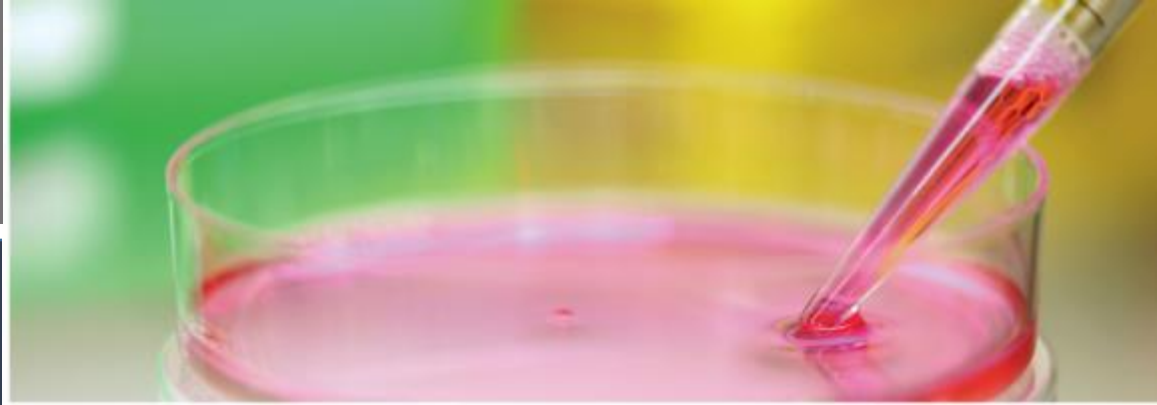


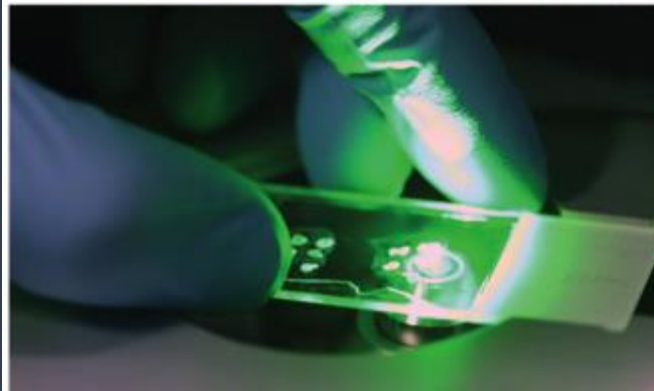
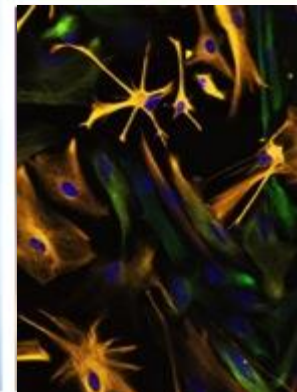


National Institute of
Neurological Disorders
and Stroke



NINDS Funding Opportunities to Support Product Development in Neurological and Brain Research Applications

Gulf Coast Consortia
March 8, 2021

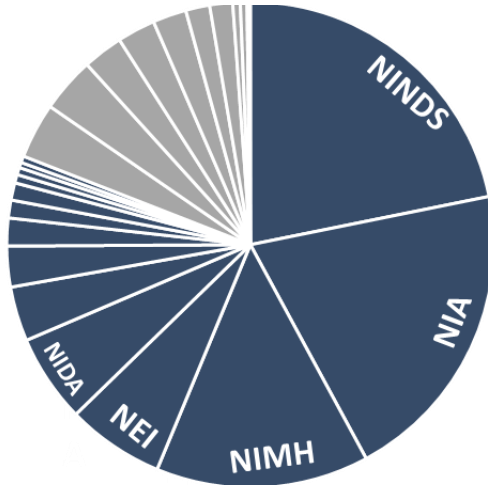


Emily Caporello, PhD
Director, NINDS Small Business Program
Division of Translational Research, NINDS
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NINDS Mission

Neuroscience is supported by many NIH Institutes



The NINDS mission space encompasses hundreds of neurological disorders, including:

- Stroke
- Epilepsy
- Neurodegenerative Disorders
- Spinal Cord Injury
- Traumatic Brain Injury
- Neurogenetic Disorders

www.ninds.nih.gov/Funding/Small-Business-Grants/Areas-Interest

Congressionally mandated set aside: ~\$77M annually at NINDS

Broad scope:

- Therapeutics
- Diagnostics
- Research Tools
- Biomarkers
- Devices
- Small molecules
- Biologics

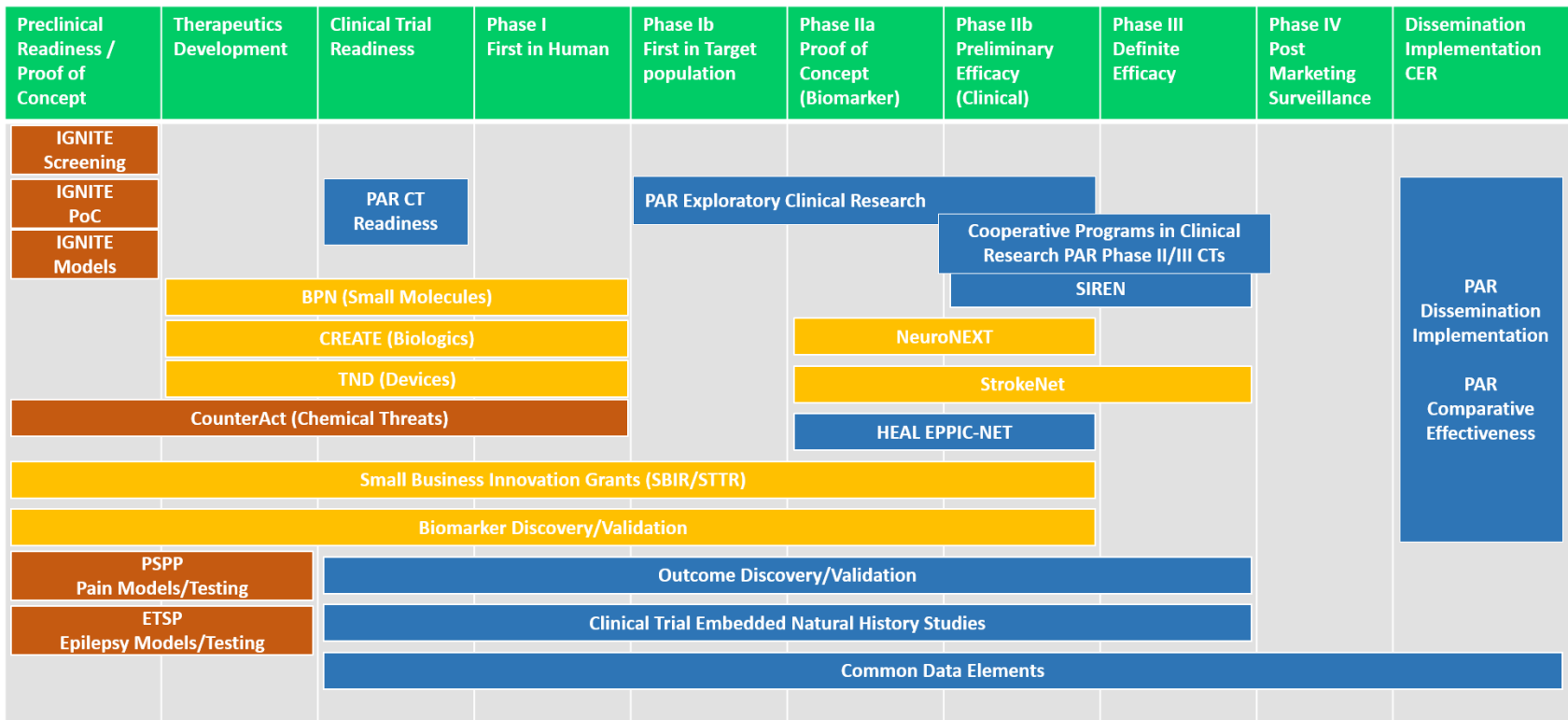
Broad range of commercialization R&D activities:

- Drug Discovery
- Device prototyping
- Preclinical validation
- IND- and IDE-enabling research
- Human Subjects Research
- Early stage Clinical Trials



NINDS Funding Opportunities

NINDS Programs Offered Across the Translational and Clinical Spectrum- Small Business Specific Opportunities



Division of Translational Research Division of Clinical Research



NINDS SBIR/STTR budget and timeline guidance

Phase I

Hard Cap: \$256,131

Under Waiver: \$700K
(not more than \$500K/yr)

Duration: 6-24 months

Phase II

Hard Cap: \$1,680,879

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

Duration: 2-3 years

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.

Additional Budget and Waiver info:

www.ninds.nih.gov/Funding/Small-Business-Grants/Budget-Information



NINDS SBIR/STTR Grant Funding Opportunities

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

Specific Technical Focus or Initiative

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

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

Phase IIb SBIR

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

CRP

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



NINDS Device Development Pipeline for Small Business and Beyond



NINDS Exploratory Research
(R21) (PA-18-358)

NSF-NIH Smart Health, AI, Data Science
(NSF-21-530)

Bioengineering Research Grants (R01)
(PAR-19-158 & PAR-19-159)

BRAIN New Concepts
(R21) (RFA-EY-21-001)

Bioengineering Research Partnerships
(U01) (PAR-19-156 & PAR-19-157)

BRAIN New Technologies
(R01) (RFA-NS-18-020)

Translational Neural Devices (Reissue has been approved)
(UG3 / UH3 / U44) (RFA-NS-18-011 / RFA-NS-18-012)

BRAIN Device Optimization
(U01) (RFA-NS-18-019)

BRAIN Next-Generation Devices (Reissue has been approved)
(UG3 / UH3 / U44) (RFA-NS-18-021 / RFA-NS-18-022)

BRAIN Next-Gen Devices
(UH3) (RFA-NS-18-023)

HEAL EPPIC-Net
(U24 / OTA)

Exploratory CTs
(U01 / R42 / R44)
(PAR-18-420 / PAR-15-277 /
PAR-15-278)

NeuroNext (R01/U01)
StrokeNET (R01/U01)

GOAL:

Support development, optimization, and translational activities and small clinical studies involving therapeutic and diagnostic devices for disorders that affect the nervous or neuromuscular systems

Nick Langhals, PhD

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Program Director

Division of Translational Research, NINDS

Program/Team Lead for HEAL, SPARC, BRAIN, and NINDS

<https://www.ninds.nih.gov/Funding>



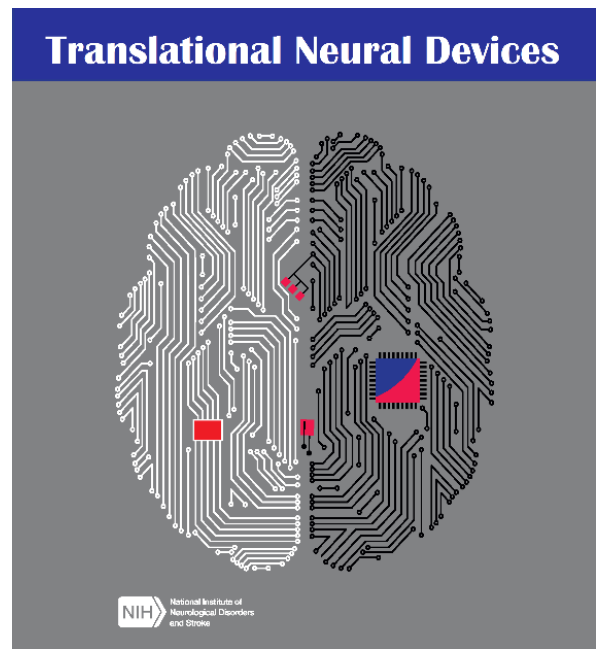
NINDS Cooperative Agreements for Device Development

NINDS Translational Neural Devices Program

(RFA-NS-18-011; RFA-NS-18-012)

- Cooperative agreement award programs support development, validation and verification, and early clinical studies of therapeutic and diagnostic devices to treat neurological disorders.
- Support for small clinical trials to collect safety and effectiveness data

Indication		Modality	
Amputation	Yellow	EMG	Yellow
Paralysis	Red	Stent	Red
Blindness	Orange	Microstim	Yellow
DBS Tool	Red	MRI	Orange
Epilepsy	Green	DBS	Green
Essential Tremor	Orange	RNS	Red
Hearing Loss	Red	Ultrasound	Yellow
Psychiatric	Light Green	Nerve Stim	Yellow
Pain	Green	SCS	Light Green
Parkinson's	Light Green	Air	Red
SCI	Green	Fiber Optic Probe	Yellow
Stroke	Light Green	Neuroprosthesis	Yellow
TBI	Orange	TMS	Red





Device Development under the BRAIN Initiative

Invasive Therapeutic and Diagnostic Devices for Central Nervous System Disorders

Milestone-driven translational and clinical projects for recording and/or stimulating devices to treat central nervous system (CNS) disorders and better understand the human brain.



RFA-NS-18-021 (UG3/UH3)

- **UG3 Phase** supports non-clinical testing toward filing of an IDE for an SR study or obtaining IRB approval for an NSR clinical trial.
- **UH3 Phase** supports a small clinical trial obtain critical information necessary to advance recording and/or stimulating devices to treat CNS disorders and better understand the human brain.

RFA-NS-18-023 (UH3)

- Supports small clinical trial to obtain critical information necessary to advance recording and/or stimulating devices to treat CNS disorders and better understand the human brain.

RFA-NS-18-022 (U44 SBIR, Fast-Track and Straight to Phase II)

- **SBIR Phase I** supports non-clinical testing toward filing of an IDE for an SR study or obtaining IRB approval for an NSR clinical trial.
- **SBIR Phase II** will support a small clinical trial obtain critical information necessary to advance recording and/or stimulating devices to treat CNS disorders and better understand the human brain.

<https://braininitiative.nih.gov>



Virtual BRAIN Initiative Investigators Meeting

Creating an inclusive scientific community, regardless of funding source



- 5 Plenary talks and several attendee-organized symposia
- Virtual poster hall, exhibit hall, networking, speaker office hours, and other meet & greets
- Research highlight talks, trainee highlight awards, “hot topics” & specialty sessions
- International roundtable discussion on data sharing
- Scientific photo and video competition

Registration open through June 15th
www.brainmeeting2021.com



Application Support for Companies new to NIH SBIR/STTR funding

Applicant Assistance Program

- AAP is aimed at helping small businesses apply for **Phase I SBIR/STTR** funding
- Companies can receive support and guidance at **no cost**, including application preparation support
- Program **open to companies that have never received NIH SBIR/STTR funding**
- **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

Application portal will open in December for April 5th Phase I application development

<https://www.evagarland.com/nih-aap-cover-page/>

NINDS Small Business Program Pre-Application Webinars

- Next date Nov 7th, 2020, posted on website afterward

Online Resources

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

FAQs, policies, eligibility info, sample applications, funding opportunities, due dates, budget and timeline guidance

Have similar projects been funded? Search NIH Reporter <http://projectreporter.nih.gov/reporter.cfm>

Contact Program Staff Directly

- Include a draft Specific Aims page and specific questions
- Anticipate 4+ week lead time for scheduling calls



NIH Support for Funded Companies

Phase I Companies

- Business Strategy Development through **I-Corps** and **C3i**
- Technical and Business Assistance (**TABA**) needs assessment

All Companies

- PA-18-837: Supplements to Promote Diversity
- Access to **Innovator Support** Consults (EIR, regulatory strategy)
- NIH-sponsored **Showcase Opportunities**
 - Speaking slots at partnership meetings (e.g., BIO, RESI, LSS)
 - Pitch Coaching with EIRs



Frequently Asked Questions

Q. What percent of SBIR and STTR applications are funded?

A: NIH SBIR/STTR rates published here : <https://sbir.nih.gov/nida/SuccessRates>

Q. When will I found out if my application will be funded?

A. Roughly 6-7 months from the time of submission

Q. What advice would you give new applicants?

A. If at first you don't succeed, try again! Resubmissions often (but not always) improve in score. It can take several rounds to be funded – incorporate this expectation into your company fundraising timeline.



Contact Us

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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/>