

Grant Title: NIH CLINICAL TRIAL PLANNING GRANT PROGRAM (R34)

Funding Opportunity Number: PA-09-186. CFDA Number(s): 93.173, 93.209, 93.271, 93.272, 93.273, 93.277, 93.278, 93.279, 93.846, 93.864, 93.865, 93.866, 93.891.

Agency/Department: Department of Health and Human Services, National Institutes of Health (NIH), National Eye Institute (NEI), National Institute on Aging (NIA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), National Institute on Drug Abuse (NIDA), Office of Dietary Supplements (ODS).

Area of Research: Support for the development of a Phase III clinical trial.

Release and Expiration: Release Date: May 15, 2009. Expiration Date: May 8, 2012.

Application Deadline: New: February 16, June 16, October 16. Renewal, resubmission, revision: March 16, July 16, November 16.

Amount: Direct costs of up to \$100,000 may be requested for the one-year period.

Length of Support: One-year.

Eligible Applicants: Public and State controlled institutions of higher education. See the full announcement for a complete list of eligible applicants.

Summary: This Funding Opportunity Announcement (FOA) invites applications under the NIH Clinical Trial Planning Grant Program, the purpose of which is to provide support for the development of a Phase III clinical trial. This includes the establishment of the research team, the development of tools for data management and oversight of the research, the definition of recruitment strategies, and the finalization of the protocol and other essential elements of the study included in a manual of operations/procedures. The Clinical Trial Planning Grant is not designed for the collection of preliminary data or the conduct of pilot studies to support the rationale for a clinical trial. An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often, the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions for disease prevention, prophylaxis, diagnosis, or therapy. Community- and other population-based intervention trials also are included.

Detail Information: <http://grants.nih.gov/grants/guide/pa-files/PA-09-186.html>