is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated 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 of which is included in the application kit. At least one member of the program review panel must be an employee (or designated representative) of the health department consistent with the Content guidelines. 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, an attachment to the quarterly summaries, the program review panel's report that all material 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 14, 1997. The letter should identify the announcement number, name of principal investigator, and specify the activity(ies) to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

2. Applications

An original and two copies of the application PHS Form 398 (OMB Number 0925–0001) 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 7, 1997.

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

A complete program description, information on application procedures, an application package and business management technical assistance may be obtained from 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, telephone (404) 842–6575, email: vxm7@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@cdc.gov.

Please refer to Announcement 750 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.

Dated: June 9, 1997.

Joseph R. Carter,

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

[FR Doc. 97–15510 Filed 6–12–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement 751]

Improving Sampling and Sexual Behavior Measurement Methods in HIV Behavioral Intervention Research

Introduction

The Centers for Disease Control and Prevention (CDC) announce the availability of fiscal year (FY) 1997 funds for a cooperative agreement program to support innovative research to improve the scientific rigor and credibility in two areas fundamental to the design and assessment of Human Immunodeficiency Virus (HIV) behavioral risk reduction interventions with populations at high risk for HIV infection and transmission. This announcement provides funds for two types of activities that will supplement or strengthen on-going behavioral intervention studies designed to prevent HIV infection and transmission: Activity 1: Obtaining representative samples of populations at high risk for HIV infection and transmission, and Activity 2: Minimizing errors in measuring reported sexual behaviors of persons participating in intervention studies with populations at high risk for HIV infection and transmission.

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 Health Service 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

All Activity 1 and Activity 2 applications must meet the eligibility criteria described in this section:

1. Applications can be submitted by public and private, nonprofit organizations and governments and their agencies. Thus, universities, colleges, research institutions, 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 women-owned non-profit businesses are eligible to apply.

2. Eligible applicants may submit applications for either or both Activity 1 (sampling) and Activity 2 (sexual behavior measurement). If applications are submitted for both types of Activities, the applicant must submit them as separate stand-alone applications. All applicants must explicitly state the Activity type of their application following the application's title listed on the application cover page, and again following the title listed at the top of the first page of the proposal's Abstract (see **Application Content** section of this announcement for further details).

3. For either Activity 1 or 2, applicants must have access to data collected as part of an on-going HIV behavioral intervention research study in the United States or its territories; such studies should be designed to develop and test interventions to reduce HIV risk behaviors (especially sexual) among populations at high risk for HIV infection or transmission.

4. 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 or cooperative agreement funds.

Availability of Funds

Approximately $600,000 is available in FY 1997 to fund a total of approximately six awards. Applications under Activity 1 and 2 will be ranked separately. CDC anticipates making at least one award under Activity 1, and at least one award under Activity 2. It is expected that the average award amount will range from $80,000 to $120,000 covering the entire award period, depending on the number and types of applications proposed. Awards are expected to be made before September 30, 1997, and will cover a 12-month budget period within a project period of one year. These funding estimates may vary and are subject to change based on availability of funds. Applications requesting greater than $120,000 for their total budget will not be considered for review.

Cooperative agreement funds awarded under this announcement are to be used to supplement and strengthen the sampling or sexual behavior measurement methods being used as part of on-going HIV behavioral intervention studies with high risk populations in the United States or its territories. Except as they relate directly to the purposes of this announcement, these funds are NOT TO BE USED for supporting the general costs of implementing an on-going HIV behavioral intervention, starting a new HIV behavioral intervention, or for any other purpose not covered under the intent of this announcement. Moreover, these funds are not to be used for the purchase of furniture, software, computers, rental of facilities, or equipment.

Use of Funds

Restrictions on Lobbying

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

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104–208, provides as follows:

> Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.
>
> (b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996).

Background

Regardless of advances in medical treatment of HIV/AIDS, success in stopping the spread of the disease will rely heavily upon the use of effective HIV behavioral risk reduction interventions. In assessing whether an intervention approach works, previous studies have shown the need for accurate measurement of sexual behaviors and their correlates, e.g., correct condom use, the number and frequency of sexual partners, and other related variables. Similarly, earlier research has indicated the need to test interventions with a sample of persons that is representative of the wider target population.

Representative samples are essential for knowing the generalizability of the results obtained from efficacy or effectiveness intervention studies. However, it is often difficult or impractical to select a true random sample of high HIV risk populations.

Researchers frequently rely on combinations of probability and non-probability sampling methods to select their samples, e.g., street intercept methods, venue sampling, snowball techniques, recruitment from STD clinics or community based service organizations. While these methods are often viewed as sufficient to identify and recruit a group of persons at risk for HIV, the methods might yield unrepresentative samples. Moreover, even representative sampling protocols are not always implemented as planned when identifying and selecting potential study participants. Differential drop-out of sampled persons can also bias research findings.

Limits on the generalizability of a HIV behavioral intervention study's findings makes it difficult for public health program managers to decide whether the intervention would be a useful tool for stopping the spread of HIV in their jurisdictions. Additional work is needed to develop ways to improve sampling methods used in HIV behavioral intervention research.

HIV intervention researchers must also obtain accurate data on study participants' sexual behaviors. Because of their highly sensitive and private nature, measurement of HIV-relevant sexual behaviors relies heavily upon self-reported information provided by participants in HIV prevention intervention studies. It is often difficult to ensure that responses to sexual behavior questions are valid, i.e., true reflections of a respondent's sexual behaviors.

In the past, different modes of sexual behavior data collection have been used, e.g., face-to-face interviews, self-administered questionnaires, audio- and telephone audio-computer assisted interviews. Efforts have been made to enhance reliability and validity of data collected, e.g., altering question order and wording, matching interviewer and respondent social and cultural backgrounds, using various recall periods, and memory assistance techniques. Other efforts have included test-retest with the same instrument, comparison of results using different data collection modes, comparison of a respondent's sexual behaviors with reports elicited from their sexual partners, and comparison of reported sexual behaviors with STD clinic medical records.

However, in spite of this past research experience, there is no established ''gold standard'' approach for measuring and ensuring the accuracy of self-reported sexual behaviors. To the greatest extent possible, it is essential for researchers to minimize sexual behavior measurement errors and maximize replicability or reliability of their findings.

Purpose

The purpose of this announcement is to fund innovative and scientifically sound research projects that will enhance the sampling (Activity 1) and sexual behavior measurement (Activity 2) methods used during on-going HIV behavioral intervention studies among populations at high risk for HIV infection and transmission. This includes sampling and sexual behavior measurement methods used during formative research phases preceding the development of behavioral interventions, as well as the efficacy or effectiveness study phases of interventions designed to prevent, modify, or decrease HIV sexual risk behaviors of populations at high risk for HIV infection and transmission.

This announcement solicits proposals to fund research for improving the sampling of populations and the measurement of sexual behaviors relevant to HIV behavioral intervention research with populations at high risk for HIV infection and transmission. In addition to evaluating the strength of the Activity 1 and Activity 2 applications submitted under this announcement, CDC may give priority to funding highly qualified applications that address a diverse range of target populations engaged in high HIV risk behaviors. Examples of these populations might include: heterosexual women, men who have sex with men, drug-using populations, adolescents or youth, or STD clinic patients. In addition, CDC welcomes applications pertaining to other groups that may be at high risk of HIV infection and transmission but which have received comparatively little HIV intervention research attention in the past, e.g., incarcerated or formerly incarcerated populations, hearing or visually impaired groups, bisexual women, severely mentally ill, homeless persons, or others. Regardless of the study's target population, awards will only be made to applicants that submit high quality applications, as assessed according to the ''EVALUATION CRITERIA'' and other instructions listed in this announcement.

This announcement provides funds for two types of activities: *Activity 1 (sampling)*—HIV behavioral intervention research to: (1) compare and contrast innovative methods to obtain representative samples of populations at high risk for HIV infection and transmission, (2) examine the extent of statistical representativeness and generalizability of the data collected from the selected samples, and/or (3) develop and test methods to improve sampling in future HIV behavioral studies with high risk populations; Activity 2 (sexual behavior measurement)—HIV behavioral intervention research to: (1) compare and contrast innovative methods to elicit respondent-reported sexual behavior data relevant to the risk of HIV infection and transmission, (2) examine the extent of reliability or validity of sexual behavior data obtained through use of different data collection methods, (3) identify specific sources for and magnitude of measurement error in obtaining sexual behavior data among different groups of persons at high risk for HIV infection and transmission, and/or (4) develop and test methods to improve the accuracy of reported sexual behavior data in future HIV behavioral studies with high risk populations.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed below under section ''RECIPIENT ACTIVITIES'' and CDC will be responsible for the activities listed under section ''CDC ACTIVITIES.''

A. Recipient Activities

1. Design sampling or sexual behavior measurement methods. The recipient will design innovative and feasible sampling or sexual behavior measurement methods that will supplement and strengthen the on-going HIV intervention study.

2. Collect and prepare data for analysis. The recipient will collect, code, enter, clean, or otherwise prepare all data to be obtained or used in meeting the objectives of the proposed work.

3. Ensure completion of the project by sustaining capability. Throughout the course of the project, the recipient has the responsibility to sustain the level of capability which was presented in their application, particularly:

a. The scientific skills to understand and conduct the sampling or sexual behavior measurement research, to conduct relevant analyses, and to assess the degree and extent of generalizability of the findings relevant to the objectives described in Activity 1 or Activity 2 sections of this announcement;

b. Adequate and appropriate technical and support services for the proposed project;

c. Adequate research facilities, computer, software, and other project resources or management systems needed for completing the proposed work; and,

d. Plan and capacity for storing the data securely and maintaining confidentiality. All applicants are fully responsible for ensuring that all appropriate human subjects review procedures have been followed.

4. Conduct the proposed research. The recipient will conduct all research-related activities pertaining to the proposed work. This includes: project design; data collection and preparation; data coding and analysis; project management and reporting; and preparation of materials for human subjects review committees and securing all necessary permissions to implement the project. All work must be carried out by the applicant in a scientifically acceptable, legal, and ethical manner.

5. Attend three CDC-organized meetings in Atlanta, GA. After receipt of their award, all recipients will attend three joint meetings in Atlanta, GA. For all meetings associated with this project, recipients are fully responsible for making all necessary travel

arrangements; applicants should plan their budgets accordingly.

Meeting 1: CDC anticipates that the first three-day meeting will take place in October or November 1997. At the first meeting, all recipients will make formal presentations describing their proposed work, and will participate in joint discussions with other recipients, CDC staff, and other individuals that may attend the meeting. Based on the meeting, recipients may choose to revise their study protocol.

Meeting 2: Toward the middle of the funding period, a one-day, mid-term meeting will be held, probably in March or April 1998. The purpose of the second meeting will be to share and discuss work progress and next steps. At the time of the second meeting, each recipient will also submit to CDC copies of a written mid-project progress report.

Meeting 3: Toward the end of the 12-month budget period, all applicants will attend a final three-day meeting. CDC anticipates this meeting will take place in August or September 1998. At the final meeting, each award recipient will make formal presentations describing the final results of their research activities related to this project. Subsequent to the meeting, each applicant will prepare their final written project report (see **TECHNICAL REPORTING REQUIREMENTS** section below).

6. Disseminate results. All recipients are expected to make oral presentations at professional meetings, write manuscripts, and publish scientific articles describing the results of this research in peer-reviewed scientific journals. The published articles form an important part of the project's permanent contribution to the HIV behavioral intervention research field as a whole, and also to increasing the effectiveness of HIV prevention public health efforts. All publications should be finished in a timely manner shortly after the completion of the research.

As part of their final project reporting requirements, all recipients will prepare a written report summarizing their study and its implications for improving sampling of representative samples, or for improving sexual behavior measurement in future research and in public health programs among populations at risk for HIV infection and transmission (see **TECHNICAL REPORTING REQUIREMENTS** section below). Finally, CDC may invite some or all recipients to participate in developing one or more joint publication(s) discussing sampling and sexual behavior measurement issues in HIV behavioral intervention research.

B. CDC Activities

1. Host three meetings of the award recipients. The purpose of these meetings is to discuss proposed work and study objectives, refine work plans as needed, review work progress and next steps, and disseminate final results.

2. Collaborate with the award recipient in the direction of activities. These activities include assisting in research design, methods, data analyses, implementation, development of project written documents, and dissemination of findings.

3. Evaluate progress reports. The purpose of this evaluation is to ensure that the objectives are being accomplished, and terms and conditions of the award are being met.

4. Participate in the preparation of results for publication.

5. Conduct site visits. CDC staff may schedule site visits with the recipients to assess project progress and discuss issues or problems, as needed.

Technical Reporting Requirements

An original and two complete copies of the following three written documents are required: (1) the revised (if appropriate) research protocol following the first Atlanta meeting, (2) the mid-term progress report at the time of the second Atlanta meeting, and (3) the final project report after the third Atlanta meeting (see previous **RECIPIENT ACTIVITIES** section). These should be sent to the Grants Management Branch, Procurement and Grants Office, CDC. Time lines for the reports will be established shortly after award. Financial status and performance reports are required no later than 90 days after the end of the project.

Application Content

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

Copies for Submission: Applicants are required to submit an original plus two complete copies of the application.

Line Spacing and Page Formats: All pages in the application should be clearly and sequentially numbered. Material in appendices should be one-sided only. The original and each copy of the application must be submitted UNSTAPLED and UNBOUND. All applications should be double spaced, in a 12-point font on 8½″ by 11″ paper, with at least 1″ margins and printed on one side only.

Table of Contents: A table of contents must list all parts of the application and its appendices, along with their corresponding page numbers.

Abstract Section Format: Applicants must provide a one-page, single-spaced abstract. The abstract is not counted in the 25-page limit of the narrative. The application title should be at the top of the first page of the abstract. ''Activity 1'' or ''Activity 2'' must be included in parentheses immediately following the title. The abstract should be placed immediately preceding the main body of the narrative.

Narrative Section Length: The narrative section may not exceed 25 double-spaced pages in length, excluding the abstract and appendices. Applications with narrative sections longer than the permissible length, or applications that fail to comply with other requirements described in this section, will not be reviewed.

Abstract and Narrative Section Content:

1. Title (Activity 1 or Activity 2) and Abstract: The abstract should be a clear 1-page summary of the proposal.

2. Introduction: Include: (1) a description of the applicant's understanding of sampling or sexual behavior measurement methods issues in HIV behavioral intervention research; (2) a brief review of relevant literature; (3) a brief introductory description of the proposed work, addressing how it pertains to either the formative research phase of an on-going behavioral intervention or how it augments the efficacy or effectiveness phases of testing the intervention; and, (4) an assessment of the scientific and public health value of the proposed work.

Provide evidence that: (1) the major intervention-related activities have already been designed and funded, and are being implemented at the time of submission of the proposal; (2) the applicant has access and permission to use data already being collected or that will be collected as part of the intervention (this evidence should be corroborated by a letter(s) of permission to use the data from the current manager of the data set(s) and applicants should include copies of such letters in the proposal's appendices); and, (3) the proposal will not conflict with the on-going activities of the intervention research study.

3. Current Intervention Design and Methods: (1) Applicants should provide a description of the research design and goals that are presently being used in the on-going behavioral intervention study; (2) a description of the target population, including their behavioral risk factors for HIV infection or transmission; (3) a description of the sampling methods that are presently

being used for sampling the intervention study population; and (4) a description of the data collection methods that are presently being used to collect sexual behavior and other key information in the intervention study.

4. Proposed Research Goals and Time Line: (1) Identify the specific sampling or sexual behavior methods research goals and objectives that will be addressed by the proposed research; (2) describe how achievement of these goals and objectives will supplement and strengthen the sampling or sexual behavior methods currently being used in the intervention study; and (3) present a detailed time line for completing the goals and objectives of the proposed project.

5. Proposed Data Set(s): (1) Describe the data set(s) to be generated and used for completing the proposed work, including data collection procedures, the specific variables involved, the quantity and scientific quality of the data, and the nature of the data and, (2) if applicable, describe any relevant previous analyses conducted on the data set(s).

6. Data Collection, Management, Analysis, and Dissemination: (1) Describe the proposed data collection plans in detail; (2) explain what specific variables will be used and which statistical or ethnographic methods will be used in the analysis; (3) describe computer and data management systems, as well as the statistical or ethnographic software packages to be used for the proposed work; (4) describe the plan and capacity for storing the data securely and confidentially; and, (5) describe the plan for disseminating the findings of the research.

7. Research Staffing Plan: (1) Explain the proposed staffing plan for the research, percentage of time each staff member will commit to this project, and division of duties and responsibilities for the project, including brief position descriptions for the proposed personnel; (2) provide evidence that the proposed staff have the capacity and experience to conduct the proposed methods research and analyses; (3) discuss general support activities such as project oversight or data management activities that will contribute to the completion of all analytic activities; and, (4) list the names and roles of staff members who are key to the completion of the project and include their curriculum vitae, highlighting any statistical and methodologic publications.

8. Budget: (1) Provide a detailed, line-item budget for the project (this should include plans for at least three trips to Atlanta to meet with CDC representatives and other researchers) and (2) a budget narrative that justifies each line item.

Evaluation Criteria

Applicants will be reviewed and evaluated individually according to the following criteria:

1. Title, Abstract, and Introduction (12 Points)

Quality and thoroughness of the title and abstract in summarizing the key features of the proposed research activities. Indication of whether the proposal falls under Activity 1 or Activity 2 of this announcement. Strength of the applicant's understanding of the scientific and public health issues related to sampling or sexual behavior measurement methods in HIV behavioral intervention research. Thorough review of relevant scientific literature and previous methods research.

Scientifically appropriate and feasible work description is proposed. The proposed work will significantly supplement and strengthen the sampling or sexual behavior measurement methods being used in the on-going behavioral intervention project. Significance of the proposed study's findings for improving the scientific credibility and public health utility of future HIV behavioral intervention research.

2. Strength of Current Behavioral Intervention Design and Methods (12 Points)

Scientific and public health merit of the on-going HIV behavioral intervention study design. The intervention is based on relevant behavioral science theory. Degree of merit of the research methods currently being used in the HIV behavioral intervention study. The applicant provides a thorough description of the intervention's target population, and provides strong evidence that the target population is at high behavioral risk for HIV infection. Information should also be provided on the extent to which the proposed work addresses the inclusion of women, racial and other ethnic minorities. Current quality of sampling methodology used for selecting the intervention study sample. Current quality of the data collection methods used to collect sexual behavior and other key information in the intervention study.

3. Useful Research Goals(s) and Appropriate Research Time Line (18 Points)

The proposed goals and objectives are practical and are based on previous scientific research. Achievement of the goals and objectives will significantly improve the sampling or sexual behavior measurement components of the intervention study. The applicant provides a clear, detailed, and realistic time line for completing all phases of the proposed project. The time line includes participation in the three Atlanta meetings and submission of required written project documents as described in previous sections of this announcement.

4. Quality and Access to Proposed Data Set(s) (18 Points)

The applicant provides a clear description of the data set(s) to be generated and used for completing the current work, including data collection procedures, the specific variables involved, the quantity and quality of the data, and nature of the data. The proposed data set(s) are not likely to contain major scientific flaws. If applicable, sufficient previous analyses conducted on existing parts of the data set(s). Strength of evidence that the applicant has or will have access to all necessary data set(s) and other information needed to achieve the goals and objectives of the proposal.

5. Quality of Data Collection, Management, Analysis, and Dissemination Plans (20 Points)

Scientific appropriateness and feasibility of the proposed plan to collect the data. Clear explanation of what variables will be used in the analysis. Selection of appropriate statistical or ethnographic methods for analysis of the data. Adequate research facilities, computer and data management systems, software, and statistical packages are available for completing all phases of the proposed work. Strength of plan to store data securely and maintain confidentiality. Explicit and clear plan for disseminating the findings of the research, including submission of articles to peer reviewed scientific journals and other dissemination activities as described in previous sections of this announcement.

6. Capability of Staff to Carry out Proposed Work (20 Points)

Clear explanation of the proposed staffing plan. Proposed staff will be available for sufficient amounts of time to carry out essential work. A reasonable division of duties and responsibilities for the project is provided, including brief position descriptions for the proposed personnel. Strength of evidence that the proposed staff have the necessary training, capacity and

experience to conduct the proposed research. Appropriate project oversight, data management, and analysis plan will contribute to the timely completion of all project activities. Curriculum vitae for key staff members are included, and demonstrate that the staff have strong credentials in terms of relevant experience, training, and capability. Key staff members have demonstrated a history of completing and publishing findings from similar or related methods studies.

7. Budget (not scored)

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

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 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 Rd., NE., Rm 300, Mailstop E15, Atlanta, GA 30305, no later than 30 days after the application deadline. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date.

Indian tribes are strongly urged 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 Rd., NE., Rm 300, Mailstop E15, Atlanta, GA 30305. This should be done no later than 30 days after the application deadline. The granting agency does not guarantee to ''accommodate or explain'' for tribal process recommendations it receives after that deadline.

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 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 or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF 424).

B. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not to exceed one page, and include the following:

1. A description of the population to be served.

2. A summary of the services to be provided; and

3. A description of the coordination plans with the appropriate State or local health agencies.

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

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.941, HIV Demonstration, Research, Public and Professional Education.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committees. 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.

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, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale 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, and 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, Procurement and Grants Office, CDC (see ''Applications'' for the address). It should be postmarked no later than July 14, 1997. The letter should identify announcement number 751, name of principal investigator, and specify the activity to be addressed by the proposed project. The letter of intent does not influence review of 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 complete copies of the application, including 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 Rd., NE., Rm 300, Mailstop E–15, Atlanta, GA 30305, or before August 7, 1997.

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. Applicants 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

A complete program description, information on application procedures, an application package and business management technical assistance may be obtained from Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Rd., NE., Rm 300, Mailstop E–15, Atlanta, GA, telephone (404) 842–6575, Internet E-mail: vxm7@cdc.gov.

Programmatic technical assistance may be obtained from Bob Kohmescher, Deputy Chief, Behavioral Intervention Research Branch, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mailstop E37, Atlanta, GA 30333, telephone (404) 639–8302, Internet E-mail: rnk1@cdc.gov.

Please refer to Announcement 751 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.

The announcement will be available on 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.

Dated: June 9, 1997.

Joseph R. Carter,

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

[FR Doc. 97–15512 Filed 6–12–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0209]

Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled, ''Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.'' This draft guidance is intended to assist the manufacturer in preparing a complete 510(k) premarket notification submission to the Center for Devices and Radiological Health (CDRH) or a third party reviewing organization. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance document may be submitted by July 28, 1997.

ADDRESSES: Submit written comments and requests for single copies of the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20852, 301–594–1212.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is making this draft guidance document available in order to assist manufacturers preparing notification submissions for diagnostic ultrasound systems and transducers. In addition to basic information on submitting a 5l0(k) for these devices, the draft guidance contains specific information on device description, predicate device comparison, acoustic output reporting, general clinical safety and effectiveness, and labeling. The draft guidance also contains information on submitting a post-clearance special report called the ''510(k) special report'' providing production acoustic output values and other information.

A guidance document does not bind FDA or the public, and it does not create or confer any rights, privileges, or benefits for or on any person, however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance document announced in this notice represents the agency's tentative thinking of the subjects discussed therein.

II. Request for Comments

Interested persons may, on or before July 28, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office