

shares of F&C Bancorp, Inc., and thereby indirectly acquire voting shares of Farmers and Commercial Bank, Holden, Missouri.

**B. Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Rodney A. Abrams*, Northbrook, Illinois, the Abrams Family Trust, Stephanie H. Denby, trustee, Buffalo Grove, Illinois; Funeral Financial Services, Ltd., Northfield, Illinois; Mortuary Financial Services, Inc., Richardson, Texas; Richard N. Abrams, Fort Worth Texas; Karen Abrams Fox, Northbrook, Illinois; Jodie Abrams Engfer, North Oaks, Minnesota; and Beverly Adams, Highland Park, Illinois; to acquire voting shares of Surety Capital Corporation, Fort Worth, Texas, and thereby indirectly acquire voting shares of Surety Bank, National Association, Fort Worth, Texas.

Board of Governors of the Federal Reserve System, March 21, 2005.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 05-5899 Filed 3-24-05; 8:45 am]

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Notice of Funding Opportunity

**AGENCY:** Department of Health and Human Services, Office of Public Health and Science, Office of Population Affairs.

**ACTION:** Notice.

#### *Funding Opportunity Title:*

Announcement of Availability of Funds for Grants for Family Planning Service Delivery Improvement Research.

*Announcement Type:* This is a standing program announcement to remain in effect through May 15, 2007, unless it is withdrawn or modified, with an annual application receipt date of May 15.

*Funding Opportunity Number:* PAR-05-185.

*CFDA Number:* 93.974.

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

**DATES:** This standing program announcement will remain in effect through May 15, 2007, unless it is withdrawn or modified. To receive consideration a package containing a signed typewritten application, including the checklist, and two photocopies of the application must be received at the address below no later than May 15 and no earlier than April

15 of each year the program announcement remains in effect. Letters of intent should be received by April 30 of the year in which an application will be submitted. Up to two amended applications may be submitted in years subsequent to the year in which the original grant application was submitted but did not receive funding.

**SUMMARY:** The Office of Population Affairs (OPA) requests applications for family planning service delivery improvement research grants. Applied research projects are encouraged in one or more of the following priority areas: (1) Quality of care in the delivery of family planning services; (2) effective approaches and interventions for addressing the reproductive health needs of adolescents and incorporating family members (particularly parents or guardians) into decisions of adolescents regarding relationships and sex; (3) reproductive health needs of males, prevention-related decisions by males and appropriate strategies for reaching male clients; (4) knowledge base for incorporating a "couples" perspective into the delivery of family planning services; (5) effective organizational approaches for delivery of family planning services in conjunction with related services, particularly HIV prevention services; (6) dissemination of findings and translation of service delivery research into practice; (7) factors associated with increasing costs and the impact of such increasing costs on service delivery; and (8) effectiveness of Title X non-clinical services with regard to information and education activities. Regulations pertaining to grants for research projects are set out at 42 CFR part 52. Section 1008 of the PHS Act provides that "none of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."

### I. Funding Opportunity Description

This announcement invites applications from public and non-profit private entities for research on selected topic areas for family planning service delivery improvement. The purpose is to support relevant research which will promote improvements in family planning services. Therefore, funds available under this announcement are for projects to conduct applied research which will be useful to family planning administrators and providers, researchers, and officials of local, State, and the Federal government, including OPA, in order to improve the delivery of family planning services to persons needing and desiring such services.

Research projects 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, (3) Increase the proportion of pregnancies that are intended, or (4) Reduce pregnancies among unmarried adolescent females.

"Healthy People 2010" is a Department of Health and Human Services initiative to achieve health promotion and disease prevention objectives. Applicants for funding under this announcement should relate proposed plans to Healthy People objectives. A copy of "Healthy People 2010" is available at the following Web site location: <http://www.health.gov/healthypeople>

#### *Background*

The Family Planning Program, authorized by Title X of the Public Health Service Act (42 U.S.C. 300, *et seq.*) is the only federal program devoted solely to funding family planning and related preventive health care services. This program supports a nationwide network of approximately 4,500 clinics and provides family planning services and supplies as well as relevant 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.

The research emphases identified for attention in this announcement are consistent with the purpose of the Title X family planning services program, which is 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 family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."

This announcement also draws on a report issued by OPA in July, 2004: *Future Directions for Family Planning Research: A Framework for Title X Family Service Delivery Improvement Research*. This report was the

culmination of a project that assembled experts to review the existing research literature, discuss the key research issues facing the field and identify future research needed to better inform family planning practitioners. Hard copies of the report are available through the OPA Clearinghouse at P.O. Box 30686, Bethesda, MD 20824-0686; ph: 866-640-PUBS (7827); fax: 866-592-FAXX (3299); e-mail: [clearinghouse@dhhsopa.net](mailto:clearinghouse@dhhsopa.net)

The experts identified future studies to address three broad concerns: (1) How can high-priority populations be reached? (2) How can family planning practices be strengthened? and (3) How can the organization and administration of services be improved? Based on Family Planning Program priorities, OPA selects and highlights below priority topics for the service delivery improvement research grants program that reflect all three of these concerns.

#### *Purposes of the Grant*

The purpose of this grant program is to expand the knowledge base in areas identified for applied research attention in this announcement. To that end, this announcement invites applications in one or more of the following areas:

#### 1. Quality of Care

Quality of care has many components. A report issued by the Institute of Medicine (IOM), *Crossing the Quality Chasm (2001)*, addresses health care in general and calls for attention to six key dimensions of service quality in order to improve service delivery on each dimension:

- Safety—Health care should be safe and should avoid injuries to patients
- Effectiveness—Health care should provide services based on scientific knowledge to all who could benefit from the services and should avoid providing services to those who are unlikely to benefit
- Patient-centeredness—Health care should provide services that are respectful and responsive to individual patient preferences, needs, and values and ensure that patient values guide all clinical decisions.
- Timeliness—Health care should reduce waits and sometimes harmful delays for both those who receive and give care.
- Efficiency—Health care should avoid waste, including waste of equipment, supplies, ideas, and energy.
- Equity—Health care should be provided that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status.

These quality dimensions are present in health care delivered in family planning clinic settings. Therefore, investigation of approaches which address any of these six dimensions in the family planning context is encouraged. Research that adapts approaches and builds on findings, tools or measures from service quality research in other health care sectors or other countries is similarly encouraged.

#### 2. Reproductive Health Care to Adolescents/Parental Involvement

Adolescents are among the hard-to-reach populations identified for attention in the current Family Planning Program priorities. These program priorities also have the goal of encouraging family participation (particularly that of parents or guardians) in the decision of minors to seek family planning services, including activities that promote positive family relationships. Key issues for the Family Planning Program are: Providing adolescents with information, skills and support to encourage abstinence from or delay of sexual activity. Two significant questions quoted in the *Future Directions* report are: (1) "What are effective practices that clinics can use to assist adolescents and young adults in sexual decision making?" and (2) "How can adolescents be better connected to their families and schools, and will these connections result in decreased sexual activity?" These perspectives provide a context for the applied research topic of adolescent reproductive health that may be addressed by applicants to this program announcement.

Over the last several years, amid growing concerns about adolescent pregnancy and high rates of sexually transmitted diseases (STDs), local communities have developed abstinence programs. Family planning practitioners can contribute to this wider effort to help teens avoid risky behaviors and make a healthy transition to adulthood, if they are provided with relevant information from service delivery improvement research. Such information will be most useful if it pertains not only to adolescent clients, but also to the parents who have such a critical role in shaping their child's development.

There is interest in a range of studies that might be designed to develop useful approaches and evaluate tailored interventions in this area. Intervention studies that target parental involvement are of particular interest.

Possible studies include:

- Identification of effective clinic techniques for counseling and

encouraging adolescent abstinence, return to abstinence, or similarly-responsible decision making regarding sexual behavior, including training for adolescents in needed skills to behaviorally carry out their decisions;

- Evaluation of abstinence programs in the family planning setting which teach abstinence knowledge, attitudes and skills in the context of preparation for future healthy family relationships;

- Evaluation of clinic strategies for promoting parent-adolescent communication about preparation for future family life through current decision-making about reproductive health matters;

- Identification of approaches to enhance the role of parents in providing information to their adolescents about sex;

- Evaluation of various kinds of outreach strategies to parents by family planning providers; and

- Evaluation of youth advocate strategies for supporting/guiding adolescents and their families in navigation of the reproductive health care system.

#### 3. Reproductive Health Services to Males

Males also are among the hard-to-reach populations identified for attention in the current priorities of the Family Planning Program. Although men play a vital role in decision-making around sexual relationships, reproductive health, and family planning, most of the attention in the past has been focused on women. A fundamental building block in the development of any program is understanding the population to be served. While we have learned much about program interventions directed at women, little is known about how to deliver reproductive health services to men. The lack of information about the knowledge, attitudes, and behavior of males regarding family planning and related preventive health needs has made it difficult to design programs that appropriately serve males.

Priority questions about males raised by the *Future Directions* report include: "What information do we need about men in their early 20s and 30s who need STD and family planning services? How do we create more male clinics? How do we look for alternative sites for these clinics?"

In order to advance our understanding in this area, research is encouraged on one or more of the following topics:

- Information about the characteristics of men who seek reproductive health services, their pattern of use, awareness of the

availability of family planning services, and intention to use such services.

- Men's experiences with the existing reproductive health care system and factors influencing or inhibiting men's use of provided services.

- Services valued by males of different age groups and their preferred context for such services, e.g., couples; male-only; traditional family planning clinic setting or other contexts, etc.

- Evaluation of outreach strategies and approaches to males by family planning clinics.

- Factors that influence prevention-related choices of males such as abstinence, return to abstinence, committed marital/monogamous relationships, or use of a condom when engaging in widespread sexual activity.

For the first time, data on males were obtained in the National Survey of Family Growth which was in the field in 2002 (Cycle 6). Please see fuller description of this data set under "Data Resources" section below. This new cycle provides an opportunity to explore male reproductive health characteristics and motivations that could improve our understanding of how best to meet the reproductive health needs of men.

#### 4. Family Planning Services to Couples

While reproductive and family planning choices likely represent a joint decision between couples, scant attention has been given to couple-focused approaches for reproductive health care. The *Future Directions* report indicates that the development and testing of approaches to serving couples in the family planning setting is a promising new area of research, given that most sexual, contraceptive, and childbearing decisions are made jointly. It also points out that there is emerging policy interest at the Federal level in enhancing the quality of relationships between intimate partners to encourage the establishment of healthy committed relationships and marriages. Some evidence indicates that the involvement of partners in reproductive health care could result in more effective use of contraceptives. Cooperation of partners is also key for the effectiveness of natural family planning. Providers oriented toward meeting the needs of couples would find results of partners research useful. There is a heightened need to focus on how couples communicate regarding the use of condoms for disease protection. Given the complex dynamics that may be present in sexual relationships, women particularly may be in need of assistance from the family planning

counseling context in order to conduct couples negotiations.

Thus, there are a number of ways to approach the building of a knowledge base for incorporating a "couples" perspective into the delivery of family planning services. There is a research literature on the role that the couple relationship plays in contraceptive decision-making, which could be usefully expanded. Almost completely unexplored is the topic of how healthy couple relationships could be fostered in family planning settings or through referral to appropriate care services such as family services or marriage and relationship education services. The goal of such care would be to benefit the health of the individual members of the couple as well as the couple unit. Overall, studies are encouraged which investigate innovative approaches for serving couples in family planning clinics or through coordination of complimentary care settings, as well as studies which evaluate strategies for involving the partner in effective reproductive health decision-making.

#### 5. Organizational Approaches to Integrated Services

Although integrated services can take many forms, this announcement directs particular attention to the integration of HIV prevention and family planning services. The *Future Directions* report indicates that research about how to integrate successfully these two types of reproductive health services is very limited and should be given the highest priority.

Family planning clinics are an ideal site for integrating HIV prevention activities because they serve sexually active, nonpregnant women, many of whom may be at great risk of becoming infected. The increased incidence of HIV infection among women, especially those whose demographic characteristics match those of the women served in publicly-funded family planning clinics, underscores the need for the Title X program to intensify efforts to provide both education and counseling regarding HIV/AIDS to users of Title X services. These important prevention considerations have made integration of early HIV prevention programs into ongoing family planning services a major public health imperative.

Studies are needed to examine the impact on the family planning service delivery system of such HIV prevention service integration. In what ways does this development impinge on the concerns and routine functioning of family planning clinics and clinic personnel? In addition to assessing what

HIV-related activities have been implemented, studies are needed to determine which strategies have been effective, and to disseminate information about successful integration approaches being implemented in the family planning setting.

#### 6. Translating Research into Practice (TRIP)

There is an increasing need for the worlds of research and practice to be in closer relationship for the mutual benefit of each. In the purely medical context, the practice of medicine is becoming increasingly evidence-based, with practice guidelines for clinicians driven by research findings about treatment effectiveness. For health-related programs with an expanded mission beyond the strictly medical, interventions and service practices are increasingly based on the best available evidence regarding what works. Like the rest of the health care system, family planning faces the challenge of utilizing practice guidelines and recommendations that are evidence-based in the delivery of clinical services and of translating knowledge into practice more generally.

Dissemination research is a first step in meeting this challenge, especially research that identifies effective strategies for disseminating tested practice innovations to the practitioner field. Areas that need exploration include: Descriptive research about where family planning practitioners actually obtain information utilized in the service delivery arena; professional-organization collaboration in conducting research about practices; and evaluations of dissemination interventions.

Of additional interest to OPA are implementation studies that provide needed details about how a given service innovation can be effectively implemented elsewhere or how a more general research finding can be given concrete expression in the service setting, using appropriately-selected "translational" clinic sites. The service innovation or research finding may initially emanate from other than family planning settings or populations, provided the proposed study bases the translation/implementation effort on sound theoretical constructs regarding transferability. For example, the applicability of findings about the utility of information technology to increase efficiency and effectiveness of medical and social services other than family planning may be explored in an implementation study utilizing a family planning clinic site.

### 7. Increasing Costs and Their Impact

Research is needed that would shed light on a number of unanswered questions related to costs including:

- How are costs affected by different types of services, the characteristics of the clients served and the setting where services are provided?

- What strategies have been employed to reduce costs while still maintaining the quality of services provided?

- What impact has the newer, more technologically advanced methods of care had on the ability to maintain the quality and level of services?

Areas of interest include, but are not limited to the following:

- The increasing cost of providing specific contraceptive methods, including the actual cost of the method(s), shifts in the demand for the method(s), and staff level and time required;

- The cost of using advanced diagnostics technologies, including the actual cost of the technology, staff level and time required, and the long range cost implications to the provider of adopting the technology;

- The cost of providing services to under-served population(s), including outreach efforts and the specific mix of services required;

- The cost involved in recruiting and retaining adequate numbers of qualified staff; and

- Factors affecting revenue, including increases in the number of clients requiring subsidized services, changes in third party reimbursement to providers, and shifts in Federal, State, and local funding sources.

### 8. Effectiveness of Title X Information and Education Activities

Promoting individual and community health is a Family Planning Program priority. Increasingly, information and education strategies have been employed by family planning practitioners to accomplish this goal. There is a need for corresponding evaluations of the effectiveness of such efforts.

A great diversity of information strategies and educational approaches have been employed by family planning practitioners. A number of OPA-funded projects provide family planning information and education services to many individuals in non-clinical and non-traditional settings. Not only has it been difficult to track thousands of non-medical users being served throughout the country by these Title X information and education projects, but it also presents a challenge to evaluate the

effectiveness of these approaches. Therefore, rigorous evaluations of these activities, utilizing appropriate methodologies, is encouraged in this program announcement.

#### Data Resources

When appropriate to the proposed topics, applicants may wish to consider using nationally-representative data sets such as the National Survey of Family Growth (NSFG). The NSFG is a cross-sectional survey of family formation and reproductive health conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention. Previous cycles have consisted of personal interviews with a national sample of women 15–44 years of age in the United States, but with the latest cycle, Cycle 6, data from men ages 15–49 were also collected. The NSFG is a source of national data, which provides information on the level of sexual activity among adolescents, incidence of unintended pregnancy, contraceptive behavior, use of family planning services, trends in marriage, divorce, and cohabitation and rates of infertility. More information on the NSFG is available at <http://www.cdc.gov/nchs/nsfg.htm> OPA encourages applications which utilize data from Cycle 6 of the NSFG, as appropriate to the particular research approach. However, whether this type of data set is used or not used is completely at the discretion of the applicant and will not influence funding decisions on applications submitted under this announcement.

#### II. Award Information

The OPA, subject to the availability of funds, intends to make available approximately \$750,000 each year (Fiscal Years 2005, 2006 and 2007) to support an estimated three to four new research projects in each of the three years. Awards will range from \$150,000 to \$200,000 in total costs (both direct and indirect costs) per year. 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. Accordingly, the mechanism of support for this program announcement will generally be the research project grant (R01), although other mechanisms may be supported.

Research applications requesting less than \$150,000 in total costs (both direct and indirect costs) per year for no more than a total of two years will be considered small research project grants (R03). Small research project grants (R03) will be subject to the review criteria listed in the “Application Review Information” section below, but

reviewers will be instructed to take into account the smaller scope of the proposed project.

OPA encourages New Investigators (as defined in the PHS 398 application instructions) to apply as Principal Investigators. New Investigator applications (whatever the funding level request) will be evaluated by the review criteria listed in the “Application Review Information” section below, but the reviewers will be instructed to take into account the Principal Investigator’s stage of career development.

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.

Earliest anticipated start date: Four months after application receipt date.

#### III. Eligibility Information

##### 1. Eligible Applicants

Any public or private nonprofit entity located in a State (which includes one of the 50 United States or 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 for a grant under this announcement. Faith-based organizations are eligible to apply for these service delivery improvement research grants.

##### 2. Cost Sharing or Matching

There is no cost sharing or matching requirement.

#### IV. Application and Submission Information

##### 1. Address to Request Application Package

Applications must be submitted on the research application form PHS 398 (revised 9/04), which is available online at: <http://grants1.nih.gov/grants/oe.htm>. This form contains instructions for the submission of amended as well as new grant applications. For additional information about obtaining the research application form PHS 398, please call Eugenia Eckard at (301) 594–4001.

##### 2. Content and Form of Application Submission

Applicants are encouraged to read all PHS Form 398 instructions prior to preparing an application in response to

this announcement. The instructions given are a useful guide to application preparation. Pay close attention to font size, page limits, and other format specifications. However, OPA is not using the Modular Grant Application and Award Process. Applicants for OPA funding should ignore instructions concerning the Modular Grant Application and Award Process, following budget instructions otherwise provided in PHS Form 398.

When submitting the application check "yes" in Block 2 of the face page, and provide PAR-05-185 for the number and "Family Planning Service Delivery Improvement (SDI) Research" as the title.

The application content should include the following:

(1) A well-organized statement of the applied research problem to be addressed;

(2) a detailed description of the research project design;

(3) the conceptual framework within which the design has been developed;

(4) the methodology to be employed;

(5) the evidence upon which the analysis will rely; and

(6) the manner in which the evidence will be analyzed.

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

### 3. Submission Dates and Times

To receive consideration, applications must be received by the Center for Scientific Review, NIH, by the deadline listed in the **DATES** section of this announcement. Applications submitted via U.S. Postal Service will be considered as meeting the deadline if they are postmarked no later than 1 week prior to the deadline date given in the **DATES** section. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. As soon as possible after the receipt date, usually within 6 weeks, the principal investigator/program director and the applicant organization will receive by electronic notification the application assignment number and the name, address, and telephone number of the Scientific Review Administrator (SRA) who will be directing the review group to which the application has been assigned. The SRA is located at the Agency for Healthcare Research and Quality

(AHRQ) which is serving as the review organization for these applications. Applications that do not meet the deadline will not be accepted for review, and will be returned. Applications sent via facsimile or by electronic mail will not be accepted for review.

The application package must be submitted to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1040-MS-C 7710, Bethesda, MD 29892-7710 (20817 for express/courier service).

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, and the title of this program announcement. 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 Eugenia Eckard, at the address listed under the "Agency Contacts" section below and received by the date indicated in the **DATES** section of this announcement.

Applicants are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711. For more information, see the OPA Web site at: <http://opa.osophs.dhhs.gov/duns.html>.

### 4. Intergovernmental Review

This program is not subject to the review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

### 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](http://www.whitehouse.gov/omb/grants/grants_circulars.html).

The Title X program is intended to address the health needs of all men and women, including all subgroups as characterized by age, class, race, and ethnicity. It is the policy of OPA that women and members of minority groups be included in all OPA supported research projects unless a clear and compelling rationale or justification establishes that such inclusion is inappropriate. Applicants should approach their research and analysis with considerations of class, race, and ethnicity in mind whenever possible.

## V. Application Review Information

### 1. Technical Review Criteria

Eligible applications will be reviewed by a panel of independent peer reviewers and assessed according to the following technical merit 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?

(6) *Adequacy of Budget*. Is the budget reasonable and adequate in relation to the proposed project?

### 2. Review and Selection Process

Each of the above 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). 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.

## 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 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, 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 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.

A Notice providing information and guidance regarding the "Government-wide Implementation of the President's Welfare-to-Work Initiative for Federal Grant Programs" was published in the **Federal Register** on May 16, 1997. This initiative was designated to facilitate and encourage grant recipients and their sub-recipients to hire welfare recipients and to provide additional needed training and/or mentoring as needed. The text of the Notice is available electronically on the OMB home page at <http://www.whitehouse.gov/omb>.

### 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 (laymen's) terms and 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 mailed to the Grants Management Specialist identified on the Notice of

Grant Award within 90 days of the project's completion.

## VII. Agency Contacts

For information on specific research or program requirements, contact Eugenia Eckard, Office of Population Affairs, 1101 Wootton Parkway, Suite 700 Rockville, MD 20852, (301) 594-4001, or via e-mail at [eeckard@osophs.dhhs.gov](mailto:eeckard@osophs.dhhs.gov). For assistance on administrative and budgetary requirements, contact the OPHS Grants Management Office, 1101 Wootton Parkway, Suite 550, Rockville, MD, (301) 594-0758, or via e-mail at [kcampbell@osophs.dhhs.gov](mailto:kcampbell@osophs.dhhs.gov).

Dated: March 21, 2005.

### Alma L. Golden,

*Deputy Assistant Secretary for Population Affairs.*

[FR Doc. 05-5945 Filed 3-24-05; 8:45 am]

**BILLING CODE 4150-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Protection of Human Subjects, Proposed Criteria for Determinations of Equivalent Protection

**AGENCY:** Department of Health and Human Services, Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** The Office of Public Health and Science, Department of Health and Human Services (HHS) solicits public comment on criteria that have been recommended to the Office for Human Research Protections (OHRP) for making determinations of whether procedures prescribed by institutions outside the United States afford protections that are at least equivalent to those provided in the Federal Policy for the Protection of Human Subjects (codified by HHS as 45 CFR part 46, subpart A, and equivalent regulations of 14 Departments and Agencies, collectively referred to as the Federal Policy or the Common Rule).

**DATES:** Submit written or electronic comments on the recommended criteria for making determinations of equivalent protection on or before May 24, 2005.

**ADDRESSES:** Submit written comments to Ms. Gail Carter, Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852, telephone number (301) 402-4521 (not a toll-free number). Comments also may be sent via facsimile to (301) 402-0527 or by e-mail to: [EQFRN@osophs.dhhs.gov](mailto:EQFRN@osophs.dhhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Glen Drew, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (301) 402-4994, facsimile (301) 402-2071; e-mail: [gdrew@osophs.dhhs.gov](mailto:gdrew@osophs.dhhs.gov).

## SUPPLEMENTARY INFORMATION:

### I. Background

The HHS codification of the Federal Policy states at 45 CFR 46.101(h):

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

No formal findings of equivalent protection have been published in the **Federal Register** since the Federal policy was finalized in June, 1991. Use of the authority provided by 45 CFR 46.101(h) has been advocated by various parties, including the National Bioethics Advisory Commission in its April, 2001 report "Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries," and the HHS Inspector General in the September, 2001 Report "The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects." The authority of the Secretary of Health and Human Services has been delegated to OHRP (68 FR 60392), and in considering use of the 45 CFR 46.101(h) authority, OHRP recognized a need for using consistent criteria as a basis for decisions regarding equivalent protections. During 2002, the OHRP Director established a working group of representatives from interested HHS agencies, with staff support from OHRP, to consider potential criteria for use in making such decisions. The working group delivered its report in July 2003. That report recommends a framework