Overview Information

Participating Organization(s)	National Institutor of Hoalth (NILL)
Participating Organization(s)	National Institutes of Health (NIH) This Funding Opportunity Apparament (FOA) is developed as
Components of Participating	This Funding Opportunity Announcement (FOA) is developed as
Organizations	a Common Fund Initiative through the NIH Office of the NIH
	Director, Office of Strategic Coordination. The FOA will be
	administered by the National Center for Advancing Translational
Funding Opportunity Title	Sciences (NCATS) on behalf of the NIH.
Funding Opportunity Title	Data Coordination, Map Synthesis, and Simulation Cores for the
	Stimulating Peripheral Activity to Relieve Conditions (SPARC) Program
Activity Code	OT3 Multi-component Research Project – Other Transactions
Activity Code	Award
Funding Announcement (FA)	RM-16-008
Number	
Related Notice	NOT-RM-16-032
Catalog of Federal Domestic	93.310
Assistance (CFDA) Number(s)	
Number of Applications	Multiple applications per applicant are allowed, provided that
	each application is scientifically distinct. Applications may be
	submitted by applicant organizations or unaffiliated individuals,
	hereinafter referred to as "applicants" (see Eligibility section).
Funding Opportunity Purpose	Awards made under this Announcement will support development
	of the Data Coordination, Anatomical and Functional Map
	Synthesis, and Modeling & Simulation functionalities of the SPARC
	Data and Resource Center (DRC). The SPARC DRC will serve as a
	hub for the research, engineering, and clinical communities,
	disseminating knowledge and tools to advance neuromodulation
	targeting organs or organ systems.
Objective Review	Objective review will be conducted in three stages. Letters of
	intent (LOIs) will be reviewed for programmatic relevance within 2
	weeks of the application due date. A subset of applicants will then
	be invited to submit a written application. A subset of these
	applicants will be invited to present their applications to an
	interactive review panel after which awardees will be selected.
	Applicants will receive written feedback from the written
	application review stage only. See Objective Review section of this
	announcement for further details.
Funding Instrument	Other: A mechanism that is not a grant, contract or cooperative
	agreement. Other Transactions awards are subject to the
	requirements of the NIH Other Transaction Award Policy Guide for
	the SPARC program:
	https://commonfund.nih.gov/sites/default/files/SPARC Policy
Eligibility	guide - 508.pdf.
Eligibility Funds Available and	See Eligibility section of this announcement The SPARC DRC hydret is currently planned for \$10 million over a
	The SPARC DRC budget is currently planned for \$10 million over a
Anticipated Number of Awards	5-year period; however, Common Fund procedures and OT

	mechanisms allow for significant flexibilities to make adjustments that may be needed to pursue catalytic and transformative initiatives. Award levels and total budget may increase or decrease over time based on programmatic needs, funding availability and awardee performance.
Award Project Period	Project duration is anticipated to be five years

Key Dates

Post Date	March 15, 2017
Letter of Intent Due Date	April 7, 2017
	Please note that submission of the Letter of Intent is required.
Application Due Date	June 2, 2017
Earliest Start Date	August 25, 2017
Funding Opportunity Expiration	June 3, 2017
Date	

Agency Contacts

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

Scientific/ Research Contact(s)	Vinay M. Pai, Ph.D. Andrew C. Weitz, Ph.D. National Institute of Biomedical Imaging and Bioengineering (NIBIB)
	Felicia Qashu, Ph.D. Office of the NIH Director (OD)
	Email: SPARC Data@mail.nih.gov
Financial/ Agreement Officer Contact(s)	Irene Haas National Center for Advancing Translational Science (NCATS) Email: SPARC Data@mail.nih.gov

Outline of this FOA:

- 1. SPARC Program Overview
- 2. SPARC DRC Core Functionalities
- 3. Eligibility
- 4. Application Content
- 5. Application Timeline
- 6. Objective Review Process
- 7. Additional Information

1. SPARC Program Overview

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. Applicants should not limit themselves to organs currently under investigation in the SPARC program. 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 specific 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 SPARC OT Priorities 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. These Cores are the subject of this funding announcement.

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.

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 SPARC4.

2. SPARC DRC Core Functionalities

Vision for the complete DRC

When fully realized, the DRC will host an interactive atlas of human and selected animal peripheral nervous systems, spanning from the end organs under study in SPARC to potential neuromodulation intervention points. Atlas users will be able to design and place nerve stimuli and observe predictions of their end effects at multiple organs, while accounting for user-defined anatomical and physiological parameters. The system will be able to offer a readout of which input uncertainties drive the output uncertainty, providing guidance for where repeated measurements and new experiments are needed. While the SPARC program is active, the DRC will serve as its central sharing hub, with the vision that it will continue to exist beyond the end of the SPARC program as a critical resource for neuromodulation target development. By making use of best open science practices and working closely with the SPARC Consortium and the broader associated ecosystem, it is envisioned that the SPARC4 teams will create an extensible and sustainable resource.

To be responsive to this opportunity announcement, proposals must be targeted to at least one of the three SPARC DRC Cores:

- 1. **Data Coordination Core [DAT-CORE]** Store, organize, manage, and track access to data and resources generated by SPARC.
- 2. **Map Synthesis Core [MAP-CORE]** Build interactive, modular, continually updated visualizations of nerve-organ anatomy and function.
- 3. **Modeling and Simulation Core [SIM-CORE]** Develop an online framework capable of hosting and connecting simulations to create predictive, multiscale, multiphysics models spanning from modulation sources acting at feasible access points through to organ functional responses.

Proposals may address multiple Cores; however, each proposed core needs to be described independently. Larger-scale applications to establish an overarching structure to coordinate multiple functions are encouraged, although this is not a requirement.

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 capabilities to address the SPARC mission.

DRC Core descriptions

Data Coordination Core [DAT-CORE]

Function Summary: Store, organize, manage, and track access to data and resources generated by SPARC.

Data Coordination Core proposals are expected to address most of the following objectives, and (subject to the availability of funds) scale up to address all of them. Applicants are encouraged to propose additional tasks relevant to the SPARC goals.

- Store and facilitate access to anatomical and physiological data sets, metadata, protocols, simulation tools, etc. This includes setting up online back-end infrastructure such as storage and cloud computing capability.
- Develop a web portal front-end that provides clear and easy management and retrieval of data and tools from the SPARC program and is accessible to the general scientific community across a variety of platforms.
- Provide a credible plan and realistic timeline to have a preliminary infrastructure up-andrunning as soon as possible.
- Manage access permissions across collaborating SPARC teams, the SPARC Consortium, and the public, per the <u>SPARC Material Sharing Policy</u>.
- Work with NIH SPARC staff and SPARC Consortium PIs to define and implement data and protocol validation methods, and a process to evaluate the quality of submitted data prior to Consortium use and public release.
- Coordinate with the SPARC Consortium to define standards for data types, format, quality, curation, annotation, and common data elements so that data sets are mineable and comparable. Monitor adherence to those standards. Create tools to harmonize disparate data formats.
- Develop with SPARC Consortium PIs standard experimental metadata required to be submitted with each dataset, including common data elements, such as clinical phenotypes, using welldefined formats and associated controlled vocabularies
- Develop a metadata repository for the Consortium with access controls that are independent of the data itself.

- Develop a framework for enabling meaningful comparison across heterogeneous data sets, including individual and population comparisons at the intra- and inter-species levels. Link analogous data sets across organisms and project teams.
- Develop a platform to enable multiple SPARC teams to collaboratively build, edit, and run data workflows.
- Work with NIH program staff and SPARC teams to develop and implement a scheme for uniquely identifying and tracking every dataset uploaded to the DRC, so that the data can be properly referenced and cited by others.
- Track usage by the research and clinical communities of SPARC material contained in the DRC, distinguishing between data citation, validation, and other uses.
- Create tools allowing incorporation, by reference or in toto, relevant data not created by the SPARC Consortium.
- Provide end-user training (online resources, remote assistance, VTC), documentation, and technical support.
- Protect research data obtained from human subjects and ensure compliance with data privacy regulations and policies.
- Serve as the main locus of cloud expertise for the SPARC program, interfacing effectively with the other DRC Cores as well as with the SPARC Consortium.
- Develop a roadmap to sustainability, ensuring that the data and tools produced and aggregated by the SPARC program remain available beyond the SPARC program funding period.

The DAT-CORE will not be tasked with acquiring data. Successful applicants to develop this Core will have demonstrated experience with the coordination of large multi-dimensional, multi-modality biomedical data sets and leading-edge tools; a "cloud-first" mentality; and openness regarding new models of data management and attribution. Other desirable qualities include demonstrated use or development of data citation models and experience with bioengineering data such as device specifications and design documents.

It is expected that anatomical and physiological experts on the DAT-CORE team will play a key role in developing the framework for storing, organizing, managing and tracking access to data and resources

Applicants are encouraged to review the abstracts of <u>current SPARC funded efforts</u> to increase their awareness of likely data types and volume.

Map Synthesis Core [MAP-CORE]

Function Summary: Build interactive, modular, continually updated visualizations of nerve-organ anatomy and function.

Map Synthesis Core proposals are expected to address most of the following objectives, and (subject to the availability of funds) scale up to address all of them. Applicants are encouraged to propose additional tasks relevant to the SPARC goals.

- For every organ under study by SPARC teams, produce a clickable, queryable, interactive, multilayered visualization that spans organizational levels from gross anatomy to circuit anatomy to cell physiology to gene expression, as appropriate, and allows drilldown to the underlying data. This capability is expected to cover all circuits under study in SPARC, including pathways to, from, or through the spinal cord or brainstem.
- Develop detailed, functional, and anatomical neural circuit maps of the autonomic and sensory innervation of multiple internal organs, interfacing with DAT-CORE to access and use data contributed by the SPARC program. Develop or adapt ontology and provenance tools for use in building these maps.
- Ensure that these dynamic and evolving maps are practical for operational use by the research community, both visually (by humans) and programmatically (by machines) through visualization tools and published application programming interfaces.
- Co-register related maps. Aspects of this may include interpolation of lower-resolution data to merge with higher-resolution data, and representation of the resulting uncertainty.
- Include uncertainty quantification to provide a continuously updated view of where more work is needed.
- Implement a version control system to track the provenance and evolution of the maps.
- Schematize disparate data in a higher-level graphical framework for browsing and hypothesis generation by users.
- Enable seamless and intuitive user interaction with DRC-hosted datasets.
- Ensure that the developed maps are dynamic, modular, and can be easily updated over time. Continuously monitor data output from other SPARC components to ensure that the latest data informs the map development/evolution.
- Enable dissemination by developing user-friendly analysis tools for the SPARC Consortium, and "apps" for use by investigators with limited experience in data mining.

The MAP-CORE will not be tasked with acquiring data, but rather with iteratively developing anatomically and physiologically reasonable, higher-level schemata from the diverse data acquired by other SPARC components.

Successful applicants to this Core will have demonstrated experience in analysis and 3D and 4D visualization of heterogeneous data sets, bridging across disciplines, as well as hands-on experimental experience with the data types involved, and experience in developing or adapting ontology and provenance tools.

It is expected that anatomical and physiological experts on the MAP-CORE team will play a key role in developing the anatomical and functional maps, collaborating with other SPARC teams, and ensuring the validity of the mapping approach.

Modeling and Simulation Core [SIM-CORE]

Function Summary: Develop an online framework capable of hosting and connecting simulations to create predictive, multiscale, multiphysics models spanning from modulation sources acting at feasible access points through to organ functional responses.

Modeling and Simulation Core proposals are expected to address most of the following objectives, and (subject to the availability of funds) scale up to address all of them. Applicants are encouraged to propose additional tasks relevant to the SPARC goals.

- Develop (in collaboration with other Cores as needed) a technical framework to host and connect simulations developed by other SPARC components.
- Build links between models to create composite multiscale, multiphysics models.
- Build an interface to the composite model that does not require access to the underlying
 models. Users should be able to run composite models by specifying a neuromodulation pattern
 and receiving a predicted organ readout, or specifying a desired organ readout and an
 intervention point and receiving a neuromodulation pattern.
- Build uncertainty quantification into composite model outputs by propagating uncertainties
 from all component model parameters. Quantify and make available to users the contributions
 to overall output uncertainty from component parameter and input uncertainties.
- Build framework to enable mechanistic representations, and causal analyses, of multiscale, multiphysics models.
- Maintain an online diary of model predictions that have been tested by experiment, allowing association of specific model versions and parameters with prediction successes and failures.
- Provide end-user training (online resources, remote assistance, video teleconferencing, etc.), documentation, and technical support.

The SIM-CORE will not be tasked with developing mathematical or statistical models for individual organs, but rather with developing a composite model framework for the models developed by various funded teams across projects, organs, and systems.

This Core will facilitate hypothesis generation and provide guidance on where repeated measurements and new experiments are needed.

Integrated components could include those created by SPARC investigators, as well as those made available by others. Users should be able to interactively alter model parameters and observe the changes to other parameters, as well as view the experimental data sources constraining key model

parameters. Models should be predictive, allowing parameters to be modified beyond what was present in their training data.

Applicants seeking to work on a single-physics model of one aspect of a system under study should contact SPARC Data@nih.gov before submitting a letter of intent.

Successful proposers to this Core will have demonstrated experience with creating solutions that bridge across multiple computational modeling and simulation tools and frameworks, simulations that update based on new data, and the evaluation and adjustment of models based on success or failure at predicting phenomena observed in human and animal systems.

It is expected that anatomical and physiological experts on the SIM-CORE team will play a key role in developing the modeling and simulation framework, collaborating with the other SPARC teams, and ensuring the validity of the modeling and simulation.

Cross-cutting Responsibilities (All Cores)

All applications must address the management requirements and administrative responsibilities appropriate to their Core, for example:

- Coordinating with the other DRC Cores, components 1-3 of the SPARC program, and other SPARC Consortium members.
- Supporting SPARC program data upload and release, as governed by consortia agreements pertaining to sharing and confidentiality and the SPARC Material Sharing Policy.
- Interacting closely with identified informatics and data science experts from the projects funded through the other components of the SPARC program.
- Upon completion or termination of the funded work, making all study materials, data and
 procedures available to the SPARC program staff, as well as making them broadly available
 (e.g., putting them into the public domain) or making them accessible to the research
 community per the NIH-approved plan submitted for each project. Availability and accessibility
 deadlines will be negotiated in the milestones.

It is anticipated that the data coordination, mapping, and modeling & simulation efforts may proceed asynchronously, with some activities such as data coordination ramping up earlier than the mapping and modeling efforts.

3. Eligibility

Applicants may be subject to financial analysis and risk assessment conducted by NIH staff.

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:

- Collaborations with investigators at a foreign site anticipated to result in co-authorship;
- Use of facilities or instruments at a foreign site;
- 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 <u>Detailed Activity Plan</u> 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. One individual must be identified as the contact Principal Investigator.

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)
- Alaska Native and Native Hawaiian Serving Institutions
- 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

4. Application Content

Letter of Intent

By April 7, 2017, prospective applicants are required to submit a letter of intent that includes the following information:

- Number and title of this funding opportunity
- Descriptive title of proposed activity
- Core(s) for which application is intended
- For each Core:
 - Designated project lead with address, phone number, email address, and organizational affiliation
 - Name and organizational affiliation for all key personnel
 - o Description of relevant expertise for all key personnel, **not to exceed 100 words per person**
 - o Description of planned activity to address the Core objectives, not to exceed 800 words
 - Description of resources available to accomplish the activity, not to exceed 500 words

• If intent is to apply for more than one Core, a description of how Cores will interact, **not to** exceed **500** words

Although a letter of intent is required, it is not binding and will not be provided to the reviewers of the subsequent application. The LOI allows SPARC staff to plan for the review.

Letters of intent should be sent to:

Drs. Vinay Pai, Andrew Weitz, and Felicia Qashu

Email: SPARC Data@mail.nih.gov

All potential applicants are strongly encouraged to contact these Program Officials for guidance and feedback at any stage of the application process, including before submission of a letter of intent.

Application

All applications should include the following (Arial 11pt, single-spaced with 1" margins).

Cover Page (up to 1 page)

- 1. Project Title
- 2. Core(s) for which application is intended
- 3. Project lead first and last name, title, email address and phone number
- 4. Type of applicant (see the Eligibility section above as a reference)
- 5. Name of the applicant 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 four months after receipt of the OT3 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:
 - o Are Human Subjects Involved: Answer "Yes" or "No"
 - o Are Vertebrate Animals Used: Answer "Yes" or "No"
 - o Are Biohazardous Materials Used: Answer "Yes" or "No"
 - o Are Select Agents Used: Answer "Yes" or "No"
 - o Are Human Embryonic Stem Cells Used: Answer "Yes" or "No"

Summary Vision Statement

Describe in less than 500 words how the applicant's expertise and resources will be used to address the objectives of one or more DRC Cores.

<u>Detailed Activity Plan (not to exceed 4000 words and 2 figures per Core)</u>

The activity plan should:

- Identify project leads and other personnel for each Core. Specify contribution levels and specific roles for each person.
- Describe how key personnel will accomplish the objectives of the Core(s), as described in the detailed responsibilities above.
- Include plans for cross-cutting administrative responsibilities, as described above.
- Include a project management plan.

Include any graphs, pictures, or data tables in the body of the text. Applicants are encouraged to provide links to videos (duration not to exceed 2 minutes total per Core) and demos/simulations. For this OT3 FOA, applicants should refer to the guidelines described at NOT-OD-12-141, unless superseded by the following. Files must be converted into MPEG4 (.mp4) format and emailed by the AOR to SPARC Data@mail.nih.gov no later than 5:00 PM local time on the receipt date. This address only accepts attachments less than 25 MB. If the video file is larger than 25 MB, a file-sharing service may be used. Once the video has successfully been downloaded, you will be emailed to confirm that it has been received.

Additional information to include in the submission:

- Include a letter of support from the applicant's organization indicating institutional commitment for the project
- Include no more than 2 letters of support from current SPARC Consortium members (encouraged, but not required)
- Include a bibliography (not to exceed 1 page)

Milestones (not to exceed 1 page per Core)

Applicants must propose a well-defined task plan with estimated cost broken out by task. Each task should include a set of milestones with quantitative metrics at 3-month intervals. Milestones should be specific and measurable. The table below is provided as an example of one way in which this information may be submitted.

	Description	Ye	ar 1	L	Yea	ar 2	Ye	ear	3	Ye	ar	4	Year 5		Total Cost (Direct + Indirect)	
Task 1	Brief description and milestones															\$ 177,386
Task 2	Brief description and milestones															\$ 210,987
Task 3	Brief description and milestones															\$ 225,782
Task 4	Brief description and milestones		4													\$ 315,761
Task 5	Brief description and milestones															\$ 433,889
Task 6	Brief description and milestones															\$ 291,592

Budget

Provide the overall expected cost for each of the following categories: personnel, equipment, travel, subawards, other direct costs, and total cost (with indirect costs included). Provide a budget justification for all years of the project. Subawards with budgets greater than \$100,000 need to provide details of cost breakdown.

Core applicants need to budget for attending annual meetings of the SPARC Consortium (these annual meetings are expected to be held in Bethesda, Maryland). Additionally, Core applicants need to budget for travel to at least 5 SPARC-funded sites annually for training and information exchange.

Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs. Indirect costs on foreign awards will be reimbursed at a rate of 8% of total direct costs, less only equipment. Any applicant that has not negotiated an indirect cost rate may elect to charge a de minimis rate of 10% of modified total direct costs. NIH does not provide F&A reimbursement on awards to individuals.

Cost Sharing is not required. Applicants may voluntarily choose to propose a financial plan that includes non-federal resources. The OT3 budget submission must clearly identify and justify the use of these resources. 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 SPARC OT Award Policy Guide.

Sample budget:

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Personnel	\$ 162,369	\$ 186,450	\$ 210,190	\$ 170,423	\$ 172,212	\$ 901,644
Equipment	\$ 31,300	\$ 10,200	\$ -	\$ -	\$ -	\$ 41,500
Travel	\$ 1,200	\$ 6,000	\$ 3,200	\$ 6,000	\$ 4,800	\$ 21,200
Subawards	\$ 42,153	\$ 58,365	\$ 95,110	\$ 116,365	\$ 118,322	\$ 430,315
Other Direct Costs	\$ 22,800	\$ 26,203	\$ 19,524	\$ 16,350	\$ 14,257	\$ 99,134
Total Direct Costs	\$ 259,822	\$ 287,218	\$ 328,024	\$ 309,138	\$ 309,591	\$ 1,493,793
Total Indirect Costs	\$ 108,418	\$ 119,364	\$ 121,989	\$ 108,832	\$ 128,662	\$ 587,265
Total Costs	\$ 368,240	\$ 406,582	\$ 450,013	\$ 417,970	\$ 438,253	\$ 2,081,058

How to submit the application

Complete applications must be emailed to SPARC_Data@mail.nih.gov. Applications must be submitted in text-recognizable PDF (Adobe) format, and file size must be no greater than 20 MB. 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 1 business day.

5. Application Timeline

Key Events	Dates	Action needed by applicants
Call for projects posted	March 15, 2016	DUNS and SAM: Verify institution has or initiate process to obtain
Letter of Intent due	April 7, 2017	Email LOI by 5pm local time
SPARC finishes reviewing LOIs	April 21, 2017	Applicants invited to submit project applications
Project applications due	June 2, 2017	Email completed application by 5pm local time
Review of written applications completed	by June 23, 2017	

Invitations to present in person sent out	by June 28, 2017	
Responses to invitations due	July 3, 2017	Accept or decline invitation to present
Presentation by invited candidates in Bethesda, MD Negotiations begin	by July 21, 2017 by August 7, 2017	*Candidates and team attend in person
SAM and DUNS number submitted	August 11, 2017	**Candidates e-mail their DUNS number and SAM account information
Awards announced	September 30, 2017	

^{*}Presentation in person by at least one team member is required. OSC may provide limited travel support.

Applicants

Applicant organizations and unaffiliated individuals **must complete and maintain** the following registrations to be eligible to receive an award. Individual applicants not affiliated with an organization 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 award issuance. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible.

- <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.
 - NATO Commercial and Government Entity (NCAGE) Code 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 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 receive an award. 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.

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

All PD(s)/PI(s) must have an eRA Commons account prior to award. 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

^{**}Required Registrations

have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

6. Objective Review Process

Applications will be evaluated in three stages. The first stage will be based on a required LOI. Following evaluation for programmatic relevance, a subset of those submitters will be invited to submit a written application. The second stage evaluation will be based on these written applications, and will be done by a committee of NIH program staff and external experts.

In the third stage of the evaluation, a subset of these applicants will be invited to present their concept in-person at an interactive in-person interview at the NIH, Bethesda, MD. If invited, presentation in person by at least one team member is required, and NIH may provide limited travel support. The in-person presentation is required to be eligible to receive an award.

All applications will be evaluated for the following:

- Plan for accomplishing the specific objectives of the relevant Core(s) [Points: 45]
- Past performance and expertise of the team members and complementarity with other awardees [Points: 40]
- Plan for addressing cross-cutting responsibilities [Points: 15]

Note that past performance and expertise could refer to, as appropriate to the Core(s) being applied to, the proposers' demonstrated track records of particular behaviors (data community participation, collaborative efforts, openness to exchanging software and data, etc.), or to traditional measures of scientific productivity such as publication counts, invited presentations, or past funding success.

As part of the objective review, only the stage two applicants (written applications) will receive a written summary.

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

7. Additional Information

Following written application and interviews (if applicable), SPARC staff may assemble teams and tasking from all or parts of proposals to develop the DRC Cores. It is likely that individual components from distinct applications will be selectively merged to achieve this goal. Additionally, if over the duration of the project, some of the components either gain relevance or lose relevance, the funding for such components may be increased or discontinued, respectively.

The other transaction award mechanism allows significant ongoing involvement from SPARC Program and Project Managers and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goal. This may mean that awarded activity could be expanded, modified, partnered, not supported or discontinued based on program needs, emerging methods or approaches, and availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary.

Data and resource sharing requirements are defined in the <u>SPARC Material Sharing Policy</u>. 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.