

**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 Organ Donation

Announcement Type: New
Announcement Number: HRSA-16-072

Catalog of Federal Domestic Assistance (CFDA) No. 93.134

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

Application Due Date: January 4, 2016

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

Release Date: September 23, 2015

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Modified 12/8/15 – Added language under the Purpose and Program Specific Instructions and Review Criteria to clarify content and review criteria for living donation applications, page numbers 2, 7 and Extended Deadline to January 4 2016.

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Transplantation is accepting applications for fiscal year (FY) 2016 Social and Behavioral Interventions to Increase Organ¹ Donation grant program. The purpose of this grant program is to 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 registration or family consent.

Funding Opportunity Title:	Social and Behavioral Interventions to Increase Organ Donation
Funding Opportunity Number:	HRSA-16-072
Due Date for Applications:	January 4, 2016
Anticipated Total Annual Available Funding:	\$2,950,000
Estimated Number and Type of Award(s):	Up to 11 awards
Estimated Award Amount:	Average \$250,000 - \$450,000 per year
Cost Sharing/Match Required:	No
Project Period:	September 1, 2016 through August 31, 2019 (three (3) years)
Eligible Applicants:	Public or nonprofit private entities [See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

Application Guide

All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 R&R Application Guide*, available online at <http://www.hrsa.gov/grants/apply/applicationguide/sf424rrguide.pdf>, except where instructed in this FOA to do otherwise. A short video for applicants explaining the *Application Guide* is available at <http://www.hrsa.gov/grants/apply/applicationguide/>.

Technical Assistance Webinar

October 15, 2015

Webinar link: https://hrsa.connectsolutions.com/ta_sbiisodgp/

Call-in Number: 866-658-5908

Participant Passcode: 8571504

¹ 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, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part 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.

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for Social and Behavioral Interventions to Increase Organ 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 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:

- 1) deceased organ donation registration among people over 50 years old
- 2) family discussion and knowledge about donation among adolescents, and actual registration among adolescents, where possible
- 3) consent of parents² for donation of a deceased minor child's organs
- 4) knowledge about the opportunities for and risks and benefits of living organ donation

Accordingly, this program will support sound applied research studies to test the effectiveness of strategies that target any of the four program objectives listed above including their potential to have wide impact on the availability of organs for transplant in the U.S. While the program focuses on organ donation, it is hoped that successful strategies may increase 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 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. The budget and timeline should reflect a strong research methodology.

Applications may propose pilot or extension projects. 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. 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 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.

² In this document reference to 'parents' is to be understood to include parents, guardians, or other persons authorized under applicable laws to consent to such donation.

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.

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. insofar as they are consistent with those specified for this FOA. Sound conceptual models of behavioral change must inform the intervention and various components of the methodology. Increased attention is given to project impact. Study designs will be reviewed for their potential to be replicated at the end of the grant period in similar or other parts of the country or with similar or other target populations. The aim is to foster more immediate and widespread use of successful interventions and ultimately increase availability of organs for transplant. Inclusion of more than one target population, oversampling specific population(s), or implementation in more than one geographic location are methods that may be employed to strengthen study findings and replication potential.

The study application should clearly describe an intervention designed to lead to increased knowledge about both the opportunities for and risks and benefits of living organ donation as indicated in the hypothesis and intervention description. The study hypothesis and intervention design will be objectively reviewed to ensure that the intervention does not promote living donation. Any application that indicates that projects will promote living organ donation will be deemed non-responsive and will not be considered for funding under this announcement. . For example, if the application states that the intervention materials will tell participants that they should get evaluated to become living donors, (as opposed to telling them that they can get evaluated to become living donors), the application will be deemed non-responsive

Applicants are required to demonstrate that their proposed intervention meets the requirements indicated in the FOA. Outcome measures must evaluate changes in knowledge about the opportunities for and risks and benefits of living organ donation. Other outcomes (for example, the intent to seek a living donor) may also be measured, as long as the purpose and implementation of the intervention is not to influence those behaviors.

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). 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 or educate about living organ donation.

2. Background

This program is authorized by Section 377A(b) of the Public Health Service (PHS) Act, (42 U.S.C. 274f-1(b)), as amended.

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 June 2015 was over 123,000. Only 8,596 deaths resulted in donation in 2014, a figure far smaller than the need (Organ Procurement and Transplantation Network (“OPTN”), June 26, 2015). Even with a national recovery average of 3.02 organs per deceased donor and with the contributions of 5,816 living donors, only 29,532 patients received transplants in the United States in 2014, while 6,972 individuals died waiting (OPTN, June 26, 2015).

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 grant research and evaluation projects 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 and is being applied and integrated into the design and evaluation of strategies for increasing donation.

This grant program, *Social and Behavioral Interventions to Increase Organ Donation*, was launched in FY 1999 and is a component of HRSA’s efforts to increase organ and tissue donation. From FY 1999-2014, HRSA/DoT has supported 108 research projects totaling \$85 million to test strategies for increasing organ and tissue donation or to replicate successful donation interventions. It is anticipated that the FY 2016 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.

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/dtcp/behavior.html>.
- A list of publications by current and previously funded DoT grantees can be obtained at <http://www.organdonor.gov/dtcp/publications.html>.
- A Report on Social and Behavioral Interventions to Increase Organ Donation Grant Program 1999-2004 is available at <http://www.organdonor.gov/images/pdfs/reportdotprogram19992004.pdf>.
- 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/conf rpt.html>.
- IOM report, “Organ Donation: Opportunities for Action,” available from <https://www.iom.edu/Reports/2006/Organ-Donation-Opportunities-for-Action.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 Application and Award

Type of applications sought: New.

Funding will be provided in the form of a grant.

2. Summary of Funding

This program will provide funding during federal fiscal years 2016 – 2019. Approximately \$2,950,000 is expected to be available annually to fund up to 11 grants. It is anticipated that the average award for each project year will be \$250,000-\$450,000. The actual amount available will not be determined until enactment of the final FY 2016 Federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for Social and Behavioral Interventions to Increase Organ Donation in subsequent fiscal years, satisfactory recipient

performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award will be subject to the Uniform Guidance [2 CFR 200](#) as codified by HHS at [45 CFR 75](#), which supersedes the previous administrative and audit requirements and cost principles that govern federal monies.

HRSA intends to fund, at a minimum, one award in each of four areas: 1) deceased organ donation registration among people over 50 years old; 2) family discussion and knowledge about donation among adolescents, and actual registration among adolescents, where possible; 3) consent of parents for donation of a deceased child's organs; and 4) knowledge about the opportunities for and risks and benefits of living organ donation.

III. Eligibility Information

1. Eligible Applicants

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

If the applicant is an Organ Procurement and Transplantation 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 HHS final rule governing the operation of the OPTN (42 CFR Part 121 or visit <http://optn.transplant.hrsa.gov>).

Foreign entities are not eligible for HRSA awards, unless the authorizing legislation specifically authorizes awards to foreign entities or the award is for research. This exception does not extend to research training awards or construction of research facilities.

Cost Sharing/Matching

Cost sharing/matching is not required for this program.

2. 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.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept the applicant's **last** validated electronic submission, under the

correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA *requires* applicants for this FOA to apply electronically through Grants.gov. Applicants must download the SF-424 Research and Related (R&R) application package associated with this FOA following the directions provided at [Grants.gov](https://www.grants.gov).

2. Content and Form of Application Submission

Section 4 of HRSA's [SF-424 R&R Application Guide](#) provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. All applicants are responsible for reading and complying with the instructions included in HRSA's [SF-424 R&R Application Guide](#) except where instructed in the FOA to do otherwise.

See Section 8.5 of the [SF-424 R&R Application Guide](#) for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge applicants to take appropriate measures to ensure the application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's [SF-424 R&R Application Guide](#) (including the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's [SF-424 R&R Application Guide](#).

ii. *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 study application should clearly describe an intervention designed to lead to increased knowledge about both the opportunities for and risks and benefits of living organ donation as indicated in the hypothesis and intervention description.

The narrative should include sufficient information to enable the evaluation of the project. Be specific and informative and avoid redundancies.

NOTE: FOR RESUBMISSIONS, MARK THE APPLICATION AS “RESUBMISSION” IN BOX 8 OF THE SF-424 R&R. For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA announcement number of the prior submission. This impacts the objective review process, as the Summary Statement of the previously reviewed application is given to reviewers to consider when assessing the resubmitted proposal.

Performance Measures

Projects must address one of the following four performance measures:

- increases in the number or rate of adults 50+ who designate their consent to become donors in their state registry, either through the motor vehicles office, online, or other verifiable method
- increases in commitment to organ donation among adolescents as measured by their increased knowledge about donation, discussion with their family, and where possible, actual registration
- increases in consent by parents for donation of a deceased minor child’s organs
- increases in knowledge about the opportunities for and risks and benefits of living organ donation

Applications must indicate which performance measure the intervention aims to address. 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 data from state donor registries and institutional data collected by OPOs, hospitals, dialysis centers, and transplant centers as applicable to support these measures. If the applicant proposes to increase donor registration, the applicant must indicate access to such data via attached supporting documentation in the proposal.

Outcome measures proposed by applications educating about living donation must evaluate changes in knowledge about the opportunities for and risks and benefits of living organ donation. Other outcomes (for example, the intent to seek a living donor) may also be measured, as long as the purpose and implementation of the intervention is not to influence those behaviors.

Use the following section headers for the Narrative:

- **INTRODUCTION** -- *Corresponds to Section V's Review Criterion 2*
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 or extension study.
- **NEEDS ASSESSMENT** -- *Corresponds to Section V's Review Criteria 1, 2, 3*
This section outlines the needs of your community and/or organization. The target population(s) and unmet health needs must be described and documented in this section. Include socio-cultural determinants of health and health disparities and barriers to organ donation or registration, impacting the population or communities served. 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, a thorough discussion of need in the study site(s) or assessment of need specific to the target population(s) is essential. 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** -- *Corresponds to Section V's Review Criteria 2, 3, 4, 5*
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 FOA. 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 proposing an extension, describe the original intervention including its purpose, funding source, research methods, findings related to its effectiveness, and justify the inclusion of the extension by clearly detailing and substantiating the potential utility of the proposed changes to the intervention.

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 (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.)
- 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 of the target population(s)
- b) description of the size and characteristics
- c) donation practices and attitudes
- d) rationale for selecting the specific geographic areas for project implementation, their appropriateness for reaching the identified target population, and the appropriateness of the geographic area for determining replicability of the intervention to other areas in the US
- e) indication that the project team has the experience and expertise necessary to understand, reach, and influence the target population
- f) plans for recruitment and retention of the target group

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 projects, a detailed description of the original project and 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) discussion of the intervention's potential effectiveness for addressing the barriers to organ donation and/or registration discussed in the Needs Assessment
- d) review of relevant descriptive information and data relating to the feasibility and effectiveness of the same or similar interventions (including recommended refinements/modifications)

- e) 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
- f) inclusion of a chart indicating the anticipated cost-effectiveness of the proposed intervention by dividing the estimated number of new registrants, consented donors, or parents committed to donation of their minor child's organs by the cost of implementing the intervention (development and research costs do not need to be included in the calculation)

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 to implement the intervention is not requested.

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

Outcome Measures and Research Methodology – all projects must include a research plan including:

- 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 research methodology
- c) discussion of how the proposed research methodology can be expected to reliably measure project impact
- d) explanation of how the proposed research methodology will determine and account for baseline 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, on letterhead and signed by an official, 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 measurement instruments to be used including psychometric properties, and if possible, copies or drafts of data collection instruments, e.g., surveys, telephone protocols, interview formats.

Protection of Human Subjects

If human subject are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45

CFR Part 46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). Please refer to instructions provided in HRSA's SF-424 R&R Application Guide, Appendix B: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, for specific instructions on preparing the human subjects section of the application.

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

Discuss plans to seek Institutional Review Board (IRB) approval. IRB approval is not required at the time of application submission but must be submitted to HRSA prior to initiation of any activities involving human subjects.

Dissemination Plan –

- a) Include a proposal to disseminate project outcomes including the development of a replication guide to be used by others in the field and a plan for distributing the guide during the funding period (electronic distribution is acceptable). The format and structure of the guide will vary depending on the project.
- b) The dissemination plan can include submission of articles to academic journals, presentation of findings via appropriate conferences, newsletters, and social media outlets to maximize the impact of the project on the field of donation outreach.

▪ *WORK PLAN -- Corresponds to Section V's Review Criteria 2, 3*

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. The work plan should reflect a strong research component. Include the submission of your project for IRB approval. Use a timeline that includes each activity and identifies responsible staff for all phases and years of the proposed project, including a plan 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.

Applicants are encouraged to submit a logic model for designing and managing their project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. Although there are many versions of logic models, for the purposes of this announcement, the logic model should summarize the connections between the:

- Goals of the project (i.e., objectives, reasons for proposing the intervention, if applicable)
- Assumptions (i.e., beliefs about how the program will work and is supporting

- resources. Assumptions should be based on research, best practices, and experience.)
 - Inputs (i.e., organizational profile, collaborative partners, key staff, budget, and other resources)
 - Target population(s) (i.e., the individuals to be studied)
 - Activities (i.e., approach, key intervention milestones, if applicable)
 - Outputs (i.e., the direct products or deliverables of program activities)
 - Outcomes (i.e., the results of a program, typically describing a change in people or systems)
- **RESOLUTION OF CHALLENGES** -- *Corresponds to Section V's Review Criterion 2*
Discuss challenges that may be encountered in designing and implementing the activities described in the Work Plan, and approaches that will be used to resolve such challenges.
 - **RESEARCH AND TECHNICAL SUPPORT CAPACITY** -- *Corresponds to Section V's Review Criterion(a) 3, 5*
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 that 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 consent to donation, deceased donor registration or education about living organ 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** -- *Corresponds to Section V's Review Criteria 5*
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 application 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.

The application must 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. Indicate if the project is to be implemented by a consortium, and identify the organizations and their roles and responsibilities. Discuss adequacy of the collective resources (the applicant agency, consortium member organizations, and key staff) for conducting the proposed project. 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.

NARRATIVE GUIDANCE

In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

<u>Narrative Section</u>	<u>Review Criteria</u>
Introduction	(1) Response
Needs Assessment	(1) Need, (2) Response and (3) Research Measures
Methodology	(2) Response, (3) Research Measures, (4) Impact, and (5) Resources/Capabilities
Work Plan	(2) Response and (3) Research Measures
Resolution of Challenges	(2) Response
Research and Technical Support	(3) Research Measures and (5)

Capacity	Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(4) Impact and (6) Support Requested

iii. *Budget*

See Section 4.1.iv of HRSA's [SF-424 R&R Application Guide](#). Please note: the directions offered in the [SF-424 R&R Application Guide](#) differ from those offered by Grants.gov. Please follow the instructions included the R&R Application Guide and, *if applicable*, the additional budget instructions provided below.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA supported project or activity. Total project or program costs include costs charged to the award and costs borne by the grantee to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the Social and Behavioral Interventions to Increase Organ Donation program requires the following:

- If a consortium of organizations is conducting the project, applicants should include as attachments itemized line-item budgets and budget narratives (see IV.2.iv. below) for each year of grant support for each organization in the consortium. These attachments are submitted on 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.

The Consolidated and Further Continuing Appropriations Act, 2015, Division G, § 203, (P.L. 113-235) states “None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.” Please see Section 4.1.iv Budget – Salary Limitation of HRSA's [SF-424 R&R Application Guide](#) for additional information. Note that these or other salary limitations will apply in FY 2016, as required by law.

iv. *Budget Justification Narrative*

See Section 4.1.v of HRSA's [SF-424 R&R Application Guide](#). In addition, the Social and Behavioral Interventions to Increase Organ Donation program requires the following:

- If a consortium of organizations is conducting the project, applicants should include as attachments budget narratives 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 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. Ensure each budget item is clearly related to the activities listed in the Work Plan.

- The budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

v. Attachments

Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled.**

Attachment 1: Work Plan (Required, counted in the page limit.)

Attach the Work Plan for the project that includes all information detailed in Section IV.

ii. Project Narrative. Include the recommended logic model in this attachment.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (Required, counted in the page limit.) (see Section 4.1.vi. of HRSA's [SF-424 R&R Application Guide](#))

Applications must contain 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. Keep each job description to one page in length to the extent possible. Include the role, responsibilities, and qualifications of proposed project staff member.

Attachment 3: Letters of Agreement and/or Description(s) of Proposed/Existing Contracts (project specific) (Required, counted in the page limit.)

Provide any documents that describe working relationships between the applicant organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the contractors and any deliverable. Letters of agreement must be dated. Letters that are not submitted as part of the application package itself will not be considered in the review.

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 itself will not be considered in the review.

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

Provide a one-page figure that depicts the organizational structure of the project; include subcontractors and other significant collaborators.

Attachment 6: Tables, Charts, etc. (Not required, counted in the page limit)

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.).

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. Dun and Bradstreet Universal Numbering System Number and System for Award Management (formerly, Central Contractor Registration)

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Applicant must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by an agency (unless the applicant is an individual or Federal agency that is exempted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the agency under 2 CFR 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If an applicant/awardee organization has already completed Grants.gov registration for HRSA or another Federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<http://fedgov.dnb.com/webform/pages/CCRSearch.jsp>)
- System for Award Management (SAM) (<https://www.sam.gov>)
- Grants.gov (<http://www.grants.gov/>)

For further details, see Section 3.1 of HRSA's [*SF-424 R&R Application Guide*](#).

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date

The due date for applications under this FOA is *January 4, 2016 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's [*SF-424 R&R Application Guide*](#) for additional information.

5. Intergovernmental Review

The Social and Behavioral Interventions to Increase Organ Donation is a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. See Executive Order 12372 in the [*HHS Grants Policy Statement*](#).

See Section 4.1 ii of HRSA's [*SF-424 R&R Application Guide*](#) for additional information.

6. 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, grantee's 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 organ donation; (b) projects that do not fall under one of the four research objectives listed in the introduction; (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 assess clinical outcomes of donation after cardiac death organs.
- to fund OPO staff time devoted to project activities that are being supported by other sources. If an OPO is proposed to receive funding, describe how the OPO staff activities are separate from their normal operations.
- to fund staff time for individuals to supervise grant project staff if their role is generally to supervise staff and activities (e.g., an organization's CEO cannot receive project funds to provide overall supervision of the project).

Unobligated funds at the end of the budget period are restricted and remain in the grant account for future HRSA disposition. However, grantees may request that these funds be carried over to the next budget period. Such 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.

The General Provisions in Division F, Title V of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011 apply to this program. Please see Section 4.1 of HRSA's [SF-424 R&R Application Guide](#) for additional information.

All program income generated as a result of awarded grant funds must be used for approved project-related activities.

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.

These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

The extent to which the study hypothesis and intervention design ensure that the intervention does not promote living donation. Any application that indicates that projects will promote living organ donation will be deemed non-responsive and will not be considered for funding under this announcement. For example, if the application states that the intervention materials will tell participants that they should get evaluated to become living donors, (as opposed to telling them that they can get evaluated to become living donors), the application will be deemed non-responsive.

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

Criterion 1: NEED (10 points) – Corresponds to Section IV 2.ii. 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:

- Discussion of the need for the intervention nationally and in the local area in which the intervention will be implemented
- The barriers to consent for organ donation and/or donor registration experienced by the target population
- Factors contributing to the problem
- The socio-cultural determinants of health and health disparities impacting the population or community in relation to organ donation
- Supporting data, citing relevant published and unpublished literature

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV 2.ii. Program Narrative, Introduction, Needs Assessment, Methodology, Work Plan, Resolution of Challenges

- Extent to which the proposed project responds to the “Purpose” included in the FOA, intent of the grant program, and performance measures
- Degree of clarity of proposed goals, objectives and performance measures and their relationship to the project activities
- Suitability and appropriate application of the theoretical foundation
- Extent to which the activities (scientific or other) described in the application are capable of addressing the problem/need, attaining the project objectives
- Extent to which the proposed intervention responds to the barriers described in the application for the target population
- 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 proposed study sites, target populations, and replication guide to assess broad replicability of the intervention
- 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, including obtaining IRB approval
- 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 an extension study; degree of adherence to the original study, and justification for the proposed adaptations
- Degree to which the application discusses the relevance of the project to the goals of Healthy People 2020

Criterion 3: RESEARCH MEASURES (20 points) – Corresponds to Section IV’s 2.ii. Program Narrative, Methodology, Work Plan, Research and Technical Support Capacity

- Degree of scientific rigor in the research design, intervention development, implementation, and assessment of the impact of the intervention
- Adequacy of the study population, supported by detailed power analysis calculations and selection procedures, geographic areas, plans for retention of target group and settings, and oversampling of specific populations, if appropriate
- Quality of the methods to monitor and assess the effectiveness of the intervention and other relevant factors. Measurement instruments and procedures 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
- Quality of plans for inclusion of minorities, members of both sexes/genders, and all ages as applicable

- Quality of plans for protection of human subjects from research risks
- To the extent applicable, the degree to which the application is in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46). See the instructions in the Grants.gov Application Guide SF424 (R&R), Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Appendix B
- To the extent applicable, the degree to which the application discusses plans to seek Institutional Review Board (IRB) review and includes it within the Work Plan (an IRB decision is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects.)

Criterion 4: IMPACT (25 points) – Corresponds to Section IV 2. ii. Program Narrative
Section: Methodology, Dissemination Plan and Budget

- Degree to which the design and evaluation will assess whether 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; cost and ease of replicating living donor education programs)
- Potential for effectiveness, and appropriateness of plans for dissemination of project results and tools for replication

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's IV 2. ii. Program Narrative
Section: Methodology, Research and Technical Support Capacity, Organizational Information

- Extent to which project organization(s) demonstrates 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, and/or design and conduct of 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 design and methods in the 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) – Corresponds to Section IV's IV 2.iii.
Budget and Budget Justification

- The reasonableness of the proposed budget and quality of the justification for each year of the project period in relation to the objectives, the complexity of the research activities, and the anticipated results
- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives

2. Review and Selection Process

Please see Section 5.3 of HRSA's [*SF-424 R&R Application Guide*](#).

HRSA will use factors other than merit criteria in selecting applications for federal award. For this program, HRSA will use program balance.

Funding Special Considerations and Other Factors

This program includes special consideration. A special consideration is defined as the favorable consideration of an application by HRSA funding officials, based on the extent to which the application addresses the specific area of special consideration. Applications that do not receive special consideration will be given full and equitable consideration during the review process.

HRSA intends to fund, at a minimum, one award in each of four areas: 1) deceased organ donation registration among people over 50 years old; 2) donation commitment, family discussion, and where applicable registration among adolescents; 3) consent of parents for donation of a deceased minor child's organs; and 4) knowledge about the opportunities for and risks and benefits of living organ donation.

Please Note: The Health Resources and Services Administration may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements ([45 CFR § 75.205](#)). The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of September 1, 2016.

VI. Award Administration Information

1. Award Notices

The Notice of Award will be sent prior to the start date of September 1, 2016. See Section 5.4 of HRSA's [SF-424 R&R Application Guide](#) for additional information.

2. Administrative and National Policy Requirements

See Section 2 of HRSA's [SF-424 R&R Application Guide](#).

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, recipients 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 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

3. Reporting

The successful applicant under this FOA must comply with Section 6 of HRSA's [SF-424 R&R Application Guide](#) and the following reporting and review activities:

1) **Progress Report(s).** The grantee 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 award notice.

2) **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>. In addition, each grantee must present an oral report of their project and findings in the TA workshop (see below) of their final project year.

VII. Agency Contacts

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

Ernsley Charles, Grants, Management Specialist
Attn.: Social and Behavioral Interventions to Increase Organ Donation
HRSA Division of Grants Management Operations, OFAM
Parklawn Building, Room 10W57A
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-8329
Fax: (301) 443-8390
Email: 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 Organ Donation*
Healthcare Systems Bureau, HRSA
Parklawn Building, Room 8W53C
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3622
Fax: (301) 594-6095
Email: 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 (International Callers, please dial 606-545-5035)
E-mail: support@grants.gov
iPortal: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Successful applicants/recipients 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 Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

VIII. Other Information

1. Logic Models:

Additional information on developing logic models can be found at the following website: http://www.cdc.gov/nccdphp/dnpao/hwi/programdesign/logic_model.htm.

Although there are similarities, a logic model is not a work plan. A work plan is an “action” guide with a timeline used during program implementation; the work plan provides the “how to” steps. Information on how to distinguish between a logic model and work plan can be found at the following website: <http://www.cdc.gov/healthyouth/evaluation/pdf/brief5.pdf>.

2. Internet Resources

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

3. Pre-Application Technical Assistance

DoT provides technical assistance (TA) to individuals who may wish to submit an application for this grant program individually per request as well as through a pre-application webinar. There is no registration fee to participate in any of these opportunities. Please contact Rita Maldonado at rmaldonado@hrsa.gov for more information.

TA Webinar

A TA webinar will be held on, Thursday, October 15, 2015 at 2:00 p.m. Eastern Time. The webinar is intended for individuals new to the grant program, *Social and Behavioral Interventions to Increase 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 webinar. (The webinar will be recorded. Please email Rita Maldonado for access to the recording.)

Webinar link: https://hrsa.connectsolutions.com/ta_sbiiisodgp/

Call-in Number: 866.658.5908

Participant Passcode: 8571504

4. 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 virtual workshops during the three years of the project period. 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 and key donation or transplantation professional from each funded project are required to participate in 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. Other attending grantees also will offer suggestions and feedback. 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.

5. 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 during the summer TA meeting of the no-cost extension year so 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.

6. Data Coordination and Management

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

7. Publication and Presentation of Project Findings

Publication of major findings is encouraged. All publications and oral presentations of work performed under, and data resulting from, this grant must contain appropriate acknowledgment of HRSA support and a disclaimer as follows:

“This publication/presentation was supported by Grant No. ____ from the Health Resources and Services Administration's Division of Transplantation (HRSA/DoT), U.S. Department of Health and Human Services. The contents of this publication/presentation are solely the responsibility of the author(s) and do not necessarily represent the views of HRSA/DoT.”

In addition, HRSA must be notified in advance of all publications and presentations to enable coordination of announcements about the oral or written presentation of information resulting from the project funded under this grant program.

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's [*SF-424 R&R Application Guide*](#).