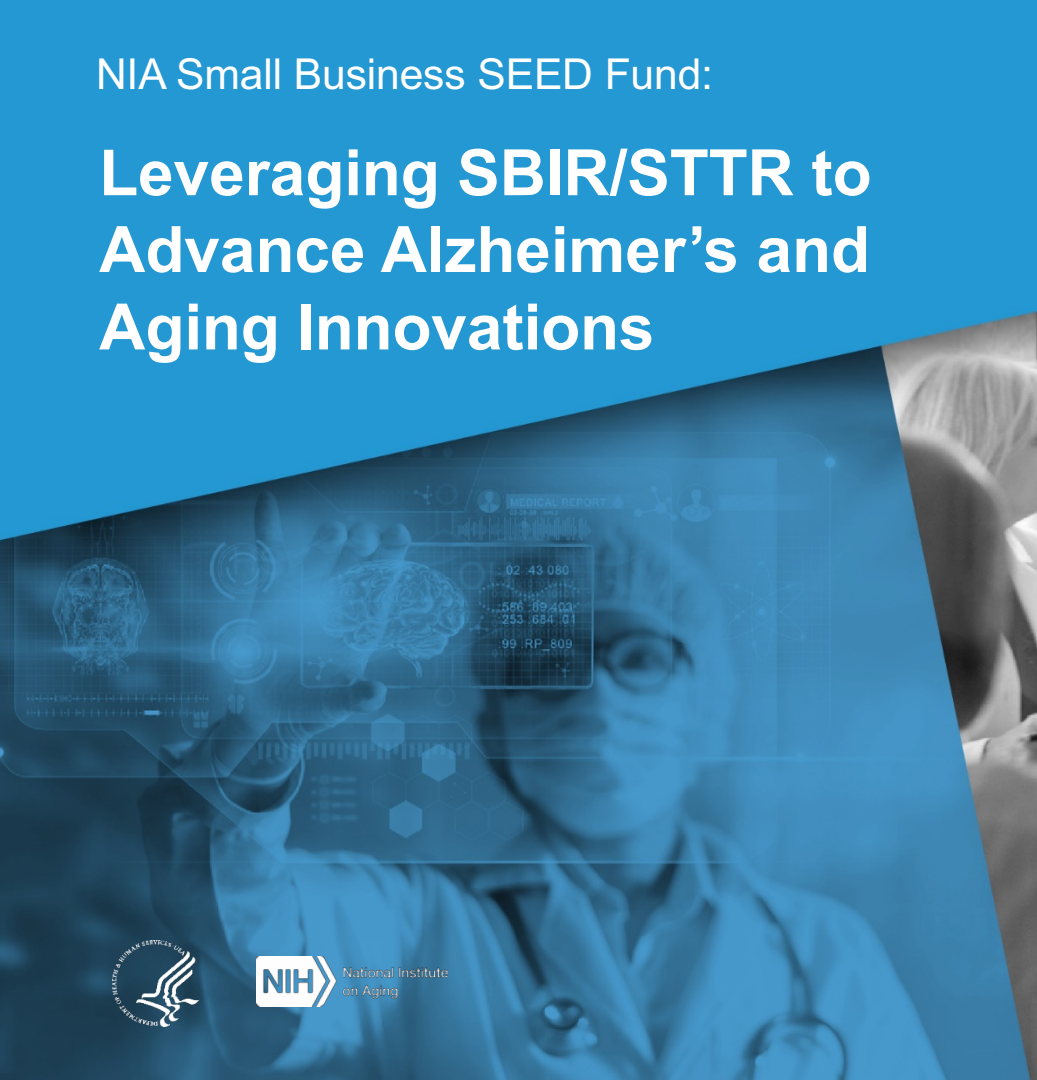
NIA Small Business SEED Fund:

Leveraging SBIR/STTR to Advance Alzheimer's and Aging Innovations



National Institute on Aging

May 6, 2020

Featured Speaker

Todd Haim, PhD

Chief
Office of Small Business Research
National Institute on Aging
National Institutes of Health

Moderators

Christopher Weber, PhD

Director
Global Science Initiatives
Alzheimer's Association

Monique LaRocque, MPH

Senior Vice President
Ogilvy | FKH

Hosts

Alzheimer's Association Business Consortium (AABC)
https://www.alz.org/research/for_researchers/partnerships/aabc

The Alzheimer's Association Business Consortium (AABC) aims to advance Alzheimer's disease and dementia research through innovation in small- and medium-size biotechnology, diagnostics, medical device and contract research organizations. AABC members work in areas of common interest pre-competitively to advance both the field of dementia research and the goals of its member organizations. The AABC provides leadership and direction to the group's areas of focus, which include, but are not limited to, collaborations, recognition and visibility, and knowledge and information sharing.

NIA Office of Small Business Research
www.nia.nih.gov/sbir

The National Institute on Aging (NIA) leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. NIA provides more than $100 million in set-aside funding for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The Institute offers non-dilutive grants to commercialize interventions that address aging, aging-related diseases, and the special needs of older Americans. NIA is the primary federal agency leading research on Alzheimer's disease (AD) and AD-related dementias (ADRD).

OUR RESEARCH STRATEGY

Dynamic, Durable, Multi-dimensional,
Multi-faceted Research Program

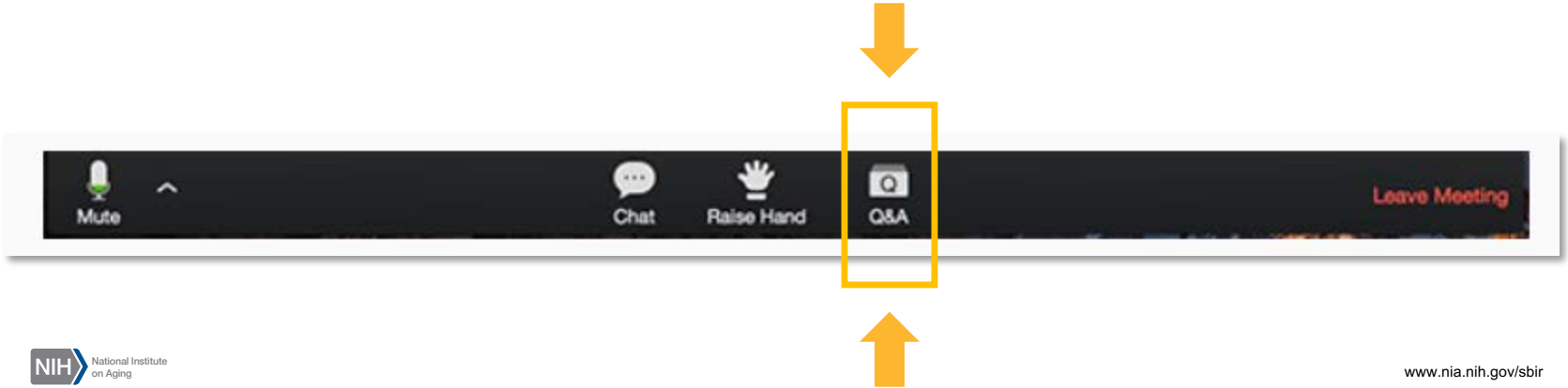
SCALE

SPEED

SEED

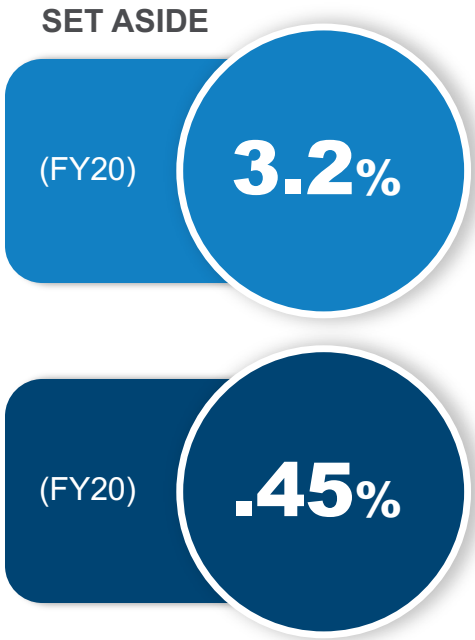
Agenda

- **Introduction and Objectives**
- **NIA's Office of Small Business Research**
  - Program Overview
  - Opportunities and Resources
- **Moderated Q&A**
  - Please use the Q&A function on your viewer dashboard to submit questions at any time during the presentation.



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

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	At least 40% of the work should be conducted by the for-profit small business, and at least of 30% by a nonprofit U.S. research institution
Eligibility: PD/PI primary employment (i.e., > 50%) MUST be with the small business for the duration of the project	**Eligibility:** IP agreement providing necessary IP rights to the small business to carry out follow-on R&D and commercialization
	PI primary employment not stipulated (at least 10% effort to project)

SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	• Up to 1 year • 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	• 2 years • 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	• 3 years • Awards up to $3 million

Budget Specifics

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 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).

NIA Office of Small Business Research: Core Activities

Central Coordination

Administer all SBIR/STTR awards at NIA

Guidance

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

Outreach

Attend conferences/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

Resources to Help Research Entrepreneurs

FIRST-TIME AND NEVER-FUNDED APPLICANTS	
Applicant Assistance Program. A 10-week coaching program to help develop your application. Offered once each standard funding period.	
ALL AWARDEES	
Technical Assistance Budget Allowance. Supports services such as access to technologies, IP protections, and market research. Offers up to $6,500 for Phase I and up to $50,000 for Phase II when requested in the grant application.	**Diversity Supplement.** Helps increase the diversity of the research workforce by supporting students, postdocs, and eligible investigators from underrepresented groups.
C3i Program for NIH. Supports medical device innovators in commercializing their products through a 24-week entrepreneurial training course.	**SEED Resources.** Support from the NIH Small Business Entrepreneurial Education and Development (SEED) Office including access to Entrepreneurs in Residence and regulatory support.
PHASE I AWARDEES	
I-Corps™ at NIH. An 8-week intensive course that offers real-world, hands-on entrepreneurship training and customer discovery in life sciences and biotechnology.	

The SBIR & STTR Programs at NIA

Available Opportunities

OMNIBUS FUNDING
Investigator-initiated
Standard application due dates:
Jan. 5, Apr. 5, Sept. 5

NIA-FOCUSED FUNDING
Focused priority areas in aging
Includes higher AD/ADRD budgets
Application due dates vary

NIA SBIR & STTR Seeks

- Innovative solutions to significant **unmet clinical needs**
- Solutions that have **significant commercial potential**
- Projects that:
  - Leverage the **expertise of the company/founder**
  - Seek funding to **produce feasibility data** (Phase I) or conduct **product-focused development activities** (Phase II)

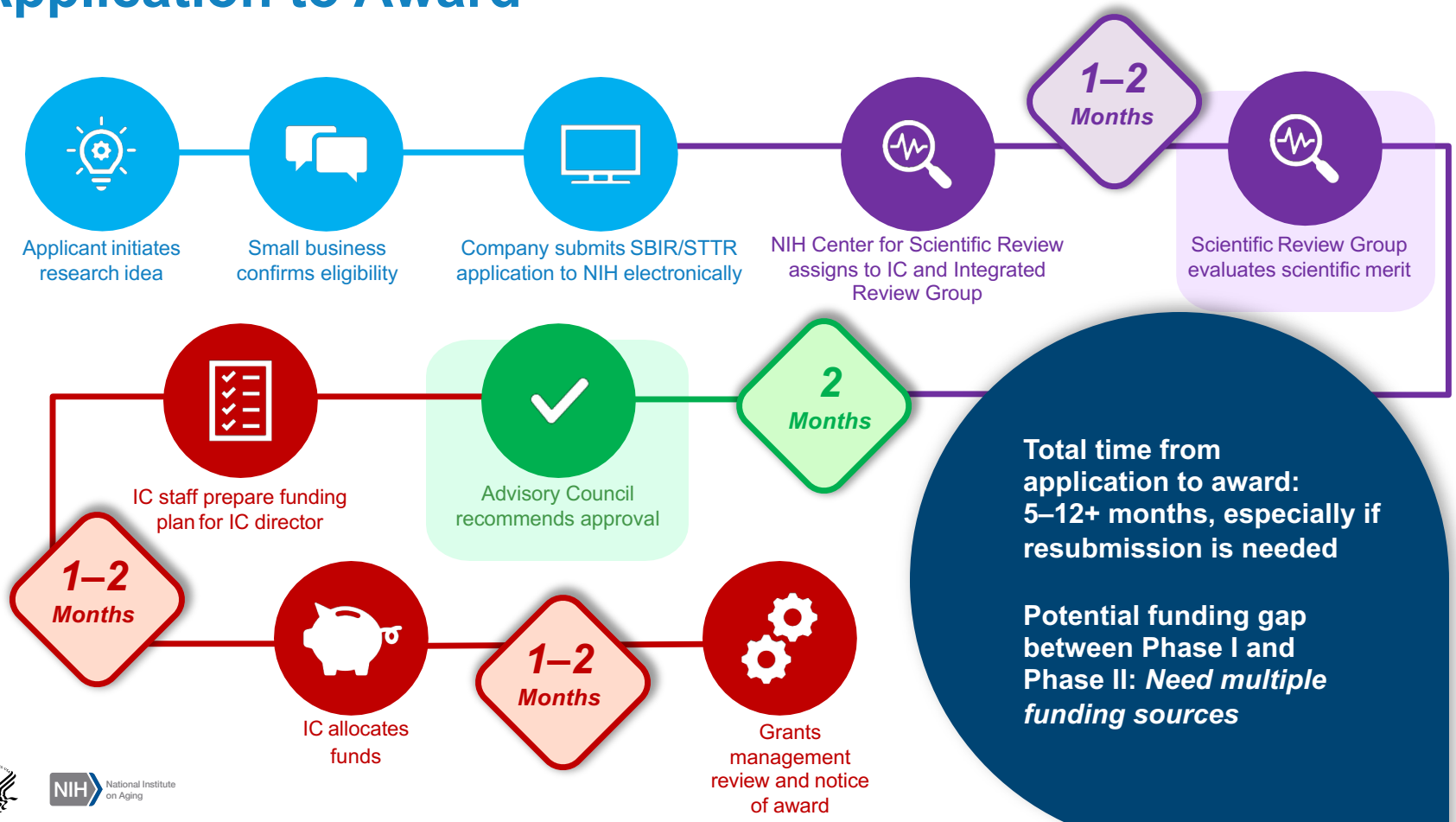
Special Research Interests in AD/ADRD

NIA's SBIR & STTR programs have funding available up to **$500,000 for Phase I** and **$2.5 million for Phase II** in AD/ADRD topics **(e.g., PAS-19-316)**.

NIA seeks AD/ADRD research focusing on:

- Prevention
- Diagnosis
- Treatment
- Care & Caregiving
- Research & Clinical Tools
- Analytical Tools
- Digital Health
- Novel Devices

Application to Award



NIH National Institute on Aging

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

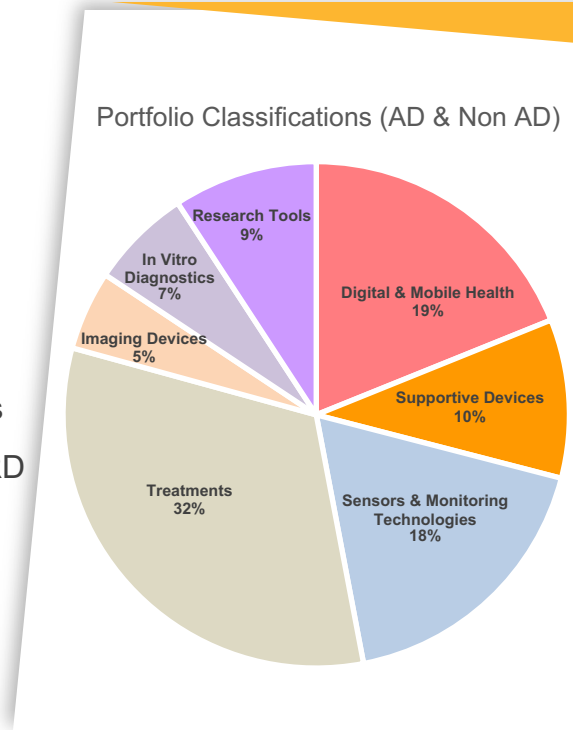
NIA Research Divisions

NIA provides SBIR/STTR support through four main 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 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

NIA Funding Opportunities

	Omnibus FOAs	AD/ADRD-Focused FOAs
SBIR	**PA-19-272** (clinical trials not allowed) **PA-19-273** (clinical trials required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-19-316** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million* **PAR-18-512** (Lifespan/Healthspan Extending Interventions for AD/ADRD Patients) *Budget limits: Phase I $350,000; Phase II $2 million*
STTR	**PA-19-270** (clinical trials not allowed) **PA-19-271** (clinical trials required) *Budget limits: Phase I $300,000; Phase II $2 million*	**PAS-19-317** (Advancing Research on AD/ADRD) *Budget limits: Phase I $500,000; Phase II $2.5 million* **PAR-18-514** (Lifespan/Healthspan Extending Interventions for AD/ADRD Patients) *Budget limits: Phase I $350,000; Phase II $2 million*

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

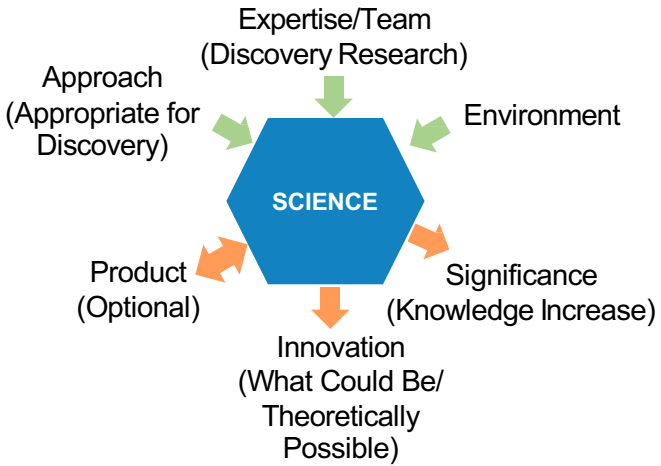
- Can be simultaneous or follow-on to Phase II and Phase IIB (both SBIR and STTR).
- SB1 mechanism enables an absence of subcontracting restriction. The subcontracting plan must still be justified in the application.
- Special review criteria include a focus on “innovation” of the product.
- Provides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

Diversity Supplement Program

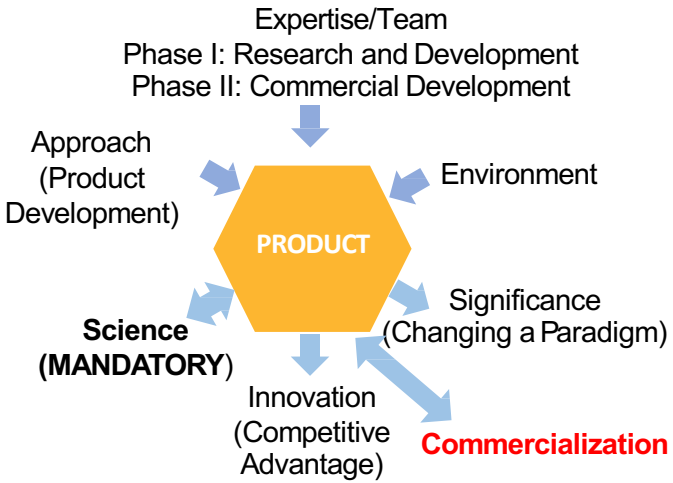
- Administrative Supplements to Promote Diversity in Research and Development Small Businesses—SBIR/STTR and SBIR Cooperative Agreements (PAR-18-837)
- **Goal:** Improve the diversity of the research workforce by recruiting and supporting students, post-doctorates, and eligible investigators from groups that have been shown to be underrepresented in health-related research or in the SBIR/STTR programs.
- **Applications:** Include identification of the candidate as well as a strong career development plan.
- **Deadline:** Applications accepted on a rolling basis.

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?

Compose a Specific Aims Page

The Executive Summary and First Impression

First 1/2 to 2/3 of page:

The Elevator Pitch—Why Is It Meritorious?

1. The technology prototype to be developed
2. The technical innovation the development would represent, the unmet need being addressed, and the technical challenges to overcome
3. The value proposition and competition
4. Textual highlights of preliminary data
5. The relevance of the R&D to NIA's mission

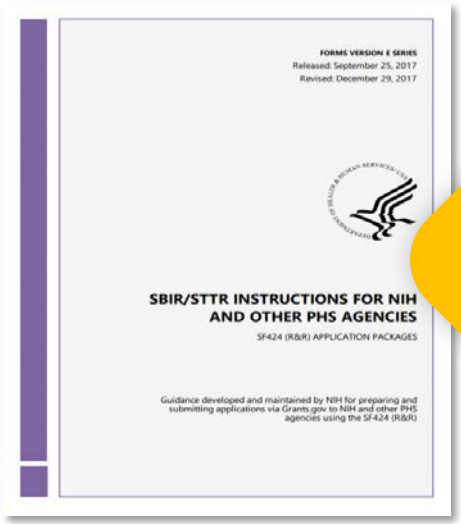
Last 1/3 to 1/2 of page:

The Specific Aims for the Proposed Project

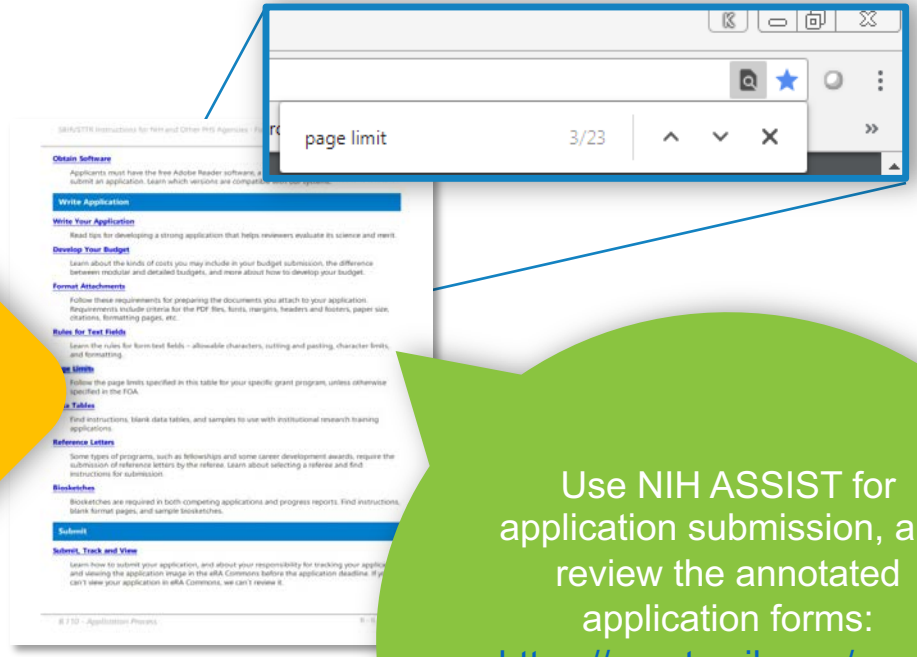
- Key models, assays, and metrics
- Quantitative performance milestones

Provide your draft Specific Aims page to NIA OSBR staff for feedback.

SF 424 Application Guide



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: https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_SmallBus_FORMS-E.pdf

NIAID Sample Applications: A Great Resource

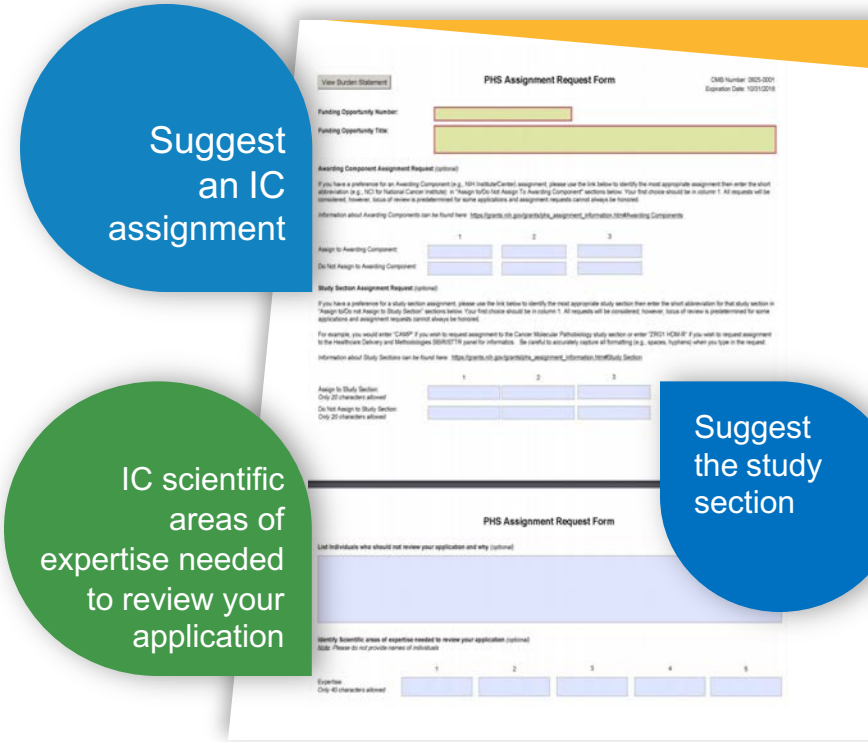
https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

PI and Grantee Institutions	Sample Application
Jose M. Galarza, Ph.D., of Technovax, Inc. "Broadly protective (universal) virus-like particle (VLP) based influenza vaccine" (SBIR Phase I / R43, Forms-B2)	Full Application
Mark Poritz*, Ph.D., of BioFire Diagnostics, LLC. "Rapid, automated, detection of viral and bacterial pathogens causing meningitis" (SBIR Phase I / R43, Forms-B1)	Full Application
Patricia Garrett, Ph.D., of Immunetics, Inc. "Rapid Test for Recent HIV Infection" (SBIR Phase II / R44, Forms-B1)	Full Application
Michael J. Lochhead, Ph.D., of MBio Diagnostics, Inc. "Point-of-Care HIV Antigen/Antibody Diagnostic Device" (SBIR Phase II / R44, Forms-B2)	Full Application
Kenneth Coleman, Ph.D., of Arietis Corporation "Antibiotics for Recalcitrant Infection" (SBIR Fast-Track, Forms-B1)	Full Application
Timothy C. Fong, Ph.D., of Cellerant Therapeutics, Inc. "Novel indication for myeloid progenitor use: Induction of tolerance" (STTR Phase I / R41, Forms-B2)	Full Application
Raymond Houghton, Ph.D., of InBios International, and David AuCoin, Ph.D., of University of Nevada School of Medicine "Antigen Detection assay for the Diagnosis of Melioidosis" (STTR Phase II / R42, Forms-B1)	Full Application

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: http://www.csr.nih.gov/Roster_proto/sbir_section.asp
  - Review the list of study section members.
  - Request study sections in the optional PHS Assignment Request Form (previously in the cover letter).



Draft a Clear Application: Research Strategy

- Address all of 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 (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

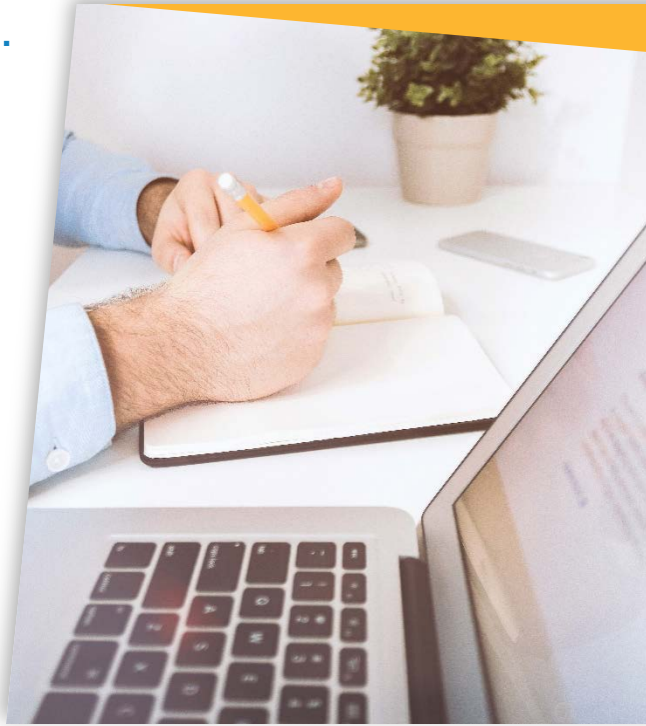
Draft a Clear Application: Other Components

- 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 (< 4 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)

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.
  - Success rate for resubmissions is **26.3%** compared to **12.5%** for non-resubmissions in FY20 thus far*
- **Learn more about SBIR/STTR grants.**
  - Talk to successful applicants.
  - Understand the review process and dynamics: http://csr.nih.gov



*As of 4/23/20

Application Resources

- Small Business Resources:
  - Sample SBIR Grant Applications from NIAID
  - Annotated Form Set for NIH SBIR Grant Applications
  - SBIR/STTR Application Process Infographic
  - Office of Small Business Research, National Institute on Aging
- Database of NIH-Supported Research: NIH RePORTER
- 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

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NIA SBIR Virtual Workshop Series

Register at https://bit.ly/3bK7sZQ

Thank you