

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Health Resources and Services Administration**

Healthcare Systems Bureau  
Division of Transplantation

***Social and Behavioral Interventions to Increase Solid Organ Donation***

**Announcement Type:** New  
**Announcement Number:** HRSA-13-150

**Catalog of Federal Domestic Assistance (CFDA) No. 93.134**

**FUNDING OPPORTUNITY ANNOUNCEMENT**

Fiscal Year 2013

*Modified on 11/14 to include lobbying certification information in Section IV.2.vii.*

**Application Due Date: November 30, 2012**

*Ensure your Grants.gov registration and passwords are current immediately!  
Deadline extensions are not granted for lack of registration.  
Registration may take up to one month to complete.*

**Release Date: July 9, 2012**

**Issuance Date: July 9, 2012**

Rita Maldonado, MPH  
Project Officer  
Public and Professional Education Branch  
Email: [rmaldonado@hrsa.gov](mailto:rmaldonado@hrsa.gov)  
Telephone: (301) 443-3622  
Fax: (301) 594-6095

Authority: Section 377A(a)-(b) of the Public Health Service (PHS) Act, as amended. (42 U.S.C. 274f-1(a)-(b))

## Table of Contents

<b>I. FUNDING OPPORTUNITY DESCRIPTION .....</b>	<b>1</b>
<b>1. PURPOSE.....</b>	<b>1</b>
<b>2. BACKGROUND .....</b>	<b>3</b>
<b>II. AWARD INFORMATION .....</b>	<b>5</b>
<b>1. TYPE OF AWARD .....</b>	<b>5</b>
<b>2. SUMMARY OF FUNDING .....</b>	<b>5</b>
<b>III. ELIGIBILITY INFORMATION.....</b>	<b>5</b>
<b>1. ELIGIBLE APPLICANTS.....</b>	<b>5</b>
<b>2. COST SHARING/MATCHING .....</b>	<b>6</b>
<b>3. OTHER .....</b>	<b>6</b>
<b>IV. APPLICATION AND SUBMISSION INFORMATION.....</b>	<b>6</b>
<b>1. ADDRESS TO REQUEST APPLICATION PACKAGE.....</b>	<b>6</b>
<b>2. CONTENT AND FORM OF APPLICATION SUBMISSION.....</b>	<b>8</b>
<i>i. Application Face Page .....</i>	<i>13</i>
<i>ii. Table of Contents.....</i>	<i>13</i>
<i>iii. Budget.....</i>	<i>13</i>
<i>iv. Budget Justification.....</i>	<i>14</i>
<i>v. Staffing Plan and Personnel Requirements .....</i>	<i>17</i>
<i>vi. Assurances .....</i>	<i>17</i>
<i>vii. Certifications.....</i>	<i>17</i>
<i>viii. Project Abstract .....</i>	<i>18</i>
<i>ix. Project Narrative .....</i>	<i>19</i>
<i>x. Attachments .....</i>	<i>24</i>
<b>3. SUBMISSION DATES AND TIMES.....</b>	<b>26</b>
<b>4. INTERGOVERNMENTAL REVIEW .....</b>	<b>26</b>
<b>5. FUNDING RESTRICTIONS .....</b>	<b>27</b>
<b>6. OTHER SUBMISSION REQUIREMENTS .....</b>	<b>28</b>
<b>V. APPLICATION REVIEW INFORMATION .....</b>	<b>29</b>
<b>1. REVIEW CRITERIA.....</b>	<b>29</b>
<b>2. REVIEW AND SELECTION PROCESS.....</b>	<b>31</b>
<b>3. ANTICIPATED ANNOUNCEMENT AND AWARD DATES .....</b>	<b>32</b>
<b>VI. AWARD ADMINISTRATION INFORMATION.....</b>	<b>32</b>
<b>1. AWARD NOTICES .....</b>	<b>32</b>
<b>2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS.....</b>	<b>32</b>
<b>3. REPORTING .....</b>	<b>35</b>
<b>VII. AGENCY CONTACTS .....</b>	<b>37</b>
<b>VIII. OTHER INFORMATION.....</b>	<b>38</b>
<b>IX. TIPS FOR WRITING A STRONG APPLICATION.....</b>	<b>40</b>

# I. Funding Opportunity Description

## 1) Purpose

This announcement solicits applications for fiscal year (FY) 2013 extramural grant program, Social and Behavioral Interventions to Increase Solid Organ<sup>1</sup> Donation, a grant program administered by the Division of Transplantation (DoT), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS).

The overall goal of this grant program is to: (1) reduce the gap between the demand for organ transplants and the supply of organs from deceased donors by identifying successful strategies that can serve as model interventions to increase deceased organ donation and, (2) increase the knowledge of options available through living donation among patients who may need transplants and/or individuals considering serving as a living donor. Accordingly, this program will support sound applied research efforts to test the effectiveness of strategies that target any of the three program objectives listed below. The first two objectives pertain to deceased donation; the third relates to living donation.

The specific objectives of this grant program are to increase, and improve understanding of how to increase:

- 1) individual commitment to be a deceased organ donor and documentation of that commitment;
- 2) consent of family (or others authorized to consent) for organ donation for a deceased relative;
- 3) the knowledge of the process, risks, advantages and disadvantages of deceased and living donation among patients who may need an organ and/or individuals considering serving as a living donor.

Applicants must indicate whether they wish to conduct a project focused on deceased donation or a project focused on living donation.

Projects to increase deceased donation may focus on community initiatives to increase the public's commitment to donation and/or hospital-based efforts to increase family consent for donation.

Projects focusing on living donation may test various models to educate individuals who may need transplants and/or individuals considering serving as a living donor of the opportunities to donate specific organs or organ segments while living and the process, risks, advantages and disadvantages of deceased and living donation. However, because of the risks associated with

---

<sup>1</sup> For purposes of this grant program, the term 'organ' is used consistently with the definition provided in the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), 42 CFR 121.2. This regulation currently provides that "Organ means a human kidney, liver, heart, pancreas, or intestine (including the esophagus, stomach, small and/or large intestines, or any portion of the gastrointestinal tract). Blood vessels recovered from an organ donor during the recovery of such organs are considered part of an organ with which they are procured ... if the vessels are intended for use in organ transplantation and labeled 'For use in organ transplantation only.'" Although the focus of this grant program concerns organ donation, a project also may have the effect of increasing the number of tissue and/or eye donors.

any major surgical procedure, this grant program will not support projects that attempt to encourage living donation, increase the number of living donors or increase individuals' readiness/willingness to pursue living donation as reflected in the goals, interventions, outcome measures, and metrics. Some examples of projects to educate about living donation include: interventions to help potential donors, potential recipients, and their families make informed choices; interventions to reduce or eliminate barriers to education about living donation for potential donors or transplant candidates; and interventions designed to improve the education of living donors and those considering living donation in a healthcare or other relevant setting (dialysis centers, transplant programs, nephrologists' offices, community venues, etc).

All projects are encouraged to include an evaluation component, as described below. The program will provide support for the evaluation of, or the implementation and evaluation of, highly promising strategies and approaches that can serve as model interventions for increasing commitment to deceased organ donation or knowledge about living donation as an option for some patients waiting for a transplant. While the program focuses on solid organ donation, it is hoped that successful strategies will have a positive effect on eye and tissue donation as well. For purposes of this program, model interventions are defined as those that are: (1) effective in producing a verifiable and demonstrable impact on any of the three program objectives identified above; (2) replicable; (3) transferable; and (4) feasible in practice. All projects must have rigorous methodology and quantitative evaluation components capable of ascertaining the effectiveness of the intervention(s). While quantitative research would most strongly demonstrate effectiveness, qualitative components may add useful information. **Development of the intervention(s) may be supported by the grant but shall be limited to no more than 20 percent of total direct costs and staff time.**

Applications may focus on pilot projects or replications of interventions already shown to be effective in a pilot study or other previous research. A pilot project tests an intervention that has not before been tested for its utility and effectiveness in the donation field. An extension project builds on results of a pilot project by adjusting or adding some new dimension to the original intervention in attempts to strengthen the intervention. A replication project tests a strategy as it was implemented in a previous project but in a different setting(s) (such as testing in education institutions an intervention that was demonstrated to be effective in faith communities) or a different population(s) (such as a different cultural or age group or area of the country where the population demographics differ substantially from the original study). Applications proposing replications or extensions must provide a strong rationale and justification for the proposed project.

Projects also may test the effectiveness of a purposefully and logically coordinated and synchronized set of multiple strategies for increasing donation in specified populations. Projects that propose the use of multiple strategies are required to measure the independent effects of each strategy as well as the interactive effect of the various strategies.

Applications that propose new ideas and novel approaches to increase organ donation that are cost-effective in achieving DoT program objectives and demonstrate utility for the donation and transplantation community are encouraged. Applicants also are encouraged to consider implementing strategies that have been successful in other public health fields and evaluating their effectiveness for use in the donation field.

Because of the disproportionately high need for kidney transplants in minority populations and the greater likelihood of finding a donor of similar blood type within the same ethnic or racial group, applications focusing on minority populations are encouraged. All replication studies must include at least one site with a large minority population. If the target population of the original study was a minority population, the replication study must include a different minority group for at least one site.

Applicants have considerable flexibility in proposing interventions, including: the focus and nature of the intervention, intervention sites(s), geographic location(s), target group(s), etc. Sound conceptual models of behavioral change must inform the intervention and various components of the methodology.

This grant program is focused solely on interventions to increase organ donation from deceased donors and the identification of successful models for educating about living donation. Funds will not be used for other types of projects. Examples of activities that will not be supported under this program are: efforts to increase living donation; biomedical and clinical research; the development and/or assessment of the efficacy of new or improved methods of donor management, organ recovery, or organ preservation; fundamental research focused on new or improved evaluation tools and methodologies; interventions inconsistent with existing Federal law or statute; and interventions to increase tissue donation alone. Proposals to evaluate clinical outcomes of donation after cardiac death (DCD) organs will not be supported.

### **Collaboration**

This grant program seeks to promote greater collaboration among the transplant community, other organizations with the potential to encourage organ and tissue donation, and organizations with research expertise and experience. Applicants are strongly encouraged, but not required, to prepare the application and, if funded, implement the project as a consortium of organizations relevant to the project goals. Specifically, applicants are encouraged to work with a consortium of project-relevant organizations to ensure the breadth of expertise required for the successful design, implementation, and evaluation of the proposed intervention(s). Specifically, applications are encouraged that will be implemented by a consortium consisting of:

- at least one organization/institution with demonstrated expertise and experience in evaluation design and methods in the behavioral and social sciences; and
- at least one organization/institution with demonstrated expertise and current involvement in community education and outreach strategies to encourage commitment to organ donation.

## **2) Background**

This program is authorized by Section 377A(a)-(b) of the Public Health Service (PHS) Act, (42 U.S.C. 274f-1(a)-(b)), as amended by the Organ Donation and Recovery Improvement Act, P.L. 108-216.

Transplantation is the therapy of choice and often the only choice to treat conditions leading to life-threatening end-stage-organ failure. Over the past two decades, advances in surgical techniques and post-transplant therapies have improved both short- and long-term graft survival. Ongoing and future research will continue to contribute to overcoming some of the remaining

medical and biological obstacles. However, even if these obstacles are overcome, the growing number of individuals needing transplants and the inadequate number of organ donors remain major barriers to providing this lifesaving treatment for all who need it. The critical shortage of donor organs and the disparity between donor potential and actual donation rates have been well documented. The number of patients waiting for transplants as of May 2012 was over 114,000. Approximately 11,000 brain deaths per year could result in organ donation; however, only 8,126 deaths resulted in donation in 2011, a figure far smaller than the need (OPTN, May 9, 2012). Although further study is necessary, the number of potential donors could eventually include out-of-hospital cardiac arrest deaths. An Institute of Medicine Report, *Organ Donation: Opportunities for Action*, cites a conservative estimate of 22,000 per year. The Report was published in 2006 by the National Academies of Science, Washington, DC. Even with a national recovery average of 3.01 organs per deceased donor and with the contributions of 6,019 living donors, only 28,535 patients received transplants in the United States in 2011, while 6,659 individuals died waiting (OPTN, May 9, 2012).

The aging of the baby boom generation and increasing life expectancy are magnifying the discrepancy between the need for transplantation and the supply of organs. Faced with the current critical shortage and the likelihood of even more pronounced supply-demand disparities, organ donation is becoming an increasingly significant public health issue. The dire shortage of organs for transplantation has been the impetus for development of protocols intended to expand the donor pool, including the use of organs from living donors and donation after cardiac death.

*Social and Behavioral Interventions and Innovations:* A broad spectrum of interventions to increase donation has been implemented at the national, State, and local levels by a variety of public and private organizations, ranging from large-scale national media and public education programs and statewide donor registries to community-based activities to raise awareness among various population groups. Some projects incorporating evaluation components have contributed to the knowledge base about important factors associated with the donation decision-making process. A great deal of information about well-validated theories and models of health behavior is found in the public health and health education literature but is only recently being applied and integrated into the design and evaluation of strategies for increasing donation.

This grant program, Social and Behavioral Interventions to Increase Solid Organ Donation, was launched in FY 1999 and is a component of HRSA's efforts to increase organ and tissue donation. From FY 1999-2012, HRSA/DoT has supported 96 research projects totaling \$77 million to test strategies for increasing organ and tissue donation or to replicate successful donation interventions. It is anticipated that the FY 2013 Social and Behavioral Grant Program will expand the number of studies using scientifically rigorous methods to identify, verify, and replicate successful interventions for increasing deceased donation and for education about living donation.

*Resources:* Several resources of potential interest to applicants are noted below.

- Brief descriptions of projects funded through this grant program can be obtained electronically at <http://www.organdonor.gov/grantProgramBehavioral.asp>.
- A list of publications by current and previously funded DoT grantees can be obtained at <http://www.organdonor.gov/grantPublications.asp>.

- A Report on Social and Behavioral Interventions to Increase Organ Donation Grant Program 1999-2004 is available at <http://www.organdonor.gov/grantsInterventionReports.asp>.
- The Final Report of an April 1998 conference, “Increasing Donation and Transplantation: The Challenge of Evaluation” is available at <http://www.aspe.hhs.gov/health/orgdonor/98conf/confrpt.html>.
- IOM report, “Organ Donation: Opportunities for Action,” available from <http://www.iom.edu/CMS/3740/24738/34249.aspx>, examines a range of proposals for increasing rates of organ donation.
- U.S. Organ Donation Breakthrough Collaborative Increases Organ Donation. Shafer TJ, Wagner D, Chessare J, Schall MW, McBride V, Zampiello FA, Perdue J, O’Connor K, Lin MJ, Burdick J. Critical Care Nursing Quarterly, 2008, Jul-Sep:31(3):190-210.
- Critical Care Nurse, 2006 April 26(2), organ donation dedicated issue.
- Siegel JT, Alvaro EM, eds. 2010. Understanding Organ Donation: Applied Behavioral Science Perspectives (Blackwell/Claremont Applied Social Psychology Series). Hoboken, NJ: Wiley-Blackwell.

## **II. Award Information**

### **1. Type of Award**

Funding will be provided in the form of a grant.

### **2. Summary of Funding**

This program will provide funding during Federal fiscal years 2013 - 2015. Approximately \$1,250,000 is expected to be available annually to fund four to five (4-5) grantees. It is anticipated that the average award for each project year will be \$250,000 - \$350,000. It is recognized, however, that budgets may vary with project reach and complexity. The project period is up to three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for the “Social and Behavioral Interventions to Increase Solid Organ Donation Program” in subsequent fiscal years, grantee satisfactory performance, and a decision that continued funding is in the best interest of the Federal Government.

## **III. Eligibility Information**

### **1. Eligible Applicants**

Eligible applicants include Federally-designated organ procurement organizations (OPO) and other public or nonprofit private entities eligible for funds under section 377A(a)-(b) of the PHS Act, (42 U.S.C. 274f-1(a)-(b)). Eligible applicants that are public or nonprofit private entities may include state and local governments, Indian Tribal Governments, institutions of higher education, other nonprofit organizations such as faith-based and community-based organizations

and Tribal organizations. For-profit organizations may participate in a grant project but are not eligible to apply as the applicant institution.

If the applicant is an Organ Procurement and Transplant Network (OPTN) member, and/or if the applicant is working with a consortium that includes OPTN members, the applicant and all other OPTN members involved in the project are expected to be in compliance with the final rule governing the operation of the OPTN (42 CFR Part 121 or visit <http://optn.transplant.hrsa.gov>).

## 2. Cost Sharing/Matching

Cost Sharing/Matching is not required for this program.

## 3. Other

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization are allowable.

# IV. Application and Submission Information

## 1. Address to Request Application Package

### Application Materials and Required Electronic Submission Information

HRSA *requires* applicants for this funding opportunity announcement to apply electronically through Grants.gov. The registration and application process protects applicants against fraud and ensures that only authorized representatives from an organization can submit an application. Applicants are responsible for maintaining these registrations, which should be completed well in advance of submitting an application. All applicants *must* submit in this manner unless they obtain a written exemption from this requirement in advance by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from [DGPWaivers@hrsa.gov](mailto:DGPWaivers@hrsa.gov), and provide details as to why they are technologically unable to submit electronically through the Grants.gov portal. If requesting a waiver, include the following in the e-mail request: the HRSA announcement number for which the organization is seeking relief, the organization's DUNS number, the name, address, and telephone number of the organization and the name and telephone number of the Project Director as well as the Grants.gov Tracking Number (GRANTXXXX) assigned to the submission along with a copy of the "Rejected with Errors" notification as received from Grants.gov. **HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received prior written approval.** However, the application must still be submitted by the deadline. Suggestion: submit application to Grants.gov at least two days before the deadline to allow for any unforeseen circumstances.

### **IMPORTANT NOTICE: CCR to be moved to SAM at the end of July 2012**

The General Services Administration (GSA) is moving the implementation date of the System for Award Management (SAM) from May 29, 2012 to the end of July 2012. The

additional sixty days will allow Federal agencies to continue preparing their staff, give agencies and commercial system providers even more time to test their data transfer connections, and will ensure SAM contains the critical, documented capabilities users need from the system.

This first phase of SAM will include the capabilities of Central Contractor Registration (CCR)/Federal Agency Registration (FedReg), Online Representations and Certifications Application (ORCA), and the Excluded Parties List System (EPLS). In preparation for the launch, GSA conducted extensive testing internally and in coordination with Federal agencies using the data from these systems in their own contracting, grants, finance, and other departments. The testing was very valuable and will focus the efforts of the next sixty days.

SAM will reduce the burden on those seeking to do business with the government. Vendors will be able to log into one system to manage their entity information in one record, with one expiration date, through one streamlined business process. Federal agencies will be able to look in one place for entity pre-award information. Everyone will have fewer passwords to remember and see the benefits of data reuse as information is entered into SAM once and reused throughout the system.

**Active CCR registration is a pre-requisite to the successful submission of grant applications!**

Grants.gov strongly suggests visiting CCR prior to this change and checking the account status. Some things to consider are:

- When does the account expire?
- Does the organization need to complete the annual renewal of registration?
- Who is the eBiz POC? Is this person still with the organization?
- Does anything need to be updated?

To learn more about the switch from CCR to SAM, more information is available at <https://www.bpn.gov/ccr/NewsDetail.aspx?id=2012&type=N>. To learn more about SAM, please visit <https://www.sam.gov>.

Note: CCR or SAM information must be updated at least every 12 months to remain active (for both grantees and sub-recipients). As of August 9, 2011, Grants.gov began rejecting submissions from applicants with expired CCR registrations. This systematic enforcement will likely catch some applicants off guard. According to the CCR Website it can take 24 hours or more for updates to take effect, or SAM Quick Guide for Grantees ([https://www.sam.gov/sam/transcript/SAM\\_Quick\\_Guide\\_Grants\\_Registrations-v1.6.pdf](https://www.sam.gov/sam/transcript/SAM_Quick_Guide_Grants_Registrations-v1.6.pdf)), an entity's registration will become active after 3-5 days. Therefore, ***check for active registration well before the grant deadline.***

An applicant can view their CCR Registration Status by visiting <http://www.bpn.gov/CCRSearch/Search.aspx> and searching by their organization's DUNS number. The [CCR Website](#) provides user guides, renewal screen shots, FAQs and other resources.

Applicants that fail to allow ample time to complete registration with CCR (prior to late July 2012) / SAM (starting late July 2012) and/or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

All applicants are responsible for reading the instructions included in HRSA's *Electronic Submission User Guide*, available online at <http://www.hrsa.gov/grants/apply/userguide.pdf>. This Guide includes detailed application and submission instructions for both Grants.gov and HRSA's Electronic Handbooks. Pay particular attention to Sections 2 and 5 that provide detailed information on the competitive application and submission process.

Applicants are also responsible for reading the Grants.gov Applicant User Guide, available online at <http://www.grants.gov/assets/ApplicantUserGuide.pdf>. This Guide includes detailed information about using the Grants.gov system and contains helpful hints for successful submission.

Applicants must submit proposals according to the instructions in the Guide and in this funding opportunity announcement in conjunction with Application Form SF-424 Research and Related (SF-424 R&R). The forms contain additional general information and instructions for applications, proposal narratives, and budgets. The forms and instructions may be obtained by:

- 1) Downloading from <http://www.grants.gov>, or
- 2) Contacting the HRSA Digital Services Operation (DSO) at: [HRSADSO@hrsa.gov](mailto:HRSADSO@hrsa.gov)

Each funding opportunity contains a unique set of forms and only the specific forms package posted with an opportunity will be accepted. Specific instructions for preparing portions of the application that must accompany the SF-424 R&R appear in the "Application Format Requirements" section below.

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

### **Application Format Requirements**

The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA. The total file size may not exceed 10 MB. The 80-page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support. Standard forms are NOT included in the page limit. **HRSA strongly urges applicants to print their application to ensure it does not exceed the 80-page limit. Do not reduce the size of the fonts or margins to save space. See the formatting instructions in Section 5 of the *Electronic Submission User Guide* referenced above.**

**Applications must be complete, within the 80-page limit, within the 10 MB limit, and submitted prior to the deadline to be considered under this announcement.**

### **Application Format**

Applications for funding must consist of the following documents in the following order:

## SF-424 R&R – Table of Contents

 **It is mandatory to follow the instructions provided in this section to ensure that the application can be printed efficiently and consistently for review.**

 **Failure to follow the instructions may make the application non-responsive. Non-responsive applications will not be considered under this funding opportunity announcement.**

 For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.

 For electronic submissions, no Table of Contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF-424 R&R Cover Page	Form	Pages 1 & 2.	Not counted in the page limit.
Pre-application	Attachment	Can be uploaded on page 2 of SF-424 R&R - Box 20.	Not Applicable to HRSA; Do not use.
SF-424 R&R Senior/Key Person Profile	Form	Supports 8 structured profiles (PD + 7 additional)	Not counted in the page limit.
Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form. One per each senior/key person. The PD/PI biographical sketch should be the first biographical sketch. Up to 8 allowed.	Counted in the page limit.
Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form.	Not Applicable to HRSA; Do not use.
Additional Senior/Key Person Profiles	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form. Single document with all additional profiles.	Counted in the page limit.
Additional Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in the Senior/Key Person Profile form. Single document with all additional sketches.	Counted in the page limit.
Additional Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in the Senior/Key Person Profile form.	Not Applicable to HRSA; Do not use.
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in SF-424 R&R Performance Site Location(s) form. Single document with all additional site location(s).	Counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Other Project Information	Form	Allows additional information and attachments.	Not counted in the page limit.
Project Summary/Abstract	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 6.	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions.
Project Narrative	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 7.	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions. If necessary provide table of contents specific to this document only as the first page. Table of contents is not counted in the page limit.
Bibliography & References	Attachment	Can be uploaded in Other Project Information form, Box 9.	Required. Counted in the page limit.
Facilities & Other Resources	Attachment	Can be uploaded in Other Project Information form, Box 10.	Required. Counted in the page limit.
Equipment	Attachment	Can be uploaded in Other Project Information form, Box 11.	Optional. Counted in the page limit.
Other Attachments	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 12. Supports multiple.	Not Applicable to HRSA; Do not use.
SF-424 R&R Budget Period (1-5) - Section A – B	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Additional Senior Key Persons	Attachment	SF-424 R&R Budget Period (1-5) - Section A - B, End of Section A. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section C – E	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Additional Equipment	Attachment	SF-424 R&R Budget Period (1-5) - Section C – E, End of Section C. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section F – K	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
SF-424 R&R Cumulative Budget	Form	Total cumulative budget.	Not counted in the page limit.
Budget Justification	Attachment	Can be uploaded in SF-424 R&R Budget Period (1-5) - Section F - K form, Box K. Only one consolidated budget justification for the project period.	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions. Provide table of contents specific to this

Application Section	Form Type	Instruction	HRSA/Program Guidelines
			document only as the first page.
SF-424 R&R Subaward Budget	Form	Supports up to 10 budget attachments. This form only contains the attachment list.	Not counted in the page limit.
Subaward Budget Attachment 1-10	Extracted Form to be attached	Can be uploaded in SF-424 R&R Subaward Budget form, Box 1 through 10. Extracted form to be attached from the SF-424 R&R Subaward Budget form and use it for each consortium/ contractual/subaward budget as required by the program funding opportunity announcement. Supports up to 10.	Filename should be the name of the organization and unique. Not counted in the page limit.
SF-424B Assurances for Non-Construction Programs	Form	Assurances for the SF-424 R&R package.	Not counted in the page limit.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for <b>specific</b> sequence. Counted in the page limit.

-  **To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.**
-  Evidence of Non-Profit status and invention related documents, if applicable, must be provided in the other attachment form.
-  Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program funding opportunity announcement.
-  Merge similar documents into a single document. Where several documents are expected in one attachment, ensure that a table of contents cover page is included specific to the attachment. Table of Contents page will not be counted in the page limit.
-  Limit the file attachment name to under 50 characters. Do not use any special characters (e.g., %, /, #) or spacing in the file name or word separation. (The exception is the underscore ( \_ ) character.) Attachments will be rejected by Grants.gov if they include special characters or attachment names greater than 50 characters.

<b>Attachment Number</b>	<b>Attachment Description (Program Guidelines)</b>
Attachment 1	Staffing plan, including personnel requirements and position descriptions (Required, counted in the page limit.)
Attachment 2	Proof of nonprofit status for applicant organization (Required, not counted in the page limit.)
Attachment 3	Indirect cost rate agreement, if applicable (Required, as applicable, not counted in the page limit.)
Attachment 4	Letters of support (Required, counted in the page limit.)
Attachment 5	Project organizational chart (Not required, counted in the page limit.)
Attachment 6	Tables, charts and other graphics, e.g. Gantt or PERT chart (Not required, counted in the page limit.)
Attachments 7-15	Other relevant documents not included elsewhere in this Table of Contents (e.g. Federal debt document, counted in the page limit.)

## **Application Format**

### **i. Application Face Page**

Complete Standard Form 424 Research and Related (SF-424 R&R) provided with the application package. Prepare according to instructions provided in the form itself. For information pertaining to the Catalog of Federal Domestic Assistance, the CFDA Number is 93.134.

### **DUNS Number**

All applicant organizations (and subrecipients of HRSA award funds) are required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at <http://fedgov.dnb.com/webform> or call 1-866-705-5711. Please include the DUNS number in item 5 on the application face page. Applications **will not** be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being “Rejected for Errors” by Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect DUNS number. Applicants should take care in entering the DUNS number in the application.

Additionally, the applicant organization (and any subrecipient of HRSA award funds) is required to register annually with the Central Contractor Registration (CCR) (soon to be SAM) in order to conduct electronic business with the Federal Government. CCR (or SAM) registration must be maintained with current, accurate information at all times during which an entity has an active award or an application or plan under consideration by HRSA. It is extremely important to verify that the applicant organization CCR registration is active and the Marketing Partner ID Number (MPIN) is current. Information about registering with the CCR can be found at <http://www.ccr.gov>. Please see Section IV of this funding opportunity announcement for IMPORTANT NOTICE: CCR to be moved to SAM at the end of July 2012.

### **ii. Table of Contents**

The application should be presented in the order of the Table of Contents provided earlier. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

### **iii. Budget**

Please complete the Research & Related Budget form included with the application kit (Sections A – J and the Cumulative Budget) for each budget period. Upload the Budget Justification Narrative for the entire project period (all budget periods) in Section K of the Research & Related Budget Form. Following completion of Budget Period 1, click on the “NEXT PERIOD” button on the final page to allow for completion of Budget Period 2. You will repeat this instruction to complete Budget Period 3.

The Cumulative Budget is automatically generated and provides the total budget information for the three-year grant request. Errors found in the Cumulative Budget must be corrected within the incorrect field(s) in Budget Period 1, 2, or 3; corrections cannot be made to the Cumulative Budget itself.

Budgets also must include travel costs for two project staff, the primary donation related expert and the evaluation researcher, for two 2-day meetings in year one and one 2-day meeting in years two and three. See also *Section VIII 2 and 3, Technical Assistance Workshop* for additional information about these meetings.

If a consortium of organizations is conducting the project, applicants should include as attachments itemized budgets for each year of grant support for each organization in the consortium. These attachments are submitted via the *SF-424 R&R Sub-award Budget Attachment(s) Form*. It is not necessary to submit cumulative budgets for the separate organizations. It is important to clearly indicate on each budget page which organization it represents. These forms will represent the full project period of Federal assistance requested. All budgets must be well justified, with explanations of each line item in the narrative of the associated budget justification.

**Salary Limitation:**

The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. 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 a HRSA 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 \$179,700 plus fringe of 25% (\$44,925) and a total of \$112,312.50 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 <i>actual</i> 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
<b>Amount that may be claimed on the application budget due to the legislative salary limitation:</b> Individual’s base full time salary <i>adjusted</i> to Executive Level II: \$179,700 50% of time will be devoted to the project	
Direct salary	<b>\$89,850</b>
Fringe (25% of salary)	<b>\$22,462.50</b>
Total amount	<b>\$112,312.50</b>

**iv. Budget Justification**

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The budget period is for ONE year. However, the applicant **must**

submit one-year budgets for each of the subsequent budget periods within the requested project period at the time of application. Line item information must be provided to explain the costs entered in the Research and Related budget form. Be very careful about showing how each item in the “other” category is justified. For subsequent budget years, the justification narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. The budget justification **MUST** be concise. Do **NOT** use the justification to expand the project narrative.

If funds are being used for intervention development, the budget section must present a separate chart itemizing the individual costs for all intervention development-related activities, including staff time, and provide a total for intervention development costs and its percentage of total direct costs. Intervention development costs, including staff time, may not exceed 20 percent of total direct costs and staff time

**Budget for Multi-Year Award**

This announcement is inviting applications for project periods up to three (3) years. Awards, on a competitive basis, will be for a one-year budget period; although the project period may be up to three (3) years. Submission and HRSA approval of the Progress Report(s) and any other required submission or reports is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the three-year project period is subject to availability of funds, satisfactory progress of the awardee, and a determination that continued funding would be in the best interest of the Federal Government.

Include the following in the Budget Justification narrative:

*Personnel Costs:* Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or \$179,700. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual’s actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of FTE	Annual Salary	Amount Requested
J. Smith	Chief Executive Officer	50	\$179,700*	\$89,850
R. Doe	Nurse Practitioner	100	\$75,950	\$75,950
D. Jones	Data/AP Specialist	25	\$33,000	\$8,250

\*Actual annual salary = \$350,000

*Fringe Benefits:* List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. (If an individual’s base salary exceeds the legislative salary cap, please adjust fringe accordingly.)

*Travel:* List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. For long distance travel, the transportation, lodging, per diem, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops. These costs should include travel for two participants to attend two technical assistance (TA) workshops in the first year of the grant and one each year thereafter as explained in *Section VIII 2-3, Technical Assistance Workshops*. Costs are for lodging, transportation, and per diem only and are based on travel costs to Washington, DC. All travel must be well justified and related to activities listed in the Work Plan.

*Equipment:* List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of computers and furniture items that meet the definition of equipment (a unit cost of \$5,000 or more and a useful life of one or more years).

*Supplies:* List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include paper, pencils, and the like; medical supplies are syringes, blood tubes, plastic gloves, etc., and educational supplies may be pamphlets and educational videotapes. Educational supplies must be justified as a reasonable, necessary, and integral part of a grant project. Also, an explanation of how the total numbers and costs of educational supplies were derived must be included. Remember, they must be listed separately.

*Contractual:* Applicants are responsible for ensuring that their organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in CCR (or SAM starting in late July 2012. See Section IV of this document for more SAM details.) and provide the recipient with their DUNS number.

*Other:* Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

Applicants may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

*Indirect Costs:* Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and

administration” is used to denote indirect costs. If an organization applying for an assistance award does not have an indirect cost rate, the applicant may wish to obtain one through HHS’s Division of Cost Allocation (DCA). Visit DCA’s website at: <http://rates.psc.gov/> to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. The indirect cost rate agreement will not count toward the page limit.

**v. *Staffing Plan and Personnel Requirements***

Applicants must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in **Attachment 1**. When applicable, biographical sketches should include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by their programs.

Biographical sketches must be submitted for key personnel using *SF-424 R&R Senior/Key Personnel Profile Form*. Include the following: A. positions and honors; B. selected peer-reviewed publications (in chronological order), and C. research support. When applicable, biographical sketches should include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by their programs. The biographical sketches count toward the allowable 80 pages.

When crafting the staffing plan please note the requirements for the Principal Investigator and Principal Researcher listed below under Project Narrative, Evaluation and Technical Support Capacity.

**vi. *Assurances***

Complete Application Form SF-424B Assurances – Non-Construction Programs provided with the application package.

If research involving human subjects is anticipated, applicants must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

**vii. *Certifications***

Use the Certifications and Disclosure of Lobbying Activities Application Form provided with the application package.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization for the following:

**Lobbying**

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the applicant, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any

cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the applicant must complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

Recipients of HRSA awards shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Any organization or individual that is indebted to the United States, and has a judgment lien filed against it for a debt to the United States, is ineligible to receive a Federal grant. By signing the SF-424 R&R, the applicant is certifying that they are not delinquent on Federal debt in accordance with OMB Circular A-129. (Examples of relevant debt include delinquent payroll or other taxes, audit disallowances, guaranteed and direct student loans, benefits that were overpaid, etc.). If an applicant is delinquent on Federal debt, they should attach an explanation that includes proof that satisfactory arrangements have been made with the Agency to which the debt is owed. This explanation should be uploaded as **Attachment 8**.

#### **viii. *Project Abstract***

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served.

In describing the research design and methods within the abstract, the proposed data collection methods must be included. The abstract will also be used in the review process. It is essential, therefore, that the abstract reflect the most critical points of the application. The abstract must identify whether the project is a pilot, extension or replication study.

Please place the following at the top of the abstract:

- Project Title
- Applicant Organization Name
- Principle Investigator Name
- Address
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address

- Web Site Address, if applicable

The project abstract must be single-spaced and limited to one page in length.

#### **ix. *Project Narrative***

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

The narrative should include sufficient information to enable the evaluation of the project. Be specific and informative and avoid redundancies. Applicants submitting revisions of proposals that were previously not funded are encouraged to include point-by-point discussion of how weaknesses identified in the summary statement have been addressed.

#### **Performance Measures**

Deceased donation projects must address one of the following two performance measures:

- increases in the number or rate of individuals who designate their consent to become donors in their state registry, either through the motor vehicles office, online, or other verifiable method, or
- increases in rates of family consent for a deceased relative.

Projects that focus on living donation must address the following performance measure:

- increases in knowledge of opportunities for and the process, risks, disadvantages and advantages of deceased and living donation.

No extra consideration is given to projects that address more than one performance measure. Applications must provide discussion and justification supporting the performance measure selected. Applications that address more than one performance measure should clearly differentiate project components, effects, and outcomes relevant to specific performance measures. Applicants are encouraged to consider the use of administrative data from state donor registries and institutional data collected by OPOs, hospitals, dialysis centers, and transplant centers as applicable to support these measures.

Use the following section headers for the Narrative:

- ***INTRODUCTION***  
Briefly describe the purpose of the proposed project and the anticipated accomplishments (goals), including knowledge gained, and describe the measurable steps (objectives) to achieve the accomplishments. Discuss why the specific interventions proposed are expected to have a substantial positive impact on the appropriate performance measure(s). Identify in the Introduction and Purpose whether the project is a pilot, extension or replication study.
- ***NEEDS ASSESSMENT***  
This section outlines the needs of your community and/or organization. The target population and its unmet health needs must be described and documented in this section. Include socio-cultural determinants of health and health disparities impacting the population or communities served and unmet. Relevant published and unpublished data and observational information with appropriate citations to support the need for and

significance of the project should be included. While data to briefly illustrate national need may provide context, discussion of local need or assessment of need specific to the target population also must be included. The purpose and usefulness of demographic data and relevant barriers that the project aims to overcome should be discussed. This section is intended to help reviewers understand the need for the specific proposed strategies within the context of the community in which the strategies will be implemented and within the broader donation field.

▪ ***METHODOLOGY***

Describe the strategies and methods to be used and their appropriateness for accomplishing the specific goals of the proposed project and each of the previously-described program requirements and expectations in this funding opportunity announcement. Discuss the utility of proposed research approaches, paying particular attention to new approaches, if employed. Document whether the proposed methodology has been successfully used in donation or other health-related research. If it is a new approach, describe its appropriateness for the proposed project. If this is a replication or an extension of a previous project, discuss the original study, including its purpose, funding source, research methods, findings, and the rationale for replication or extension. All replication studies must include at least one site with a large minority population. If proposing an extension, describe the extension and justify its inclusion by clearly detailing and justifying the proposed changes to the intervention and replication projects including justification of the new location, setting or population for the study. A description of the original intervention and findings related to its effectiveness must be provided for extension and replication projects.

Provide a comprehensive review of studies, knowledge, and/or practices relevant to the proposed topic, referencing donation research and/or relevant studies from the broader health education and public health literature. Since 2003, the Donation and Transplantation Community of Practice (DTCP) (previously known as Breakthrough Collaboratives) have been implemented by HRSA and by Donate Life America. Applicants must demonstrate awareness of these initiatives as relevant to their project and propose and justify methods to distinguish the impact of the proposed project from the impact of these or other on-going efforts to increase donation, random news events or television programming. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities of culturally, linguistically, socio-economically and geographically diverse backgrounds if applicable. Describe how this project addresses the goals of Healthy People 2020.

The methodology section also must provide a complete description of the following elements:

**Theoretical Foundation** – a description of the conceptual model of behavior change, upon which the intervention is based, including:

- a) main concepts
- b) key theorists

- c) comparison, based on a critical review of the literature, of existing models of behavior change and the rationale for selecting the particular conceptual model applied
- d) description of how these models inform the intervention and other components of the methodology (measurement instruments, print and electronic materials, messages, etc.) must be described in the application
- e) clarification of adaptations to the theory, if any, for the proposed project and discussion of the planned methods to reduce threats to validity resulting from the adaptation

**Target Population** –

- a) justification for the target population; description of the size and characteristics of the target population and its donation practices and attitudes
- b) rationale for selecting the specific geographic area(s) for project implementation and its appropriateness for reaching the identified target population
- c) indication that the project team has the experience and expertise necessary to understand, reach, and influence the target population
- d) plans for recruitment and retention of the target group
- e) all replication studies must include at least one site with a large minority population

**Settings** – description of and rationale for the specific setting(s) in which the intervention will be implemented.

**Intervention** –

- a) detailed description of the intervention including a thorough description of all components of any multifaceted interventions being used; for extension and replication projects a detailed description of the original project, and for extensions, a description of the similarities and differences between the original work and the proposed extension intervention
- b) discussion of the intervention’s potential effectiveness for accomplishing the specific objectives and performance measure(s) addressed in the project
- c) review of relevant descriptive information and data relating to the feasibility and effectiveness of the same or similar interventions (including recommended refinements/modifications)
- d) potential of the intervention to be effectively replicated, transferred, and applied:
  - 1) by institutions/organizations with similar competencies
  - 2) to target populations with similar socio-demographic profiles

Even if funding is requested only for evaluation and not for intervention implementation activities, the application must include a description of the intervention and an indication that funding is not requested.

**Variables** – specification of the variables, including delineation between independent and dependent variables.

**Outcome Measures and Evaluation Plan** – all projects are encouraged to include an evaluation plan

- a) description of and justification for specific outcomes that will be used to determine effectiveness of the intervention
- b) thorough description of, and rationale for, the proposed evaluation plan
- c) discussion of how the proposed evaluation plan can be expected to reliably measure project impact
- d) explanation of how the proposed evaluation plan will determine and account for baseline for measurement, e.g., how the analysis will control for individuals who already have declared consent
- e) description of the methods to control for the independent effects of the proposed intervention and such external influences as ongoing donation outreach activities, news and media events, etc.
- f) data collection and analysis plans; as appropriate, describe the strategy to collect, analyze and track data to measure process and impact/outcomes, with different cultural groups (e.g. race, ethnicity, language) and explain how the data will be used to inform program development and service delivery. (If the data must be obtained from an organization that is not the applicant organization (such as registry data from the department of motor vehicles) include a letter of support from that organization confirming the applicant's access to the data.)
- g) descriptions of qualitative approaches to be used, if any, and process evaluation, if proposed

**Instruments** – descriptions of instruments to be used including psychometric properties, and if possible, copies or drafts of data collection instruments, e.g., surveys, telephone protocols, interview formats.

▪ ***WORK PLAN***

Describe the activities or steps that will be used to achieve each of the activities proposed during the entire project period in the Methodology section. If the project includes development of any part of the intervention, this must also be represented in the Work Plan. (Note: development costs, including staff time, may not exceed 20 percent of total direct costs or staff time.) Use a timeline that includes each activity and identifies responsible staff for all phases and years of the proposed project, including a proposal for dissemination of project outcomes. This timeline will contribute to the assessment of each year's progress. A graphic representation (e.g., Gantt or PERT chart) as an attachment is helpful in the review process. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application and, further, the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the populations and communities served.

▪ ***RESOLUTION OF CHALLENGES***

Discuss challenges that are likely to be encountered in designing and implementing the activities described in the Work Plan, and approaches that will be used to resolve such challenges.

▪ ***EVALUATION AND TECHNICAL SUPPORT CAPACITY***

Discuss relevant experience, skills, and knowledge of key project staff to conduct this project, including materials published and previous work of a similar nature. It is not

necessary to repeat all information included in biographical sketches, but rather to justify qualifications and appropriateness for the project role.

When crafting the staffing plan, please note the following:

### **Principal Investigator**

The project shall be headed by a single Principal Investigator (PI) designated by the applicant institution who will be responsible for the technical, programmatic, and administrative aspects of the grant and for the day-to-day management of the project, including oversight of all consortium-related activities. The PI must have experience and expertise relevant to the objectives of this grant program in one or both of the following areas:

- design and implementation of interventions to increase deceased donation or to educate about living donation, and/or
- design and conduct of evaluation studies to assess the effectiveness of social-behavioral interventions.

The PI must have a substantive and substantial role in the project. Women, minorities, and persons with disabilities are encouraged to apply as principal investigators. A PI who is not employed by the applicant institution must be employed by a public or nonprofit institution and must have a position of influence in (e.g., officer or board member) and a formal written agreement with the applicant institution that specifies the official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PI is not an employee of the applicant institution, HRSA will assess whether the arrangement will result in the organization being able to fulfill its grant-related responsibilities, if awarded.

### **Principal Researcher/Evaluator**

The principal researcher/evaluator (PR) shall have primary responsibility for design and conduct of the project methodology component. This professional must have expertise in social and behavioral research/evaluation as demonstrated by professional experience, education, and relevant publications. The principal researcher or another member of the research team must demonstrate education and expertise sufficient to conduct social science statistical analysis consistent with the proposed intervention and evaluation.

#### ▪ ***ORGANIZATIONAL INFORMATION***

The applicant institution shall be legally and financially responsible and accountable to HRSA for the use and disposition of funds awarded, including funds utilized by subcontractors and consortium members, if any. The applicant must demonstrate the availability of personnel and facilities capable of performing and supporting the necessary administrative functions for carrying out the role of the applicant institution. This institution shall be responsible for maintaining functions, e.g., dissemination of information among project staff members and organizations, sharing in decision making, and participating in the preparation of reports.

Demonstrate expertise and experience relevant to the focus of the proposed project, including organizational expertise and current involvement in donation or transplantation outreach as well as demonstrated expertise and experience in research and evaluation

design and methods in behavioral and social sciences. A consortium of organizations may be necessary to ensure adequate expertise and resources are available to carry out the project. Discuss adequacy of the collective resources (the applicant agency, consortium member organizations, and key staff) for conducting the proposed project. Indicate if the project is to be implemented by a consortium, and identify the organizations and their roles and responsibilities. For all key organizations, including any potential faith based and community organizations, briefly describe their current mission and structure, scope of current activities, and how these contribute to the ability of the project team to conduct the project and meet program requirements and expectations. Provide information on the program's resources and capabilities to support provision of culturally and linguistically competent and health literate services. Describe how the unique needs of target populations of the communities served are routinely assessed and improved. In order to conserve space, it is recommended that applicants provide this information in the project narrative in approximately one paragraph per consortium member.

**x. Attachments**

Please provide the following items to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Unless otherwise noted, attachments count toward the application page limit. **Each attachment must be clearly labeled.**

*Attachment 1: Staffing Plan, Personnel Requirements, and Position Descriptions (Required, counted in the page limit.)*

Applicants must present a staffing plan and justification for the plan that includes rationale for the amount of time being requested for each project component. Position descriptions that include the roles, responsibilities, and qualifications for proposed project positions must be included.

*Attachment 2: Proof of nonprofit status for applicant organization (Required, **not** counted in the page limit)*

**Documentation of non-profit status.**

Documentation of nonprofit status of the applicant institution must be included in the application. Applications that fail to provide documentation to meet the eligibility criteria will not be considered for review.

Any of the following constitutes acceptable proof of nonprofit status:

- a. A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code.
- b. A copy of a currently valid IRS tax exemption certificate.
- c. A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals.
- d. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.
- e. Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

*Attachment 3: Indirect Cost Rate Agreement (Required, as applicable, **not** counted in the page limit)*

Required for organizations that have Federally approved Indirect Cost Rate Agreement.

*Attachment 4: Letters of support (Required, counted in the page limit.)*

Documentation from organizations and individuals who are not consortium members but have important roles in the project, e.g., implementation or control sites, associated community organizations. Form letters or letters indicating only vague support generally are not useful. **Include only letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of support must be dated. List all other support letters on one page.** Letters that are not submitted as part of the application package will not be considered in the review.

*Attachment 5: Project Organizational Chart (Not required, counted in the page limit)*

Graphic/logic model illustrating proposed project and project organizational chart; include subcontractors and other significant collaborators.

*Attachment 6: Tables, Charts, and Other Graphics (Not required, counted in the page limit)*

Include graphics that provide further detail about the proposal, e.g., Gantt- or PERT-type chart outlining work plan.

*Attachments 7 – 15: Other Relevant Documents (e.g. Federal documentation, counted in the page limit.)*

Include here any other documents that are relevant to the application.

### 3. Submission Dates and Times

#### Application Due Date

The due date for applications under this funding opportunity announcement is *November 30, 2012 at 8:00 P.M. ET*. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by the organization's Authorized Organization Representative (AOR) through Grants.gov and validated by Grants.gov on or before the deadline date and time.

**Receipt acknowledgement:** Upon receipt of an application, Grants.gov will send a series of email messages to document the progress of an application through the system.

- 1) The first will confirm receipt in the system;
- 2) The second will indicate whether the application has been successfully validated or has been rejected due to errors;
- 3) The third will be sent when the application has been successfully downloaded at HRSA; and
- 4) The fourth will notify the applicant of the Agency Tracking Number assigned to the application.

The Chief Grants Management Officer (CGMO) or designee may authorize an extension of published deadlines when justified by circumstances such as natural disasters (e.g., floods or hurricanes) or other disruptions of services, such as a prolonged blackout. The CGMO or designee will determine the affected geographical area(s).

#### Late applications:

Applications which do not meet the criteria above are considered late applications and will not be considered in the current competition.

### 4. Intergovernmental Review

The Social and Behavioral Interventions to Increase Solid Organ Donation is a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application packages made available under this funding opportunity will contain a listing of States which have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on States affected by this program and State Points of Contact may also be obtained from the Grants Management Specialist listed in the Agency Contact(s) section, as well as from the following Web site: [http://www.whitehouse.gov/omb/grants\\_spoc](http://www.whitehouse.gov/omb/grants_spoc).

All applicants other than federally recognized Native American Tribal Groups should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State's process used under this Executive Order.

Letters from the SPOC in response to Executive Order 12372 are due sixty days after the application due date.

## 5. Funding Restrictions

Applicants responding to this announcement may request funding for a project period of up to three (3) years. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for the following purposes:

- to purchase or improve land, or to purchase, construct, or make permanent improvements to any building except for minor remodeling.
- to make payments to recipients of services, except for reimbursement of reasonable and allowable out-of-pocket expenses associated with participation in project activities, for more information on cost principles please see page II-25 of the HHS Grants Policy Statement available online at <ftp://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf>.
- to support: (a) projects that promote living donation; (b) projects that propose outcome measures such as pursuit of, or readiness or willingness to pursue, living donation, seeking a living donor; (c) biomedical and clinical research; (d) the development and/or assessment of the efficacy of new or improved clinical methods of donor management, organ recovery, or organ preservation; (e) fundamental research focused on new or improved evaluation tools and methodologies; (f) fundamental research focused on the development of new behavioral theories relevant to health attitudes, practices, and decision-making; or (g) interventions inconsistent with existing Federal law.
- to fund interventions to increase tissue donation alone.
- to fund proposals to evaluate clinical outcomes of donation after cardiac death (DCD) organs.
- to fund OPO staff time devoted to project activities that is being supported by other sources.

Unobligated funds at the end of the budget period are restricted and remain in the grant account for future HRSA disposition. These funds may be requested for carryover to the next budget period. Requests for carryover must be submitted with the Financial Status Report. Unobligated funds are those reported on the annual Federal Financial Report (SF-425), which is required to be submitted to the Division of Grants Management Operations, HRSA 90 days after the end of the budget period for each project year.

**Salary Limitation:** The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. 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 a HRSA grant or cooperative agreement.

Per Division F, Title V, Section 503 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011 (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

Per Division F, Title V, Section 523 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

## 6. Other Submission Requirements

As stated in Section IV.1, except in very rare cases HRSA will no longer accept applications in paper form. Applicants submitting for this funding opportunity are **required** to submit **electronically** through Grants.gov. To submit an application electronically, please use the APPLY FOR GRANTS section at <http://www.grants.gov>. When using Grants.gov applicants will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site.

It is essential that organizations **immediately register** in Grants.gov and become familiar with the Grants.gov site application process. Applicants that do not complete the registration process will be unable to submit an application. The registration process can take up to one month.

To be able to successfully register in Grants.gov, it is necessary to complete all of the following required actions:

- Obtain an organizational Data Universal Numbering System (DUNS) number
- Register the organization with Central Contractor Registration (CCR) (or System for Award Management (SAM) starting late July 2012. See Section IV of this document for more SAM details.)

- Identify the organization’s E-Business Point of Contact (E-Biz POC)
- Confirm the organization’s CCR (or SAM – starting late July 2012) “Marketing Partner ID Number (M-PIN)” password
- Register and approve an Authorized Organization Representative (AOR)
- Obtain a username and password from the Grants.gov Credential Provider

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at <http://www.grants.gov>. Assistance is also available 24 hours a day, 7 days a week (excluding Federal holidays) from the Grants.gov help desk at [support@grants.gov](mailto:support@grants.gov) or by phone at 1-800-518-4726. Applicants should ensure that all passwords and registration are current well in advance of the deadline.

**It is incumbent on applicants to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline.** Therefore, an organization is urged to submit an application in advance of the deadline. If an application is rejected by Grants.gov due to errors, it must be corrected and resubmitted to Grants.gov before the deadline date and time. Deadline extensions will not be provided to applicants who do not correct errors and resubmit before the posted deadline.

**If, for any reason, an application is submitted more than once prior to the application due date, HRSA will only accept the applicant’s last validated electronic submission prior to the Grants.gov application due date as the final and only acceptable application.**

**Tracking an application:** It is incumbent on the applicant to track their application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking an application can be found at <https://apply07.grants.gov/apply/checkApplStatus.faces>. Be sure the application is validated by Grants.gov prior to the application deadline.

## V. Application Review Information

### 1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

Review Criteria are used to review and score applications. The Social and Behavioral Interventions to Increase Solid Organ Donation program has six (6) review criteria:

*Criterion 1: NEED (10 points)*

See IV. 2.ix. Program Narrative Section: Needs Assessment.

- Extent to which the application provides a detailed description of the significance of the problem and the intervention components including:

- The socio-cultural determinants of health and health disparities impacting the population or community,
- National and local supporting data;
- Factors contributing to the problem;
- Citation of relevant literature supporting the need.

*Criterion 2: RESPONSE (20 points)*

See IV. 2.ix. Program Narrative Section: Methodology, Resolution of Challenges.

- Extent to which the proposed project responds to the “Purpose” included in the FOA, intent of the grant program, and the relevant program objectives and performance measures;
- Degree of clarity of proposed goals, objectives and performance measures and their relationship to the project activities;
- Extent to which the activities (scientific or other) described in the application are capable of addressing the problem/need, attaining the project objectives;
- Quality of and justification for the proposed intervention and an explanation of how and why the specific intervention(s) is expected to have a substantial positive impact on the proposed performance measure(s);
- Adequacy of the work plan in describing the activities or steps that will be used to achieve each of the activities proposed during the entire project period;
- Adequacy of the discussion of potential challenges and ways to address them
- Adequacy of the discussion of the original study if the proposed project is a replication or extension study; degree of adherence to the original study, or justification for deviations, if a replication is being conducted;
- Degree to which the application discusses the relevance of the project to the goals of Healthy People 2020.

*Criterion 3: EVALUATIVE MEASURES (25 points)*

See IV. 2.ix. Program Narrative Section: Methodology, Evaluation Plan.

- Degree of scientific rigor in the research design, intervention development, implementation, and evaluation of the project;
- Suitability and appropriate application of the theoretical foundation;
- Adequacy of the target population, including proposed sample size and selection procedures, geographic areas, plans for retention of target group and settings;
- Quality of one site with a large minority population for replication projects
- Quality of the methods to monitor and evaluate effectiveness of the intervention and other relevant factors. Evaluative measures must be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the intervention.
- Quality of the applicant’s access to necessary data (e.g. through letters of support) and the explanation of how the data will be used to inform program development and service delivery.

*Criterion 4: IMPACT (20 points)*

See IV. 2. ix. Program Narrative Section: Methodology, Dissemination Plan and Budget

- Degree to which the intervention can be effectively replicated, transferred and applied by other organizations given similar fiscal resources;

- Cost-effectiveness of the intervention relative to the size or magnitude of the impact (e.g., potential number of new registrants or donors per cost of implementing the project);
- Extent, potential for effectiveness, and appropriateness of plans for dissemination of project results.

*Criterion 5: RESOURCES/CAPABILITIES (15 points)*

See IV. 2. ix. Program Narrative Section: Methodology, Evaluation and Technical Support Capacity, Organizational Information.

- Extent to which project organization(s) demonstrate expertise and experience relevant to the focus of the proposed project, including organizational expertise and current involvement in donation or transplantation outreach;
- Demonstration that the Principal Investigator has experience and expertise in either design and implementation of interventions to increase deceased donation or to educate about living donation, and/or design and conduct of evaluation studies to assess the effectiveness of social-behavioral interventions;
- Adequate involvement of the Principal Investigator in the day-to-day management of the project demonstrating a substantive and substantial role in the project;
- Demonstrated expertise and experience by the Principal Researcher in research and evaluation design and methods in behavioral and social sciences;
- Extent to which project personnel are qualified by training and/or experience to implement and carry out the project;
- Expertise and experience of proposed project staff as supported by education, relevant publication in peer-reviewed journals, and work history;
- Sufficiency of staffing for the magnitude of the project;
- Appropriateness of staff for reaching the target population;
- Quality and availability of facilities, resources and personnel to fulfill the needs and requirements of the proposed project;
- Quality and strength of proposed collaborative arrangements with other organizations including faith based and community based organizations, if any.

*Criterion 6: SUPPORT REQUESTED (10 points)*

See IV. 2.v. Budget Justification.

- Reasonableness of the proposed budget for each year in the project period (up to three) in relation to project objectives, complexity of the activities, and anticipated results;
- Clarity and adequacy of budget detail for all project years;
- Thoroughness of line item explanations in the budget justification, including a clear and separate indication of any costs related to developing the intervention (intervention costs not to exceed 20% of total direct costs and staff time).

## **2. Review and Selection Process**

The Division of Independent Review is responsible for managing objective reviews within HRSA. Applications competing for Federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of

the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria noted above. The committee provides expert advice on the merits of each application to program officials responsible for final selections for award.

Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in Section V. 1. Review Criteria of this funding opportunity announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application.

### **3. Anticipated Announcement and Award Dates**

It is anticipated that awards will be announced prior to the start date of September 1, 2013.

## **VI. Award Administration Information**

### **1. Award Notices**

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

The NoA sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant's Authorized Organization Representative, and reflects the only authorizing document. It will be sent prior to the start date of September 1, 2013.

### **2. Administrative and National Policy Requirements**

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 [Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations](#) or 45 CFR Part 92 [Uniform Administrative Requirements For Grants And Cooperative Agreements to State, Local, and Tribal Governments](#), as appropriate.

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at <http://www.hrsa.gov/grants/hhsgrantspolicy.pdf>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the NoA).

### **Non-Discrimination Requirements**

To serve persons most in need and to comply with Federal law, services must be widely accessible. Services must not discriminate on the basis of age, disability, sex, race, color, national origin or religion. The HHS Office for Civil Rights provides guidance to grant and cooperative agreement recipients on complying with civil rights laws that prohibit discrimination on these bases. Please see <http://www.hhs.gov/ocr/civilrights/understanding/index.html>. HHS also provides specific guidance for recipients on meeting their legal obligation under Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color or national origin in programs and activities that receive Federal financial assistance (P. L. 88-352, as amended and 45 CFR Part 80). In some instances a recipient's failure to provide language assistance services may have the effect of discriminating against persons on the basis of their national origin. Please see <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html> to learn more about the Title VI requirement for grant and cooperative agreement recipients to take reasonable steps to provide meaningful access to their programs and activities by persons with limited English proficiency.

### **Human Subjects Protection**

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, grantees must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

### **Financial Conflict of Interest**

HHS requires awardees and investigators to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending this PHS regulation (and the companion regulation at 45 CFR part 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). An Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the rule must be in full compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the regulation.

### **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.hrsa.gov/grants/trafficking.html>.

## **Smoke-Free Workplace**

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

## **Cultural and Linguistic Competence**

HRSA programs serve culturally and linguistically diverse communities and multiple cultures. Although race and ethnicity are often thought to be dominant elements of culture, HRSA-funded programs embrace a broader definition to incorporate diversity within specific cultural groups including but not limited to cultural uniqueness within Native American populations, Native Hawaiian, Pacific Islanders, and other ethnic groups, language, gender, socio-economic status, sexual orientation and gender identity, physical and mental capacity, age, religion, housing status, and regional differences. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served. HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, materials delivered by competent providers in a manner that factors in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS) published by HHS and available online at <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>. Additional cultural competency and health literacy tools, resources and definitions are available online at <http://www.hrsa.gov/culturalcompetence> and <http://www.hrsa.gov/healthliteracy>.

## **Healthy People 2020**

Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy behaviors across all life stages. The program consists of over 40 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at <http://www.healthypeople.gov/>.

## **National HIV/AIDS Strategy (NHAS)**

The National HIV/AIDS Strategy (NHAS) has three primary goals: (1) reducing the number of people who become infected with HIV; (2) increasing access to care and optimizing health outcomes for people living with HIV; and (3) reducing HIV-related health disparities. The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of early entrance into care for people living with HIV to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention, care and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to identify people who are HIV-positive but do not know their serostatus and

reduce stigma and discrimination against people living with HIV.

To the extent possible, program activities should strive to support the three primary goals of the NHAS. As encouraged by the NHAS, programs should seek opportunities to increase collaboration, efficiency, and innovation in the development of program activities to ensure success of the NHAS. Programs providing direct services should comply with federally-approved guidelines for HIV Prevention and Treatment (see <http://www.aidsinfo.nih.gov/Guidelines/Default.aspx> as a reliable source for current guidelines). More information can also be found at <http://www.whitehouse.gov/administration/eop/onap/nhas>.

### **Health IT**

Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

### **Related Health IT Resources:**

- 1) [Health Information Technology \(HHS\)](#)
- 2) [What is Health Care Quality and Who Decides? \(AHRQ\)](#)

## **3. Reporting**

The successful applicant under this funding opportunity announcement must comply with the following reporting and review activities:

### **a. Audit Requirements**

Comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at [http://www.whitehouse.gov/omb/circulars\\_default](http://www.whitehouse.gov/omb/circulars_default).

### **b. Payment Management Requirements**

Submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to <http://www.dpm.psc.gov> for additional information.

### **c. Status Reports**

1) **Federal Financial Report.** The Federal Financial Report (SF-425) is required according to the following schedule: <http://www.hrsa.gov/grants/manage/technicalassistance/federalfinancialreport/ffrschedule.pdf>. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through EHB. More specific information will be included in the NoA.

2) **Progress Report(s).** The awardee must submit a progress report to HRSA on a semi-annual basis. Submission and HRSA approval of grantee Progress Report(s) triggers the

budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates grantee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the NoA.

3) **Final Report.** A final report is due within 90 days after the project period ends. A final report is required including a description and assessment of the grantee's use of funds provided under this grant program with a detailed description of the research, the intervention, and its effectiveness, especially as related to the performance measures (described in *Performance Measures* in *Section IV.2.x. Program Narrative*). The final report shall include recommended strategies for replication, e.g., implementation guidelines, materials and software to be shared. One copy of all publications associated with the project shall be included. Grantees will receive more information about the specific requirements and format of this report. The final report must be submitted on-line by awardees in the Electronic Handbooks system at <https://grants.hrsa.gov/webexternal/home.asp>.

4) **Tangible Personal Property Report.** If applicable, the awardee must submit the Tangible Personal Property Report (SF-428) and any related forms. The report must be submitted within 90 days after the project period ends. Awardees are required to report all federally-owned property and acquired equipment with an acquisition cost of \$5,000 or more per unit. Tangible personal property means property of any kind, except real property, that has physical existence. It includes equipment and supplies. Property may be provided by HRSA or acquired by the recipient with award funds. Federally-owned property consists of items that were furnished by the Federal Government. Tangible personal property reports must be submitted electronically through EHB. More specific information will be included in the NoA.

**d. Transparency Act Reporting Requirements**

New awards ("Type 1") issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109-282), as amended by section 6202 of Public Law 110-252, and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier subaward of \$25,000 or more in Federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (FFATA details are available online at <http://www.hrsa.gov/grants/ffata.html>). Competing continuation awardees, etc. may be subject to this requirement and will be so notified in the NoA.

## VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this funding opportunity announcement by contacting:

Ernsley Charles, Grants Management Specialist  
Attn.: Social and Behavioral Interventions to Increase Solid Organ Donation  
HRSA Division of Grants Management Operations, OFAM  
Parklawn Building, Room 11A-05  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-8329  
Fax: (301) 443-8390  
Email: [ECharles@hrsa.gov](mailto:ECharles@hrsa.gov)

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Rita Maldonado, MPH  
Project Officer, Division of Transplantation  
Attn: Social and Behavioral Interventions to Increase Solid Organ Donation  
Healthcare Systems Bureau, HRSA  
Parklawn Building, Room 12C-06  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-3622  
Fax: (301) 594-6095  
Email: [rmaldonado@hrsa.gov](mailto:rmaldonado@hrsa.gov)

Applicants may need assistance when working online to submit their application forms electronically. Applicants should always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding Federal holidays at:

Grants.gov Contact Center  
Telephone: 1-800-518-4726  
E-mail: [support@grants.gov](mailto:support@grants.gov)  
iPortal: <http://grants.gov/iportal>

Successful applicants/awardees may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Call Center, Monday-Friday, 9:00 a.m. to 5:30 p.m. ET:

HRSA Contact Center  
Telephone: (877) 464-4772  
TTY: (877) 897-9910  
E-mail: [CallCenter@HRSA.GOV](mailto:CallCenter@HRSA.GOV)

## **VIII. Other Information**

### **1) Internet Resources**

Applicants are encouraged to refer to DoT's Web site, <http://www.organdonor.gov>, for general information about donation, government donation initiatives, and transplantation issues.

### **2) Pre-Application Technical Assistance Conference Calls**

The Division of Transplantation (DoT) will conduct two Pre-Application telephone conference to provide technical assistance (TA) and consultation for individuals who may wish to submit an application for the Social and Behavioral Interventions to Increase Solid Organ Donation Grant Program. This year DoT will also conduct a webinar providing information regarding the grant program. The webinar will be targeted to individuals who are new to both the grant program and to the field of organ donation.

#### **TA Conference Calls:**

TA telephone conference calls will be held on Wednesday, August 8 and Tuesday, September 4, 2012 at 2:00 p.m. Eastern Time. (The calls will be recorded, please email Rita Maldonado for access.)

Call-in Number: (888) 848-6719

Participant Passcode: 8739034

Leader: Rita Maldonado, MPH

#### **TA Webinar**

A TA Webinar for individuals new to the donation and transplantation field will be held on Wednesday, August 1 at 2:00 p.m. Eastern Time. The purpose of this webinar is to provide an overview of the field and an overview of this grant program, Social and Behavioral Interventions to Increase Solid Organ Donation and to encourage people who have not before submitted an application to this grant program to consider doing so. Newcomers to the field also are encouraged to participate in the TA conference calls noted above. More specific information about this FOA will be covered in those calls.

Call-in Number: (888) 848-6719

Participant Passcode: 8739034

Leader: Rita Maldonado, MPH

Adobe Connect Meeting.

Meeting Name: Grant to Increase Organ Donation

When: 08/01/2012 2:00 PM - 3:30 PM Eastern Time

To join the meeting: <https://hrsa.connectsolutions.com/grantorgdonate/>

If you have never attended an Adobe Connect meeting before:

Test your connection:

[https://hrsa.connectsolutions.com/common/help/en/support/meeting\\_test.htm](https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm)

Get a quick overview: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview)

### **3) Technical Assistance Workshops for Grantees**

In order to maximize effectiveness and efficiency and promote creative exchange of ideas, all funded projects are required to participate in a total of four workshops during the three years of the project. There will be two (2) Grantee Technical Assistance (TA) Workshops during the first project year, a pre-implementation meeting in early fall and an all-grantee meeting in the summer. An all-grantee meeting also will be held in the summer of all subsequent project years. The researcher/evaluator and key donation or transplantation professional from each funded project are required to attend all TA workshops.

The purpose of the Technical Assistance Workshops is to discuss the critical components of each project, assess progress, identify problem areas and potential solutions, develop strategies for achieving maximum efficacy of each project, and promote networking among grantees with like interests. Workshop consultants will review progress reports and other materials and provide suggestions to grantees on issues such as project intervention, design, approach, outcome measures, budget, and parameters. Suggested budget revisions commensurate with project revisions must be submitted to the Federal government for review and approval. Additionally, project review conference calls may be held periodically with staffs of individual projects or small groups of projects.

There is no registration fee to attend any of the required workshops. However, applicants should include in the budget section funding for lodging, transportation, and per diem for two participants to attend each required workshop. Grant funds may be used to support workshop attendance for the two individuals whose attendance is required. Other individuals associated with the grant program may attend the meetings but grant funds may not be used to support their travel. The pre-implementation workshop will be in the Washington, D.C. area. The location of the summer technical assistance workshop varies.

In calculating lodging, per diem, and airfare costs for the pre-implementation workshop and the summer all grantee TA workshop, applicants should use the government lodging and per diem rates for Washington, D.C. in September 2012 (\$297) per day plus hotel taxes, and the cost of airfare from their city to Washington, D.C. To estimate travel costs for subsequent summer TA meetings, applicants may increase their year 1 estimates by 5%. Government lodging and per diem rates are available at <http://www.gsa.gov/portal/category/21287>.

### **4) Final Presentation**

Grantees must make an oral presentation of their intervention and outcomes during the summer TA meeting of the final project year. Grantees who obtain a no-cost extension shall make the final presentation in-person during the summer TA meeting of the no-cost extension year so that final data can be reported. Information shall include: description of the intervention and approach, findings, conclusions, challenges and solutions experienced, and contributions of the project in terms of impact on donation.

### **5) Data Coordination and Management**

Each grantee will be responsible for the collection, entry, quality control, and analysis of all project data. Grantees will provide interim data and plans for proposed analyses to their government project officers as requested. All data resulting from this grant shall be made available to the grantor and shall be dispersed at the grantor's discretion. Patient privacy and confidentiality must be protected in accordance with the Privacy Act, (5 U.S.C. § 522a).

## **6) Publications and Presentations of Project**

As a means of sharing knowledge, HHS expects grantees to submit manuscripts for publication of the results and accomplishments of HHS-supported activities. HRSA/DoT prior approval is not required for publishing the results of an activity under a grant. Grantees also may assert copyright in scientific and technical articles based on data produced under the grant and transfer it to the publisher or others where necessary to effect journal publication or inclusion in proceedings associated with professional activities. Any such transfer is subject to the royalty-free, non exclusive and irrevocable license to the Federal government and any agreement should note explicitly that the assignment is subject to the government license.

Journal and other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 45 CFR 74.36 and 92.34). The recipient should account for royalties and other income earned from a copyrighted work (see Part IV and the NoA).

For each publication that results from HHS/HRSA/DoT grant-supported activities, grantees must include an acknowledgement of grant support using one of the following statements:

“This project/publication was made possible by Grant Number \_\_\_\_\_ from the Division of Transplantation, Health Resources and Services Administration, U.S. Department of Health and Human Services. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Division of Transplantation, Health Resources and Services Administration, U.S. Department of Health and Human Services.”

If the grantee plans to issue a press release concerning the outcome of HHS grant-supported activities, it should notify the Division of Transplantation, Health Resources and Services Administration, U.S. Department of Health and Human Services in advance to allow for coordination. One paper and electronic copy of each publication resulting from work performed under an HHS grant-supported project must accompany the annual or final progress report submitted to the Division of Transplantation, HRSA, HHS.

## **IX. Tips for Writing a Strong Application**

HRSA has designed a technical assistance webpage to assist applicants in preparing applications. Resources include help with system registration, finding and applying for funding opportunities, writing strong applications, understanding the review process, and many other topics which applicants will find relevant. The website can be accessed online at:

<http://www.hrsa.gov/grants/apply/index.html>.

In addition, a concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at:

<http://www.hhs.gov/asrt/og/grantinformation/apptips.html>.