Clinical Trial Protocol Summary for

Projects Requesting >$500,000 direct costs per year

Division of Clinical Research, NINDS

**Date:**

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| **Title:** | | |
| **Contact PI Name:** | **Institution:** | |
| **Contact PI email:** | **Which phase best describes this clinical trial?**  **Phase I**  **Phase II**  **Phase III** | |
| **Number of years of funding to be requested:**  **Year 1 Direct costs:**  **Year 2 Direct costs:**  **Year 3 Direct costs:**  **Year 4 Direct costs:**  **Year 5 Direct costs:** | | **What is the target disease or condition?** |
| **When do you expect to submit an application for review to NINDS?** | | |
| **Is a pharmaceutical or device manufacturing company currently involved in any research or development related to this proposal?**  **YES**  **NO** | | |
| **If there is involvement of industry, why do you need funds from NINDS to proceed?** | | |
| **If there is involvement of industry, what financial or in-kind contributions if any will they be making?** | | |
| **What qualifications does the PI have to successfully lead this study?** | | |

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| **Describe the project in less than five sentences.** |
| **Why is it important?** |
| **How will it impact patients?** |
| **What is the potential public health impact of this proposal?** |
| **What is the primary objective of the proposed study?** |
| **Do you have any secondary objectives? If so, list them:** |
| **Briefly describe the scientific rationale for the study. Cite any support from basic or lab reserch and prior clinical work:** |
| **Have prior studies been replicated? What work has been done to ensure the rigor of any previous studies?** |
| **Briefly describe the study design. How** **will it ensure the an informative study?** |
| **Number of participants to be enrolled:** |
| **Number of clinical centers:** |
| **Participant inclusion criteria:** |
| **Participant exclusion criteria:** |
| **What plan is in place for the equitable recruitment of men, women and minorities?** |
| **Describe method for identifying and recruiting participants for the trial:** |
| **Describe how the intervention will be administered, including dose and duration as applicable:** |
| **Describe extent and type of blinding/masking:** |
| **How long will you be following the participants?** |
| **What is the Primary Study Endpoint?** |
| **Describe the statistical and clinical basis for the sample size calculation:** |
| **If you are proposing a Phase I or Phase II trial, list the milestones that would justify moving to the next Phase:** |
| **Every research study has *strengths*. List no more than three of them:** |
| **Every research study has *weaknesses*. What is the biggest weakness of this study and how will you mitigate it?** |
| **Are you aware of any competing studies for this patient population and/or any other ongoing studies in the US or abroad that are investigating a similar question or intervention in this population?**  **No**  **Yes**  **If yes, please detail:** |
| **In many studies, the intervention, drug or device does not work, and the study is negative. If this happens in your study, what will have been learned, and how will it change how you will proceed?** |

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| **List the statistical methods to be used to analyze the primary and secondary outcomes.** |
| **Describe the interim monitoring plan, including the schedule of interim analyses and guidelines for stopping the study for reasons of efficacy, safety, futility, or poor study performance:** |
| **Describe any special ethical and consent considerations of the proposed protocol:** |
| **Will the proposed study be performed under an IND/IDE? Yes**  **No**    **If yes, has this protocol been submitted to the FDA? Yes**  **No**  **If no, has the FDA provided a written exemption from the IND/IDE requirement? Yes**  **No**  ***Please read our policy requiring documentation from the FDA regarding the status of the protocol you wish to implement*** [***here***](https://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-018.html)***.*** |
| **Do you or any member of the study group have a financial conflict of interest or hold a patent with the use of the intervention on this protocol?**  **Yes**  **No** |
| **Have you discussed with and considered a collaboration with one of the NINDS clinical research networks (e.g., NeuroNext, StrokeNet, SIREN)?**  **No**  **Yes**  **If yes, what was the outcome of the discussion?** |

**What happens next?**

1. Once all the material has been received by NINDS the project will be scheduled for the next available meeting of the Extramural Scientific Committee (ESC).
2. The meeting is attended by senior NINDS leadership and will be presented by one of the NINDS project officers.
3. The PI will then be contacted and informed of the decision.

The ESC meets every two weeks, and a decision is usually ready a week after the meeting.

**What else do I need to send to NINDS?**

Please email the following to [Jeremy.brown@nih.gov](mailto:Jeremy.brown@nih.gov):

1. This form, completed.
2. A detailed draft budget spreadsheet, showing the total budget (excluding NIH overhead) for each year of the project.
3. Biosketch of each of the project PIs
4. A list of other support for each of the PIs

