

PAR-15-345

INFORMATION TO APPLICANTS

BRAIN Initiative: Pre-Applications for Industry Partnerships to Provide Early Access to Devices for Stimulation and Recording in the Human Central Nervous System (X02)

Friday, October 30, 2015
3:30PM EDT

Pre-application Receipt date: November 18, 2015

***Please use the WebEx messaging feature to message your questions to the host.
If your question is not addressed please email it to BRAIN-FOAs@nih.gov***

Program Goals:

To facilitate partnerships between clinical investigators and manufacturers of the latest-generation **implantable stimulating and/or recording devices** for clinical neuroscience research in humans

- Device companies have signed Memoranda of Understanding (MOU) with the NIH to provide information on materials (devices, software, surgical tools, etc.) and support that each are willing to make available - http://braininitiative.nih.gov/BRAIN_PPP/PPP_devices_and_support.htm
- Template Collaborative Research Agreements (CRAs) have been developed to streamline agreements between academic institutions and commercial device manufacturers - http://braininitiative.nih.gov/BRAIN_PPP/PPP_template_agreements.htm

Contact: BRAIN-FOAs@nih.gov

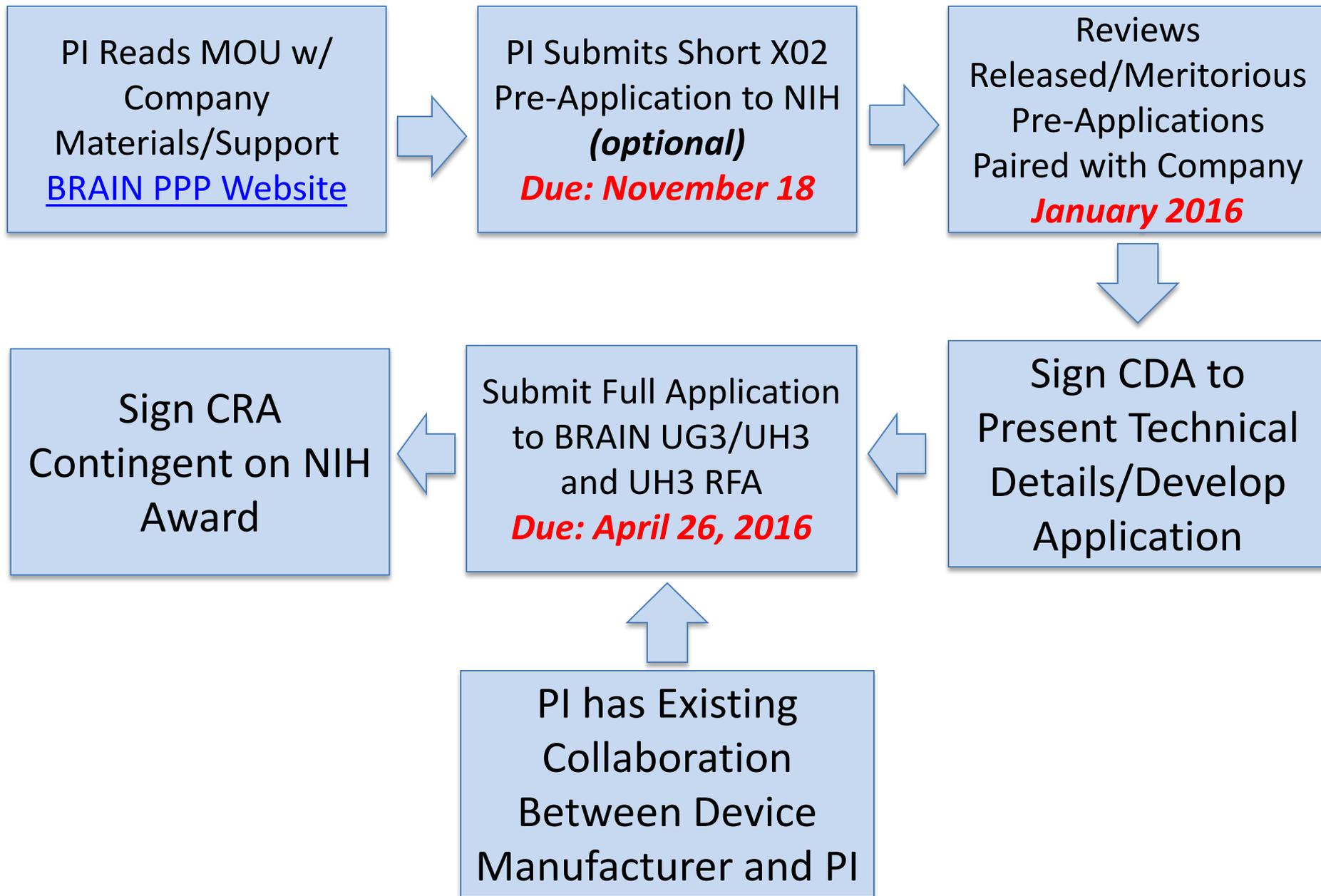
Types of Research to be Supported:

- IRB-approved Non Significant-Risk (NSR) clinical research studies
- New Significant Risk (SR) clinical studies requiring amendments to existing Investigational Devices Exemptions (IDEs)
- SR clinical studies in which a new IDE would require no or minimal additional non-clinical testing
- SR clinical studies in which a new IDE would require significant additional non-clinical testing, but leverages existing company device data

Examples of Exploratory Clinical Studies:

Proposed studies are anticipated to vary based on the selected devices' stage of clinical development and the strength of the evidence supporting the biological rationale for the proposed therapeutic use or biological study

- Proof-of-concept of device functionality for new therapeutic indications
- Identification of neural signals relevant to potential closed-loop control of device functionality for new therapeutic strategies
- Utilization of device functionality to address fundamental human neuroscience questions
- Studies utilizing device functionality to inform selection of patients likely to respond to therapies of interest



Application Process:

- X02 Pre-application ([PAR-15-345](#))
 - PIs should review the list of devices and support available for the Program (http://braininitiative.nih.gov/BRAIN_PPP/)
 - **Due November 18th**
 - Evaluated by a panel of outside experts for scientific and technical merit
 - Applicants will receive feedback by mid/late January
 - Meritorious X02 applicants will be:
 - Notified of the opportunity to submit a full application
 - Provided contact information to work with the relevant manufacturer to develop a full application

Application Process:

- X02 Pre-application ([PAR-15-345](#)) con't
 - Maximum of six pages and should include:
 - **Specific Aims** – Outline the aims (no separate specific aims page)
 - **Significance** – Summary of the clinical impact and feasibility, including patient population to be targeted and the intended use
 - **Supporting data for entry** – Comprehensive data and information that validate the feasibility of conducting the proposed clinical study and/or non-clinical testing and brief proof of concept data
 - **Plans for the Research Strategy** – Device testing strategy to enable the clinical studies/research plans for the clinical study.

Application Process:

- UG3/UH3 Application ([RFA-NS-16-009](#))
 - **UG3 phase - Non-clinical testing** to answer key questions about the function or final design of a device and *to enable IRB approval and/or a successful IDE submission* necessary to conduct a small clinical study
 - Applicants must have comprehensive supporting data, including proof-of-concept demonstration with a near final prototype in a relevant animal model prior to entry
 - FDA IDE Pre-Submission meeting with NIH staff in attendance is required as a year 1 milestone
 - **UH3 phase - Small clinical study** (e.g., Early Feasibility Study)

Application Process:

- UH3 Application ([RFA-NS-16-010](#))
 - **Directly to the UH3 clinical phase**
 - Project does not require UG3 non-clinical testing to obtain approval for the proposed clinical study
 - PIs are ready to submit for approval of an IRB NSR or FDA IDE study in the first year of the award

Additional Opportunities for Human Neuroscience Research

- Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain ([RFA-NS-16-008](#))

Applications Due: 12/15/2015

- Human research studies aimed at understanding brain function and disorders
- Studies will take advantage of surgical settings using implantable stimulation and recording devices
- Contact: BRAIN_ResOppHu@mail.nih.gov

Visit http://braininitiative.nih.gov/funding_active.htm for a full list of active funding opportunities

FAQs:

- Am I required to partner with a company?
 - No. PIs developing their own invasive stimulating/recording device are welcome to submit applications to the Program.

- What if I have an existing collaboration with a company?
 - Existing collaboration between institutions/PIs and Device Manufacturers are welcome to submit a full UG3/UH3 or UH3 application to the Program.
 - The X02 pre-application step is not required but is recommended.

- What about non-invasive technologies?
 - While this specific program is for invasive technologies, a future BRAIN program is planned for non-invasive technologies.

Questions?

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Thank you for your participation!

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