Grant Title: NIDCD PHASE I/II PRELIMINARY CLINICAL TRIALS IN COMMUNICATION DISORDERS (R01)

Funding Opportunity Number: PAR-12-123. CFDA Number(s): 93.173.

Agency/Department: National Institutes of Health (NIH), National Institute on Deafness and Other Communication Disorders (NIDCD).

Area of Research: Identifying effective interventions for the treatment or prevention of communication disorders.


Amount: Application budgets are not limited, but need to reflect actual needs of the proposed project.

Length of Support: Up to 5 years.

Eligible Applicants: Public/State Controlled Institutions of Higher Education. See the full announcement for a complete list of eligible applicants.

Summary: The NIDCD is committed to identifying effective interventions for the treatment or prevention of communication disorders by supporting robust, well-designed, and well-executed clinical trials. This funding opportunity announcement (FOA) supports a cooperative agreement between NIDCD project collaborator and investigator to support phase I and II clinical trials of preliminary efficacy and phase III clinical trials of definitive efficacy. Phase III clinical trial applications must include a complete detailed Manual of Procedures (MOP) in the appendix (see http://www.nidcd.nih.gov/research/clinicaltrials for an example of a complete, detailed MOP). The NIDCD Planning Grant for Phase III Clinical Trials in Communication Disorders (U34) (PAR-12-124) may be used to gather information and prepare the MOP. This announcement is part of the NIDCDs clinical research program in communication disorders (hearing, balance, taste, smell, voice, speech and language) with the goal of producing research findings that have significant clinical use and public health impact through the design and implementation of phase III clinical trials. Phase I and II clinical trials provide data that are necessary to address core scientific, design, and clinical issues prior to the conduct of the phase III clinical trial. Phase I clinical trials test a new biomedical or behavioral intervention in a small group of people for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects), in anticipation of a phase II clinical trial of preliminary efficacy. The phase I research application should directly address how the phase I study will guide the development of subsequent phase II and III clinical trials. Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people to determine preliminary efficacy and further evaluate safety, in anticipation of a phase III clinical trial of definitive efficacy. The phase II clinical trial should collect and develop essential preliminary information rather than simply address the clinical question with lower power, i.e. a phase II trial should not simply be a miniature version of a phase III trial. Phase III clinical trials determine efficacy of the biomedical or behavioral intervention in large groups of people by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely. Basic elements of the phase III clinical trial application are similar to those of phase II clinical trials, described above. Also see Section V. Application Review Information, Significance, Investigators and Approach.

Detailed Information: http://grants.nih.gov/grants/guide/pa-files/PAR-12-123.html