

## **Informational Webinar**

February 7, 2022

A recording of this webinar will be posted on neuromodprize.com.



### Introductions: NIH



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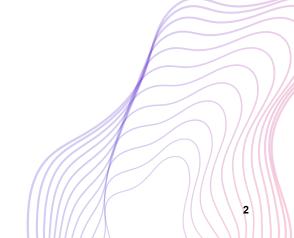
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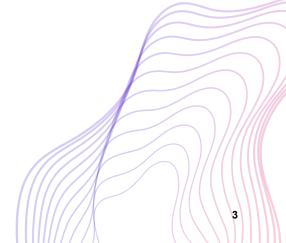
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#### **Alex Leader**

**Engagement Manager** 

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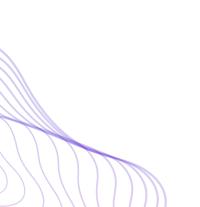
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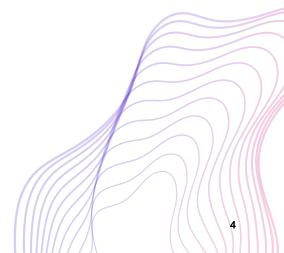


# **Agenda**



- 1. Overview
- 2. Prize details
- 3. How to enter
- 4. Q&A





# Overview



# **NIH Common Fund programs**





**Transformative:** Must have the potential to dramatically benefit biomedical and/or behavioral research.

Catalytic: Must achieve a defined set of goals within

5-10 years.

**Synergistic:** Outcomes must synergistically advance individual missions of NIH's Institutes and Centers.

**Cross-cutting:** Program areas cut across missions of multiple Institutes and Centers, requiring a coordinated approach.

**Unique:** No other entity is likely or able to do.













### **About SPARC**

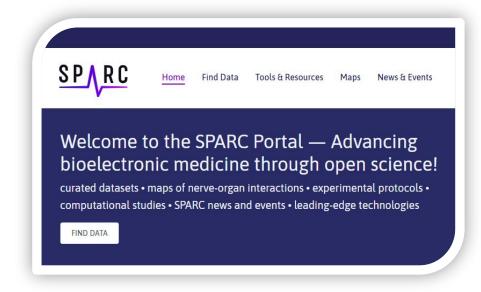




Stimulating Peripheral Activity to Relieve Conditions

The Common Fund's SPARC program seeks to accelerate development of therapies that precisely modulate electrical activity in nerves to improve organ function.

Visit the **SPARC Portal** at **https://sparc.science**.



## Advancing the SPARC program

In Stage 1, SPARC supported new tools and technologies and created the SPARC portal. In Stage 2, three complementary initiatives will build on these accomplishments:

#### **SPARC-V**

Mapping of the human vagus nerve

#### **SPARC-O**

Open-source and modular neuromodulation platform

#### **SPARC-X**

Prize competitions to demonstrate next-generation capabilities

## Why the Neuromod Prize?





The Neuromod Prize aims to bridge the gap between early-stage research and clinical application for targeted neuromodulation therapies.

- Given the extensive innervation by autonomic nerves, neuromodulation has the potential to treat many conditions.
- Advances in both device technology and scientific understanding of the peripheral nervous system may allow more effective and selective neuromodulation.
- Although autonomic nerve modulation often causes multi-physiological effects, these effects are usually studied in isolation.

# **Prize details**



### **Prize overview**



The first phase calls on scientists, engineers, and clinicians to submit novel concepts and plans for development.

Current

### PHASE 1

Concepts and plans for development

January - April 2022

Planned

### PHASE 2

Proof-of-concept studies

Summer 2022-2023

Planned

### PHASE 3

IDE-enabling studies

Summer 2023-2025

## Prize pool



Phase 1 is open to all eligible participants, with winners exclusively invited to compete for future prizes, contingent upon availability of appropriated funds.

Phase 1 prize pool

\$800,000

Up to eight winners will receive a share of the up to \$800,000 prize pool.

Phase 2 prize pool

### \$4 million

Up to four winners will receive a share of the up to \$4 million prize pool.

Phase 3 prize pool

### \$5 million

One or more winners will receive a share of the up to \$5 million prize pool.

### **Timeline**



Submission period

JANUARY 18 - APRIL 28, 2022

Virtual information session

**FEBRUARY 7, 2022** 

Technical considerations panel

MARCH 7, 2022

Submission deadline

APRIL 28, 2022

Judging

**MAY - JUNE 2022** 

Phase 1 winner announcement

**JUNE 2022** 

Phase 2 launch

LATE SUMMER 2022

# **Submission requirements**



The primary component of a submission will be a concept paper (15 pages maximum) that summarizes your solution and proposed experiments, responding to the following four considerations:

## THERAPEUTIC APPROACH

Detail your proposed solution's methodology.

#### **PERFORMANCE**

Describe how your solution would be capable of achieving its targets.

#### **IMPACT**

Describe the potential therapeutic applications of your solution

## PLANS FOR DEVELOPMENT

Describe the current state of clinical maturity and development of your solution.

## **Judging process**



Submissions will be evaluated by a judging panel composed of federal employees from across NIH and potentially other government agencies:

- Depending on the volume of entries, submissions may initially be evaluated by a multidisciplinary group of technical reviewers.
- Submissions will be assigned 1 to 5 points (5 being the highest; 1 being the lowest) for each of the five criteria, for a maximum of 25 points.
- Up to eight Phase 1 winners will be selected based on the official judging criteria, subject to a final decision by NIH.

## **Judging criteria**



#### **Targeting performance**

Selectively modulate two or more target indications High degree of tunability, accuracy, and precision

#### **Off-target mitigation**

Identifies clinically relevant risks Monitors off-target outcomes

#### **Technical readiness**

Readiness for proof-of-concept Identifies the barriers to clinical translation Articulates next steps to bridge gaps

#### **Scientific contribution**

Increases understanding of underlying mechanisms
Yields additional insight into targeting specificity

### **Clinical impact**

Addresses pressing therapeutic need(s)

Translatable and enhances or replaces existing treatments

## Target performance considerations



#### **OPERATING PARAMETERS**

For any and all target indications identified, describe how the proposed approach to stimulation achieves:

- **Tunability** of both the stimulation parameters (e.g., pulse width) and protocols (e.g., current steering).
- Accuracy of stimulation outcomes to a generally accepted standard of error for the target indication(s).
- Precision of stimulation outcomes within a generally accepted range of variability.

See the full table of target performance considerations on the competition website: neuromodprize.com/resources.

## Target performance considerations



#### **BIOMARKER OBSERVATIONS**

Provide a quantitative assessment of both on-target and off-target events that occur within seconds to minutes of stimulation. For example:

- Describe in detail the biomarker(s) that will be measured to determine the outcomes of stimulation on target autonomic functions. Identified biomarkers must include those that are regulated by the same nerve being modulated.
- Explain the level of confidence in the biomarker(s) to reliably correlate with the intended outcomes, for example: No more than X% change in biomarker(s) during specified time frame during and after stimulation.
- Assess the ability to independently control autonomic functions, for example: Selectively adjust Function A by X% without change in Function B, and adjust Function B by X% without change in Function A.

See the full table of target performance considerations on the competition website: neuromodprize.com/resources.

### Solution needs



The competition seeks groundbreaking uses of peripheral nerve stimulation that can independently regulate two or more desired autonomic functions without unintended effects on non-target organs:

- Tunable, accurate, and precise.
- Capable of completing investigational device exemption (IDE) enabling studies by 2025.
- Addressing pressing therapeutic needs.
- Translatable for immediate or near-term in-human use.
- Enhancing or replacing existing treatments, and benefit patients and/or practicing clinicians.

# How to enter



## **Eligibility overview**



The Neuromod Prize is open to individuals, teams, and entities. See the competition website for the full eligibility policy on receiving a prize.



#### **INDIVIDUALS**

Registration: on behalf of

yourself

Team size: one person

**Requirements:** individual must be a U.S. citizen or permanent

resident

Prize: awarded to the individual



#### **TEAMS**

**Registration:** Team Captain registers on behalf of the team

Team size: two or more

Requirements: Team Captain lead must be a U.S. citizen or permanent resident, other members do not have to be

**Prize:** awarded to the Team

Captain



#### **ENTITIES**

**Registration:** point of contact registers on behalf of an entity

Team size: one or more

**Requirements:** entity must be incorporated and maintain a primary place of business in the U.S.

**Prize:** awarded to the entity

## Intellectual property



### Submission license policy summary:

- Participants retain ownership of their solutions.
- Entering the competition means granting NIH license to reproduce, publish, post, link to, share, and display publicly the submission title, headline, and executive summary.

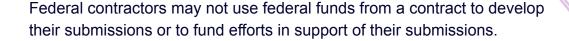
See the competition website for the full IP policy: neuromodprize.com/rules-terms-and-conditions.

# Requirements for federal grantees



Have you received other federal grant awards for your project? *If you intend to use those funds to develop your submission, several conditions must be met:* 

- The use of funds for this competition must be consistent with the purpose, terms, and conditions of the grant or award.
- You must register for and participate in the competition as an Entity on behalf of the awardee institution or organization.
- If you are awarded a prize, it must be treated as program income.



# **Solver community**



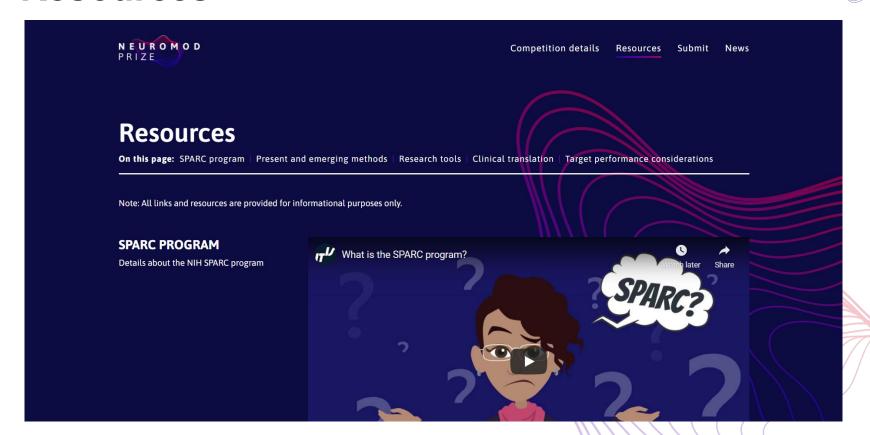
Success in all phases of the Neuromod Prize will require a breadth of expertise. Joining the solver community is an opportunity to discover and share your contact details with others looking to collaborate.

- By signing up, you will receive contact details for others looking to collaborate.
- Your details will only be shared with others who have also signed up.
- Joining does <u>NOT</u> come with an obligation to join a team or submit a solution.

Fill out the form on the competition website to share your information with others interested in collaborating: neuromodprize.com/solver-community.

### Resources





### **Interested in participating?**



# Register your team

Set up an account so you can submit as soon as your concept paper is ready.

# Read the details

Learn more about the timeline, submission requirements, judging criteria, and judging process.

# **Explore the resources**

Explore the resource hub and consider opportunities to collaborate.

# Enter the submission

Log in to your account to upload your concept paper by April 28.

### **New SPARC Initiatives**



### **SPARC-V: Human vagus nerve mapping and physiology**

- Reconstructing human vagal anatomy (REVA)
  - Notice ID 75N98022-SPARC-RFP-28Jan2022 -> Applications Due Apr 4, 2022
- VNS Endpoints from Standardized Parameters (VESPA) Center (U54) will implement a large multisite clinical study of the multi-organ effects of vagus nerve stimulation
  - RFA-RM-22-002 -> Applications due April 1, 2022

### **SPARC-O: Open-source neuromodulation technologies**

- Human Open Research Neural Engineering Technologies (HORNET) Centers (U41) will create interoperable open-source modules that can be combined into custom profiles for neuromodulation studies
  - RFA-RM-22-002 Applications closed January 12, 2022

#### **SPARC-X: Neuromod Prize**

- Competition to incentivize selective neuromodulation of multiple outcomes without off-target effects
  - <u>Neuromodprize.com</u> -> Submissions due April 28, 2022



# Q&A





# Thank you

For support or questions, please email <a href="mailto:hello@neuromodprize.com">hello@neuromodprize.com</a>.

Subscribe for updates:

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