

**MEMORANDUM OF UNDERSTANDING  
BETWEEN  
NATIONAL INSTITUTES OF HEALTH  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
COMPANY  
CONCERNING**

**SPARC Initiative NIH-Industry Partnership towards Clinical Utility  
of Market-approved Devices to Support New Market Indications**

This Memorandum of Understanding (“MOU”) is between the National Institutes of Health (“NIH”), part of the U.S. Department of Health & Human Services, and [Company] (“COMPANY”). NIH and COMPANY are referred to herein individually as a Party and collectively as the Parties.

WHEREAS industry, academic, and government partnerships have always been important to the process of developing new therapies for disorders, and there is a compelling need for a streamlined path for developing, implementing and integrating innovative new technologies for human peripheral neuromodulation research through the cooperation of clinical and academic research teams and private companies;

WHEREAS The Stimulating Peripheral Activity to Relieve Conditions (SPARC) is a Common Fund program aimed at revolutionizing our understanding of the peripheral nervous system control of internal organs in humans, leading to new ways to treat, cure and prevent disorders;

WHEREAS the NIH Institutes and Centers contributing to the SPARC program (listed at <https://commonfund.nih.gov/sparc/>) intend to work with experts in academia and the medical device industries to consider how extant neuromodulatory technologies, knowhow, and materials can be used to better understand human organ function mediated by peripheral innervation, mechanisms of disorders, and novel therapeutic indications;

WHEREAS in October of 2014 NIH issued a Request for Information (NOT-RM-14-015), and on February 25-26, 2015 NIH held a workshop (<https://commonfund.nih.gov/sparc/meetings/>) to invite public input, including input from COMPANY, from outside experts and other stakeholders on a potential Common Fund Program for researchers to partner with manufacturers of nerve stimulating and recording devices;

WHEREAS the SPARC program's template research agreement documents will be based substantially on templates from previous NIH initiatives (e.g. drug repurposing program, BRAIN initiative) to facilitate partnerships between researchers and corporate manufacturers of nerve stimulating and recording devices;

WHEREAS COMPANY is a medical device corporation with the capability to manufacture and distribute devices for stimulating and/or recording peripheral nerve activity with regulatory approval to use in humans for investigational studies;

WHEREAS COMPANY owns or controls certain nerve stimulating/recording devices and associated capabilities (as more specifically defined below, the “COMPANY Materials”) that have been advanced to clinical studies previously, or could be advanced to clinical studies in the near term without the need for significant additional pre-clinical testing;

WHEREAS the COMPANY Materials, because of their potential as therapeutics, have been the subject, collectively, of extensive research and development efforts funded by COMPANY, which provide an extensive base of knowledge regarding their safety profiles;

WHEREAS COMPANY seeks to explore development of certain novel partnerships with the public sector that include a robust and rigorous process to jointly assess the feasibility of new ideas for identifying and testing therapeutic and experimental uses for COMPANY Materials, as proposed by academic and clinical researchers who are experts in understanding peripheral nervous system control of organ function and treating related disorders;

WHEREAS COMPANY, to support public health by advancing science and potential new therapeutic understanding, approaches, and indications, is willing to make the COMPANY Materials available for translational and clinical research upon Company review and approval of the Project Plan provided as defined below, and subject to the terms and conditions of this Memorandum of Understanding;

WHEREAS the discovery of new therapeutic indications for, or new human biology and disease insights regarding, any of the COMPANY Materials could facilitate the development of novel therapeutics and/or diagnostics to benefit public health;

WHEREAS NIH is uniquely able to: i) solicit and receive proposals for investigator-initiated research that will explore new therapeutic or experimental uses of the COMPANY Materials, ii) evaluate such proposals for scientific merit using an appropriate review system, iii) distinguish and determine projects of high public health relevance and benefit, and iv) fund research of high scientific merit and public health relevance while establishing expectations that said research will be performed to the highest safety and ethical standards;

WHEREAS COMPANY, in support of public health and academic research goals, expects to structure Collaborative Research Agreements (“CRA”) (as defined below) under the SPARC Initiative NIH-Industry Partnership towards Clinical Utility of Market-approved Devices to Support New Market Indications

to permit dissemination of research results and the right of the participants to grant non-exclusive research use licenses to non-profit and government entities, as more fully provided under such agreements;

WHEREAS the NIH and COMPANY believe that a public-private collaboration using nerve stimulating/recording devices currently owned or controlled by private medical device companies and involving government, academia and industry for the purpose of advancing science and identifying new therapeutic indications may serve the best interests of the public;

WHEREAS, on the terms and conditions defined below, NIH and COMPANY expect that a collaboration between the Parties will take the form of an opportunity for research funding, the SPARC Initiative NIH-Industry Partnership towards Clinical Utility of Market-approved Devices to Support New Market Indications, that will be funded and administered by NIH and for which COMPANY will provide COMPANY Materials to the NIH funding recipients (“NIH Awardees”) under separate agreements between COMPANY and prospective NIH Awardees;

NOW, THEREFORE, the Parties agree as follows:

## **A. Activities**

### **1. NIH Activities**

- a. SPARC Initiative NIH-Industry Partnership towards Clinical Utility of Market- approved Devices to Support New Market Indications (“Common Fund Program”). NIH intends to develop, fund and administer this Common Fund Program through use of a combination of Cooperative Agreements and Other Transaction Authority (OTA) focusing on research using materials from corporate manufacturers of nerve stimulating/recording devices, including COMPANY. This Common Fund Program will be for the purpose of discovering new therapeutic uses for or information regarding COMPANY Materials in order to develop new treatments for or new understanding of the human peripheral control of organ function and related disorders. Under this Common Fund Program, NIH intends to seek additional candidate nerve stimulating/recording devices and associated materials from other sources, including other medical device companies. Regarding the additional candidates potentially received from other device companies, NIH intends to negotiate separate MOUs with said companies, which may be managed in a similar manner as this NIH-COMPANY MOU but not requiring any COMPANY participation.
- b. Procedures to be followed. NIH intends to issue a Funding Opportunity Announcement (“FOA”) to initiate the Common Fund Program and will include information with respect to each COMPANY Material (defined below) to allow investigators to prepare applications. Applicants will engage with COMPANY to develop and submit a proposal, which will include documentation of access to the relevant COMPANY Materials and confidential information pursuant to a CRA and related Project Plan. Each application submitted in response to a FOA will undergo NIH review. Applications will be selected for funding based on scientific merit, program priorities, the availability of funds, and whether a CRA (including a Project Plan) has been executed with COMPANY. Any revisions in go/no go milestones (the

“Go-Forward Decision Criteria”), based on feedback from review, and the Terms and Conditions of the award will be incorporated into the NIH Notice of Award. No COMPANY devices will be transferred to any applicant unless and until the applicant is awarded.

- c. Administration in accordance with Law. NIH intends to administer the Common Fund Program in accordance with applicable law and agency policy, including the use of an appropriate review group to determine and ensure scientific excellence. NIH will not disclose confidential COMPANY or applicant information without appropriate permission.
- d. Use of COMPANY Material. In no event shall NIH or any other entity have any right, license or title to COMPANY Material for any commercial purpose or purpose beyond research specifically agreed in the cooperative or other agreement.

## 2. COMPANY Activities

- a. Templates for Confidential Disclosure Agreements (“CDA”) and Collaborative Research Agreements (“CRA”). Templates for CDAs and CRAs are attached as Exhibits A and B, respectively. COMPANY agrees that these template agreements shall serve as starting point documents for research agreements between COMPANY and research institutions participating in the Common Fund Program. The templates are based on drafts that received substantial input from clinical researchers, representatives from government agencies, including the U.S. Food and Drug Administration, representatives from the medical device industry, from institutional tech-transfer and contracts offices, and from the general public, via the aforementioned NIH Requests for Information and NIH Workshop. In order to efficiently operate the Common Fund Program, applicants submitting an application will agree to enter into the standard form CDA and CRA, or make mutually agreeable alterations as provided in this section. Financial terms applicable to a specific CRA may be specified in the related Project Plan. Changes may be made to the standard form of CDA or CRA by mutual agreement of COMPANY and the applicant. A copy of any revised form shall be substituted for the respective Exhibit. Following the issuance of an award, COMPANY and the NIH awardee may modify or amend the Project Plan of the CRA upon written agreement of the NIH awardee and COMPANY and the approval of NIH as specified in the NIH Notice of Award.
- b. Execution of CDA. COMPANY and each applicant will execute the standard CDA prior to COMPANY reviewing any confidential information of the applicant or providing any COMPANY Material or COMPANY confidential information to the applicant.
- c. Preparing Proposal. Under the CDA, COMPANY and applicants will share such information as they each deem necessary to provide in order for the applicant to prepare, with the Company’s advice if the Company so provides, a proposal. COMPANY or the applicant may determine at any time prior to submission of a proposal to the NIH not to proceed with the proposal and COMPANY shall have no further obligations with respect to such application. Each proposal will include:
  - i. An executed CRA or equivalent agreement, or letter from COMPANY indicating interest in entering into an agreement with applicant’s research institution, providing for the Project Plan to be conducted under the award requested by the proposal, to become

effective upon issuance of award, containing as an exhibit of the Project Plan described below. For applications not having an executed CRA or equivalent, NIH issuance of award will be contingent on execution of said agreement.

- ii. A Project Plan describing the proposed research, the specific activities to be undertaken by each of COMPANY and the applicant, and support to be provided by the applicant and COMPANY under the Project Plan, including the COMPANY Materials and any of the other support that may be provided by COMPANY, the funding to be provided by the NIH, and any specific Go-Forward Decision Criteria applicable to the Project Plan. Subsequent to NIH review of the proposal and prior to NIH issuing a Notice of Award, the Project Plan may be modified based on feedback from NIH, subject to consent of all three parties (COMPANY, NIH awardee, and NIH).
- iii. A Data Sharing Plan comporting with NIH policies on data sharing, as expressed in the NIH Final Statement on Sharing Research Data (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>) and NIH Data Sharing Policy and Implementation Guidance ([http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)), as may be amended, and in accordance with policies specific to, and described in, the FOA(s) issued for the Common Fund Program.
- d. COMPANY Materials to be provided to NIH awardees as part of the Common Fund Program are included in Exhibit C.

[ATTACH LIST OF COMPANY MATERIALS IN EXHIBIT C]

- e. COMPANY Support for Research Programs. COMPANY's support for any research program will be described in the Project Plan covered by a CRA. The types of support which may be included in Project Plans include those listed in Exhibit D. Not all forms of support may be provided in regard to any particular Project Plan. COMPANY's support will generally be provided by COMPANY directly to the NIH awardee and, except as otherwise provided in any CRA or Project Plan, will generally be provided on an "in kind" basis at no cost to NIH or the NIH awardee. In some circumstances, COMPANY may determine to provide additional support for the Project Plan, beyond the categories of support indicated in Exhibit D, including additional in-kind support or direct funding.

[ATTACH LIST OF COMPANY SUPPORT IN EXHIBIT D]

## B. General Provisions

1. **Effective Date.** This MOU becomes effective on the date of the last signature and shall remain in full force and effect for five (5) years, unless modified or terminated. Either Party may terminate this MOU by providing written notice to the other Party of its intent to terminate the MOU, not later than sixty (60) days before the proposed effective date of termination.
2. **Effect of Termination.** Termination of this MOU shall not terminate any award, CDA or CRA entered into prior to the termination of this Agreement. The terms of the applicable award or CRA, as appropriate, shall govern the rights of the NIH awardee and COMPANY

under such circumstances.

- 3. No Prohibition on Similar Arrangements.** Nothing in this MOU restricts, in any way, the United States, the U.S. Department of Health & Human Services, or NIH from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals. Nothing in this MOU restricts, in any way, COMPANY or its affiliates from participating in similar activities or arrangements with other public or private agencies, organizations or individuals.
- 4. No Endorsement by NIH.** Nothing in this MOU may be interpreted to imply that the United States, the U.S. Department of Health & Human Services, or NIH endorses COMPANY, COMPANY Materials, COMPANY's products, or COMPANY's services. COMPANY will not take any action or make any statement that suggests or implies such an endorsement.
- 5. Contingent on Availability of Funds.** It is understood that the issuance of any NIH award under the Common Fund Program is contingent upon the availability of funds and the discretion of the NIH to engage in the activities enumerated herein. It is understood and agreed that NIH has no obligation under this MOU to issue any award. Any monies allocated by the NIH for purposes covered by this MOU shall be obligated and expended by the NIH in accordance with the terms and the manner prescribed by the fiscal regulations and/or administrative policies of the NIH. Transfers of funds, goods or services from NIH to COMPANY are not authorized by this MOU.
- 6. Governing Law.** This Agreement shall be governed by U.S. Federal Law as applied in the Federal Courts of the District of Columbia.
- 7. Entire Agreement; Amendment.** This MOU incorporates all Exhibits and Schedules (if any) hereto and constitutes the entire agreement and understanding between the Parties in respect of the subject matter hereof and replaces in its entirety any prior discussions, negotiations, agreements or other arrangements in relation to the subject matter, whether written or oral, all of which are replaced by the terms of this Agreement. No amendment or modification of this Agreement shall be valid or binding unless made in writing and signed by authorized representatives of both parties.
- 8. Counterparts.** This MOU may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute a single document. The Parties acknowledge and agree that the exchange of electronic or fax signatures will have the same legal validity as the Parties' signatures would have if signed in hard copy form.
- 9. Authority.** Sections 301, 402, 443, 448, 455, 457, 464, 464H, 464L, 464R, 464Z, 485D of the Public Health Service (PHS) Act, 42 U.S.C. §§ 241, 282, 285e, 285g, 285i, 285j, 285m, 285n, 285o, 285p, 285r, 287c-21.
- 10. Notices and Meetings.** All notices pertaining to or required by this MOU will be in writing, signed by an authorized representative of the notifying Party, and delivered by registered, certified or by an express/overnight delivery service and sent to the other Party at the address designated below. The contacts listed below will establish a schedule of periodic meetings for

the Parties to discuss the administration of this MOU and the progress and coordination of the Common Fund Program.

COMPANY Contact.

Name:  
Title:  
Address:  
Phone number:  
Fax number:

NIH Contact.

Name: Danilo Tagle, Ph.D.  
Title: Associate Director for Special Initiatives - National Center for Advancing Translational Sciences  
Address: 6701 Democracy Blvd Room 992, Bethesda, MD 20892  
Phone number: (301) 594-8064  
Fax number: (301) 480-3661  
Email address: [Danilo.Tagle@nih.gov](mailto:Danilo.Tagle@nih.gov)

Name: Siavash Vaziri, Ph.D.  
Title: Program Analyst - National Center for Advancing Translational Sciences  
Address: 6701 Democracy Blvd, Room 925, Bethesda, MD 20892  
Phone number: (301) 594-8921  
Email address: [siavash.vaziri@nih.gov](mailto:siavash.vaziri@nih.gov)

***SIGNATURES BEGIN ON NEXT PAGE***

In witness whereof each Party has caused this MOU to be executed by its duly authorized representative, as of the dates set forth below.

**COMPANY**

**THE NATIONAL INSTITUTES OF HEALTH**

**By:** \_\_\_\_\_

**By:** \_\_\_\_\_

**Printed Name:**

**Printed Name:** James M. Anderson, M.D., Ph.D.

**Title:**

**Title:** Director - Division of Program  
Coordination, Planning and Strategic  
Initiatives

**Date:** \_\_\_\_\_

National Institutes of Health

**Date:** \_\_\_\_\_