



**SPARC** Stimulating Peripheral Activity  
to Relieve Conditions

SPARC Human Open Research  
Neural Engineering Technologies  
(HORNET) Initiative: U41 Centers

**RFA-RM-21-024**

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**NIH**

National Institutes of Health

Office of Strategic Coordination – The Common Fund





Thank You!



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## SPARC-O/HORNET Team

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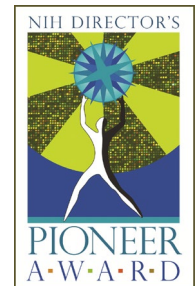
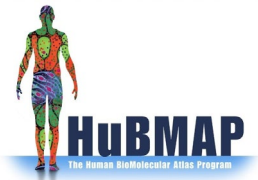
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Michael Wolfson, PhD (NIBIB)



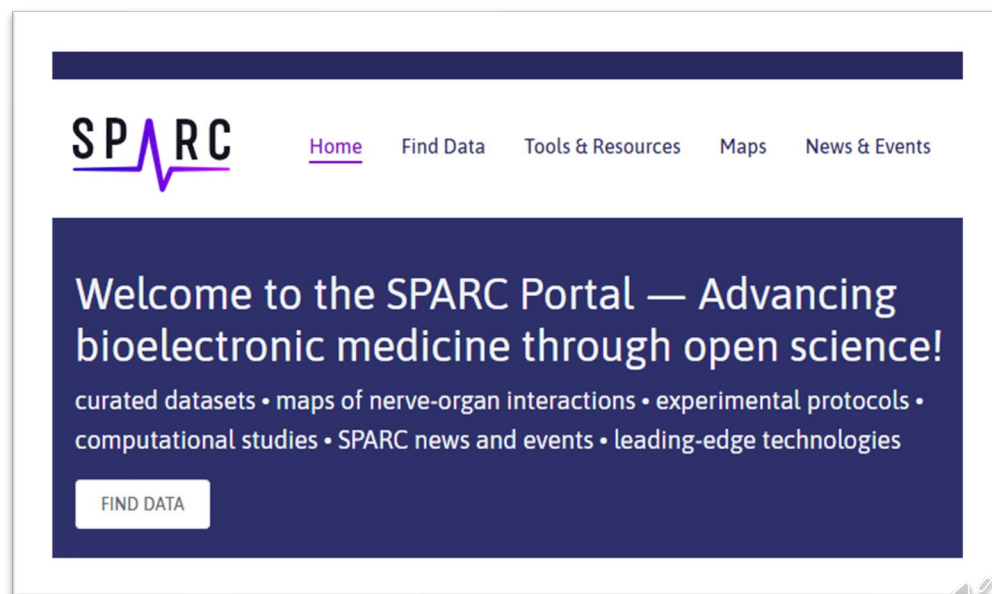
- Transformative** Must have the potential to dramatically benefit biomedical and/or behavioral research
- Catalytic** Must achieve a defined set of goals within 5-10 years
- Synergistic** Outcomes must synergistically advance individual missions of Institutes and Centers
- Cross-cutting** Program areas must cut across missions of multiple Institutes and Centers, requiring a coordinated approach
- Unique** No other entity is likely or able to do



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

Visit the **SPARC website** at [commonfund.nih.gov/sparc](https://commonfund.nih.gov/sparc)

Check out the **SPARC Portal**  
at [sparc.science](https://sparc.science)



## HORNET: Human Open Research Neural Engineering Technologies

**Program Motivation:** Clinical translation of neurotechnologies requires the availability of clinical-grade neuromodulation platforms

- Platforms are costly to develop from the ground up
- Can be difficult to access for exploratory use from large medical device companies

**Mission:** To develop interoperable technology modules and full neuromodulation systems to lower regulatory hurdles to better facilitate translation of new therapies to humans.

**Goal:** To advance the clinical translation of neuromodulation therapies in humans by supporting the development of this open-source ecosystem.





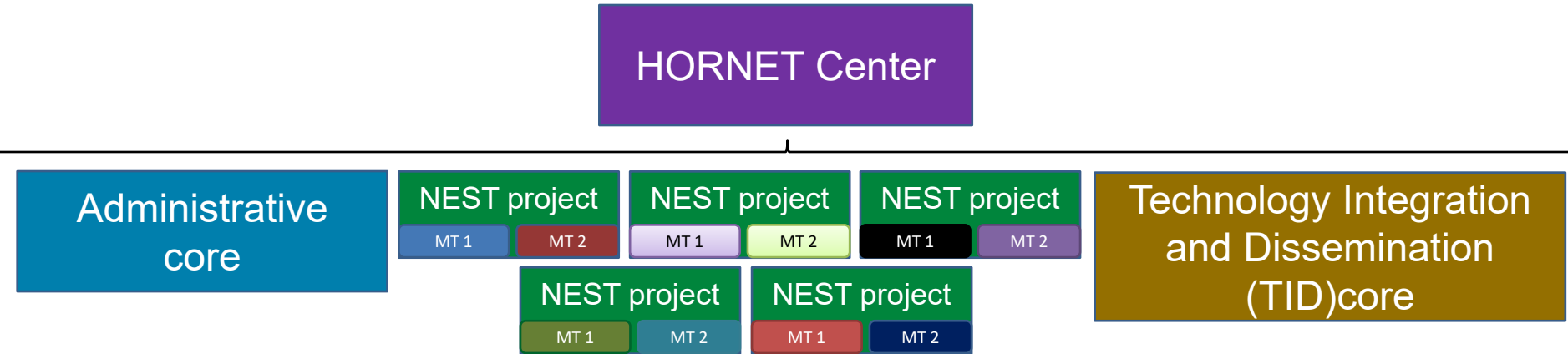
# HORNET Centers



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Assemble technological and other resources to develop open-source, modular neuromodulation systems for use in human clinical research.





## HORNET Center

### Administrative core

- Manages the HORNET Center
- Coordinates and oversees Nested Elements for SPARC Technologies (NEST) Projects
- Monitors integration and dissemination activities in the TID Core
- Oversees bridge between NEST Projects and the TID Core
- Coordinates development of regulatory templates
- Co-organizes HORNET consortium meetings with other HORNET Centers
- May appoint external representatives to advise on system concepts, designs, and integration and dissemination plans







- Should be at the cutting edge of their technological field
- Will design and develop one or more open-source, modular neuromodulation technologies
- Will work with the TID Core to
  - ensure integration and interoperability of modules
  - validate the integrated NESTs in benchtop, computational, and/or animal models for future use in neuromodulation applications

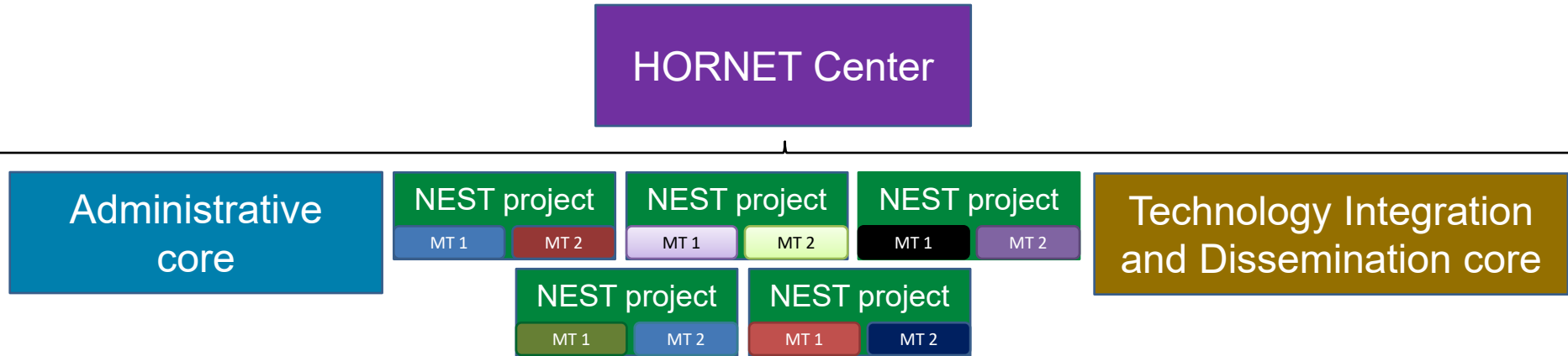


## HORNET Center

Technology Integration  
and Dissemination core

- Fully integrate modules from NEST Projects towards a functional neuromodulation system
- Coordinate with other HORNET Centers in support of integration and interoperability of modules
- Disseminate the Center's neuromodulation system templates to the research community
  - Dissemination plans should be geared toward researchers and end-users at various levels of clinical and technical expertise
- Establish and facilitate a user community for technology dissemination and collaborations both during and after the end of the award
- *Industrial partnerships are not required, but they are welcome when appropriate.*

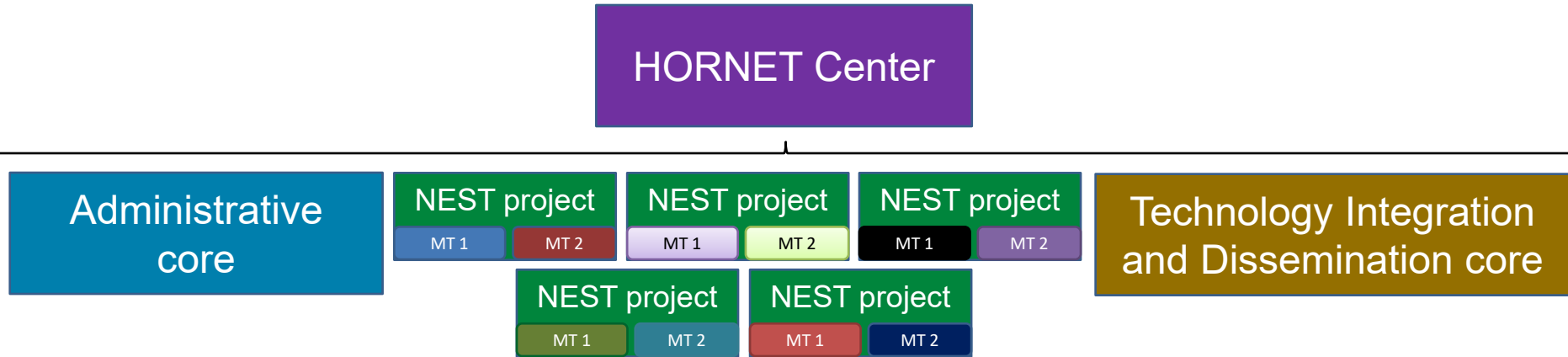




Meet twice per year (one in-person, one virtual) to:

- Facilitate collaboration across Centers
- Allow the NIH and NIH-appointed HORNET Steering Committee members to evaluate progress towards the Centers' goals and milestones





- Develop, test, validate, and integrate modules in support of an open neuromodulation ecosystem
- Publish open neuromodulation libraries in SPARC Data and Resource Center (DRC) or another NIH-approved location
- Build collaborations with partners planning to incorporate HORNET technologies into their medical devices





# Not Supported by this FOA



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Applications that include the following activities will be considered non-responsive, will be withdrawn, and will not be reviewed:

- Development of new animal models
- Development of new proprietary technologies
- Development of modules intended only for animal use
- Development of technologies for augmentation of healthy individuals
- Development of technologies that lack any potential use as elements of a neuromodulation system acting in the peripheral nervous system or spinal cord to modulate electrical activity to improve organ function
- Clinical evaluation of safety and effectiveness





# Letter of Intent



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A letter of intent is not required but would be appreciated.  
Letters of intent should be submitted by December 13, 2021:

[SPARC-O@od.nih.gov](mailto:SPARC-O@od.nih.gov)

## **Please include:**

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity announcement





# Application Information



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Multi-Component Application consisting of:

- Overall: required
- Administrative Core: required, maximum of one
- NEST Projects: required - minimum of three, maximum of five
- Technology Integration and Dissemination Core: required, maximum of one

The required information for each component is described in [Section IV. Application and Submission Information](#).

***Please read carefully and ask questions!***

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	6	Required	1	1
Admin Core	Admin Core	6	Required	1	1
NEST projects	Projects	6	Required	3	5
Technology Integration and Dissemination (TID) Core	Core	6	Required	1	1





# Application Requirements



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Look out for “**required**” and “**must**” throughout the FOA.

- All required registrations (e.g., DUNS, SAM, etc.)
- All required Cores and Projects
- Timelines (module development and release)
- Milestone Plan
- Resource Sharing Plan (Specifically Data Sharing) – All modules must be open source
- Project Narrative in Overall component
- Letter(s) of support from institutional officials
- Effort: PD/PI must devote at least 3.0 person months to the entire Center, within which 1.2 person months must be devoted to the Administration component. For MPI applications, a minimum of 3.0 person months EACH to the entire Center and a combined minimum of 1.2 person months to the Admin Core.
- Sustainability Plan (Component: Admin Core)





FOA is designated Clinical Trial Not Allowed, however certain human subjects studies may be allowable

If “YES”:

- There must be at least 1 human subjects study record - ***Study Record: PHS Human Subjects and Clinical Trials Information*** form
- The study record must be included in the component where the work is being done, unless the same study spans multiple components.
- To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the **Overall** component when the same study spans multiple components.





# Application Review Information



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Described in FOA under [Section V. Application Review Information](#)

- Panelists will be evaluating all cores and projects to provide an overall impact score.
- Please review the additional items listed by component.





# Terms and Conditions



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Described in FOA under [Section VI. Award Administration Information](#)

- Cooperative Agreement → Greater involvement from NIH Program Staff
- Final milestone plan will be negotiated and agreed to before award
- NIH Program staff will periodically assess progress toward achieving the milestones





# RFA-RM-21-024



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Letter of intent due: December 13, 2021

**Applications Due:** January 12, 2022

Scientific Merit Review: March 2022

- Special Emphasis Panel convened by the NIH Center for Scientific Review

Advisory Council Review: May 2022

Earliest Start Date: August 2022

3-year project period





# Additional Information



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## **HORNET: Human Open Research Neural Engineering Technologies**

**Contact us: SPARC HORNET Mailbox**

- [SPARC-O@od.nih.gov](mailto:SPARC-O@od.nih.gov)

**Applications Due: January 12, 2022**

<https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-024.html>

