Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, on or before March 31, 1998.

1. Deadline

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

A. Received on or before the deadline date, or

B. Sent on or before the deadline date and received in time for submission for the review process. 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.

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director, and telephone number.

Where to Obtain Additional Information

To receive additional written information, call 1–888-GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 98018. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE, Room 300, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6796 (Internet address lgt1@cdc.gov).

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 98018 when requesting information and submitting an application.

Technical assistance on CLPP program or Part C. activities may be obtained from Claudette A. Grant, Acting Chief, Program Services Section, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop F–42, Atlanta, GA 30341–3724, telephone (770) 488–7330 (Internet address cag4@cdc.gov).

Technical assistance on CBLS program activities may be obtained from Sharunda D. Buchanan, Ph.D., Epidemiologist, Surveillance and Programs Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop F–47, Atlanta, GA 30341–3724, telephone (770) 488–7060 (Internet address sdb4@cdc.gov).

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) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: January 27, 1998.

Joseph R. Carter,

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

Appendix A: Background on CDC's estimate of number and proportion of children at high risk for lead exposure by state.

To provide states with general guidance about the appropriate amount of funding to request under this Program Announcement, CDC estimated the number and percentage of children with EBLLs for each state. CDC used a logistic-regression model to estimate the contribution of four major risk factors to the probability that an individual child would have a blood lead level (BLL) of at least 10 µg/dL. The selected risk factors were based on data from Phase 2 of the Third National Health and Nutrition Examination Survey (NHANES III, Phase 2) and included the age and race of children, age of housing, and family income. The model established a relative contribution or ''coefficient'' for each of these factors. These coefficients were then applied to the relevant categories of 1990 census data for each state to produce an estimate of both *the number* and *the percentage* of children with elevated BLLs in the state.

CDC's purpose in estimating the number and percentage of children with EBLLs in each state is to approximate the level of effort that may be required to provide prevention services to the entire population of a state. In accordance with this purpose, CDC adjusted the level of effort projected for state-level CLPP Programs in states with one or more locales currently funded under this grant program.

To derive the funding category for each state, CDC gave twice as much weight to the estimated percentage of children with elevated BLLs as to the estimated number of children with elevated BLLs.

Note: The categorization scheme developed for use in this Program Announcement is likely to be of only limited usefulness for other purposes. The use of an approximation is necessary because of the wide variation among states in the extent to which their pediatric populations are exposed to lead.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 813]

Research Studies Evaluating Demonstration Projects on Feasibility of STD Treatment for HIV Prevention in the United States

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds for a cooperative agreement program for demonstration projects on the feasibility of STD treatment for HIV prevention.

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 HIV Infection. (To order a copy of ''Healthy People 2000,'' see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**

Authority

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

Applicable program regulations are set forth in 42 CFR Part 52, entitled ''Grants for Research Projects.''

Smoke-Free Workplace

CDC strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive

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

Eligible Applicants

Eligible applicants are the direct recipients of Federal Sexually Transmitted Disease/Accelerated Prevention Campaign (STD/APC) project grants or HIV Prevention cooperative agreements. Eligibility is further limited to areas with a gonorrhea case rate of more than 200 per 100,000 or a syphilis case rate of more than 9 per 100,000 (based on National Surveillance Data) for calendar year 1996. The HIV prevention program and STD prevention program within the same locale must collaborate with each other and submit one application. These areas are: Alabama, Arkansas, Baltimore, Chicago, Delaware, Georgia, Louisiana, Maryland, Mississippi, North Carolina, Philadelphia, San Francisco, South Carolina, Tennessee, Virgin Islands, and Washington, D.C. These applicants have access to STD clinic and other clinic populations at risk for HIV and other STDs and have continuing high incidence of syphilis or gonorrhea.

Availability of Funds

Approximately $400,000 is available in FY 1998 to fund up to two awards for demonstration projects on the feasibility of STD treatment for HIV prevention. It is expected that the average new award will be approximately $200,000 and will begin on or about April 1, 1998. Awards will be funded for a 12-month budget period within a project period of up to 2 years. Funding estimates are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Use of Funds

Funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant State or local health department funds or for inpatient care, medications, or construction.

Restrictions on Lobbying

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

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act (Pub. L. 105–78) states in Section 503(a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative 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 or any State legislature, except in presentation to the Congress itself or any State legislature. 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

The AIDS epidemic continues in the United States with over 548,102 cases of AIDS, including 78,654 cases in females and 7,296 cases in children reported to the CDC as of June 30, 1996. More than 275,000 persons are reported to be living with HIV infection. Both HIV cases and HIV-associated deaths are expected to continue to increase over the next decade. Surveillance data indicate that heterosexual transmission accounts for an increasing number of new infections in the U.S. Among women, heterosexual transmission was the most common exposure category for new cases of AIDS reported in 1995–96, accounting for 41 percent of cases. In addition, African Americans, Hispanics, women, adolescents, and persons living in the Southeastern U.S. are increasingly represented in both AIDS cases and new HIV infections.

Current evidence suggests that the growth in the heterosexual HIV epidemic, particularly among the most vulnerable populations is, in part, fueled by other STDs that increase transmission efficiency. STDs in the HIV-uninfected increase their susceptibility to HIV; STDs in the HIV-infected increase their likelihood of transmitting HIV to others. Studies have demonstrated the increased risk of HIV seroconversion to be associated with both genital ulcer disease (GUD) and non-ulcerative STDs. HIV transmission has been associated with concurrent infection with syphilis, herpes, chancroid, gonorrhea, chlamydia, or trichomoniasis. STDs increase both the prevalence of HIV shedding and the magnitude of HIV RNA in semen and cervico-vaginal secretions. Treatment of the STD reduces the prevalence and magnitude of viral shedding. For example, gonococcal infection increases quantitative shedding of HIV RNA among men by about 10-fold, and treatment restores HIV shedding to near baseline levels. Similar effects have been demonstrated in HIV infected women with gonorrhea, chlamydia and cervico-vaginal ulcers. The Mwanza trial, which randomized communities in rural Tanzania to either their existing standard of care or an intervention that established an infrastructure to diagnose and treat STDs, found a 42 percent reduction in HIV incidence over 2 years in the intervention communities. Sexual behavior and condom use remained unchanged in the communities. Thus, there is compelling individual and community-level evidence that treating STDs can decrease HIV transmission.

Despite sound scientific evidence for treating STDs to prevent HIV, the question remains how best to structure such an intervention in the U.S. To effectively target STD treatment for HIV prevention in the U.S., an intervention must target populations with a high incidence of STDs and HIV. Because STDs increase both infectivity and susceptibility, detection and treatment should target both HIV-infected and HIV-uninfected persons. These projects will focus on both persons infected with STDs who are reached by the health care system but not diagnosed and treated (e.g., patients in clinical situations who do not receive STD screening, diagnosis and treatment), and on persons not reached by the health care system (e.g., because of asymptomatic infection or problems of accessing health services). In this program we are particularly interested in structural or other interventions aimed at changing the environment. An intervention might include such program elements as referral of HIV-infected and HIV-uninfected-at-risk persons for STD care (e.g., screening, diagnosis and treatment for STDs), increasing access to STD care, promoting risk assessment and screening of persons asymptomatically

infected with STDs, diagnosing symptomatic STDs, ensuring effective treatment and follow-up for STDs, including STD risk-reduction counseling, and partner management for persons with STDs. Because populations-at-risk may access health care settings that are not providing the full array of services, study sites might include health care settings that serve those at high risk. Additionally, since populations-at-risk may not access health care, study sites might also include non-health care venues where high-risk persons may be found.

The National Center for HIV, STD, and TB Prevention (NCHSTP) goals are to:

1. Increase public understanding of, involvement in, and support for, HIV, STD, and TB prevention.

2. Ensure completion of therapy for persons identified with active TB or TB infection.

3. Prevent or reduce behaviors or practices that place persons at risk for HIV and STD infection or, if individual is already infected, place others at risk.

4. Increase individual knowledge of HIV serostatus and improve referral systems to appropriate prevention and treatment services.

5. Assist in building and maintaining the necessary State, local, and community support infrastructure and technical capacity to carry out the necessary prevention programs.

6. Strengthen current systems and develop new systems to accurately monitor the HIV epidemic, STDs, and TB, as a basis for assessing and directing prevention programs.

Purpose

The purpose of this program is to evaluate the feasibility of establishing an HIV prevention program in the U.S. that incorporates effective STD screening, diagnosis and treatment, in addition to existing HIV prevention services. Following the identification of existing problems in HIV and STD services, those problems will be prioritized, a protocol will be designed and implemented in a pilot fashion to establish the feasibility of a health service intervention package (focusing on STD treatment), and a set of evaluation tools will be developed to measure the intervention's effectiveness. The demonstration projects will likely form the basis for an expanded future multi-site initiative, and provide important information on such operational and evaluation issues as implementation, longitudinal follow-up, data collection, and assessment of outcomes.

This project is conceived as a pilot effort to assess the feasibility and likely prevention effectiveness of improving access to, and the quality of, STD services for heterosexuals at risk of transmitting HIV and of becoming infected with HIV. This project will describe the feasibilities and barriers to improving and better linking STD diagnostic and treatment services and HIV counseling, testing and treatment services within a variety of settings (e.g., drug treatment sites, STD clinics, HIV counseling and testing sites, prenatal and family planning clinics, correctional facilities including juvenile detention facilities, emergency medical and urgent care facilities, adolescent clinics, school clinics, primary care settings in the private sector, community health centers, existing outreach settings, and potential new outreach settings).

In a defined population where high levels of HIV and STD coexist, this project will have three phases consisting of: (I) An assessment and prioritization phase; (II) an intervention and protocol development phase; and (III) an implementation and evaluation phase.

In Phase I (to be accomplished in the first year of the project), a community-based assessment will be conducted to determine who is at highest risk within the community (i.e., who has HIV and STD, and who has STD and is at risk for acquiring HIV), and how best to reach them. This phase would focus on a review of the epidemiology of HIV and STD trends in the community, on identifying where high-risk persons are currently accessing health care and other social services, what types of services are available (e.g., screening, diagnosis and treatment, and counseling), and what are the gaps in available services. This assessment could draw on existing data (e.g., through HIV community planning data collection) or on newly collected data, and may include data derived from public and private sources of care. Arising from this assessment, a local prioritization process would be used to develop Phase II activities. If most high-risk persons are utilizing health care services but are not being screened, diagnosed, or treated, then interventions will focus on improving the quality of STD care (increasing screening and treatment in existing sites and developing referral networks). If high-risk persons are not accessing health care (for reasons including: asymptomatic infections, lack of knowledge about STD status and need for care, perceived or actual barriers to health care, etc.), then interventions will focus these specific problems and include establishing new opportunities for provision of services to expand access and utilization (e.g., increasing screening and health services at correctional facilities, drug treatment centers, or outreach settings).

In Phase II (to be accomplished by the end of the first year of the project, with the exception of developing and testing the evaluation criteria which is expected to extend into the second year of the project), the intervention and protocol development phase, interventions will be developed to address the specific priority needs. Following development of the intervention, a study protocol will be designed to test the feasibility, acceptability, operational requirements of the interventions, and to develop an evaluation plan including appropriate process and outcome measures for the interventions. The protocol will include choice of sites, implementation methods, use of comparison groups, and details of the evaluation plan.

In Phase III (to be accomplished by the end of the second year of the project), the implementation and evaluation phase, the model intervention(s) will be implemented and evaluated in a pilot feasibility study.

Program Requirements

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

A. Recipient Activities

1. Collaborate on Study Design for the Three Phases: Recipients will meet together with CDC to discuss potential study designs and formative research required to develop the study protocol, process, and operations procedures.

2. Collaborate with Other Recipient and CDC During the Three Study Phases: Collaboration will begin with approaches to study design aimed at content, operations, and process of ultimately conducting the three study phases. Collaboration will include (a) communication with CDC staff and the other recipient, and (b) development of common study protocols, common data collection instruments, common specimen collection protocols, and common data management procedures. Recipients will collaborate with each other in all quality control procedures, and in regularly scheduled meetings and conference calls.

3. Conduct Productive and Scientifically Sound Studies: Recipients will identify, recruit, obtain informed

consent forms, and enroll and follow to completion, a minimum of 500 participants as determined by the study protocol and the program requirements. Recipients will perform laboratory tests as determined by the study protocol, and will follow study participants over time as determined by the protocol.

4. Share Data and Specimens: Recipients will share data and specimens (when appropriate) with CDC to answer specific research questions.

5. Collaborate on Publication of Results: Recipient researchers will work closely with CDC staff to develop at least one publication recording results from both sites for a peer-reviewed journal on the study findings. Recipients will also, as appropriate and relevant, develop secondary study hypotheses or site-specific hypotheses and for these, analyze data gathered over the course of the study and in collaboration with CDC staff, present and publish data.

Recipient Activities Specific to the Study Phases Will Include:

During Phase I (assessment and prioritization):

6. Identify Those with STDs (among HIV-infected and HIV-uninfected persons): Within a defined population or geographic area, existing data will be reviewed and new information may be obtained through surveys to determine the extent of STDs and HIV in a study area, the demographic characteristics of these populations of infected persons, and trends in the epidemiology of STD and HIV. The focus should be on persons at risk for acquiring STDs heterosexually.

7. Assess How Good the Current Health Care System Is at Reaching and Providing Care for HIV and STD Infected Populations: This activity will include determining where the STD infected population are getting care, and what care they are getting (e.g., type and quality of care), what services are actually available at the site to which they are referred, where they are getting other services (e.g., social services, drug treatment), and where else they might be found (e.g., correctional facilities). Determine what can be done to increase the numbers of infected (asymptomatic or symptomatic) persons who are diagnosed and treated for STDs within the existing organizational infrastructure. (This work could be done through individual and community level analysis, including site surveys, and interviews with at-risk persons (HIV/STD infected or uninfected) and service providers.)

8. Identify and Prioritize Needed Services and the Venues for These Services: Evaluate the opportunity for improving the quality of existing services. If additional services are needed, should they be through direct on-site provision or via referral? If referral, how can linkages be developed between sites to better coordinate service delivery? (This work could be done through site observations, in-depth interviews with community members and service providers, literature review on direct service vs. referral models vs. other approaches to coordinated service delivery.)

9. Identify Important Barriers, Including Patients' and Potential Patients' Perceptions of the Barriers, for Those with STDs (HIV-infected and HIV-uninfected) to Access Needed Services: Determine what can be done to increase the numbers of symptomatic infected persons diagnosed and treated, and to decrease the time it takes to receive diagnostic and treatment services within the existing organizational infrastructure. Determine what can be done to increase the numbers of asymptomatic infected persons screened, diagnosed and treated. (This work could be done through individual interviews and focus groups with at-risk (HIV/STD infected or uninfected) persons, and with health and social service providers and community planners and community-based organizations.)

During Phase II (intervention and protocol development):

10. In Collaboration with Other Recipient, Design Model Intervention(s) Based on the Specific Needs, as Identified and Prioritized in Phase I.

11. In Collaboration with Other Recipient, Develop a Protocol to Implement and Evaluate the Intervention(s) that Will Include Specific Outcome Measures.

Phase III (implementation and evaluation):

12. Implement and Assess the Feasibility of the Intervention(s) to Improve Delivery of and Access to High Quality HIV/STD Services.

13. Develop, Implement, and Test Evaluation Techniques for Assessing Outcomes of a Future, Full Scale Demonstration Project: Explore the use of behavioral outcomes, biological disease-related outcomes (incidence of STD/HIV), and health services measures (such as cost, utilization, access).

B. CDC Activities

1. Provide Technical Assistance and Coordination: CDC staff may assist in the design and conduct of the research and provide coordination of the project. The final design will be determined by a collaborative process.

2. Provide Scientific Expertise: CDC staff will provide current scientific and programmatic information relevant to the project, and may provide technical assistance in the design and conduct of the research (including plan, operations, and evaluation) throughout the project. CDC staff will assist in designing a data management system and may coordinate research activities among the different study sites. CDC staff may also provide technical guidance in the development and dissemination of study protocols, consent forms, and questionnaires.

3. Analyze Study Data and Coordinate Publication: CDC staff may assist in the analysis of data gathered over the course of the study in each site and in cross-site comparisons and may assist the recipients to develop at least one overall publication describing the project results.

4. Share Data and Specimens: CDC staff may assist in the dissemination of study results and distribution of specimens.

5. Monitor and Evaluate Scientific and Operational Accomplishments of the Project: This will be accomplished through periodic site visits, telephone calls, and review of technical reports and interim data analysis.

Technical Reporting Requirements

An original and two copies of semi annual progress reports must be submitted no later than 30 days after the end of each 6-month budget period. An original and two copies of a financial status report (FSR) are required no later than 90 days after the end of each budget period. A final progress report and FSR are due no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Application Content

Applications must be developed in accordance with PHS Form 5161–1 (OMB Number 0927–0189), information contained in the program announcement, and the instructions and format provided below.

Applicants are required to submit an original and two copies of the application. Number each page clearly and sequentially, and provide a complete index to the application and its appendices. The original and each copy of the application set must be submitted UNSTAPLED and UNBOUND. All material must be typewritten, double spaced, with unreduced type on 8½″ × 11″ paper, with at least 1″ margins, headings and footers, and printed on one side only. Materials which should be part of the

basic application will not be accepted if placed in the appendices. The application should not exceed 25 pages (exclusive of official PHS application pages and relevant attachments).

Applicants for demonstration projects on the feasibility of STD treatment for HIV prevention must demonstrate in the application an ability to access persons infected with STDs or HIV, and persons at high risk for acquiring STDs or HIV. Applicants must also demonstrate an ability to provide appropriate HIV and STD prevention counseling and HIV and STD testing for persons with STDs or at risk of acquiring STDs. In addition, applicants must demonstrate an ability to enroll at least 500 participants per year, of whom at least 35 percent are women. Applicants must demonstrate high prevalence of STDs (>15 percent) and high prevalence of HIV (>2 percent) in STD clinic settings, an ability to complete high rates of participant follow-up, collection and handling of laboratory specimens, and collection of other relevant data. Applicants must demonstrate cost-efficient local availability of staff to complete data entry and data management. Applicants must be willing to participate collaboratively with each other and with CDC in conducting this research study.

The application must address the following:

1. Background

a. Describe the STD clinical and preventive health services available in the community through both public and private sources of care, including current collaboration between STD and HIV prevention programs. Describe availability of STD services in HIV counseling and testing (C & T) sites.

b. Describe the epidemiology of HIV, gonorrhea, chlamydia, and primary and secondary (P&S) syphilis in calendar year 1996 for the proposed project area.

c. Describe those at risk for heterosexually acquired STDs and HIV, and their access to health care. Information on the percentage uninsured, unemployed, under the poverty level, and those receiving public assistance is desirable.

d. Include additional background on any health care policies and additional environmental and socio-demographic factors that may be relevant to the study of STD services. Examples include privatization of categorical STD clinics, existing or pending Federal Medicaid waivers, existing contracts, memoranda of understanding, agreements or arrangements between health plans and health departments.

2. Objectives

Provide a focused research agenda with long-term and short-term objectives that are realistic, specific, measurable, time-phased, and consistent with the objectives of the announcement.

3. Site Selection

Applicants must document access to populations with high syphilis or gonorrhea rates and high HIV prevalence rates. High HIV prevalence rates can be documented by surveys such as job corps, other seroprevalence surveys (e.g., among patients attending STD clinics, adolescent clinics, drug treatment centers, and among incarcerated populations), or survey of child bearing women data.

Define a research site based on specific information included in the background. Provide information on participating clinics and community programs in the project area. Include available information on monthly and annual numbers of clinic patients and their STD and HIV prevalence rates, and STD and HIV prevalence rates in persons participating in community programs in the project area.

Emphasis will be placed on applicant's demonstration of access to relevant clinic populations and community program populations such as adolescents, women, minorities, and Medicaid populations.

4. Methods

Describe the methods and activities that will be undertaken to accomplish the objectives, including, when possible, outcomes to be evaluated (i.e., health services-related outcomes, program-related outcomes, or STD and HIV specific health-related outcomes), the use of appropriate comparison groups, the sampling scheme and sample size calculations, qualitative and quantitative methods, and how data will be accessed, collected, and used. The methods should address the different phases (Phase I, II & III) of the project. Provide a detailed time line with beginning and end dates for each phase, with the anticipation of completing Phase I and part of Phase II in the first year of the project and all of Phases II & III in the second year of the Project.

5. Evaluation Plan

Provide an evaluation plan to monitor the effectiveness of the project activities and the progress made toward meeting the objectives.

6. Research Capacity

Provide evidence of research capability. Describe past and current research experience, including the experience of the proposed staff who will participate in this project (include details of experience and competence in research design, data collection, analysis and dissemination). Attach the curriculum vitae of key staff. Describe your plan for project administration including details of the proposed collaboration between STD clinic and program staff and HIV program staff. The research team should include qualified and experienced personnel in epidemiology, health services research, and behavioral science, and the team should have a demonstrable balance of experience in STD management and HIV prevention. The eligible applicants are encouraged to collaborate with other organizations such as colleges, universities, research institutions, hospitals and other public and private organizations to carry out project activities. Minimum requirements for the research team are a principle investigator, project supervisor, and staff capable of providing data collection, data management, laboratory support, and clerical services.

7. Letters of Support

Because each eligible locale can submit only one application, a Letter of Support is required by each Project Director, if the HIV prevention program and STD prevention program are administered separately.

8. Budget

Provide a detailed, line-item annualized budget for the first year of the Project which should cover Phase I in its entirety (as defined above) and part of Phase II and a budget narrative that justifies each line-item. Provide a summary budget for the second year of the Project covering the remaining part of Phase II and all of Phase III.

The budget should anticipate the need for appropriate staff (noted above in ''6. Research Capacity''), travel for principal investigator and project supervisor to meet with CDC two times per year, travel for outreach, supplemental needs related to STD and HIV clients and their longitudinal participation, and other needs. The budget should allocate at least 50 percent of resources to the STD prevention program activities (e.g., screening, diagnosis, treatment, and counseling for STDs).

Evaluation Criteria

Applications for demonstration projects on the feasibility of STD treatment for HIV prevention will be reviewed and evaluated according to the following criteria:

1. Background and Objectives (5 Points)

Understanding of purpose and objectives of this research and its relation to national program goals as reflected in the statement of research background and research questions.

2. Site Selection (25 Points)

The extent to which the choice of the project area and specific clinic and community sites to conduct this research will be generalizable to other settings or populations, and is appropriate to the local and national objectives, STD and HIV epidemiology, social demography, and health care system. Emphasis will be placed on demonstrated access to populations at high risk for heterosexual transmission of STDs and HIV in the project area, particularly persons who currently may not be reached by the health care system. Evidence of high gonorrhea, syphilis, and HIV prevalence should be demonstrated. Prevalence of other STDs might also be demonstrated. Highest points will be given to applications demonstrating the capacity to enroll a substantial number of participants at risk for STDs and HIV (>500 persons annually) and undertake longitudinal follow-up of these persons.

Consideration will also be given to the extent to which the proposed site includes appropriate participation of women and racial and ethnic minority populations.

3. Methods (25 Points)

The appropriateness and adequacy of the research design and methodology proposed to answer the research questions. This includes: (a) The selection of appropriate outcomes related to health services, STD and HIV programs, and STD morbidity; (b) the use of appropriate comparison groups; (c) the inclusion of appropriate sampling schemes, sample size calculation, handling of sampling biases; (d) access to the relevant data sources and the plan for data collection; and (e) the description of the specific quantitative and qualitative analytic technique to be used to answer the research questions.

4. Evaluation (20 Points)

The extent to which the applications present a sound evaluation plan that includes aspects such as: Research progress measurements and communications, baseline data collection; intervention(s) testing, ability to measure specific intervention outcomes (including but not exclusively STD and HIV outcomes); and economic evaluation.

5. Research Capacity (25 Points)

Overall ability to perform the technical aspects of the project including: (a) The availability of qualified and experienced personnel for a multi-disciplinary team in health services research including level of education and training, and relevant research experience of the principle investigator and key research personnel; (b) the availability of adequate facilities, general environment, and resources for the conduct of the proposed research; (c) assurance that staff can be hired within 4 months of award of monies; (d) plans for the administration of the project(s), including a detailed and realistic time line for the specified activities; (e) details of the proposed project-level collaboration between STD clinic and program staff and HIV program staff; and, (f) demonstration of the applicant's ability, willingness, and need to collaborate with CDC and researchers from other study site in study design and analysis, including use of common study protocols and data collection instruments, and (when appropriate) sharing of data and specimens.

6. Budget (not Scored)

The appropriateness of budget estimates in relation to the proposed research. The extent to which budget is reasonable, clearly justified, and consistent with the intended use of funds. The budget should allocate at least 50 percent of resources to the STD prevention program activities. (e.g., screening, diagnosis, treatment, and counseling for STDs).

7. Human Subjects (not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

Funding Preferences

CDC reserves the right to make final funding selections based on geographic diversity and applicants with higher documented prevalence of STDs and HIV in proposed clinic study sites.

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 governmental 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 application submitted to CDC, they should send them to Adrienne S. Brown, Acting Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE, Atlanta, Georgia 30305, no later than 60 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Numbers are: 93.941, HIV Demonstration, Research, Public and Professional Education Projects; and 93.978, Preventive Health Services Sexually Transmitted Diseases Research, Demonstration, and Public Information and Education Grants.

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

This program involves research on human subjects. Therefore, all applicants must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

HIV Program Review Panel

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 a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance form 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.

Patient Care

Applicants should provide assurance that all STD or HIV-infected patients enrolled in the proposed studies will be linked to an appropriate local care system that can address their specific needs such as medical care, counseling, social services, and therapy.

Women, 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 both sexes and the various racial and ethnic groups will be included in CDC/ATSDR supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity 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.

Confidentiality

Recipients must have confidentiality and security provisions to protect data collected through HIV/AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information.

Recipients must describe any laws, rules, regulations, or health department policies that require or permit the release of patient identifying information collected under the HIV/AIDS surveillance system to entities outside of the public health department and measures the health department has taken to ensure that the confidentiality of individuals reported to the surveillance system is protected from further or unlawful disclosure.

Application Submission and Deadlines

1. Preapplication Letter of Intent (LOI)

A non-binding letter of intent-to-apply is requested from potential applicants. An original and two copies of a two-page, typewritten LOI should be submitted to the Grants Management Branch, CDC (see ''Applications'' for address). It should be postmarked no later than February 13, 1998. The letter should identify the announcement number, title of the specific research activity for which application is being submitted, the name and institutional affiliation of the principal investigator, and the identity of other key participants and participating institutions. No attachments, booklets, or other documents accompanying the LOI will be considered. The letter should also include the estimated total cost of the research activity and the percentage of the total cost being requested from CDC. The LOI does not influence review or funding decisions, but it will enable CDC to plan 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 Form PHS 5161–1 (Revised 7/92, OMB No. 0937–0189) must be submitted on or before March 13, 1998 to Adrienne S. Brown, Acting Grants Management Officer, Attention: Kathy Raible, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, GA 30305.

3. Deadlines

A. Applications will meet 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 committee. (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 accepted as proof of timely mailing.)

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

Where To Obtain Additional Information

A complete program description and information on application procedures, are contained in the application package. Business management technical assistance may be obtained from Kathy Raible, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6649, or via email at: <kcr8@cdc.gov>.

Programmatic technical assistance may be obtained from Mary Kamb, Division of HIV/AIDS Prevention, National Center for HIV/STD/TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC), 1600 Clifton Road; Mailstop E–46, Atlanta, Georgia 30333, telephone (404) 639–2080, or via email at: <mlk5@cdc.gov>, or Kathleen Irwin, Division of STD Prevention, NCHSTP, CDC, 1600 Clifton Road; Mailstop E–07, Atlanta, Georgia 30333, telephone (404) 639–8276, or via email at: <kli1@cdc.gov>.

Please refer to announcement number 813 when requesting information and submitting an application.

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>.

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: January 27, 1998.

Joseph R. Carter,

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

[FR Doc. 98–2571 Filed 2–2–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Revised Diphtheria, Tetanus, and Pertussis (DTD/DTaP/DT) Vaccine Information Materials; Amendment

A notice published in the **Federal Register** on January 9, 1998, [63 FR 1730]. The notice is amended as follows:

On page 1733, first column, under number 9. After ''Visit the CDC website at http://www.cdc.gov/nip'' line and before ''DTP/DTaP/DT***'' add the following:

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Immunization Program

All other information and requirements of the January 9, 1998, notice remain the same.

Dated: June 27, 1998.

Joseph R. Carter,

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

[FR Doc. 98–2570 Filed 2–2–98; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 19, 1998, 8 a.m. to 5 p.m., and on February 20, 1998, 8:30 a.m. to 2 p.m.

Location: Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 19, 1998, the committee will discuss new drug applications (NDA's) 50–747 and 50–748 quinupristin/dalfopristin (Synercid®, Rhone-Poulenc Rorer Pharmaceuticals, Inc.) for use in the treatment of vancomycin-resistant *Enterococcus faecium* (VREF) infections, complicated skin and skin structure infections, community-acquired pneumonia, and hospital-acquired (nosocomial) pneumonia. On February 20, 1998, the committee will meet in closed session to permit discussion and review of trade secret and/or confidential information.

Procedure: On February 19, 1998, from 8 a.m. to 5 p.m. the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 13, 1998. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on February 19, 1998. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before February 13, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 20, 1998, from 8:30 a.m. to 2 p.m. the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). The investigational new drug (IND) and Phase I and II drug products in process will be presented.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2577 Filed 2–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Abuse Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Drug Abuse Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 19, 1998, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the scientific evidence for initiating a scheduling action for ULTRAM® (tramadol hydrochloride), R. W. Johnson Pharmaceutical Research Institute, under the Controlled Substances Act. The committee will also evaluate the effectiveness of the independent steering committee in detecting, moderating, and preventing the physical dependence and abuse of ULTRAM® and make suggestions for improving the surveillance of its misuse.

Procedure: On February 19, 1998, from 8:30 a.m. to 3:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views,