

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Cooperative Agreement to Support a Single-Source Application—The  
Critical Path Institute: Collaborative Cardiovascular Drug Safety and  
Biomarker Research Program—ACTION; Availability of Sole Source  
Cooperative Agreement; Request for Application**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**I. Funding Opportunity Description**

The Food and Drug Administration (FDA), Office of the Commissioner (OC) is announcing its intent to accept and consider a single source application (RFA-FDA-OC-2006-1) for the award of a Cooperative Agreement to the Critical Path Institute. FDA anticipates providing up to \$750,000 (direct and indirect costs combined) in fiscal year 2006 to support this multiphased research program that will include, but will not be limited to, the development of an infrastructure to support this program and subsequent related studies in cardiovascular disease and genomic/proteomic biomarker research, as stipulated by Congress.

Subject to the availability of Federal funds and successful performance, an additional 2 years of support up to \$750,000 (direct and indirect costs combined) per year may be available.

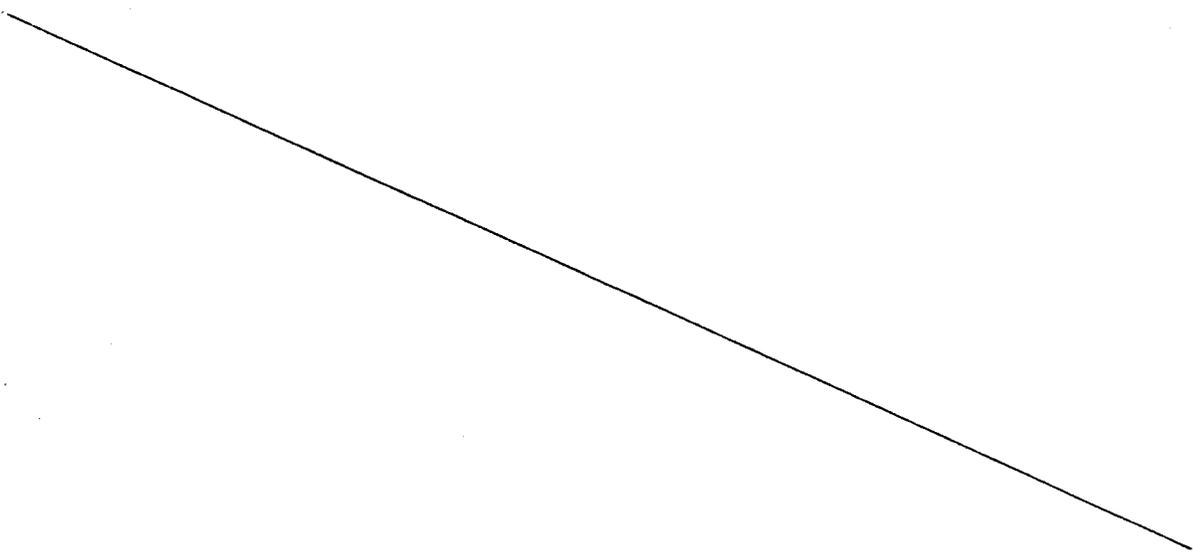
FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance

No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The cooperative agreement ensures FDA's continued participation in the Collaborative Cardiovascular Drug Safety and Biomarker Research Program, as proposed by Congress and to be conducted under FDA's Critical Path Initiative. A goal of the Critical Path Initiative is to foster the development of new tools to both promote drug safety and accelerate the development of innovative new therapies, through appropriate collaboration with multiple parties. This collaborative research program is expected to be conducted in a multiphase process, leveraging resources and expertise from the awardee, other collaborators, and FDA to address public health needs involving cardiovascular disease and biomarker research.

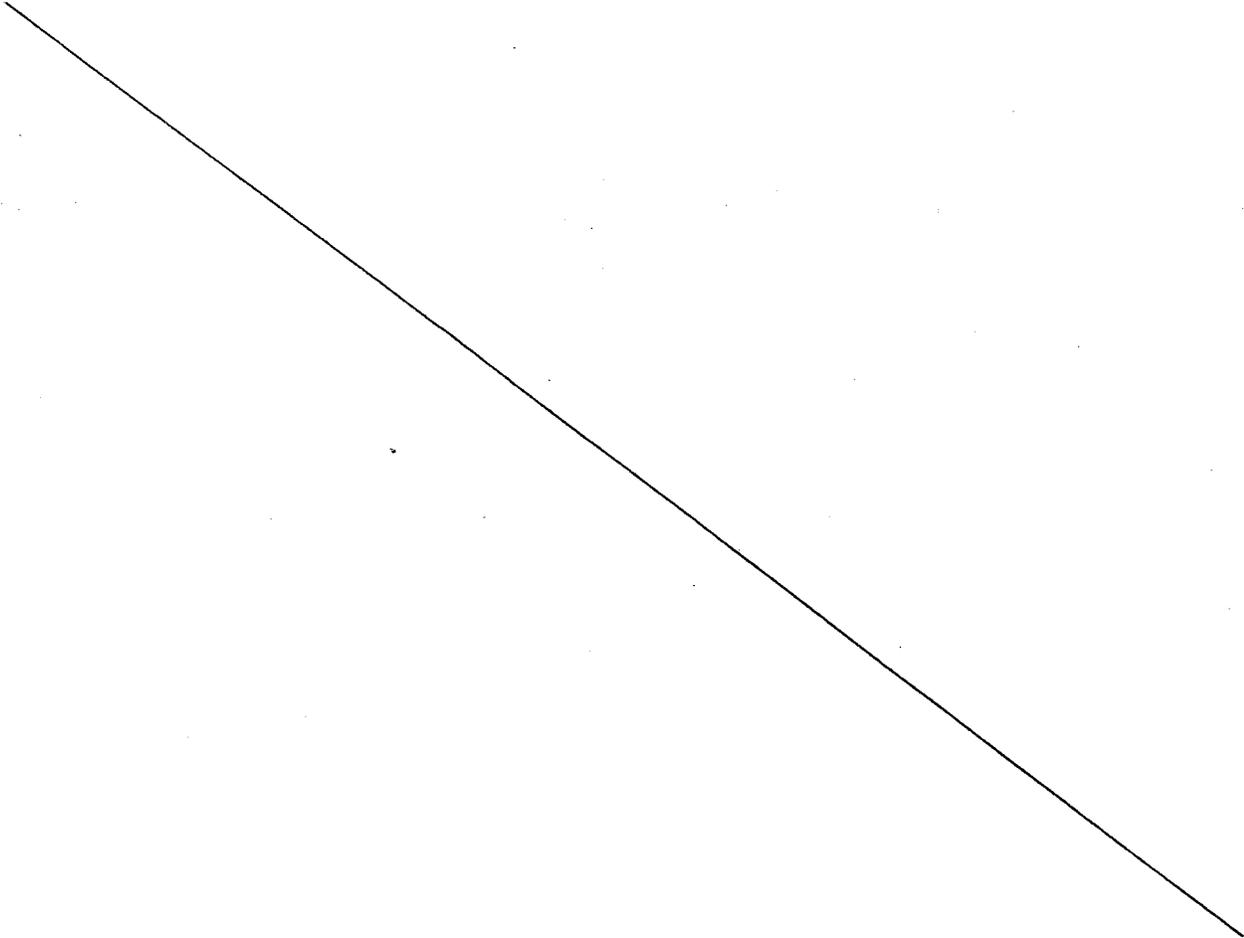
## **II. Eligibility Information**

Competition is limited because of Congressional mandate, the mission of the Critical Path Institute, its established collaboration with the University of Utah, and the combined ability of these parties to leverage existing databases, specimen repositories, clinical and other technical expertise in support of this program.



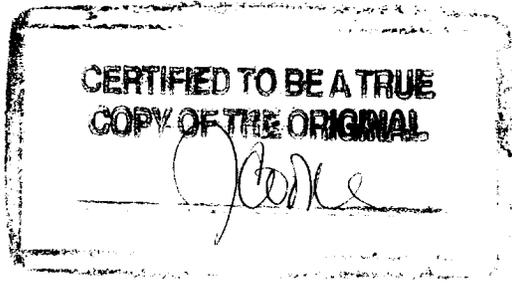
### III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Officer, Division of Contracts and Grants Management (HFA-500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7180, e-mail: *cynthia.polit@fda.hhs.gov*. This RFA can be viewed on *Grants.gov* under "Grant Find." A copy of the complete RFA can also be viewed on the FDA Web site at <http://www.fda.gov/oc/initiatives/criticalpath/>. For issues regarding the programmatic and scientific aspects of this notice contact Wendy Sanhai, Ph. D.,



Senior Scientific Advisor, Office of the Commissioner (HF-1), Food and Drug Administration, 5600 Fishers Lane, rm. 1471, Rockville, MD 20857, 301-827-7867, e-mail: *wendy.sanhai@fda.hhs.gov*.

Dated: 3/31/06  
March 31, 2006.



[Handwritten Signature]  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

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