

Part I Overview Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of Secretary, Office of Public Health and Science,
Office of Population Affairs

FUNDING OPPORTUNITY TITLE: Family Planning Service
Delivery Improvement Research (R01)

Note: The policies, guidelines, terms, and conditions stated in this
announcement may differ from those used by the NIH.

ANNOUNCEMENT TYPE: Initial Competitive Grants

ANNOUNCEMENT NUMBER: PAR-08-999

NOTICE: Applications submitted in response to this Funding Opportunity
Announcement (FOA) for Federal assistance must be submitted

electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in [Grants.gov/Apply for Grants](http://Grants.gov/Apply%20for%20Grants) (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See [Section IV](#).

CFDA NUMBER: 93.974

DATES:

Opening Date: April 15, 2008

Letters of Intent Receipt Date(s): May 1 in 2008; January 2 in 2009 and 2010

NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).

Application Due Date(s): May 15 in 2008; January 15 in 2009 and 2010

Peer Review Date(s): July in 2008; May/June in 2009 and 2010

Council Review Date(s): August in 2008, 2009 and 2010

Earliest Anticipated Start Date(s): September 15 in 2008, 2009 and 2010

Expiration Date: January 16, 2010

ADDITIONAL OVERVIEW CONTENT

EXECUTIVE SUMMARY

Purpose. This FOA issued by the Office of the Secretary/Office of Public Health and Science/Office of Population Affairs encourages Research Project Grant (R01) applications from institutions/organizations that propose to conduct relevant studies which will promote improvements in the delivery of services in the Title X family planning program administered by the Office of Family Planning in the Office of Population

Affairs. The purpose of this grant announcement is to encourage applied research attention to the following areas: 1) Clinic Efficiency Models; 2) Service Integration; and 3) Targeted Populations. Descriptions of previously-funded Service Delivery Improvement Research projects in other focused areas of study and improvement can be found at the following web address:

<http://www.hhs.gov/opa/familyplanning/grantees/research/index.html>

- **Mechanism of Support.** This FOA will utilize the R01 grant mechanism
- **Funds Available and Anticipated Number of Awards.** Subject to the availability of funds, OPA intends to award \$750,000 in Fiscal Year 2008 to support an estimated three to four new research projects.
- **Budget and Project Period.** Budgets for total costs of up to \$200,000 per year and a project duration of up to three years may be requested for a maximum of \$600,000 total costs over a three-year project period.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.

- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.
- **Resubmissions.** Resubmission applications are allowed in response to this FOA.
- **Renewals.** Renewal applications are not permitted in response to this FOA.
- **Special Date(s).** This FOA uses non-standard due dates. See Receipt, Review and Anticipated Start Dates.
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - SF424 (R&R) Application and Electronic Submission Information:
<http://grants.nih.gov/grants/funding/424/index.htm>
 - General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088.

Part II. Full Text of Announcement

1. FUNDING OPPORTUNITY DESCRIPTION

This FOA issued by the Office of Population Affairs (OPA) encourages research grant (R01) applications from public or non-profit private organizations for research on selected topic areas for family planning service-delivery-improvement. The purpose is to support applied research which will promote improvements in the delivery of family planning services offered under Title X of the Public Health Service Act. Projects funded under this program will conduct research, which is intended to help family planning administrators to achieve the goals of the Title X program. These goals, briefly stated, are to provide family planning services in order to help families and individuals attain the number and spacing of children they desire. In addition, Title X providers often make available related preventive health services, which help preserve reproductive health. It is anticipated that other providers of family planning services beyond Title X including officials of local, State and Federal government, as well as private organizations, will benefit from this research.

Research grants supported under this announcement are expected to be consistent with one or more of the following performance goals for the

Family Planning Program in the Department of Health and Human Services:

1) Improve health outcomes, 2) Increase utilization of preventive health care, particularly among vulnerable and special needs populations, or 3) Increase the proportion of pregnancies that are intended.

Background

The Family Planning Program, authorized by Title X of the Public Health Service Act (42 U.S.C. 300, *et seq.*) and administered by the Office of Family Planning located in OPA is the only federal program devoted solely to funding family planning and related preventive, health-care services. This program supports a nationwide network of more than 4,400 clinics and provides family planning services and supplies as well as related preventive health services to approximately 5 million persons per year. Family planning, like many health-care services, faces continuing and emerging challenges to delivering quality care. This announcement calling for service-delivery improvement research applications is intended to help family planning programs meet those challenges. Section 1004 of the Public Health Service Act authorizes the Secretary to “make grants to public or nonprofit private entities ... for projects for, research in... program implementation fields related to family planning and population.”

The research emphases identified for attention in this announcement reflect the goals of the Title X family planning program whose purpose, according to Section 1001 of the statute, is to “assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).”

Section 1008 of the statute provides that “none of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.”

By law (Section 1006 (c) (1)), a priority of the Title X program is to provide services to persons from low-income families. The program regulations describe Title X projects as consisting of “... the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.”(42 CFR 59.1)

The research emphases of this announcement also are consistent with the current Title X Family planning program priorities. Regulations pertaining to grants for research projects are set out at 42 CFR part 52.

Purpose of the Grant Announcement

The purpose of the Family Planning Service Delivery Improvement Research program is to increase the ability of grantees to provide the range of Title X services more effectively. Title X's range of services includes: pre-conceptual counseling and care; contraceptive counseling and care; preventive health screening and counseling; screening, counseling, and treatment of STIs; pregnancy diagnosis and referral for continuing care.

Within this framework, this announcement invites applications using one or more of the following approaches:

1. *Clinic Efficiency Models*

According to the recommendations in the report released in 2004, entitled Future Directions for Family Planning Research: A Framework for Title X Family Service Delivery Improvement Research there is a need for more research “about the actual services they [Title X clients] receive, the effectiveness of those services, and how those services might be improved.”

Therefore more rigorous studies that identify and test promising practices in delivering family planning services are urged.

In times of rising of health care costs and limited resources, it is critical for health care systems to maximize efficiency while maintaining quality care.

Towards this end, investigations are needed that shed light on how maximum efficiency in family planning clinic settings can be attained while still providing quality care in these settings. The basic concern is to identify strategies at the clinic level that can be shown simultaneously to maximize all desired outcomes in the delivery of family planning services, including numbers served.

For the purposes of this announcement, research is encouraged in, but not limited to identifying innovative strategies or models which maximize clinic efficiency. Attention should be given to actual services received; patient satisfaction with these; health benefits received from specific kinds of services; and the organizational and logistical arrangements that best deliver these client outcomes within a limited budget for operation. Among possible approaches to investigate are improved clinic arrangements in such areas as staffing, scheduling, waiting times, and other aspects affecting patient flow. Mix of services and staffing relative to types of clients served may also be considered. Research that adapts approaches to the Title X

context or builds on findings from research in other health care sectors is encouraged. Previous research may have identified approaches which have proven successful in a particular area. Research replicating promising strategies in newly selected sites is also encouraged.

2. Service Integration

Studies are needed to analyze trends toward greater integration of family planning services with other health care provision, along with the causes of and implications of such trends. It is important to learn more about processes of integrating family planning services with other types of care, including primary health care services. Data from the National Survey of Family Growth (2002) reveal that Title X clients are more likely to engage in behaviors which place them at risk of HIV, which suggest the need to further integrate HIV and other STI screenings in the Title X clinics. Thus attention should be given to the integration of family planning services with care for women infected with, or at increased risk of, STI's including HIV. At the same time, the family planning visit provides the much-needed window of opportunity for addressing other reproductive health issues, including infant mortality and low birthweight or involuntary sexual activity, particularly for female clients.

This announcement encourages research that demonstrates strategies which have been effective in the integration of family planning services with other health services. Research which investigates, under what conditions various approaches are likely to be successful and the consequences for family planning service delivery (i.e., the impact on staffing, cost, quality of care, patient recruitment, satisfaction, etc) is appropriate under this program.

Other pertinent questions include: what role can integration of family planning services with other health services play in enhancing the overall well-being of family planning clients while still promoting family planning service delivery goals? How might any promising or evidence-based strategies arising in other programs be replicated or adapted for the Title X setting?

3. Targeted Populations

There continues to be a need for research that would shed light on a number of unanswered questions related to special populations. Vulnerable clients who engage in high-risk behaviors and who may pose unusual challenges to Title X providers are among such groups who might be offered for research attention. For the purposes of this announcement, three populations are highlighted: adolescents; males; and recent immigrants. However, proposals presenting a compelling case for studying a population other than these three

also will be considered. Extensive research has helped to inform the development of interventions that have targeted some segments of the population but there is a need for innovative approaches that impact previously underserved populations. For example, recent findings from CDC reveal a slight rise in the teen birth rate for the first time in 14 years, which underscores the need to identify successful strategies for reaching adolescents with a prevention message.

Males are among the hard-to-reach populations identified for attention in the current priorities of the Family Planning Program. While efforts have been successful in targeting males for reproductive health services as demonstrated by OPA-funded projects for only males, there continues to be a need to evaluate the effectiveness of programs designed to address their needs in the Title X clinic setting. Previously funded SDI research projects have brought forward the awareness that reproductive health needs of men in the U.S. are not generally well-understood, but have also given insights about further needed research. According to an OPA-funded study conducted by Kalmuss (2007), the reproductive health needs of men in the U.S. are not adequately being addressed.

Research has shown that health disparities involving Hispanics or Latinos, who constitute the fastest-growing immigrant population in the U.S, are due

to access barriers, including cultural and language barriers. OPA has funded research that focuses on Mexican immigrants and Latino immigrants in rural areas, and there is interest in broadening this research to other immigrant populations.

Successful proposals must demonstrate a well-developed understanding of the family planning and reproductive health needs of the target population chosen for study. Relevant areas of inquiry include, but are not limited to: how best to tailor services to targeted populations; physical or location barriers which may inhibit client access; the implications for client access, of the attitudes and behavior of clinic personnel; the development and testing of targeted outreach strategies which improve health outcomes; and the replication of strategies or interventions which are adapted for different subgroups.

II. AWARD INFORMATION:

1. Mechanism of Support. This FOA will use the RO1 award mechanism. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts (see [SF424 \(R&R\) Application Guide](#)). It also uses the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Hence, modular budget formats do not apply in this case.

2. Funds Available. The OPA, subject to the availability of funds, intends to make available approximately \$750,000 each year (Fiscal Years 2008, 2009 and 2010) to support an estimated three to four new research projects in each of the three years. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Budgets for total costs of up to \$200,000 per year and a project duration of up to three years may be requested for a maximum of \$600,000 total costs over a three-year project period. The awards to be made are for applied research and do not cover costs of delivering services that the applied research project may propose to evaluate.

Grants will be funded in annual increments (budget periods) and may be approved for a project period of up to three years. Funding for all budget periods beyond the first year of the grant is contingent upon the availability

of funds, satisfactory progress of the project, and adequate stewardship of Federal funds.

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private nonprofit entity located in any State, the District of Columbia, or any United States territory, commonwealth, or possession is eligible to apply for an R01 grant under this announcement. Faith-based organizations are eligible to apply for these service delivery improvement research grants.

2. Cost Sharing or Matching

No cost sharing or matching of non-Federal funds is required

3. Other-Special Eligibility Criteria

- **Resubmissions.** Resubmission applications are permitted in response to this FOA.
- **Renewals.** Renewal applications are not permitted in response to this FOA

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the “Apply for Grant Electronically” button in this FOA or link to <http://www.grants.gov/Apply/> and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) Organizational/Institutional Registration in [Grants.gov/Get Registered](#)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.

- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:

[Grants.gov Customer Support](#)

Contact Center Phone: 800-518-4726

Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time

Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "List of Grantee Organizations Registered in NIH eRA Commons."
- Direct questions regarding the Commons registration to:

eRA Commons Help Desk

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time

Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual(s) designated as PDs/PIs on the application must be registered also in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an NIH Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

Both the PDs/PI(s) and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note that if a PD/PI is also an NIH peer reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](https://www.grants.gov) and the [Commons](https://www.nih.gov/era/commons). The NIH will accept electronic applications only from organizations that have completed all necessary registrations.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](https://www.grants.gov/Apply).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo -- Telephone 301-435-0714;

Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](https://grants.nih.gov/apply).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are required by NIH (*e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI's assigned eRA Commons User ID*). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see

“Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#).”

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/APPLY](#) includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

Required Components:

SF424 (R&R) (Cover component)

Research & Related Project/Performance Site Locations

Research & Related Other Project Information

Research & Related Senior/Key Person

PHS398 Cover Page Supplement

PHS398 Research Plan

PHS398 Checklist

PHS398 Research & Related Budget

Optional Components:

PHS398 Cover Letter File

Research & Related Subaward Budget Attachment(s) Form

3. Submission Dates and Times

See [Section IV.3.A.](#) for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: April 15 in 2008(Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): May 1 in 2008; January 2 in 2009 and 2010

Application Due Date(s): May 15 in 2008; January 15 in 2009 and 2010

Peer Review Date(s): July in 2008; May/June in 2009 and 2010

Council Review Date(s): August in 2008, 2009 and 2010

Earliest Anticipated Start Date(s): September 15 in 2008, 2009 and 2010

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research.

- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel.
- Number and 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 is to be sent by the date listed in [Section IV.3.A.](#)

The letter of intent should be sent to:

Eugenia Eckard, Office of Population Affairs

1101 Wootton Parkway, Suite 700

Rockville, MD 20852,

(240) 453-2800

Eugenia.eckard@hhs.gov.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow Steps 1-4. Note: Applications must only be submitted electronically.

PAPER APPLICATIONS WILL NOT BE ACCEPTED.

3.C. Application Processing

Applications may be submitted on or after the opening date and must be successfully received by Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization) on the application due date(s). (See [Section IV.3.A.](#) for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application

within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- If the two-day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the

- submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the [NIH late policy](#) guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
 - Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness by the CSR.

Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons

acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.

The NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

4. Intergovernmental Review

Applicants 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.

5. Funding Restrictions

The allowability, allocability, reasonableness and necessity of direct and indirect costs that may be charged to grants are outlined in the following

documents: OMB Circular A-21 (Institutions of Higher Education); OMB Circular A-87 (State and Local Governments); OMB Circular A-122 (Nonprofit Organizations); and 45 CFR part 74, Appendix E (Hospitals).

Copies of the Office of Management and Budget (OMB) Circulars are available on the Internet at

http://www.whitehouse.gov/omb/grants/grants_circulars.html

6. Other Submission Requirements and Information

PD/PI Credential (e.g., Agency Login)

The NIH requires the PD(s)/PI(s) to fill in his/her Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications.](#)”

PHS398 Research Plan Component Sections

Page limitations of the PHS398 Research Plan component must be followed as outlined in the SF424 (R&R) Application Guide. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See <http://grants.nih.gov/grants/funding/424/index.htm>).

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not comply with the required page limitations may be delayed in the review process.

V. APPLICATION REVIEW INFORMATION

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Center for Scientific Review using the review criteria stated below.

Each of the technical review criteria will be addressed and considered by independent peer reviewers in assigning an overall or global priority score, using a score range from 1.0 to 5.0 (with 1.0 indicating highest priority and 5.0, lowest priority).

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top

half of applications under review, will be discussed and assigned a priority score;

- Receive a written critique; and
- Receive a second level of review by OPA

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 the availability of funds.

Eligible family planning service delivery improvement research applications will be reviewed according to the following criteria:

(1) Significance. If the aims of the project are achieved, how much will applied research knowledge be advanced? Does the project employ novel or creative concepts, approaches or methods that are insightful and likely to move forward the applied research area addressed in the application?

(2) Scientific Merit. Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the project?

(3) Feasibility and Likelihood of Producing Meaningful Results. Are the plans for organizing and carrying out the project, including the responsibilities of key staff, the time line, and the proposed project period, adequately specified and appropriate? Does the application acknowledge

potential problem areas and consider alternative tactics? For intervention evaluation studies, is adequate funding for the intervention already in place or assured for the intervention period to be evaluated, making the proposed evaluation feasible?

(4) Competency of Staff. Are the principal investigator, and other key research staff, appropriately trained and well suited to carry out this project?

(5) Adequacy of Facilities and Resources. Are the facilities and resources of the applicant institution and other study sites adequate?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the rating:

.Resubmission Applications (formerly “revised/amended” applications):

Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424

(R&R).

Inclusion of Women and Minorities in Research: The adequacy of plans to include subjects from both genders, and all racial and ethnic groups (and subgroups), as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R)

2.B. Additional Review Considerations

Budget and Period of Support: The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

New Investigator: New Investigator applications (whatever the funding level request) will be evaluated by the review criteria listed in this section, but the reviewers will be instructed to take into account the Principal Investigator’s stage of career development.

3. Anticipated Announcement and Award Dates

OPA anticipates awarding three to four Family Planning Service Delivery Improvement Research (R01) Grants by September 15, 2008, announcing the awards shortly thereafter.

VI. AWARD ADMINISTRATION INFORMATION

1. Notification of Award

The OPA does not release information about individual applications during the review process. When a final funding decision has been made, each applicant will be notified by OPA of the outcome. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award, which specifies the amount of money awarded, the purpose of the grant, the length of the project period, and the terms and conditions of the award.

2. Administrative and National Policy Requirements

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

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 non-governmental sources.

3. Reporting Requirement

At the completion of the project, the grant recipient must submit a brief summary in 2,500 to 4,000 words, written in non-scientific (layman's) terms and a Financial Status Report (SF-269). The narrative should highlight the findings and their implications for improving family planning service delivery. A plan for disseminating research findings should accompany the narrative. This plan should indicate how products of the research will be made accessible to the Office of Population Affairs, as well as to the Title X family planning administrators and practitioners, researchers, and State and local policy-makers. The summary, plan, and Financial Status Report must be submitted to the Grants Management Specialist identified on the Notice of Grant Award within 90 days of the project's completion.

VII. AGENCY CONTACT(S):

For information on specific research or program requirements, contact

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For assistance on administrative and budgetary requirements, contact

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VIII. Other Information

The authority for this funding program is Section 1004 of the Public Health Service (PHS) Act.

Dated: [March 25, 2008]

Susan Orr

Deputy Assistant Secretary for Population Affairs