

FOR FURTHER INFORMATION CONTACT:*Programmatic/Review Contact:*

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Grants Management Contact: Gladys M. Bohler, OAGS, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168,

gmbohler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Funding Opportunity Description**

Funding Opportunity Number: RFA-FD-09-011

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

The Critical Path Initiative, launched by FDA in 2004, has the objective of helping modernize the development, evaluation, manufacture, and use of FDA-regulated products. Through nationwide collaboration with other Federal, academic, scientific, and industry organizations, the initiative seeks to develop new tools to facilitate innovation in FDA-regulated product development. Examples of tools include novel biomarkers, laboratory assays, genetic tests, and state-of-the-art information technologies, etc. In this initiative, FDA plays the role of a facilitator in the creation of partnerships and collaborations to support specific scientific projects.

FDA and Duke University's Department of Translational Medicine Institute (DTMI) co-founded CTTI. CTTI's goal is to systematically modernize the clinical trial process, a goal shared by FDA's Critical Path Initiative. CTTI is made up of a broad representation of member organizations including government, industry, patient advocacy groups, professional societies, and academia. The participants are working together to identify practices that through broad adoption will increase the quality and efficiency of clinical trials.

CTTI is generating evidence about how to improve the design and execution of clinical trials. Projects about design will address principles generally applicable to clinical trials to ensure that they are fit to accomplish their intended purpose.

B. Research Objectives

The goals of this program are to develop an administrative and scientific infrastructure to support the creation

and execution of a series of projects under the auspices of CTTI, to complement the goals of FDA's Critical Path Initiative.

This funding opportunity will use a cooperative agreement award mechanism (U19). In the cooperative agreement mechanism, the Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with FDA staff being substantially involved as a partner with the PD/PI. Substantive involvement includes, but is not limited to, the following: (1) FDA will work closely with the DTMI throughout the lifetime of this program and throughout all phases of planning, implementation, conduct and reporting of this program and all related projects; (2) FDA will appoint project officer (s) for the task(s) associated with this program and related projects; (3) FDA will identify appropriate staff to provide strategic and scientific input, as needed, throughout the life of this program and related projects.

C. Eligibility Information

This is a sole source award to DTMI located within Duke University to support the CTTI. Only one award will be made to the DTMI to support the CTTI.

II. Award Information/Funds Available*A. Award Amount*

FDA anticipates providing up to \$1.5 million (direct and indirect costs combined) during fiscal year 2009 to support research and related efforts of identified projects that are part of the Critical Path Initiative.

B. Length of Support

Subject to the availability of Federal funds and successful performance of the funding opportunity announcement (FOA) stated goals and objectives, 4 additional years of support may be available depending on annual appropriations. This award will be funded based on the quality of the application received and is subject to availability of Federal funds to support the program.

III. How to Submit a Paper Application

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/SpotlightonCPIProjects/ucm083241.htm>. Persons interested in applying for a grant may obtain

application forms and instructions at <http://grants.nih.gov/grants/forms.htm>. For paper submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) Number
 - Step 2: Register with Central Contractor Registration (CCR)
- Instructions on how to complete these steps can be found at http://www07.grants.gov/applicants/organization_registration.jsp

Submit paper applications to: Gladys M. Bohler, OAGS/GAAT, Food and Drug Administration, 5630 Fishers Lane (HFA-500), rm. 2105, Rockville, MD 20874.

Dated: June 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Office of Child Support Enforcement**

AGENCY: Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice to administratively impose a matching requirement.

CFDA Number: 93.564.

Legislative Authority

Section 1115 of the Social Security Act [42 U.S.C. 1315] provides funds for experimental, pilot or demonstration projects that are likely to assist in promoting the objectives of Part D of the Title IV. The projects must be designed to improve the financial well-being of children or otherwise improve the operation of the child support program. Projects may not permit modifications in the child support program that would have the effect of disadvantaging children in need of support.

SUMMARY: The Office of Child Support Enforcement (OCSE) in the Administration for Children and Families (ACF) hereby gives notice to the public that a matching requirement of five percent (5%) will be administratively imposed upon awards made under competitions governed by the following "Section 1115" funding opportunities in Fiscal Year 2009.

Funding opportunity No.	Funding opportunity title	CFDA No.
HHS-2009-ACF-OCSE-FD-0093	Partnership to Strengthen Families—Child Support Enforcement/Temporary Assistance for Needy Families—University Partnership Demonstration Project.	93.654
HHS-2009-ACF-OCSE-FD-0095	Projects to Address the Sudden and Prolonged Effect of the Economic Downturn on the IV-D Caseload and Program Operations.	93.654
HHS-2009-ACF-OCSE-FD-0098	Health Care/Medical Support in Child Support Enforcement: Reform Strategy Grants.	93.654

Historically, the imposition of a matching requirement on awards under this program resulted in an increased level of commitment to the project and its success and sustainability, without creating an undue financial burden on the grantee.

Section 1115 funds awarded to each project will represent 29 percent (29%) of the total project costs. The total approved project cost is the sum of the ACF grant award under Section 1115, regular Federal Financial Participation (FFP), and the State share. For the purposes of the demonstration projects, the total expenditures will be treated as State expenditures under Title IV-D that will be reimbursed by the regular Title IV-D FFP match of 66 percent (66%). Applicants must prepare a formal budget on the required standard forms, as listed in *Section IV.2, Content and Form of Application Submission* of the funding opportunity announcements.

Grantees must provide at least five percent (5%) of the total approved project cost. This non-Federal, i.e., State share, may be met by cash, incentive funds (awarded under section 458 of the Social Security Act), or in-kind contributions. The five percent (5%) match may be provided through in-kind contributions, as allowed by section 1115(a)(2)(A) of the Social Security Act. For example, if an applicant's total project budget is \$150,000, this would be made up of three funding sources: Section 1115 funds (29% = \$43,500), cost sharing (5% = \$7,500) and regular Title IV-D Federal Financial Participation/FFP (66% = \$99,000).

Title IV-D applicants that anticipate satisfying the matching requirement through in-kind contributions, or the use of incentive funds awarded under section 458 of the Social Security Act, must request prior approval as part of the required budget justification (see *Section IV.2, Budget and Budget Justification* in the published funding opportunity announcements) in accordance with section 1115(a)(2)(A) of the Social Security Act. Costs borne by matching contributions are subject to the regulations governing allowability found under and 45 CFR 92.24.

Eligible applicants for these Section 1115 demonstration project grants are State (including the District of Columbia, Guam, Puerto Rico, and the Virgin Islands) Title IV-D agencies or the umbrella agencies of the IV-D program.

Planned ACF funding opportunity announcements may be found at the HHS Grants Forecast Web site at <http://www.hhs.gov/grantsforecast/>. The HHS's Grants Forecast is a database of planned funding opportunities proposed by its operating divisions, including ACF. Each Forecast record contains actual or estimated dates and funding levels for awards that an operating division intends to award during the fiscal year. ACF's publicly published funding opportunity announcements are available on <http://www.Grants.gov>, where applicants may also apply for funding electronically, and on the ACF Grant Opportunities Web page at <http://www.acf.hhs.gov/grants/>.

FOR FURTHER INFORMATION CONTACT: Myles Schlank, Office of Child Support Enforcement, 370 L'Enfant Promenade, SW., Washington, DC 20047. Telephone: 202-401-9329, e-mail: myles.schlank@acf.hhs.gov.

Dated: June 15, 2009.

Robert Cohen,

Acting Commissioner, Program Office: Child Support Enforcement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Response to solicitation of comments on amendment to program follow-up period and publication of

amended Program Eligibility Guidelines.

SUMMARY: This notice finalizes an amendment to the eligibility guidelines proposed on March 4, 2009 in the **Federal Register** (74 FR 9407). The purpose of this notice was to solicit comments on the amendment to the Program Eligibility Guidelines proposed by HRSA concerning the Reimbursement of Travel and Subsistence Expenses Program follow-up period.

FOR FURTHER INFORMATION CONTACT: Richard Durbin, Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or E-mail: rdurbin@hrsa.gov.

SUPPLEMENTARY INFORMATION: In the existing Program eligibility guidelines, under the *Qualifying Expenses Section*, the first paragraph states:

"For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, qualifying expenses presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:

(1) Donor evaluation, clinic visit or hospitalization,

(2) Hospitalization for the living donor surgical procedure, and/or

(3) Medical or surgical follow-up clinic visit or hospitalization within 90 days following the living donation procedure."

HRSA proposed amending the first bullet of this paragraph to read: "(1) Donor evaluation, and/or". In addition, HRSA proposed amending the third bullet of this paragraph to read: "(3) Medical or surgical follow-up clinic visit or hospitalization within two calendar years or beyond—if exceptional circumstances exist—following the living donation procedure." The purpose of this proposed change was to bring the NLDAC follow-up period in line with the OPTN policies of a 2-year follow-up of living organ donors.

HRSA received six public comments on this request. All the respondents