

Dated: April 25, 2002.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02044]

A Community-Based Intervention with Opinion Leaders to Achieve Syphilis Elimination; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year FY 2002 funds for a cooperative agreement research program for a Community-Based Intervention with Popular Opinion Leaders (CPOL) to Achieve Syphilis Elimination. This program addresses the "Healthy People 2010" objectives for Sexually Transmitted Diseases (STDs). This project also addresses the "National Plan to Eliminate Syphilis from the United States" pertaining to the strengthening of community involvement and partnerships and enhanced health promotion. For a copy of the "National Plan to Eliminate Syphilis from the United States," visit the Internet site: <http://www.cdc.gov/stopsyphilis>.

It is intended that this research program will be conducted in communities that are located in high morbidity areas (HMAs) for syphilis as defined by the CDC on Attachment A. Funding is available for two demonstration sites for up to three years.

The goal of this research program is to implement and evaluate a community level intervention to prevent transmission of primary and secondary syphilis in rural and urban communities by training key community members (*i.e.* opinion leaders) within the affected communities to promote risk reduction and health seeking behaviors. The intervention that will be evaluated in this demonstration project is the Popular Opinion Leader (POL) model (Kelly, St. Lawrence, Stevenson, *et al.*, 1992). For the purposes of this announcement and research program, POL will be referred to as the Community Popular Opinion Leader (CPOL) model. The CPOL model is based on Diffusion of Innovation Theory

(Rogers, 1985), which suggests that changes can be rapidly disseminated and subsequently adopted by identifying, enlisting, and training opinion leaders within the affected community to endorse the desired behaviors. The Community Opinion Leaders function as "agents of change" by disseminating and personally endorsing health promotion (*e.g.* syphilis prevention) messages. They utilize their ability to influence other community members and facilitate changes in social norms and behaviors by sharing factual information, expressing their concern for syphilis prevention, and endorsing and modeling effective behavior change strategies within their social and sexual networks.

It has been empirically determined that the CPOL model is effective in reducing HIV-related sexual risk of men who have sex with men (MSM) in U.S. cities (*e.g.* Kelly, St. Lawrence, Stevenson, Hauth, *et al.*, 1992; Kelly, Murphy, Sikkema, McAuliffe *et al.*, 1997), and ethnic minority women who lived in urban low-income housing (Sikkema, Kelly, Winett, Solomon *et al.*, 2000). The Popular Opinion Leader model is also included in the "Compendium of HIV Prevention Interventions with Evidence of Effectiveness." For a copy of the "Compendium of HIV Interventions," visit the Internet site: <http://www.cdcnpi.org/Reports/HIVcompendium.pdf>. Although the CPOL model is effective in reducing HIV risk, its efficacy in preventing STDs other than HIV has never been empirically determined.

The goal of this research project is to evaluate the utility of the CPOL model in preventing primary and secondary syphilis in rural and urban HMA communities. It is required that the proposed research program be implemented in communities located in HMAs for syphilis. Applications should target heterosexually active adults at risk for syphilis due to sexual risk behaviors. It is also required that the program include collaboration between the local health department, community-based organizations (CBOs) that work directly with the at-risk population, and university researchers experienced in designing, implementing, and evaluating community-level interventions for STD/HIV prevention.

Overall Study Objectives

The overall objectives for this research program are:

(1) To design and implement a community-level intervention to

prevent syphilis based on the (CPOL) model and using an experimental design.

(2) To target the CPOL intervention for heterosexually active adults at risk for syphilis infection and living in counties identified as HMAs.

(3) To evaluate the effectiveness of the CPOL intervention by identifying changes in attitudes, beliefs, health care seeking, sexual risk behaviors, and syphilis incidence in the intervention community, as compared to a similar community that does not receive the CPOL intervention.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies including public and nonprofit faith-based organizations; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, and federally recognized Indian Tribal Governments, Indian Tribes, or Indian Tribal Organizations.

Note: Title 2 of the United State Code Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

Other eligibility criterias include the following:

(1) Applicants must use the CPOL model as a basis for the community level intervention.

(2) Applicants must target male and female heterosexually active adults at-risk for syphilis infection.

(3) Applicants must implement the research program in two rural or two urban communities within project areas that are defined as (HMAs) for syphilis and received 2002 funding for syphilis elimination (*see* Attachment A).

(4) The two urban or two rural communities must be a matched pair, similar in population and demographic characteristics. The matched pair should also be located in the same state. One community must serve as the study community and have the interventions implemented immediately, while the matched community must serve as the control and have the interventions offered after the completion of the research program.

(5) The locations of the communities, within each matched pair of urban or rural sites, must be such that activities implemented in one community are unlikely to have any impact in the other.

C. Availability of Funds

Approximately \$400,000 is available in FY 2002 to fund up to two awards. It is expected that the average award will be \$200,000. It is expected that one application proposing two matched urban sites and one application proposing two matched rural sites will be awarded. It is expected that awards will be made on or before September 30, 2002 and will be made for a 12 month budget period within a project period of up to three years. Funding estimates may change depending upon the availability of funds.

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.

1. 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, provide direct medical care (e.g., purchase of pharmaceuticals) or prevention case management.

2. Funding Preferences

Funds may be awarded in such a way as to achieve geographic distribution, and representation of counties affected by high syphilis morbidity.

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 activities listed under 2. CDC Activities.

1. Recipient Activities

a. Design and conduct a research program to address the study objectives in Section A by implementing and evaluating a community-level intervention to prevent syphilis using the er (CPOL) model and targeting heterosexually active adults at risk for syphilis infection in urban or rural HMA communities.

b. Identify appropriate personnel for the project. Skills and experience of project personnel must include: (1) Familiarity with syphilis transmission, treatment and prevention. (2) Experience working within communities experiencing high rates of syphilis. (3) Experience working with community-based organizations that serve target population living in high

syphilis morbidity areas. (4) Experience implementing and managing theory-driven and community based intervention projects. (5) Evaluation expertise.

c. Have in place or establish collaborative relationships with appropriate partners to accomplish project goals. Partnerships must include health departments, university based researchers and community based organizations that serve and are able to access and work with at-risk heterosexually active men and women in the targeted communities.

d. Collaborate with other recipients in developing and collecting a common set of core variables to permit systematic comparisons.

e. Collaborate with other recipients and CDC during the development, implementation and evaluation of the project.

f. Collaborate with other recipients and CDC to disseminate interim reports of research activities to regional, state and local partners.

g. Submit and obtain approval of the study protocols by the recipient's local institutional review board(s) and the CDC Institutional Review Board (IRB). Activities must be conducted in compliance with Protection of Human Subjects (45 CFR part 46).

h. Establish procedures to maintain the rights and confidentiality of all study participants, including securing any assurances necessary to conduct research involving human subjects.

i. Conduct local data management activities including data collection and management. Data collection may include street intercept interviews, focused individual interviews, role play assessment, paper and pencil measures, and process measures. Management of the data will include security of data, assurance of participant confidentiality, data entry, and timely forwarding of data to the CDC project officer.

j. Analyze and disseminate results through reports, presentations, and publications.

k. Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures must be objective/quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of the evaluation.

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 and/or technical management of this research and or technical management of this research during its performance. With this in mind, CDC will:

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

b. Provide technical assistance to awardees in developing and collecting a common set of core variables to enable comparison between project areas. Collaborative activities may include assistance on the development of common data collection instruments and developing a centralized system for data management for the core set of data elements collected by each funded project area.

c. Assist in the development of a common research protocol for annual IRB review by all 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, including analyses, is completed.

d. Assist in ensuring human subjects assurances are in place as needed.

e. Provide technical assistance on data collection methods, sampling methodology, intervention delivery, and quality assurance.

f. Assist in analysis and dissemination of results, including the preparation of manuscripts, as needed.

g. Monitor and evaluate the scientific and operational accomplishments of the project. This will be accomplished through periodic site visits, telephone calls, electronic communication, technical reports and interim data analyses.

h. Convene meetings of recipients for the exchange of information.

E. Content

Letter of Intent (LOI)

A Letter of Intent (LOI) is required for this research program. The narrative should be no more than three single spaced pages, printed on one side, with one-inch margins, and un-reduced font. Your LOI will be used to prepare for the special emphasis panel (SEP) that will review the scientific merit of the applications, and should include the following information: Program Announcement Number 02044; name and address of institution; name and telephone number of a contact person; specific objectives to be addressed by the proposed project; and a brief description of project plans. Although

an LOI is required, the terms of the LOI are not binding and will not be used in the review of the application.

Applications

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. Use the information in the Purpose, Program Requirements, and Evaluation Criteria to develop the application content. Your application will be evaluated on the criteria listed below, so it is important to address each, preferably in order, with sufficient detail. Applicants may submit only one proposal.

The narrative should be no more than 25 double spaced pages, printed on one side, with one-inch margins, un-reduced font, and a number on each page. Applications with more than 25 pages will be returned and not reviewed. Please provide only attachments or appendices that are directly relevant to this request for funding. The budget and attachments/appendices, including letters of support, are not included in the count for the 25-page limit. All pages, including appendices, should be numbered sequentially. To document eligibility, the narrative must contain the following sections in the order presented below:

1. Abstract (1 page recommended)

Provide a brief abstract of the project. The abstract must reflect the project's focus and the length of the project period (maximum of 3 years) for which assistance is being requested (see "Availability of Funds" for additional information).

2. Specific Aims/Objectives (1 page recommended)

List the objectives and the specific research questions the application is intended to address. State the hypotheses to be tested.

3. Background and Significance (2–5 pages recommended)

Briefly sketch the background leading to the present application, including the theoretical or conceptual framework, and evaluate existing knowledge. Additional information regarding syphilis elimination is included in Attachment B. Specifically document how the proposed intervention may impact on syphilis morbidity in the targeted communities. Describe any available STD or syphilis specific prevention services. Describe the syphilis morbidity in the proposed project locations. Describe the

characteristics of the targeted communities including whether they are urban or rural. Provide evidence of the communities' urban or rural characteristics. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the objectives.

4. Preliminary Studies (2–3 pages recommended)

Use this section to provide an account of the research team members' preliminary studies pertinent to the application that will help to establish the experience and competence of the research team members to pursue this proposed project. Include information about the experience of the research team and its members with the target population, behavioral and/or community level interventions, evaluation, and history of collaboration with relevant community partners including CBO's. References to appropriate reports, presentations, 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 ten such items of background material may be submitted in an appendix.

5. Research Design and Methods (15–20 pages recommended)

a. Describe the research design and the procedures to be used to accomplish the specific aims of the project. Applications must address heterosexually active men and women at risk for syphilis infection. Applications must include the CPOL model as the community level intervention. Communities in counties within HMA project areas must be matched, similar in population and demographic characteristics, while being geographically placed such that activities in the study community do not have an impact on the control community.

b. Describe the intervention development process, content and delivery, including specific intervention protocols or plans for the development of intervention protocols. Also, include the intent to offer the intervention to the control communities after the completion of the research program. Applications must demonstrate a comprehensive understanding of the CPOL model and how it can be applied in a community affected by syphilis. The application must also include a description of how members of the target population will be involved in the intervention activities.

c. Describe the recruitment, sampling, and retention plans.

d. Describe the measures to be used to evaluate the community level impact of the intervention. Applications should include self-report, social cognitive, behavioral and biological measures. Outcomes should include: (1) Social cognitive outcomes (*e.g.* changes in attitudes and beliefs). (2) Behavioral outcomes (*e.g.* changes in health seeking behavior, sexual risk behavior, syphilis screening) (3) Biological outcomes (*e.g.* syphilis serology, other bacterial STDs) (4) Process outcomes (*e.g.* participant tracking of conversation initiations, opinion leader attendance at training sessions). (5) Morbidity outcomes (*e.g.*, rates of syphilis and other STDs among members of the targeted community). Assessment of outcomes should be appropriate for the target population and community.

e. Describe how the data will be collected. Sampling schemes should be the same in the study and control communities. Choose and justify the sample size(s) considering the principles of Diffusion Theory (Rogers, 1995) and the different outcomes of interest. Power calculations are not necessary for biological outcome measures.

f. Describe the data analysis plan, including a justification for the statistical techniques chosen to analyze the intervention data.

g. Describe quality assurance plans.

h. Provide a tentative sequence or timetable for the project.

i. Describe the nature and extent of collaboration with CDC and/or others during various phases of the project.

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

6. Inclusion of Women and Racial and Ethnic Populations

Describe the proposed plan for the inclusion of both sexes and racial and ethnic minority populations. Describe the proposed justification when representation is limited or absent. Include a statement as to whether the design of the study is adequate to measure differences when warranted.

7. Human Subject Involvement

Describe procedures that will provide for the protection of human subjects, including procedures to obtain appropriate parental consent where necessary. List how these procedures adequately address the requirements of 45 CFR part 46 for the protection of human subjects.

F. Submission and Deadline

Letter of Intent (LOI)

On or before June 1, 2002, submit the LOI to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398) and, if applicable, the Optional Form 310, "Protection of Human Subjects Assurance Identification Certification Declaration". Forms are available in the application kit and at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

On or before July 15, 2002, submit the application to the Technical Information Management Section, Office of the Director, Procurement and Grants Office, 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341.

Deadline: 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 independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable proof of timely mailing.)

Late Applications: Applications that do not meet the criteria in 1. or 2. above will be returned to the applicant.

G. Evaluation Criteria

Applications will be reviewed and evaluated only on the basis of the evidence submitted. Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

Applications will be reviewed by CDC for completeness and responsiveness to the purpose of this program announcement (as described in Section A), and as outlined under Eligible Applicants and Program Requirements. 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 applications will be independently reviewed for scientific

merit to evaluate the methods and scientific quality of the application. Factors to be used to evaluate the application include:

1. Specific Aims (5 points)

The specific aims of the research project, including the objectives, and documenting the hypotheses to be tested.

2. Background (10 points)

The background of the project, *i.e.*, the basis for the present proposal, the critical evaluation of existing knowledge, and identification of how the intervention will effect syphilis morbidity and its anticipated impact on the affected communities. The description of available STD or syphilis specific prevention services and the syphilis morbidity in the proposed project locations. A description of the targeted communities including evidence of the communities' urban or rural characteristics.

3. Significance (15 points)

The significance and innovation from scientific and programmatic standpoints of the proposed research, including the operationalization of the theoretical model and conceptual framework for the research and the rigor and appropriateness with which the outcomes are evaluated.

4. Research Design and Methods (45 points)

- a. The adequacy of the proposed research design to address the overall objectives.
- b. Plans for the development of intervention content and delivery, including specific intervention protocols or plans for the development of intervention protocols, and how members of the target population are involved in that process.
- c. The recruitment and retention plan.
- d. The self-report, social-cognitive, behavioral and biological outcome measures to be assessed. Outcomes should include: (1) Social cognitive outcomes (*e.g.* changes in attitudes and beliefs). (2) Behavioral outcomes (*e.g.* changes in health seeking behavior, sexual risk behavior, syphilis screening). (3) Biological outcomes (*e.g.* syphilis serology, other bacterial STDs). (4) Process outcomes (*e.g.* participant tracking of conversation initiations, opinion leader attendance at training sessions). (5) Morbidity outcomes (*e.g.*, rates of syphilis and other STDs among members of the targeted community). Assessment of outcomes should be appropriate for the target population and community.

e. Describe how the data will be collected. Sampling schemes should be the same in the study and control communities. Choose and justify the sample size(s) considering the principles of Diffusion Theory (Rogers, 1995) and the different outcomes of interest. Power calculations are not necessary for biological outcome measures.

f. The plan for data collection and data management, including quality assurance procedures.

g. A statistical analysis plan appropriate to the intervention evaluation.

h. The project time line.

i. Measures of Effectiveness. The Peer Review Panel shall assure that measures set forth in the application are in accordance with CDC's performance plans (See Attachment 4 in the application kit).

5. Research Program Team (15 points)

The qualifications and appropriateness of the proposed personnel to accomplish the proposed activities. Applications should include multi-disciplinary teams, including (but not limited to) health department staff, experienced with syphilis transmission and prevention, staff from participating CBO's and university scientists. The combined members of the research team must demonstrate a history of familiarity with, access to, and success working with the target populations (*e.g.* high risk heterosexually active adults at risk for syphilis), delivery of behavioral and/or community level interventions, and evaluation expertise. This familiarity, access and success may be demonstrated through biographical sketches, previous studies, and letters of support. Applicants must demonstrate a collaborative relationship between the local health departments, CBOs, and university researchers. The degree of commitment and cooperation of proposed collaborators must be confirmed by letters of support detailing the nature and extent of the involvement.

6. Research Capacity (10 points)

Availability of appropriate scientific oversight necessary to fulfill research program objectives. These will include development, implementation, and evaluation of the intervention, recruitment and retention of participants, and collection and management of project-related data. The application should describe the experience and capacity of the project team, and should include curriculum vitae (CVs) and position descriptions for all key staff in an attachment.

7. Human Subjects (Not scored)

Restate the strategies for the recruitment and retention of human subjects and how the applicant will obtain appropriate consent, when necessary. Are the procedures proposed adequate for the protection of human subjects and are they fully documented? Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research, including: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation. (2) The proposed justification when representation is limited or absent (3) A statement as to whether the design of the study is adequate to measure differences when warranted.

8. Budget (Not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds. All budget categories must be itemized and appropriately justified.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of—

1. Annual progress report (the results of the Measures of Effectiveness shall be a data requirement to be submitted with or incorporated into the progress report. See CDC's Performance Plans at internet site: <http://www.cdc.gov/od/perfplan/2001perfplan>).

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

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.

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-5 HIV Program Review Panel 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-15 Proof of Non-Profit Status

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

AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 318 and 318A of the Public Health Service Act (42 U.S.C. sections 247c and 247c-1). The Catalog of Federal Domestic Assistance number is 93.977.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Gladys T. Gissentanna, Grants Management Specialist, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341-4146. Telephone: (770) 488-2753. Fax: (770) 488-2777. E-mail address: gcg4@cdc.gov.

For program technical assistance, contact: Janet S. St. Lawrence, Ph.D., Division of STD Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, MS E44, Atlanta, GA 30333. Telephone: (404) 639-8298. Fax: (404) 639-8622. E-mail address: nzsy@cdc.gov.

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Sandra R. Manning,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02087]

Distribution and Evaluation of Hepatitis Curricula for Inmates and Correctional Staff; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for distribution and evaluation of hepatitis curricula for inmates and correctional staff. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

The purpose of the program is to provide assistance for the printing, distribution and evaluation of an existing educational curriculum that addresses the prevention counseling, testing and treatment of viral hepatitis in correctional settings in the United States. Specifically, applications are solicited for viral hepatitis curricula aimed at the education and training of inmates and correctional staff.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private non-profit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations and Faith-based organizations are eligible to apply.

Applicants must have ready access to corrections facilities for distribution and evaluation of their educational curricula.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

C. Availability of Funds

Approximately \$150,000 is available in FY 2002 to fund one award. It is