number for information collections that impose no burden upon the public. A request for public comments was published at 63 FR 19264, April 17, 1998. No comments were received.

DATES: Comment Due Date: July 24, 1998.

ADDRESSES: Comments regarding this collection of information should be submitted to: Edward Springer, GSA Desk Officer, Room 3235, NEOB, Washington, DC 20503 and to Marjorie Ashby, General Services Administration (MVP), 1800 F Street NW, Washington, DC, 20405.

FOR FURTHER INFORMATION CONTACT: Al Matera, Office of GSA Acquisition Policy (202) 501–1224.

SUPPLEMENTARY INFORMATION: The GSA is requesting the Office of Management and Budget (OMB) to reinstate information collection, 3090–0250, Zero Burden Information Collection Reports. This information collection consists of reports that do not impose collection burdens upon the public. These collections require information which is already available to the public at large or that is routinely exchanged by firms during the normal course of business. A general control number for these collections decreases the amount of paperwork generated by the approval process. Since May 1992, GSA has published two rules that fall under Information Collection 3090–0250: ''Implementation of Public Law 99–506'' published at 56 FR 29442, June 27, 1991, and ''Industrial Funding Fee'' published at 62 FR 38475, July 18, 1997.

Copy of Proposal

A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 1800 F Street, NW, Washington, DC, 20405 or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: June 16, 1998.

Ida M. Ustad,

Deputy Associate Administrator for Acquisition Policy.

[FR Doc. 98–16728 Filed 6–23–98; 8:45 am]

BILLING CODE 6820–61–M

GENERAL SERVICES ADMINISTRATION

Public Buildings Service; Notice of Availability of Record of Decision; Construction of the New Federal Courthouse, Seattle, WA

Pursuant to Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, as implemented by the Council of Environment Quality, the General Services Administration (GSA) has filed with the U.S. Environmental Protection Agency and made available to other government and interest private parties, the Record of Decision concerning the construction of the new Federal Courthouse, Seattle, Washington.

The Record of Decision is available for review at the following location: Seattle Public Library, 1000 Fourth Avenue, Seattle, WA (Documents Desk). Additional copies are available by contacting Michael D. Levine, 400 15th St., SW., Auburn, WA 98001 or call 253/931–7263. The document is also available at the following Internet address: www.northwest,gsa.gov/pbs/eis.htm.

L. Jay Pearson,

Regional Administrator.

[FR Doc. 98–16737 Filed 6–23–98; 8:45 am]

BILLING CODE 6820–34–M

GENERAL SERVICES ADMINISTRAITON

Public Buildings Service; Notice of Availability of Draft Environmental Impact Statement Disposition of Governors Island, Upper New York Bay, NY

Pursuant to Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, as implemented by the Council on Environmental Quality (40 CFR Parts 1500–1508), the General Services Administration (GSA) has filed with the U.S. Environmental Protection Agency and made available to other government and interested private parties, the Draft Environmental Impact Statement (DEIS) for the disposition of surplus federal real property known as Governors Island, Upper New York Bay, New York.

The Draft EIS is on file at New York City Hall, Manhattan Community District #6, Brooklyn Community District #6, Andrew Heiskell Library for the Blind and Physically Handicapped, Mid-Manhattan Library, NY Public Library—New Amsterdam Branch, NY Public Library—Carroll Gardens Branch, NY Public Library—Red Hook Branch and General Services Administration.

Copies of the Executive Summary of the Draft EIS are available upon request. Additional information may be obtained from General Services Administration, Region 2, Attention: Peter A. Sneed, 26 Federal Plaza, New York, New York, 10278, (212) 264–3581.

Written comments regarding the DEIS may be submitted until July 27, 1998 and should be addressed to General Services Administration in care of the above noted individual. A public hearing is scheduled for June 24, 1998 at the U.S. Customs House, 1 Bowling Green, Lower Manhattan, New York; and for June 25, 1998 at the US District Court, 225 Cadman Plaza East, 1st Floor, Brooklyn, New York. Both hearings will be held from 6:00 pm to 8:00 pm.

Dated: June 1, 1998.

Robert Martin,

Acting Regional Administrator (2A).

[FR Doc. 98–16725 Filed 6–23–98; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Fiscal Year 1998 Program Announcement; Availability of Funds and Notice Regarding Applications: Extension of Application Deadline Date

AGENCY: Administration on Aging, HHS.

ACTION: Notice of extension of deadline date for applications to carry out research on Alzheimer's Disease Caregiving Options.

SUMMARY: This notice extends the deadline date for the submission of applications under Program Announcement AoA 98–6, Research on Alzheimer's Disease Caregiving Options, through July 17, 1998.

Dated: June 15, 1998.

Jeanette C. Takamura,

Assistant Secretary for Aging.

[FR Doc. 98–16763 Filed 6–23–98; 8:45 am]

BILLING CODE 4150–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 98085]

Young People in Alternative Education Settings: Preventing HIV and Other Sexually Transmitted Diseases Notice of Availability of Fiscal Year 1998 Funds

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for cooperative agreements for the prevention of human immunodeficiency virus (HIV), and other sexually transmitted diseases (STDs) among young people in alternative educational

settings. Applied research programs that implement and evaluate promising, multicomponent interventions to reduce unprotected sexual intercourse among young people in alternative educational settings will be supported under this cooperative agreement.

Young people in high-risk situations for HIV and other STDs are served in alternative educational settings, which include: alternative schools, and school-based or school-linked dropout prevention programs, and dropout recovery programs. Alternative schools, dropout prevention programs, and dropout recovery programs serve students primarily who are at high risk of not progressing in regular high schools (or who have previously stopped attending school), and as a result, not graduating, as well as students who have already gotten into disciplinary trouble, usually related to illegal drug use or violence. Of particular interest are alternative educational settings targeting adjudicated young people (that is, young people in contact with the juvenile justice system), although interventions may target other young people in high risk situations served within alternative educational settings. (See Attachment 1 for the CDC's definition of young people in high risk situations.)

The CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and death and improve the quality of life. This announcement is related to priority areas of Family Planning, HIV Infection, and Sexually Transmitted Diseases. (To order a copy of ''Healthy People 2000,'' see the section ''Where To Obtain Additional Information.'')

Authority

This program is authorized under sections 301(a) and 317(k)(2) [42 U.S.C. 241(a) and 247b(k)(2)] of the Public Health Service Act, as amended. Regulations are set forth in 42 CFR Part 51b.

Smoke-free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse 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 educational, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are the official educational, juvenile corrections, public health, family planning, and substance abuse agencies of the State; the District of Columbia and Puerto Rico, as well as local governments, nonprofit organizations, academic institutions, and other nonprofit health, family planning, substance abuse, or social service providers. All applicants must provide evidence that demonstrates a successful history of working in partnership with interdisciplinary groups of health researchers and local racial and ethnic minority communities on applied social and behavioral science projects.

Residential programs in which participants receive interventions while institutionalized both weekdays and weekends are not eligible to avoid duplication of current CDC initiatives targeting incarcerated young people.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Availability of Funds

Approximately $600,000 is available in FY 1998 to fund up to two awards. It is expected that 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 4 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory performance and the availability of funds.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Public Law 105–78) states in Section 503 (a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relations, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

CDC has prioritized programs reducing sexual risk behavior among young people in high risk situations, particularly among young men having sex with men, injection drug using young people, and adjudicated young people. High rates of HIV, STDs, and unintended pregnancies among young people point to a need for interventions that effectively address adolescent sexual and drug use behavior. Several ''Healthy People 2000'' objectives call for effective interventions in these areas. The 1992 National Health Interview Survey Youth Risk Behavior supplement revealed that sexual risk and drug-use behaviors among out-of-school young people are more common than among their in-school counterparts. Programs designed to reach students at risk for school dropout are an important strategy to provide health education and activities to prevent behavior that may put them at risk for HIV and STDs. Evaluating the effectiveness of prevention programs within these settings is important and has been rarely undertaken.

Alternative schools are one important avenue for reaching young people who have dropped out or who are at risk of dropping out of regular school programs. Within the United States there are over 1300 free-standing alternative schools that serve 280,000 young peoples in grades 8 or higher. The number of students enrolled in such programs is even greater when alternative school programs within regular schools, and after-school diploma and GED programs are included. Such educational services are

needed given the number of young people dropping out of schools: in 1994, 11.4 percent of young people aged 16–24 dropped out of school without obtaining a high school diploma or GED.

Studies of alternative school students in Texas, Montana, Minnesota, and Florida demonstrate high rates of sexual risk behaviors strongly correlated with HIV, STDs, and unintended pregnancy. Young people in drop-out prevention programs and alternative schools exhibit higher rates of sexual risk behavior than their counterparts in regular schools including higher prevalence of sexual activity (between 83 percent and 97 percent), lower prevalence of condom use at last intercourse (between 40 percent and 60 percent), and higher prevalence of sex with multiple partners (between 31 percent and 43 percent). Young people in drop-out prevention programs and alternative school settings are also more likely to report a prior pregnancy (between 25 percent and 40 percent) than their regular school counterparts. Further, alternative school students report a high prevalence of drug use, including alcohol, marijuana, and cocaine.

Low academic and occupational expectations, academic failure, and school dropout are strongly and persistently associated with contact with the juvenile justice system. Federal Bureau of Investigation arrest statistics reveal that criminal offenses for males and females increase in early adolescence, peak in late adolescence, and decrease thereafter, bringing a higher proportion of young people into contact with the justice system than other age groups. Alternative school and dropout prevention programs that serve adjudicated young people, are detailed in ''Reaching Out to Youth Out of the Education Mainstream.'' (To order a copy of ''Reaching Out to Youth Out of the Education Mainstream,'' see the section ''Where To Obtain Additional Information.'') Community-based follow-up programs for young people that reinforce risk reduction behaviors have been shown to be promising strategies, and could be implemented in alternative educational settings. Such programs vary in the timing with which they intervene as young people progress through the juvenile justice system. Some alternative educational programs are preventive and implemented at the time of first offense, some provide model school experiences for incarcerated young people, and some are implemented after juveniles are released from incarceration to reintegrate them with the mainstream educational system.

Although there is a clear need for interventions to reduce sexual risk behaviors among young people at risk for school dropout, little research has been conducted to determine intervention efficacy for this population. While alternative and dropout prevention program students have been exposed to mainstream school HIV and STD prevention programs at relatively high rates, these programs may not adequately meet the needs of young people at high risk. One study of students in a dropout recovery program in Illinois found that a lack of tailored interventions has resulted in low basic knowledge regarding sexual risk, as well as high levels of risk behavior.

Purpose

These awards will support evaluation of promising interventions to decrease sexual risk behaviors among young people in alternative educational settings. This cooperative agreement will support applied research that meets the following criteria:

1. Identifies a promising group-level intervention based on a sound theoretical foundation. Promising programs are those with demonstrated effectiveness based on preliminary evaluation data, expert appraisal, or favorable response by participants. A rationale should be provided that justifies use of the intervention in the current population and setting. Programs may be revised, improved, or updated for purposes of the current research.

2. Implements and evaluates intervention strategies among young people in alternative educational settings to reduce sexual risk behavior.

3. Collaborates with academic, program, and community partners in conducting, and evaluating the proposed intervention, and proposes to work with partners throughout the project period to sustain successful interventions beyond the project's duration.

Program Requirements

Studies will be quasi-experimental or experimental in design and should measure knowledge, attitudes, and behavior related to HIV and other STDs. Measures of behavior should include, but are not limited to, abstinence, correct and consistent condom use among sexually active young people, past sexual experience including victimization, measures of number of partners, and frequency of sexual intercourse. While the major focus of the cooperative agreement is to decrease HIV and STD related risk behaviors, interventions may include as a secondary focus reducing the prevalence of alcohol and drug use, or sexual behaviors related to unintended pregnancy, including increasing effective contraceptive use among sexually active young people.

Studies should include at least two sites in which the intervention will be implemented, and sites or individual participants (or some other justified sampling unit) should be randomized to the control or comparison condition or the experimental condition. Studies should be designed to follow-up participants at least 12 months after the end of the intervention. Extensive strategies to maintain an adequate response rate throughout the follow-up will be of critical importance. The overall evaluation of these programs will include both process and outcome evaluation components.

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 conducting activities under B. (CDC Activities).

A. Recipient Activities

1. Establish and maintain staff positions allocated to specific responsibilities, with at least a 50 percent time research director and a 100 percent time project director with training, experience, and authority sufficient to achieve the objectives of this program announcement.

2. Identify and implement a promising intervention designed to reduce sexual risk behavior among young people in alternative educational settings. Examples include, but are not limited to, the following:

(a) Increasing knowledge about HIV and other STDs, and promoting attitudes and behavioral intentions that support reductions in sexual risk behavior.

(b) Providing skill-based training that increases, through modeling and practice, decision-making and communication skills that support reduction of sexual risk behaviors.

(c) Identifying, creating, or mobilizing school, family, peer, and other social networks to support and reinforce sexual risk reduction through activities including, but not limited to, mentoring, peer-influence, familial involvement, increased communication with sexual partners, community involvement, or social diffusion.

(d) Promoting resiliency, social skills, and youth assets through a youth development approach.

(e) If alcohol and drug-related behavior is a secondary focus, then promoting knowledge, attitudes,

behavioral intentions, and behavior to reduce alcohol and illegal drug use, or to reduce harm associated with use.

(f) If pregnancy prevention is a secondary focus, then increasing knowledge, attitudes, and behavioral intentions and behavior to increase effective contraceptive use (which may include multiple methods of contraception) to prevent HIV, STD, and unintended pregnancy among sexually active young people.

3. Measure the success of interventions with targeted populations in comparison to a control/comparison group. Self-reported outcome measures may include, but are not limited to:

(a) Past sexual experience, including sexual victimization;

(b) Sexual initiation;

(c) Correct and consistent condom use among sexually active young people;

(d) Knowledge, attitudes, and behavioral intentions to reduce sexual risk behavior;

(e) Number of sexual partners and frequency of sexual intercourse;

(f) Number of STDs diagnosed;

(g) HIV testing reported by participants;

(h) Social assets, communication skills, perception of peer norms, increased integration in familial and community networks;

(i) If alcohol and drug-related behavior is a secondary focus, then knowledge, attitudes, behavioral intentions, and alcohol and drug use behavior, and the impact of alcohol and drug-use on sexual risk behaviors; and

(j) If pregnancy prevention is a secondary focus, then knowledge, attitudes, behavioral intentions, and behavior. Measures may include, but are not limited to, number of pregnancies in the sample, and effective contraception use (including multiple methods) among sexually active young people.

4. Develop and refine research questions and methods, conceptual frameworks, measurement and analysis strategies, and intervention protocols so that findings can be used to facilitate national efforts to prevent HIV and STDs among young people in alternative educational settings. This may require modifying conceptual frameworks, sampling plans, data collection instruments, intervention activities, and other elements of the applicant's proposal to meet the program goals.

5. Develop, revise, and submit a written justification package and other documentation necessary for obtaining Office of Management and Budget (OMB) clearance.

6. Collaborate and coordinate efforts with appropriate educational, corrections, health, substance abuse, youth-serving, community-based, and minority organizations who deliver services or interventions to the targeted populations. Include members of the targeted population in planning, developing, and revising the research and intervention activities whenever appropriate and feasible. Collaborate with service providers to sustain successful interventions beyond the duration of the project.

7. Develop a plan for disseminating results of the research to members of the scientific, programmatic, and targeted communities.

8. Disseminates evaluation findings through peer-reviewed publications and presentations.

B. CDC Activities:

1. Provide scientific and technical assistance in the design and development of the research, and evaluation protocols, selection of measures and instruments, operational plans and objectives, and data analysis strategies.

2. Provide scientific and technical coordination of the general operation of the research project, including data management support.

3. Participate in the analysis of data gathered from program activities and the reporting of results.

4. Conduct site visits to assess program progress.

5. Assist 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.

Technical Reporting Requirements

An original and two copies of the progress report and financial status report must be submitted on an annual basis and are due 90 days after the end of the budget period. The progress report must include the following for each program, function, or activity involved: (1) a brief program description; (2) a comparison of actual accomplishments to goals and objectives established for the 12-month period; (3) explanations for all goals or objectives either delayed or not accomplished and a plan of corrective action; (4) data on participation in intervention and research activities, including numbers of completed baseline and follow-up interviews, and recruitment and retention rates (5) other pertinent information including, when appropriate, analysis and explanation of unexpectedly high costs for performance. All manuscripts supported in part or whole by the cooperative agreement will be required to go through CDC clearance before submission for publication.

A final financial report is required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Office, CDC.

Application Content

Applications must be developed in accordance with PHS Form 5161–1 (OMB Number 0937–0189), information contained in the program announcement, and the instructions and format provided below.

Applications should describe:

1. The identification of a promising program to reduce sexual risk behavior among young people in alternative educational settings, including a theoretical basis, rationale, and explanation of previous use.

2. Implementation and evaluation of an intervention to reduce unprotected sexual intercourse among young people in alternative educational settings, including the evaluation design, sampling plan, and analysis strategy.

3. A feasible and timely strategy for disseminating findings from this research to scientific, public health, and community partners, and efforts to be made throughout the project to ensure that the intervention will be sustained once Federal funding ends.

The application should include a general introduction, followed by one narrative subsection per application content element (A–H) in the order in which the elements appear below. Each narrative subsection should be labeled with the element title and contain all of the information needed to evaluate that element of the application (except for curriculum vitae, references, intervention descriptions and materials, and letters of support that are appropriate for the appendixes).

A. Intervention Plan

1. Provide a review of the relevant literature to provide a theoretical, empirical, and programmatic justification for the proposed research, and clearly describe how the proposed intervention will advance efforts to prevent HIV and STDs among young people in alternative educational settings.

Specifically, the application should include explicit models (with schematic drawings) that illustrate factors to be modified through the intervention and to explain the mechanisms by which outcome effects are produced.

2. Discuss why the intervention is promising, to include a discussion of

the settings and populations in which the intervention was previously implemented. Intervention descriptions and materials should be provided if possible. Discuss feasibility and acceptability of the intervention in the selected setting.

B. Research Plan

1. Specify a set of clear and testable research questions and hypotheses that are responsive to the intended purposes of the research sought under this cooperative agreement.

2. Describe all aspects of the study design and methods including the evaluation design (both process and outcome) and how threats to validity will be handled; a detailed description of the targeted population, including but not limited to age, grade, sex, race, socioeconomic status, HIV and STD risk factors, and how the population will be accessed; instrumentation; the sampling strategy (including a justification for the sampling unit), sample size, and power analysis justifying the sample size and including an indication of expected effect sizes, the randomization strategy; training plans for individuals collecting data, and data collection plans, including but not limited to, linking participants' responses between measurement periods.

3. Describe expected sample attrition. Describe how study participants will be tracked and what strategies will be used to increase retention.

4. Describe how the intervention implementation process will be measured and how the findings will be used to monitor implementation and provide feedback to staff, and to explicate other findings. Include plans to maintain detailed records of the costs involved in implementation such that cost-effectiveness estimates can be derived.

5. Describe the plans and quality assurance monitoring for data management, analysis, and interpretation.

6. Describe key dissemination products including peer-reviewed publications and presentations that can be used by program planners, policy makers, and other interested parties.

7. Describe the potential limitations of the results given the complexity of the research focus, the targeted population, and the applied nature of the evaluation; to whom the findings will be generalizable; and how they can be used to develop national recommendations for reducing unprotected sexual intercourse among young people in alternative educational settings.

8. As appropriate and necessary, provide for the inclusion of women and racial and ethnic minority groups as required by CDC/ATSDR policy, or, where inclusion is inappropriate or not feasible, provide an explanation for the exclusion of women and racial and ethnic minority groups from the research design. (See ''Other Requirements'' section of this announcement for details.)

C. Research and Intervention Capacity

1. Demonstrate the feasibility of the proposed research by providing a detailed timeline, with specific products, specifying which staff person will be responsible for which task.

2. Describe the research team and show that the proposed research staff for the project represent an interdisciplinary team of behavioral and social scientists with the scientific training and the previous scientific and practical experience needed to conduct and complete high quality research within the specified timeline, as evidenced by the successful completion of past research in the areas proposed in this application. Describe previous service or research conducted with this population.

3. Demonstrate the adequacy of the proposed staff, through curriculum vitae and position descriptions that detail responsibilities, to carry out all proposed activities (i.e., sufficient in number, percentage of time commitments, behavioral or social scientists in key project positions, and qualifications).

4. Describe the facilities, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

D. Collaboration and Sustainability

1. Describe how academic, program, and community partners will participate in developing, conducting, and evaluating the proposed research. Specifically, describe the involvement of appropriate key organizations and members of the targeted population and discuss previous work of the proposed collaborators. Include letters of support from proposed collaborating organizations indicating willingness to participate in the proposed research, including but not limited to, evidence of past successful collaboration, willingness to be randomized to a control/comparison or experimental condition, and containing information on the number and demographic characteristics of young people served.

2. Define the responsibilities of collaborating partners.

3. Discuss efforts to be made throughout the project period to ensure that the intervention will be sustained once Federal funding ends.

E. Dissemination

Provide a clear dissemination plan to include but not limited to, the timely sharing of findings with local partners; and include a plan to work with CDC and other sites to ensure that analysis and production of peer-reviewed papers, and reports give priority to findings that can be used to develop national prevention recommendations for young people in alternative educational settings to prevent HIV and STDs.

F. Budget with Justification

Provide a detailed budget request and complete line-item justification that is consistent with the proposed activities.

G. Human Subjects

Describe any risks to human subjects and the procedures that will be used to protect human subjects both through local institutional review boards. Involvement by the CDC in the design, analysis, and dissemination of research involving human subjects also requires the study to be cleared through the CDC human subjects review process. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Typing and Mailing

Applicants are required to submit an original and two copies of the application. The application may not exceed 60 single-spaced pages in length, excluding appendixes. Provide a one-page abstract of the proposal. Number all pages clearly and sequentially and include a complete Table of Contents to the application and its appendixes. The original and each copy of the application must be submitted unstapled and unbound. Print all material, single-spaced, in a 12-point or larger font on 8.5″ by 11″ paper, with at least 1″ margins and printed on one side only.

Evaluation Criteria (Total 100 Points)

Objective Review panels evaluate the scientific and technical merit of applications and their responsiveness to the information requested in the ''Application Content'' section above. Applications will be reviewed and evaluated according to the following criteria:

A. Intervention Plan (20 Points)

1. The extent to which the research proposed will advance efforts to reduce the risk of HIV and other STDs among

young people in alternative educational settings. The extent to which the intervention represents a careful application of a theoretically, empirically, and programmatically justified prevention approach; can be expected to produce the intended effect; and can be evaluated by using a scientifically rigorous evaluation design and methods.

2. The extent to which the intervention is promising, and has the potential for use with young people in alternative educational settings or with populations served in alternative educational settings (such as interventions designed for adjudicated young people).

B. Research Plan (30 Points)

1. The clarity and testability of the research questions and hypotheses, and the extent to which the questions are responsive to the intended purposes of the research sought under this cooperative agreement.

2. The extent to which the study and evaluation design and methods are scientifically sound and capable of producing the intended results, and will result in the adequate recruitment of participants.

3. The adequacy with which study participants will be tracked, and the extent to which strategies presented are likely to produce adequate retention of participants.

4. The extent to which the intervention implementation process can be measured and findings used to replicate the intervention in other settings, including cost-benefit estimates.

5. The extent to which the plans for data management, analysis, and interpretation are clear, appropriate and are adequately monitored for quality.

6. The extent to which dissemination products will result in the generation of peer-reviewed papers and presentations.

7. The extent to which the evaluation will provide results that are scientifically sound, generalizable, and useful for developing national recommendations for reducing unprotected sexual intercourse among young people in alternative educational settings.

8. The extent to which the applicant has met the CDC Policy requirements regarding the inclusion of women and 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 proposed justification when representation is limited or absent.

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

(d) 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 will be documented.

C. Research and Intervention Capacity (25 Points)

1. The feasibility of the proposed research plan and the adequacy of the timeline with specific products.

2. The extent to which the proposed research staff for the project represent an interdisciplinary team of behavioral and social scientists with the scientific training and the previous scientific and practical experience needed to conduct and complete high quality research within the specified timeline, as evidenced by the successful completion of past research in the areas proposed in this application. The extent of the applicant's familiarity with, access to, and good working relationships with young people in this setting, as evidenced by previous service or research with proposed population.

3. The adequacy of the proposed staff to conduct all proposed activities (i.e., sufficient in number, percentage of time commitments, behavioral scientists in key project positions, and qualifications).

4. The adequacy of facilities, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

D. Collaboration and Sustainability (15 Points)

The extent to which the applicant includes academic, program, and community partners in developing, conducting, and evaluating the proposed research, and to sustain the intervention after completion of the research as evidenced by inclusion of appropriate key organizations, members of the targeted population, and selected collaborators; defined responsibilities for organizations and individuals; and planned efforts to ensure that the intervention will be sustained once Federal funding ends.

E. Dissemination (10 Points)

The extent to which the dissemination plan is clearly articulated and includes the timely sharing of findings with local partners and a plan to work with appropriate others to ensure production of papers and presentations.

F. Budget (Not Weighted)

Extent to which the budget is reasonable, itemized, clearly justified, and consistent with the intended use of the funds.

G. Human Subjects (Not Weighted)

Whether or not exempt from the Department of Health and Human Services regulations, procedures must be adequate for the protection of human subjects. Recommendations on the adequacy of protections include: (1) protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Content of Noncompeting Continuation Applications

In compliance with 45 CFR 74.51(b)(d), 45 CFR 92.10(b)(4) and 92.40(b), annual noncompeting continuation applications submitted within the project period need only include:

A. A brief progress report that describes the accomplishments of the previous budget period.

B. Any new or significantly revised items or information (objectives, scope of activities, operational methods, evaluation, etc.) not included in the year 01 application.

C. An annual budget and justification. Existing budget items that are unchanged from the previous budget period do not need rejustification. Simply list the items in the budget and indicate that they are continuation items. Supporting justification should be provided where appropriate.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372, which sets up a system for State and local government review of proposed Federal assistance applications. Applicants should 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, the applicant is advised to contact the SPOC for 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 should send them to Sharon P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Atlanta, GA 30305, no later than 30 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is 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 (SF 424).

b. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not to 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 93.938.

Other Requirements

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 (OMB) under the Paperwork Reduction Act.

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 an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women and Racial and Ethnic Minority Groups

It is the policy of the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-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 or Alaska Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, and White. There will be two categories for data on ethnicity: ''Hispanic or Latino'' and ''Not Hispanic or Latino.'' 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 of scoring.

This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947-47951, dated Friday, September 15, 1995.

HIV/AIDS Requirements

Recipients must comply with the document entitled Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance for CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

Application Submission and Deadline

An original and two copies of the application PHS Form 5161-1 (Revised 5/96, OMB Number 0937–0189) must be submitted to Sharron P. Orum, 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, Mail Stop E–18, Atlanta, GA 30305, on or before August 3, 1998.

1. 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 objective review group. (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 shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. 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 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. You will receive a complete program description and information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Glynnis Taylor, 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, Mail Stop E–18, Atlanta, GA 30305, telephone (404) 842–6593, by fax (404) 842–6513, or by the Internet address: gld1@cdc.gov.

Programmatic technical assistance and information about studies cited in this announcement may be obtained from Leah Robin, Ph.D., Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4700 Buford Highway, NE., Mail Stop K–33, Atlanta, GA 30341-3717; telephone (770) 488–3210, or by the Internet address: ler7@cdc.gov.

You may obtain this announcement, and other CDC announcements, from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Please refer to Announcement Number 98085 when requesting information and submitting an application.

Potential applicants may obtain a copy of:

1. ''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.

2. ''Reaching Out to Youth Out of the Education Mainstream'' (NCJ 163920), referenced in the section entitled ''Background,'' through the Office of Juvenile Justice and Delinquency Prevention's Juvenile Justice Clearinghouse, P.O. Box 6000, Rockville, MD 20849–6000; telephone (800) 638–8736; E-mail: aksncirs@ncirs.org.

Dated: June 18, 1998.

John L. Williams,

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

Attachment 1

Youth in High-Risk Situations

The following is the Centers for Disease Control and Prevention's definition of youth in high-risk situations. (From CDC, ''Report of the Fourth Meeting of the CDC Advisory Committee on the Prevention of HIV Infection,'' November 7–8, 1990.)

Young people between the ages of 10 and 24 who fit at least one of the following categories are considered at high risk for HIV infection:

1. Homeless youth
2. Runaway youth
3. Youth not in school and unemployed
4. Youth requiring drug or alcohol rehabilitation
5. Youth who interface with the juvenile corrections system
6. Medically indigent youth
7. Youth requiring mental health services
8. Youth in foster homes
9. Migrant farm worker youth
10. Gay or lesbian youth
11. Youth with STDs, especially genital ulcer disease
12. Sexually abused youth
13. Sexually active youth
14. Pregnant youth
15. Youth seeking counseling and testing for HIV infection
16. Youth with signs and symptoms of HIV infection or AIDS without alternative diagnosis
17. Youth who barter or sell sex
18. Youth who use illegal injected drugs (including crack cocaine)

Some characteristics of youth who fit the definition of youth at high risk for HIV infection pose barriers to effective intervention. Those characteristics include:

1. feeling invulnerable to disease;
2. having little adult supervision, whether at home, having run away from home, or having been asked to leave home;
3. a history of emotional, sexual, and/or physical abuse;
4. distrust of adults;
5. serious emotional and personal problems;
6. disenfranchised from institutions that normally provide structure and support; and
7. difficulty filling basic human needs for food, shelter, money, and safety—consequently placing prevention of HIV infection a low priority.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0376]

Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem.'' The guidance, which is included in this notice, is a Level 1 guidance that is immediately effective in accordance with FDA's good guidance practices (GGP's) criteria, which allow immediate implementation of guidance that is necessary for public health reasons. FDA will receive comments on the guidance at any time and consider them in determining whether to amend the current guidance.

DATES: This guidance is effective June 24, 1998. Submit written comments by September 22, 1998. After the close of the comment period, written comments may be submitted at any time to Thomas B. Shope (address below).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance in this notice.

Submit comments during the comment period to: Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance. Comments should be identified with the docket number found in brackets in the heading of this document.

Submit comments at any time after the close of the comment period to: Thomas B. Shope (address below). Comments may not be acted upon by the agency until the document is next revised or updated.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 32.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance entitled ''Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem'' reviews the legal responsibilities of device manufacturers under the Federal Food, Drug, and Cosmetic Act in ensuring the uninterrupted functioning of any medical device that might be impacted by the Year 2000 date problem. It also reviews legislative and regulatory requirements applicable to device manufacturers with regard to correcting potential Year 2000 problems, to indicate when corrective action is or is not required, to present recommendations for device assessment, and to encourage reporting on the status of devices that are adversely affected by the Year 2000 date problem.

II. Significance of Guidance

This guidance document represents the agency's current thinking on FDA's