NIH StrokeNet Regional Coordinating Stroke Centers (U24)
Limited Submission Internal Call for Proposals
Internal Due Date: Thursday July 8, 2017

Please distribute to all relevant faculty.

NIH Letter of Intent Due Date: August 26, 2017
NIH Full Proposal Deadline: September 26, 2017
ORD Internal Proposal Due: Thursday July 8, 2017

To Apply:
Due by 5:00 pm, Thursday July 8, 2017:
Submit the following in ONE .doc or .pdf file to Denise Lindley, Office of Research Development,
Limited_Submissions@unc.edu

1. Biosketch or CV of PI (Please limit to five pages)
2. Two page project summary
3. List of potential collaborators (internal and external to UNC)
4. Names of three internal (to UNC) faculty who could speak knowledgeably about the project, in the event of an internal review. Please do not include the names of faculty named on the project, chairs, deans, directors, direct reports or others who have a conflict of interest.

Funding Opportunity Purpose

The purpose of this funding opportunity announcement (FOA), issued by NINDS, is to invite currently awarded NIH StrokeNet centers and potential new stroke centers to participate as a Regional Coordinating Stroke Center in the NIH StrokeNet clinical trials network. The goal of this existing network is to maximize efficiencies to develop, promote and conduct high-quality, multi-site clinical trials focused on key interventions in stroke prevention, treatment, and recovery with the objective to have a balanced portfolio between all three approaches. Exploratory Phase 1/2 and confirmatory Phase 3 clinical trials as well as biomarker-validation studies that are immediately preparatory to trials will be coordinated through separate National Clinical Coordinating (NCC) and National Data Management Centers (NDMC).

Funded regional coordinating stroke centers in the network will have both clinical science excellence and specialized expertise in stroke management, a strong background in stroke research, and a proven ability to recruit stroke patients. Each regional stroke center will also have strong collaborative relationships between vascular neurology, emergency medicine, interventional neuroradiology, neurosurgery, neurointensive care, neuroimaging, stroke rehabilitation, and pediatric neurology, indicating a commitment to offer every eligible patient the opportunity to participate in a trial conducted through the network. In addition, the NIH Stroke Trials Network will include an active stroke research career enhancement program. All network stroke centers will be committed to increasing the value of clinical research data through an aggressive data sharing plan.

Background

Stroke is a disabling, often fatal and expensive disorder that is a major public health burden. Globally it is the second leading cause of death, but in North America stroke has fallen to the fourth most common cause of
mortality as the result of ongoing successes in prevention and acute care. Vascular disease of the brain can manifest not only as overt stroke but also as silent infarction and diffuse white matter disease with cognitive and functional decline. Stroke is a syndrome, with two broad types (ischemic and hemorrhagic) and with multiple possible underlying causes. Although stroke impacts all age groups (including children and especially neonates), the incidence is strongly linked to aging. Stroke will become increasingly prominent in the next 30 years with the projected rise in the proportion of elderly in the US, and it will impose an even more significant toll on individuals, families, and society.

NIH-funded basic, translational and clinical research offers the promise to reduce the burden of stroke.

The Stroke Progress Review Group and NINDS stroke planning efforts identified a need for stroke trial network infrastructure to effectively pursue a number of scientific opportunities and to accelerate translation (see http://www.ninds.nih.gov/find_people/ninds/OSPP/Stroke-Research-Priorities-Meeting-2012.htm). The unbiased evaluation of newly-developed and existing interventions—drugs, devices and systems of care—in randomized, controlled clinical trials are necessary to establish efficacy of interventions for improving important clinical outcomes. Phase 1/2 trials explore safety, target engagement, proof of biological concept, and dose response to inform Phase 3 efficacy trials. Phase 3 efficacy trials are designed to demonstrate clinical benefit that patients consider meaningful. Comparative effectiveness trials examine how to best apply established efficacious treatments.

In 2013, the NIH StrokeNet was established to conduct clinical trials in a centrally coordinated network that includes 25 regional centers that are linked to over 350 stroke hospitals across the United States. The NIH StrokeNet was designed to rapidly initiate and efficiently implement small and large multi-site exploratory and confirmatory clinical trials focused on promising interventions for stroke prevention, treatment and recovery, as well as validation studies of biomarkers or outcome measures. The network includes an education platform designed to train the next generation of stroke clinical researchers and collaborations from a variety of health professionals across multiple disciplines. The interdisciplinary nature of the NIH StrokeNet is expected to build research capabilities that match the scientific opportunities across the spectrum of stroke research. Additional information on the current structure of the network can be found at: www.nihstrokenet.org.

Research Objectives
The aims of the network are to harness multidisciplinary stroke expertise to collaboratively and efficiently conduct exploratory NINDS-sponsored Phase 1/2 clinical trials for stroke interventions with the goal to quickly move potential treatments into larger, confirmatory Phase 3 trials. In addition, the network may perform biomarker validation studies that are immediately preparatory to clinical trial(s). Collaboration with international consortia will facilitate the execution of the larger, Phase 3 definitive trials. Together with the larger U.S. and the international stroke research community, stroke patients, and stroke-related nonprofit associations, the investigators at the RCC's will work to design and execute the most clinically impactful stroke research.

Study execution and performance will be monitored by the NINDS and the National Clinical Coordinating (NCC) and National Data Management (NDMC) Centers to ensure that all eligible stroke patients are considered for NINDS-funded trials.

The NINDS intends that the NIH StrokeNet will be the primary and first-line infrastructure involved in implementing all multi-site stroke trials submitted to the NINDS.

To view the full solicitation please click on the link below. https://grants.nih.gov/grants/guide/pa-files/PAR-17-276.html#_3._Additional_Information
Number of applications per institution: 1

Funds Available and Anticipated Number of Awards: The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

NIH intends to fund up to 25 awards, corresponding to a total of $8,700,000, for fiscal year 2018. Future year amounts will depend on annual appropriations.

Anticipated Funding Amount: Application budgets are limited to $200,000 in annual direct costs for a 5 year period

Please do not hesitate to contact Denise Lindley with questions at Limited_Submissions@unc.edu or 962-7503