Dated: June 8, 1998.

**Charles W. Gollmar,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

**[Program Announcement 98070]**

## Evaluation of Violence Prevention Programs for High-Risk Youth

### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for the Evaluation of Violence Prevention Programs. This program addresses the ''Healthy People 2000'' priority area of Violent and Abusive Behavior.

The purpose of this cooperative agreement is to support the implementation and evaluation of interventions which are designed to prevent violence-related injuries among high-risk youth (ages 13–21). For the purpose of this announcement, high-risk youth does not include youth that are detained.

Applicants may propose to implement and evaluate interventions to prevent injuries due to interpersonal youth (ages 13–21) violence. The aim for these interventions is to reduce the risk of violence related injury among high-risk youth and refers to impact assessment of efforts to target youths (ages 13–21) who are in alternative schools, or have been injured in a violent incident or have received treatment for a violence related assault or trauma.

### B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, and State and local governments or their bona fide agents.

**Note:** Pub. L. 104–65, which became effective January 1, 1996, states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

### C. Availability of Funds

Approximately $1,500,000 is available in FY 1998 to fund approximately four awards. It is expected that the average award will be $375,000 ranging from $350,000 to $400,000. It is expected that the awards will begin on or about September 30, 1998 and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Non-competing continuation awards for new budget periods within an approved project period are made on the basis of satisfactory performance and availability of funds.

*Funding Preferences*

In making awards, priority consideration will be given to ensuring geographic balance, a representative mixture of target groups, diversity of intervention strategies, and settings. Priority will be given to proposed projects evaluating efforts to reduce risk of violence related injury among high-risk youth.

### D. Cooperative Activities

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

1. Recipient Activities

a. Develop and implement an intervention protocol.

b. Develop and pilot test data collection instruments.

c. Analyze data and interpret findings.

d. Establish an advisory committee (who represents the target population) that will address issues related to violence to ensure community engagement.

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

f. Compile and disseminate the results from the project.

2. CDC Activities

a. Collaborate on the development of the intervention protocol.

b. Provide technical assistance on the development and evaluation of the data collection instruments.

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

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

### E. Application Content

Use the information in the Cooperative Activities, Other Requirements, Evaluation Criteria sections and the Errata Sheet (Addendum III), included in the application package to develop the 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 be no more than 30 double-spaced pages, printed on one side, with one inch margins, and unreduced font (no smaller than 10 cpi).

### F. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) and adhere to the instructions on the Errata Instruction Sheet for PHS 398. Forms are in the application kit.

On or before AUGUST 13, 1998, submit to: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98070, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305–2209.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

### G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent reviewer group appointed by CDC. Applicants will be evaluated according to the following criteria (Maximum of 100 total points):

1. Intervention Plan (35 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. 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/Agency for Toxic Substances and Disease Registry (ATSDR) policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes:

i. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

ii. The proposed justification when representation is limited or absent.

iii. A statement as to whether the design of the study is adequate to measure differences when warranted.

iv. A statement as to 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. 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, avoidance/prevention of 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. The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable.

2. Evaluation Design and Analysis (35 Points)

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. The extent to which the proposed goals and objectives are clearly stated, time-phased, and measurable.

3. Project Management and Staffing Plan (10 Points)

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.

4. Collaboration (20 Points)

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.

5. Human Subjects (Not Scored)

If human subjects will be involved, how they will be protect, i.e., describe the review process which will govern their participation.

6. Proposed Budget (Not Scored)

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. Budgets should include costs for travel for two project staff to attend two meetings per year in Atlanta with CDC staff.

**H. Other Requirements**

1. Technical Reporting Requirements

Provide CDC with an original plus two copies of:

a. Semi-annual progress reports.

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

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

Send all reports to: Joanne 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 E–13, Atlanta, GA 30305–2209.

*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 or unless written, voluntary informed consent is provided by persons who received services.

1. Nonpersonal identifying, unlinked information, which preserves the individual's anonymity, derived from any such program may be disclosed without consent:

a. In summary, statistical, or other similar form, or

b. For clinical or research purposes.

2. Personal identifying information: Recipients of CDC funds who must obtain and retain personal identifying information as part of their CDC-approved work plan must:

a. Maintain the physical security of such records and information at all times;

b. Have procedures in place and staff trained to prevent unauthorized disclosure of client-identifying information;

c. Obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made.

Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A Department of Health and Human Services (DHHS) certificate of confidentiality may be required for some projects.

The following additional requirements are applicable to this

program. For a complete description of each, see Addendum I (included in the application kit).

AR98–1 Human Subjects Requirements

AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR98–9 Paperwork Reduction Act Requirements

AR98–10 Smoke-Free Workplace Requirements

AR98–11 Healthy People 2000

AR98–12 Lobbying Restrictions

AR98–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

### I. Authority and Catalog of Federal Domestic Assistance Number

This program announcement is authorized under Sections 391, 392, 393, and 394 [42 U.S.C. 280b, 280b–1, 280b–1a, and 280b–2] of the Public Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

### J. Where To Obtain Additional Information

The program announcement and application forms may be downloaded from the Internet: www.cdc.gov (look under funding). You may also receive a complete application kit by calling 1–888–GRANTS4. You will be asked to identify the program announcement number and provide your name and mailing address. A complete announcement kit will be mailed to you.

Please refer to Program Announcement 98070 when you request information.

If you have questions after reviewing the forms, for business management technical assistance, contact: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98070, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305–2209, telephone (404) 842–6535, E-mail address jcw6@cdc.gov.

For program technical assistance, contact Wendy Watkins, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–60, Atlanta, GA 30341–3724, telephone (770) 488–4646, E-mail address dmw7@cdc.gov.

Dated: June 8, 1998.

**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

### Food and Drug Administration

**[Docket No. 98D–0307]**

### Draft Guidance for Industry; Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled, ''FDA Draft Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.'' The draft guidance document addresses issues pertaining to the exportation of human drugs, animal drugs, biologics, food additives, and devices as well as the importation of components, parts, accessories, or other articles for incorporation or further processing into articles intended for export.

**DATES:** Written comments on the draft guidance document may be submitted by August 26, 1998. General comments on the agency's guidance documents may be submitted at any time.

**ADDRESSES:** Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance document entitled, ''FDA Draft Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.'' Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for human drugs, animal drugs, biologics, devices, and, to a limited extent, food additives. For example, before the law was enacted, most exports of unapproved new drug products could only be made to 21 countries identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act), and these exports were subject to various restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA). (Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.)

The draft guidance document provides information on the statutory requirements for exporting human drugs, animal drugs, biologics, and medical devices, general requirements for products exported under section 801 of the act (21 U.S.C. 381), labeling requirements for drugs and biologics exported under section 801(e) of the act, export requirements for unapproved drugs, biologics, and devices under section 802(b) of the act (21 U.S.C. 382(b)), exports of unapproved drugs and devices for investigational use, exports of unapproved drugs and devices in anticipation of foreign approval; exports of drugs and devices for diagnosing, preventing, or treating a tropical disease or a disease ''not of significant prevalence in the United States,'' export notifications to FDA, and ''import for export.''

The draft guidance document represents the agency's current thinking on exports and imports-for-export under sections 801 and 802 of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments may be seen in the office