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 Availability of Funds for Embryo Donation and/or Adoption Grant Projects

ACTION: Notice

ANNOUNCEMENT TYPE: INITIAL COMPETITIVE GRANT, FUNDING OPPORTUNITY NUMBER: PA-EAA-15-001

CFDA NUMBER: 93-007

CFDA PROGRAM: Public Awareness Campaigns on Embryo Adoption

DATES:

Applications are due April 21, 2015 by 5 p.m. ET. To receive consideration, applications must be received electronically via Grants.gov by the HHS Office of the Assistant Secretary for Health (HHS/OASH), Office of Grants Management (OGM) no later than this due date. Applications which do not meet the specified deadlines will be returned to the applicant unread. All applicants must submit electronically via Grants.gov unless they obtain a written exemption from this requirement 2 business days in advance of the deadline by the Director, HHS/OASH Office of Grants Management. To obtain an exemption, applicants must request one via email from the HHS/OASH Office of Grants Management, and provide details as to why they are technologically unable to submit electronically through Grants.gov portal. Requests

should be submitted at least 4 business days prior to the application deadline to ensure the request can be considered prior to 2 business days in advance of the deadline. If requesting an exemption, include the following in the e-mail request: the HHS/OASH announcement number; the organization's DUNS number; the name, address and telephone number of the organization; the name and telephone number of the Authorizing Official; the Grants.gov Tracking Number (PA-EAA-15-001) assigned to the submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to ogm.oash@hhs.gov. Note: failure to have an active System for Account Management (SAM) registration will not be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH Office of Grants Management will only accept applications via alternate methods (hardcopy paper via US mail or other provider or PDF via email) from applicants obtaining prior written approval. The application must still be submitted by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via US mail or other service or PDF via email) with an approved written exemption will be accepted. *See* the heading "**APPLICATION and SUBMISSION INFORMATION**" for information on application submission mechanisms.

Executive Order 12372 comment due date: The State Single Point of Contact (SPOC) has 60 days from the application due date to submit any comments. For more information on the SPOC see section IV.4 Intergovernmental Review.

To ensure adequate time to successfully submit the application, HHS/OASH recommends that applicants register as early as possible in Grants.gov since the registration process can take up to one month. For information on registering for Grants.gov, refer to

http://www.grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Applicants are strongly encouraged to register multiple authorized organization representatives.

EXECUTIVE SUMMARY: The Office of Population Affairs (OPA) announces the availability of funds for Fiscal Year (FY) 2015 grant awards under the authority of Division G, Title II of the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law No. 113-235), and Section 1704 of the Public Health Service Act (42 U.S.C. § 300u-3). This notice solicits applications for competing grant awards, 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. OPA anticipates approximately $775,000 will be available to support 2-6 new grants. Funding for each of the grants will range from $100,000 to $300,000 per year.

I. FUNDING OPPORTUNITY DESCRIPTION:

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 embryos for use by other infertile couples. Embryo donation is a relatively new process in which individuals with extra frozen embryos agree to

release the embryos for use by another woman who wishes to achieve pregnancy. The recipient can be either anonymous or known to the donor(s).

This notice solicits applications for projects in two 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. Applicants may also propose a project that addresses both the public awareness aspect of the program and the "services" aspect in a single grant.

Public Awareness: This aspect of the program comprises traditional media and advertising modalities, "new media" efforts (such as blogging) as well as generalized education in the basic principles of embryo donation/adoption that can be offered to large audiences. Applicants should make reasonable efforts to ensure that the individuals who design and implement the public awareness projects are knowledgeable in all facets of the embryo donation and/or adoption process and are experienced in providing such information.

Applicants are encouraged to incorporate, to the extent possible, the concepts of Reproductive Life Planning in their public awareness messaging. Reproductive Life Planning (RLP) is a process by which an individual 1) establishes goals about the number and spacing of children that she or he wants; and, 2) marshals resources (including physical health and time) in an effort to meet those goals. More information about RLP is available at www.cdc.gov/preconception/reproductiveplan.html.

Applicants are also encouraged to develop a plan to counter common misconceptions about frozen embryo adoption that appear in traditional and social media (e. g. that frozen embryos only remain viable for a limited time) by employing recent findings from the medical, legal and social science literature.

In the narrative section of the application, 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 an awareness campaign focused on the general public or on professional audiences. Applicants are encouraged to present a description of approaches that will be employed, as well as any supplemental materials (resource manuals, brochures, handouts, visual aids, and other resources) that will be used.

Administrative or Medical Services: This aspect of the program will include administrative and/or medical services to couples who are currently or potentially involved in embryo donation or 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 overcome the financial, legal, and other non-medical obstacles that may occur in the process of embryo donation/adoption. Training of professionals, for the purpose of enabling them to provide administrative and/or medical services, is also included within this aspect of the program.

In the narrative section of the application, applicants are advised to describe in detail the means they intend to use to assist couples who are in the process of embryo donation or adoption. Applicants are encouraged to develop strategies for delivering services that increase the ability of couples to donate or 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. In particular, applicants are urged to devise strategies that "front load" services such as counseling so as to provide early information about the advantages (and disadvantages) of embryo donation/adoption to infertile couples. In other words, applicants in this category are advised to develop counseling interventions that approach infertile couples who may be considering embryo donation/adoption before they actually commit to the process of in vitro fertilization. For the purposes of this Funding Opportunity Announcement (FOA), applicants are advised to develop approaches that inform infertile couples who may be considering embryo donation/adoption about the possibilities and costs of embryo donation/adoption early in the couple's infertility journey. To this end, projects involving Ob/Gyn medical practices are strongly encouraged.

Projects that support administrative services for people who are contemplating embryo donation/adoption may also be funded. A project that proposes a call-in center to give specific information on State and Federal regulations pertaining to frozen embryo transfer would be an example of this aspect of the Embryo Donation/Adoption program.

Embryo donation and/or adoption is an emerging field. 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 little 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 for the purpose of preparing them to provide supportive services to potential donors. 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 focused training activities

Training professionals to offer medical or administrative services to couples who are involved in embryo donation/adoption is included in the "services" aspect of the program. Applicants may conduct training activities for professionals that offer couples or individuals help with the medical, legal, psycho-social, ethical, and practical issues surrounding embryo donation and/or adoption. This training should be designed to enhance the ability of multiple levels of providers to share information and to assist potential donors with embryo donation and/or adoption. Training design and content should be adjusted to the skill and practice role of the target audience. OPA expects that appropriate 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 of the course as well as professional preparation of the participants. Distance learning strategies may be incorporated as part of the training offerings.

Applicants are encouraged to devise strategies to identify the various professional audiences associated with embryo donation and/or adoption and to provide training to 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.

Services provided by applicant organizations must be offered 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 with potential donor or recipient populations.

The applicant should document its capacity to undertake a grant project 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.

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. 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.

Faith-based and community-based organizations that meet the eligibility requirements are eligible to apply for these embryo donation and/or adoption grant projects. Please note, however, that grant 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.

Project funds cannot be used to pay for human tissues, nor for any approach that may be construed as involving compensation for the donation of human tissues. Reimbursement of a donor's already accrued storage fees is not considered an acceptable practice under this program.

AUTHORITY: This program is authorized by Division G, Title II of the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law No. 113-235), and Section 1704 of the Public Health Service Act (42 U.S.C. § 300u-3).

II. AWARD INFORMATION

The Office of Population Affairs intends to make available approximately $775,000 for 2-6 competing grants.

Grants will be funded in annual increments (budget periods) and are generally approved for a project period of up to 2 years, although shorter project periods may be approved. Funding for all approved budget periods beyond the first year of the grant is generally level with the

initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, and adequate stewardship of Federal funds.

Award Information

Estimated Funds Available for Competition: $775,000

Anticipated Number of Awards: 2-6

Range of Awards: $100,000 to $300,000 per budget period

Anticipated Start Date: 07/01/2015

Period of Performance: Not to exceed 2 years

Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov **ONLY unless an exemption is granted**

III. ELIGIBILITY INFORMATION

1. Eligible

Only agencies and organizations, not individuals, are eligible to apply. Eligible applicants include public agencies, non-profit organizations, or 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 this agency will have legal responsibility for the project.

Additional agencies and organizations can be included as co-participants, subgrantees, subcontractors, or collaborators if they assist in providing expertise and in helping to meet the needs of the recipients.

2. *Cost Sharing or Matching*: none

3. *Responsiveness and Screening Criteria*

Application Screening Criteria

All applications appropriately submitted will be screened to assure a level playing field for all applicants. If duplicate applications from the same organization for the same project are successfully submitted, only the last application received by the deadline will be reviewed. Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via www.grants.gov (unless an exemption was granted 2 business days prior to the deadline) by April 21, , 2015 at 5:00 p.m. The Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.
2. The Project Narrative must not exceed 35 pages. NOTE: The following items do not count toward the page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary and Budget narrative.
3. The total application including Appendices must not exceed 60 pages. NOTE: items noted above do not count toward total page limit.
4. Proposed budget does not exceed maximum indicated in Range of Awards.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Information to Request Application Package

Application packages may be obtained electronically by accessing Grants.gov at http://www.grants.gov/. If you have problems accessing the application or difficulty downloading, contact:

Grant Operations Center, Office of Grants Management Operations Center, telephone 1-888-203-6161, or email ASH@LCGnet.com.

2. Content and Form of Application Submission

Application Format

Applications must be prepared using forms and information provided in the online grant application package.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Screening Criteria.

Project Narrative pages must be double-spaced.

The applicant should use an easily readable typeface, such as Times New Roman or Arial, 12-point font. Tables may be single spaced and use alternate fonts but must be easily readable. The page limit does not include budget, budget narrative/ justification, required forms, assurances, and certifications as described in Application Screening Criteria. All pages, charts, figures, and tables, whether in the narrative or appendices, should be numbered. Applications that exceed the specified page limits when printed on 8.5" X 11" paper by HHS/OASH/OGM

will not be considered. We recommend applicants print out their applications before submitting electronically to ensure that they are within the page limit and are easily readable.

Appendices

Appendices should include any specific documents outlined in the Application Content section of this FOA. If not specified, appendices may include curriculum vitae, organizational structure, examples of organizational capabilities, or other supplemental information which supports the application. Brochures and bound materials should not be submitted. Appendices are for supportive information only and should be clearly labeled. All information that is critical to the proposed project should be included in the body of the application. Appendices created specifically for the application should use the same formatting required for the Project Narrative, including double-line spacing. However, appendix documents that were not created directly in response to this funding announcement, especially those imported from other sources and documents, may use other formatting but must be easily readable (e.g., organizational structure).

Project Abstract

Applicants must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application, and will form the basis for the application summary in grants management and program summary documents. Abstracts may be published by HHS/OASH and should not include sensitive or proprietary information.

Budget Narrative

The Budget Narrative text should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

Electronic Submission

The HHS Office of the Assistant Secretary for Health (HHS/OASH) requires all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, *will not* be accepted for review.

You may access the Grants.gov website portal at http://www.grants.gov. All HHS/OASH funding opportunities and grant application packages are made available on Grants.gov.

Applications will not be considered valid until all application components are received via Grants.gov by the HHS/OASH Office of Grants Management according to the deadlines specified in the DATES section on page 1 of this announcement. Application submissions that do not adhere to the due date and time requirements will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process. This will aid in addressing any problems with submissions prior to the application deadline. Any files uploaded or attached to the Grants.gov application must be of the following file formats – Microsoft Word, Excel or PowerPoint, 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, HHS/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. The application must be submitted in a file format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. All documents that do not conform to the above will be excluded from the application during the review process.

A. **Important Grants.gov Information**

You may access the electronic application for this program on http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Number or CFDA number.

To ensure successful submission of applications, applicants should carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-grants.html . These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information.

Applicants should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov.

- You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.

- Instructions are available on the Grants.Gov web site as part of the organization registration process at http://www.grants.gov/web/grants/applicants/organization-registration.html.
- All applicants must register in the System for Account Management (SAM)). You should allow a *minimum* of five days to complete the SAM registration. Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You can register with the SAM online and it will take about 30 minutes (https://www.sam.gov.)
- You must renew your SAM registration each year. Organizations registered to apply for Federal grants through http://www.grants.gov will need to *renew* their registration in SAM.
- It may take 24 hours or more for SAM updates to take effect in Grants.gov, so potential applicants should ***check for active registration well before the application deadline.***
- Applicants must maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an HHS agency.

An award cannot be made until the applicant has complied with these requirements. In accordance with 2 CFR 25.205, at the time an award is ready to be made, if the intended recipient has not complied with these requirements, HHS/OASH:

- May determine that the applicant is not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number at the time the recipient makes a sub-award.

B. Application Content

Successful applications will contain the following information:

Project Narrative

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether or not your project meets the minimum requirements for a grant under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

1) Project Summary: Provide a summary of the project not to exceed one page. Care should be taken to produce a summary that accurately and concisely reflects the proposed project, especially in regard to the project's major goals and objectives. This summary will be used to provide reviewers with an overview of the application. 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 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. Note that grant funds may only be used for domestic purposes and activities. 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 and 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 that are specific, measurable, achievable, realistic and time-framed (SMART) for 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/or 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.

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 this accomplishment of objectives can be attributed to the action of the project. The evaluation should be based on a logic model that visually links the program interventions to the

program's objectives. The applicant should discuss the criteria used to evaluate results, and explain the methodology that will be used to decide if the identified needs are being met and if the project results 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. For service grants that offer counseling, project effectiveness will be evaluated by the number of couples given counseling as well as by the number of couples making decisions to donate their embryos for adoption.

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.

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, including those who are consultants or subcontractors; and, 4. Suitability of the organizational structure for the proposed project. Applicants are expected to present a feasible management plan for

implementing the proposed program. This section should detail how the program will be structured and managed, how timeliness of activities will be ensured, how quality will be maintained, and how costs will be controlled. The role and responsibilities of the lead agency should be clearly defined and applicants should describe the management and coordination of activities carried out by any partners, subcontractors, or consultants.

Budget Narrative

You are required to submit a combined multi-year Budget Narrative, as well as a detailed Budget Narrative for each year of the potential grant. Unless specified, you should develop your multi-year budgets based on level funding for each budget period. A level-funded budget is equal to the exact dollar figure of the year one budget. ***Please Note:*** Because the proposal must demonstrate a clear and strong relationship between the stated objectives, project activities, and the budget, the budget justification should describe the ***cost estimated per proposed project, activity, or product.*** This budget justification should define the amount of work that is planned and expected to be performed and what it will cost. The Budget Narrative does not count toward your total application page limit.

3. Submission Dates and Times

The deadline for the submission of applications under this Program Announcement is **5:00 p.m. Eastern Time on the date indicated in the DATES section on page 1 of this announcement.** Applications must be submitted by that date and time.

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the

event you encounter technical difficulties, either on your end or with http://www.grants.gov . Grants.gov can take up to 48 hours to notify you of a successful submission. Unsuccessful submissions will require authenticated verification from http://www.grants.gov indicating system problems existed at the time of your submission. For example, you will be required to provide an http://www.grants.gov submission error notification and/or tracking number in order to substantiate missing the cut off date.

4. Intergovernmental Review

Applications under this announcement are subject to the requirements of Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as implemented by 45 CFR part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.'' As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for the State in which the applicant is located. The current listing of the SPOCs is available at http://www.whitehouse.gov/omb/grants_spoc. For those states not represented on the listing, further inquiries should be made by the applicant regarding submission to the relevant SPOC. The SPOC should forward any comments to the Department of Health and Human Services 1101 Wootton Parkway, Suite 550, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH Office of Grants Management at 240–453–8822.

5. Funding Restrictions

The allowability, allocability, reasonableness, and necessity of direct and indirect costs may be charged to HHS/OASH grants in accordance with Department regulations and policy effective at the time of the award. Current requirements are outlined at 45 CFR Part 75 Uniform

Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 79 Federal Register 75871 (December 19, 2014).

Indirect costs may be included per 45 CFR 75.414. Applicants should indicate which method and/or rate is used for this application. To obtain a negotiated indirect cost rate with the Federal Government you may contact the Health and Human Services Division of Cost Allocation (DCA) Regional Office that is applicable to your State. A list of DCA Regional Offices is included in the grant application package for this announcement.

Applicants should note that the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45CFR § 75.215 Special Provisions for Awards to Commercial Organizations as Recipients) indicate 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.

Pre-Award Costs:

Pre-award costs are not allowed.

Salary Limitation:

The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) limits the salary amount that may be awarded and charged to HHS/OASH grants and cooperative agreements. Award funds should not be budgeted to pay the salary of an individual at a rate in excess of Executive Level II. Currently, the Executive Level II salary of the Federal Executive Pay scale is $183,300. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HHS/OASH grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is $350,000 per year plus fringe benefits of 25% ($87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to $183,300, their direct salary would be $91,650 (50% FTE), fringe benefits of 25% would be $22,912.50, and a total of $114,562.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $350,000 50% of time will be devoted to project	
Direct salary	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual's base full time salary *adjusted* to Executive Level II: $183,300 50% of time will be devoted to the project	
Direct salary	**$91,650**
Fringe (25% of salary)	**$22,912.50**
Total amount	**$114,562.50**

Appropriate salary limits will apply as required by law.

V. APPLICATION REVIEW INFORMATION

1. Criteria: Eligible applications will be assessed according to the following criteria:

Criterion 1: Project Summary **(5 Points)**

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

Criterion 2: Need for Assistance (**25 Points**)

Specific considerations for this section include: (1) The extent to which the application reflects an understanding of: (a) the goals of the embryo donation / adoption program, 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: a) increase public awareness of embryo donation and/or adoption: or, (b) make services, including counseling, 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 project.

Criterion 3: Approach and Objectives (**30 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 and should be specific, measurable, achievable, realistic and time-framed (SMART). Applicants are advised to describe a preliminary, yet appropriate and feasible work plan 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 the activities that they will develop pursuant to the project. Applicants should discuss the intended audiences for these activities (e.g., ART centers, Ob-Gyn practices, 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 considerations for this criterion include:

(A) Design of the Project:

(1) The extent to which the application reflects an 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 of embryo donation/adoption, and

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

(B) Implementation of the Project:

(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 of the Project:

(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 target 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 should describe how the project will be evaluated so as 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. Service projects that provide counseling should have a record keeping system that enables them to keep track of the number of couples counseled as well as the number of couples who decide to donate their embryos. Grantees must report on their evaluation results in their final report to the OPA upon completion of the project period.

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 (10 Points)

This criterion consists of three broad topics: (A) organizational capacity and resources, (B) staff qualifications, and (C) management plan. This section should demonstrate the staff's 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 sub-recipient agencies/organizations, and these organizations are known at the time of application, 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. If yet to be identified, describe the process and criteria for selecting sub-recipients. Specific considerations for this criterion 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 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. Or, if not yet identified, the process and criteria for selection.

Criterion 6: Budget and Budget Justification (**10 Points**)

Applicants are expected to present a detailed budget for each budget year of the proposed project. 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 considerations for this criterion 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

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that pass the screening and meet the responsiveness criteria if applicable. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section V.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance. Final award decisions will be made by the Deputy Assistant Secretary of Population Affairs or designee.

Review of Risk Posed by Applicant

The HHS/OASH will evaluate each application in the fundable range for risks posed by an applicant before issuing an award in accordance with 45 CFR Part 75.20. This evaluation may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed by the applicant will be applied to the Federal award. OASH will use a risk-based approach and may consider any items such as the following:

(1) Applicant's financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

3. Anticipated Announcement and Award Dates

HHS/OASH seeks to award funds as much in advance of the estimated project start date shown in Section II "Award Information," as practicable, with a goal of 10-15 days.

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The HHS Office of the Assistant Secretary for Health does not release information about individual applications during the review process. If you would like to track your application, please see instructions at http://www.grants.gov/web/grants/applicants/track-my-application.html. The official document notifying an applicant that a project application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH Office of Grants Management. Successful applicants will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail.

This document notifies the successful recipient of the amount of money awarded, the purposes of the grant, the anticipated length of the project period, terms and conditions of the grant award, and the amount of funding to be contributed by the grantee to project costs, if applicable. Grantees should pay specific attention to the terms and conditions of the award as indicated on the NOA, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the grant.

Unsuccessful applicants will be notified by the program office by email and/or letter and will receive summary comments pertaining to the application resulting from the review process. On occasion, some applicants may receive a letter indicating that an application was approved but unfunded. These applications are kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

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

In addition, recipients must comply with all terms and conditions outlined in their grant awards, the Department of Health and Human Services (HHS) Grants Policy Statement, requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts.

Grant funds may only be used to support activities outlined in the approved project plan. The successful applicant will be responsible for the overall management of activities within the scope of the approved project plan.

Smoke- and Tobacco-free Workplace

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

Acknowledgement of Funding

Federal grant support must be acknowledged in any publication developed using funds awarded under this program. All publications developed or purchased with funds awarded under this program must be consistent with the requirements of the program. Pursuant to 45 CFR § 74.36(a), HHS may reproduce, publish, or otherwise use materials developed under this grant for Federal purposes, and may authorize others to do so.

Trafficking in Persons

Awards issued under this funding opportunity announcement 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. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at http://dhhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html.

Pilot Whistleblower Protection

A standard term and condition of award will be in the final notice of award; all applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award, and requires that grantees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

Same-sex Spouses, Marriages, and Households

A standard term and condition of award will be included in the final Notice of Award (NOA) that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign

country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage."

Programmatic Reporting

Grantees are required to submit semi-annual programmatic reports due 30 days after the end of each 6-months of performance. Progress reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module

A final progress report covering the entire project period is due 90 days after the end of the project period. Final reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

Financial Reporting

Grantees are required to submit quarterly and annual Federal Financial Reports (FFR) (SF-425). Reporting schedules will be issued as a condition of grant award. A final FFR covering the entire project period is due 90 days after the end of the project period. FFRs must be submitted via upload to our grants management system (GrantSolutions.gov), in the FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note these FFR reports are separate submissions via the Division of Payment Services. At this time, data is not transferable between the two systems and you will report twice on certain data elements. Grantees receiving $500,000 or greater of Federal funds must also

undergo an independent audit in accordance with OMB Circular A-133 or regulations and policy effective at the time of the award.

Non-competing Continuation Applications and Awards

Each year of the approved project period, grantees are required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well advance of the application due date.

FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (http://www.FSRS.gov) for all sub-awards and sub-contracts issued for $25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

VII. AGENCY CONTACTS

Administrative and Budgetary Requirements and Program Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH Office of Grants Management grants specialist listed below.

Deborah Hayes

1101 Wootton Parkway, Suite 550

Rockville, MD

Phone: 240-453-8822

Email:Deborah.Hayes@hhs.gov

For information on program requirements, contact the program office

Robert Scholle

1101 Wootton Parkway, Suite 700

Rockville, MD

Phone: 240-453-2848

Email: Robert.Scholle@hhs.gov

VIII. OTHER INFORMATION

Application Elements

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Budget Narrative

Assurances for Non-construction Programs (SF-424B)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative

Appendices

Susan B. Moskosky

Susan B. Moskosky, MS, WHNP-BC
Acting Director
Office of Population Affairs

January 21, 2015