U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

Healthcare Systems Bureau
Division of Transplantation

Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation
Funding Opportunity Number: HRSA-19-047
Funding Opportunity Type(s): New and Competing Continuation
Catalog of Federal Domestic Assistance (CFDA) Number: 93.134

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2019

Application Due Date: February 15, 2019

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
HRSA will not approve deadline extensions 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 16, 2018

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2019 Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program. The purpose of this program is to provide means-tested reimbursement to living organ donors for travel and subsistence expenses and other incidental nonmedical expenses related to the transplant that the Secretary of the U.S. Department of Health and Human Services (HHS) may authorize.

Funding Opportunity Title:	Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation
Funding Opportunity Number:	HRSA-19-047
Due Date for Applications:	February 15, 2019
Anticipated Total Annual Available FY 2019 Funding:	Up to $3,250,000
Estimated Number and Type of Award(s):	One cooperative agreement
Estimated Award Amount:	Up to $3,250,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2019 through August 31, 2024 (5 years)
Eligible Applicants:	All public and private entities are eligible to apply for this cooperative agreement. See Section III-1 of this notice of funding opportunity (NOFO) 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 Application Guide,* available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Friday, December 20, 2018
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-888-989-6484
Participant Code: 4830643
Weblink: https://hrsa.connectsolutions.com/nofo_pre-appl_ta_webinar/

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I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program for the fiscal year (FY) 2019 funding cycle. The purpose of this Program is to provide reimbursement of travel and subsistence expenses and other incidental non-medical expenses that the Secretary of the U.S. Department of Health and Human Services (HHS) may authorize by regulation to living organ donors and up to two relatives or other individuals accompanying the living donor in the United States. This notice authorizes reimbursement for travel and subsistence expenses only. Types of travel expenses that will be supported include travel for donor evaluation, organ donation, and donor follow-up visit(s). Funds under this program cannot be used for reimbursement of blood, marrow, or tissue donation expenses.

The authorizing statute allows the Secretary to support the reimbursement of additional incidental non-medical expenses by regulation. You, the applicant, should address in your proposal your approach to implement the reimbursement for other incidental non-medical expenses such as lost wages should the Secretary authorize them by regulation.

In addition, the award recipient shall not use these funds to provide reimbursement to living organ donors if reimbursement or payment for qualified expenses was provided or can reasonably be expected to be provided:

- by the recipient of the organ, or
- under a State or Federal program or an insurance policy, or
- by an entity that provides health services on a prepaid basis.

The authorizing statute requires the award recipient to provide preference to living donors would be most likely unable to afford the qualified allowable expenses associated with the donation process.

Collaboration

The applicant should include a description of proposed efforts to engage stakeholders such as transplant centers, dialysis centers, patients on the transplant waitlist and organizations working on behalf of individuals in need of transplants. The applicant should also include strategies to work closely with the Lost Wages Support for Living Organ Donors Demonstration Project award recipient to leverage the resources available from both programs to support living organ donors. Information about the Lost Wages Support for Living Organ Donors Demonstration Project is available here.

Eligibility Determination Mechanism

The Health Resources and Services Administration (HRSA), with input from the public, developed Eligibility Guidelines for this program. The [Guidelines](#) include qualified expenses, reimbursement ceilings, living donor and transplant recipients' eligibility requirements, and income eligibility requirements that provide preference to living donors who can least afford the travel expenses associated with the donation process. The applicant may propose a new mechanism or modification to the existing Eligibility Guidelines to assess transplant recipients' ability to pay for living organ donors' qualifying expenses and/or overall operations of the program. Any proposed mechanism must be fair and equitable to transplant recipients and living donors. While the applicant may propose a new mechanism or modification, any proposed changes to the existing Eligibility Guidelines must go through public comment via the *Federal Register* Notice process.

Information Technology Security Requirements

The award recipient may need to collect and store personal information from both the transplant recipient and the living organ donor to assess the living organ donor's eligibility. Therefore, the recipient must have the ability to maintain the confidentiality of personal information collected and stored under this program. Applications must include a description of the system to protect the confidentiality of data collected and stored under this program. HRSA also requires that any website developed to support this program be compliant with Section 508 of the Rehabilitation Act of 1973, available online at https://www.section508.gov/manage/laws-and-policies.

Financial System Integrity

You must propose a financial system that meets these objectives:

- Account for all funds approved and disbursed by the program;
- Provide funds in a timely manner to approved living donor applicants;
- Assure donors use the funds for the authorized purpose; and
- Maintain transaction records for third party audits.

Program Policies and Procedures

You must include proposed policies and procedures for the operation of this Program. These proposed policies and procedures must comply with the authorizing statute and the program's Eligibility Guidelines. The award recipient is responsible for establishing relationships with living organ transplant programs to promote the availability of this program and to communicate eligibility requirements and program policies and procedures. The award recipient may delegate to transplant programs the responsibility to screen living donors and transplant candidates to determine if they meet eligibility requirements and to submit the necessary application materials. In such cases, the award recipient shall establish safeguards to ensure the transplant centers follow program requirements. Transplant centers shall not receive reimbursement for this service. Applicants must describe the processes for reviewing, approving, and funding applications submitted by transplant centers on behalf of donors.

Performance Measures

You must set clear attainable annual goals regarding the number of donors the program expects to serve each month and the average reimbursement to donors. You must include proposed efforts that will be undertaken to disseminate information about the program to stakeholders such as transplant centers, dialysis centers, patients on the transplant waitlist, and organizations working on behalf of individuals in need of a transplant. In addition, you may propose efforts to make information regarding living donation, including potential risks, available to individuals who wish to become living donors.

The proposal must include a plan to address the performance measures below:
- Effectiveness of the program in meeting its goals;
- Participants' satisfaction with the program;
- Support to transplant centers
- Application review and approval process; and
- Efficiency and effectiveness of program's internal processes.

In addition, the proposal must include a plan to provide a quarterly report to HRSA on the following:
- Number of applications received from potential organ donors;
- Demographics on donors and recipients such as ethnicity, gender, and household income;
- Number of applications approved and denied;
- Number of approved applicants who underwent donor evaluation, transplant surgery, and follow-up visits
- Number of applications by preference category as defined in the program's Eligibility Guidelines, as amended;
- Program funds committed and disbursed to donors; and
- Performance measure updates.

2. Background

This program is authorized by section 377 of the Public Health Service (PHS) Act, 42 U.S.C. 274f, as amended. This specific authority was established by the Organ Donation and Recovery Improvement Act (P.L. 108-216). This grant program supports the mission of HRSA's Organ Transplantation Program to extend and enhance the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment.

There is a critical shortage of organs to meet the needs of individuals with end-stage organ failure who can benefit from an organ transplant. As of June 30, 2018, more than 114,000 individuals were on the national waiting list for an organ. Every day approximately 20 individuals die waiting for an organ. After peaking at 6,992 in 2004, the number of living donors continued to decline, reaching a low of 5,819 in 2014. The number of living donors has fluctuated within the past 5 years, reaching a high of 6,183 in 2017 (See Table 1). Nonetheless, living donation is still an important source of organs for transplantation. Many individuals may want to become living donors for

family or acquaintances, but lack the necessary resources to cover transplant related expenses not covered by insurance or other sources.

Table 1. US Transplants Performed Each Year by Donor Type

	Deceased Donor	Living Donor	Total Transplants
2004	20,049	6,992	27,041
2005	21,213	6,905	28,118
2006	22,207	6,733	28,940
2007	22,053	6,313	28,366
2008	21,746	6,218	27,964
2009	21,850	6,610	28,460
2010	22,101	6,561	28,662
2011	22,518	6,022	28,540
2012	22,187	5,866	28,053
2013	22,967	5,988	28,955
2014	23,720	5,819	29,539
2015	24,985	5,989	30,974
2016	27,630	5,980	33,610
2017	28,588	6,183	34,771

Source: Based on OPTN data as of July 1, 2018
(https://optn.transplant.hrsa.gov)

On September 14, 2006, HRSA awarded a 4-year cooperative agreement under the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program to establish a national program to provide reimbursement to living donors for travel and subsistence expenses related to organ donation. The recipient, in partnership with the American Society of Transplant Surgeons (ASTS) established the National Living Donor Assistance Center (NLDAC) to operate this national program. In October 2007, NLDAC was officially launched and is located at the ASTS headquarters in Arlington, Virginia. While the recipient of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program has changed, ASTS continues to operate the NLDAC and to date, has partnered with more than 300 living transplant programs throughout the United States to submit applications for reimbursement on behalf of living donors. Visit the NLDAC's Website at https://www.livingdonorassistance.org for more information.

Since its inception through June 30, 2018, the NLDAC facilitated more than 4,400 living organ transplants. Through this period, the NLDAC received more than 8,400

applications for funding, of which more than 7,500 were approved. The average reimbursement per living donor is approximately $2,350. The median household income for the transplant recipient is approximately $27,500 while the donor's median household income is approximately $35,500.

II. Award Information

1. Type of Application and Award

Type of applications sought: Competing Continuation

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance where substantial collaboration is anticipated between HRSA and the recipient during the period of performance of the award.

HRSA program involvement will include:
- Working collaboratively with the recipient to establish policies and procedures governing the program's operations;
- Assessing the program for the following administrative characteristics:
  - Administrative efficiency and accuracy
  - Responsiveness
  - Data collection structure – accuracy, timeliness, simplicity
  - Fiscal integrity;
- Reviewing quarterly reports;
- Reviewing and providing feedback on all major tasks, policies, procedures;
- Assisting in the coordination of efforts with the Lost Wages Support for Living Organ Donors Demonstration Project award recipient;
- Participating in major program planning meetings; and
- Maintaining ongoing communication with the award recipient.

The cooperative agreement recipient's responsibilities will include:
- Working collaboratively with HRSA to establish policies and procedures governing the operation of the program;
- Collaborating with the Lost Wages Support for Living Organ Donors Demonstration Project award recipient to leverage the resources available from both programs to support living organ donors;
- Establishing a system to operate and evaluate the effectiveness of the program with guidance from HRSA;
- Reviewing and processing applications for reimbursement;
- Making timely disbursements to donors approved for reimbursement;
- Ensuring the financial integrity of the program;
- Submitting quarterly reports to HRSA; and
- Maintaining ongoing communication with HRSA regarding operation of the program.

HRSA will work with the recipient in the event that responsibilities or requirements need to be added or revised. HRSA and the award recipient will review the processes and outcomes as needed, and determine whether adjustments in the areas listed above are required.

2. Summary of Funding

HRSA expects approximately $3,250,000 to be available annually to fund one recipient. Applicants may apply for a ceiling amount of up to $3,250,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2019 through August 31, 2024 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce recipient funding levels beyond the first year based on the projected number of living donors that will be supported by the award recipient.

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

Limitations on indirect cost rates. The recipient cannot charge indirect costs to funds allocated to support living donors. Indirect costs rate can be charged only to direct cost of operations of this program.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include States, transplant centers, qualified organ procurement organizations (OPOs) under section 371 of the Public Health Service Act, or other public or private entities. Faith-based and community-based organizations, Tribes, and tribal organizations are also eligible to apply.

2. Cost Sharing/Matching

No cost sharing or matching funds are required. Programs that supplement Government funding with in-kind contributions are encouraged; however, this is not a required activity under this grant program. In addition, applicants may use their own funds to increase the capacity of the program. If cost sharing is included, applicants must make clear which budget items are supported with Federal funds.

3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider it for funding under this notice.
Maintenance of Effort - *Maintenance of effort is not applicable for this program.*
NOTE: Multiple applications from an organization are not 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 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. HRSA encourages you to apply through Grants.gov using the SF-424 workspace application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

If you are reading this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) and reviewing or preparing the workspace application package, you will automatically be notified in the event HRSA changes and/or republishes the NOFO 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 For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

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

See Section 8.5 of the *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, program and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count 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
1) 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).
3) Where the prospective recipient is unable to attest to the statements in this
   certification, an explanation shall be included in Attachment 9 -15: Other
   Relevant Documents.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on all
certifications.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424
Application Guide* (including the budget, budget narrative, staffing plan and personnel
requirements, assurances, certifications, and abstract), include the following:

i.   Program Abstract
   See Section 4.1.ix of HRSA's *SF-424 Application Guide.*

ii.   Program Narrative
   This section provides a comprehensive framework and description of all aspects of
   the proposed program. It should be succinct, self-explanatory, consistent with forms
   and attachments, and well organized so that reviewers can understand the proposed
   program.

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

   ▪ *INTRODUCTION -- Corresponds to Section V's Review Criterion 1*
     Briefly describe the purpose and anticipated outcome(s) of the proposed program.
     Address why this specific proposal can most effectively meet HRSA's purpose for
     this program.

   ▪ *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion 1*
     Describe the needs of living donors and patients with end stage renal failure the
     program seeks to address. Describe the target population and document relevant
     needs. Use demographic data and cite the source whenever possible to support

the information provided. Discuss any anticipated barriers that the program hopes to overcome.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion 2*
  Propose methods to address the needs of the target population and expectations in this funding opportunity. As appropriate, include development of tools and strategies for outreach, collaborations, communication, and information sharing/dissemination to involve patients, families and communities of culturally diverse, socio-economic, and geographic backgrounds. Include a plan to disseminate reports, products, and program outputs to key target audiences.

  Describe proposed strategies, methods, and their appropriateness to achieve the objectives, requirements and expectations in this funding opportunity.

  This section must cover at least the following four elements:

  - Population
    - A mechanism to satisfy the authorizing legislation to identify transplant candidates and living donors eligible for this support.
    - An objective analysis of the number and characteristics of the transplant candidates and living donors the program will serve.
  - Location
    - The program setting in relation to the individuals it will serve.
    - Proposed arrangement with other appropriate institutions to facilitate this service.
  - Service
    - Description of the service to be provided under the proposed program.
    - Strategy to disseminate information to stakeholders such as transplant centers, individuals on the transplant waiting list and other appropriate organizations in the transplant field.
  - Outcome Measures and Evaluation Plan
    - Outcome measures to determine the program effectiveness.
    - Performance measures to assess the program efficiency and internal processes.
    - Evaluation plan to ensure continuing program improvements.
    - Instruments you will use including surveys and application forms.

- *WORK PLAN -- Corresponds to Section V's Review Criterion 2,4 and 6*
  Describe the activities or steps you will use to achieve each of the activities proposed during the period of performance in the methodology section. Use a time line that includes each activity and identifies responsible staff. 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 must submit a logic model (Attachment 6) for designing and managing the program. A logic model is a one-page diagram that presents the conceptual

framework for a proposed program and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:

- Goals of the program (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products or deliverables of program activities); and
- 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 you are likely to encounter in designing and implementing the activities described in the Work Plan, and approaches you will to resolve such challenges.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion 3 and 5*
  You must describe the plan for the performance evaluation that will contribute to continuous quality improvement. The performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the program. Include descriptions of the inputs, key processes, and expected outcomes of the funded activities.

  You must describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assign skilled staff, use data management software) in a way that allows for accurate and timely reporting of performance outcomes. You must describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the strategy to collect, analyze and track data to measure process and impact/outcomes across different cultural groups (e.g., race, ethnicity, language) and explain how the data will be used to inform program development and service delivery. You must describe any potential obstacles for implementing the program performance evaluation and how those will be addressed.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5*
  Discuss your organization's current mission, organizational structure, and scope of current activities conducted. Include an organizational chart as Attachment #9, and describe how these components contribute to your organization's ability to meet the program's requirements and expectations. Provide information on the

organization's available resources and capabilities to provide language translation services.

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	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response (4) Impact and (6) Support Requested
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

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iii.   *Budget*

See Section 4.1.iv of HRSA's *SF-424 Application Guide*. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following it, the approved plan can avoid audit issues during the implementation phase. For year 5 budget, submit a copy of Section B of the SF-424A as an Attachment (see attachment 7).

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

The Consolidated Appropriations Act, 2018 (P.L. 115-245, 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." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following FY, as required by law.

iv.   Budget Narrative
See Section 4.1.v. of HRSA's *SF-424 Application Guide*.

v.   Attachments
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. You must clearly label **each attachment**.

Attachment 1: Work Plan
   Attach the Work Plan for the program that includes all information detailed in Section IV. i. Program Narrative.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see section 4.1. of the HRSA's SF-424 Application Guide)
   Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed program staff.

Attachment 3: Biographical Sketches of Key Personnel
   Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (program-specific)
   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.

Attachment 5: Program Organizational Chart
   Provide a one-page figure that depicts the organizational structure of the program.

Attachment 6: Tables, Charts, Logic Model, etc.
   To provide further details about the proposal (e.g., Gantt or PERT charts, flow charts). See Section VIII for more information on logic models.

Attachment 7: 5th *Year Budget (NOT counted in page limit),*
　　After using columns (1) through (4) of the SF-424A Section B for a 5-year period of performance, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B. See Section 4.1.iv of HRSA's *SF-424 Application Guide.*

Attachment 8:　Accomplishment Summary

　　A well-planned accomplishment summary can be of great value, providing a record of achievements. It is an important source of material for HRSA in communicating program-specific accomplishments. The accomplishments of competing continuation applicants are considered during the review process; therefore, applicants are advised to include previously stated goals and objectives in their application and emphasize the progress made in attaining these goals and objectives. Because the Accomplishment Summary is considered when applications are reviewed and scored, **competing continuation applicants who do not include an Accomplishment Summary will not receive any additional points**. The accomplishment summary will be evaluated by the HRSA Program Team and applicants can receive five (5) additional points if they meet this requirement. The review will be based on the extent that the applicant made progress in attaining previously stated goals and objectives based on the progress report.

　　The accomplishment summary should be a brief presentation of the accomplishments, in relation to the objectives of the program during the current period of performance. The report should include:

(1) The period covered (dates).

(2) Specific objectives - Briefly summarize the specific objectives of the program as actually funded. Because of peer review recommendations and/or budgetary modifications made by the awarding unit, these objectives may differ in scope from those stated in the competing application.

(3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 9 – 15:　Other Relevant Documents
　　Include here any other documents that are relevant to the application, including organizational chart and letters of support. Letters of support must be dated and specifically indicate a commitment to the program/program (in-kind services, dollars, staff, space, equipment, etc.) List all other support letters on one page.

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 the registration 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 Application Guide.*

UPDATED SAM.GOV ALERT: For your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018. Read the updated FAQs to learn more.

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 15, 2019 at 11:59 p.m. Eastern Time*. HRSA suggests submitting applications to Grants.gov at least **3 days before the deadline** to allow for any unforeseen circumstances.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program 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 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than $3,250,000 per year (inclusive of direct **and** indirect costs). Awards to support programs beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the program's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in the FY 2019, as required by law.

You cannot use funds under this notice for the following purposes:
- Support for blood, bone marrow, and blood stem cell donation;
- Reimbursement for lost wages expenses and other incidental expenses such as childcare expenses;
- Reimbursement or payment for travel expenses provided or could be expected to be provided under or can reasonably be expected to be provided:

  o by the recipient of the organ, or
  o under a State or Federal program or an insurance policy, or
  o by an entity that provides health services on a prepaid basis.

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.

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators 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. See the review criteria 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 except for the competing continuation's progress report, which will be reviewed by HRSA program staff after the objective review process.

Review criteria are used to review and rank applications. The Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program has six review criteria:

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Need Assessment
The extent to which the applicant describes the problem and the proposed program plans to:
- Demonstrate an in-depth knowledge of living organ donation to include potential barriers faced by living organ donors and individuals on the transplant waiting list; and
- Demonstrate how the proposed program can reduce or eliminate these barriers.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology
The extent to which the applicant responds to the "Purpose" included in the program description. The strength of the proposed goals, objectives, and their relationship to the identified program. The extent to which activities described in the application are capable of addressing the problem and attaining the program's objectives.

More specifically, the extent to which the applicant:
- Clarifies the proposed activities;
- Justifies the proposed activities;
- Includes meaningful partnerships with stakeholders such as transplant centers and organizations working for individuals on the waitlist; and
- Is likely to achieve program's objectives.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capabilities
The strength and effectiveness of the method proposed to monitor and evaluate the program results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program purpose has been met, and 2) to what extent these can be attributed to the program.

Specifically, the extent to which the applicant addresses the effectiveness of the proposed methodology to monitor and evaluate the program in the areas below:
- Efficiency of program operations to provide reimbursement to donors;
- Financial integrity of operations;
- Protection of confidential information;
- Completeness, timeliness and accuracy of data collected by the program; and
- Participants' satisfaction with the program (program beneficiaries and transplant centers).

Criterion 4: IMPACT (15 points) – Corresponds to Section IV's Work Plan
The extent to which the proposed program assists economically disadvantaged individuals to find potential living donors who might not otherwise become donors because of financial barriers.

Criterion 5: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
The extent to which program personnel are qualified by training and/or experience to implement and carry out the program. The capability of the applicant organization, quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed program.

More specifically, the extent to which the applicant addresses the:
- Capabilities of the organization(s) involved;
- Familiarity of organization(s) with organ transplantation and healthcare related issues;
- Expertise and experience of proposed program staff; and
- Appropriateness of resources available to carry out the proposed activities.

Criterion 6: SUPPORT REQUESTED (15 points) – Corresponds to Section IV's Work Plan
The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives and the anticipated outcomes.
- 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 program to achieve program 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. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

See Section 5.3 of HRSA's *SF-424 Application Guide* 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).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the 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. HRSA may ask you 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 HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, 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.

HRSA will report to FAPIIS a determination that an applicant is not qualified ([45 CFR § 75.212]()).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 1, 2019.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 1, 2019. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's *SF-424 Application Guide*.

Requirements of Subawards
The terms and conditions in the Notice of Award (NOA) apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NoA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See [45 CFR § 75.101 Applicability]() for more details.

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 you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

3. Reporting

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **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 available in the award notice.

2) **Other required reports and/or products**
   The award recipient must submit quarterly status updates 30 days following the end of the reporting period. Quarterly status updates must include the following information:
   - Effectiveness of the program in meeting its goals;
   - Participants' satisfaction with the program;
   - Support to transplant center staff;
   - Application review and approval process; and
   - Efficiency and effectiveness of program's internal processes.
   - Number of applications received from potential organ donors;
   - Demographics on donors and recipients such as ethnicity, gender, and household income;
   - Number of applications approved and denied;
   - Number of approved applicants who underwent donor evaluation, transplant surgery, and follow-up visits
   - Number of applications by preference category as defined in the Program's Eligibility Guidelines as amended;
   - Program funds committed and disbursed to donors; and
   - Performance measure updates.

   Quarterly status updates will be discussed further after an award is made.

3) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in [FAPIIS](#), as required in [45 CFR part 75 Appendix XII](#).

VII. Agency Contacts

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

Devon Cumberbatch
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop xxx
Rockville, MD 20857
Telephone: (301) 443-7532
Fax: (301) 443-6343
Email: DCumberbatch@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Mesmin Germain
Supervisory Public Health Analyst,
Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 8W50
Rockville, MD 20857
Telephone: (301) 443-0053
Fax: (301) 594-6095
Email: mgermain@hrsa.gov

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

You can find additional information on developing logic models 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. You can find information on how to distinguish between a logic model and work plan at the following website: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Friday, December 20, 2018
Time: 2 p.m. – 3 p.m. ET
Call-In Number: 1-888-989-6484
Participant Code: 4830643

Weblink: https://hrsa.connectsolutions.com/nofo_pre-appl_ta_webinar/

Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 Application Guide*.