DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of Public Health and Science, Office of Population Affairs, Office of Family Planning.

FUNDING OPPORTUNITIY TITLE: Announcement of Availability of Funds for Male Family Planning Research Cooperative Agreements.

ACTION: Notice.

ANNOUNCEMENT TYPE: Initial Competitive Grant

CFDA NUMBER: 93.974

DATES: To receive consideration, applications must be received by the Office of Public Health and Science (OPHS), Office of Grants Management, no later than 60 days from the date of publication in Grants.gov **July 25, 2008**. Applications will be considered as meeting the deadline if they are received by the OPHS Office of Grants Management, c/o Grant Application Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, no later than 5 P.M. Eastern Time on the application due date. Applications that are electronically submitted through GrantSolutions.gov or Grants.Gov will be accepted until 11:00 P.M. Eastern Time on this date. Applications will not be accepted by fax, nor will the submission deadline be extended. The application due date requirement specified in

this announcement supersedes the instructions in the OPHS–1. Applications which do not meet the deadline will be returned to the applicant unread. See heading ‘‘APPLICATION and SUBMISSION INFORMATION’’ for information on application submission mechanisms.

EXECUTIVE SUMMARY: The Office of Population Affairs (OPA), Office of Family Planning (OFP) announces the availability of funds for cooperative agreements to coordinate and participate in a multi-site research study testing a comprehensive family planning service delivery model for males. The purpose of this cooperative agreement is to test a comprehensive service delivery model and evaluate its effectiveness and replicability in Title X clinics. This current research announcement is based in-part on past approaches and theories developed during previous research grant periods. Five cooperative agreements will be awarded to participating study sites where the models will be tested; one cooperative agreement will be awarded to a study coordinating center.

I. FUNDING OPPORTUNITY DESCRIPTION

This announcement seeks proposals from public and private nonprofit organizations to participate in a multi-site research study on the delivery of family planning and related reproductive health education and clinical services to males. Respondents to this request for applications (RFA) may apply to participate either as one of five (5) *study sites* or as the *coordinating center* for the study. The study will measure the effectiveness of a comprehensive service delivery model aimed at increasing the number of males who access family planning and related reproductive health services in

clinical settings. The model is comprised of three components: 1) the restructuring of the clinic environment, 2) the training of clinic staff at all levels on the delivery on male services, and 3) targeted community outreach and promotion of services. All *participating study sites* will receive training and technical support on the implementation of the service delivery model and will be expected to adhere to the same research protocol. The *coordinating center* will develop the research protocol, manage the delivery of training and technical assistance to study sites, and conduct the overall evaluation (including the data collection and analyses) of the service delivery model, in conjunction with the Office of Population Affairs (OPA), Office of Family Planning (OFP).

AUTHORITY: Section 1004 of the Public Health Service (PHS) Act.

Statutory Background

Title X of the PHS Act, 42 U.S.C. 300 et seq., authorizes grants for projects to provide family planning services to persons from low-income families and others. Section 1001 of the Act, as amended, authorizes grants "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective methods and services (including natural family planning methods, infertility services, and services for adolescents)."

Section 1004 of the Act, as amended, authorizes the Secretary of Health and Human Services to support "research in the biomedical, contraceptive development, behavioral and program implementation fields related to family planning and population." Although there are no regulations specific to Title X research projects,

regulations that generally pertain to health-related research project grants administrated by the Public Health Service or its components are set out at 42 CFR part 52.

Background:

The family planning program authorized by Section 1001 of Title X is required by law to provide family planning services, including information, education and clinical services, to all persons desiring such services. One subgroup of the population that continues to have low participation in family planning services is males. Over the past 10 years, males have comprised only three to five percent of clients served by the Title X family planning clinic service delivery system each year. This would seem to indicate that simply allowing men access to clinical services alone does not result in them using those services.

Young and adult men have reproductive health concerns; however, these concerns may not readily translate into contact with the health care system. During adolescence and young adulthood, sexual and reproductive health issues and behaviors have a great influence on all individuals' lives, including males. Accurate information, skills, and support should be available to encourage delay of sexual debut until after adolescence and preferably until marriage. For sexually active young males, this time of life may bring with it such health concerns as sexually transmitted infections (STIs) including HIV/AIDS, unintended pregnancy and the emotional stress of interpersonal and intimate relationships.

Among middle-aged and older men, health concerns around sexual and reproductive behavior continue, though the nature of these concerns may differ from those of younger males. Even when they visit a health care provider, males are more reluctant than females to bring problems of a reproductive or sexual nature to the attention of the clinician. Involving males in seeking reproductive health services requires a different approach than that which has been successful with females.

Since 1997, the OPA, OFP has funded two cycles of Male Family Planning and Reproductive Health (RH) research initiatives that have evolved. During the first cycle, ten grantees were funded across the nation, ranging from community-based organizations to academic institutions. The focus of this early research was to identify perceptions and barriers to access among males. The first cycle of research projects provided evidence as to the unmet demand among males for reproductive health services and clarified some of the barriers to access, such as services not being provided in a male-friendly environment or services not being provided in the broader context of men's health concerns. The second cycle of research funded in 2003 incorporated these qualitative findings and was aimed at the identification of service delivery models—ranging from curriculum-based health education to innovative strategies for the offsite delivery of clinical reproductive health services for male clients.

The important work carried out during these first two cycles of research generated key insights into the perceptions and attitudes of males regarding family planning and reproductive health services. It also resulted in the identification of the strategies and key

considerations summarized below that appear to have a critical role in increasing the number of male clients utilizing reproductive health services:

- There is an unmet need for family planning and reproductive health education and services for males; they want and need education, counseling, and access to clinical services. The low levels of utilization of clinical services by males is not an indication of a lack of need by males for services but rather an indication of the health system's failure to tailor services appropriately to meet their needs.
- Males have an important role to play in the planning of families as well as the prevention of unintended pregnancies and sexually transmitted infections; adherence and compliance with contraceptive methods increases when both partners are involved.
- The provision of services needs to be carried out in a culturally appropriate manner; reproductive health issues need to be incorporated into a holistic approach for male health and delivered through non-traditional venues such as work sites, schools, sports and recreational centers.
- Programs that have been most effective at reaching and retaining males are well integrated in a network of health and social service providers. Males that practice high-risk behaviors are often in need of referrals for social services, and while no single program can provide all services, it is important to have a network of referrals in place. Targeted community outreach and education program activities need to be linked to quality clinical services.

- RH services often act as the primary entry point into the healthcare system for males who otherwise would not seek health care. Increasing access to RH services and providers is critical to ensuring the good health of these males.

Purpose of the cooperative agreement:

A number of promising strategies for delivering services to males were identified during the second cycle of OFP-funded male family planning research. Although these strategies were developed independently and in different settings, many of these programs shared common elements. The purpose of this cooperative agreement is to test the effectiveness and replicability of a comprehensive service delivery model based on some of the promising strategies identified during the first and second cycles of family planning male research. The model will be tested in five research sites that are located in culturally and geographically diverse settings and will be managed by a coordinating center in close collaboration with OFP. The primary outcome to be measured in this study will be the utilization of clinical family planning and reproductive health services consistent with Family Planning Annual Report (FPAR) data. The FPAR is the only source of annual, uniform reporting by all Title X family planning services grantees. It provides consistent, national-level data on the Title X Family Planning Program and its users.

Interested organizations may apply to participate as one of five (5) study sites *or* to be the coordinating center for the study; organizations may not apply to do both. Study sites must be willing and able to implement the service delivery model described

below as well as to provide data on clinic usage by males as needed. The coordinating center for the study will be responsible for developing the study protocol, implementing the necessary training(s) during the first year for the participating sites, as well as overall oversight of the evaluation, including data collection and analysis. In subsequent years, the coordinating center will be responsible for monitoring the progress of the study and the development of annual reports, overseeing the data collection, as well as providing training and technical assistance as needed (within the allocated budget) to participating study sites.

Description of service delivery model to be tested

The comprehensive service delivery model will be comprised of three main components: 1) restructuring the clinical environment to accommodate male clients; 2) provision of training to clinical staff at all levels on the delivery of reproductive health services to males; and 3) the use of targeted outreach and promotion of services.

- Restructuring the clinic environment: In order to better serve male clients, the clinical environment (including waiting rooms, laboratories, exam rooms) must be modified, as necessary, to reflect the needs and comfort of male clients. In addition to the enhancements made to the overall clinic environment, the clinic schedule will be restructured to include times dedicated specifically for male clients.
- Training of staff: Clinical providers including physicians (MDs), nurse practitioners (NPs), physician assistants (PAs), and others will receive training on conducting and performing male exams and other related screening procedures for males. Additionally, all clinic staff (including administrative and support staff) will receive

training on being responsive to the needs of males as well as cultural competence. The purpose of these trainings is to sensitize clinic staff to the specific needs of males seeking reproductive health services as well as to improve their comfort level and interactions with male clients.

- Targeted community outreach and promotion of clinical services: Intensive outreach and education targeting males will be conducted through linkages with community-based organizations, including faith-based organizations, schools, and various other community venues and events. Additionally, clinical services for males will be promoted through existing female clients through referrals to their friends and families.

Organizations interested in participating as a study site are not expected to propose how they will implement this service delivery model. They must indicate their willingness and capacity to implement changes to their existing clinical structure to incorporate the three components described above. During the first year of the project, selected organizations will receive detailed program guidelines and technical assistance to establish and implement the service delivery model and research protocols.

Funds provided through this cooperative agreement may be used by *participating study sites* to support staff time (including the project director, clinical providers, health educators/outreach staff, and administrative/support staff), overhead expenses, equipment/software for data collection, training (that is not provided by the coordinating center), information and educational materials required for health education and outreach activities, and required travel for up to three (3) project team members.

During the first year, *participating study sites* will be required to attend to three (3) study-related training meetings and one (1) OFP sponsored national conference. Due to the intensity of training and technical support required to implement the service delivery model and research protocols at each of the participating study sites, the training will be delivered in three phases during the first year and will focus on the following components of the study.

- The first training phase will focus on the orientation to the project and study protocols, which will include guidance on the establishment and implementation of the comprehensive service delivery model at each clinic site. Participating study sites will receive detailed guidelines governing the program requirements of the service delivery model and other necessary support to implement the model. Having all projects participate in this meeting will help to ensure the consistency of the program model and the comparability of the study results among the different sites.
- The second training phase will focus on integrating males into the clinical environment, with specific emphasis on skills development for clinical providers and staff working with males. Staff will be trained on how to serve males in the clinic as well as how to counsel and educate males. Clinical providers will receive specific training on the provision of clinical reproductive health services to males.
- The third phase of the training during the first year will focus on the implementation of the research protocols and data collection management systems. Participating sites will receive training on basic research methods,

ethics, and data management. The study sites will also receive guidance on the study objectives, outcomes, and evaluation processes.

In addition to these trainings, the participating sites will be required to attend a national conference sponsored by OFP. This conference will provide study participants with an opportunity to network and develop linkages with other organizations providing reproductive health and ancillary services to males. The conference will also provide the study sites with updated science and technology as well as best practices relating to male reproductive health. This will assist in the development and improvement of the sites.

In subsequent years, participating study sites will be required to attend one (1) study-related training meeting and one (1) OFP-sponsored national conference. The first meeting will be a study specific meeting that will focus on the following:

- Implementation and management of the service delivery models at each of the participating study sites: Participants will discuss challenges and progress in delivering clinical services to males and share strategies for overcoming these barriers.
- Management of data collection: Data will be collected at six (6) month intervals and submitted to the study coordinating center. Collected data will be reviewed and any discrepancies or missing data will be discussed.
- On-going monitoring of the study progress. The study coordinating center will be required to develop an annual report highlighting the progress made on the delivery of services to males as well as initial research study outcomes.

Funds provided through this cooperative agreement may be used by the *study coordinating center* to support staff time (including the project director, evaluation specialist, statistician, and administrative/support staff), overhead expenses, fees and travel for consultant trainers/technical assistance providers, required travel to OFP-sponsored meetings for up to three (3) project team members, equipment/software for data analysis, as well as related conference logistic expenses.

Timeline of activities

The planned duration of this research study is five years. During Year One of the research cycle, participating sites will receive training and technical assistance on the implementation of the comprehensive service delivery model, research methods, and data collection. During years two through five, programs will be intensively monitored and data collected from each of the study sites. Annual progress reports summarizing activities and preliminary data analyses will be prepared by the study coordinating center at the end of years one through four. A final report, with study outcomes, will be completed during the last six months of the cooperative agreement.

II. AWARD INFORMATION

The Office of Family Planning intends to make available approximately $1.5 million for the conduct of this multi-site research study. To support the intensity of the initial training and technical assistance required to set up the study sites during the first year, the study coordinating center will be funded at $375,000 in Year One; participating study sites will be funded at $225,000 in Year One. In each of the subsequent years, it is

anticipated that the coordinating center will receive a maximum award of $300,000, and that each of the five (5) study sites will receive a maximum award of $250,000 per year. Cooperative agreements for the coordinating center and participating study sites will each be funded in annual increments for a project period of up to five years. A match of non-Federal funds will not be required. Funding for all years beyond the first year of the cooperative agreement will be contingent upon the availability of funds, satisfactory progress on the project, and adequate stewardship of Federal resources. All amounts are inclusive of direct and indirect costs.

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

Participating study sites: Any public or private nonprofit entity currently providing family planning and related reproductive health clinical services located in a State (which includes one of the 50 United States, the District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands) is eligible to apply to participate as a study site in this research study. Faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply for this male family planning research cooperative agreement as a participating study site. Organizations with experience in the provision of family planning and related reproductive health services to males are encouraged to apply.

As the purpose of this research is to measure the effect of the implementation of a comprehensive and deliberate service delivery model on the utilization of services by males, *participating study sites* should not already be implementing all three components (restructuring of environment, training of staff, and targeted outreach) of this model. Eligible organizations are those that are currently not utilizing any of these three components or those utilizing some, but not all, of the three components together. Organizations with programs that already incorporate ***all*** three components as a comprehensive and deliberate model will not be considered as study sites. Such organizations are encouraged to apply to be the study coordinating center (see below). Organizations providing clinical family planning services not currently serving males or those currently serving males through other service delivery models are encouraged to apply to be a participating study site. If selected as a *participating study site*, organizations will be required to make any necessary modifications to existing services in order to implement the comprehensive service delivery model and study protocols as outlined by OFP and the coordinating center.

Study coordinating center: Any public or private nonprofit entity located in a State (which includes one of the 50 United States, the District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the republic of the Marshall Islands) is eligible to apply to be the study coordinating center in this research study. Faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply for this male

family planning research cooperative agreement as the study coordinating center. Organizations with experience in the conduct of training and research related to family planning and reproductive health services for males are encouraged to apply.

Organizations applying to be the study coordinating center should be experienced in the implementation of the comprehensive service delivery model (or the three components) to be tested in this research; they should also have expertise in health services training and research, including the management of data collection in multiple sites and the conduct of bio-statistical analyses.

2. Cost Sharing: None Required

IV. APPLICATION AND SUBMISSION

Letter of Intent (LOI)

Prospective applicants are asked to submit a letter of intent as early as possible but by no later than two weeks prior to the application deadline indicated in the "DATES" section of this announcement. The LOI should include the following information:

- name and location (city and state) of the applicant organization;
- name, address, and telephone number of the Project Director;
- names of other key personnel; and
- the title of this funding opportunity.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows OPA staff to estimate the potential review workload and plan the review. The letter of intent should be sent to Mr. David Johnson, at the address listed under the "Agency Contacts" section below.

1. Address to Request Application Package

Application kits may be obtained electronically by accessing grants.gov at http://www.grants.gov or GrantSolutions at http://www.grantsolutions.gov. Application kit requests may also be made through the OPHS Office of Grants Management, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852; telephone 240-453-8822 or fax 240-453-8823. Instructions for use of the GrantSolutions system can be found on the OPA web site at http://hhs.gov/opa or requested from the OPHS Office of Grants Management.

2. Content and Form of Application

Applications must be submitted on the Form OPHS–1 and in the manner prescribed in the application kit. Applications should include an abstract of the proposed project. The abstract will be used to provide reviewers with an overview of the application, and will form the basis for the application summary in grants management documents. The application narrative should be limited to 30 double-spaced pages using an easily readable serif typeface such as Times Roman, Courier, or GC Times, 12 point font. The page limit does not include budget; budget justification; required forms,

assurances, and certifications as part of the OPHS–1; or appendices. All pages, charts, figures and tables should be numbered.

The application narrative should be numbered separately and clearly show the 30 page limit. If the application narrative exceeds 30 pages, only the first 30 pages of the application narrative will be reviewed. Appendices may provide curriculum vitae, organizational structure, examples of organizational capabilities, progress report for a continuing competitive application, or other supplemental information which supports the application. However, appendices are for supportive information only, and should be limited to only that which is necessary to support the application narrative. All information that is critical to the proposed project should be included in the body of the application. Appendices should be clearly labeled.

For all non-governmental applicants, documentation of nonprofit status must be submitted as part of the application. Any of the following constitutes acceptable proof of such status:

a. A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS tax code;
b. A copy of a currently valid IRS tax exemption certificate;
c. A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a nonprofit

status and that none of the net earnings accrue to any private shareholders or individuals; and

d. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.

For local, nonprofit affiliates or State or national organizations, a statement signed by the parent organization indicating that the applicant organization is a local nonprofit affiliate must be provided in addition to any one of the above acceptable proof of nonprofit status.

A Dun and Bradstreet Universal Numbering System (DUNS) number is required for all applications for Federal assistance. Organizations should verify that they have a DUNS number or take the steps needed to obtain one. Instructions for obtaining a DUNS number are included in the application package, or may be downloaded from the grants.gov website.

Program Requirements

This notice seeks applications to participate in a multi-site research study to test the effectiveness and replicability of a comprehensive service delivery model for the provision of family planning and related reproductive health services to males. Applicants may apply to participate as one of five study sites *or* to be the coordinating center; applicants may *not* apply to do both.

Applications to be a *participating study site* should include the following:

1) A demographic and epidemiologic profile of the community served by the applicant organization with specific reference to reproductive health indicators for the male population;
2) A description of the need for family planning and related reproductive health services by males in the community served by the applicant organization;
3) A description of existing family planning and related reproductive health services (including clinical, education, and referral) for males in the community served by the applicant organization;
4) Evidence that the applicant organization has experience and documented success in providing clinical family planning and reproductive health services;
5) Evidence that the applicant organization is willing and has the capacity (infrastructure, staff, skills, leadership, and networks) to expand the scope of its current services to reach male clients in a culturally relevant manner;
6) Evidence of the applicant organization's capacity to reach males, either through documented linkages with schools, community and/or faith-based organizations serving males or documentation of the organization's internal capacity to conduct outreach to males;
7) An assurance of willingness and ability to implement all components of the comprehensive service delivery model described in this announcement including the following activities:
    a. restructure the clinical environment and hours to facilitate increased client visits by males;

b. require clinical and administrative staff to receive training as part of the comprehensive service delivery program;
c. conduct health education and outreach activities to promote clinical services for males in the community;
d. promote clinical services for males to existing female clients;
e. collect and report electronic FPAR and other study data to the study coordinating center as needed; and
f. contribute data and related information to dissemination activities (presentations, papers, publications, etc.) as requested by the OFP project officer;

8) Evidence of ability to collect, compile, process and electronically transmit FPAR and other related study data to the coordinating center;
9) Evidence of the applicant organization's ability to manage grants and of the organization's fiscal competence; and
10) Curriculum Vitae (CV) of proposed project staff.

Applications to be the *study coordinating center* should include the following:

1) Evidence of the applicant organization's experience *or* expertise in providing family planning and related reproductive health services to males using the service delivery model described or any of its components;
2) Evidence of the applicant organization's ability to provide technical assistance and training conferences/workshops on family planning and reproductive health;

3) Evidence of the applicant organization's ability to conduct and manage research in the field of family planning and reproductive health;
4) Evidence of the applicant organization's capacity (infrastructure and human resources) to process data and conduct statistical analyses;
5) An assurance of willingness and ability to manage all components of the research study including the following activities:
    a. coordinate three training workshops and one meeting in conjunction with the OFP-sponsored national male conference for participating study sites during the first year (the coordinating center will pay for logistic as well as consultant/trainer expenses for the training meetings; participants will cover their own travel);
    b. coordinate one research training meeting and one meeting in conjunction with the OFP-sponsored national male conference in years 2-5;
    c. provide on-going technical assistance as needed to participating study sites in subsequent years two through five;
    d. develop and maintain a system for communication and storage of resource materials that can be accessed by *participating study sites*;
    e. collect, process and analyze data from participating study sites;
    f. prepare annual and cumulative final reports to OFP of the study findings; and
    g. develop a strategy for the dissemination of the study results;
6) Evidence of the applicant organization's ability to manage grants and of the organization's fiscal competence; and

7) Curriculum Vitae of proposed project staff.

Protection of Human Subjects

All applicants must comply with the HHS Protection of Human Subjects regulations (which require obtaining Institutional Review Board approval), set out at 45 CFR part 46, if applicable. General information about Human Subjects regulations can be obtained through the Office for Human Research Protections (OHRP) at http://www.hhs.gov/ohrp, ohrp@osophs.dhhs.gov, or toll free at (866) 447-4777.

Submission Mechanisms for Applications

The Office of Public Health and Science (OPHS) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OPHS Office of Grants Management after the deadlines described below will not be accepted for review. Applications which do not conform to the requirements of the grant announcement will not be accepted for review and will be returned to the applicant. While applications are accepted in hard copy, the use of the electronic application submission capabilities provided by the Grants.gov and GrantSolutions.gov systems is encouraged. Applications may only be submitted electronically via the electronic submission mechanisms specified below. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review.

In order to apply for new funding opportunities which are open to the public for competition, applicants may access the Grants.gov website portal at http://www.grants.gov. All OPHS funding opportunities and application kits are made available on Grants.gov. If an applicant organization has/had a grantee business relationship with a grant program serviced by the OPHS Office of Grants Management, and is applying as part of ongoing grantee related activities, please access http://www.GrantSolutions.gov.

Electronic grant application submissions must be submitted no later than 11:00 P.M. Eastern Time on the deadline date specified in the DATES section of the announcement using one of the electronic submission mechanisms specified. All required hardcopy original signatures and mail-in items must be received by the Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS) c/o Grant Application Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, no later than 5:00 p.m. Eastern Time on the next business day after the deadline date specified in the DATES section of the announcement. Hard copy applications must be received no later than 5:00 P.M. Eastern Time on the deadline specified in the Dates section of this announcement.

Applications will not be considered valid until all electronic application components, hardcopy original signatures, and mail-in items are received by the OPHS Office of Grants Management according to the deadlines specified above. Application

submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible. Applicants are encouraged to initiate electronic applications early in the application development process, and to submit early on the due date or before. This will aid in addressing any problems with submissions prior to the application deadline.

Electronic Submissions via the Grants.gov Website Portal

The Grants.gov Website Portal provides organizations with the ability to submit applications for OPHS grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system is available on the Grants.gov website, http://www.grants.gov. In addition to electronically submitted materials, applicants may be required to submit hard-copy signatures for certain program-related forms, or original materials as required by the announcement. It is imperative that the applicant review both the grant announcement, as well as the application guidance provided within the Grants.gov application package, to determine such requirements. Any required hard-copy materials, or documents that require a signature, must be submitted separately via mail to the Office of Grants Management at the address specified above, and if required, must contain the original signature of an individual authorized to act for the applicant agency, and the obligations imposed by the terms and conditions of the grant award. When submitting the required forms, do not send the entire application. Complete, hard-copy applications submitted after the electronic submission will not be considered for review.

Electronic applications submitted via the Grants.gov Website Portal must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. Any files uploaded or attached to the Grants.gov application must be of the following file formats – Microsoft Word, Excel or PowerPoint, Corel WordPerfect, ASCII Text, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only). Even though Grants.gov allows applicants to attach any file format as part of their application, OPHS restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format identified above will not be accepted for processing and will be excluded from the application during the review process.

All required mail-in items must received by the due date requirements specified above. Mail-in items may include only publications, resumes, or organizational documentation. When submitting the required forms, do not send the entire application. Complete hard-copy applications submitted after the electronic submission will not be considered for review. Upon completion of a successful electronic application submission via the Grants.gov Website Portal, the applicant will be provided with a confirmation page from Grants.gov indicating the date and time (Eastern Time) of the electronic application submission, as well as the Grants.gov Receipt Number. It is critical that the applicant print and retain this confirmation for their records, as well as a copy of the entire application package.

All applications submitted via the Grants.gov Website Portal will be validated by Grants.gov. Any applications deemed "Invalid" by the Grants.gov Website Portal will not be transferred to the GrantSolutions system, and OPHS has no responsibility for any application that is not validated and transferred to OPHS from the Grants.gov Website Portal. Grants.gov will notify the applicant regarding the application validation status. Once the application is successfully validated by the Grants.gov Website Portal, applicants should immediately mail all required hard copy materials to the OPHS Office of Grants Management, c/o Grant Application Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, to be received by the deadlines specified above. It is critical that the applicant clearly identify the Organization name and Grants.gov Application Receipt Number on all hard copy materials.

Once the application is validated by Grants.gov, it will be electronically transferred to the GrantSolutions system for processing. Upon receipt of both the electronic application from the Grants.gov Website Portal, and the required hardcopy mail-in items, applicants will receive notification via mail from the OPHS Office of Grants Management confirming the receipt of the application submitted using the Grants.gov Website Portal. Applicants should contact Grants.gov regarding any questions or concerns regarding the electronic application process conducted through the Grants.gov Website Portal.

Electronic Submissions via the GrantSolutions System

OPHS is a managing partner of the GrantSolutions.gov system. GrantSolutions is a full life-cycle grants management system managed by the Administration for Children and Families (ACF), Department of Health and Human Services (HHS), and is designated by the Office of Management and Budget (OMB) as one of the three Government-wide grants management systems under the Grants Management Line of Business initiative (GMLoB). OPHS uses GrantSolutions for the electronic processing of all grant applications, as well as the electronic management of its entire Grant portfolio.

When submitting applications via the GrantSolutions system, applicants are still required to submit a hard copy of the application face page (Standard Form 424) with the original signature of an individual authorized to act for the applicant agency and assume the obligations imposed by the terms and conditions of the grant award. If required, applicants will also need to submit a hard copy of the Standard Form LLL and/or certain Program-related forms (e.g., Program Certifications) with the original signature of an individual authorized to act for the applicant agency. When submitting the required hardcopy forms, do not send the entire application. Complete hard-copy applications submitted after the electronic submission will not be considered for review. Hard-copy materials should be submitted to the OPHS Office of Grants Management at the address specified above.

Electronic applications submitted via the GrantSolutions system must contain all completed online forms required by the application kit, the Program Narrative, Budget Narrative and any appendices or exhibits. The applicant may identify specific mail-in

items to be sent to the Office of Grants Management (see mailing address above) separate from the electronic submission; however, these mail-in items must be entered on the GrantSolutions Application Checklist at the time of electronic submission, and must be received by the due date requirements specified above. Mail-in items may include only publications, resumes, or organizational documentation.

Upon completion of a successful electronic application submission, the GrantSolutions system will provide the applicant with a confirmation page indicating the date and time (Eastern Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components, required hard-copy original signatures, and mail-in items. As items are received by the OPHS Office of Grants Management, the electronic application status will be updated to reflect the receipt of mail-in items. It is recommended that the applicant monitor the status of their application in the GrantSolutions system to ensure that all signatures and mail-in items are received.

Mailed or Hand-Delivered Hard Copy Applications

Applicants who submit applications in hard copy (via mail or hand-delivered) are required to submit an original and two copies of the application. The original application must be signed by an individual authorized to act for the applicant agency or organization and to assume for the organization the obligations imposed by the terms and conditions of the grant award.

Mailed or hand-delivered applications will be considered as meeting the deadline if they are received by the Office of Grants Management, Office of Public Health and Science (OPHS), Department of Health and Human Services (DHHS), c/o Grant Application Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209, on or before 5:00 p.m. Eastern Time on the deadline date specified in the DATES section of the announcement. The application deadline date requirement specified in this announcement supersedes the instructions in the OPHS-1. Applications that do not meet the deadline will be returned to the applicant unread.

4. Intergovernmental Review

Review under Executive Order 12372

Applications under this announcement are exempt from the review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs", as implemented by 45 CFR part 100.

V. APPLICATION REVIEW INFORMATION

1. Criteria

Eligible applications for cooperative agreements to be a *participating study site* will be evaluated using the criteria listed below.

1) Significance: The demonstrated need for family planning and related reproductive health services for males in the target community. The applicant demonstrates the ability to fully participate in the research project and contribute to the research aims identified, including but not limited to, demonstrating that the provision of services in the target community will address a significant health gap

for males and that the research findings from this community can be generalizable to a significant proportion of the larger target population. (20 points total):

a. Evidence of high rates of unintended pregnancies and sexually transmitted infections (STI) and lack of existing services for males (10 points);
b. Ability to advance applied research through increasing access to family planning and related reproductive health services of males (10 points);

2) Feasibility and Likelihood of Producing Meaningful Results: The capacity of the applicant to provide quality family planning and related reproductive health clinical services to males and deliver health education and conduct outreach to males in the community, during the proposed project period, through linkages and partnerships with community-based organizations. The applicant proposes an appropriate management plan and demonstrates the ability to address and resolve potential and/or actual problems that could endanger the success of the research project in a timely and efficient manner. (40 points total):

a. Documented experience providing wide range of family planning and reproductive health clinical services (10 points);
b. Documented experience serving male clients (10 points);
c. Documented experience providing family planning and reproductive health education and information (10 points);
d. Evidence of prior collaborations with community partners and/or established partnerships/linkages with community organizations serving males (10 points);

3) Competency of Staff and Adequacy of Facilities, Resources and Budget: The administrative capability of the applicant in relation to the work required under this agreement and the adequacy of the applicant's resources for the project, the (20 points total)*:*

   a. Clear management infrastructure and documented willingness of senior management to implement necessary changes to existing services (10 points);
   b. Ability to make rapid use of grant funds as demonstrated by documented experience managing grant funds (5 points);
   c. Qualifications of the proposed staff (5 points);

4) Scientific Merit: The capacity of the applicant to conduct research. The applicant demonstrates the ability to implement the appropriate scientific research components necessary for successful data collection, analysis and other elements related to evaluation and rigors of scientific research. (20 points total):

   a. Documented experience collecting and managing client data (10 points); and
   b. Documented experience in program monitoring and evaluation activities or other research (10 points).

Eligible applications for the cooperative agreement to be the *study coordinating center* will be evaluated using the criteria listed below.

1) Significance: The experience and expertise of the applicant on the provision of family planning and related reproductive health information, education and clinical services to males, especially the applicant's familiarity with the components of the service delivery model tested in this study. The applicant demonstrates the ability to identify research findings and facilitate the advancement of applied research and exhibits competencies related to determining meaningful results from the research effort described. (25 points total):

    a. Documented experience delivering family planning and reproductive health clinical services to males (10 points);
    b. Documented experience providing education and information to males through community linkages and partnerships (10 points);
    c. Demonstrated knowledge of service delivery approaches for working with male clients (5 points);

2) Feasibility and Likelihood of Producing Meaningful Results: The capacity of the applicant to develop and implement training programs on family planning and related issues for clinical and non-clinical health providers. The applicant proposes an appropriate management plan and demonstrates the ability to address and resolve potential and/or actual problems, throughout the proposed project period, that could endanger the implementation and progress of the research project in a timely and efficient manner. (25 points total):

a. Documented experience developing and implementing training activities and delivering technical assistance on family planning and related health topics for clinical and non-clinical providers (10 points);
b. Documented experience developing curricula, training manuals, and guidance for program implementation (10 points);
c. Documented experience organizing large workshops and/or conferences (5 points);

3) Scientific Merit: The capacity of the applicant to conduct and coordinate research activities. The applicant demonstrates the ability to implement the appropriate scientific research components necessary for successful data collection, analysis and other elements related to evaluation and rigors of scientific research. (25 points total):
    a. Documented success in the conduct of large research studies and dissemination of findings in peer-reviewed journals (10 points);
    b. Documented experience collecting and managing data from multiple sources and evidence of technical competency in statistical analyses (10 points);
    c. Affiliation with research institute or center (5 points);

4) Competency of Staff, Adequacy of Facilities, Resources and Budget: The administrative and organizational capability of the applicant in relation to the work required under this cooperative agreement. (25 points total):

a. Clear management infrastructure and ability to make rapid use of grant funds (10 points);
b. Evidence of ability to manage activities in multiple sites including documentation of infrastructure to manage communication and information electronically (10 points); and
c. Qualifications of the proposed staff (5 points).

2. Review and Selection Process

Eligible applications will be reviewed by an objective review committee made up of independent reviewers who will apply the above criteria in order to derive priority scores. Final awards will be made by the Deputy Assistant Secretary for Population Affairs (DASPA). The award decisions will take into account the priority score as well as the extent to which the applicants approved for funding will provide an appropriate geographic distribution of resources and the populations to be served. Awards will be made only to those organizations or agencies which have demonstrated the capacity to implement the activities of this research study and those which have met all applicable requirements.

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The OPA does not release information about individual applications during the review process. When final funding decisions have been made, each applicant will be notified by letter of the outcome. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award (NGA),

signed by the Director of the OPHS Office of Grants Management. This document specifies to the grantee the amount of money awarded, the purposes of the grant, the length of the project period, terms and conditions of the grant award, and the amount of funding, if any, to be contributed by the grantee to project costs. In addition, the NGA identifies the Grants Specialist and the OFP Project Officer assigned to the grant.

These cooperative agreement grants will be awarded for a project period of up to five years. The cooperative agreements will be funded in annual increments (budget periods). Funding for all approved budget periods beyond the first year of the cooperative agreement is contingent upon the availability of funds, satisfactory progress on the project, and adequate stewardship of Federal resources.

2. Administrative and National Policy Requirements

In accepting this award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 45 CFR parts 74 and 92, currently in effect or implemented during the period of the grant.

The successful applicants will be responsible for the overall management of activities within the scope of the approved project plan, and will work closely with the OFP project officer. The project officer will review and approve all aspects of the planning, implementation, and evaluation of the project components, as well as plans for the use of resources as part of this cooperative agreement.

The OPHS requires all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the OPHS mission to protect and advance the physical and mental health of the American people.

When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees shall clearly state the percentage and dollar amount of the total costs of the program or project which will be financed with Federal money and the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

Federal grant support must be acknowledged in any publication developed using Title X funds. All publications developed or purchased with Title X funds must be consistent with the requirements of the program. The grantee will be expected to make available, at cost, all materials developed with Title X funds as requested by other Title X projects.

3. Reporting

Each year of the project period, the grantee is required to submit a non-competing application which includes an annual progress report, project work plan, budget, and budget justification for the upcoming year. Also, successful applicants are required to submit annual data using the Family Planning Annual Report (FPAR). Refer to the instructions and reporting requirements for the FPAR in the Application Kit and the http://opa.osophs.dhhs.gov website. Grantees are required to submit an annual Financial Status Report within 90 days after the end of each budget period.

VII. AGENCY CONTACTS

For questions regarding administrative and budgetary requirements, the submission process or cooperative agreement requirements, please contact the OPHS Office of Grants Management, 1101 Wootton Parkway, Suite 550, Rockville, MD 20852; or by phone at (240) 453-8822.

For questions regarding program requirements, please contact Mr. David Johnson, Office of Population Affairs, Office of Family Planning, by email at david.johnson@hhs.gov, by phone at (240) 453-2888 or by fax at (240) 453-2889.

VIII. OTHER INFORMATION

There will be an opportunity for a technical assistance conference call for organizations interested in responding to this announcement to be held within one month after publication of this Notice. For more information regarding this opportunity, including date, registration information, and how to join the call, please consult the OPA Web site at http://hhs.gov/opa.

Definitions: For the purposes of this announcement, the following definition applies:

Cooperative Agreement – An award instrument of financial assistance where "substantial involvement" is anticipated between the HHS awarding agency and the recipient during performance of the contemplated project or activity. "Substantial involvement" means that the recipient can expect Federal programmatic collaboration or

participation in managing the award. The entity that receives a Federal cooperative agreement assumes the legal and financial responsibility and accountability for the awarded funds and performance of activities approved for funding, and is held to all requirements for Federal grants.

Dated: 17 June 2008

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Susan Orr, Ph.D.

Deputy Assistant Secretary for Population Affairs.