U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Healthcare Systems Bureau Division of Transplantation

Increasing Organ Donation Awareness

Funding Opportunity Number: HRSA-18-095
Funding Opportunity Type(s): New
Catalog of Federal Domestic Assistance (CFDA) Number: 93.134

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: February 12, 2018

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 1 month to complete.

Issuance Date: November 14, 2017

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Transplantation is accepting applications for fiscal year (FY) 2018 Increasing Organ Donation Awareness¹ grant program. The purpose of this program is to reduce the gap between the demand for organ transplants and the supply of organ donors.

Funding Opportunity Title:	Increasing Organ Donation Awareness
Funding Opportunity Number:	HRSA-18-095
Due Date for Applications:	February 12, 2018
Anticipated Total Annual Available FY18 Funding:	\$1,000,000
Estimated Number and Type of Award(s):	Up to 4 grants
Estimated Award Amount:	
	Up to \$400,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	September 1, 2018 through
	August 31, 2021 (3 years)
Eligible Applicants:	Domestic public and nonprofit private entities
	See <u>Section III-1</u> of this notice of funding opportunity (NOFO), formerly known as
	the funding opportunity announcement
	(FOA), for complete eligibility information.
	(1 OA), for complete eligibility information.

Application Guide

You (the applicant organization/agency) 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/sf424rrguidev2.pdf, except where instructed in this NOFO to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

¹ For purposes of this grant program, the terms 'organ' and 'vascular composite allograft' are 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 (VCA) (also defined in 42 CFR 121.2). The VCAs eligible for study under this grant program are limited to hands and face.

Technical Assistance

DoT provides technical assistance 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 Venus Walker at wwalker@hrsa.gov for more information.

The following technical assistance webinar has been scheduled to provide technical assistance to individuals who may wish to submit an application for this grant program:

Webinar

Day and Date: Tuesday, December 5, 2017

Time: 2-3 p.m. ET

Call-In Number: 1-888-636-8945 Participant Code: 65153619

Weblink: https://hrsa.connectsolutions.com/hrsa-dot/

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I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Increasing Organ Donation Awareness Award Program. The overall purpose of the program is to reduce the gap between the demand for organ transplants and the supply of organ donors.

The specific goals for the FY 2018 award cycle include:

- Identify successful strategies for increasing registration for deceased donation through traditional portals such as the Department of Motor Vehicles and online registries.
- Identify non-traditional donor registration portals and ascertain their effectiveness for increasing donor registration as compared with traditional portals.
- 3) Increase awareness and knowledge about opportunities for, as well as the risks and benefits associated with living donation.
- Increase knowledge about vascularized composite allografts (VCA) and willingness to become a VCA deceased donor or provide authorization for a deceased relative to become a VCA donor.

Accordingly, HRSA will support research studies to test the effectiveness of strategies that target any of the specified program goals with the potential to have a wide impact and be readily adaptable within the donation and transplantation community. For purposes of this program, model interventions are defined as those that are: (1) effective in producing a verifiable and demonstrable impact on either 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 description, budget, and timeline should reflect a strong research methodology.

You may propose studies that are pilot projects or extension projects. A pilot project implements and tests an intervention that has not been tested before for its utility and effectiveness in the donation field. An extension project builds on results of a pilot project or an existing strategy by adjusting or adding some new dimension to the original intervention to strengthen the intervention. Studies 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. You are required to demonstrate that your proposed intervention meets the requirements indicated in the NOFO.

You are encouraged to propose new ideas and novel approaches that are cost-effective in achieving these program goals and demonstrate utility for the donation and transplantation community. You may also implement strategies that have been successful in other public health fields and evaluate their effectiveness for use in the donation field.

You have flexibility in proposing interventions, including: the focus and nature of the intervention, intervention site(s), geographic location(s), target population(s), etc. insofar as they are consistent with the program goals specified for this NOFO. Sound conceptual models of knowledge acquisition and/or behavior change must inform the intervention and methodology as relevant to the specific goal being addressed. Substantial attention is given to project impact. Study designs will be reviewed for their potential to be replicated after the award period in similar or other parts of the country or with similar or other target populations. 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, impact, and replication potential.

• Applications that focus on Living Donation must clearly describe an intervention designed to increase the target population's knowledge about opportunities for, and the risks and benefits associated with living organ donation. 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 the project will promote or encourage living organ donation or willingness or readiness to become a living donor will be deemed non-responsive and will not be considered for funding under this notice. For example, if an application states that the intervention strategies or materials will encourage participants to get evaluated as potential living donors (as opposed to telling them that they can get evaluated to become living donors), the application will be deemed non-responsive. Outcome measures must evaluate changes in knowledge about the opportunities for and risks and benefits of living organ donation.

Applications that focus on **VCA Donation** can include strategies to increase knowledge and/or willingness to be a VCA donor at the time of one's death or to authorize VCA donation for a deceased relative or significant other. The aim is to foster greater public awareness of the availability, need for, and success of these types of transplants and/or the identification of successful interventions for increasing public willingness to donate one's own or a relative's hands or face for transplantation.

Collaboration

HRSA seeks to promote greater collaboration among the donation and transplantation community and organizations with research expertise and experience, and other organizations with potential to enhance or facilitate the project. You are encouraged, but not required, to prepare the application and, if funded, implement the project as a consortium of organizations and individuals relevant to the project goals to ensure the breadth of expertise and knowledge required for the successful design, implementation, and evaluation of the proposed intervention(s).

2. Background

This program is authorized by Section 377A(b) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 274f-1(b). The Increasing Organ Donation Awareness Award Program was initiated in FY 1999 in response to the large and growing disparity between the high number of people needing transplants and the comparatively small number of available organs. The program has supported a broad spectrum of interventions to increase donation 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 development and enhancement of statewide donor registries to community-based activities to raise awareness among various population groups. Grant-sponsored research and evaluation projects have contributed to the knowledge base about important factors associated with the donation decision-making process for oneself, and the delicate process of requesting family authorization for a deceased relative's donation.

With the annual number of waiting list deaths hovering between 6,000 - 7,000 since 2001, the transplant community has continued to look to living donation as a life-saving option for patients. Similarly, for many years, this award program has offered the opportunity for projects to focus on increasing the public's awareness of living donation. The FY 2018 award program continues this focus on projects related to living donation. Recognizing that there are both benefits and risks to the donor for being involved in living donation, this award program supports projects to educate the public about the opportunity for as well as the risks and benefits associated with living donation but does not support efforts to encourage people to be living donors.

In recent years, VCA donation and transplantation, particularly hand and face transplants, have become more prevalent. Public sentiment toward VCA donation and transplantation is fairly positive, perhaps due in part to recognition of the need for these types of procedures by wounded soldiers. A 2012 national survey conducted for HRSA by the Gallup Organization revealed that the portion of the public willing to donate their hands and face after death was 80.3 percent and 58.2 percent, respectively. However, the absolute number of people who are not familiar with or supportive of VCA donation and transplantation is estimated to be high based on the newness of the field. Much work remains to be done to fully inform the public about this type of transplantation.

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

 Brief descriptions of projects funded through this award program can be obtained electronically at: http://www.organdonor.gov/about-dot/grants/programs/behavioral-interventions.html

- A list of publications by current and previously funded DoT award recipients 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 2012 national survey conducted for HRSA by the Gallup Organization is available at: http://www.organdonor.gov/dtcp/nationalsurveyorgandonation.pdf
- 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(s) of applications sought: New

HRSA will provide funding in the form of a grant.

2. Summary of Funding

Approximately \$1,000,000 is expected to be available annually to fund up to four (4) recipients. Applicants may apply for a ceiling amount of up to \$400,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2018 federal appropriation. This program notice 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 awarded in a timely manner. The project period is September 1, 2018 through August 31, 2021 (3 years). Funding beyond the first year is dependent on the availability of appropriated funds for the Increasing Organ Donation Awareness Award Program, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include domestic public or non-profit private entities. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply.

If your organization is an Organ Procurement and Transplantation Network (OPTN) member, and/or if you are working with a consortium that includes OPTN members, you 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). You can find more information about the OPTN and the final rule at https://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/.

Foreign entities are not eligible for these awards.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this notice.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this notice.

NOTE: Multiple applications from an organization with the same DUNS # are allowable if the applications propose separate and distinct projects. For example, one institution might submit an application focusing on living donation and another focusing on VCA donation. However, it is not acceptable for one institution to submit an application to increase knowledge about VCA or living donation in one state and submit an application to conduct the same study in another state.

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 your 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* you to apply electronically through Grants.gov. You must use the SF-424 Research and Related (R&R) application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

Effective December 31, 2017 - You **must** use the <u>Grants.gov Workspace</u> to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF Application Packages.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. Please note you are ultimately responsible for reviewing the <u>Find Grant Opportunities</u> page for all information relevant to desired opportunities.

2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 R&R Application Guide</u> provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the *R&R Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 R&R Application Guide</u> except where instructed in the NOFO to do otherwise. Applications must be submitted in the English language and must be in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the <u>SF-424 R&R Application Guide</u> 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 including biographical sketches (biosketches), and letters of commitment and support required in HRSA's <u>SF-424 R&R Application Guide</u> and this NOFO. Standard OMB-approved forms that are included in the application package do not count in the page limitation. Biographical sketches **do** count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge you to take appropriate measures to ensure your 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 this notice.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 6-15: Other Relevant Documents.

See Section 4.1 viii of HRSA's <u>SF-424 R&R Application Guide</u> for additional information on all certifications.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>R&R Application Guide</u> (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 must be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion #2 Response 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 which performance measure is being addressed and whether the project is a pilot or extension study.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criteria #1 Need, #2 Response, and #3 Evaluative Measures This section must provide justification for the need of your project in the community and/or organizations where you plan to conduct your project. Identify, discuss, and document the needs of your target population(s). Include socio-

cultural factors that may amplify the need for your project. Include relevant published and unpublished data and observational information with appropriate citations to support the need for and significance of the project. National data to briefly illustrate national need and provide context and a thorough discussion of need in the study site(s) or assessment of need specific to the target population(s) is essential. Discuss the purpose and usefulness of demographic data and relevant barriers that the project aims to overcome. 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 Response, #3 Evaluative Measures, #4 Impact, and #5 Resources/Capabilities

Describe the strategies and methods to be used and their appropriateness for accomplishing the specific goals of the proposed project and each of the program requirements in this NOFO. 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 using 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, and findings related to its effectiveness, and justify the extension by clearly detailing 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. Applications must demonstrate awareness of other initiatives with relevance to their project and propose and justify methods to distinguish the impact of the proposed project from the impact of other on-going efforts, random news events or television programming. As appropriate, include discussion of effective tools and strategies for ongoing staff training; outreach activities; anticipated collaborations; efforts to involve patients, families and communities of culturally, linguistically, socioeconomically and geographically diverse backgrounds; and information sharing/dissemination of the project and findings. 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(s) of public health education or other relevant models or theories, upon which the intervention is based, including:

- a) Main concepts
- b) Key theorists/developers
- c) Comparison, based on a critical review of the literature, of existing models or theories and the rationale for selecting the particular 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) Overview of current 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 United States
- e) Indication that the project team has the experience and expertise necessary to understand, reach, and influence the target population, and
- 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 addressed.
- c) Discussion of the intervention's potential effectiveness for addressing any barriers that the project might encounter as 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) Discussion of the anticipated cost-effectiveness of the proposed project including the metrics and rationale for this calculation (development and research costs do not need to be included in the calculation).

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 some experience with deceased solid organ or VCA donation and transplantation or living organ donation.
- 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 data must be obtained from an organization that is not the applicant organization, it is critical to 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

When human subjects are involved, the project must 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 discussion on how you propose 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 but must include other strategies as well such as 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 Response, and #3 Evaluative Measures

Describe the steps that will be used to achieve each of the activities proposed for 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 must 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) in attachment 5 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 continuation applications, and 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 notice, the logic model must summarize the connections between the:

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

Discuss challenges that you are likely to encounter 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 -- Corresponds to Section V's Review Criteria #3 Evaluative Measures, and #5 Resources/Capabilities

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. Applicants must make sure that the requisite knowledge and experience for conducting their specific study are clearly evident within the project team.

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. The PI must have experience and expertise in one or both of the following areas:

- design and implementation of interventions to educate the public about living donation or to educate about and increase willingness to be a deceased VCA donor, and/or
- design and conduct research studies to assess the effectiveness of socialbehavioral interventions.

The PI must have a substantive and substantial role in the project. Women, minorities, and persons with disabilities are encouraged to apply as the principal investigator. 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.

Key Organ Donation Professional

The Key Organ Donation Professional shall provide information and guidance for the development and actual conduct of the project's outreach efforts. This professional shall have substantial experience in conducting outreach and education efforts related to organ donation.

ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 Resources/Capabilities
Succinctly describe your organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs so as to avoid audit findings. Describe how the unique needs of target populations of the communities served are routinely assessed and improved.

The staffing plan and job descriptions for key faculty/staff must be included in Attachment 2 (Staffing Plan and Job Descriptions for Key Personnel). However, the biographical sketches must be uploaded in the SF-424 RESEARCH & RELATED Senior Key Person Profile form that can be accessed in the Application Package under "Mandatory."

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	Review Criteria
Introduction	(2) Response
Needs Assessment	(1) Need, (2) Response, and (3) Evaluative Measures
Methodology	(2) Response, (3) Evaluative Measures, (4) Impact, and (5) Resources/Capabilities
Work Plan	(2) Response, and (3) Evaluative Measures
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested

iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 R&R Application Guide</u>. Please note: the directions offered in the <u>SF-424 R&R Application Guide</u> may differ from those offered by Grants.gov. Please follow the instructions included in the *R&R Application Guide* and the additional budget instructions provided below. A budget that follows the *R&R Application Guide* will ensure that, if the application is selected for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

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 recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the Increasing Organ Donation Awareness Program requires the following:

If a consortium of organizations is conducting the project, applicants must 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 Appropriations Act, 2017 (P.L. 115-31), Division H, § 202, 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 may apply in FY 2018, as required by law.

iv. Budget Justification Narrative

See Section 4.1.v of HRSA's SF-424 R&R Application Guide.

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

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative. If applicable, also include the required logic model in this attachment. If funds will be sub-awarded or expended on contracts, describe how your organization will ensure the funds are properly documented.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1.vi. of HRSA's <u>SF-424 R&R Application Guide</u>)

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's time keeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements must clearly describe the roles of the contractors and any deliverable. Letters of agreement must be signed and dated.

Attachment 4: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

Attachment 5: Tables, Charts, etc.

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

Attachments 6-15: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a

commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You 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 you have 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 you have 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://www.dnb.com/duns-number.html)
- 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.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you 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 NOFO is February 12, 2018 at 11:59 p.m. Fastern Time.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 R&R</u> <u>Application Guide</u> for additional information.

5. Intergovernmental Review

The Increasing Organ Donation Awareness Program is subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 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

You may request funding for a project period of up to three (3) years, at no more than \$400,000 per year (inclusive of direct **and** indirect costs). 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 notice 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 Organ Procurement Organization (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).

The General Provisions in Division H of the Consolidated Appropriations Act, 2017, (P.L. 115-31) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 R&R Application Guide</u> for additional information. Note that these or other restrictions will apply in FY 2018, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative(s) applied to the award(s) under the program will be an addition. Post-award requirements for program income can be found at 45 CFR § 75.307.

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 you in understanding the standards against which your application will be judged. Critical indicators have been developed for each review criterion to assist you 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 and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The Increasing Organ Donation Awareness Award Program has six (6) review criteria:

Criterion 1: NEED (10 points) – Corresponds to Section IV's Needs Assessment. The extent to which the application provides a detailed description of the significance of the problem and the intervention components including:

 The need for the intervention nationally and in the local area in which the intervention will be implemented, with respect to the general population and the specific target population, if any.

- The level of knowledge about VCA or barriers to authorization for VCA donation for oneself or another individual for organ donation and/or donor registration experienced by the target population.
- The level of knowledge about and attitudes toward living donation experienced by the target population.
- The socio-cultural determinants of health and health disparities impacting the population or community in relation to living organ donation or VCA deceased donation, or organ donation in general.
- Supporting data, citing relevant published and unpublished literature.

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's Introduction, Needs Assessment, Methodology, Work Plan, and Resolution of Challenges

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives. The above will be measured by the extent to which the following are addressed:

- 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 strategies (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 general and/or 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 performance measure(s).
- Adequacy of the proposed study sites and target populations.
- 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 and preparing non-competing applications.
- 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: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's, Needs Assessment, Methodology, Work Plan, and Evaluation and Technical Support Capacity

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) the extent to which the program objectives have been met, and 2) the extent to which these can be attributed to the project.

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) the extent to which the program objectives have been met, and 2) the extent to which 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 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's Methodology, and Budget

The feasibility and effectiveness of plans for dissemination of project results, the extent to which project results may be national in scope, the degree to which the project activities are replicable and the sustainability of the program beyond the federal funding.

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., cost and ease of replicating the proposed intervention).
- Potential for effectiveness, and appropriateness of plans for dissemination of project results and tools for replication.
- Adequacy of the replication guide to assess broad replicability of the intervention.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Methodology, Evaluation and Technical Support capacity, Organizational Information

The 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 related to the proposed focus and/or design and conduct of studies to assess the effectiveness of socialbehavioral 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 the Key Donation Professional is involved in all aspects of the project.
- 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 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

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's <u>SF-424 R&R Application Guide</u> for more details.

3. Assessment of Risk and Other Pre-Award Activities

HRSA 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).

Applications receiving a favorable objective review are reviewed for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. You may be asked to submit additional

programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, HRSA's approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 1, 2018. See Section 5.4 of HRSA's *SF-424 R&R Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's SF-424 R&R Application Guide.

Human Subjects Protection:

Federal regulations (45 CFR part 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, you 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

3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 R&R Application Guide</u> and the following reporting and review activities:

- 1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an **annual** basis. 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 award recipient'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. Project Narrative*). The final report shall include recommended strategies for replication, e.g., implementation guidelines, and copies of the materials and software that would need to be shared. One copy of all publications associated with the project shall be included. Award recipients 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 award recipient must present an oral report of their project and findings in the TA workshop (see below) of their final project year.
- Integrity and Performance Reporting. The Notice of Award will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR part 75 Appendix XII</u>.

VII. Agency Contacts

You may request additional information regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Denise Boyer
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10N146
Rockville, MD 20857

Telephone: (301) 594-4256

Fax: (301) 443-5461 Email: dboyer@hrsa.gov You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Venus Walker

Public Health Analyst, Division of Transplantation

Attn: Organ Transplantation Program

Healthcare Systems Bureau

Health Resources and Services Administration

5600 Fishers Lane, Room 08W49D

Rockville, MD 20857

Telephone: (301) 443-7578

Fax: (301) 594-6095 Email: <u>VWalker@hrsa.gov</u>

You may need assistance when working online to submit your application forms electronically. 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, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base: 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 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center

Telephone: (877) 464-4772

TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Logic Models

Additional information on developing logic models can be found at the following website: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line 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/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

The following technical assistance webinar has been scheduled to provide technical assistance to individuals who may wish to submit an application for this grant program:

Webinar

Day and Date: Tuesday, December 5, 2017

Time: 2 p.m. - 3 p.m. ET

Call-In Number: 1-888-636-8945 Participant Code: 65153619

Weblink: https://hrsa.connectsolutions.com/hrsa-dot/

Technical Assistance (TA) Workshops for Award Recipients

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) Award Recipient Technical Assistance Workshops during the first project year, a pre-implementation meeting in early fall and an all-grant recipient meeting in the summer. An all Award Recipient 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 TA 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 award recipients with like interests. Workshop consultants will review progress reports and other materials and provide suggestions to award recipients on issues such as project intervention, design, approach, outcome measures, budget, and parameters. Other attending award recipients 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.

Final Presentation

Award recipients must make an oral presentation of their intervention and outcomes during the summer virtual TA meeting of the final project year. Award recipients 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.

Data Coordination and Management

Each award recipient shall be responsible for the collection, entry, quality control, and analysis of all project data. Award recipients shall provide interim data and plans for proposed analyses to their government project officer as requested. All data resulting from this award 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).

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 award 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.