data which directly supports the basis for the health disparity in the priority area(s) selected.

2. Organizational Summary: (20 Points)

a. Extent to which applicant describes the history, nature, and extent of its relevant experience in organizing community activities and details at least two years of relevant experience within that past four years with supporting documentation.

b. Extent to which the applicant describes existing facilities and staff (including resumes and job descriptions) to accomplish the desired outcomes of Phase I.

c. The adequacy of proposed staffing and collaborations with partners, particularly to meet the design and evaluation needs of the project. Include the nature of coalition and members of coalition by type of organization and relevant organizational experience. The applicant must show strong representation by the minority community in the coalition.

3. History and Experience in working on public health programs with Ethnic/Racial Groups: (25 Points)

a. Extent to which the applicant documents its experience and successes in operating and centrally administering a coordinated public health or related program serving the target population for at least two years (within the past four years) for the selected priority area(s) (including appended letters of support).

b. Extent of experience in other public health programs, and public health research or related data collection.

4. Community Action Plan (CAP): (20 Points)

Extent to which the applicant demonstrates a thorough and reasonable plan for the development of their CAP, including the assurance of community participation and participation of coalition members in the planning of the CAP.

5. Evaluation plan: (10 points)

a. Extent to which the applicant presents a reasonable and thorough evaluation plan for Phase I.

b. Appropriateness of evaluation methods, goals, objectives, and time lines to the development of the community action plan and the overall planning effort, and identification of data and information sources needed to track progress toward the project's objectives.

6. Budget (Not Scored)

Extent to which a line-item budget is presented, justified, and is consistent with the purposes and objectives of the cooperative agreement.

7. Human Subjects (Not Scored)

Does the application include a plan to 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 semiannually;

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

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

Send all reports to the business management contact listed in Section J., ''Where to Obtain Additional Information.''

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–4 HIV/AIDS Confidentiality Provisions
AR–5 HIV Program Review Panel Requirements
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 2000
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance (CFDA) Number

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a)and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.945.

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 Program Announcement Number 99064.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Adrienne S. Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99064, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2755, E-mail: asm1@cdc.gov

For this and other CDC announcements, see the CDC home page on the Internet: http://www.cdc.gov

For program technical assistance, contact: Letitia Presley-Cantrell, Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 4770 Buford Hwy, NE, Mailstop K–30, Atlanta, Georgia 30341, Telephone: (770) 488–5426, E-mail: ccdinfo@cdc.gov

Dated: May 12, 1999.

Henry S. Cassell,

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

[FR Doc. 99–12532 Filed 5–17–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99115]

Cooperative Agreements for Strategies To Prevent Genital Herpes Infections: Building A National Prevention Program, Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for prevention research on genital herpes simplex virus (HSV) infections. This program addresses the ''Healthy People 2000'' priority area Sexually Transmitted Diseases. The purpose of the program is to stimulate and support projects that will address existing gaps in our knowledge about the psycho social and economic burden of HSV and strategies to prevent transmission of genital herpes simplex infections in the United States in the context of new diagnostic technologies and new therapeutic strategies.

This program has four general objectives: (1) to assess behavioral and psycho social impact and indirect and

intangible costs of genital herpes infections; (2) to assess acceptability of screening for genital HSV using type-specific tests likely to soon become commercially available for clinical use; (3) to determine correlates of infectivity among asymptomatic and symptomatic infected persons; and (4) to assess relative risks of HSV transmission from asymptomatic and symptomatic infected persons to sex partners.

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 and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

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 $790,000 is available in FY 1999 to fund two to three projects. It is expected that the average award will be $350,000, ranging from $250,000 to $500,000. It is expected that the awards will begin on or about September 30, 1999 and will be made for a 12-month budget period within a project period of up to three 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.

Funding Preference

Preference will be given to applicants with access to subjects attending a wide variety of clinical service delivery settings in addition to traditional public STD clinics such as managed care organizations, family planning clinics, and community-based clinics. Preference will also be given to proposals that address all four study questions.

D. Study Questions

Applicants must address at least three of the following:

1. What is the behavioral and psycho social burden of diagnoses of genital HSV infection on asymptomatic and symptomatic infected persons and their sex partners? What are the indirect and intangible costs of a diagnosis of genital HSV infection on asymptomatic and symptomatic infected persons and their sex partners?

There is programmatic interest in determining the impact of a genital HSV diagnosis on the ability to recognize genital lesions and symptoms, frequency of sex when lesions/symptoms are present, notification of sex partners, consistent and correct condom use, health care seeking behaviors, adherence to counseling messages, willingness to take medication and compliance with treatment regimens, work status, general psycho social status, interpersonal relationships, perceived stigma, partners' willingness to be tested, partners' willingness to change sexual behaviors, and partners' willingness to take postexposure prophylaxis. Preference will be given to proposals that (1) compare outcomes for asymptomatic persons with those of symptomatic persons and (2) compare these outcomes to those of persons with symptomatic and asymptomatic curable STDs such as gonorrhea and chlamydia. Comparisons with other sexually active persons not known to be infected with HSV are also encouraged. A prospective design may be used for newly diagnosed persons, and a cross-sectional design used for other infected persons.

There is programmatic interest in developing, implementing, and evaluating methods to assign costs to psycho social burden, pain, and suffering (''intangible costs'') and economic costs related to lost work or productivity or job choice (''indirect costs'') and to changes in personal relationships associated with a diagnosis of genital HSV infection in asymptomatic and symptomatic persons with newly diagnosed infection, persons with infections diagnosed more than one year prior to interview, and their sex partners. Preference will be given to proposals that (1) use more than one method to assign costs to psycho social burden, such as willingness-to-pay, quality of life, or other methods; (2) compare outcomes for asymptomatic persons with those of symptomatic persons; (3) compare outcomes to those of persons with symptomatic and asymptomatic curable STDs such as gonorrhea.

2. What is the acceptability of screening tests to identify persons infected with genital HSV?

There is programmatic interest in assessing acceptability of one or more new type-specific serologic tests for genital HSV infection in asymptomatic and symptomatic infected persons, including reasons why tests are accepted or refused, predictors of sero positivity, and predictors of receiving test results. Assessment of acceptability of rapid ''point-of-service'' tests (whereby results are available to the client during a visit to a health care provider) with other tests is strongly encouraged. Applicants are encouraged to involve State Public Health Department Laboratories in the performance of serologic tests that are not point-of-service.

3. What are the correlates of infectivity among asymptomatic men and women?

There is programmatic interest in determining correlates of infectivity in asymptomatic persons who test positive on new type-specific serologic tests for HSV infection, using viral culture, PCR for HSV DNA, or other appropriate methods to determine viral shedding including quantitative methods, in conjunction with assessment of sero status of current sex partners. Determining relative frequency of viral shedding from various anatomic sites in men (including penis, foreskin, and scrotum) in a small sample of infected men is strongly encouraged. Viral cultures and PCR should be performed by a reference laboratory with a record of high performance.

4. What are the relative and absolute risks of transmission to sex partners from asymptomatic infected persons, persons with symptoms not recognized as HSV, and symptomatic persons?

There is programmatic interest in comparison of risk factors for transmission of HSV from asymptomatic and symptomatic infected persons, with respect to sexual practices, frequency of intercourse when symptoms are present, duration of diagnosed genital herpes, consistent and correct condom use, number of partners with genital herpes, length of relationships with infected partners, age at diagnosis of genital herpes, severity of symptomatic first episodes, frequency of recurrences, and HSV–1 infection. A prospective or cross-sectional design may be used. Identification of likely source contacts of newly diagnosed persons is desirable. Consideration will be give to analyses of existing databases.

E. 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 of conducting activities under 2. CDC Activities:

1. Recipient Activities

a. Design and conduct a study to address the chosen study questions listed in

Programmatic Interests. Recipients must address at least 3 of the four study questions.

b. Evaluate and analyze data.

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

2. CDC Activities

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

b. Assist in the development of a research protocol for 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 is completed.

c. Monitor and evaluate scientific and operational accomplishments of the project through periodic site visits, telephone calls, and interim data analyses.

d. Assist, as needed, in the analysis and interpretation of data.

e. Assist in the dissemination of finding to the public health community for use in prevention programs.

F. Application Content

Follow the PHS–398 (Rev. 5/95) application and Errata sheet, and include the following information. Applicants must document access to men, persons of color, and young adults (e.g., age 18–24) to address existing gaps in knowledge about HSV transmission.

1. Summarize current knowledge of transmission and burden of genital herpes infections among asymptomatic and symptomatic infected persons and their sex partners in the United States and the potential role of new type-specific serologic tests for HSV likely to become commercially available. Describe how activities evaluated in this project can be implemented into public health practice.

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

3. A detailed plan describing the methods by which the objectives will be achieved and evaluated, including their sequence. Describe the extent to which the selected study sites and study populations will enable the results from this research to be generalizable to other settings or populations likely to be screened or at risk for genital HSV infection, including clinical service delivery settings in addition to traditional public STD clinics such as managed care organizations, family planning clinics, and community-based clinics.

4. Describe procedures to disseminate the study findings through presentation and publication.

5. Describe the principal investigator's role and responsibilities.

6. Describe qualifications of proposed staff and their previous experience and achievements in genital herpes research, health services research, health economics, behavioral and social sciences, epidemiology and biostatistics, and laboratory sciences as appropriate for the proposed project. For each member of the research team, include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the cooperative agreement, and identify specific assigned responsibilities.

7. Describe the nature and extent of collaboration with State and local health departments or research institutions and CDC during various phases of the project. Provide in an appendix, letters of support from all key participating organizations which clearly indicate their commitment to participate as described in the operational plan. Collaboration with experts and organizations that have expertise in genital herpes education, counseling, and advocacy is encouraged.

8. Describe proposed procedures for adequate protection of human subjects. Describe how women and racial and ethnic minorities are appropriately represented in the proposed research.

9. Provide a line-item budget and an accompanying detailed line-by-line justification that demonstrates the request is consistent with the purpose and goals of this program. Include a detailed first year's budget for the cooperative agreement with future annual projections, if relevant.

G. Submission and Deadline

Letter of Intent (LOI)

A letter of intent to apply is requested but not required from potential applicants. Your letter of intent should include the following information: announcement number 99115; 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 postmarked on or before June 25, 1999, to: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99115, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341.

Application

Applicants should follow the PHS–398 (Rev. 4/97) and Errata sheet. Forms are in the application kit. On or before July 25, 1999, submit the application to: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99115, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341.

Deadline: Applications shall be considered as meeting the deadline if they are either received on or before the deadline date or sent on or before the deadline date and received in time for orderly processing. (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.) Applications that do not meet these criteria are considered late applications, will not be considered, and will be returned to the applicant.

H. Evaluation Criteria

Applications that are complete and responsive may be subjected to a preliminary evaluation (triage)to determine if the application is of sufficient technical and scientific merit to warrant further review; CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator or program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process. Awards will be made based on priority score by Peer Review, programmatic priorities and needs as determined by a secondary review panel, and the availability of funds.

1. The first review will be a peer review of all applications. Evaluation factors will be:

a. The background of the proposal, e.g., the basis for the present proposal, a critical evaluation of existing knowledge, and the specific knowledge gaps that the applicant intends to fill.

b. The specific aims of the research project, i.e., the objectives and the hypothesis to be tested.

c. The originality of the proposed research from a scientific or technical standpoint, including the adequacy of the theoretical and conceptual framework.

d. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures and plans for data management and statistical analyses, and evaluation.

e. The extent to which the study population included men, racial and ethnic minorities, and young adults, i.e., age 18–24.

f. The extent to which the research findings are likely to lead to new policies and recommendations by advisory groups or feasible, cost-effective interventions.

g. Qualifications, adequacy, and appropriateness of the interdisciplinary

research team to accomplish proposed activities. The extent to which the research team includes expertise in genital herpes research, behavioral and social sciences, health services research, health economics, epidemiology, biostatistics, and laboratory sciences as appropriate for the proposed project.

h. The degree of commitment and cooperation of proposed collaborators and participating organizations, as evidenced by letters detailing the nature and extent of the involvement.

i. Capacity to carry out the project, including adequacy of existing and proposed facilities and resources.

j. Inclusion of Women and Racial and Ethnic Minorities in Research: 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. 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 communities and recognition of mutual benefits.

k. Human subjects: The extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects.

l. The reasonableness of the proposed budget to the proposed research.

2. The second review will be conducted by a secondary review committee of Senior Federal officials. The factors to be considered will include:

a. The results of the peer review.

b. Geographic distribution.

c. The overall match between the proposal and the program interests.

d. Overall balance among the four major areas of interest: (1) the behavioral and psycho social impact and indirect and intangible costs of genital herpes infections; (2) acceptability of screening for genital HSV; (3) correlates of infectivity among asymptomatic and symptomatic infected persons; and (4) relative risk of HSV transmission from asymptomatic and symptomatic infected persons to sex partners.

e. Budgetary considerations.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports semiannually;

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

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

Send all reports to the Grants Management Specialists 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–7—Executive Order 12372 Review
AR–9—Paperwork Reduction Act
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2000
AR–12—Lobbying Restrictions

J. 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. 247c], as amended. The Catalog of Federal Domestic Assistance number is 93.978.

K. Where To Obtain Additional Information

This and other CDC announcements may be downloaded from the CDC Internet home page—http://www.cdc.gov. Click on ''funding.''

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: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99115, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone (770)488–2716, E-mail address: spo2@cdc.gov

For program technical assistance, contact: Katherine Stone, Division of STD Prevention, Centers for Disease Control and Prevention (CDC), Mail Stop E–02, 1600 Clifton Road, Atlanta, Georgia 30333, Telephone (404) 639–8183; FAX (404) 639–8610, E-mail address: kms1@cdc.gov

Dated: May 12, 1999.

John L. Williams,

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

[FR Doc. 99–12438 Filed 5–17–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1220]

Draft Civil Money Penalty Reduction Policy for Small Entities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a draft civil money penalty reduction policy for small entities as required by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995. This draft policy is being issued for public comment only and will not be implemented until a final policy is published in the **Federal Register**.

DATES: Written comments on the draft policy may be submitted by August 16, 1999.

ADDRESSES: Submit written comments on the draft policy to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft policy.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is issuing a draft civil money penalty (CMP) reduction policy for small entities (draft penalty reduction policy) as mandated by SBREFA (Pub. L. 104–121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies as follows:

Sec. 223—Rights of Small Entities in Enforcement Actions

(a) In General—Each agency regulating the activities of small entities shall establish a policy * * * to provide for the reduction, and under appropriate circumstances for the waiver, of civil penalties for violations of a statutory or regulatory requirement by a