

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office of Population Affairs.

FUNDING OPPORTUNITY TITLE: Announcement of the Anticipated Availability of Funds for Embryo Donation and/or Adoption Cooperative Agreement Projects.

ANNOUNCEMENT TYPE: This is the initial announcement of a competitive funding opportunity for two (2) cooperative agreement projects.

FUNDING OPPORTUNITY NUMBER: OPA-2011-EA.

CFDA Number: 93.007.

ACTION: Notice.

DATES: To receive consideration, applications must be received by the Office of Grants Management, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services c/o Grants Operation Center, 1400 Key Blvd., Suite 910 Arlington, VA 22209, Attention: Embryo Adoption and/or Donation Cooperative Agreement Projects, no later than 6:00 p.m. Eastern Time on June 28, 2011 for hard-copy applications and no later than 9:00 P.M. on the same deadline date for electronic

applications at either the Grants.gov Website or the GrantSolutions System. The application due date requirement in this announcement supersedes the instructions in the Application Kit.

EXECUTIVE SUMMARY: The Office of Population Affairs (OPA), within the Office of the Assistant Secretary for Health (OASH) announces the availability of Fiscal Year (FY) 2011 funds to support a total of four to eight new cooperative agreement projects, with the goals of 1) increasing public awareness of embryo donation and/or adoption or 2) providing “to individuals adopting embryos ...medical and administrative services, deemed necessary for” embryo donation/adoption. For the purposes of this announcement, counseling is considered a “medical service.” “Administrative services” are those that help an embryo donation/adoption patient (or couple) to negotiate the process of embryo donation/adoption without the involvement of medical or allied health professionals. Included in this category are services that help potential donor couples to find satisfactory matches with potential frozen embryo adopters. OPA anticipates approximately \$1,700,000 will be available to support two to four new cooperative agreements to promote public awareness as well as two to four new cooperative agreements to promote embryo donation/adoption through the provision of services. Funding for each of the cooperative agreements will range from \$200,000 to \$500,000 per year. Projects will be funded in annual increments (budget periods) and for a project period of two years. Funding for all budget periods beyond the first year of the cooperative agreement is contingent upon the availability of funds, satisfactory progress of the project, and adequate stewardship of Federal funds.

OPA intends to fund at least one project in each of two distinct categories:

Category 1 (Embryo Adoption and/or Donation Public Awareness Campaign) public awareness projects (including those that provide education for professionals who are involved in in-vitro fertilization (IVF) or adoption to equip them with the specific knowledge and skills to support the unique needs of embryo donors and recipients); and Category 2 (Embryo Adoption and/or Donation Administrative or Medical Services) projects which provide administrative or medical services (including counseling) to patients who are in the process of embryo donation/adoption as well as those who may initiate a process of embryo donation or adoption in the near future. Entities may apply for both categories of funding; however, a separate application is required for each category identified in this announcement. Applicants should demonstrate experience with embryo donation and/or adoption programs that conform to professionally recognized standards governing embryo donation and/or adoption and other applicable Federal or State requirements. For the purposes of this announcement, embryo donation and/or adoption is defined as the donation of frozen embryo(s) from one party to a recipient who wishes to bear and raise a child or children.

I. Funding Opportunity Description

Authority: This program is authorized by Division D, Title II of the Consolidated Appropriations Act, 2010 (Public Law No. 111-117), and subsequent Continuing Resolutions (Public Law Nos. 111-242, 111-290, 111-317, 111-322, 112-4, 112-6, 112-8 and 112-10). OPA is under the direction of the Deputy Assistant Secretary for Population Affairs

(DASPA), who serves as the senior advisor to the Assistant Secretary for Health (ASH) on reproductive health issues.

OPA announces the anticipated availability of funds for FY 2011 and requests applications for cooperative agreement projects that will contribute either to increasing public awareness of embryo donation and/or adoption, or to providing services which facilitate embryo donation and/or adoption. The increasing success of assisted reproductive technologies (ART) has enabled some infertile couples to create embryos through in-vitro fertilization (IVF) that are then cryopreserved (frozen) for future use. If a couple becomes pregnant without using all of the stored embryos, they may choose to donate the remaining unused embryos for use by other infertile couples. Embryo donation is a relatively new process in which individuals who have extra frozen embryos agree to release the embryos for use by another woman. The recipient can be either known or anonymous to the donor(s).

Legislative History

In Fiscal Years (FYs) 2002, 2004 and 2005, Congress appropriated approximately \$1 million to the Department of Health and Human Services and directed the Secretary to conduct a public awareness campaign to educate Americans about the existence of frozen embryos for adoption. In FYs 2002, 2004, and 2005, the Department, on a competitive basis, funded project grants to increase public awareness of embryo adoption. No funds were appropriated for this activity in FY 2003. In FYs 2006 and 2007, Congress appropriated \$2 million for embryo adoption activities. In FY 2008, the total appropriation approximated \$4 million. The appropriations for FY 2009 and for FY 2010 were \$ 4.2 million.

The Consolidated Appropriations Act, 2010 (Public Law 111-117) authorizes the Secretary to conduct a public awareness campaign to educate Americans about the existence of frozen embryos available for donation and/or adoption, and “to provide, to individuals adopting embryos, through grants and other mechanisms, medical and administrative services deemed necessary for such adoptions.” Continuing Resolutions enacted in FY 2011 have continued funding and authority for this program.

Program Requirements/Application Content

This notice solicits applications for cooperative agreement grant projects in two distinct categories: (1) Projects that increase public awareness of embryo donation and/or adoption; and (2) Projects that offer services, including counseling, to couples that are currently involved, or soon may be involved in the process of embryo donation and/or adoption.

Category 1: OPA anticipates funding two to six projects that focus on increasing public awareness of embryo donation and/or adoption. This includes increasing awareness of embryo donation /adoption among professionals through specific training programs.

Embryo donation and/or adoption is an emerging field and the practice of embryo donation and/or adoption is complicated by the different attitudes and expectations that professionals, as well as potential donors, have about this option. Many potential donors have limited knowledge of embryo donation and access to information to aid them in making a decision on the donation of their embryos. Potential donors may benefit from the provision of information and connection to support networks or peers. OPA is

interested in assisting potential donors with this difficult decision and in providing training to professionals to support potential donors with their specific needs.

The current and emerging body of knowledge related to embryo donation and/or adoption should provide the basis for training content. Successful applicants will be able to incorporate current, evidence-based information in all phases of training design, delivery, and evaluation. Applicant organizations should demonstrate significant experience in the design, development, implementation, successful completion, and evaluation of training activities. In addition, the successful applicant must demonstrate skill and experience in providing training to diverse groups. The successful applicant will provide evidence of familiarity with embryo donation and/or adoption and the ability to translate evidence-based information into training activities.

Applicants funded under this announcement will be expected to conduct training activities with continuing education content relevant to the medical, legal, psycho-social, ethical, and practical issues involved with embryo donation and/or adoption. This continuing education content may be offered to professionals working with populations who may be interested in embryo donation and/or adoption. Training provided is intended to enhance the ability of multiple levels of providers to share information about and assist potential donors with embryo donation and/or adoption. Training content and design should be adjusted to the skill and practice role of the target audience. OPA expects that continuing education credits will be available for training activities provided under this announcement. The content and number of offerings should be based on an assessment of the need and these offerings should be designed and delivered in a manner

appropriate to the content and professional preparation of the participants. Distance learning components may be part of the training offerings.

Category 1 applicants should make reasonable efforts to ensure that the individuals who design and implement the public awareness projects are knowledgeable in all elements of the embryo donation and/or adoption process and are experienced in providing such information. In the narrative section of the application for this category, applicants are advised to describe the strategies and processes that they will use to design a public awareness campaign. The applicant should document its capacity to undertake a public awareness campaign focused on the public or on professional audiences. Applicants are encouraged to present a description of approaches (seminars, media, website, training and others) that may be used, as well as supplemental materials (resource manuals, brochures, handouts, visual aids, and other resources).

Category 2: OPA anticipates funding two to four organizations that will provide administrative and/or medical services—including counseling—to couples who are currently involved in or considering embryo donation and/or adoption. In the narrative section of the application, applicants are advised to describe the processes they intend to use to assist couples who are in the process of embryo donation or adoption. Applicants are encouraged to propose strategies for delivering services that increase the ability of couples to adopt frozen embryos. Strategies aimed at increasing the percentage of currently frozen embryos that are made available for donation/adoption are acceptable under this program.

The applicant should document its capacity to undertake a cooperative agreement that offers medical or administrative services to couples involved in embryo donation/adoption. Applicants are encouraged to present a description of approaches which they propose to use in their service delivery. These approaches should be economically feasible, equitable and ethically sound.

For the purposes of this announcement, counseling is considered a “medical service.” “Administrative services” are those that help an embryo donation/adoption patient (or couple) to negotiate the process of embryo donation/adoption without the involvement of medical or allied health professionals. Included in this category are services that help potential donor couples find satisfactory matches with potential frozen embryo adopters.

Projects cannot fund payments for human tissues, or any practice that may be construed as involving compensation for the donation of human tissues. Reimbursement of a donor couple’s accrued storage fees is not considered an acceptable strategy under this program.

Applicants are encouraged to devise strategies to target the various professional audiences associated with embryo donation and/or adoption and educate the involved professionals (e.g., reproductive medicine physicians, nurses, embryologists, family practice lawyers, adoption counselors, ethicists, social workers, IVF clinic staff, embryo storage facility staff, etc.) in the complex legal, medical, psycho-social, ethical and practical issues that confront the embryo donor and recipient populations. The successful applicant will use evidence-based information and approaches to (1) identify potential embryo donors; (2) provide education, counseling and support services to potential

donors; and (3) assist potential donors in the decision-making process should they choose to donate and transfer embryos to recipients.

Category 2 applicants should include information about the organization's capacity to provide services to facilitate embryo donation and/or adoption. Services provided by Category 2 applicants must be provided consistent with 42 CFR 59.5(a)(4), which requires that services be provided "without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status."

Applicants are advised to demonstrate a familiarity with, and understanding of, professionally recognized standards or practices (both medical and legal) pertaining to embryo donation and/or adoption, as well as supportive services for potential donor or recipient couples. The applicant organization should clearly demonstrate its professional knowledge and experience in embryo adoption whether with potential donor or recipient populations.

Application Narrative

In the narrative section of the application, organizations should include information about their history in working with embryo donation and/or adoption, and the organization's capacity to further the goal of increasing public awareness of embryo donation and/or adoption and providing related services to facilitate embryo donation and/or adoption. As part of the project narrative, applicants are advised to describe the methods they will use to recruit, select, train and evaluate individuals who will implement the project.

In the project narrative, applicants are encouraged to present a plan for evaluation of the project. The evaluation plan should be two-tiered to address: (1) process, including the planning, content, and quality of the products (e.g., videos, pamphlets, journal articles, presentations, survey instruments, focus group projects, pilot test reports, conference proceedings, etc.) produced; and (2) participant satisfaction and/or project effectiveness, as appropriate. Applicants that do not have the in-house capacity to conduct an evaluation are advised to propose contracting with a third-party evaluator to conduct the evaluation.

Applicants should prepare a project description statement in accordance with the following general instructions and use the information provided in this section and the evaluation criteria section to develop the application content. Applications will be evaluated on the criteria listed, so it is important to follow them in describing your program plan. The narrative should contain the following sections in the order presented below:

1. Project Summary /Abstract: Provide a summary of the project description not to exceed one page. Care should be taken to produce an abstract/summary that accurately and concisely reflects the proposed project since the abstract will be used to provide reviewers with an overview of the application and will form the basis for an application summary in official documents. The summary should describe the objectives of the project, the approach to be used and the results or benefits expected. This project summary may be posted on the OPA website if the project is awarded a grant.

2. Need for Assistance: Demonstrate a clear understanding of the program goals and explain how the particular approach to the project design and objectives will contribute to achieving these goals. Clearly identify the physical, economic, social, legal, financial, institutional and/or other problem(s) requiring a solution. The need for assistance should be demonstrated and the principal and subordinate objectives of the project should be clearly stated.

Outline the specific geographic region that will be served by the organization. This section should include a justification for the selection of the region, based on, for example, geographic size or the number and types of Assisted Reproductive Technology (ART) centers in the area. There are no geographic restrictions on where prospective projects may be conducted.

Describe the rationale for use of the proposed approach based upon previous practice and review of the literature and/or evaluation findings. Any relevant data based on studies should be included or referred to in the proposed approach based upon previous practice and review of the literature and/or evaluation findings. Any relevant data based on studies should be included or referred to in the endnotes/footnotes.

3. Approach and Objectives: The applicant should provide a detailed work plan and timetable as well as goals and objectives for both years of the proposed project. Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions and activities identified in the application. Cite factors that might accelerate or

decelerate the work, and state reasons for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement. Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of program activities to be held, or appropriate measurable outcomes. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of the accomplishments and their target dates.

In formulating their objectives, applicants may want to use the S.M.A.R.T. model described in *How to Get Grants*, a 1981 publication of the Public Management Institute. Applicants should ensure all proposed objectives are S.M.A.R.T that is, specific, measurable, achievable, realistic and time-framed. Please note the following explanation of terms:

Specific: An objective should specify one major result directly related to the program goal, state who is going to be doing what, to whom, by how much and in what time-frame. It should specify what will be accomplished and how the accomplishment will be measured.

Measurable: An objective should be able to describe in realistic terms the expected results and to specify how such results will be measured.

Achievable: The accomplishment specified in the objective should be achievable within the proposed time line and as a direct result of program activities.

Realistic: The objective should be reasonable in nature. The specified outcomes and expected results should be described in realistic terms.

Time-framed: An objective should specify a target date or time for its accomplishments. It should state who is going to be doing what, by when etc.

4. Evaluation: Provide a narrative addressing how results of the project and conduct of the project will be evaluated. In addressing the evaluation of results, the successful applicant will determine the extent to which the project has achieved its stated objectives and the extent to which the accomplishment of objectives can be attributed to the project. The evaluation should include a logic model that visually ties the program interventions to the program objectives. The logic model should include activities, outputs, short, intermediate and long-term outcome, goals and moderating effects /assumptions. The applicant should discuss the criteria used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the project results and benefits are being achieved. With respect to the conduct of the project, the applicant should define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

5. Organizational Profiles: Provide information on the applicant organization and cooperating partners such as organizational charts, documentation of professional accreditation, documentation of experience in the

program area, and other pertinent information. Applicants should demonstrate an understanding of the intended audience as well as the information and skills needed by the designated staff. Applicants are advised to show that they have the organizational capacity and resources to carry out the project on time and to a high standard of quality, including the capacity to resolve a variety of technical and management problems that may occur. Capacity includes: (1) previous experience with similar projects; (2) experience with the target audience; (3) qualifications and experience of the project leadership; (4) experience and commitment of any consultants and subcontractors; and, (5) appropriateness of the organizational structure. Applicants are expected to present a sound and feasible management plan for implementing the proposed program. This section should detail how the program will be structured and managed, how the timeliness of activities will be ensured, how quality control will be maintained, and how costs will be controlled. The role and responsibilities of the lead agency should be clearly defined and, if appropriate, applicants should discuss the management and coordination of activities carried out by any partners, subcontractors, and consultants.

6. Budget and Budget Justification: Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs. Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), and time commitment to the

project (as a percentage or full-time equivalent). Include the costs of consultants or personnel, costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant. Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, and taxes, unless treated as part of an approved indirect cost rate. Include information on the costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel). For each trip, show the total number of travelers, travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Applicants are expected to allocate sufficient funds in the budget to provide for one meeting each year with the Project Officer in Rockville, Maryland, and regular conference calls for programmatic collaboration during the performance of the project. For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use of the equipment in the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

List general categories of supplies and their costs. Show computations and provide other information, which supports the amount requested. Include information on the costs of all contracts for services and goods except for those, which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary

recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant, should be included under this category. Whenever the applicant intends to delegate part of the project to another agency, the applicant should provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information

II. Award Information

Funding Instrument Type: Cooperative Agreement.

Anticipated Total Funding: \$1,700,000.

Anticipated Number of Awards: OPA anticipates funding four to eight new projects.

Expected Amounts of Individual Awards: \$200,000-\$500,000 per 12-month budget period.

Ceiling of Award Range: \$500,000 for the first 12-month budget period. OPA will not accept or review applications with budgets greater than the ceiling of the award range.

Project Periods for Awards: The projects will be awarded for a project period of 24 months. The initial grant award will be for a 12-month budget period. Continued funding beyond the initial 12-month budget period will be subject to the availability of funds, satisfactory progress as determined by OPA, and a determination that continued funding would be in the best interest of the government.

Applications are encouraged from organizations that are currently operating programs that have the capability of providing services (including counseling) to people who are considering embryo donation and/or adoption. Moreover, applications are encouraged from organizations that have the capability to conduct a rigorous evaluation of the funded project.

A cooperative agreement is a grant award instrument establishing an “assistance-relationship” between OPA and a recipient, in which substantial programmatic involvement with the recipient is anticipated during the performance of the funded activities. The recipient will have lead responsibilities in all aspects of the project, including any modifications to the project, conduct of the project, and preparation of any publications. The OPA project officer will collaborate with the recipients, as appropriate, and provide consultation, assistance, and support in planning, implementing, and evaluating all aspects of the proposed project plan. OPA will have substantial programmatic involvement during conduct of the project, through technical assistance, advice and coordination. Substantial involvement as a partner would include, for example, assisting in planning an agenda, selecting speakers, organizing a symposium, determining the content of training curricula and related educational materials, determining the topics or data to be reviewed as part of an assessment, and determining the acceptability of articles or reports. OPA will provide assistance in the preparation and review of any reports that may be disseminated as part of a funded project.

III. Eligibility Information

1. Eligible Applicants:

Eligible applicants should demonstrate previous experience with embryo donation and/or adoption and be knowledgeable in all elements of the process of embryo donation and/or adoption. Only agencies and organizations, not individuals, are eligible to apply. Eligible applicants include public agencies, non-profit organizations, and for-profit organizations. Educational institutions—including academic medical centers and/or their affiliated clinics—are eligible to apply for this grant. American Indian/Alaskan Native/Native American (AI/AN/NA) organizations are also eligible to apply. One agency must be identified as the applicant organization and will have legal responsibility for the project. Additional agencies and organizations can be included as co-participants, subgrantees, subcontractors, or collaborators if they will assist in providing expertise and in helping to meet the needs of the recipients.

Only those organizations or agencies that demonstrate the capability of providing the proposed services and that meet the requirements of this announcement, will be considered for awards. Faith-based and community-based organizations that meet the eligibility requirements are encouraged to apply for these embryo donation and/or adoption cooperative agreement projects. Please note, however, that cooperative agreement funds may not be used for inherently religious activities, such as worship, religious instruction, and proselytization. If an organization engages in such activities, they must be offered separately in time or location from the grant program and participation must be voluntary for program beneficiaries. In providing services and outreach related to program services, a funded entity may not discriminate against current or prospective program beneficiaries on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

Applicants should note that section 45 CFR Part 74.81 of the DHHS Uniform Administrative Requirements indicates that, except for awards under certain small business programs, no grant funds may be paid as profit to any recipient even if the recipient is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.

2. Cost Sharing or Matching:

Cost Sharing or Matching is not required for this cooperative agreement.

3. Other:

OPA will not accept or review applications with budgets greater than the ceiling of the award range. Applications that are received in an unreadable format will be returned to the applicant unread and will not proceed to Objective Review.

IV. Application and Submission Information

1. Address to Request Application Package:

Detailed instructions and supplemental materials for responding to this application are compiled in an application kit, which may be obtained by accessing Grants.gov at <http://www.grants.gov> or the GrantSolutions system at <http://www.GrantSolutions.gov>.

To obtain a hard copy of the application kit, contact the Grants Operation Center at 1-888-203-6161. Applicants may fax a written request to (240) 453-8823 or email the request to OASH@LCGnet.com. Applicants must use the application kit which can be obtained at the websites noted above.

2. Content and Form of Application Submission:

Hard copy applications must be prepared on the forms supplied and in the manner prescribed in the application kits provided by OPA. Every application must be signed by an individual authorized to act for the applicant organization or agency and to assume responsibility for the obligations imposed by the terms and conditions of the grant award. In the case of applications made through the Grants.gov system, the signature will be electronic.

Applicants submitting hard copies must submit one signed original and two photocopies of the application in one package, including all forms and attachments. Please label the application envelope: *Attention: Embryo Adoption and/or Donation Public Awareness Campaign* for [Category 1 applications](#) or *Attention: Embryo Adoption and/or Donation Administrative or Medical Services* for [Category 2 applications](#). The application should be typed and should be no more than 40 double-spaced pages, printed on one side, with one-inch margins, and in 12-point font, unreduced. The page limit does not include budget; budget justification; required forms, assurances and certifications as part of the Application Kit; or appendices. All pages, charts figures and tables should be numbered. The application narrative should be numbered separately and clearly show the 40 page limit. If the application exceeds 40 pages, only the first 40 pages of the application narrative will be reviewed. Appendices may provide curricula vitae, organizational structure, examples of organizational capabilities, 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.

Applications must include a one-page abstract of the proposed project, which is also included in the overall 40 page limit. The abstract will be used to provide reviewers with an overview of the application, and will form the basis for the applications summary in grants management documents.

3. Submission Dates and Times:

To be considered for review, applications must be received by the Office of Grants Management, Office of the Assistant Secretary for Health (OASH) Department of Health and Human Services c/o Grants Operation Center, by 9:00 p.m. Eastern Time for electronic applications and 6:00 p.m. Eastern Time for mailed-in applications on June 28, 2011. Applications will be considered as meeting the deadline if they are received on or before the deadline date. The application due date requirement in this announcement supersedes the instructions in the Application Kit.

Submission Mechanisms:

The Office of the Assistant Secretary for Health (OASH) provides multiple mechanisms for the submission of applications, as described in the following sections. Applicants will receive notification from the OASH Office of Grants Management confirming the receipt of applications submitted using any of these mechanisms. Applications submitted to the OASH 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, you may access the Grants.gov website portal. All OASH funding opportunities and application kits are made available on Grants.gov. If your organization has/had a grantee business relationship with a grant program serviced by the OASH Office of Grants Management, and you are applying as part of ongoing grantee related activities, please access GrantSolutions.gov.

Electronic grant application submissions must be submitted no later than 9:00 p.m. Eastern Time on the deadline date specified in the DATES section of the announcement using one of the electronic submission mechanisms specified below. All required hardcopy original signatures and mail-in items must be received by the Office of Grants Management, Office of the Assistant Secretary for Health (OASH) Department of Health and Human Services (DHHS) c/o Grants Operation Center, 1400 Key Blvd. Suite 910, Arlington VA 22209, no later than 6:00 p.m. Eastern Time on the next business day after the deadline date specified in the DATES section of the announcement. Applications will not be considered valid until all electronic application components, hardcopy original

signatures, and mail-in items are received by the OASH Office of Grants Management according to the deadlines specified above.

Paper grant application submissions must be submitted no later than 6:00 p.m. Eastern Time on the deadline date specified in the DATES section of the announcement. The address to be used for paper application submissions is Office of Grants Management, Office of the Assistant Secretary for Health OASH, Department of Health and Human Services (DHHS) c/o Grants Operation Center 1400 Key Blvd., Suite 910, Arlington VA 22209. The application deadline date requirement specified in the announcement supersedes the instructions in the Application Kit. Application submissions that do not adhere to the due date requirements will be considered late and will be deemed ineligible, and may be returned to the applicant unread.

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 OASH grant opportunities. Organizations must successfully complete the necessary registration processes in order to submit an application. Information about this system as well as the required registration process is available on the Grants.gov website (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 B 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, OASH 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 be received by the due date requirements specified above. **Mail-In items may only include publications, resumes, or organizational documents.** 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 AInvalid@ by the Grants.gov Website Portal will not be transferred to the GrantSolutions system, and OASH has no responsibility for any application that is not validated and transferred to OASH 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 OASH Office of Grants Management, c/o Grants Operation Center 1400 Key Blvd., Suite 910, 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 OASH 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

OASH 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, 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). OASH 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 OASH Grants Operation Center 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 OASH Grants Operation Center at the address specified 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. **Mailed items should only include 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 hardcopy original signatures, and mail-in items.

As items are received by the OASH Grants Operation Center, 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 the Assistant Secretary for Health (OASH), Department of Health and Human Services (DHHS) c/o Grants Operation Center 1400 Key Blvd., Suite 910, Arlington VA 22209, on or before 6:00 p.m. Eastern Time on the deadline date specified in the DATES section of the announcement.

4. Intergovernmental Review:

This program is not subject to the intergovernmental review requirements of Executive Order 12372, AIntergovernmental 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 OASH 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 Parts 74 and 92, (Hospitals). Copies of the Office of Management and Budget (OMB) Circulars are available on the Internet at www.whitehouse.gov/omb/grants/grants_circulars.html.

Applicants for cooperative agreements are expected to anticipate and justify their funding needs and the activities to be carried out with those funds in preparing the budget and accompanying narrative portions of their applications. If applicants are uncertain whether a particular cost is allowable, they should contact the OASH Office of Grants Management at (240) 453-8822 for further information.

6. Other Submission Requirements:

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 necessary to obtain one. Instructions for obtaining a DUNS number are included in the application kit and may be downloaded from the grants.gov website.

New DUNS Requirement:

Grantee: If you are authorized to make sub-awards under this award, you:

- Must notify potential sub-recipients that no entity may receive a sub-award from you unless the entity has provided its DUNS number to you.
- May not make a sub-award to an entity unless the entity has provided its DUNS number to you.

Central Contractor Registry (CCR) Requirement:

Grantees: Unless your entity is exempt from this requirement under 2 CFR 25.110, it is incumbent upon you, as the recipient, to maintain the accuracy/currency of your information in the CCR until the end of the project. Additionally, this term requires your entity to review and update the information at least annually after the initial registration,

and more frequently if required by changes in your information or another award term.

Transparency Act Disclaimer Language:

Awards issued with a start date after October 1, 2010 may be subject to the following award term. All HHS Grants, Cooperative Agreements, Loans, and other forms of Federal Financial Assistance are subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR Part 170, as defined in §170.320. For further guidance and award applicability information see:

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title02/2cfr170_main_02.tpl

Trafficking in Persons: Awards issued under this funding opportunity are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term go to:

http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html.

V. Application Review Information

1. Criteria

Each application for a cooperative agreement grant project will be evaluated individually according to the following criteria by a panel of independent reviewers. Before the review panel convenes, each application will be screened for applicant organization eligibility, timeliness and completeness.

A panel of at least three independent reviewers will use the evaluation criteria listed below to determine the strengths and weaknesses of each application, provide comments and assign numerical scores. Applicants should address each criterion in the project application. The point values (summing up to 100) indicate the maximum numerical weight each criterion will be accorded in the review process.

Criterion 1: Project Summary/Abstract (5 Points)

Applicants are expected to summarize the proposed project in an abstract not to exceed one page. The abstract must include the project's objectives, its approach and the results or benefits that are expected from the project.

Criterion 2: Need for Assistance (15 pts)

Specific review criteria include: (1) The extent to which the application reflects an understanding of: (a) the goals of the public awareness campaign for embryo donation and/or adoption, and how implementation will contribute to achieving these goals; or (b) The extent to which the application reflects a knowledge and understanding of the challenges involved with offering services to facilitate embryo donation and/or adoption; (2) The extent to which the application clearly describes and documents the need for assistance to enhance efforts to increase: a) public awareness of embryo donation and/or adoption; or, (b) to make services available to people that are currently involved or soon may be involved in the process of embryo donation or adoption; (3) The extent to which the application reflects an understanding of the medical and legal framework of embryo donation/ and/or adoption, and the services and resources in the geographic area

in which the proposed project will be conducted; (4) The extent to which the application explains how the proposed project will contribute to increased knowledge of the problems, issues, and effective strategies and best practices in the field of embryo donation and/or adoption; and (5) The extent to which the application presents a vision of how the project will advance: (a) public awareness of embryo donation and/or adoption, or , (b) the ability of couples to use embryo donation/adoption services; and, (6) The extent to which the applicant discusses the broad contextual factors that will facilitate or impede the proposed project.

Criterion 3: Approach and Objectives (35 Points)

In this section, applicants are expected to define goals and specific, measurable objectives for the project. Goals are an end product of an effective project. Objectives are measurable steps for reaching goals. Applicants are advised to describe a preliminary, yet appropriate and feasible workplan pertaining to the scope of the proposed project and provide details on how the proposed project will be accomplished. If the project involves partnerships with other agencies and organizations, then the roles of each partner should be clearly specified.

Applicants should describe how the project will be evaluated to determine the extent to which it has achieved its stated goals and objectives. Applicants are expected to present a project design that includes detailed procedures for documenting project activities that is sufficient to implement goals and provide for an evaluation. The evaluation designs are expected to include process and outcome analyses if feasible. Applicants are expected to report on their evaluation results in their final report to the

OPA upon completion of the project period. Applicants should describe the activities that they will develop pursuant to the project. Applicants should discuss the intended audiences for these activities (e.g., ART centers, adoption organizations, professional organizations that work with infertile couples, embryo storage facilities, potential recipients, or donors) and present a dissemination plan specifying the venues for conveying the information. This criterion consists of three broad topics: (A) project design, (B) implementation, and (C) dissemination. Specific review criteria include:

(A) Design of the Project

(1) The extent to which the application reflects a familiarity with and understanding of professionally recognized standards and/or other relevant Federal or State requirements pertaining to embryo donation and/or adoption.

(2) The extent to which the proposed project goals, objectives, and outcomes are clearly specified and measurable, and reflect an understanding of the context, and

(3) The extent to which the application presents an approach that: (a) is competency based; and, (b) can be evaluated.

B) Implementation

(1) The extent to which the application clearly describes and provides a justification for the selection of the geographic region that will be served by the project;

(2) The extent to which the application presents an appropriate, feasible, and realistic plan for conducting the project;

(3) The extent to which the application presents an appropriate, feasible and realistic plan for recruiting, selecting, and training individuals to conduct the project;

(4) The extent to which the application provides an appropriate, feasible and realistic plan for documenting project activities and results, that can be used to describe and evaluate the project, and participant satisfaction; and,

(5) The extent to which the proposed project will establish and coordinate linkages with other appropriate agencies and organizations.

(C) Dissemination

(1) The extent to which the application provides an appropriate, feasible and realistic plan for dissemination of information and related educational materials;

(2) The extent to which the intended audience is clearly identified and defined and is appropriate to the goals of the proposed program;

(3) The extent to which the program's products will be useful to the respective audiences;

(4) The extent to which the applicant presents a realistic schedule for developing these products, and provides a dissemination plan that is appropriate in scope and budget to each of the audiences; and,

(5) The extent to which the products being developed during the program are described clearly and will address the goal of dissemination of information and are designed to support evidence-based improvements of practices in the field.

Criterion 4: Evaluation (20 Points)

Applicants are expected to present evaluations which provide (A) a logic model that visually links the program interventions to the program objectives and (B) clear descriptions of the process and outcome evaluation which include:

(1) The extent to which the methods of evaluation are feasible, comprehensive, and appropriate to the goals, objectives, and context of the project;

(2) The extent to which the applicant offers an appropriate, feasible, and realistic plan for evaluating the project, including performance feedback and assessment of program progress that can be used as a basis for program adjustments;

(3) The extent to which the methods of evaluation include process and outcome analyses, as appropriate, for assessing the effectiveness of the program strategies and implementation process; and,

(4) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the program and which will produce quantitative and qualitative results

Criterion 5: Organizational Profile (15 Points)

This criterion consists of three broad topics: (A) organizational capacity and resources, (B) staff qualifications, and (C) management plan. Include information on staff knowledge of the medical and legal issues concerning embryo donation and/or adoption, and experience working in this area. Brief resumes of current and proposed staff, as well as job descriptions, should be included. Resumes should indicate the position that the individual will fill, and each position description should specifically describe the job as it relates to the proposed project. If the proposed project involves partnering and/or

subcontracting with other agencies/organizations, then the application should include an organizational capability statement for each participating organization documenting the ability of the partners and/or subcontractors to fulfill their assigned roles and functions.

Specific review criteria include:

(A) Organizational Capacity and Resources

(1) The extent to which the management plan presents a realistic approach to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, time lines and milestones for accomplishing project tasks; (2) The extent to which the role and responsibilities of the lead agency are clearly defined and the time commitments of the project director and other key project personnel (including consultants) are appropriate and adequate to meet the objectives of the proposed project; and, 3) The extent to which the applicant discusses factors that may affect the development and implementation of the project and presents realistic strategies to resolve these difficulties.

(B) Staff Qualifications

(1) The extent to which the proposed project director, key project staff, and consultants have the necessary technical skill, knowledge, and experience to successfully carry out their responsibilities; and, (2) The extent to which staffing is adequate for the proposed project, including administration, program services, data processing and analysis, evaluation, reporting and implementation of the project.

(C) Management Plan

Applicants should provide letters of commitment or Memoranda of Understanding from organizations, agencies, and consultants that will be partners or collaborators in the

proposed project. These documents should describe the role of each agency, organization, or consultant and detail specific tasks to be performed.

Criterion 6: Budget and Budget Justification (10 Points)

Applicants are expected to present a detailed budget for the two-year grant period. The budget should present reasonable project costs, appropriately allocated across component areas and sufficient to accomplish the objectives. Consideration shall be given to project delays due to start-up when preparing the budget. Specific review criteria include:

(1) The extent to which the applicant demonstrates that the project costs and budget information submitted for the proposed program are reasonable and justified in terms of the proposed tasks and the anticipated results and benefits; and,

(2) The extent to which the fiscal control and accounting procedures are adequate to ensure prudent use, proper and timely disbursement, and an accurate accounting of funds received under this announcement.

2. Review and Selection Process

The results of a competitive review are a primary factor in making funding decisions. In addition, Federal staff will conduct administrative reviews of the applications and, in light of the results of the competitive review, will recommend applications for funding to the Deputy Assistant Secretary for Population Affairs (DASPA). The DASPA may also solicit and consider comments from others within DHHS in making funding decisions. Final grant award decisions will be made by the

DASPA. The DASPA will fund those projects which will, in her judgment, best promote the purposes of this program, within the limits of funds available for such projects.

VI. Award Administration Information

1. Award Notices

OPA does not release information about individual applications during the review process. When final decisions have been made, successful applicants will be notified by letter of the outcome of the final funding decisions. The official document notifying an applicant that a project has been approved for funding is the Notice of Grant Award (NGA), signed by the OASH Grants Management Officer, which sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the grant, the budget period for which initial support will be given, and the total project period for which support is contemplated.

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 in 45 CFR parts 74 and 92 currently in effect or implemented during the period of the grant.

Review of Grant Materials: Grantees shall submit all materials proposed for use in the funded project (including, but not limited to, web sites, videos, training materials, brochures, fact sheets, press releases, agendas, curricula, reports, journal articles, promotional pieces, advertisements, Public Service Announcements (PSA=s), articles, mailings) to the OPA Project Officer for review and approval prior to use in the funded

program. The review shall ensure that materials are consistent with the requirements of this announcement and other applicable grant requirements.

Grant Attribution: OPA is interested in making available to the public the results and accomplishments of activities that it funds. Therefore, grantees shall place an acknowledgment of OPA grant support and a disclaimer, as appropriate, on any publication written or published with such support and, if feasible, on any publication describing or reporting the results of a grant-supported activity.

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 Requirements

A successful applicant under this notice will submit: (a) semi-annual progress reports; (b) Quarterly Federal Financial Reports; and c) a final performance report, including an evaluation report, and a Final Financial Report. Reporting formats are established in accordance with provisions of the general regulations which apply under 45 CFR parts 74 and 92. Successful applicants must submit all required reports in a timely manner, in recommended formats, and submit a final report on the project, including any information on evaluation results, at the completion of the project period. The final performance report should contain an overview of the program from start to finish,

including information on: (a) the summary of the project, (b) the state of the major goals and objectives of the project, (c) a list of significant accomplishments, (d) a description of innovative features, (e) a statement of significant problems encountered and solutions developed, (f) a complete written disclosure of any invention, curriculum, publication, video, pamphlet conceived or produced as part of the grant funded project, (g) a copy of any products developed in association with the project. The final evaluation report should reflect an assessment of the program. It should describe factors contributing to both program success and problem areas. The report should include a description of the project's objectives, interventions, evaluation model and hypotheses, findings, and conclusions. The report should include a summary of the program statistics and findings. It should discuss the implications of project findings as they relate to the project objectives, as well as a set of recommendations based on the findings (where appropriate). The appendices to the evaluation report should include any data collection instruments and relevant references. Copies of any published articles, based on the project or project evaluation findings are also requested.

Agencies receiving \$500,000 or more in total Federal funds are required to undergo an annual audit as described in OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations".

VII. Agency Contacts

For application kits, submission of applications, and information on budget and business aspects of the application, please contact: Office of Grants Management, Grants Operation Center at 1-888-203-6161, e-mail: OASH@LGCnet.com.

Program Office Contact: For information relating to program requirements, contact: Robert Scholle, Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs, 1101 Wootton Parkway, Suite 700, Rockville, Maryland, 20852. E-mail: Robert.Scholle@hhs.gov; telephone: (240) 453-2848.

DATED:

Marilyn Keefe,

Deputy Assistant Secretary for Population Affairs