

FOA 12-019

Pilot Studies to Develop and Test Novel, Low-cost Methods for the conduct of Clinical Trials

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*The views expressed in this talk represent my own and not necessarily those
of NHLBI, NIH or the federal government.*

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Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Heart, Lung, and Blood Institute (NHLBI)
Funding Opportunity Title	Pilot Studies to Develop and Test Novel, Low- Cost Methods for the Conduct of Clinical Trials (R01)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	<ul style="list-style-type: none"> • June 10, 2011 - See Notice NOT-HL-12-150 NHLBI announces correction to the eligibility criteria.
Funding Opportunity Announcement (FOA) Number	RFA-HL-12-019
Companion FOA	None
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.837
FOA Purpose	The funding announcement solicits R01 applications that develop and test new, low cost methods to conduct clinical trials. Responsive applicants will address four challenges to the conduct of clinical trials: (1) minimize specialized infrastructure, (2) minimize visits designed solely for the trial, (3) explore novel methods of obtaining consent that minimize burden, and (4) employ low-cost methods of monitoring study conduct. The proposed methodology must be tested in a pilot trial. New and innovative designs that have not been tested in previous studies but hold potential for increasing the efficiency and reducing the cost of conduct of clinical trials are especially encouraged.

Key Dates

Posted Date	April 11, 2011
Open Date (Earliest Submission Date)	September 13, 2011
Letter of Intent Due Date	September 13, 2011
Application Due Date(s)	October 13, 2011, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	March, 2012
Advisory Council Review	May 2012
Earliest Start Date(s)	July 2012
Expiration Date	October 14, 2011
Due Dates for E.O. 12372	Not Applicable

Rationale for FOA #1

- Clinical Trials are among the strongest type of medical evidence
 - Properly conducted these studies are at low risk of bias, confounding, and can determine causation
- Clinical Trials are expensive
 - \$15,000-26,000/participant for industry sponsored
- Recent legislation increases demand for high quality evidence
 - PCORI

Rationale for FOA #2

- If clinical trials cannot be conducted in a less expensive fashion, they run the risk of extinction

RFA-HL-12-019

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RFA-HL-019: Safety Monitoring?

- Although not a specific challenge, included in #4: employ low-cost methods of monitoring study conduct
- Can this be done?



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Lung and Blood Institute**
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