

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

Overview and Goals

The overall goal of this program is to facilitate partnerships between clinical investigators and manufacturers of latest-generation stimulating and/or recording devices that are FDA-designated as Class III (invasive, posing significant risk of harm), to conduct clinical research in the CNS. As part of The BRAIN InitiativeSM, NIH is interested in reducing barriers to negotiating such partnerships, and also want to ensure that new clinical studies leverage manufacturers' existing data demonstrating safety and utility of these devices, data that are very costly to obtain and pose a substantial barrier to research progress.

The types of research NIH plans to support as part of this program are IRB-approved Non Significant-Risk (NSR) clinical research studies, new Significant Risk (SR) clinical studies requiring amendments to existing Investigational Devices Exemptions (IDEs) from the FDA, or SR clinical studies in which a new IDE would require no or minimal additional non-clinical testing. Studies envisioned would range from obtaining proof of concept of device functionality for a new indication, to identification of neural signals relevant for closed loop control of device therapies, to utilizing device functionality to address fundamental human neuroscience questions.

With this program, we hope to spur human research bridging the "valley of death" that has been a barrier to translating pre-clinical research into therapeutic outcomes. We expect the new framework will allow academic researchers to test innovative ideas for new therapies, or to address scientific unknowns regarding mechanisms of disease or device action, which will facilitate the creation of solid business cases by industry and venture capital for the larger clinical trials required to take these ideas to market.

To advance these goals, NIH is pursuing general agreements (Memoranda of Understanding, MOUs) with device manufacturers to set up a framework for this funding program. In the MOUs, we expect each company to specify the capabilities of their devices, along with information, support and any other concessions they are willing to provide to researchers. We anticipate posting the MOUs publicly to serve as a guide for investigators to pursue specific agreements with manufacturers for submission of research proposals to the NIH. To facilitate negotiations of specific agreements between manufacturers and academic research institutions, we are developing template Collaborative Research Agreements that we expect to serve as a starting point.

As a model for our efforts we are using a previous NIH "drug repurposing" program¹ involving similar partnerships with a number of large pharmaceutical companies, giving academic researchers the opportunity to apply compounds with established safety profiles to new therapeutic indications. This program's success in generating template agreements for negotiations between industry and university technology transfer offices, and the facilitating effect of these templates, are cause for optimism that

¹ <http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/therapeutic-uses.html>

we can create a similar framework for research using invasive devices in the CNS. By creating general template agreements that have been pre-vetted by industry partners, clinical researchers, and representatives from institutional tech-transfer and contracts offices, we hope to lower the barriers to early stage clinical research utilizing latest-generation devices and broaden the knowledge base regarding their mechanisms of action and potential therapeutic possibilities.