

COLLABORATIVE RESEARCH AGREEMENT
BETWEEN
[MEDICAL DEVICE COMPANY] AND [RESEARCH INSTITUTION]

THIS COLLABORATIVE RESEARCH AGREEMENT (hereinafter "Agreement") is entered into by and between **[Medical Device Company]** a **[TYPE OF ENTITY]** at **[INSERT ADDRESS]** (hereinafter "COMPANY") and **[Research Institution]**, a **[TYPE OF INSTITUTION]** having an office at **[INSERT ADDRESS]** (hereinafter "INSTITUTION") for the conduct of collaborative clinical exploratory research studies utilizing existing COMPANY devices to record and/or stimulate from the central nervous system.

Institution's clinical research investigator **[RESEARCHER NAME]**, **[RESEARCHER ADDRESS IF DIFFERENT THAN INSTITUTION]**, (hereinafter "RESEARCHER") is employed by INSTITUTION and has prepared a project plan (hereinafter "PROJECT PLAN", defined below) related to the following Grant Program from the National Institutes of Health ("NIH"):

BRAIN Initiative Industry Partnership Program to Facilitate Early-Access to Latest-Generation Stimulating/Recording Devices for Human Clinical Studies

WHEREAS, COMPANY is a party to a Memorandum of Understanding (the "MOU") with the NIH, part of the U.S. Department of Health & Human Services, dated **[INSERT DATE]**, the goal of which MOU is to encourage the exploratory clinical research utilizing existing devices to record and/or stimulate from the central nervous system, and COMPANY owns or controls certain brain stimulating/recording devices and associated capabilities (the "COMPANY MATERIALS", defined below) and data related thereto; and

WHEREAS, INSTITUTION desires to expand its capabilities and leading expertise in education, research and/or clinical care, and INSTITUTION desires to apply for funding from NIH under the aforementioned NIH Grant Program to perform studies related to the COMPANY MATERIALS; and

WHEREAS, the studies contemplated by this Agreement will be of mutual interest and benefit to COMPANY and INSTITUTION and the general public, and shall further the instructional and research objectives of INSTITUTION in a manner consistent with its status as a nonprofit research, education and healthcare institution; and

WHEREAS, the Parties desire to engage in collaborative research that will advance scientific knowledge and patient care through human clinical studies utilizing the COMPANY MATERIALS, because the Parties believe the results of such research will produce information with potential to improve clinical outcomes and will be of interest to the COMPANY. It is anticipated that the RESEARCHER and/or their INSTITUTION will be the sponsor for any regulatory approvals necessary to conduct such human clinical studies.

WHEREAS, the Parties have cooperated on the development of a PROJECT PLAN entitled **[INSERT PROJECT PLAN NAME]**, referenced and incorporated herein as **EXHIBIT A**, which is the basis for a research project grant application for funding submitted by INSTITUTION to NIH.

NOW THEREFORE, in consideration of the mutual premises and covenants set forth in this agreement and intending to be legally bound the Parties hereby agree as follows:

AGREEMENT

The parties hereby agree as follows:

1. RESEARCH ACTIVITIES

- 1.1 Scope: This Agreement governs work performed in a collaborative research project described in the PROJECT PLAN. The parties understand that the PROJECT PLAN is the basis for a separate submission of a grant application by the INSTITUTION to NIH, and that this Agreement will not be in force and effect until such time as INSTITUTION and NIH have executed the NIH Notice of Grant Award. This Agreement and the Project Plan shall be consistent with the terms and conditions of the NIH Award.
- 1.2 Research Activities: For the purpose of this agreement RESEARCH ACTIVITIES means the conduct of research by the INSTITUTION towards the goals of the PROJECT PLAN. INSTITUTION'S duties will involve conducting and/or coordinating all aspects of the PROJECT PLAN.
- 1.3 COMPANY Materials and Support: COMPANY agrees to provide materials and associated information as incorporated in this agreement as **EXHIBIT B**, and referenced as COMPANY MATERIALS. Costs associated with materials, technical and regulatory support, etc. under Exhibit B will be included as part of the budget for the NIH grant application. COMPANY agrees to provide support for research using said materials, and any other funding or in-kind support from the COMPANY for the RESEARCH ACTIVITIES not to be financially supported by the NIH Award as incorporated in this agreement as **EXHIBIT C**, and referenced as COMPANY SUPPORT.

With respect to COMPANY MATERIALS and COMPANY SUPPORT, INSTITUTION agrees to the following:

- i. INSTITUTION will use COMPANY MATERIALS and COMPANY SUPPORT solely for the RESEARCH ACTIVITIES conducted pursuant to the PROJECT PLAN and the terms of this Agreement, and
 - ii. INSTITUTION will not to reverse engineer or otherwise analyze COMPANY MATERIALS by any means, nor to allow third parties to so reverse engineer or analyze COMPANY MATERIALS on behalf of INSTITUTION. No other use of COMPANY MATERIALS is authorized. INSTITUTION will report on and keep adequate records to show receipt, use, and disposition of all COMPANY MATERIALS provided for the RESEARCH ACTIVITIES.
 - iii. Additional stipulations outlined in Exhibits B and C that are specific to the COMPANY MATERIALS and COMPANY SUPPORT.
- 1.4 Research Funding: Each Party will bear any costs, expenses, or other charges of whatever nature incurred by such Party and which are not expressly detailed in the PROJECT PLAN or in COMPANY MATERIALS (Exhibit B) or COMPANY SUPPORT (Exhibit C). COMPANY will provide no funding to INSTITUTION for the work under this Agreement unless otherwise specified by separate agreement. The Parties anticipate that INSTITUTION will obtain funding sufficient to complete PROJECT ACTIVITIES from the NIH Award. No royalties are payable under this Agreement. INSTITUTION, through its RESEARCHER, agrees not to seek reimbursement from Medicare, Medicaid, or any other public or private insurer or health care payor, for any goods or services provided or funded by COMPANY under this Agreement.
- 1.5 Applicable Regulations and Laws: As the sponsor of the study, and if applicable the associated Investigational Device Exemption, RESEARCHER and INSTITUTION will follow all appropriate regulations, including the FDA regulations relating to Good Clinical Practice, Investigational Device Exemption or Investigational New Drug regulations, as applicable, financial disclosure requirements, other applicable regulations and conditions imposed by the reviewing ethics board, the Food and Drug Administration, and the National Institutes of Health, as well as each Party's internal rules.

Without limiting the foregoing, RESEARCHER and other research staff involved in the RESEARCH ACTIVITIES as applicable will, in accordance with 21 C.F.R. 812.43(c):

- i. provide INSTITUTION with their current c.v., statement of relevant experience, and indication of whether they were involved in any investigation or other research that was terminated, an explanation of the circumstances that led to termination;
- ii. conduct the investigation in accordance with this Agreement, the PROJECT PLAN, 21 C.F.R. Part 812 and other applicable FDA regulations, and any conditions of approval imposed by the reviewing IRB or FDA;
- iii. supervise all testing of the device involving human subjects;
- iv. ensure that the requirements for obtaining informed consent are met; and
- v. monitor the study and report adverse events in accordance with FDA requirements.

Further, in accordance with 21 C.F.R. §812, INSTITUTION and RESEARCHER will conduct the RESEARCH ACTIVITIES in accordance with all applicable State of [INSERT NAME STATE(s)] and United States laws and regulations regarding the protection of human subjects. Failure of INSTITUTION or RESEARCHER to comply in a manner that is substantially consistent with such guidelines as contemplated by this Agreement will be grounds for termination of this Agreement by either Party.

- 1.6 **Project Reporting:** INSTITUTION, through its RESEARCHER, will periodically provide data and written reports to COMPANY and FDA as required by 21 CFR 812.150(a)&(b). INSTITUTION shall ensure that research subjects' Informed Consents and HIPAA Authorizations permit disclosure of this data to COMPANY and regulatory agencies. Data will be transferred according to a secure transmission/storage method agreed to by INSTITUTION and COMPANY, which will incorporate necessary security measures to protect the data. INSTITUTION shall ensure that the research subjects' Informed Consents and HIPAA Authorizations will allow the processing, transfer and storage of the data in the agreed upon data transmission/storage method and the access of COMPANY to the data.

Reports and data to be provided by INSTITUTION to COMPANY are as follows:

- i. **Notification of Patient Implants:** INSTITUTION will notify COMPANY within one week of each patient implant and will provide appropriate information (e.g., device serial number) on COMPANY MATERIALS used in the procedure.
- ii. **Quarterly Progress Reports:** INSTITUTION will submit reports on at least a quarterly basis in sufficient detail to demonstrate the progress of the work. These reports will include all relevant Project Data. Project Data shall include, but are not limited to, raw and analyzed data signals (e.g., electrophysiological recordings) as well as any necessary annotations and interpretations of the data necessary for appropriate analyses and interpretation of such Project Data. After COMPANY's receipt and review of each report, RESEARCHER will engage in a conference call with COMPANY to discuss such report.
- iii. **Adverse Event Reporting:** INSTITUTION will provide COMPANY annual reports, beginning one year after the effective date of this Agreement and final report, listing all adverse events, which will include: patient data; device serial numbers; device model numbers; date of event; country/state of event; diagnosis (signs/symptoms); event description/summary; interventions including system modifications; technical observations; diagnostic tests/results; patient outcomes, and description of how and when this information was reported to FDA. Should COMPANY have questions about the adverse event reports, RESEARCHER will provide any additional information requested by COMPANY. INSTITUTION will notify COMPANY of an unanticipated adverse device effect or complaint related to the COMPANY device within five working days after the INSTITUTION becomes aware of the same. In the event that FDA requires more frequent reporting, INSTITUTION will provide COMPANY with reports according to FDA approved protocol.

Comment [NINDS1]: Note, first definition of Project Data is in this section. This may need to be moved for readability.

- iv. Final Project Report: Within six months of completion of the RESEARCH ACTIVITIES, RESEARCHER will submit a final written report summarizing the results of the research and will provide to COMPANY a complete copy of the raw signal Project Data combined with all relevant clinical annotations and interpretations resulting from this research.

- 1.8 HIPAA Privacy Authorizations: To the extent that INSTITUTION, RESEARCHER, or any other person or entity involved in the RESEARCH ACTIVITIES (other than as a research subject) is a "hybrid covered entity" under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), INSTITUTION warrants that INSTITUTION will obtain either (i) a waiver of the individual authorization requirement of the privacy rule issued under HIPAA ("HIPAA Privacy Rule"), 45 C.F.R. Parts 160 & 164, from a qualified Institutional Review Board or Privacy Board, consistent with the requirements for such waiver, 45 C.F.R. §§164.512(i)(1)(i) & 164.512(i)(2), or (ii) a valid HIPAA Privacy Rule authorization, as prescribed in 45 C.F.R. §164.508(b), from each individual participating in the research permitting disclosures from INSTITUTION and/or RESEARCHER to COMPANY and any and all other research service providers, regulatory agencies, and others, of the individual's "protected health information" (PHI, as defined in the HIPAA Privacy Rule) as required by and in accordance with the research. The form of the authorization is subject to prior review and approval by COMPANY.

2. TERM AND TERMINATION

- 2.1 Effective Dates: This Agreement is effective [INSERT DATE] and continues in effect through [INSERT DATE]. The Agreement terminates automatically without notice at the end of the stated period. The Agreement may be extended by a period of time as the Parties may agree, by a written amendment to this Agreement signed by both Parties. See Section 10.5 for contingency on NIH award.
- 2.2 Early Termination: Either party may terminate this Agreement with or without cause upon 30 days prior written notice to the other party. COMPANY may terminate this Agreement at its discretion at any time in the event RESEARCHER terminates his/her association with INSTITUTION or no longer wishes to conduct the RESEARCH ACTIVITIES. If this Agreement is terminated by either party or expires prior to the completion of the RESEARCH ACTIVITIES, INSTITUTION, through its RESEARCHER, will promptly provide to COMPANY a complete copy of all Project Data through the date of termination. Such data will be treated in accordance with Section 1.6 above. It is acknowledged that early termination by either party, for any reason, may result in concurrent termination of NIH grant award in its entirety.
- 2.4 Surviving Provisions: The following provisions will survive the expiration or other termination of this Agreement as prescribed in each: CONFIDENTIALITY (Section 4), INTELLECTUAL PROPERTY (Section 5), FINANCIAL DISCLOSURE (Section 8), and MISCELLANEOUS (Section 10).

3. PUBLICITY AND PUBLICATION

- 3.1 The parties agree not to use, expressly or by implication, any trademark, trade name, or any contraction, abbreviation or adaptation thereof of any other party, or the name of any other party's staff in any news, publicity release, policy recommendation, advertising, or any commercial communication without the express written approval of that party, except as required by law or by NIH for its public databases on awards, such as REPORTeR.
- 3.2 INSTITUTION and/or RESEARCHER may, at their discretion, publish the results of activities performed under this Agreement. INSTITUTION and RESEARCHER shall comply with this paragraph such that publication(s) in a peer-reviewed scientific journal article or abstracts or presentation(s) made at a scientific meeting ("Publication") will not violate the confidentiality terms of the Agreement

- i. Should publishing be contemplated, INSTITUTION and/or RESEARCHER will provide a draft of any Publication to COMPANY to review for Confidential Information at least 45 calendar days prior to submittal for publication or presentation. INSTITUTION and/or RESEARCHER will provide a final copy of any Publication to COMPANY for review at least 10 business days prior to submittal for publication or presentation, if a draft of the same was previously submitted and reviewed by COMPANY; otherwise, COMPANY will have 30 calendar days to review prior to submittal for publication or presentation.
- ii. All Publications shall include (a) a statement disclosing COMPANY's contributions to the RESEARCH ACTIVITIES, and (b) disclosure of any third party (e.g. medical writer) contribution (authorship or contributorship) according to the International Committee of Medical Journal Editors (ICMJE) requirements for disclosure in publications and/or the journal specific requirements.
- iii. COMPANY will limit its review to: determine whether COMPANY Confidential Information is disclosed, allow COMPANY to protect its rights in patentable or copyrightable material, and to correct or adjust, if necessary, any descriptions or characterizations of COMPANY MATERIALS. COMPANY will not attempt to censor or in any way interfere with presentation or conclusions beyond the extent necessary to protect COMPANY Confidential Information or to ensure that COMPANY MATERIALS are accurately described.
- iv. When reasonably requested by COMPANY, INSTITUTION and/or RESEARCHER will delay publication up to an additional 45 days to allow COMPANY to protect its rights in patentable or copyrightable material. At COMPANY's request, INSTITUTION and /or RESEARCHER agree to remove any COMPANY Confidential Information contained in the Publication and to correct any incorrect COMPANY information. If available, COMPANY will identify and supply a substitute for any Confidential Information.

Comment [NINDS2]: Point of discussion for workshop. Initial notification of intent to submit for publication or presentation is 45 days. Discussion will center on what is a reasonable expectation for providing the Company with a final copy prior to submission for publication/presentation.

3.3 Ownership of copyright in any Publication by RESEARCHER or INSTITUTION relating to the RESEARCH ACTIVITIES that is prepared in accordance with Section 3.2 will vest in RESEARCHER or INSTITUTION or as otherwise required by the publisher. To the extent possible and subject to the rights of the publisher of any such Publication and any federal applicable laws, INSTITUTION hereby grants to COMPANY a worldwide, unlimited, perpetual, and royalty-free nonexclusive license to use, reproduce, and distribute such copyrightable work. INSTITUTION, through its RESEARCHER, agrees to sign and deliver to COMPANY any documents required to secure COMPANY's rights under this paragraph.

4. CONFIDENTIALITY

- 4.1. CONFIDENTIAL INFORMATION means any information acquired by RESEARCHER or INSTITUTION from COMPANY that:
 - i. is identified as confidential at the time of disclosure by COMPANY to RESEARCHER or INSTITUTION, or within a reasonable time after such disclosure; or
 - ii. RESEARCHER or INSTITUTION has a reasonable basis to believe is confidential.

Comment [NINDS3]: Point of discussion for workshop. As written, there is no counter-provision in this section (Section 4) for COMPANY to protect RESEARCHER or INSTITUTION confidential information. CONFIDENTIAL INFORMATION is described as information acquired by RESEARCHER/INSTITUTION from COMPANY. Is there a need for a Counter-Provision in both the CDA and the CRA for information acquired by COMPANY from RESEARCHER/INSTITUTION?

4.2 INSTITUTION, through its RESEARCHER, will keep the CONFIDENTIAL INFORMATION secret and confidential and will take all reasonable precautions to protect the CONFIDENTIAL INFORMATION from disclosure as though such CONFIDENTIAL INFORMATION were INSTITUTION's to protect. INSTITUTION will not use or exploit the CONFIDENTIAL INFORMATION for the benefit of RESEARCHER, INSTITUTION or any third party and may only use the CONFIDENTIAL INFORMATION for the conduct of the RESEARCH ACTIVITIES under this Agreement, as necessary for submission of a grant application by the INSTITUTION to NIH for the

Note rights and obligations for Project Data created under this agreement are delineated in Section 3 (Publicity and Publication) and Section 5 (Intellectual Property).

NIH Grant Program or to satisfy NIH reporting and disclosure requirements, as specifically authorized by COMPANY in writing, or as required by law or a court of competent jurisdiction. Any disclosure of CONFIDENTIAL INFORMATION by INSTITUTION, through its RESEARCHER, to INSTITUTION's employees or contractors will be only to those who have a need to know the CONFIDENTIAL INFORMATION. To the extent necessary to protect COMPANY's rights, INSTITUTION, through its RESEARCHER, must have and continue to maintain appropriate written agreements with its employees or contractors engaged in the RESEARCH ACTIVITIES sufficient to enable them to comply with this Agreement. To the extent permitted by state law, INSTITUTION is responsible for any disclosure of CONFIDENTIAL INFORMATION by its employees or contractors other than pursuant to this Agreement.

Comment [NINDS4]: Please note, this passage indicates Institution has responsibility for employees and contracts engaged in the RESEARCH AGREEMENT to comply with all Confidentiality Requirements of the Collaborative Research Agreement.

- 4.3 CONFIDENTIAL INFORMATION does not include information:
- i. after it becomes publicly available through no fault of RESEARCHER or INSTITUTION;
 - ii. that is lawfully obtained from third parties who are under no restriction of disclosure; or
 - iii. that can be shown as evidenced in writing to be previously known or developed by RESEARCHER or INSTITUTION independently of COMPANY.
- 4.4 All CONFIDENTIAL INFORMATION remains the property of COMPANY. Nothing in this Agreement will be deemed to grant RESEARCHER or INSTITUTION any license to COMPANY's intellectual property except as may be necessary for RESEARCHER and INSTITUTION to use the COMPANY MATERIALS or COMPANY SUPPORT for the RESEARCH ACTIVITIES.
- 4.5 In the event that, on the advice of legal counsel, INSTITUTION is compelled by law to disclose CONFIDENTIAL INFORMATION, INSTITUTION will notify COMPANY in advance of such disclosure about the need for, and the exact text of, any such disclosure so that COMPANY may seek a protective order or other remedy. INSTITUTION will cooperate with COMPANY, if requested, in seeking such protective order or other remedy. INSTITUTION will take every reasonable action to ensure protection of the disclosed CONFIDENTIAL INFORMATION to the extent allowable by law. Notwithstanding the above, the parties acknowledge that under [Section xxxxx, State Statutes], INSTITUTION shall disclose upon request the name of the RESEARCHER, the title and short description of the Research Activity, the amount and source of funding or research support, if applicable, without prior approval of COMPANY..
- 4.6 Researcher and INSTITUTION may not copy or duplicate any materials containing CONFIDENTIAL INFORMATION except as necessary to accomplish the purposes of this Agreement. RESEARCHER and INSTITUTION will return, at COMPANY's expense if reasonably requested, or will destroy all materials containing CONFIDENTIAL INFORMATION, including all copies, upon demand by COMPANY, provided that INSTITUTION may retain on secure copy as may be required by law or to fulfill any continuing obligations under this Agreement.
- 4.7 The restrictions and obligations assumed by INSTITUTION, by RESEARCHER, and by COMPANY under this section expire five (5) years from the expiration of this Agreement, except that to the extent any Trade Secrets are included in the CONFIDENTIAL INFORMATION, such restrictions and obligations will continue for the longest time permitted by law, so long as such Trade Secrets qualify as Trade Secrets under applicable law.

5. INTELLECTUAL PROPERTY

- 5.1.1. INTELLECTUAL PROPERTY means any inventions, proprietary information, research data, software, works of authorship not subject to Section 3.2, improvements, or suggestions, whether or not patentable or copyrightable, conceived, created, adapted, or reduced to practice by INSTITUTION, whether made alone or in conjunction with others, and arising from or relating to the PROJECT PLAN or derived from CONFIDENTIAL INFORMATION. This includes 'Joint Intellectual

Comment [NINDS5]: IP considerations will be a topic of focused discussion at the Workshop. Subjects that will be addressed include IP terms, and how IP created by the Company or created jointly under this agreement will be managed.

Property', generated including contributions from one or more employees of "INSTITUTION" and one or more employees of "COMPANY."

- 5.1.2 COMPANY INTELLECTUAL PROPERTY, defined as any of the above conceived without contribution from one or more employees of "INSTITUTION", and arising from or relating to the PROJECT PLAN or derived from CONFIDENTIAL INFORMATION shall only be subject to section 5.7 of this agreement.
- 5.1.3 All rights, title and interest in and to any inventions or technologies of "INSTITUTION" or of "COMPANY", respectively, existing on or before the effective date of this agreement, and all rights, title and interest in and to any inventions or technologies developed by "RESEARCHER" or "COMPANY" outside the PROJECT PLAN or CONFIDENTIAL INFORMATION described in this agreement shall be the exclusive property of the respective party.
- 5.2.1 INSTITUTION hereby grants to COMPANY a perpetual, royalty-free, fully paid-up, unlimited, worldwide, and nonexclusive license, including the right to sub-license, to make, have made, use, sell, offer for sale, import, export, lease, donate, reproduce, publish, distribute, create derivative works of, and modify products, methods, or services incorporating such INTELLECTUAL PROPERTY.
- 5.2.2 COMPANY grants to INSTITUTION the right to use Project Data for all noncommercial, research and educational, and for publications purposes under the terms of this Agreement.
- 5.3 INSTITUTION agrees to (i) disclose INSTITUTION INTELLECTUAL PROPERTY promptly and fully to COMPANY; and (ii) if requested by COMPANY, help COMPANY, or anyone COMPANY designates, prepare, file, prosecute, issue, and maintain patent or copyright applications or seek other protection relating to INTELLECTUAL PROPERTY licensed to COMPANY hereunder, at no cost to INSTITUTION.
- 5.4 INSTITUTION offers COMPANY the first opportunity to enter into a royalty-bearing or fully paid up exclusive license or assignment, as appropriate, of the Patent Rights. For purposes of this Section 5, "Patent Rights" means any patents or patent applications of INSTITUTION INTELLECTUAL PROPERTY that relate to or arise from the RESEARCH ACTIVITIES or that are derived from CONFIDENTIAL INFORMATION. COMPANY may exercise such opportunity to negotiate within ninety (90) days of INSTITUTION's disclosure to COMPANY of an issued patent of the Patent Rights. In the event that INSTITUTION and COMPANY are not able to agree to terms for such license or assignment within 180 days from COMPANY's exercise of such opportunity, INSTITUTION shall be free to negotiate with any third party for rights to the Patent Rights. INSTITUTION shall not offer to any third party better terms than were offered to COMPANY.
- 5.5 RESEARCHER and INSTITUTION represents and warrants that (a) RESEARCHER and INSTITUTION have and will have the full right to license the INTELLECTUAL PROPERTY, free from all claims, liens, security interests, or other encumbrances, and (b) all employees and contractors engaged in RESEARCH ACTIVITIES for RESEARCHER or INSTITUTION are and will be able, bound and have the right to assign such INTELLECTUAL PROPERTY to INSTITUTION, free from all claims, liens, security interests or other encumbrances.
- 5.6 Concepts, information and inventions made by or belonging to RESEARCHER or INSTITUTION other than INTELLECTUAL PROPERTY as defined above will also remain the property of RESEARCHER or INSTITUTION and will not be disclosed to COMPANY in the absence of a separate agreement specifically pertaining to such disclosure. All such information disclosed by RESEARCHER or INSTITUTION to COMPANY in the absence of such agreement may be used by COMPANY for any purpose and without additional compensation.
- 5.7 COMPANY hereby grants to RESEARCHER and INSTITUTION a fully paid up, non-exclusive, non-transferable license to use COMPANY's Intellectual Property for the RESEARCH ACTIVITIES provide the RESEARCH ACTIVITIES remain non-commercial, and, to the extent the

Comment [NINDS6]: Point of discussion at the workshop. As worded, this clause is meant only for the situation where the INSTITUTION does not wish to seek protection for INSTITUTIONAL INTELLECTUAL PROPERTY to the extent the COMPANY would prefer. If additional filings are requested by the COMPANY to obtain COMPANY preferred protections, the COMPANY will reimburse the costs associated with obtaining this protection.

Comment [NINDS7]: Point of discussion for workshop. Patents take years to issue, should this 90 day exercise period instead be triggered at the disclosure of Intellectual Property to the Company.

Intellectual Property is not COMPANY's Confidential Information, for educational purposes directly related to the RESEARCH ACTIVITIES.

- 5.8 All negotiations and contracting related to licensing and INTELLECTUAL PROPERTY shall be conducted through [INSERT INSTITUTION OFFICE NAME, which may be Institution's Office for Technology Licensing, Contract Office, or other appropriate office at Institution].
- 5.9 Data/Information Ownership and Disclosure: COMPANY will own such copies of Project Data (as defined in Section 1.6.ii) and relevant reports provided by INSTITUTION, and may use them for any purpose in accordance with applicable laws, provided, however, that COMPANY shall not publicly disclose information derived from the Project Data or contained in such reports until INSTITUTION has published such information pursuant to Section 3.2, except as needed in regulatory and patent filings in the United States and all other countries and regions, or with the prior written permission of INSTITUTION. If a publication is not released within one (1) year after completion of the RESEARCH ACTIVITIES or termination of this Agreement, COMPANY will have the right to use the data and reports for any purpose without INSTITUTION's approval. If COMPANY uses Project Data in a publication COMPANY shall follow the third party (e.g. medical writer) contribution (authorship or contributorship) guidelines according to the International Committee of Medical Journal Editors (ICMJE) requirements for disclosure in publications and/or the journal specific requirements.

6. INDEPENDENT CONTRACTOR

- 6.1 INSTITUTION is an independent contractor for all purposes. Neither INSTITUTION, nor RESEARCHER, nor any agent, representative, contractor nor employee of INSTITUTION will be considered an agent, representative or employee of COMPANY for any purpose including, but not limited to, workers' compensation insurance, unemployment insurance, social security insurance, federal, provincial and state taxes and COMPANY employee benefits and coverages.
- 6.2 Conduct and control of the work to be performed under this Agreement by INSTITUTION lies solely with INSTITUTION, and institution shall exercise reasonable diligence in conducting and completing the PROJECT PLAN..
- 6.3 Except as explicitly permitted in this Agreement, INSTITUTION may not incur any liability on COMPANY's behalf nor bind COMPANY to any contractual or payment obligation without the prior written consent of COMPANY.

7. REPRESENTATIONS AND COVENANTS

- 7.1 INSTITUTION represents that all of its employees, agents, contractors and consultants whose services may be used to perform RESEARCH ACTIVITIES in accordance with this agreement, or otherwise fulfill the obligations under this Agreement, including RESEARCHER, are or will be appropriately informed of the terms of this Agreement, and that all such persons are under legal obligation to INSTITUTION, by contract or otherwise, sufficient to fully comply with this Agreement.
- 7.2 INSTITUTION represents that it has and will have full right and authority to enter into this Agreement under applicable law, including its internal rules and that, where and whenever required, INSTITUTION will secure in a timely manner, any and all necessary notifications or approvals, administrative or governmental, including authorizations from any medical institutions where the RESEARCH ACTIVITIES are to be performed in whole or in part.
- 7.3 INSTITUTION, on its own behalf and on behalf of RESEARCHER, represents that neither INSTITUTION nor the RESEARCHER has any outstanding obligations or agreements that would interfere with or undermine the execution of this Agreement or performance of the PROJECT PLAN.
- 7.4 INSTITUTION, on behalf of RESEARCHER, represents that RESEARCHER has not participated in a clinical investigation or other research activity that has been terminated by any regulatory or governmental authority, hospital review board or ethics committee, or the sponsor of such activities,

Comment [NINDS8]: Point of discussion for the workshop. Is 1 year a reasonable time for publication release, given the timing of the submission and review process for most journals? Moreover, the question of who owns the data created initially, and long-term will be discussed. NIH will develop a specific data sharing policy for these projects, which will be published as part of the RFA. Ideally, all Project Data would be made public after an appropriate interval to mine for publications and Intellectual Property. The NIH recognizes this would depend on HIPAA/privacy requirements, and if an appropriate data resource is available. Funds for data sharing are appropriate for inclusion in the budget of the NIH application.

due to RESEARCHER's non-compliance with any applicable laws, rules, regulations or protocol requirements.

8. FINANCIAL DISCLOSURE

- 8.1 FDA regulations require disclosure of any significant financial interests that RESEARCHER holds in COMPANY. INSTITUTION agrees that RESEARCHER will, and RESEARCHER hereby agrees, to disclose to COMPANY any financial interest RESEARCHER may have in COMPANY, as defined by the federal regulations. This disclosure should be submitted before the initiation of the RESEARCH ACTIVITIES on a form acceptable to COMPANY. INSTITUTION agrees that COMPANY may provide this information to the FDA in satisfaction of its reporting requirements. INSTITUTION will have the RESEARCHER, and RESEARCHER will, update the financial information if any changes occur during the period of the RESEARCH ACTIVITIES and for one year after the closing of the RESEARCH ACTIVITIES.

Disclosure includes:

- i. More than U.S. \$50,000 ownership of stock or other equity interests in COMPANY (including, but not limited to, any options, warrants, or other financial interests convertible into equity) which RESEARCHER, RESEARCHER's spouse, and dependent children may hold collectively or individually;
- ii. Grants, honoraria, consulting fees, royalty fees, or equipment provided by COMPANY to RESEARCHER or INSTITUTION for RESEARCHER's benefit, the total value of which exceeds U.S. \$25,000; and
- iii. Any proprietary interest RESEARCHER may have in the research device (including, but not limited to, patent ownership, royalties, license fees, or other payments).

9. Project Advisory Committee and Primary Project Contacts

9.1 Project Advisory Committee: The Parties understand that the collaborative nature of the project requires ongoing communication between INSTITUTION and COMPANY, for consideration of issues that may arise during execution of the PROJECT PLAN. Accordingly, the Parties will establish a Project Advisory Committee, with one Primary Contact from each of INSTITUTION and COMPANY (the "Primary Contacts"), and up to four (4) additional members from each of INSTITUTION and COMPANY. The names of the Primary Contact for each of COMPANY and INSTITUTION are set out in Exhibit A. Decisions of the Program Advisory Committee require a unanimous vote, with each Party having one vote to be given by its Primary Contact. Each Party which designates a primary contact or additional member to the Project Advisory Committee, may remove or replace each such contact or member at will, subject to section 9.3.

The functions of the Program Advisory Committee are as follows:

- i. Monitor and facilitate the timely progress of the PROJECT PLAN. Review and make recommendations regarding possible changes to the PROJECT PLAN based on emerging data;
- ii. Monitor and consider the protection of INTELLECTUAL PROPERTY arising from results of the PROJECT PLAN, as necessary, and specifically prior to public disclosures;
- iii. Address such other matters relating to the activities of the Parties under this Agreement as either Party may bring before the committee, including any matters that are expressly for the Program Advisory Committee to decide as provided in this Agreement. Attempt to resolve any disputes on an informal basis.

- iv. Facilitate communications with the steering committee of the NIH Grant Award, if appropriate. Steering committee composition will be defined in the NIH grant application, consistent with the terms of the relevant NIH Funding Opportunity Announcement.

9.2 Responsibilities of Primary Contacts from COMPANY and INSTITUTION:

- i. The Primary Contacts will communicate and coordinate day-to-day decisions regarding PROJECT ACTIVITIES and other project-related issues, except those issues that are expressly designated as the responsibility of other individuals or offices as explicitly described in this Agreement.
- ii. The Primary Contacts will bear overall accountability to their respective organizations for the conduct of the Program.
- iii. The Primary Contacts will convene meetings of the Project Advisory Committee at least every three (3) months at such times and places as agreed by the Parties, either in person or by teleconference, and will endeavor to schedule such meetings at least three months in advance. The Primary Contacts will chair the meetings of the Project Advisory Committee on an alternating basis. They will be responsible for circulating a written agenda in advance of the meetings, for preparation and circulation of written minutes after each meeting, and for ensuring timely execution of follow-up actions as warranted. Each Party shall be responsible for its own expenses in participating in the Project Advisory Committee meetings. Minutes and reports associated with the quarterly meetings of the Project Advisory Committee will be made available to the NIH Program Officer assigned to the NIH award.

9.3 Replacement of Contacts. Each Party's Contact may only be replaced by the written agreement of the other Party, such agreement not to be unreasonably withheld or delayed.

9.4 Limits to Program Advisory Committee Authority: Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in the Program Advisory Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The Program Advisory Committee shall not have the power to amend, modify or waive compliance with this Agreement, other than as expressly permitted hereunder. Notwithstanding anything in this agreement to the contrary, neither Party shall require the other Party to (i) breach any obligation or agreement that such Party may have with or to a Third Party or (ii) perform any activities that are materially different or greater in scope or more costly than those provided for in the PROJECT PLAN, without express written agreement. It is outside the scope of the Project Advisory Committee authority, and outside the Primary Contacts' authority, to negotiate license agreements as described in Section 5 of this Agreement.

9.5 Data and Safety Monitoring Plan: INSTITUTION and COMPANY acknowledge that for NIH Awards applicants must include a Data and Safety Monitoring (DSM) Plan that is commensurate with the risk level of the proposed clinical trial (see <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>). For exploratory clinical trials it generally will be acceptable for the data and safety monitoring to be conducted by an investigator-appointed Study Monitoring Committee (SMC), an Independent Medical Monitor (IMM), or, for single-site trials involving low risk, the Program Director/Principal Investigator and his/her IRB. However, NIH may decide to establish an independent Data and Safety Monitoring Board (DSMB) depending on the scope and risk of the trial. Applicants should refer to NIH's policy on data and safety monitoring (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>) as well as the NINDS Guidelines for Data and Safety Monitoring

(http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm). RESEARCHER will be responsible for timely communication of DSM/SMC/IMM/DSMB findings to NIH, and will relay all DSM/SMC/IMM/DSMB written notifications to within 45 days.

10. MISCELLANEOUS

10.1 This Agreement supersedes all prior oral agreements and understandings between the parties with respect to the activities under this Agreement. No amendments, changes, extensions, modifications to, or waivers of this Agreement shall be valid and binding except if in writing and signed by the parties, except that either party may change its address by written notice to the other. No waiver by either party of any default of the other party will be held to be a waiver of any other or subsequent default. This Agreement may be signed in one or more copies, including facsimile, each of which equally evidences this Agreement. This Agreement may be executed in one or more counterparts, all of which are considered one and the same agreement, and will become a binding agreement when one or more counterparts have been signed by each party and delivered to the other party.

10.2 In the event that any provision contained in this agreement is held to be invalid or unenforceable, all other provisions of this Agreement shall be deemed severable and shall remain enforceable to the full extent permitted by law. Should the terms of this Agreement and that of any associated protocol or Project Plan conflict, this Agreement shall supersede and prevail. As provided in Section 1.1, nothing in this Agreement may be construed to conflict with or supersede the rights and requirements of the NIH under the terms and conditions of the NIH Award or by operation of law or regulation.

10.3 All references to COMPANY shall include [INSERT PARENT COMPANY AND/OR AFFILIATES INCLUDED IN THIS AGREEMENT]. All references to INSTITUTION mean the [INSERT INSTITUTION INFORMATION], which is governed under the laws of the State of [INSERT STATE]. INSTITUTION may not assign its rights or obligations under this Agreement absent prior written approval from COMPANY.

10.4 Notices. Notices to be given under this Agreement shall be in writing and sent to the Parties as follows:

If to COMPANY, to:

[INSERT CONTACT AND ADDRESS]

With copy to:

[INSERT CONTACT AND ADDRESS]

If to INSTITUTION," to:

[INSERT CONTACT AND ADDRESS]

With copy to:

[INSERT CONTACT AND ADDRESS]

Any such notice will be validly given if delivered in person, by certified mail, return receipt requested, by courier or by confirmed facsimile transmission, and shall be deemed effective on receipt.

10.5 Contingent upon Execution of NIH Notice of Grant Award. This Agreement will not be in force and effect until such time as INSTITUTION and NIH have executed the NIH Award. Changes to any terms or conditions of this Agreement or to the PROJECT PLAN which are requested by NIH during the review process must be approved by COMPANY and INSTITUTION in writing before they are effective.

10.6 This Agreement shall remain silent on the issue of governing law.

Comment [NINDS9]: Please note section 10.5 which delineates the 'start date' of the agreement

Comment [NINDS10]: Point of discussion for workshop. If a conflict of law, usually have to follow a process to resolve conflicts (Uniform Trade Secrets Act). Some states may not have adopted Uniform Trade Secrets act, and therefore section 10.6 may need an additional contingency in this case.

The parties hereto have executed two (2) duplicate originals in the manner appropriate to each.

COMPANY, INC.

INSTITUTION

By _____

xxx, PhD
xxxx
COMPANY NEUROMODULATION

Date _____

By _____

Print Name _____

Title _____

Date _____

By _____

xxx
Vice President
Research, Technology and Development
COMPANY EXECUTIVE OFFICER

Date _____

**READ AND ACKNOWLEDGED BY:
<RESEARCHER, NAME AND TITLE>**

By _____

Date _____

Draft

**EXHIBIT A
PROJECT PLAN**

**EXHIBIT B
COMPANY MATERIALS**

Examples of additional stipulations that may be specific to certain COMPANY MATERIALS and COMPANY SUPPORT as referenced in Section 1.3:

INSTITUTION agrees to the following:

- i. INSTITUTION is responsible for COMPANY MATERIALS and agrees to return all unused, explanted, or otherwise requested COMPANY MATERIALS to COMPANY upon completion of the RESEARCH ACTIVITIES. RESEARCHER maintains primary responsibility for the use and return of all such COMPANY MATERIALS. If applicable and reasonably requested, COMPANY shall pay the costs of such return.
- ii. COMPANY will provide one device system per patient enrolled in the PROJECT PLAN. COMPANY will not provide replacement devices. When the device system reaches its end-of-life or needs to be explanted for any reason, the patient may choose to receive a device as a replacement. The cost for any replacement is the responsibility of the patient or his/her public or private insurance.
- iii. INSTITUTION recognizes that COMPANY has a limited supply of COMPANY MATERIALS. If enrollment milestones described in the PROJECT PLAN are not being met, COMPANY may choose to reduce the number of systems it will provide to INSTITUTION.

Comment [NINDS11]: Please note this particular clause will be discussed at the BRAIN PPP Workshop.

**EXHIBIT C
COMPANY SUPPORT**