

this mission, seven NLTN offices were established at various sites throughout the nation giving all states and territories access to laboratory training through this Network.

NLTN staff was charged with (1) Assessing the training needs (2) developing programs, (3) delivering training and, (4) evaluating the effectiveness of the training. Staff in the seven offices must meet unique needs in the geographical area for which they are responsible. Assessing need is particularly important because more than 100,000 laboratories are doing 16,380 different tests of 631 analytes. NLTN staff must determine the most efficient and effective means to provide training where the greatest need exists.

Need for training in laboratories may be dependent on where the laboratories are located and what population they serve. For example, small laboratories in physicians' offices (POLs) may have very different needs than large, independent laboratories, hospital or state laboratories. Manufacturers develop different products for laboratories that test in high volumes and can afford very sophisticated equipment than for small laboratories that do a limited number of tests. Education and training of personnel in the laboratories also very considerably. Current training needs are vastly different for people who have complete bachelor's degrees in medical technology or a science and those who have no formal laboratory education.

This information collection request is for clearance of a bank of questions from which NLTN staff may periodically select certain ones to use in survey to assess needs—and for flexibility to develop questions in specified formats to address specific practices related to the many tests available. This will allow the NLTN to focus on the appropriate lab type, target audience and test.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)
Laboratory	2,800	1	0.5

The total annual burden is 1400. Send comments to Desk officer, CDC; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Dated: June 14, 1996.
Wilma G. Johnson,
*Acting Associate Director of Policy Planning
And Evaluation, Centers for Disease Control
and Prevention (CDC).*
[FR Doc. 96-15718 Filed 6-19-96; 8:45 am]
BILLING CODE 4163-18-P

Agency for Health Care Policy and Research
Notice of Health Care Policy and Research; Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of July 1996:

Name: Health Care Policy and Research Special Emphasis Panel.
Date and Time: July 10, 1996, 9:30 a.m.
Place: DoubleTree Hotel, 1750 Rockville Pike, Conference Room TBA, Rockville, Maryland 20852.

Open July 10, 9:30 a.m. to 9:45 a.m.
Closed for remainder of meeting.

Purpose: This Panel is charged with conducting the initial review of grant applications proposing medical effectiveness research. The three main areas of emphasis are: (1) Determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes.

Agenda: The open session of the meeting on July 10, from 9:30 a.m. to 9:45 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C. Appendix 2 and 5 U.S.C. 552b(c)(6), the Administrator, AHCPR, has made a formal determination that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Linda Blankenbaker, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1437 x1603.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 12, 1996.
Clifton R. Gaus,
Administrator.
[FR Doc. 96-15717 Filed 6-19-96; 8:45 am]
BILLING CODE 4160-90-M

Notice of Health Care Policy and Research; Special Emphasis Panel Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of July 1996:

Name: Health Care Policy and Research Special Emphasis Panel.
Date and Time: July 9, 1996, 9:30 a.m.
Place: Agency for Health Care Policy and Research, 2101 E. Jefferson Street, Suite 400, Rockville, Maryland 20852.

Open July 9, 9:30 a.m. to 9:45 a.m.
Closed for remainder of meeting.

Purpose: This Panel is charged with conducting the initial review of grant applications proposing medical effectiveness research. The three main areas of emphasis are: (1) Determining what clinical interventions are most effective, cost effective, and appropriate; (2) methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes.

Agenda: The open session of the meeting on July 9, from 9:30 a.m. to 9:45 a.m., will be devoted to a business meeting covering administrative matters. During the closed session, the committee will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6), the Administrator, AHCPR, has made a formal determination that this latter session will be closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Linda Blankenbaker, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1437 x1603.

Agenda items for this meeting are subject to change as priorities dictate.

Clifton R. Gaus,
Administrator.
[FR Doc. 96-15723 Filed 6-19-96; 8:45 am]
BILLING CODE 4160-90-M

Centers for Disease Control and Prevention
[Announcement 601]
Prevention of HIV Infection in Youth at Risk: Developing Community-Level Strategies That Work

Introduction

The Centers for Disease Control and Prevention (CDC) announces the

availability of fiscal year (FY) 1996 funds for a cooperative agreement program for the prevention of HIV infection in youth at risk.

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 the priority area of Human Immunodeficiency Virus (HIV) Infection. (For ordering a copy of "Healthy People 2000," see the section **"WHERE TO OBTAIN ADDITIONAL INFORMATION."**)

Authority

This program is authorized under Sections 301 and 317(k)(2), of the Public Service Health Act (42 U.S.C. 241 and 247b(k)(2)) as amended.

Smoke-Free Workplace

CDC strongly encourages all 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

Applications may be submitted by public and private, nonprofit and for-profit organizations and governments and their agencies. Thus, universities, colleges, research institutes, hospitals, other public and private organizations, State and local health departments or their bona fide agents or instrumentalities, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- and/or women-owned businesses are eligible to apply.

Each applicant must demonstrate collaboration with community-based organizations (CBOs) that have histories of familiarity with, access to, and success working with the target population. Collaboration with CBOs will be demonstrated through letters from the organizations stating their willingness to participate in the proposed project. It is the intention of this announcement to stimulate collaborative, interdisciplinary research between research institutions and public health agencies and CBOs; therefore, applications by agencies taking the lead with teams composed of collaborators from each of the other entities are encouraged. The application should be submitted by the lead institution, agency, or organization.

Applicants who have conducted formative research on the target population are encouraged to apply.

Note: Organizations described in section 501(c)(4) of the Internal Revenue Code of 1986 that engage in lobbying are not eligible to receive Federal grant/cooperative agreement funds.

Availability of Funds

Approximately \$2.8 million will be available in FY 1996 to fund approximately six awards. It is expected that the average award will be \$500,000, ranging from \$400,000 to \$900,000. Awards are expected to begin on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to five years (two years for all Phase I recipients and three additional years for successful recipients of Phase II. Approximately three Phase I recipients will receive Phase II funding through a competitive announcement). Funding estimates may vary and are subject to change.

Phase II competition will in part include the following factors:

1. Have completed their formative research and summaries, pilot-testing, data reduction, and final Phase I report;
2. Have established access to the target population in sufficient numbers to provide meaningful sample sizes for intervention and control areas;
3. Have demonstrated that their proposed catchment areas are minimally affected by confounding factors of competing interventions and research;
4. Have demonstrated data collection and analysis capacity to execute the protocols for data analysis and evaluation of impact;
5. Be able to implement the common intervention selected through consensus, including having a sufficient number of trained staff to devote full-time to the intervention and;
6. Have written the final draft of at least one publication on Phase I data.

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

Definitions

Youths are defined as persons 15 to 25 years of age. Men who have sex with men (MSM) are men who have sex with men, regardless of their declared sexual identity. Young men who have sex with men (YMSM) are males 15 to 25 years of age who have sex with other males, express intention to have sex with other males, or acknowledge sexual attraction to other males. Communities can be groups defined by behavior (sexual orientation, IV drug use), by

identification (ethnicity, sexual identity), by geographic boundaries, or by places where people are available for education (schools, prisons). Catchment area is the contiguous geographic area that encompasses at least one access site and that is distinct in geography and population membership. Access site is a location within a catchment area where the target population congregates and is available for intervention. Community-level intervention is an approach to HIV prevention that (1) Results from a mobilization of community members and institutions; (2) can be expected to reach a large proportion of the population at risk in their daily setting; (3) may involve the use of outreach and facility-based services; and (4) can be expected to alter individual behaviors and community norms. Community assessment is the systematic collection and critical analysis of data to determine the adequacy and effectiveness of specific services, infrastructure, and formal and informal resources available to a community. Multi-site is defined as the same or similar intervention, sampling methods and measurements used in multiple sites, but does not imply a nationally representative sample of sites.

Purpose

This program is to conduct research that will develop and evaluate approaches to encourage youth who engage in risky behaviors associated with HIV acquisition and transmission to change these behaviors. This program also seeks to develop methods that may build on evaluated, community-level intervention efforts, and where advisable, previous work, but will focus entirely on YMSM, including those who are members of racial or ethnic minorities.

Funds will be used in two phases to develop, implement, analyze, and evaluate an effective community-level behavioral change intervention, with potential for sustainability, to prevent HIV in YMSM who engage in high-risk behaviors related to the acquisition and transmission of HIV.

Phase I of the research program will focus on formative research to characterize populations, identify constraints on and opportunities for behavior change, and identify components of a targeted intervention and determine its feasibility. Approximately six awards will be made for a 12-month budget period within a project period of up to two years.

Phase II of the research program will focus on the implementation of a common intervention protocol, randomization of catchment areas, and

systematic analysis and evaluation of the intervention's impact. Eligible applicants for Phase II will be recipients of Phase I. Phase II will be competitively announced. Approximately three awards will be made for a 12-month budget period within a project period of up to three years.

The intervention for this project will be based on the combined formative research completed by award recipients in Phase I and will be implemented in Phase II. Although CDC is not requiring proposals for Phase II intervention activities at this time, a brief description of Phase II is included here for the applicants' information. In the first eight months of Phase II, recipients will conduct two to three baseline assessments. The recipients then will implement, analyze, and evaluate the impact of the community-level intervention. Examples of behaviors that may be appropriate for the intervention to address are:

1. Maintaining abstinence;
2. Reducing high-risk sexual behaviors among sexually active YMSM and;

3. Using barrier methods when engaging in sexual activity.

By the end of the 5-year project, recipients and participating agencies will produce guidelines for technology transfer of the intervention to control sites and other interested organizations. Recipients are also encouraged to assist participating agencies in developing the skills to sustain successful intervention components after the study.

Applicants must agree to follow the intervention and implementation protocol developed jointly by recipients with input from CDC project officers. It is anticipated that the Phase II protocol for intervention, analysis, and evaluation will be a common protocol with many components that are applicable to all study areas. Such a protocol also will permit tailoring to individual communities to accommodate variations (e.g., cultural, geographic) among them. YMSM representing diverse segments of the target population should participate actively in research and intervention design and review in Phase I and Phase II.

Program Requirements

Work performed under this agreement will be the result of collaborative efforts among recipients, resulting in common protocols and methods across sites. Individual recipients will be responsible for research design, intervention development and implementation, data collection and analysis, and publication. CDC will coordinate these collaborative

efforts and expects to work closely with each award recipient.

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

A. Recipient Activities

1. Characterize the HIV risk of the target population and any subgroups in at least two matched catchment areas and prioritize the subgroups according to probable risk and other criteria.

- a. The recipient will have proposed in their application at least two catchment areas that are matched in:

- (1) Population demographic characteristics;
- (2) Risk behaviors;
- (3) Population sizes;
- (4) Numbers of the same types of access sites (e.g., bars, bookstores, parks) and;
- (5) Other relevant variables.

- b. During Phase I, the recipient will further study the proposed catchment areas to finalize selection of catchment areas for conducting the Phase II intervention:

- (1) The selected catchment areas must be geographically discrete and have less than 10% overlap of the target population in each area.

- (2) The catchment areas will be places where (a) hundreds of eligible subjects can be reached, (b) that have an estimated high HIV seroprevalence rate among youth, and (c) that, ideally, have minimal confounding factors introduced by ongoing or proposed HIV prevention efforts.

- (3) After Phase I, the catchment areas will be randomly assigned to a study condition—the intervention or comparison.

- c. The recipient will characterize the target population and any of its subgroups in each catchment area.

- d. The recipient will document, using whatever qualitative and quantitative data are available, that the targeted populations and any of their subgroups in the selected catchment areas are at risk for HIV infection and will prioritize the subgroups according to the relative risk.

- e. The recipient will justify its identifications of catchment areas, access sites, subgroup, and YMSM accessible at those sites in terms of the potential to address the research goals of this program announcement and in terms of ultimately translating the research findings into HIV prevention activities among the target populations.

By the end of Phase I, the recipient will have finalized the selection of a

minimum of two matched catchment areas and conducted research to justify the selection of catchment areas, determine the demographic characterization of the target population and any subgroups, and justify selection of a particular subgroup. The recipient also will have identified sites within the catchment areas where YMSM are accessible both for interviewing and for the intervention and will have secured commitment of collaborating organizations in these catchment areas and access sites to participate in Phase II and to be randomly assigned to a research condition.

2. Conduct qualitative and quantitative behavioral research of YMSM at risk in the study catchment areas.

- a. The recipient will build a multi disciplinary research team and program support capability:

- (1) A multi disciplinary team should be assembled with the appropriate expertise to undertake Phase I activities. Such a team will include experienced senior researchers, technical staff, and support staff and will be led by behavioral scientists;

- (2) The team will have CBO members or collaborators and;

- (3) The team will involve persons from the target population in research and intervention design.

- b. The recipient will develop a common protocol to conduct the behavioral research:

- (1) The research will include sexual behavior, partner characteristics, social networks, substance abuse behavior, trading sex for money or drugs, perceptions of social norms, attitudes, self-efficacy, perceptions of current HIV interventions, health-care-seeking behaviors, health-information-seeking behaviors, developmental issues influencing the above, and structural influences on behavior to identify which segments or subgroups of YMSM would be best served by the intervention;

- (2) Questionnaires and survey instruments will be constructed at a literacy level appropriate to the target population;

- (3) The research will involve members of the targeted population and other community partners in determining which types, designs, and deliveries of interventions would be (a) best accepted and most influential in their communities, (b) most likely to work synergistically with other community efforts, (c) most likely to stimulate changes in community norms, and (d) most likely to be sustained.

The recipient will demonstrate further understanding of factors influencing the

behavior of YMSM, document the participation of the target population in the formative research design and their contribution in development of the intervention to be pilot-tested, and propose a sound theoretical and data-driven approach to influencing behaviors of YMSM.

3. Use an existing or develop and conduct a community assessment and document HIV interventions and research involving the target population in the catchment areas.

a. The purpose of the community assessment is to determine:

(1) Community-wide needs for HIV/AIDS prevention among YMSM;
(2) Existing and potential capacity;
(3) Available resources and;
(4) Current prevention efforts and further understand key issues (e.g., identifying access sites, influences of political climate) relevant to intervening with the target population.

b. Recipients will:

(1) Review community needs assessments and community planning documents and;
(2) Summarize what is known about the proposed communities, and if necessary, recipients will develop, in collaboration with CDC and other recipients, a common assessment instrument to be implemented in Phase I.

c. Part of the community assessment must include:

(1) The current activities and functions of the health department's HIV program in the catchment areas;
(2) Implications of the formative research and potential interventions on those activities and functions and;
(3) The HIV community planning priorities related to YMSM.

The recipient will have produced a summary synthesizing knowledge of the community's HIV needs and planning, participated in cross-site implementation of the assessment instrument, as appropriate, and analyzed and reported the results of the assessment.

4. In partnership with persons from relevant communities, other recipients, and CDC project officers, develop an appropriate community-level intervention to reduce HIV risk behaviors in the target population.

a. Recipients will collaborate in developing a common intervention and research protocol for all recipients to implement in Phase II:

(1) The basis for the intervention should include (a) the recipient's experience with the target population, (b) formative research from Phase I, and (c) a review of current primary prevention strategies and research;

(2) The intervention selection should be a logical result of program requirements 4.a.(1)(a-c) above, but not be limited to their exclusive consideration;

(3) The intervention approach should be culturally sensitive, developmentally appropriate, and suitable for the target population's literacy level and should stimulate community action, mobilization, and adoption of a supportive environment and community norms and;

(4) An effective community-level intervention for these youth may combine several elements, e.g., (a) efficient targeting of outreach, (b) development of an environment supportive of long-term HIV/AIDS risk reduction, and (c) links to local resources that encourage healthy behaviors.

b. Local resources that encourage healthy behaviors may include:

(1) STD treatment and prevention services;
(2) Substance abuse treatment facilities;
(3) Shelters or drop-in facilities for runaway and homeless youth;
(4) Mental health clinics;
(5) Other health care facilities such as community health centers;
(6) Facilities "without walls" that provide outreach to street youth and;
(7) Providers of foster care and supervised independent living.

c. Recipients will participate in monthly conference calls with CDC project officers and other recipients.

d. Each recipient will travel to Atlanta or another location and participate with other recipients and CDC representatives in four meetings during Phase I. At one of these meetings, the Phase II intervention design and protocols for pilot testing will be established.

e. The protocols for the Phase II intervention will be finalized at a later meeting.

At the end of Phase I, the recipient will have summarized activities and participated in the development of a common intervention, research protocol, operational plan, process and impact objectives, analysis strategies, and evaluation instruments for Phase II.

5. Through pilot-testing, determine the feasibility and sustainability of implementing the proposed intervention, including cost, acceptance, and participation by the target population.

a. During the second year of Phase I, components of the collaboratively developed intervention will be pilot-tested by the recipients to determine modifications in design,

implementation, and other relevant considerations.

These considerations may include:

(1) The likelihood that the intervention will change behavior among YMSM;
(2) The probable level of acceptability of the intervention to the target populations and to the communities around the intervention access sites;
(3) The recipient's potential for recruiting, training, and retaining intervention workers;
(4) The acceptability of intervention workers to the targeted population;
(5) The likelihood that the intervention will stimulate changes in community norms;
(6) Clarity of or difficulties with data collection instruments;
(7) The projected overall cost of the intervention component;
(8) The likelihood that the intervention can be maintained during the entirety of Phase II;
(9) The likelihood that successful components of the intervention will be institutionalized in the community after Phase II and;

(10) More effective ways for project staff to systematically focus resources (i.e., financial and personnel).

b. Recipients with substantial, previously collected formative data from their finalized catchment areas may pilot-test potential intervention components in the first year of Phase I instead of collecting additional formative data.

Recipients will have conducted and reported pilot-test results of one or more components of the common intervention. The primary expectation at the completion of Phase I is a finalized common protocol for implementation, analysis, and evaluation, including validated instruments, for a community-level intervention that can reasonably be expected to influence behaviors related to HIV transmission in the study population.

6. Recipients and CDC project officers collaboratively develop a common research protocol for the proposed intervention to be conducted during Phase II

a. The recipients, in collaboration with CDC, will select and develop a common research protocol, including:

(1) A common research design;
(2) Operational plan and;
(3) Analysis and evaluation methods and instruments.

b. The protocol will include a within-catchment-area sampling strategy and mechanisms for obtaining the consent and protecting the confidentiality of study subjects.

c. Analysis and evaluation plans will be developed concurrently with intervention plans.

d. Recipients will establish a set of outcomes to determine the effectiveness or impact of the intervention that are measurable, valid, and reliable in terms of behavioral and social science theories. It is expected that the evaluation will measure changes in behaviors, intentions, and attitudes and the target population's awareness and acceptance of the intervention.

e. To evaluate a common intervention, the recipients and CDC project officers must:

- (1) Reach consensus concerning the specific outcomes to target;
- (2) Develop methods of measuring these outcomes, including common data collection instruments and;
- (3) Pilot-test measures and instruments.

Recipients will have established a common research protocol, operational plan, process and impact objectives, and instruments for systematically analyzing and evaluating the intervention in Phase II. Each recipient must agree, if selected for continuation into Phase II, to implement this common protocol and accept randomization of their selected catchment areas (as specified above).

7. Manage, analyze, and interpret data.

a. Data from the Phase I activities must be collected, managed, and stored securely and confidentially.

b. Recipients will use common computer and data management systems.

c. Recipients will be primarily responsible for site-specific analyses.

d. Recipients will share data for aggregate analyses with CDC project officers.

Recipients will have common computer and data management systems and will have submitted the cleaned data on their intervention trials to CDC project officers.

B. CDC Activities

1. Host a meeting of the recipients to plan the research program (e.g., the format for community assessments). CDC will host approximately three additional meetings of recipients during Phase I to promote progress toward national objectives.

2. Act as mediator on the recipients' collaborative design or selection of the assessment plan and instruments, research protocol, operational plan, objectives, analysis strategies, and evaluation instruments.

3. Provide technical assistance on pilot testing the common intervention, or elements thereof, and on tailoring the

collaboratively designed, common intervention for local applications.

4. Provide scientific and technical coordination of the general operation of this HIV prevention project and of the specific Phase I activities in order to keep all recipients on track with the common protocols and their timelines.

5. Conduct the random selection of intervention and control catchment areas among those presented by each recipient, according to a randomization protocol collaboratively determined by the recipients.

6. Coordinate cross-site aggregation of data and its analysis.

7. Conduct site visits to assess program progress and mutually solve problems, as needed.

At approximately month 12 of the project, recipients and CDC project officers will meet to design the common intervention and pilot tests of its components. At approximately month 20 of the project, recipients and CDC project officers will meet to finalize the common intervention for Phase II. At approximately month 22 of the project, applications for a competing continuation award for the implementation and evaluation of community-level intervention (Phase II) will be due. Supplementary guidance for Phase II awards will be provided to the recipients of Phase I awards.

Evaluation Criteria

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

1. Applicant's Team (15 points)

The extent to which all items in the application content element are addressed, including the extent to which the applicant has:

- a. Involved other key organizations on the project team;
- b. Clearly defined the responsibilities of these other organizations;
- c. Involved team members in planning and developing the application and demonstrated their commitment to the project (as evidenced by letters of support or memoranda of agreement) and;
- d. Previously worked with other team members, including potential CBO collaborators if they are not part of the team.

2. Research and Intervention Capability (20 points)

The extent to which all items in the application content element are addressed:

- a. Capacity of the applicant research team to conduct the proposed research as evidenced by their previous related research;

b. Experience with multisite research designs and formative research on MSM;

c. Extent of the team's familiarity with, access to, and good working relations with MSM, as evidenced by service or research involving this population and;

d. Capacity of the team to conduct behavioral interventions as evidenced by description of their previous experience.

3. Identification of Catchment Areas (20 points)

The extent to which all items in the application content element are addressed:

a. Extent to which the catchment areas meet matching criteria (e.g., matched population demographics, risk behaviors, population sizes that are similar and of sufficient size, access sites), and the extent to which the matching was based on available data;

b. Extent to which the target populations within the catchment areas have similar rates of HIV infection and the extent to which the rates are based on available data and;

c. Thoroughness of description of potential conflict between the proposed research and other research or prevention efforts in the catchment areas.

4. Proposed Research Plan—Formative and Intervention (25 points)

The extent to which all items in the application content element are addressed:

a. Quality of the proposed formative research plan, sampling strategies, sample size estimates, power analysis, and mechanisms to obtain subjects' consent and protect their confidentiality;

b. Appropriateness of the theoretical bases for the proposed intervention;

c. Quality of the type of multi-site intervention proposed and its likelihood to yield new insights on opportunities for long-term risk reduction among the targeted population and;

d. Feasibility of the strategy to involve the target population and affected communities in the research and intervention design and to inform them of research results:

(1) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation;

(2) The proposed justification when representation is limited or absent;

(3) A statement as to whether the design of the study is adequate to measure differences when warranted and;

(4) 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.

5. Project Management (20 points):

The extent to which all items in the application content element are addressed:

a. Adequacy of staffing to carry out proposed activities (i.e., sufficient in number, percentage of time commitments, behavioral scientists in key project positions, and qualifications), as evidenced by their curriculum vitae and position descriptions;

b. Adequacy of facilities, data processing and analysis capacity, and systems for management of data security and participant confidentiality and;

c. Extent to which the applicant demonstrates assurance of compliance with the multisite research requirements (e.g., randomization of catchment areas and common protocol, data collection, and computer and data management systems).

6. Budget (Not scored)

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

7. Human Subjects (Not scored)

The applicant must clearly state whether or not human subjects will be used in research.

Funding Preferences

CDC's intention is to achieve a long-term health benefit for youth at risk for HIV infection. This announcement is exclusively for proposals that address HIV risk reduction for YMSM. Consideration will be given to obtaining diversity of target population subgroups and geographic representation among proposals selected for funding. YMSM of color are of particular interest.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) 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 Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E15, Atlanta, GA 30305, no later than 30 days after the application deadline (the appropriation for this financial assistance program was received late in the fiscal year and would not allow for an application receipt date which would accommodate the 60-day State recommendation process period). The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to the CDC, they should forward them to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E15, Atlanta, GA 30305. This should be done no later than 30 days after the application deadline date. The granting agency does not guarantee to "accommodate or explain" for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program 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 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 Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.941.

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. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) 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, Alaskan Native, Asian, 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 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 Deadlines

1. Preapplication Letter of Intent

A non-binding 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 Branch, CDC (see "Applications" for the address). It should be postmarked no later than July 19, 1996. 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 prior to application submission.

2. Applications

An original and two copies of the application PHS Form 5161-1 (OMB Number 0937-0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-15, Atlanta, GA 30305, on or before August 21, 1996.

3. Deadlines

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

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the 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.)

B. Applications that do not meet the criteria in 3.A.1. or 3.A.2. 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 and will need to refer to Announcement 601. 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 Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-15, Atlanta, GA 30305, telephone (404) 842-6634, email: <asm1@opspgo1.em.cdc.gov>. Programmatic technical assistance may be obtained from Robert Kohmescher, Division of HIV/AIDS Prevention, National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-44, Atlanta, GA 30333, telephone (404) 639-8302, email: <rnk1@cidhiv2.em.cdc.gov>.

Please refer to Announcement 601 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.

Internet Home Page

The announcement will be available on one of two Internet sites on the

publication date: CDC's home page at <<http://www.cdc.gov>>, or at the Government Printing Office home page (including free access to the Federal Register) at <<http://www.access.gpo.gov>>.

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

Dated: June 13, 1996.

Joseph R. Carter,

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

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Health Resources and Services Administration

Maternal and Child Health Services; Federal Set-Aside Program; Continuing Education and Development Cooperative Agreements

AGENCY: Health Resources and Services Administration (HRSA) DHHS.

ACTION: Pre-application technical assistance telephone conference.

SUMMARY: The HRSA is conducting a pre-application technical assistance telephone conference concerning the fiscal year 1996 funding available under Public Law 104-134 for Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS) Continuing Education and Development (CED) cooperative agreements. An Availability of Funds notice for these CED cooperative agreements was published in the Federal Register on April 26, 1996 at 61 FR 18613. These CED cooperative agreements are intended to support national education, information, and public policy projects in maternal and child health. Two categories of CED cooperative agreements will be awarded this year: 1 concerned with resource, educational and analytic activities; and the other concerned with population-focused analytic and related activities.

PURPOSE: To encourage and stimulate development of high quality applications. The telephone conference will offer programmatic and technical assistance and an overview of the requirements for funding projects in both categories. Further, it will provide an opportunity for prospective