

Dated: May 21, 2001.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science

Announcement of Availability of Funds for Research in Family Planning Service Delivery Improvement

AGENCY: Office of Population Affairs, OPHS, DHHS.

ACTION: Notice.

SUMMARY: The Office of Population Affairs (OPA) requests applications for family planning service delivery improvement research grants. Applications should address Title X Family Planning Program priorities in two general areas: (1) Providing family planning and reproductive health services to underserved populations; and (2) assessing the impact of increasing costs on the delivery of family planning and reproductive health services.

DATES: The closing date for this grant announcement is July 26, 2001. Applications will be considered as meeting the deadline date if they are: (1) Received on or before the deadline date or (2) postmarked on or before the deadline date and received in time to be considered during the competitive review process. A legible date receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applications which do not conform to requirements of this announcement will be accepted for review. Applicants will be so notified and the applications will be returned.

ADDRESSES: Application kits may be obtained from the Office of Population Affairs, Office of Grants Management, 4350 East-West Highway, Suite 200, Bethesda, MD 20814. Application kits may also be downloaded from the OPA web site at <http://www.hhs.gov/opa> or requests may be faxed to (301) 594-5980. To facilitate the handling of written requests, please include: name, title, organization, mailing address, telephone number and e-mail address. All completed applications must be submitted to the Office of Grants Management at the above mailing address. Please label the application envelope: "Attention: Family Planning Research."

FOR FURTHER INFORMATION CONTACT: For information on specific research issues: Eugenia Eckard, Office of Population Affairs, (301) 594-6534. For questions about the technical preparation of the grant application: Andrea Brandon, Grants Management Officer, (301) 594-4012.

SUPPLEMENTARY INFORMATION: Title X of the Public Health Service Act (42 U.S.C. 300a-2) authorizes the Secretary of Health and Human Services to award grants and enter into contracts with public agencies or private nonprofit entities to provide research in behavioral and program implementation fields related to family planning. (Catalogue of Federal Domestic Assistance No. 93.974.) This research program is not subject to the intergovernmental review requirements of Executive Order 12372 and 45 CFR 100.

It is the policy of OPA that women and members of minority groups and their subpopulations be included in all OPA supported research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subject or the purpose of the research.

All investigators proposing research involving human subject should read the updated "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", published in the NIH Guide for Grants and Contracts on August 2, 2000 and available at: http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm.

In the interest of making data available to others, copies of data sets and accompanying documentation produced with funds granted through this announcement will be deposited with a public use data archive or with the OPA. The cost of making such data available should be budgeted in the proposal.

Applications should address how findings from the proposed study will have general applicability to the improvement of the delivery of family planning services, and a plan must be presented on how information from the research findings will be disseminated.

Healthy People 2010: The OPA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA) is related to one or more of the priority areas, in particular the focus area on family planning.

Potential applicants may obtain "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Research Goals and Scope: The primary purpose of the Title X Family Planning Program is to provide family planning and reproductive health services to all persons desiring them. To that end, the program is guided by a set of priorities: maintain a high level of quality in the family planning and reproductive health services delivered; ensure comprehensiveness in the range of services offered, and; increase access to services through partnerships with other public health providers and community-based organizations, as well as outreach to underserved populations. This RFA invites proposals for applied research to address these priorities in two general areas: (1) Providing family planning and reproductive health services to underserved populations; and (2) assessing the impact of increasing costs on the delivery of family planning and reproductive health services.

Underserved Populations

It has been demonstrated that access to family planning and reproductive health services has a positive impact on reducing the incidence of sexually transmitted diseases (STD)/HIV infection, unintended pregnancy, abortion, maternal and infant morbidity and mortality, and diseases of the reproductive system. The Title X Family Planning Program was established in 1970 to facilitate such access by offering a broad range and family planning and reproductive health services-at low or no cost, on a voluntary and confidential basis, and without regard to race, national origin, age, gender, or disability.

The Title X program currently serves approximately 4.5 million persons annually and service data indicate the program is meeting its mandate of providing family planning and reproductive health services to many of those in need. For example, a major barrier to receiving health care is its cost. Title X regulations specify that priority in the provision of services be given to persons from low income families and, in 1999, 83 percent of Title X clients had family incomes at or below 150 percent of the poverty level. There are, however, factors other than low income that can have a negative impact on the ability of some populations to obtain family planning and reproductive health services. Of particular concern are the social, cultural, physical, and language barriers that may hinder access for certain populations subgroups. These factors

must be better understood and addressed, and protocols to meet the unique service delivery requirements of affected populations need to be developed and tested.

Under this announcement, funds are available for research, directly applicable to service provision, on one or more of the following underserved populations: Homeless persons, migrant workers, recent immigrants, substance abusers, disabled persons, and males. Proposals must demonstrate a well developed understanding of the family planning and reproductive health needs of the target population(s) chosen. Relevant areas of inquiry include, but are not limited to: Client behavior—when and why they do or do not seek services; physical or location barriers which may inhibit client access; the implications of clinic personnel knowledge, attitudes and behavior on client access; providing services in nontraditional settings; the development and testing of outreach and communication strategies, and; the development and testing of information and education materials specifically targeting underserved populations.

Increasing Costs

Even as the Title X Family Planning Program works to provide outreach and services to underserved populations, increasing costs are having an impact on the program's ability to maintain the level and quality of the services it provides to currently enrolled clients. Inflationary pressures are easily quantified; for example, during the past decade, the medical care component of the Consumer Price Index (CPI) increased at an average annual rate of 5.1 percent, compared with an average annual increase of 2.7 percent in the overall CPI. What are not as easily quantified are the cost increases incurred by technology advances, changes in the population served and the mix of services they require, and maintaining adequate clinic staffing in terms of both number and qualification.

A fundamental charge to the Title X program is to ensure contraceptive choice; program regulations and guidelines require that a full range of contraceptive methods and related counseling be available to clients. Hormonal methods of contraception are highly effective and nearly three-quarters of Title X clients choose them. They are also costly, particularly in the case of implants and injectables. Other contraceptive methods, such as the diaphragm or natural family planning, while not costly in terms of supplies, do require extensive instruction and counseling—which are costly.

Similarly, screening for STDs, cancers and other diseases of the reproductive system are core Title X services and an integral element in maintaining high standards of care and comprehensiveness of services. There are new diagnostic technologies available that have the potential to better manage diagnoses and reduce the need for invasive procedures; they are often significantly more expensive than the traditional technologies.

The true cost of providing services is, however, more complicated than the cost of a contraceptive method or a diagnostic test multiplied by the number of persons receiving the service. Who is receiving services would also have an impact on cost. For example, the reported influx of uninsured or underinsured clients into the Title X system has implications for the type and quantity of services required, as well as for provider revenue. Efforts to reach underserved, and often hard-to-serve, populations could have similar effects. Demands for increased staff time spent providing counseling as well as clinical services are another consideration, as are increases in personnel costs as State requirements for masters degree level nurse practitioners are implemented.

Under this announcement, funds are available for research on the complex interplay of factors that contribute to the increasing costs of providing family planning and reproductive health services and to document and assess the extent and impact of such increases. It is preferable that analyses address change over time rather than one single point in time. Relevant areas of inquiry include, but are not limited to: the increasing cost of providing specific contraceptive methods, including the actual cost of the method(s), shifts in demand for the method(s), and staff level and time required; the cost of using advanced diagnostic technologies, including the actual cost of the technology, staff level and time required, and the long range cost implications—to the provider—of adopting the technology; the cost of providing services to underserved populations(s), including outreach efforts and the specific mix of services required; the costs involved in recruiting and retaining adequate numbers of qualified clinical and nonclinical staff, and; factors affecting provider revenue, including increases in the number of clients requiring subsidized services, changes in third party reimbursement to providers, and shifts in Federal, state, and local funding sources.

Eligible applicants: Any public or private nonprofit entity is eligible to

apply for a grant under this announcement.

Funds Available: The OPA intends to make available approximately \$1,000,000 in Fiscal Year (FY) 2001 to support an estimated three to four new research grants, each in the range of \$150,000 to \$250,000. Grants will be funded in annual increments (budget periods) and may be funded for a project period of up to two years. A match will not be required. Funding for the second approved budget period is contingent upon the availability of funds, satisfactory progress on the project, and adequate stewardship of federal funds. Funding decisions can be expected by September 30, 2001.

Review Procedures and Criteria: Applications in response to this solicitation will be reviewed and scored, in competition with other submitted applications, by an independent review panel. Review criteria include:

1. Potential usefulness. How the results of the proposed research project are expected to advance knowledge in the field of family planning and reproductive health service delivery with respect to underserved populations or assessing the extent and impact of increasing costs. (30 points)

2. Quality and soundness of research design. The strength and appropriateness of the conceptual framework underlying the project, as well as the methodology and analytic strategies proposed. (30 points)

3. Qualifications of personnel and organizational capacity. The qualifications of project personnel for conducting the proposed research as evidenced by professional training and experience. Principal investigator and staff time commitments will also be considered, as will the capacity of the organization to provide necessary infrastructure and support. (20 points)

4. Adequacy of work plan and budget. The reasonableness and sufficiency of the work plan and budget to ensure timely implementation and completion of the proposed research. (20 points)

Final grant award decisions will be made by the Deputy Assistant Secretary for Population Affairs (DASPA) on the basis of priority score, program relevance, and availability of funds.

Applicants will be notified, by letter, of final funding decisions. The official document notifying an applicant that an application has been approved for funding is the Notice of Grant Award, which specifies the amount of money awarded, the purpose of the grant, and the terms and conditions of the grant award.

Method of Applying: Applications should be prepared on form PHS 5161,

which is included in the application kit for this announcement and also available from the business or grant and contracts office at most academic and research institutions, as well as at: <http://forms.psc.gov/forms/PHS/phs.html>. Submissions should include a signed typewritten original of the application and two signed photocopies. Application submissions may not be faxed or sent electronically.

Dated: May 18, 2001.

Mireille B. Kanda,

Acting Director, Office of Population Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Minority Health

AGENCY: Office of the Secretary, Office of Public Health and Science, Office of Minority Health, HHS.

ACTION: Notice is given of the second meeting.

The Advisory Committee on Minority Health will meet on Thursday, June 21, 2001 from 9:00 am to 5:00 pm, and Friday, June 22, 2001, from 8:30 am–12 Noon. The meeting will be held at the Hilton Washington and Towers Hotel, The State Room, 1919 Connecticut Avenue, NW., Washington, DC.

The Advisory Committee will discuss racial and ethnic disparities in health, as well as, other related issues.

The meeting is open to the public. There will be an opportunity for public comment which will be limited to five minutes per speaker. Individuals who would like to submit written statements should mail or fax their comments to the Office of Minority Health at least two business days prior to the meeting.

For further information, please contact Ms. Patricia Norris, Office of Minority Health, Rockwall II Building, 5515 Security Lane, Suite 1000, Rockville, Maryland 20852. Phone: 301-443-5084 Fax: 301-594-0767.

Dated: May 25, 2001.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01085]

Integrating Prevention Services for Persons With Bleeding and Clotting Disorders; 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 to demonstrate the effectiveness of the comprehensive care model in preventing or reducing bleeding and clotting disorder related complications through hemostasis and thrombosis centers. This program addresses the "Healthy People 2010" focus areas of access to quality health services, disability and secondary conditions, educational and community-based programs, and public health infrastructure.

The purpose of the program is to (1) determine the efficacy of integrated multi-disciplinary care and prevention services for persons with hemophilia, other hereditary bleeding disorders including women with bleeding disorders, and thrombophilia to reduce morbidity and mortality associated with bleeding and clotting diseases; (2) assess unmet needs for service delivery and identify outreach strategies designed to improve access to care; (3) develop effective messages aimed at disease management and prevention; and (4) foster the development of training programs to enhance provider skills for the delivery of hemostasis and thrombosis care.

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: 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.

C. Availability of Funds

Approximately \$1,000,000 is available in FY 2001 to fund approximately four awards. It is expected that the average award will be \$250,000, ranging from \$200,000 to \$300,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of up to two years. The funding estimate may change.

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

D. Program Requirements

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. Using the principles of the multi-disciplinary comprehensive care model utilized in hemophilia treatment center prevention programs, implement the model in a health care setting that features strong clinical, research, outreach, education, support and provider training programs for persons with hemophilia, other hereditary bleeding disorders including women with bleeding disorders, and thrombophilia.

Specifically:

(1) Identify unmet needs of target populations and establish outreach mechanisms to improve access to care for persons with bleeding and clotting disorders for the purpose of evaluating prevention interventions.

(a) Determine strategies that will address unmet needs, assess the efficacy of prevention activities and improve access to under-served populations such as women with bleeding disorders and individuals with thrombophilia.

(b) Conduct outreach efforts to increase prevention intervention awareness and availability of comprehensive care among the affected population and referring providers and establish referral patterns.

(c) Facilitate communication with other sub-specialties concerning awareness and prevention of the complications of bleeding and clotting disorders.

(2) Develop and implement a plan that will provide clinical expertise for diagnosing underlying causes of coagulation disorders and provide management and prevention services. Experience with bleeding and clotting