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New Requests for Information (RFIs): Device-based Clinical Neuromodulation Studies

Submissions are due by December 1, 2017.

Our team has released two Request-For-Information (RFI) calls soliciting public input on device-based clinical neuromodulation studies, specifically involving peripheral or spinal cord neuromodulation of organ function. One RFI, NOT-RM-17-023, seeks input from surgeons, interventionalists and other relevant clinicians. The other, NOT-RM-17-015, targets industry stakeholders. The overall goal of these RFIs is to obtain strategic input on ways to improve both the therapeutic potential and scientific impact of clinical studies involving neuromodulation devices. Clinician perspectives are needed on various topics such as the state of surgical planning and access tools, clinical considerations related to device design and functionality, and the potential use of clinical settings to collect physiology data for research. Input from industry scientists and engineers is sought on ways to establish effective public-private partnerships around clinical studies, to pursue new therapeutic opportunities using existing technology and to explore the use of devices with expanded research capabilities to maximize data yield from clinical device-based studies.

As explained in the RFIs, responses can be submitted via email SPARC_TPNI@mail.nih.gov, through tele-conference meetings with the SPARC team requested at http://nihsparc.setmore.com, or through voice mail messages left at the provided telephone number. Responses must be communicated by December 1, 2017.

NIH Policy: Early Stage and Early Established Investigators (ESI/EEI)

Other Transaction awards do not impact ESI status.

NIH recently released the new Next Generation Researchers policy (NOT-OD17-101) intended to provide opportunities for earlier research independence while enhancing workforce diversity. The policy specifies the requirements for Early Stage Investigator (ESI) and Early Established Investigator (EEI) status. It is important to note that a PD/PI can be an Other Transaction (OT2 and OT3) awardee and still be considered an ESI similar to when receiving these exempted grants and awards. Please view the policy FAQs for additional information and consider applying for SPARC funding in the future.

SPARC Funds 19 New Awards in 2017

SPARC adds new Other Transaction (OT2 and OT3) and Cooperative Agreement awards (U01 and U18) to the existing research portfolio.

The Stimulating Peripheral Activity to Relieve Conditions (SPARC) program recently funded 19 new awards, summarized below, that address knowledge gaps and technological limitations standing in the way of effective neuromodulation therapies. The new projects encompass new innervation mapping efforts, including work on organs with understudied innervation, technology development, new translational partnerships, and three projects that comprise the SPARC Data and Resource Center. Taken together, these projects round out the envisioned scope of the program with central data science capabilities and a significant targeted investment in novel technologies for understanding PNS organ control.

Comprehensive and Foundational Mapping Projects: provide data for developing predictive functional and anatomical neural circuit maps for neural control of major functions of organs and their functionally-associated structures

• Paul Frenette – Albert Einstein College of Medicine – U01
Map the neural circuitry of the bone marrow and characterize the role of sympathetic and sensory nerves in regulating hematopoietic stem cell proliferation and migration using a combination of viral tracing technology, pharmacologic approaches, and chemogenetics in multiple lines of transgenic mice.

• Charles Hubscher – University of Louisville – OT2
Capitalize on recent advances in epidural stimulation below the level of motor-complete spinal cord injury to improve bladder function, and systematically map from the human spinal cord to bowel and bladder functions.

• Marian Kollarik – John Hopkins University – U01
Elucidate the anatomy and function of sensory nerve innervation of the esophagus using a multi-scale approach including genetic analysis, ion channel characterization, and nerve fiber mapping.

• John Osborn – University of Minnesota – U01
Create a structural map of afferent and efferent renal nerves in mouse and human kidneys and assess the functional significance of their diversity using a combination of state-of-the-art neuroanatomical and neurophysiological approaches.

• Erica Scheller – Washington University – U01
Map the sympathetic and sensory innervation of the skeleton, characterize the relevant neuron and nerve types and their points of origin, and assess the functional relationship of neural signals and end organ response using bioelectrical stimulation and bone microdialysis.

• Yvette Tache – UCLA – OT2
Comprehensively map neural innervation of the colon, filling knowledge gaps in the intrinsic and extrinsic neuronal circuits in two animal models and humans, using both established techniques and newly developed, cutting edge approaches.

Technology Projects: develop new and/or enhance existing tools and technologies to be used to elucidate the neurobiology and neurophysiology underlying autonomic control of organ

Neural interfaces

• John Seymour & Cindy Chestek – University of Michigan – OT2
Develop an electrode that wraps around a nerve and uses penetrating tines to pierce the epineureum for better quality recordings or finer control over stimulation. Also, develop hair-like, carbon fiber electrodes that produce minimal foreign body response.

• Bryan McLaughlin – Micro-Leads, Inc. – OT2
Develop a high-resolution (64 channel) flexible paddle electrode array suitable for use over dorsal rootlets to tap into otherwise inaccessible sacral pathways.

• Michael Jenkins – Case Western Reserve University – OT2
Advance the use of infrared light for neuromodulation through a combination of modeling, mechanistic studies, and by imaging nodose ganglion activity during application of infrared light.

• Sarah Stanley – Mount Sinai – OT2
Develop and validate magnetogenetic technology for the peripheral nervous system that offers the cell-type specificity of optogenetics combined with

non-invasive neuromodulation with radiowaves or magnetic fields.

Nerve terminal and organ sensors

• Heather Clark – Northeastern University – OT2
Optimize fluorescence nanosensors for acetylcholine to measure transmitter release in vivo under physiological conditions.

• Robert Gaunt – Pittsburgh – OT2
Develop a new class of 3D printed soft silicone electrode nets augmented with strain gauge sensors and electrical impedance tomography electrodes to measure the physical and electrophysiological properties of the bladder and urethra.

• Hans Gregersen – California Medical Innovations Institute – OT2
Development of a wireless simulated stool that can measure transit, position, and mechanical force through the entire colon and anorectal region.

Biophysical targeting

• Warren Grill – Duke University – OT2
Develop and validate a computational modeling framework for autonomic nerves incorporating nerve microanatomy, electrode-nerve interface spatial representation and optimization of electrical current waveforms to produce selective activation or block of specific fiber types.

Translational Projects: evaluate the utility of industry devices for new therapeutic applications at a pre-clinical stage

• Peng-Sheng Chen – Indiana University-Purdue University Indianapolis – U18
Conduct pre-clinical testing to evaluate the safety and efficacy of a minimally invasive neuromodulation approach based on subcutaneous nerve stimulation for the control of atrial fibrillation, by repurposing a market-approved device from Medtronic.

• Charles Horn – University of Pittsburgh – U18
Develop and conduct pre-clinical testing of a novel closed-loop neuromodulation platform for the control of gastroparesis, based on monitoring of gastric myoelectric activity and the subsequent delivery of vagal stimulation to improve gastric motility, utilizing devices from Micro-leads and Ripple.

Data and Resource Center Projects: support creation of a multifunctional online hub facilitating coordination, mapping, and modeling of SPARC data

• Peter Hunter – Auckland Bioengineering Institute – OT3
Build the SPARC Map Synthesis Core on top of the Auckland Bioengineering Institute's ApiNATOMY and OpenCMISS platforms, in order to provide tools for visualizing PNS mapping data generated by the SPARC Consortium.

• Niels Kuster – Foundation for Research on Information Technologies in Society (IT'IS) – OT3
Build the SPARC Modeling & Simulation Core based upon IT'IS's existing platform, Sim4Life, to enable simulation of interactions between nerve electrophysiology and organ physiology within the environment of the body.

• Joost Wagenaar – Blackfynn, Inc. – OT3
Build the SPARC Data Coordination Core based on the existing Blackfynn cloud platform, which is designed for scientific data management, visualization, and analysis of neuroscience data.

NIH-CF_SPARC@mail.nih.gov
https://commonfund.nih.gov/sparc/index