

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Care Systems Bureau
Division of Transplantation

Lost Wages Support for Living Organ Donors Demonstration Project

Funding Opportunity Number: HRSA-19-069

Funding Opportunity Type(s): Initial New

Catalog of Federal Domestic Assistance (CFDA) Number: 93.134

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2019

Letter of Intent Due Date: September 20, 2018

Application Due Date: November 27, 2018

MODIFIED September 14, 2018 to update Technical Assistance Webinar Information

*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: August 24, 2018

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2019 *Lost Wages Support for Living Organ Donors Demonstration Project*. The purpose of this demonstration project is to assess whether reimbursing lost wages increases individuals' willingness to become living organ donors. Specifically, this demonstration project seeks to (1) ascertain the effect of providing reimbursement of lost wages on individuals' decisions to initiate the process of becoming living donors as indicated by the decision to undergo donor evaluation; and (2) inform HRSA on the most effective and efficient mechanism to provide this support to living donors.

This notice is a contingency action taken to ensure that, should funds become available for this specified purpose, HRSA can process applications and award funds in a timely manner. You should note that this notice may be cancelled prior to award recommendations.

Funding Opportunity Title:	Lost Wages Support for Living Organ Donors Demonstration Project
Funding Opportunity Number:	HRSA-19-069
Due Date for Applications:	November 27, 2018
Anticipated Total Annual Available Funding:	\$2,000,000
Estimated Number and Type of Award(s):	One cooperative agreement
Estimated Award Amount:	Up to \$2,000,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	June 1, 2019 through May 31, 2022, (3 years)
Eligible Applicants:	Public and nonprofit private entities 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 R&R Application Guide*, available online at <https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-rr-guide-v2.pdf>, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, September 26, 2018

Time: 2 p.m. – 3 p.m. ET

Call-In Number: 1-888-566-1292

Participant Code: 379871

Weblink: https://hrsa.connectsolutions.com/hrsa_dot_nofo_pre_application_ta_webinar/

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I. Project Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the *Lost Wages Support for Living Organ Donors Demonstration Project*. The primary purpose of this project is to assess whether reimbursing lost wages increases individuals' willingness to become living organ donors. Specifically this demonstration project will study whether and how reimbursement for lost wages affect individuals' behaviors towards living donation, as indicated by willingness to undergo donor evaluation. Funding for this project will:

- (1) Ascertain the effect of providing reimbursement of lost wages on individuals' decisions to initiate the process of becoming living donors by undergoing donor evaluation; and
- (2) Inform HRSA on the most effective and efficient mechanism to provide this support to living donors.

The project scope includes designing, implementing, and evaluating a demonstration project to assess whether reimbursing lost wages increases individuals' willingness to become living organ donors, by studying the effect of reimbursement of lost wages on individuals' decision to consider living donation. This award includes funding for the recipient to reimburse eligible prospective living donors, regardless of income, up to \$5,000 in lost wages for donor evaluation and surgical procedures. However, if the eligible prospective donor is also eligible for reimbursement under HRSA's Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, which funds the National Living Donor Assistance Center (NLDAC), then the combined reimbursement amount shall not exceed \$8,000. For more information about the NLDAC, visit its website at <https://www.livingdonorassistance.org>.

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 a transplant. The applicant should also include strategies to work closely with the NLDAC in order to use and disburse available resources, in adherence with combined maximum limits, to support the purpose of this project.

Information Technology Security Requirements

The recipient may need to collect and store personal information from both the transplant recipient and living organ donor to assess the living organ donor eligibility, therefore will be required to maintain the confidentiality of personal information collected and stored under this project. Applications should include a description of the system to protect the confidentiality of data collected and stored under this project. HRSA also requires that any website developed to support this project 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

The applicant must propose a financial system that meets these objectives:

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

2. Background

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

Organ transplantation is considered the most appropriate and often the only therapeutic treatment available for individuals with end-stage organ failure. At the end of 2017, more than 115,000 individuals were on the national waiting list for an organ. Although the number of deceased donor kidney transplants has increased slowly; overall, the number of living donor transplants has been declining. After peaking at 6,992 in 2004, the number of living donors has 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)

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

	Deceased Donor	Living Donor	Total Transplants
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>)

There is a critical shortage of organs to meet the needs of individuals with end-stage organ failure whose lives could be saved by organ transplants. The number of patients who need life-saving kidney transplants continues to grow more quickly than the number of organs available from deceased donors. Although a kidney, a portion of a lung, and a portion of a liver can all be donated by a living individual, kidney donation is much more common. Living kidney donors account for nearly 30 percent of the total number of kidney transplants (14,038 deceased donor transplants vs 5,812 living donor transplants in 2017)¹.

NLDAC provides financial assistance for people who wish to be living organ donors and who might not otherwise be able to donate. Qualified expenses include reimbursement of travel and subsistence expenses related to a donor's evaluation, surgery, and follow-up visits.

Funds are available to donors under this program only if funding is not available from: (1) any state compensation program, any insurance policy, or any federal or state health benefits program; (2) any entity that provides health services on a prepaid basis; or (3) the recipient of the organ. Eligibility on both, transplant recipient and living organ donor, household income with ability to pay is based on 300 percent of the HHS Poverty Guidelines.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: Initial New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

¹ Based on the OPTN Data Source (<https://optn.transplant.hrsa.gov>).

HRSA involvement will include:

- Working collaboratively with the recipient to ensure study design and proposed policies and procedures align with the purpose of the project;
- Working collaboratively with recipient on aligning the structure of the project's evaluation with agency needs and requirements
 - o Refining variables and factors impacting the outcomes of the project, including donor and organ recipient criteria;
- Assessing the administrative characteristics of the project:
 - o Administrative efficiency and accuracy,
 - o Responsiveness,
 - o Data collection structure – accuracy, timeliness, simplicity, and
 - o Fiscal integrity;
- Reviewing quarterly reports;
- Reviewing and providing feedback on all major tasks, policies, procedures;
- Participating in major project planning meetings; and
- Maintaining ongoing communication with the recipient.

The cooperative agreement recipient's responsibilities will include:

- Seeking guidance from HRSA to establish policies and procedures governing this project;
- Identifying meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities;
- Establishing a system to operate and evaluate the effectiveness of the project with guidance from HRSA;
 - o Providing for ease and flexibility in the ability to manipulate evaluation assessment variables and factors impacting outcomes,
 - o Providing for independent evaluations of results;
- Reviewing and processing applications for reimbursement;
- Making timely disbursements to donors approved for reimbursement;
- Ensuring the financial integrity of the project;
- Submitting quarterly reports to HRSA; and
- Maintaining ongoing, close communication with HRSA regarding the operation of this project.

HRSA will work with the recipient in the event that responsibilities, requirements, or evaluation criteria need to be added or revised. HRSA and the 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 \$2,000,000 to be available annually to fund one recipient. You may apply for up to \$2,000,000 in total costs (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 2019 federal appropriation. This project notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The period of performance is June 1,

2019 through May 31, 2022 (3 years). Funding beyond the first year subject to the availability of appropriated funds for Lost Wages Support for Living Organ Donors Demonstration Project in subsequent fiscal years, 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](#).

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

III. Eligibility Information

1. Eligible Applicants

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

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

Foreign entities are not eligible for funding under this notice.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this project.

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 project.* 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](https://www.grants.gov) using the SF-424 Research and Related (R&R) workspace application package associated with this NOFO following the directions provided at <http://www.grants.gov/applicants/apply-for-grants.html>.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing this notice of funding opportunity (NOFO) (also known as “Instructions” on Grants.gov) or workspace application package. This allows Grants.gov to email organizations 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 R&R Application Guide](#) provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the *R&R Application Guide* in addition to the project-specific information below. You are responsible for reading and complying with the instructions included in HRSA’s [SF-424 R&R 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 [SF-424 R&R Application Guide](#) for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches (bio-sketches), and letters of commitment and support required in HRSA’s [SF-424 R&R Application Guide](#) and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Biographical sketches **do** count in the page limitation. 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 Attachments 6-15: Other Relevant Documents.

See Section 4.1 viii of HRSA's [SF-424 R&R Application Guide](#) for additional information on all certifications.

Project-Specific Instructions

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

i. Project Abstract

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

ii. Project Narrative

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

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 of the proposed project, along with a brief discussion of current issues related to living donation in the United States and the potential impact of this project on living organ donation.
- **NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion(1)**
This section will help reviewers understand how this project will serve the donation and transplantation community at the national level. Outline the needs of the transplant community, including the need of individuals on the waiting list as well as the needs of potential living donors. Describe and document the target population for the proposed project and its unmet needs. Use and cite data whenever possible to support information provided. Discuss any relevant barriers that the project hopes to overcome.
- **METHODOLOGY -- Corresponds to Section V's Review Criterion(2)**
Propose methods that you will use to address the stated need(s) and purpose of the project and meet each of the previously described project requirements, including collaborative efforts, along with expectations to design, implement, and

evaluate a project to provide reimbursement of lost wages. Propose an overall strategy, methodology, and analyses that are relevant, valid, rigorous, practical, and appropriate to accomplish the specific aims of the project. Propose measures and analyses that are relevant to the project purpose to assess whether offering reimbursement of lost wages increases individuals' willingness to become living organ donors along with the sub-component of increasing the number of individuals willing to undergo an evaluation to become a living donor. Provide details about the design of the project including, but not limited to, target population recruitment, screening and eligibility, expenses to be reimbursed, and data to be collected. Discuss the implementation approach. As appropriate, include details/information about the development of effective tools and strategies for ongoing staff training, outreach, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities.

Include a description of any innovative theoretical concepts/framework, approaches or methodologies, e.g., causal inference and implementation research, that you will use to address the stated needs. Include a plan to disseminate reports, products, and/or project outputs to ensure key target audiences receive project information.

- *WORK PLAN -- Corresponds to Section V's Review Criterion (2) and Criterion (4)*
Describe in the work plan section the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance. Use a timeline that includes each activity and identifies responsible staff. Identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including developing the application. Describe your 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 a transplant including strategies to work closely with the NLDAC to use available resources to support the objectives of this project.

You must submit a logic model for designing, managing and evaluating the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among project elements and how they are related to each other. 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 project (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the project 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);
- List of barriers and facilitators (e.g., a list of factors that can either (a) present challenges to project design, implementation, evaluation and project success; and (b) facilitate or help achieve effective project design, implementation, evaluation and project success);
- 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 associated with project activities); and
- Outcomes (i.e., the results of a project, typically describing a change in people or systems).

▪ *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion(2)*

Discuss challenges that you might encounter in designing, implementing, and evaluating the activities described in the work plan, and approaches that you will use to resolve such challenges.

▪ *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion (3) and Criterion (5)*

Describe the plan for project performance evaluation that will contribute to continuous quality improvement. The project performance evaluation should monitor ongoing processes and the progress towards the goal(s) and objective(s) of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities.

Detail the evaluation approach of the project. Evaluation strategies can include (but not be limited to) observational, experimental, quasi-experimental, and simulation modeling that produce relevant and valid evidence on outcomes, costs, and/or unanticipated consequences. Describe the data collection strategy to gather, analyze and track data to measure process and impact/outcomes, and explain how the data will be used to inform continued project enhancements and service delivery improvements. Describe how the approach on evaluation efforts will be administered to allow for an independent evaluation of results.

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., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature.

▪ *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion(5)*

Succinctly describe your organization's current mission and structure, scope of current activities and how these elements all contribute to the organization's ability to conduct the project requirements and meet project expectations. Include an organizational chart. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audits. Describe how you will routinely assess and improve the unique needs of target population that you serve.

The staffing plan and job descriptions for key faculty/staff must be included in

Attachment 2 (Staffing Plan and Job Descriptions). 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.	
<u>Narrative Section</u>	<u>Review Criteria</u>
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
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.

iii. **Budget**

See Section 4.1.iv of HRSA’s [SF-424 R&R Application Guide](#). Please note: the directions offered in the [SF-424 R&R Application Guide](#) may differ from those offered by Grants.gov. 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 HRSA selects the application 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 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 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. 115-141), 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](#)

[R&R Application Guide](#) for additional information. Note that these or other salary limitations may apply in FY 2019, as required by law.

iv. Budget Justification Narrative

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

v. Project-Specific Forms

vi. 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 project that includes all information detailed in Section IV. ii. Project Narrative. Also include the required logic model in this attachment. If you will make sub-awards or expend funds on contracts, describe how your organization will ensure proper documentation of funds expenditures.

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

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 studies cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are 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.

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

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 (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*](#).

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.

[SAM.gov](#) is experiencing high volume and delays. If you have tried to create or update your SAM.gov registration but have not been able to complete the process, you may not be able to apply for a HRSA funding opportunity via Grants.gov in a timely manner prior to the application deadline. If so, please email DGPwaivers@hrsa.gov, per the instructions in Section 3.6 of your HRSA 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 November 27, 2018 *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 R&R Application Guide](#) for additional information.

5. Intergovernmental Review

The Lost Wages Support for Living Organ Donors Demonstration Project is a project subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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 period of performance of up to 3 years, at no more than \$2,000,000 per year (inclusive of direct **and** indirect costs). The FY 2019 President's Budget does not request funding for this project. This project notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. 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.

The General Provisions in Division H of the Consolidated Appropriations Act, 2018 (P.L. 115-141) apply to this project. Please see Section 4.1 of HRSA's [SF-424 R&R Application Guide](#) for additional information. Note that these or other restrictions will apply in 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 travel and related expenses for living organ donors
- Reimbursement for any lost wages expenses and similar expenses if this support is available under other state or prepaid health or insurance program

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.

7. Other Submission Requirements

Letter of Intent to Apply

The letter should identify your organization and its intent to apply, and briefly describe the proposal. HRSA will **not** acknowledge receipt of letters of intent.

Send the letter via email by September 20, 2018 to:

HRSA Digital Services Operation (DSO)

Please use the HRSA opportunity number as email subject (HRSA-19-069)

HRSADSO@hrsa.gov

Although HRSA encourages letters of intent to apply, they are not required. You are eligible to apply even if you do not submit a letter of intent.

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 judged. HRSA has developed 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.

Review criteria are used to review and rank applications. The Lost Wages Support for Living Organ Donors Demonstration Project has six review criteria:

Criterion 1: NEED (10 points) – Corresponds to Section IV's (ii) Introduction and Needs Assessment

The extent to which the proposal

- Demonstrates an in-depth knowledge of the problem and associated contributing factors to the problem as well as a thorough understanding of the field of organ donation and the various organizations involved.
- Clearly addresses the purpose, scope, complexity and need for the project; and the issues related to the need to increase living organ donation in the United States.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's (ii) Methodology, Work Plan, and Resolution of Challenges

The extent to which the proposal

- Offers an overall strategy, methodology, and analyses that are relevant, valid, rigorous, practical, and appropriate to accomplish the specific aims of the project.

- Uses novel theoretical concepts/framework, approaches, methodologies, or instrumentation.
- Describes 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 a transplant and includes strategies to work closely with the NLDAC to use available resources to support the objectives of this project.
- Includes measures and analysis plans that are linked to the project purpose.
- Clearly describes the activities to address the problem and meet the project purpose; including the sub-component of increasing the number of individuals who make the decision to undergo an evaluation to become a living donor.
- Addresses potential challenges and strategies to address these challenges.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's (ii) Evaluation and Technical Support Capacity

The extent to which

- The data collection strategy describes how (1) data will be gathered, analyzed and tracked; (2) process and impact/outcomes are measured; and (3) data and analytic results will be used to inform improvements in project development, service delivery, project implementation, and project performance.
- The method proposed to monitor and evaluate the project results should have sufficient methodological rigor to effectively assess to what extent:
 - o The project objectives have been met,
 - o The outcomes can be attributed to interventions, processes and activities implemented by the project, and
 - o The outcomes can be independently verified.

In addition, the evaluation approach can include the adoption of varied methodological approaches used in studies such as observational, experimental, quasi-experimental, and simulation modeling that produce relevant and valid evidence on outcomes, costs, and/or unanticipated consequences.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's (ii) Work Plan

The extent to which the proposed project has the potential to increase access to organ transplant for patients on the national transplant waiting list if funded.

- The projected number of individuals that can be recruited to participate in the study.
- The manner in which potential living donors can be identified.
- The degree to which the project activities are replicable.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV’s (ii) Evaluation and Technical Support Capacity and Organizational information

- The extent to which project personnel are qualified by training and experience to implement and carry out the project.
- The capabilities of the applicant organization and the quality and availability of physical resources and personnel to fulfill the needs and requirements of the proposed project.

Criterion 6: SUPPORT REQUESTED (15 points) – Corresponds to Section IV’s (iii) Budget and (iv) Budget Justification Narrative

The reasonableness of the proposed budget for each year of the period of performance 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. 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 R&R 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 project 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 June 1, 2019.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of June 1, 2019. See Section 5.4 of HRSA's [SF-424 R&R Application Guide](#) for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's [SF-424 R&R 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 project, 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 R&R 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 recipient must submit **quarterly status updates** 30 days following the end of the reporting period. Quarterly status updates must include the following information:
 - Number of applications received from potential organ donors;
 - Demographics information such as ethnicity, gender, household income of living donors and transplant recipients;
 - Number of applications by organ donors funded;
 - o Number of approved applications undergone donor evaluation, surgery, and follow-up visits
 - o Funds committed and disbursed to living donors;
 - o Purpose of the funds committed and disbursed (Donor Evaluation, Surgery, follow-up visits);
 - o Collaboration efforts and activities with stakeholders
 - o Project status based on the approved work plan.

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 [FAPIS](#), 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:

Contact Name
Kaleema Muhammad
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-7061
Email: KMuhammad@hrsa.gov

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

Melanie Deal, Health Communication Specialist
Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 8W-53D
Rockville, MD 20857
Telephone: (301) 443-9412
Fax: (301) Fax: (301) 594-6095
Email: mdeal@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 project 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/healthyouth/evaluation/pdf/brief5.pdf>.

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Day and Date: Wednesday, September 26, 2018

Time: 2 p.m. – 3 p.m. ET

Call-In Number: 1-888-566-1292

Participant Code: 379871

Weblink: https://hrsa.connectsolutions.com/hrsa_dot_nofo_pre_application_ta_webinar/

Tips for Writing a Strong Application

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