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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 000147]

Innovative HIV Testing: Operational Research Among People of Color Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program to conduct Human Immunodeficiency Virus (HIV) related operational research for the control and prevention of HIV. The purpose of this program is to: (1) Encourage studies of using the new rapid HIV tests in different settings (Operational Research), specifically focused on African American, Latino, and other racial and ethnic minorities that are underserved and/or disproportionately affected by the HIV epidemic, and conducted by researchers who have experience working with these populations; (2) learn more about the effects of rapid HIV testing on motivators and barriers to HIV testing at the individual, provider and system levels; and (3) foster collaborations between organizations serving minority communities and their respective state and local health departments in the design and implementation of innovative practical strategies using rapid HIV tests to increase knowledge of HIV serostatus and facilitate entry into prevention and care systems.

For the purpose of this announcement, operational research is defined as the design, implementation, and systematic observation of model health service delivery systems to evaluate their performance and improve their effectiveness.

For the purpose of this program announcement, research studies should specifically focus on racial and ethnic minorities that are underserved and/or disproportionately affected by the HIV epidemic (African Americans, Hispanics, American Indians, Asian and Pacific Islanders). Applicants should demonstrate access to and experience working with the selected minority

population(s). Applications are encouraged from research organizations involving minority researchers as principal investigators (PIs) or major co-investigators.

This program addresses the "Healthy People 2010" focus area of HIV. For the conference copy of "Healthy People 2010" visit the internet site: <<http://www.health.gov/healthypeople>>.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations, community-based, national, and regional organizations, State and local governments or their bona fide agents or instrumentalities, federally recognized Indian Tribal governments, Indian tribes or organizations.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$800,000 is available in FY 2000 to fund approximately four awards. It is expected that the average award will be \$200,000, ranging from \$100,000—\$300,000. It is expected that awards will begin September 30, 2000, and will be made for a 12 month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period are based on the availability of funds and success in demonstrating progress toward achievement of objectives.

Funding Preferences

Preference for awards will be given to: (1) Ensuring geographic and risk group diversity; and (2) applicants with at least two years of demonstrated experience conducting operational research with minority populations that are underserved and/or disproportionately affected by the HIV epidemic.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1 (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

- a. Develop and draft a research protocol.
- b. Implement activities according to the approved research protocol.

- c. Share study-related data with CDC as appropriate, with the frequency and in the format agreed upon after protocol development.
- d. Compile and disseminate findings of the operational research.

2. CDC Activities

- a. Assist as needed in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.
- b. Monitor and evaluate scientific and operational accomplishments of the project through periodic site visits, telephone calls, and review of technical reports and interim data analysis.
- c. Assist as needed in facilitating the planning and implementation of the necessary linkages with local or State health departments, and with the logistics of using investigational rapid HIV tests in operational research projects.
- d. Facilitate the technological and methodological dissemination of successful prevention and intervention models to appropriate target audiences such as State and local health departments, community based organizations, and other health professionals.
- e. Provide technical assistance in planning and evaluating strategies and protocols, as requested, and ongoing consultation and technical assistance for effective program planning and management.
- f. Convene meetings annually or as necessary for protocol development, information sharing, problem solving, and training.

E. Application Content

Application

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop your application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should consist of:

1. Abstract (Not to exceed 1 page): An executive summary of the program proposed under this announcement.
2. Program Plan (Not to exceed 10 pages): In developing the application under this announcement, please review the recipient activities and, in particular, evaluation criteria and respond concisely and completely.

3. Budget: Submit an itemized budget and supporting justification that is consistent with your proposed program plan.

F. Submission and Deadlines

Application

Submit the original and five copies of the application on Form PHS 398 (OMB Number 0925-0001) (Adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available at the following Internet address: www.cdc.gov/. . . Forms, or in the application kit. On or before September 8, 2000, submit your application to the Grants Management Specialist listed in the "Where to Obtain Additional Information" section of this announcement. Eligible applicants are encouraged to call the contact person for program technical assistance, also listed in the "Where to Obtain Additional Information" section of this announcement, before developing and submitting their applications.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Need: Inclusion of a brief review of the scientific literature related to the use of rapid HIV testing and pertinent to the study being proposed; statement of specific research questions or hypotheses and techniques that will guide the operational research, the originality and need for the proposed research, the extent to which it does not replicate past or present research efforts, and how findings will be used to guide prevention and control efforts. (15 points)

2. Scientific Merit: The quality of the research design and plans to develop and implement the study, including

identification of the rapid HIV tests to be used and a statement as to whether the design of the study is adequate to measure outcomes, including sample size calculations, when warranted. (25 points)

3. Collaboration and Minority Participation: Plans and supporting evidence for:

(a) Established and proposed linkages with community-based organizations serving racial and ethnic minorities that are underserved and/or disproportionately affected by the HIV epidemic, and the health department with jurisdiction for the proposed project area. This should include a description of the demographics of clients served by the CBO, evidence of past cooperative projects, and/or letters of intent which describe the relationship, roles, and responsibilities under the planned collaboration.

(b) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation, the proposed justification when representation is limited or absent, and a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits. (20 points)

4. Operational Feasibility. Extent to which the proposed activities, if well executed, support attaining project objectives and, if successful, lend themselves to replication in similar program settings to facilitate diffusion of innovation in rapid HIV testing to other communities. (20 points)

5. Project Management, Implementation Plan and Schedule.

(a) Extent to which personnel involved in this project are qualified, with realistic and sufficient time commitments. This should include curriculum vitae and evidence of past achievements appropriate to the project.

(b) Evidence of access to sufficient numbers of potential participants, and for the adequacy of facilities and other resources necessary to carry out the project.

(c) Inclusion of a time line with realistic and measurable milestones for major project activities (20 points)

6. Other (not scored)

(a) Budget: Will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of the funds, and

allowable. All budget categories should be itemized.

(b) Human Subjects: Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements
Provide CDC with original plus two copies of:

1. A quarterly progress report,
2. Financial status report, no more than 90 days after the end of the budget period, and

3. Final financial status report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see attachment 1 in the application kit.

AR-1—Human Subjects Requirements

AR-2—Inclusion of Women and Racial and Ethnic Minorities in Research Requirements

AR-4—HIV/AIDS Confidentiality Provisions

AR-5—HIV Program Review Panel Requirements

AR-6—Patient Care Prohibitions

AR-7—Executive Order 12372 Review

AR-8—Public Health System Reporting Requirements

AR-9—Paperwork Reduction Act Requirements

AR-10—Smoke-Free Workplace Requirements

AR-11—Healthy People 2010

AR-12—Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, Section 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number 93.943, Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

To receive additional written information and to request an

application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Roslyn Currington, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: (770) 488-2720, Facsimile at (770) 488-2777, Email address: http://www.RCURRENTHON@CDC.GOV

For program technical assistance, contact: Bernard Branson, M.D. National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, MS E46, Atlanta, GA 30333, Telephone (404) 639-6166, Email address: HTTP://BBranson@CDC.GOV

Dated: July 25, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: Head Start Family and Child Experiences Survey (FACES).

OMB No.: Revision of a currently approved collection (OMB No. 0970-0151).

Description: The Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF) of the Department of Health and Human Services (DHHS) is requesting comments on plans to extend the Head Start Family and Child Experience Survey (FACES). This study is being conducted under contract with Westat, Inc. (with Elsworth Associates and the CDM Group as their subcontractors) (#105-96-1912) to collect information on Head Start performance measures. This revision is intended to extend the current design to a national probability sample of 43 additional Head Start programs in order to ascertain what progress has been made since 1997 in meeting Head Start program performance goals.

FACES currently involves seven phases of data collection. The first phase was a Spring 1997 Field test in which approximately 2400 parents and children were studied in a nationally stratified random sample of 40 Head Start programs. The second and third phases occurred in Fall 1997 (Wave 1) and Spring 1998 (Wave 2) when data

were collected on a sample of 3200 children and families in the same 40 programs. Spring 1998 data collection included assessments of both Head Start children completing kindergarten (kindergarten field test) as well as interviews with their parents and ratings by their kindergarten teachers. In the fourth and fifth phases, follow-up continued for a second program year, plus a kindergarten follow-up. The sixth and seventh waves of data collection involve data collection in spring of the first-grade year for both cohorts of children, those completing kindergarten in spring 1999, and those completing kindergarten in spring 2000. The current plan is to extend data collection to a new cohort of 2825 children and families in a new sample of 43 Head Start programs.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures, and by the 1994 reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649 (d)), which requires periodic assessments of Head Start's quality and effectiveness.

Respondents: Federal Government, Individuals or Households, and Not-for-profit institutions.

Annual Burden Estimates

Estimated Response Burden for Respondents to the Head Start Family and Child Experience Survey (FACES 2000)—Fall 2000, Spring 2001, Spring 2002, Spring 2003.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 1 (2000):				
Head Start Parents	2825	1	1.00	2825
Head Start Children	2825	1	0.66	1865
Head Start Teachers (child ratings)	195	14	0.25	706
Center Directors	172	1	1.00	172
Education Coordinators	172	1	0.75	129
Classroom Teachers	195	1	1.00	195
Year 2 (2001):				
Head Start Parents	2400	1	0.75	1800
Head Start Children	2400	1	0.66	1584
Head Start Teachers (child ratings)	195	12	0.25	600
Family Services Coordinators	172	1	0.75	129
Year 3 (2002):				
Head Start Parents	800	1	0.75	600
Head Start Children	800	1	0.66	528
Head Start Teachers (child ratings)	65	12	0.25	200
Kindergarten Parents	1600	1	0.75	1200
Kindergarten Children	1600	1	0.75	1200
Kindergarten Teachers	1600	1	0.50	800
Year 4 (2003):				
Kindergarten Parents	800	1	0.75	600
Kindergarten Children	800	1	0.75	600