

Americans have been infected with hepatitis C virus (HCV), 2.7 million of which are chronically infected. Not including the cost of liver

transplantation, the estimated cost associated with HCV infections is \$600 million a year in medical care and lost work days.

The annual burden hours are estimated to be 2403.

Form name	Number of respondents	Number of responses/re-spondent	Avg. burden per responses (in hours)
Phone	20	1	10/60
Written	14400	1	10/60

Dated: May 16, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00080]

Optimizing Strategies To Provide Sexually Transmitted Disease (STD) Partner Services; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement research program for Optimizing Strategies to Provide STD Partner Services. CDC is committed to achieving the health promotion and disease prevention objective of "Healthy People 2010", a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area(s) of Sexually Transmitted Diseases. For the conference copy of "Healthy People 2010", visit the Internet site: <http://www.health.gov/healthypeople>. The goal of this cooperative agreement research program is to develop and evaluate the delivery of cost-effective, innovative, and confidential approaches to providing effective partner services within a time frame that interrupts the chain of STD transmission. Partner services (PS) are a critical component of STD control and prevention in public health practice.

Initially, this process was named "contact tracing," but was renamed "partner notification" in the past two decades. Three primary strategies for partner notification are described in the literature, although other variations are also employed. The most common

strategies are patient referral (patients are encouraged to notify sexual partners); provider referral, (health care staff, traditionally in the health department, notify partners); or contract referral (a time limit is agreed upon for patient referral, after which provider referral is initiated). In this program announcement, "partner services" is used to describe the constellation of services that should be provided to the sexual partners of individuals in whom a sexually transmitted disease has been detected and treated.

The purpose of PS is to break the chain of infection and re-infection that can occur when a STD is treated in only a part of a sexual dyad or network. STDs are often asymptomatic, many infected individuals are unaware of their infection, thus symptom-driven patient presentation for diagnosis and treatment fails to reach many people with STDs. PS may shorten the duration of infection in many additional individuals by identifying, treating, and counseling the sex partners of patients with STDs. Furthermore, PS offers a unique opportunity to assist at-risk, infected and uninfected people to adopt safer behaviors that will enable them to remain STD-free and is a key component of public health practice. The objectives of partner services include identifying, locating, notifying, testing, treating, and providing counseling to reduce STD risk for the sex partners of an individual diagnosed with chlamydia, gonorrhea, syphilis, trichomoniasis, herpes, or human immunodeficiency virus (HIV).

Despite the importance of partner services in public health practice, relatively little scientific information is available on the impact on disease transmission or cost effectiveness of various approaches, particularly for STDs that are treated in the private sector. Another limitation of the current science base is that existing data on partner services has been generated from federal, state, and local public health programs that have a legal responsibility to provide PS. This information does not reflect partner services in other clinical settings where

the majority of STD diagnosis and treatment take place. At least half of STD care is sought from private providers. Therefore, further research across the full spectrum of STD treatment providers with respect to PS is clearly needed. Current data from a national survey of providers suggests that the most common method of notification in the private sector is patient referral, although the rate of new infections uncovered in the private sector from this method is not known. Fewer than 5 percent of providers reported engaging in provider referral and less than 50 percent consistently reported patients' names to health departments after a diagnosis of chlamydia, gonorrhea, syphilis, or HIV infection. Case reporting from providers and from laboratories enables the local health department to provide partner services. However, providers may also diagnose and treat presumptively without performing a laboratory test, and relatively little is known about case reporting or partner services following presumptive treatment.

Provider-perceived barriers to offering partner services include concerns about negative effects on relationships with patients and their partners, lack of training and time for these activities, and lack of reimbursement.

Nevertheless, providers agreed that PS could promote appropriate behavior and attitude change, and reduce (re)infection rates. In summary, this survey confirmed that the effectiveness of PS in the private sector is unknown and reporting of names to agencies that conduct PS is limited.

Current methods of PS require substantial time and effort from public health staff, although data estimating the magnitude of the reduction in STD incidence or prevalence within communities that is attributable to PS are currently lacking. Recent advances in STD detection and treatment, information system hardware and software, and behavioral interventions offer an unprecedented opportunity to:

(1) Design and evaluate innovative strategies that increase the effectiveness of partner elicitation;

(2) Improve the timely connection of partners with appropriate detection, treatment, and counseling services;

(3) Intervene to lower STD risk among sex partners; and

(4) Evaluate the cost-effectiveness of new methods in comparison to current strategies.

This is likely to require complex evaluation that moves from the index patient to the patient-partner dyad, to sexual networks, and to community levels of evaluation.

CDC envisions that data from this research program will be used to design cost-effective strategies that

(a) Augment the effectiveness of PS in the public and private sectors;

(b) Reduce the incidence and the prevalence of curable STDs; and

(c) Utilize the opportunities inherent in partner services to lower partners' risk behaviors.

Incidence and prevalence reductions should be demonstrably attributable to innovations in PS.

This program has four general objectives:

1. To develop, apply, and evaluate confidential and innovative partner services across a variety of practice settings using new techniques or technologies and to assess their effectiveness and acceptability in comparison with current PS methods;

2. To develop and assess the feasibility of policy level interventions that may be needed to make innovative strategies feasible;

3. To assess the cost-effectiveness of proposed alternatives in comparison with current methods of partner services; and

4. To develop mathematical models that assess the impact of current and alternative partner service approaches on rates of incident and prevalent infections.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit and for-profit organizations; governments and their agencies; that is, universities, colleges, research institutions, managed care organizations, hospitals; State and local governments or their bona fide agents; and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations. Eligible applicants should collaborate with their local or state health department because this linkage is critical to the successful conduct of this research.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an

award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$750,000 is available in FY 2000 to fund the first year of approximately 2-3 awards. It is expected that the average award will be \$250,000, ranging from \$100,000 to \$350,000. It is expected that the awards will begin by September 30, 2000 and will be made for a 12-month budget period for a maximum project period of four years. Funding estimates may change. Continuation awards within an approved project period will be based on satisfactory progress as evidenced by required reports and on the availability of funds.

Funding Preferences

Funding preference will be given:

1. To applicants with access to subjects in public and private settings where STDs are diagnosed and treated;
2. To achieve geographic distribution;
3. To applications that address more than one STD;
4. To applications that involve collaboration with health departments; and
5. To applications that incorporate a mix of provider settings where chlamydia, gonorrhea, syphilis, trichomoniasis, herpes, or human immunodeficiency virus (HIV) are detected and treated.

Collaborative partnerships are strongly encouraged with managed care organizations, private practice settings, family planning clinics, or community and migrant health centers in addition to traditional public STD clinics.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Design and conduct research to address the study question(s) as listed below. Applicants may address one or more of the study questions listed and are encouraged to address at least two.

Study Questions

(1) In comparison to current strategies, what innovative methods can be developed and evaluated to increase the timeliness, effectiveness, and cost-effectiveness of partner services across a variety of practice settings?

PS interventions should be tailored to patient, partner, or provider characteristics, to specific STDs, and to

different practice settings in order to produce the most effective partner services. It is also important to assess methods that increase patient's cooperation, recall, and accuracy with respect to (a) providing names and locating information for partners or (b) following through with patient referral. Evaluation of the barriers that inhibit patients from naming partners or delivering patient referral in conjunction with interventions that overcome those barriers and increase the proportion of partners who receive medical evaluation, treatment, and counseling are encouraged.

Development and evaluation of strategies that promote the timely and appropriate delivery of partner services are encouraged. There is also interest in identifying methods for delivering partner services that promote changes in partners' risk behaviors and how this may vary by whether or not the exposed partner had acquired an STD.

For new strategies, techniques, or technologies, identify how they can be implemented in public and private health care settings. Evaluations should address to what extent and how the use of the new technologies or techniques increase the productivity of staff and reduce the barriers to timely and effective partner services for staff, patients, and partners.

Finally, there is programmatic interest in assessing the cost-effectiveness of innovative strategies, new techniques, and new technologies. Such interest includes accurately determining the incremental cost of identifying and locating partners and infections using innovative strategies and their comparison with the cost of current strategies. Cost-effectiveness measures should include research, training, and program costs separately so that implementation can be examined independently of research costs.

Applications that combine some or all of the above elements are encouraged. Preference will be given to applications that:

- (a) Propose the development, implementation, and evaluation of innovative strategies;
- (b) Present a detailed plan for measuring and evaluating outcomes;
- (c) Will be able to identify which elements of a proposed strategy account for its effectiveness;
- (d) Make the incremental value of the strategy visible; and
- (e) Incorporate technology transfer to settings where STDs are diagnosed and treated.

(f) Compare proposed innovative strategies with traditional methods of partner services and clarify whether

these new techniques or technologies offer any added value to current partner service activities.

(2) What policy level interventions can be developed, implemented, and evaluated to promote partner services across a broad spectrum of health care settings?

This may include identification of the policy sources, their policy function (advisory, regulatory, implementation), and the introduction and evaluation of policy-level changes that promote the improved delivery of partner services. There is interest in funding interventions that can produce the necessary policy changes, including linking the process of such interventions with specific outcomes (e.g., policy changes in health care plans that make partner services reimbursable).

(3) Apply mathematical models to assess the impact of current and alternative partner service approaches on rates of incident and prevalent infections?

The application of mathematical models to assess which current strategies and proposed alternatives may be most valuable in increasing the timeliness and effectiveness of partner services are also encouraged. Consideration will be given to the use of existing databases. The use of cost-effectiveness data as part of a model (or series of models) is encouraged.

b. Evaluate and analyze the research data.

c. Disseminate study findings through presentations at scientific meetings and publications in peer-reviewed journals.

2. CDC Activities

A cooperative agreement reflects an assistance relationship between the Federal Government and the recipient in which substantial programmatic involvement is anticipated about the scientific or technical management of an activity during its performance. The CDC program office will:

a. Provide up-to date scientific information, technical assistance, and guidance in the design and conduct of the research.

b. As needed, assist in the development of a research protocol for local IRB review at cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. As needed, assist in data analysis and the preparation of manuscripts.

d. Convene meetings of all grantees for the exchange of information.

E. Application Content

Applications must be developed in accordance with the information contained in this program announcement, the PHS 398 Grant Application, and the instructions provided in this section. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

Instructions

The program narrative for sections 1–5 below should be no more than 25 single-spaced pages, printed on one side, with one-inch margins, and 10 or 12 cpi typeface. All pages, including appendices, should be numbered sequentially. The narrative must contain the following sections in the order presented below:

1. *Abstract:* Provide a brief abstract of the project. The abstract must reflect the project's focus and the length of the project period (maximum is 4 years) for which assistance is being requested (see "Availability of Funds" for additional information).

2. *Specific Aims:* List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypotheses to be tested. One page is recommended.

3. *Background and Significance:* Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objections. Two to three pages are recommended.

4. *Preliminary Studies:* Use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application information that will help to establish the experience and competence of the investigator to pursue the proposed project. The complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed and are not part of the page limitations. Five collated sets of no more than 10 such items of background material may be submitted in an appendix. Six to eight pages are recommended for the narrative portion of the Preliminary Studies section.

5. *Research Design and Methods:* Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how

the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Describe specific study protocols or plans for the development of study protocols. Describe the nature and extent of collaboration with CDC and/or others during various phases of the project. Describe in detail a plan for evaluating study results and for evaluating progress toward achieving project objectives.

6. *Inclusion of Racial and Ethnic Populations:* Describe the degree to which applicant will meet requirements regarding the inclusion of women, and members of minority groups in the proposed study.

7. *Human Subject Involvement:* Describe procedures that will provide for the protection of human subjects. Address how these procedures are in compliance with Federal regulations.

F. Submission and Deadline

Letter of Intent (LOI)

For planning purposes, a letter of intent to apply is requested and needed to staff the review panels, but not required, from potential applicants. Your letter of intent should include the following information: Program Announcement Number [00080], name and address of institution; name address, and telephone number of contact person; and specific objectives to be addressed by the proposed project.

The letter of intent must be submitted on or before June 12, 2000 to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Applicants should submit five copies of PHS-398 (OMB Number 0925-0001) and adhere to the instructions on the Errata Instruction Sheet for PHS 398.

Forms are available at the following Internet address: www.cdc.gov/...Forms, or in the application kit. On or before July 14, 2000 submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

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 distribution to the review panel. (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.)

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

G. Evaluation Criteria

Upon receipt, applications will be reviewed by CDC for completeness and responsiveness to the purpose of this request for applications (RFA) (as described in Section A), and as outlined under Eligible Applicants and Program Requirements (Items A to B). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

All proposals will be independently reviewed for scientific merit by no less than three reviewers with appropriate expertise using current National Institutes of Health (NIH) review criteria to evaluate the methods and scientific quality of the proposal. Factors to be considered will include:

1. The specific aims of the research project, *i.e.*, the intended accomplishment of the specific research proposal, and the hypothesis to be tested. (5 percent)

2. The background of the proposal, *i.e.*, the basis for the present proposal, the critical evaluation of existing knowledge, and identification of specific knowledge gaps which the proposal is intended to fill. (10 percent)

3. The significance and innovation from scientific and programmatic standpoints of the proposed research, including the adequacy of the theoretical and conceptual framework for the research. (20 percent)

4. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures, plan for data management, statistical analysis plan, and evaluation plan. (40 percent)

5. The extent to which the research will lead to feasible, cost-effective interventions. (10 percent)

6. Qualifications and appropriateness of the proposed personnel to accomplish the proposed activities as

well as the degree of commitment and cooperation of proposed collaborators and organizations (as evidenced by letters detailing the nature and extent of the involvement). (10 percent)

7. Research Capacity—adequacy of existing and proposed facilities and resources. (5 percent)

8. Gender and minority issues. Does the application include:

- a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

- b. The proposed justification when representation is limited or absent.

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

- d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

9. Human Subjects—What are the strategies for the recruitment and retention of human subjects? Are the procedures proposed adequate for the protection of human subjects and are they fully documented? Are all procedures in compliance with applicable published regulations and 45 CFR 46?

10. The reasonableness of the proposed budget to the proposed research and demonstration program. Applications that propose to address more than one of the study questions described in Section D: Program Requirements should include a separate budget breakdown for each study question to be addressed.

Final awards will be determined by the Director of the Division of STD Prevention (DSTD) based on priority scores assigned by the independent review group appointed by CDC, consultation with DSTD senior staff, the match between the proposal and the program announcement, the relevance and balance of proposed research relative to DSTD priorities, and the availability of funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Progress reports annually, no later than 90 days after the end of the budget period;

2. Financial status report, no later than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

AR-14 Accounting System Requirements

AR-21 Small, Minority, And Women-owned Business

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 318 of the Public Health Service Act, [42 U.S.C. Section 247c, as amended. The Catalog of Federal Domestic Assistance Number is 93.978.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

To obtain additional information, contact: Kang W. Lee, Grants Management Specialist, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146; Telephone number (770) 488-2733; FAX number (770) 488-2847; Email address ki18@cdc.gov.

See also the CDC home page on the Internet: <http://www.cdc.gov>.

For program technical assistance, contact: Janet S. St. Lawrence, Division of STD Prevention, Centers for Disease Control and Prevention (CDC), Mail Stop E44, 1600 Clifton Road NE, Atlanta, GA 30333, (404) 639-8298; FAX: (404) 639-8622; Email address: nzs4@cdc.gov.

Dated: May 16, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00072]

Project CHOICES Efficacy Study; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Project CHOICES (Changing High-risk Alcohol Use and Increasing Contraception Effectiveness Study) Efficacy Study. The purpose of the study is to establish efficacy of Project CHOICES, a behavioral intervention approach to reducing alcohol-exposed pregnancies, in a multi-site, randomized clinical trial. Project CHOICES targets non-pregnant women at high risk for an alcohol-exposed pregnancy with a dual focused intervention aimed at reducing risk drinking and engaging in effective contraception until risk drinking is resolved. High-risk women will be accessed in high prevalence, community-based settings. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life.

This announcement is related to the focus areas of Substance Abuse: Alcohol and Other Drugs; and Maternal, Infant, and Child Health. For the conference copy of "Healthy People 2010," visit the internet site: <<http://www.health.gov/healthypeople>>

B. Eligible Applicants

Eligible applicants are limited to those previously funded under Program Announcement No. 746: Nova Southeastern University, The University of Texas—Houston, and Virginia Commonwealth University.

These applicants have been funded by CDC since 1997 to develop and implement the Project CHOICES Feasibility Study. This new cooperative agreement would allow the grantees to implement the study as a clinical trial.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$900,000 is available in FY 2000 to fund approximately 3 awards. It is expected that the average award will be \$300,000, ranging from \$250,000 to \$350,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

Project CHOICES targets non-pregnant, fertile women, 18–44 years of age, who are moderate to heavy alcohol consumers. Potentially high prevalence populations of targeted women have been defined from previous studies, including the Project CHOICES Feasibility Study which is currently underway. Applicants must select from the following list of high prevalence populations two settings in which they will conduct the Project CHOICES Efficacy Study: A jail; an alcohol and drug treatment center; an Obstetrical-Gynecological clinic; a Sexually Transmitted Disease (STD) Clinic; a media-recruited population of high-risk women; a Women, Infants, and Children (WIC) clinic; or an HMO. Applicants will then implement a behavior intervention protocol drawn from the Project CHOICES Feasibility study in two selected settings. Applicants must demonstrate the ability to maintain a minimum of 200 women from each selected setting (to be equally randomized to experimental and control groups) in the clinical study.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Refine Project CHOICES protocol and implement as a clinical trial in two diverse settings.

b. Recruit and train staff in a timely manner to ensure study implementation within the 3-year project period.

c. Implement appropriate quality assurance procedures to assure that

protocols for the efficacy study are being properly implemented.

d. Develop manuscripts and presentations describing the Project CHOICES Efficacy Study, results and recommendations.

2. CDC Activities

a. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

b. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Assist in the overall coordination of the implementation and evaluation of the intervention protocol.

d. Provide current scientific information, and ensure adherence to appropriate scientific standards including human subject regulations.

E. Application Content

Applications

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 double-spaced pages (excluding attachments), printed on one side, with one inch margins, and unrounded font. Do not include any spiral or bound materials or pamphlets.

Program Narrative (not to exceed 25 pages):

The Program narrative should follow the PHS-398 (Rev. 4/98) application and Errata sheet, and should include the following information:

1. A demonstrated understanding of the problem of FAS and other prenatal alcohol-related conditions, and the role of brief intervention and treatment approaches to preventing these disorders; a justification of the need for the proposed study and the grantee's rationale for targeting the two selected settings as ones in which high prevalence populations of women at risk for an alcohol-exposed pregnancy can be accessed; and a description of how this study addresses Health People 2010 Objectives and the recommendations of the Institute of Medicine report: Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention and Treatment.

2. Specific, measurable, and time-framed objectives.

3. A detailed plan describing the approach to be taken in implementing