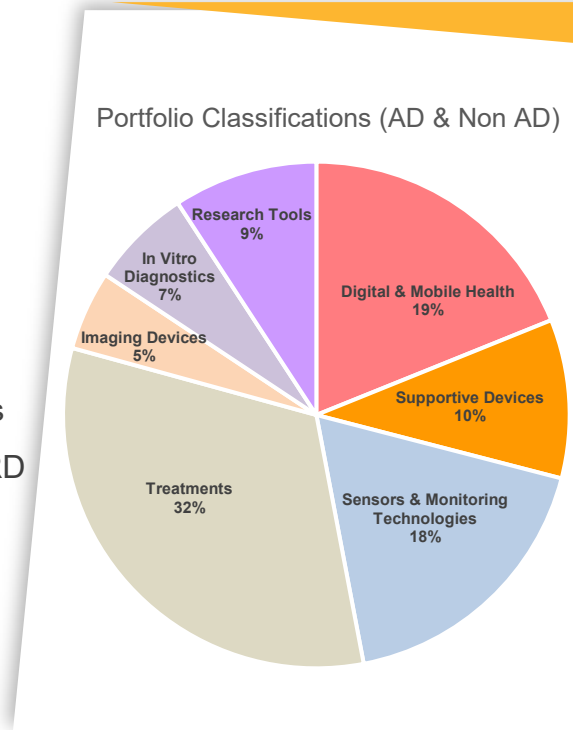
NIA Research Divisions

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

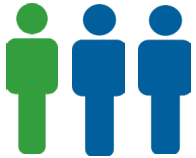
- Companion diagnostics and other forms of personalized medicine
- Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand and predict health outcomes
- Novel cell and gene therapies, as well as other novel 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

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

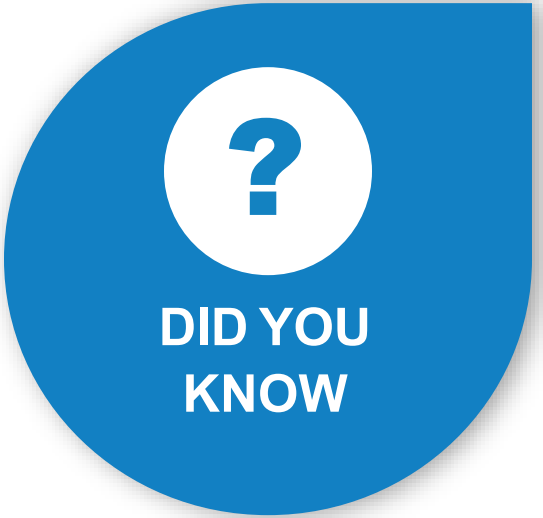
These caregivers provide an estimated

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	**PA-22-176** (clinical trial not allowed) **PA-22-177** (clinical trial required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-22-196** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million*
STTR	**PA-22-178** (clinical trial not allowed) **PA-22-179** (clinical trial required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-22-197** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million*

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

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

NIH National Institute on Aging

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-062.html

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.

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.

NIA 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

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

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

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:** Joshua Hooks

AAP application portal:

http://bit.ly/2020AAP

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

Submissions due December 12th!

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

More Than Funding: Get to Know SEED

Small business Education and Entrepreneurial Development (SEED)

- Supports the NIH innovator community with funding and resources to validate and advance discoveries into products that improve patient care and health
- Develops relationships with strategic partners and builds opportunities for NIH innovators to further their product development efforts
- **Website: https://seed.nih.gov**

Investor Showcase and Partnering Opportunities

Showcase Efforts at NIA

NIA maintains a virtual showcase for select NIA-funded companies that are chosen to participate in various investor showcases.

Learn more about the companies: www.nia.nih.gov/research/sbir/nia-small-business-showcase

Healthy Aging Start-Up Challenge and Accelerator to Foster Diversity and Accelerate Innovation

NIA Healthy Aging Start-up Challenge and Bootcamp to Foster Diversity and Accelerate Innovation

Launched in FY22

Program Coordinator: Joy Toliver, M.P.H. (NIA)

Entrepreneurial Bootcamp → 1:1 Mentorship → Five $60,000 Cash Prizes

Winners
- $60,000 cash prize
- Ongoing coaching and mentoring
- Follow up to encourage SBIR/STTR application

Finalists
- 1:1 Coaching & mentoring
- Live pitch
- Networking (peer to peer & industry)
- Deliverables due

Applicants
- Concise Application

Addressing challenges faced by diverse innovators & those addressing health disparities

2022 Challenge Cohort includes 20 finalist teams:

- A diverse representation across states, biomedical sectors, and indications
  - Therapeutics, Diagnostics, Tech and Digital Health
  - Innovations addressing health disparities, women's health, nursing research, oral health, Alzheimer's Disease, and enhancing healthy aging

Mayowa Agbaje-Williams, PharmD, MPH

Co-Founder

Moremee VA, LLC

Wheaton, IL

Non-hormonal therapeutic for vulvo-vaginal atrophy in post-menopausal women

Cameron Carter

Co-Founder & CEO

Rose Management Group, LLC

Centennial, CO

ML-driven platform to match providers and patients to affordable and vetted home modification products and services

Brittany Cassin, MBA

Co-Founder & CEO

DigiCARE Realized Inc.

Old Bridge, NJ

SaMD that uses ML predictive algorithms and EHR data for early detection of AD/ADRD

Steffany Chamut, DDS, MPH

Boston, MA

Digital health application to promote oral health in older adults

Jayfus Tucker Doswell, PhD

Founder

Juxtopia, LLC

Baltimore, MD

Intelligent, socially assistive robot to combat loneliness and detect AD/ADRD in elderly African American women

Christin Glorioso, MD, PhD

Founder & CEO

NeuroAge Therapeutics

San Francisco, CA

Therapeutic leveraging proprietary screening platforms using multi-omics biologics aging clocks to rejuvenate biological brain aging and treat neurodegenerative disorders

Zachary Hermes, MD, MBA, MPA, JM

ThetaSense, Inc.

Wilmington, DE

Cloud-based, device-agnostic, heart-brain-mind monitoring platform for early detection of cognitive impairment

Corey Hubbard

Founder

DreamHighr, Inc.

Battle Creek, MI

Platform leveraging AI, blockchain, and social media to engage and recruit underrepresented groups for Alzheimer's disease clinical trials

Robert Izuta

Elvee Performance Technologies, LLC

Ashland, NE

Easy-to-use, wearable gait monitor to detect the subtle gait changes that occur with MCI and dementia onset

Brenda Jamerson, PharmD

iSimcha, LLC

RTP, NC

Clinical trial recruitment platform leveraging community engagement and medical research education to increase participation from older, ethnically diverse populations

Katalin Janosi-Fair, DMD, MPH

Harvard Dental Group

San Juan Capistrano, CA

Multi-pronged oral care treatment for chronic oral inflammatory conditions linked to Alzheimer's disease

Eric Jutkowitz, PhD

Providence, RI

A scalable person-centered digital educational and coaching program for caregivers of people living with dementia

Tamara Lambert

Atlanta, GA

Wearable patch for continuous physiological monitoring that enables sepsis detection

Reginald Mbawuike

Co-Founder & CEO

Generating Innovation Ventures & Enterprises, Inc.

Boston, MA

SaaS software providing symptoms pathology data to improve health outcomes and reduce health disparities

Devita Stallings, PhD, RN

St. Louis, MO

Digital health app for the self-management of hypertension in African American older adults

NIH National Institute on Aging

Jennifer Villwock, MD, FAAOA

Kansas City, KS

Affordable, Rapid, Olfactory Measurement Array (AROMA) with ML on a web-based app for non-invasive dementia screening

Karen Webber, CPA, CFE

CEO

Webber Systems, LLC

Rochester, NY

SaaS product that provides data collection, analysis and reporting for financial exploitation cases

Denice Wharton, MBA

Founder & CEO

Suma

Oxnard, CA

Online management system that simplifies and streamlines the licensing and renewal process for CNAs, HHAs, and other medical professionals

Lanie Yeung

Hydro Gummy

Thousand Oaks, CA

Hydro Gummy is 90% water and electrolyte-enhanced, designed and formulated for hydration delivery to older adults

Maryam Zolnoori, PhD

New York, NY

A speech-processing based ADRD screening algorithm for home healthcare with unique capacities for modeling patient abilities

Tips for a Successful Application

When NOT to Apply

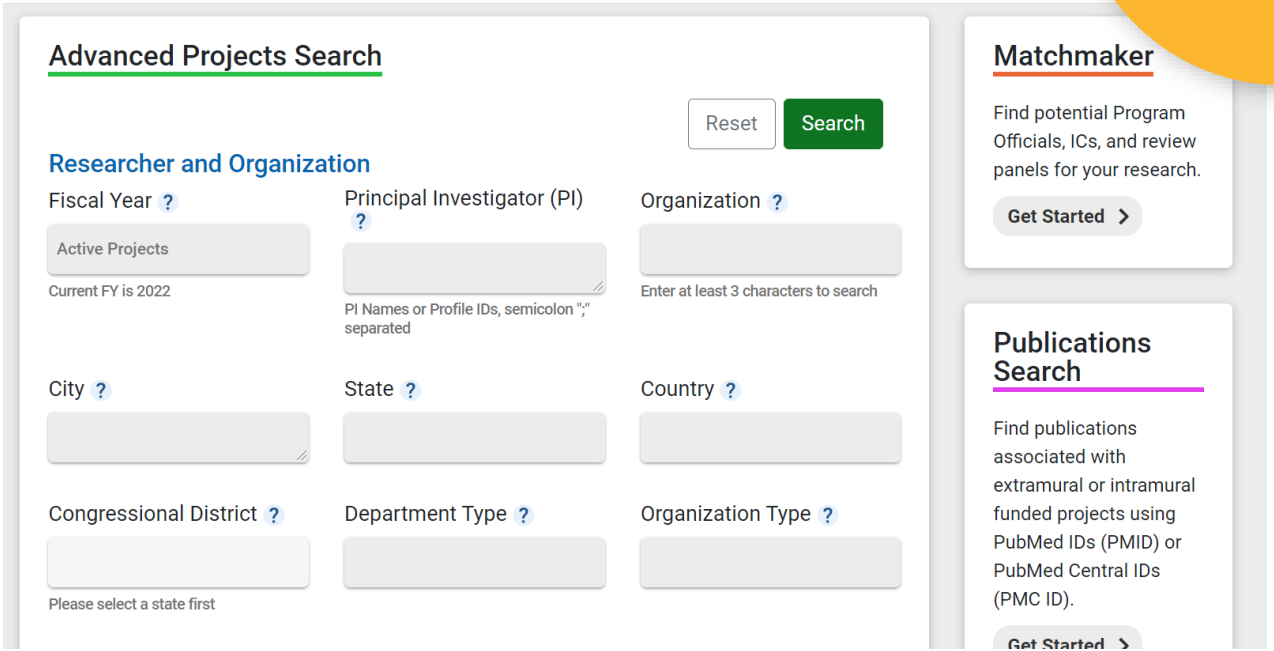
- Chasing NIH funding solicitations—“why not?”
- Need cash urgently
  - Time from application to award is 6–9 months
  - Applications usually require a resubmission to get a fundable score, resulting in 12+ months from submission of first application
- “Me too” product matching competitor’s capabilities (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



https://reporter.nih.gov/advanced-search

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

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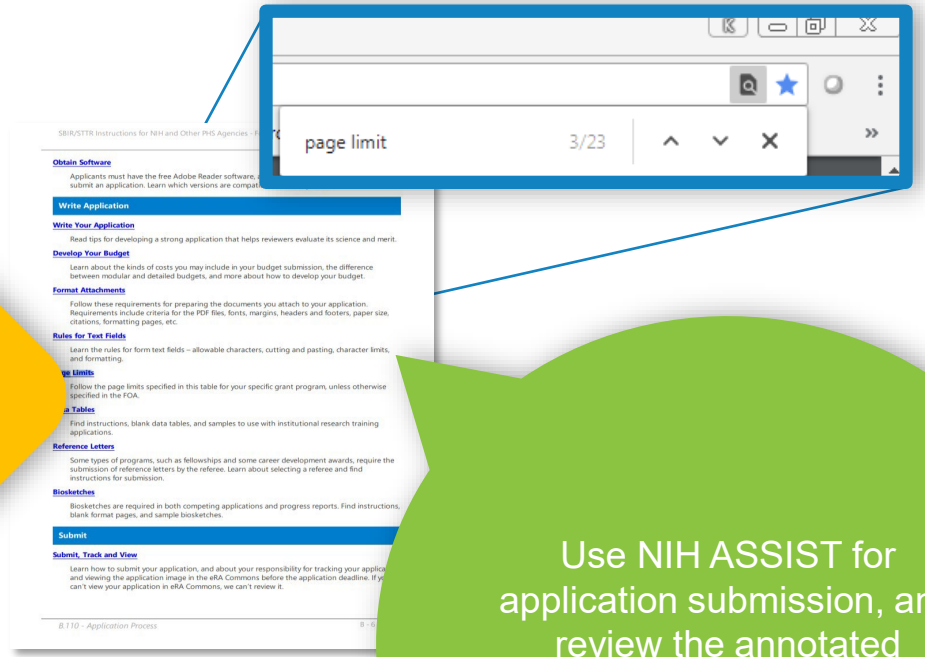
R&R Senior/Key Person Profile (Expanded)	8
R&R Budget	9
R&R Subaward Budget Attachment(s) Form	13
PHS 398 Research Plan	14
SBIR/STTR Information	15
PHS Human Subject and Clinical Trial Form	17
Study Record	18
Inclusion Enrollment Report	19
PHS Assignment Request Form	24

Use “**Ctrl F**” keyword search on this document. That’s what I do!



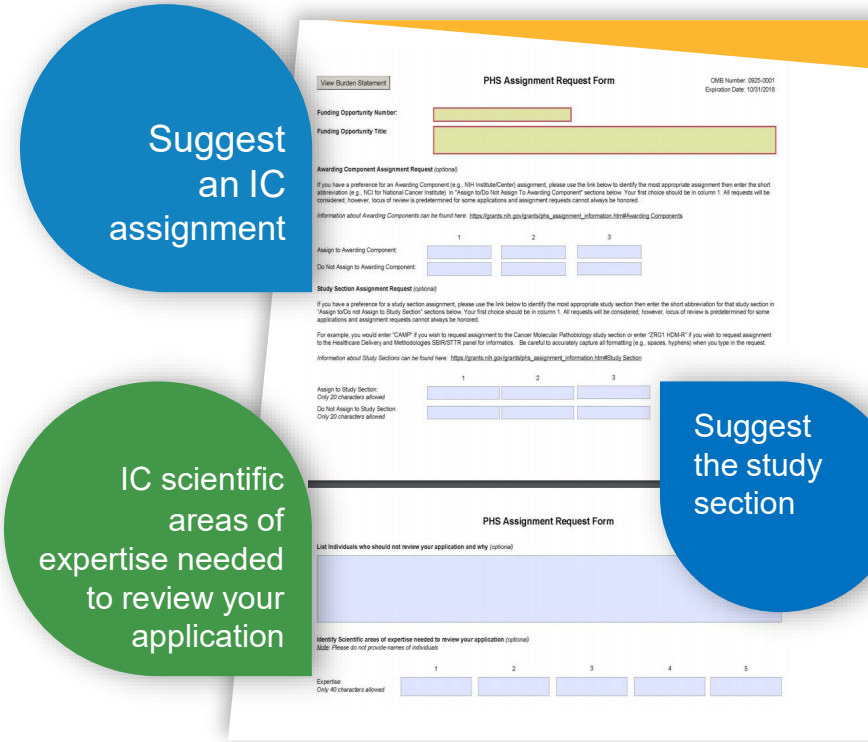
Use NIH ASSIST for application submission, and review the annotated application forms: bit.ly/3oukfFI

NIH National Institute on Aging

Specify Institute and Study Section

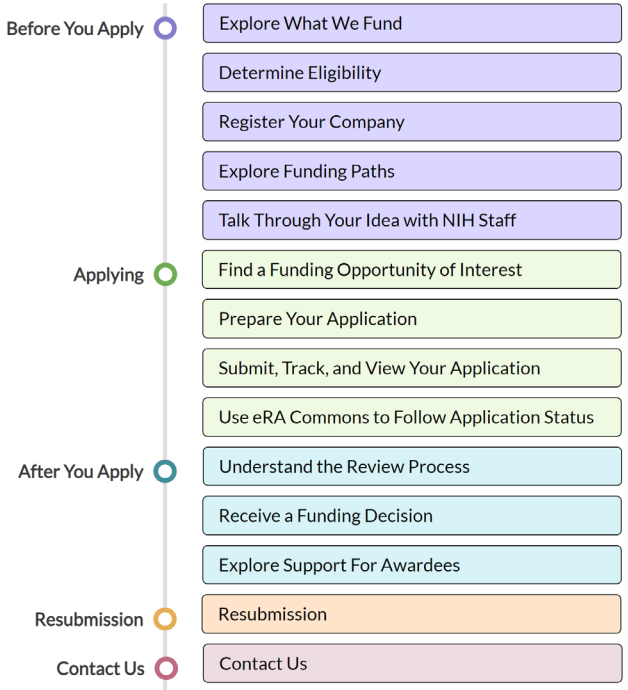
- Who is going to review your application?
  - A combination of academic and industry reviewers
    - Primary reviewers read your application and lead the discussion.
    - All members of the Review Panel will score your application.

- 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).



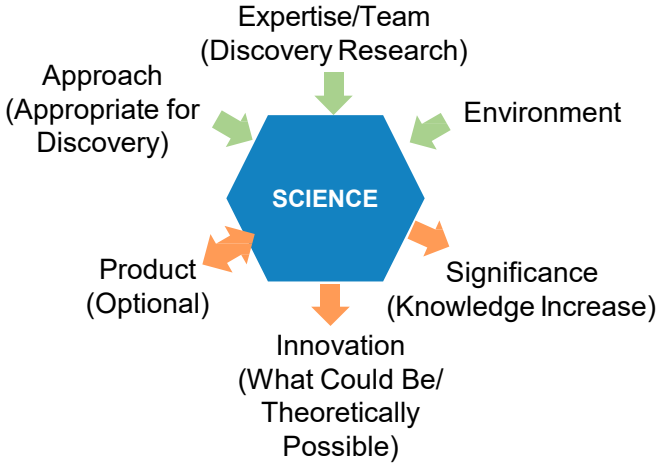
Tip 1: Start Early

- **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

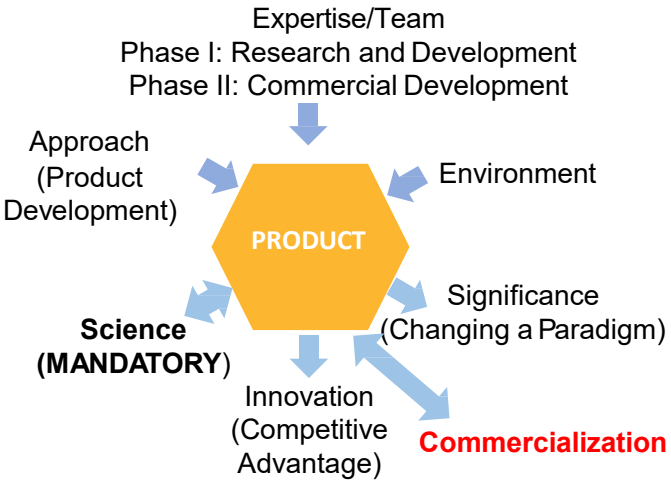


Remember: Focus on Product

ACADEMIC GRANT



SBIR/STTR GRANT

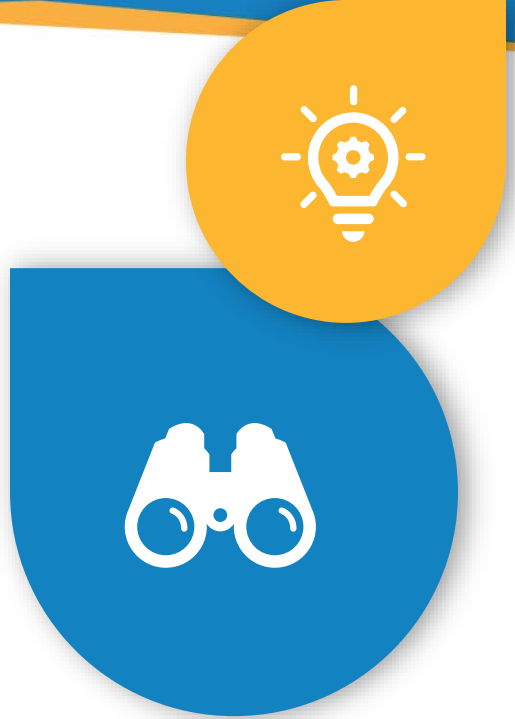


Review Criteria

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 you 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.

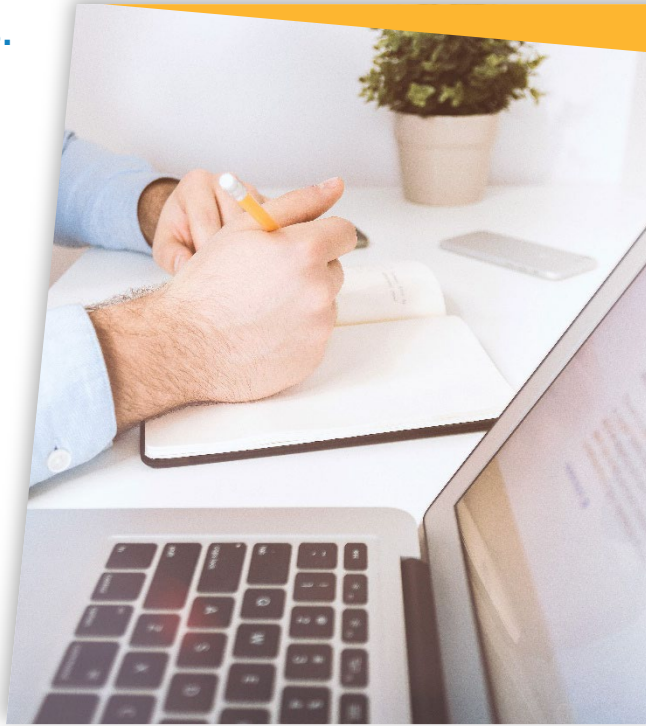
The Just-in-Time process follows for successful applications:

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



- 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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Thank you