Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and 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, 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 exists that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application Form PHS–5161–1 (Revised 7/92) 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 314, Mailstop E–18, Atlanta, Georgia 30305, on or before August 15, 1997. No applications or additional materials will be accepted after the deadline.

1. *Deadline:* Applications will 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 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, call (404) 332–4561. You will be asked to leave your name, address, and telephone number. Please refer to Announcement Number 792. You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, the business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6801, facsimile (404) 842–6513.

Programmatic technical assistance may be obtained from Earl Long, Ph.D., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C–12, 1600 Clifton Road, NE., Atlanta, GA, 30333, telephone 404–639–2456. You may obtain this announcement 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). Other CDC Announcements are also listed on the Internet on the CDC homepage.

Please refer to Announcement Number 792 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.

Potential applicants may obtain a copy of ''Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States'' via the CDC homepage (http://www.cdc.gov/ncidod/publications/eid—plan/home.htm) or through the Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Office of Planning and Health Communication—EP, Mailstop C–14, 1600 Clifton Road, Atlanta, GA 30333. Requests may also be sent by facsimile to (404) 639–3039.

Dated: June 25, 1997.

Joseph R. Carter,

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

[FR Doc. 97–17124 Filed 6–30–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 774]

Young Women at Risk: Prevention of Unplanned Pregnancies, HIV, and Other Sexually Transmitted Diseases

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for cooperative agreements for the prevention of unplanned pregnancies, human immunodeficiency virus (HIV), and other sexually transmitted diseases (STDs) among young women aged 15–25 years, in the United States (U.S.). Applied research programs that design, implement, and evaluate interventions to reduce unprotected sexual intercourse among young women and their male partners will be supported under this cooperative agreement. Applications are sought that focus on the dynamics of heterosexual relationships and the factors that may contribute to successful risk reduction. Research should assess factors that affect sexual decision-making, disease and pregnancy prevention behavior, such as the nature and the effect of implicit or explicit communication between heterosexual partners about sex and protective behavior; the importance of gender roles, relationship stage, concordance of couples' reproductive desires, the balance of power in the relationship; and the influence of other network, family, and sociocultural factors.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality 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 the Public Health Services Act, Section

301(a) [42 U.S.C. 241(a)], Section 317(k)(2) [42 U.S.C. 247b(k)(2)], and Section 318(b)(3) [42 U.S.C. 247c(b)(3)], as amended.

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 education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are the official public health, family planning, and substance abuse agencies of the States, 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.

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 $1.2 million is available in FY 1997 to fund approximately three awards. It is expected that the average award will be $450,000, ranging from $300,000 to $650,000. It is expected that awards will begin on or about September 30, 1997, and will be made for a 12-month budget period within a project period of up to 5 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 Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. 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 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Public Law No. 104–208 (September 30, 1996), provides as follows:

> Section 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, 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, * * * except in presentation to the Congress or any State legislative body itself.
>
> Section 503(b) 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

Adolescent and young women in racial and ethnic communities are at increased risk for a range of preventable health threats such as unplanned pregnancy, human immunodeficiency virus (HIV) infection, and other sexually transmitted diseases (STDs). Although CDC promotes abstinence as the most effective strategy for prevention of these public health problems, many women will choose to become sexually active during adolescence and young adulthood. An estimated one million adolescents become pregnant every year, and teenagers undergo one-third of the 1.5 million abortions performed in the U.S. each year. There are adverse consequences of having a baby during early adolescence for both the mother and the infant. These include increased risk of low birth weight and developmental problems for the child, as well as detrimental effects on the lifelong physical, educational, and financial well-being of the young mother. These problems are compounded for young women who are living in communities characterized by high rates of violence, illegal drug use, and poverty.

HIV infection and STDs are a significant threat to young people—one out of every eight adolescents contracts an STD, and 20 percent of the acquired immunodeficiency syndrome (AIDS) cases reported are among persons younger than 29 years of age. Because the median time between infection with HIV and the onset of AIDS symptoms is 8 to 10 years, most of these young people were probably infected during their teenage years. Further, the pattern of HIV infection in the U.S. has made a significant shift toward women. The overall slowing in the growth rate of the AIDS epidemic in the U.S. has not been seen among women—the proportion of AIDS cases among women has risen from 11 percent of cases reported in 1989, to 20 percent of cases reported in 1996. AIDS is now the third leading cause of death among U.S. women aged 25–44 years. Heterosexual transmission accounts for at least 40 percent of current AIDS cases among women, and in 1992, surpassed injecting drug use as the most common mode of HIV transmission to U.S. women. The increase in rates of AIDS has especially affected racial and ethnic minority women—78 percent of all women and 85 percent of children diagnosed with AIDS are Black or Hispanic.

Eighty percent of women with AIDS are of childbearing age and 90 percent of AIDS cases reported among children are believed to have been transmitted from the mother. With the recent finding that zidovudine (AZT) given to HIV-positive pregnant women can significantly reduce the risk of perinatal transmission, there is hope of significantly reducing this mode of HIV transmission to children. Still, as of the end of 1996, 7,629 pediatric AIDS cases had been reported. Preventing primary HIV infection among women and helping women who are already infected with HIV to avoid unintended pregnancies will help reduce HIV infection among infants.

In 1991, in response to the growing threat of HIV to women and infants, and in recognition of the need to integrate pregnancy and disease prevention strategies for women at risk, CDC funded cooperative agreements for the prevention of HIV among women and infants (Announcement Number 124).

This project, known as Project CARES (Comprehensive AIDS and Reproductive Health Education Study), provided reproductive health services in nontraditional settings and enhanced counseling services offered by peer para-professionals to women aged 15–44 years. Women at risk for unplanned pregnancy, HIV, and other STDs, as well as women living with HIV infection, participated in a counseling intervention tailored to each woman's readiness to change her sexual risk behavior.

Findings from Project CARES suggest that the male sex partner's influence on condom and other contraceptive use among young women at risk is an important area for further research and intervention. The partner's reproductive desires, length of the relationship, the partner's support for using contraceptives, and communication with one's partner about condom use, are associated with condom and other contraceptive use. Very little research has been done that focuses on the influence of sex partners on each other and the effect of other social and normative factors on the sexual dyad.

Thus, this announcement seeks research that expands the conceptual framework for understanding the sexual behavior of young women at high risk for unplanned pregnancy, HIV, and other STDs, by taking into consideration individual-level, relationship-level, and social-level factors, and to using this foundation to design interventions to reduce sexual risk behavior.

Purpose

These awards will support advancing efforts to prevent unplanned pregnancy, HIV, and other STDs among young women in the U.S. by focusing on sexual behavior as a social or dyadic phenomenon best understood by considering the joint influence of sex partners on behavior. To reach this goal, the program will support applied research that meets the following criteria:

1. Extends or enhances existing social and psychological models of sexual behavior change, and develops and tests new hypotheses and measures to examine the dynamics of heterosexual relationships, taking into consideration the influence of sex partners on each other. Individual-level variables (e.g., perception of partners' attitude toward condom use, etc.), relationship-level variables (e.g., length of relationship, concordance of partners' attitudes toward risk reduction, etc.), and social and cultural-level variables (e.g., culturally prescribed sexual behavior norms for young men and women, etc.) should be assessed.

2. Designs, conducts, and evaluates new intervention strategies, or extensions of existing strategies, to promote safer sexual behavior, including condom and other contraceptive use, among young women (who have chosen not to abstain) and their male sex partners.

All proposed projects must be grounded in social and behavioral science theory and past research, and applicants must provide theoretical, scientific, and programmatic justification for the activities proposed.

The research program is intended to benefit populations of young women (aged 15–25 years) who are currently having sex with men (or who are likely to do so in the future), and who live in communities in which there are elevated rates of social and health problems among the adolescent and young adult population, and who have had, or are at risk for unintended pregnancy, STDs, using crack cocaine or other illegal drugs, trading sex for money, drugs, or other things, sex with partners who have known risks for HIV infection, running away from home, dropping out of school, becoming involved with the juvenile justice system.

Interventions may target young women as described above, and may also include (1) their male sexual partner(s), (2) other young men in the community who are not necessarily current sex partners, or (3) other important peer, family, or social network members. Research and measurement activities may extend beyond those who directly participate in the intervention. For example, applicants who intervene with young women only may propose to limit research questions and outcome evaluation to the individual-level (e.g., perception of partners' attitude, perceived social norms regarding gender-appropriate behavior, etc.), or they may include assessment of male partners or other peer, family, or social network members not directly targeted by the intervention to examine diffusion effects of the intervention and to further understand contextual factors that affect the sexual risk behavior of young women and their male partners.

Program Requirements

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).

Recipient Activities

1. Develop a theory-based, and empirically supported, conceptual model of heterosexual risk behavior for young women at risk for unplanned pregnancies, HIV and other STDs that focuses on the dynamics of heterosexual relationships and the factors that may contribute to successful risk reduction including comprehensive measures of key intrapersonal, interpersonal, and sociocultural factors that affect sexual relationships.

2. Validate the conceptual model through the development and testing of measures of key interpersonal, intrapersonal, and/or sociocultural influences, and through the answering of specific research questions, such as, but not limited to, the following:

(a) How do women come to understand and interpret partner attitudes toward family planning, contraception, and STD and HIV prevention?

(b) How are reproductive and disease prevention values communicated between young women and their sex partners, and within their social networks?

(c) How is a couple's sexual behavior affected by their agreement or disagreement on goals for childbearing, contraception, and HIV and other STD prevention?

(d) How do changes in a couple's relationship over time affect their sexual behavior, family planning, contraceptive use, and HIV and other STD prevention behavior?

(e) What are the positive and negative influences of a partner's attitude and behavior on sexual risk behavior? How important are partner influences relative to other personal, family, network, or cultural influences?

(f) How can male partners and other social and family network members support young women in achieving proximal pregnancy and disease prevention goals, and more long-term reproductive health preservation goals?

3. Develop and conduct an intervention based on theory and data that will influence specific intrapersonal, interpersonal and sociocultural factors to reduce unprotected sexual intercourse among young women and their male partners. Examples include, but are not limited to, the following:

(a) Providing theory-based training to help young women negotiate sexual risk reduction.

(b) Identifying and enlisting family, peer, and social networks to support and reinforce sexual risk reduction.

(c) Creating and mobilizing new networks of communication, influence, and support concerning sexual risk reduction.

(d) Providing opportunities for acquisition and practice of

communication skills and risk reduction strategies.

4. Measure the success of interventions with targeted populations in comparison to a control/comparison group (or community) with outcome measures of interpersonal, intrapersonal, and sociocultural changes such as, but not limited to, self-reports, observations, and other measures of:

(a) Cognitive, emotional, and behavioral change among individuals,

(b) Interpersonal changes such as changes in distribution of power in sexual relationships, changes in network characteristics or functioning, and

(c) Cultural and normative changes such as changes in content of media messages on reproductive health, changes in distribution of reproductive health services funds, changes in community attitudes, etc.

5. Work with other cooperative agreement recipients and CDC to 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 unplanned pregnancy, HIV, and other STDs among young women at risk. 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.

6. Collaborate and coordinate efforts with appropriate health, substance abuse, youth-service, 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.

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

CDC Activities

1. Host meetings each year to plan the research program and to promote progress toward national objectives.

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

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

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

5. Conduct site visits to assess program progress.

Technical Reporting Requirements

Semiannual progress reports are required and must be submitted no later than 30 days after each semiannual reporting period. The semiannual progress reports of activities conducted and accomplishments during the previous period should include:

1. A brief program description.

2. A comparison of actual accomplishments to goals and objectives established for the 6-month period.

3. Explanations for all goals or objectives either delayed or not accomplished and a plan of corrective action.

4. Documentation of the applicant's ability to conduct the research and intervention activities, including implementation of the intervention and evaluation protocol activities within the required timelines, recruitment and follow-up of required number of participants, recruitment and maintenance of appropriate personnel, and efficient use of funds.

5. Data on participation in intervention and research activities, including numbers of completed baseline and follow-up (if appropriate) interviews, and recruitment and retention rates, should be presented in tabular form for the 6-month period and cumulatively.

6. Activities planned for the next six months to accomplish the goals and objectives, including the following (as appropriate to the design):

a. Procedures and strategies for tracking and contacting the target population for follow-up interviews within the required time period.

b. Projected numbers of baseline and follow-up interviews to be completed.

c. Intervention activities, and projected numbers of participant contacts.

d. Monitoring/quality assurance.

e. Training (if any).

f. Process evaluation (data collection and entry).

g. Outcome evaluation (interview data collection and entry).

h. Plans for data transfer to data management contractor.

i. Qualitative and quantitative data analysis plans (both process and outcome), including amount of staff resources designated for site specific and cross-site data analysis and paper/presentation preparation.

Report for the first 6-month period should detail progress in accomplishing program objectives. The second report should detail progress in the preceding 6 months and summarize the entire year's accomplishments. The final progress report is required no later than 90 days after the end of the project period. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.

An annual financial status report (FSR) must be submitted no later than 90 days after the end of each budget period. The final financial status report is due no later than 90 days after the end of the project period.

An original and two copies of all reports should be submitted to the Grants Management Officer, Grants Management Branch, 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. How the applicant will assess predictors of sexual risk behavior, including the specific research questions that will be addressed and conceptual models used.

2. The design and evaluation of an intervention to reduce unprotected sexual intercourse between young women and their male sex partners.

3. A feasible and timely strategy for disseminating findings from this research to scientific, public health, and community partners.

The application should include a general introduction, followed by one narrative subsection per application content element 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 vita, references, and letters of support, that are appropriate for the appendixes).

A. Significance, Impact, and Theoretical Basis of the Proposed Research

The applicant should clearly describe how the proposed research will advance efforts to prevent unplanned pregnancy, HIV, and other STDs among young women in the U.S. Specifically, the application should describe how existing social and psychological models of sexual behavior change will be expanded or extended to take into consideration the influence of both members of a couple on each other, and

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

Applicants should discuss how the research and intervention is innovative and represents a new approach to the integration and extension of known theoretical models and intervention strategies to reduce unprotected sexual intercourse among young women and their male sex partners.

Applicants should describe what results are expected from the research; the potential limitations of the results given the complexity of the research focus, the target 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 women at risk for unplanned pregnancy, HIV, and other STDs.

B. Research and Intervention Plan

The applicant should describe in detail the proposed research and intervention plan, including:

1. A review of the relevant literature to provide a theoretical, empirical, and programmatic justification for the proposed research.

2. 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.

3. A description of all aspects of the study design and methods, including a detailed description of the targeted population and comparison group and how they will be accessed; the sampling strategy, and if applicable, the randomization strategy; the evaluation design (both process and outcome) and how threats to validity will be handled; the plans for instrument development, pilot-testing, interviewer training, data collection, analysis, interpretation, and quality assurance.

4. A description of the intervention including how theory and past research will be operationalized; and a justification for how and why the intervention can be expected to produce the intended effect. Discuss feasibility of the intervention in the selected setting and acceptability and potential sustainability of the intervention for the targeted population.

5. A description of 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. Discuss how findings could be used to sustain the intervention or replicate it in other settings.

6. Describe the quality assurance monitoring plan for all research and intervention activities.

7. Describe the plans for data management, analysis, and interpretation; highlight how they are innovative (for example, integrate qualitative and quantitative data); and present a realistic and detailed timeline for the generation of papers, reports, and other products that can be used by program planners and policy makers.

C. Research and Intervention Capacity

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

2. Demonstrate the capacity to obtain the participation of, and retain for follow-up if appropriate, adequate numbers of the targeted population for assessment by providing detailed information about the targeted population (characteristics, risk factors, numbers available for intervention in specific settings, etc.), and describe how they will be accessed and previous service or research conducted involving this population (include letters from organizations, journal articles, etc.).

3. 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.

4. Demonstrate the adequacy of the proposed staff 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), and the adequacy of the staff time allocated for specific responsibilities, with at least a 50 percent time Ph.D.-level research director and a 100 percent time project director, through curriculum vita and position descriptions that detail responsibilities. Include a list of all grants and other sources of support (include percent of time on project) for all investigators.

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

6. Provide assurances that the applicant and all members of the applicant's research and intervention team are willing to work closely with other funded sites and CDC, and are willing to modify research questions, sampling plans, instruments, and protocols. The applicant must assure that no organizational or institutional barriers will impede this process or the successful completion of the research and intervention project. Applicant must also state a commitment to participate with other sites and CDC on data analysis, presentation, and publication of research findings.

D. Collaboration

Describe how academic, program, and community partners will participate in developing, conducting, and evaluating the proposed research. Specifically:

1. Describe the involvement of appropriate key organizations, and members of the targeted population (as evidenced by letters of support describing their role in the proposed scope of work, etc.).

2. Define the responsibilities of these other organizations and individuals.

3. Discuss previous work of the proposed collaborators and request evidence of past successful collaboration and commitment to participation in the proposed project.

E. Dissemination and Sustainability

Provide a clear dissemination plan that includes a plan for the timely sharing of findings with local partners; describes efforts that will be made to secure separate funding to continue prevention activities that are proven to be effective in reducing sexual risk behavior; and includes a plan to work with CDC and other sites to ensure that analysis and production of papers, presentations, and reports give priority to findings that can be used to develop national prevention recommendations for young women at risk for unplanned pregnancy, HIV, and other 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. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

H. Women, Racial, and Ethnic Minorities

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.

Typing and Mailing

Applicants are required to submit an original and two copies of the application. The application may not exceed 30 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 index 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 ½'' by 11'' paper, with at least 1'' margins and printed on one side only.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Significance and Impact of the Proposed Research (20 Points)

The extent to which the research proposed will advance efforts to prevent unplanned pregnancy, HIV, and other STDs among young women in the U.S. Specifically, the extent to which:

1. The research proposed will extend or enhance existing social and psychological models of sexual behavior change that take into consideration the influence of both members of a couple on each other.

2. The research and intervention is innovative and represents a new approach to the integration and extension of known theoretical models and intervention strategies to reduce unprotected sexual intercourse among young women and their male sex partners.

3. The research and intervention evaluation will provide results that are scientifically sound, generalizable, and useful for developing national recommendations for reducing unprotected sexual intercourse among young women at risk for unplanned pregnancy, HIV, and other STDs.

B. Research and Intervention Plan (30 Points)

The quality of the proposed research and intervention plan, including:

1. The theoretical, empirical, and programmatic justification for the proposed research.

2. 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.

3. The extent to which the study design and methods, the plans for instrument development, data collection, and analysis are scientifically sound and capable of producing the intended results.

4. 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.

5. The extent to which the intervention implementation process can be measured and findings used to replicate the intervention in other settings;

6. The extent and rigor of the quality assurance monitoring plan for both research activities and intervention activities.

7. The extent to which the plans for data management, analysis, and interpretation are clear and innovative (for example, integrate qualitative and quantitative data) and will result in the timely generation of papers, reports and other products that can be used by program planners and other interested parties.

8. 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 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, and (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.

C. Research and Intervention Capacity (25 Points)

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

2. The applicant's demonstrated capacity to obtain the participation of, and retain for follow-up, adequate numbers of the targeted population for assessment; and the extent of the applicant's familiarity with, access to, and good working relations with, young women at risk (and young men, if applicable), as evidenced by previous service or research involving this population.

3. 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.

4. 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), and the adequacy of the staff time allocated for specific responsibilities, with at least a 50 percent time Ph.D.-level research director and a 100 percent time project director, as evidenced by their curriculum vita and position descriptions.

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

6. The extent to which the applicant is willing to work with other funded sites and CDC to modify research questions, sampling plans, instruments, and protocols, and is committed to working with other sites and CDC on data analysis, presentation, and publication of research findings.

D. Collaboration (15 Points)

The extent to which the applicant includes both academic, program, and community partners in developing, conducting, and evaluating the proposed research. Specifically, the extent to which the applicant has:

1. Involved other appropriate key organizations, and members of the targeted population (as evidenced by letters of support, etc.).

2. Clearly defined the responsibilities of these other organizations and individuals.

3. Previously worked with the proposed collaborators and provided evidence of past successful collaboration and commitment to participation in the proposed project.

E. Dissemination and Sustainability (10 Points)

The extent to which the dissemination plan is clearly articulated and includes the timely sharing of findings with local partners, reasonable efforts to secure separate funding for continuation of effective interventions, and a plan to work with other sites and CDC to ensure that analysis and production of papers, presentations, and reports give priority to findings that can be used to develop national prevention recommendations for young women at risk for unplanned pregnancy, HIV, and other STDs.

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)

The extent to which the applicant adequately describes the procedures that will be used to protect human subjects, and provides assurance to demonstrate that the project will be subject to initial and continuing review by appropriate institutional review committees.

Content of Noncompeting Continuation Applications

In compliance with 45 CFR 74.51(b)(d), 45 CFR 92.10(b)(4) and 92.40(b), 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. E.O. 12372 sets up a system for State and local governments 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 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 305, Mail Stop E–18, Atlanta, GA 30305, no later than 30 days after the application deadline date (the appropriation for this financial assistance program was received late in the fiscal year and would not allow for an application receipt date that would accommodate the 60-day State recommendation process period). 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 department(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 or local health department 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 should include the following:

1. A description of the population to be served.

2. A summary of the services to be provided.

3. A description of the coordination plans with the appropriate State and local health departments.

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

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 individuals 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 committees. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Racial and Ethnic Minorities

The policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) is to ensure that individuals of 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 Alaskan Native, Asian or Pacific Islander, Black, and Hispanic. Applicants shall ensure that 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. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, or sex of participants. 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 Deadlines

Preapplication Letter of Intent

A nonbinding letter of intent-to-apply is required from potential applicants. An original and two copies of the letter should be submitted to the Grants Management Officer, Grants Management Branch, CDC (see Applications for the address). It should be postmarked no later than July 15, 1997. The letter should identify the announcement number, name of principal investigator, and specify the activity(ies) to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information before the application is submitted. Notification may be provided by facsimile or postal mail to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E–18, Atlanta, GA 30305, facsimile (404) 842–6513.

Application

An original and two copies of the application PHS Form 5161–1 (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 305, Mail Stop E–18, Atlanta, GA 30305, on or before August 15, 1997.

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 that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (404) 332–4561. You will be asked to leave your name, address, and telephone number. Please refer to Announcement #774. You will receive a complete program description, 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 Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E–18, Atlanta, GA 30305, telephone (404) 842–6801.

Programmatic technical assistance may be obtained from Christine Galavotti, Ph.D., Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4700 Buford Highway, NE., Mail Stop K–34, Atlanta, GA 30341–3724, telephone (770) 488–5245. The announcement will also be available on one of two Internet sites on the publication date: CDC's homepage at <http://www.cdc.gov>, or at the Government Printing Office homepage (including free access to the **Federal Register**) at <http://www.access.gpo.gov>. Other CDC Announcements are also listed on the Internet on the CDC homepage.

Please refer to Announcement Number 774 when requesting information and submitting an application.

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 25, 1997.

Joseph R. Carter,

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

[FR Doc. 97–17123 Filed 6–30–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Goals for Working Safely With Mycobacterium tuberculosis in Clinical, Public Health, and Research Laboratories; Amendment To Extend Comment Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Extension of request for comments.

A notice requesting comments from all interested parties concerning goals for working safely with *Mycobacterium tuberculosis* in clinical, public health, and research laboratories was published in the **Federal Register** on April 28, 1997 (62 FR 23066).

This notice is amended as follows: On page 23066, first column, under the heading **DATES,** line 8, the date for submitting written comments to this notice has been extended from June 27, 1997, to July 27, 1997.

All other information and requirements of the April 28, 1997, **Federal Register** notice remain the same.

Dated: June 25, 1997.

Joseph R. Carter,

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

[FR Doc. 97–17125 Filed 6–30–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HSQ–243–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Exemption of Laboratories Licensed by the State of Washington

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.