

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

**BRAIN Initiative Industry Partnership Program to Facilitate Early Access to
Neuromodulation and Recording Devices for Human Clinical Studies**

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 brain disorders and brain injury, and there is a compelling need for a streamlined path for developing, implementing and integrating innovative new technologies for human brain research through the cooperation of clinical and academic research teams and private companies;

WHEREAS The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is a Presidential project aimed at revolutionizing our understanding of the human brain, leading to new ways to treat, cure and prevent brain disorders;

WHEREAS the NIH Institutes and Centers contributing to the BRAIN Initiative (listed at <http://braininitiative.nih.gov/>) intend to work with experts in academia and the medical device industries to consider how extant technologies, knowhow, and materials can be used to better understand human brain function, mechanisms of brain disorders, and novel therapeutic indications;

WHEREAS in September of 2014 NIH issued a Request for Information (NOT-NS-14-054), and on June 3-4, 2015 NIH held a workshop (<http://braininitiative.nih.gov/meetings/June-2015-PPP.htm>) to invite public input, including input from COMPANY, from outside experts and other stakeholders on a potential Grant Program for researchers to partner with manufacturers of brain stimulating and recording devices;

WHEREAS in July of 2015 NIH issued a subsequent Request for Information (NOT-NS-15-032), and on August 11, 2015 NIH held a webinar for public input, including input from COMPANY, on template research agreement documents to facilitate partnerships between researchers and corporate manufacturers of brain stimulating and recording devices;

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

WHEREAS COMPANY owns or controls certain brain 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 brain function and treating brain 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 its peer 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 BRAIN Initiative Industry Partnership Program to Facilitate Early Access to Neuromodulation and Recording Devices for Human

Clinical Studies 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 brain 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 BRAIN Initiative Industry Partnership Program to Facilitate Early Access to Neuromodulation and Recording Devices for Human Clinical Studies, that will be funded and administered by NIH and for which COMPANY will provide COMPANY Materials to the NIH funding recipients (“NIH Grantees”) under separate agreements between COMPANY and prospective NIH Grantees;

NOW, THEREFORE, the Parties agree as follows:

A. Activities

1. NIH Activities

- a. BRAIN Initiative Industry Partnership Program to Facilitate Early Access to Neuromodulation and Recording Devices for Human Clinical Studies (“Grant Program”). NIH intends to develop, fund and administer this Grant Program of cooperative agreements focusing on research using materials from corporate manufacturers of brain stimulating/recording devices, including COMPANY. This Grant 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 brain and brain disorders. Under this Grant Program, NIH intends to seek additional candidate brain 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 Request for Application (“RFA”) to initiate the Grant Program and will include information with respect to each COMPANY Material (defined below) to allow investigators to construct meaningful pre-applications, as described below.

The NIH expects to conduct its activities under the Grant Program in two phases as follows:

- i. Pre-proposals. Pre-proposals submitted by applicants (“pre-applications”) in response to an RFA will be reviewed for scientific merit by NIH peer review. Applicants whose pre-applications are in the top tier of the initial phase of peer review will be invited to submit a full application to the Pilot Grant Program subject to obtaining access to the relevant COMPANY Material and confidential information from COMPANY and other program requirements. These applicants will be notified to engage with COMPANY to develop and submit a full proposal, which will include documentation of access to the relevant COMPANY Materials and confidential information pursuant to a CRA and related Project Plan, as specified below. No COMPANY devices will be transferred to any applicant unless and until the applicant is awarded the NIH Grant.
- ii. NIH Review of Full Proposals and Grant Award. Each full application submitted in response to an RFA for full proposals will undergo NIH peer review. After a second level of review by the appropriate NIH Advisory Council, 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 peer review, and the Terms and Conditions of the cooperative agreement will be incorporated into the NIH Notice of Award.
- c. Administration in accordance with Law. NIH intends to administer the Grant Program in accordance with applicable law and agency policy, including the use of peer review 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 Grant 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, NIH Workshop, and NIH Webinar. In order to efficiently operate the Grant Program, applicants invited to submit a full 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 award of any grant, COMPANY and the NIH Grantee may modify or amend the Project Plan of the CRA upon written agreement of the NIH Grantee and COMPANY and the approval of NIH as specified in the NIH Notice of Award.

- c. 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.
- d. Preparing Full 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 full proposal. COMPANY or the applicant may determine at any time prior to submission of a full proposal to the NIH not to proceed with the full proposal and COMPANY shall have no further obligations with respect to such application. Each full 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 Grant requested by the full proposal, to become effective upon award of the Grant, containing as an exhibit of the Project Plan described below. For applications not having an executed CRA or equivalent, NIH award of the Grant 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 full 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 Grantee, 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), as may be amended, and in accordance with policies specific to, and described in, the RFA(s) issued for the Grant Program.
- e. COMPANY Materials to be provided to NIH Grantees as part of the Grant Program are included in Exhibit C.

[ATTACH LIST OF COMPANY MATERIALS IN EXHIBIT C]

- f. 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 Grantee 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 Grantee. 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 grant, CDA or CRA entered into prior to the termination of this Agreement. The terms of the applicable grant or CRA, as appropriate, shall govern the rights of the NIH Grantee 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 award of any NIH grant under the Grant 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 award any grant. 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 Pilot Grant Program.

COMPANY Contact.

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

NIH Contact.

Name:
Title:
Address:
Phone number:
Fax number:
Email address:

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:

Title:

Title:

Date: _____

Date: _____