

Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-09, Atlanta, Georgia 30305; by telephone on (404) 842-6512; by fax on (404) 842-6513; or by Internet or CDC WONDER electronic mail at <nea1@opspgo1.em.cdc.gov>.

Programmatic technical assistance may be obtained from Joseph E. McDade, Ph.D., Associate Director for Laboratory Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30333; by telephone on (404) 639-3967; by fax (404) 639-3039; by Internet or CDC WONDER electronic mail at <jem3@cidod1.em.cdc.gov>.

Please refer to Announcement Number 639 when requesting information regarding this program.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

There may be delays in mail delivery and difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics. Therefore, CDC suggests using Internet, following all instructions in this announcement and leaving messages on the contact person's voice mail for more timely responses to any questions.

Dated: June 11, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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[Announcement 633]

Violence Prevention Programs; Notice of Availability of Funds for Fiscal Year 1996

Introduction

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 1996 funds for cooperative agreements for Violence Prevention Programs. These projects will develop, implement, and evaluate multifaceted violence prevention programs to reduce the incidence of injuries, disabilities, and deaths due to interpersonal violence among youth. The cooperative agreements which supported the

development of scientific understanding of interventions and programs that are effective in preventing violence-related injuries, disabilities, and deaths among adolescents and young adults will extend and build upon the work begun in the group of cooperative agreements funded under CDC's Program Announcement No. 329, which began in FY 1993.

CDC is committed to achieving the health promotion and disease prevention objectives described in "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Violent and Abusive Behavior—(For ordering a copy of "Healthy People 2000," see the Section "Where to Obtain Additional Information").

Authority

This program announcement is authorized under Sections 301, 317, and 391-394 (42 U.S.C. 241, 247b, and 280b-280b-3) of the Public Health Service Act as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications will be accepted from public and private, non-profit and for-profit organizations and governments and their agencies. Thus, community-based organizations, other public and private organizations, State, territorial, and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, hospitals, churches, and small, minority- and/or women-owned businesses, universities, colleges, and other research institutions, are eligible to apply.

Availability of Funds

Approximately \$1,600,000 is available in FY 1996 to fund up to four projects to develop, implement, and evaluate intervention programs designed to prevent violent injury in one, or some combination, of the two priority areas, Creating Pro-social Environments for Child Development and Creating Opportunity for Youth-at-risk. Awards are expected to range from \$350,000 to

\$420,000 with an average award of \$400,000 for each 12-month budget period.

It is expected that the new awards will begin on or about September 30, 1996. Awards will be made for a 12-month budget period within a 3-year project period. Funding estimates may vary and are subject to change.

Continuation awards within the project periods will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds. At the request of the applicant, Federal personnel may be assigned to a project area in lieu of a portion of the financial assistance.

Purpose

The purpose of this cooperative agreement program is to support the implementation and evaluation of multifaceted interventions which are designed to prevent violence-related injuries and demonstrate strong potential for broad-scale implementation in the Nation's communities. Applicants may propose to develop, implement, and evaluate interventions to prevent injuries due to interpersonal youth violence in one, of two main areas:

A. Creating Pro-Social Environments for Child Development—refers to efforts to encourage development of pro-social behavior and attitudes among children between 3 and 10 years of age by modifying institutional environments in communities exhibiting high rates of violent behavior (e.g., homicide rates). Numerous interventions have already been evaluated in schools, and, while school settings are appropriate, we strongly encourage applications whose proposed interventions occur in other settings, such as; homes, churches, daycare, after school programs, and other community settings, or in some combination of school and other settings.

Interventions proposed in this priority area must include significant components in non-school settings, and must be directed toward strengthening parent-child relationships and pro-social family environments. Efforts to strengthen parent-child relationships are one of the most challenging, and one of the most promising areas for preventing the development of violent behavior among youth. In particular, strategies that attempt to improve training in parenting skills and provide support services to empower parents to monitor and supervise their children more effectively are of interest.

B. Creating Opportunity for Youth-at-Risk—refers to efforts to create economic opportunities for youth.

Efforts to identify, recruit, and retain youth from high-risk environments and situations into programs designed to improve their life-choices and opportunities and reduce their risk of being victims or perpetrators of violence should also be incorporated. Youth in high-risk environments include youth who are found: (1) in settings with limited opportunities to develop the skills needed to participate adequately in societal institutions, and/or (2) in environments that are associated with elevated risk for becoming victims or perpetrators of violent behavior.

In an effort to develop economic opportunity for youth in high risk environments, applicants who propose interventions in this priority area must develop collaborative relationships with business, corporate, or business alliance partners that will, at a minimum, provide assistance in development of job training and placement components.

Whenever possible, applicants are encouraged to utilize existing delivery systems rather than create new ones in order to maximize acceptance of the program by potential participants, increase the likelihood that the intervention will be continued after research has been completed, and expedite the evaluation.

Program Requirements

Successful completion of the project will require a close working relationship between the recipient and CDC. Recipient and CDC activities are listed below:

A. Recipient Activities

In conducting activities to achieve the purpose of this program, the recipient will:

1. Collect, compile, and analyze information relevant to the proposed project.
2. Develop a final written scientific protocol for a comprehensive evaluation of the specific intervention(s) through consultation with CDC staff. This protocol will contain the following elements:
 - a. Statement of the questions to be answered (hypotheses to be tested);
 - b. Description of the intervention to be evaluated;
 - c. Data collected and analyzed to assess intervention implementation (monitoring), outcome (impact), and cost, including data used to monitor and manage the intervention;
 - d. Description of data collection methods (both scientific and operational) for monitoring, impact assessment, and cost data;

e. Description of how data will be maintained (i.e., in what databases); and,

f. Description of statistical techniques that will be used to analyze the data.

3. Obtain the necessary clearances and agreements to proceed with all aspects of the proposed violence prevention project. These shall include appropriate human subjects clearances and agreements with other organizations and individuals needed to complete the project.

4. Identify or develop, and pilot test data collection instruments.

5. Establish baseline rates for the pertinent outcomes within the target group.

6. Monitor progress toward achievement of project goals through use of realistic, measurable, time-oriented objectives for all phases of the project.

7. Implement the proposed intervention(s).

8. Evaluate the impact of the intervention.

9. Collect and compile monitoring and prevention effectiveness data in an ongoing fashion. Compile "lessons learned" from the project.

10. Establish an advisory structure to address issues related to violence to ensure community input, and to generate community support. This advisory structure must include individuals, or representatives of agencies or organizations with experience, expertise and interest in preventing violence. Additionally, the advisory structure must include individuals who represent the target population.

11. Develop collaborative relationships with voluntary, community-based public and private organizations and agencies already involved in preventing violence.

B. CDC Activities

As required for the proper direction of these cooperative agreements, CDC will:

1. Provide technical consultation on implementing the intervention, determining the impact of the evaluation, and designing the scientific protocols.
2. Collaborate in the design of all phases of the project, consult with the applicant on data collection instruments and procedures, on the choice and timing of the intervention, and on training needs and composition of the implementation team.
3. Monitor intervention implementation, and the collection and analysis of process and impact assessment (outcome) data.
4. Facilitate information sharing among DVP/NCIPC's various evaluation

projects, and with similar projects funded by other agencies or private foundations.

5. Provide up-to-date scientific information about youth violence prevention.

6. Assist in the transfer of information and methods developed in these projects to other prevention programs.

Evaluation Criteria

Applicants will be evaluated according to the following criteria (Maximum of 100 total points):

A. Target Group

The extent to which the target group is described and access to the target population is demonstrated. The extent to which the target group has a high incidence or prevalence of the risk factors to be influenced by the proposed intervention and the extent to which appropriate demographic and morbidity data are described. The extent to which youth, who are the direct or indirect target group, have a high incidence of interpersonal violence and violence-related injuries, disabilities, and deaths. (13 points)

The extent to which the applicant demonstrates a capability to achieve a sufficient level of participation by the target group in order to evaluate the intervention in an unbiased fashion.

In addition, 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:

- a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.
- b. The appropriateness of the proposed justification when representation is limited or absent.
- c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

B. Goals and Objectives

The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable. The extent to which they encompass monitoring both process and outcome features of the intervention. The extent to which specific questions to be answered about the effectiveness and replicability of the intervention are described. (12 points)

C. Intervention Description

The extent to which the potential effectiveness of the intervention is theoretically justified and supported by epidemiologic, or social and behavioral research. The extent to which the intervention is feasible and can be expected to produce the expected results in the target group of interest. The extent to which the intervention, its implementation, the development of all necessary materials, and all necessary training are clearly described. The extent to which the desired outcomes (e.g., behavioral change, injury, disability, or death) are specified and definitions of measurable endpoints are provided. The extent to which the setting in which the intervention is to be implemented is clearly described and shown to be adequate for reaching the target group and achieving the desired objectives. The status of all necessary measurement instruments or training materials must be described; if any of this material is not extant, methods and time frames for their development must be described. Necessary collaborators must be identified, and evidence of their ability and intention to participate must be supplied. (25 points)

D. Evaluation Design and Analysis

The extent to which the evaluation design and the data analysis plan are clearly described and are appropriate for the target group, intervention, data collection opportunities, and proposed project period. The extent to which the various threats to the validity of the evaluation are recognized and addressed. The extent to which the sampling methods, sample size estimates, power estimates, and attrition of the participating population are clarified. The extent to which data collection, data processing, and management activities are clearly described.

The extent to which the major phases of the project are clearly presented and logically and realistically sequenced. (25 points)

E. Project Management and Staffing Plan

The extent to which project management staff and their working partners are clearly described, appropriately assigned, and possess pertinent skills and experiences to conduct the project successfully to completion. The extent to which the applicant has arranged to involve appropriate researchers and other personnel who reflect the racial/ethnic composition of the target group. The extent to which the applicant or a full

working partner demonstrates the capacity and facilities to design, implement, and evaluate the proposed intervention. (13 points)

F. Collaboration

The extent to which the necessary partners are clearly described and their qualifications and intentions to participate explicitly stated. The extent to which the applicant provides proof of support (e.g., letters of support and/or memoranda of understanding) for proposed activities. The extent to which a full working partnership between a community-based organization, a university or other academic institution, and a State or local health department has been established for applicants seeking funds for a 3-year project period. Evidence must be provided that these funds do not duplicate already funded components of ongoing projects. (12 points)

G. Proposed Budget

The extent to which the budget request is clearly explained, adequately justified, reasonable, sufficient for the proposed project activities, and consistent with the intended use of the cooperative agreement funds. (Not scored)

H. Human Subjects

If human subjects will be involved, how they will be protected, i.e., describe the review process which will govern their participation. (Not scored)

Funding Priority

Important considerations for funding will be geographic balance, a representative mixture of target groups, and diversity of intervention strategies.

Interested persons are invited to comment on the proposed funding priority. All comments received on or before July 19, 1996 will be considered before the final funding priority is established. If the funding priority should change as a result of any comments received, a revised Announcement will be published in the Federal Register prior to the final receipt of applications.

Written comments should be addressed to Ron S. Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive

Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) must contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, applicants are advised to contact the SPOC of each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they must forward them to Ron S. Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, GA 30305, no later than 30 days after the application deadline. (The appropriation for this financial assistance program was received late in the fiscal year and would not allow for the application receipt date which would accommodate the 60-day State recommendation process period.) The Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Ron S. Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305. This should be done no later than 30 days after the application deadline date. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that

may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application.

B. A summary of the project that should be titled —Public Health System Impact Statement— (PHSIS), not exceed one page, and include the following:

1. A description of the population to be served;

2. A summary of the services to be provided; and

3. A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.136.

Other Requirements

A. Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

B. Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by the appropriate institutional review committees. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

C. Confidentiality of Records

All identifying information obtained in connection with the provision of

services to any person in any program that is being carried out with a cooperative agreement made under this announcement shall not be disclosed unless required by a law of a State or political subdivision thereof unless written, voluntary informed consent is provided by persons who received services.

D. Women, Racial, and Ethnic Minorities

It is the policy of CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting review for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and scoring. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subject. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947–47951, Friday, September 15, 1995.

E. Accounting Systems

The services of a certified public accountant licensed by the State Board of Accountancy or equivalent must be retained throughout the budget period as a part of the recipient's staff, or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement.

F. Audits

Funds claimed for reimbursement under this cooperative agreement must be audited annually by an independent certified public accountant (separate and independent of the consultant referenced above or recipient's staff certified public accountant). This audit must be performed within 60 days after

the end of the budget period, or at the close of an organization's fiscal year. The audit must be performed in accordance with generally accepted auditing standards (established by the American Institute of Certified Public Accountant (AICPA)), governmental auditing standards (established by the General Accounting Office (GAO)), and Office of Management and Budget (OMB) Circular A–133.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Joanne A. Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E13, Atlanta, GA 30305, on or before August 13, 1996.

A. Deadlines

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

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the independent review committee. For proof of timely mailing, applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.

B. Late Applications

Applications that do not meet the criteria in A.1. or A.2. above are considered late. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional information call (404) 332–4561. You will be asked to leave your name, address and phone number and will need to refer to Announcement 633. You will receive a complete program description, information on application procedures and application forms. The announcement is also available through the CDC home page on the Internet. The address for the CDC home page is <http://www.cdc.gov>.

If you have questions after reviewing the contents of all documents, business management assistance may be obtained from Joanne A. Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and

Grants Office, Centers for Disease Control and Prevention (CDC), 255 E. Paces Ferry Road, NE., Mailstop E13, Atlanta, GA 30305, telephone (404) 842-6535, or INTERNET address jcw6@opspgo1.em.cdc.gov.

Programmatic assistance may be obtained from Mark S. Long, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K60, Atlanta, GA 30341-3724, telephone, (770) 488-4224, INTERNET address, msl1@cipcod1.em.cdc.gov.

Please Refer to Announcement Number 633 When Requesting Information and Submitting an Application

There may be delays in mail delivery as well as difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics (July 19-August 4). Therefore, in order to receive more timely response to questions please use INTERNET/E-Mail, follow all instructions in this announcement and leave messages on the contact person's voice mail.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone, (202) 512-1800.

Dated: June 11, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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[Announcement 634]

Violence Prevention Programs (Longitudinal Evaluations)

Introduction

The Centers for Disease Control and Prevention (CDC), announces the availability of fiscal year (FY) 1996 funds for cooperative agreements for Violence Prevention Programs (Longitudinal Evaluations). These projects will evaluate injury prevention programs designed to reduce the incidence of injuries, disabilities, and deaths due to interpersonal violence among youth. The cooperative agreements will extend and build upon the work begun in the group of cooperative agreements funded under CDC's Program Announcement 329, which began in fiscal year (FY) 1993.

The cooperative agreements funded under Program Announcement 329 supported the continuing development of applied research to evaluate the effectiveness of interventions and programs designed to prevent violence-related injuries, disabilities, and deaths among children, adolescents, and young adults.

CDC is committed to achieving the health promotion and disease prevention objectives described in "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Violent and Abusive Behavior (to order a copy of "Healthy People 2000," see the Section Where to Obtain Additional Information).

Authority

This program announcement is authorized under Sections 301, 317, and 391-394 (42 U.S.C. 241, 247b, and 280b-280b-3) of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications will be accepted from public and private, non-profit and for-profit organizations and governments and their agencies. Thus, community-based organizations, other public and private organizations, State, territorial, and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, hospitals, and small, minority- and/or women-owned businesses, universities, colleges, and other research institutions, are eligible to apply.

Availability of Funds

Approximately \$500,000 is available in FY 1996 to fund up to four follow-up evaluations of previously implemented and evaluated violence prevention programs that targeted youth below the age of 19 years. Institutions may request funds for more than one project as long as the proposed projects are submitted separately and are distinctly different. Awards are expected to range from \$100,000 to \$166,000 with an average award of

\$125,000 for each 12-month budget period.

It is expected that the new awards will begin on or about September 30, 1996, and will be made for a 12-month budget period. Programs funded under this announcement will have a 3-year project period. Funding estimates may vary and are subject to change.

Continuation funds within the project periods will be awarded on the basis of satisfactory progress as evidenced by required reports and the availability of funds. The estimates outlined above may vary, based on the quality of the applications received within each project period.

Purpose

The purpose of this cooperative agreement is to support extended assessments of the impact of previously implemented and evaluated violence prevention programs that targeted youth below the age of 19 years which demonstrated promising outcomes. Specifically, this announcement seeks applications to assess the residual effects of previously evaluated interventions that initially exhibited significant effects in reducing violent behavior, violence-related injuries, or intermediate indicators (e.g. aggressiveness).

Of particular interest are: (1) assessing whether the effects of the initial intervention persist, and (2) assessing the effects of continued long-term intervention such as efforts to reinforce gains made in the initial intervention against both those who receive no significant additional reinforcement and those who received no significant intervention.

Program Requirements

Successful completion of the project will require a close working relationship between the recipient and CDC. Recipient and CDC Activities are listed below:

A. Recipient Activities

In conducting activities to achieve the purpose of this program, the recipient will:

1. Collect, compile, and analyze information relevant to the proposed project.
2. Develop a final written protocol for a comprehensive longitudinal evaluation of the intervention's impact. This protocol must contain the following elements:
 - a. Statement of the questions to be answered (hypotheses to be tested);
 - b. Description of the intervention to be evaluated;
 - c. Specific monitoring data that has been collected and analyzed;