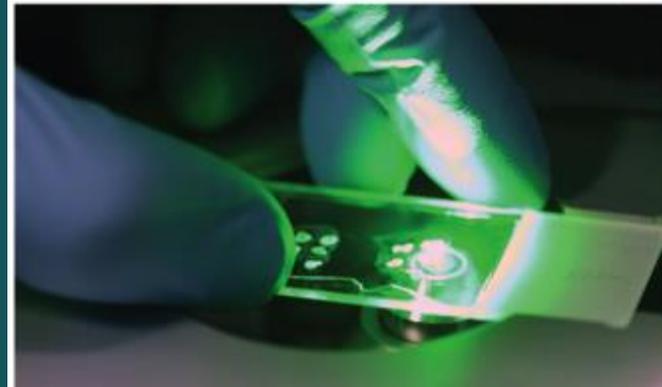
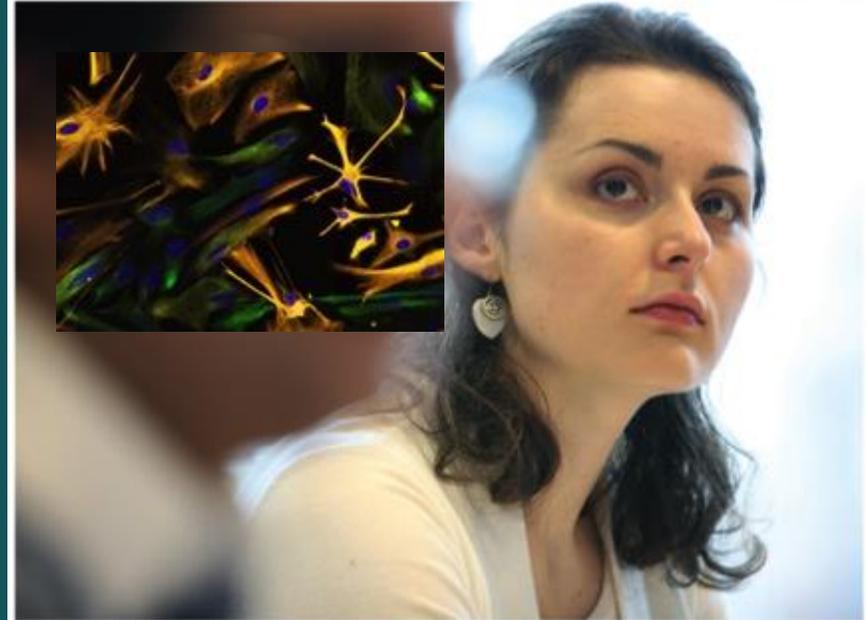


NINDS Small Business Program

Pre-Application Webinar

November 5, 2020

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Welcome

Scope of today's webinar:
We will review NINDS SBIR/STTR policy, Funding Opportunities, and FAQs, to aid potential Small Business applicants

- This webinar will be recorded
- The webinar recording and slides will be posted on the [NINDS SBP website](#)
- PDF of slides with embedded links will be emailed to registered attendees
- Please use the chat box for technical issues
- Please use Q&A box to post all questions for the presenter
- Questions can be entered at any time and will be read by the moderator for Q&A following the presentation



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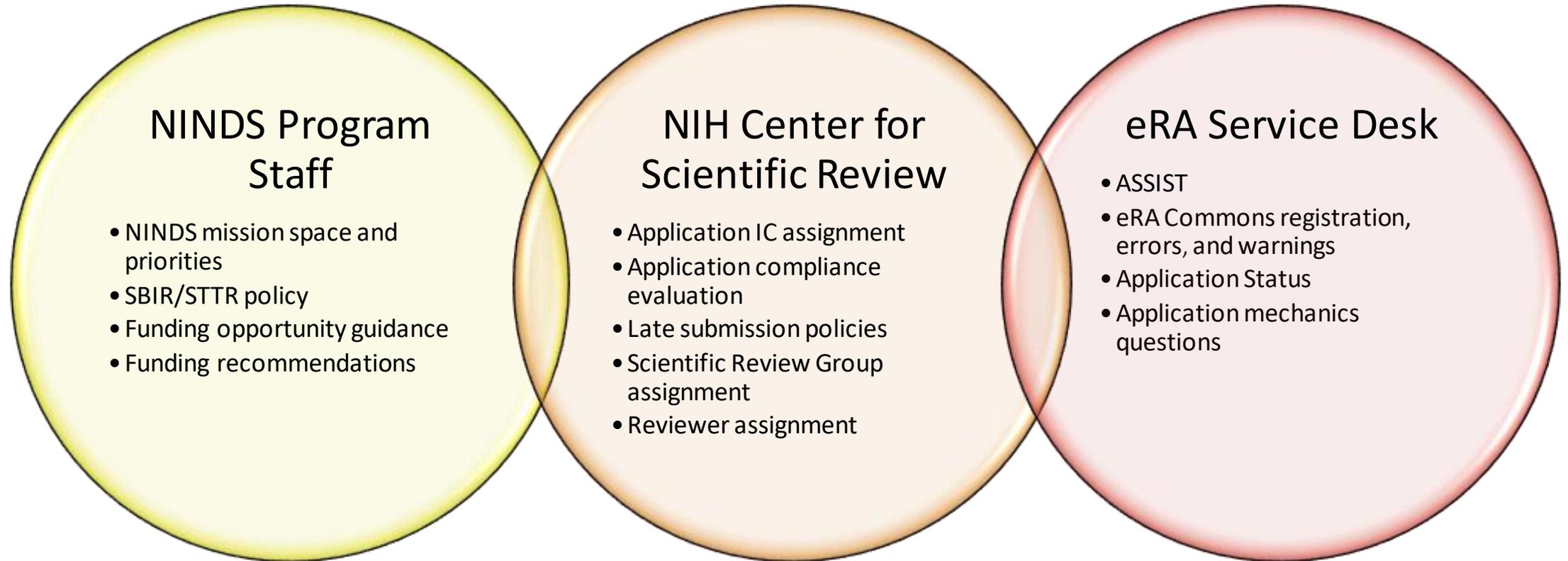


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NIH Roles Related to Applications



1. Prepare to Apply

Confirm small business eligibility

US owned and operated
 For profit organization
 No more than 500 employees

Begin required registrations

DUNS, SAM, Grants.gov, eRA
 Commons, SBA Company
 Registry
May take 6-8 weeks

Review NIH SBIR/STTR processes and policies

Phases and mechanisms
Sample Applications
 Funding Timeline
 Review information
FAQs

Determine target application date

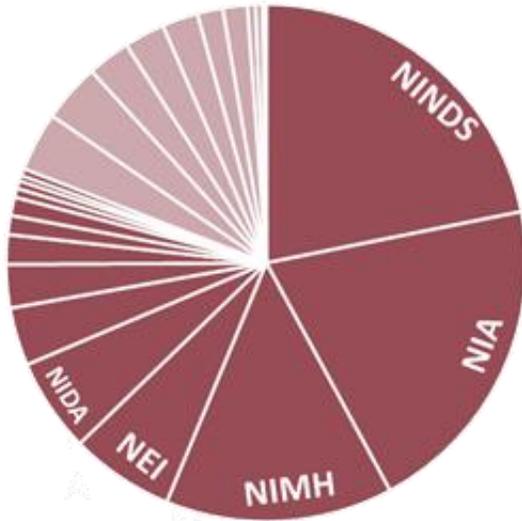
Standard SBIR/STTR due dates:
 January 5, April 5, September 5

Standard Due Date	Review Meeting	Council Review	Earliest Award Date
Jan 5	Feb-March	May-June	July-Sept
Sept 5	Oct-Nov	Jan-Feb	March-May
April 5	June-July	Aug-Sept	Sept-Dec



2. Determine Fit with NINDS Mission

Neuroscience is supported by many NIH Institutes



~\$77M in annual funding for small businesses

Broad Scope

Therapeutics

Diagnostics

Research tools

Biomarkers

Devices

Small molecules

Biologics

The **NINDS mission space** encompasses hundreds of neurological disorders

Stroke

Neurogenetic Disorders

Spinal Cord Injury

Traumatic Brain Injury

Epilepsy

Neurodegenerative Disorders

Chronic Pain

Broad range of translational R&D activities

Drug discovery

Device prototyping

Preclinical validation

IND- and IDE-enabling research

Human subjects research

Early-stage clinical trials

Mission Fit FAQs

My product is a platform technology or meant for more than just neurological indications—is my project too broad for NINDS?

The NINDS Small Business Program supports efforts primarily focused on neurological indications. Broadly-focused projects may be appropriate for other NIH Institutes and Centers (ICs). If your product will be regulated and marketed to individual indications, it is recommended that you focus on a single first-to-market indication in your application and contact the IC best aligned with that indication.

I found a Funding Opportunity Announcement (FOA) that fits my project, can NINDS fund it?

NINDS must be a participating IC listed on the FOA to fund an application to that FOA. If you do not see NINDS listed, check the expiration, affiliated notices, and whether the FOA has been re-issued.

Will my project be assigned to NINDS?

Your project will be assigned the most applicable IC participating in the FOA to which you apply.

3. Identify a Target Funding Opportunity Announcement (FOA)

Omnibus FOA

Investigator Initiated projects within NINDS mission

PA-20-260 (SBIR), PA-20-265 (STTR)

NINDS accepts NON-CT Phase I, Phase II, D2PII, and Fast-Track apps to Omnibus

Research Tools (BRAIN Initiative)

PA-18-870 (STTR)
PA-18-871 (SBIR)

Pain Management (HEAL Initiative)

RFA-NS-20-008 (STTR, CT), -009 (STTR, no CT)
RFA-NS-20-010 (SBIR, CT), -011 (SBIR, no CT)

AD/ADRD

PAS-19-317 (STTR)
PAS-19-316 (SBIR)

Later Stage Activities

Exploratory Clinical Trials

PAR-18-617 (STTR)
PAR-18-618 (SBIR)

Phase IIb SBIR

PAR-17-480 (pre-clinical)
PAR-18-665 (clinical research and CT)

Commercialization Readiness Pilot (CRP)

PAR-19-333 (no CT), PAR-19-335 (CT)

Most opportunities have standard SBIR/STTR due dates (next date January 5th, 2021)

SBIR vs. STTR FAQs

	SBIR	STTR
Nonprofit Research Institute Partnering (e.g. university)	<u>Permitted</u>	<u>Required</u>
Small Business work requirement and outsourcing	Small business may outsource up to 33% of Phase I activities* and up to 50% of Phase II activities *NINDS allows some flexibility in Phase I work requirement	At least 40% of the work should be conducted by the eligible small business, and at least of 30% by a nonprofit U.S. research institution *no exceptions made in work requirement for STTR
PI Requirement	PI must be primarily employed by the small business	PI must be primarily employed by small business or by partner research institute

Can an Investigator be a PI on an SBIR if they are employed more than half-time by a small business and hold a full-time academic position?

No, this would not qualify as being primarily employed by the small business. This investigator can have another role on the SBIR team **including MPI**, and they can be PI on an STTR.

Phase I, II, and Fast-Track FAQs

	Phase I	Phase II	Fast-Track
Development Stage	Proof of Concept and Feasibility	Pre-commercial R&D	Feasibility and R&D (Combined Ph I and II)
Commercialization Plan	Not Required	Required	Required

What should I consider when determining Phase I vs Phase II?

Stage of development, amount of preliminary data, and company readiness (e.g. strength of Commercialization Plan)

Should I address commercialization potential in a Phase I proposal?

Yes, commercialization potential of the product should be addressed. This may include IP status, market size, advantages over competitors, or other factors that could affect commercialization

Is my project right for a Fast-Track mechanism application?

A fast-track may be appropriate when clear no-go criteria are established for feasibility, when Phase I will not further inform the activities to be conducted in Phase II, and when the commercialization plan is well established

I have a Phase I award, when can I apply for Phase II funding?

You do not need to wait for your Phase I project period to be complete to apply to Phase II. However, you will need to include results from Phase I in your Phase II application to demonstrate success and readiness

Can I apply for Phase II funding if I don't have a funded Phase I?

Yes, if you have the equivalent of Phase I feasibility data, you can apply through the **Direct to Phase II** mechanism

Phase IIb vs CRP FAQs

	Phase IIb	Commercialization Readiness Pilot (CRP)
Require funded Phase II	Yes	Yes
NINDS time and budget limits	Up to \$3M total cost for 2-3 years	Up to \$3.36M total cost for 2-3 years
Outsourcing	50% Small Business work requirement	No Small Business work requirement, at least 10% effort from Small Business expected
Scope	Research and development (same direct cost restrictions as Phase II funding)	Technical assistance and later-stage R&D including activities to comply with FDA regulations, process optimization, synthesis, scale-up manufacturing, Clinical studies and trials

When are these funding opportunities appropriate?

Applicants should be able to justify the need for additional NIH grant support for the project. Please note matching funding expectations in the NINDS Phase IIB funding opportunities.

Clinical Trial FAQs

How do I know if my project qualifies as a Clinical Trial according to NIH?

Utilize [the NIH clinical trial decision tool](#)

Do Clinical Trial FOAs have specific requirements?

NINDS Exploratory Clinical Trial SBIR/STTR FOAs require either FDA approval of IDE or IND or IRB confirmation that the study is nonsignificant risk; see FOAs ([PAR-18-617](#), [PAR-18-618](#)) for additional detail

Do I need to have IRB or IACUC approval at time of application?

Often no, though you should review the FOA carefully. Funding may be restricted if not in place at time of award

NINDS SBIR/STTR Cooperative Agreement Funding Opportunities (U44)

What is the difference between the SBIR grants and U44 FOAs?

NINDS has several translational programs that offer dedicated SBIR cooperative agreement (U44) funding opportunities open only to small businesses. Several of these programs provide resources in the form of consultants and contracted services to support late-stage preclinical and early-stage clinical R&D.

Who do I contact to find out more?

Utilize the links for each program to identify the appropriate Program contacts

I'm interested in a U44 opportunity, but my project isn't quite ready to be competitive. What can I do?

Consider applying for traditional SBIR and STTR grant funding opportunities to support additional R&D

Devices:

- [Translational Neural Devices U44](#)
- [BRAIN Initiative U44](#)



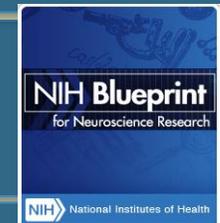
BRAIN Initiative



Translational Neural Devices

Small Molecules:

- [Blueprint Neurotherapeutics U44](#)



NIH National Institutes of Health

Biologics:

- [CREATE Bio U44s](#)



Biomarkers:

- [Biomarkers U44](#)



Biomarkers

Clinical Trial Networks:

- [NeuroNEXT U44](#)
- [StrokeNet U44](#)



4. Review NINDS SBIR/STTR budget and timeline guidance

Phase I

Hard Cap: \$256,131 Total Cost

Under Waiver: \$700K (not more than \$500K/year) Total Cost

Duration: 6-24 months

Phase II

Hard Cap: \$1,680,879 Total Cost

Under Waiver: \$3,000,000 (not more than \$1.5M/year) Total Cost

Duration: 2-3 years

** SBIR funding cannot be used to support foreign-based work (including foreign-based consulting services) or to purchase foreign-sourced materials **

General NINDS Waiver Topics:

- ***In vivo* animal testing** required for therapeutics and diagnostics development
- **Drug and biologics preclinical discovery and development** activities for regulatory submission
- **Device preclinical discovery and development** activities for regulatory submission
- **Clinical testing** of therapeutics, diagnostics, clinical and rehabilitation tools, and technologies for clinical research
- *In vivo* animal testing of technologies for animal research and development of animal models for drug development and neuroscience research
- Research that requires special facilities to contain hazardous or infectious materials

BRAIN Initiative Waiver Topics:

- Development of **research tools** and technologies to understand the dynamic activity of neural circuits
- Development of novel tools and technologies to facilitate the detailed analysis of complex circuits to provide insights into cellular interactions that underlie brain function
- Development of invasive and non-invasive devices for recording and modulation in the human central nervous system

Budget FAQs

Do I need to get written Program staff approval that a waiver applies to my project?

Waiver topic applicability should be initially determined by the applicant. Program staff will not confirm waiver eligibility until after the full application has been submitted. As long as you are requesting a budget in line with NINDS guidance, you do not need prior Program approval.

How do I utilize NINDS waiver topics in my application?

No additional information (such as form or program approval) is necessary to request a budget in line with NINDS guidance. You can simply request the budget in your application.

How large can my indirect rate be?

If your company has not negotiated an indirect rate with the government, you can request up to 40% by default.

How big of a fee can I request, and does this count in the budget limit?

Companies can include up to 7% fee calculated on top of direct and indirect costs. Fee should be included as part of the total cost.

Can I use my fee for [patent costs, foreign work, etc.]?

Fee is considered company profit and is not subject to the restrictions of direct and indirect funds

5. Prepare to contact NIH Program Staff

Draft a Specific Aims page

- Review Specific Aims pages in [sample applications](#)

Send Specific Aims page directly to NINDS Program staff

- Program staff will respond confirming IC fit and best fit funding opportunity
- If NINDS Small Business funding is not the best fit for your project, we may refer you to another IC or another NINDS Program Officer

Include any specific questions about your application

- We can often quickly address specific questions via email and direct you to any additional helpful resources
- **Note that Program staff cannot provide technical direction or intellectual contribution to your project**

**** We recommend you send your Specific Aims page to Program staff *at least 1-2 months prior to the due date* ****

6. Develop your application

Program Tips

Propose rigorous research and development activities. NINDS has [several resources](#) on rigor available

Build a strong team – do you have the necessary technical, business, and clinical expertise to develop the product and bring it to market?

- Academic collaborations when appropriate
- Consultants and CROs to fill technical gaps
- Experienced entrepreneurs or industry experts who understand product development in your space
- Clinical experts in the targeted indication

Utilize letters of support – from collaborators, potential and existing partners, potential customers, key opinion leaders

Be cautious about including links in your application – puts you at risk for violating “overstuffing” policies and having your application withdrawn. For guidance on use of hyperlinks see notice [NOT-OD-20-174](#). When in doubt, do not include links.

Use PHS Assignment form

- to identify the specific expertise you want in assigned reviewers
- to request a specific Scientific Review Group
- to identify any reviewers in Conflict of Interest (COI)
- to request a specific IC

7. Apply!

Apply to the targeted funding opportunity through ASSIST or grants.gov
Specific instructions are included in each FOA

SF424 SBIR/STTR
(R&R) [Application
Guide](#) contains
registration and
application
instructions

The SBIR/STTR
[Annotated Form Set](#)
provides step-by-
step instructions to
fill out the
application

The [eRA Service
Desk](#) should be
contacted for
question related to
the application
process

Applicant Assistance Program (AAP)

AAP is aimed at helping small businesses apply for **Phase I SBIR/STTR** funding

AAP provides:
Knowledgeable coaching support for application preparation at no cost

AAP does not provide:
A grant writer, small business registration, technical consulting

- **Open to companies that have never received NIH SBIR/STTR funding**
- **Intended for applicants with little NIH grant writing experience, limited networks, and sparse access to support**
- **Diverse applicants highly encouraged to apply**

Each participating NIH Institute and Center has a finite number of slots for applicants

Participating institutes: NINDS, NCI, NIA, NHLBI, NCCIH, NCATS, NIEHS, NINR

For eligible companies developing a Phase I application for April 5th

Submission Portal Opens: November 12, 2020

NIH AAP outreach webinar: November 12, 2020 at 2:00 PM ET - [register here](#)

NIH AAP Q&A webinar: December 9, 2020 at 2:00 PM ET

Applications Due: December 10, 2020 at 5:00 PM ET

[AAP Webpage](#)

Women-Owned & Disadvantaged Small Business FAQs

The mission of the SBIR/STTR Program includes fostering and encouraging participation in innovation and entrepreneurship by socially and economically disadvantaged small businesses and women-owned small businesses.

Women-owned business

Must be at least 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).

How do I become recognized as a woman-owned or disadvantaged business?

Businesses can self-certify during the application process. Certification is encouraged, but not required.

Is my certification visible to reviewers?

Certification information is no longer in application materials and is not visible to reviewers.

8. The Review Process



NIA SBIR/STTR VIRTUAL WORKSHOP

SBIR·STTR
America's Seed Fund

National Institutes of Health
Turning Discovery Into Health

Understanding the NIH Peer-Review Process

Tuesday, November 10, 2020
12:30 p.m. ET

REGISTER TODAY

Co-hosted by:

National Institute on Aging

National Center for Advancing Translational Sciences

National Institute on Minority Health and Health Disparities

Center for Scientific Review

Review guidance [for scoring](#) and for the [overall review process](#)

Register for the [Understanding the NIH Peer-Review Process](#) webinar

View CSR's presentation on [Advice for SBIR/STTR Applicants](#)

Standard SBIR/STTR Review Criteria

Significance

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

Approach

- Are design and methods well developed and appropriate?
- Are potential pitfalls and alternative approaches provided?

Innovation

- How novel are the technology/product and the approaches proposed to test feasibility?
- Does the product fill a significant market gap?

Investigators

- Does the team have the appropriate training and expertise to complete the project?

Environment

- Does the scientific environment contribute to the probability of success?
- Are there appropriate facilities and equipment to conduct the studies?

Commercialization

- Does the company's business strategy have a high potential for success?

Review FAQs

How do I request a specific study section?

You may enter up to three preferences for study sections in the “Assign to Study Section” row of the [PHS Assignment form](#). You may list specific individuals who should not review your applications due to conflict of interest along with enough justification. In addition, use the [PHS Assignment form](#) to request reviewer expertise, and be sure to carefully describe the technology. SROs work hard to put your application in the best spot – this may not always be the SRG you suggest. Panel expertise shifts and your application is meant to go to the reviewers and panels with the most appropriate expertise.

How often do reviewers change in SBIR/STTR study sections?

The SBIR/STTR panels are not standing panels, they are special emphasis panels assembled ad-hoc each round with appropriate expertise to cover the assigned applications.

I have questions and concerns about my study section assignment

If you have additional concerns or questions about the appropriateness of the study section assignment, please contact the Center for Scientific Review at csrdr@mail.nih.gov

Will I have the same reviewers on my resubmission?

Reviewers may shift between submissions.

How do I become a reviewer?

If you are interested in acting as a reviewer, please contact us.

Can you tell me more about the review discussion of my application?

No, Program staff cannot disclose review information outside of what is included in the review Summary Statement

9. The Award Process

The NINDS small business program does not have a set pay line

NINDS limits consideration of SBIR applications to a zone of scores. Within this zone, all applications are further evaluated for funding recommendations based on a combination of factors and in accordance with our priority statement.

- Potential for high impact on advancing the NINDS mission and the other programmatic priorities described
- Commercialization potential
- Portfolio balance
- The quality of the previous performance of the applicant and/or company in the SBIR and/or STTR program, including evidence of Phase III activities
- For Phase II applicants, the results of the Phase I
- The peer review scores and critiques
- Availability of funds

NINDS funding recommendations are reviewed by the National Advisory Neurological Disorder and Stroke (NANDS) Council

Funding Decision FAQs

I received a funding recommendation letter from NINDS – am I getting an award?

No, a funding recommendation is not an indication of funding. Funding is not guaranteed until a Notice of Award is issued, typically 1-2 months following a funding recommendation.

When will I find out my funding recommendation?

Typically funding recommendation notifications are sent out 2-3 weeks following the NINDS Council meeting. Please view the [NANDS council](#) page for updates.

What if my small business loses eligibility prior to a notice of award?

You will need to sign a certification of eligibility prior to receiving an award. If you lose eligibility prior to the award issuance, you will need to forfeit your award.

What percent of SBIR and STTR applications are funded?

NIH SBIR/STTR rates are [published](#) by year and mechanism. Roughly 20% of Phase I apps and 40% of Phase II apps are funded.

Resubmission

If You Weren't Funded on the First Try:

Carefully review the critiques in your Summary Statement

- Use reviewer comments to improve your application

Revise and resubmit the application.

- Introduction Page: Respond to reviewer critiques
- Be constructive, not defensive
- Resubmission typically improves odds of funding

Take advantage of available resources

- Consider AAP if you are eligible

Resubmission FAQs

How many times can I resubmit an application?

You may resubmit an application **one** more time. After a resubmission you may submit the same project as a new application.

Can I switch between SBIR/STTR mechanisms in a resubmission?

Yes

Can I switch between FOAs in a resubmission?

Often yes, but please check the terms in the FOA.

My Phase II resubmission was not funded. Can I resubmit as a Phase II again?

A Phase II application can only be resubmitted once. If a resubmission is not funded, applicants to the [omnibus FOAs](#) can consider re-applying as a Direct to Phase II application. Language for other FOAs should be closely reviewed.

Contact Us

NINDS Small Business Program
NINDS_SBIR@ninds.nih.gov

Hear from Us



@NINDStranslate, [@NIHsbir](#)

Sign up for NINDS DTR and NIH SBIR/STTR listservs

Visit Us

<https://www.ninds.nih.gov/Funding/Small-Business-Grants>
<https://sbir.nih.gov/>