THIS OPPORTUNITY IS CLOSED – 12/12/2017

Overview Information

Participating Organization(s)	National Institutes of Health (<u>NIH</u>)
Components of Participating Organizations	This Funding Opportunity Announcement (FOA) is developed as a <u>Common Fund</u> Initiative through the NIH Office of the NIH Director, <u>Office of Strategic Coordination</u> . The FOA will be administered by the <u>National Center for Advancing Translational</u> <u>Sciences</u> (NCATS) on behalf of the NIH.
Funding Opportunity Title	Pre-application: Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT1)
Activity Code	OT1 Pre-application for an Other Transaction Award
Announcement Type	Reissue of <u>RFA-RM-16-002</u>
Related Notices	None
Funding Opportunity Announcement (FOA) Number	RM-17-009
Companion Funding Opportunity	<u>RFA-RM-17-010</u> , OT2 Research Project — Other Transaction Award
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.310
Eligible Applicants	Applications may be submitted by applicant organizations or unaffiliated individuals, hereinafter referred to as "applicants", see the "Eligible Applicants" section <u>1. Eligible Applicants</u> .
Number of Applications	Multiple applications per applicant are allowed, provided that each application is scientifically distinct.
Funding Opportunity Purpose	The purpose of this OT1 Funding Opportunity Announcement (FOA) is to invite pre-applications from applicants who have an interest in submitting an application to "Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT2)" (RFA-RM-17-010). Applicants whose OT1 pre-applications are found to be meritorious and programmatically relevant will be invited to submit a full application to the OT2 FOA (<u>RFA-RM-17-010</u>). An Invitation to

	Submit is required to apply to the OT2 FOA. The Invitation to Submit an OT2 application is not an indication of any award. No Other Transaction awards will be made under this OT1 FOA. Applicants should read both the OT1 and OT2 FOA. This NIH Funding Opportunity Announcement (FOA) solicits pre- applications to develop new and/or enhance existing tools and technologies to facilitate the progress of other components of the SPARC program. The scope encompasses a wide range of capabilities, spanning the fields of photonics, systems engineering, virology and genomics, device design and manufacture, surface chemistry, tissue engineering, neural interfacing, biomarker sensing, and more. The specific tools and technology priorities will vary for each receipt date, as described at https://commonfund.nih.gov/sparc/FOApriorities.
Funding Instrument	Other: A mechanism that is not a grant, contract, or cooperative agreement. Other Transactions awards are subject to the requirements of the SPARC Other Transaction Award Policy Guide https://commonfund.nih.gov/sparc/OTawardpolicyguide
Funds Available and Anticipated Number of Awards	No awards will be made under this OT1 FOA. If invited to submit an OT2 application, it would be considered under the companion announcement FOA RFA-RM-17-010.
Award Budget	Not applicable to this FOA.
	Awards resulting from the OT2 companion announcement <u>RFA-RM-17-010</u> are anticipated to have a minimum budget of \$250,000 direct costs per year per application and a maximum budget of \$5,000,000 direct costs per year per application.
	OT2 applications will be required to provide a well-justified budget that is appropriate for the scope of the proposed work. Costs should be based upon how much money is required to produce the deliverables.
	Performance will be evaluated quarterly, and continued support (i.e. project budget) will be adjusted based on the outcome of those evaluations.

Key Dates

Post Date	March 17, 2017
Application Due Date(s)	Applications are no longer being accepted quarterly on or around the 1st of the month:
	OPPORTUNITY IS CLOSED
	Applications submitted on a rolling basis may receive early feedback.
	Applications submitted on the due date after 5:00 PM local time of the applicant will automatically roll forward to the next due date except for the last due date, for which no late applications will be accepted. Please note that some Priorities may be removed from the next due date.
Scientific Merit Review	Objective review will be conducted approximately four weeks following the applicable due date. Applicants will receive written feedback.
Award Timeline	Award will be made upon selection and award negotiation.
Award Project Period	Concepts submitted through this OT1 mechanism are expected to be four years or less in duration.
Expiration Date	November 2, 2018

Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Scientific/ Research Contact(s)	Michael B. Wolfson, Ph.D. Andrew C. Weitz, Ph.D. National Institute of Biomedical Imaging and Bioengineering (NIBIB)) Email: <u>SPARC_NextGen-Tools@mail.nih.gov</u>
Financial/ Agreement Officer Contact(s)	Irene Haas National Center for Advancing Translational Science (NCATS) Email: <u>haasi@mail.nih.gov</u>

Funding Opportunity Description

Purpose

The purpose of this FOA is to invite pre-applications from applicants who have an interest in submitting an application to Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to

Understand the Control of Organ Function by the Peripheral Nervous System (OT2), companion announcement <u>RFA-RM-17-010</u>.

Successful applications to this FOA will receive an Invitation to Submit to RFA-RM-17-010.

Background

Peripheral nerve stimulation to modulate organ function is rapidly developing as a therapeutic approach to a wide range of conditions. Rigorous clinical studies have yielded both promising successes and puzzling failures, highlighting an urgent need for clearer anatomical and physiological understanding of the neural control of organ function. While rough outlines are emerging, significant gaps exist which demand innovative programmatic approaches. The goal of the SPARC program is to transform the study of the neural control of organ function by addressing these gaps with primary focus on a few organs. By constructing an open atlas of comprehensive anatomy and functional peripheral nerve connectivity with organs, SPARC teams will provide the scientific foundation for the next generation of therapeutic closed-loop neuromodulation devices and protocols.

Specific major gaps to be addressed include, but are not limited to:

- Understanding the specific and diverse peripheral neural signals carried by nerve fibers to or from end-organs;
- Understanding the functional relationships between neural signals and end-organ cellular activity;
- Developing tools, techniques, and mechanisms to functionally modulate specific portions of peripheral nerves;
- Validating particular animal models to human neuroanatomy and functional neurobiology of organs;
- Characterizing the anatomical and physiological variability at potential peripheral nerve therapeutic access points and organ targets;
- Integrating anatomical and functional mapping data across methodologic approaches, animal models, and organs in order to develop predictive computational models of peripheral nerve and end-organ activity.

SPARC is composed of four interdependent components, as follows:

SPARC1: Anatomical and Functional Mapping of the Innervation of Major Organs

SPARC1 supports the creation of new anatomical and physiological data sets able to generate and address hypotheses in areas such as the coursing and branching of nerves and the distribution of axon terminals, the structure of nerve-organ synapses, the cross-sectional organization of nerves, the organ functional effects mediated by firing patterns, and the relevance of particular animal models to human systems. These studies will proceed in relevant animal models and in humans, including cadaveric tissue when necessary.

SPARC2: Next-generation Tools and Technologies

SPARC2 supports the development of tools and technologies to facilitate the progress of other components, particularly SPARC1. The scope encompasses a wide range of capabilities, spanning the fields of photonics, systems engineering, virology and genomics, device design and manufacture, surface

chemistry, tissue engineering, neural interfacing, biomarker sensing, and more. A list of <u>SPARC OT</u> <u>Priorities</u> will be posted on the SPARC website and frequently updated.

SPARC3: Translational Partnerships for Human Functional Mapping and New Indications

SPARC3 supports translational partnerships between <u>industry</u> and SPARC investigators to produce proofs of concept for new nerve stimulation indications and to study functional neuromodulation in the context of human clinical studies.

SPARC4: Data and Resource Center

SPARC4 supports the creation of a multifunctional online hub facilitating coordination, synthesis, and prediction via three Core functionalities: Data Coordination, Map Synthesis, and Modeling & Simulation.

Current SPARC projects can be browsed, by organ, at the SPARC <u>website</u>. All funded teams are part of the SPARC Consortium. All teams are expected to frequently interact with each other, sharing data, protocols, and tools within the Consortium and, as rapidly as possible, with the broader scientific community. Consortium governance is described in the <u>SPARC OT Award Policy Guide</u> and <u>Material Sharing Policy</u>. All members of the Consortium are required to agree to these policies. SPARC is actively managed, and the Consortium will continually be adjusted by adding or subtracting research elements to achieve the overall SPARC goal.

About the NIH Common Fund

SPARC (<u>http://commonfund.nih.gov/sparc/index</u>) is a program of the NIH Common Fund, which supports cross-cutting programs that are expected to have exceptionally high impact. Common Fund programs invite investigators to develop bold, innovative, and often risky approaches to address problems that may seem intractable or to seize new opportunities that offer the potential for rapid scientific progress.

Although the description above pertains to the entire SPARC program, and is included so potential applicants can consider formulation of their project with an overview of the entire program, THIS ANNOUNCEMENT APPLIES ONLY TO PRE-APPLICATIONS (OT1) for Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to Understand the Control of Organ Function by the Peripheral Nervous System, described here and in companion announcement <u>RFA-RM-17-010</u> (OT2).

Specific Objectives for Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (This FOA)

This FOA solicits applications for Other Transaction awards to develop tools and technologies to support physiological, anatomical, and/or functional mapping of the peripheral nervous system.

Only tool and technology categories listed on the <u>SPARC Priorities</u> page for the current receipt date are responsive to this FOA. These Priorities are posted at the above link two months prior to each receipt date, along with a list of potential Priorities for future receipt dates. For example, for the August 1, 2017 receipt date, a final list of Priorities will be posted on or before June 1, 2017. Applications that address Priorities listed in a previous or future receipt date will be considered not responsive, including late applications. Potential applicants are strongly advised to consult with the Scientific/Research Contact listed below to discuss the interests of the SPARC program under this announcement.

Priority categories will be determined and updated by the SPARC management team based on developing science and technology and program needs. Priorities may be influenced by: needs expressed by SPARC-funded investigators, other investigators, and broader stakeholders; gaps in available technological approaches, gaps in models for systems of interest, and portfolio balance in terms of technological approach and deliverable maturity. The SPARC management team may solicit potential Priorities from the broader scientific community and NIH Program staff.

Because SPARC supports projects investigating a variety of organs, each supplied by nerves having a variety of properties and courses across individuals and species, it is desirable that proposed technologies are adaptable to multiple needs. Single-purpose solutions for specialized high-value needs are also acceptable. Technologies are not required to be on a pathway towards translation to human use, unless specifically stated in the SPARC Priorities.

If appropriately justified, any degree of preliminary technology maturity is acceptable, from theoretical and unproven to integration or improvement of commercial off-the-shelf (COTS) products. Applicants are strongly encouraged to demonstrate use of quantitative models and methods to drive the design, development and validation of the proposed technologies.

SPARC is not part of the BRAIN Initiative <u>https://www.braininitiative.nih.gov</u>; however, technologies to study brain and spinal circuits may be in scope for SPARC to the extent that their study is necessary to a first- or second-order understanding of organ-specific peripheral nerve circuits. Examples might include tools to functionally assess a particular nerve-organ connection via spinal cord stimulation, or to study the alteration of peripheral nerve responsiveness by synaptic plasticity in the brainstem.

With respect to peripheral nerves, this FOA will accept technology development tailored for the study of all relevant pathways pertaining to an organ of interest. Where organ function is dependent on a mixture of autonomic, sensory and voluntary innervation, investigation of any of these circuits is considered to be within the scope of the program. Applicants must provide justification, and must describe the relevance of proposed technologies to the SPARC Mission.

With regard to tool development and validation, the specific choice of animal or human model must be justified. The proposed technology should be tailored appropriately for use in said animal or human model. Justification must be provided for the <u>sample size and sex distribution</u>, the technology verification plan and expected knowledge to be gained from its use, and the eventual applicability of these results to humans.

Tool validation strategies making use of preparations outside the scope of currently funded SPARC organs will be accepted, provided the applicants justify the tool's relevance to a system under investigation by SPARC awardees. Applicants may propose to develop tools intended for organs or nerves not currently under investigation in the SPARC program, but must justify the importance of the organ or nerve for potential inclusion in SPARC and explain why current tools prevent its study.

It is expected that applicants will utilize a multidisciplinary team approach when needed, for example: consulting with experts in anatomical and functional mapping of innervation for each organ system in animal models, surgeons who routinely access the nerves for each organ system, technologists with expertise in multiple academic technologies, and translational engineers. The current state of

knowledge of functional innervation varies based on the scientific foundation underlying each organ. Technologies currently being developed to study the brain may be adapted to study the periphery.

It is expected that final deliverables (and interim deliverables if possible) will be mature enough to share with the SPARC Consortium, or be collaboratively developed with them. Data, designs, and services developed by SPARC2 projects will be made available to the SPARC Data and Resource Center, and to the research community to assist the SPARC program and the community.

Finally, it is important to note that innovation is not the primary objective of this FOA. Applicants are encouraged to instead focus on the utility of their developments to address the SPARC mission.

Please see the <u>FAQ</u> for clarifications to common questions.

SPARC Program Other Transaction Management

No award will be made based on responses to this announcement. Awards under the companion OT2 announcement (<u>RFA-RM-17-010</u>) will be made as Other Transactions, which are not grants, contracts or cooperative agreements. The <u>NIH Other Transaction Award Policy Guide for the SPARC Program</u> describes the OT mechanism, and describes other policies that all awardees must comply with.

SPARC OT awards are actively managed by SPARC Program and Project Managers and an Agreements Officer. This active management allows for flexibility in soliciting new awardees, combining projects, and modifying review processes. SPARC Program and Project Managers will have significant programmatic input into awarded activities, providing substantial scientific programmatic involvement in quality control, research coordination, performance monitoring, technical assistance, and final decisions for award directions. The Program Manager will also oversee coordination across individual projects to combine, add to, or subtract from research being done in order to increase quality, accelerate the progress of research, realize economies, or discontinue duplicative or low-priority approaches.

Projects within SPARC must propose information sharing and include expertise for material exchange among teams and with the Data and Resource Center. The <u>SPARC Material Sharing Policy</u> defines these expectations. Awards issued under this FOA will adopt the prescriptions and requirements of the Bayh-Dole Act of 1980, which pertains to the ownership of intellectual property.

It is anticipated that there will be two face-to-face meetings of the SPARC investigators per year, in addition to more frequent programmatic web-assisted meetings as deemed necessary by the SPARC Program Manager. Travel for face-to-face meetings must be included in the project budget.

NIH policies as described in the <u>NIH Other Transaction Award Policy Guide for the SPARC Program</u> will apply to the applications submitted and awards made in response to this FOA.

Eligible Applicants

Applicants may be subject to financial analysis and risk assessment conducted by NIH staff. One individual must be identified as the contact Principal Investigator.

Federally Funded Research and Development Centers (FFRDC) and University Affiliated Research Centers (UARC)

FFRDCs and UARCs are eligible to apply and/or participate as partnering organizations. NIH will not award funds specifically for laboratory directed research and development (LDRD) costs. Laboratory contractors may recover LDRD costs within the total funding included in the award. Other costs will be reviewed and negotiated prior to award.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Applicants) **are** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply. Foreign components, as defined here, **are** allowed:

The performance of any significant scientific element or segment of a project outside of the United States, either by the awardee or by a researcher employed by a foreign organization, whether or not funds are expended, is considered a foreign component. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the awardee that may have an impact on U.S. foreign policy through involvement in the affairs of environment of a foreign country. Examples of other award-related activities that may be significant are:

- o Collaborations with investigators at a foreign site anticipated to result in co-authorship;
- Use of facilities or instruments at a foreign site; or
- Receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component.

Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals not affiliated with an organization, or who want to submit an application independently of their current organization, may apply. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Applicants do not have to be U.S. citizens or permanent residents but must have a U.S. tax payer identification number.

Eligible individual(s) must have documented (in the "Key Personnel & Experience" section) technical expertise directly related to the scientific area in which the application is targeted and be capable of providing both administrative and scientific leadership to the development and implementation of the proposed project, monitoring and assessing the project, and submitting all documents and reports as required.

Multiple Principal Investigators

More than one individual may be named as Principal Investigator on a single application.

Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- o Alaska Native and Native Hawaiian Serving Institutions
- o Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)
- Federally funded research and development centers (FFRDC)
- University affiliated research centers (UARC)
- Unaffiliated individuals or individuals who want to submit an application independently

Required Registrations for OT2 Applicants (RFA-RM-17-010)

Applicants must complete and maintain the following registrations to be eligible to apply for the companion OT2 FOA (RFA-RM-17-010) or to receive an OT2 award. Individual applicants not affiliated with an organization or who want to submit an OT2 application independently must complete all the required registrations as though they are an organization. There should **not** be any cost associated with **any** of these registrations. All registrations must be completed prior to the corresponding OT2 application being submitted. Registration can take 6 weeks or more, so successful OT1 applicants should begin the registration process immediately after being invited to submit an OT2 application. (Note that these registrations are **not** required prior to submitting an OT1 application.) Failure to complete registrations in advance of an OT2 due date is not a valid reason for a late submission.

- <u>Dun and Bradstreet Universal Numbering System (DUNS)</u> All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - <u>NATO Commercial and Government Entity (NCAGE) Code</u> Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application. Unaffiliated individuals will be registered as "independent scholars" and will also act as the SO, with the same authority in eRA Commons that the Authorized Organizational Representative(s) has in Grants.gov.
- Grants.gov Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) applying for the companion OT2 FOA (<u>RFA-RM-17-010</u>) must have an eRA Commons account (eRA Commons accounts are **not** required for submitting OT1 applications). PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Application Content and Submission Information

Instruction for Research Plan Submission

Applications must include the following, with the total application package not to exceed six (6) pages:

• Cover Page (up to one page)

- 1. Project Title
- 2. SPARC Priority being addressed
- 3. Contact PI's first and last name, title, email address and phone number
- 4. Type of applicant (see the "Eligible Applicants" section above as a reference)
- 5. Name of the organization and department, if any
- 6. Authorized Organizational Representative (AOR) first and last name, email address and phone number (only applies to organizational applicants)
- 7. Period of support requested; assume project start would be five months after receipt of the OT1 application
- 8. Approximate budget (direct and total) for the entire project
- 9. Other key personnel names and organizations (MPIs, co-Investigators, collaborators, etc.)
- 10. Resources required:

- Are Human Subjects Involved: Answer "Yes" or "No"
- Are Vertebrate Animals Used: Answer "Yes" or "No"
- Are Biohazardous Materials Used: Answer "Yes" or "No"
- Are Select Agents Used: Answer "Yes" or "No"
- o Are Human Embryonic Stem Cells Used: Answer "Yes" or "No"

• Project Summary (up to one page)

Do not consider this to be a traditional Specific Aims page for hypothesis-driven research. This page should provide an outline of the project. Briefly state the objective of the project and how the deliverable(s) address the currently posted SPARC Priorities. As appropriate, describe target nerve(s) and/or organ(s). Provide a summary of major tasks to be accomplished with milestones and benchmarks, a timeline, and deliverables.

• Development Strategy (three pages maximum)

Do not consider this to be a traditional Research Strategy. The objective of this FOA is to identify projects and teams who can provide needed tools and technology to the SPARC Consortium and the broader research community. This section should be structured to provide reviewers with sufficient information to gauge the applicant's likelihood of producing the deliverables and achieving their objectives.

- **Impact and Significance:** Identify the SPARC Priority being addressed in this application. Briefly describe the relevant major knowledge gaps and/or barriers within that Priority that the proposed technology will overcome. Highlight any conceptual, technical, and/or methodological innovations for the proposed project.
- Preliminary Data: Provide a description of the technology's maturity. One approach is to use <u>Technology Readiness Levels</u>. Describe the Preliminary Data, if available. Preliminary data is not required for a successful application.
- **Risk Analysis (optional for OT1):** Provide a description of potential pitfalls and limitations, and approaches to retire and/or mitigate them.
- Tasks, Benchmarks, Timeline, and Deliverables: Include a description of the expected outcomes and deliverables from each major task. Each benchmark should be designed to evaluate interim or final progress, and include an estimated timeline. The first year should conclude with either a clear demonstration that shows that major risks have been retired or mitigated, or a demonstration of capability. All demonstration benchmarks should use quantifiable criteria for success relevant to the overall objective of the project (i.e. go/no-go criteria). The OT2 application should provide quantitative estimates for the benchmarks. The timeline must include transfer of material to the SPARC Data and Resource Center.

Examples of benchmarks are available at <u>https://www.ninds.nih.gov/Funding/Apply-Funding/Application-Support-Library/Neural-Prosthetics-Milestones</u>

• **Key Personnel & Experience:** Include a table of the key personnel, briefly describing each individual's planned contribution and technical expertise directly related to the scientific area in

which the application is targeted. Identify the performance site for each individual. Responsibility for interfacing with the SPARC Data and Resource Center must explicitly be assigned to one or more individual(s) planned contributions.

• **Budget:** A direct and total cost estimate for each major task. Further breakdown is not required for OT1 applications. This is not meant to be the final budget, but should be an informative estimate which may be revised in the OT2 application.

Cost sharing is not required. Applicants may voluntarily choose to propose a financial plan that includes non-federal resources. Successful OT1 applicants must clearly identify and justify the use of these resources as part of their OT2 budget submission. Any voluntary cost share must be supported by a letter of support from the providing organizations/individual. All voluntary cost share provided is also required to adhere to the <u>SPARC OT Award Policy Guide</u>.

- Resource Sharing Plan: All applications, regardless of the amount of direct costs requested for any one year, must include a Resource Sharing Plan. This plan must include timely sharing of material to the SPARC Data and Resource Center, as well as to other projects within SPARC, and more broadly to the research community in general. The SPARC Material Sharing Policy is provided at https://commonfund.nih.gov/sparc/materialsharing.
- **Bibliography (up to one page):** References to support the Research Strategy.
- **Post Submission Materials** Post submission materials will not be accepted for the OT1 pre-application.
- How to submit the application

Complete applications must be emailed to <u>SPARC_NextGen-Tools@mail.nih.gov</u>. Applications must be submitted in text-recognizable PDF (Adobe) format and file size must be no greater than 20MB. Paper applications will not be accepted. Applications from institutions must be submitted by an authorized organizational representative. The Scientific/ Research Contact(s) will review your application for completeness and acknowledge receipt within 12 hours.

Application Review Information

As part of the objective review, all applications will receive a written summary.

<u>Appeals</u> of the objective review will not be accepted for applications submitted in response to this FOA.

Responsiveness to this FOA

Applications with an emphasis on the following will be considered **not responsive** to this FOA:

- Major deliverables which are not new technologies.
- Development of tools or technologies solely justified by a treatment or therapeutic strategy.
- Deliverables which are outside the SPARC Priorities for the receipt date.
- Tools and techniques to neuromodulate sensory organs of the head, named voluntary muscles, and the central nervous system above the spine.

SPARC is focused on understanding healthy organ function. Study of disease states may be necessary to further understand innervation or the effects of modulation on normal organ function. Inclusion of such studies in a project must be justified in the application.

For the purposes of this FOA, preganglionic neurons of the autonomic nervous system located in the brainstem or spinal cord, as well as dorsal and ventral roots of neurons coming from or going to the spinal cord are considered part of the PNS and are thus responsive.

Criteria

OT1 applications will be reviewed according to the following criteria. More weight (non-numerical) is assigned to the Relevance and Justification.

Relevance and Justification

Will the proposed work contribute to the collection, sharing, or analysis of the anatomical and physiological data sought by the SPARC Program? Factors in this assessment may include:

- 1. Is the proposed work likely to provide significant new capabilities, or to make existing capabilities more widely available?
- 2. Does the proposed tool or technology to be developed fit the SPARC Priorities for this receipt date?

Benchmarks and Deliverables

- 1. Are the proposed project benchmarks and deliverables feasible and congruent with the goals outlined in the specific call for applications?
- 2. Are there any deficiencies in the proposed benchmarks, deliverables, timeline, budget, resource sharing plan, and risk analysis (if present)?
- 3. Is there sufficient interaction proposed with the Data and Resource Center?

Expertise

- 1. Is the necessary expertise enlisted and the environment and facilities appropriate for a multidisciplinary approach to the proposed research?
- 2. Is expertise for data processing and communication to the SPARC Data and Resource Center included?
- 3. Is there evidence of sufficient commitment on the part of the key investigators for the project?

Resource Sharing Plans

1. Reviewers will comment on whether the following Resource Sharing Plans are reasonable: <u>SPARC Material Sharing Policy</u>.

Selection Process

OT1 pre-applications that are judged to be meritorious and align with the SPARC research mission will be invited to submit an OT2, SPARC Research Project — Other Transaction Award application under <u>RFA-</u>

<u>RM-17-010</u>.

The following will be considered in making selections for OT2 applications:

- Scientific and Technical Merit of the proposed project as determined by objective review.
- Relevance of the proposed project to program priorities.