

Title: NIH CLINICAL TRIAL PLANNING GRANT PROGRAM (R34)

Application Deadlines:

- *Investigator Initiated:* February 1, June 1, October 1 annually; May 1, September 1, and January 2 annually (AIDS and AIDS-related grant application receipt dates).
- *Response to RFP/RFA:* Varies by request.

Scope of Support: Direct costs of up to four \$25,000 modules or \$100,000 per year.

Length of Support: One year

Eligible applicants: For-profit or non-profit organizations, public or private institutions (universities, colleges, hospitals, and laboratories), units of State and local governments, eligible agencies of the Federal government, domestic or foreign, and faith-based or community-based organizations.

Agency/ Department: National Institutes of Health: See specific Institute guidelines for investigator-initiated invitations; NIA, NIAAA, NIAMS, NICHD, NCCAM, NIDCD, NIDA, NINDS, ORWH, OBSSR, ORD, ODS.

Summary: R34s can be investigator initiated or can be in response to a program announcement (PA) or request for proposal/application (RFP/RFA). The R34 award was developed to provide support for the development of Phase III clinical trials. This program supports 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.

The planning grant is designed to:

permit early peer review of the rationale for the proposed clinical trial;
permit assessment of the design/protocol of the proposed trial in its current, early form;
provide support for the development of a detailed MOP; and
support the development of other essential elements of a clinical trial as defined by the individual participating ICs.
lead to the timely submission of an application for support of a full-scale trial, incorporating the elements developed under the R34 funding mechanism.

Detailed Information: <http://grants1.nih.gov/grants/guide/pa-files/PA-04-008.html>