

foundation being utilized in determining the proposed intervention.

- c. Description of the theoretical framework underlying the intervention.
- d. Description of the study goals, objectives and/or hypotheses.
- e. Intended use and applicability of study findings

2. Research Approach

Evaluation will be based on:

- a. The overall strength and feasibility of the research design.
- b. Description and justification of the study population, including case definitions, number of participants, selection criteria, and methods for recruiting, enrolling, and sustaining participation.
- c. Description of the consent process, including procedures for informing participants about the study and methods for obtaining consent.
- d. A detailed description of the intervention.
- e. Description of all study instruments, including survey questionnaires, and a discussion of their reliability and validity.
- f. Data handling and analysis plans, including statistical methodology, data entry, storage, and disposition.
- g. Plans for disseminating and reporting results to multiple target audiences.

3. Investigators/Collaborators/and Management Plans Evaluation Will Be Based on:

- a. A description of the major collaborators and their explicit contributions to project objectives.
- b. A description of investigator(s) qualifications, roles, tasks, time commitments, and responsibilities.
- c. A detailed work plan with specific time frames for implementation of the project. This includes the presentation of overarching goals for the full three year project period with a detailed work plan outlining monthly or quarterly objectives covering the first two budget years.
- d. Evidence that people with disabilities will participate in all phases of the research.

4. Evaluation

Evaluation will be based on:

- a. A description of how progress will be monitored and evaluated over the course of the intervention.
- b. The extent to which project goals are attained and specific objectives accomplished.
- c. A description of expected outcomes and the overall effectiveness of the intervention. This includes methods for detecting meaningful changes in

outcomes of interest such as improved health, reductions in health disparities, and fewer or less severe secondary conditions among the targeted populations.

- d. A description of the expected cost/benefit of the intervention.

5. Budget

This includes the comprehensiveness and adequacy of the applicant's proposed budget in relation to program operations, collaborations, and services; the degree of cost-sharing; and the extent to which the budget is reasonable, clearly justified, accurate, and consistent with the purposes of this announcement.

6. Human Subjects

This includes the extent to which the application adequately addresses the requirements of title 45 CFR part 46 for the protection of human subjects. If the proposed project involves research on human participants, assurance and evidence must be provided that the project will be subject to initial and continuous reviews by an appropriate institutional review board. Does the applicant adequately address the requirements of 45 CFR part 46 for the protection of human subjects?

7. The Degree to Which the Applicant Has Met the CDC Policy Requirements Regarding the Inclusion of Women, Ethnic Minorities, and Racial Groups in the Proposed Research

This includes: The proposed plan for the inclusion of racial ethnic minority populations and both sexes for appropriate representation; the proposed justification when representation is limited or absent; a statement as to whether the design of the study is adequate to measure differences when warranted; 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.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

- 1. Progress Report for a PHS Research Grant (form PHS-2590 found on the CDC Web site), no less than 90 days before the end of the budget period (date to be determined at time of award).

- A. The progress report should represent the accomplishments of the project during the reporting period. You do not need to limit the progress report to two pages as specified in the standard

PHS-2590 form instructions (page 2, item A).

- B. The report should describe the work which has been accomplished to date, please describe accomplishments in terms of the specific aims/timetable.

- C. List each specific aim separately and elaborate on the progress that has been made and where you are in terms of the time schedule.

- D. Include a detailed budget with justification.

- E. Include a copy of your most current IRB approval.

- 2. Financial status report, no more than 90 days after the end of the budget period.

- 3. Final financial and performance reports, 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.

Additional Requirements

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

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity

Executive Order 12372 does not apply to this program.

J. Where to Obtain Additional Information

For this and other announcements, the necessary applications and associated forms can be found on the CDC home page Internet address: <http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341-4146. Telephone: (770) 488-2700.

For business management and budget assistance in the states, contact: Sheryl Heard, Grants Management Specialist, Procurement and Grants Office Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Atlanta, Georgia 30341-4146. Telephone: (770)