

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports (semiannual);
2. Financial status report, no more 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.

For descriptions of the following Other Requirements, see Attachment I.

- 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-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act [42 U.S.C. sections 241 and 247b] as amended, and Section 102 of the Children's Health Act of 2000 (Pub. L. 106-310). The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

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

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.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2721, Email: nfp6@cdc.gov.

For program technical assistance, contact: Diana Schendel, Ph.D., National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, Mail Stop F-15, Atlanta, Georgia 30341, Telephone number: 770-488-7359, Email: dcs6@cdc.gov.

Dated: May 8, 2001.

John L. Williams,

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

[FR Doc. 01-11997 Filed 5-11-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01095]

Building Quality Parent Components for School-Based Health Programs in Elementary and Middle Schools; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Building Quality Parent Components for School-Based Health Programs in Elementary and Middle Schools. This program addresses the "Healthy People 2010" focus areas of Family Planning, HIV, Nutrition and Over weight, Physical Activity and Fitness, Sexually Transmitted Disease, and Tobacco Use. A goal of this program is to eliminate health disparities among different segments of the population.

The purpose of this cooperative agreement is to develop and evaluate parent-focused intervention components to be used as a supplement for school-based sexual risk reduction and chronic disease risk factor prevention programs in elementary and middle schools. These intervention components would be designed to assist parents in reducing the risk behaviors of their children. The risk factors among young people being targeted by this program are sexual risk behaviors and chronic disease risk factors which include tobacco use, physical inactivity, poor nutrition, and being overweight or at risk of becoming overweight. Interventions will target parents (i.e., primary caregivers) of elementary or middle school students.

For the purposes of this announcement, parents are defined as primary caregivers who are biological parents or legal guardians (e.g., adoptive parent, stepparent, grandparent) of

elementary and middle school students. Primary caregivers are individuals who take primary responsibility for providing care for their children. Parents (i.e., primary care-givers) are eligible for the study if their elementary or middle school children currently reside with them and if they have lived in the same residence with their elementary or middle school children for at least one year prior to the study.

Sexual risk reduction interventions are programs that show promise of success or have demonstrated evidence of efficacy in delaying initiation of sexual activity among young people, increasing condom or contraceptive use among sexually active young people, or decreasing frequency of intercourse or number of sexual partners among sexually active young people. Chronic disease risk factor prevention interventions are programs that show promise of success or have demonstrated evidence of efficacy in preventing initiation or promoting a decrease of tobacco use among young people, increasing physical activity, increasing healthy eating, or decreasing the number of children who are overweight or at risk of becoming overweight. Youth tobacco use prevention programs are included in this announcement, however, youth tobacco cessation programs are not within the scope of this announcement.

Please reference to Appendix 1 for background information relevant to this program announcement.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State, territorial, and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Successful applicants shall demonstrate a history of conducting evaluation research in partnership with interdisciplinary groups of health researchers and local racial and ethnic minority communities on applied social and behavioral science projects.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 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.

A. Availability of Funds

Approximately \$300,000 is available in FY 2001 to fund one award. It is expected that the award will begin on or about August 31, 2001, and will be made for a 12-month budget period within a project period of up to five years. First year funding will be approximately \$300,000 because the first year of the project is expected to be a planning year.

Subsequent funding years are expected to be funded at approximately \$700,000. Funding estimates may vary and are subject to 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.

B. 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. Establish and maintain appropriate staff positions allocated to specific responsibilities including a Research Director and a Project Director with research and training experience and allocated time sufficient to achieve the objectives of this program announcement.

b. Lead an expert panel of individuals with demonstrated experience in conducting research on parental influences on adolescent risk behaviors or who have developed and implemented parent-based interventions. The purpose of the panel should be to refine and further develop the parent intervention components. Develop final version of the parent components.

c. Develop a quasi-experimental or experimental evaluation design in which sites or individual participants (or some other justified unit) will be randomized to the control or comparison condition or the experimental condition. An evaluation plan should be developed to include both process and outcome evaluation components. Refine research questions, conceptual frameworks, measurement and analysis strategies, and intervention protocols to meet program goals. Develop strategies to maintain an adequate response rate through the follow-up period.

d. Collaborate and coordinate efforts with appropriate school, parent, and community organizations to identify

schools to participate in the study and obtain approvals. Efforts should be made to include members of the targeted population in developing and revising the research and intervention activities whenever appropriate and feasible. Plans to collaborate with schools to sustain successful interventions beyond the duration of the project should be made.

e. Develop a research protocol for local and CDC Institutional Review Board review.

f. Recruit participants into the study. Conduct intervention components designed to assist parents in reducing sexual risk behavior and preventing chronic disease risk factors among young people in elementary or middle school.

g. Collect data from participants at baseline (i.e., prior to the delivery of the intervention), immediately following the completion of the intervention, and 12 months following the completion of the intervention.

h. Analyze data according to planned strategies in order to measure the success of interventions with targeted populations in comparison to a control/comparison group, which should consist of the existing sexual risk reduction and chronic disease risk factor prevention programs without the parent component supplements. Behavioral outcomes (e.g., increasing condom use, preventing tobacco initiation, increasing healthy eating) should be measured, on both parents and children. Knowledge and attitude assessment may be included, in addition to behavioral outcomes. Parental outcomes (e.g., measures of parental monitoring, communication, parental modeling) should be measured with both parents and children.

i. Develop a plan for disseminating results of the research to members of the scientific, programmatic, and targeted communities through scientific publications, presentations and other appropriate methods.

2. CDC Activities

a. Assist in selection of the student interventions. Participate in an expert panel to refine and further develop the parent intervention components. Assist with the development of the final version of the parent components.

b. Assist in the development of research and evaluation protocols for the study and for IRB review by all cooperating institutions participating in the research project. The CDC IRB will review the protocol initially and on at least an annual basis until the research project is completed.

c. Assist with the scientific and technical coordination of the general operation of the research project, including data management support.

d. Assist in the analysis of data gathered from program activities and the reporting of results.

e. Collaborate in the dissemination of evaluation findings through scientific publications and presentations.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections and the instructions and format provided below to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 double-spaced pages, printed on one side, with one inch margins, and unredacted font.

The application should include an abstract and general introduction, followed by one narrative subsection per application content element (1–7) in the order in which the elements appear below. Each narrative subsection should be labeled with the element title and contain all of the information needed to evaluate that element of the application (except for curriculum vitae, references, intervention descriptions and materials, and letters of support). The referenced exception materials should be placed in the appendices section of the application.

1. Specific Aims, Background and Significance

a. 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.

b. Provide a review of the relevant literature to specify a theoretical and empirical justification for the proposed research, and clearly describe how the proposed intervention will advance efforts to reduce sexual risk behaviors and prevent chronic disease risk factors among young people in elementary or middle school by intervening with parents (i.e., primary caregivers) of elementary or middle school young people. Specifically, the application should include explicit models (with schematic drawings) that illustrate factors to be modified through the intervention and that explain the mechanisms by which outcome effects are produced.

2. Intervention Plan

a. Describe, in detail, the school-based sexual risk reduction and chronic

disease risk factor prevention curricula to which a parent component will be added. Provide evidence that the selected programs have been found to be efficacious or promising with elementary or middle school students. Describe the proposed potential parent components to be added to these curricula and how these will fit into the proposed interventions for young people. Provide evidence justifying inclusion of the proposed parent components as promising strategies to reduce risk behaviors.

b. Discuss why the planned parent intervention components are promising. Intervention descriptions should be provided if possible. Discuss feasibility and acceptability of the intervention in a school setting and among parents and why it is expected that the planned intervention components will avoid the problems of parent recruitment and retention encountered by other parent programs.

3. Research Plan

a. Describe all aspects of the study design and methods, including the evaluation design (both process and outcome), and how threats to validity will be handled; a detailed description of the targeted population, including but not limited to age, grade, sex, race, socioeconomic status, and how the population will be accessed; instrumentation; the sampling strategy (including a justification for the sampling unit, sample size, power analysis justifying the sample size, an indication of expected effect sizes, and the randomization strategy); and training plans for individuals collecting data, and data collection plans, including but not limited to, linking participants' responses between measurement periods.

b. Describe plans for recruitment and retention of both parents and children into the study, including expected sample attrition during both intervention and measurement phases. Describe how study participants will be tracked and what strategies will be used to increase retention.

c. Describe how the intervention implementation process will be measured and how the findings will be used to monitor implementation and provide feedback to staff, and to explicate other findings. Include plans to maintain detailed records of the costs involved in implementation such that cost-effectiveness and cost-benefit analyses can be performed.

d. Describe the plans and quality assurance monitoring for data management, plans for data analysis, and interpretation.

e. Describe the potential limitations of the results given the complexity of the research focus, the targeted population, and the applied nature of the evaluation; to whom the findings will be generalizable; and how they can be used to develop national recommendations for including parents in efforts to reduce sexual risk behaviors and prevent chronic disease risk factors among children in elementary and middle schools.

f. Discuss how the proposed study will meet the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

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.

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

4. Research and Intervention Capacity

a. Demonstrate the feasibility of the proposed research by providing a detailed time-line, with specific products, specifying which staff person will be responsible for which task.

b. Describe the research team and show that the proposed research staff for the project represents an interdisciplinary team of behavioral and social scientists with the scientific training and the previous scientific and practical experience needed to conduct and complete high quality research within the specified time-line, as evidenced by the successful completion of past research in the areas proposed in this application. Describe previous service or research conducted with this population.

c. Demonstrate the adequacy of the proposed staff, through curriculum vitae and position descriptions that detail responsibilities, to carry out all proposed activities (i.e., sufficient in number, percentage of time commitments, behavioral or social scientists in key project positions, and qualifications).

d. Describe the facilities, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

5. Collaboration, Sustainability, and Dissemination

a. Describe how academic, program, and community partners will participate in developing, conducting, and evaluating the proposed research. Specifically, describe the involvement of appropriate key organizations and members of the targeted population and discuss previous work of the proposed collaborators. Include letters of support from proposed collaborating organizations indicating willingness to participate in the proposed research, including but not limited to, evidence of past successful collaboration, willingness to be randomized to a control/comparison or experimental condition, and the number and demographic characteristics of young people served.

b. Define the responsibilities of collaborating partners and identify a primary contact within collaborating organizations.

c. Discuss efforts to be made throughout the project period to ensure that the intervention will be sustained once Federal funding ends.

d. Provide a clear dissemination plan to include, but not limited to, the timely sharing of findings with local partners; and include a plan to work with other sites to ensure that analysis and production of scientific papers and reports give priority to findings that can be used to develop national prevention recommendations for inclusion of parents in efforts to reduce sexual risk behavior and prevent chronic disease risk factors among young people in elementary or middle school. Describe key dissemination products including peer-reviewed publications and presentations that can be used by program planners, policy makers, and other interested parties.

6. Budget with Justification

Provide a detailed budget with a line-item justification that is consistent with the proposed activities.

7. Human Subjects

Does the applicant adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

F. Submission and Deadline

Application

Submit the original and five copies of PHS 398 (OMB Number 0925-0001). Forms are available at the following Internet address: <http://forms.psc.gov>, or in the application kit.

On or before June 22, 2001, 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 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 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 (Total 100 Points)

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC:

1. Specific Aims, Background, and Significance (10 points)

a. The extent to which the specific aims and objectives of the proposed research are clearly stated and justified and the stated hypotheses are testable.

b. The extent to which a comprehensive review of the relevant literature and specification of a theoretical and empirical justification for the proposed research is provided.

2. Intervention Plan (25 points)

a. The extent to which the applicant adequately describes the school-based sexual risk reduction and chronic disease risk factor prevention intervention curricula to which a parent component will be added and describes the proposed parent components. The extent to which evidence is provided that the selected programs have been found to be efficacious or promising with elementary or middle school students.

b. The extent to which the applicant addresses the issues of feasibility and acceptability of the intervention in a school setting and among parents. The extent to which the planned intervention components can be expected to avoid the problems of parent recruitment and retention encountered by other parent programs.

3. Research Plan (30 points; a–e, 25 pts.; f, 5 pts.)

a. The extent to which the study and evaluation design (both process and

outcome) and methods are scientifically sound. Demonstrated ability to access the target population. The adequacy of the proposed instrumentation; the sampling strategy; training plans for individuals collecting data, and data collection plans.

b. The adequacy with which study participants will be tracked, and the extent to which strategies presented are likely to produce adequate recruitment and retention of participants (includes expected attrition).

c. The extent to which the intervention implementation process can be measured and findings used to monitor implementation and provide feedback to staff as well as to replicate the intervention in other settings, including the ability to perform cost-effectiveness and cost-benefit analyses.

d. The extent to which the plans for data management, data analysis, and interpretation are clear, appropriate and are monitored adequately for quality.

e. The extent to which the evaluation will provide results that are scientifically sound, generalizable, and useful for developing national recommendations for the inclusion of parent components in school programs.

f. The extent to which the applicant has met the CDC Policy requirements regarding the inclusion of women and ethnic and racial groups in the proposed research.

4. Research and Intervention Capacity (20 points)

a. The feasibility of the proposed research plan and the adequacy of the time-line with specific products, specifying which staff person will be responsible for which task.

b. The extent to which the proposed research staff represents an interdisciplinary team of behavioral and social scientists with the scientific training and the previous experience needed to conduct high quality research within the specified time-line.

c. The adequacy of the proposed staff, as evidenced by curriculum vitae and position descriptions that detail responsibilities, to conduct all proposed activities (i.e., sufficient in number, percentage of time commitments, behavioral scientists in key project positions, and qualifications).

d. The adequacy of facilities, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

5. Collaboration, Sustainability, and Dissemination (15 points)

a. The extent to which the applicant includes academic and community partners in developing, conducting, and

evaluating the proposed research, and includes the involvement of appropriate key organizations and members of the targeted population. Degree to which applicant includes letters of support from proposed collaborating organizations. The extent to which the responsibilities of collaborating partners are defined.

b. The adequacy of efforts to be made throughout the project period to ensure that the intervention will be sustained once Federal funding ends.

c. The extent to which the dissemination plan is clearly articulated and includes the timely sharing of findings with local partners.

6. Budget (Not Scored)

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

7. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports (annual, semiannual, or quarterly);
2. Financial status report, no more 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.

For a description of the following Other Requirements, 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–4 HIV/AIDS Confidentiality Provisions

AR–5 HIV Program Review Panel Requirements

AR–8 Public Health System Reporting Requirements

AR–9 Paperwork Reduction Act Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–14 Accounting System Requirements

AR–15 Proof of Non-Profit Status

AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a), 311(b) and (c) and 317(k)(2)[42 U.S.C. section 241(a), 243(b) and (c), and 247b(k)(2)], of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.938.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on “Funding” then “Grants and Cooperative Agreements.”

For more information on effective programs, visit the Department of Justice website, <http://www.usdoj.gov>, the Department of Education website, <http://www.ed.gov> and CDC’s “Programs That Work” website, <http://www.cdc.gov/nccdp/hp/dash/rhc/index.htm>.

Should you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Cynthia Collins, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 01095, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2757, E-mail address: coc9@cdc.gov.

For program technical assistance, contact: Patricia Dittus, Ph.D., Division of Adolescent and School Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS K-33, Atlanta, GA 30341, Telephone number: 770-488-6196, E-Mail address: pdittus@cdc.gov.

Dated: May 08, 2001.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
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[FR Doc. 01-11998 Filed 5-11-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01061]

Longitudinal Studies of Rodent Reservoirs of Hantaviruses in the Southwestern United States; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement to provide assistance for longitudinal studies of rodent reservoirs of hantaviruses in the Southwestern United States. This program addresses the “Healthy People 2010” focus area of Immunization and Infectious Diseases.

The purpose of the program is to continue to improve understanding of the ecological dynamics of the transmission cycle of hantaviruses in their natural host populations and to provide precise data linking environmental changes to changes in rodent population densities and prevalence of infection. These data will be used to parameterize mathematical models that will use satellite-derived environmental descriptors to predict changes in risk of hantavirus disease at precise times and places in North America.

The preliminary success of the current studies in identifying environmental factors that lead to increased risk of human disease has illustrated that (1) more precise and detailed measurements of environmental variables are required as input parameters and to calibrate accurate, predictive, mathematical models of disease risk; (2) mathematical models must be calibrated using data from many years and geographically dispersed sites; and (3) fine-scale remotely sensed (satellite) data must be used in order to make predictive models generalizable and applicable across wide geographic areas.

B. Eligible Applicants

Assistance will be provided only to the University of New Mexico (UNM), Colorado State University (CSU), and Yavapai College (YC).

Hantaviruses have been shown in the United States to be responsible for serious human disease, specifically, Hantavirus Pulmonary Syndrome (HPS). There have been over 280 identified cases of HPS, the majority of which have occurred in the Southwestern

United States. Other North American species of Hantavirus have now been described from various sigmodontine rodent reservoirs, including *Sigmodon hispidus*, *Peromyscus leucopus*, *Oryzomys palustris*, *Peromyscus boylii*, and *Reithrodontomys megalotis*. All of these species, except *O. palustris*, coexist in the Southwestern U.S.

A complete understanding of the cycle of HPS in humans will require knowledge of the dynamics of viral infection in the rodent reservoir. Cross-sectional studies have identified several reservoir species, demonstrated the widespread distribution of infection in populations of these species and shown that the prevalence of infection is highly variable on a spacial scale. Long-term studies of reservoir populations are necessary to determine temporal patterns of infection, incidence rates, mechanisms of transmission, effects of climate, habitat quality, and host populations dynamics on the transmission cycle, and effects of infection on host movements, growth, longevity and population dynamics.

Longitudinal mark-recapture studies of reservoir populations have been conducted at established trapping sites in Arizona, Colorado, and New Mexico since 1994 through separate cooperative agreements with UNM, CSU, and YC. These academic institutions established the trapping sites, performed the research, collected and interpreted the data, and published the results in peer-reviewed scientific literature. Due to the inherent temporal variability in environmental, climatological, and population parameters at the sites, comparative data must be collected over a period of many years for the objectives of long-term studies to be met.

The previous longitudinal studies have greatly improved understanding of hantavirus-host ecology and have elucidated general patterns that implicate environmental factors that are associated with increased risk of human hantaviral disease. Nevertheless, these data have shown that discerned patterns vary tremendously both spatially and temporally. In addition, many environmental changes are extremely rare events and conditions that lead to rodent population irruptions and human epidemics are infrequent. Thus, the ultimate usefulness of these studies depends upon adequate replication in time and space and their long-term maintenance.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 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